National Health Normative Standards Framework for Interoperability in eHealth in South Africa

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LIST OF ACRONYMS

AIDS	Acquired Immunodeficiency Syndrome
ANSI	American National Standards Institute
API	Application Program Interface
ART	Antiretroviral Treatment
ARV	Antiretroviral
ASTM	American Society for Testing and Materials
AZT	Azidothymidine
BCG	Bacillus Calmette–Guérin vaccine
BoD	Burden of Disease
BRICS	Brazil, Russia, India, China and South Africa
BSD	Berkeley Software Distribution
CCD	Continuity of Care Document
CCR	Continuity of Care Record
CD4	CD4 cells (Helper T cells)
CDA	Clinical Document Architecture
CEN	European Committee for Standardization
CHC	Community Health Centre
CIO	Chief Information Officer
CPT	Current Procedural Terminology
DHIS	District Health Information System
DICOM	Digital Imaging and Communications in Medicine
EA	Enterprise Architecture
edXML	Electronic Business using eXtensible Markup Language
EMR	Electronic Medical Record
epSOS	European Patients Smart Open Services
ESB	eHealth Standards Board
EU	European Union
GP	General Practitioner
HAART	Highly active antiretroviral therapy
EHR	Electronic Health Record
HIMSS	Health Information and Management Systems Society
HIQA	Health Information and Quality Authority
HIT	Health Information Technology
HIV	Human Immunodeficiency Virus
HIX	Health Information Exchange
HL7	Health Level Seven
ICD-10	International Classification of Diseases, Tenth Revision
ICT	Information and Communications Technology
ID	Identifier
IETF	Internet Engineering Task Force
IHE	Integrating the Healthcare Enterprise
ISO	International Standards Organisation
IT	Information Technology
ITU	International Telecommunication Union

IVR	Interactive Voice Response
JIC	Joint Initiative Council
LOINC	Logical Observation Identifiers Names and Codes
MIOS	Minimum Interoperability Standard
MOU	Maternal Obstetric Unit
NDoH	National Department of Health
NeHC	National eHealth Collaborative
NEHTA	National E-Health Transition Authority
NHC/MIS	National Healthcare Management Information System
NHI	National Health Insurance
NHLS	National Health Laboratory Service
NHS	National Health Service
NIDS	National Indicator Dataset
NHISSA	National Health Information System of South Africa
HNSF	National Health Normative Standards Framework for Interoperability in eHealth in South Africa
OASIS	Organization for the Advancement of Structured Information Standards
OMG	Object Management Group
OSI	Open Systems Interconnection
PAHO	Pan American Health Organization
PCR	Polymerase Chain Reaction (test for HIV)
PDF	Portable Document Format
PHCIS	Primary Healthcare Information System
PHR	Personal Health Record
PMI	Patient Master Index
PMTCT	Preventing mother to child transmission
PoC	Point of Care
RFP	Request for Proposal
RIM	Reference Information Model
SABS	South African Bureau of Standards
SANS	South African National Standards
SDO	Standards Development Organisation
SGPGI	Sanjay Gandhi Postgraduate Institute of Medical Sciences
SMS	Short Message Service
TB	Tuberculosis
UK	United Kingdom
UML	Unified Modelling Language
USA	United States of America
W3C	World Wide Web Consortium
WHO	World Health Organisation
XML	Extensible Markup Language

A SOUTH AFRICAN HEALTH STORY

Lindiwe is an unemployed, 19 year old single mother of one. She lives in a two-room shack with her grandmother and two siblings. Lindiwe is 5 months pregnant with her 2nd child. She decides to go to the community health centre (CHC) to register for antenatal care.

On arrival at the CHC, Lindiwe reports to Sarah, the registration clerk, and tells her she is pregnant. Sarah asks Lindiwe for her healthcard. Lindiwe says that she does not have one but she did bring her national ID book with her, as instructed by the posters and signs outside the clinic. Sarah keys Lindiwe's national ID number into the computer and generates a new record for her in the NDoH's patient master index (PMI). Sarah asks Lindiwe for her contact detail, including her address and her mobile phone number. Sarah prints a bar-coded label, which she fixes to Lindiwe's new health card. Sarah gives Lindiwe her new health card and a pamphlet describing how this card will help her access health services. Sarah asks Lindiwe to wait in the waiting area.

Mary, a nurse at the CHC, invites all the pregnant women in the waiting area to come with her to a separate room. Mary gives a health talk, focusing on the importance of being tested for HIV and the benefits of breast-feeding their babies. After the talk each of the pregnant women are called into a consulting room for one-on-one consultation.

When her turn comes, Lindiwe goes in to see Mary, who scans the barcode on Lindiwe's card to call up Lindiwe's file on the computer. Mary asks Lindiwe questions about her health history and records a number of clinical observations; everything is logged in Lindiwe's electronic health record (EHR).

Mary and Lindiwe discuss the importance of doing an HIV test. Lindiwe agrees to be tested, and her consent is scanned and saved to her EHR. The quick test indicates Lindiwe is HIV positive and the repeat test yields the same result. This is very difficult news for Lindiwe. Lindiwe and Mary discuss the implications and what it will mean for Lindiwe's care plan during the pregnancy and for her baby after it is born. Mary puts Lindiwe on a prevention of mother-to-child transmission (PMTCT) protocol. Mary records details of the test results and the PMTCT protocol in Lindiwe's EHR. Based on the protocol, Lindiwe is dispensed antiretroviral (ARV) medications from the clinic's pharmacy. The medications dispensed are logged in Lindiwe's EHR. Lindiwe schedules her next antenatal care appointment with Sarah, and returns home. Sarah logs the appointment in Lindiwe's EHR.

Over the next few months, Lindiwe receives an SMS reminder the day before each of her antenatal care visits. Each time she returns to the clinic, Sarah scans Lindiwe's healthcard to confirm her visit when she arrives and Mary scans her card to retrieve her EHR when it is time for her consultation. Lindiwe's clinical observations and ARV medicines dispensed are added to her EHR at each visit. On one of these visits, Lindiwe told Sarah that she has moved. When looking up Lindiwe's record, Sarah discovers that her mobile phone number is also out of date. Sarah makes the changes to Lindiwe's record in the shared EHR.

Two weeks before her due date, Lindiwe takes the bus to visit her aunt at a nearby town. While she is at her aunt's house, Lindiwe goes into premature labour. Her labour is progressing quite rapidly, so her aunt's neighbour takes Lindiwe to the local hospital.

At the hospital, the registration clerk scans Lindiwe's healthcard and retrieves her EHR. Therafter, Lindiwe is admitted to the maternity ward. Nala, a nurse in the maternity ward, scans Lindiwe's card and retrieves her EHR. From Lindiwe's EHR, Nala sees that Lindiwe's birth is to follow a PMTCT protocol and she immediately makes the appropriate preparations. Lindiwe delivers a beautiful, healthy baby girl. Based on the protocols, Nala administers ARV to the baby. Nala records information about the birth in Lindiwe's EHR. Nala then creates a record for Lindiwe's new baby girl and so begins a new South African health story.

EXECUTIVE SUMMARY

This report was commissioned by the National Department of Health (NDoH). The purpose of the report is to develop a first version of a National Health Normative Standards Framework for eHealth in South Africa (HNSF). The primary objective of the HNSF is to set the foundational basis for interoperability as articulated in the eHealth Strategy South Africa 2012-2016 [National Department of Health, 2012b]. The HNSF was developed by the Meraka Institute of the Council for Scientific Research (CSIR) in collaboration with the Nelson Mandela Metropolitan University (NMMU).

To date, eHealth investments made by NDoH have yielded local benefits but have not created the desired 'network effect' because of a lack of interoperability between heterogeneous IT systems. The role of the standards-based strategy outlined in this report is to articulate an interoperability framework that may be used to achieve the desired network effect. It represents a *first step towards a complete health enterprise architecture specification* for South Africa. When fully developed, this enterprise architecture will define how eHealth solutions, across all levels of healthcare in both the public and private health systems, will interoperate with each other to support person-centric continuity of healthcare.

Because of the explicit focus on interoperability, the scope of the study was limited to the pervasive eHealth services needed to support the sharing of longitudinal, person-centric health information on a system-wide (national) basis. This system-wide focus excludes the various IT standards associated with technologies and devices located within the four walls of specific physician offices, labs, pharmacies or hospitals. Rather, it focuses on information sharing between these and other health delivery partners. However, in order to be interoperable with external systems, there is an implicit inference that the same approach and standards should be used for the systems within the four walls of a facility.

The process to develop the National Health Normative Standards Framework for Interoperability in eHealth (hereafter referred to as the HNSF) is illustrated in Figure 0-1. The study commenced with an in-depth review of the existing international eHealth standards landscape. The outcome of this review was a set of base standards for eHealth, which had to be assessed for their applicability to the South African healthcare context.

The process started with developing a set of business use case scenarios reflecting the quadruple burden of disease (BoD) in South Africa [National Department of Health, 2012a], and included:

- HIV/AIDS diagnosis and management.
- Tuberculosis diagnosis and management.
- Diabetes diagnosis and management (as an example of chronic disease / non-communicable management).
- Child health (in the form of an immunisation scenario).
- Maternal health (in the form of antenatal, intra-natal and post-natal care).
- Management of emergencies (focusing on injury and violence).

The use cases reflect four levels of health information system (HIS) maturity, ranging from a completely paper-based system, through to a fully integrated electronic eHealth system making use of a shared national electronic health record (EHR) system and infrastructure. The necessary information exchanges were established for each healthcare scenario and were mapped to Unified Modelling Language (UML) sequence diagrams. Site visits (using interviews and questionnaires as data collection methods) were conducted with Provincial healthcare delivery organisations to verify the care scenarios.

The collective set of information exchanges, once verified, were then abstracted to provide a set of generic e-heath functions that should be supported in eHealth applications based on the South African healthcare

landscape. Based on the generic functions, a set of international base standards that could be appropriate for the South Africa eHealth landscape were identified from the base standards found in our initial study.

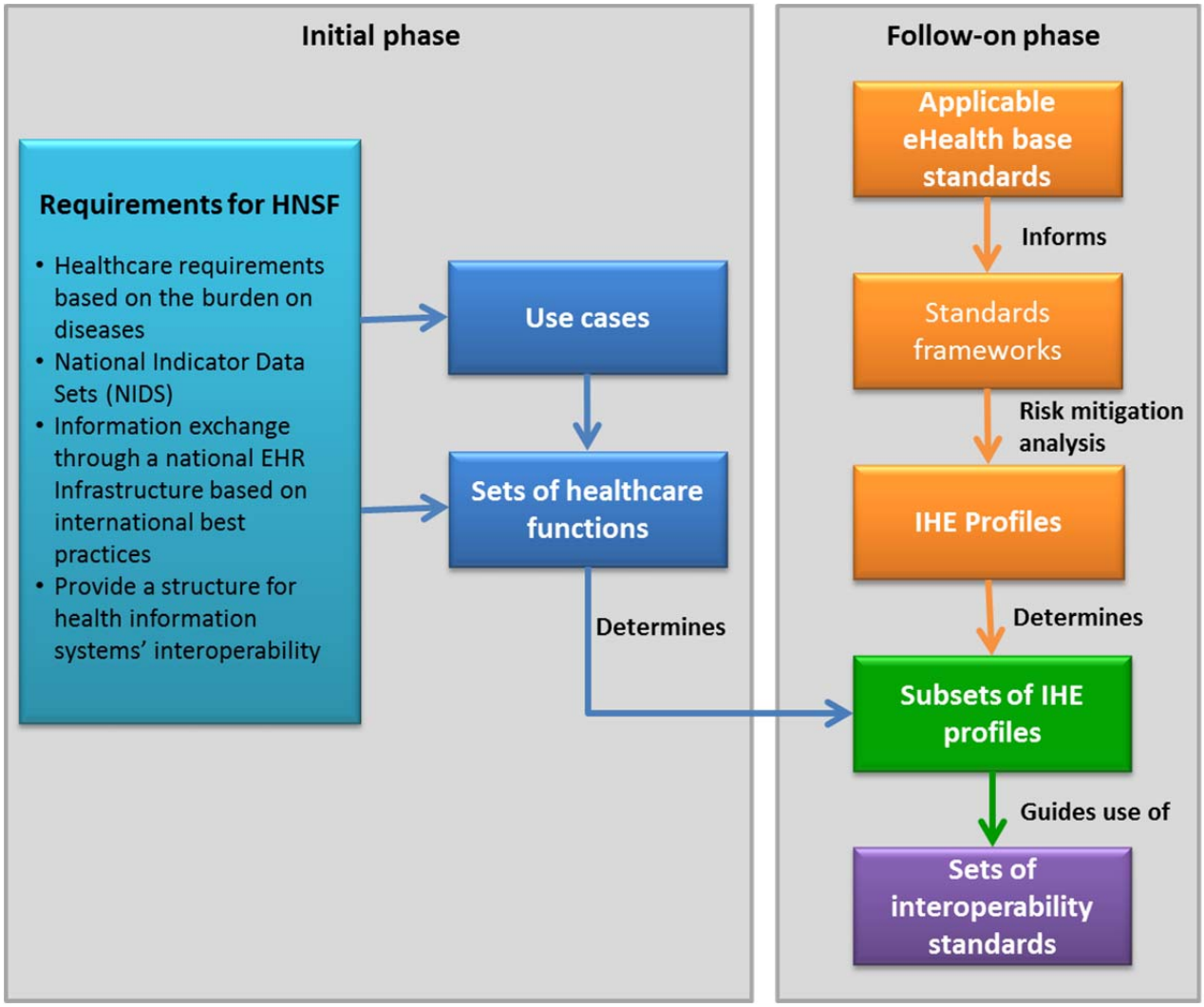

Figure 0-1: Process to develop the HNSF

The analytical work done on the resulting set of base standards, led the research team to the conclusion that at least three stacks of end-to-end standards were contained therein. Due to the scientific coherence of these stacks of standards, the research team took the decision to narrow down the vast eHealth standards landscape by focusing primarily on such cohesive 'stacks' of standards that have been internationally balloted [CEN/TC 251, 2009a]. This approach tied in with the interoperability focus and mitigated implementation risk. The three stacks of standards identified are:

1. The family of standards based on the HL7 V3 Reference Information Model (RIM) [Health Level Seven International, 2013e].
2. The standards based on the ISO 13606 Parts 1-5 / OpenEHR Reference Model (RM) [The EN 13606 Association].
3. The interoperability standards-based profiles developed by the global organisation, Integrating the Health Enterprise (IHE) [IHE International, 2012].

The NDoH's eHealth Strategy South Africa 2012-2016 [National Department of Health, 2012b] document, other published reports and expert input, led to the determination of a set of evaluation criteria reflective

of South Africa's requirements. Leveraging published analyses, the candidate standards stacks were evaluated against the criteria using a risk assessment template. The results of the evaluation are shown in Figure 0-2 (● indicates that a standard stack meets the criteria).

Criteria	HL7 V3	ISO 13606	IHE
Scalability	●	●	●
Implementability			●
Conformance testable			●
Market acceptance			●
Economically feasible	●	●	●
Technical capacity			●
Maturity	●		●
Extensibility and flexibility	●	●	●
Support clinical and healthcare initiatives	●	●	●

Figure 0-2: Standards 'stacks' evaluation matrix

Based on this initial evaluation, the IHE option (and its underlying standards) was explored in detail. The goal was to investigate IHE's ability to support South Africa's current requirements and those proposed in the NDoH's eHealth Strategy South Africa 2012-2016 [National Department of Health, 2012b].

The information exchanges in the use case scenarios were then mapped to applicable IHE profiles. Each function was also mapped to relevant IHE profiles, which can support that function. Each IHE profile is in turn based on a number of base standards. The standards-based profiles and base standards were also assessed to determine coverage of the National Indicator Data Sets (NIDS)). The relationship between care scenarios, interoperability standards-based profiles and base standards is shown in Figure 0-3.

In each case, if gaps were found they were documented. These gaps included any cases with no applicable IHE profile that satisfied the information exchange requirements, or where the data included in the standards-based profiles was insufficient to generate the appropriate National Indicator Data Set (NIDS) element.

The resulting set of functions, standards-based profiles and standards were compiled into a coherent whole to form the Normative Standards Framework for Interoperability in eHealth in South Africa.

In addition, implementation guidelines for applying the HNSF was developed. The implementation guidelines consists of an assessment instrument and a governance model. Incorporating the assessment instrument as central to the governance processes is important to ensure the relevance of standards-based profiles to practical use cases, their open availability, and the controls to be applied for their correct application.

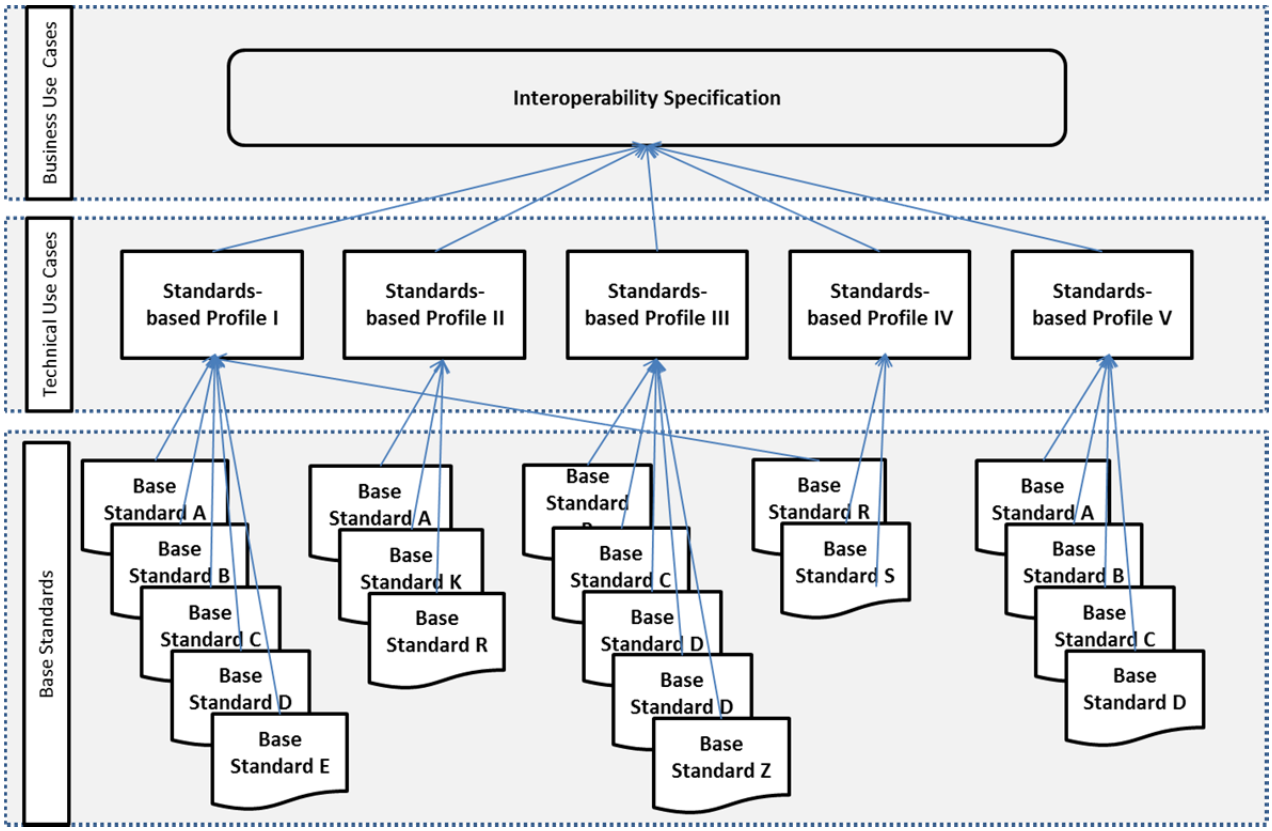

Figure 0-3: Relationships between base standards, interoperability standards-based profiles and case scenarios

Based on the analyses and investigations a set of recommendations were developed. These may be summarised as follows:

1. It is recommended that the NDoH's eHealth infrastructure investments should focus on supporting person-centric healthcare. Reportable indicators (e.g. NIDS) should be developed by aggregating person-centric data.
2. It is recommended that an eHealth Standards Board for South Africa (ESB) be established to oversee the implementation of the HNSF. The ESB should work closely with healthcare providers and other relevant stakeholders to develop, adopt and maintain eHealth standards-based profiles and base standards.
3. It is recommended that the IHE profiles and the base standards underlying these standards-based profiles be used as a starting point for the interoperability aspects of the HNSF. Additional base standards were recommended in the HNSF where gaps were identified in the IHE profiles.
4. It is recommended that the document content standards (such as HL7 CDA and CCD) be localised to ensure that the information, exchanged with the shared electronic health record infrastructure, supports healthcare service delivery in the context of the South African burden of disease.
5. It is recommended that a data dictionary for eHealth in South Africa be established. A data dictionary lays down a uniform national data set that promotes data uniformity, availability, validity, completeness, reliability, and consistency. Further, the use of the dictionary will ensure uniform collection, presentation and sharing of data throughout the health sector.
6. It is recommended that the development and publication of a national eHealth enterprise architecture for South Africa be undertaken immediately. The analyses and findings of this report provide a significant input towards the development of such an artefact.

7. Although the aim and mandate of this project was not to suggest a technology infrastructure or complete enterprise architecture for eHealth in South Africa, it is recommended that a cloud-based shared national eHealth infrastructure be established; similar to the centralised shared infrastructure or the fully integrated infrastructure used in the care scenarios.
8. It is recommended that this shared infrastructure be deployed as the crucial enabler for nationwide eHealth interoperability and the HNSF. The recommendations of standards in the HNSF were made with such shared infrastructure in mind; with a focus on retrieving and updating patient records in such infrastructure.
9. In order to implement the HNSF it is recommended that, the NDoH must publish applicable policies and legislation in support of the sharing of health information for purposes of person-centric healthcare delivery. The eHealth Strategy South Africa 2012-2016 [National Department of Health, 2012b] document, proposes that such legislation should entrench the rights of South Africans to continuity of care over time and across sites of care within the country.
10. It is recommended that the NDoH, through the ESB, set up a mechanism to conduct interoperability conformance testing of vendor/supplier products and existing health information systems against the HNSF.
11. It is recommended that the HNSF and its underlying standards are made applicable to facility-based electronic medical record (EMR) systems as well. This is especially important when patient information is shared or exchanged between different systems at the same facility, and essential when such information is shared or exchanged with any other system outside of the facility. As a minimum, the standards related to identification, authentication and authorisation should apply. Other standards that would be applicable will depend on the patient record content being stored and exchanged. When NDoH has determined the minimum data set that should be included in a shared electronic health record (EHR), the relevant standards applicable to that content should also apply at facility level.

1 INTRODUCTION

South Africa's healthcare information system is fragmented, unwieldy, and inoperable caused in part by the decentralization of the National Healthcare Management Information System (NHC/MIS) which came into force in 1996. Not all the components of NHC/MIS were implemented as initially envisaged, because of varying degrees of capabilities at provincial levels. Furthermore, the Provinces procured systems that were neither compatible nor interoperable with each other [Presidential National Commission on Information Society and Development, n.d; South African Government Information, 1997].

The World Health Organization (WHO) defines eHealth as "the use, in the health sector, of digital data — transmitted, stored and retrieved electronically — in support of healthcare, both at the local site and at a distance" [WHO, 2004: p.2]. eHealth is a means to ensure that "the right health information is provided to the right person at the right place and time in a secure, electronic form to optimise the quality and efficiency of healthcare delivery, research, education and knowledge" [Deloitte Touche Tohmatsu, 2008: p.4]. Information exchange through electronic health records (EHRs), patient registries and shared knowledge resources is critical in a national healthcare system. Information systems and tools for diagnosis, prevention and treatment can support healthcare at all levels, and can also enable the efficient and accountable delivery of essential supplies and equipment through the management of procurement, supply and distribution chains [WHO and ITU, 2012].

Lack of interoperability between heterogeneous systems is a key obstacle to realizing the potential benefits of eHealth. Interoperability refers to the ability of two or more information and communication technology (ICT) systems or components and of the business processes they support to exchange information/data and to enable the sharing of information and knowledge exchanged [IDABC, 2004]. Four types of interoperability exist [IDABC, 2004; Kotzé & Neaga, 2010; Van der Veer & Wiles, 2008]:

- *Technical interoperability*: Covers the technical matters of connecting systems and services through interfaces, protocols etc. applying appropriate software engineering techniques and methodologies. It is usually associated with the hardware/software components, systems and platforms enabling machine-to-machine communication. In eHealth, its focus is often on communication protocols and the infrastructure needed for those protocols to operate.
- *Syntactical interoperability*: Is concerned with data formats and message formats. Messages transferred by the communication protocols must have a well-defined syntax and encoding, but also carry data or content at the same time. This is a core issue in eHealth.
- *Semantic interoperability*: Is associated with the meaning of content, focused on the human rather than machine interpretation of the content. It refers to a common understanding between people of the meaning of the content (information) being exchanged. In eHealth, its focus is often on coding standards.
- *Organizational interoperability*: Is concerned with the definition of business goals, modelling business processes and organisational collaboration issues. It refers to the ability of organisations to effectively communicate and transfer meaningful data/information, whilst using a variety of different information systems over different infrastructures, across different geographic regions and cultures. Organisational interoperability depends on the success of technical, syntactical and semantic interoperability.

One of the methods of achieving interoperability in eHealth systems is through standardization. A standard is an agreed-upon, repeatable way of doing something. From a standards perspective, eHealth is one of the most complicated and challenging areas of standardization, for several reasons such as [ITU, 2012]:

- eHealth systems inherently involve large data sets including multimedia diagnostic images, patient records, test results, research samples, financial codes, etc.

- eHealth standards do not address one unified area of technology but multiples of areas, ranging for example from standardization at the content level (e.g. patient data, diagnostic images, and medical research), device level, software systems (e.g. mobile applications, database management systems), process management, infrastructure and network management (e.g. telecommunication systems, security, and identification and authentication).
- The eHealth standards arena involves competing or overlapping standards initiatives taking place in different institutions, many of which are charging fees for accessing or implementing standards in products. This phenomenon can drive up the cost of eHealth products or discourage innovation based on eHealth standards.

The advantages of approaching the development of IT systems based on an agreed set of standards include alignment, integration, flexibility, reusability, portability and reduced time to market. Standards are used to set a baseline for healthcare system development, whether electronic or manual. The introduction of standards, however, often requires a culture change in designing and using the resulting system. The latter issue should be addressed via change management interventions and is beyond the scope of this project.

The National Department of Health (NDoH) recently developed the eHealth Strategy South Africa 2012-2016 [National Department of Health, 2012b], which provides a roadmap for the envisioned state of integrated national healthcare systems that is grounded in 'agreed upon scientific interoperability standards' for efficient and effective healthcare outcomes. However, as described above, the large numbers of eHealth interoperability standards currently available make the selection of appropriate standards difficult, especially since some of these standards also conflict with one another.

This document describes the outcome of a project to develop a 'National Health Normative Standards Framework for Interoperability in eHealth in South Africa' (hereafter in this document referred to as the Health Normative Standards Framework (HNSF)). The HNSF provides guidance in 'making sense' of eHealth standards, and assist in the assessment of the applicability of international eHealth standards to healthcare information systems currently deployed in South African healthcare institutions. The HNSF also provides guidelines as to which standards to consider and use when interoperability between systems is of primary concern. The NDoH commissioned the Meraka Institute of the Council for Scientific and Industrial Research (CSIR) in conjunction with the Nelson Mandela Metropolitan University's School of ICT to develop the HNSF.

1.1 Where does the HNSF fit into the bigger picture?

1.1.1 The context for eHealth development

The delineation of the scope of the HNSF was done in line with the WHO-ITU eHealth Strategy Toolkit [WHO and ITU, 2012]. This toolkit offers a framework and method for the development of a national eHealth vision, action plan and monitoring framework. All governments that are developing or revitalizing a national eHealth strategy can apply it, whatever the level of eHealth maturity is.

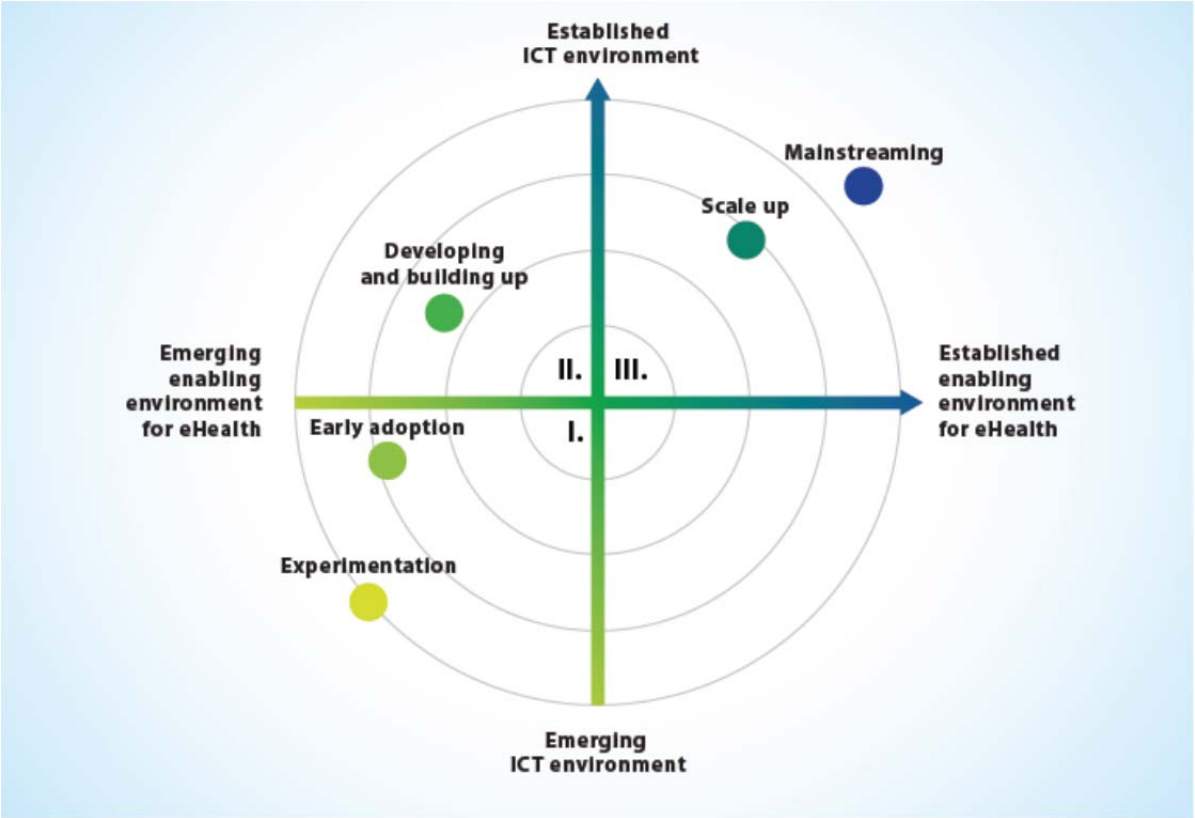

Figure 1-1: National context for eHealth development [WHO and ITU, 2012: p. 4]

The enabling environment for eHealth includes aspects such as governance, policy, legislation, standards and human resources, and is fundamental to scaling up and sustaining ICT adoption in the health sector. As illustrated in Figure 1-1, the maturity level of a country in terms of eHealth can be described as [WHO and ITU, 2012]:

I. *Experimentation and early adoption*: Both the ICT and enabling environments are at an early stage.
II. *Developing and building up*: The ICT environment grows at a faster rate than the enabling environment.
III. *Scaling up and mainstreaming*: The enabling environment matures to support the broader adoption of ICT.

A national plan for a country in stage I should focus on creating an enabling environment by making the case for eHealth, creating awareness and establishing a foundation for investment, workforce education and adoption of eHealth in priority systems and services. There is a common misconception that countries can 'leapfrog' to more advanced eHealth systems without creating such an enabling environment, but in reality such actions will lead to innovations in ICT that will remain isolated and only have a limited impact on health [WHO and ITU, 2012].

A national plan for a country in stage II should focus on strengthening the enabling environment for eHealth, creating legal certainty, establishing the policy context for delivering eHealth and identifying the standards to be adopted to ensure that building ever-larger silo systems is avoided. The major drivers for eHealth in stage II is access to care and quality of care [WHO and ITU, 2012].

In stage III the commercial ICT market is well established with larger international and local vendors. Drivers for eHealth in this stage are cost and quality. A national plan for a country in stage III should focus on [WHO and ITU, 2012]:

- Interoperability and adoption of standards.
- Providing incentives for innovation and integration of eHealth into core services.
- Identifying funding for medium-to-long term implementation.
- Responding to the expectations of citizens for more efficient, effective and personalized services.
- Using data and information for public health planning, policies for privacy and security of information.
- Undertaking monitoring and evaluation to ensure that eHealth delivers according to health priorities.

The HNSF addresses only the interoperability and adoption of standards aspects of levels II and III. South Africa is currently somewhere between stages I and II. The development of the HNSF represents South Africa's movement from stages I and II to stage III of eHealth maturity. In stage III, the vision articulated in the NDoH's eHealth Strategy South Africa 2012-2016 [National Department of Health, 2012b] for scale-up and mainstreaming of eHealth begins to be implemented and 'the enabling environment matures to support the broader adoption of ICT'.

1.1.2 eHealth components

According to the WHO and ITU National eHealth Strategy Toolkit [WHO and ITU, 2012], a -national eHealth environment is made up of a number of enabling environment and ICT environment components, as illustrated in Figure 1-2 and Table 1-1:

- *Enabling environment*: leadership, governance and multi-sector engagement; strategy and investment; legislation, policy and compliance; workforce; and standards and interoperability.
- *ICT environment*: infrastructure; and services and applications.

These components aligns closely with the 10 priorities of the eHealth Strategy South Africa 2012-2016 [National Department of Health, 2012b], which was drafted before the publication of the WHO and ITU Strategy Toolkit. The corresponding South African priority areas for each of these components are:

- Leadership, governance and multi-sector engagement: Strategy and leadership (Priority 1); Governance and regulation (Priority 4); Stakeholder engagement (Priority 2); Benefits realisation (Priority 6).
- Strategy and investment: Strategy and leadership (Priority 1); Investment, affordability and sustainability (Priority 5).
- Legislation, policy and compliance: Governance and regulation (Priority 4); Monitoring and evaluation of eHealth strategy (Priority 10).
- Workforce: Capacity and workforce (Priority 7).
- Standards and interoperability: Standards and interoperability (Priority 3).
- Infrastructure: eHealth foundations (Priority 8).
- Services and applications: eHealth foundations (Priority 8); Applications and tools to support healthcare delivery (Priority 9).

Leveraging the NDoH's progress (highlighted in blue stripes in Figure 1-2), the HNSF, provides a crucial foundation upon which eHealth infrastructure and services will rest. The HNSF addresses the standards and interoperability component (highlighted in orange stripes in Figure 1-2). The introduction of standards that enable consistent and accurate collection and exchange of health information across health systems and services, as addressed in the HNSF, are therefore part of the enabling environment.

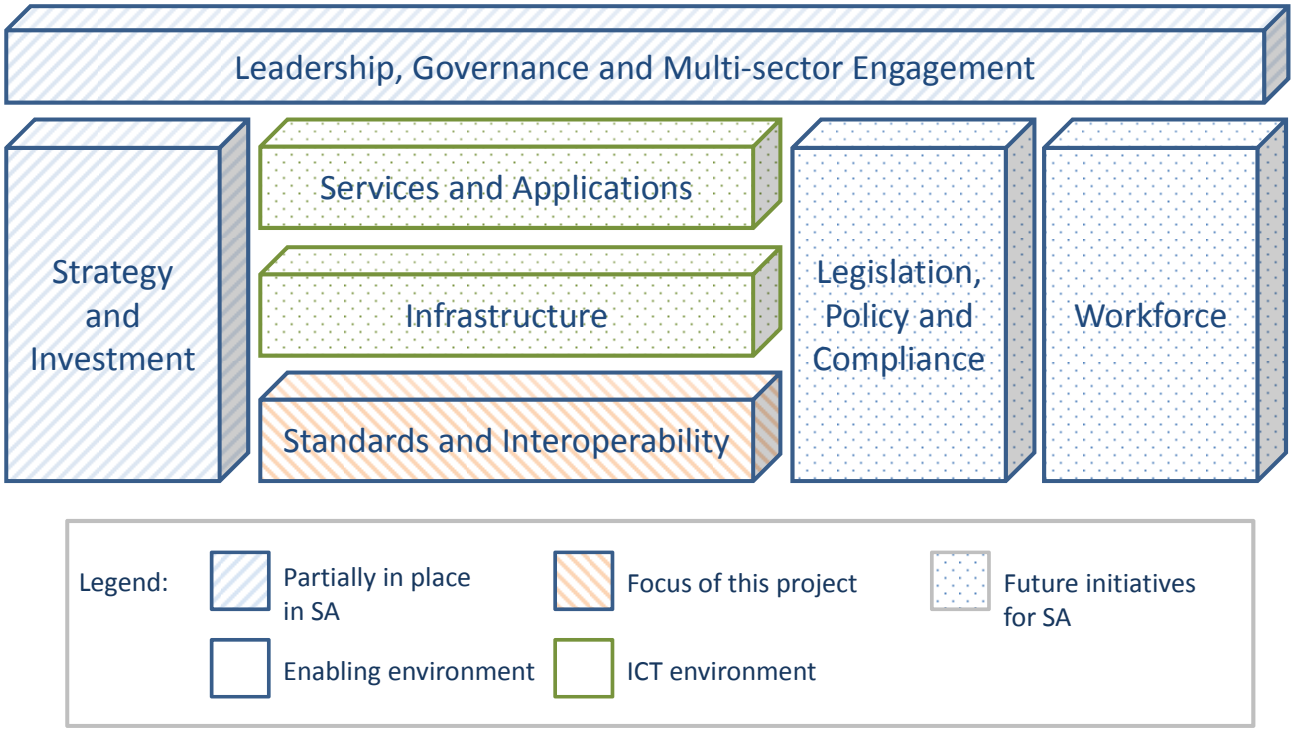

Figure 1-2: eHealth components and the South African context (adapted from the WHO-ITU eHealth Strategy Toolkit, 2012)

Table 1-**1: Role of eHealth components (adapted from [WHO and ITU, 2012: p. 9] and [National Department of Health, 2012b: p. 29]**

Role	Component	Description
Enabling environment	Leadership, governance and multi-sector engagement	Identify a governance structure to lead the implementation of eHealth; direct and coordinate eHealth at the national level; ensure alignment with health goals and political support; promote awareness and engage stakeholders. Use mechanisms, expertise, coordination and partnerships to implement the eHealth strategy an develop or adopt eHealth components (e.g. standards); develop the necessary mechanisms to support the development of an enterprise architecture for eHealth. Support and empower required change, implementation of recommendations and monitoring results for delivery of expected benefits.
	Strategy and investment	Ensure a responsive strategy and plan for the national eHealth environment; mobilise resources for implementation of the eHealth strategy; lead planning, with involvement of major stakeholders and sectors.

		Ensure consistency between the eHealth strategy and other healthcare strategic plans, i.e. infrastructure. Align financing with priorities; donor, government and private sector funding identified for medium term.
	Legislation, policy and compliance	Develop and approve a national eHealth policy framework; adopt national policies and legislation in priority areas such as privacy, confidentiality and security; develop and approve a national eHealth regulatory framework; review sectorial policies for alignment and comprehensiveness; establish regular policy reviews. Create a legal and enforcement environment to establish trust and protection for consumers and industry in eHealth practice and systems; establish a national standards compliance body; develop a licencing policy.
	Workforce	Make eHealth knowledge and skills available through internal expertise, technical cooperation or the private sector. Build national, regional and specialized networks for eHealth implementation. Establish eHealth education and training programmes for eHealth workforce capacity building; leverage partnerships and collaboration for health informatics/eHealth training.
	Standards and interoperability	To introduce standards that enable consistent and accurate collection and exchange of health information across health systems and services. Develop a standards framework for interoperability in eHealth; establish a mechanism for conformance testing/accreditation; establish an eHealth Standards Board.
ICT Environment	Infrastructure	The foundations for electronic information exchange across geographical and health sector boundaries. This includes the physical infrastructure (e.g. networks), core services and applications that underpin a national eHealth environment. Develop rules for procurement of eHealth applications, infrastructure, and alignment to national enterprise architecture.
	Services and application	May be supplied by government or commercially. Provide : • Tangible means for enabling services and systems. • Access to, and exchange and management of, information and content. Users include the general public, patients, providers, medical aids (NHI), and others.

1.1.3 Interoperability

Within eHealth, the focus of the HNSF project is primarily on semantic, syntactic and organisational interoperability (limited to the data flows in certain work processes) within the context of patient-centric healthcare management information systems. Technical interoperability is referred to only as far as messaging is concerned.

Furthermore the HNSF does not focus on systems that aggregate data at district/provincial, etc. level, or clinical care IT systems itself (for example, cardio-vascular care systems, radiology or pathology systems, etc.). The HNSF may include systems that allow for requests for information produced by such systems (for example, ordering diagnostic tests, and recording the results of such tests in a patient record, etc.) or to produce data that can be used by such systems (for example, producing data for the National Indicator Data Set (NIDS)). The HNSF does not address other systems found in healthcare facilities, and which focus on non-patient centric functions, such as accounting systems or human resource or payroll systems.

1.1.4 Enterprise architecture

Enterprise architecture (EA) can be described as a comprehensive framework used to manage and align an organisation's technology assets (in this case IT), people, operations, and projects with its operational characteristics. In other words, the EA would define how information and technology should support the business (healthcare in this case) operations and provide benefit for the business.

The HNSF can be considered as a component that can feed into the overall enterprise architecture (EA) for the national healthcare system. Such an EA does not exist yet, but would be a prerequisite for the development of a comprehensive standards framework covering all aspects of eHealth (i.e. beyond the interoperability issues covered by the HNSF for interoperability in eHealth). The implementation and application of the HNSF cannot be done in isolation from such an EA. Both these components need to feed into the finalisation of the National Department of Health's ICT strategy. The ICT strategy is required to lift the moratorium of the acquisition of information and communication technology in the public health sector [National Department of Health, 2010b]. Furthermore, the focus of the NSF is demarcated exclusively on a subset of information technology (IT) aspects as they relate to eHealth, and excludes any other healthcare technology or healthcare infrastructure norms and standards (the latter which is the focus of another NDoH-CSIR project).

An analogy with city planning can be used to clarify the concept of EA. In city planning, building structures that are to be constructed must adhere to municipal *standards* so they do not ruin the flow of traffic and/or overwhelm the available city resources. New buildings must be able to plug into common, shared assets like the electrical grid, and the water and sewer systems. If a building does not follow the city plan and standards when it is constructed, it would need to construct its own roads, set up its own power generator, provide its own water supply, and install its own sewerage system.

Likewise, it is through EA that enterprise systems become 'civilized' so it can efficiently interoperate, scale and grow. In order for the healthcare system to operate in a coherent and integrated way, it should make use of a standards-based approach to underpin, define and describe the components feeding into its EA and eHealth system.

An overall enterprise architecture for healthcare can be described using six viewpoints:

1. *The executive perspective*: Focuses on the purpose, scope and policies for the 'healthcare system'. This view describes the business purpose and strategy, which defines the playing field.
2. *The business perspective*: Describes the business requirements and how to meet them (i.e. the business models). This is a description of the organisation within which the healthcare information

system must function. Analysing this view reveals which parts of the enterprise can be supported by technology.

3. *The architect perspective*: Describes the puzzle pieces that deliver the system's functionality and the way those pieces interact with each other, and also outlines how the system will satisfy the organisation's information needs (sometimes referred to as the computational and information viewpoints). The representation is free from solution-specific aspects or production-specific constraints.
4. *The engineering perspective*: Describes the technology specification models and is concerned with the infrastructure required to support system implementation and distribution. This is a representation of how the system will be implemented. It makes specific solutions and technologies apparent and addresses production constraints.
5. *The technical perspective*: Describes the tool configuration models. These representations illustrate the implementation-specific details of certain system elements: parts that need further clarification before production can begin. This view is less architecturally significant than the others are because it is more concerned with an individual part of the system than with the whole.
6. *The operational/implementation perspective*: Refers to operational systems.

The HNSF, which is the subject of this document, only refers to the first three of these viewpoints: executive, business and architect perspectives, and *does not* refer to a particular instantiation (i.e. a particular healthcare system). Systems built using different topologies, or different technologies, can achieve interoperability as long as their executive, business and architect perspectives are consistent with each other, or can be made to align. The HNSF provides the 'standards' for developing interoperable eHealth systems and is not prescriptive regarding the specific infrastructure or technology stack that a particular eHealth system employs, although a suggestion for such an infrastructure is made. The goal of the HNSF is to enable interoperability between eHealth solutions that are based on the Framework.

The contribution/link of the HNSF to each of the executive, business and architect perspectives is briefly discussed below.

1.1.4.1 *Executive perspective*

The development of the executive perspective for the HNSF was guided exclusively by the eHealth Strategy for South Africa 2012-2016 [National Department of Health, 2012b] and typical healthcare processes in South Africa (see business perspective).

The research team also studied international best practice (for example the WHO-ITU eHealth Strategy Toolkit and other strategies for eHealth [WHO, 2004; WHO and ITU, 2012]) and typical approaches followed by other countries, for example Europe [CEN/TC 251, 2009a; European Commission, 2008; HIMSS, 2010; HIQA, 2011; Van der Veer & Wiles, 2008], Australia [Deloitte Touche Tohmatsu, 2008; NEHTA, 2007], the USA [NeHC, 2012], Africa [Anon, 2010], Canada [Canada Health Infoway, 2011b], Philippines [Department of Health Republic of the Philippines, 2010, 2011], BRICS countries [de Faria Leão, 2007; SGPGI Telemedicine Programme, n.d.; Zhao et al., 2009; Zhao et al., 2010], to determine a baseline for determining the concepts to study in developing the Normative Standards Framework.

The research team also had discussions with health standards experts, including representatives of international standards bodies and the World Bank, and studied the current eHealth standards accepted by the SABS (SANS).

The outcome of this study enabled the research team to establish a context that can be used to determine the set of eHealth standards that might be applicable and relevant to the future development of health information systems in South Africa.

1.1.4.2 *Business perspective*

The business perspective of the HNSF describes the healthcare delivery workflows and functions that characterise the healthcare system.

The business perspective was expressed through:

1. Developing a set of use case stories, which personify specific healthcare delivery use cases.
2. Using a scenario-based approach to develop the use cases representing typical healthcare processes/functions. Several of the use cases are generic and can be used to support a number of other care scenarios. The scenarios were developed at four levels of maturity (see section 3.1.2), taking cognizance of the fact that various levels of maturity may exist in the South African healthcare information systems context, and the HNSF should make provision for such maturity levels (see architect perspective).
    a. The typical scenarios were selected to reflect the quadruple burden of disease in South Africa [National Department of Health, 2010a] and include: HIV/AIDS diagnosis and management; tuberculosis diagnosis and management; diabetes diagnosis and management (as an example of chronic disease / non-communicable management); child health (in the form of an immunisation scenario); maternal health (in the form of antenatal, intra-natal and post-natal care); and the management of emergencies (focusing on injury and violence). These scenarios were defined in detail and verified for completeness and correctness through interactions with knowledgeable healthcare professionals and during the fieldwork visits to the Provinces and selected NHI Districts.
    b. The scenarios and use cases were described at different levels of maturity, allowing for growth and adaptation from a paper-based system up to a fully integrated IT system, whether point-to-point systems, centralized repositories or cloud-based implementations (the specific technology architectures to be used are beyond the scope of the HNSF project).
3. A study of typical baseline functions (business processes) was done by studying healthcare information systems deployed internationally and systems currently in use at public healthcare institutions in South Africa, as deployed by the Provinces and the NHI Districts (see [CSIR and NDoH, 2013a] and section 3.1.4).
4. The resulting set of functions was mapped to the scenarios and refined (calibrated) and verified during the fieldwork in order to address any misconceptions or omissions.

1.1.4.3 *Architect perspective*

The architect perspective describes how the 'conversations' in the business (healthcare) are conducted and addresses both the information flows needed to drive the use cases documented, and which participants (actors) in the workflow must exchange the information documented.

In order to illustrate the combined use of the various standards and to ensure interoperability, the architect perspective was documented using sequence diagrams (see Appendix D for an example), describing the sequence of information exchanges between workflow participants (or actors). Wherever possible, standards-based specifications/profiles have been leveraged and referenced. Where no existing standards exist, the gaps were identified.

1.1.5 WHO resolution on eHealth standardization and interoperability

The work on the HNSF is directly relevant to a January 2013 resolution by the Executive Board of the World Health Organization (WHO). At the 132nd session of the Executive Board of the WHO, which took place on 28 January 2013, the following resolution was passed under Item 10.5. The text is taken verbatim from the WHO documentation [World Health Organisation, 2013a].

132nd session **EB132.R8**
Agenda item 10.5 **28 January 2013**

eHealth standardization and interoperability

The Executive Board,
Having considered the report on eHealth and health Internet domain names,
RECOMMENDS to the Sixty-sixth World Health Assembly the adoption of the following resolution:
The Sixty-sixth World Health Assembly,
Recalling resolution WHA58.28 on eHealth;

- Recognizing that information and communication technologies have been incorporated in. the Millennium Development Goals;
- Recognizing that the Regional Committee for Africa adopted resolution AFR/RC60/5 on eHealth in the African Region and that the 51st Directing Council of PAHO adopted resolution CD51.R5 on eHealth and has approved the related Strategy and Plan of Action;
- Recognizing that the secure, effective and timely transmission of personal data or population data across information systems requires adherence to standards on health data and related technology;
- Recognizing that it is essential to make appropriate use of information and communication technologies in order to improve care, to increase the level of engagement of patients in their own care, as appropriate, to offer quality health services, to support sustainable financing of health-care systems, and to promote universal access;
- Recognizing that the lack of a seamless exchange of data within and between health information systems hinders care and leads to fragmentation of health information systems, and that improvement in this is essential to realize the full potential of information and communication technologies in health system strengthening;
- Recognizing that, through standardized electronic data: health workers can gain access to fuller and more accurate information in electronic form on patients at the point of care;
- Pharmacies can receive prescriptions electronically; laboratories can transmit test results electronically; imaging and diagnostic centres have access to high-quality digital images; researchers can carry out clinical trials and analyse data with greater speed and accuracy; public health authorities have access to electronic reports on vital events in a timely manner, and can implement public health measures based on the analysis of health data; and individuals can gain access to their personal medical information, which supports patient empowerment;
- Recognizing that advances in medical healthcare, coupled with an exponential increase in the use of information and communication technologies in the health sector and other related fields, including environment, have brought about a need to collect, store and process more data about patients and their environment in multiple computer and telecommunication systems;
- Recognizing that the electronic collection, storage, processing and transmission of personal health data require adherence to the highest standards of data protection;
- Recognizing that the electronic transmission of personal or population data using health information systems based on information and communication technologies requires adherence to standards in health data and technology in order to achieve a secure, timely and accurate exchange of data for health decision-making;
- Emphasizing that scientific evaluation of the impact on healthcare outcomes of health information systems based on information and communication technologies is necessary to justify strong investment in such technologies for health;

- Highlighting the need for national eHealth strategies to be developed and implemented, in order to provide the necessary context for the implementation of health data standards, and in order that countries undertake regular, scientific evaluation;
- Recognizing that it is essential to ensure secure online management of health data, given their sensitive nature, and to increase trust in eHealth tools and health services as a whole.

1. URGES Member States:
    a. to consider, as appropriate, options to collaborate with relevant stakeholders, including national authorities, relevant ministries, health-care providers, and academic institutions, in order to draw up a road map for implementation of health data standards at national and subnational levels;
    b. to consider developing, as appropriate, policies and legislative mechanisms linked to an overall national eHealth strategy, in order to ensure compliance in the adoption of health data standards by the public and private sectors, as appropriate, and the donor community, as well as to ensure the privacy of personal clinical data;

1. REQUESTS the Director-General, within existing resources:
    a. to provide support to Member States, as appropriate, in order to integrate the application of health data standards and interoperability in their national eHealth strategies through a multi-stakeholder and multi-sectoral approach including national authorities, relevant ministries, relevant private sector parties, and academic institutions;
    b. to provide support to Member States, as appropriate, in their promotion of the full implementation of health data standards in all eHealth initiatives;
    c. to provide guidance and technical support, as appropriate, to facilitate the coherent and reproducible evaluation of information and communication technologies in health interventions, including a database of measurable impacts and outcome indicators;
    d. to promote full utilization of the network of WHO collaborating centres for health and medical informatics and eHealth in order to support Member States in related research, development and innovation in these fields;
    e. to promote, in collaboration with relevant international standardization agencies, harmonization of eHealth standards; and
    f. to report regularly through the Executive Board to the World Health Assembly on progress made in the implementation of this resolution.

1.2 eHealth context

In developing the HNSF and the scenarios, the following health record dimensions were used:

- The *completeness of the information* can be defined along two dimensions [Canada Health Infoway, 2011a]:
    - A partial health record that holds a portion of the relevant health information about a person over their lifetime.
    - A complete health record that holds all relevant health information about a person over their lifetime.
- The possible *custodian of the health information* can be a [Canada Health Infoway, 2011a]:
    - Healthcare provider(s).
    - Person(s).
- The *foundation of messaging*: In a fully integrated eHealth system, each of the services within the system exposes their functionality through a messaging paradigm. For example, when a system that implements the shared electronic health record (EHR) needs to validate patient demographic

information, it consumes the patient registry service as part of its data validation process [Fyfe, 2012]. The messaging paradigm is core in eHealth and forms an essential foundation in the scenarios.

The HNSF refers to three types of health records:

1. *Electronic medical record* (EMR): An electronic medical record (EMR) is an electronic record of an episode of medical care within a single institution e.g. a general practitioner (GP) practice or a single hospital. It is a partial health record under the custodianship of a healthcare provider(s) that holds a portion of the relevant health information about a person over their lifetime [Canada Health Infoway, 2011a]. This is often described as a provider-centric or health organisation-centric partial health record of a person [Canada Health Infoway, 2011a].
   Scope of EMR: A combination of person and provider.
2. *Electronic health record* (EHR): A longitudinal complete health record, under the custodianship of a healthcare provider(s), of patient health information across multiple care settings that holds all relevant health information about a person over the person's lifetime. This is often described as a person-centric health record, which can be used by many approved healthcare providers or healthcare organisations [Canada Health Infoway, 2011a; HIQA, 2011]. It includes " (1) longitudinal collection of electronic health information for and about persons, where health information is defined as information pertaining to the health of an individual or healthcare provided to an individual; (2) immediate electronic access to person- and population-level information by authorised, and only authorised, users; (3) provision of knowledge and decision-support that enhance the quality, safety, and efficiency of patient care; and (4) support of efficient processes for healthcare delivery" [IOM, 2003: 1]
   Scope of EHR: A longitudinal, person-centric and shared health record.
3. *Personal health record* (PHR): A personal health record (PHR) is a complete or partial patient-held record under the custodianship of a person(s) (e.g. a patient or family member) that holds relevant health information about that person over their lifetime [Canada Health Infoway, 2011a; HIQA, 2011]. It may include information provided by a healthcare provider as well as information provided by the patient [HIQA, 2011]. This is also a person-centric health record.
   Scope of PHR : A person-maintained and managed health record; potentially a superset of EHR.

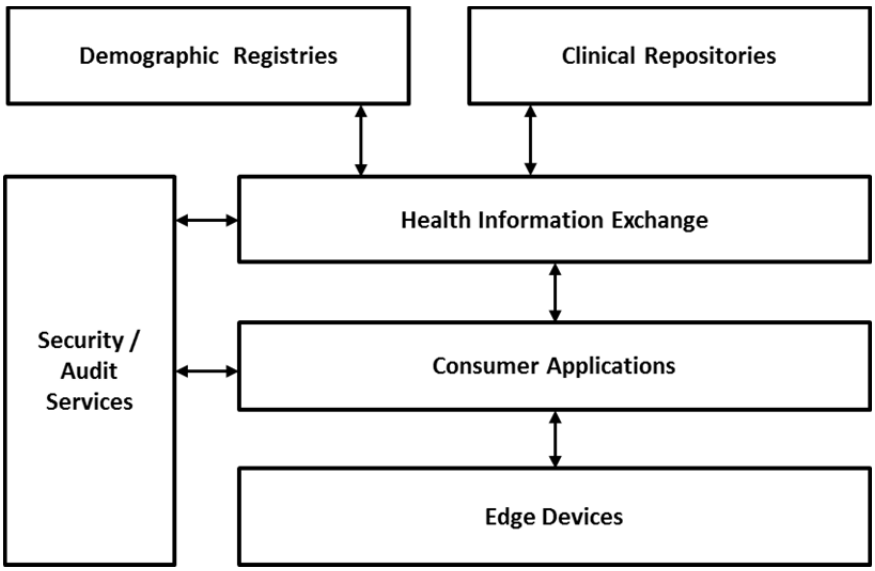

Figure 3: Generic eHealth architectural components

The HNSF references the following eHealth related generic architectural components (services). Figure 3 illustrates, on a high level, the relationship between these components [Fyfe, 2012]:

- *Demographic registries*: The storage and matching of demographic information related to various entities that participate in healthcare events.
  - *Patient registry (or patient master index (PMI):* Maintains demographic information related to any of the patients within the system. One should be able to do searches in the registry based on demographic information (search by name, age, gender, etc.) and recording of patient demographic information (add/update patient demographic data, etc.). The PMI is a synonym for a master patient index (MPI).
  - *Provider registry*: Maintain provider data such as name, role within the healthcare system, address, etc. One should be capable of searching for providers by demographic information (names, roles, address, etc.).
  - *Facilities registry:* Register of healthcare facilities. It is responsible for the maintenance and search of facilities (service locations) within the system. Facilities data includes attributes such as name, physical locations, offered services, contact information, etc. It should support searching facilities by name, service offered and physical location.
  - *Equipment registry:* Register of expensive/scarce/uncommon healthcare equipment. It is responsible for maintaining a register of where a particular type of healthcare equipment is located. Equipment data includes attributes such as type/name of equipment, model, physical location, uses, contact for use, etc.
- *Clinical repositories*: Clinical repositories are responsible for the storage of data related to healthcare events. These repositories can be general purpose (such as a document repository) or targeted repositories for a specific purpose (e.g., HIV or TB programme repositories). Examples include a document repository, shared health records, lab repositories, imaging repositories, etc.
  - *Electronic health record*: Used to describe a logical clinical repository that is responsible for the aggregation of data related to patient care during the lifetime of a patient.
  - *Document repository*: Responsible for the registration, query and maintenance of clinical documents within the system.
  - *Terminology registry*: Responsible for the maintenance, validation, mapping, query and relation of codified concepts within the system. Maintains a master set of concepts and provides the ability to map concepts between different codification systems such as ICD-10.
- *Health information exchange (HIX):* The HIX is middleware and responsible for the orchestrating (managing the workflow) and of integrating the jurisdictional registries and clinical repositories. It is responsible for providing a single, coherent set of interfaces through which consumer applications can communicate with registries.
- *Security and audit services*: The security and audit services are a set of federated services that are used by the HIX, repositories and registries, and clients to facilitate enterprise authentication, and auditing. It includes:
  - *Audit repository*: Responsible for the storage of audits generated by various services within the health enterprise. It represents a federated audit platform that facilitates health systems monitoring and reporting. The audits sent to the audit repository are expected to be near real-time in nature and should contain the following information: who was involved in the clinical act, when the act occurred, where the act occurred, what information was affected, and how the information was affected.
  - Federated security system.
  - Certificate services.
- *Consumer applications*: Refer to gateways, frameworks and application programming interfaces (APIs) that will be used to integrate edge devices into the system. This may, for example, include:
  - Health information systems (HIS) for electronic medical records.

  - Short Message Service (SMS) gateways.
  - Interactive Voice Response (IVR) gateways.
  - Integration APIs / toolkits.
- *Edge devices*: The physical hardware devices that will be used by end-users to access consumer applications.

1.3 Scope of the HNSF

The scope of the HNSF is defined within the following context:

1. Within eHealth, the focus of the HNSF is primarily on semantic, syntactic and organisational interoperability (limited to the data flows in certain work processes) within the context of patient-centric healthcare management information systems. Technical interoperability is referred to only as far as messaging is concerned.
2. Four levels of technical maturity can be defined in healthcare information systems sharing electronic health record information with each other (see section 3.1.2 for details):
   - Level 1: Local paper-based medical records.
   - Level 2: Local paper-based medical records with some IT support.
   - Level 3: A centralised shared electronic health record (EHR) system with mixed-mode local medical records (both papers based and electronic medical records (EMRs)).
   - Level 4: A fully integrated national shared EHR system with local EMRs.

   The HNSF applies to Levels 3 and 4.
3. Interoperability standards are required for the sharing of patient-centric data, held in the shared national EHR and other clinical repositories, with accredited health information systems.
4. The HNSF focuses on interoperability concerning interacting with a shared national eHealth infrastructure and a shared electronic health record (EHR) system, and specifically on patient-centric functions. It only focuses on systems that use and update data in such a shared infrastructure and shared EHR.
5. The HNSF does not address the internal design of systems that support on non-patient centric functions (e.g. financial (payment) and accounting systems, human resource systems, etc.), aggregate data at district/provincial, etc. level, or clinical care IT systems (e.g., cardiovascular care systems, radiology or pathology systems, etc.). However, if any of these system interact with, or use data from, or upload data to the shared national eHealth infrastructure and a shared electronic health record (EHR) system, the HNSF will apply.
6. The set of general IT standards that are applicable to the selected IHE profiles are also identified and their compatibility with the Minimum Interoperability Standards for Government Information Systems (MIOS V5) determined. Although compatibility with MIOS V5 has been determined, it will only be used as reference point to the standards underlying the selected profile, but any verification, adherence testing or enhancement to the complete MIOS V5 remains the role of SITA.
7. The content of the shared EHR should be tested to determine to what extent business requirements are satisfied. The shared content in the EHR must be a reliable source to support continuity of care and for the generation of national indicators. Since the data model for the shared EHR is not available as yet, the National Indicator Data Set (NIDS) [National Department of Health, 2010c] was used as baseline to determine the functions and data requirements to be supported by the HNSF. Once the data model for the shared infrastructure and shared EHR have been established, the HNSF will be adapted to accommodate any shortcomings that may not be covered by the current version of the HNSF.

1.4 Assumptions of the HNSF and general philosophy followed

The general philosophy followed for developing the HNSF is that of *adopt*, *adapt* and *develop* (in that order). The approach adopted is to first consider existing standards that could meet the requirements, only adapt these when essential and only develop a new standard when there is no other alternative. Adherence to these principles would ensure that the research team could leverage international best practice and avoid duplication of effort, as well as ensuring that only tried and tested standards, which are already used in the development of software products, are selected for use.

The development of both the Normative Standards Framework and its associated implementation guidelines and governance model is based on the following assumptions:

1. A *shared national infrastructure and national electronic health record for eHealth* exists.
2. Interoperability is required for the exchange of patient-based transactional data between the *point of care* and/or the *local EMR system* and the *shared national infrastructure and the national* EHR, in order to support continuity of care, service remuneration and the aggregation of data health metrics.
3. The HNSF and its associated assessment instrument directly affects any exchange of patient-based transactional data, from a regional or healthcare facility-based EMR system, to the *shared national infrastructure and the national electronic health record*.
4. Interoperability between the various modules of a regional or local healthcare facility-based EMR system is *not directly affected* by the HNSF. However, the interactions with the shared EHR will be simplified if the same principles and standards were used for the local healthcare facility-based EMR system, i.e. if the healthcare facility-based EMR is based on the same standards as required for the shared EHR and interacting with the shared EHR.
5. The data held in the shared national EHR will primarily be used for:
    a. Provision of continuity of care for patients across different service providers and healthcare facilities.
    b. Generation of national healthcare metrics, which are defined in the National Indicator Dataset (NIDS) [National Department of Health, 2010c].
6. The HNSF only focuses on interoperability with a national shared electronic health record (EHR) system, and specifically only on patient-centric functions. It only focuses on systems that use and update data in such a shared EHR. Peripheral systems, such as financial (payment) and accounting systems, human resource systems, etc. are excluded.
7. Interoperability standards are also required for the sharing of patient-based data, held in the shared national EHR, with accredited healthcare service providers.
8. As per the eHealth Strategy South Africa 2012-2016 [National Department of Health, 2012b], an eHealth Standards Board for South Africa exists, or is to be established, to maintain and govern the implementation of the HNSF, as well as the standards referred to in the HNSF. The ESB should work closely with healthcare providers and other relevant stakeholders to govern the implementation of the HNSF, and develop, adopt and maintain eHealth standards-based profiles and standards. The role of the ESB should include:
    a. Identification of care guidelines, workflows, activities and information sharing requirements for each specific business use case occurring in the South African patient care context.
    b. Ongoing review of standards-based profiles and base standards to ensure that these support the business use cases and business processes.
    c. Creation and maintenance of a data model for a shared EHR repository for South Africa. The data model must define the exact data structure for the shared electronic health record and the information that must be exchanged with the shared infrastructure. This will be determined by the minimum essential information required for continuity of care,

reimbursement and generation of the national health metrics, the NIDS. This data structure will be accompanied by a national data dictionary, defining all data elements to be used in eHealth and other health information systems in South Africa. The ESB should work closely with key officials in NDoH in order to ensure that the data model and the related national data dictionary are aligned with the NIDS at all times, and that any changes in workflows, care protocols and functions are reflected in the mandatory standards-based profiles and base standards where necessary.

d. Adoption, adaption, localisation and development of standards-based profiles and base standards for South Africa, whenever gaps emerge. This would include a set of content standards (coding and terminologies and information display) and guidelines for their implementation.
e. Establishing a national compliance function within the ESB to test and certify that eHealth solutions comply with national eHealth standards, rules and protocols.
f. Provision of guidelines to developers and suppliers of health information systems with respect to the use of standards-based profiles and standards.
g. Establishing a set of evaluation criteria against which to test whether a candidate software application complies with the adopted, localised and mandated standards-based profiles and their related base standards.
h. Provision of a platform for developers and suppliers to test their software applications against the mandatory requirements of the HNSF.
i. With the guidance of IHE, organising a South African national or regional '*connectathon*'[1] to test the interoperability capability of systems that are currently implemented or candidates for implementation.
j. The ESB should also have the role to represent South Africa on international standards development organisations and other entities related to eHealth standardisation.

9. The *moratorium on the acquisition of new health information systems in public healthcare* cannot be lifted based on the proposed *National Health Normative Standards Framework for Interoperability in eHealth* alone. The National Department of Health's ICT strategy and the enterprise architecture (EA) for eHealth must be completed first: i.e. the Infrastructure and Services and Applications components must be specified first, and the architecture for the national data centre (shared infrastructure) for eHealth, which will store and manage the shared national electronic health records, all the registries and manage the workflows and security aspects must be established.

1.5 Layout of the rest of the report

To put the development of the HNSF in perspective, Section 2 of this report analyses the eHealth standards landscape. Section 3 describes the development of the HNSF and the result, i.e. the HNSF. Section 4 describes the operationalization of the HNSF. Section 5 uses the HNSF to evaluate the health information systems currently deployed in the country. Section 6 concludes with recommendations on the way forward.

[1] The testing process employed by the IHE is called a 'connectathon'. It provides coordination, tools and opportunities for face-to-face interoperability testing for vendors and developers of healthcare IT systems implementing IHE profiles and integration capabilities. Connectathons are held regularly in Europe and North America, with events in other countries becoming more frequent.
A connectathon allows participating software vendors or developers to test their implementation of IHE profiles and to benchmark their products against their peers. During a connectathon the participating systems exchange information with each other, performing all of the transactions required for the particular use cases and roles they have opted to be tested in. The results of testing are recorded and made available for review.

2 THE STANDARDS LANDSCAPE

This section analyses the eHealth standards landscape. It highlights some of the barriers in standards adoption with a focus on the two core issues, namely selecting the best standard (see section 2.1) and the implementability of standards (see section 2.2). The classification of the various levels of standards used in eHealth is discussed in section 2.3.

2.1 Selecting the 'best' standard

Any standard that supports interoperability should have a clearly expressed scope, purpose and statement of relationship to other standards with a plan to provide enhancements only on an 'as required' and incremental basis. In this regard, issues that affect the selection of appropriate standards are [CEN/TC 251, 2009a; Van der Veer & Wiles, 2008]:

- *Gaps in the coverage of standards (incompleteness)*: Individual or expected sets of standards often fail to cover all the necessary aspects required for implementation. Specifications are often incomplete (even though unintentionally), with aspects essential to interoperability missing, or only partially specified. This often results in a so-called 'local' adaptation, which leads to a lack of interoperability.
- *Overlap between standards*: Sets of standards often have duplicated coverage of specification at crucial points, which would lead either to unwanted optionality or to inherent inconsistency and conflicting provisions with conflicting coverage of analogous concepts. Adopting a set of standards therefore requires an analysis of incompatibilities and interdependencies with other existing and widely used standards.
- *Combination of standards from different SDOs*: When different standards from different sources are combined, it is generally required to make choices regarding the linkages between these standards. It is not unusual for interfaces critical to interoperability to be inadequately identified or not clearly defined. Implementations of the same combination of standards with different approaches to linking them results in incompatibilities and non-interoperability. The interdependencies between standards should clearly be described.
- *Standards do not address all communication levels*: A standard may have invalid assumptions about the ability of another aspect of the operational, process or technical infrastructure to support its provisions. A standard should be specific about the nature and quality of services expected of other communication levels.

2.2 Implementability of standards

The technical excellence of a standard may reduce its implementability, especially if it has no relationship to other relevant standards. A technically comprehensive standard inclines to be inaccessible to those not involved in its production, which may in turn result in implementation errors and lack of interoperability. Other issues that influence the implementability of standards are [CEN/TC 251, 2009a; Van der Veer & Wiles, 2008]:

- *Standards evolve faster than the time to implement the standard*: The temptation exists amongst technical experts to polish a finished, or completing, a standard on a timescale that is shorter than the time taken to align to it in a product life cycle. Any standard expected to support interoperability should be stable and revised only when it serves the needs of the market to do so.
- *Standards can only be implemented if finalised*: The attempt to achieve perfection in a standard can cause a resource to be redeployed before delivery is achieved. Uncertainty caused by stalled production introduces adoption paralysis amongst would-be implementers, whilst waiting for the definitive version of a standard.

- *Standards offer too many options*: Since standards development is often a consensus-based approach, the wish to accommodate the 'needs' of different parties typically results in unsought, and often undocumented, optionality. A standard may contain too many options, or the options may be poorly specified. Unintended optionality results in variability of implementation to the extent that interoperability is lost. For example, there may be an imprecise understanding of the consequences if certain options are not implemented. Worse still, there may be inconsistencies – even contradictions – between various options. Any standard expected to assist interoperability should have a clear constraint of optionality and dependency. Incomplete, unclear standards with poorly specified options can contribute to the biggest single cause of non-interoperability, with the implementer forced to make potentially non-interoperable design decisions on critical parts of the system based on a lack of information.
- *Poor maintenance of standards*: Lack of version control, unclear indications of exactly which requirements (mandatory and optional) are covered by a certain release of a standard, and lax change request procedures can have a negative impact on interoperability.
- *Standards address application needs only in a generic way*: A standard may be so non-specific about addressing healthcare domain requirements that it must be interpreted to make it adequately specific. Generic standards are useful to assist coherence of architectural strategy but should not be produced or used, without clear declaration of the application domain, as the sole basis for interoperability.
- *Lack of clarity*: There is a distinct skill in writing a good standard, which is well structured and distinguishes between what needs to be standardized and what not. It should not mix concepts; specify the same thing in several different ways; be confusing; too verbose or too cryptic.
- *Poor implementer inputs to standards writing*: Lack of implementer engagement can result in theoretical standards with little or no real-world value, resulting in standards that are too complex or technically demanding to be applied.
- *Poorly defined, or absent, conformance criteria*: Any standard expected to assist interoperability should contain clear and rigorous conformance criteria. The absence of clear and rigorous conformance criteria allows for poor implementations and contract disputes. Lack of specified ways to test genuine conformance to a standard, can prevent proper implementation and successful application of a standard.
- *Paper only informatics standards*: Paper only standards are the default means of publication by many official standards organisations, but are unsuited to support information system implementations. Any standard expected to assist interoperability should have either the content available in electronic form and used 'as is' to produce a test implementation, or informative and web-based material and tools freely available to support dissemination and testing.

2.3 How are standards categorised

Standards for eHealth can be classified according to the different perspectives/levels they support, each with a varied target group, for example [CEN/TC 251, 2009a]:

- Business level, e.g., standards for the definition of user use cases.
- Semantic level, e.g., standards for information, nomenclatures, coding, and conceptual models.
- Syntactic level, e.g., data formats; message formats (syntax and encoding), etc.
- Functional level, e.g., definitions of the functions supported by systems and reflecting the needs of users (e.g. creating a patient identifier).
- Application level, e.g. description of the architecture based on a grouping of functions.
- Technical level, e.g. communication protocols.

The perspective classification is closely linked to the types of interoperability found in the healthcare domain (as discussed in section 1.1.3) and to enterprise architecture (see section 1.1.4).

Within the healthcare environment it is, however, not sufficient to specify a list of standards that are mandatory for eHealth projects and to which developers and vendors should comply. What is needed is an agreed set of guidelines that define how these standards will be applied, in a coordinated way, within a specific healthcare domain or setting. These guidelines form building blocks referred to as 'standards-based profiles'. For example, a profile for the sharing of electronic health record documents between providers and facilities will specify exactly which standards apply and how they should be implemented.

The HNSF makes use of three sets of standards-based building blocks: *base standards*, *standards-based profiles* and *interoperability specifications*, as illustrated in Figure 2-1. These building blocks are used to specify business and technical use cases. A typical business use case for eHealth would be a 'chronic disease management system. Business use cases for eHealth are broken down into several technical use cases, for example patient identification, patient registration, etc. A specific technical use case can be reused in several business use cases. The technical use case specifications create an intermediate layer of interoperability building blocks, which should be modular to allow for flexible recombination, form a manageable portfolio and reduce the risk of building incompatible solutions to the same use case.

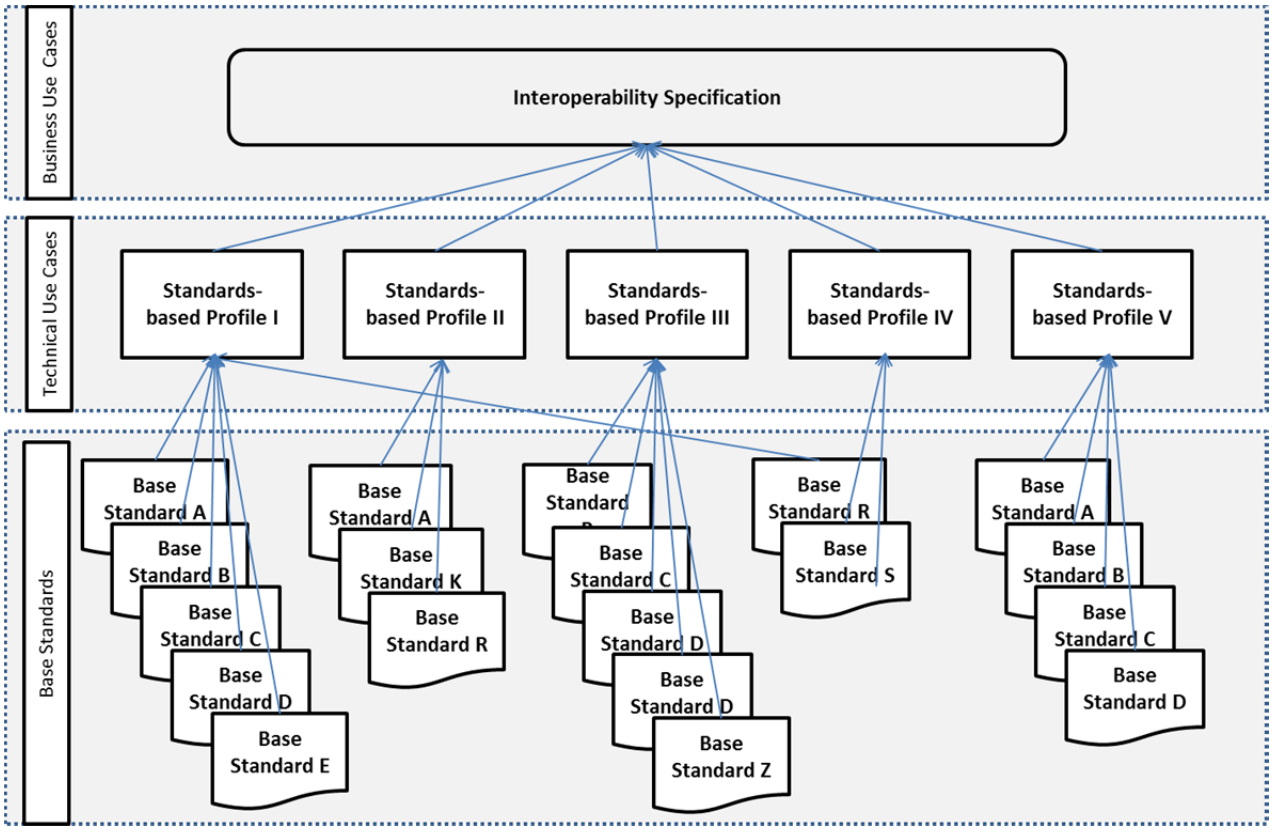

Figure 2-1: Standards-based building blocks (adapted from [CEN/TC 251, 2009a])

2.3.1 Base standards

Base standards define terminologies, data structures and protocols that are foundational to delivering interoperability and are required for consistency. Examples of base standards for interoperability are the various ISO and ANSI standards related to eHealth, HL7 V2.X, etc.

Base standards may be healthcare specific or can be applicable across a wide range of industries to achieve fundamental information technology (IT) communication or security management. Base standards are foundations to enable the creation of elementary services, messages and documents to support any possible use case domain. In general, such base standards are generic and either:

1. broad in scope and range of use cases they may support, so that in reality only a subset of provisions is generally used, or
2. very specific and need to be combined with other base standards to address any real-world use case .

The base standards related to eHealth can be classified into different categories. The HNSF applies the following categories [European Commission, 2008; WHO and ITU, 2012]:

- Identifier standards (functional, syntactic, semantic).
- Messaging standards (syntactic).
- Coding and clinical terminology and classification standards (semantic).
- Content and data structure standards (functional).
- Electronic health record standards (application).
- Health specific security and access control standards (technical).
- General IT standards (technical).

Selecting a base standard for a specific use case from scratch would in general start with anywhere between 500 and 800 relevant standards to analyse for applicability, ending up with between 20 and 30 standards to apply. This is not only a major effort, but would need to be repeated for every project, often leading to significant variance in the set of standards selected and consequently leading to non-repeatability and failing to deliver interoperability with other projects of similar and sometimes identical scope, within the same country or across different countries.

As a point of departure, the research team conducted an in-depth baseline literature review and a study of leading international healthcare information systems to determine the set of eHealth base standards that could be applicable to the South African healthcare landscape. The resulting list of standards is presented in Appendix A.

2.3.2 Standards-based profiles

Within the healthcare environment it is, however, not sufficient to specify a list of base standards that are mandatory for eHealth projects and to which developers and vendors should comply. To address the challenges of organising the many facets of interoperability in eHealth, which address different and distinct domains, but recognising that any eHealth project would require a patchwork of different standards, an intermediate level of standards-based profiles is required, which would allow flexibility without a negative impact on interoperability requirements

A *standards-based profile* is an agreed set of guideline building blocks that define how the *base standards* will be applied, in a coordinated way, to address a specific *technical use case* within a specific healthcare domain or setting. These standards based profiles are required to specify interoperability requirements and are interoperable building blocks, which can be re-used on many projects. They form a ‘glue’ layer

specification that both combines and refines the use of a set of base standards to address a specific technical use case [CEN/TC 251, 2009a]. For example, a profile for the 'sharing of patient medical summaries between providers and facilities' technical use case will specify exactly which standards apply and how they should be implemented.

eHealth profiles address a broad range of interoperability aspects covering security, privacy, patient identification, record sharing and access, care coordination record content, specialty record content, home monitoring, referral and consultation workflows. eHealth profiles are defined to ensure relative independence and allow for different approaches to their orchestration (e.g. address a broad range of country specific security and privacy policies).

The most well-known and widely used example of a set of profiles for eHealth is the profiles developed by *Integrating the Healthcare Enterprise* (IHE) and is the set of profiles used in the HNSF. Each IHE profile describes the solution to a specific integration problem, and document the system roles (actors), standards and design details for implementers to develop systems that cooperate to address that problem. The profiles only constrain the way information is exchanged and their interoperability behaviour. It does not specify how these communicating systems are designed internally, but rather focuses on their engagement

Standards generally operate at a domain-focused level in that multiple standards are required to define an integration profile. The integration and content profile level is the most practical level at which to perform interoperability conformance testing.

2.3.3 Interoperability specifications

The *standards-based profiles* would form the middle layer of the three levels of standards related specifications, as illustrated in Figure 2-1. The bottom layer is the *base standards* (on which the standards-based profiles are based) and the top layer the *interoperability specifications* (directly related to the business use cases).

Every eHealth project needs to deliver to its participants a clear set of specifications dictating the way to interface the systems used for healthcare with a shared IT infrastructure supported by a district/provincial/national health information network. Such specifications are called *interoperability specification*s (sometimes called interface specifications, implementation specifications, project specifications, etc.) and are directly related to the business use cases they aim to support. This represents the business view of IT systems, for example a 'chronic disease management system'. It has some fuzziness and flexibility due to the many ways in which one can identify and structure a business use case. Business use cases are the most successful when they cover a small and achievable scope for implementing requirements, each providing value whilst remaining achievable.

Interoperability requirements/specifications assure implementability by :

- Specifying the standards-based profiles to use, as well as their underlying norms and standards.
- Combining the right set of standards-based profiles to address the business-level use case, and would therefore be specific to a project (national, provincial, district or local to an institution).
- Enabling faster implementation, reuse of software and test tools, and an easier understanding of the customisation required by each project engaged in leveraging standards-based interoperability due to their construction being largely based on standards-based profiles.
- Addressing the specifications related to the 'interfacing' of health related management information systems to a home/point of care, district/provincial/national infrastructure, but not the internal design specification of all aspects of any such networks, or that of any IT system connected to it.

- Offering a specification on how to exchange information, not a piece of software, ensuring technology independence to support various systems, operating system environments, hardware architectures and business models.
- Being written into procurement documents when eHealth systems are required or developed.

The reuse of standards-based profiles across eHealth projects in South Africa is critical to improving the quality of interoperability specifications used in national/provincial/district/local eHealth projects. Quality control management in the profile specifications is a critical success factor. Quality assurance for profile implementations requires the development and maintenance of test plans, processes and tools, which should be easy for implementers of eHealth projects to use.

In addition to interoperability specifications, the following must also be done [CEN/TC 251, 2009a]:

- Implementation architecture choices (configurations, technical performance targets, etc.) must be made.
- Policy decisions in terms of security, privacy, data management, etc. should be taken.

These are extremely important elements in order to achieve interoperability, but are considered to be beyond the scope of this project. However, it is critical that the standards-based profiles used for assembling interoperability specifications be aligned with the range of systems architectures, security and privacy policies and regulations to be supported [CEN/TC 251, 2009a]. The standards-based profiles suggested in this report may therefore have to be adapted to suit such critical decisions.

2.3.4 From standards to implementations

Base standards, standards-based profiles and interoperability specifications form the foundation to deliver the interoperability that users of such systems (i.e. care providers, patients and health authorities) expect in implemented health information systems.

When a specification is not correctly implemented, or cannot be implemented because of internal inconsistencies or errors, it cannot deliver its promise. This is especially true in terms of interoperability, where a minor discrepancy between the information sent and the processing of the information in the receiving system, may result in a failure of interoperability. This issue is compounded in eHealth since interoperability must be assured across many systems and devices from a broad range of implementers and vendors. It is a well-known problem to the IT and Telecommunications industry, but a relatively new priority in the domain of healthcare and at a scale and in a market environment where the management of such processes among stakeholders is not yet in place. Effective quality assurance and governance are therefore extremely important and require both a process and governance mechanism [CEN/TC 251, 2009a].

The process part should address both the quality of specifications and the quality of implementations [CEN/TC 251, 2009a]:

- *Specifications*: Although much effort usually goes into the development of base standards, the quality is often difficult to assess until the standard is implemented. The same applies to profile specifications, although the narrower focus on specific technical use cases makes their quality easier to assess. Once the quality of profile specifications has been achieved, the quality of the interoperability specifications, based on well-specified business cases, can be greatly simplified.
- *Implementations*: Quality of implementations must be judged against the related use cases and interoperability specifications. It requires a strong quality assurance at profile level. Offering controlled benefits such as the right level of specification, step size, reuse, flexibility and focus.

The governance part should address issues related to [CEN/TC 251, 2009a]:

- Use case definition and prioritisation.
- Base standards adoption, adaptation, development and maintenance.
- Profile development and maintenance.
- Quality assurance of profile implementations.
- Risk management.

The process and governance aspect should both be managed by a relevant eHealth standards authority, specifically set up to address health information system issues. This authority should not only consists of standards experts: it should include representatives who have the necessary expertise to advise on all of the eHealth components (enabling and ICT environments) discussed in section 1.1.2. Development and maintenance of interoperability specifications and quality assurance of interoperability specification implementations do not fall within the direct scope of the mandate of this project. However, they need to be highlighted since they are closely related and are critical to achieve effective eHealth overall, specifically as it is related to this report.

3 DEVELOPING THE NATIONAL HEALTH NORMATIVE STANDARD FRAMEWORK FOR INTEROPERABILITY IN EHEALTH

This section addresses the development of the Health Normative Standard Framework for Interoperability in eHealth (HNSF). It investigates categories of standards, the set of functions to be supported by the HNSF, the baseline set of standards to consider, choosing between stacks of standards, and how to ensure that the selected set of standards meets the South African healthcare landscape.

The WHO/ITU National eHealth Strategy Toolkit [WHO and ITU, 2012] articulates the recommended process for development of the norms and standards to include brainstorming and working sessions to identify the required eHealth standards and interoperability components, and link these back to eHealth outcomes. In developing the Normative Standards Framework, a business-centric process consistent with the Toolkit, was followed. This process of categorising interoperability artefacts was informed by research published in support of the EU's epSOS project [CEN/TC 251, 2009a].

In developing the HNSF, a person-centric approach was adopted:

- A framework of norms and standards that support individual care delivery was considered.
- The possibility to obtain reportable indicators by de-identifying, analysing and aggregating the person-centric transaction logs was investigated.

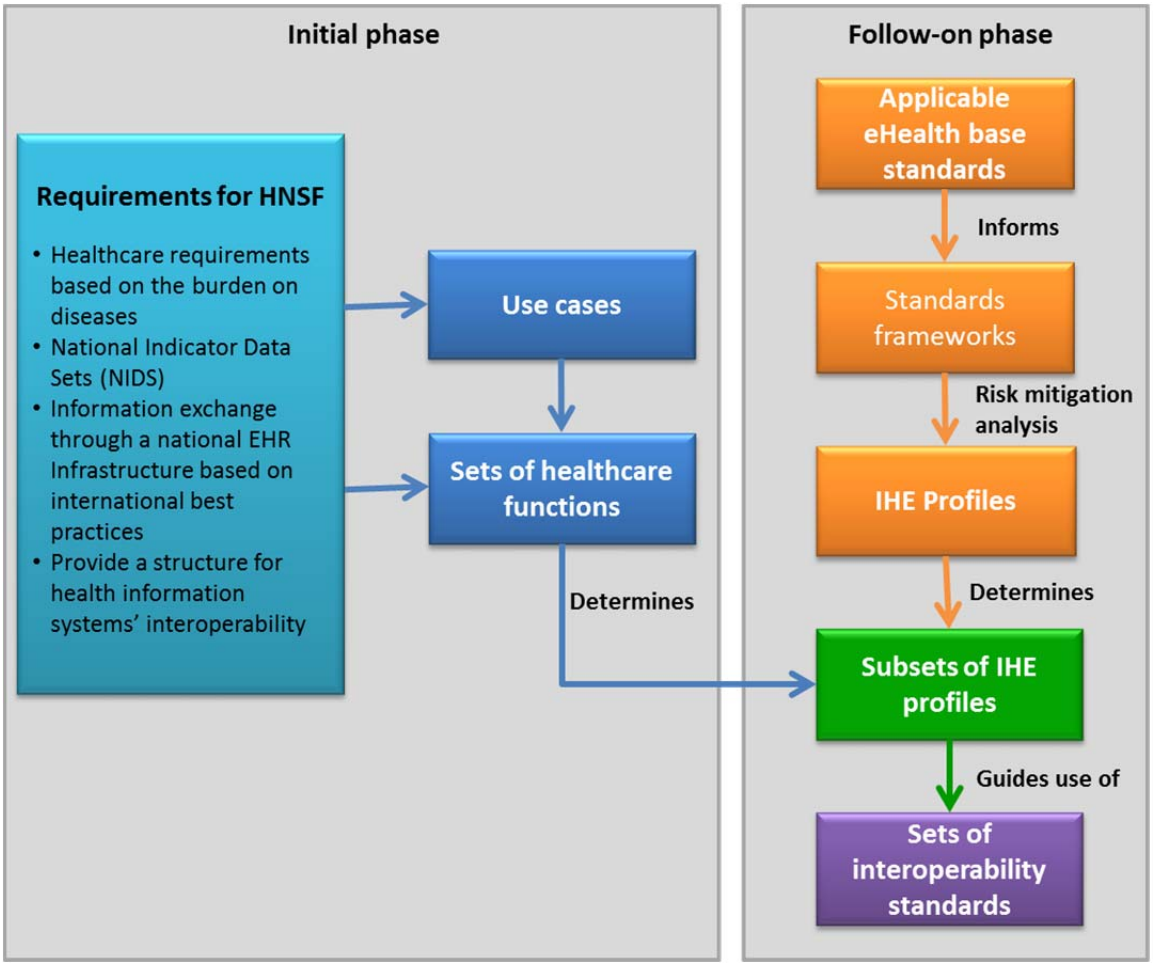

Figure 3-1: Process to develop the HNSF

Using the classification of standards as discussed in section 2.3 the process followed to develop the HNSF, at a top level, consisted of the following steps (as illustrated in Figure 3-1):

1. Determine a generic set of functions that should be supported in eHealth applications based on South African business cases.
2. Determining the baseline set of standards to consider and classify these standards.
3. Make a decision on which stack of standards to use.
4. Identify appropriate interoperability standards-based profiles for the standard stack.
5. Map the resulting set of functions to interoperability standards-based profiles.
6. Extract the relevant base standards that support the standards-based profiles.
7. Assess the suitability of the standards-based profiles and base standards (determine coverage of the Indicator Data Sets (NIDS)).
8. Identify other standards that are applicable, or which may apply to eHealth in South Africa in future.
9. Integrate the functions, profile and standards to form the HNSF.

These steps are discussed in detail in the sections 3.1 to 3.6.

3.1 Determining the set of functions to be supported

This phase in the development of the HNSF consisted of a study to determine the generic eHealth functions to be supported by the HNSF:

1. Characteristic care scenarios were developed, reflective of the South African health system context.
2. The business cases (interactions and functions/activities) for each of these scenarios were documented using sequence diagrams.
3. The set of generic functions underlying the business cases were extracted.
4. A survey of the current healthcare information systems in use by the Provinces was conducted to determine their functionality and to amend the set of functions where gaps were identified.

3.1.1 Characteristic care scenarios

Typical use cases addressing the workflows, functions and activities in South African public healthcare facilities were identified and documented. The workflows focused on were those addressing the quadruple burden of disease (BoD) in South Africa [National Department of Health, 2012a]:

1. HIV and AIDS and TB.
2. High maternal and child mortality.
3. Non-communicable diseases.
4. Violence and injury.

The care scenarios were therefore specifically themed around the BoD and included:

HIV / AIDS: The scenario features the journey of a young woman through the health system, starting from when she presents for a voluntary counselling and testing for HIV. It describes the processes that take place at the local clinic where she is tested for HIV using the finger-prick test kits. It illustrates the interactions between the patient and healthcare providers, from the reception clerk, to the nurse, counsellor, doctor, pharmacist etc., as well as her initiation on life-long Antiretroviral treatment (ART).

- *Tuberculosis (TB):* The scenario illustrates the process for diagnosing and managing tuberculosis. It reflects a common circumstance of migration from rural areas to the city in search of jobs, and the associated problem of lack of proper housing and overcrowding as contributor to the prevalence of TB.

- *Maternal and neonatal health*: This scenario (used as example in this report) is about the journey of a young pregnant mother, Pinkie, diagnosed to be HIV positive, and giving birth to a baby.
- *Immunisation (childcare):* The scenario illustrates how a baby is able to re-enter the childhood immunisation programme after she falls ill, and is taken to the clinic. It reflects the typical case of children cared for by their grandmothers, who may not necessarily understand the need for immunisation.
- *Diabetes (chronic disease management):* This scenario illustrates the care processes for a patient who has been diagnosed with diabetes. It describes the initial contact with health worker at a local clinic, from where he is referred for specialised care at district hospital because the clinic does not have a full-time doctor. The scenario illustrates the referral process, attendance at the district hospital where the patient was diagnosed with diabetes, in addition to hypertension (the primary reason for referral), the process of hospitalisation in the ward, as well as follow-up care for chronic condition.
- *Violence and injury*: The scenario reflects the common consequences of gang-related violence in the country, where an innocent boy is caught in crossfire and sustains a gunshot wound. It illustrates the processes involved in the initial care by paramedics at the scene, through to transportation of the patient in an ambulance to a hospital where he has surgery for wound debridement. It also includes his admission to the ward, as well as his follow-up care after discharge.

In drafting the scenarios, the research team also took cognizance of the fact that various level of eHealth maturity may exist in the South African healthcare information systems context, and that the HNSF should take into account such eHealth maturity levels and assist in making decisions that will enable a move to a higher level of maturity. These maturity levels are briefly:

1. A complete paper-based system using standardised forms and stationery.
2. A localised computer system for patient administration (e.g. registration, appointment scheduling). In this case, clinical information is still predominantly paper-based, but standardised forms and stationeries are used.
3. Fully networked, centralised IT-based system for clinical and patient administration. Clinical and patient administration information is primarily captured on the system by a data capturer or clerk.
4. Fully networked, centralised IT-based systems, where clinical data is captured at the point of care (PoC) directly by the healthcare professionals. Extra devices for PoC entry of data are required.

The maturity levels are discussed in more detail in section 3.1.2. The workflows for these four levels of maturity will differ considerably between the lowest and highest levels. Using the scenarios, those healthcare functions that can be supported using eHealth tools were identified where appropriate. The eHealth concepts (different types of patient records and the architectural component), as defined in section 1.2, are used to describe the four maturity levels.

The use cases were verified and refined in five NHI pilot districts (in Western Cape, Eastern Cape, Mpumalanga, North-West and Kwazulu-Natal).

3.1.2 eHealth maturity levels and care scenarios

The scenario that focuses on antenatal and postnatal care and management is used as an example to illustrate the process across the four maturity levels.

The scenario is about Pinkie Ntshoni, a 19-year-old single mother of one, Bridget, who is 10 months old. Pinkie is unemployed. She lives in a two-room shack with her grandmother, Naledi, and two siblings, Piladi (15 years) and Banda (10 years). Pinkie is 5 months pregnant with her second child. Pinkie has decided to

go to the local community health centre (CHC) to register for antenatal care. Pinkie is diagnosed as HIV positive during her first visit at the CHC.

This scenario has been described in two use cases:

1. A typical use case, where antenatal care is received at the community health centre (CHC) and delivery takes place at the centre's maternal obstetric unit (MOU). Being HIV positive is not an indication for referral to hospital for antenatal care and delivery.
2. An exceptional use case, where other maternal and/or foetal condition(s) necessitate referral to hospital for antenatal care and delivery.

3.1.2.1 *Local paper-based patient medical records*

The health information system for this maturity level is entirely paper-based. The scenario for the paper-based patients records (Level 1) is presented in detail in Appendix I. The health information system is completely paper-based and no eHealth applications are in use.

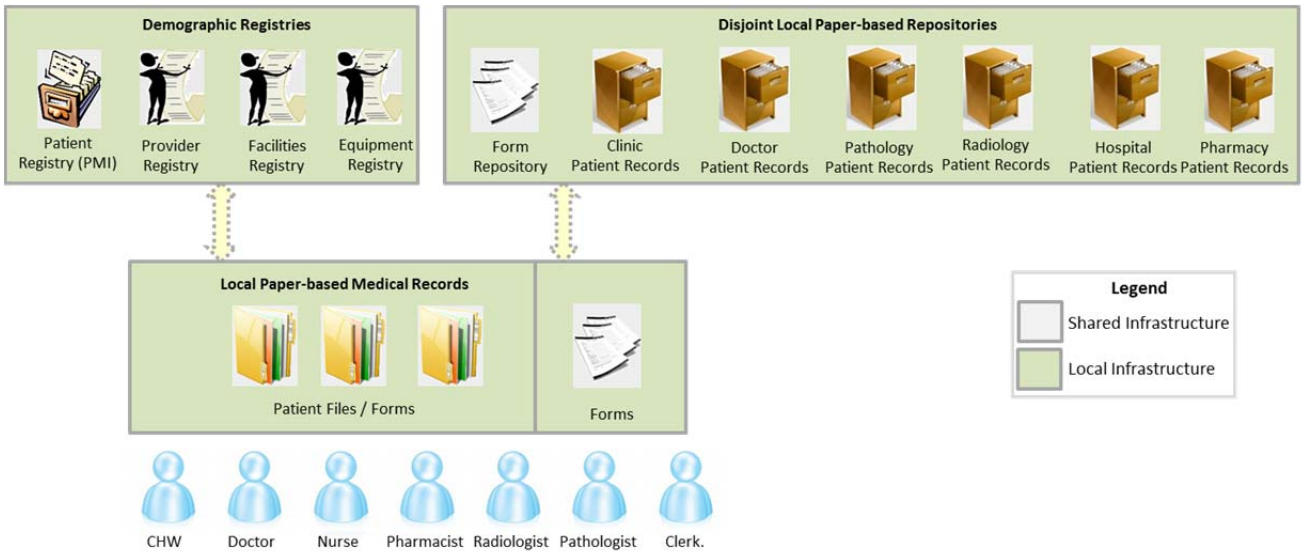

Figure 3-2: Local paper-based medical record system

In a completely paper-based system, as illustrated in Figure 3-2, all Pinkie's *medical record* information is paper-based and kept locally at the CHC for the standard use case, and at both the CHC and the hospital in the exceptional use case. Pinkie's two records at the CHC and hospital are disjoint and not directly related to each other. Pinkie's details and medical history will be captured at the CHC, the laboratory, and the hospital. The CHC and the hospital may even use different forms to capture the same information.

A local paper-based patient master index (PMI) or local patient repository may exist, but is in the vast majority of cases it is not shared with any other healthcare provider at a different facility. Pinkie is most likely to have different patient identifiers at the CHC and at the hospital. The same applies to a provider registry and a facility registry.

The vast majority of clinics, CHCs and rural hospitals, in the majority of Provinces, currently operate under this model.

In order to enable such a health information system to prepare for integration into an eHealth system based on a national shared electronic health record (EHR), the first step is to align the paper-based records to those required and stored in the EHR. This would, as a first step, be done by:

- Using standardised forms for all medical records, requests/results for pathology (laboratory) tests, request/results for radiology examinations, prescriptions, referrals, etc., according to the norms prescribed in the HNSF for data structure and content standards, and clinical terminology and classification standards.
- Aligning patient identifiers with the relevant national population index or patient-master index (PMI).

3.1.2.2 *Local paper-based patient medical record system with some IT support*

The scenario for the paper-based patients records (Level 2) is presented in detail in Appendix J. The health information system is primarily still paper-based, although some form of IT support may exist. The IT system is mainly used to record the patient identifiers and the basic patient demographics.

In this type of system, as illustrated in Figure 3-3, all Pinkie's *medical record* information is paper-based and kept locally at the CHC for the standard use case, and at both the CHC and the hospital in the exceptional use case. The two records are still disjoint and not directly related to each other. Pinkie's details and medical history will be captured at both the CHC and the hospital. The CHC and the hospital may even use different forms to capture the same information.

A local IT-based patient master index (PMI) or local patient repository may exist, but in the vast majority of cases, the record is not shared with any other healthcare provider at a different facility. Pinkie is most likely to have different patient identifiers at the CHC, the laboratory, and at the hospital. The same applies to a provider registry and a facility registry.

The IT system hosting the local demographic registries is mostly accessed by a clerk, who uses it to look up a patient identifier and the patient demographics and issue patient cards, print labels, etc. The system may in addition also be able to record care event dates (i.e. dates of clinic visits, admission and discharge dates at hospitals, etc.), but no other information. If the demographics have changed, it can also be updated by the clerk. The demographic registries usually reside on a local computer (that may or may not be part of a local network of computers), which can be directly accessed using a dedicated software application installed on a desktop or notebook computer. The system may in more advanced cases, also allow for the use of a mobile phone to retrieve and update the relevant information. In this case, special pieces of software (consumer applications) need to be installed on both the mobile phone and the computer system that hosts the demographic registries. No messages are however sent/received across different IT systems and across different facilities.

Once the patient's identifier has been located, the identifier is used to locate the patient's physical paper file. All the details regarding a specific care event are captured in the paper file only and are kept locally at the applicable facility.

Most of the current patient record systems in the public healthcare facilities in South Africa, which make use of a computer-based system, operate under this model.

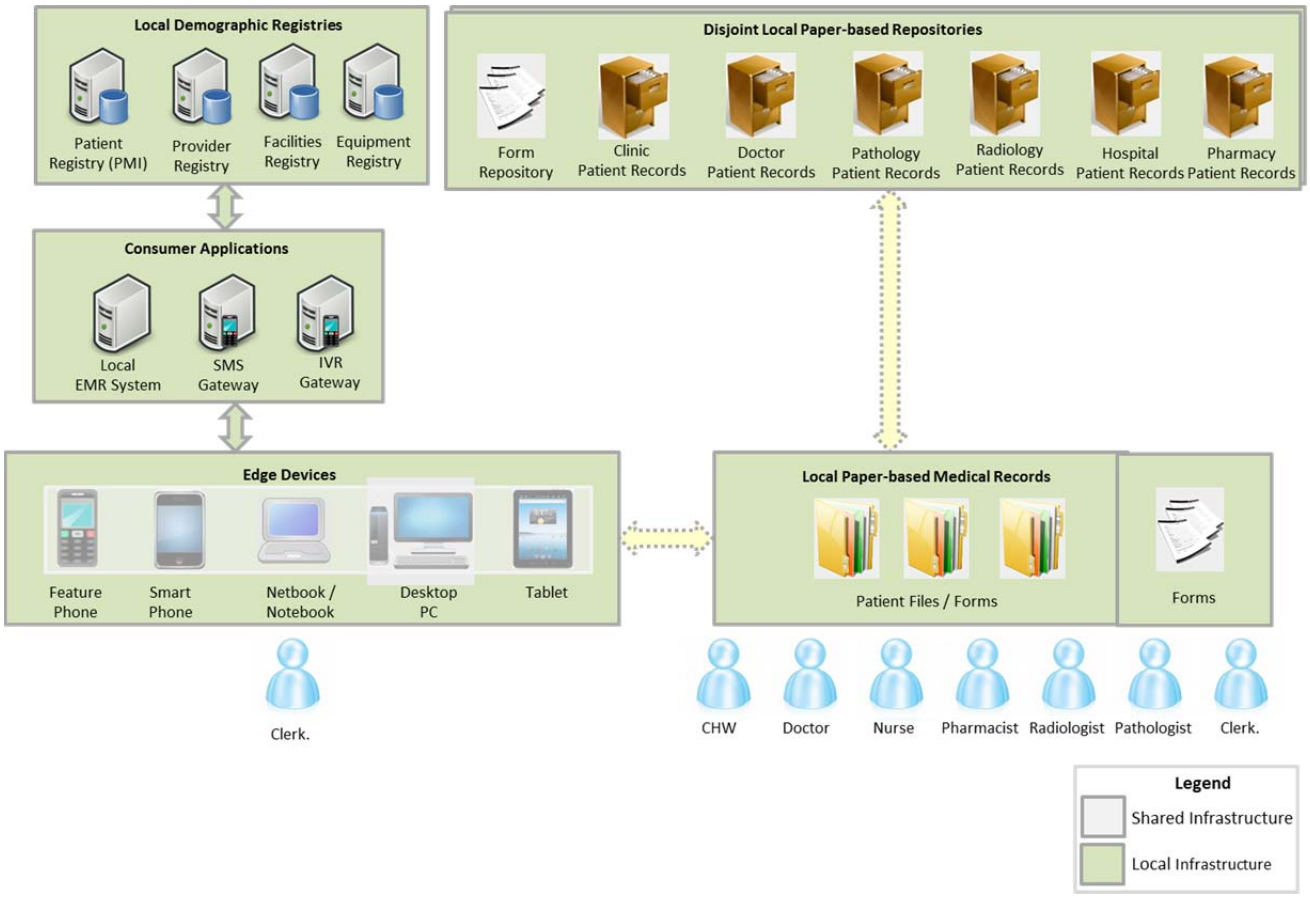

Figure 3-3: Local paper-based medical records with a local electronic medical record system

In order to enable such a health information system to prepare for integration into an eHealth system based on a national shared electronic health record (EHR), the first step is to align the paper-based and electronic records to those required and stored in the EHR. This would, as a first step, be done by:

- Using standardised forms for all medical records, requests/results for pathology (laboratory) tests, request/results for radiology examinations, prescriptions, referrals, etc., according to the norms prescribed in the HNSF for data structure and content standards, and clinical terminology and classification standards.
- Aligning patient identifiers with the relevant national population index or patient-master index (PMI).

3.1.2.3 *Centralised electronic patient record system*

The scenario for the centralised electronic patients records (Level 3) is presented in detail in Appendix K.

In this type of system/scenario, as illustrated in Figure 3-4, all Pinkie's *record* information is a hybrid between local paper-based medical records and electronic and centrally stored and shared electronic health records. Some (or all) of the *patient record* information is kept in electronic form on the local EMR as well as in the paper-based records of the particular healthcare facility. A pre-defined subset (or all) of the patient record information is also stored centrally in the shared EHR. The relevant EMRs in this case would also include local systems for clinics, community health centres (CHCs), general practitioners, laboratories, radiology units, pharmacies and other healthcare related facilities that record patient-centric information. The shared EHR system may be centralised for a hospital complex, a district, a province or nationally.

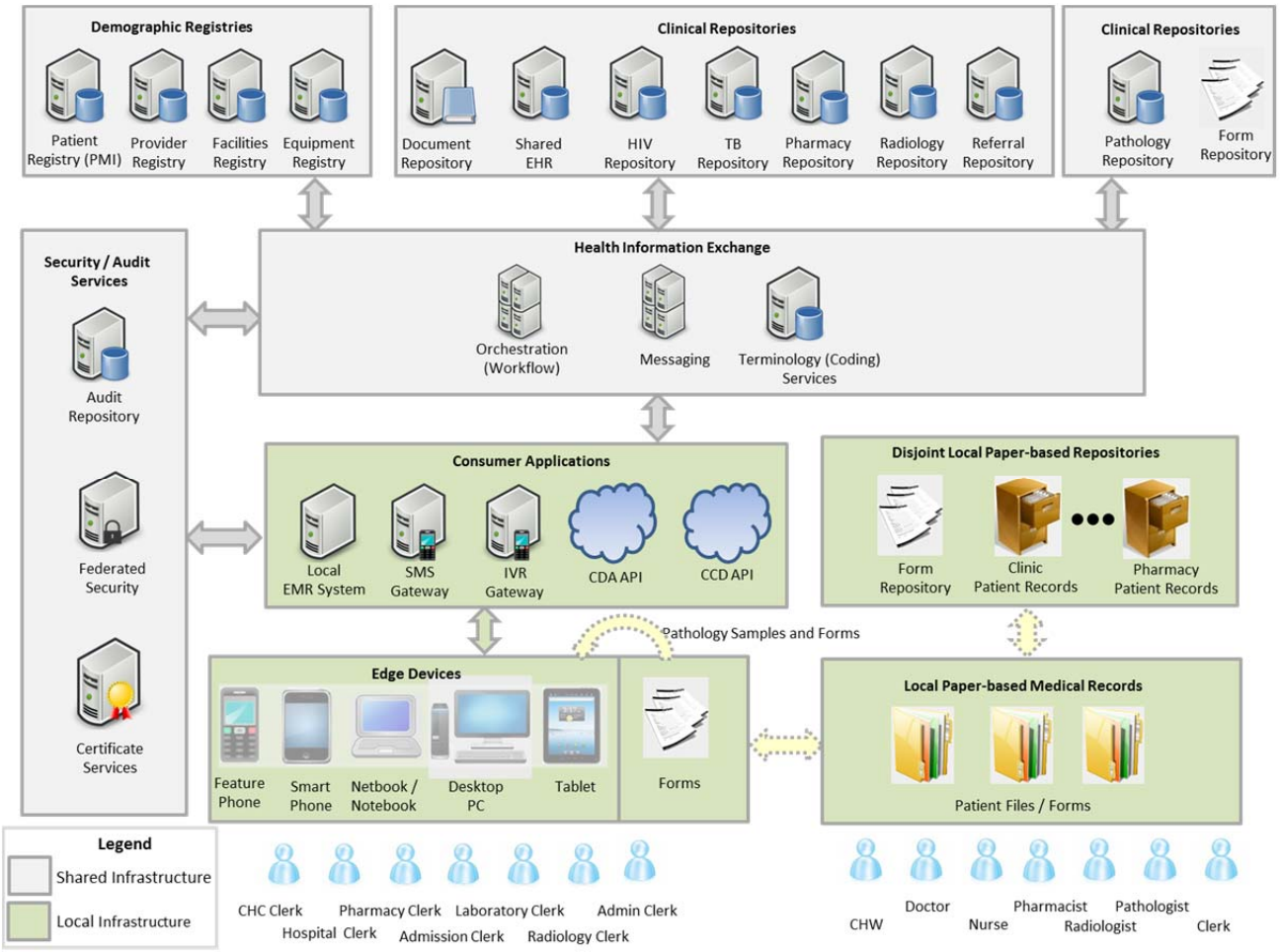

Figure 3-4: Centralised electronic health record system with mixed-mode local medical records

The health information system makes use of a shared infrastructure and a local infrastructure:

- At healthcare worker level, the system is still paper-based: each patient has a patient file in which the healthcare worker records medical record information, and in which paper-based test results, etc. are stored. Information is recorded on standardised forms throughout.
- All or selected parts of the paper-based medical record are also recorded electronically (i.e. as EMRs) and stored locally on an IT system. A healthcare facility-based clerk still mainly does the data entry on the local IT system.
- All or part (e.g. summaries) of this local electronic medical records may be uploaded and stored in the centrally shared electronic health record (EHR).
- The electronic health records (EHRs) and clinical repositories are shared across a healthcare complex, hospital complex, a district, a province or nationally.
    - The patient record is entirely electronic in the shared EHR, the clinical repositories and demographic registries.
    - A central patient registry and patient master index (PMI) exists, which is shared across all healthcare facilities served by the shared infrastructure (the patient will have the same identifier across all the healthcare facilities.)
    - A central provider registry exists, which is shared across all healthcare facilities served by the shared infrastructure.

  - A central facility registry exists, which is shared across all healthcare facilities served by the shared infrastructure.
  - A central equipment registry exists, which is shared across all healthcare facilities served by the shared infrastructure.
- The shared clinical repositories can be accessed and updated by authorised users at all the healthcare facilities served by the shared infrastructure.
- A health information exchange (HIX) exists which manages the workflow and activities, such as messaging, in the shared infrastructure.
- Security and audit services are in place to facilitate authentication across the shared infrastructure.
- Specialised consumer applications exists at local healthcare facility level to handle the various edge devices (computers, mobile phones, etc.) used to access and record the information kept in the shared repositories and registries.
- Specialised consumer applications exist at local healthcare facility level to handle the various messages required to access and record information in the shared infrastructure.
- The only paper-based transactions with the shared infrastructure that will persist are related to samples (e.g. blood) sent for pathology investigations. The outcomes of such investigations, however, are recorded in the shared infrastructure by the pathology EMR system and can be accessed by the local healthcare facility through the shared infrastructure. The paper-based forms accompanying the samples are standardised.

3.1.2.4 *Fully integrated national shared electronic health record system*

The scenario for the full integrated, centralised electronic patients records (Level 4) is presented in detail in Appendix L.

In the fully integrated, centralised electronic patients records system, as illustrated in Figure 3-5, all the *patient record* information is kept in electronic form on the local EMR of the particular healthcare facility, and a pre-defined subset (or all) of the patient record information is also stored centrally in the shared EHR. The EMRs would also include local systems for clinics, community health centres (CHCs), general practitioners, laboratories, radiology units, pharmacies and other healthcare related facilities that record patient-centric information. The shared EHR system may be centralised for a hospital complex, a district, a province or nationally.

The health information system makes use of a shared infrastructure:

- The health information system is primarily electronic as far as healthcare facility-based transactions are concerned, and the data entry and access can be done at point-of-care (PoC) by the healthcare providers using edge devices.
- Electronic health records (EHR) and clinical repositories are shared across a healthcare complex, hospital complex, a district, a province or nationally.
  - The patient record is electronic as far as all clinical repositories and demographic registries are concerned.
  - A central patient registry and patient master index (PMI) exists, which is shared across all healthcare facilities served by the shared infrastructure (the patient will have the same identifier across all the healthcare facilities.)
  - A central provider registry exists, which is shared across all healthcare facilities served by the shared infrastructure.
  - A central facility registry exists, which is shared across all healthcare facilities served by the shared infrastructure.
  - A central equipment registry exists, which is shared across all healthcare facilities served by the shared infrastructure.

- The shared clinical repositories can be accessed and updated by authorised users at all the healthcare facilities served by the shared infrastructure.
- A health information exchange (HIX) exists which manages the workflow and activities, such as messaging, in the shared infrastructure.
- Security and audit services are in place to facilitate authentication across the shared infrastructure.
- Specialised consumer applications exists at local healthcare facility level to handle the various edge devices (computers, mobile phones, etc.) used to access and record the information kept in the shared repositories and registries.
- Specialised consumer applications exist at local healthcare facility level to handle the various messages required to access and record information in the shared infrastructure.
  The only paper-based transactions with the shared infrastructure that will persist are related to samples (e.g. blood) sent for pathology investigations. The outcomes of such investigations, however, are recorded in the shared infrastructure by the pathology EMR system and can be accessed by the local healthcare facility through the shared infrastructure. The paper-based forms accompanying the samples are standardised.

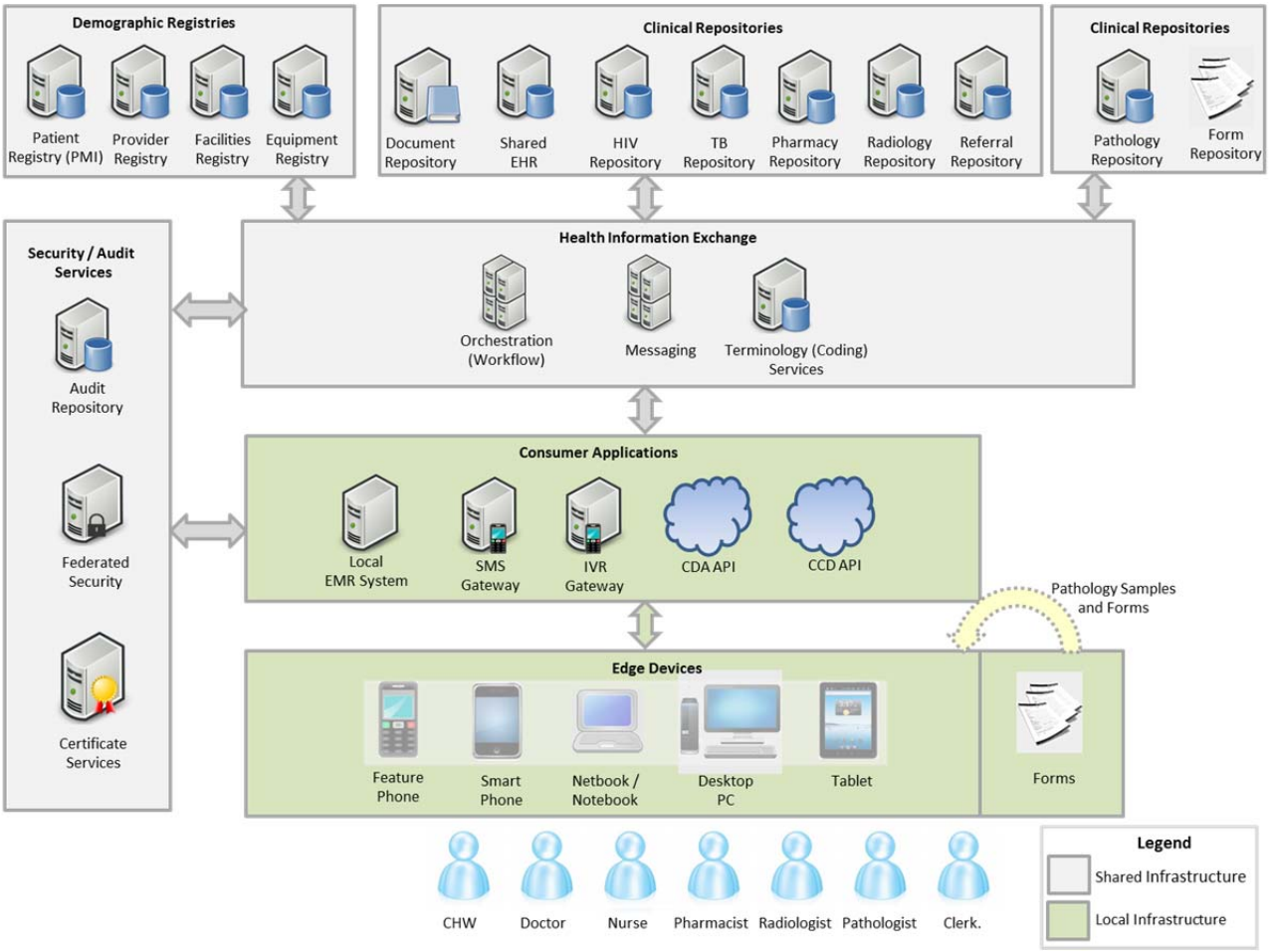

Figure 3-5: Fully integrated national shared electronic health record system

Recommendation

Although the aim and mandate of this project was not to suggest a technology infrastructure or complete enterprise architecture for eHealth in South Africa, a recommendation can be made for a cloud-based shared national infrastructure, similar to the fully integrated infrastructure used here as illustration to be established. The recommendations of standards in the HNSF were made with such infrastructure in mind.

3.1.3 Business cases (interoperability specifications)

As a next step the business use cases (interactions, workflows and functions/activities) for each of these scenarios were extracted and documented:

- The detailed scenario was documented and checked for accuracy.
- The activities or functions in the workflows were documented using UML sequence diagrams, and those functions that would be supported by an eHealth application specified. Figure 3-6, as an example of such a UML sequence diagram, illustrates the sequence for Pinkie's first antenatal visit based on Level 3 or Level 4. Pinkie's story illustrates a typical scenario in healthcare service delivery in South Africa. This scenario plays out in a setting that is at Level 4 of eHealth maturity, as described in section 3.1.2. The patient, Pinkie Ntshoni aged 19, receives antenatal care at a community health centre (CHC) and delivery takes place at the maternal obstetric unit (MOU) attached to the CHC.
- Within the detailed description of the scenario, functions resulting in patient-based transactions with content that would be sent to the shared electronic health record were identified.

Site meetings (using interviews and questionnaires as data collection methods) with provincial government staff and service providers (hospitals and clinic staff) in six NHI pilot districts informed the evolution and verification of the care scenarios. The Districts were Eden District (George, Mossel Bay, Riversdale (Western Cape)), OR Tambo District (Nyandeni (Eastern Cape)), Gert Sibande (Bethal, Secunda, Ermelo (Mpumalanga)), Dr K Kaunda (Potchefstroom (North West)), and to a limited extent in uMzinyathi and uMgungundlovu (KwaZulu Natal).

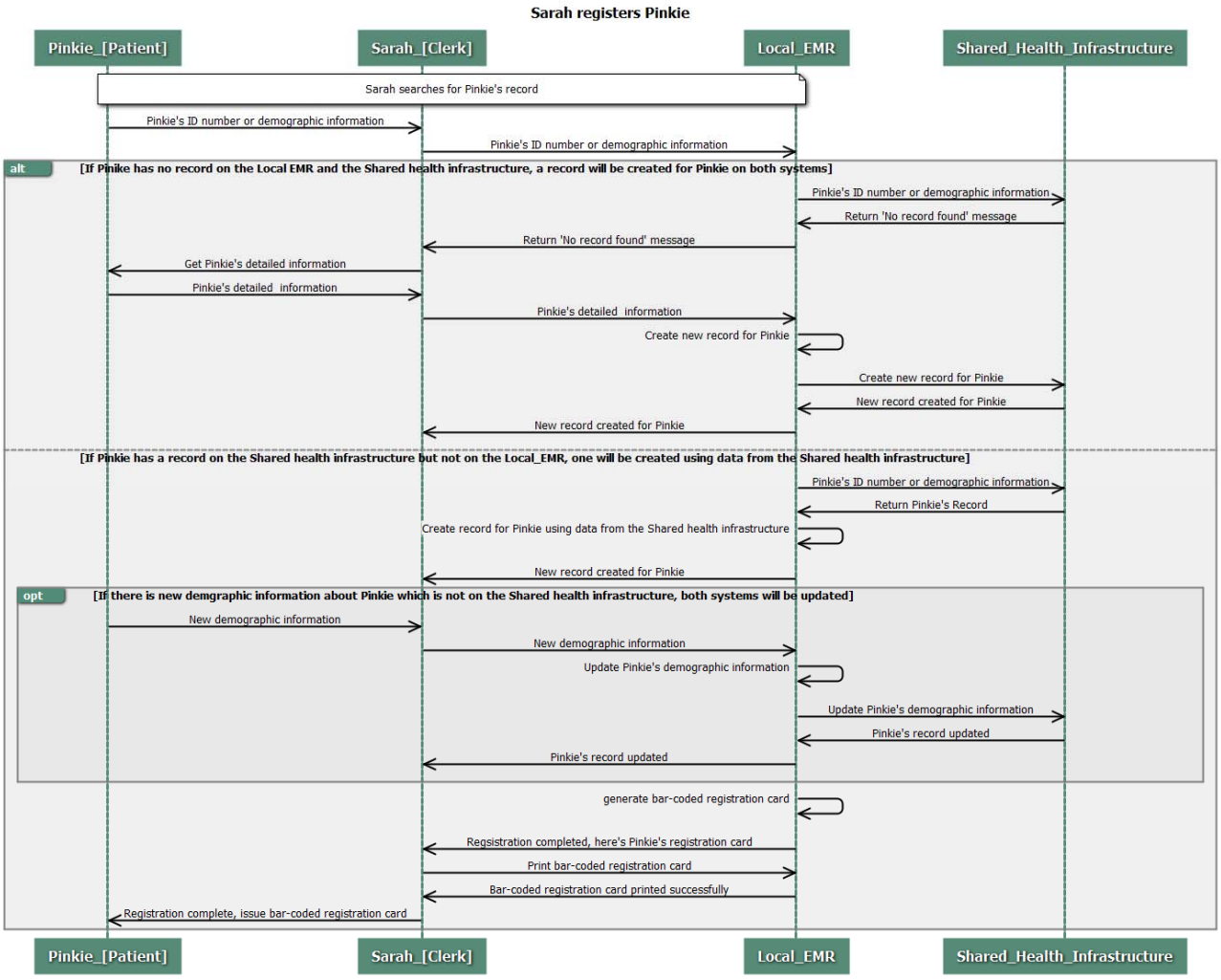

Figure 3-6: Sequence diagram for Pinkie's registration during her first antenatal visit.

3.1.4 A survey of the current healthcare information systems

To verify whether the set of functions covers all the functions provided by current healthcare information systems in use by the Provinces, a survey was conducted to determine The HISs' functionality. The detailed report on the survey and the results is presented as a separate report [CSIR and NDoH, 2013b].

Data was collected by means of interviews with the various stakeholders and role-players and where it was not possible to interview such persons, the stakeholders completed an electronic questionnaire that was returned to the team leader via email. The findings from the interviews and questionnaires were captured and analysed using descriptive statistics techniques combined with theme analysis.

The set of functions supported by these systems, and their role in the business process of the specific healthcare institution were extracted and classified. It was found that the set of functions derived from the care scenarios and a related literature study, were covering all the existing functionality of HISs installed as far as patient-centric functions or activities are concerned.

3.1.5 The generic set of eHealth functions (technical use cases)

All the functions from all the scenarios were extracted, integrated and classified. Since this set of functions is based on distinctive South African healthcare scenarios and business cases, the resulting set of functions should be the basis of the typical set of functions to support in a national eHealth system for South Africa.

The result of this is the generic eHealth functions for the South African public healthcare arena, and is presented in Table 3-1.

Table 3-1: List of generic eHealth functions

FUNCTION GROUP	FUNCTIONS
Identification, authentication and authorisation	Identify location
	Identify provider
	Identify patient
	Authenticate patient
	Authenticate provider
	Authorise provider roles and permissions
Record look-up	Search for patient record
Add patient record	Create new patient record
	Link baby patient to mother patient
	Create temporary patient record
	Merge temporary and permanent record
Retrieve patient record	Retrieve and display patient record
Admission, discharge and transfer	Admit patient
	Discharge patient
	Add and query discharge summary
	Add, query and update transfer
Update patient record	Add, query and update demographic details
	Add, query and update medical history
	Add, query and update clinical observations
	Add, query and update interventions
	Add and query referrals
	Add and query pharmacy orders
	Add and query drugs dispensed
	Add and query orders for laboratory tests
	Add and query laboratory test results
	Add and query orders for radiology test s
	Add and query radiology test results
	Add, query and update “doctor’s notes”
	Add and query out-patient encounter outcome
	Add, query and update ante-natal care events
	Add and query birth details
	Add and query death details
	Add, query and update care plan
	Scan and upload paper document
	Add, query and update records via mobile device

Scheduling	Schedule appointment
	Send reminders
	Confirm attendance or cancellation
Emergency medical services – peripheral	Contact ambulance
	Dispatch ambulance
	Route ambulance
Supply chain management - peripheral	Update pharmacy stock
records	Notify clinician lab results are ready
Create billing account	Add, query and update bills
	Submit medical bills for payment
Generate metrics	Add, query and update health indicator
Essential Non-health specific functions	
Node authentication	Authenticate system
Maintain system clock	Maintain system clock

3.2 Determining the baseline set of standards to consider

There is hundreds of existing eHealth standards. Selecting the set of standards to use requires a careful analysis of each standard for its appropriateness. An initial study of the international eHealth base standards landscape as well as the SABS accepted eHealth standards (SANS) was conducted. The set of standards from the literature study were classified into the following categories (see Appendix A):

- Identifier standards.
- Electronic health record standards.
- Health smart card standards.
- Messaging standards.
- Structure and content standards.
- Clinical terminology and classification standards.
- Security and access control standards.
- General eHealth standards
- General IT standards (not health specific), including interoperability standards applicable to all government information systems (MIOS V5).

The set of typical healthcare functions were then used as guidance to determine a (super) set of standards that could be applicable to the current South African healthcare context.

Based on the epSOS research [CEN/TC 251, 2009a] as well as other studies in standards selection, such as the European Telecommunications Standards Institute [Van der Veer & Wiles, 2008], expert input (e.g. eStrategies Africa Forum [2012] and the WHO Forum on Health Data Standardization and Interoperability [WHO, 2012]), the research team directed the scope of our investigation to working only with standards-based 'frameworks' or portfolios of standards that can work together in a cohesive interoperable stack. The vast eHealth standards landscape was narrowed down by looking only at 'stacks' of standards that have been internationally balloted. This technique mitigated the implementation risks associated with the incompatibility of base standards.

When the research team analysed the resulting set of standards from our study and the standards landscape in general, it was concluded that embedded in the set of eHealth standards identified were three sets of international standards stacks, which had to be further investigated and winnowed down:

- The family of end-to-end stack of modelled interactions/standards based on the HL7 V3 Reference Information Model (RIM) [Health Level Seven International, 2013e].
- The end-to-end stack of modelled interactions based on the ISO 13606/OpenEHR data archetypes and underlying reference model (ISO 13606 Parts 1-5) [The EN 13606 Association].
- The stacks of standards underlying the interoperability standards-based profiles developed by the global organisation 'Integrating the Health Enterprise' (IHE) [IHE International, 2012]. It is a pragmatic collections of base standards defined in terms of use-case driven interoperability standards-based profiles, relying on underlying base standards from ISO, HL7v2 / HL7v3, ebXML, OMG, etc.

Each of these stacks of standards is briefly introduced in section 3.2.1. Section 3.2.2 describes the process the research team followed in determining the appropriate stack of standards to use.

3.2.1 Stacks of standards

3.2.1.1 *HL7*

Health Level Seven (HL7) [Health Level Seven International, 2013e] is an international standards development organisation (SDO) that develops standards for exchange, management and integration of electronic healthcare information for clinical and administrative purposes. Its messaging standard, HL7 Version 2 (HL7 V2), is the most widely used healthcare interoperability standard in the world [Benson, 2010; Health Level Seven International, 2013e].

HL7 has its headquarters in the USA with central offices, international country affiliates, and topic-oriented working groups internationally. HL7 develops specifications, standards, and in some cases tools related to the electronic documentation of its standards. HL7 is based on individual or corporate membership (unlike the representational structures of European Committee for Standardisation (CEN) and the International Standards Organization (ISO) and their national counterparts). HL7 is American National Standards Institute (ANSI) accredited, and an open dialogue platform (Joint Initiative Council – JIC) with ISO and CEN has been established. In Europe there are established affiliates in Finland, Germany, The Netherlands and the UK, with newer affiliates in Sweden, Lithuania, Poland, the Czech Republic, Slovenia, Greece, France, etc. [CEN/TC 251, 2009a].

'Level Seven' refers to the seventh level of the ISO seven-layer communications model for Open Systems Interconnection (OSI) [ITU, 1994], namely the application level [Health Level Seven International, 2013e]. Although an application layer standard, HL7 also produces infrastructure (transport) specifications for its messages, by building upon a selection of IT standards, such as ebXML [eBES, 2009; OASIS, 2009].

HL7 is pragmatic in its origin, using events as triggers and roles as central information flow entities. Although it started as a message exchange standard, HL7 is no longer only a point-to-point messaging standard. HL7 products presently come in two main modes, namely HL7 Version 3 (HL7 V3) and HL7 Version 2 (HL7 V2.X (X=7 currently)), but there are complementary standards covering other aspects of communication in healthcare.

HL7 V2 is a base standard. HL7 V2 supports the exchange of information about admissions, discharges and transfers (ADT), orders and results for tests, treatments, as well as billing information. It has undergone several revisions since its first publication in 1988, with the current version being 2.7. One of the main benefits of HL7 V2 is its backward compatibility, which makes newer versions compatible with versions before it. HL7 V2 supports the majority of the common interfaces that are used in the healthcare industry

globally, and provide a framework for negotiations of what is not supported by the standard. Its high level of flexibility makes it adaptable for any healthcare environment.

HL7 V2.X is the predominant means of communicating eHealth information in the world. It is particularly effective in traditional message-based interconnectivity applications within well-controlled ICT environments. Its capabilities continue to be extended. It has a large community support internationally, its current range of uses is well supported by existing knowledge, tooling, consulting services and implementation guides [CEN/TC 251, 2009a; NEHTA, 2007]. Although many implementations claim to use HL7 V3, the use is often limited to using only the Clinical Document Architecture (CDA) and the Continuity of Care Document (CCD), whilst depending on HL7 V2.X for the messaging.

HL7 V3, published in 2005, is designed to be highly comprehensive, complete in detail, extensible, and model-based. HL7 V3, like V2.X, is a base standard for exchanging health information among information systems that support healthcare applications, but also has an associated environment in the form of a Reference Information Model (RIM). The RIM is described as the backbone of HL7 V3, as it provides explicit representation of the semantic and grammar of its messages. The other information models defined in HL7 V3 are: the Domain Message Model (D-MIM) (used to describe all the data elements required by HL7 messages of a business domain); the Refined Message Information Model (R-MIM) (used to describe the information model of a HL7 message or a set of HL7 messages); and the Domain Analysis Model (DAM) (used to describe the business use cases, information flows, scenarios, vocabulary, and business rules). HL7 V3 Specifications (e.g. HL7 V3 messages, structured documents, etc.) permit loosely coupled information systems to interoperate (i.e. exchange data) in a variety of healthcare delivery contexts including those found in disparate provider organisations, perspectives, and jurisdictions.

HL7 V3 is not backward compatible with HL7 V2 and has a steep learning curve compared to V2. In fact, V3 is not an 'improved' version of V3: V2 and V3 are in fact completely different. Both versions are still supported and being developed by HL7.

In V3, HL7 volunteers have sought to improve the V2 process and its outcomes. The development principles behind HL7 V3 are intended to lead to a more robust, fully specified standard. Not all areas covered by V2.X are yet addressed by V3, and some inherently close-coupled processes may not benefit from the functions of V3 in the short term. For that reason, and because V2.X is more widespread in use [CEN/TC 251, 2009a], content of both versions are presented in our analysis.

Two of the components of HL7 V3, namely CDA and CCD, are, however, widely used in conjunction with other standards, including HL7 V2.X. These two components are briefly discussed in more detail below.

3.2.1.1.1 CDA

The Clinical Document Architecture (CDA) in HL7 V3 is designed to support standards for storing and retrieving persistent information, such as medical records. CDA is a standard specification for the structure and semantics of clinical documents to support common representation of clinical documents, and is the most widely adopted application of HL7 V3 in the world [Dolin et al., 2006].

The HL7 Version 3 Clinical Document Architecture (CDA) is a document mark-up standard that specifies the structure and semantics of 'clinical documents' for the purpose of exchange between healthcare providers and patients. It defines a clinical document as having the following six characteristics[Dolin et al., 2006; Health Level Seven International, 2013a]:

- Persistence.
- Stewardship.
- Potential for authentication.

- Context.
- Wholeness.
- Human readability.

A CDA can contain any type of clinical content. Typical CDA documents would be a discharge summary, imaging report, procedure report admission, pathology report, etc.[Dolin et al., 2006]. The most popular use is for inter-enterprise information exchange, such as is envisioned for eHealth in South Africa.

CDA grew out of work that originated outside of HL7 in early 1996 when a group of medical doctors began to meet to discuss the potential for structured mark-up in clinical documents. The earliest draft was called the Kona Architecture and was developed in 1997 after the group had joined HL7. Since then several people have worked on it and the basic ideas have been refined and developed along with the HL7 V3 framework and the Reference Information Model (RIM).

CDA introduces the concept of incremental semantic interoperability, i.e. that there is a range of complexity allowed within the specification and users must set their own level of compliance. CDA documents are encoded in Extensible Markup Language (XML) [Dolin et al., 2006]. The minimal CDA is a small number of XML-encoded metadata fields (such as provider name, document type, document identifier, etc.) and a body, which can be any commonly used Multipurpose Internet Mail Extensions (MIME) type such as .PDF, .DOC (Microsoft Word) or even a scanned image file. While the body of such a document would not be interpretable for applications like decision support, the minimal, standard metadata set and display characteristics mean that such a document could be filed, searched, categorized and retrieved along with more richly-encoded documents, and all documents would be equally readable at the point of care [Health Level Seven International, 2013a].

The most recent version of CDA is Release 2, which is used as the foundation for all current CDA Implementation Guides. CDA R2 became an ANSI-approved HL7 standard in May 2005 [Dolin et al., 2006]. CDA Release 3 is currently under development.

CDAs can be used in Continuity of Care Documents.

3.2.1.1.2 CCD

The Continuity of Care Document (CCD) is a joint effort of HL7 and the American Society for Testing and Materials (ASTM) to foster interoperability of clinical data to allow physicians to send electronic medical information to other providers without loss of meaning, which will ultimately improve patient care. HL7 and ASTM International [ASTM, 2013b] created the CCD [Health Level Seven International, 2010a, 2013g] to integrate two complementary healthcare data specifications: ASTM's Continuity of Care Record (CCR) [ASTM, 2013a] and HL7's Clinical Document Architecture (CDA) [Health Level Seven International, 2013a]. The CCD was selected by the Healthcare Information Technology Standards Panel (HITSP) [HITSP, 2009] as the harmonized format for the exchange of clinical information, including patient demographics, problems, medications and allergies.

The HL7/ASTM Continuity of Care Document (CCD) is an implementation guide for sharing Continuity of Care Record (CCR) patient summary data using the HL7 Clinical Document Architecture (CDA). CCDs can be seen as carrying patient's medical history. CCD establishes a rich set of templates representing the typical sections of a summary record and expresses these templates as constraints on CDA. These same templates, for example, for vital signs, family history, plan of care, etc., can be reused in other CDA document types, establishing interoperability across a wide range of clinical use cases. The CCD is the basis for interoperability in the US Health Information Technology Standards Panel (HITSP) [HITSP, 2009] and Integrating the Healthcare Enterprise (IHE) [IHE International, 2012] use cases.

The CCD is an XML-based standard that specifies the structure and encoding of a patient summary clinical document. It provides a 'snapshot in time', constraining a summary of the pertinent clinical, demographic, and administrative data for a specific patient. CCD supports the ability to represent professional society recommendations, national clinical practice guidelines, standardized data sets, etc. [Health Level Seven International, 2010a].

3.2.1.2 *The CEN/ISO EN13606 standard*

The CEN/ISO EN13606 is a five-part European Standard for EHR Communication from the European Committee for Standardization (CEN), and approved as an international ISO standard. It is designed to achieve semantic interoperability in electronic health record communication [EN 13606 Association, 2012]:

1. Electronic Health Record Communication (Reference Model).
2. Electronic Record Communication (Archetypes Interchange Specification).
3. Electronic Record Communication (Reference Archetypes and Term Lists).
4. Electronic Health Record Communication (Security).
5. Electronic Health Record Communication (Interface Specification).

CEN/ISO 13606 is a standard to define a rigorous and stable information architecture for communicating part or all of the electronic health record (EHR) of a single subject of care (patient) between EHR systems, or between EHR systems and a centralized EHR data repository. It can also be used for EHR communication between an EHR system or repository and clinical applications or middleware.

It follows a dual model architecture that defines a clear separation between information and knowledge, respectively structured around a reference model that contains the basic entities for representing any information of the EHR, and a set of archetypes, which are formal definitions of clinical concepts in the form of structured and constrained combinations of the entities of a reference model. A reference model represents the generic and stable properties of health record information. It comprises a small set of classes that define the generic building blocks to construct EHRs. It specifies how health data should be aggregated to create more complex data structures and the context information that must accompany every piece of data in order to meet ethical and legal requirements. It does encode what is meant, not how it is intended to be presented. An archetype is a structured and constrained combination of entities of a reference model that represents a particular clinical concept, such as a blood pressure measurement or a laboratory analysis result. This structure should be defined by a health domain expert [EN 13606 Association, 2012].

3.2.1.3 *Integrating the Healthcare Enterprise (IHE)*

Implementing integrated information systems can be complex, expensive and frustrating. Healthcare professionals who wish to acquire or upgrade systems do not have a convenient, reliable way of specifying a sufficient level of adherence to communication standards to achieve truly efficient interoperability. Substantial progress has been made in establishing base standards, but a gap persists between identifying the base standards that make interoperability possible and the actual implementation of integrated systems. To fill in that gap requires expensive, site-specific interface development to integrate even base standards-compliant systems. The IHE initiative is designed to bridge the gap.

IHE [IHE International, 2012] is an organisation established to assist users and developers of IT for healthcare to achieve interoperability of systems through the precise definition of healthcare tasks, the specification of standards-based communication between systems required to support those tasks, and the testing of systems to determine that they conform to the specifications [CEN/TC 251, 2009a]. IHE is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare

share information. IHE is thus not a base standards development organisation (SDO), but a profiling and conformance-testing organisation, which explicitly integrates existing base standards to enable fulfilment of identified tasks. IHE's products are implementation guides, promoting the coordinated use of established base standards such as ISO, DICOM, HL7, IETF, OASIS, W3C, etc., to address specific clinical needs in support of optimal patient care [CEN/TC 251, 2009a; IHE International, 2012; Witting & Moehrke, 2012]. For this reason, the research team examine the work and processes of IHE in a little more detail than for most of the other organisations.

One of the most significant applications of healthcare information technology is the exchange of health information between disparate healthcare information systems and unaffiliated care providers. Various communities from around the world have developed, or are developing, methods to exchange health information among healthcare providers, patients, and other authorised parties. Within IHE, healthcare professionals identify the integration capabilities they need to work efficiently in providing optimal patient care. Representatives of the clinical modality and information systems companies then reach consensus on a specific implementation of established communication standards that provides those capabilities. Their selections are recorded in the IHE Technical Framework, a detailed resource for the implementation of base standards that is freely available to the whole industry. The collection of IT infrastructure profiles, for example, includes support for patient identification, health document location and retrieval, provider directories, and the protection of privacy and security. The Technical Framework is open to public comment and is proven via an industry-wide testing and implementation process. The process works by annual cycles, expanding the scope of integration capabilities each year [CEN/TC 251, 2009a; IHE International, 2013; Witting & Moehrke, 2012].

The work of IHE is managed at international level by a broad-based Board (overseeing IHE Domain committees developing Standards-based Integration and Content Profile Specifications), which relates to a number of national (e.g., in Europe: Austria, France, Netherlands, Germany, Italy, Spain, UK, etc.) and regional (IHE-Europe, IHE- Asia-Pacific) deployment organisations engaged in conformance testing and education activities. IHE membership includes over 200 stakeholder organisations (professional societies, healthcare providers, vendors, governmental entities, standards development organisations, etc.). IHE has a liaison Category A status, alongside the WHO, with the ISO Health Informatics Technical Committee (ISO/TC215), allowing IHE to participate in the collaborative development and publishing of standards through ISO. IHE's standards adoption process was approved as ISO TR23830 in 2007 [CEN/TC 251, 2009a; IHE International, 2012].

3.2.1.3.1 Integration Profiles and Standards

The IHE Integration Profiles organise and leverage the integration capabilities that can be achieved by coordinated implementation of communication standards. They do not replace conformance to base standards, and users should continue to request that vendors provide statements of their conformance to relevant base standards, such as DICOM and HL7 V2.X.

Integration Profiles rather provide a more precise definition of how base standards are implemented. They define a specific implementation of standards in order to meet identified clinical needs. The IHE implementation of standards also has wide support by industry partners, where the standards-based profiles are documented, reviewed and tested.

IHE publishes a series of Technical Frameworks. Each IHE Technical Framework consists of two parts:

1. The business process problem and the solution to the interoperability problem (Integration and Content Profiles).

2. The transactions and content to support these Integration and Content Profiles in detail, using current, established standards to solve the business problem defined by each IHE Integration or Content Profile.

IHE Integration and Content Profiles are based on the modelling concepts of actors, transactions and content [CEN/TC 251, 2009a; Witting & Moehrke, 2012]:

- A *use case* is a textual and graphical depiction of the actors and operations that address information exchange in the context of specific tasks for a workflow performed by different systems or devices.
- The *development process* is part of the IHE process that identifies and prioritizes use cases, select interoperability standards, defines the necessary constraints and documents these specifications in the form of either an *Integration Profile* or a *Content Profile*.
- An IHE *integration profile* specifies the information exchanges to support a specific business process. Integration profiles are common interoperability building blocks, easily implemented in various software architectures that can be effectively factored in order to achieve maximum re-use of specification and implementation methods. It also allows for evolutionary growth.
- The integration profiles form a coordinated set of interactions exchanged between the functional components of communicating healthcare IT systems and devices. These functional components are called IHE *actors*. An actor abstracts a system or part of a system that creates, manages or acts upon data.
- An IHE integration profile specifies the interactions between the *actors* in terms of a set of coordinated, *standards-based transactions*. A *transaction,* or a content module, specifies a specific interaction between *actors* to exchange information. It is a specification for a set of messages exchanged between pairs of *actors* in support of the integration profile.
- An IHE c*ontent profile* specifies a coordinated set of *standards-based information content* exchanged between functional components of communicating healthcare IT systems and devices. It also specifies an element of *content* (e.g. a document) that may be conveyed through the transaction of one or more associated integration profiles.

Appendix C provides a list and short description of IHE Integration Profiles that can be used as reference by the reader in the remainder of this document.

3.2.1.3.2 Levels of Requirements

The definition of interoperability requirements can be done at different levels of granularity to fit the target audience. To clarify where the IHE Global Standards adoption process operates, four levels of requirements can be defined, as illustrated in Figure 3-7 [IHE International, 2007; ISO TC215, 2007; Witting & Moehrke, 2012]:

1. *Business case level*: This represents the business view of IT systems, for example a 'chronic disease management system'. It has some fuzziness and flexibility due to the many ways in which one can identify and structure a use case. Business use cases are the most successful when they cover a small and achievable scope for implementing requirements, each providing value whilst remaining achievable.
2. *Interoperability service level*: An interoperability service defines a number of related means and constraints to exchange specific types of health information for communicating this information from one or more systems to another. They should define the core interoperability services that are most likely required to support a broad range of business level use cases. Examples are 'electronic drug prescribing', 'sharing of patient medical summaries', etc.
3. *Integration and Content Profile level*: This is more granular than the interoperability service level in order to provide maximum flexibility in terms of implementation architectures. To achieve this architecture independence actors from multiple integration profiles are combined. Integration

profiles are common interoperability building blocks, easily implemented in various software architectures that can be effectively factored in order to achieve maximum re-use of specification and implementation methods. It also allows for evolutionary growth. Standards generally operate at a domain-focused level in that multiple standards are required to define an Integration Profile. The Integration and Content Profile level is the most practical level at which to perform interoperability conformance testing.

4. *Base standard level*: Base standards are in some cases healthcare specific, or can be applicable across a wide range of industries to achieve fundamental IT communication or security management. Base standards are foundations to enable the creation of elementary services, messages and documents to support any possible use case domain. They are also use case driven, but address the significant challenge of anticipating a greater variety of needs and market evolution. Since base standards are not necessarily healthcare specific, their use requires a number of constraints provided at Profile level (e.g. the selection of base standards among a set of competing standards to identify healthcare suitable options).

The business case levels combined with the interoperability services would constitute the interoperability specifications, as defined in our categories of standards in section 2.3. Figure 3-7 illustrates how these four levels support each other, by adding technical depth as one moves from business level use cases, to the middle where it is possible to accomplish effective, testable and robust interoperability (at the IHE level), and all the way to the most granular details provided by the base standards. Business level use cases are many, varied and naturally overlapping. Base standards are also varied and have complex foundational specifications delicate to combine. The middle two layers are where a critical rationalisation and definition of common 'solution building blocks' are best conducted.

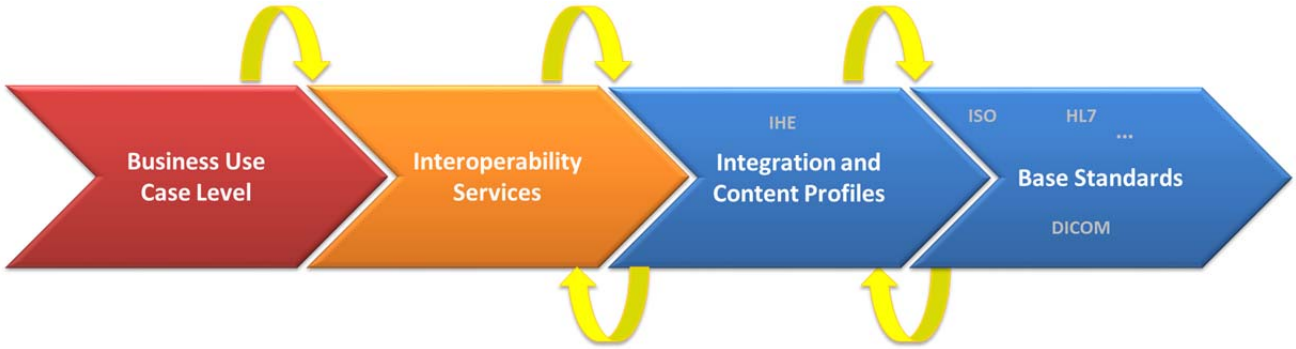

Figure 3-7: Levels of requirements (adapted from IHE International [2007]: p. 11)

3.2.1.3.3 The Four Steps of the IHE Development and Deployment Process

IHE follows a defined, coordinated process for standards adoption. IHE brings together users and developers of healthcare information technology (HIT) in an annually recurring four-step process, promoting steady improvements in integration: [CEN/TC 251, 2009a; IHE International, 2007, 2012; ISO TC215, 2007]:

1. *Development process*: The development process is executed at the global level in order to produce internationally agreed upon Integration and Content Profiles:
    a. *Identify interoperability problems*: Clinical and technical experts work to define critical use cases for information sharing, focusing on, for example, common interoperability problems with information access, clinical workflow, administration and the underlying infrastructure.

b. *Specify integration profiles*: Technical experts create detailed specifications for communication among systems to address these use cases, selecting and optimizing established base standards. They identify relevant base standards and define how to apply them to address the problems, documenting them in the form of IHE Integration Profiles.

2. *Deployment process*: The deployment-validation process is carried out at the level of specific countries or regions. There are some extensions or adaptations to the globally agreed upon Profiles and these are specified in this process:
   a. *Test systems at the connectathon*: Industry implements these specifications (IHE Integration Profiles) in HIT and tests their systems for interoperability at the carefully planned and supervised events called *connectathons*. This allows them to assess the maturity of their implementation and resolve issues of interoperability in a supervised testing environment.
   b. *Publish Integration Statements* (for use in requests for proposals (RFPs)): Vendors publish IHE integration statements to document the IHE Integration Profiles their products support. Users can reference the IHE Integration Profiles in RFPs, greatly simplifying the systems acquisition process.

Note: The concept of a Connectathon

The testing process employed by the IHE is called a 'connectathon'. It provides coordination, tools and opportunities for face-to-face interoperability testing for vendors and developers of healthcare IT systems implementing IHE profiles and integration capabilities. Connectathons are held regularly in Europe and North America, with events in other countries becoming more frequent.

A Connectathon allows participating software vendors or developers to test their implementation of IHE profiles and to benchmark their products against their peers. During a connectathon the participating systems exchange information with each other, performing all of the transactions required for the particular use cases and roles they have opted to be tested in. The results of testing are recorded and made available for review.

3.2.1.3.4 Acquiring Integrated Systems

The IHE Integration and Content Profiles provide a common language for buyers and vendors to discuss integration needs of the healthcare providers/enterprises and the integration capabilities of products. They are especially useful for writing the integration portions of purchasing specifications. The goal for most healthcare organisations is to implement practical capabilities such as distributed access to diagnostic images or smooth departmental workflow. The IHE Integration and Content Profiles allow communication about those high-level capabilities, while referencing the underlying technical precision necessary to make them work. By using IHE Integration Profiles, purchasers have a tool that reduces the difficulty, cost and anxiety associated with implementing integrated systems. Implementers are expected to publish 'integration statements' that list the specific IHE Integration and Content Profiles supported by a version of a product. These integration statements are made available on the IHE web site (www.IHE.net).

3.2.2 Comparing the stacks of standards

Applying risk mitigation criteria, the three standards frameworks, or stacks of standards (HL7 V3, ISO 13606 / OpenEHR and IHE) were evaluated as potential baseline candidates for the HNSF. The stacks of standards were also assessed to determine their applicability to the South African healthcare landscape. To further

mitigate the risks regarding the reliability of the underlying standards themselves, only internationally balloted standards were considered.

Informed by the NDoH's eHealth Strategy South Africa 2012-2016 [National Department of Health, 2012b] document, the risk assessment outcome, other published analysis of the stacks (e.g. [CEN/TC 251, 2009a; HIQA, 2011; NEHTA, 2007]) and expert input, a set of evaluation criteria was established reflective of South Africa's requirements. The comparatives (benchmark evaluation criteria) presented below were used as 'engineering constraints' in assessing stacks of standards for their appropriateness and applicability to the South African public healthcare environment, as well as for the interoperability of these standards (i.e. whether these standards can 'work' together) [CEN/TC 251, 2009a; HIQA, 2011; Van der Veer & Wiles, 2008; WHO and ITU, 2012]:

- *Scalability*: The ability of the set of standards to handle a growing amount of work in a capable manner or its ability to be enlarged to accommodate that growth.
- *Must be demonstrably implementable (implementability):* The extent to which the realization of the standards can be demonstrated. There should be a minimum of adaptation required of the standards to meet the requirements of South Africa.
- *Must be readily conformance testable*: The ease in which conformance to the set of standards can be demonstrated.
- *Market acceptance*: The extent to which the set of standards are already widely adopted by vendors / products. International standards that are the fully implemented and validated will be preferred.
- *Economically feasible*: What are the cost barriers for obtaining the set of standards. Open standards will be preferred over proprietary ones. The standards proposed should ensure value for money and minimise cost of compliance.
- *Technical capacity*: The availability of health informatics and IT professionals who are experts in the standards.
- *Maturity*: How mature is the use of the set of standards, its implementation documentation, and the community of its users.
- *Extensibility and flexibility*: To what extent can the set of standards be extended or allow for flexibility of its use.
- *Support clinical and healthcare initiatives*: the extent (degree of coverage) to which the set of standards support clinical and other healthcare initiatives.

When winnowed down, the set of standards was checked against a final criterion:

- *Alignment with South African needs and standards*: Can the set of standards support the business cases South Africa healthcare system landscape? Based on the assessment criteria an investigation of the three stacks of standards for their ability to satisfy South Africa's current requirements and those proposed in the NDoH's eHealth Strategy South Africa 2012-2016 [National Department of Health, 2012b] document was done. The research team also identified gaps in the stacks of standards and how the set of standards can incorporate existing standards adopted for South Africa.

Based on an intensive literature study on the use, coverage, advantages, disadvantages, existing implementations and usability of the three stacks of standards, an assessment of the three standard stacks was done using a risk matrix (based on the method developed by the ecGroup Inc. [2012]). The risk matrix evaluated the standard stack with respect to suitability as an eHealth interoperability specification from the point of view of health system stakeholders, addressing the following issues:

- Are the standard's messages a scalable option?
  - Is the specification based on mature messaging standards?
  - Is high capacity, commercial enterprise service bus products able to be employed to process the message traffic?

  - Are design documents and developer specifications readily available to eHealth vendors?
- Are the standard's messages implementable?
  - Are commercial client applications readily available that support the specification?
  - Is there a ready mechanism to conformance-test vendor products?
  - Are implementers with expertise in the standard's messages readily available?
  - Can the standard's messages be localized and/or extended to reflect requirements specific to South Africa?
- Is the NDoH able to provide input to the standard's specifications and influence the evolution of the specification over time?
  - Are the standards development processes transparent and open?
  - Is it easy for NDoH to participate in the standards organisation?
  - Are there cost barriers to joining the organisation?
- Are the standards technologically advanced?
  - Are new innovations reflected in the specifications?
  - Is the maintenance cycle for specifications very regular?
  - Is there a core, underlying data model?

The assessment for each standard stack is provided in Appendix G. Table 3-2 summarizes the outcome, with IHE presenting the lowest risk.

Table 3-2: Risk matrix outcome for assessing standard stacks

Stack	Content	Average Risk	Maximum Risk
HL7 V3	Evaluate HL7v3 messaging with respect to suitability as an eHealth interoperability specification from the point of view of health system stakeholders.	8.2	16.0
ISO 13606	Evaluate ISO 13606 / OpenEHR with respect to suitability as an eHealth interoperability specification from the point of view of health system stakeholders.	10.0	20.0
IHE Profiles	Evaluate IHE Profiles with respect to suitability as an eHealth interoperability specification from the point of view of health system stakeholders.	5.5	12.0

Using the set of evaluation criteria, the results of the evaluation summarised in Table 3-3 (• indicates that a standard stack meets the criteria).

Table 3-3: Standards 'stacks' evaluation matrix

Criteria	HL7 V3	ISO 13606	IHE
Scalability	•	•	•
Implementability			•
Conformance testable			•
Market acceptance			•
Economically feasible	•	•	•
Technical capacity			•
Maturity	•		•
Extensibility and flexibility	•	•	•
Support clinical and healthcare initiatives	•	•	•

Based on the outcome of the initial assessment, and at this juncture in eHealth standards development and the implementation of the eHealth Strategy South Africa 2012 – 2016 [National Department of Health, 2012b], the IHE model is the most valuable in a South African standards context. The IHE option was therefore investigated in more depth to test its efficacy.

3.3 Exploring the IHE option

The investigation into the IHE standards stack option in presented in this section. The goal was to investigate IHE's ability to support South Africa's current requirements and those proposed in the NDoH's eHealth Strategy South Africa 2012-2016 [National Department of Health, 2012b].

3.3.1 Mapping information exchanges to functions, interoperability standards-based profiles and standards

As a first step, the necessary information exchanges, which were earlier established for each of our care scenarios and mapped onto sequence diagrams, were also mapped to applicable IHE profiles. This was to demonstrate the IHE profile applicability to the South African public healthcare environment. See Table 3-4 for an example, illustrating the process for Pinkie's first antenatal care visit. The remainder of the care scenario mappings can be found in Appendix D.

The eHealth technical use cases (interoperability standards-based profiles) necessary to support these scenarios and function/activities were selected from the standard IHE profile base [IHE International, 2013] (see Appendix C for a description of the IHE profiles). In each case, if gaps were found they were documented. These gaps might include any cases where there was not an applicable IHE profile that satisfied the information exchange requirements, or where the data included in the standards-based profiles was insufficient to generate the appropriate National Indicator Data Set (NIDS) element (see section 3.4).

Table 3-4: Mapping information exchanges to IHE profiles

Antenatal care	
Scenario	**Applicable IHE Interoperability Profiles**
Pinkie **Ntshoni** is a 19 year old single mother of one, Bridget who is 10 month old. Pinkie is unemployed. She lives in a two-room shack with her grandmother, Naledi, and two siblings, Piladi (15 years) and Banda (10 years). Pinkie is 5 months pregnant with her 2nd child. Pinkie decides to go to the local CHC to register for antenatal care. On arrival at the CHC, Pinkie reports at the registry desk. She tells the clerk, Sarah, that she is pregnant and would like to see the nurse or doctor.	
Sarah asks Pinkie if she has been to the CHC or MOU before. Although Pinkie replies that she has not, Sarah goes ahead and searches the local electronic medical record (EMR) system, which is linked to the national shared electronic health record (EHR) system. She uses Pinkie's national ID number and when using it that does not find Pinkie on the system, she searches on Pinkie's name, surname and date of birth. No record matching Pinkie's details is found.	Identify patient: **PIX,PDQ**

Sarah then creates a new EMR for Pinkie using the demographic information she provides – her name, surname, date of birth and address. A unique identification number is generated for Pinkie by the national patient master index (PMI) which responsible for the allocation patient identifiers.	Create new patient record: **PAM, BPPC** Add demographic details: **PAM**
As part of the registration process, Sarah prints a barcoded label and sticks it onto a small card. This label will identify Pinkie to both the EMR and the national shared EHR in future. Sarah then asks Pinkie to wait in the waiting area. After a while, Mary a nurse at the MOU, comes to the waiting area and calls all the pregnant women to follow her to a room for the day's health talk. The focus of the talk is on breastfeeding and the importance of being tested for HIV.	
After the talk, each of the pregnant women is called into the consulting room for a one-on-one consultation with Mary. When her turn comes, Pinkie goes in to see Mary, who scans the barcode on Pinkie's card to retrieve Pinkie's EMR.	Identify patient: **PIX**
She notes that this is Pinkie's first antenatal care visit. Mary asks Pinkie questions about her health history, including how many children she has, number of previous pregnancies and any previous health conditions, with dates and outcomes. She also carries out a number of clinical observations (Pinkie's weight, blood pressure, temperature, urine analysis, fundal height, Pinkie's heart rate, and the baby's heart rate). Mary records the information obtained from Pinkie, as well as the clinical observation data in Pinkie's EMR.	Add medical history: **XDS-APS** Add clinical observations: **XDS-APS** Add "doctor's notes": **XDS-APS** Add and update care plan: **XDS-APS**
Mary then discusses with Pinkie the importance of being tested for HIV. She explains to her that the result of the test will be confidential, and that disclosure of the result to family members would be Pinkie's choice. After the counselling, Pinkie agrees to do the HIV test. Mary asks Pinkie to sign a standard HIV consent form, so that her consent is documented. Pinkie signs the consent form as requested. The signed form is later scanned and uploaded to Pinkie's EMR.	Scan and upload paper document: **XDS-SD**
Mary cleans Pinkie's finger with an alcohol swab and does a finger prick HIV test. She asks Pinkie to wait outside for the result. After 20 minutes Mary calls Pinkie to the consulting room; she tells Pinkie that the test is positive, but that a second test is required to be sure. Mary performs a second finger prick HIV test using a test kit from another manufacturer. About half an hour later, Mary calls Pinkie in again. She is very sorry, she says, but the second test is also positive. Pinkie is understandably devastated and begins to cry. Mary comforts her and provides post-test counselling to Pinkie.	
Mary discusses the prevention of mother to child transmission (PMTCT) program with Pinkie and explains that people with HIV can live normal, healthy lives. She also explains that the PMTCT program will reduce the risk of her unborn baby being infected with HIV. Mary also tells Pinkie that she needs to do more blood tests, so they could put her on appropriate treatment. She then draws blood for three tests: full blood count, CD4 count and Alamine Aminotransferase. Pinkie is also screened	Add clinical observations: **XDS-APS**

for tuberculosis (TB) and Mary asks specific questions regarding and previous TB treatment and symptoms of TB.	
A laboratory order form for the blood tests is completed by Mary and accompanies the blood samples, which are labelled and taken to the laboratory by a courier service.	
Mary initiates Pinkie on prophylactic antiretroviral treatment (ART) with Zidovudine, and iron and folate supplements as per the PMTCT clinical guidelines. She records this prescription in Pinkie's EMR and asks Pinkie to come back to the CHC after one week, so she can be seen by the doctor and her blood results reviewed.	Add pharmacy orders: **XDS-PRE** or Medication Section of: **XDS-APS**
Pinkie stops at the CHC's pharmacy to collect her medicines. She gives her plastic card to Bongi, the pharmacy assistant. Bongi scans the card to retrieve Pinkie's EMR with the prescription; she then dispenses a one-week supply of Zidovudine and the supplements as prescribed. She labels the medicine containers with dosage instructions. Bongi also updates the pharmacy system with details of the dispensed medicines. These details are also recorded in the EMR.	Identify patient: **PIX** Add drugs dispensed: **XDS-DIS** or Medication Section of: **XDS-APS**
Pinkie returns to Sarah, who schedules her appointment using the appointment-scheduling module. Pinkie also receives a text message on her cell phone with the date and time of the appointment. A day before the scheduled appointment, Pinkie receives another text message reminding her about the appointment for the next day. Pinkie's blood tests are completed, and the results are sent directly from the laboratory information system to her EMR.	Add and query test results: **XD-LAB** or Laboratory Section of: **XDS-APS**
On the date of her appointment, Pinkie returns to the CHC. She gives her plastic card to Sarah, who scans the card to confirm Pinkie's appointment. Sarah also checks that Pinkie's details are still the same.	Identify patient: **PIX** Add, query and update demographic details: **PAM**
Pinkie is seen by Dr White. Dr White scans Pinkie's plastic card to retrieve her EMR. He reviews the previous week's encounter, as well as the blood results. Dr White asks Pinkie how she is doing and carries out routine clinical observations. He notes her CD4 count is in the normal range that she is asymptomatic. He assures Pinkie that she and her baby were doing well, and recommends that she continue with the prophylactic ART, which was initiated by the nurse during her last visit. Dr White then completes an electronic prescription for Zidovudine, iron and folate. He also records the day's encounter in Pinkie's EMR. Dr White discusses breast and formula feeding with Pinkie; and the implications of the various options. He tells her she still has to decide whether or not to breastfeed her baby after birth. Pinkie promises to think about it.	Identify patient: **PIX** Add clinical observations. **XDS-APS** Add and update "doctor's notes": **XDS-APS** Add pharmacy orders: X**DS-PRE** or Medication Section of **XDS-APS** Update care plan: **XDS-APS**

Pinkie continues to receive antenatal care at the MOU until she is due to have her baby.	Add and update clinical observations**:** **XDS-APS** Add and update "doctor's notes": XDS-APS Update care plan: **XDS-APS** Add drugs dispensed: **XDS-DIS** or Medication Section of: **XDS-APS**

The sequence diagrams were then updated to include the relevant standards-based profiles linked to each information exchange. See Figure 3-8 for the result of the information exchanges for the registration process, Figure 3-9 for the first antenatal visit, and Figure 3-10 for the follow-up visits.

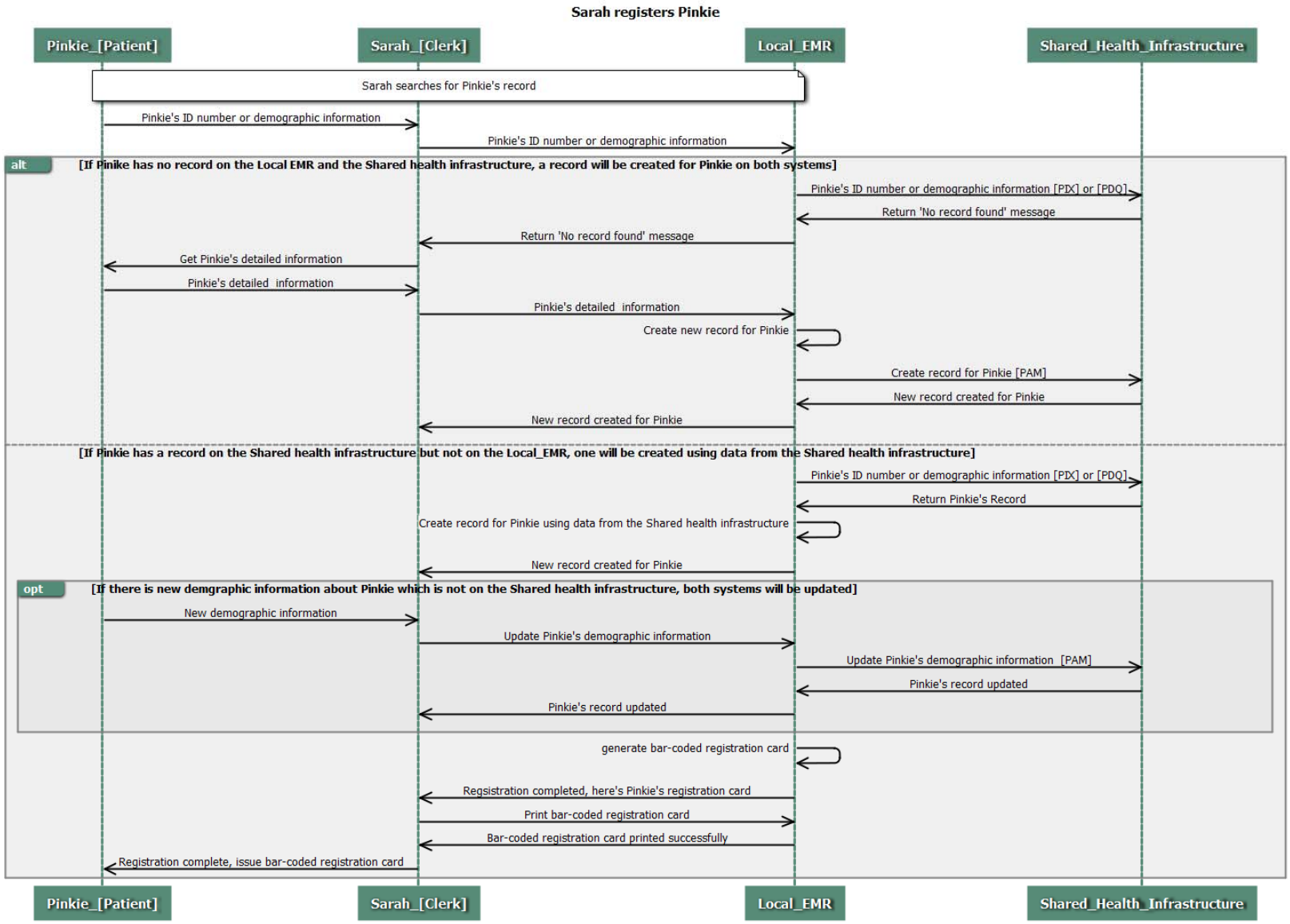

Figure 3-8: Sequence diagram for Pinkie's registration during her first antenatal visit with mappings to IHE profiles

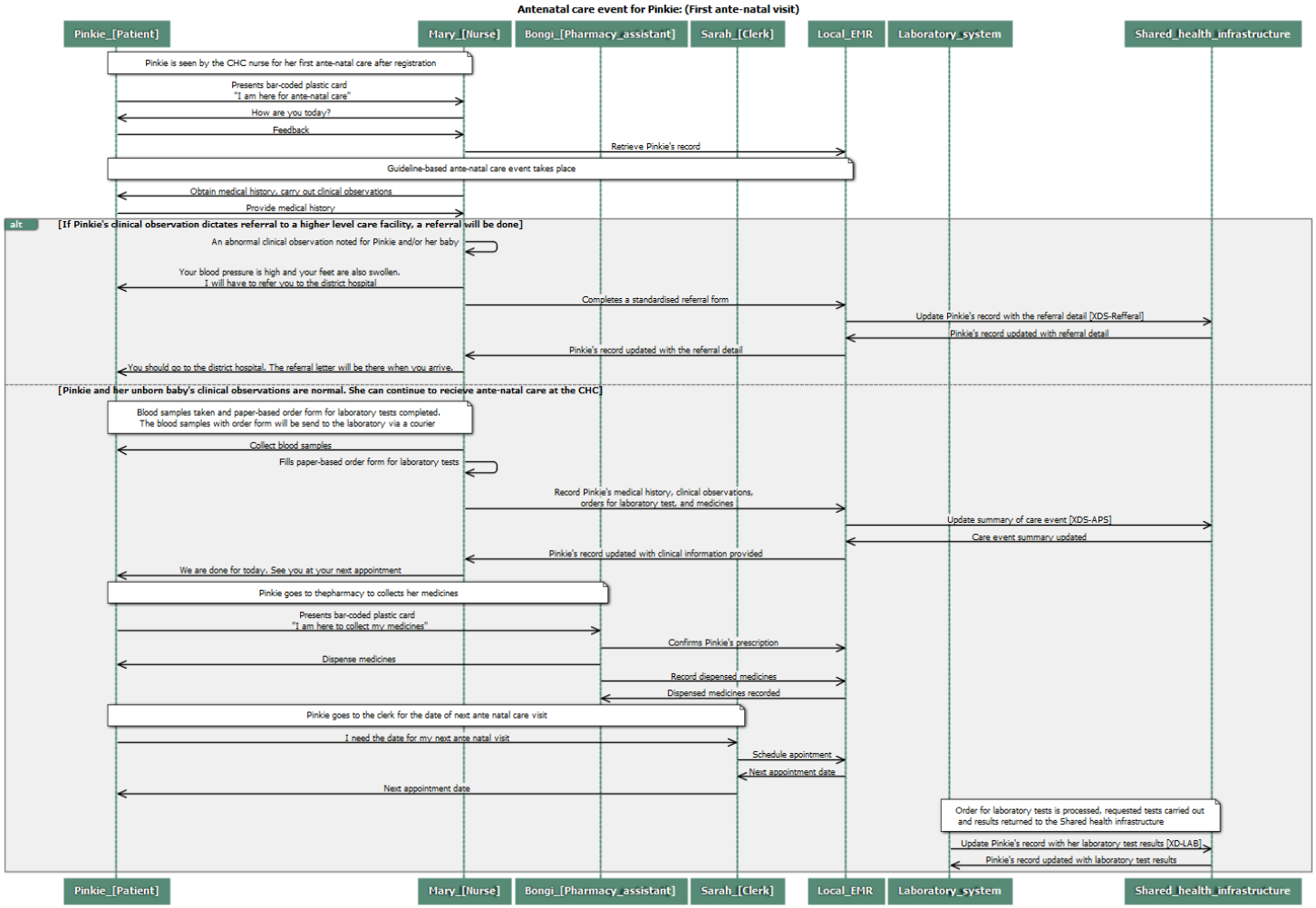

Figure 3-9: Sequence diagram for Pinkie's first antenatal visit with mappings to IHE profiles

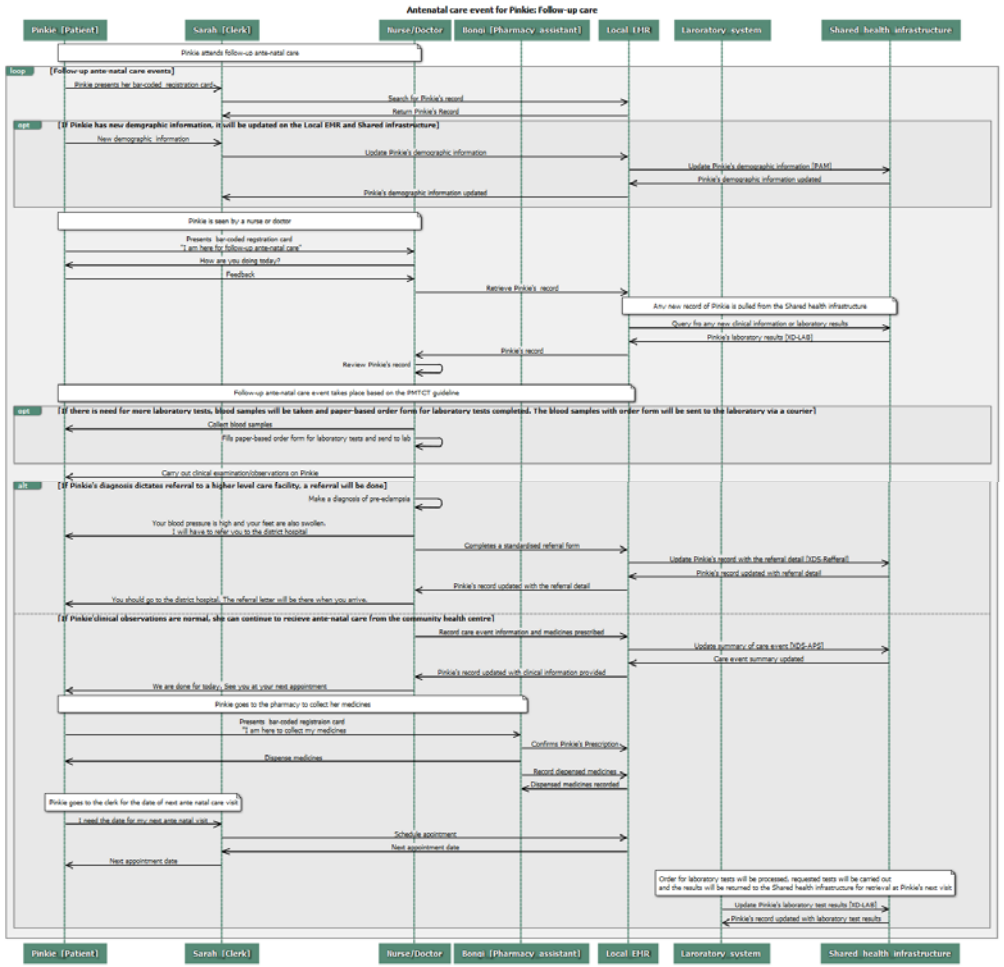

Figure 3-10: Sequence diagram for Pinkie's follow-up antenatal visits with mappings to IHE profiles

Each IHE profile is in turn based on a number of base standards. The relationship between care scenarios, interoperability standards-based profiles and base standards was shown Figure 2-1. Figure 3-11 and Figure 3-12 respectively indicate the IHE Infrastructure and IHE Content Profile and the underlying base standards applicable to Pinkie's scenario. Each of the interoperability standards-based profiles may be reused to support multiple care scenarios. In this way, these standards-based profiles may be thought of as providing conformance-testable 'eHealth building blocks' which support data sharing across many care contexts.

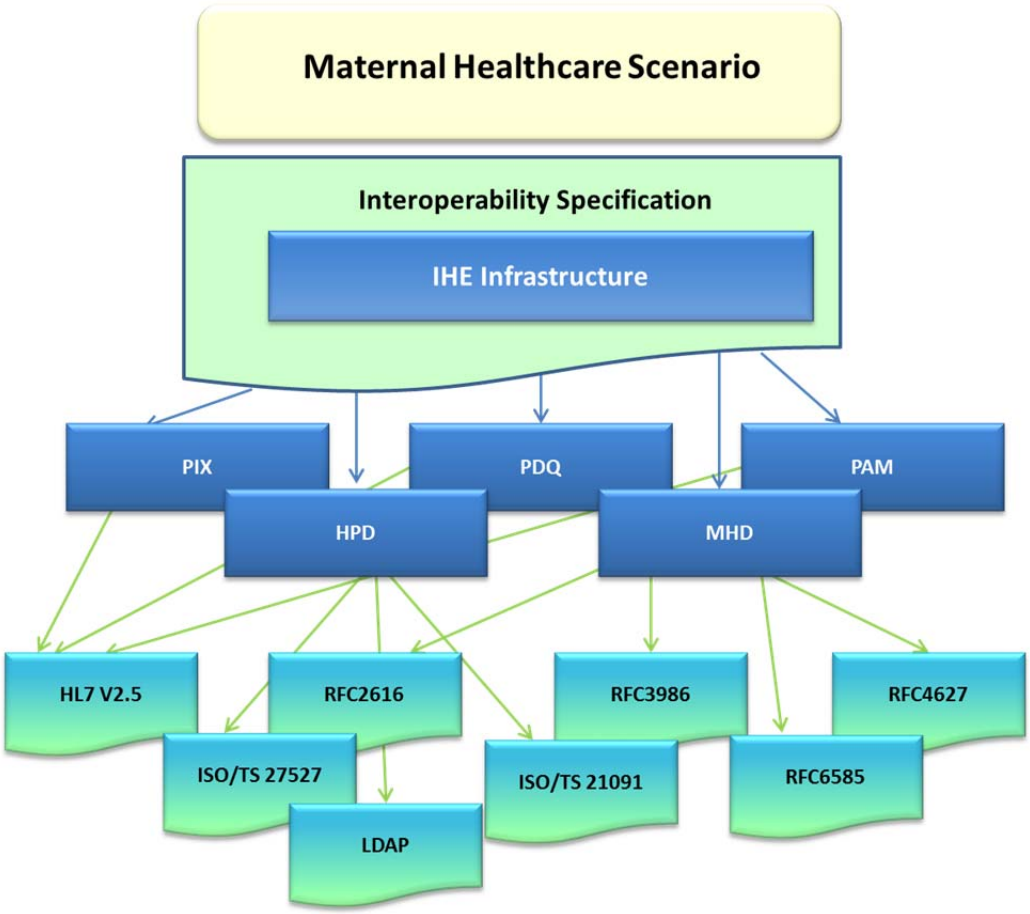

Figure 3-11: IHE Infrastructure Profile and associated base standards applicable to the Pinkie scenario

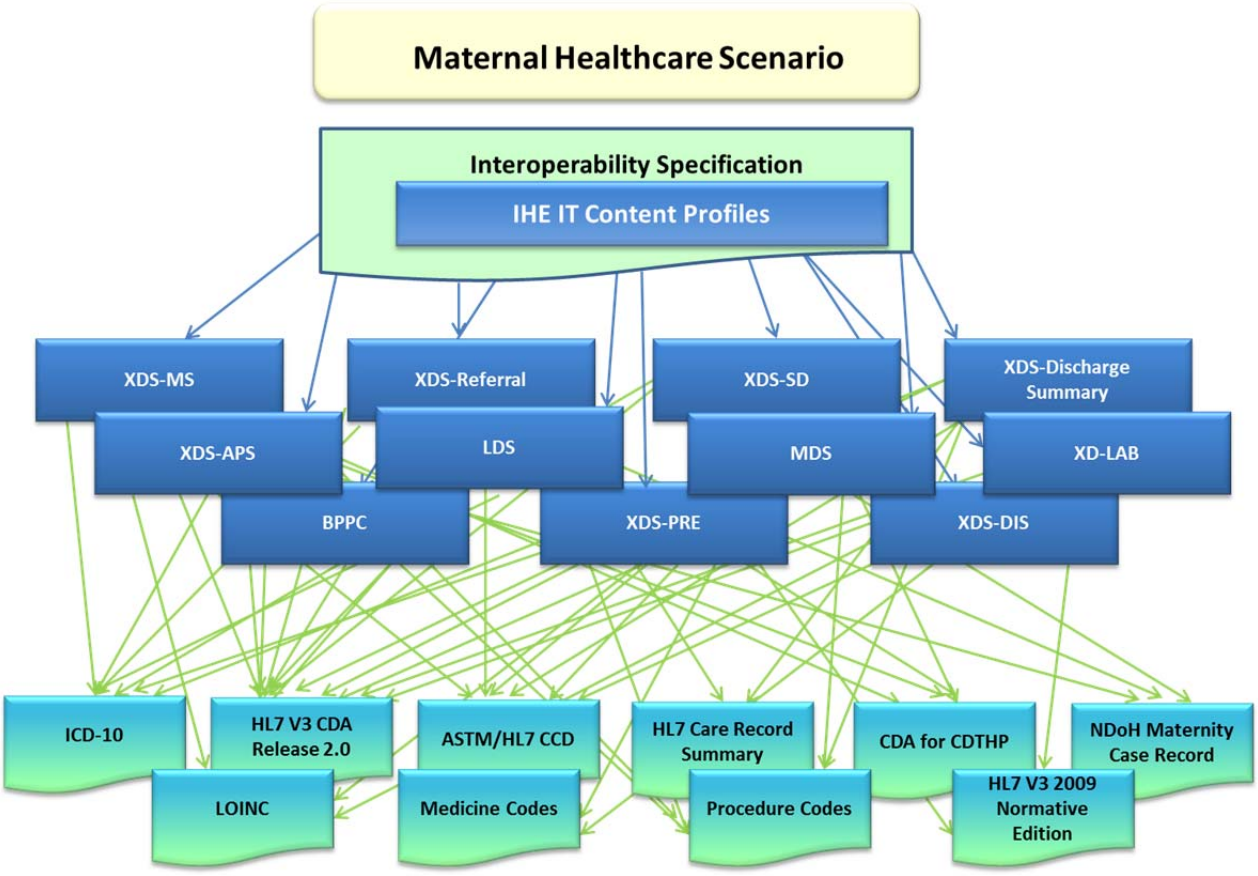

Figure 3-12: IHE Content Profiles and associated base standards applicable to the Pinkie scenario

3.3.2 Mapping the functions to interoperability standards-based profiles and standards

The next step was to map the representative generic set of eHealth functions to the interoperability standards-based profiles. The primary requirement for the standards-based profiles is that they must enable content to be shared with a national shared electronic health record. For each function, a suitable set of interoperability standards-based profiles was determined. These standards-based profiles, in turn, are underpinned by a set of applicable base standards. The set of eHealth standards underlying the resulting set of standards-based profiles were then determined. Not all functions have a corresponding IHE profile and in these instances, appropriate local standards-based profiles will have to be adopted or developed, where necessary. Table 3-5 provides the mapping of the functions to the IHE profiles and the base standards on which these standards-based profiles were based (the mapping is also presented in Appendix E).

The research team also determined the set of general IT standards that are applicable to the selected IHE profiles and determine its compatibility with the Minimum Interoperability Standards for Government Information Systems (MIOS V5) [State Information Technology Agency, 2011b]. Although compatibility with MIOS V5 was determined, it will only be used as reference point to the standards underlying the selected profile, but any verification, adherence testing or enhancement to the complete MIOS V5 is beyond the scope of the HNSF project and resides with the State Information Technology Agency (SITA).

Table 3-5: Mapping the set of functions to IHE Profiles

FUNCTION GROUP	FUNCTIONS	IHE PROFILES	UNDERLYING STANDARDs
Identification, authentication and authorisation	Identify location	HPD	LDAP V3 (MIOS) ISO/TS 21091:2005 DSML V2 SOAP 1.2
	Identify provider	HPD	LDAP V3 (MIOS) ISO/TS 21091:2005 DSML V2 SOAP 1.2
	Identify patient	[2]* - None	
	Authenticate patient	[3]** - None	
	Authenticate provider	[4]** - None	
	Authorise provider roles and permissions	[5]** - None	
Record look-up	**Search for patient record**	PIX	HL7 V2.3.1 HL7 V 2.5
		PDQ	HL7 V 2.5
Add patient record	**Create new patient record**	PAM	HL7 V 2.5
		BPPC	HL7 V3 CDA Release 2.0
	Link baby patient to mother patient	PAM	HL7 V 2.5
	Create temporary patient record	PAM	HL7 V 2.5
	Merge temporary and permanent record	PAM	HL7 V 2.5
Retrieve patient record	**Display only**	RID	RFC1738 XML WSDL XHTML
	Retrieve and display	XDS	HL7 V 2.3.1 HL7 V 2.5 XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS
		MHD	RFC 2616 (MIOS) RFC 3986

[2] There is no IHE Profile for this function; however, a base standard as well as the national population register could be sufficient for this purpose

[3] There is no IHE Profile for this function.

[4] There is no IHE Profile for this function.

[5] There is no IHE Profile for this function.

			RFC 4627 RFC 6585
Update patient record	**Add, query and update demographic details**	PAM	HL7 V2.5
	Add, query and update medical history	XDS-MS	HL7 V 2.3.1 HL7 V 2.5 XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0 CDA for CDTHP
	Add, query and update clinical observations	XDS-MS	HL7 V 2.5 XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0
	Add, query and update interventions	XDS-MS	HL7 V 2.5 XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0
	Add and query referrals	XDS-MS Referral Summary	HL7 V 2.3.1 HL7 V 2.5 XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0 HL7 CRS ASTM/HL7 CCD
	Add and query pharmacy orders	XDS-PRE	HL7 V 2.3.1 HL7 V 2.5 XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS

			HL7 V3 Normative Edition (CMET only) ASTM/HL7 CCD
	Add and query drugs dispensed	XDS-DIS	HL7 V 2.3.1 HL7 V 2.5 XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 Normative Edition (CMET only) ASTM/HL7 CCD
	Add and query orders for laboratory tests	XDS	HL7 V 2.3.1 HL7 V 2.5 XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS
	Add and query laboratory test results	XD-LAB	HL7 V 2.3.1 HL7 V 2.5 XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0 LOINC SNOMED
	Add and query orders for radiology tests	XDS	DICOM 2011, [ISO/IEC 12052] (MIOS) HL7 V 2.3.1 HL7 V 2.5 XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0
	Add and query radiology test results	SINR	DICOM 2011, [ISO/IEC 12052]) (MIOS) HL7 V3 CDA Release 2.0
		XDS-I.b	DICOM 2011, [ISO/IEC 12052]) (MIOS)

			[6]ISO 19005-1 (PDF/A-1) SOAP-MTOM XML-binary OP HL7 V3 CDA Release 2.0
	Add, query and update "doctor's notes"	XDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0
	Add and query discharge summary (incl. transfer)	XDS-MS Discharge summary	HL7 V 2.3.1 HL7 V 2.5 XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0 HL7 V3 CDA Release 2.0 HL7 Care Record Summary ASTM/HL7 CCD
		XDS-MDS	HL7 V 2.3.1 HL7 V 2.5 XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0 ASTM/HL7 CCD NDoH Maternal Case Record HL7 Care Record Summary
	Add and query OP encounter outcome	XDS-MS	HL7 V 2.3.1 HL7 V 2.5 XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0
	Add, query and update ante-natal care events	XDS-APS	HL7 V 2.3.1 HL7 V 2.5

[6] Based on an earlier version of MIOS (SANS 32000-1)

			XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0 ASTM/HL7 CCD NDoH Maternal Case Record HL7 Care Record Summary
	Add and query birth details	XDS XDS-LDS	HL7 V 2.3.1 HL7 V 2.5 XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0 ASTM/HL7 CCD NDoH Maternal Case Record HL7 Care Record Summary
	Add and query death details	XDS	HL7 V 2.3.1 HL7 V 2.5 XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0
	Add, query and update care plan	XDS	HL7 V 2.3.1 HL7 V 2.5 XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0
		[7]PPOC	HL7 V 2.3.1 HL7 V 2.5 XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS)

[7] PPOC is based on the American Nursing Association (ANA) Nursing Scope and Standard of Practice

			ebMS ebRIM ebRS HL7 V3 CDA Release 2.0 ASTM/HL7 CCD
	Scan and upload paper document	XDS-SD	RFC 3778 [8]ISO 19005-1 (PDF/A-1) RFC 3066 HL7 V3 CDA Release 2.0
	Exchange documents using electronic document media (Email, USB, CD, etc.)	XDM	DICOM Media Formats CD, USB, ZIP, Email media formats XHTML ebRIM ebXML
	Add, query and update records via mobile device	MHD	RFC 2616 (MIOS) RFC 3986 RFC 4627 RFC 6585
Scheduling	**Schedule appointment**	[9]** - None	
	Send reminders	[10]** - None	
	Confirm attendance or cancellation	XDS	HL7 V 2.3.1 HL7 V 2.5 XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS
Emergency medical services - peripheral	**Contact ambulance**	[11]** - None	
	Dispatch ambulance	[12]** - None	
	Route ambulance	[13]** - None	
Supply chain management – peripheral	**Update pharmacy stock**	[14]** - None	
Create billing account	**Add, query and update bills**	[15]** - None	
Generate metrics	**Aggregated data query**	MPQ	ebRIM ebRS
	Add, query and update health	[16]** - None	

[8] Based on an earlier version of MIOS (SANS 32000-1)
[9] There is no IHE Profile for this function.
[10] There is no IHE Profile for this function.
[11] There is no IHE Profile for this function.
[12] There is no IHE Profile for this function.
[13] There is no IHE Profile for this function.
[14] There is no IHE Profile for this function.
[15] There is no IHE Profile for this function.
[16] There is no IHE Profile for this function.

	indicator		
[17]Non eHealth specific functions			
Node authentication	**Authenticate system**	ATNA	[18]RFC 2246 WS-I Basic Security Profile 1.1 [19]S/MIME V3.1 AES (MIOS) [20]SHA-1 (MIOS) RSA X.509 (MIOS) RFC 5424 RFC 5425 RFC 5426 RFC 3164 RFC 3881
Maintain system clock	Maintain system clock	CT	NTP V3 (RFC 1305) SNTP (RFC 4330)

3.3.3 Addressing the gaps

In cases where there are no IHE profiles suitable to the identified functions (annotations were made identifying these cases in Table 3-5), applicable underlying base standards were identified for the functions (as listed in Table 3-6). If the decision is made by NDoH to go the profile route based on IHE Profiles, then South African standards-based profiles for these 'missing' IHE profiles will have to be established.

In a number of instances, the underlying base standards were found not to be sufficient for the HNSF or the South African context. In these cases, alternative underlying base standards that are applicable, based on literature studies of international eHealth standards, were identified (annotated with footnotes in Table 3-6).

3.4 Determining the suitability of the standards-based profiles and base standards

The content of the shared electronic health record should be tested to determine to what extent business requirements are satisfied. The shared content in the EHR must be a reliable source to support continuity of care and for the generation of national indicators. At this point, no specification for the requirement for continuity of care exists for a South African eHealth system (based on a shared infrastructure). However, there is a national indicator data set (NIDS) [National Department of Health, 2010c], which the research team used to illustrate the concept (the version of the NIDS used is presented in Appendix H).

The standards-based profiles applied to health use cases must be able to support sufficient data exchange to the shared health infrastructure so that all base data necessary for the calculation of the National Indicator Data Set (NIDS) data elements and indicators is accessible from the shared health infrastructure. NIDS indicators that cannot reliably be generated from the data model that form the basis of the shared EHRs, will illustrate the extent to which the standards-based profiles and base standards are inadequate

[17] The IHE profiles listed are required for the other IHE profiles
[18] This is an earlier version of MIOS (RFC 5246)
[19] This is a later version of MIOS (S/MIME V3)
[20] MIOS specifies SHA-2

and need to be included and/or localised. Whether this can be done, should be confirmed by the underlying data model used in the shared EHR:

- Can health indicators be reliably generated from the data model?
- Can continuity of care be supported by the data provided via this data model?

The shared content therefore requires a corresponding data structure. This data structure must contain the patient-based transactional data where each transaction is uniquely indexed by a *Patient ID*, a *Facility ID*, a *Provider ID*, a *Document ID*, a *Document Type* and a *Timestamp*. Figure 3-13 shows a generic example of such a data model.

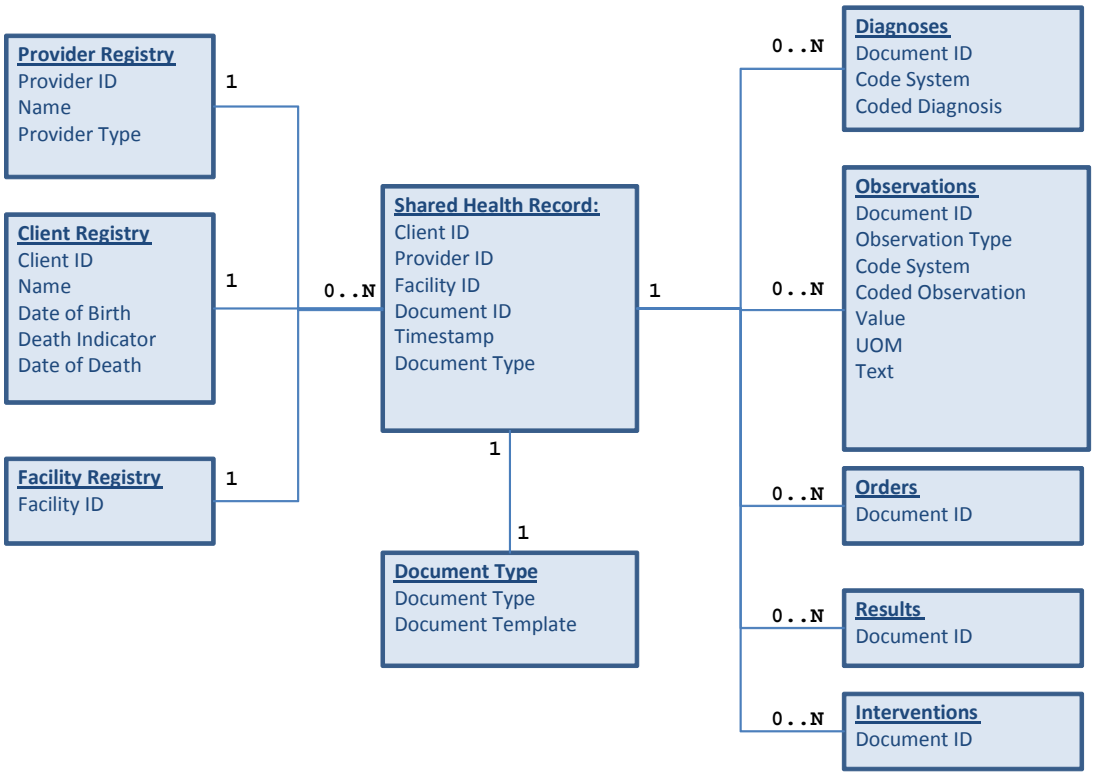

Figure 3-13: Example of data model for a shared health record

For the Pinkie use case, the resulting data model must be tested to determine whether the health indicators applicable to antenatal care, delivery and post-natal care can be reliably generated from this. Those indicators that cannot be generated are identified as a gap in the content delivered. This indicates that the standards-based profiles and related base standards mandated are inadequate and must be improved.

This process is illustrated in Figure 3-14 and illustrated below using the Pinkie use case as an example.

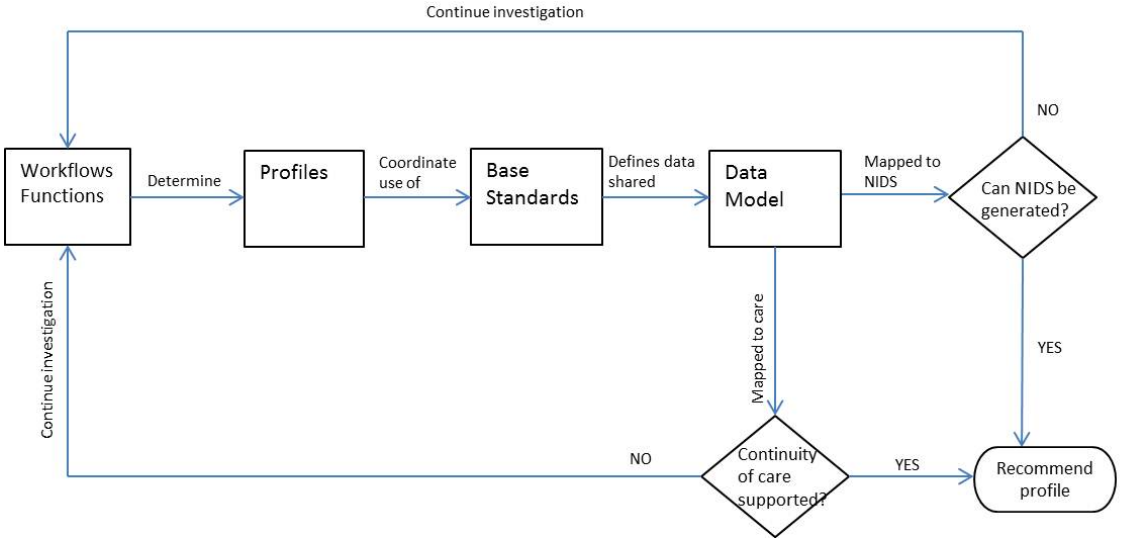

Figure 3-14: Assessing the standards-based profiles and base standards

Using the IHE profiles in an application means that along the way, the content will be structured and encoded according to a specific interoperability profile, for example, the IHE XDS-APS (Cross-Enterprise Document Sharing: Antepartum Summary), which summarises the patient-based transactions within the antenatal care, delivery and post-natal care context. For this interoperability profile, base standards must be used to:

1. Code the clinical message, in this case HL7 Clinical Document Architecture (CDA).
2. Code the document content, using base standards such as ICD-10. (Note that different standards apply to the coding of the message and the content.)
3. Pinkie's shared health record would be updated according to the guidelines in the IHE XDS-APS profile. The message will be coded in an HL7 CDA document as recommended in the IHE profile XDS-APS. The message format for HL7 CDA is highly structured, with the content encoded. Extracts from an HL7 CDA document are shown in Figure 3-15, Figure 3-16 and Figure 3-17. Relevant content is highlighted.

```
<recordTarget>
   <patientRole>
    <id root="1.3.6.1.4.1.33349.3.1.2.1.0" extension="494825-231102-2022M"/>
    <addr nullFlavor="NI">
    </addr>
    <telecom value="+11 5559234"/>
    <patient>
     <name>
      <given>Pinkie</given>
      <family>Ntshoni</family>
     </name>
     <administrativeGenderCode code="F" displayName="Female" codeSystem="2.16.840.1.113883.5.1"
codeSystemName="HL7 AdministrativeGender"/>
     <birthTime value="19930803"/>
    </patient>
   </patientRole>
  </recordTarget>
```

Figure 3-15: Extract from HL7 CDA document: Subject of Care

```
<author>
   <time value="20130121"/>
   <assignedAuthor>
    <id root="1.3.6.1.4.1.33349.3.1.2.1.1" extension="0009" assigningAuthorityName="Department of Health"/>
    <telecom value="+11 5552109"/>
    <assignedPerson>
     <name>
      <given>Sarah</given>
      <family>Witbooi</family>
     </name>
    </assignedPerson>
    <representedOrganization>
     <name>Department of Health</name>
    </representedOrganization>
   </assignedAuthor>
  </author>
```

Figure 3-16: Extract from HL7 CDA document: Provider of Care

```
<observation classCode="OBS" moodCode="EVN" negationInd="false">
  <templateId root="2.16.840.1.113883.10.20.1.28" assigningAuthorityName="CCD"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5" assigningAuthorityName="IHE PCC"/>
  <id root="FBB577C2-DBC0-4ba0-B25B-97FE763AC29F"/>
  <code code="64572001" codeSystemName="SNOMED-CT" codeSystem="2.16.840.1.113883.6.96"
displayName="Condition"/>
  <text>
   <reference value="#Preg"/>
  </text>
  <statusCode code="active"/>
  <effectiveTime>
   <low value="20130121"/>
   <high nullFlavor="UNK"/>
  </effectiveTime>
  <value xsi:type="CV" code="Z34" codeSystem="2.16.840.1.113883.6.3" codeSystemName="ICD10"
codeSystemVersion="10" displayName="Supervision of normal pregnancy"/>
  <performer typeCode="PRF">
   <assignedEntity>
    <id root="1.3.6.1.4.1.33349.3.1.2.1.1" extension="0009" assigningAuthorityName="Department of Health"/>
   </assignedEntity>
  </performer>
</observation>
```

Figure 3-17: Extract from HL7 CDA document: Clinical observation

In order to be sufficient, the coded clinical message and document content should carry sufficient data to be stored in the shared health infrastructure (for maturity levels 3 and 4) to allow calculation of the NIDS data elements.

For example, the NIDS data element ‘PHC case seen by Professional Nurse’ is defined as ‘a patient/client (child or adult) seen by a professional nurse for a Primary Healthcare service’. In the use case describing Pinkie’s (patient) visit to the CHC, each transaction exchanged with the shared health infrastructure will, as described above, be uniquely indexed by a *Patient ID*, a *Facility ID*, a *Provider ID*, a *Document ID*, a *Document Type* and a *Timestamp*. The accompanying encoded message (called a document), identified by

the *Document ID*, will provide coded information about the care event, including reason for visit, diagnosis and treatment.

Now there should be sufficient data in the shared health infrastructure to allow the counting of 'PHC case seen by Professional Nurse' at the specific CHC within the month of February 2013. The *Provider ID* will locate the *Provider* record in the *Provider Registry*, where it will have the attribute of '*Professional Nurse*'. The *Facility ID* will locate the facility record for the PHC in the *Facility Registry*, where it will have the attribute of '*PHC clinic*'. The *Timestamp* will show that the case was seen in February 2013. The document will contain the reason for the visit, which will indicate that a curative service was provided.

It was determined that the standards-based profiles indicated for sharing transaction-based content in in the course of Pinkie's antenatal care, delivery and post-natal care (section 3.3.1) would provide sufficient data to derive the following NIDS indicators:

1. Number of people 5 years and older seen at the CHC
2. Number of people seen by a Professional Nurse
3. Number of women given vitamin A supplement within 8 weeks after delivery
4. Total number of antenatal 1st visit
5. Total number of antenatal follow-up visit
6. Total number of antenatal 1st visit at 20 weeks or later
7. Total number of antenatal 1st visit before 20 weeks
8. Total number of pregnant women who received 2nd/Booster dose of Tetanus Toxoid
9. Total number of antenatal client on HAART at delivery
10. Total number antenatal client eligible for HAART
11. Total number of babies initiated on HAART (under 18 months)
12. Total number of babies eligible for HAART
13. Total number of antenatal client on HAART at 1st visit
14. Total number of antenatal client who were re-tested for HIV at 32 weeks or later
15. Total number of antenatal client re-tested at 32 weeks or later with positive HIV result
16. Total number of antenatal client on AZT before labour
17. Total number of antenatal client Nevirapine taken during labour
18. Total live births to HIV positive women
19. Total number of babies given Nevirapine within 72 hours after birth
20. Total number of babies initiated on Co-Trimoxazole around 6 weeks
21. Total number of babies who had PCR test done around 6 weeks
22. Total number of babies whose PCR test was positive around 6 weeks
23. Total number of antenatal client known to be HIV positive but NOT on HAART at 1st visit
24. Total number of antenatal client who had the 1st HIV test done
25. Total number of antenatal client whose 1st HIV test was positive
26. Total number of antenatal client who had 1st CD4 test done
27. Number of patients with a CD4 count below 100 at baseline
28. Total number of antenatal client initiated on AZT
29. Total number of antenatal client initiated on HAART
30. Total number of delivery in facility under 18 years
31. Total number of delivery in facility 35 years and older
32. Total number of delivery in facility
33. Total live birth in facility under 2500g
34. Total live birth in facility
35. Total number of maternal death in facility
36. Total number of normal delivery in facility
37. Total still birth in facility
38. Total births in facility
39. Number of babies who received post-natal care within 6 days after birth
40. Number of mothers who received post-natal care within 6 days after delivery
41. Total birth defects case - mother 35 years and older
42. Total birth defects case - mother under 18 years
43. Total number of children with common priority Birth Defects
44. Number of children under 5 years that were weighed
45. Number of children under 1 year that had the 1st dose of BCG.

The above steps must be repeated for each possible use case in the clinical care context (where that use case generates patient-based transactions that must be shared). Applying this method, the research team worked through each scenario or use case, establishing which NIDS data elements could be derived from the data shared according to the standards-based profiles for each health function. It was established that

all NIDS data elements, which derive from patient encounters, could be calculated from the data sent to the shared health infrastructure.

3.5 Map Profiles to Maturity Level 4

To give an indication as to where the various IHE profiles and their associate base standards will apply, the appropriate standards-based profiles were mapped to the figure illustrating maturity Level 4. As illustrated, the standards-based profiles and associated base standards are applicable wherever any component in the eHealth system interfaces with any other component, i.e. interoperability plays a role over the entire eHealth system, from the local infrastructure right through to every component in the shared infrastructure.

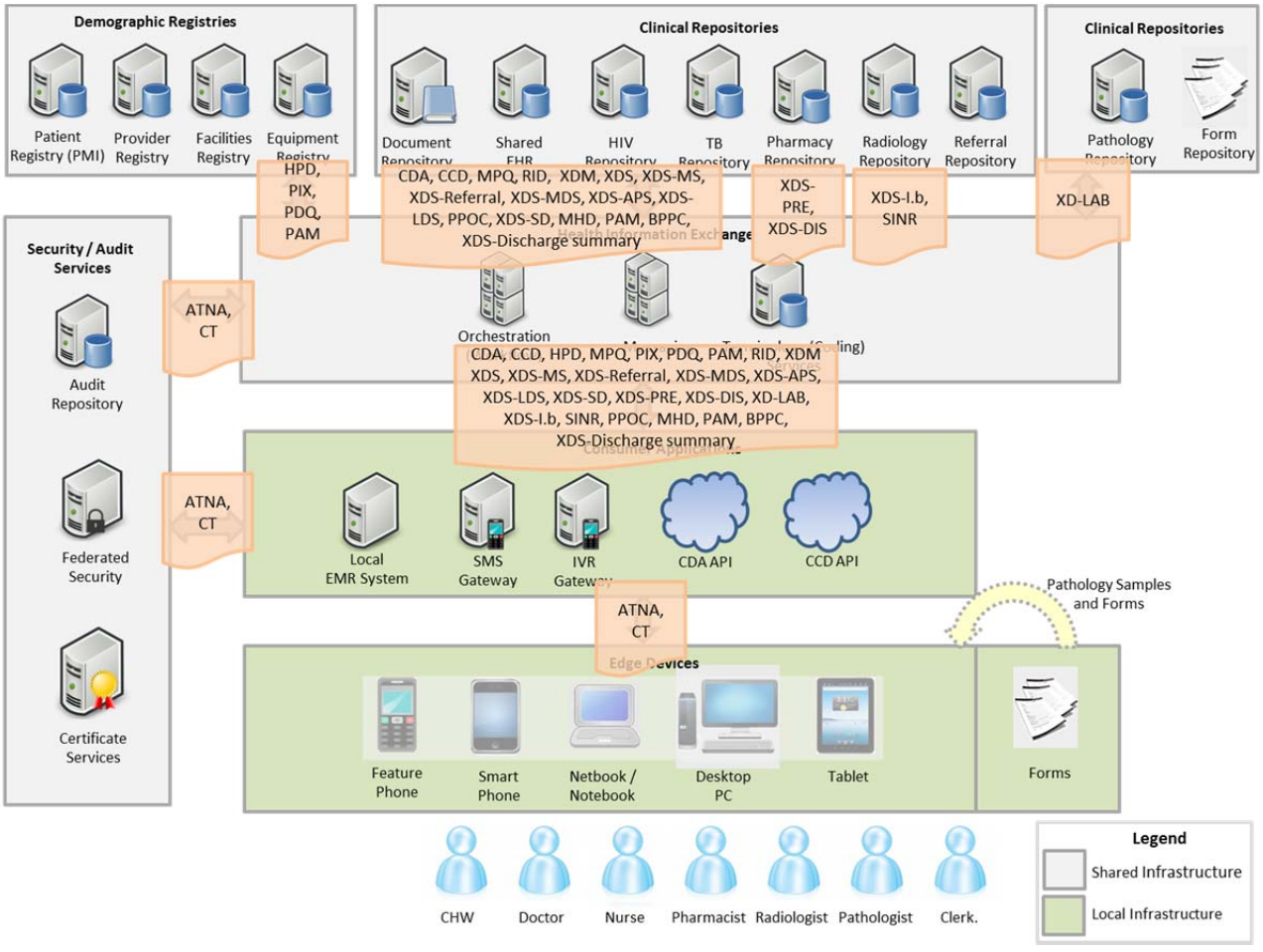

Figure 3-18: IHE profiles mapped to eHealth maturity level 4 diagram

3.6 The result – the National Health Normative Standard Framework for Interoperability in eHealth

The outcomes of these activities resulted in the first version of the National Health Normative Standards Framework for Interoperability in eHealth in South Africa (HNSF). The relationship between the components of the HNSF is illustrated in Figure 3-19. The functions, derived from the workflows, are mapped to the standards-based profiles. The functions determine standards-based profiles that will be

applicable. The standards-based profiles coordinate several base standards to ensure the outcome of the function. From the function and the base standards, the shared content is identified. The NIDS can be calculated based on the data stored in the shared content.

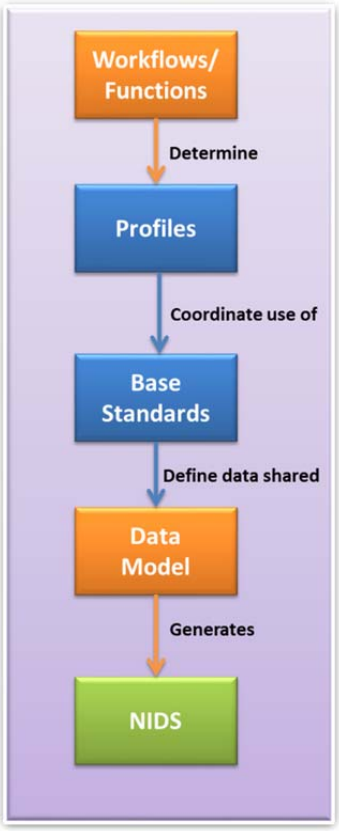

Figure 3-19: Relationships between the components of the National Health Normative Standards Framework for Interoperability in eHealth

The integrated data set forming the HNSF is presented in Table 3-6 (the mapping is also presented in Appendix F). The base standards used in the HNSF are classified into the following categories:

- General IT standards.
- Identifier standards.
- Messaging standards.
- Coding and terminology standards.
- Content and structure standards.
- Electronic health record (EHR) standards.
- Security standards.

Section 3.6.1 gives more detail on each of the base standards referenced in the HNSF.

In addition to the HNSF, section 3.6.2 names a number of other standards that could be applicable to eHealth in South Africa, namely healthcard standards, biometric standards, and barcode standards.

Table 3-6: The Normative Standards Framework for interoperability in eHealth

FUNCTION GROUP	FUNCTION	IHE PROFILES	General IT standards	Identifier standards	Messaging standards	Coding and terminology	Content and structure standards	EHR standards	Security standards
Identification, authentication and authorisation	**Identify location**	HPD	LDAP (MIOS) ISO/TS 21091:2005 DSML V2 SOAP 1.2 (MIOS)	ISO/TS 27527:2010					
	Identify provider	HPD	LDAP (MIOS) ISO/TS 21091:2005 DSML V2 SOAP 1.2 (MIOS)	NPR (MIOS) ISO/TS 27527:2010					
	Identify patient	[21]None		NPR (MIOS) ISO 22220:2011					
	Authenticate patient	[22]None							
	Authenticate provider	[23]None							
	Authorise provider roles and permissions	[24]None	ANSI INCITS 359-2004						ISO/TS 22600:1-3
Record look-up	**Search for patient record**	PIX	XML V1.0 (MIOS)		[25]HL7 V2.X				
		PDQ	XML V1.0 (MIOS)		[26]HL7 V2.X				
Add patient record	**Create new patient record**	PAM	XML V1.0 (MIOS)		[27]HL7 V2.X			ISO/TR 20514:2005 ISO 18308:2011	
		BPPC					HL7 V3 CDA Release 2.0	ISO/TR 20514:2005 ISO 18308:2011	

[21] Although there is no IHE profile for this function, the identifier standard (ISO 22220:2011) and the NPR could be sufficient for our purpose
[22] There is no IHE profile for this function
[23] There is no IHE profile for this function
[24] Although there is no IHE profile for this function, the security standard (ISO/TS 22600:1-3) and general role-based access control could be could be sufficient for our purpose
[25] IHE profile specifies 2 versions of HL7 (v2.3.1 and v2.5). A higher version, which uses XML syntax, is adopted.
[26] IHE profile specifies IHE v2.5. A higher version, which uses XML syntax, is adopted.
[27] IHE profile specifies IHE v2.5. A higher version, which uses XML syntax, is adopted.

FUNCTION GROUP	FUNCTION	IHE PROFILES	General IT standards	Identifier standards	Messaging standards	Coding and terminology	Content and structure standards	EHR standards	Security standards
	Link baby patient to mother patient	PAM	XML V1.0 (MIOS)		[28]HL7 V2.X		HL7 V3 CDA Release 2.0	ISO/TR 20514:2005 ISO 18308:2011	
	Create temporary patient record	PAM	XML V1.0 (MIOS)		[29]HL7 V2.X				
	Merge temporary and permanent record	PAM	XML V1.0 (MIOS)		[30]HL7 V2.X				
Retrieve patient record	**Display only**	RID	RFC1738 XML WSDL XHTML						
	Retrieve and display	XDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS		[31]HL7 V2.X				
		MHD	RFC 2616 (MIOS) RFC 3986 RFC 4627 RFC 6585						
Update patient record	**Add, query and update demographic details**	PAM	XML V1.0 (MIOS)		[32]HL7 V2.X				

[28] IHE profile specifies IHE v2.5. A higher version, which uses XML syntax, is adopted.
[29] IHE profile specifies IHE v2.5. A higher version, which uses XML syntax, is adopted.
[30] IHE profile specifies IHE v2.5. A higher version, which uses XML syntax, is adopted.
[31] IHE profile specifies two versions of HL7 (v2.3.1 and v2.5). A higher version, which uses XML syntax, is adopted.
[32] IHE profile specifies IHE v2.5. A higher version, which uses XML syntax, is adopted.

FUNCTION GROUP	FUNCTION	IHE PROFILES	General IT standards	Identifier standards	Messaging standards	Coding and terminology	Content and structure standards	EHR standards	Security standards
	Add, query and update medical history	XDS-MS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS			ICD-10 (MIOS) Procedure codes (e.g. CPT)	HL7 V3 CDA Release 2.0 CDA for CDTHP		
	Add, query and update clinical observations	XDS-MS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS				HL7 V3 CDA Release 2.0		
	Add, query and update interventions	XDS-MS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS			ICD-10 (MIOS) Procedure codes (e.g. CPT)			
	Add and query referrals	XDS-MS Referral Summary	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS			ICD-10 (MIOS) Procedure codes (e.g. CPT)	HL7 V3 CDA Release 2.0 HL7 CRS ASTM/HL7 CCD		
	Add and query pharmacy orders	XDS-PRE	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS			Medicine codes (e.g. ATC, NAPPI, RxNorm, AMT)	HL7 V3 Normative Edition (CMET only) ASTM/HL7 CCD		

FUNCTION GROUP	FUNCTION	IHE PROFILES	General IT standards	Identifier standards	Messaging standards	Coding and terminology	Content and structure standards	EHR standards	Security standards
	Add and query drugs dispensed	XDS-DIS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS			Medicine codes (e.g. ATC, NAPPI, RxNorm, AMT)	HL7 V3 Normative Edition (CMET only) ASTM/HL7 CCD		
	Add and query orders for laboratory tests	XDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS			ICD-10 (MIOS) LOINC	HL7 V3 CDA Release 2.0		
	Add and query laboratory test results	XD-LAB	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS		DICOM 2011, [ISO/IEC 12052] (MIOS) HL7 V2.X	ICD-10 (MIOS) LOINC	HL7 V3 CDA Release 2.0		
	Add and query orders for radiology test s	XDS				ICD-10 (MIOS)	HL7 V3 CDA Release 2.0		
	Add and query radiology test results	SINR			DICOM 2011, [ISO/IEC 12052]) (MIOS)	ICD-10 (MIOS)	HL7 V3 CDA Release 2.0		
		XDS-I.b	[33]ISO 19005-1 (PDF/A-1) SOAP-MTOM XML-binary OP		DICOM 2011, [ISO/IEC 12052]) (MIOS)	ICD-10 (MIOS)	HL7 V3 CDA Release 2.0		

[33] Based on an earlier version of MIOS (SANS 32000-1)

FUNCTION GROUP	FUNCTION	IHE PROFILES	General IT standards	Identifier standards	Messaging standards	Coding and terminology	Content and structure standards	EHR standards	Security standards
	Add, query and update "doctor's notes"	XDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS				HL7 V3 CDA Release 2.0		
	Add and query discharge summary (incl. transfer)	XDS-MS Discharge Summary	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS			ICD-10 (MIOS) Procedure codes (e.g. CPT)	HL7 V3 CDA Release 2.0 HL7 CRS ASTM/HL7 CCD		
		XDS-MDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS			ICD-10 (MIOS) Procedure codes (e.g. CPT)	HL7 V3 CDA Release 2.0 ASTM/HL7 CCD NDoH Maternal Case Record HL7 CRS		
	Add and query OP encounter outcome	XDS-MS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS			ICD-10 (MIOS) Procedure codes (e.g. CPT)	HL7 V3 CDA Release 2.0		
	Add, query and update antenatal care events	XDS-APS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS			ICD-10 (MIOS) Procedure codes (e.g. CPT)	HL7 V3 CDA Release 2.0 ASTM/HL7 CCD NDoH Maternal Case Record HL7 CRS		

FUNCTION GROUP	FUNCTION	IHE PROFILES	General IT standards	Identifier standards	Messaging standards	Coding and terminology	Content and structure standards	EHR standards	Security standards
	Add and query birth details	XDS XDS-LDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS			ICD-10 (MIOS) Procedure codes (e.g. CPT)	HL7 V3 CDA Release 2.0 ASTM/HL7 CCD NDoH Maternal Case Record HL7 CRS		
	Add and query death details	XDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS			ICD-10 (MIOS) Procedure codes (e.g. CPT)	HL7 V3 CDA Release 2.0		
	Add, query and update care plan	XDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS			ICD-10 (MIOS) Procedure codes (e.g. CPT) Medicine codes (e.g. ATC, NAPPI, RxNorm, AMT) LOINC	HL7 V3 CDA Release 2.0		
		[34]PPOC	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS				HL7 V3 CDA Release 2.0 ASTM/HL7 CCD		
	Scan and upload paper document	XDS-SD	RFC 3778 [35]ISO 19005-1 (PDF/A-1) RFC 3066				HL7 V3 CDA Release 2.0		

[34] PPOC is based on the American Nursing Association (ANA) Nursing Scope and Standard of Practice
[35] Based on an earlier version of MIOS (SANS 32000-1)

FUNCTION GROUP	FUNCTION	IHE PROFILES	General IT standards	Identifier standards	Messaging standards	Coding and terminology	Content and structure standards	EHR standards	Security standards
	Exchange documents using electronic document media (Email, USB, CD, etc.)	XDM	DICOM Media Formats XHTML ebRIM ebXML Media formats ZIP format						
	Add, query and update records via mobile device	MHD	RFC 2616 (MIOS) RFC 3986 RFC 4627 RFC 6585						
Scheduling	**Schedule appointment**	[36]None							
	Send reminders	[37]None							
	Confirm attendance or cancellation	XDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS		HL7 V2.X				
Emergency medical services - peripheral	**Contact ambulance**	[38]None							
	Dispatch ambulance	[39]None							
	Route ambulance	[40]None							
Supply chain management - peripheral	**Update pharmacy stock**	[41]None							

[36] There is no IHE profile for this function
[37] There is no IHE profile for this function
[38] There is no IHE profile for this function
[39] There is no IHE profile for this function
[40] There is no IHE profile for this function
[41] There is no IHE profile for this function

FUNCTION GROUP	FUNCTION	IHE PROFILES	General IT standards	Identifier standards	Messaging standards	Coding and terminology	Content and structure standards	EHR standards	Security standards
Create billing account	**Add, query and update bills**	[42]None	XML V1.0 (MIOS)		HL7 V2.X	ICD-10 (MIOS) Procedure codes (e.g. CPT) Medicine codes (e.g. ATC, NAPPI, RxNorm, AMT) LOINC [43]UPFS			
	Submit medical bills for payment		UN/EDIFACT						
Generate metrics	**Aggregated query**	MPQ	ebRIM ebRS						
	Add, query and update health indicator				SDMX-HD				

[42] Although there is no IHE profile for this function, there is HL7 message specification for creating and updating patient account

[43] The Uniform Patient Fee Schedule (UPFS) has been developed by the NDoH to guide the tariffs that are charged to full paying and subsidised patients for health serviced rendered at public health facilities

[44]Essential non-health specific functions									
Node authentication	**Authenticate system**	ATNA	[45]RFC 2246 WS-I Basic Security Profile 1.1 [46]S/MIME V3.1 AES (MIOS) [47]SHA-1 (MIOS) RSA X.509 (MIOS) RFC 5424 RFC 5425 RFC 5426 RFC 3164 RFC 3881						
Maintain system clock	Maintain system clock	CT	NTP V3 (RFC 1305) SNTP (RFC 4330)						

[44] The IHE profiles listed are required for the other IHE profiles
[45] This is an earlier version of MIOS (RFC 5246)
[46] This is a later version of MIOS (S/MIME V3)
[47] MIOS specifies SHA-2

3.6.1 Applicable standards

The standards that are applicable to eHealth in South Africa, as presented in Table 3-6, are classified into the following categories:

1. Identifier standards
2. Messaging standards:
3. Coding and terminology standards
4. Content and structure standards
5. EHR standards
6. Health specific security standards
7. General IT standards

The appropriate standards applicable to each category are provided below.

3.6.1.1 *Identifier standards*

Table 3-7: Identifier standards

Standard	Name	Description
ISO 22220:2011	Identification of subjects of healthcare	This standard provides specification for the data elements, as well as the structure and content of the data used to manually identify individuals in a healthcare setting. In addition, it provides support for identification of individuals in a consistent way between systems that will support the natural changes in usage and application of the various names that are used by people over time. It addresses the business requirements of identification as well as the data needed to improve the confidence of healthcare providers and subjects of care identification. [International Organisation for Standardisation, 2011d]
ISO/TS 27527:2010	Provider identifier standard	This standard provides guidelines for the creation of unique identifiers for individual healthcare provider as well as the healthcare institution from where the care was provided. It specifies the data elements that are required to support both manual and automated identification of providers and healthcare institutions.[International Organisation for Standardisation, 2010f].

3.6.1.2 *Messaging standards*

Table 3-8: Messaging Standards

Standard	Name	Description
HL7 V2.X	Health Level Seven Version 2.X (X is 7 at this stage)	This messaging standard allows the exchange of clinical data between systems. It is designed to support a central patient care system as well as a more distributed environment where data resides in departmental systems. Enable the interchange of clinical and administrative data among

		heterogeneous healthcare applications in the form of patient demographics, health insurance data, clinical observations, appointment schedules and patient referrals. Unlike other healthcare messaging standards, which focus on specific healthcare domain (e.g. the exchange of laboratory results), HL7 messaging standards support the exchange of different types healthcare data [Health Level Seven International, 2013d]
DICOM 2011, [ISO/IEC 12052]) (MIOS)	Digital imaging and communication in medicine	Specifications for information object definitions, data structures and their semantics, protocols for the exchange of medical information among imaging equipment and other healthcare applications, file format and storage of medical images [National Electrical Manufacturer Association 2011]. DICOM has been adopted as an international standard for medical images by ISO under the title ISO 12052:2006.
SDMX-HD	Statistical Data and Metadata Exchange – Health Domain	SDMX-HD is a statistical and metadata exchange-based standard adapted by the WHO for the exchange of health indicator definitions, as well as data in aggregate data systems (e.g. DHIS). It specifies the structure and format of aggregate data for health indicator messages that are exchanged between HISs and monitoring and evaluation systems like the DHIS [SDMX-HD, nd].

3.6.1.3 *Coding and terminology standards*

Table 3-9: Coding and terminology standards

Standard	Name	Description
ICD-10 (MIOS)	International Classification of Diseases	ICD-10 is an international coding system for classifying diseases, health conditions and causes of death. ICD has undergone many revisions, with the current tenth edition endorsed by the World Health Assembly in 1990 and has been implemented by member states since 1994. The ICD coding scheme facilitates compilation of vital health statistics, including morbidity and mortality, as well as for medical care reimbursement. [ICD-10 National Task Team, 2012; World Health Organisation, 2010, 2013b]
Procedure codes (e.g. CPT)	Current Procedural Terminology	CPT is a coding system developed and maintained by American Medical Association (AMA). It supports the recording and reporting of medical and surgical procedures, as well as the transmission of information about these procedures among healthcare providers and healthcare systems [American Medical Association, nd]
Medicine codes (eg. NAPPI, RxNorm, AMT, ATC)	NAPPI: National Pharmaceutical Product Index	NAPPI is a unique identifier coding system for pharmaceutical, surgical and healthcare consumable products in South Africa. It is developed and maintained by Medikredit to support electronic transfer of information on pharmaceutical, surgical and healthcare consumables across

		the healthcare delivery chain [Medikredit, nd].
	RxNorm	RxNorm is a medicine terminology system developed and maintained by the United States National Library of Medicine. The database consists of the names of prescription and over-the-counter medicines available in the United States. It supports interoperability among eHealth applications through normalisation of medicine information received from multiple sources. Medicines are assigned normalised names, which consists of the component, strength and dose of the specific medicine and unique identifiers. The National Library of Medicine provides monthly release of RxNorm, with weekly updates for newly approved medicines [US National Library of Medicine, n.d].
	Australian Medicine Terminology	AMT is a national standard for coding and identification of commonly used medicines in Australia. It is developed and maintained by the national clinical terminology and information service (NCTIS), a unit of the Australian national eHealth transition authority (NEHTA). AMT supports the exchange of medicines information among healthcare providers, reduces adverse effects of medication errors that could occur from incorrect prescription and transcribing and enable access to information that could support the decision-making processes of care providers. AMT is updated on a monthly basis from items on the Australian Register of Therapeutic Goods and those that are listed on the Pharmaceutical Benefits Scheme [NEHTA, 2010].
	ATC/DDD Codes: Anatomical Therapeutic Chemical Classifications Systems with Defined Daily Doses	A drug classification scheme maintained by the WHO. The scheme classifies drugs into different groups (using five different levels) based on the organ or system on which they act upon, as well as their chemical, pharmacological and therapeutic properties. The first level of the code indicates the anatomical main group, the second denotes the therapeutic sub-group, the third level indicates the pharmacological sub-group, the fourth indicate the chemical sub-group, while the fifth level indicates the chemical substance. The DDD is a definition of the assumed average maintenance dose per day for a drug used for its main indication in adults. DDDs are allocated only to drugs with ATC codes [WHO Collaborating Centre for Drug Statistics Methodology, 2011]
LOINC	Logical Observation Identifiers Names and Codes	LOINC [Regenstrief Institute, 2013]is a universal coding system for reporting of laboratory and clinical observations. Before the development of LOINC, laboratory results that are sent electronically to healthcare institutions through HL7 messages utilises different identifiers for the same laboratory test. The scope of LOINC codes extent to cover laboratory observations (such as chemistry, haematology, serology, microbiology, and urinalysis), as well as clinical observations (such as vital signs, intake/output,

		Electrocardiogram, endoscopy, and obstetric ultrasound) [McDonald et al., 2003].
UPFS	Uniform Patient Fee Schedule For Paying Patients Attending Public Hospitals	The Uniform Patient Fee Schedule has been developed to provide a simpler charging mechanism for public sector hospitals. Many hospitals currently treat patients for health services rendered. These tariffs are applicable to all full paying and subsidised patients. The UPFS replaces the itemised billing approach with a grouped fee approach. [National Department of Health, 2012d]

3.6.1.4 *Content and structure standards*

Table 3-10: Content and structure standards

Standard	Name	Description
ASTM/HL7 CCD	Continuity of Care Document	The CCD is an integration of HL7 CDA and ASTM CCR to harmonise the data formats of these standards. It provides a set of templates for different sections of a typical summary record, for example, vital signs, family history and care plan, to facilitate reusability and interoperability [Health Level Seven International, 2010a, 2011, 2013g].
HL7 V3 CDA Release 2.0	Clinical Document Architecture	The CDA is a standard specification for the structure and semantics of clinical documents to support common representation of clinical documents e.g. clinical summaries, discharge note, and radiology reports. CDA is based on HL7 Reference Information Model (RIM), a model of healthcare data consisting generic classes from which concrete classes can be derived and supports the use of standardised coding systems, such as LOINC and SNOMED, to enhance semantic interoperability [Health Level Seven International, 2013a].
CDA for CDTHP	CDA for Common Document Types History and Physical Notes (DSTU) (Part of CDA)	CDA for CDTHP is used to record information for a History and Physical Note. A History and Physical Note is a two-part medical report that documents the current and past conditions of the patient. It contains essential information that helps determine an individual's health status. The information forms the basis of most treatment plans. [Health Level Seven International, 2010b, 2013b]
HL7 CRS	Care Record Summary (Part of CDA)	A Care Record Summary document contains patient's relevant health history for some time period. It is intended for communication between healthcare providers and provides disparate hospital systems a standard format to report back to a primary care provider or other parties interested in the patient's hospital care. It is also called a discharge summary by HL7. [Health Level Seven International, 2009, 2013c]
HL7 V3 Normative	HL7 V3: Common Message Element	Common Message Element Types (CMETs) are standardized model fragments intended to be building

Edition (CMET only)	Types	blocks that individual content domains can "include" in their designs. These blocks reduce the effort to produce a domain-specific design and assure that similar content across multiple domains is consistently represented.[Health Level Seven International, 2010c, 2013f]
NDoH Maternal Case Record		

3.6.1.5 *Electronic health record standards*

Table 3-11: Electronic health record standards

Standard	Name	Description
ISO/TR 20514:2005 ISO 18308:2011	Electronic Health Record – Definition, Scope and Context	A technical report that provides a practical classification of electronic health records, giving simple definitions of the main categories of EHR and provides supporting descriptions of the characteristics of EHRs and record systems [International Organisation for Standardisation, 2005b].

3.6.1.6 *Health specific security standards*

Table 3-12: Health specific security standards

Standard	Name	Description
ISO/TS 22600-1:2006	Privilege Management and Access Control (Part 1): Overview and Policy Management	Specification to support requirements for sharing healthcare information among independent healthcare providers, institutions, health insurers companies, patients, staff members and trading partners. It supports collaboration between several authorization managers that may operate over organisational and policy borders [International Organisation for Standardisation, 2006f].
ISO/TS 22600-2:2006	Privilege Management and Access Control (Part 2): Formal Model	Specification of the underlying paradigm of formal high level models for architectural components based on ISO/IEC 10746. It introduces the Domain Model, the Document Model, the Policy Model, the Role Model, the Authorization Model, the Delegation Model, the Control Model and the Access Control Model [International Organisation for Standardisation, 2006g].
ISO/TS 22600-3:2009	Privilege Management and Access Control (Part 3): Implementations	Implementation specification for ISO/TS 22600-2:200 through the instantiation of requirements for repositories for access control policies and privilege management infrastructures for health informatics [International Organisation for Standardisation, 2009j].

3.6.1.7 *General IT standards*

Table 3-13: General IT Standards

Standard	Name	Description
MIOS V5	Minimum Interoperability Standards (MIOS) for Government Information Systems	MIOS V5 prescribes open system standards that will ensure minimum level of interoperability within and between IS/ICT systems that are utilised in the South African Government, industry, citizens and the international community in support of the e-Government objectives [SITA, 2011]
AES (MIOS)	Advanced Encryption Standard	The Advanced Encryption Standard (AES) specifies a FIPS-approved cryptographic algorithm that can be used to protect electronic data. The AES algorithm is a symmetric block cipher that can encrypt (encipher) and decrypt (decipher) information. Encryption converts data to an unintelligible form called ciphertext; decrypting the ciphertext converts the data back into its original form, called plaintext [National Institute of Standards and Technology, 2001].
DSML V2	Directory Services Markup Language v2.0	The Directory Services Markup Language v1.0 (DSMLv1) provides a means for representing directory structural information as an XML document[OASIS, 2001]
ebXML MS (ebMS)	OASIS ebXML Messaging Services 3.0	Specification for communication protocol neutral method for the exchange of electronic business messages. It defines specific enveloping constructs that supports reliable and secure delivery of business information [OASIS, 2007].
ebXML RIM (ebRIM)	OASIS/ebXML Registry Information Model 3.0	Definition of the metadata and content that can be stored in an ebXML Registry, which is an information system that securely manages any content type and the standardised metadata that describes it. The registry provides a set of services that enable sharing of content and metadata between organisational entities in a federated environment [OASIS, 2005a].
ebXML RS (ebRS)	OASIS/ebXML Registry Services Specifications 3.0	Definition of the services provided by an ebXML Registry and the protocols used by clients of the registry to interact with the services [OASIS, 2005b]
ISO 19005-1 (PDF/A-1)	Electronic document file format for long-term preservation – Part 1: Use of PDF 1.4 (PDF/A-1)	ISO 19005-1:2005 is a specification for the use of Portable Document Format (PDF) 1.4 for long-term preservation of electronic documents [International Organisation for Standardisation, 2005a]. The South African minimum interoperability standard (MIOS) specifies a newer version of this standard, i.e. SANS 32000-1 [State Information Technology Agency, 2011a].
ISO/IEC 9075 (MIOS)	Database Languages – Structure Query Language	ISO/IEC 9075:2011 is a multi-part standard that defines structured query language (SQL). It specifies the data structure, as well as the operations on the data stored in the structure. Parts 1, 2, and 3 of the standard are the minimum requirements for SQL, while the remaining parts define their extension [International Organisation for Standardisation, 2011a]. The South African minimum interoperability

		standard (MIOS) specifies part 14, which is an XML extension to the standard [State Information Technology Agency, 2011a].
ISO/TS 21091:2005	Directory Services for Security, Communications and Identification of Professionals and Patients	Specification for the minimal requirements for directory services in healthcare using the X.500 framework. It gives the common directory information and services required for secure exchange of healthcare information over public networks. The standard is forward looking in that it addresses the requirements for the communication of healthcare information within and across healthcare institutions, as well as beyond country boundaries. It also supports directory for identification of care givers, health institutions and patients/consumers of health services (i.e. the MPI) [International Organisation for Standardisation, 2005c].
LDAP (MIOS) / RFC 4510	Lightweight directory access protocol (LDAP)	This is an Internet protocol for accessing distributed directory services that act in accordance with X.500 data and service models. It is a lightweight version of directory access protocol, which is part of the X.500 standard [Internet Engineering Steering Group, 2005a].
RFC 1305 (NTP V3)	Network Time Protocol (NTP)	The NTP provides the mechanisms to synchronise time and the coordination of time distribution in a large, diverse Internet, which can operate at different rates [Internet Engineering Steering Group, 1992].
ANSI INCITS 359-2004 (RBAC)	Role Based Access Control (RBAC)	This standard provides a mechanism for controlling users' access to computing resources based on their assigned role. It specifies the Reference Model (users, roles, permissions, operations, and objects), as well as the System and Administrative Functional features of an RBAC system [ANSI/INCITS, 2004].
RFC 2246	The Transport Layer Security (TLC) protocol	Specification for communications privacy over the Internet. It enables client/server applications to communicate in a way that is designed to prevent eavesdropping, tampering, or message forgery [Internet Engineering Steering Group, 1999].
RFC 2616 (MIOS)	The Transport Layer Security (TLC) protocol	Specification for communications privacy over the Internet. It enables client/server applications to communicate in a way that is designed to prevent eavesdropping, tampering, or message forgery [Internet Engineering Steering Group, 1999].
RFC 3066	Tags for the Identification of Languages	Describes identifier mechanism of tags for language, a registration function for values to be used with that identifier mechanism, and a construct for matching against the values [Internet Engineering Steering Group, 2001b].
RFC 3164	The BSD syslog Protocol	Description of the various implementation of Syslog protocol, which is used to record the system events typically for audit trail purposes [Internet Engineering Steering Group, 2001a].
RFC 3778	The application/pdf	Provides description of the PDF format, the mechanisms for

	Media Type	digital signatures and encryption within PDF files, as well as updates for the media type registration of 'application/pdf' [Internet Engineering Steering Group, 2004a].
RFC 3881	Security Audit and Access Accountability Message: XML Data Definitions for Healthcare Applications	Definition of the format of data to be collected, and the minimum set of attributes that must be captured for security auditing in healthcare application systems [Internet Engineering Steering Group, 2004c].
RFC 3986	Uniform resource identifier	Specification for generic URI syntax, as well as a process for resolving URI references that might be in relative form, together with guidelines and security considerations for the use of URIs on the Internet. The URI syntax defines a grammar that is a superset of all valid URIs, allowing an implementation to parse the common components of a URI reference without knowing the scheme-specific requirements of every possible identifier [internet Engineering Steering Group, 2005b].
RFC 4627	The application/JSON Media Type for JavaScript Object Notation (JSON)	Definition of a lightweight, text-based, language-independent data interchange format, called JavaScript Object Notation (JSON). JSON is capable of representing four primitive types, namely: strings, numbers, Booleans and null, as well as two structured types, objects and arrays [Internet Engineering Steering Group, 2006a].
RFC 5424	The Syslog Protocol	Specification for protocol to convey event notification messages. It utilises a layered architecture that enable the use of any number of transport protocols for transmission of syslog messages. It also provides a message format that allows vendor-specific extensions to be provided in a structured way [Internet Engineering Steering Group, 2009a].
RFC 5425	Transport Layer Security (TLC) Transport Mapping for Syslog	Specification for the use of Transport Layer Security (TLS) to provide a secure connection for the transport of syslog messages [Internet Engineering Steering Group, 2009c].
RFC 5426	Transmission of Syslog Messages over UDP	Specification for the transport for syslog messages over UDP/IPv4 or UDP/IPv6 [Internet Engineering Steering Group, 2009b].
RFC 6585	Additional Hypertext Transfer Protocol (HTTP) Status codes	Specification for additional status codes for HTTP to improve interoperability and prevent the confusion that could arise when other, less precise status codes are used [Internet Engineering Steering Group, 2012].
RSA X.509 (MIOS)	Public Key Infrastructure Certificates	This is an International Telecommunication Union (ITU) standard specification for the definition of digital certificate. It provides a framework for public-key certificates, as well as the attributes of the certificates [International Telecommunication Union, 2008].
RFC3851 (S/MIME V3.1)	Secure/Multipurpose Internet Mail	S/MIME provides a consistent way to send and receive secure MIME data. Digital signatures provide

	Extensions (S/MIME) Version 3.1	authentication, message integrity, and non-repudiation with proof of origin. Encryption provides data confidentiality. Compression can be used to reduce data size. [The Internet Society, 2004]
SHA-1 (MIOS)	Secure Hash Algorithm	This Standard specifies a Secure Hash Algorithm, SHA-1, for computing a condensed representation of a message or a data file. When a message of any length < 264 bits is input, the SHA-1 produces a 160-bit output called a message digest. The message digest can then be input to the Digital Signature Algorithm (DSA) which generates or verifies the signature for the message[National Institute of Standards and Technology, 1995].
SNTP (RFC 4330)	Simple Network Time Protocol Version 4	The Simple Network Time Protocol Version 4 (SNTPv4), which is a subset of the Network Time Protocol (NTP) used to synchronize computer clocks in the Internet. SNTPv4 can be used when the ultimate performance of a full NTP implementation based on RFC 1305 is neither needed nor justified [The Internet Society, 2006].
SOAP 1.2 (MIOS)	SOAP Version 1.2 Part 1: Messaging Framework (Second Edition)	SOAP Version 1.2 is a lightweight protocol intended for exchanging structured information in a decentralized, distributed environment. "Part 1: Messaging Framework" defines, using XML technologies, an extensible messaging framework containing a message construct that can be exchanged over a variety of underlying protocol [W3C, 2007a].
SOAP-MTOM	SOAP Message Transmission Optimization Mechanism	SOAP –MTOM is a concrete implementation of it for optimizing the transmission and/or wire format of SOAP messages. The concrete implementation relies on the [XML-binary Optimized Packaging] format for carrying SOAP messages [W3C, 2005a].
UN/EDIFACT	United Nations rules for Electronic Data Interchange for Administration, Commerce and Transport	A set of internationally agreed standards, directories, and guidelines for the electronic interchange of structured data, between independent computerized information systems [United Nations, nd].
UPFS	Uniform Patient Fee Schedule For Paying Patients Attending Public Hospitals	The Uniform Patient Fee Schedule has been developed to provide a simpler charging mechanism for public sector hospitals. Many hospitals currently treat patients for health services rendered. These tariffs are applicable to all full paying and subsidised patients. The UPFS replaces the itemised billing approach with a grouped fee approach [National Department of Health, 2012c].
WS-I Basic Security Profile 1.1	WS-I Basic Security Profile 1.1	Provides non-proprietary Web Services specifications to enable interoperability and ensure transport layer security and SOAP messaging integrity [Web Services Interoperability Organisation, 2010]
XML V1.0 (MIOS)	Extensible Markup	The Extensible Markup Language (XML) is a subset of SGML

	Language (XML) 1.0 (Fifth Edition)	that is described in this document. Its goal is to enable generic SGML to be served, received, and processed on the Web in the way that is now possible with HTML. XML has been designed for ease of implementation and for interoperability with both SGML and HTML [W3C, 2008a].
XML-binary OP	XML-binary Optimized Packaging	The XML-binary Optimized Packaging (XOP) convention is a means of more efficiently serializing XML Infosets that have certain types of content [W3C, 2004].

3.6.2 Other standards that could be applicable

Other standards could apply, depending on the infrastructure decisions taken for the implementation of eHealth in South Africa, for example healthcards, biometrics, infrastructure specific standards, etc. A number of examples are provided below.

3.6.2.1 *Healthcards*

For example, if the decision is made to make use of health smartcards instead of a shared national EHR to store a patient's medical records, then the standards related to patient healthcards will apply (see Table 3-14). A patient healthcard is a form of a personal health record (PHR) (see section 1.2) in that the health record remains in the possession of the patient and the information is not kept in a shared EHR. The clinical content that can be kept is minimal.

Table 3-14: Healthcard standards

Standard	Name	Description
ISO 21549-1:2004	Patient Healthcard Data – (Part 1): General Structure	Defines the general structure of data held on patient healthcards (i.e. healthcards compliant with the physical dimensions of ID-1 cards as defined by ISO/IEC 7810) [International Organisation for Standardisation, 2004a].
ISO 21549-2:2004	Patient Healthcard Data – (Part 2): Common Objects	Provides framework for the content and structure of common objects used to construct or referenced by other data-object data held on patient healthcare data cards. It specifies the basic structure of the data without defining or stipulating the particular data-sets for storage on devices. [International Organisation for Standardisation, 2004b].
ISO 21549-3:2004	Patient Healthcard Data – (Part 3): Limited Clinical Data	Specifies the basic structure of data contained within the limited clinical data object, without specifying the particular data sets for storage on devices. The data is intended to facilitate the delivery of emergency care. It is thus not suitable for the provision of all the information required [International Organisation for Standardisation, 2004c].
ISO 21549-4:2006	Patient Healthcard Data – (Part 4): Extended Clinical data	Specifies the basic structure of the data contained in the extended clinical data object. It is only applicable to situations where such data are recorded on, or transported by patient healthcare data cards [International Organisation for Standardisation, 2006b].
ISO 21549-5:2008	Patient Healthcard Data – (Part 5)	Provides a common framework for the content and the structure of identification data held on healthcare data

	Identification Data	cards. It gives the specification for the basic structure of the data, without specifying the particular data-sets for storage on devices [International Organisation for Standardisation, 2008f].
ISO 21549-6:2008	Patient Healthcard Data – (Part 6) Administrative Data	Specification for the basic structure of the data held within the administrative data object, without specifying or mandating the particular data sets for storage on devices [International Organisation for Standardisation, 2008g].
ISO 21549-7:2007	Patient Healthcard Data – (Part 7) Medication Data	Specification for the basic structure of the data held within the medication data object without specifying or mandating the particular data sets for storage on devices. It describes and defines the medication data objects used within or referenced by patient held health data cards using UML, plain text and Abstract Syntax Notation (ASN.1) [International Organisation for Standardisation, 2007b].
ISO 21549-8:2010	Patient Healthcard Data – (Part 8): Links	Definition of the structure and elements of "links" that is stored in healthcards. It defines a way to facilitate access to distributed patient records and/or administrative information using the healthcards through references to individual patients' records and their subcomponents. The standard does not cover services relating to access control mechanisms, data protection mechanisms, access methods and other security services [International Organisation for Standardisation, 2010b].

3.6.2.2 *Biometrics for identification and authentication*

If the decision is made to use a biometric or a set of biometrics for patient identification and authentication, standards related to such biometrics will apply.

Standard	Name	Description
ISO/IEC 19784-1	BioAPI Specification	BioAPI is intended to provide a high-level generic biometric authentication model–one suited for any form of biometric technology. It covers the basic functions of enrolment, verification, and identification, and includes a database interface to allow a biometric service provider (BSP) to manage the technology device and identification population for optimum performance [International Organisation for Standardisation, 2006d].
(ISO/IEC 19785-1	Common Biometric Exchange Formats Framework	The Common Biometric Exchange Formats Framework (CBEFF) describes a set of data elements necessary to support biometric technologies and exchange data in a common way. These data can be placed in a single file used to exchange biometric information between different system components or between systems. The result promotes interoperability of biometric-

		based application programs and systems developed by different vendors by allowing biometric data interchange [International Organisation for Standardisation, 2006e].
ANSI-INCITS	Biometric Data Format Interchange Standards: ANSI-INCITS 377-2004 - Finger Pattern Based Interchange Format ANSI-INCITS 378-2004 - Finger Minutiae Format for Data Interchange ANSI-INCITS 379-2004 - Iris Interchange Format ANSI-INCITS 381-2004 - Finger Image Based Interchange Format ANSI-INCITS 385-2004 - Face Recognition Format for Data Interchange ANSI-INCITS 395-2005 - Signature/Sign Image Based Interchange Format ANSI-INCITS 396-2004 - Hand Geometry Interchange Format	ANSI-INCITS has created a series of standards specifying the interchange format for the exchange of biometric data [Yen, 2005]. These standards specify a data record interchange format for storing, recording, and transmitting the information from a biometric sample within a CBEFF data structure. The ISO equivalent standards for each are in process but not yet finalized.
ISO/IEC 19794	ISO/IEC 19794 series on biometric data interchange formats	Part 1 is the framework; Part 2 defines the finger minutiae data; Part 3 defines the finger pattern spectral data; Part 4 defines the finger image data; Part 5 defines the face image data; Part 6 defines the iris image data, and still in development; Part 7 will define the signature/sign time series data; Part 8 will define the finger pattern skeletal data; and Part 9 will define the vascular image data [International Organization for Standardization, n.d.].

3.6.2.3 *Barcode standards*

The Pinkie scenario referred to scanning a barcode from her plastic patient card. In order for the barcode to be readable by scanners at various healthcare providers, a decision will have to be made on the specific standard to use for producing the barcodes.

Barcode standards specifically for the health industry exist, for example the Health Industry Barcode Provider Applications Standard [Health Industry Business Communications Council, 2010], which defines a list of attributes that can be used to identify the type of item or transaction within a provider facility. An example of a standard that encodes a patient identifier is ISB 1077 [Information Standards Board for Health and Social Care, 2012], used by the NHS in the UK. The standard uses the GS1 System of Standards for code

numbering and bar coding and ISB 0099 Patient Identifiers for Identity Bands for the required data items. The resulting dataset is the AIDC for Patient Identification data set.

The Western Cape Department of Health makes use of the Code 39 (3 of 9) for the patient identification on its patient cards. Code 39 is a general barcode standard, widely used in many industries and is the standard for many government barcode specifications, including the U.S. Department of Defence. Code 39 is defined in American National Standards Institute (ANSI) standard MH10.8M-1983, and is also known as USD-3 and 3 of 9 [Measurement Equipment Corporation, n.d.; Wikipedia, 2012]. Code 39 can be read by just about every scanner on the market, and is widely used for in-house solutions and for transferring data between companies.

4 OPERATIONALISING THE HNSF

In order to operationalize the National Health Normative Standards Framework for Interoperability in eHealth, implementation guidelines are required. The implementation guidelines consist of a governance model and an assessment instrument. Incorporating the assessment instrument as central to the processes of governance is important to ensure the relevance of standards-based profiles to practical use cases, their open availability, and the various controls to be applied for their correct application.

The assumptions made in developing the implementation guidelines are discussed in section 4.1 and are core to the validity of the implementation guidelines. The assessment instrument, as discussed in section 4.3, is an evaluation tool for designers and developers of eHealth systems to determine the standards that are applicable to typical healthcare functions, and which should be implemented for adherence to the Normative Standards Framework. The tool can also be used to determine the standards that should apply to existing eHealth applications. The assessment instrument was derived from the various components developed and verified during setting up the HNSF. The assessment instrument is designed around the concept of integration profiles and mapping typical eHealth functions or healthcare activities to appropriate integration profiles, as discussed in section 3. The assessment instrument will be applied to determine the extent to which a software application complies with the set of standards-based profiles adopted for the business functions (or uses cases) being supported by that application. The instrument is used within the context of eHealth standards governance and the eHealth Standards Board for South Africa, as outlined in section 4.2.

4.1 Assumptions made in developing the implementation guidelines

The development of the HNSF and its associated implementation guidelines and governance model was based on the assumptions stated in section 1.4. Since these assumptions are core to the development of the implementation guidelines, they are repeated here:

1. A *shared national infrastructure and national electronic health record for eHealth* exists.
2. Interoperability is required for the exchange of patient-based transactional data between the *point of care* and/or the *local EMR system* and the *shared national infrastructure and the national* EHR, in order to support continuity of care, service remuneration and the aggregation of data health metrics.
3. The HNSF and its associated assessment instrument directly affects any exchange of patient-based transactional data, from a regional or healthcare facility-based EMR system, to the *shared national infrastructure and the national electronic health record*.
4. Interoperability between the various modules of a regional or local healthcare facility-based EMR system is *not directly affected* by the HNSF. However, the interactions with the shared EHR will be simplified if the same principles and standards were used for the local healthcare facility-based EMR system, i.e. if the healthcare facility-based EMR is based on the same standards as required for the shared EHR and interacting with the shared EHR.
5. The data held in the shared national EHR will primarily be used for:
    a. Provision of continuity of care for patients across different service providers and healthcare facilities.
    b. Generation of national healthcare metrics, which are defined in the National Indicator Dataset (NIDS) [National Department of Health, 2010c].
6. The HNSF only focuses on interoperability with a national shared electronic health record (EHR) system, and specifically only on patient-centric functions. It only focuses on systems that use and update data in such a shared EHR. Peripheral systems, such as financial (payment) and accounting systems, human resource systems, etc. are excluded.

7. Interoperability standards are also required for the sharing of patient-based data, held in the shared national EHR, with accredited healthcare service providers.
8. As per the eHealth Strategy South Africa 2012-2016 [National Department of Health, 2012b], an eHealth Standards Board for South Africa exists, or is to be established, to maintain and govern the implementation of the HNSF, as well as the standards referred to in the HNSF. The ESB should work closely with healthcare providers and other relevant stakeholders to govern the implementation of the HNSF, and develop, adopt and maintain eHealth standards-based profiles and standards.

4.2 HNSF governance and processes

In order to implement the HNSF, a governance structure must be established. This calls for the establishment of the eHealth Standards Board for South Africa, as per the eHealth Strategy South Africa 2012-2016 [National Department of Health, 2012b].

The role of the ESB should include:

1. Identification of care guidelines, workflows, activities and information sharing requirements for each specific business use case occurring in the South African patient care context.
2. Ongoing review of standards-based profiles and base standards to ensure that these support the business use cases and business processes.
3. Creation and maintenance of a data model for a shared EHR repository for South Africa. The data model must define the exact data structure for the shared electronic health record and the information that must be exchanged with the shared infrastructure. This will be determined by the minimum essential information required for continuity of care, reimbursement and generation of the national health metrics, the NIDS. This data structure will be accompanied by a national data dictionary, defining all data elements to be used in eHealth and other health information systems in South Africa. The ESB should work closely with key officials in NDoH in order to ensure that the data model and the related national data dictionary are aligned with the NIDS at all times, and that any changes in workflows, care protocols and functions are reflected in the mandatory standards-based profiles and base standards where necessary.
4. Adoption, adaption, localisation and development of standards-based profiles and base standards for South Africa, whenever gaps emerge. This would include a set of content standards (coding and terminologies and information display) and guidelines for their implementation.
5. Establishing a national compliance function within the ESB to test and certify that eHealth solutions comply with national eHealth standards, rules and protocols.
6. Provision of guidelines to developers and suppliers of health information systems with respect to the use of standards-based profiles and standards.
7. Establishing a set of evaluation criteria against which to test whether a candidate software application complies with the adopted, localised and mandated standards-based profiles and their related base standards.
8. Provision of a platform for developers and suppliers to test their software applications against the mandatory requirements of the HNSF.
9. With the guidance of IHE, organising a South African national or regional '*connectathon'* to test the interoperability capability of systems that are currently implemented or candidates for implementation.
10. The ESB should also have the role to represent South Africa on international standards development organisations and other entities related to eHealth standardisation.

Figure 4-1 illustrates the recommended governance model, which includes use of the assessment instrument outlined in section 4.3. The ESB should work closely with key officials in NDoH in order to ensure that the data model and the related national data dictionary are aligned with the NIDS at all times,

and that any changes in workflows, care protocols and functions are reflected in the mandatory standards-based profiles and base standards where necessary. It also calls for the ESB to work closely with healthcare providers and other relevant stakeholders to develop, adopt and maintain eHealth standards-based profiles and base standards.

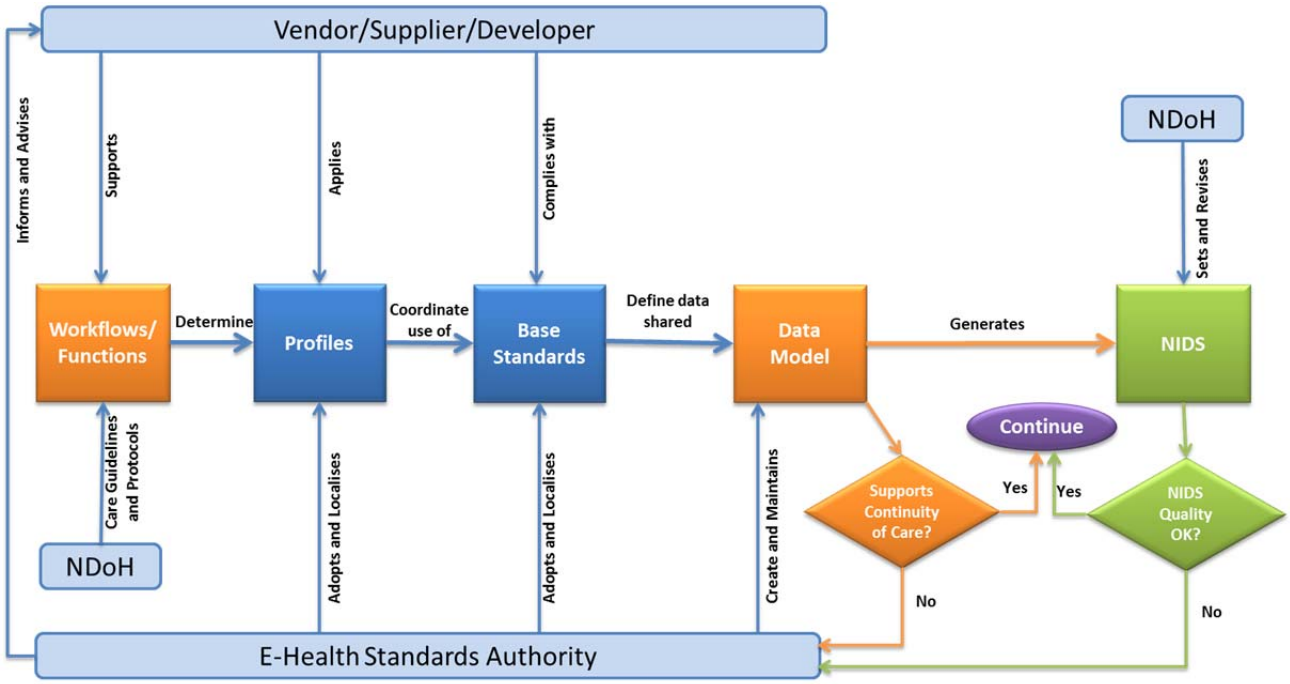

Figure 4-1: Recommended governance model

Figure 4-2, adapted from the EU's epSOS project [CEN/TC 251, 2009a], suggests how the development, implementation and maintenance of standards-based profiles and base standards can be managed. Five major interdependent processes must be available, with some overall governance to empower and accredit them, monitor their progress and increase efficiency of the overall process as maturity and experiences develops:

1. The definition and prioritisation of specific South African use cases. This work requires substantial input from healthcare providers and clinicians, as it is critical to ensure that the use cases accurately reflect workflows and treatment protocols.
2. The adoption and localisation of base standards, with the development of new standards if required.
3. The adoption and localisation of standards-based profiles, with the development of new standards-based profiles if required.
4. Maintenance of tools and test plans for quality assurance, such as the plan outlined in Figure 4-1.
5. Providing a forum for the sharing of best practices in eHealth projects.

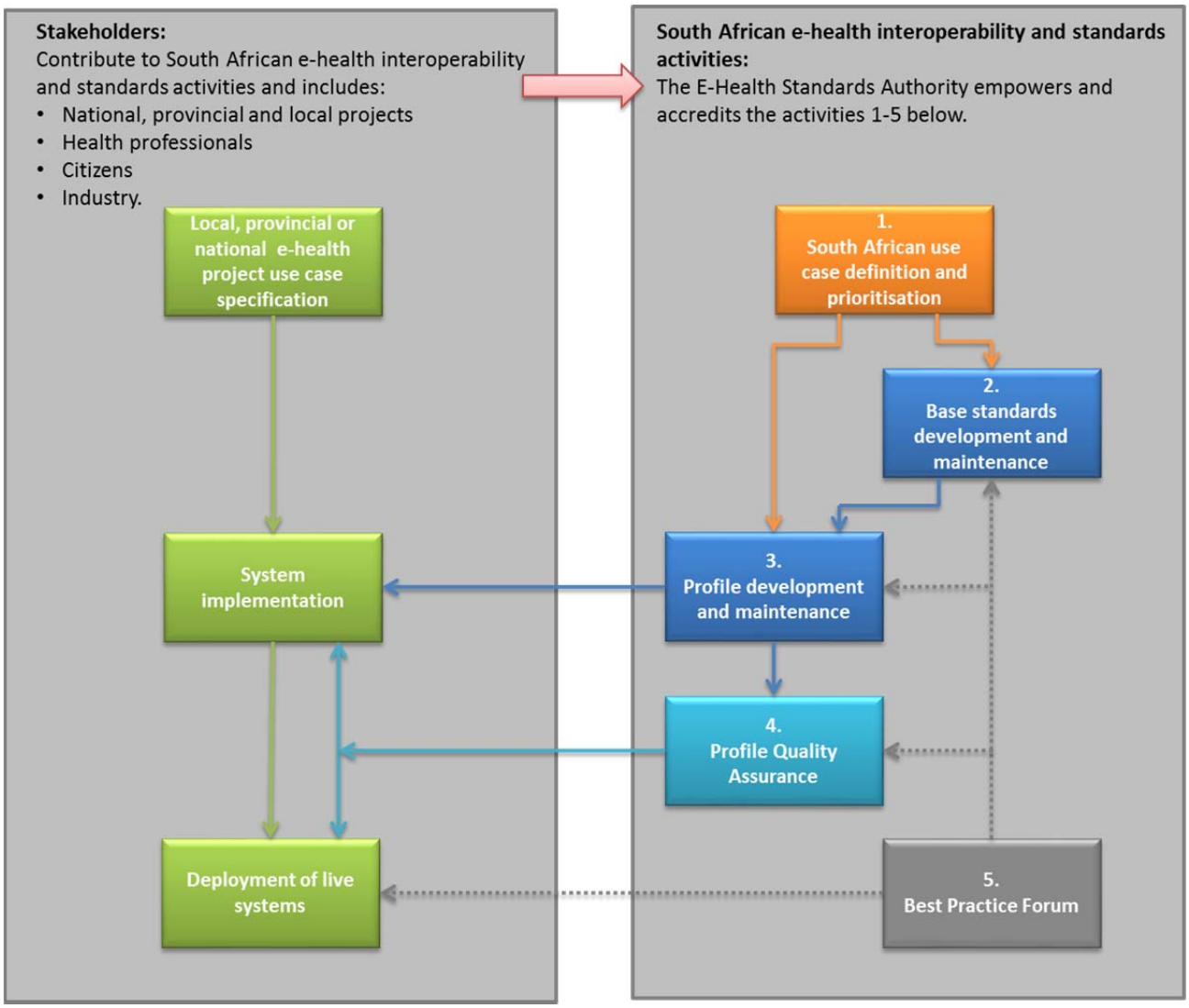

Figure 4-2: Management of standards-based profiles and base standards (adapted from [CEN/TC 251, 2009a])

4.3 Assessment instrument for benchmarking of eHealth applications against the HNSF

An assessment instrument is required in order to benchmark software applications against a set of acceptance criteria related to the HNSF, and against each other. It also serves as a guideline and reference for system designers and developers. Such a tool is central to the processes and governance needed to ensure the relevance of standards-based profiles to practical use cases, their open availability, and the controls to be applied for their correct application.

The assessment focus on whether applications are able to exchange accurate information with and within the shared health infrastructure, while complying with the standards-based profiles and base standards adopted for specific use cases. The assessment tool does not apply to other features of applications such as usability, platform or database management system.

To determine the set of base standards that must be supported in *developing a new eHealth application,* to *revising an existing system*, or *assessing an existing system*, to support a specific business case, the following steps must be followed:

1. Determine the care scenarios to which the eHealth application is to apply. Specify the care actors and the workflow between the actors in detail. See section 3.1.1 for examples.
2. Identify the activities or functions in the care scenario workflows and document these use cases using UML sequence diagrams, for example. See section 3.1.3 for examples.
3. Determine which of these functions will be supported by the eHealth application specified. See section 3.1.5 for examples.
4. Identify which of these functions will result in patient-based transactions with content that would be sent to the shared infrastructure and shared EHR.
5. Identify the content that is required to be sent to the shared EHR by these functions and draft a data model that represents this data. See section 3.4 for examples.
6. Using the HNSF, map these functions to applicable standards-based profiles. See section 3.6 .
7. Identify the relevant base standards as prescribed by the applicable profile in the HNSF.
8. Determine how the shared content will be structured and encoded according to the applicable IHE interoperability profile, which summarises the patient-based transactions. The relevant base standards must be used to:
    a. Code the clinical message.
    b. Code the document content.
9. Determine the degree to which the outcomes of steps 6, 7 and 8 above will meet the requirement identified in Step 5 and note any gaps. If gaps exists, it could mean one or more of the following:
    a. The design is inherently sub-standard because it does not support the accurate and/or complete capture of information for the use case.
    b. The design of the eHealth application does not implement the mandated standards-based profiles and base standards correctly.
    c. The gaps could indicate that the standards-based profiles and related base standards mandated are inadequate and must be improved. Identify additional standards from the HNSF to meet these gaps. If no such standards exist, refer the 'gap' to the eHealth Standards Board to address.

If, in addition, support for calculating certain National Indicator Data Set (NIDS) [National Department of Health, 2010c] elements is required, the following steps must be followed:

10. For a new application, test the data model derived in step 5 to determine whether the NIDS health indicators applicable to the specific care scenario can be reliably generated from the data. For an existing system, test whether the data supplied by the system compared to the data model derived in step 5 will support reliable generation of the NIDS health indicators applicable to the specific care scenario.
11. For a new application, those indicators that cannot be generated are identified as a gap in the content delivered and would require revision of the business case and a repeat of steps 1 to 11. For an existing application, those indicators that cannot be generated are identified as a gap in the content delivered and would require revision of the way the system applies the mandated standards-based profiles and base standards.

The above steps must be repeated for each possible use case in the clinical care context (where that use case generates patient-based transactions that must be shared).

It is recommended that the concept of an IHE *Connectathon* (see section 3.2.1.3.3), or a similar South African event, be employed in order to test the interoperability capabilities of patient-centric eHealth applications in South Africa.

The assessment process in relation to the ESB's activities is illustrated in Figure 4-3. If an application is found to meet all the requirements set by the HNSF, NIDS and the data requirements and interoperability requirements specified by the ESB for the shared infrastructure, the application would be placed on the accredited list of eHealth applications.

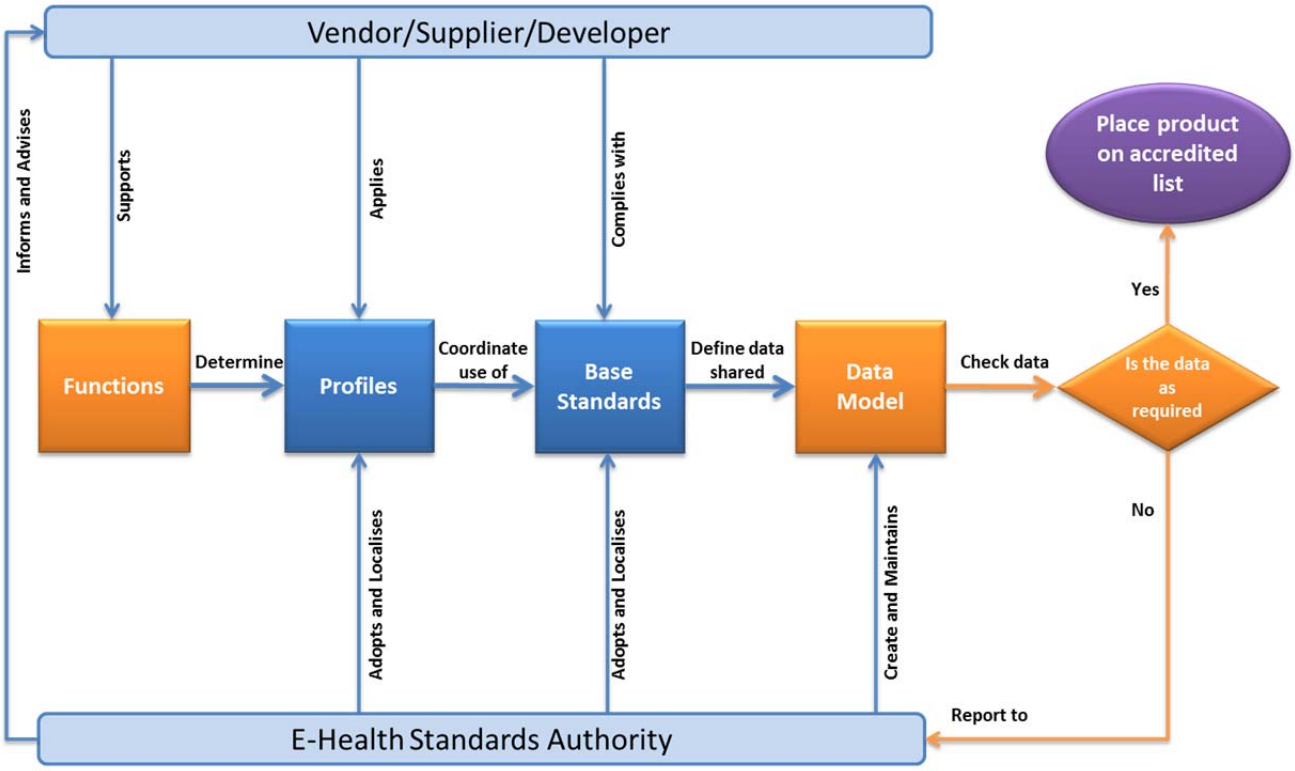

Figure 4-3: Assessing an existing eHealth application

5 ASSESSING CURRENTLY DEPLOYED HEALTH INFORMATION SYSTEMS

As part of this project, a study was conducted of all patient-centric health information systems (HISs) currently deployed in public healthcare facilities in the country (see CSIR and NDoH [2013a] for details). The study focussed on systems that were 'patient-centric', i.e. systems that recorded transactions specifically in support of patient administration and care. The study found 42 systems currently in use in the country, with deployment ranging from one to 1085 sites. The findings are summarised here. A first level assessment of the systems against the proposed benchmark assessment instrument is also included (see section 5.2).

5.1 Summary of findings of health information systems study

The findings are summarised under two headings, namely general system attributes (see section 5.1.1) and interoperability (see section 5.1.2).

5.1.1 General system attributes

5.1.1.1 *Number of systems deployed by province*

Figure 5-1 shows the total number of HISs currently deployed in each of the Provinces, with the majority being in the Western Cape, followed by Gauteng and KwaZulu-Natal.

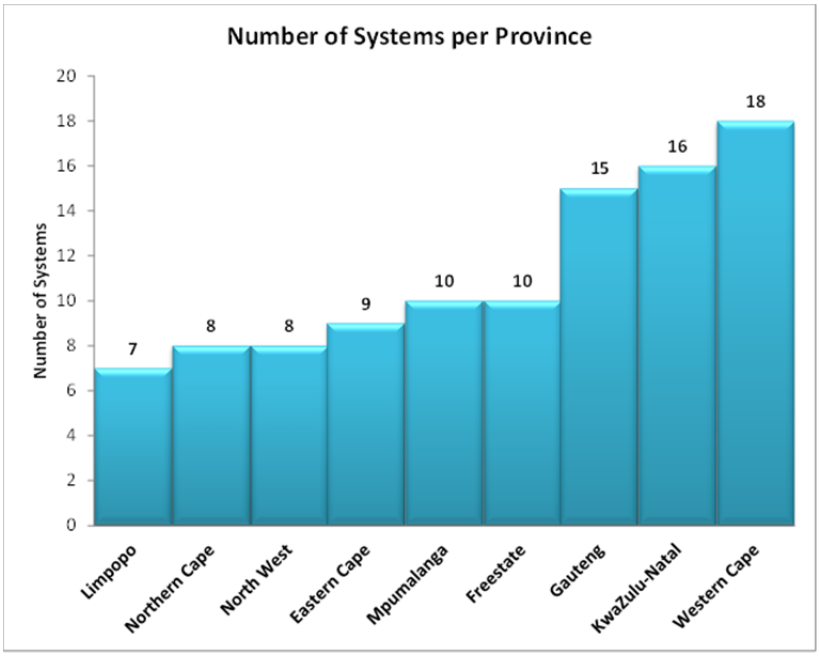

Figure 5-1: Total number of HISs in use in each Province

5.1.1.2 *Number of Provinces in which the various systems are installed*

Figure 5-2 shows the prevalence of systems across Provinces. It is clear that besides the *NHLS TrakCare Lab* implementation and *RxSolution*, the systems that are implemented in seven or more provinces are systems for surveillance and monitoring (*DHIS, Tier.Net, ETR.Net, EDR.Web, PPIP*). The majority of systems is implemented in only one province.

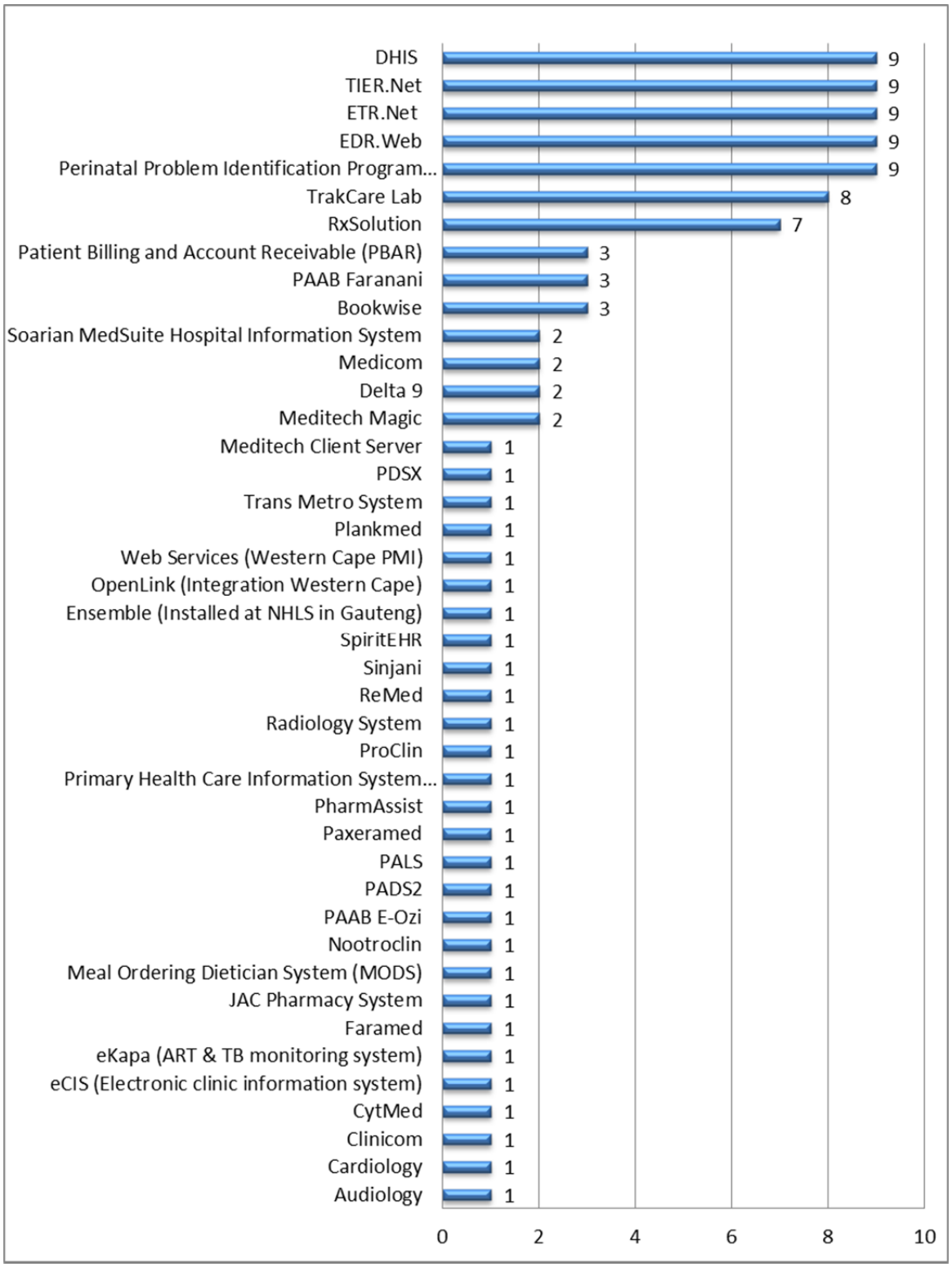

Figure 5-2: Number of Provinces in which the various systems are installed

5.1.1.3 *Types of systems installed*

Figure 5-3 shows that of the 42 HISs, the majority can be classified as being either a software application and/or a database.

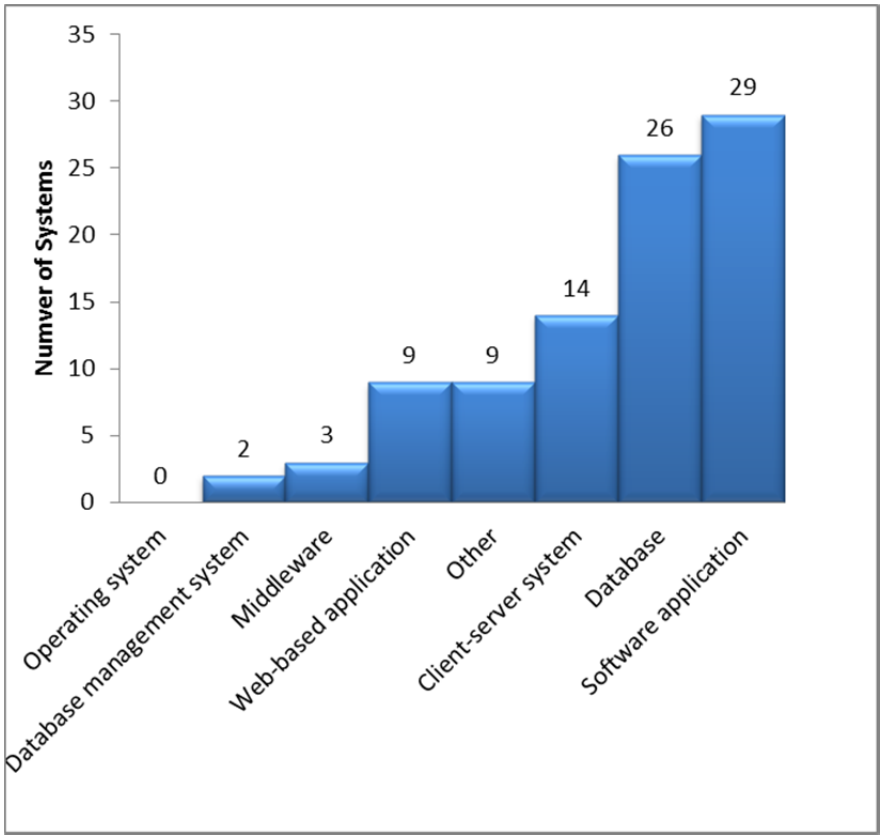

Figure 5-3: Category of systems installed

Figure 5-4 shows that *Microsoft Windows* is the most prevalent operating system used. Browser-based systems are not widely implemented. This may be related to poor access to broadband connectivity. The research found two legacy systems that were still *MS-DOS* based (*PDSX* and *Plankmed*), and these may need to be replaced as a matter of urgency. It was also apparent that system operators did not know what operating system was applicable in the software applications that were in use.

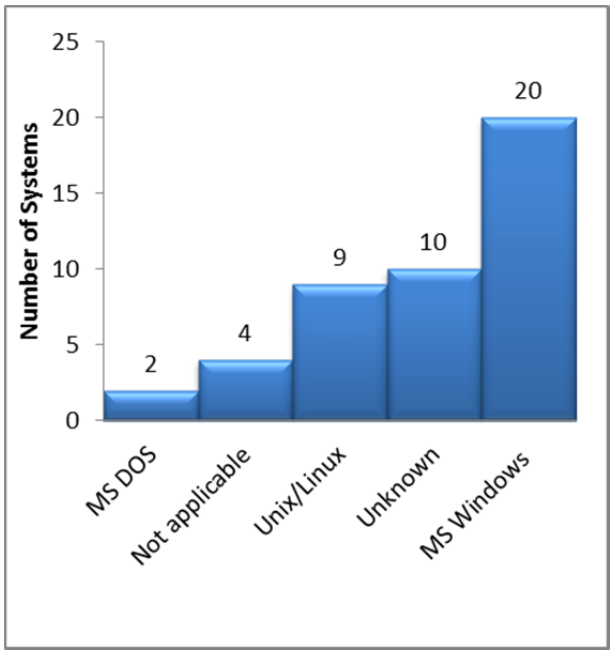

Figure 5-4: Operating systems in use

Figure 5-5 shows that Microsoft SQL Server is the most prevalent database management system in use, followed closely by Oracle. However, some legacy technologies, such as *Clarion* and *Informix*, are still in use.

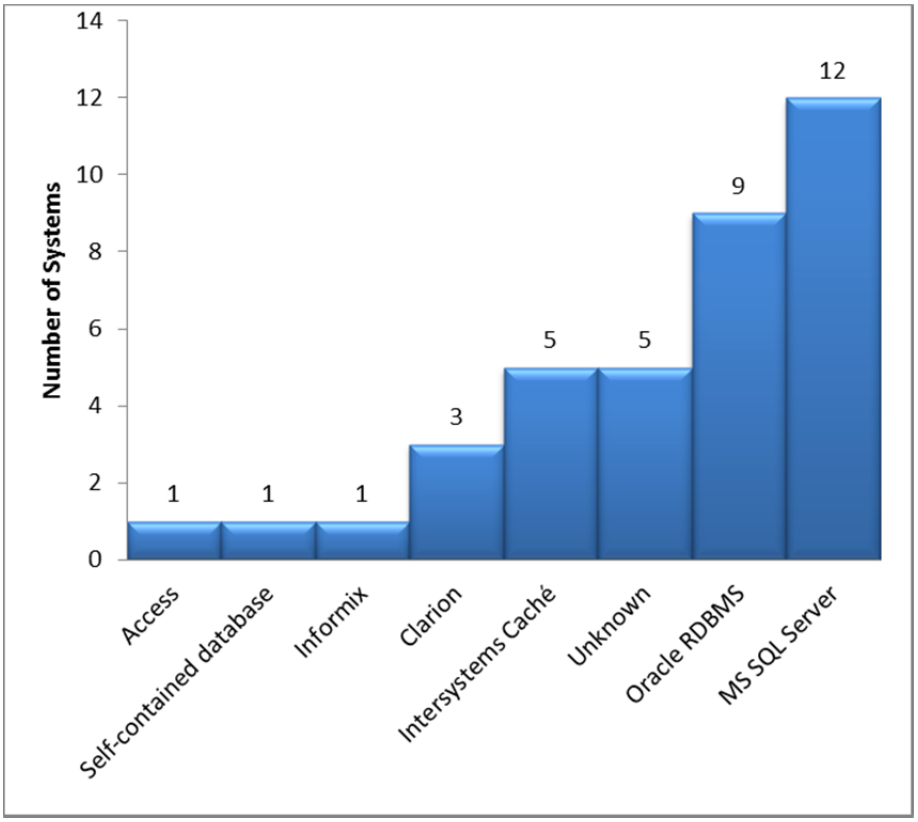

Figure 5-5: Database management systems in use

Windows Server is the most prevalent when it comes to application servers, as illustrated in Figure 5-6, although the majority of application server could not be identified.

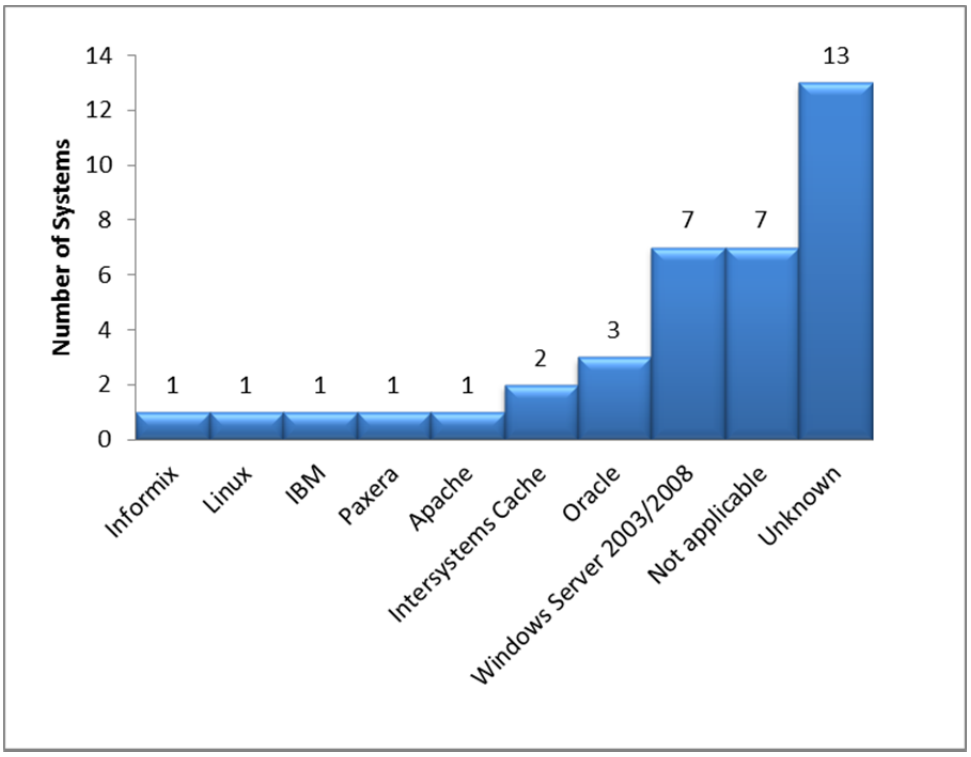

Figure 5-6: Application servers in use

5.1.1.4 *Vendors*

As illustrated in Figure 5-7, just over 50% of the vendors were provided with a requirement specification when the systems were procured. The majority of vendors provide technical support and provided training on the use of the systems.

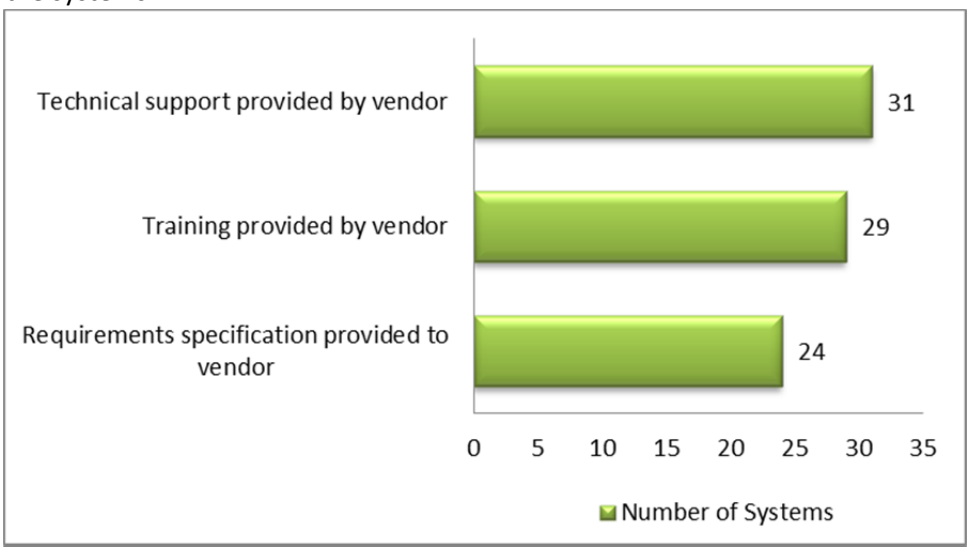

Figure 5-7: Vendor support

5.1.1.5 *Patient-centric processes*

Figure 5-8 represents the number of patient-centric administrative processes supported by the different systems. Support for the various processes is fairly even between the various systems, although less than 50% of the system do support typical patient administration processes. Processes listed as 'other', included data entry by registration clerk for outpatients, recording patient visits to audiology clinic, registration of visit, recording of aggregated data in data repository, recording of complaints and compliments, client statistical surveys, patient demographic maintenance, management of patient transport, etc.

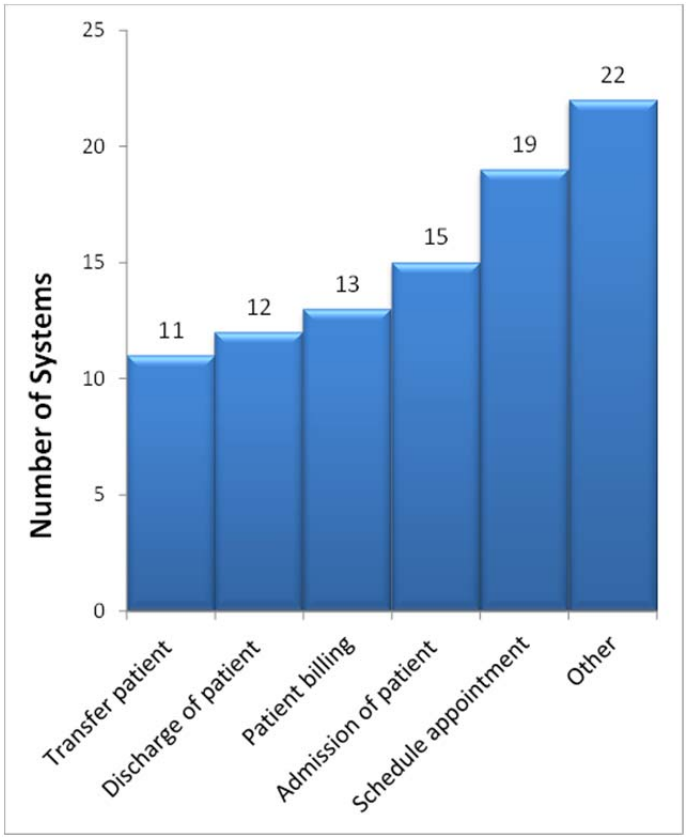

Figure 5-8: Patient administration processes

The support by the systems for typical patient care processes is presented in Figure 5-9. Capturing patient medical history is the most prevalent, with a relatively equal distribution for the other processes. Less than a third of the systems in the survey supported patient care processes though. Patient care processes listed as 'other' included record clinical vital signs, dispense medication, clinical visit notes, support for EDI, track pharmacy orders, etc. Again, less than a third of the systems are able to support data collection on typical patient care processes.

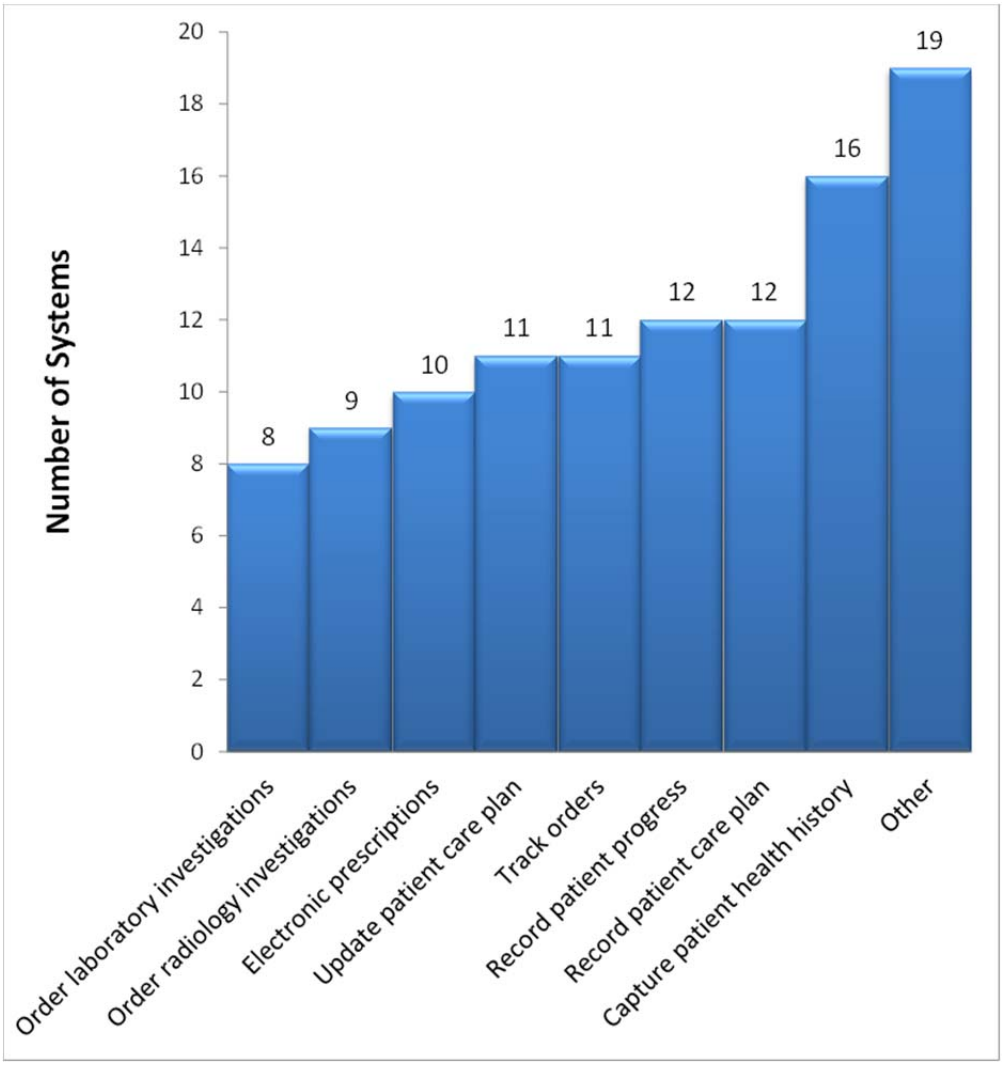

Figure 5-9: Patient care processes

5.1.1.6 *Security and Access*

Figure 5-10 illustrates the measures in place to authorise access to the HISs and the measures in place to ensure the confidentiality of patient information. Password protected and role-based access is predominant, whilst encryption is used for confidentiality. It is, however, concerning that less than 50% of the systems have such security controls in place.

Access to the systems are predominantly monitored using database audit trails (24 of the 42 systems), whilst eight systems makes use of operating system monitors.

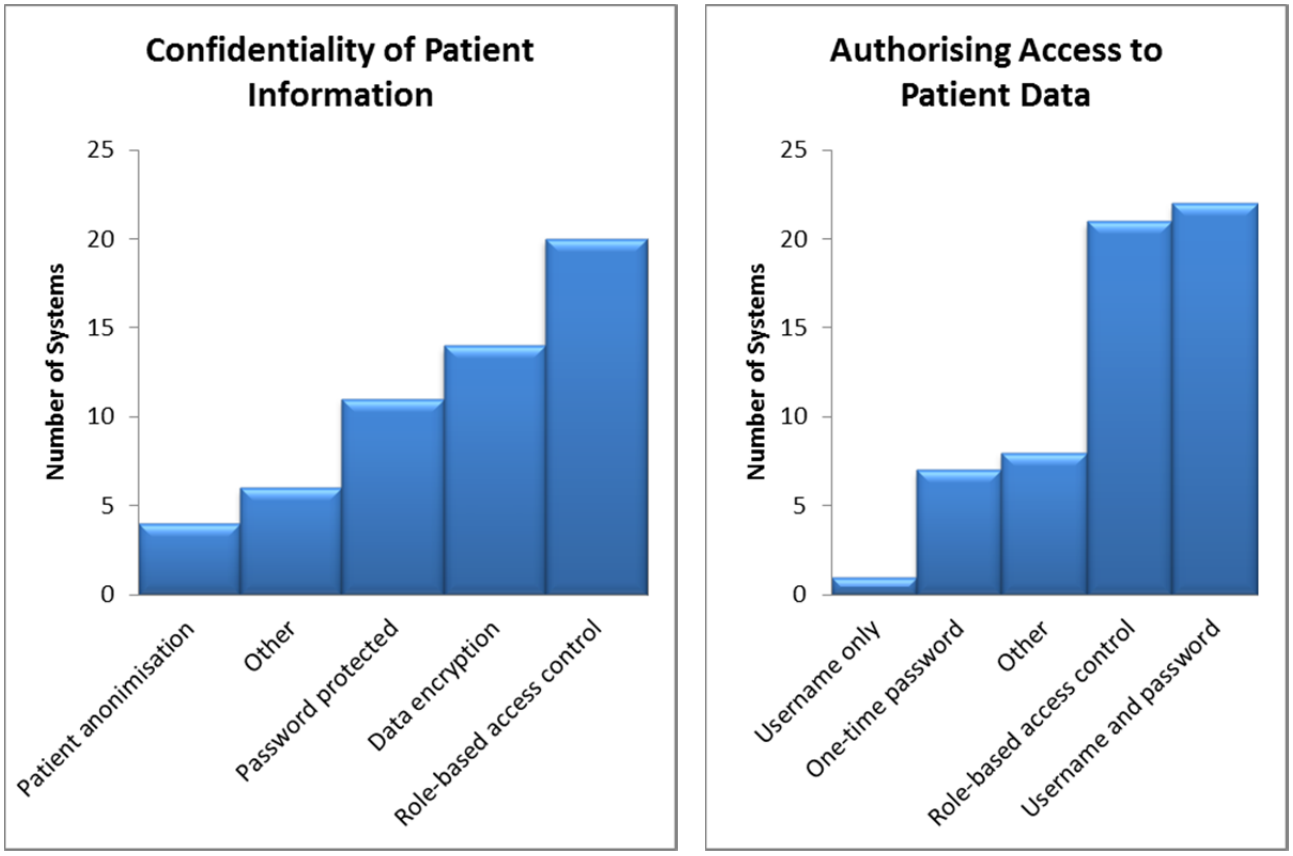

Figure 5-10: Authorising access and confidentiality of patient information

5.1.1.7 *Age of systems*

The research team collected information on the age of the current HISs installed. For some of the systems the information could not be determined. Figure 5-11 provides the information for the systems for which the information is known. Although the date the system was first commissioned could be some time ago, some systems were installed in new facilities as recently as October 2012 (e.g. PAAB Faranani in Mpumalanga). The age of the following systems could not be determined: CytMed, PALS, PharmAssist, Proclin, EDR.Web. ETR.Net, OpenLink, Web Services, PDSX, Plankmed.

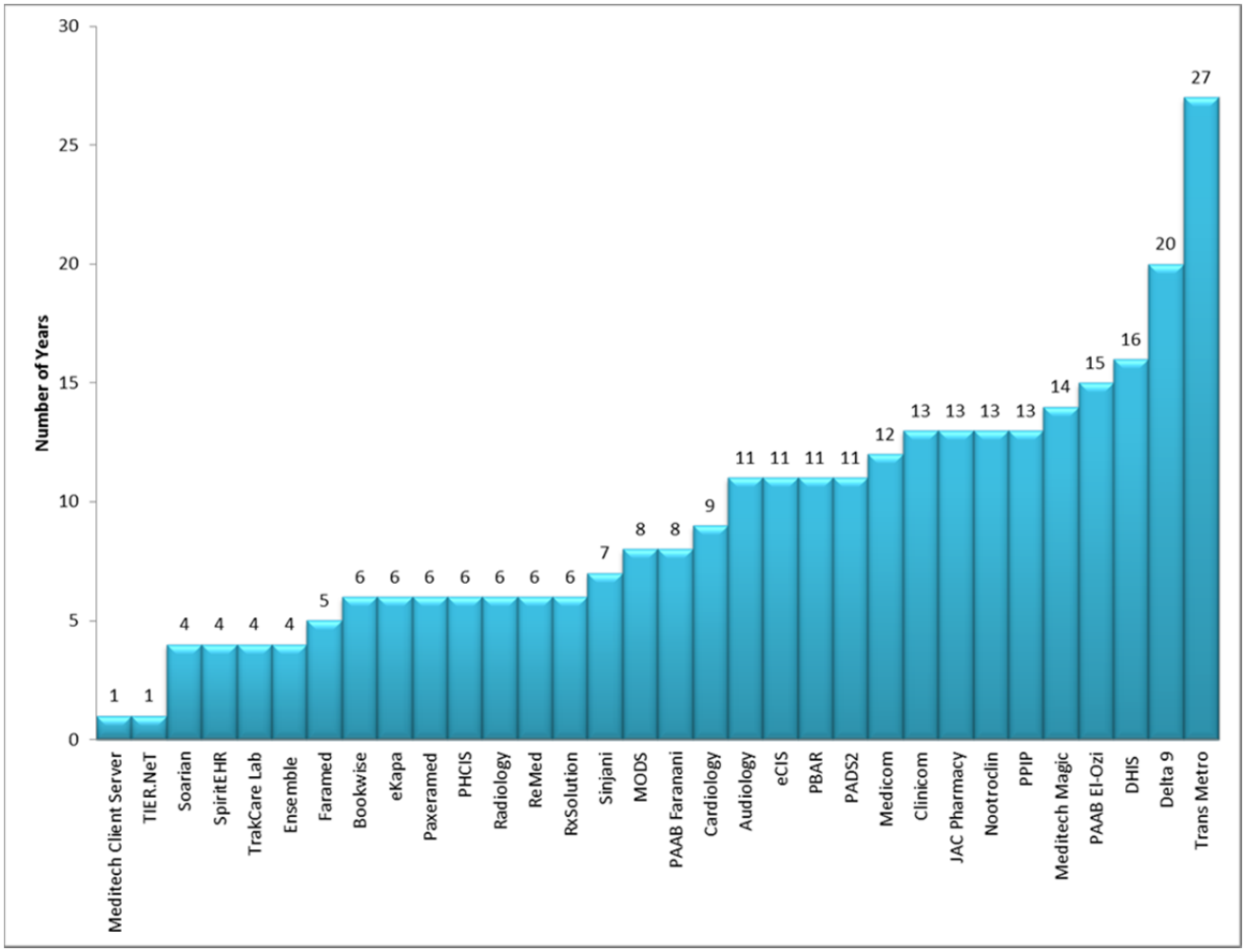

Figure 5-11: Years since system was first commissioned

5.1.2 Interoperability

5.1.2.1 *Sharing information with other systems*

Figure 5-12 illustrates the extent to which the 42 systems share or exchange information with other systems in the local facility (26) or in another facility (24). Twenty two (22) of these systems share information both in the local facility and externally. Thirteen (13) systems are standalone and do not share information locally or externally. For four (4) systems, no information was received on whether systems share information locally or not, and for five (5) whether they share info externally or not. In calculating these numbers, adherence to interoperability standards was not taken into account.

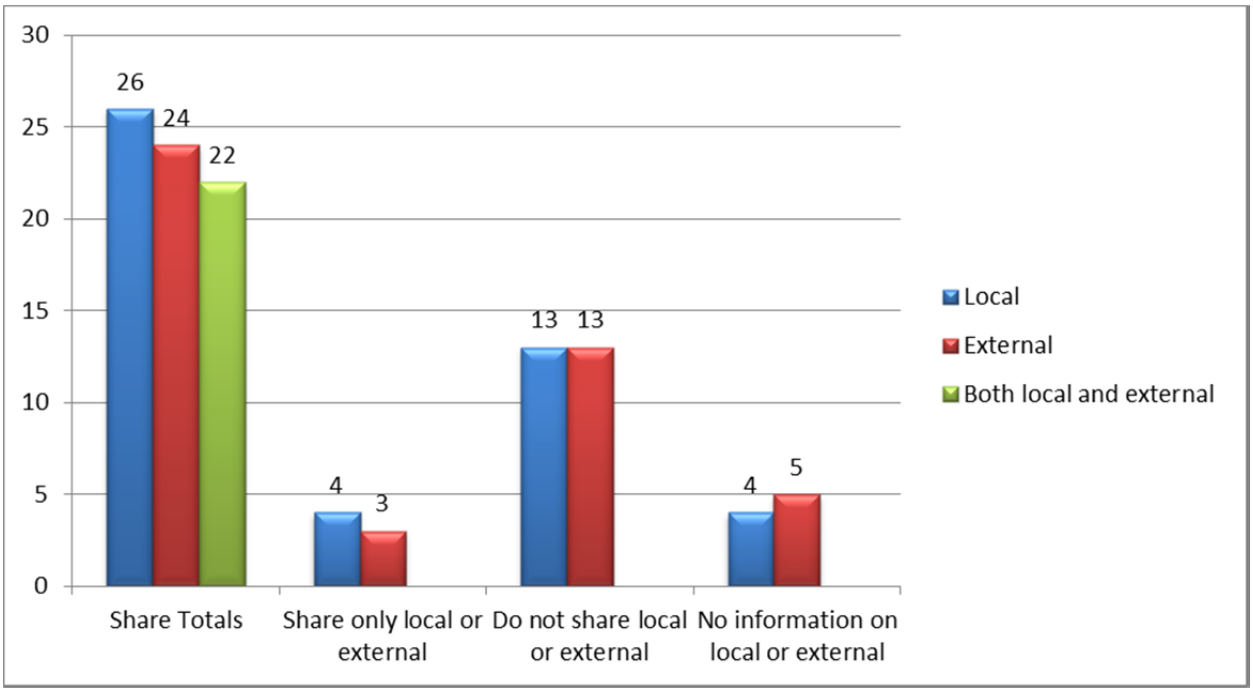

Figure 5-12: Interfacing with other systems

5.1.2.2 *Adherence to standards*

Figure 5-13 illustrates the adherence to interoperability (messaging and content) standards. Even though a substantial number of systems (at least 17) share or exchange information with other systems, only six (6) are based on international messaging and coding standards, of which four (4) is based on IHE profiles. This means that for at least 17 of the 26 systems that do exchange information with others systems, do not make use of standard-based messaging. An additional five of the 13 systems that do not currently exchange information with other systems are 'enabled' to handle HL7 V2.X messages. This means that only 12 of the 42 systems are based on interoperability standards. See Table 5-1 for details on the standards used by the various systems.

The majority of the patient admission systems make use of ICD10, procedure codes and UPFS as coding standards.

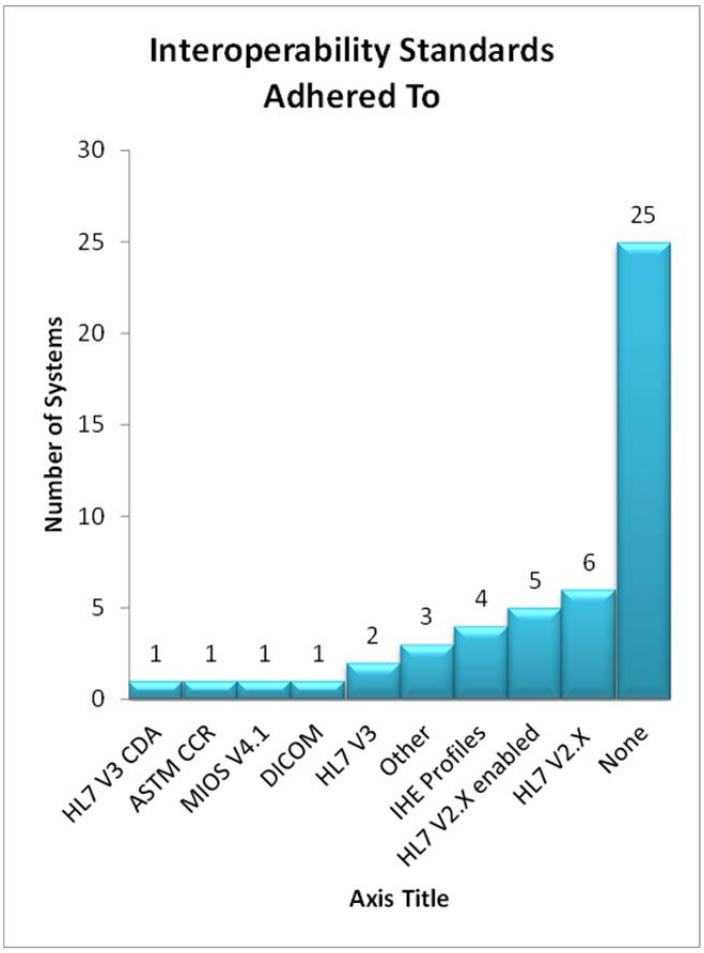

Figure 5-13: Interoperability standards adherence

Table 5-1: Standards supported by HISs

Systems	Standards supported	Systems it exchange messages with	Note
Bookwise	HL7 V2.5.1-enabled	None	Bookwise currently supports a number of HL7 messages e.g. ADT, OML and messages, but because it does not interface with any system at the moment it does not exchange HL7 messages with any system.
Clinicom	HL7 V2.x enabled		
JAC Pharmacy	HL7 V2.x enabled		
Meditech	HL7 V2.X Hl7 V3		Not verified: Awaiting response from vendor
Nootroclin	HL7 V2.3	Radiology (RIS) TrakCare Lab	The following HL7 messages are exchanged with systems that

			Nootroclin interfaces with: ADT, ORM, ORU
Paxeramed	HL7 V2.x	Interfaces with different imaging modalities	Paxeramed is capable of exchanging HL7 messages with any HISs from any vendor: ADT, ORM,ORU
		IHE	IHE Radiology profiles, as documented in its IHE integration statement: SWF, ARI, CPI, PIR, KIN, and MAMMO
		DICOM 3.0	
ReMed	HL7 V2-enabled	None	ReMed does not exchange any HL7 messages with any system at the moment because it does not currently interface with any system
[48]Soarian	HL7 V2.6	TrakCare LabSyngo Workflow Innovian Megacare LANTIS PBAR BAS SAP Materials Management	Message segments used in communication with other systems: PID, PV1, IN1, DG1, ORC,OBR, OBX, OCX, NTE
	IHE		PIX, PDQ, XDS-MS
	HL7 V3 CDA		
	ASTM CCR		
TrakCare Lab	HL7 V2.x HL7 V3	Meditech Soarian Nootroclin	
	IHE		No IHE profile implemented in SA as yet, though many at different facilities across Europe and the US
	ANSI/NCCLS: LIS1-A; LIS02-A2		
Ensemble	HL7 V2.x HL7 V3	Integration engine; enables communication between TrakCare Lab at NHLS and Meditech, Soarian, Nootroclin	
	IHE		No IHE profile implemented in SA as yet, though many at different facilities across Europe and the US
	ANSI/NCCLS: LIS1-A; LIS02-A2		
	MIOS V4.1		
OpenLink	HL v2.x-enabled		

Figure 5-14 illustrates the number of Provinces where a standards-based system is installed. Ensemble is indicted as being installed in one Province, but it serves eight Provinces. Figure 5-15 indicates the number of sites served by a specific standards-based system. *Trakcare Lab* is omitted from the figure, but was already serving 186 sites at the time of writing this report.

[48] No confirmation received from supplier

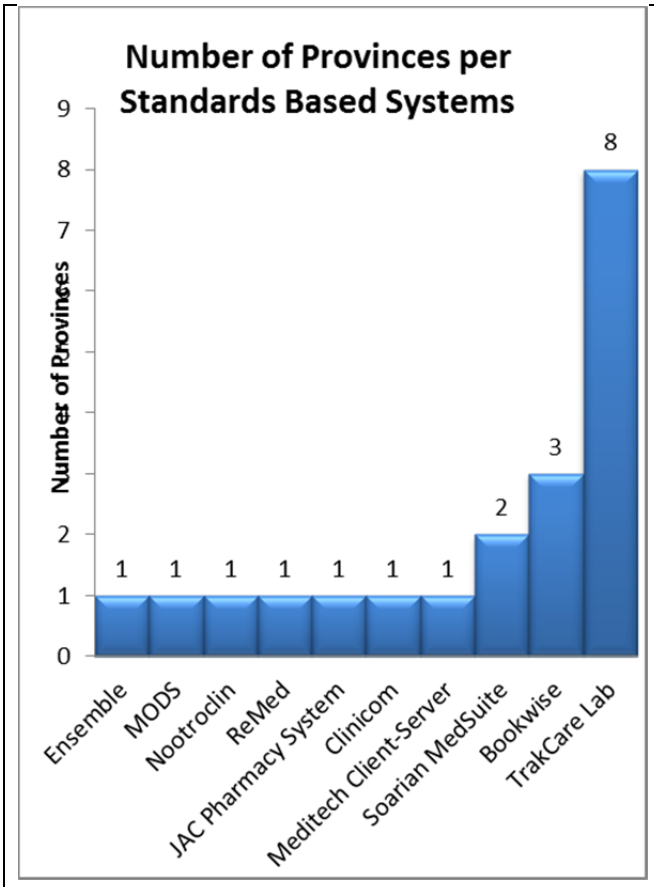

Figure 5-14: Number of Provinces served by a standards-based system

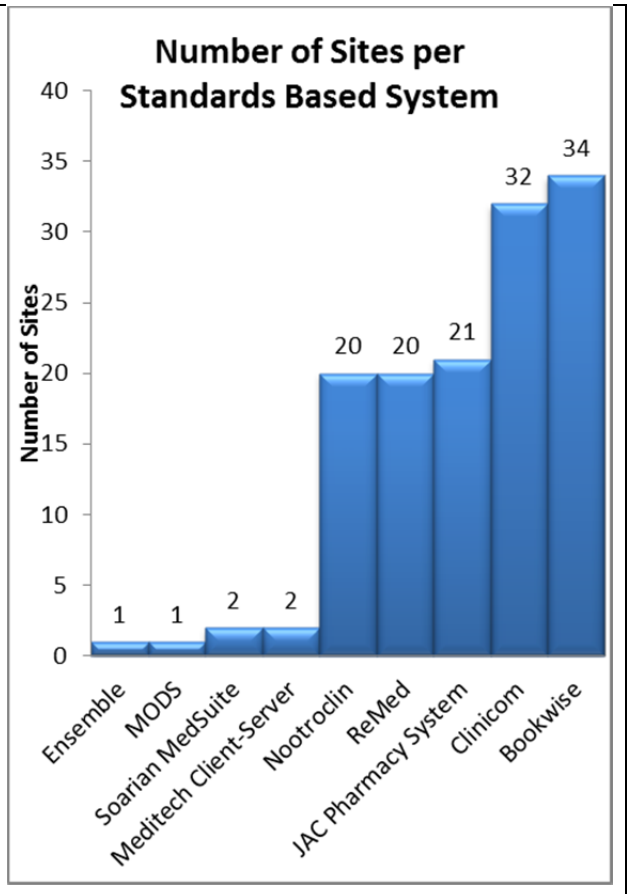

Figure 5-15: Number of sites served by a standards-based system

5.2 Assessment against HNSF assessment instrument

To conclude this section, the results of a first-level assessment of the existing HIS, based on the information gathered, against the HNSF is presented.

According to the assessment instrument (see section 4.3), the following steps should be followed to determine the standards that an existing HIS has to adhere to, if this system is to be integrated with its current full functionality into the shared EHR system:

1. Determine which of the HISs functions will be supported by the eHealth application specified.
2. Identify which of these functions will result in patient-based transactions with content that would be sent to the shared EHR.
3. Identify the content that is required to be sent to the shared EHR by these functions, and draft a data model that represents this data. See section 3.4 for examples.
4. Using the HNSF, map these functions to applicable standards-based profiles. See section 3.6 .
5. Identify the relevant base standards as prescribed by the applicable profile in the HNSF.

Applying these steps using the current functionality of the systems, resulted in the set of standards illustrated in Table 5-2 . The current standards that systems adheres to, according to the data collected, are indicated with a • next to the standard.

Table 5-2: Applying the HNSF to existing HIS

Systems	Functionality	Mappings to generic health functions	Applicable standards	
			eHealth standards	Others
Patient-centric systems implemented by provinces				
AUDIOLOGY	Recording of patients' information Stock control Reports (patient visits, patients seen at clinic, tests done, test results)	Identify patient (not explicit) Search for patient record Create new patient record Add, query and update "doctor's notes"	ISO 22220:2011 HL7V2.X ISO 18308:2011 ISO/TR 20514:2005	NPR (MIOS) XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS
BOOKWISE/VEMR	Identify patient (through fingerprints at some facilities) Register patient Schedule appointment Admission, discharge and transfer (ADT) Capture health history Record vital signs Order laboratory tests Order radiology tests Record update care plan Update care plan Track orders E-prescription Dispense medicine Counsellor module (PMTCT counselling) Report generation Clinical indicators reports Print labels SMS module Patient billing ICD coding	Identify patient Search for patient record Create new patient record Add, query and update demographic details Admit patient Discharge patient Add, query and update medical history Add, query and update clinical observations Add, query and update transfer Add and query pharmacy orders Add and query drugs dispensed Add and query orders for laboratory tests Add and query laboratory test results Add and query orders for radiology tests Add, query and update "doctor's notes" Schedule appointment Confirm attendance or cancellation Send reminders Add, query and update bills Add, query and update health indicator	ISO 22220:2011 HL7 V2.X (● HL7 V2.x Enabled) ISO 18308:2011 ISO/TR 20514:2005 HL7 V3 CDA Release 2.0 CDA for CDTHP HL7 V3 Normative Edition (CMET only) ASTM/HL7 CCD ICD-10 (● MIOS) Procedure codes (e.g. CPT) Medicine codes (e.g. NAPPI, ATC/DDD, RxNorm, AMT Codes) LOINC UPFS SDMX-HD	NPR (MIOS) XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS

Systems	Functionality	Mappings to generic health functions	Applicable standards	
			eHealth standards	Others
CARDIOLOGY	Capture previous visits Recording of reports from Echo Lab and Cardiac Catheter Lab Recording of previous medical history and previous procedures	Identify patient (not explicit) Search for patient record Create new patient record Add, query and update "doctor's notes" Add, query and update medical history Add and query laboratory test results (cardiac catheter lab)	ISO 22220:2011 HL7V2.X ISO 18308:2011 ISO/TR 20514:2005HL7 V3 CDA Release 2.0 CDA for CDTHP ICD-10 (MIOS) Procedure codes (e.g. CPT)	NPR (MIOS) XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS
CLINICOM	Register patient Patient master index (PMI) Admission, discharge and transfer (ADT) Record and update patient care plan Record patient observations Appointment scheduling and cancellation Case file tracking Duplicate folder management Pre-admission Borders and escorts Theatre (for time management only) Patient billing by providing ADT transactions to PBAR Access management, for the management and control of user access to Clinicom Report Generation View treatment facility View attending health professional ICD coding Procedure coding	Identify patient Identify location Identify provider Authorise provider roles and permissions Search for patient record Create new patient record Add, query and update demographic details Merge temporary and permanent record Admit patient Discharge patient Add, query and update transfer Add, query and update medical history Add, query and update clinical observations Add, query and update care plan Add and query referrals Schedule appointment Confirm attendance or cancellation Add, query and update health indicator	ISO 22220:2011 ISO/TS 27527:2010 ISO/TS 22600:1-3 HL7 V2.X (● HL7 V2.x Enabled) ISO 18308:2011 ISO/TR 20514:2005 HL7 V3 CDA Release 2.0 CDA for CDTHP ASTM/HL7 CCD HL7 CRS ICD-10 (MIOS) (●) Procedure codes (e.g. CPT) (●) LOINC SDMX-HD	NPR (MIOS) XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) LDAP (MIOS) ISO/TS 21091:2005 DSML V2 SOAP 1.2 (MIOS) ANSI INCITS 359-2004 ebMS ebRIM ebRS

Systems	Functionality	Mappings to generic health functions	Applicable standards	
			eHealth standards	Others
CYTMED	Record patient information and drug courses Schedule appointments E-prescription Dispense medicines Print labels Manage drug information View list of appointments and their associated medicines	Identify patient (not explicit) Search for patient record Create new patient record (chemotherapy record) Add and query pharmacy orders Add and query drugs dispensed Update pharmacy stock	ISO 22220:2011 HL7 V2.X ISO 18308:2011 ISO/TR 20514:2005 HL7 V3 Normative Edition (CMET only) ASTM/HL7 CCD Medicine codes (e.g. NAPPI, ATC/DDD, RxNorm, AMT Codes)	NPR (MIOS) XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS
DELTA9	Patient registration Patient master index (PMI) Admission, discharge and transfer (ADT) Appointment scheduling Patient folder tracking Dietary management Electronic prescription Order laboratory tests Order radiology tests Discharge summaries Patient billing EDI to Medikredit Report generation ICD coding	Identify patient Search for patient record Create new patient record Add, query and update demographic details Admit patient Discharge patient Add, query and update transfer Add and query discharge summary Add and query pharmacy orders Add and query orders for laboratory tests Schedule appointment Confirm attendance or cancellation Add, query and update bills Submit medical bills for payment	ISO 22220:2011 HL7 V2.X ISO 18308:2011 ISO/TR 20514:2005 HL7 V3 CDA Release 2.0 CDA for CDTHP HL7 V3 Normative Edition (CMET only) ASTM/HL7 CCD HL7 CRS ICD-10 (MIOS) (●) Procedure codes (e.g. CPT) Medicine codes (e.g. NAPPI, ATC/DDD, RxNorm, AMT Codes) LOINC UPFS (●) UN/EDIFACT	NPR (MIOS) XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS

Systems	Functionality	Mappings to generic health functions	Applicable standards	
			eHealth standards	Others
ECIS	Master Patient Index Patient Registration Change Patient Details Outpatient Management Visit Registration Cancel Visit Manage Queue Appointment Scheduling Clinician Access (Consultation): General Clinic, Antenatal Care Clinic, Postnatal Care Clinic, MOU, Medico Legal Clinic, Family Planning Clinic, TB Clinic, Sexually Transmitted Infections Clinic, Well baby Clinic ICD coding	Identify patient Search for patient record Create new patient record Add, query and update demographic details Schedule appointment Add, query and update medical history Add, query and update “doctor’s notes”	ISO 22220:2011 HL7 V2.X ISO 18308:2011 ISO/TR 20514:2005 HL7 V3 CDA Release 2.0 CDA for CDTHP ICD-10 (MIOS) (●)	NPR (MIOS) XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS
EKAPA	Master patient index Patient Registration (only if patient is not registered on Clinicom) Search for patient Admit patient Appointment scheduling Capture medical history Record patient progress Track orders Report generation Map care provider to care provided to patient ICD coding Display patient visits summary	Identify patient Identify provider Search for patient record Create new patient record Add, query and update demographic details Schedule appointment Confirm attendance or cancellation Add, query and update medical history Add, query and update “doctor’s notes” Retrieve and display patient record	ISO 22220:2011 ISO/TS 27527:2010 HL7 V2.X ISO 18308:2011 ISO/TR 20514:2005 HL7 V3 CDA Release 2.0 HL7 CRS CDA for CDTHP ICD-10 (MIOS) (●)	NPR (MIOS) XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ISO/TS 21091:2005 LDAP (MIOS) DSML V2 SOAP 1.2 (MIOS) ebMS ebRIM ebRS

Systems	Functionality	Mappings to generic health functions	Applicable standards	
			eHealth standards	Others
JAC	Dispensing Generate labels Bulk issue to wards or clinics Ordering and invoicing Manufacturing and trading Manufacturing and management of chemotherapy and intravenous infusions Stock maintenance Drug management Financial management Report generation Patient management (add patient manually if Clinicom is offline) System management and control	Identify patient (linked to Clinicom) Search for patient record Add and query drugs dispensed Update pharmacy stock Authorise provider roles and permissions	ISO 22220:2011 HL7 V2.X (● HL7 V2.x Enabled) HL7 V3 Normative Edition (CMET only) ASTM/HL7 CCD Medicine codes (e.g. NAPPI, ATC/DDD, RxNorm, AMT Codes) ISO/TS 22600:1-3	NPR (MIOS) XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ANSI INCITS 359-2004 ebMS ebRIM
MEDICOM	Patient registration Patient master index (PMI) Search for patient Admission, discharge and transfer (ADT) Report generation Appointment scheduling Patient folder tracking Dietary management Capture health history Record and update care plans Track orders Patient billing EDI to Medikredit ICD codes	Identify patient Search for patient record Create new patient record Add, query and update demographic details Admit patient Discharge patient Add, query and update transfer Add, query and update medical history Add, query and update clinical observations Add, query and update care plan Schedule appointment Confirm attendance or cancellation Add, query and update bills Submit medical bills for payment	ISO 22220:2011 HL7 V2.X ISO 18308:2011 ISO/TR 20514:2005 HL7 V3 CDA Release 2.0 CDA for CDTHP ICD-10 (MIOS) (●) Procedure codes (e.g. CPT) V UPFS (●) UN/EDIFACT	NPR (MIOS) XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS

Systems	Functionality	Mappings to generic health functions	Applicable standards	
			eHealth standards	Others
MEDITECH (client-server)	(NB: Functionality currently implemented) Master Patient Index Patient registration Search for patient Merge duplicate folder Admission, discharge and transfer (ADT) Billing and Accounts Receivable Order Management Electronic medical record Customer Wide Scheduling Imaging and Therapeutic Systems (includes Radiology IS) Laboratory and Microbiology Modules Data Repository Executive Summary System EDI with Medikredit MIS	Identify patient Search for patient record Create new patient record Add, query and update demographic details Admit patient Discharge patient Add, query and update transfer Add, query and update medical history Add, query and update clinical observations Add, query and update care plan Add and query orders for laboratory tests Add and query laboratory test results Add and query orders for radiology test s Add and query radiology test results Add, query and update “doctor’s notes” Schedule appointment Confirm attendance or cancellation Add, query and update bills Submit medical bills for payment	ISO 22220:2011 HL7 V2.X (●) ISO 18308:2011 ISO/TR 20514:2005 HL7 V3 CDA Release 2.0 (●) CDA for CDTHP DICOM 2011, [ISO/IEC 12052] (MIOS) ICD-10 (MIOS) Procedure codes (e.g. CPT) LOINC (●) UPFS UN/EDIFACT	NPR (MIOS) XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) SOAP-MTOM XML-binary OP ebMS ebRIM ebRS

Systems	Functionality	Mappings to generic health functions	Applicable standards	
			eHealth standards	Others
MEDITECH (Magic)	Medical record index (MRI) Register patient Admission, discharge and transfer (ADT) Track patient files Schedule appointments Order entry Billing and account receivable Capture health history Record vital signs Order laboratory tests Order radiology tests Record update care plan Update care plan Track orders E-prescription EDI with Medikredit	Identify patient Search for patient record Create new patient record Add, query and update demographic details Admit patient Discharge patient Add, query and update medical history Add, query and update clinical observations Add, query and update care plan Add, query and update transfer Add and query pharmacy orders Add and query orders for laboratory tests Add and query laboratory test results Add, query and update “doctor’s notes” Schedule appointment Confirm attendance or cancellation Add, query and update bills Submit medical bills for payment	ISO 22220:2011 HL7 V2.X ISO 18308:2011 ISO/TR 20514:2005 HL7 V3 CDA Release 2.0 CDA for CDTHP HL7 V3 Normative Edition (CMET only) ASTM/HL7 CCD ICD-10 (MIOS) (●) Procedure codes (e.g. CPT) Medicine codes (e.g. NAPPI, ATC/DDD, RxNorm, AMT Codes) LOINC UPFS (●) UN/EDIFACT	NPR (MIOS) XML V1.0 (MIOS) RFC 2616 (MIOS) ebMS ebRIM ebRS
MODS	Automatic assignment of meal Special dietary request (by ward staff or dietician)Reports (printed at the kitchen)Management of meal routing to wards	Identify patient (Not explicit) Search for patient Add, query and update care plan	ISO 22220:2011 HL7V2.X HL7 V3 CDA Release 2.0 ICD-10 (MIOS)	NPR (MIOS) XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS
NOOTROCLIN	Admissions Discharges Transfers Patient registration Appointment scheduling Search for patient record Update patient record Clinical data recording Patient billing Pharmacy dispensing (NootroPharm)	Identify patient Search for patient record Create new patient record Add, query and update demographic details Admit patient Discharge patient Add, query and update medical history Add, query and update clinical observations Add and query care plan Link baby patient to mother patient	ISO 22220:2011 HL7 V2.X (●) ISO 18308:2011 ISO/TR 20514:2005 HL7 V3 CDA Release 2.0 CDA for CDTHP HL7 CRS ASTM/HL7 CCD NDoH Maternal Case Record HL7 V3 Normative Edition (CMET only)	NPR (MIOS) XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) SOAP-MTOM XML-binary OP ebMS ebRIM ebRS

Systems	Functionality	Mappings to generic health functions	Applicable standards	
			eHealth standards	Others
	Pharmacy stock ordering (NootroDepot) User account set-up and EDI with Medikredit and Mediswitch	Add and query discharge summary Add, query and update transfer Add and query pharmacy orders Add and query orders for laboratory tests Add and query laboratory test results Add, query and update "doctor's notes" Schedule appointment Confirm attendance or cancellation Add, query and update bills Submit medical bills for payment	DICOM 2011, [ISO/IEC 12052] (MIOS) ICD-10 (MIOS) (●) Procedure codes (e.g. CPT) (●) Medicine codes (e.g. NAPPI, ATC/DDD, RxNorm, AMT Codes) (●) LOINC UPFS UN/EDIFACT	
PAAB EL-Ozi	Patient registration Searching for patient Update of patient information Appointment scheduling Recording of patient visits Patient billing ICD coding Statistical reporting	Identify patient Search for patient record Create new patient record (only demographics) Add, query and update demographic details Schedule appointment Add, query and update bills	ISO 22220:2011 HL7 V2.X ICD-10 (MIOS) (●) UPFS (●)	NPR (MIOS) XML V1.0 (MIOS)
PAAB Faranani	Master patient index Register patient Patient admission, discharge and transfer Inpatient/outpatient management Billing and revenue collection Duplicate file management Chronic disease management (ARV, TB, VCT, PMTCT) Patient file tracking Meal ordering Appointment scheduling Barcode scanning ICD10 EDI with Mediswitch Report generation Health indicator reporting as part of the ARV module	Identify patient Search for patient record Create new patient record Add, query and update demographic details Admit patient Discharge patient Add, query and update medical history Add, query and update transfer Add, query and update "doctor's notes" Schedule appointment Confirm attendance or cancellation Add, query and update bills Submit medical bills for payment Add, query and update health indicator	ISO 22220:2011 HL7 V2.X ISO 18308:2011 ISO/TR 20514:2005 HL7 V3 CDA Release 2.0 CDA for CDTHP ICD-10 (MIOS) (●) Procedure codes (e.g. CPT) LOINC UPFS (●) UN/EDIFACT SDMX-HD	NPR (MIOS) XML V1.0 (MIOS) RFC 2616 (MIOS) ebMS ebRIM ebRS

Systems	Functionality	Mappings to generic health functions	Applicable standards	
			eHealth standards	Others
PADS2	Patient admission and discharge Billing Report generation	Identify patient (not explicit) Search for patient record Create new patient record (demographics only) Add, query and update demographic details Admit patient Discharge patient Add, query and update bills	ISO 22220:2011 HL7 V2.X ICD-10 (MIOS) (●) UPFS (●)	NPR (MIOS) XML V1.0 (MIOS)
PAXERAMED (RIS)	Scheduling of radiology appointments Order radiology tests Track orders View radiology images Generate radiology reports View hospital and patient lists	Identify patient (not explicit) Search for patient record Schedule appointment Add and query orders for radiology test s Add and query radiology test results	ISO 22220:2011 HL7 V2.X (●) DICOM 2011, [ISO/IEC 12052] (MIOS) (●)	NPR (MIOS) XML V1.0 (MIOS) (●) ISO 19005-1 (PDF/A-1) (●) SOAP-MTOM XML-binary OP
PBAR	Health Information System Interfacing to capture health-care events ADT transactions Automatic classification of patient Automatic calculation of bill based on type of care received Posting out accounts 7 days after discharge Month-end aging of account receivable Charging of patient using Uniform Patient Fee Schedule (UPFS) Automated billing using EDI Reporting	Identify patient (linked to HISs in facility) Search for patient record Add, query and update bills Submit medical bills for payment	ISO 22220:2011 HL7 V2.X ICD-10 (MIOS) (●) Procedure codes (e.g. CPT) Medicine codes (e.g. NAPPI, ATC/DDD, RxNorm, AMT Codes) LOINC UPFS (●) UN/EDIFACT	NPR (MIOS) XML V1.0 (MIOS)

Systems	Functionality	Mappings to generic health functions	Applicable standards	
			eHealth standards	Others
PHCIS	Patient master index Search for patient record Patient registration (only if patient is not registered on Clinicom) Recording of past medical and surgical history Appointment scheduling Report generation Patient admission, discharge and transfer Recording of clinical observations Recording of baby information(after delivery) ICD and procedure coding Record type of service provided (as part of NIDS) Computer asset management Human resource management	Identify patient Search for patient record Create new patient record Add, query and update demographic details Schedule appointment Confirm attendance or cancellation Add, query and update medical history Add, query and update “doctor’s notes” Add, query and update health indicator	ISO 22220:2011 HL7 V2.X ISO 18308:2011 ISO/TR 20514:2005 HL7 V3 CDA Release 2.0 CDA for CDTHP ICD-10 (MIOS) (●) Procedure codes (e.g. CPT) (●) SDMX-HD	NPR (MIOS) XML V1.0 (MIOS) RFC 2616 (MIOS) ebMS ebRIM ebRS
RADIOLOGY	Scheduling of radiology appointments Order radiology tests Track orders View radiology images View hospital and patient lists	Identify patient (not explicit) Search for patient record Schedule appointment Add and query orders for radiology test s Add and query radiology test results	ISO 22220:2011 HL7 V2.X DICOM 2011, [ISO/IEC 12052] (MIOS)	NPR (MIOS) XML V1.0 (MIOS) ISO 19005-1 (PDF/A-1) SOAP-MTOM XML-binary OP
REMED	Record patient information Dispense medicines View dispensing history Report generation Track pharmacy stock orders Role-based access control Pharmacy stock management	Identify patient (not explicit) Search for patient record Add and query pharmacy orders Add and query drugs dispensed Update pharmacy stock Authorise provider roles and permissions	ISO 22220:2011 HL7 V2.X (● HL7 V2.x Enabled) HL7 V3 Normative Edition (CMET only) ASTM/HL7 CCD Medicine codes (e.g. NAPPI, ATC/DDD, RxNorm, AMT Codes)	NPR (MIOS) XML V1.0 (MIOS)

Systems	Functionality	Mappings to generic health functions	Applicable standards	
			eHealth standards	Others
RX SOLUTIONS	Record patient information Dispense medicines Record treatment interventions Record adverse drug reactions Track pharmacy stock orders Pharmacy stock management	Identify patient (not explicit) Search for patient record Add and query pharmacy orders Add and query drugs dispensed Update pharmacy stock	ISO 22220:2011 HL7 V2.X HL7 V3 Normative Edition (CMET only) ASTM/HL7 CCD Medicine codes (e.g. NAPPI, ATC/DDD, RxNorm, AMT Codes)	NPR (MIOS) XML V1.0 (MIOS)
SOARIAN	Master patient index Patient registration Search for patient record Patient admission, discharge and transfer Appointment scheduling Duplicate folder management Capture medical history Record and update care plan Record patient progress Electronic prescription Order laboratory Order radiology tests Receive laboratory test results Receive radiology test results Track orders Full clinical documentations Discharge and patient visits summaries Patient billing Submit medical bills for payment Procedure and diagnosis coding	Identify patient Search for patient record Create new patient record Add, query and update demographic details Admit patient Discharge patient Add, query and update medical history Add, query and update clinical observations Add and query care plan Add and query discharge summary Add, query and update transfer Add and query pharmacy orders Add and query orders for laboratory tests Add and query laboratory test results Add and query orders for radiology tests Add and query radiology test results Add, query and update “doctor’s notes” Schedule appointment Confirm attendance or cancellation Add, query and update bills Submit medical bills for payment	ISO 22220:2011 HL7 V2.X (●) ISO 18308:2011 ISO/TR 20514:2005 HL7 V3 CDA Release 2.0 (●) CDA for CDTHP HL7 CRS ASTM/HL7 CCD (●) HL7 V3 Normative Edition (CMET only) DICOM 2011, [ISO/IEC 12052] (MIOS) ICD-10 (MIOS) (●) Procedure codes (e.g. CPT) Medicine codes (e.g. NAPPI, ATC/DDD, RxNorm, AMT Codes) LOINC UPFS UN/EDIFACT	NPR (MIOS) XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) SOAP-MTOM XML-binary OP ebMS ebRIM ebRS

Systems	Functionality	Mappings to generic health functions	Applicable standards	
			eHealth standards	Others
SPIRITEHR	Master patient index (linked to Soarian at Sebokeng hospital) Patient registration Patient admission, discharge and transfer Appointment scheduling Capture medical history Record and update care plan Electronic health record (linked to Soarian at Sebokeng hospital) Electronic prescription Record patient progress	Identify patient Search for patient record Create new patient record Add, query and update demographic details Admit patient Discharge patient Add, query and update medical history Add, query and update clinical observations Add query, and update care plan Add, query and update transfer Add and query pharmacy orders Add, query and update “doctor’s notes” Schedule appointment	ISO 22220:2011 HL7 V2.X ISO 18308:2011 ISO/TR 20514:2005 HL7 V3 CDA Release 2.0 CDA for CDTHP HL7 CRS ASTM/HL7 CCD HL7 V3 Normative Edition (CMET only) ICD-10 (MIOS) Procedure codes (e.g. CPT) Medicine codes (e.g. NAPPI, ATC/DDD, RxNorm, AMT Codes)	NPR (MIOS) XML V1.0 (MIOS) RFC 2616 (MIOS) ebMS ebRIM ebRS
Patient-centric systems implemented nationally				
TRAKCARE LAB (NHLS)	Support for various laboratory workflows, including: data capture, automated routing of lab results (e-mail, fax, and electronic message), registration of specimens etc.) View lab results (with Web viewer) Report generation Patient billing	Identify patient Search for patient record Add and query orders for laboratory tests Add and query laboratory test results Add, query and update bills Submit medical bills for payment	ISO 22220:2011 HL7 V2.X (●) HL7 V3 CDA Release 2.0 (●) LOINC UPFS ICD-10 (●)	NPR (MIOS) XML V1.0 (MIOS) (●) RFC 2616 (MIOS) (●) ebMS (●) ebRIM (●) ebRS (●)
Surveillance or data aggregation systems				
SINJANI	Data capture Data repository for aggregated routine data for reporting Client satisfaction survey Complaints and complements	Add, query and update health indicator	SDMX-HD	
DHIS	Capturing of aggregated data on health indicators	Add, query and update health indicator	SDMX-HD	

Systems	Functionality	Mappings to generic health functions	Applicable standards	
			eHealth standards	Others
EDR.WEB	User access control Data entry (for monitoring of drug resistant TB treatment) Report generation Capture case registration details, lab results and treatment outcomes	Identify patient (not explicit) Search for patient record Authorise provider roles and permissions Add and query laboratory test results Add, query and update health indicator	ISO 22220:2011 HL7 V2.XISO/TS 22600:1-3 HL7 V3 CDA Release 2.0 ICD-10 (MIOS) LOINC SDMX-HD	ANSI INCITS 359-2004 XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS
ETR.NET	User access control Data entry (for monitoring of TB treatment) Report generation Capture case registration details, lab results and treatment outcomes Export data on health indicators to DHIS	Identify patient (not explicit) Search for patient record Authorise provider roles and permissions Add and query laboratory test results Add, query and update health indicator	ISO 22220:2011 HL7 V2.X ISO/TS 22600:1-3 HL7 V3 CDA Release 2.0 ICD-10 (MIOS) LOINC SDMX-HD	ANSI INCITS 359-2004 XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS
PPIP	Capturing of aggregated data on health indicators	Add, query and update health indicator	SDMX-HD	
TIER.NET (e-register for ARV treatment)	Patient registration Search for patient record Capture medical history Record visits, lab tests, drug dispensed and outcomes Record patient progress Record care plan (limited to drug regimen, lab tests) Capturing of aggregated data on health indicators	Identify patient (not explicit) Search for patient record Authorise provider roles and permissions Add, query and update medical history Add query, and update care plan Add, query and update health indicator	ISO 22220:2011 ISO/TS 22600:1-3 HL7 V2.X HL7 V3 CDA Release 2.0 CDA for CDTHP ICD-10 (MIOS) LOINC SDMX-HD	ANSI INCITS 359-2004 NPR (MIOS) XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS
Middleware				
ENSEMBLE (Middleware)	Ensemble is an Integration Engine that supports interoperability to and from TrakCare Lab at NHLS and the HIS applications (such as Meditech, Soarian, Nootroclin) in provincial Health Departments	N/A	HL7 V2.X (●)	RFC 2616 (MIOS) (●) ebMS (●) ebRIM (●) ebRS (●)
OPENLINK (Middleware)	Generic function to interpret messages between two systems	N/A	HL7 V2.X (● HL7 V2.x Enabled)	RFC 2616 (MIOS) ebMS ebRIM

Systems	Functionality	Mappings to generic health functions	Applicable standards	
			eHealth standards	Others
				ebRS
WEB SERVICES (Middleware)	Capability to extract patient's demographic information from Clinicom database so that the MPI could be used in allocation single patient registration number across facilities.	N/A	HL7 V2.X	RFC 2616 (MIOS) ebMS ebRIM ebRS
Other systems				
PDSX	No data	No data		
PHARMASSIST	Pharmacy stock ordering Receiving Stock Returning Stock Issuing Stock Reports Stock taking Reports Audit trails	Update pharmacy stock	Medicine codes (e.g. NAPPI, ATC/DDD, RxNorm, AMT Codes	
PLANKMED	Stock management Ordering stock Check stock balances Generate stock reports Expenditure per cost centre	Update pharmacy stock	Medicine codes (e.g. NAPPI, ATC/DDD, RxNorm, AMT Codes	
Transmetro	Booking of patient's transport to and from the facility where the patient is referred Transport schedule Maintenance of vehicle availability Tracking of vehicle location	Identify patient (not explicit) Identify location Appointment scheduling (transport)	ISO 22220:2011 ISO/TS 27527:2010 HL7 V2.X	NPR (MIOS) LDAP (MIOS) ISO/TS 21091:2005 DSML V2 SOAP 1.2 (MIOS

6 CONCLUSION AND RECOMMENDATIONS

This report detailed the process and outcome to determine the National Health Normative Standards Framework for Interoperability in eHealth (HNSF). Based on the analyses and investigations a set of findings and recommendations were developed and are dealt with below.

6.1 Findings

6.1.1 Maturity of current HIS

The study of existing healthcare settings found the following on the maturity of HIS in use:

- Almost all the clinics visited during the survey are still at maturity Level 1 (see section 3.1.2.1), i.e. completely paper based and not sharing their patient records with any other facility. Only paper-based patient medical records exist.
- The vast majority of the current hospitals, which make used of an IT-based HIS, are operating at maturity Level 2 (see 3.1.2.2), i.e. IT support for admission and discharge, but no direct IT support for, or users of, the IT-based HIS beyond the 'admission'[49] clerks. The patient-demographics are printed out by the admission clerks and included in a paper file, which is used to record the patient medical record whilst the patient is at the facility. When the patient leaves the facility, the admission clerks record the discharge information on the IT-based HIS. Patient information is hardly shared with any other facility.
- Where an electronic medical record (EMR) system is in place, this kind of hospital-based admission system can in most cases be scaled up to maturity Level 3 (see section 3.1.2.3), by developing appropriate middleware that meets the standards identified in the HNSF, which will allow the system to communicate with a shared infrastructure and share patient demographics with the Patient Registry (PMI) of such a shared infrastructure.
- Reaching maturity Level 3 (see section 3.1.2.3), however, would also require that a minimum set of medical record information be recorded electronically and stored in the shared EHR. At Level 3 the medical records are still predominantly recorded in a paper-based patient files by the healthcare worker, but the minimum set of medical record data is recorded electronically by the admission clerk at the end of the care encounter. Only a small number of existing HISs can operate at this level.
- Only one hospital currently claimed to be operating at Level 4 as far as in-house activities are concerned. However, the research team could not verify if this is in fact the case, since the team were not allowed into the wards. The hospital, however, does not share any information with the 'outside' world.
- Although maturity Level 4 is the ultimate to aim for, the current South African environment would most probably only allow development up to maturity Level 3 for the vast majority of care settings. The reason for this is the availability of a suitably trained workforce, infrastructure and the cost related to obtaining ICT-based edge devices for all healthcare workers who would need to access the EHRs in the shared infrastructure. An additional factor is that Level 4 would require a complete change in work practices of all healthcare workers (including nurses and doctors), and would require a huge investment in change management to be successful.

[49] We use the term 'admission clerk' here, but it can be any clerk/administrator who has the duty of recording patient-centric data.

6.1.2 Standards in use

The following interoperability standards are currently in use in HISs in public healthcare facilities under the auspices of the Provinces. Table 5-1 provide the full details:

- HL7 V2.X-enabled: Six systems.
- HL7 V2.X: Six systems.
- HL7 V3 CDA: Six system
- HL7 CCD/ ASTM CCR: One system.
- HL7 V3: Three systems.
- MIOS V4.1: One system.

ICD-10 codes, procedure codes and UPFS (all coding standards) are also used in a variety of the systems. IHE Profiles are used in three systems.

6.2 Recommendations

The first recommendation is related to the HNSF governance structure and processes, as discussed in section 4.

Recommendation

It is recommended that an eHealth Standards Board for South Africa (ESB) be established to oversee the implementation of the HNSF. The ESB should work closely with healthcare providers and other relevant stakeholders to develop, adopt and maintain eHealth standards-based profiles and base standards.

Concerning the HNSF itself, the overall recommendation is that the NDoH's eHealth infrastructure investments should focus on supporting person-centric health and healthcare. Reportable indicators (e.g. NIDS) may be developed by aggregating such person-centric data.

The report suggests making use of the levels of standards classification as proposed by CEN/TC 251 [2009a], consisting of base standards, standards-based profiles and interoperability specifications (directly related to business use cases). Three candidate stacks of standards were analysed for their suitability to the South African context:

- The family of end-to-end stack of modelled interactions/standards based on the HL7 V3 Reference Information Model (RIM) [Health Level Seven International, 2013e].
- The end-to-end stack of modelled interactions based on the ISO 13606/OpenEHR data archetypes and underlying reference model (ISO 13606 Parts 1-5) [The EN 13606 Association].
- The stacks of standards underlying the interoperability standards-based profiles developed by the global organisation 'Integrating the Health Enterprise' (IHE) [IHE International, 2012]. It is a pragmatic collections of base standards defined in terms of use-case driven interoperability standards-based profiles, relying on underlying base standards from ISO, HL7v2 / HL7v3, ebXML, OMG, etc.

Following the analysis, the use of IHE integration profiles [IHE International, 2013] were further investigated. The research team has determined that, amongst the options, IHE profiles (and its underlying standards) are the candidate to be explored in order to support the target workflows and

care scenarios for South Africa. IHE's set of IT infrastructure profiles addresses specific aspects of sharing healthcare information, e.g. establishing identity (PIX), using demographic data to establish identity (PDQ), patient administration across healthcare enterprises (PAM) and sharing documents between healthcare enterprises (XDS). These infrastructure profiles are not likely to require much change in order to be applied successfully for all use cases occurring in care pathways in South Africa.

Recommendation

It is recommended that the IHE profiles and the base standards underlying these profiles be used as a starting point for the HNSF. Additional base standards were recommended in the HNSF where gaps were identified in the IHE profiles.

The IHE implementation of standards enjoys wide support from industry partners and is well documented, reviewed and tested [CEN/TC 251, 2009a]. The decision whether the suggested IHE profiles would be the exhaustive set of standards-based profiles to use is beyond the scope and mandate of this project, but would be a task for the eHealth Standards Board for South Africa (ESB).

However, an investment will have to be made in the localisation of the document content standards (such as HL7 CDA and CCD) to ensure that the information, which is exchanged with the shared electronic health record infrastructure, supports healthcare service delivery in the context of the South African burden of disease and provides all data necessary for the derivation of the National Indicator Data Set (NIDS).

Recommendation

It is recommended that the document content standards (such as HL7 CDA and CCD) be localised to ensure that the information, exchanged with the shared electronic health record infrastructure, supports healthcare service delivery in the context of the South African burden of disease. See IHE Patient Care Coordination Technical Committee [2011] for an example on the localization of CDA Content.

In addition to interoperability specifications, as dealt with in the proposed HNSF, the following must also be addressed: [CEN/TC 251, 2009a]:

- The development of a national eHealth enterprise architecture for South Africa.
- Implementation architecture choices (configurations, technical performance targets, etc.
- The establishment of a data dictionary for eHealth in South Africa.
- Policy decisions in terms of security, privacy, data management, etc.

These are extremely important elements in order to achieve interoperability, but are considered to be beyond the scope of this project. However, it is critical that the standards-based profiles used for assembling interoperability specifications be aligned with the range of architectures, security and privacy policies and regulations to be supported [CEN/TC 251, 2009a]. The standards-based profiles suggested in this report may therefore be adapted to suit such critical decisions.

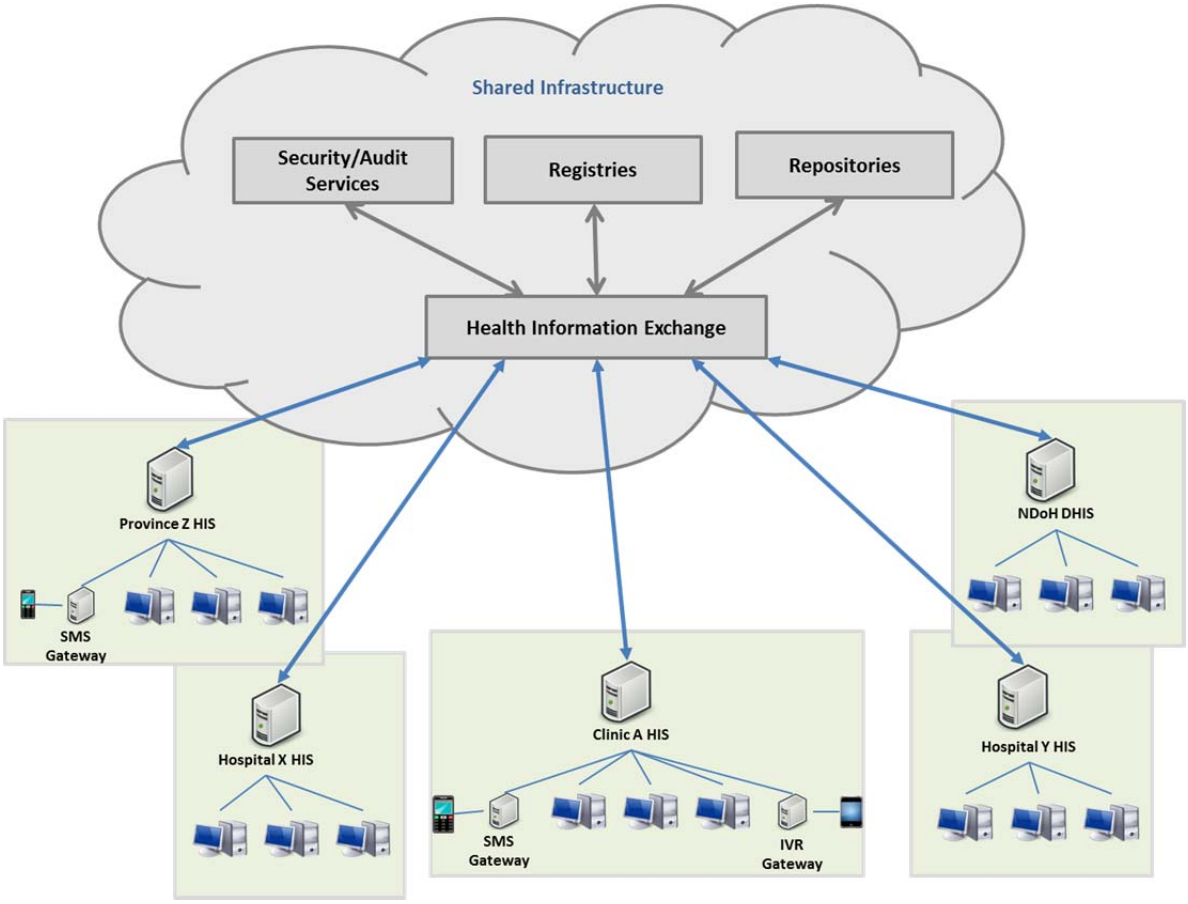

Figure 6-1: Develop a national enterprise architecture and establish a shared infrastructure to integrate disjoint HISs

Recommendation

It is recommended that the development and publication of a national eHealth enterprise architecture for South Africa be undertaken immediately, as recommended in the eHealth Strategy South Africa 2012-2016 [National Department of Health, 2012b]. The analyses and findings of this report provide significant progress towards the development of such an artefact.

Recommendation

Although the aim and mandate of this project was not to suggest a technology infrastructure or complete enterprise architecture for eHealth in South Africa, it is recommended that a cloud-based shared national eHealth infrastructure be established. Such an infrastructure should ideally support fully integrated eHealth applications (similar to the one used in section 3.1.2.4 as illustration) in order to integrate health information from all the disjoint HISs currently in use (see Figure 6-1 for the basic idea). A shared eHealth infrastructure approach is to be favoured over a point-to-point (peer based) approach.

Furthermore, it is recommended that this shared infrastructure be deployed as the crucial enabler for nationwide eHealth interoperability. The recommendations of standards in the HNSF were made with such infrastructure in mind; with a focus on communicating with such an infrastructure from the local infrastructure, retrieving patient records from such infrastructure and updating patient records in such infrastructure.

Recommendation

It is recommended that a data dictionary for eHealth in South Africa be established. A data dictionary lays down a uniform national data set that promotes data uniformity, availability, validity, completeness, reliability, and consistency. Further, the use of the dictionary will ensure uniform collection and sharing of data throughout the health sector. Good examples of such dictionaries are the Australian Health Data Dictionary [Australian Institute of Health and Welfare, 2010], the various data dictionaries for New Zealand [Ministry of Health New Zealand, 2012], and The NHS Data Model and Dictionary from the UK [NHS Connecting for Health, 2012].

Recommendation

The recommended standards-based interoperability framework (the HNSF) relies upon an appropriate legislative and policy framework. If the HNSF is to be implemented, the research team recommend that NDoH should ensure the necessary legislation and policies, to support the sharing of health information for purposes of person-centric care delivery and public health, are drafted. As expressed in the eHealth Strategy South Africa 2012-2016 [National Department of Health, 2012b] document, such legislation should entrench the rights of South Africans to continuity of care over time and across sites of care within the country.

It is also noteworthy that the interoperability specification option based on IHE profiles, provides the NDoH with a ready mechanism to conduct interoperability conformance testing of vendor/supplier products. The IHE organisation [IHE International, 2012] conducts three conformance testing events each year. These '*connectathons*' are annually held in North America, Europe and Asia. There is an opportunity to establish an IHE South Africa chapter and, at some future time as adoption of IHE grows in the region, for a fourth 'connectathon' event to be held annually in southern Africa.

Recommendation

It is recommended that the NDoH, through the eHealth Standards Board for South Africa (ESB), set up a mechanism to conduct interoperability conformance testing of vendor products and existing health information systems against the HNSF.

Although the HNSF was developed based on the assumption that interoperability between the various modules of a regional or facility-based electronic medical record (EMR) system is *not directly affected* by the HNSF or the assessment instrument, the research team highly recommends that the standards proposed in the HNSF also be made applicable to facility-based EMR systems.

Recommendation

It is recommended that the HNSF and its underlying standards are also made applicable to facility-based electronic medical record (EMR) systems. This is especially *important* when patient information is shared or exchanged between different systems at the same facility, and *essential* when such information is shared or exchanged with any other system outside of the facility. As a minimum, the standards related to identification, authentication and authorisation should apply. Other standards that would be applicable will depend on the patient record content being exchanged. When NDoH has determined the minimum data set that should be included in a shared electronic health record (EHR), the relevant standards applicable to that content should also apply at facility level.

6.3 Way Forward

In conclusion the way forward is suggested based on the ten proprieties for eHealth for the period 2012 –2017, as identified in the eHealth Strategy South Africa 2012-2016 [National Department of Health, 2012b]. The actions recommended following the delivery of this National Health Normative Standards Framework for Interoperability in eHealth (HNSF) are closely linked to these ten priorities and in some instances, echo the activities called for by the Strategy:

1. *Strategy and leadership*:
    - Adopt an incremental approach to the development of shared, national electronic health record.
    - Accelerate the delivery of high priority eHealth solutions in a nationally aligned manner.

2. Stakeholder engagement:
   - Workshop the HNSF, as proposed in this document, with relevant stakeholder groups in order to gain acceptance of the proposed framework and refine it where necessary.
   - Establish national eHealth stakeholder forums and working groups with cross-sectorial representation and clearly defined objectives and goals.
   - Establish a national chapter for HL7, including all stakeholders.
   - Establish a national IHE affiliate, including all stakeholders.
   - Working closely with SABS, support the national ISO TC 215 mirror committee and maintain South Africa's status as an active Participating Member of ISO TC 215.

3. *Standards and interoperability*:
   - Establish a properly mandated entity, for the purposes of this document referred to as the eHealth Standards Board for South Africa (ESB), to work closely with healthcare providers and other relevant stakeholders to develop, adopt and maintain eHealth standards-based profiles and base standards. See 4.2 on the recommended governance model.
   - Provide sufficient resources to the ESB so that it can develop, adopt and maintain national eHealth standards-based profiles and information standards for data and message structures, coding and terminologies and information display.
   - Establish a national compliance function within the ESB to test and certify that eHealth solutions comply with national eHealth standards, rules and protocols. See 4.2 on local management of standards-based profiles and base standards.
   - With the guidance of IHE, organise a national or regional *connectathon* to test the interoperability capability of systems that are currently implemented or candidates for implementation.

4. *Governance and regulation*:
   - Design and implement a consistent national legislative framework for information protection, privacy and consent.
   - Establish an independent national eHealth regulation function to implement and enforce national eHealth regulatory frameworks.
   - Develop a governance regime, which allows strong coordination, visibility and oversight of national eHealth work program activities.

5. *Investment, affordability and sustainability/* 9. *Applications and tools to support healthcare delivery*:
   - Encourage investment in the development and deployment of high priority, standards compliant and scalable eHealth solutions.
   - Establish mechanisms to encourage care providers to invest in the implementation and maintenance of an acceptable baseline of computing infrastructure.

6. *Benefits realisation*:
   - Establish programs to encourage the adoption and use of high priority eHealth solutions.
   - Implement national awareness campaigns that focus on communicating the scope and benefits of high priority solutions to consumers and care providers.
   - Encourage healthcare participants to adopt and use high priority eHealth solutions and modify their work practices to support these solutions.

7. *Capacity and workforce*:
   - Implement changes to vocational and tertiary training programs to increase the number of skilled, nationally available eHealth practitioners.

8. *eHealth foundations*:
   - Coordinate the rollout of appropriate national broadband services to all care providers.
   - Implement a set of national eHealth foundations that will provide a platform for health information exchange across geographic and health sector boundaries.
   - Design and implement a national solution to enable the unique identification and authentication of South African patients/consumers and care providers.

10. *Monitoring and evaluation of the eHealth Strategy South Africa 2012-2016*:
    - Establish capacity within the ESB for monitoring and evaluation of the eHealth Strategy South Africa 2012-2016 [National Department of Health, 2012b].

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A APPENDIX LIST OF INTERNATIONAL STANDARDS

APPROPRIATE EHEALTH STANDARDS (SABS Approved Standards (SANS) are indicate with a ●)		
Identifier standards		
Standards No	**Title**	**Abstracts**
1. ASTM E1714 - 07	Standard guide for properties of a universal healthcare identifier	The purpose of this standard is to ensure uniformity in the identification of patients in face-to-face encounter and computer-to-computer communication, the recording and reporting of patient identification data, and to ensure that the correct information is linked to the correct patient. It provides specification for the structure and data elements required for positive identification of patients in both face-to-face and computer technology supported environments. It defines the demographic, and other identifying data elements that should be captured, provides guidance on their implementation in paper-based and computerised environments, the management organisation to oversee patient identification, as well as computer support that should be provided for the identification process [ASTM International, 2007a].
2. ISO / TS 22220:2011	Identification of subjects of healthcare	This standard provides specification for the data elements, as well as the structure and content of the data used to identify individuals manually in a healthcare setting. In addition, it provides support for identification of individuals in a consistent way between systems that will support the natural

		changes in usage and application of the various names that are used by people over time. It addresses the business requirements of identification as well as the data needed to improve the confidence of healthcare providers and subjects of care identification. [International Organisation for Standardisation, 2011d]
3. ISO/TS 27527:2010	Provider identifier standard	This standard provides guidelines for the creation of unique identifiers for individual healthcare provider as well as the healthcare institution from where the care was provided. It specifies the data elements that are required to support both manual and automated identification of providers and healthcare institutions.[International Organisation for Standardisation, 2010f].
Messaging standards		
4. DICOM	Digital imaging and communication in medicine	Specifications for information object definitions, data structures and their semantics, protocols for the exchange of medical information among imaging equipment and other healthcare applications, file format and storage of medical images [National Electrical Manufacturer Association 2011]. DICOM has been adopted as an international standard for medical images by ISO under the title ISO 12052:2006.
5. HL7	Health Level Seven	Enable the interchange of clinical and administrative data among heterogeneous healthcare applications in the form of patient demographics, health insurance data, clinical observations, appointment schedules and patient referrals. Unlike other healthcare messaging standards, which focus on specific healthcare domain (e.g. the exchange of laboratory results), HL7 messaging standards support the exchange of different types healthcare data [Health Level 7, n.d-a, n.d-b].
6. ISO 18232:2006	Messages and communication -- Format of length limited globally unique string	Specification for encoding and the length of globally unique identifiers for data objects used in healthcare exchanged as alphanumeric strings

	identifiers	[International Organisation for Standardisation, 2006a].
7. ISO 13606-5:2010	Electronic Health Record Communication (part 5): Interface Specification	An EHR communication standard that specifies the information architecture required to support meaningful communications between systems and services that need or provide EHR data. It defines the Computational Viewpoint for different interfaces, without specifying or restricting their implementation approaches as messages or service interfaces [International Organisation for Standardisation, 2010a].
8. ISO/HL7 27931:2009	Data Exchange	This standard provides an application protocol for the electronic exchange of data in healthcare environments [International Organisation for Standardisation, 2009e].
9. ISO/HL7 27951:2009	Common Terminology Services	Framework for the development of an application programming interface (API) that can be used by messaging software when accessing terminological content. It is not intended to be a complete terminology service in and of itself [International Organisation for Standardisation, 2009f].
10. SDMX-HD	Statistical Data and Metadata Exchange – Health Domain	SDMX-HD is a statistical and metadata exchange-based standard adapted by the WHO for the exchange of health indicator definitions, as well as data in aggregate data systems (e.g. DHIS). It specifies the structure and format of aggregate data for health indicator messages that are exchanged between HISs and monitoring and evaluation systems like the DHIS [SDMX-HD, nd].
Electronic health record standards		
11. ASTM E1239 – 04: 2010	Standard Practice for Description of Reservation/Registration-Admission, Discharge, Transfer (R-ADT) Systems for Electronic Health Record (EHR) Systems	Definition of the minimum information capabilities of R-ADT system. It describes the processes of patient registration, inpatient admission into healthcare institutions and the use of registration data in establishing and using the demographic segments of the electronic health record. It also identifies a common core of information elements needed in this R-ADT process and outlines those organizational elements that may use these

		segments. Furthermore, this guide identifies the minimum general requirements for R-ADT and helps identify many of the additional specific requirements for such systems. It provides guidance to designers of R-ADT through a clear description of the consensus of healthcare professionals regarding a uniform set of minimum data elements used by R-ADT functions in each component of the larger system [ASTM International, 2010c].
12. ISO/TR 20514:2005 ●	Electronic Health Record – Definition, Scope and Context	A technical report that provides a practical classification of electronic health records, giving simple definitions of the main categories of EHR and provides supporting descriptions of the characteristics of EHRs and record systems [International Organisation for Standardisation, 2005b].
13. ISO 13606-1:2008	Electronic health record communication (Part 1): Reference model	Specification for the exchange of part/entire EHR between EHR systems or between EHR systems and a centralised EHR data warehouse. It provides an information model for representing health information using UML class diagrams and the relationships among them [International Organisation for Standardisation, 2008a].
14. ISO 13606-2:2008	Electronic health record communication (Part 2): Archetype interchange specification	Specification for the information architecture required for interoperability in the exchange of patients' clinical healthcare data between EHR systems [International Organisation for Standardisation, 2008b].
15. ISO 13606-3:2009	Electronic health record communication (Part 3): Reference archetypes and term lists	Definition of list of terms and the set of values that attributes in the Reference model may hold. It also defines the informative reference archetypes that correspond to the entry-level compound data structures in the Reference Models of openEHR and HL7 V3. This is to enable these instances to be represented in a consistent structure when communicated using ISO 13606-3 standard [International Organisation for Standardisation, 2009d].
16. ISO 18308:2011 ●	Requirements for an Electronic Health	Specification for the set of requirements for an EHR architecture to ensure EHR systems meet the needs for healthcare delivery, are clinically valid and

	Record Architecture	reliable, ethically sound, satisfy the prevailing legal requirements, support good clinical practices, and facilitate data analysis for various purposes. While the standard does not specify the full set of requirements that are necessary in an EHR system for direct patient care or for other use cases, it contributes to the governance of EHR information within such systems [International Organisation for Standardisation, 2011b].
Architecture standards		
17. ISO 12967-1:2009	Service Architecture (Part 1): Enterprise Viewpoint	Guidelines for the description, planning and development of new healthcare information systems, or the integration of existing ones (e.g. systems within one healthcare institution or across many institutions). It supports the specification of architecture that integrates the common data and business logic into a specific architectural layer, i.e. the middleware, by separating each applications and making them available throughout the system in the form of services [International Organisation for Standardisation, 2009a].
18. ISO 12967-2:2009	Service Architecture (Part 2): Information Viewpoint	Specifications for the essential characteristics of the information model to be implemented by the middleware of an information system in order to provide comprehensive and integrated storage of the common enterprise data and to support the fundamental business processes of the healthcare organization, as defined in ISO 12967-1 [International Organisation for Standardisation, 2009b].
19. ISO 12967-3:2009	Service Architecture (Part 3): Computational Viewpoint	Specification for the essential characteristics of the computational model to be implemented by the middleware of an information system in order to ensure a comprehensive and integrated interface to the common enterprise information and to support the core business processes of the healthcare institution, as defined in ISO 12967-1 [International Organisation for Standardisation, 2009c].

20. ISO/HL7 1731:2006	Reference Information Model	Specification for static modelling of healthcare information as viewed within the scope of HL7 standard development activities. It provides graphical representation of information requirements of HL7 version 3 standards in the form of class diagrams, use case models, state machines diagrams, and data type models [Health Level 7, 2011; International Organisation for Standardisation, 2006c].
21. ISO 21090:2011	Harmonized data types for information interchange	Specification of data types of the basic concepts in the healthcare domain, the semantics of the data types using terminologies, notations and the data types defines in ISO/IEC 11404, presents the UML definitions of the data types, and specifies the XML representation of the data types [International Organisation for Standardisation, 2011c].
22. ISO/TR 12773-1:2009	Business Requirements for Health Summary Records (Part 1): Requirements	A technical report that provides a general description of health summary records (HSRs) and their specific instances, together with common use cases. It summarises the business drivers of HSR development efforts and their common content. The scope of the technical report is limited to the unique requirements of HSRs. It also gives recommendations on future ISO/TC 215 activities to support international standardization of HSRs [International Organisation for Standardisation, 2009g].
Structure and content standards		
23. HL7 CDA (ISO/HL7 27932:2009)	Clinical Document Architecture	The CDA is a standard specification for the structure and semantics of clinical documents to support common representation of clinical documents e.g. clinical summaries, discharge note, and radiology reports. CDA is based on HL7 Reference Information Model (RIM), a model of healthcare data consisting generic classes from which concrete classes can be derived and supports the use of standardised coding systems, such as LOINC and SNOMED, to enhance semantic interoperability [Health Level Seven International, 2011, 2013a].

24. ASTM E2369-05	Continuity of Care Record (CCR)	This standard provides specification for the creation of patient care information document and the exchange of such document among healthcare providers. It enables a healthcare provider or a system to aggregate all the essential clinical demographic and administrative data about a specific patient and forward it to another practitioner or system to support the continuity of care. To ensure interoperability, the standard specifies the use of XML schema to structure an electronic CCR. The XML specification also enable flexibility, which allows users to prepare, transmit, and view the CCR in multiple ways, for example, through a browser, as an element in a HL7 message or CDA compliant document, in a secure email, as a PDF file, as an HTML file, or as a word processing document. It also enables users to display the fields of the CCR in multiple formats [ASTM International, 2005b].
25. ASTM E2436-05 2010	Standard specification for the representation of human characteristics data in healthcare information systems	This standard provides specification for representation of the content and structure of human characteristics data for use in healthcare information systems. It supports interoperability through a single, uniform representation of human characteristics at the data layer of healthcare information systems architecture [ASTM International, 2010b].
26. ASTM E1744-04: 2010	Standard Practice for View of Emergency Medical Care in the Electronic Health Record	Specification on essential information that should be documented in an emergency medical care for an electronic patient record system. To ensure interoperability, the data structure specified in the standard also conforms with other ASTM standards for the EHR [ASTM International, 2010a].
27. HL7/ASTM CCD	Continuity of Care Document	The CCD is an integration of HL7 CDA and ASTM CCR to harmonise the data formats of these standards. It provides a set of templates for different sections of a typical summary record, for example, vital signs, family history and care plan, to facilitate reusability and interoperability [Health Level Seven International, 2010a, 2013g].

28. HL7 CRS	Care Record Summary (Part of CDA)	A Care Record Summary document contains patient's relevant health history for some time period. It is intended for communication between healthcare providers and provides disparate hospital systems a standard format to report back to a primary care provider or other parties interested in the patient's hospital care. It is also called a discharge summary by HL7. [Health Level Seven International, 2009, 2013c]
29. CDA for CDTHP	CDA for Common Document Types History and Physical Notes (DSTU) (Part of CDA)	CDA for CDTHP is used to record information for a History and Physical Note. A History and Physical Note is a two-part medical report that documents the current and past conditions of the patient. It contains essential information that helps determine an individual's health status. The information forms the basis of most treatment plans. [Health Level Seven International, 2010b, 2013b]
30. HL7 V3 Normative Edition (CMET only)	HL7 V3: Common Message Element Types	Common Message Element Types (CMETs) are standardized model fragments intended to be building blocks that individual content domains can "include" in their designs. These blocks reduce the effort to produce a domain-specific design and assure that similar content across multiple domains is consistently represented.[Health Level Seven International, 2010c, 2013f]
Health smart card standards		
31. ISO 21549-1:2004	Patient Healthcard Data – (Part 1): General Structure	Defines the general structure of data held on patient healthcards (i.e. healthcards compliant with the physical dimensions of ID-1 cards as defined by ISO/IEC 7810) [International Organisation for Standardisation, 2004a].
32. ISO 21549-2:2004	Patient Healthcard Data – (Part 2): Common Objects	Provides framework for the content and structure of common objects used to construct or referenced by other data-object data held on patient healthcare data cards. It specifies the basic structure of the data without defining or stipulating the particular data-sets for storage on devices.

		[International Organisation for Standardisation, 2004b].
33. ISO 21549-3:2004	Patient Healthcard Data – (Part 3): Limited Clinical Data	Specifies the basic structure of data contained within the limited clinical data object, without specifying the particular data-sets for storage on devices. The data is intended to facilitate the delivery of emergency care. It is thus not suitable for the provision of all the information required [International Organisation for Standardisation, 2004c].
34. ISO 21549-4:2006	Patient Healthcard Data – (Part 4): Extended Clinical data	Specifies the basic structure of the data contained in the extended clinical data object. It is only applicable to situations where such data are recorded on, or transported by patient healthcare data cards [International Organisation for Standardisation, 2006b].
35. ISO 21549-5:2008	Patient Healthcard Data – (Part 5) Identification Data	Provides a common framework for the content and the structure of identification data held on healthcare data cards. It gives the specification for the basic structure of the data, without specifying the particular data-sets for storage on devices [International Organisation for Standardisation, 2008f].
36. ISO 21549-6:2008	Patient Healthcard Data – (Part 6) Administrative Data	Specification for the basic structure of the data held within the administrative data object, without specifying or mandating the particular data sets for storage on devices [International Organisation for Standardisation, 2008g].
37. ISO 21549-7:2007	Patient Healthcard Data – (Part 7) Medication Data	Specification for the basic structure of the data held within the medication data object without specifying or mandating the particular data-sets for storage on devices. It describes and defines the medication data objects used within or referenced by patient held health data cards using UML, plain text and Abstract Syntax Notation (ASN.1) [International Organisation for Standardisation, 2007b].

38. ISO 21549-8:2010	Patient Healthcard Data – (Part 8): Links	Definition of the structure and elements of "links" that is stored in healthcards. It defines a way to facilitate access to distributed patient records and/or administrative information using the healthcards through references to individual patients' records and their subcomponents. The standard does not cover services relating to access control mechanisms, data protection mechanisms, access methods and other security services [International Organisation for Standardisation, 2010b].
Security and access control standards		
39. ISO 13606-4:2009	Electronic Health Record Communication (part 4): Security	This standard describes the methods for specifying access privileges to EHR data [International Organisation for Standardisation, 2009i].
40. ISO 17090-1:2008 ●	Public Key Infrastructure (Part 1): Overview of Digital Certificate	Defines the basic concepts which underlie the use of digital certificates in healthcare. It the interoperability requirements for establishing a digital certificate-enabled secure communication of health information. It also identifies the major stakeholders who are communicating health-related information, and the main security services required for health communication where digital certificates may be required [International Organisation for Standardisation, 2008c].
41. ISO 17090-2:2008 ●	Public Key Infrastructure (Part 2): Certificate Profile	Specification for the certificate profiles that is essential for the exchange of healthcare information within a single organization, between different organizations and across jurisdictional boundaries. It provides typical usage of digital certificates in the healthcare domain, with special focus on the specific healthcare issues relating to certificate profiles [International Organisation for Standardisation, 2008d].
42. ISO 17090-3:2008 ●	Public Key Infrastructure (Part 3): Policy Management of Certificate Authority	Guidelines for management of certificate issue that are related to the distribution of digital certificates in healthcare. It specifies a structure and minimum requirements for certificate policies, and provides a structure for associated certification practice statements [International Organisation for

		Standardisation, 2008e].
43. ISO/TS 21091:2005	Directory Services for Security, Communications and Identification of Professionals and Patients	Specification for the minimal requirements for directory services in healthcare using the X.500 framework. It gives the common directory information and services required for secure exchange of healthcare information over public networks. The standard is forward looking in that it addresses the requirements for the communication of healthcare information within and across healthcare institutions, as well as beyond country boundaries. It also supports directory for identification of care givers, health institutions and patients/consumers of health services (i.e. the MPI) [International Organisation for Standardisation, 2005c].
44. ISO/TS 21547:2010	Security Requirements for Archiving of Electronic Health Records – Principles	Specification for the basic principles required for long-term, secure preservation of health records in any format. This standard is specifically focused on document management and related privacy protection issues that are related to document archiving. It defines the architecture and technology-independent security requirements for long-term preservation of EHRs by complementing ISO/TR 21548 [International Organisation for Standardisation, 2010d].
45. ISO/TR 21548:2010	Security Requirements for Archiving of Electronic Health Records – Guidelines	An implementation guideline for ISO/TS 21547 that provides a methodology for the implementation of ISO/TS 21547 for long term archiving of EHRs [International Organisation for Standardisation, 2010c].
46. ISO/TS 22600-1:2006	Privilege Management and Access Control (Part 1): Overview and Policy Management	Specification to support requirements for sharing healthcare information among independent healthcare providers, institutions, health insurers companies, patients, staff members and trading partners. It supports collaboration between several authorization managers that may operate over organizational and policy borders [International Organisation for Standardisation, 2006f].

47. ISO/TS 22600-2:2006	Privilege Management and Access Control (Part 2): Formal Model	Specification of the underlying paradigm of formal high level models for architectural components based on ISO/IEC 10746. It introduces the Domain Model, the Document Model, the Policy Model, the Role Model, the Authorization Model, the Delegation Model, the Control Model and the Access Control Model [International Organisation for Standardisation, 2006g].
48. ISO/TS 22600-3:2009	Privilege Management and Access Control (Part 3): Implementations	Implementation specification for ISO/TS 22600-2:200 through the instantiation of requirements for repositories for access control policies and privilege management infrastructures for health informatics [International Organisation for Standardisation, 2009j].
49. ISO 22857:2004	Guidelines on Data Protection to Facilitate Trans-border Flows of Personal Health Information	Guidelines on data protection requirements to support the transfer of personal health data across national borders. While the standard is primarily concerned with international exchange of personal health data, it is nevertheless still applicable to the protection of health information transmitted within the borders of a country [International Organisation for Standardisation, 2004d].
50. ISO/TS 25237:2008	Pseudonymization	Specifications on the principles and requirements for privacy protection through the use of pseudonym services in order to protect personal health information. It defines the basis concept for pseudonymization; provides an overview of different use cases for pseudonymization (reversible and irreversible); defines a basic methodology for pseudonymization services; provides a guide to risk assessment for re-identification; specifies a policy framework and minimal requirements for trustworthy practices for the operations of a pseudonymization service; specifies policy framework and minimal requirements for controlled re-identification; and the interfaces for the interoperability of services interfaces. [International Organisation for Standardisation, 2008i].

51. EN12251:2000	Secure User Identification for Healthcare (Management and Security of Authentication by Passwords)	Guidelines to improve user authentication in healthcare IT systems through the strengthening of the automatic software procedures that are associated with the management of user identifiers and passwords, without the use of additional hardware facilities. The scope of the standard is limited to healthcare information systems using only passwords for user authentication before accessing sensitive, person identifiable health information. Systems that use other methods of identification and authentication, e.g. smart cards and biometrics, are not covered by this standard [European Committee for Standardization, 2004].
52. ASTM E1985–98: 2005	Standard Guide for User Authentication and Authorisation	Guidelines on mechanisms for authenticating users of healthcare information systems and authorise specific actions by users. The standard is applicable to both centralised and distributed environments; it defines the requirements that a single system shall meet and the types of information which shall be transmitted between systems to provide distributed authentication and authorisation services. It also addresses the technical specifications for how to perform user authentication and authorisation. [ASTM International, 2005a].
53. ASTM E1986–09	Standard Guide for Information Access Privileges to Health Information	Specification for granting access privileges to health information. It covers the requirements to keep as confidential personal, provider, and organisational data in the healthcare domain. It also addresses a wide range of data and data elements that are not traditionally defined as healthcare data, but which are essential in the provision of data management, data services, and administrative and clinical healthcare services. It also covers specific requirements for granting access privileges to patient-specific health information during health emergencies [ASTM International, 2009b].
54. ASTM E1762–95 2009	Standard Guide for Electronic Authentication of Healthcare Information	This standard provides guidelines on (i) the structure of document used in electronic signature mechanisms, (ii) the characteristics of an electronic signature process, (iii) the minimum requirements for different electronic

		signature mechanisms, (iv) the attributes of the signature for use in electronic signature mechanisms, (v) the acceptable electronic signature mechanisms and technologies, (vi) specification for minimum requirements for user identification, access control, and other security requirements for electronic signatures, and (vii) an outline of the technical details for all electronic signature mechanisms in sufficient detail to allow interoperability between systems supporting the same signature mechanism [ASTM International, 2009a].
55. ASTM E2147–01:2009	Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems	Specification for the design of access audit log to record all access to patient identifiable information maintained in computer systems. It includes principles for developing policies, procedures, and functions of health information logs to document all disclosure of confidential healthcare information to external users for use in manual and computer systems [ASTM International, 2009c].
56. ASTM E2595-07	Standard Guide for Privilege Management Infrastructure	Definition of interoperable mechanisms to manage privileges in distributed environments, such as service-oriented architecture (SOA) environment where the security services are distributed and applications are the consumers of the distributed services. The standard also incorporates the privilege management mechanisms specified in ASTM E1986 It supports policy-based access control mechanism, e.g. role, entity and contextual-based access control, the application of policy constraints, patient-requested restrictions and delegation. It also supports hierarchical, enterprise-wide privilege management [ASTM International, 2007b].
Clinical terminology and classification standards		
57. SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms	SNOMED CT is a comprehensive international and multilingual clinical terminology, with over 300 000 medical concepts that represent clinical information. It supports quality healthcare by enabling access to essential

		clinical information in a meaningful way. Each concept in SNOMED CT is organised in hierarchy, and is linked to other concepts through relationships. This allows clinical information to be captured at the required level of detail. SNOMED CT supports cross mapping to other clinical terminology and coding schemes, for example, the ICD-10 coding, thus enabling the reuse of coded data for purposes other than originally intended (e.g. medical claims reimbursement) [Benson, 2010; IHTSDO, n.d].
58. LOINC	Logical Observation Identifiers Names and Codes	LOINC [Regenstrief Institute, 2013]is a universal coding system for reporting of laboratory and clinical observations. Before the development of LOINC, laboratory results that are sent electronically to healthcare institutions through HL7 messages utilises different identifiers for the same laboratory test. For example, one laboratory system might use the identifier code "C4567" for a creatinine test, while another laboratory system might use the code "GDTR" (or any other code) to identify the same test. This made it difficult for the receiving system to properly interpret the result and 'file' it in the appropriate medical record. LOINC provides universal coding system that supports interoperable exchange of clinical data between the laboratory system and the hospital system so that the exchanged results can be understood and properly interpreted. The scope of LOINC codes extent to cover laboratory observations (such as chemistry, haematology, serology, microbiology, and urinalysis), as well as clinical observations (such as vital signs, intake/output, Electrocardiogram, endoscopy, and obstetric ultrasound). The LOINC database also provide a mapping program called Regenstrief LOINC Mapping Assistant (RELMA), which enables the mapping of local laboratory codes to LOINC codes and facilitate the search for test results. LOINC and RELMA has over 16 000 users form 145 countries and is provided free of charge by the developers [McDonald et al., 2003].
59. ICD -10 Codes	International Classification of Diseases	ICD-10 is an international coding system for classifying diseases, health conditions and causes of death. ICD has undergone many revisions, with the

		current tenth edition endorsed by the World Health Assembly in 1990 and has been implemented by member states since 1994. The ICD coding scheme facilitates compilation of vital health statistics, including morbidity and mortality, as well as for medical care reimbursement. [ICD-10 National Task Team, 2012; World Health Organisation, 2010, 2013b]
60. ATC/DDD Codes	Anatomical Therapeutic Chemical Classifications Systems with Defined Daily Doses	A drug classification scheme maintained by the WHO. The scheme classifies drugs into different groups (using five different levels) based on the organ or system on which they act upon, as well as their chemical, pharmacological and therapeutic properties. The first level of the code indicates the anatomical main group, the second denotes the therapeutic sub-group, the third level indicates the pharmacological sub-group, the fourth indicate the chemical sub-group, while the fifth level indicates the chemical substance. The DDD is a definition of the assumed average maintenance dose per day for a drug used for its main indication in adults. DDDs are allocated only to drugs with ATC codes [WHO Collaborating Centre for Drug Statistics Methodology, 2011]
61. NAPPI	National Pharmaceutical Product Index	NAPPI is a unique identifier coding system for pharmaceutical, surgical and healthcare consumable products in South Africa. It is developed and maintained by Medikredit to support electronic transfer of information on pharmaceutical, surgical and healthcare consumables across the healthcare delivery chain [Medikredit, nd].
62. RxNorm	RxNorm	RxNorm is a medicine terminology system developed and maintained by the United States National Library of Medicine. The database consists of the names of prescription and over-the-counter medicines available in the United States. It supports interoperability among eHealth applications through normalisation of medicine information received from multiple sources. Medicines are assigned normalised names, which consists of the component, strength and dose of the specific medicine and unique

		identifiers. The National Library of Medicine provides monthly release of RxNorm, with weekly updates for newly approved medicines [US National Library of Medicine, n.d].
63. AMT	Australian Medicine Terminology	AMT is a national standard for coding and identification of commonly used medicines in Australia. It is developed and maintained by the national clinical terminology and information service (NCTIS), a unit of the Australian National e-Health Transition Authority (NEHTA). AMT supports the exchange of medicines information among healthcare providers, reduces adverse effects of medication errors that could occur from incorrect prescription and transcribing and enable access to information that could support the decision making processes of care providers. AMT is updated on a monthly basis from items on the Australian Register of Therapeutic Goods and those that are listed on the Pharmaceutical Benefits Scheme [NEHTA, 2010].
64. ICHI	International Classification of Health Intervention (still under development)	ICHI is an International classification system by the WHO. Its aim is to provide Member States, healthcare service providers and organizers, and researchers with a common tool for reporting and analysing the distribution and evolution of health interventions for statistical purposes. It is structured with various degrees of specificity for use at the different levels of the health systems, and uses a common accepted terminology in order to permit comparison of data between countries and services. ICHI is still under development [WHO, nd].
65. CPT	Current Procedural Terminology	CPT is a coding system developed and maintained by American Medical Association (AMA). It supports the recording and reporting of medical and surgical procedures, as well as the transmission of information about these procedures among healthcare providers and healthcare systems [American Medical Association, nd]
66. NCIT	National Cancer Institute Thesaurus	NCIT, developed by the United State National Cancer Institute, is a reference

		terminology coding system for cancer diseases by providing unique codes, preferred terms and synonyms for biomedical concepts. It also provides cross references between the various concepts [National Cancer Institute, n.d].
67. ISO/HL7 27951:2009	Common Terminology Services	To establish an international framework for the development of an application programming interface (API) that can be used by messaging software when accessing terminological content. It is not intended to be a complete terminology service in and of itself [International Organisation for Standardisation, 2009f].
68. ISO 17115:2007	Vocabulary for Terminological Systems	This standard provides the definition of the basic concepts required to describe formal concept representation systems, especially for health sciences, and the representation of concepts and characteristics, for use in formal computer-based concept representation systems. Its purpose is to enable precise description of content models that are described in other International Standards. The scope of this standard does not cover detailed content of health terminology systems i.e. classifications, nomenclatures or reference terminology of health concepts [International Organisation for Standardisation, 2007a].
69. ISO 17117:2002	Controlled health terminology -- Structure and High-level Indicators	Specification for the principal ideas which are necessary and sufficient to assign value to a controlled health terminology. The standard is aimed at terminology developers by providing the minimum sets of requirements that will ensure that developed terminologies are useful and maintainable. It is applicable to all healthcare specialities about which information is kept or utilized.
70. ISO 27799:2008	Information Security Management in Health Using ISO/IEC 27002	This standard provides guidelines on the application of ISO/IEC 27002 health informatics domain. It provides specifications for necessary control mechanisms required to manage health information security, together with

		best practices guidelines. Implementation of the standard should provide a minimum requisite security level to ensure confidentiality, integrity and availability of personal health information [International Organisation for Standardisation, 2008h].
71. ISO/TS 22789:2010	Conceptual Framework for Findings and Problems in Terminologies	Specification to provide categorical structure, within the subject field of patient findings and problems, through the definition of a set of common domain constraints for use within terminological systems (e.g. classification, coding scheme, coding system, reference terminology and clinical terminology). It describes a concept system which specifies domain constraint of permissible characteristics that is composed of a semantic link and an applicable characterizing category [International Organisation for Standardisation, 2010e].
72. ISO/TR 25257:2009	Business Requirements for an International Coding System for Medicinal Products	This technical report provides specification for international business requirements for an international coding system for medicinal products. It gives an analysis of relevant international coding systems for medicinal products currently being used, taking into account the primary purpose of each coding system. It provides an assessment of the potential ability of each international coding system to fulfil the identified international business requirements of an international coding system for medicinal products and a careful analysis of the various issues associated with the development of a unified international coding system that could meet all business requirements. It also provides recommendations on what should be done to achieve a unified international coding system for medicinal products [International Organisation for Standardisation, 2009h].
73. UPFS	Uniform Patient Fee Schedule For Paying Patients Attending Public Hospitals	The Uniform Patient Fee Schedule has been developed to provide a simpler charging mechanism for public sector hospitals. Many hospitals currently treat patients for health services rendered. These tariffs are applicable to all full paying and subsidised patients. The UPFS replaces the itemised billing

		approach with a grouped fee approach [National Department of Health, 2012d].
General eHealth **standards**		
74. ISO/TR 18307:2001	Interoperability and Compatibility in Messaging and Communication Standards (Key Characteristics)	A general guidelines for the developers and implementers of standards for messaging and communications in the healthcare domain that describes the key characteristics required to achieve interoperability and compatibility for the exchange of healthcare information among healthcare applications, and the interoperability requirements of the various stakeholders in the healthcare domain (e.g. patients, the healthcare professionals, and institutions [Begoyan, 2007; International Organisation for Standardisation, 2001].
75. ISO 18812:2003	Clinical Analyser Interfaces to Laboratory Information Systems	Specification for general messages and their syntax for information exchange between analytical instruments (AIs) and laboratory information systems (LISs) in a clinical laboratory environment. The scope of the standard covers clinical chemistry/biochemistry, haematology, toxicology, microbiology, virology and immunology, excluding blood transfusion and blood bank speciality. [International Organisation for Standardisation, 2003].
76. ISO/TS 27790:2009	Document Registry Framework	This is a general-purpose technical specification for document registry framework for transmitting, storing and sharing documents in clinical and personalized health environments. It is applicable to various healthcare domains such as laboratory, cardiology, eye care, and radiology, as well as the personalized healthcare domains. [International Organisation for Standardisation, 2009k].
77. ISO/TR 27809:2007	Measures for Ensuring Patient Safety of Health Software	This technical report gives an analysis of the various control measures which are necessary to ensure patient safety in respect to health software products. Primarily aimed at developers of health software products, its purpose it to facilitate identification of which standards might best be used

		or created, and their nature, if health software products were to be regulated or controlled in some other formal or informal or voluntary manner whether national, regional or local. The scope of this standard does not cover software that is required for proper application of a medical device, an accessory to a medical device, or a medical device in its own right [International Organisation for Standardisation, 2007c].
General IT standards (not health-specific)		
78. MIOS V5	Minimum Interoperability Standards (MIOS) for Government Information Systems	MIOS V5 prescribes open system standards that will ensure minimum level of interoperability within and between IS/ICT systems that are utilised in the South African Government, industry, citizens and the international community in support of the e-Government objectives [SITA, 2011]
79. ANSI INCITS 359-2004	Role Based Access Control (RBAC)	This standard provides a mechanism for controlling users' access to computing resources based on their assigned role. It specifies the Reference Model (users, roles, permissions, operations, and objects), as well as the System and Administrative Functional features of an RBAC system [ANSI/INCITS, 2004].
80. AES (MIOS)	Advanced Encryption Standard	The Advanced Encryption Standard (AES) specifies a FIPS-approved cryptographic algorithm that can be used to protect electronic data. The AES algorithm is a symmetric block cipher that can encrypt (encipher) and decrypt (decipher) information. Encryption converts data to an unintelligible form called ciphertext; decrypting the ciphertext converts the data back into its original form, called plaintext [National Institute of Standards and Technology, 2001].
81. DSML V2	Directory Services Markup Language v2.0	The Directory Services Markup Language v1.0 (DSMLv1) provides a means for representing directory structural information as an XML

		document [OASIS, 2001]
82. ISO/IEC 9075:2011	Database Languages – Structure Query Language	ISO/IEC 9075:2011 is a multi-part standard which defines structured query language (SQL). It specifies the data structure, as well as the operations on the data stored in the structure. Parts 1, 2, and 3 of the standard are the minimum requirements for SQL, while the remaining parts define their extension [International Organisation for Standardisation, 2011a]. The South African minimum interoperability standard (MIOS) specifies part 14, which is an XML extension to the standard [State Information Technology Agency, 2011a].
83. ISO 19005-1:2005	Electronic document file format for long-term preservation – Part 1: Use of PDF 1.4 (PDF/A-1)	ISO 19005-1:2005 is a specification for the use of Portable Document Format (PDF) 1.4 for long-term preservation of electronic documents [International Organisation for Standardisation, 2005a]. The South African minimum interoperability standard (MIOS) specifies a newer version of this standard, i.e. SANS 32000-1 [State Information Technology Agency, 2011a].
84. RFC 1305	Network Time Protocol (NTP)	The NTP provides the mechanisms to synchronise time and the coordination of time distribution in a large, diverse Internet, which can operate at different rates [Internet Engineering Steering Group, 1992].
85. RFC 1738	Uniform Resource Locators (URL)	Ppecifies a Uniform Resource Locator (URL), the syntax and semantics of formalized information for location and access of resources via the Internet [Network Working Group, 1994]
86. RFC 2246	The Transport Layer Security (TLC) protocol	Specification for communications privacy over the Internet. It enables client/server applications to communicate in a way that is designed to prevent eavesdropping, tampering, or message forgery [Internet Engineering Steering Group, 1999].
87. RFC 2616	The Transport Layer Security (TLC) protocol	Specification for communications privacy over the Internet. It enables client/server applications to communicate in a way that is designed to

		prevent eavesdropping, tampering, or message forgery [Internet Engineering Steering Group, 1999].
88. RFC 3066	Tags for the Identification of Languages	Describes identifier mechanism of tags for language, a registration function for values to be used with that identifier mechanism, and a construct for matching against the values [Internet Engineering Steering Group, 2001b].
89. RFC 3164	The BSD syslog Protocol	Description of the various implementation of Syslog protocol, which is used to record the system events typically for audit trail purposes [Internet Engineering Steering Group, 2001a].
90. RFC 3851	Secure/Multipurpose Internet Mail Extensions (S/MIME) Version 3.1	S/MIME provides a consistent way to send and receive secure MIME data. Digital signatures provide authentication, message integrity, and non-repudiation with proof of origin. Encryption provides data confidentiality. Compression can be used to reduce data size [Internet Engineering Steering Group, 2004b]
91. RFC 3881	Security Audit and Access Accountability Message: XML Data Definitions for Healthcare Applications	Definition of the format of data to be collected, and the minimum set of attributes that must be captured for security auditing in healthcare application systems [Internet Engineering Steering Group, 2004c].
92. RFC 3778	The application/pdf Media Type	Provides description of the PDF format, the mechanisms for digital signatures and encryption within PDF files, as well as updates for the media type registration of 'application/pdf' [Internet Engineering Steering Group, 2004a].
93. RFC 3986	Uniform resource identifier	Specification for generic URI syntax, as well as a process for resolving URI references that might be in relative form, together with guidelines and security considerations for the use of URIs on the Internet. The URI syntax

		defines a grammar that is a superset of all valid URIs, allowing an implementation to parse the common components of a URI reference without knowing the scheme-specific requirements of every possible identifier [internet Engineering Steering Group, 2005b].
94. RFC 4330	Simple Network Time Protocol (SNTP) Version 4	The Simple Network Time Protocol Version 4 (SNTPv4), which is a subset of the Network Time Protocol (NTP) used to synchronize computer clocks in the Internet. SNTPv4 can be used when the ultimate performance of a full NTP implementation based on RFC 1305 is neither needed nor justified [Internet Engineering Steering Group, 2006b].
95. RFC 4510	Lightweight directory access protocol (LDAP)	This is an Internet protocol for accessing distributed directory services that act in accordance with X.500 data and service models. It is a lightweight version of directory access protocol, which is part of the X.500 standard [Internet Engineering Steering Group, 2005a].
96. RFC 4627	The application/json Media Type for JavaScript Object Notation (JSON)	Definition of a lightweight, text-based, language-independent data interchange format, called JavaScript Object Notation (JSON). JSON is capable of representing four primitive types, namely: strings, numbers, Booleans and null, as well as two structured types, objects and arrays [Internet Engineering Steering Group, 2006a].
97. RFC 5424	The Syslog Protocol	Specification for protocol to convey event notification messages. It utilises a layered architecture that enable the use of any number of transport protocols for transmission of syslog messages. It also provides a message format that allows vendor-specific extensions to be provided in a structured way [Internet Engineering Steering Group, 2009a].
98. RFC 5425	Transport Layer Security (TLC) Transport Mapping for Syslog	Specification for the use of Transport Layer Security (TLS) to provide a secure connection for the transport of syslog messages [Internet Engineering Steering Group, 2009c].

99. RFC 5426	Transmission of Syslog Messages over UDP	Specification for the transport for syslog messages over UDP/IPv4 or UDP/IPv6 [Internet Engineering Steering Group, 2009b].
100. RFC 6585	Additional Hypertext Transfer Protocol (HTTP) Status codes	Specification for additional status codes for HTTP to improve interoperability and prevent the confusion that could arise when other, less precise status codes are used [Internet Engineering Steering Group, 2012].
101. ebXML MS	OASIS ebXML Messaging Services 3.0	Specification for communication protocol neutral method for the exchange of electronic business messages. It defines specific enveloping constructs that supports reliable and secure delivery of business information [OASIS, 2007].
102. ebXML RIM	OASIS/ebXML Registry Information Model 3.0	Definition of the metadata and content that can be stored in an ebXML Registry, which is an information system that securely manages any content type and the standardised metadata that describes it. The registry provides a set of services that enable sharing of content and metadata between organisational entities in a federated environment [OASIS, 2005a].
103. ebXML RS	OASIS/ebXML Registry Services Specifications 3.0	Definition of the services provided by an ebXML Registry and the protocols used by clients of the registry to interact with the services [OASIS, 2005b]
104. SHA-1 (MIOS)	Secure Hash Algorithm-1	This is a 160-bit hash function. It is one of the cryptographic hash functions defined by the National Institute of Standards Technology (NSIT) and used in digital signature algorithms, or random number generation [National Institute of Standards Technology, 2012].
105. SOAP 1.2 (MIOS)	SOAP Version 1.2 Part 1: Messaging Framework (Second Edition)	SOAP Version 1.2 is a lightweight protocol intended for exchanging structured information in a decentralized, distributed environment. "Part 1: Messaging Framework" defines, using XML technologies, an extensible messaging framework containing a message construct that can be exchanged over a variety of underlying protocol [W3C, 2007b]

106. SOAP-MTOM	SOAP Message Transmission Optimization Mechanism	SOAP –MTOM is a concrete implementation of it for optimizing the transmission and/or wire format of SOAP messages. The concrete implementation relies on the [XML-binary Optimized Packaging] format for carrying SOAP messages [W3C, 2005b]
107. UN/EDIFACT	United Nations rules for Electronic Data Interchange for Administration, Commerce and Transport	A set of internationally agreed standards, directories, and guidelines for the electronic interchange of structured data, between independent computerized information systems [United Nations, nd].
108. WS-I Basic Security Profile 1.1	WS-I Basic Security Profile 1.1	Provides non-proprietary Web Services specifications to enable interoperability and ensure transport layer security and SOAP messaging integrity [Web Services Interoperability Organisation, 2010]
109. RSA X.509 (MIOS)	Public Key Infrastructure Certificates	This is an International Telecommunication Union (ITU) standard specification for the definition of digital certificate. It provides a framework for public-key certificates, as well as the attributes of the certificates [International Telecommunication Union, 2008].
110. XML V1.0 (MIOS)	Extensible Markup Language (XML) 1.0 (Fifth Edition)	The Extensible Markup Language (XML) is a subset of SGML that is completely described in this document. Its goal is to enable generic SGML to be served, received, and processed on the Web in the way that is now possible with HTML. XML has been designed for ease of implementation and for interoperability with both SGML and HTML [W3C, 2008b].
111. XML-binary OP	XML-binary Optimized Packaging	The XML-binary Optimized Packaging (XOP) convention is a means of more efficiently serializing XML Infosets that have certain types of content [W3C, 2005c].
Biometric Standards		
112. ISO/IEC 19784-1	BioAPI Specification	BioAPI is intended to provide a high-level generic biometric authentication model–one suited for any form of biometric technology. It covers the basic

		functions of enrolment, verification, and identification, and includes a database interface to allow a biometric service provider (BSP) to manage the technology device and identification population for optimum performance [International Organisation for Standardisation, 2006d].
113. ISO/IEC 19785-1	Common Biometric Exchange Formats Framework	The Common Biometric Exchange Formats Framework (CBEFF) describes a set of data elements necessary to support biometric technologies and exchange data in a common way. These data can be placed in a single file used to exchange biometric information between different system components or between systems. The result promotes interoperability of biometric-based application programs and systems developed by different vendors by allowing biometric data interchange [International Organisation for Standardisation, 2006e].
114. ANSI-INCITS	Biometric Data Format Interchange Standards: • ANSI-INCITS 377-2004 - Finger Pattern Based Interchange Format • ANSI-INCITS 378-2004 - Finger Minutiae Format for Data Interchange • ANSI-INCITS 379-2004 - Iris Interchange Format • ANSI-INCITS 381-2004 - Finger Image Based Interchange Format • ANSI-INCITS 385-2004 - Face Recognition Format for Data Interchange • ANSI-INCITS 395-2005 - Signature/Sign Image Based Interchange Format ANSI-INCITS 396-2004 - Hand Geometry	ANSI-INCITS has created a series of standards specifying the interchange format for the exchange of biometric data [Yen, 2005]. These standards specify a data record interchange format for storing, recording, and transmitting the information from a biometric sample within a CBEFF data structure. The ISO equivalent standards for each are in process but not yet finalized.

	Interchange Format	
115. ISO/IEC 19794	ISO/IEC 19794 series on biometric data interchange formats	Part 1 is the framework; Part 2 defines the finger minutiae data; Part 3 defines the finger pattern spectral data; Part 4 defines the finger image data; Part 5 defines the face image data; Part 6 defines the iris image data, and still in development; Part 7 will define the signature/sign time series data; Part 8 will define the finger pattern skeletal data; and Part 9 will define the vascular image data [International Organization for Standardization, n.d.].

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B APPENDIX – LIST OF GENERIC EHEALTH FUNCTIONS

FUNCTION GROUP	FUNCTIONS
Identification, authentication and authorisation	Identify location
	Identify provider
	Identify patient
	Authenticate patient
	Authenticate provider
	Authorise provider roles and permissions
Record look-up	Search for patient record
Add patient record	Create new patient record
	Link baby patient to mother patient
	Create temporary patient record
	Merge temporary and permanent record
Retrieve patient record	Retrieve and display patient record
Admission, discharge and transfer	Admit patient
	Discharge patient
	Add and query discharge summary
	Add, query and update transfer
Update patient record	Add, query and update demographic details
	Add, query and update medical history
	Add, query and update clinical observations
	Add, query and update interventions
	Add and query referrals
	Add and query pharmacy orders
	Add and query drugs dispensed
	Add and query orders for laboratory tests
	Add and query laboratory test results
	Add and query orders for radiology test s
	Add and query radiology test results
	Add, query and update “doctor’s notes”
	Add and query OP encounter outcome
	Add, query and update ante-natal care events
	Add and query birth details
	Add and query death details
	Add, query and update care plan
	Scan and upload paper document
	Add, query and update CHW update report
Scheduling	Schedule appointment
	Send reminders
	Confirm attendance or cancellation
EMS – peripheral	Contact ambulance
	Dispatch ambulance
	Route ambulance
SCM – peripheral	Update pharmacy stock
SMS – peripheral	Notify clinician lab results are ready

Create billing account	Add, query and update bills
	Submit medical bills for payment
Generate metrics	Add, query and update health indicator
Non eHealth **specific functions**	
Node authentication	Authenticate system
Maintain system clock	Maintain system clock

C APPENDIX – IHE INTEGRATION PROFILES

C.1 Introduction to Integrating the Healthcare Enterprise

Integrating the healthcare enterprise (IHE) is an initiative by healthcare professionals and industry working together, with the aim of promoting coordinated use of eHealth standards, such as DICOM and HL7, to address a particular clinical requirement [Integrating the Healthcare Enterprise, nd]. Its goal is to help users and developers of health information systems (HISs) to achieve interoperability of systems by precisely defining healthcare tasks, specifying the requisite standards-based communication between systems to support the tasks, and the testing of systems to determine that they conform to the specifications [CEN/TC 251, 2009b].

IHE promotes the coordinated use of established Base Standards (e.g. ISO, DICOM, HL7, IETF, OASIS, W3C standards) to address specific clinical needs in support of optimal patient care by creating profiles that guide the implementation of interoperable systems. IHE implementation guidelines, termed technical frameworks are open and freely available to interested stakeholders.

C.2 List of IHE Profiles

IHE creates technical frameworks for different healthcare domains, as well as technical frameworks that are applicable to all healthcare domains across board. This section provides the lists of IHE profiles for the various health domains [Iintegrating the Healthcare Enterprise, nd]:

C.2.1 IHE Anatomic Pathology Profiles

- Anatomic pathology workflow (APW) – establishes the continuity and integrity of basic pathology data acquired for examinations being ordered for an identified inpatient or outpatient. It focuses on the main transactions of the ordering, reporting and imaging aspects of the workflow
- Anatomic Pathology Reporting to Public Health (ARPH) – transmits anatomic pathology reports to public health organizations (e.g. cancer registries, centres for diseases control, screening organizations, etc.)
- Anatomic Pathology Structured Report (APSR) – provides templates for building Anatomic Pathology structured reports in all fields of anatomic pathology (e.g. cancers, benign neoplasms as well as non-neoplastic conditions).

C.2.2 IHE Cardiology Profiles

- Cardiac Cath Workflow (CATH) – integrates the ordering, scheduling, imaging acquisition, storage and viewing for Cardiac Catheterization procedure.
- Echocardiography Workflow (ECHO) – this profile integrates ordering, scheduling, imaging acquisition, storage and viewing for digital echocardiography.
- Retrieve ECG for Display (ECG) – provides access throughout the enterprise to electrocardiogram (ECG) documents for review purposes.
- Evidence Document (ED) – adds Cardiology-specific options to the Radiology ED profile for DICOM Structured Reports.

- Stress testing Workflow (STRESS) – provides ordering and collecting multi-modality data during diagnostic Stress testing procedures.
- Display reports (DRPT) – manages creation and distribution of “display ready” (PDF or CDA) clinical reports from the creating application, to the department, and to the enterprise.
- Resting ECG Workflow (REWF) – a workflow for collecting ECG data in both ordered and unordered procedures, data storage and access, and ECG reporting.
- Image-Enabled Office Workflow (IEO) – integration of an imaging suite (modalities, storage server, and workstations) with an electronic health record system in an ambulatory office setting, including ordering and performance of an imaging exam, report creation, and web-based imaging exam review integration.
- Cardiac Imaging Report Content (CIRC) – format for a CDA report of a cardiac diagnostic imaging procedure, including discrete data elements.
- Cath Report Content (CRC) - format for a CDA report of a cardiac Cath/PCI procedure, including discrete data elements.

C.2.3 IHE Eyecare Profiles

- Advanced Eye Care Workflow (A-EYECARE) – it manages and distributes the workflow across equipment within the eye clinic.
- Basic Eye Care Workflow (B-EYECARE) – manages and distributes the workflow across equipment within the eye clinic.
- Charge Posting (CHG) – collects and posts timely billable claims related to Eye Care procedures.
- Eye care Evidence Documents (ECED) – manages observations, measurements, and peri-procedural results.
- Eye Care Displayable Report (ECDR) – supports the creation, query/retrieve and reading of ubiquitous display–ready eye care reports.
- Eye Care Appointment Scheduling (ECAS) – standardises the means of requesting patient appointments.
- General Eye Evaluation (GEE) – manages and distributes the workflow across equipment within the eye clinic.

C.2.4 IHE IT Infrastructure Profiles

- Audit Trail and Node Authentication (ATNA) – basic security through (i) functional access controls, (ii) defined security audit logging, and (iii) secure network communications.
- Basic Patient Privacy Consents (BPPC) – method for recording a patient's privacy consent acknowledgement to be used for enforcing basic privacy appropriate to the use.
- Consistent Time (CT) – enables system clocks and time stamps of computers in a network to be synchronised, with median error less than 1 second.
- Cross-Community Access (XCA) – facilitates the query and retrieve of patient electronic health records held by other communities.

- Cross-Enterprise Document Media Interchange (XDM) – transfers documents and metadata using CDs, USB memory, or email attachments.
- Cross-Enterprise Document Reliable Interchange (XDR) – exchanges health documents between health enterprises using a web-service based point-to-point push network communication.
- Cross-Enterprise Document Sharing (XDS) – share and discover electronic health record documents between healthcare enterprises, physician offices, clinics, acute care in-patient facilities and personal health records.
- Cross-Enterprise Sharing of Scanned Documents (XDS-SD) – enables electronic records to be made from legacy paper, film, and other unstructured electronic documents.
- Cross-Enterprise User Assertion (XUA) – communicates claims about the identity of an authenticated principal (user, application, system etc.) across enterprise boundaries i.e. Federated Identity.
- Enterprise User Authentication (EUA) – enables single sign-on inside an enterprise by facilitating one name per user for participating devices and software.
- Multi-Patient Queries (MPQ) – enables aggregated queries to a Document Registry based on certain criteria for data analysis such as provider accreditation, clinical research trial data collection or population health monitoring.
- Patient Administration Management (PAM) – establishes the continuity and integrity of patient data in and across acute care settings, as well as among ambulatory caregivers.
- Patient Demographic Query (PDQ) – allows applications query by patient demographics for patient identity from a central patient information server.
- Patient Identifier Cross Referencing (PIX) – allows applications query for patient identity cross-references between hospitals, sites, health information exchange networks, etc.
- Patient Demographic Query HL7 v3 (PDQv3) – extends the Patient Demographics Query profile leveraging HL7 version 3.
- Patient Identifier Cross Referencing HL7 v3 (PIXv3) – extends the Patient Identifier Cross-Reference profile leveraging HL7 version 3.
- Patient Synchronised Application (PSA) – allows cooperating applications on a workstation to synchronise to selected patient context.
- Personnel White Pages (PWP) – provides basic directory information on human workforce members within an organization.
- Retrieve Form for Data Capture (RFD) – enables EHR applications to directly request forms from clinical trial sponsors and public health reporting.
- Retrieve Information for Display (RID) – provides simple (browser-based) read-only access to clinical information (e.g. allergies or lab results).
- Cross-Community Fetch (XCF) – fetches a single or small pre-negotiated list of documents from another community.
- Cross-Community Patient Discovery (XCPD) – supports locating communities with patient electronic health records and the translation of patient identifiers across communities.
- Cross Enterprise Workflow (XDW) – coordinates human and applications mediated workflows across multiple organizations.

- Document Encryption (DEN) – encrypts individual documents and portable media content.
- Document-Based Referral Request (DRR) – supports referral requests that are transferred by document sharing (e.g., XDS, XDR, XDM).
- Document Digital Signature (DSG) – specifies digital signatures for documents.
- Document Metadata Subscription (DSUB) – describes the use of subscription and notification mechanism for use within an XDS Affinity Domain and across communities.
- Healthcare Provider Directory (HPD) – supports discovery and management of healthcare provider information, both individual and organizational, in a directory structure.
- Notification of Document Availability (NAV) – supports out-of-band notifications of documents of interest between systems or users.
- Sharing Value Sets (SVS) – distributes centrally managed common, uniform nomenclatures.
- XAD-PID Change Management (XPID) – updates the relationship between XDS Affinity Domain patient identifiers and other patient identifiers.
- Mobile Access to Health Documents (MHD) – provides a RESTful interface to Document Sharing including XDS.

C.2.5 IHE Laboratory Profiles

- Laboratory Testing Workflow (LTW) – integrates ordering and performance of in-vitro diagnostic tests by a clinical laboratory inside a healthcare institution.
- Sharing of Laboratory Reports (XD-LAB) – describes the content, both human and machine readable, of an electronic clinical laboratory report.
- Laboratory Device Automation (LDA) – integrates an Automation Manager and robotic laboratory equipment (pre-analytical devices, analyzers, post-analytical devices) in a clinical laboratory.
- Laboratory Barcode Labelling (LBL) – integrates robotic specimen container labelling systems with sources of order-related labelling information.
- Laboratory Point of Care Testing (LPOCT) – integrates performing and collecting the results of in-vitro testing at the point of care or patient's bedside.
- Laboratory Code Sets Distribution (LCSD) – distributes managed sets of clinical laboratory codes (battery, test and observation codes).
- Inter Laboratory Workflow (ILW) – supports the workflow of orders and results with a subcontracting laboratory.
- Laboratory Analytical Workflow (LAW) – supports the workflow of test orders and results with IVD specimens on Analyzers.

C.2.6 IHE Patient Care Coordination Profiles

- Medical Summaries (MS) – describes the content and format of Discharge Summaries and Referral Notes.
- Exchange of Personal Health Record (XPHR) – describes the content and format of summary information extracted from a PHR system for import into an EHR system, and vice versa.

- Functional Status Assessments (FSA) – describes the content and format of Functional Status Assessments that appear within summary documents.
- Query for Existing Data (QED) – queries data repositories for clinical information on vital signs, problems, medications, immunizations, and diagnostic results.
- Immunization Content (IC) – exchanges immunization data.
- Care Management (CM) – exchanges information between HIT systems and applications used to manage care for specific conditions.
- Patient Plan of Care (PPOC) – exchanges data related to creating and managing individualised patient care between and among HIT systems.
- Request for Clinical Guidance (RCG) – obtains decision support when ordering medications, determining appropriate immunizations, diagnostic tests, etc.
- Emergency Department Referral (EDR) – communicates medical summary data from an EHR System to an EDIS System.
- Triage Note (TN) – records the act of triaging a patient upon presentation to the emergency department.
- Nursing Note (NN) – records the act of nursing care delivered to a patient in the emergency department.
- Composite Triage and Nursing Note (CTNN) – records the act of both triage and nursing care delivered to a patient in the emergency department.
- ED Physician Note (EDPN) – records care delivered to a patient in the emergency department.
- Antepartum Summary (APS) – records the aggregation of significant events, diagnoses, and plans of care during an antepartum episode.
- Antepartum History and Physical (APHP) – records data often collected at the initial ambulatory office visit for a pregnant patient.
- Antepartum Laboratory (APL) – records results from standard laboratory tests administered during an antepartum episode.
- Antepartum Education (APE) – records educational material provided during the office visit(s) for the antepartum episode.
- Labour and Delivery History and Physical (LDHP) – records data that is often collected during initial admission to a birthing facility.
- Labour and Delivery Summary (LDS) – records data often collected during the labour and delivery period at a birthing facility.
- Maternal Discharge Summary (MDS) – records data often collected post-delivery until discharge from the birthing facility.

C.2.7 IHE Patient Care Device Profiles

- Device Enterprise Communication (DEC) – transmits information from medical devices at the point of care to enterprise applications.
- Point of Care Infusion Verification (PIV) – communicates medication orders to an infusion pump or pump management system.

- Implantable Device Cardiac Observation (IDCO) – specifies the creation, transmission, and processing of discrete data elements and report attachments associated with cardiac device interrogations (observations) or messages.
- Rosetta Terminology Mapping (RTM) – harmonises the use of existing nomenclature terms defined by the ISO/IEEE 11073-10101 nomenclature standard, which is required to be used in all PCD transactions (Note: RTM is a constrained value set).
- Alarm Communication Management (ACM) – communicates alarms, ensuring the right alarm with the right priority gets to the right individuals with the right content.
- Retrospective Data Query (RDQ) – queries archived point-of-care device observations for clinical decision support or other data analysis purposes.
- Infusion Pump Event Communication (IPEC) – communicates clinical and technical events from an infusion pump to an information system for recording, action or presentation to a user.
- Waveform Content Module (WCM) – provides guidance concerning the inclusion of waveform data in applicable IHE PCD profiles such as DEC and ACM.
- Pulse Oximetry Integration (POI) – provides guidance concerning the implementation of pulse oximetry devices using IHE PCD profiles.

C.2.8 IHE Pharmacy Profiles

- Community Medication Prescription and Dispense (CMPD) – integrates the prescription, validation and dispensing of medication in an ambulatory sector.
- Pharmacy Prescription (PRE) – describes the content and format of a prescription document generated by a medical practitioner or other designated healthcare professional prescribes medication.
- Pharmacy Dispense (DIS) – describes the content and format of a dispense document generated when a pharmacist or other designated healthcare professional hands out a medication to a patient.
- Pharmacy Pharmaceutical Advice Document (PADV) – record pharmaceutical advice in response to a prescription
- Hospital Medication Workflow (HMW) – integrates the prescription, validation, dispensing, distribution and administration of medication inside healthcare institutions.

C.2.9 IHE Quality, Research, and Public Health Profiles

- Clinical Research Document (CRD) – describes the content pertinent to the clinical research use case required within the Retrieve Form for Data-Capture (RFD) pre-population parameter.
- Drug Safety Content (DSC) – describes the content pertinent to the drug safety use case required within the Retrieve Form for Data-Capture (RFD) pre-population parameter.
- Early Hearing Care Plan (EHCP) – assists with the early detection, documentation of and intervention for hearing loss by enabling electronic communication of care plan content and

instructions available to all authorised providers of care as jurisdictionally directed by the Public Health EHDI Program.

- Maternal Child Health-Birth and Foetal Death Reporting (MCH-BFDrpt) – defines the EHR content that may be used to pre-populate and transmit birth and foetal death information to vital records systems for vital registration purposes.
- Physician Reporting to a Public Health Repository– Cancer Registry (PRPH-Ca) – defines the data elements to be retrieved from the EMR and transmitted to the cancer registry or to a healthcare provider.
- Retrieve Process for Execution (RPE) – enables a healthcare provider to access a process definition, such as a research protocol and to execute automated activities, without leaving an EMR session.

C.2.10 IHE Radiation Oncology Profiles

- Basic Radiation Therapy Objects (BRTO) – integrate the flow of treatment planning data from CT to Dose Review for basic treatments.
- Multimodality Registration for Radiation Oncology (MMRO) – integrates PET and MRI data into the contouring and dose review process.
- Advanced Radiotherapy Objects Interoperability (ARTI) – adds additional Radiation T therapy treatment techniques to those defined in BRTO.
- Treatment Delivery Workflow (TDW) – standards-based radiation therapy treatment scheduling using workflow.
- Dose Compositing (DCOM) – transfers spatially-related dose information between systems.

C.2.11 IHE Radiology Profiles

- Scheduled Workflow (SWF) – integrates ordering, scheduling, imaging acquisition, storage and viewing for Radiology exams.
- Patient Information Reconciliation (PIR) – coordinates reconciliation of the patient record when images are acquired for unidentified (e.g. in an emergency), or misidentified patients.
- Post-Processing Workflow (PWF) – provides work-lists, status and result tracking for post-acquisition tasks, such as Computer-Aided Detection or Image Processing.
- Reporting Workflow (RWF) – provides work-lists, status and result tracking for reporting tasks, such as dictation, transcription and verification.
- Import Reconciliation Workflow (IRWF) – manages importing images from CDs, hardcopy, XDS-I, etc. and reconciling identifiers to match local values.
- Mammography Acquisition Workflow (MAWF) – handles mammography-specific exceptions to routine image acquisition based on Scheduled Workflow.
- Post-Acquisition Workflow (PAWF) – provides work-lists, status and result tracking for post-acquisition tasks and application hosting.
- Nuclear Medicine Image (NMI) – specifies how Nuclear Medicine images and result screens are created, exchanged, used and displayed.

- Mammography Image (MAMMO) – specifies how Mammography images and evidence objects are created, exchanged, used and displayed.
- Evidence Documents (ED) – specifies how data objects such as digital measurements are created, exchanged, and used.
- Simple Image and Numeric Report (SINR) – specifies how Diagnostic Radiology Reports (including images and numeric data) are created, exchanged, and used.
- Radiation Exposure Monitoring (REM) – specifies how radiation details from imaging procedures are created, exchanged and used.
- CT/MR Perfusion Imaging (PERF) – specifies encoding of Contrast Perfusion imaging data using Enhanced CT/MR DICOM objects.
- MR Diffusion Imaging (DIFF) – specifies encoding of MR Diffusion imaging data using Enhanced MR DICOM objects.
- Chest X-ray CAD (CXCAD) – specifies how Chest X-Ray images and evidence objects are created, exchanged, used and displayed.
- Key Image Note (KIN) – lets users flag images as significant (e.g. for referring, for surgery, etc.) and add notes.
- Consistent Presentation of Images (CPI) – maintains consistent intensity and image transformations between different hardcopy and softcopy devices.
- Presentation of Grouped Procedures (PGP) – facilitates viewing and reporting individual requested procedures (e.g. head, chest, abdomen etc.) that an operator has grouped into a single scan.
- Image Fusion (FUS) – integrates different systems creating, registering and displaying fused image sets and storing their results.
- Basic Image Review (BIR) – defines baseline features and user interface relevant to simple review of DICOM images.
- Portable Data for Imaging (PDI) – provides reliable exchange of image data and diagnostic reports on CDs, DVDs or USB for importing, printing, or optionally, displaying in a browser.
- Cross-enterprise Document Sharing for Imaging.b (XDS-I.b) – extends XDS to share images, diagnostic reports and related information across a group of care sites.
- Teaching File and Clinical Trial Export (TCE) – enable users to flag images and related information for automatic routing to teaching file authoring or clinical trials management systems.
- Access to Radiology Information (ARI) – shares images, diagnostic reports, and related information inside a single network.
- Audit Trail and Node Authentication - Radiology Option (ATNA) – defines Radiology-specific audit trail messages and security measures to protect the confidentiality of patient information.
- Charge Posting (CHG) – provides timely procedure details from modalities to billing systems.
- Cross-Community Access for Imaging (CXA-I) – extends XCA to share images, diagnostic reports and related information across communities.
- Cross-Enterprise Reliable Document Interchange for Imaging (XDR-I) – extends XDR to push images, diagnostic reports and related information between healthcare providers.

- Imaging Object Change Management (IOCM) – communicates image replacement or deletion instructions between multiple image managers.

C.3 IHE Profiles Applicable to South African Context

This section provides an overview of the set of IHE profiles that are relevant to South African healthcare context, based on the scenarios and health functions. If these profiles are adopted, South Africa may need to localise some of them to fit our explicit need.

It is not the intention of this document to provide implementation details, such as, the Required (R) and Optional (O) Transactions specified for Actors in the profiles, or recommendations for the groupings of Actors from different profiles. Developers are advised to consult the relevant IHE technical framework documentations, which are freely available on the IHE website.

C.3.1 Patient Identity Cross-Reference Manager

The patient identity cross-referencing (PIX) is an IHE IT infrastructure profile that supports the cross-referencing of patient identifiers from multiple patient identifier domains. All the identifiers associated with a single patient from different domains (e.g. ADT, Laboratory, Radiology systems) are stored in a central location, e.g. the MPI. It enables any of the domains within the facility to query the central location for the identifiers that are associated with the same patient in other domains. The actors and transactions that are directly involved in PIX profile are illustrated in Figure C-1.

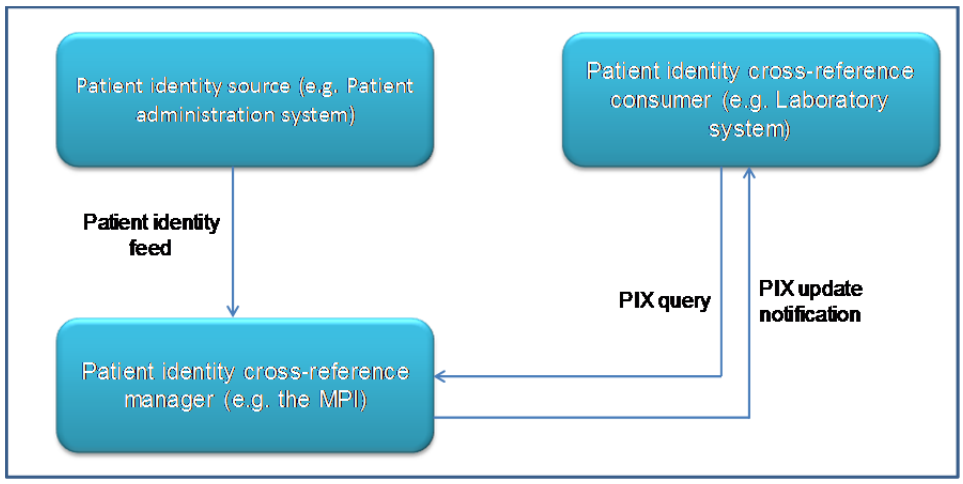

Figure C-1: PIX Actors and Transactions

C.3.2 Patient Demographics Query

The patient demographics query (PDQ) enables applications to query a central patient registry using the patient's demographic data as the search criteria. The central patient registry returns a list of patients matching the search criteria. The appropriate patient can then be selected from the returned list. The actors and transactions that are directly involved in PDQ profile are illustrated in Figure C-2.

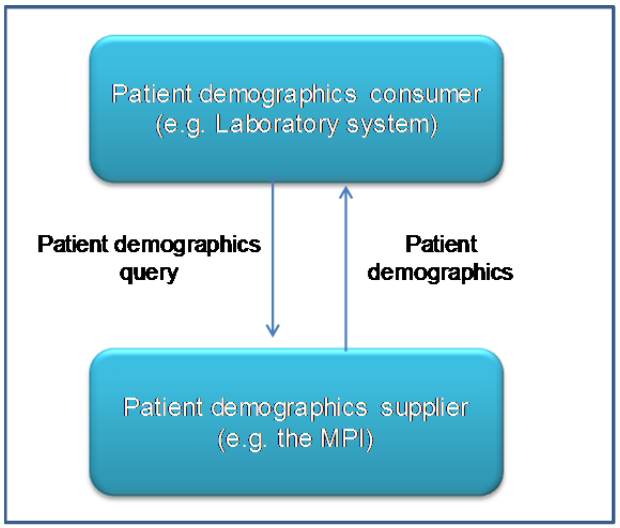

Figure C-2: PDQ Actors and Transactions

C.3.3 Retrieve Information for Display

The Retrieve Information for Display (RID) Integration Profile provides simple and rapid read-only access to patient-centric clinical information that is located outside the user's current application but is important for better patient care (for example, access to lab reports from radiology department). It supports access to existing persistent documents in well-known presentation formats such as CDA (Level 1), PDF, JPEG, etc. It also supports access to specific key patient-centric information such as allergies, current medications, summary of reports, etc. for presentation to a clinician. It complements workflows with access from within the users' on-screen workspace or application to a broad range of information.

C.3.4 Patient Administration Management

The patient administration management profile (PAM) supports the exchange of patient demographics data and patient encounter within and between acute care settings, e.g. hospitals, as well as between acute care settings and ambulatory (outpatient) healthcare providers. It enables consistencies in demographics information of patients stored in applications in these facilities, as well as the exchange of patient encounter information amongst them. The actors and transactions that are directly involved in PAM profile are illustrated in Figure C-3.

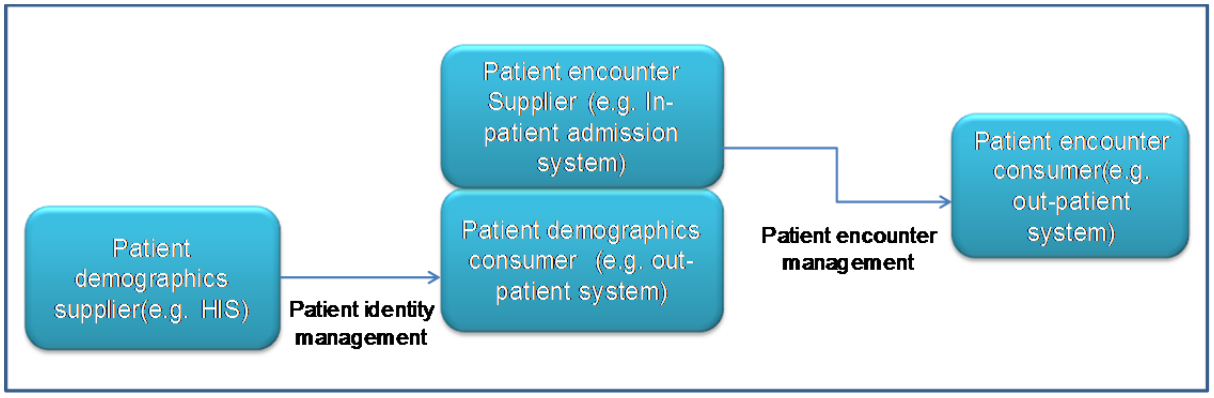

Figure C-3: PAM Actors and Transactions

C.3.5 Health Provider Directory

The health provider directory (HPD) profile supports the management of healthcare provider information, which include individual providers (e.g. nurses and doctors), and organisational providers (e.g. hospitals) in a directory structure, i.e. the listing of the various categories of providers. The actors and transactions that are directly involved in HPD profile are illustrated in Figure C-4.

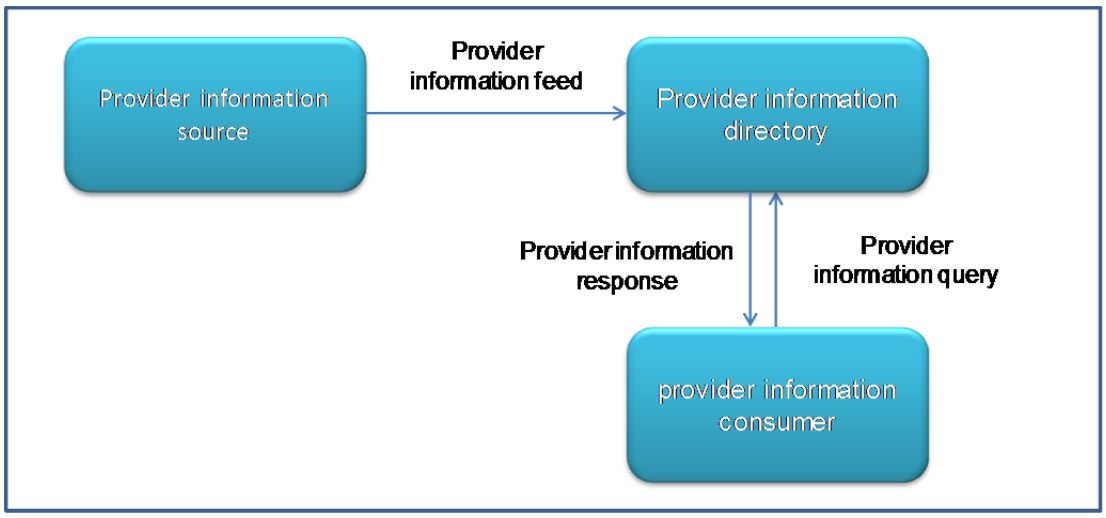

Figure C-4: HPD Actors and Transactions

C.3.6 Mobile Access to Health Document

The Mobile access to Health Documents (MHD) profile specifies a single standard interface to health documents that are accessed through mobile devices, such as, smart phones, tablets, and embedded devices. Such devices are typically constrained with regard to the amount of information that could be displayed, as well as the resources they have. The actors and transactions that are directly involved in MHD profile are illustrated in Figure C-5. The dotted arrows indicate that the document consumer actor must implement at least one of the three transactions while the document responder actor should be able to process any of these transactions.

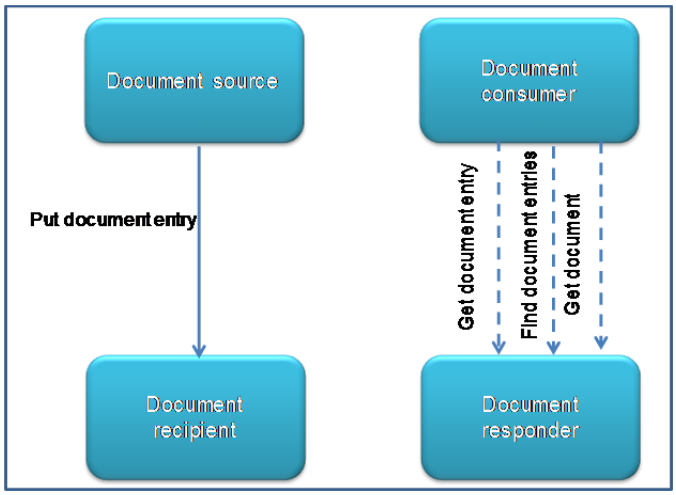

Figure C-5: MHD Actors and Transactions

C.3.7 Cross-Enterprise Document Sharing

The cross-enterprise document sharing (XDS) profile is a content profile that supports the registration, distribution and access across health enterprises of patient electronic health records. It is analogous to an envelope, which is used to hold the actual medical record that is intended for sharing among care providers. The profile is based on the assumption that a healthcare institution is part of one or more XDS affinity domain (e.g. national EHR, which is a group of health facilities using common set of policies and sharing a common infrastructure). The actors and transactions that are directly involved in XDS profile are illustrated in Figure C-6.

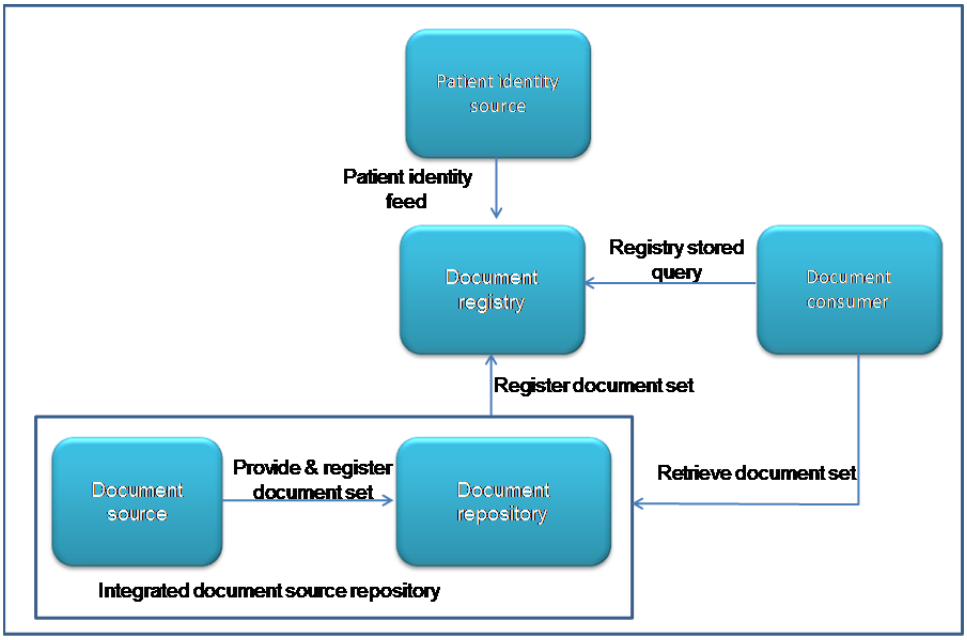

Figure C-6: XDS Actors and Transactions

C.3.8 Cross-Enterprise Sharing of Scanned Document

The cross-enterprise sharing of scanned document (XDS-SD) profile specifies how to combine clinical information having different types of legacy formatting (e.g. paper, film, scans etc.), and representing such information in a structured HL7 CDA Release 2 header. XDS-SD defines the minimum elements of the CDA Release 2 header (patient identity, patient demographics, scanner operator identity, scanning technology, scan time, and best available authoring information) that is required to annotate these documents. This enables the use of portions of CDA Release 2 header, and the supplementary document registration information, to populate XDS document entry metadata. Figure C-7 illustrates the actors and transactions that are involved in XDS-SD profile.

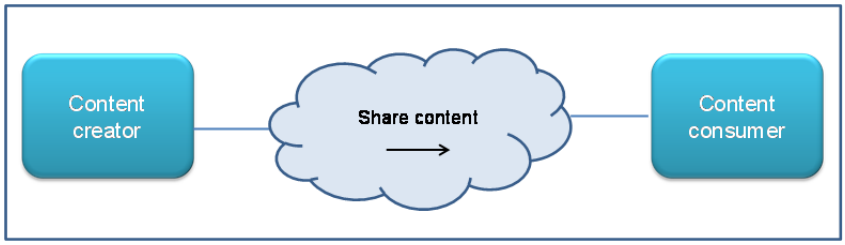

Figure C-7: XDS-SD Actors and Transactions

C.3.9 Cross-enterprise Document Media Interchange

The Cross-Enterprise Document Media Interchange (XDM) provides document interchange using a common file and directory structure over several standard media. This permits the patient to use physical media to carry medical documents. This also permits the use of person-to-person email to convey medical documents. XDM is document format agnostic, supporting the same document content as XDS and XDR. Document content is described in XDS Document Content Profiles. Examples are XDS-MS, XPHR, XDS-SD, and XDS-LAB. The actors and transactions that are directly involved in XDM are illustrated in Figure C-8.

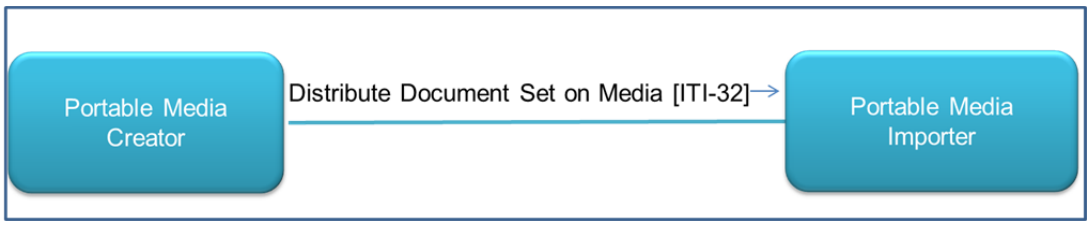

Figure C-8: XDM Actors and Transactions

C.3.10 Basic Patient Privacy Consents

The basic patient privacy consents profile (BPPC) provides support for capturing a patient's privacy consent(s), as well as a method for content consumers within an XDS affinity domain to only access the patient's record in an appropriate manner such that the privacy consent granted by the patient is enforced. A patient's acknowledgement or consent to share health information with other care providers could be captured using the XDS-SD profile. The actors and transactions that are directly involved in BPPC are illustrated in Figure C-9. Note that the content creator actor must implement the basic patient privacy acknowledgement transaction, and optionally, the basic patient privacy acknowledgement with scanned document transaction; while the content consumer must implement the basic patient privacy acknowledgement view transaction.

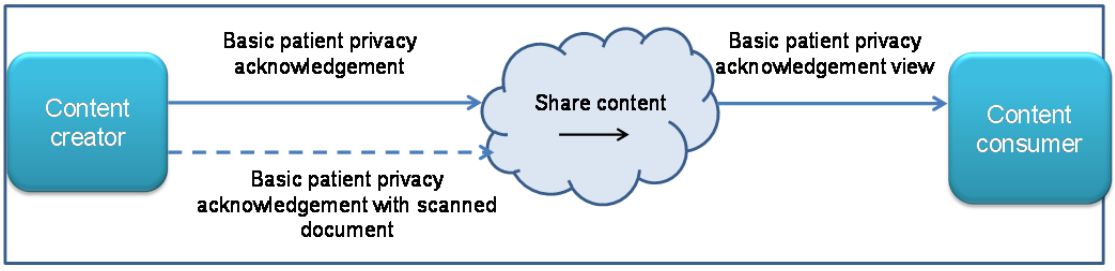

Figure C-9: BPPC Actors and Transactions

C.3.11 Patient Plan of Care

The Patient Plan of Care (PPOC) is a content profile that provides a framework to document the critical thinking that is required for excellent evidence-based care outcomes. It is an individualised, mutually agreed upon plan, which includes problem issues, i.e. nursing diagnoses, expected healthcare outcomes, implementable interventions, and evaluation of progress toward outcomes based on follow up assessment. The profile provides a mechanism to capture and exchange data related to the creation and individualised patient care management between and among HIT systems. The profile is primarily based on the American Nurses Association (ANA) nursing process.

The actors and transactions that are directly involved in PPOC profile are illustrated in Figure C-10. The dotted arrows indicate that the content consumer actor must be able to support at least one of the four transactions.

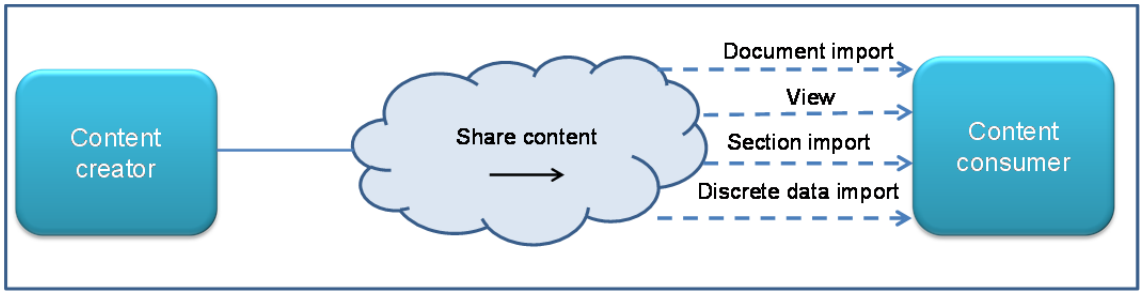

Figure C-10: PPOC Actors and Transactions

C.3.12 Cross-Enterprise Document Sharing of Medical Summary

The Cross-Enterprise Sharing of Medical Summary (XDS-MS) is a content profile that facilitates sharing of the most relevant part of clinical documents by defining the appropriate standards for document transmission, and the minimum set of 'record entries' that must be sent to providers that would be taking over the care of a patient. In addition, this integration profile should also define the utilisation requirements/options for the receiving application in order to ensure that the 'care context' of the sending application is appropriately maintained following the information transfer. The actors and transactions that are directly involved in XDS-MS profile are illustrated in Figure C-11. The dotted arrows indicate that the content creator actor must support at least one of the two transactions and the content consumer actor must support at least one of the four transactions.

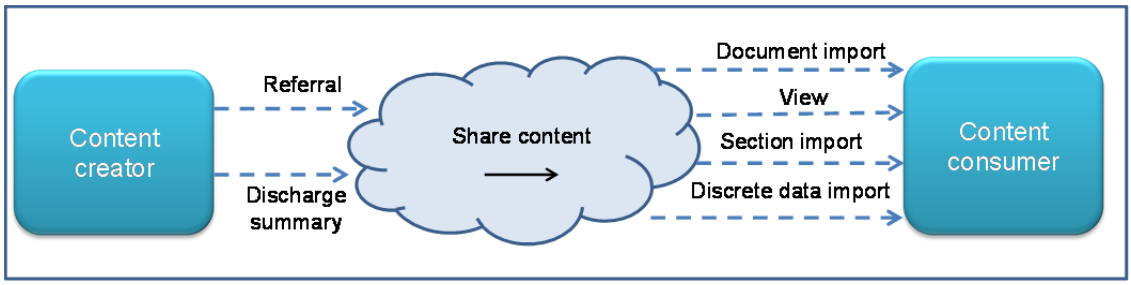

Figure C-11: XDS-MS Actors and Transactions

i. Referral Summary

A referral summary is a type of medical summary, transmitted using XDS profile. It specifies, using HL7 CDA template, the data elements that are required (R), e.g. reasons for referral and history of current illness; data elements that must be provided if such information is available (R2), e.g. immunisations and list of surgeries; and optional data elements (O), e.g. pertinent review of systems. The primary actors involved in this profile and transactions directly involved in this profile are illustrated in Figure C-12. Note the similarity to XDS-MS actors and transactions, except that the referral option is implemented here.

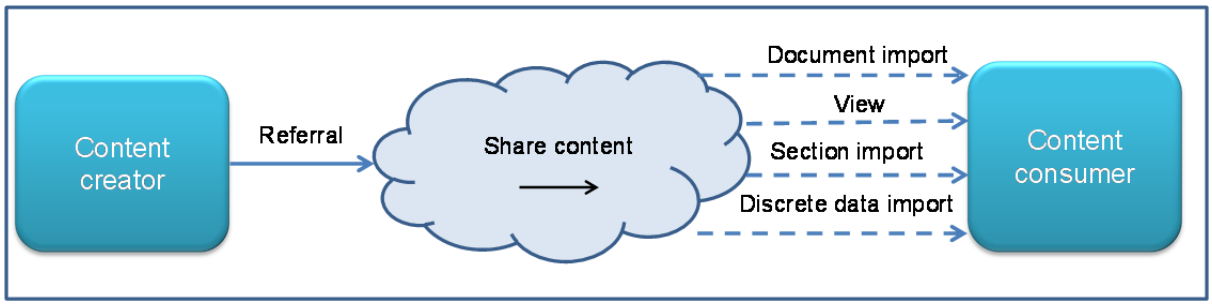

Figure C-12: Referral Summary Actors and Transactions

ii. Discharge Summary

A discharge summary is another type of medical summary that specifies the content and format of the document transmitted at the discharge of a patient following a care episode. Similar to the referral summary, it specifies the required, required if available and optional data elements that should be provided in a discharge summary document. The primary actors involved in this profile and transactions directly involved in this profile are illustrated in Figure C-13. Also, note the similarity to XDS-MS actors and transactions, except that the discharge option is implemented here.

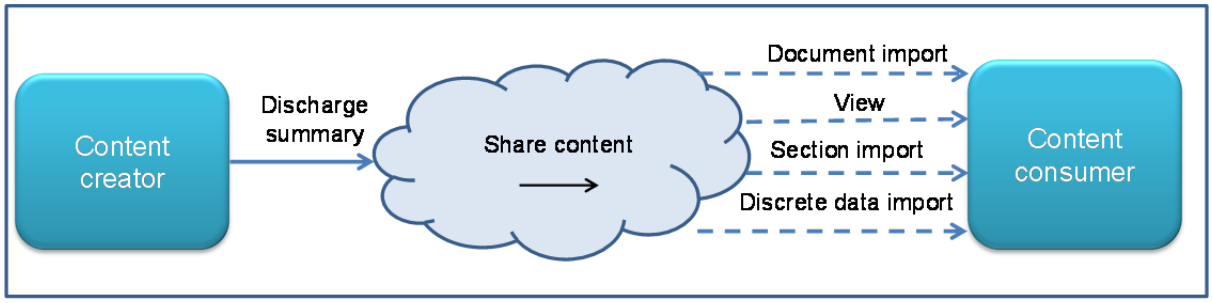

Figure C-13: Discharge Summary Actors and Transactions

C.3.13 Pharmacy Prescription

The pharmacy prescription profile (XDS-PRE) is a content profile that provides specifications for the content and format of a prescription document. It specifies the required, required if available and optional data elements for such a document. The actors and transactions that are directly involved in this profile are similar to those illustrated in Figure C-10.

C.3.14 Pharmacy Dispense

The pharmacy dispense profile (XDS-DIS) is a content profile that specifies the content and format of the documentation of medications that has been dispensed by providing the required, required if available and optional data elements of such document. The actors and transactions that are directly involved in this profile are similar to those illustrated in Figure C-10.

C.3.15 Sharing Laboratory Report

The sharing laboratory report (XD-LAB) profile is a content profile that specifies the content and format of laboratory reports for sharing among healthcare providers to support continuity of care.

The actors and transactions that are directly involved in this profile are similar to those illustrated in Figure C-10.

C.3.16 Simple Imaging and Numeric Report

The simple imaging and numeric report (SINR) profile is a content profile that supports the creation, exchange and use of diagnostic radiology reports. It enables the use of digital dictation, voice recognition, and specialised reporting packages, by partitioning reporting functions into discrete actors for creation, management, storage and viewing. This allows a vendor to include one or more of these functions in an actual system. The actors and transactions that are directly involved in SINP profile is shown in Figure C-14.

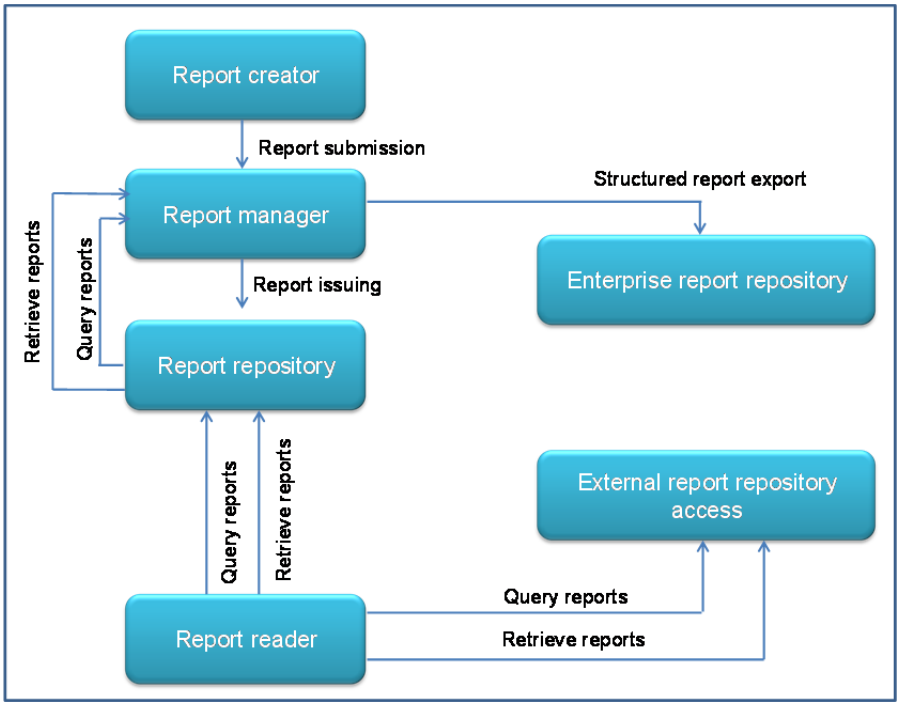

Figure C-14: SINP Actors and Transactions

C.3.17 Cross-Enterprise Document Sharing for Imaging

The cross-enterprise document sharing for imaging (XDS-I.b) profile is an extension of XDS profile that supports sharing of medical images, reports and other related information among healthcare providers. The actors and transactions that are directly involved in XDS-I.b profile is shown in Figure C-15. The actors in green are the other endpoints of the associated transactions.

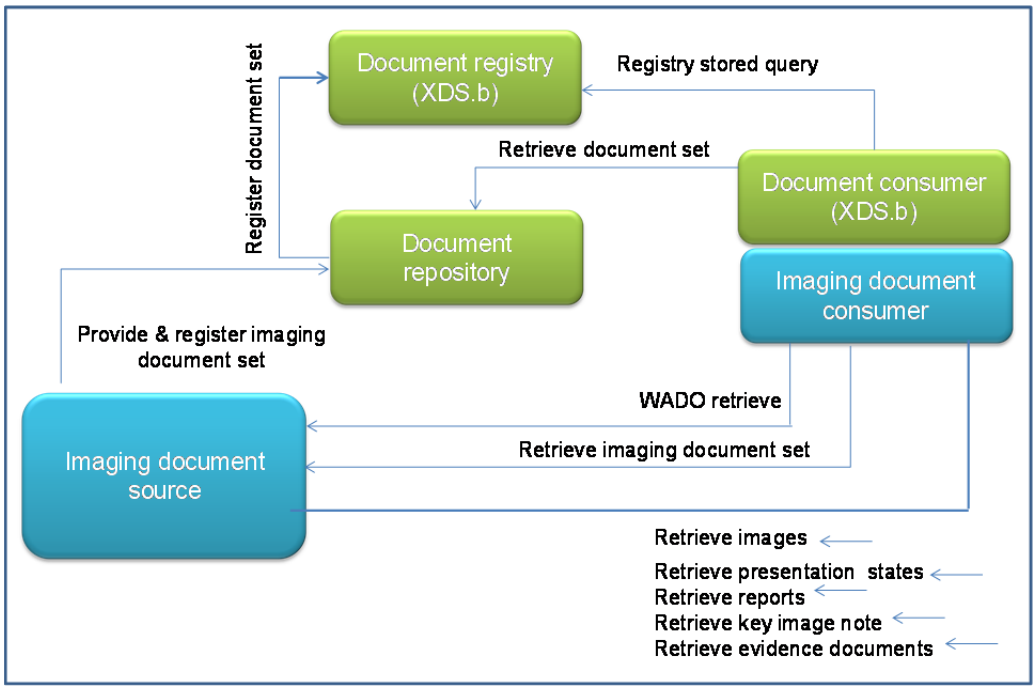

Figure C-15: XDS-I.b Actors and Transactions

C.3.18 Multi-Patient Queries

The Multi-Patient Queries (MPQ) profile defines a mechanism to enable aggregated queries to a Document Registry based on certain criteria needed by areas related to data analysis, such as quality accreditation of healthcare practitioners or healthcare facilities, clinical research trial data collection or population health monitoring. The actors and transactions that are directly involved in MPQ profile is shown in Figure C-16.

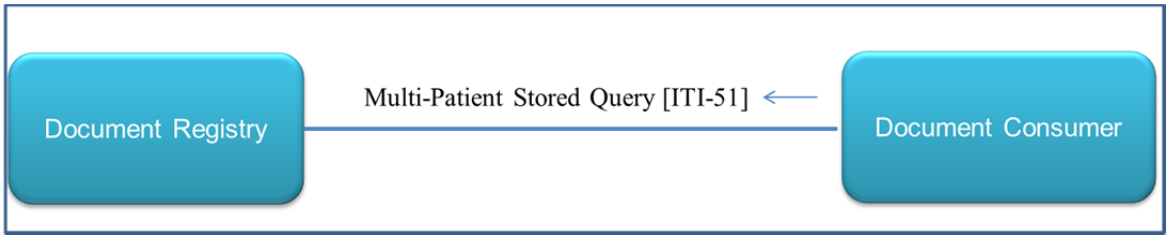

Figure C-16: PMQ Actors and Transactions

C.3.19 Antepartum Summary Content Profile

The antepartum summary profile is a content profile that specifies the structure for aggregating the significant events, diagnoses, and plans of care derived from visits over the course of an antepartum episode (antenatal period). It is a special type of medical summary document that specifies the required, required if available, and optional data elements for such a document. The primary actors involved in this profile are the content creator and content consumer (see Figure C-10).

C.3.20 Labour and Delivery Summary Content Profile

The labour and delivery summary (LDS) profile is a content profile that specifies the structure and format of the data collected during the labour and delivery period at a delivery facility. It includes, maternal information, such as, demographics, histories, allergies, physical examinations, vital signs, delivery type, postpartum complications (if any), and neonatal information, such as, delivery method, gender, birth time, APGAR score, medications and immunisations received in the delivery room, among others. It defines the required, required if available, and optional data elements that should be included in the document. The actors and transactions that are directly involved in the profile are similar to those illustrated in Figure C-10.

C.3.21 Maternal Discharge Summary Content Profile

The maternal discharge summary that specifies the structure and format of the data collected from delivery until discharge at a delivery facility. It is a special type of discharge summary document that facilitates follow-up care during the post-natal period for both mother and baby. It includes, maternal information, such as, demographics, histories, allergies, physical examinations, vital signs, delivery type, postpartum complications (if any), and neonatal information, such as, delivery method, gender, birth time, APGAR score, medications and immunisations received in the delivery room, among others. It defines the required, required if available, and optional data elements that should be included in the document. The actors and transactions that are directly involved in this profile are similar to those illustrated in Figure C-10.

C.3.22 Audit Trail and Node Authentication

The Audit trail and node authentication (ATNA) profile establishes the security measures which, together with the security policies and procedures of an organisation, ensure the confidentiality of patient information, data integrity, and user accountability. ATNA assumes that within a secure environment (e.g. a health facility or XDS affinity domain):

(i) All nodes/machines are authenticated; unknown machines may be allowed access to information that is authorised for the public,

(ii) The host identification is used to determine the type of access that should be granted to automated processes on that host, and/or persons under the direction of that host's access,

(iii) It is the responsibility of the secure node to enforce access controls, e.g. user authentication and authorisation, and

(iv) It is the responsibility of the secure node to provide security audit log to track security events.

All IHE actors must support the implementation of ATNA profile. The actors and transactions that are directly involved in ATNA are illustrated in Figure C-17.

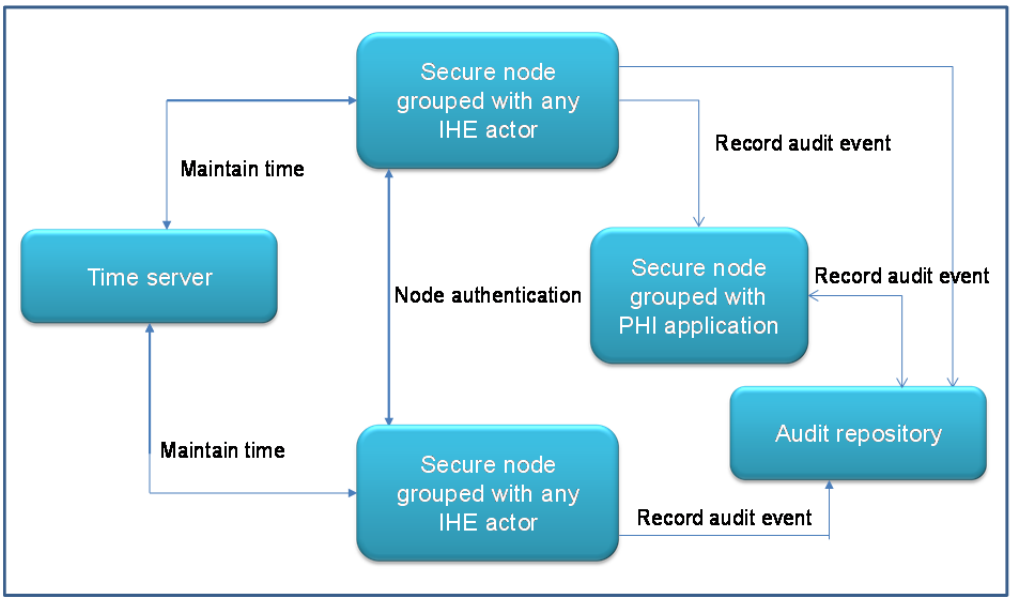

Figure C-17: ATNA Actors and Transactions

C.3.23 Consistent Time

The consistent time (CT) profile provides a mechanism to ensure the system clocks and time stamps of multiple computers in a network are well synchronised. It specifies synchronisation with a median error of less than 1 second. Various infrastructure, security, and acquisition profiles require the use of a consistent time base on multiple computers. The actors and transactions that are directly involved in CT are illustrated in Figure C-18.

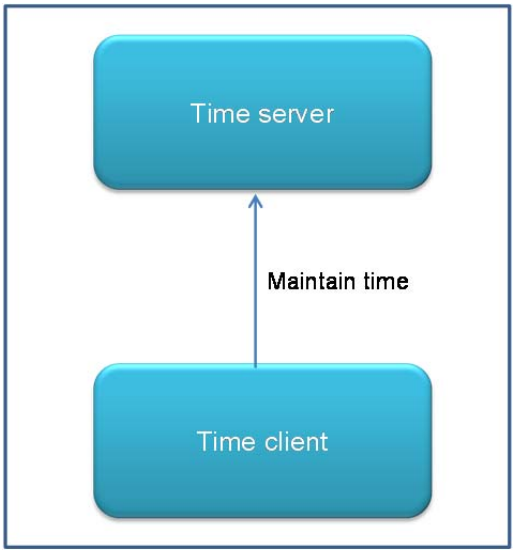

Figure C-18: CT Actors and Transactions

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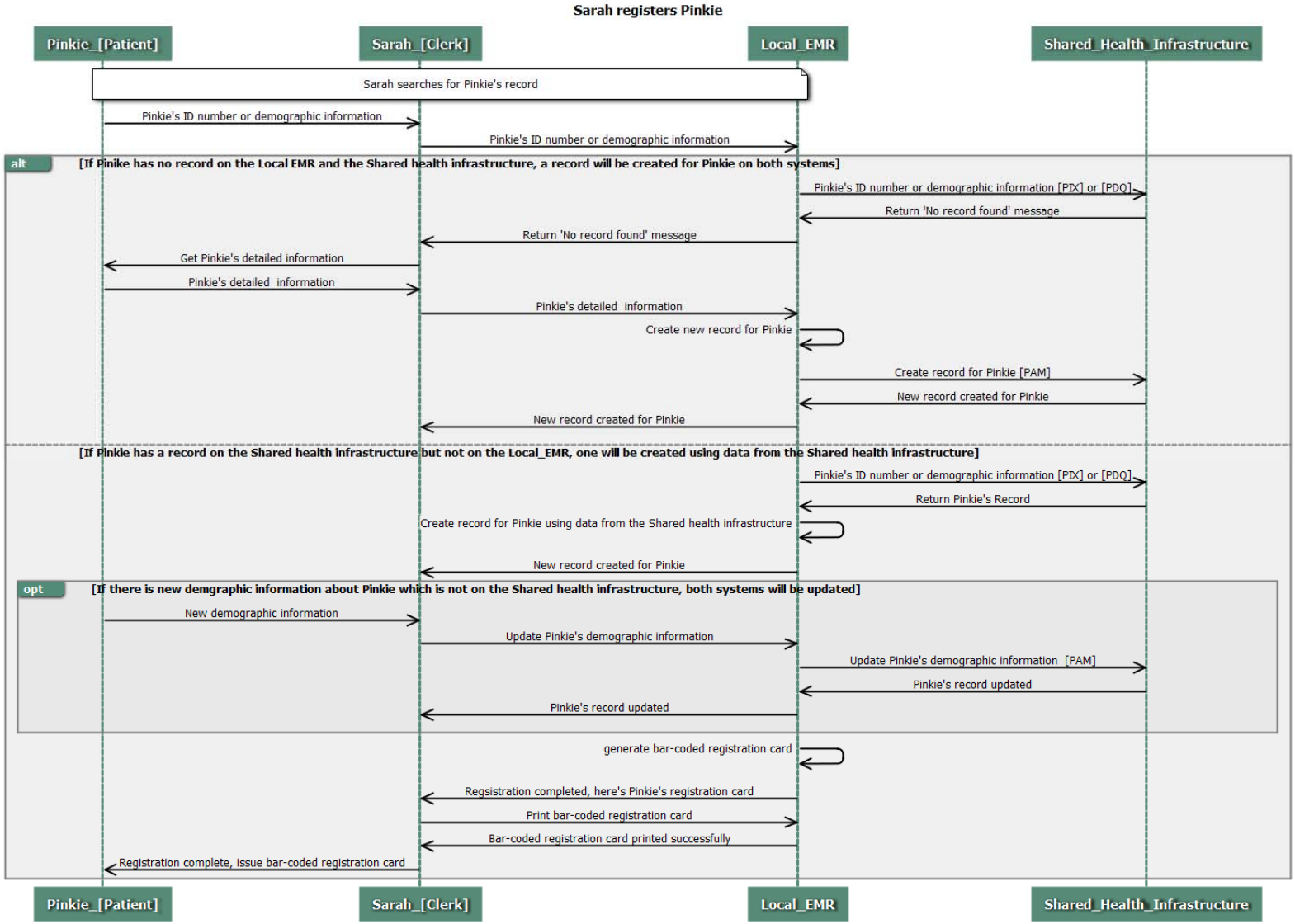
D APPENDIX – MAPPING SCENARIOS TO IHE PROFILES

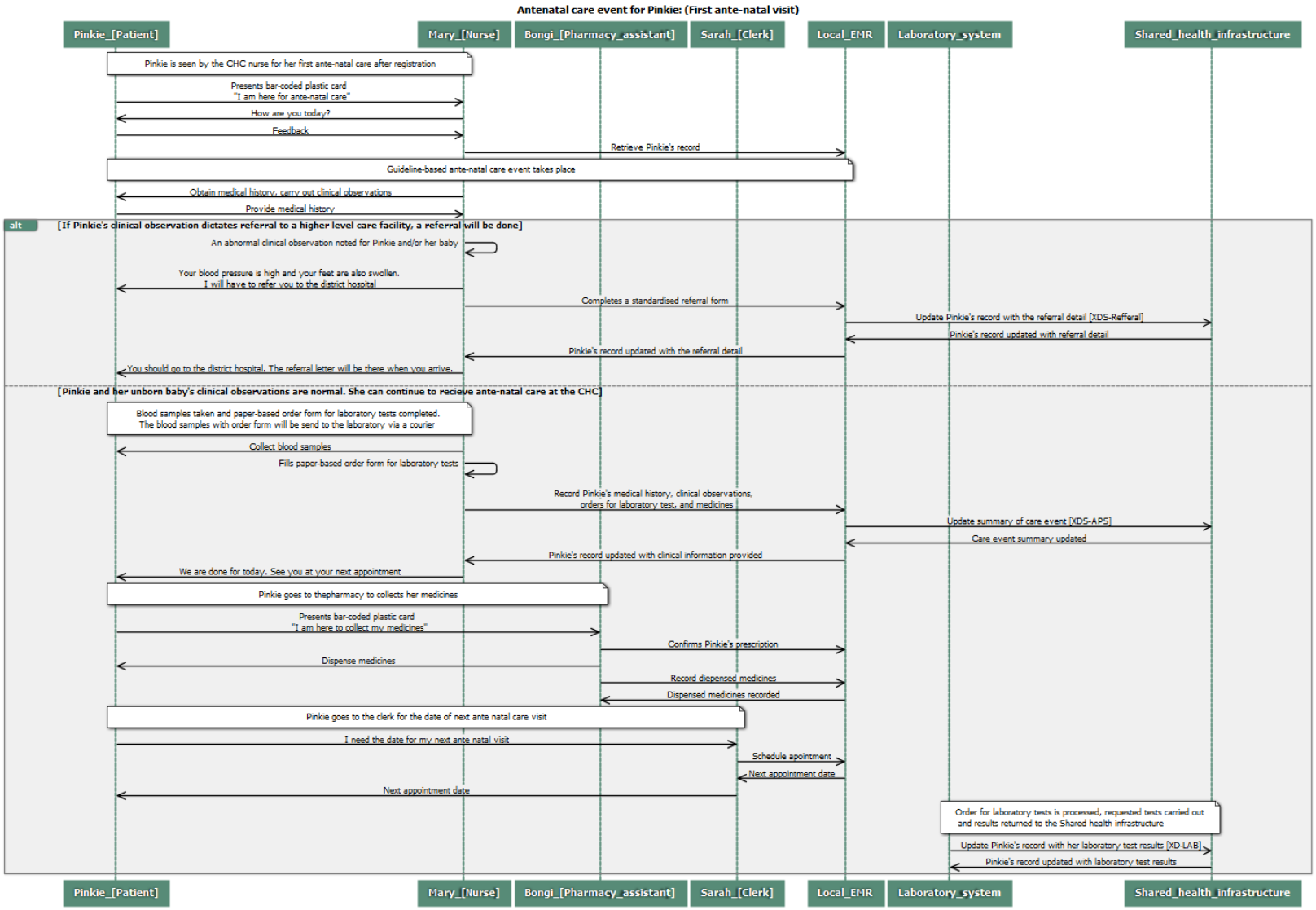
Antenatal care	
Scenario	**Applicable IHE Interoperability Profiles**
Pinkie is a 19 year old single mother of one, Bridget who is 10 month old. Pinkie is unemployed. She lives in a two-room shack with her grandmother, Naledi, and two siblings, Piladi (15 years) and Banda (10 years). Pinkie is 5 months pregnant with her 2nd child. Pinkie decides to go to the local CHC to register for antenatal care. On arrival at the CHC, Pinkie reports at the registry desk. She tells the clerk, Sarah, that she is pregnant and would like to see the nurse or doctor.	
Sarah asks Pinkie if she has been to the CHC or MOU before. Although Pinkie replies that she has not, Sarah goes ahead and searches the local electronic medical record (EMR) system, which is linked to the national shared electronic health record (EHR) system. She uses Pinkie's national ID number and when that does not find Pinkie on the system, she searches on Pinkie's name, surname and date of birth. No record matching Pinkie's details is found.	Identify patient: **PIX,PDQ**
Sarah then creates a new EMR for Pinkie using the demographic information she provides – her name, surname, date of birth and address. A unique identification number is generated for Pinkie by the national patient master index (PMI) which responsible for the allocation patient identifiers.	Create new patient record: **PAM, BPPC** Add demographic details: **PAM**
As part of the registration process, Sarah prints a barcoded label and sticks it onto a small card. This label will identify Pinkie to both the EMR and the national shared EHR in future. Sarah then asks Pinkie to wait in the waiting area. After a while, Mary a nurse at the MOU, comes to the waiting area and calls all the pregnant women to follow her to a room for the day's health talk. The focus of the talk is on breastfeeding and the importance of being tested for HIV.	
After the talk each of the pregnant women is called into the consulting room for a one-on-one consultation with Mary. When her turn comes, Pinkie goes in to see Mary, who scans the barcode on Pinkie's card to retrieve Pinkie's EMR.	Identify patient: **PIX**
She notes that this is Pinkie's first antenatal care visit. Mary asks Pinkie questions about her health history, including how many children she has, number of previous pregnancies and any previous health conditions, with dates and outcomes. She also carries out a number of clinical observations (Pinkie's weight, blood pressure, temperature, urine analysis, fundal height, Pinkie's heart rate, and the baby's heart rate). Mary records the information obtained from	Add medical history: **XDS-APS** Add clinical observations: **XDS-APS** Add "doctor's notes": **XDS-APS** Add and update care plan: **XDS-APS**

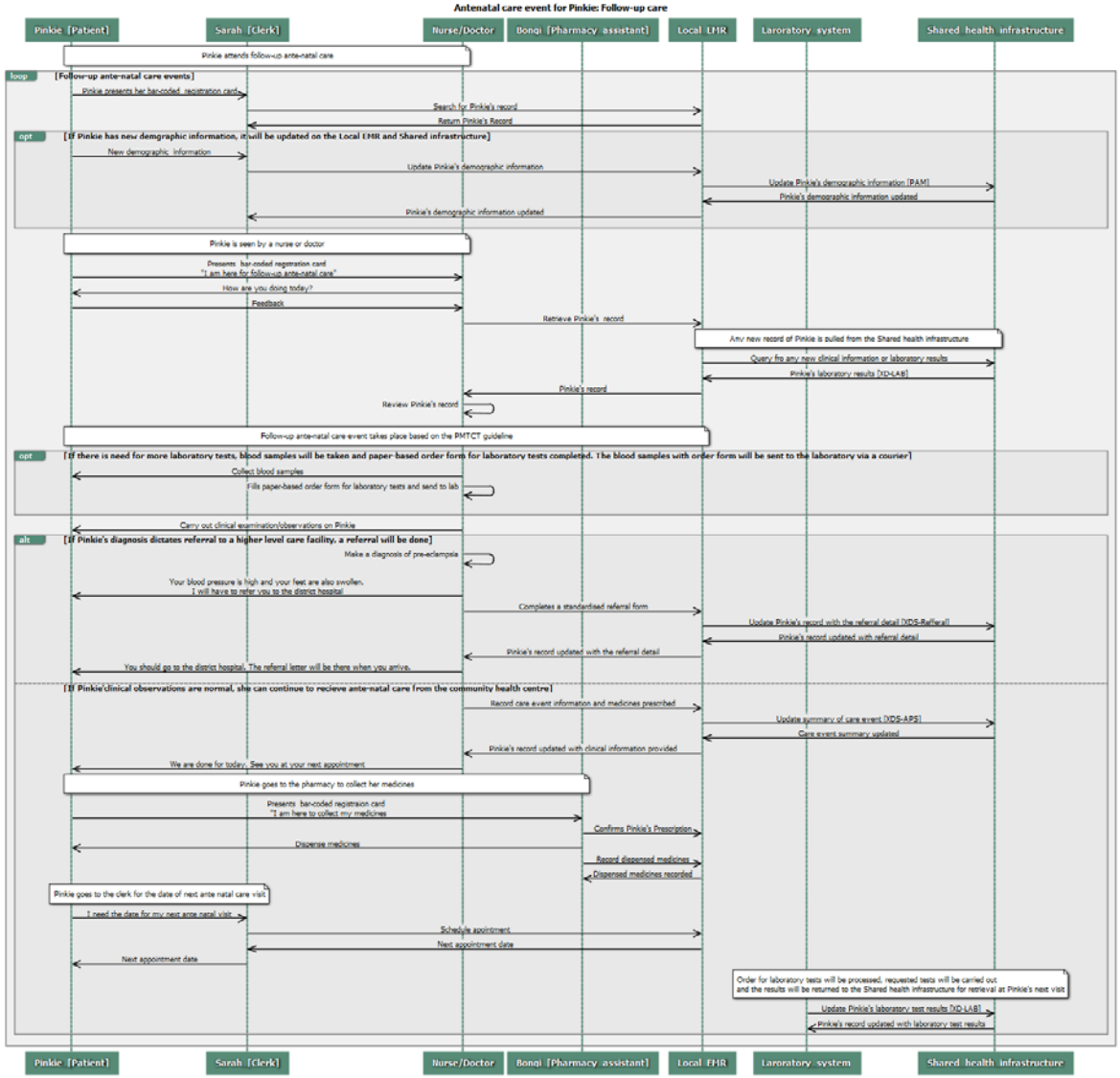
Pinkie, as well as the clinical observation data in Pinkie's EMR.	
Mary then discusses with Pinkie the importance of being tested for HIV. She explains to her that the result of the test will be confidential, and that disclosure of the result to family members would be Pinkie's choice. After the counselling, Pinkie agrees to do the HIV test. Mary asks Pinkie to sign a standard HIV consent form, so that her consent is documented. Pinkie signs the consent form as requested. The signed form is later scanned and uploaded to Pinkie's EMR.	Scan and upload paper document: **XDS-SD**
Mary cleans Pinkie's finger with an alcohol swab and does a finger prick HIV test. She asks Pinkie to wait outside for the result. After 20 minutes Mary calls Pinkie to the consulting room; she tells Pinkie that the test is positive, but that a second test is required to be sure. Mary performs a second finger prick HIV test using a test kit from another manufacturer. About half an hour later, Mary calls Pinkie in again. She is very sorry, she says, but the second test is also positive. Pinkie is understandably devastated and begins to cry. Mary comforts her and provides post-test counselling to Pinkie.	
Mary discusses the prevention of mother to child transmission (PMTCT) program with Pinkie and explains that people with HIV can live normal, healthy lives. She also explains that the PMTCT program will reduce the risk of her unborn baby being infected with HIV. Mary also tells Pinkie that she needs to do more blood tests, so they could put her on appropriate treatment. She then draws blood for three tests: full blood count, CD4 count and Alamine Aminotransferase. Pinkie is also screened for tuberculosis (TB) and Mary asks specific questions regarding and previous TB treatment and symptoms of TB.	Add clinical observations: **XDS-APS**
A laboratory order form for the blood tests is completed by Mary and accompanies the blood samples which are labelled and taken to the laboratory by a courier service.	
Mary initiates Pinkie on prophylactic antiretroviral treatment (ART) with Zidovudine, and iron and folate supplements as per the PMTCT clinical guidelines. She records this prescription in Pinkie's EMR and asks Pinkie to come back to the CHC after one week, so she can be seen by the doctor and her blood results reviewed.	Add pharmacy orders: **XDS-PRE** or Medication Section of: **XDS-APS**
Pinkie stops at the CHC's pharmacy to collect her medicines. She gives her plastic card to Bongi, the pharmacy assistant. Bongi scans the card to retrieve Pinkie's EMR with the prescription; she then dispenses a one-week supply of Zidovudine and the supplements as prescribed. She labels the medicine containers with dosage instructions. Bongi also updates the pharmacy system with details of the dispensed medicines. These details are also recorded in the EMR.	Identify patient: **PIX** Add drugs dispensed: **XDS-DIS** or Medication Section of: **XDS-APS**
Pinkie returns to Sarah, who schedules her appointment using the appointment-scheduling module. Pinkie also receives a text message	Add and query test results: **XD-LAB**

on her cell phone with the date and time of the appointment. A day before the scheduled appointment, Pinkie receives another text message reminding her about the appointment for the next day. Pinkie's blood tests are completed, and the results are sent directly from the laboratory information system to her EMR.	or Laboratory Section of: **XDS-APS**
On the date of her appointment, Pinkie returns to the CHC. She gives her plastic card to Sarah, who scans the card to confirm Pinkie's appointment. Sarah also checks that Pinkie's details are still the same.	Identify patient: **PIX** Add, query and update demographic details: **PAM**
Pinkie is seen by Dr White. Dr White scans Pinkie's plastic card to retrieve her EMR. He reviews the previous week's encounter, as well as the blood results. Dr White asks Pinkie how she is doing and carries out routine clinical observations. He notes her CD4 count is in the normal range that she is asymptomatic. He assures Pinkie that she and her baby were doing well, and recommends that she continue with the prophylactic ART, which was initiated by the nurse during her last visit. Dr White then completes an electronic prescription for Zidovudine, iron and folate. He also records the day's encounter in Pinkie's EMR. Dr White discusses breast and formula feeding with Pinkie; and the implications of the various options. He tells her she still has to decide whether or not to breastfeed her baby after birth. Pinkie promises to think about it.	Identify patient: **PIX** Add clinical observations. **XDS-APS** Add and update "doctor's notes": **XDS-APS** Add pharmacy orders: X**DS-PRE** or Medication Section of **XDS-APS** Update care plan: **XDS-APS**
Pinkie continues to receive antenatal care at the MOU until she is due to have her baby.	Add and update clinical observations**:** **XDS-APS** Add and update "doctor's notes": **XDS-APS** Update care plan: **XDS-APS** Add drugs dispensed: **XDS-DIS** or Medication Section of: **XDS-APS**

The associated sequence diagrams are:


Sarah registers Pinkie
Pinkie_[Patient]
Sarah_[Clerk]
Local_EMR
Shared_Health_Infrastructure
Sarah searches for Pinkie's record
Pinkie's ID number or demographic information
Pinkie's ID number or demographic information
alt
[If Pinike has no record on the Local EMR and the Shared health infrastructure, a record will be created for Pinkie on both systems]
Pinkie's ID number or demographic information [PIX] or [PDQ]
Return 'No record found' message
Return 'No record found' message
Get Pinkie's detailed information
Pinkie's detailed information
Pinkie's detailed information
Create new record for Pinkie
Create record for Pinkie [PAM]
New record created for Pinkie
New record created for Pinkie
[If Pinkie has a record on the Shared health infrastructure but not on the Local_EMR, one will be created using data from the Shared health infrastructure]
Pinkie's ID number or demographic information [PIX] or [PDQ]
Return Pinkie's Record
Create record for Pinkie using data from the Shared health infrastructure
New record created for Pinkie
opt
[If there is new demgraphic information about Pinkie which is not on the Shared health infrastructure, both systems will be updated]
New demographic information
Update Pinkie's demographic information
Update Pinkie's demographic information [PAM]
Pinkie's record updated
Pinkie's record updated
generate bar-coded registration card
Regsistration completed, here's Pinkie's registration card
Print bar-coded registration card
Bar-coded registration card printed successfully
Registration complete, issue bar-coded registration card
Pinkie_[Patient]
Sarah_[Clerk]
Local_EMR
Shared_Health_Infrastructure

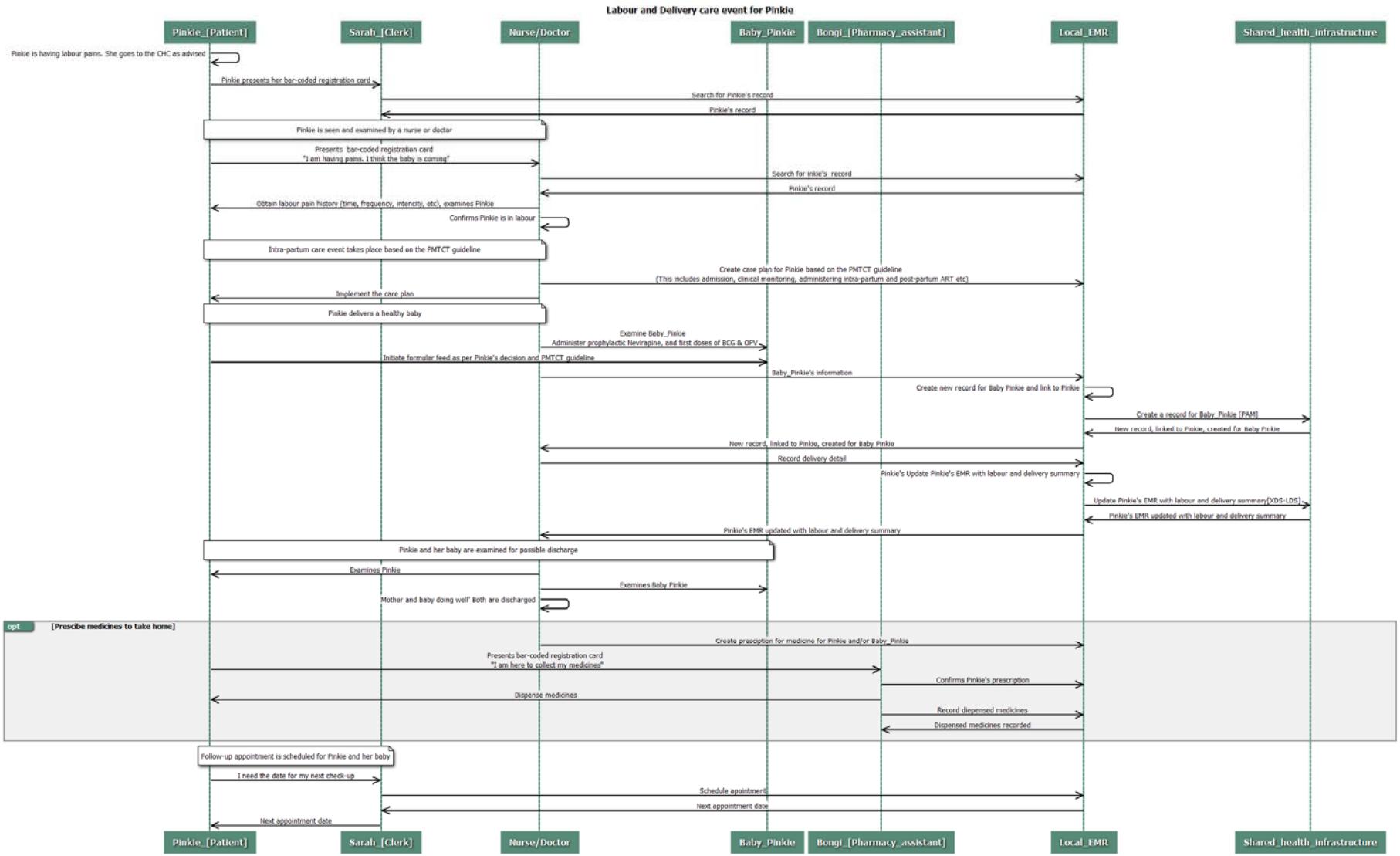

Antenatal care event for Pinkie: (First ante-natal visit)
Pinkie_[Patient]
Mary_[Nurse]
Bongi_[Pharmacy_assistant]
Sarah_[Clerk]
Local_EMR
Laboratory_system
Shared_health_infrastructure
Pinkie is seen by the CHC nurse for her first ante-natal care after registration
Presents bar-coded plastic card
"I am here for ante-natal care"
How are you today?
Feedback
Retrieve Pinkie's record
Guideline-based ante-natal care event takes place
Obtain medical history, carry out clinical observations
Provide medical history
alt
[If Pinkie's clinical observation dictates referral to a higher level care facility, a referral will be done]
An abnormal clinical observation noted for Pinkie and/or her baby
Your blood pressure is high and your feet are also swollen.
I will have to refer you to the district hospital
Completes a standardised referral form
Update Pinkie's record with the referral detail [XDS-Refferal]
Pinkie's record updated with referral detail
Pinkie's record updated with the referral detail
You should go to the district hospital. The referral letter will be there when you arrive.
[Pinkie and her unborn baby's clinical observations are normal. She can continue to recieve ante-natal care at the CHC]
Blood samples taken and paper-based order form for laboratory tests completed.
The blood samples with order form will be send to the laboratory via a courier
Collect blood samples
Fills paper-based order form for laboratory tests
Record Pinkie's medical history, clinical observations,
orders for laboratory test, and medicines
Update summary of care event [XDS-APS]
Care event summary updated
Pinkie's record updated with clinical information provided
We are done for today. See you at your next appointment
Pinkie goes to thepharmacy to collects her medicines
Presents bar-coded plastic card
"I am here to collect my medicines"
Confirms Pinkie's prescription
Dispense medicines
Record dispensed medicines
Dispensed medicines recorded
Pinkie goes to the clerk for the date of next ante natal care visit
I need the date for my next ante natal visit
Schedule apointment
Next appointment date
Next appointment date
Order for laboratory tests is processed, requested tests carried out
and results returned to the Shared health infrastructure
Update Pinkie's record with her laboratory test results [XD-LAB]
Pinkie's record updated with laboratory test results
Pinkie_[Patient]
Mary_[Nurse]
Bongi_[Pharmacy_assistant]
Sarah_[Clerk]
Local_EMR
Laboratory_system
Shared_health_infrastructure


Antenatal care event for Pinkie: Follow-up care
Pinkie [Patient]
Sarah [Clerk]
Nurse/Doctor
Bongi [Pharmacy assistant]
Local EMR
Laboratory system
Shared health infrastructure
Pinkie attends follow-up ante-natal care
loop
[Follow-up ante-natal care events]
Pinkie presents her bar-coded registration card
Search for Pinkie's record
Return Pinkie's Record
opt
[If Pinkie has new demgraphic information, it will be updated on the Local EMR and Shared infrastructure]
New demographic information
Update Pinkie's demographic information
Update Pinkie's demographic information [PAM]
Pinkie's demographic information updated
Pinkie's demographic information updated
Pinkie is seen by a nurse or doctor
Presents bar-coded registration card
"I am here for follow-up ante-natal care"
How are you doing today?
Feedback
Retrieve Pinkie's record
Any new record of Pinkie is pulled from the Shared health infrastructure
Query fro any new clinical information or laboratory results
Pinkie's laboratory results [XD-LAB]
Pinkie's record
Review Pinkie's record
Follow-up ante-natal care event takes place based on the PMTCT guideline
opt
[If there is need for more laboratory tests, blood samples will be taken and paper based order form for laboratory tests completed. The blood samples with order form will be sent to the laboratory via a courier]
Collect blood samples
Fills paper-based order form for laboratory tests and send to lab
Carry out clinical examination/observations on Pinkie
alt
[If Pinkie's diagnosis dictates referral to a higher level care facility, a referral will be done]
Make a diagnosis of pre-eclampsia
Your blood pressure is high and your feet are also swollen.
I will have to refer you to the district hospital
Completes a standardised referral form
Update Pinkie's record with the referral detail [XDS-Referral]
Pinkie's record updated with referral detail
Pinkie's record updated with the referral detail
You should go to the district hospital. The referral letter will be there when you arrive.
[If Pinkie'clinical observations are normal, she can continue to recieve ante-natal care from the community health centre]
Record care event information and medicines prescribed
Update summary of care event [XDS-APS]
Care event summary updated
Pinkie's record updated with clinical information provided
We are done for today. See you at your next appointment
Pinkie goes to the pharmacy to collect her medicines
Presents bar-coded registraion card
"I am here to collect my medicines
Confirms Pinkie's Prescription
Dispense medicines
Record dispensed medicines
Dispensed medicines recorded
Pinkie goes to the clerk for the date of next ante natal care visit
I need the date for my next ante natal visit
Schedule appointment
Next appointment date
Next appointment date
Order for laboratory tests will be processed, requested tests will be carried out
and the results will be returned to the Shared health infrastructure for retrieval at Pinkie's next visit
Update Pinkie's laboratory test results [XD-LAB]
Pinkie's record updated with laboratory test results
Pinkie [Patient]
Sarah [Clerk]
Nurse/Doctor
Bongi [Pharmacy assistant]
Local EMR
Laboratory system
Shared health infrastructure

Labour and delivery	
Scenario	**Applicable IHE Interoperability Profiles**
As soon as Pinkie suspects that she is in labour, she goes to the CHC as advised. She reports at the registration desk where her plastic card is scanned in order to retrieve her EMR.	Identify patient: **PIX** Add, query and update demographic details: **PAM**
Pinkie is seen by Mary as it is not Dr White's day at the CHC. She asks Pinkie when the pain started and how often she feels it. She examines her and confirms that she is in labour. Mary then admits Pinkie to the MOU of the CHC.	
Pinkie is received by Beatrice, a midwife at the MOU. Beatrice measures and records Pinkie's vital signs, i.e. temperature, heart rate, blood pressure, foetal heart rate, frequency and intensity of abdominal contraction, cervical dilatation and urine analysis. She also draws up a care plan for Pinkie according to the PMTCT guidelines on intra-partum care for HIV positive women in labour. Beatrice administers a single-dose of Nevirapine, a single dose of Truvada , and three-hourly doses of Zidovudine to Pinkie. She continues to monitor Pinkie throughout labour and records her progress until the baby is delivered. After delivery, Pinkie is given post-partum ARV medicines in the form of single doses of Tenofovir and Emtracitabine.	Add and update clinical observations: **XDS-APS** Update "doctor's notes": **XDS-APS** Update care plan: **XDS-APS**
An EMR is created for the baby and linked to Pinkie's EMR. A unique identification number is generated for Pinkie's baby by the national patient master index (PMI) which responsible for the allocation patient identifiers. Beatrice conducts a physical examination of Pinkie's baby and records her findings in the baby's EMR. The baby also receives the first doses of BCG and oral polio vaccines according to the childhood immunisation guideline, as well as prophylactic nevirapine, according to the PMTCT guidelines. Details of the vaccination and prophylactic are recorded in the baby's EMR.	Add birth details XD**S-LDS** Create new patient record: **PAM** Link baby to mother: **PAM** Add clinical observations: **XDS-LDS** Add interventions: **XDS-LDS** Add and query pharmacy orders: **XDS-PRE** Add drugs dispensed: **XDS-DIS**
Pinkie decides not to breast feed her baby and the baby is started on formula feed at the MOU. Since Pinkie's delivery process has been without complications, she and her baby are discharged the same day.	Add and query discharge summary: **XDS-MS**
Pinkie is given an appointment to come back with her baby for a post-	

natal check-up in two days.

The associated sequence diagram is:


Labour and Delivery care event for Pinkie
Pinkie_[Patient]
Sarah_[Clerk]
Nurse/Doctor
Baby_Pinkie
Bongi_[Pharmacy_assistant]
Local_EMR
Shared_health_infrastructure
Pinkie is having labour pains. She goes to the CHC as advised
Pinkie presents her bar-coded registration card
Search for Pinkie's record
Pinkie's record
Pinkie is seen and examined by a nurse or doctor
Presents bar-coded registration card
"I am having pains. I think the baby is coming"
Search for inkie's record
Pinkie's record
Obtain labour pain history (time, frequency, intencity, etc), examines Pinkie
Confirms Pinkie is in labour
Intra-partum care event takes place based on the PMTCT guideline
Create care plan for Pinkie based on the PMTCT guideline
(This includes admission, clinical monitoring, administering intra-partum and post-partum ART etc)
Implement the care plan
Pinkie delivers a healthy baby
Examine Baby_Pinkie
Administer prophylactic Nevirapine, and first doses of BCG & OPV
Initiate formular feed as per Pinkie's decision and PMTCT guideline
Baby_Pinkie's information
Create new record for Baby Pinkie and link to Pinkie
Create a record for Baby_Pinkie [PAM]
New record, linked to Pinkie, created for Baby Pinkie
New record, linked to Pinkie, created for Baby Pinkie
Record delivery detail
Pinkie's Update Pinkie's EMR with labour and delivery summary
Update Pinkie's EMR with labour and delivery summary[XDS-LDS]
Pinkie's EMR updated with labour and delivery summary
Pinkie's EMR updated with labour and delivery summary
Pinkie and her baby are examined for possible discharge
Examines Pinkie
Examines Baby Pinkie
Mother and baby doing well' Both are discharged
opt
[Prescibe medicines to take home]
Create prescription for medicine for Pinkie and/or Baby_Pinkie
Presents bar-coded registration card
"I am here to collect my medicines"
Confirms Pinkie's prescription
Dispense medicines
Record dispensed medicines
Dispensed medicines recorded
Follow-up appointment is scheduled for Pinkie and her baby
I need the date for my next check-up
Schedule apointment
Next appointment date
Next appointment date
Pinkie_[Patient]
Sarah_[Clerk]
Nurse/Doctor
Baby_Pinkie
Bongi_[Pharmacy_assistant]
Local_EMR
Shared_health_infrastructure

Post-natal care	
After two days, Pinkie returns to the centre with her baby for the post-natal check-up. Since it is the doctor's visiting day to the CHC, Pinkie and her baby are seen and examined by Dr White.	Identify patient: **PIX** Add, query and update demographic details: **PAM**
Dr White decides that Pinkie's baby should continue taking nevirapine for six weeks according to the PMTCT guidelines. Dr White creates an electronic prescription in the baby's EMR and the medicine is dispensed by Bongi, the pharmacy assistant.	Add clinical observations: **XDS** Add pharmacy orders: **XDS-PRE** Add drugs dispensed: **XDS-DIS**
Pinkie is given an appointment to come for check-up within six weeks of delivery. Another appointment was scheduled accordingly. On the date of her appointment, Pinkie was back at the CHC.	Identify patient: **PIX** Add, query and update demographic details: **PAM**
During this visit, blood was drawn for another CD4 count, and an electronic laboratory order was completed accordingly. Pinkie was also screened for TB and clinical staging of HIV was done.	
Pinkie was given one-week appointment to come for the results of blood tests. Pinkie's CD4 count is more than 350 cells/mm3 and so she is referred for wellness services and family planning.	Add test result: **XD-LAB**
Follow-up care for Pinkie's baby is done according to the PMTCT guidelines.	

E APPENDIX – FUNCTION TO IHE PROFILE MAPPING

FUNCTION GROUP	FUNCTIONS	IHE PROFILES	UNDERLYING STANDARDs
Identification, authentication and authorisation	**Identify location**	HPD	LDAP V3 (MIOS) ISO/TS 21091:2005 DSML V2 SOAP 1.2
	Identify provider	HPD	LDAP V3 (MIOS) ISO/TS 21091:2005 DSML V2 SOAP 1.2
	Identify patient	[50]* - None	
	Authenticate patient	[51]** - None	
	Authenticate provider	[52]** - None	
	Authorise provider roles and permissions	[53]** - None	
Record look-up	**Search for patient record**	PIX	HL7 V2.3.1 HL7 V 2.5
		PDQ	HL7 V 2.5
Add patient record	**Create new client record**	PAM	HL7 V 2.5
		BPPC	HL7 V3 CDA Release 2.0
	Link baby patient to mother patient	PAM	HL7 V 2.5
	Create temporary patient record	PAM	HL7 V 2.5
	Merge temporary and permanent record	PAM	HL7 V 2.5
Retrieve patient record	**Retrieve and display**	RID	RFC1738 XML WSDL XHTML
		XDS	HL7 V 2.3.1 HL7 V 2.5 XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS

[50] There is no IHE Profile for this function; however, a base standard as well as the national population register could be sufficient for this purpose

[51] There is no IHE Profile for this function.

[52] There is no IHE Profile for this function.

[53] There is no IHE Profile for this function.

FUNCTION GROUP	FUNCTIONS	IHE PROFILES	UNDERLYING STANDARDs
		MHD	RFC 2616 (MIOS) RFC 3986 RFC 4627 RFC 6585
Update patient record	**Add, query and update demographic details**	PAM	HL7 V2.5
	Add, query and update medical history	XDS-MS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0 CDA for CDTHP
	Add, query and update clinical observations	XDS-MS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0
	Add, query and update interventions	XDS-MS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0
	Add and query referrals	XDS-Referral	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0 HL7 Care Record Summary ASTM/HL7 CCD

FUNCTION GROUP	FUNCTIONS	IHE PROFILES	UNDERLYING STANDARDs
	Add and query pharmacy orders	XDS-PRE	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 Normative Edition (CMET only) ASTM/HL7 CCD
	Add and query drugs dispensed	XDS-DIS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 Normative Edition (CMET only) ASTM/HL7 CCD
	Add and query orders for laboratory tests	XDS	HL7 V 2.3.1 HL7 V 2.5 XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS LOINC
	Add and query laboratory test results	XD-LAB	HL7 V 2.3.1 HL7 V 2.5 XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0 LOINC SNOMED

FUNCTION GROUP	FUNCTIONS	IHE PROFILES	UNDERLYING STANDARDs
	Add and query orders for radiology test s	XDS	HL7 V 2.3.1 HL7 V 2.5 DICOM 2011, [ISO/IEC 12052] (MIOS) XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0
	Add and query radiology test results	SINR	DICOM 2011, [ISO/IEC 12052]) (MIOS) HL7 V3 CDA Release 2.0
		XDS-I.b	DICOM 2011, [ISO/IEC 12052]) (MIOS) [54]ISO 19005-1 (PDF/A-1) SOAP-MTOM XML-binary OP HL7 V3 CDA Release 2.0
	Add, query and update "doctor's notes"	XDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0
	Add and query discharge summary (incl. transfer)	XDS-Discharge summary	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0 HL7 V3 CDA Release 2.0 HL7 Care Record Summary ASTM/HL7 CCD

[54] Based on an earlier version of MIOS (SANS 32000-1)

FUNCTION GROUP	FUNCTIONS	IHE PROFILES	UNDERLYING STANDARDs
		XDS-MDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0 ASTM/HL7 CCD NDoH Maternal Case Record HL7 Care Record Summary
	Add and query OP encounter outcome	XDS-MS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0
	Add, query and update ante-natal care events	XDS-APS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0 ASTM/HL7 CCD NDoH Maternal Case Record HL7 Care Record Summary
	Add and query birth details	XDS XDS-LDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0 ASTM/HL7 CCD NDoH Maternal Case Record HL7 Care Record Summary
	Add and query death details	XDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0

FUNCTION GROUP	FUNCTIONS	IHE PROFILES	UNDERLYING STANDARDs
	Add, query and update care plan	XDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0
		[55]PPOC	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS HL7 V3 CDA Release 2.0 ASTM/HL7 CCD
	Scan and upload paper document	XDS-SD	RFC 3778 [56]ISO 19005-1 (PDF/A-1) RFC 3066 HL7 V3 CDA Release 2.0
	Add, query and update records via mobile device	MHD	RFC 2616 (MIOS) RFC 3986 RFC 4627 RFC 6585
Scheduling	**Schedule appointment**	[57]** - None	
	Send reminders	[58]** - None	
	Confirm attendance or cancellation	XDS	HL7 V 2.3.1 HL7 V 2.5 XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS
Emergency medical services - peripheral	**Contact ambulance**	[59]** - None	
	Dispatch ambulance	[60]** - None	
	Route ambulance	[61]** - None	

[55] PPOC is based on the American Nursing Association (ANA) Nursing Scope and Standard of Practice
[56] Based on an earlier version of MIOS (SANS 32000-1)
[57] There is no IHE Profile for this function.
[58] There is no IHE Profile for this function.
[59] There is no IHE Profile for this function.
[60] There is no IHE Profile for this function.
[61] There is no IHE Profile for this function.

FUNCTION GROUP	FUNCTIONS	IHE PROFILES	UNDERLYING STANDARDs
Supply chain management - peripheral	**Update pharmacy stock**	[62]** - None	
Create billing account	**Add, query and update bills**	[63]** - None	
Generate metrics	**Add, query and update health indicator**	[64]** - None	
[65]Non eHealth specific functions			
Node authentication	**Authenticate system**	ATNA	[66]RFC 2246 WS-I Basic Security Profile 1.1 [67]S/MIME V3.1 AES (MIOS) [68]SHA-1 (MIOS) RSA X.509 (MIOS) RFC 5424 RFC 5425 RFC 5426 RFC 3164 RFC 3881
Maintain system clock	Maintain system clock	CT	NTP V3 (RFC 1305) SNTP (RFC 4330)

[62] There is no IHE Profile for this function.
[63] There is no IHE Profile for this function.
[64] There is no IHE Profile for this function.
[65] The IHE profiles listed are required for the other IHE profiles
[66] This is an earlier version of MIOS (RFC 5246)
[67] This is a later version of MIOS (S/MIME V3)
[68] MIOS specifies SHA-2

F APPENDIX – FUNCTION TO PROFILE AND STANDARDS MAPPING

FUNCTION GROUP	FUNCTIONs	IHE PROFILES	STANDARDS						
			General IT standards	Identifier standards	Messaging standards	Coding and terminology standards	Content and structure standards	EHR standards	Security standards
Identification, authentication and authorisation	**Identify location**	HPD	LDAP (MIOS) ISO/TS 21091:2005 DSML V2 SOAP 1.2 (MIOS)	ISO/TS 27527:2010					
	Identify provider	HPD	LDAP (MIOS) ISO/TS 21091:2005 DSML V2 SOAP 1.2 (MIOS)	NPR (MIOS) ISO/TS 27527:2010					
	Identify patient	[69]None		NPR (MIOS) ISO 22220:2011					
	Authenticate patient	[70]None							
	Authenticate provider	[71]None							
	Authorise provider roles and permissions	[72]None	ANSI INCITS 359-2004						ISO/TS 22600:1-3
Record look-up	**Search for patient record**	PIX	XML V1.0 (MIOS)		[73]HL7 V2.X				
		PDQ	XML V1.0 (MIOS)		[74]HL7 V2.X				

[69] Although there is no IHE profile for this function, the identifier standard (ISO 22220:2011) and the NPR could be sufficient for our purpose
[70] There is no IHE profile for this function
[71] There is no IHE profile for this function
[72] Although there is no IHE profile for this function, the security standard (ISO/TS 22600:1-3) and general role-based access control could be could be sufficient for our purpose
[73] IHE profile specifies 2 versions of HL7 (v2.3.1 and v2.5). We may adopt higher version which uses XML syntax
[74] IHE profile specifies IHE v2.5. We may adopt higher version which uses XML syntax

FUNCTION GROUP	FUNCTIONs	IHE PROFILES	STANDARDS						
			General IT standards	Identifier standards	Messaging standards	Coding and terminology standards	Content and structure standards	EHR standards	Security standards
Add patient record	**Create new patient record**	PAM	XML V1.0 (MIOS)		[75]HL7 V2.X			ISO 18308:2011 ISO/TR 20514:2005	
		BPPC					HL7 V3 CDA Release 2.0	ISO 18308:2011 ISO/TR 20514:2005	
	Link baby patient to mother patient	PAM	XML V1.0 (MIOS)		[76]HL7 V2.X		HL7 V3 CDA Release 2.0	ISO 18308:2011 ISO/TR 20514:2005	
	Create temporary patient record	PAM	XML V1.0 (MIOS)		[77]HL7 V2.X				
	Merge temporary and permanent record	PAM	XML V1.0 (MIOS)		[78]HL7 V2.X				
Admission, discharge and transfer	**Admit patient**	PAM	XML V1.0 (MIOS)		[79]HL7 V2.X				
	Discharge patient	PAM	XML V1.0 (MIOS)		[80]HL7 V2.X				
	Add and query discharge summary	XDS-Discharge summary	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS			ICD-10 (MIOS) Procedure codes (e.g. CPT)	HL7 V3 CDA Release 2.0 HL7 CRS ASTM/HL7 CCD		
		XDS-MDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS)			ICD-10 (MIOS) Procedure codes (e.g. CPT)	HL7 V3 CDA Release 2.0 ASTM/HL7 CCD NDoH Maternal		

[75] IHE profile specifies IHE v2.5. We may adopt higher version which uses XML syntax
[76] IHE profile specifies IHE v2.5. We may adopt higher version which uses XML syntax
[77] IHE profile specifies IHE v2.5. We may adopt higher version which uses XML syntax
[78] IHE profile specifies IHE v2.5. We may adopt higher version which uses XML syntax
[79] IHE profile specifies IHE v2.5. We may adopt higher version which uses XML syntax
[80] IHE profile specifies IHE v2.5. We may adopt higher version which uses XML syntax

FUNCTION GROUP	FUNCTIONs	IHE PROFILES	STANDARDS						
			General IT standards	Identifier standards	Messaging standards	Coding and terminology standards	Content and structure standards	EHR standards	Security standards
			ebMS ebRIM ebRS				Case Record HL7 CRS		
	Add, query and update transfer	PAM	XML V1.0 (MIOS)		[81]HL7 V2.X				
Retrieve patient record	**Retrieve and display**	RID	RFC1738 XML WSDL XHTML						
		XDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS		[82]HL7 V2.X				
		MHD	RFC 2616 (MIOS) RFC 3986 RFC 4627 RFC 6585						
Update patient record	**Add, query and update demographic details**	PAM	XML V1.0 (MIOS)		[83]HL7 V2.X				
	Add, query and update medical history	XDS-MS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS			ICD-10 (MIOS) Procedure codes (e.g. CPT)	HL7 V3 CDA Release 2.0 CDA for CDTHP		

[81] IHE profile specifies IHE v2.5. We may adopt higher version which uses XML syntax
[82] IHE profile specifies 2 versions of HL7 (v2.3.1 and v2.5). We may adopt higher version which uses XML syntax
[83] IHE profile specifies IHE v2.5. We may adopt higher version which uses XML syntax

FUNCTION GROUP	FUNCTIONs	IHE PROFILES	STANDARDS						
			General IT standards	Identifier standards	Messaging standards	Coding and terminology standards	Content and structure standards	EHR standards	Security standards
	Add, query and update clinical observations	XDS-MS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS				HL7 V3 CDA Release 2.0		
	Add, query and update interventions	XDS-MS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS			ICD-10 (MIOS) Procedure codes (e.g. CPT)			
	Add and query referrals	XDS-Referral	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS			ICD-10 (MIOS) Procedure codes (e.g. CPT)	HL7 V3 CDA Release 2.0 HL7 CRS ASTM/HL7 CCD		
	Add and query pharmacy orders	XDS-PRE	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS			Medicine codes (e.g. NAPPI, ATC/DDD, RxNorm, AMT Codes)	HL7 V3 Normative Edition (CMET only) ASTM/HL7 CCD		
	Add and query drugs dispensed	XDS-DIS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS			Medicine codes (e.g. NAPPI, ATC/DDD, RxNorm, AMT Codes)	HL7 V3 Normative Edition (CMET only) ASTM/HL7 CCD		

FUNCTION GROUP	FUNCTIONs	IHE PROFILES	STANDARDS						
			General IT standards	Identifier standards	Messaging standards	Coding and terminology standards	Content and structure standards	EHR standards	Security standards
	Add and query orders for laboratory tests	XDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS			LOINC ICD-10 (MIOS)	HL7 V3 CDA Release 2.0		
	Add and query laboratory test results	XD-LAB	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS			LOINC ICD-10 (MIOS)	HL7 V3 CDA Release 2.0		
	Add and query orders for radiology test s	XDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS		DICOM 2011, [ISO/IEC 12052] (MIOS) [84]HL7 V2.X	ICD-10 (MIOS)	HL7 V3 CDA Release 2.0		
	Add and query radiology test results	SINR			DICOM 2011, [ISO/IEC 12052] (MIOS)	ICD-10 (MIOS)	HL7 V3 CDA Release 2.0		
		XDS-I.b	[85]ISO 19005-1 (PDF/A-1) SOAP-MTOM XML-binary OP		DICOM 2011, [ISO/IEC 12052] (MIOS)	ICD-10 (MIOS)	HL7 V3 CDA Release 2.0		
	Add, query and update "doctor's notes"	XDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS)				HL7 V3 CDA Release 2.0		

[84] IHE profile specifies IHE v2.5. We may adopt higher version which uses XML syntax
[85] Based on an earlier version of MIOS (SANS 32000-1)

FUNCTION GROUP	FUNCTIONs	IHE PROFILES	STANDARDS						
			General IT standards	Identifier standards	Messaging standards	Coding and terminology standards	Content and structure standards	EHR standards	Security standards
			ebMS ebRIM ebRS						
	Add and query OP encounter outcome	XDS-MS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS			ICD-10 (MIOS) Procedure codes (e.g. CPT)	HL7 V3 CDA Release 2.0		
	Add, query and update ante-natal care events	XDS-APS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS			ICD-10 (MIOS) Procedure codes (e.g. CPT)	HL7 V3 CDA Release 2.0 ASTM/HL7 CCD NDoH Maternal Case Record HL7 CRS		
	Add and query birth details	XDS XDS-LDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS			ICD-10 (MIOS) Procedure codes (e.g. CPT)	HL7 V3 CDA Release 2.0 ASTM/HL7 CCD NDoH Maternal Case Record HL7 CRS		
	Add and query death details	XDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS			ICD-10 (MIOS) Procedure codes (e.g. CPT)	HL7 V3 CDA Release 2.0		
	Add, query and update care plan	XDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS			ICD-10 (MIOS) Procedure codes (e.g. CPT) Medicine codes (e.g. NAPPI,	HL7 V3 CDA Release 2.0		

FUNCTION GROUP	FUNCTIONs	IHE PROFILES	STANDARDS						
			General IT standards	Identifier standards	Messaging standards	Coding and terminology standards	Content and structure standards	EHR standards	Security standards
			ebRIM ebRS			ATC/DDD, RxNorm, AMT Codes) LOINC			
		[86]PPOC	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS				HL7 V3 CDA Release 2.0 ASTM/HL7 CCD		
	Scan and upload paper document	XDS-SD	RFC 3778 [87]ISO 19005-1 (PDF/A-1) RFC 3066				HL7 V3 CDA Release 2.0		
	Add, query and update records via mobile device	MHD	RFC 2616 (MIOS) RFC 3986 RFC 4627 RFC 6585						
Scheduling	**Schedule appointment**	[88]None							
	Send reminders	[89]None							
	Confirm attendance or cancellation	XDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS		HL7 V2.X				
Emergency	**Contact**	[90]None							

[86] PPOC is based on the American Nursing Association (ANA) Nursing Scope and Standard of Practice
[87] Based on an earlier version of MIOS (SANS 32000-1)
[88] There is no IHE profile for this function
[89] There is no IHE profile for this function

FUNCTION GROUP	FUNCTIONs	IHE PROFILES	STANDARDS						
			General IT standards	Identifier standards	Messaging standards	Coding and terminology standards	Content and structure standards	EHR standards	Security standards
medical services - peripheral	ambulance								
	Dispatch ambulance	[91]None							
	Route ambulance	[92]None							
Supply chain management - peripheral	Update pharmacy stock	[93]None							
Create billing account	Add, query and update bills	[94]None	XML V1.0 (MIOS) [95]UPFS		HL7 V2.X	ICD-10 (MIOS) Procedure codes (e.g. CPT) Medicine codes (e.g. NAPPI, ATC/DDD, RxNorm, AMT Codes) LOINC			
	Submit medical bills for payment	UN/EDIFACT							
Generate metrics	Add, query and update health indicator				SDMX-HD				
[96]Non-health specific functions									

[90] There is no IHE profile for this function
[91] There is no IHE profile for this function
[92] There is no IHE profile for this function
[93] There is no IHE profile for this function
[94] Although there is no IHE profile for this function, there is HL7 message specification for creating and updating patient account
[95] The Uniform Patient Fee Schedule (UPFS) has been developed by the NDoH to guide the tariffs that are charged to full paying and subsidised patients for health serviced rendered at public health facilities

FUNCTION GROUP	FUNCTIONs	IHE PROFILES	STANDARDS						
			General IT standards	Identifier standards	Messaging standards	Coding and terminology standards	Content and structure standards	EHR standards	Security standards
Node authentication	**Authenticate system**	ATNA	[97]RFC 2246 WS-I Basic Security Profile 1.1 [98]S/MIME V3.1 AES (MIOS) [99]SHA-1 (MIOS) RSA X.509 (MIOS) RFC 5424 RFC 5425 RFC 5426 RFC 3164 RFC 3881						
Maintain system clock	Maintain system clock	CT	NTP V3 (RFC 1305) SNTP (RFC 4330)						

[96] The IHE profiles listed are required for the other IHE profiles
[97] This is an earlier version of MIOS (RFC 5246)
[98] This is a later version of MIOS (S/MIME V3)
[99] MIOS specifies SHA-2

G APPENDIX – RISK MATRIX FOR STANDARD STACKS

G.1 HL7 V3

#	Content	Avg Risk	Max Risk	POV
1	Evaluate **HL7v3 messaging** with respect to **suitability as an eHealth interoperability specification** from the point of view of **health system stakeholders**.	8.2	16.0	Systems Analyst
	Rationale			

		Best Case	Worst Case	Impact	Risk	Notes
1.1	Are HL7v3 messages a scalable option?					
1.1.1	Is the specification based on mature messaging standards?	Very mature	Pre-commercial or beta level products	Moderate	6	Implemented in UK, NL and Canada
1.1.2	Are high-capacity, commercial ENTERPRISE EERVICE BUS products able to be employed to process the message traffic?	Readily available COTS and open source products	Bespoke solutions must be developed	Major	8	There are commercial products which can be configured to carry HLv3 messages (e.g. MS Biztalk)
1.1.3	Are design documents and developer specifications readily available to eHealth vendors?	Comprehensive, easily understandable documentation freely available	No documentation	Moderate	9	The HL7v3 docs are difficult to digest
1.2	Are HL7v3 messages implementable?					
1.2.1	Are commercial client applications readily available that support the specification?	Readily available COTS and open source products	Bespoke solutions must be developed	Major	16	Very poor selection of client products

1.2.2	Is there a ready mechanism to conformance-test vendor products?	Free, 3rd party, online test facilities continuously available	Conformance tests must be developed	Major	16	There are tools… but HL7v3 testing is not mature and there are few products; no "connectathons"; no generic certification services
1.2.3	Are implementers with expertise in HL7v3 messages readily available?	Large community of implementers available across the country	Few international experts	Major	16	Small group of HL7v3 experts
1.2.4	Can HL7v3 messages be localized and/or extended to reflect requirements specific to South Africa?	Easily extensible	Extensions not permitted; must advocate for mods to the standard	Moderate	6	Tools may be employed to localize HL7v3 message models (MIFs)
1.3	Is the DoH able to provide input to the HL7v3 specifications and influence the evolution of the specification over time?					
1.3.1	Are the standards development processes transparent and open?	Free, open, transparent process	Proprietary standards; no opportunity to participate	Minor	2	The processes are open and transparent; good governance
1.3.2	Is it easy for DoH to participate in the standards organization?	Easy to join; local chapter	Prevented from participating	Minor	6	It is difficult for NDoH to participate in HL7 without a national body
1.3.3	Are there cost barriers to joining the organization?	Free	prohibitively expensive	Minor	6	There are non-trivial costs to participating in HL7
1.4	Is HL7v3 technologically advanced?					
1.4.1	Are new innovations reflected in the specifications?	Always the latest interfaces & technologies	Obsolete technologies	Minor	6	There is a significant "inertia" to the HL7v3 specifications; new technologies are being developed under the FIHR project but these are very nascent
1.4.2	Is the maintenance cycle for specifications very regular?	Continuous updates and upgrades available	Not maintained; unsupported legacy spec	Minor	4	The maintenance cycle is quite regular

1.4.3	Is there a core, underlying data model?	Comprehensive core data model	No model	Moderate	6	There is an underlying message model; from this an underlying data model is implied

G.2 ISO 13606

#	Content	Avg Risk	Max Risk	POV
2	Evaluate **ISO 13606 / OpenEHR** with respect to **suitability as an eHealth interoperability specification** from the point of view of **health system stakeholders**.	**10.0**	**20.0**	Systems Analyst
	Rationale			

		Best Case	Worst Case	Impact	Risk	Notes
2.1	Is ISO 13606 / OpenEHR a scalable option?					
2.1.1	Is the specification based on mature messaging standards?	Very mature	Pre-commercial or beta level products	Moderate	12	Archetype message extracts are not mature; there are few implementations and only one company with tooling that has any degree of field-use
2.1.2	Are high-capacity, commercial ENTERPRISE EERVICE BUS products able to be employed to process the message traffic?	Readily available COTS and open source products	Bespoke solutions must be developed	Major	16	Very thin adoption of archetypes by the vendor community
2.1.3	Are design documents and developer specifications readily available to eHealth vendors?	Comprehensive, easily understandable documentation freely available	No documentation	Moderate	9	Copyrighted documentation is available from ISO; the openEHR community sites have documentation but it is not well curated
2.2	Is ISO 13606 / OpenEHR implementable?					

2.2.1	Are commercial client applications readily available that support the specification?	Readily available COTS and open source products	Bespoke solutions must be developed	Major	20	Practically none
2.2.2	Is there a ready mechanism to conformance-test vendor products?	Free, 3rd party, online test facilities continuously available	Conformance tests must be developed	Major	20	This must be done using bespoke test harnesses
2.2.3	Are implementers with expertise in ISO 13606 / OpenEHR readily available?	Large community of implementers available across the country	Few international experts	Major	20	Very few experts available, worldwide
2.2.4	Can ISO 13606 / OpenEHR archetypes be localized and/or extended to reflect requirements specific to South Africa?	Easily extensible	Extensions not permitted; must advocate for mods to the standard	Moderate	6	using the tooling available from one vendor, archetypes may be readily localized; otherwise must "hand develop" customizations
2.3	Is the DoH able to provide input to the ISO 13606 (or OpenEHR) specifications and influence the evolution of the specification over time?					
2.3.1	Are the standards development processes transparent and open?	Free, open, transparent process	Proprietary standards; no opportunity to participate	Minor	4	Good transparency on openEHR processes; ISO processes require country participation in TC215
2.3.2	Is it easy for DoH to participate in the standards organization?	Easy to join; local chapter	Prevented from participating	Minor	6	It is difficult for NDoH to participate actively in ISO; it is relatively easy to participate in openEHR
2.3.3	Are there cost barriers to joining the organization?	Free	prohibitively expensive	Minor	6	ISO participation is expensive; openEHR is free
2.4	Is ISO 13606 / OpenEHR technologically advanced?					

2.4.1	Are new innovations reflected in the specifications?	Always the latest interfaces & technologies	Obsolete technologies	Minor	4	The technology of openEHR is very up-to-date; the ISO refresh cycle is quite long and so the ISO standard is not regulgarly refreshed
2.4.2	Is the maintenance cycle for specifications very regular?	Continuous updates and upgrades available	Not maintained; unsupported legacy spec	Minor	4	openEHR is continuously maintained; the ISO standard referesh is 5 years
2.4.3	Is there a core, underlying data model?	Comprehensive core data model	No model	Moderate	3	openEHR/13606 has an underlying data model

G.3 IHE

#	Content	Avg Risk	Max Risk	POV
3	Evaluate **IHE Profiles** with respect to **suitability as an eHealth interoperability specification** from the point of view of **health system stakeholders**.	5.5	12.0	Systems Analyst
	Rationale			

		Best Case	Worst Case	Impact	Risk	Notes
3.1	Are IHE Profiles a scalable option?					
3.1.1	Is the specification based on mature messaging standards?	Very mature	Pre-commercial or beta level products	Moderate	3	the ebXML message spec is mature and widely used
3.1.2	Are high-capacity, commercial ENTERPRISE EERVICE BUS products able to be employed to process the message traffic?	Readily available COTS and open source products	Bespoke solutions must be developed	Major	4	many commercial and open source options available

3.1.3	Are IHE profile design documents and developer specifications readily available to eHealth vendors?	Comprehensive, easily understandable documentation freely available	No documentation	Moderate	6	the specifications are very detailed and are freely available from the IHE website
3.2	Are IHE Profiles implementable?					
3.2.1	Are commercial client applications readily available that support the specification?	Readily available COTS and open source products	Bespoke solutions must be developed	Major	8	IHE profiles are broadly supported by commercial and open source products
3.2.2	Is there a ready mechanism to conformance-test vendor products?	Free, 3rd party, online test facilities continuously available	Conformance tests must be developed	Major	4	annual Connectathons are held 3 times in 3 regions: North America, Europe, Asia
3.2.3	Are implementers with expertise in IHE readily available?	Large community of implementers available across the country	Few international experts	Major	12	although IHE expertise is readily available (worldwide) there are not many companies offering such services in South Africa
3.2.4	Can IHE content profiles be localized and/or extended to reflect requirements specific to South Africa?	Easily extensible	Extensions not permitted; must advocate for mods to the standard	Moderate	6	CDA templates make localisation very approachable
3.3	Is the DoH able to provide input to the IHE specifications and influence the evolution of the specification over time?					
3.3.1	Are the standards development processes transparent and open?	Free, open, transparent process	Proprietary standards; no opportunity to participate	Minor	2	IHE processes are free, open and transparent

3.3.2	Is it easy for DoH to participate in the standards organization?	Easy to join; local chapter	Prevented from participating	Minor	6	DoH could readily join IHE -- there are no barriers; there is no local IHE South Africa chapter and no IHE Africa umbrella group (altho such an initiative is in its early stages)
3.3.3	Are there cost barriers to joining the organization?	Free	prohibitively expensive	Minor	2	IHE is free to join
3.4	Is IHE technologically advanced?					
3.4.1	Are new innovations reflected in the specifications?	Always the latest interfaces & technologies	Obsolete technologies	Minor	6	new profiles employ modern standards; legacy profiles are retired and superceded by the new ones
3.4.2	Is the maintenance cycle for specifications very regular?	Continuous updates and upgrades available	Not maintained; unsupported legacy spec	Minor	4	IHE profiles are developed and maintained on an annual cycle
3.4.3	Is there a core, underlying data model?	Comprehensive core data model	No model	Moderate	9	XDS content profiles are based on CDA; the underlying HL7v3-based data model is implied, but is not explicit

G.4 Outcome

G.5 Legend

		Likelihood					
		Best Case	Good	Medium	Poor	Worst Case	Unknown
Impact		1	2	3	4	5	5
Catastrophic	5	5	10	15	20	25	25
Major	4	4	8	12	16	20	20

Moderate	3	3	6	9	12	15	15
Minor	2	2	4	6	8	10	10
Insignificant	1	1	2	3	4	5	5
Unknown	5	5	10	15	20	25	25

High Risk	
Medium Risk	
Low Risk	

G.6 Summary

#	Content	Avg Risk	Max Risk	POV
1	Evaluate HL7v3 messaging with respect to suitability as an eHealth interoperability specification from the point of view of health system stakeholders.	8.2	16.0	Systems Analyst
2	Evaluate ISO 13606 / OpenEHR with respect to suitability as an eHealth interoperability specification from the point of view of health system stakeholders.	10.0	20.0	Systems Analyst
3	Evaluate IHE Profiles with respect to suitability as an eHealth interoperability specification from the point of view of health system stakeholders.	5.5	12.0	Systems Analyst

H APPENDIX H- VERSION OF NIDS USED IN THIS PROJECT

NIDS 2010 data Elements [National Department of Health, 2010c]

No	DE_Name	Data Element definition	Guide for use and Context	DHIS Data Element Group	Collected at PHC Clinics	Collected at CHC/CDC	Collected at Hospitals for Inpatients	Collected at Hospitals for Outpatients	Collected at place of delivery (MOU)
1	PHC headcount 5 years and older	All individual patients five years (60 months) and older attending the facility during the reporting period (usually month) for Primary Healthcare. Each patient is counted once for each day they appear at the facility, regardless of the number of services provided on the day(s) they were seen.	DOTS visits to the facility (NOT DOTS in community/workplace/home) are included in total headcount	Headcount PHC	Yes	Yes	No	No	No
2	PHC headcount under 5 years	All individual patients not yet reached five years (60 months) of age attending the facility during the reporting period (usually month) for Primary Healthcare. Each patient is counted once for each day they appear at the facility, regardless of the number of services provided on the day(s) they were seen.	Include any child given individual service(s) during e.g. a home or crèche visit.	Headcount PHC	Yes	Yes	No	No	No
3	Day patients - total	A day patient is an admitted patient who receives hospital treatment and is admitted and separated from the hospital on the same date (he/she does not occupy a bed at midnight). The definition of a Day Patient excludes patients who were intended to stay overnight but		Headcount Inpatients	No	No	Yes	No	Yes

		left of their own accord, patients who died, or patients who were transferred to another hospital on the first day of their stay.							
4	Inpatient deaths - total	An inpatient death - Total is a death recorded against any admitted patient during the reporting period.		Headcount Inpatients	No	No	Yes	No	Yes
5	Inpatient days - total	Inpatient days - Total is the number of days spent in the institution for all inpatients during the reporting period. Inpatient days exclude lodgers. A day is measured at midnight. Thus: A patient admitted and separated on the same date has zero patient days, and is counted as a DAY patient. A patient separated on the date following the date of admission, has one patient day, and so on. A patient on leave at midnight is not counted as a patient day. A patient admitted and then dying or being transferred out on the same day has zero patient days, but the patient is regarded as an inpatient and is NOT counted as a day patient.		Headcount Inpatients	No	No	Yes	No	Yes
6	Inpatient death under 1 year	An inpatient death under 1 year is a death recorded against any admitted patient under 1 year during the reporting period. This include the death of newborn babies, even if they are not admitted separate from their mothers.		Headcount Inpatients	No	Yes	Yes	No	No

7	Inpatient death under 5 years	An inpatient death under 5 years is a death recorded against any admitted patient under 5 years during the reporting period. This include the death of newborn babies, even if they are not admitted separate from their mothers.		Headcount Inpatients	No	Yes	Yes	No	No
8	Inpatient discharges - total	An Inpatient discharge - Total is any admitted patient who complete a hospital stay and are discharged to their usual residence including home, family, prison, hostel etc. It will include self discharges (patient absconding), but exclude deaths and transfers to other hospitals and step-down facilities.		Headcount Inpatients	No	No	Yes	No	Yes
9	Inpatient discharge under 1 year	An Inpatient discharge under 1 year is any admitted patient under 1 year who complete a hospital stay that includes at least one night and are discharged to their usual residence including home, family, prison, hostel etc. It excludes deaths and transfers to other hospitals and step-down facilities.		Headcount Inpatients	No	Yes	Yes	No	No
10	Inpatient discharge under 5 years	An inpatient death under 5 years is a death recorded against any admitted patient under 5 years - including those under 1 year - during the reporting period. This include the death of new-born babies, even if they are not admitted separately from their mothers.		Headcount Inpatients	No	Yes	Yes	No	No

11	Inpatient transfers out - total	A Inpatient Transfer Out is an admitted patient in the hospital who is directed or physically transferred to another hospital for immediate admission there. It excludes patients referred to a primary healthcare clinic, community health centre or any other primary healthcare facility. It also excludes patients referred to other hospitals for a specialist OPD visit and similar.		Headcount Inpatients	No	No	Yes	No	Yes
12	Inpatient transfer out under 1 year	The number of inpatients under 1 year transferred to another hospital during the reporting period.		Headcount Inpatients	No	Yes	Yes	No	No
13	Inpatient transfer out under 5 years	The number of inpatients under 5 years transferred to another hospital during the reporting period. This includes those under 1 year, even if they are captured separately.		Headcount Inpatients	No	Yes	Yes	No	No
14	Emergency total headcount	All patients attending the casualty/emergency/trauma unit in a facility with conditions requiring emergency treatment. Typical examples are assaults, gunshots, motor vehicle accidents, rape cases, strokes and cardiac arrests, drowning, poisoning, patients in shock.	Do not count non-emergency cases that attend the Casualty department after hours when OPD is closed. Non-emergency cases should be couted as one of the OPD General Clinic data elements (new cases with or without referral letters or follow-up cases)	Headcount OPD	No	No	No	Yes	No
15	OPD headcount - follow-up visit	A headcount of all outpatients attending an outpatient clinic for a follow-up visit for an existing condition. This would include visits to Service Groups like Physiotherapist, Dietitian, X-rays, etc - as well as		Headcount OPD	No	No	Yes	Yes	No

		previous ward attenders returning to the hospital for check-up.							
16	OPD headcount - new case not referred	A headcount of all outpatients attending an outpatient clinic, seeking medical attention for a condition for the first time at this facility, without being referred from a PHC facility or doctor (including General Practitioners).		Headcount OPD	No	No	No	Yes	No
17	OPD headcount - new case referred	A headcount of all outpatients attending an outpatient clinic, seeking medical attention for a condition for the first time at this facility, that was seen in a PHC facility or by a doctor (including General Practitioners) and have a referral letter from the PHC facility or doctor.		Headcount OPD	No	No	No	Yes	No
18	Usable beds - total	Usable beds are beds actually available for use within the facility (regardless of whether they are occupied by a patient or lodger). Include acute care beds, chronic care beds, maternity beds for antenatal and postnatal care, surgical days beds, and temporary beds. Exclude delivery beds, surgical tables, recovery trolleys, cots for normal neonates (well baby cots), stretchers, chairs and recliners (e.g. as used for renal dialysis patients etc.).		Utilisation	No	No	Yes	No	Yes

19	CHCs/CDCs with resident doctor - total	The number of CHCs or CDCs in the province with at least one full-time doctor		Management	No	Yes	No	No	No
20	CHCs/CDCs - total	The total number of CHCs or CDCs in the province		Management	No	Yes	No	No	No
21	Fixed clinics supported by a doctor at least once a week - total	The number of fixed clinics open at least 4 days per week for at least 8 hours per day where a doctor is supporting clinical services at least once per week		Management	Yes	Yes	No	No	No
22	Fixed clinics - total	The total number of fixed clinics in the province open at least 4 days per week for at least 8 hours per day		Management	Yes	Yes	No	No	No
23	Doctor clinical work days	The number of actual work days by doctors, irrespective of rank or specialty, used to perform clinical services in the facility during the reporting period (usually month). One actual work day is normally equivalent to an 8-hour shift (40 hours)	This figure should include ONLY clinical work (i.e. handling patients/clients), including normal administrative work related to patients/clients. Paid days related to e.g. training courses, meetings and other administrative issues.	Management	Yes	Yes	No	No	No
24	PHC case seen by Professional Nurse	A patient/client (child or adult) seen by a professional nurse for a Primary Healthcare service		Management	Yes	Yes	No	No	No
25	Professional Nurse clinical work days	The number of actual work days by Professional Nurses, irrespective of rank, used to perform clinical services in the facility during the reporting period (usually month). One actual work day is normally equivalent to an 8-hour shift (40 hours).	Do not confuse this data element with `Clinical days open during month` - the two would only be equal when there is only ONE nurse in the facility. Only days PRIMARILY used to handle patients are included, NOT days primarily used for e.g. training courses	Management	Yes	Yes	No	No	No

26	PHC case seen by doctor	A patient/client (child or adult) seen by a doctor for a Primary Healthcare curative service (diagnosis and treatment)	This data element should be collected in all PHC facilities with full- or part-time doctors	Management	Yes	Yes	No	No	No
27	Supervisor visit this month	The number of fixed PHC facility visited by a dedicated clinic supervisor, who performs a visit according to the clinic supervision manual	Dropping in for tea, delivering mail, and/or delivering drugs and supplies do NOT qualify as a supervisor visit, even when done by the supervisor. This data element will always be a 0 (no visit this month) or a 1 (one or more visits this month)	Management	Yes	Yes	No	No	No
28	Child under 5 years weighed	A child weighed and the weight plotted onto the Road to Health Card/Booklet, the patient folder and a relevant register for the first time this month	All children under five years should be weighed whenever visiting a facility, but the child should be COUNTED as weighed only once per month even if they come more frequently (e.g. for a follow-up visit).	Child Health	Yes	Yes	No	No	No
29	Diarrhoea with dehydration under 5 years - death	Children being diagnosed for diarrhoea with severe or mild dehydration, admitted as an inpatient, and dying during the stay.		Child Health	No	No	Yes	No	No
30	Diarrhoea with dehydration under 5 years - admitted	Children being diagnosed for diarrhoea with severe or mild dehydration and admitted as an inpatient.		Child Health	No	No	Yes	No	No

31	Diarrhoea with dehydration under 5 years - new ambulatory	The number of children with diarrhoea presenting with severe or mild dehydration. Diarrhoea occurs when stools contain more water than normal. Mothers usually know whether their children have diarrhoea. Dehydration is present when a diarrhoea is accompanied by two of the following signs: lethargic or unconscious, sunken eyes, not able to drink or drinking poorly or drinking eagerly , skin pinch goes back very slowly, restless / irritable, and or thirsty. `Ambulatory` means that the patient is able to walk (or equivalent condition for infants not yet walking) as opposed to bedridden.	The child is only counted the first time it presented with the current diarrhoea at the facility (new case). Follow-up visits for the same episode of diarrhoea should not be counted here.	Child Health	Yes	Yes	No	Yes	No
32	Diarrhoea under 5 years - new	Sum of Diarrhoea with dehydration under 5 years - new ambulatory and Diarrhoea without dehydration under 5 years - new ambulatory		Child Health	Yes	Yes	No	Yes	No
33	Diarrhoea without dehydration under 5 years - new ambulatory	The number of children with diarrhoea with NO visible dehydration. Diarrhoea occurs when stools contain more water than normal. Mothers usually know whether their children have diarrhoea. Diarrhoea with NO visible dehydration is present when the child has diarrhoea with not enough signs to classify as severe or mild dehydration. `Ambulatory` means that the patient is able to walk (or equivalent condition for infants not yet walking) as opposed to	The child is only counted the first time it presented with the current diarrhoea at the facility (new case). Follow-up visits for the same episode of diarrhoea should not be counted here.	Child Health	Yes	Yes	No	Yes	No

		bedridden.							
34	Not gaining weight under 5 years	A child under 5 years that has not gained weight compared to the weight recorded at least one month earlier on the Road-to-Health Card/Booklet	All children under five years should be weighed when visiting a clinic, but the child should be recorded only ONCE PER MONTH even if they come more frequently (e.g. for a follow-up visit).	Child Health	Yes	Yes	No	No	No
35	Pneumonia under 5 years - new ambulatory	The number of children with pneumonia. Pneumonia is defined as cough or difficult and fast breathing and any one of the following general danger signs: child unable to drink or breastfeed, child vomits everything, child has convulsions during this illness, child is lethargic or unconscious or chest drawing or stridor in a calm child. The definition of fast breathing depends on the age of the child: age 1 week up to 2 months: 60 breaths per minute or more = fast breathing age 2 months up to 12 months: 50 breaths per minute or more age 12 months up to 5 years: 40 breaths per minute or more	The child should be counted only for the first visit presenting with pneumonia. Follow-up visits for the same episode of pneumonia should not be counted here.	Child Health	Yes	Yes	No	Yes	No
36	Pneumonia under 5 years - admitted	Children being diagnosedwith Pneumonia and admitted as an inpatient.		Child Health	No	No	Yes	No	No

37	Pneumonia under 5 years - death	Children being diagnosed with pneumonia, admitted and then died as an inpatient.		Child Health	No	No	Yes	No	No
38	Severe malnutrition under 5 years - death	A child under 5 years found to weigh less than 60% of Estimated Weight for Age (EWA), or to suffer from Marasmus, Kwashiorkor, or similar, EXCLUDING new-born babies, that were admitted and then died as an inpatient. Severe malnutrition might also be denoted as CLINICALLY malnourished.		Child Health	No	No	Yes	No	No
39	Severe malnutrition under 5 years - new ambulatory	The weight-for-age chart in the Road-to-Health Card/Booklet shows body-weight relative to age in comparison to the median (0-line). A child whose weight-for-age is below the -3 line is severely underweight. Clinical signs of Marasmus and/or Kwashiorkor might be observed.	Only count each case when encountered for the FIRST time during that episode - the child must NOT be counted again during repeat visits. Since such cases might be referred to a hospital, the referral hospital should NOT count cases referred	Child Health	Yes	Yes	No	Yes	No
40	Severe malnutrition under 5 years - admitted	A child under 5 years found to weigh less than 60% of Estimated Weight for Age (EWA), or to suffer from Marasmus, Kwashiorkor, or similar, EXCLUDING new-born babies, that were admitted. Severe malnutrition might also be denoted as CLINICALLY malnourished.		Child Health	No	No	Yes	No	No

41	Underweight for age under 5 years - new case	he weight-for-age chart in the Road-to-Health Card/Booklet shows body-weight relative to age in comparison to the median (0-line). A child whose weight-for-age is below the -2 line but above the -3 line is underweight.	Only count each episode ONCE, do NOT count repeat visits for the same episode (incidence!). The child will also be entered into the Malnutrition Register if that is used at the facility. A child previously identified as underweight for age who recovered, but then become underweight again should be counted (new episode).	Child Health	Yes	Yes	No	No	No
42	BCG dose under 1 year	BCG (tuberculosis) vaccine given to a child under 1 year of age - preferably immediately after birth.	All babies/infants receiving BCG should be counted, including babies coming to clinics after home deliveries and babies/infants that got their BCG later than usual due to e.g. temporary shortages of vaccine.	Immunisation	Yes	Yes	Yes	No	Yes
43	DTaP-IPV/Hib 1st dose	DTaP-IPV/Hib (also known as Pentaxim) 1st dose vaccination 1st dose given to a child under one year - preferably at around 6 weeks after birth. This vaccine provides protection against against diphtheria, tetanus, pertussis, poliomyelitis and invasive infections caused by Haemophilus influenzae type b (such as meningitis, septicaemia, cellulitis, arthritis, epiglottitis, pneumopathy and osteomyelitis). The vaccine contains acellular pertussis and inactivated polio vaccine, both of which have been found to be effective and have a better side effect profile.		Immunisation	Yes	Yes	No	No	No

44	DTaP-IPV/Hib 3rd dose	DTaP-IPV/Hib (also known as Pentaxim) 3rd dose given to a child under one year - preferably at around 14 weeks after birth. This vaccine provides protection against against diphtheria, tetanus, pertussis, poliomyelitis and invasive infections caused by Haemophilus influenzae type b (such as meningitis, septicaemia, cellulitis, arthritis, epiglottitis, pneumopathy and osteomyelitis). The vaccine contains acellular pertussis and inactivated polio vaccine, both of which have been found to be effective and have a better side effect profile.		Immunisation	Yes	Yes	No	No	No
45	DTaP-IPV/Hib 4th dose	DTaP-IPV/Hib (also known as Pentaxim) 4th dose vaccination given to a child older than 1 year preferably around 18 months. This vaccine provides protection against against diphtheria, tetanus, pertussis, poliomyelitis and invasive infections caused by Haemophilus influenzae type b (such as meningitis, septicaemia, cellulitis, arthritis, epiglottitis, pneumopathy and osteomyelitis). The vaccine contains acellular pertussis and inactivated polio vaccine, both of which have been found to be effective and have a better side effect profile.		Immunisation	Yes	Yes	No	No	No
46	DTP-Hib 1st dose	DTP-Hib (Diphtheria/Tetanus/Pertussis-		Immunisation	Yes	Yes	No	No	No

		Haemophilus influenzae B) vaccine 1st dose given to a child under one year - preferably at around 6 weeks after birth							
47	DTP-Hib 3rd dose	Hepatitis B vaccine 3rd dose given to a child under one year - preferably at around 14 weeks after birth		Immunisation	Yes	Yes	No	No	No
48	HepB 1st dose	Hepatitis B vaccine 1st dose given to a child under one year - preferably at around 6 weeks after birth		Immunisation	Yes	Yes	No	No	No
49	HepB 3rd dose	Hepatitis B vaccine 3rd dose given to a child under one year - preferably at around 14 weeks after birth		Immunisation	Yes	Yes	No	No	No
50	Immunised fully under 1 year - new	A child who have completed his/her primary course of immunisation before the age of one. A Primary Course includes BCG, OPV 1, DTP-Hib 1 / Pentaxim 1, OPV 2 & 3 + DTP-Hib 2 & 3 / Pentaxim 2 & 3, HepB 1,2 & 3, and 1st measles dose before 1 year.	The child should only be counted ONCE as fully immunised when receiving the last vaccine in the course - usually the 1st measles immunisation - AND there is documentary proof of all required vaccines (e.g. on the Road to Health Card/Booklet).	Immunisation	Yes	Yes	No	No	No
51	Measles 1st dose under 1 year	Measles vaccine 1st dose given to a child under one year of age (preferably at 9 months after birth)	Other doses given to YOUNGER children during an outbreak should NOT be counted here, but 1st doses given to children between 10 and 12 months should be included. Also do not count doses given as part of mass vaccination campaigns.	Immunisation	Yes	Yes	No	No	No
52	Measles 2nd dose	Measles vaccine 2nd dose given to a child above one year of age (preferably at 18 moths)	Do not count doses given as part of mass vaccination campaigns.	Immunisation	Yes	Yes	No	No	No

53	OPV 1st dose	OPV (Poliomyelitis) vaccine 1st dose given to a child under one year, preferably around 6 weeks after birth	Do not count possible repeat doses (e.g. given during large vaccination campaigns), only doses given and noted on the Road-to-Health card.	Immunisation	Yes	Yes	No	No	No
54	OPV 3rd dose	OPV (Poliomyelitis) vaccine 3rd dose given to a child under one year, preferably around 14 weeks after birth	Do not count possible repeat doses (e.g. given during large vaccination campaigns), only routine doses given and noted on the Road-to-Health card/Booklet	Immunisation	Yes	Yes	No	No	No
55	PCV7 1st dose	Pneumococcal (PCV7) vaccine 1st dose given to a child under one year, preferably around 6 weeks after birth.		Immunisation	Yes	Yes	No	No	No
56	PCV7 3rd dose	Pneumococcal (PCV7) vaccine 3rd dose given to a child under one year, preferably around 9 months after birth.		Immunisation	Yes	Yes	No	No	No
57	RV 1st dose	Rota Virus (RV) vaccine 1st dose given to a child under one year, preferably around 6 weeks after birth and NOT later than 14 weeks after birth		Immunisation	Yes	Yes	No	No	No
58	RV 2nd dose	Rota Virus (RV) vaccine 2nd dose given to a child under one year, preferably around 14 weeks after birth and NOT later than 24 weeks after birth		Immunisation	Yes	Yes	No	No	No
59	Td dose at 12 years	Td last booster doses given to children around 12 years of age.	Only include Td doses given routinely, including `mopping up` campaigns, but NOT any doses given as part of mass vaccination campaigns.	Immunisation	Yes	Yes	No	No	No

60	Td dose at 6 years	Td booster dose given to a child around 6 years of age. Note that this replaced DT booster dose at 5 years from February 2008.	Only include DT doses given routinely, including `mopping up` campaigns, but NOT any doses given as part of mass vaccination campaigns.	Immunisation	Yes	Yes	No	No	No
61	Vitamin A supplement to 6-11 months infant	The number of Vitamin A doses, 100,000 units, given once to infants aged at least 6 months and not yet 12 months		Nutrition	Yes	Yes	No	Yes	No
62	Vitamin A supplement to 12-59 months child	Vitamin A doses of 200,000 units given to each child every six months from 12 to 59 months		Nutrition	Yes	Yes	No	Yes	No
63	Vitamin A supplement to woman within 8 weeks after delivery	The number of Vitamin A doses, 200,000 units, given to women immediately after delivery and not later than 8 weeks after delivery	Each newly delivered woman should receive a single dose of 200,000 units of Vitamin A, preferably immediately after delivery and not later than 8 weeks after delivery.	Nutrition	Yes	Yes	No	Yes	No
64	Antenatal 1st visit	Sum of Antenatal 1st visit before 20 weeks and Antenatal 1st visit 20 weeks or later		Reproductive Health	Yes	Yes	No	Yes	No
65	Antenatal follow-up visit	Any antenatal visit other than a first antenatal visit.	Count any follow-up antenatal visit where an antenatal protocol is followed, whether the woman is receiving other services (e.g. curative) or not.	Reproductive Health	Yes	Yes	No	Yes	No
66	Antenatal 1st visit 20 weeks or later	A first visit by a pregnant woman to a health facility for the primary purpose of receiving antenatal care, often referred to as a `booking visit`, that occur at 20 weeks after conception or later. The actual protocol followed during the visit might vary, but it should	A visit purely to take a pregnancy test should NOT be counted as a first antenatal visit.	Reproductive Health	Yes	Yes	No	Yes	No

		include relevant screening procedures, laboratory tests (e.g. for syphilis), and counselling / health promotion (the latter often done in groups).							
67	Antenatal 1st visit before 20 weeks	A first visit by a pregnant woman to a health facility for the primary purpose of receiving antenatal care, often referred to as a `booking visit`, that occur before 20 weeks after conception. The actual protocol followed during the visit might vary, but it should include relevant screening procedures, laboratory tests (e.g. for syphilis), and counselling / health promotion (the latter often done in groups).	A visit purely to take a pregnancy test should NOT be counted as a first antenatal visit. Maternal health.	Reproductive Health	Yes	Yes	No	Yes	No
68	Cervical smear in woman 30 years and older	A cervical (pap) smear done for women between thirty and sixty years for screening purposes ccording to the national policy of screening all women in this age category every 10 years. Diagnostic smears or repeat smears are NOT included, and the smear must be of sufficient quality to enable screening (e.g. include endo-cervical cells).		Reproductive Health	Yes	Yes	No	No	No

69	Male condoms distributed	Male condoms from the stock of the facility which were given out at distribution points at the facility or elsewhere in the community (i.e. campaigns, non-traditional outlets etc.).	Condoms should preferably be counted per box or per carton once they leave the store of the facility, i.e by using the local stock register. Another method would be to count stock at the beginning of each reporting period (for instance month).	Reproductive Health	Yes	Yes	No	No	Yes
70	IUCD inserted	Intra Uterine Contraceptive Device (IUCD) inserted into a woman	IUCDs are relatively uncommon in developing countries, and the numbers are small compared to e.g. injectable or oral contraceptives. Facility numbers above 10 during one reporting period should be verified.	Reproductive Health	Yes	Yes	No	No	No
71	Medroxyprogesterone injection	Medroxyprogesterone acetate (Depo Provera / Petogen) injection given to a woman between 15 and 45 years. This injection provides contraceptive protection for 3 months	Ensure that Medroxyprogesterone and Norethisterone enantate injections are not mixed up.	Reproductive Health	Yes	Yes	No	No	No
72	Norethisterone enanthate injection	Any Norethisterone enantate (Nuristerate) injection given to a woman between 15 and 45 years. This injection provides contraceptive protection for 2 months	Ensure that Medroxyprogesterone and Norethisterone enantate injections are not mixed up.	Reproductive Health	Yes	Yes	No	No	No

73	Oral pill cycle	A packet (cycle) of oral contraceptives issued to a woman between 15 and 45 years, each containing pills for one cycle (28 days)	Count each packet issued. This would normally range from around 3 given to e.g. new/young users that need closer monitoring for side effects and up to 6 given to older women that have used pills for many years without known side-effects.	Reproductive Health	Yes	Yes	No	No	No
74	Sterilisation - female	Any planned operative procedure that results in a woman being sterilised	Count each case only in the facility where the operation is actually performed.	Reproductive Health	No	Yes	Yes	No	Yes
75	Sterilisation - male	Any planned operative procedure that results in a man being sterilised (also called vasectomy)	Count each case only in the facility where the operation is actually performed.	Reproductive Health	No	Yes	Yes	No	No
76	Tet Tox 2nd/Booster dose to pregnant woman	The second Tet Tox dose given to a pregnant women. Women who have proof of being fully immunised during a previous pregnancy are considered fully immunised after receiving one booster dose of tetanus toxoid during this pregnancy. All others are regarded as fully immunised against Tetanus Toxoid after 2 doses.		Reproductive Health	Yes	Yes	No	Yes	No
77	Termination of Pregnancy performed	A Termination of Pregnancy performed under safe conditions in a health facility	Count each case ONLY in the facility where the termination is actually performed. PHC facilities that want to count clients counselled and referred elsewhere for a TOP should use the data element `Referred for Termination of Pregnancy`.	Reproductive Health	No	Yes	Yes	No	No

78	Antenatal client on HAART at delivery	HIV positive antenatal client who was on lifelong ART at delivery in facility providing delivery services (including BBAs)		PMTCT	Yes	Yes	Yes	No	No
79	Antenatal client eligible for HAART	HIV positive antenatal client with a CD4 count under the specified threshold and/or a WHO staging of 4.		PMTCT	Yes	Yes	No	Yes	No
80	Baby initiated on HAART (under 18 months)	Baby tested PCR positive under the age of 18 months who was initiated on HAART.	This may be viewed as an ART data element but is crucial for monitoring effective implementation of the PMTCT program.	PMTCT	Yes	Yes	No	Yes	No
81	Baby eligible for HAART	HIV positive baby under 18 months with a CD4 count under the specified threshold and/or a WHO staging of 4.		PMTCT	Yes	Yes	No	Yes	No
82	Antenatal client on HAART at 1st visit	HIV positive antenatal client who is on HAART at the time of her first antenatal visit.	This element indicates the women who fell pregnant while on HAART.	PMTCT	Yes	Yes	No	Yes	No
83	Antenatal client HIV re-test positive at 32 weeks or later	Antenatal client who was re-tested positive for HIV at 32 weeks gestation or later after testing negative for HIV during an earlier antenatal visit.	Count ONLY once on the day the HIV test was confirmed positive.	PMTCT	Yes	Yes	No	Yes	No
84	Antenatal client on AZT before labour	HIV positive antenatal client (NOT on HAART) who was on AZT for any period during her current pregnancy before going into labour.	Although the antenatal client received AZT during antenatal care, this data should be collected at point of delivery only and NOT during antenatal care.	PMTCT	No	Yes	Yes	No	No

85	Antenatal client Nevirapine taken during labour	HIV positive antenatal client (NOT on HAART) who took Nevirapine during labour. This data should be collected at point of delivery only and NOT during antenatal care.	Even if the antenatal client received Nevirapine at a primary healthcare facility during antenatal care, ONLY clients who took Nevirapine during labour, should be counted for this element.	PMTCT	No	Yes	Yes	No	No
86	Live birth to HIV positive woman	Live birth to HIV positive women. Includes babies born before arrival (BBA) at health facilities and babies born outside health facilities. Live birth is a baby, irrespective of the duration of the pregnancy, who breathes or shows any other signs of life after birth. Women with unknown HIV status at delivery and tested during or after delivery and found HIV positive should also be counted.		PMTCT	No	Yes	Yes	No	No
87	Baby given Nevirapine within 72 hours after birth	Baby born to HIV positive woman who received Nevirapine within 72 hours after birth. Also count babies not delivered in health facilities (BBAs and known home deliveries) who were given Nevirapine within 72 hours after birth.		PMTCT	No	Yes	Yes	No	No
88	Baby initiated on Co-Trimoxazole around 6 weeks	Baby born to HIV positive woman who was initiated on Co-Trimoxazole around 6 weeks after birth to prevent opportunistic infections		PMTCT	Yes	Yes	No	Yes	No

89	Baby PCR test around 6 weeks	Baby born to HIV positive woman who was PCR tested for the first time around 6 weeks after birth. Babies PCR tested for the first time between 4 and 12 weeks must be included. Do NOT include repeat tests.		PMTCT	Yes	Yes	No	Yes	No
90	Baby PCR test positive around 6 weeks	Baby born to HIV positive woman who tested PCR positive around 6 weeks after birth for the first PCR test. Babies PCR tested for the first time between 4 and 12 weeks must be included.	Count ONLY once on the day the HIV test was confirmed positive.	PMTCT	Yes	Yes	No	Yes	No
91	Baby HIV antibody test at 18 months	Baby born to HIV positive woman who was tested positive for HIV antibodies 18 months after birth.	Count ONLY once on the day the HIV test was confirmed positive.	PMTCT	Yes	Yes	No	Yes	No
92	Antenatal client known HIV positive but NOT on HAART at 1st visit	Antenatal client with known HIV positive status but not on HAART at her first antenatal visit. In the absence of documented proof, verbal confirmation of HIV status is acceptable and a CD4 count test must be done.		PMTCT	Yes	Yes	No	Yes	No
93	Baby HIV antibody test positive at 18 months	Baby born to HIV positive woman who was tested positive for HIV antibodies 18 months after birth.	Count ONLY once on the day the HIV test was confirmed positive.	PMTCT	Yes	Yes	No	Yes	No
94	Antenatal client HIV 1st test	Antenatal client eligible for HIV testing (NOT known positive) who was tested for the first time during her current pregnancy. Antenatal clients should preferably be tested at		PMTCT	Yes	Yes	No	Yes	No

		first antenatal visits but may be tested for the first time at a subsequent follow-up visit.							
95	Antenatal client HIV 1st test positive	Antenatal client who tested positive for the first HIV test done during her current pregnancy.	Count ONLY once on the day the HIV test was confirmed positive.	PMTCT	Yes	Yes	No	Yes	No
96	Antenatal client CD4 1st test	HIV positive antenatal client (NOT on HAART) who was CD4 tested for the first time during her current pregnancy (preferably on the same day her HIV status was confirmed positive).	All antenatal clients with known HIV positive status and NOT on HAART should have a CD4 count test done, preferably at the first antenatal visit.	PMTCT	Yes	Yes	No	Yes	No
97	Antenatal client initiated on AZT	HIV positive antenatal client (NOT on HAART) who was initiated on AZT at any stage during her current pregnancy before going into labour. This data should be collected during antenatal care only and NOT at point of delivery.		PMTCT	Yes	Yes	No	Yes	No
98	Antenatal client initiated on HAART	HIV positive antenatal client who was initiated on HAART during her current pregnancy.	This may be viewed as an ART data element but is crucial for monitoring effective implementation of the PMTCT program.	PMTCT	Yes	Yes	No	Yes	No
99	Antenatal client HIV re-test at 32 weeks or later	Antenatal client who was re-tested for HIV at 32 weeks gestation or later after testing negative for HIV during an earlier antenatal visit.	Each ANC client whose first HIV test was negative should be re-tested at 32 weeks or later to detect late sero-converters. The period between the first test and re-test should be at least 6 weeks. If the 32 week re-test result is not available on the ANC	PMTCT	Yes	Yes	No	Yes	No

100	Caesarean section in facility	A Caesarean Section delivery in facility is the removal of the foetus, placenta and membranes by means of an incision through the abdominal and uterine walls - obviously only done in health facilities by doctors. This be further divided into i) Caesarean section in labour and ii) Caesarean section, no labour also known as an elective Caesarean section.		Maternal Health	No	No	Yes	No	Yes
101	Delivery in facility under 18 years	Delivery in facility to woman under 18 years is the number of women delivering in a health facility under the supervision of trained medical/nursing staff, and where the mother is under 18 years on the day of delivery.		Maternal Health	No	Yes	Yes	No	Yes
102	Delivery in facility 35 years and older	Delivery in facility to woman 35 years and older is the number of women delivering in a health facility under the supervision of trained medical/nursing staff, and where the mother is 35 years and older on the day of delivery.		Maternal Health	No	Yes	Yes	No	Yes
103	Delivery in facility	Delivery in facility is women who delivered in a health facility under the supervision of trained medical/nursing staff. Note that this number can be less than the Total Births in facility if multiple births occur.		Maternal Health	No	Yes	Yes	No	Yes

104	Inpatient death - early neonatal	An early neonatal death is a death to a live born baby within 7 completed days after birth. The neonatal period is exactly four weeks or 28 completed days, with the first 7 days called the `early` neonatal period and the period from 8-27 completed days the `late` neonatal period. The weight range, if used, relates to the weight of the baby immediately after delivery. The most common ranges are under 500g, 500-999g, 1000-1499g, 1500-2499g (or 1500-1999g and 2000-2499g), and 2500g and above.		Maternal Health	No	Yes	Yes	No	Yes
105	Live birth in facility under 2500g	Live birth is the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of the pregnancy, which, after such separation, breathes or shows any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of involuntary muscles, whether or not the umbilical cord has been cut or the placenta is attached. The weight range relates to the weight of the baby immediately after delivery. The most common ranges are under 2500g versus 2500g and over, but the low weight range might be sub-divided further.		Maternal Health	No	Yes	Yes	No	Yes

106	Live birth in facility	Live birth is the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of the pregnancy, which, after such separation, breathes or shows any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of involuntary muscles, whether or not the umbilical cord has been cut or the placenta is attached.		Maternal Health	No	Yes	Yes	No	Yes
107	Inpatient death - late neonatal	A late neonatal death is a death to a live born baby between 8 and 28 completed days after birth. The neonatal period is exactly four weeks or 28 completed days, with the first 7 days called the `early` neonatal period and the period from 8-28 completed days the `late` neonatal period. The weight range, if used, relates to the weight of the baby immediately after delivery. The most common ranges are under 500g, 500-999g, 1000-1499g, 1500-2499g (or 1500-1999g and 2000-2499g), and 2500g and above.		Maternal Health	No	Yes	Yes	No	Yes
108	Maternal death in facility	The number of women who die while in a facility as a result of child-bearing, during pregnancy or within 42 days of delivery or termination of pregnancy		Maternal Health	No	Yes	Yes	No	Yes
109	Normal delivery in facility	A normal delivery in facility is a vaginal delivery, including vaginal breech, taking place in		Maternal Health	No	Yes	Yes	No	Yes

		a health facility under the supervision of trained medical/nursing staff.							
112	Still birth in facility	Still birth resulting from a delivery in a facility under supervision. Still birth is death prior to the complete expulsion or extraction from its mother of a product of conception; the death is indicated by the fact that after such separation the foetus does not breathe or show any evidence of life, such as beating of the heart, pulsation of the umbilical cord or definite movement of the involuntary muscles. Still births should only be counted when the foetus is of 26 or more weeks gestational age and/or weighs 500g or more. A still-born foetus might have been dead for a while (maserated) or died just before or during expulsion or extraction (fresh) from its mother. The weight range relates to the weight of the baby immediately after delivery. The most common ranges are 500-999g, 1000-1499g, 1500-2499g (or 1500-1999g and 2000-2499g), and 2500g and above.		Maternal Health	No	Yes	Yes	No	Yes
113	Total births in facility	Sum of Live births in facility and Still births in facility		Maternal Health	No	Yes	Yes	No	Yes
110	Postnatal care baby within 6 days after birth	The number of postnatal visits to a facility, or a postnatal home visit by facility staff, by a baby within 6 days after delivery, and the purpose of the	Count only the first visit after delivery. The postnatal protocol should be followed.	Maternal Health	Yes	Yes	No	Yes	Yes

		visit is for a postnatal check-up							
111	Postnatal care mother within 6 days after delivery	The number of postnatal visits to a facility, or a postnatal home visit by facility staff, by a mother within 6 days after delivery, and the purpose of the visit is for a postnatal check-up	Count only the first visit after delivery. The postnatal protocol should be followed.	Maternal Health	Yes	Yes	No	Yes	Yes
114	Mental health visit 18 years and older	Any visit of a client who is 18 years or older with identified mental health problems, and where this is the primary reason for the consultation. Cases counted relate to problems that can affect an individual psychologically, emotionally and/or physically and where there seems to be a need for mental health intervention (e.g. counselling, psychotropic medication or referral to a mental health worker/service). Typical examples are mood disorders, anxiety, post traumatic stress disorder, schizophrenia, organic brain disease, dementia, substance abuse disorders, psychosis, mental handicap, attention defect disorders and enuresis. Bereavement, psychosomatic problems, relationship difficulties, stress and burn out, adjustment problems, behavioural problems in children and adolescents or any other problem that		Mental Health	Yes	Yes	No	No	No

		seriously affect the person psychologically, emotionally and/or physically would also qualify.							
115	Mental health visit under 18 years	Any visit of a client who is younger then 18 years, with identified mental health problems, and where this is the primary reason for the consultation. Cases counted relate to problems that can affect an individual psychologically, emotionally and/or physically and where there seems to be a need for mental health intervention (e.g. counselling, psychotropic medication or referral to a mental health worker/service). Typical examples are mood disorders, anxiety, post traumatic stress disorder, schizophrenia, organic brain disease, dementia, substance abuse disorders, psychosis, mental handicap, attention defect disorders and enuresis. Bereavement, psychosomatic problems, relationship		Mental Health	Yes	Yes	No	No	No

		difficulties, stress and burn out, adjustment problems, behavioural problems in children and adolescents or any other problem that seriously affect the person psychologically, emotionally and/or physically would also qualify.							
116	Dental visit	All individual patients attending the Oral Health facility/unit during the reporting period. Each patient is counted once for each day they appear, regardless of the number of services provided on the day(s) they were seen.		Oral Health	No	Yes	No	Yes	No
117	Tooth extraction	The actual number of teeth extracted during the month by an Oral Health worker.		Oral Health	No	Yes	No	Yes	No
118	Tooth restoration	The actual number of teeth that were restored by an Oral Health worker		Oral Health	No	Yes	No	Yes	No
119	Tooth fissure sealant application (6-12 years)	The actual number of 6 and 12 year old children that received fissure sealant applications on their first and second permanent molar teeth by an Oral Health worker.		Oral Health	No	Yes	No	Yes	No
120	Asthma case 18 years and older - new	A patient diagnosed with asthma (this facility or any other facility like a hospital) 18 years and older, put on treatment for asthma according		Chronic care	Yes	Yes	No	No	No

		the protocol and entered in the chronic register for the first time at this facility.							
121	Asthma case under 18 years - new	A patient diagnosed with asthma (this facility or any other facility like a hospital) under 18 years, put on treatment for asthma according the protocol and entered in the chronic register for the first time at this facility.		Chronic care	Yes	Yes	No	No	No
122	Diabetes mellitus case put on treatment - new	A client diagnosed with diabetes mellitus (in this facility or any other facility like a hospital) for the first time and put on treatment		Chronic care	Yes	Yes	No	No	No
123	Diabetes-related amputation case	Number of patients with amputations resulting from diabetes related complications		Chronic care	No	No	Yes	No	No
124	Epilepsy case 18 years and older - new	A patient diagnosed with epilepsy (this facility or any other facility like a hospital) 18 years and older, put on treatment for epilepsy according the protocol and entered in the chronic register for the first time at this facility.		Chronic care	Yes	Yes	No	No	No
125	Epilepsy case under 18 years - new	A patient diagnosed with epilepsy (this facility or any other facility like a hospital) under 18 years, put on treatment for epilepsy according to protocol and entered in the chronic register for the first time at this facility.		Chronic care	Yes	Yes	No	No	No

126	High risk diabetes case - new	Patient diagnosed with diabetes that has one ore more of the following conditions that puts the patient in the high risk category: - Obese (BMI >30) - Smoking - Dyslipidaemia (elevated blood cholestrol) - Hypertension	Patients that fall in the high risk category should be reported as `Diabetes case put on treatment new` as well as `High risk diabetes case - new`	Chronic care	Yes	Yes	No	No	No
127	High risk hypertension case - new	Patient diagnosed with hypertention that has one ore more of the following conditions that puts the patient in the high risk cate gory: - Obese (BMI >30) - Smoking - Dyslipidaemia (elevated blood cholestrol) - Diabetes	Patients that fall in the high risk category should be reported as `Hypertension case put on treatment - new` as well as `High risk hypertension case - new`	Chronic care	Yes	Yes	No	No	No
128	Hypertension case put on treatment - new	A client diagnosed with hypertension (in this facility or any other facility like a hospital) and put on treatment for the first time		Chronic care	Yes	Yes	No	No	No
129	Cataract surgery with IOL 18 years and older performed	Cataract surgery with intra-occular lens implant 18 years and older		Eye care	No	No	Yes	No	No
130	Cataract surgery with IOL under 18 years performed	Cataract surgery with intra-occular lens implant under the age of 18 years		Eye care	No	No	Yes	No	No
131	Cataract surgery without IOL 18 years and older planned	Cataract surgery without intra-occular lens implant 18 years and older.		Eye care	No	No	Yes	No	No
132	Cataract surgery without IOL under 18 years performed	Cataract surgery without intra-occular lens implant under the age of 18 years		Eye care	No	No	Yes	No	No
133	Diabetic laser follow-up treatment	Diabetic laser follow-up treatment performed		Eye care	No	No	Yes	No	No

134	Diabetic laser treatment initiated	Diabetic laser treatment performed for the first time		Eye care	No	No	Yes	No	No
135	Glaucoma surgery 18 years and older	Glaucoma surgery 18 years and older		Eye care	No	No	Yes	No	No
136	Glaucoma surgery under 18 years	Glaucoma surgery under 18 years		Eye care	No	No	Yes	No	No
137	Expenditure - total	Total expenditure in the facility or administrative unit - often referred to as `cost centre` - for the reporting period.		Finance	No	No	No	No	No
138	Birth defects case - mother 35 years and older	Birth defect case where mother was 35 years and older. Birth Defects is an abnormality of body structure or function that is present (not necessarily detectable at birth). The cause may be either genetic or environmental.	The child is only reported the first time the birth defect is diagnosed.	Human Genetics	No	Yes	Yes	No	Yes
139	Birth defects case - mother under 18 years	Birth defects with mother under 18 years. Birth Defects is an abnormality of body structure or function that is present (not necessarily detectable at birth). The cause may be either genetic or environmental. Down Syndrome, neural tube defects, Albinism, club feet.	The child is only reported the first time the birth defect is diagnosed.	Human Genetics	No	Yes	Yes	No	Yes
140	Child with common priority Birth Defects	Birth Defects is an abnormality of body structure or function that is present (not necessarily detectable at birth). The cause may be either genetic or environmental. Common priority birth defects include: Down Syndrome, neural tube defects, Albinism, club feet.		Human Genetics	No	Yes	Yes	No	Yes

141	STI treated - new episode	A new episode of a symptomatic Sexually Transmitted Infection (STI) treated according to the Syndromic Approach.	The data element counts new episodes, not patients. Count ONLY NEW episodes of a SYMPTOMATIC STI.	STI	Yes	Yes	No	Yes	No
142	STI partner treated - new	Any patient/client that presented with a notification for STI treatment and received treatment for a suspected or confirmed STI. ONLY the FIRST visit after a notification is counted	The patient/client can be symptomatic or asymptomatic. If the patient presents with a new episode of a symptomatic STI, the new episode must ALSO be counted under `STI treated – new episode`. If the client is asymptomatic, NO tally should be made	STI	Yes	Yes	No	Yes	No
143	Sputum results received within 48 hours	The number of sputum samples where the result was received by the facility within 48 hours of sending the sample		TB control	Yes	Yes	No	No	No
144	All sputum samples sent	All sputum samples sent to the lab	Include all samples, whether they are samples from suspected cases or samples from patients already on treatment.	TB control	Yes	Yes	No	No	No
145	Suspected TB case with sputum sent	Any case where one or more sputum specimens were sent to the laboratory with the possible diagnosis of tuberculosis	Each patient must be counted only ONCE, regardless of the number of sputum samples sent. Do NOT include cases that are culture positive but smear negative and where treatment is started.	TB control	Yes	Yes	No	No	No
146	Suspected TB case smear positive	Any case where one or more sputum specimens of a patient were sent to the laboratory and the result of that patient is confirmed as a smear positive Pulmonary TB. It can be a new	Each patient must be counted only ONCE, regardless of the number of sputum samples sent. Do NOT include cases that are culture positive but smear	TB control	Yes	Yes	No	No	No

		or a retreatment case	negative.						
147	Suspected TB case smear positive - treatment start	Suspected TB case smear positive - treatment start	Any case where a patient confirmed as a smear positive Pulmonary TB is starting treatment. It can be a new or a retreatment case	TB control	Yes	Yes	No	No	No
148	Complaint received	Total number of complaints received during the reporting period		Quality Control	Yes	Yes	Yes	Yes	Yes
149	Complaint resolved	Total number of complaints resolved within 25 days during the reporting period		Quality Control	Yes	Yes	Yes	Yes	Yes
150	Nosocomial infection - new	Nosocomial infections (also known as hospital- aquired infection) are infections which are a result of treatment in a hospital, but not secondary to the patient's original condition. Infections are considered nosocomial if they first appear 48 hours or more after hospital admission or within 30 days after discharge.		Quality Control	No	No	Yes	No	No
151	Any tracer item drug stock-out at fixed facility	Whether any item on the tracer item list in current use have been out of stock and ANY time during the reporting period		Stock outs	Yes	Yes	Yes	No	Yes
152	Any ARV drug stock out at fixed facility	Whether any Anti-Retro-Viral drugs have been out of stock at ANY time during the reporting period		Stock outs	Yes	Yes	Yes	No	Yes
153	Any TB drug stock out at fixed facility	Whether any Tuberculosis drugs have been out of stock at ANY time during the reporting period		Stock outs	Yes	Yes	Yes	No	Yes

154	Theatre time in minutes	Total number of minutes all theatres were in use in the month. Theatre time is the time in minutes recorded in the theatre register for each theatre case. This excludes time in the recovery room and time spent to clean theatres after each case.		Theatre	No	No	Yes	No	No
155	Theatre 8-hours	The number of theatres operating on normal week-days for 8 hours per day		Theatre	No	No	Yes	No	No
156	Theatre 24-hours	The number of emergency/after hours theatres operating 24 hours per day 7 days per week		Theatre	No	No	Yes	No	No
157	HIV pre-test counselled (excluding antenatal)	All clients that have been pre-test counselled for HIV/AIDS and then offered testing, excluding antenatal clients		VCT	Yes	Yes	Yes	Yes	Yes
158	HIV test positive - new (excluding antenatal)	Any client/patient tested positive for HIV for the first time, excluding antenatal clients		VCT	Yes	Yes	Yes	Yes	Yes
159	HIV client tested (excluding antenatal)	Any client/patient tested for HIV except antenatal clients		VCT	Yes	Yes	Yes	Yes	Yes
160	HIV positive new patient screened for TB	The number of HIV positive clients who have been screened for TB immediately after being diagnosed with HIV for the first time		VCT	Yes	Yes	No	No	No
161	HIV positive new patient with confirmed TB	The number of HIV positive clients who have been screened for TB immediately after being diagnosed with HIV for the first time, and who was confirmed with TB		VCT	Yes	Yes	No	No	No

162	HIV positive adult patient eligible for ART	Eligible to start ART criteria: CD4 count <200cells/mm3 irrespective of clinical stage: All HIV positive patients with CD4 count of <200cells/mm3 excluding TB patients and pregnant women as these patients have different staging criteria. OR CD4 count ≤350cells/mm3: In patients with TB/HIV or All TB patients or pregnant women with CD4 count <350cells/mm3. OR MDR/XDR-TB irrespective of CD4 count.All HIV positive MDR/XDR cases regardless of CD4 count or clinical staging. MDR-TB (Multidrug Resistant TB) describes strains of tuberculosis that are resistant to at least the two main first-line TB drugs - isoniazid and rifampicin. XDR-TB, or Extensive Drug Resistant TB (also referred to as Extreme Drug Resistance) is MDR-TB that is also resistant to three or more of the six classes of second-line drug (WHO). OR WHO stage IV irrespective of CD4 count: HIV Stage 4 is diagnosed if any of the following diseases occur in a HIV positive patient: Unexplained severe wasting, stunting or severe malnutrition	Count only once when CD4 drops below minimum threshold for all categories of patients.	Pre-ART	Yes	Yes	No	Yes	No

		not responding to standard therapy, Pneumocystis pneumonia, Recurrent severe bacterial infections (such as empyema, pyomyositis, bone or joint infection or meningitis but excluding pneumonia), Chronic herpes simplex infection (orolabial or cutaneous of more than one month's duration or visceral at any site), Extrapulmonary tuberculosis, Kaposi sarcoma, Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs), Central nervous system toxoplasmosis (after one month of life), HIV encephalopathy, Cytomegalovirus infection: retinitis or cytomegalovirus infection affecting another organ, with onset at age older than one month, Extrapulmonary cryptococcosis (including meningitis), Disseminated endemic mycosis (extrapulmonary histoplasmosis, coccidiomycosis), Chronic cryptosporidiosis, Chronic isosporiasis, Disseminated non-tuberculous mycobacterial infection, Cerebral or B-cell non-Hodgkin lymphoma, Progressive multifocal leukoencephalopathy, Symptomatic HIV-associated nephropathy or HIV-associated cardiomyopathy, HIV-								

		associated rectovaginal fistula							

163	HIV positive child under 15 years eligible for ART	HIV positive child under 15 years eligible to start ART: Child under 5 years with clinical stage III or IV or CD4 ≤25% orabsolute CD4 count< 750 cells/mm3 OR Child 5-15 years with clinical stage III and IV or CD4 ≤350 cells/mm.	Count only once when CD4 drops below minimum threshold for children 1-15 years as per data element definition	Pre-ART	Yes	Yes	No	Yes	No
164	HIV positive new patient started on Co-trimoxazole prophylaxis	The number of HIV positive clients started for the first time on Co-trimoxazole prophylaxis during the reporting period	Only count clients starting Co-trimoxazole prophylaxis for the first time.	Pre-ART	Yes	Yes	No	No	No
165	HIV positive new patient started on INH prevention therapy	The number of HIV positive clients started on INH prevention therapy for the first time during the reporting period. Criteria for excluding active TB refers to the 4 questions on the TB screening tool:	Only count clients starting INH prevention therapy for the first time.	Pre-ART	Yes	Yes	No	No	No
166	Newly diagnosed HIV positive patient (excluding antenatal client) with Blood drawn for CD4	Blood taken for CD4 count from newly diagnosed HIV positive patients excluding pregnant women (counted under PMTCT data). Ideally all HIV positive patients should have CD4 count done for staging.	Do not include follow-up CD4 tests here	Pre-ART	Yes	Yes	No	Yes	No
167	Wheelchair issued - new	Wheelchair issued to a patient that did not have this before	Do not count replacements of existing wheelchairs, due to them being broken or not functioning as expected	Rehab Services	Yes	Yes	No	Yes	No
168	Rehab clients on register requiring wheelchair	The number of rehabilitation clients on the rehab register who requires wheelchair for the first time	Do NOT count rehab clients requiring a replacement wheelchair	Rehab Services	Yes	Yes	No	Yes	No

169	Hearing aid issued - new	Hearing aid issued to a patient that did not have this before	Do NOT count replacements of existing hearing aids, due to them being broken or not functioning as expected	Rehab Services	Yes	Yes	No	Yes	No
170	Rehab clients on register requiring hearing aid	The number of rehabilitation clients on the rehab register who requires hearing aid for the first time	Do NOT count rehab clients requiring a replacement hearing aid	Rehab Services	Yes	Yes	No	Yes	No
171	Walking aid issued - new	Walking aid issued to a patient that did not have this before	Do NOT count replacements of existing walking aids, due to them being broken or not functioning as expected	Rehab Services	Yes	Yes	No	Yes	No
172	Rehab clients on register requiring walking aid	The number of rehabilitation clients on the rehab register who requires walking aid for the first time	Do NOT count rehab clients requiring a replacement walking aid	Rehab Services	Yes	Yes	No	Yes	No
173	Adult patient started on ART during this month - new	New adult patients is the sum of the following patients: - ART naïve patients - Treatment experienced patients - Patients from the PEP		ART	Yes	Yes	No	Yes	No
174	Adult patients remaining on ART at end of the month - total	Total adult patients remaining on ART is the sum of the following: - Any adult patient that has a current regimen in the column designating the month you are reporting on - Any adult patient that has a star without a circle (someone who is not yet considered lost to care (LTF)) in the column designating the month you are reporting on.	Please note: patients who have an outcome in the specified month or months previous should not be counted in this total	ART	Yes	Yes	No	Yes	No

175	New child under 15 years started on ART during this month	New childeren is the sum of the following patients under 15 years: - ART naïve patients - Treatment experienced patients. - Patients from the PEP programme - Patient from the PMTCT programme		ART	Yes	Yes	No	Yes	No
176	Children under 15 years remaining on ART at end of the month - total	Total patients under 15 years remaining on ART is the sum of the following: - Any patient under 15 years that has a current regimen in the column designating the month you are reporting on - Any patient under 15 years that has a star without a circle (someone who is not yet considered lost to care (LTF)) in the column designating the month you are reporting on.	Please note: patients who have an outcome in the specified month or months previous should not be counted in this total	ART	Yes	Yes	No	Yes	No
177	On TB treatment at start of ART	Patients on TB treatment when starting ART		ART	Yes	Yes	No	Yes	No
178	ART CD4 below 100 (adults) or 15 percent TLC (paeds) at baseline	Patient with CD4 below 100 (adults) or 15% TLC (paeds) should be fast-track patients that should receive ART within 2 weeks of clinical staging		ART	Yes	Yes	No	Yes	No
179	ART CD4 counts taken at baseline (CDD)	Total number of CD4 counts taken at baseline		ART	Yes	Yes	No	Yes	No
180	ART died (RIP) at 3 months	Number of patients discontinuing treatment due to death at 3 months		ART	Yes	Yes	No	Yes	No

181	New adult patients started on ART 3 months ago	The number of new adult patients 3 months ago. New adults is the sum of the following patients : - ART naïve patients - Treatment experienced pat	ART	Yes	Yes	No	Yes	No
182	New children under 15 years started on ART 3 months ago	The number of new children 3 months ago. New children is the sum of the following patients under 15 years: - ART naïve patients - Treatment experienced patients.	ART	Yes	Yes	No	Yes	No
183	Adult continuing first-line ART regimen (FLR) at 6 months	Adult patients on first line regimen alive and on treatment after 6 months	ART	Yes	Yes	No	Yes	No
184	Child continuing first-line ART regimen (FLR) at 6 months	Child on first line regimen alive and on treatment after 6 months	ART	Yes	Yes	No	Yes	No
185	Adult on second line ART regimen (SLR) at 6 months	Adult on second line regimen alive and on treatment after 6 months	ART	Yes	Yes	No	Yes	No
186	Child on second line ART regimen (SLR) at 6 months	Child on second line regimen alive and on treatment after 6 months	ART	Yes	Yes	No	Yes	No
187	New adult patients started on ART 6 moths ago	The number of new adult patients 6 months ago. New adult patients is the sum of the following patients: - ART naïve patients - Treatment experienced patient	ART	Yes	Yes	No	Yes	No
188	New children under 15 years started on ART 6 moths ago	The number of new children 6 months ago. New children is the sum of the following patients under 15 years: - ART naïve patients - Treatment experienced patients.	ART	Yes	Yes	No	Yes	No
189	ART CD4 counts done (CDD) at 6 months	Total number of CD4 counts done at 6 months	ART	Yes	Yes	No	Yes	No
190	ART CD4 counts above 200 cells/microL or 20 percent TLC (CDA) at 6 months	Patients with CD4 counts above 200 cells/µl or 20% TLC at 6 months	ART	Yes	Yes	No	Yes	No

191	ART Viral load done (VLD) at 6 months	Total number of viral loads done at 6 months		ART	Yes	Yes	No	Yes	No
192	ART Viral load under 400 copies/mL (VLS) at 6 months	Patients with voral load < 400 copies/ml at 6 months indicates that HIV is not actively reproducing and that the risk of disease progression is low.		ART	Yes	Yes	No	Yes	No
193	ART Died between 3 and 6 months (RIP)	Number patients discontinuing treatment due to death between 3 and 6 months		ART	Yes	Yes	No	Yes	No
194	ART Lost to follow-up between 3 and 6 months (LTF)	Number of patients who have not attended the ARV clinic for three months between 3 and 6 months		ART	Yes	Yes	No	Yes	No
195	ART CD4 counts done (CDD) at 12 months	Total number of CD4 counts done at 12 months		ART	Yes	Yes	No	Yes	No
196	ART CD4 counts above 200 cells/microL or 20 percent TLC (CDA) at 12 months	Patients with CD4 counts above 200 cells/µl or 20% TLC at 12 months		ART	Yes	Yes	No	Yes	No
197	ART Viral load done (VLD) at 12 months	Total number of viral loads done at 12 months		ART	Yes	Yes	No	Yes	No
198	ART Viral load under 400 copies/mL (VLS) at 12 months	Patients with viral load < 400 copies/ml at 12 months indicates that HIV is not actively reproducing and that the risk of disease progression is low.		ART	Yes	Yes	No	Yes	No
199	ART Lost to follow-up between 6 and 12 months (LTF)	Number of patients who have not attended the ARV clinic for three months between 6 and 12 months.		ART	Yes	Yes	No	Yes	No
200	Adult continuing first-line ART regimen (FLR) at 12 months	Adult patients on first line regimen alive and on treatment after 12 months		ART	Yes	Yes	No	Yes	No
201	Child continuing first-line ART regimen	Child on first line regimen alive and on treatment after 12		ART	Yes	Yes	No	Yes	No

	(FLR) at 12 months	months							
202	Adult on second line ART regimen (SLR) at 12 months	Adult on second line regimen alive and on treatment after 12 months		ART	Yes	Yes	No	Yes	No
203	Child on second line ART regimen (SLR) at 12 months	Child on second line regimen alive and on treatment after 12 months		ART	Yes	Yes	No	Yes	No
204	New adult patients started on ART 12 months ago	The number of new adult patients12 months ago. New adult patients is the sum of the following patients: - ART naïve patients - Treatment experienced patient		ART	Yes	Yes	No	Yes	No
205	New children under 15 years started on ART 12 months ago	The number of new children 12 months ago. New children is the sum of the following patients under 15 years: - ART naïve patients - Treatment experienced patients.		ART	Yes	Yes	No	Yes	No
206	Adult continuing first-line ART regimen (FLR) at 24 months	Adult patients on first line regimen alive and on treatment after 24 months		ART	Yes	Yes	No	Yes	No
207	Child continuing first-line ART regimen (FLR) at 24 months	Child on first line regimen alive and on treatment after 24 months		ART	Yes	Yes	No	Yes	No
208	Adult on second line ART regimen (SLR) at 24 months	Adult patients on second line regimen alive and on treatment after 24 months		ART	Yes	Yes	No	Yes	No
209	Child on second line ART regimen (SLR) at 24 months	Child on second line regimen alive and on treatment after 24 months		ART	Yes	Yes	No	Yes	No
210	New adult patients started on ART 24 months ago	The number of new adult patients 24 months ago. New adults is the sum of the following patients : - ART naïve patients - Treatment experienced patients.		ART	Yes	Yes	No	Yes	No
211	New children under 15 years started on ART 24months ago	The number of new children 24 months ago. New children is the sum of the following patients under 15 years: - ART naïve patients - Treatment experienced patients.		ART	Yes	Yes	No	Yes	No

212	ART CD4 counts done (CDD) at 24 months	Total number of CD 4 counts done at 24 months		ART	Yes	Yes	No	Yes	No
213	ART CD4 counts above 200 cells/microL or 20 percent TLC (CDA) at 24 months	Patients with CD4 counts above 200 cells/µl or 20% TLC at 24 months		ART	Yes	Yes	No	Yes	No
214	ART Viral load done (VLD) at 24 months	Total number of viral loads done at 24 months		ART	Yes	Yes	No	Yes	No
215	ART Viral load under 400 copies/mL (VLS) at 24 months	Patients with viral load < 400 copies/ml at 24 months indicates that HIV is not actively reproducing and that the risk of disease progression is low.		ART	Yes	Yes	No	Yes	No
216	Confirmed MDR-TB case succsessfully treated - new	The number of new confirmed MDR-TB cases successfully treated - new		TB EDR_Net	Yes	Yes	No	No	No
217	Confirmed MDR-TB case started on treatment - new	The number of new confirmed MDR-TB cases started on treatment		TB EDR_Net	Yes	Yes	No	No	No
218	Confirmed MDR-TB case started on treatment - total	The total number of confirmed MDR-TB cases started on treatment		TB EDR_Net	Yes	Yes	No	No	No
219	Confirmed XDR-TB case who died during treatment	The number of confirmed XDR-TB cases who died during treatment		TB EDR_Net	Yes	Yes	No	No	No
220	Confirmed XDR-TB case successfully treated	The number of confirmed XDR-TB cases successfully treated		TB EDR_Net	Yes	Yes	No	No	No
221	Confirmed XDR-TB case started on treatment	The number of confirmed XDR-TB cases started on treatment		TB EDR_Net	Yes	Yes	No	No	No
222	MDR-TB case who died during treatment - new	The number of new MDR-TB cases who died during treatment		TB EDR_Net	Yes	Yes	No	No	No
223	MDR-TB case eligible for ART - total	The total number of MDR-TB cases eligible for ART		TB EDR_Net	Yes	Yes	No	No	No

224	MDR-TB case started on ART	The number of MDR-TB cases started on ART		TB EDR_Net	Yes	Yes	No	No	No
225	MDR-TB case started on treatment - total	The total number of MDR-TB cases started on treatment		TB EDR_Net	Yes	Yes	No	No	No
226	MDR-TB case diagnosed - new	The number of new MDR-TB cases diagnosed		TB EDR_Net	Yes	Yes	No	No	No
227	XDR-TB case eligible for ART - total	The total number of XDR-TB cases eligible for ART		TB EDR_Net	Yes	Yes	No	No	No
228	XDR-TB case started on ART	The number of XDR-TB cases started on ART		TB EDR_Net	Yes	Yes	No	No	No
229	XDR-TB case diagnosed - new	The number of new XDR-TB cases diagnosed		TB EDR_Net	Yes	Yes	No	No	No
230	Total new TB cases	All new TB cases in the reporting period.		TB ETR_Net	Yes	Yes	No	No	No
231	New smear positive TB cases - cured	The number of new smear positive TB cases who were cured		TB ETR_Net	Yes	Yes	No	No	No
232	New smear positive TB cases - defaulted from treatment	A defaulter is a person who has missed his or her scheduled dose of treatment for a period of two months		TB ETR_Net	Yes	Yes	No	No	No
233	New smear positive TB cases - died during treatment	All patients that die while taking treatment during the reporting period.		TB ETR_Net	Yes	Yes	No	No	No
234	New smear positive TB cases - total (outcome)	A total of new TB cases diagnosed through smear		TB ETR_Net	Yes	Yes	No	No	No
235	All pulmonary TB cases	The number of pulmonary TB cases		TB ETR_Net	Yes	Yes	No	No	No
236	Pulmonary TB cases with no smear 0-7 years	The number of pulmonary TB cases with no smear in children 0-7 years		TB ETR_Net	Yes	Yes	No	No	No
237	Re-treatment smear positive TB cases - treatment completed	The number of re-treatment smear positive TB cases who completed their treatment		TB ETR_Net	Yes	Yes	No	No	No
238	Re-treatment smear positive TB cases - cured	The number of re-treatment smear positive TB cases who were cured		TB ETR_Net	Yes	Yes	No	No	No

239	Re-treatment smear positive TB cases - defaulted from treatment	The number of re-treatment smear positive TB cases who defaulted from treatment		TB ETR_Net	Yes	Yes	No	No	No
240	Re-treatment smear positive TB cases - died during treatment	The number of re-treatment smear positive TB cases who died during treatment		TB ETR_Net	Yes	Yes	No	No	No
241	Re-treatment smear positive TB cases - total (outcome)	The total number of re-treatment smear positive TB cases with an outcome		TB ETR_Net	Yes	Yes	No	No	No
242	Smear negative pulmonary TB cases	The number of smear negative pulmonary TB cases		TB ETR_Net	Yes	Yes	No	No	No
243	Smear positive pulmonary TB cases	All smear positive pulmonary TB cases		TB ETR_Net	Yes	Yes	No	No	No
244	TB patient pre-test counselled for HIV (ETR)	The number of TB patients pre-test counselled for HIV (ETR)		TB ETR_Net	Yes	Yes	No	No	No
245	TB patient tested positive for HIV (ETR)	The number of TB patients tested positive for HIV (ETR)		TB ETR_Net	Yes	Yes	No	No	No
246	TB patient tested for HIV (ETR)	The number of TB patients tested positive for HIV (ETR)		TB ETR_Net	Yes	Yes	No	No	No
247	EMS rostered ambulances	The average number of rostered ambulances at an ambulance station during the reporting period. This is calculated by the number of rostered ambulances during each shift divided by the number of shifts.		EMS	No	No	No	No	No
248	EMS code red with response under 15 min - urban	The number of code red calls in an urban area where the response time was under 15 minutes. Response time is the time it takes an ambulance to reach an emergency medical scene, calculated from the time of the first call to the control room and up to the time of arrival on the scene. This should not take more then 15 minutes for an urban call. The control centre is expected to note the exact time of the first call and the exact time of arrival on the scene. Emergency Care Practitioner is expected to notify the control centre by radio when arriving on the scene.		EMS	No	No	No	No	No

249	EMS code red with response under 40 min - rural	The number of code red calls in a rural area where the response time was under 40 minutes. Response time is the time it takes an ambulance to reach an emergency medical scene, calculated from the time of the first call to the control room up to the time of arrival on the scene. This should not take more then 40 minutes for a rural call. The control centre is expected to note the exact time of the first call and the exact time of arrival on the scene. Emergency Care Practitioner is expected to notify the control centre by radio when arriving on the scene.	EMS	No	No	No	No	No
250	EMS all calls with response within 60 min	The number of calls where the response time was within 60 minutes. Response time is the time it takes an ambulance to reach an emergency medical scene, calculated from the time of the first call to the control room up to the time of arrival on the scene. The control centre is expected to note the exact time of the first call and the exact time of arrival on the scene. Emergency Care Practitioner is expected to notify the control centre by radio when arriving on the scene.	EMS	No	No	No	No	No
251	EMS Emergency trips total	The number of local urban or rural emergency ambulance trips, regardless of the number of patients transported. This excludes inter-hospital transfers by ambulance or bus.	EMS	No	No	No	No	No

I APPENDIX - ANTENATAL AND POSTNATAL CARE AND MANAGEMENT: LEVEL 1 - SCENARIO

This scenario has been described in two use cases:

1. A typical use case, where antenatal care is received at the community health centre (CHC) and delivery takes place at the centre's maternal obstetric unit (MOU). Being HIV positive is not an indication for referral to hospital for antenatal care and delivery.
2. An exceptional use case, where other maternal and/or foetal condition(s) necessitate referral to hospital for antenatal care and delivery.

I.1 CHARACTERS

- Pinkie – pregnant mum
- Sarah – local community health centre (CHC) registration clerk
- Mary – general nurse at the CHC
- Dr White – physician at CHC (visits the centre twice per week between 08:00 AM and 4:00 PM)
- Bongi – pharmacy assistant at the CHC
- Beatrice – midwife at CHC maternal obstetric unit (MOU)
- Thando – lab technician at the district hospital lab
- Busi – regional hospital registration clerk
- Dr. Naidoo – physician at the regional hospital
- Precious – pharmacist
- Dr Mandla – doctor on duty at regional hospital
- Linah – midwife at regional hospital labour ward.

I.2 TYPICAL USE CASE (ANTENATAL CARE AND DELIVERY TAKES PLACE AT THE CHC)

I.2.1 Antenatal care

Pinkie is a 19 year old single mother of one, Bridget who is 10 month old. Pinkie is unemployed. She lives in a two-room shack with her grandmother, Naledi, and two siblings, Piladi (15 years) and Banda (10 years).

Pinkie is 5 months pregnant with her 2nd child. Pinkie has decided to go to the local community health centre (CHC) to register for ante natal care.

On arrival at the CHC, Pinkie reported at the registration clerk's (Sarah) desk. She told Sarah she is pregnant and would like to see the nurse or doctor.

Sarah asked Pinkie if she has been to the centre before. Pinkie replied no. Sarah created a new folder for Pinkie and wrote her name and registration number on it. She also gave Pinkie a small clinic card on which she wrote the clinic registration number.

If Pinkie has been to the centre previously and she has her registration card with her, Sarah will search for Pinkie's file using her registration number. Otherwise, Sarah will search for Pinkie's record in the paper-based register using a combination of her demographics data (name, surname, date of birth, etc.) in order to determine the location of Pinkie's file in the filing room.

Sarah then asked Pinkie to wait in the waiting area.

After a while, Mary the centre nurse came to the waiting area and collected all the files of those who have come for ante-natal care from the clerk's window and called all the pregnant women to follow her to a room for the day's health talk. The focus of the talk was on the importance of getting tested for HIV and breastfeeding.

After the talk each of the pregnant women was called in to the consulting room for one-on-one consultation.

When her turn came, Pinkie went in to see Mary. Mary noted that this is Pinkie's first ante-natal care visit. Mary asked Pinkie questions about her health history (number of children, previous pregnancies, her last menstrual period, previous conditions, with dates and outcomes). She also carried out a number of clinical observations (Pinkie's weight, blood pressure, temperature, urine analysis, fundal height, Pinkie's heart rate, and the baby's heart rate). Mary records the information and the readings in the appropriate section of the standard 'Maternity case record' booklet supplied by the department of health.

Thereafter, Mary again discussed the importance of getting tested for HIV with Pinkie. She explained to her that the result of the test would be confidential, and that disclosing the result to her family member would be Pinkie's choice.

After the counselling, Pinkie agreed to do the HIV test. Mary asked Pinkie to sign a standard HIV consent form, so that her consent is documented. Pinkie signed the consent form as requested. The signed form was filed in her file.

Mary cleaned Pinkie's finger with an alcohol swab and did a finger prick HIV test. She asked Pinkie to wait outside for the result. After 20 minutes Mary called Pinkie to the consulting room; she told Pinkie the test was positive, but they would need to do another one to be sure. Mary did a second finger prick HIV test using a test kit from another manufacturer.

About half an hour later, Mary called Pinkie in again. She was very sorry, she said, but the second test was also positive. Pinkie was understandably distraught and began to cry. Mary comforted Pinkie and carried out a post-test counselling.

Mary discussed Government's prevention of mother to child transmission (PMTCT) program with Pinkie and explained that people with HIV could live normal, healthy lives, and that the PMTCT program will reduce the risk of her unborn baby being infected with HIV. Mary also told Pinkie that she needs to do more blood tests, so they could put her on appropriate treatment. She then took blood for Full blood count, CD4 count and Alamine Aminotransferase. Pinkie was also screened for tuberculosis (TB) and the WHO clinical staging was derived. Mary asked Pinkie specific questions regarding symptoms of TB and whether she has been previously treated for TB. The blood samples were labelled and sent to the laboratory via a courier.

Mary initiated Pinkie on prophylactic antiretroviral treatment (ART) with Zidovudine and iron + folate supplements, as per the NDoH PMTCT clinical guidelines. She asked Pinkie to return after one

week so she could be seen by the doctor and her blood results reviewed. At the end of the care event, Mary recorded all actions performed on, and treatment given to Pinkie in the appropriate section of the standard 'Maternity case record' booklet.

Pinkie stopped at the centre's pharmacy to collect her medicines. She gave her file to Bongi, the pharmacy assistant. Bongi dispensed one week supply of the medicines as prescribed and labelled the medicine containers with dosage instructions.

Pinkie returned to Sarah, who scheduled the appointment and wrote the date on Pinkie's small card.

A day before Pinkie's appointment, Sarah pulled out the files of all patients that have been scheduled for appointment to reduce the waiting time.

Pinkie's blood results have since been brought back from the lab by the courier and filed in Pinkie's file.

On her appointment date, Pinkie was at the centre. Sarah confirmed the appointment and brought out Pinkie's file.

Pinkie was later seen by Dr White, who reviewed the information in Pinkie's 'Maternity case record' booklet, including the blood results. Dr White asked Pinkie how she was doing; he carried out and recorded Pinkie's clinical observations. He assured Pinkie that she and her baby were doing well, and recommend that she continue with the prophylactic ART, which was initiated by the nurse during her last visit. Dr White then wrote a repeat prescription of Zidovudine, iron and folate supplements for Pinkie.

Dr White also discussed breast and formula feeding with Pinkie; and the implications of the various options. He told her she still has to decide whether or not to breastfeed her baby after birth. Pinkie promised to think about it.

Pinkie continues to receive ante natal care at the CHC until she is due to have her baby.

I.2.2 Labour and delivery

As soon as Pinkie suspects that she is in labour, she went to the CHC as advised. She reported at the registration clerk who searched for and retrieved her file.

Pinkie was seen by Mary (it was not Dr White's visiting day); she asked Pinkie when the pain started and the frequencies. She also examined her and confirmed that she is in labour. Mary then admits Pinkie to the maternal obstetric unit (MOU) of the CHC.

Pinkie was received by Beatrice, a midwife at the MOU. Beatrice measured and recorded Pinkie's vital observation (e.g. temperature, heart rate, blood pressure, fetal heart rate, frequency and intensity of abdominal contraction, cervical dilatation, urine analysis etc.) in the appropriate section of the 'Maternity case record' booklet . She also draws a care plan for Pinkie according to the NDoH PMTCT guidelines on intra-partum care of HIV+ women in labour. Beatrice administered a single-dose of Nevirapine, single dose of Truvada , and 3hourly Zidovudine to Pinkie, according to the NDoH PMTCT guidelines. After the admission 'routine', Beatrice recorded Pinkie's detail in the MOU 'admission' book.

Beatrice continues to monitor Pinkie throughout labour and recorded her progress in the appropriate section of the 'Maternity case record' booklet, until she delivered her baby.

After delivery, Pinkie is given post-partum ARV medicines (single dose of Tenofovir and Emtracitabine).

Beatrice carried out a physical examination on baby Pinkie and recorded her findings in the appropriate section of the 'Maternity case record' booklet. The baby also received the first doses of BCG and oral polio vaccines according to the childhood immunisation guideline, as well as prophylactic nevirapine according to the NDoH PMTCT guidelines. Details of the vaccination were recorded in a new 'Road to health' card.

Beatrice records the birth in the MOU's delivery book and completes the 'summary of labour' section of the 'Maternity case record' booklet.

Pinkie has decided not to breast feed her baby; hence the baby was started on formula feed at the centre.

Since Pinkie's delivery process was uneventful; she and her baby were discharged the same day (patients are admitted in MOUs for six hours). Pinkie was given an appointment to come back with her baby for post-natal check-up after two days. Beatrice completed the standard 'discharge summary' section of the 'Maternity case record' booklet. A copy of the discharge summary was filed in Pinkie's file.

I.2.3 Post-natal care

After two days, Pinkie came back to the centre with her baby for post-natal check-up. Since it was the doctor's visiting day to the centre, Pinkie and her baby were seen and examined by Dr White.

Dr White decides that Pinkie's baby should continue taking nevirapine for six weeks according to the NDoH PMTCT guidelines.

Pinkie is given appointment to come for check-up within six weeks of delivery. Another appointment was scheduled accordingly.

On the date of her appointment, Pinkie was back at the CHC. During this visit, blood was drawn for CD4 count and clinical staging of HIV is done. Pinkie was also screened for TB.

Pinkie is given one week appointment to come for the results of blood tests.

If Pinkie's CD4 count is more than 350 cells/mm^3, she will be referred for wellness services and family planning.

(NB: Wellness service is follow-up program of HIV-infected individuals not yet on ART and includes: provision of TB screening, INH prophylaxis, cortrimoxazole prophylaxis, nutritional and psychosocial support, cervical cancer screening, monitoring of CD4 count, clinical staging and preparedness for ART).

If Pinkie's CD4 count is below 350 cells/mm^3 or she is in clinical stage 3 or 4, she will be initiated on lifelong ART.

Follow-up care for baby Pinkie, according to the according to the NDoH PMTCT guidelines is as follows:

- Follow-up care basically follows the childhood immunisation schedule
- First visit within three days after birth
- Ten days after birth
- Six weeks after birth
- At six weeks of age, baby's blood is drawn for HIV and Polymerase Chain Reaction (PCR)
- Baby discontinues prophylactic Nevirapine
- Doctor prescribes cotrimoxazole for baby
- Baby will continue exclusive formula feeding
- PCR is repeated six weeks after the mother stops breast feeding
- If both HIV and PCR are negative, doctor discontinues cotrimoxazole
- Another HIV test is done when baby is 18 months
- If PCR is positive, baby will continue with cotrimoxazole; confirmatory HIV test and viral load will be done (for initiation on ART)

I.3 EXCEPTIONAL USE CASE (REFERRAL TO HOSPITAL FOR ANTENATAL CARE AND DELIVERY)

Pinkie is a 19 year old single mother of one, Bridget who is 10 month old. Pinkie is unemployed. She lives in a two-room shack with her grandmother, Naledi, and two siblings, Piladi (15 years) and Banda (10 years).

Pinkie is 5 months pregnant with her 2nd child. Pinkie has decided to go to the local community health centre (CHC) to register for ante natal care.

On arrival at the CHC, Pinkie reported at the registration clerk's (Sarah) desk. She told Sarah she is pregnant and would like to see the nurse or doctor.

Sarah asked Pinkie if she has been to the centre before. Pinkie replied no. Sarah created a new folder for Pinkie and wrote her name and registration number on it. She also gave Pinkie a small clinic card on which she wrote the clinic registration number.

If Pinkie has been to the centre previously and she has her registration card with her, Sarah will search for Pinkie's file using her registration number. Otherwise, Sarah will search for Pinkie's record in the paper-based register using a combination of her demographics data (name, surname, date of birth, etc.) in order to determine the location of Pinkie's file in the filing room.

Sarah then asked Pinkie to wait in the waiting area.

After a while, Mary the clinic nurse came to the waiting area and collected all the files of those who have come for ante-natal care from the clerk's window and called all the pregnant women to follow her to a room for the day's health talk. The focus of the talk was on the importance of getting tested for HIV and breastfeeding.

After the talk each of the pregnant women were called in to the consulting room for one-on-one consultation.

When her turn came, Pinkie went in to see Mary. Mary noted that this is Pinkie's first ante-natal care visit. Mary asked Pinkie questions about her health history (number of children, previous pregnancies, her last menstrual period, previous conditions, with dates and outcomes).

She also carried out a number of clinical observations (Pinkie's weight, blood pressure, temperature, urine analysis, fundal height, Pinkie's heart rate, and the baby's heart rate).

Mary notes that Pinkie's blood pressure was slightly elevated and both feet are swollen; her urine dipstick test also tested positive for protein. She records the information obtained from Pinkie and the clinical readings in the appropriate section of the standard 'Maternity case record' booklet supplied by the department of health.

Thereafter, Mary again discussed the importance of getting tested for HIV with Pinkie. She explained to her that the result of the test would be confidential, and that disclosing the result to her family member would be Pinkie's choice.

After the counselling, Pinkie agreed to do the HIV test. Mary asked Pinkie to sign a standard HIV consent form, so that her consent is documented. Pinkie signed the consent form as requested. The signed form was filed in her file.

Mary cleaned Pinkie's finger with an alcohol swab and did a finger prick HIV test. She asked Pinkie to wait outside for the result. After 20 minutes Mary called Pinkie to the consulting room; she told Pinkie the test was positive, but they would need to do another one to be sure. Mary did a second finger prick HIV test using a test kit from another manufacturer.

About half an hour later, Mary called Pinkie in again. She was very sorry, she said, but the second test was also positive. Pinkie was understandably distraught and began to cry. Mary comforted Pinkie and carried out a post-test counselling.

Because the doctor does not come to the centre that day, Mary explained to Pinkie that she will be referring her to the district hospital due the high blood and swollen feet, so she could be reviewed by a doctor.

Mary filled the standard referral form and asked Pinkie to go to the district hospital, preferably the same day since the hospital is not far from the centre. She also gave Pinkie her 'maternity case record' booklet to take along to the hospital.

Pinkie left the CHC and immediately went to the district hospital. She showed the referral letter to the hospital registration clerk. Busi (the registration clerk) asked Pinkie if she has previously been to the hospital, and she replied no. Busi opened a new patient folder and recorded Pinkie's details on it.

If Pinkie has been to the hospital previously and she has her registration card with her, Busi will search for the location of Pinkie's file using her registration number. Otherwise, Busi will search for Pinkie's record in the paper-based hospital register using a combination of her demographics data (name, surname, date of birth, etc.) in order to determine the location of the file in the filing room.

Pinkie was seen by the doctor on duty, Dr Naidoo. Dr Naidoo read the referral letter and asked Pinkie how she was doing. He asked her questions about her previous pregnancy and birth. He also asked specific questions about TB. For example has she ever had TB? Is she coughing at present? The information was recorded in Pinkie's folder.

Thereafter, Dr Naidoo carried out detail physical examination on Pinkie (weight, height, blood pressure, temperature, fundal height, Pinkie's heart rate, and the baby's heart rate, and the swollen feet). He also derived the WHO clinical, using history and his clinical observations.

Dr Naidoo explained to Pinkie that he needs to draw some blood for testing (Full blood count, CD4 count Alamine Aminotransferase, and liver function test), so that Pinkie could be started on appropriate treatment. The blood samples were labelled, the order form was filled and the blood was sent to the hospital laboratory.

Dr Naidoo made a diagnosis of pre-eclampsia; he then explained to Pinkie that he would place her on bed rest (at home) and prescribe medicines for the high blood pressure. He also told Pinkie that he would start her on prophylactic antiretroviral treatment (ART) as per the NDoH PMTCT clinical guidelines.

Dr Naidoo then wrote prescriptions for high blood pressure medicine and ART, as well as routine iron and folate supplements. He asked Pinkie to come back after one week.

Pinkie went back to Busi, who wrote Pinkie's detail in the appointment book and the appointment date Pinkie's registration card.

Thereafter, Pinkie went to the pharmacy where the pharmacist (Precious) dispensed the medicines according to the doctor's prescription; she wrote the dosage instructions on their containers.

On the date of her appointment, Pinkie went back to the district hospital. She gave her registration card to Busi, who confirmed the appointment and retrieved Pinkie's file. Busi asked Pinkie if any of her demographic detail has changed. Pinkie answered no.

Pinkie was seen by Dr Naidoo, who repeated the physical and clinical observations and recorded the WHO clinical staging. The blood result is now available and has been filed in Pinkie's folder. Pinkie's blood results has since been returned and filed in her file. Dr Naidoo noted that the CD4 count is above 350 cells/mm^3 and the WHO clinical staging is stage 2. He also noted that Pinkie's blood pressure is reducing gradually and the swollen feet are subsiding. Thus, he decides Pinkie should continue with the anti-hypertensive medicines and prophylactic Zidovudine, as well as the routine iron and folate supplements.

Dr Naidoo also discussed breast and formula feeding with Pinkie and implications of the various options. He told her she still has to decide whether or not to breastfeed her baby after birth. Pinkie promised to think about it.

Dr Naidoo informed Pinkie that she would be seen every two weeks during her pregnancy but advised her to come to the hospital if there is any problem in-between her appointments.

Pinkie continues to receive antenatal care at the district hospital. At each visit, a full physical and clinical observation (weight, blood pressure, heart rate, fetal heart rate, fundal height, urine analysis etc.) is carried out by the doctor and recorded in her file. She also continued with the prophylactic ART and antihypertensive medicines.

I.3.1 Labour and delivery

As soon as Pinkie suspects that she is in labour, she went to the district hospital as advised. She reported at the registration clerk who retrieved her file.

She was seen by the doctor on duty (Dr Mandla), who examined Pinkie and confirmed that she is in labour. Dr Mandla ordered that Pinkie be admitted to the labour ward.

Dr Mandla initiated Pinkie on intra-partum ARV (single-dose Nevirapine, single dose of Truvada and 3 hourly Zidovudine) according to the NDoH PMTCT guidelines.

Pinkie was received by Linah, a midwife in the labour ward. Linah measured and recorded Pinkie's vital observation (e.g. temperature, heart rate, blood pressure, fetal heart rate, urine analysis, frequency and intensity of abdominal contraction, cervical dilatation, etc.) in the appropriate section of the 'Maternity case record' booklet . She also draws a care plan for Pinkie according to the NDoH PMTCT guidelines on intra-partum care of HIV+ women in labour. Linah administered a single-dose of Nevirapine, single dose of Truvada , and 3hourly Zidovudine to Pinkie, according to the NDoH PMTCT guidelines. She also recorded Pinkie's detail, as well as the ART administered in the delivery book.

Linah continues to monitor Pinkie throughout labour and recorded her progress in the appropriate section of the 'Maternity case record' booklet, until she delivered her baby.

If the condition of Pinkie and/or her baby necessitates that a procedure be carried out (e.g. forceps delivery, vacuum extraction or caesarean section, the appropriate procedure would be carried out by the doctor.

After delivery, Pinkie is given post-partum ARV medicines (single dose of Tenofovir and Emtracitabine) and the baby also receives prophylactic nevirapine according to the NDoH PMTCT guidelines. Linah also completes the 'summary of labour' section of the 'Maternity case record' booklet.

Linah records the birth in the delivery book, and the baby's detail in a new 'Road to health' card. The baby received the first doses of BCG and oral polio vaccines according to the childhood immunisation guideline. Details of the vaccination were recorded in the appropriate section of the 'Road to health' card. Pinkie has decided not to breast feed her baby; hence the baby was started on formula feed soon after birth in the ward.

Pinkie's delivery process was uneventful. Pinkie and her baby were examined by Dr Mandla, who noted that mother and baby are well; hence Pinkie and her baby were discharged a day after delivery. Linah completes the 'discharge summary' section of the 'maternity case record' booklet and kept a copy in Pinkie's hospital file.

Pinkie is asked to come back to the hospital for check-up with her baby two days after discharge.

Linah sent the hospital attendant to the OPD to schedule an appointment for Pinkie. She also recorded the date Pinkie's was discharged against her detail in the ward's admission book.

I.3.2 Post-natal care

Two days after discharge, Pinkie came back to the hospital's OPD with her baby as per the scheduled appointment. She showed her registration card to the clerk, who confirmed the appointment in the appointment book and pulled out Pinkie's file.

Pinkie and her baby were seen by Dr Mandla. He asked how she and her baby were doing, whether the baby is feeding well, and if she has anything the report. Pinkie answered that there was no problem with her and the baby. Dr Mandla examined mother and baby and recorded his observations in Pinkie's file. Dr Mandla decides that Pinkie's baby should continue taking nevirapine for six weeks according to the NDoH PMTCT guidelines.

Pinkie is given appointment to come for check-up within six weeks of delivery. Another appointment was scheduled accordingly.

On the date of her appointment, Pinkie was back at the hospital. During this visit, blood is drawn for CD4 count and clinical staging of HIV is done. Pinkie is also screened for TB.

Pinkie is given one week appointment to come for the results of blood tests.

If Pinkie's CD4 count is more than 350 cells/mm^3, she will be referred for wellness services and family planning.

(NB: Wellness service is follow-up program of HIV-infected individuals not yet on ART and includes: provision of TB screening, INH prophylaxis, cortrimoxazole prophylaxis, nutritional and psychosocial support, cervical cancer screening, monitoring of CD4 count, clinical staging and preparedness for ART).

If Pinkie's CD4 count is below 350 cells/mm^3 or she is in clinical stage 3 or 4, she will be initiated on lifelong ART.

Follow-up care for baby Pinkie, according to the according to the NDoH PMTCT guidelines is as follows:

- Follow-up care basically follows the childhood immunisation schedule
- First visit within three days after birth
- Ten days after birth
- Six weeks after birth
- At six weeks of age, baby's blood is drawn for HIV and Polymerase Chain Reaction (PCR)
- Baby discontinues prophylactic Nevirapine
- Doctor prescribes cotrimoxazole for baby
- Baby will continue exclusive formula feeding
- PCR is repeated six weeks after the mother stops breast feeding
- If both HIV and PCR are negative, doctor discontinues cotrimoxazole
- Another HIV test is done when baby is 18 months
- If PCR is positive, baby will continue with cotrimoxazole; confirmatory HIV test and viral load will be done (for initiation on ART)

I.4 HEALTH INDICATORS ARE ASSOCIATED WITH THIS SCENARIO

1. How many people 5 years and older were seen at the clinic
2. How many children under 5 years were seen at the clinic
3. Inpatient days – total
4. Inpatient deaths - total
5. Inpatient discharges – total
6. Inpatient transfers out - total
7. OPD headcount - follow-up visit
8. How many cases were seen by a Professional Nurse
9. How many women were given vitamin A supplement within 8 weeks after delivery
10. Total number of antenatal 1st visit
11. Total number of antenatal follow-up visit
12. Total number of antenatal 1st visit at 20 weeks or later
13. Total number of antenatal 1st visit before 20 weeks
14. Total number of pregnant women who received 2nd/Booster dose of Tetanus Toxoid
15. Total number of antenatal client on HAART at delivery
16. Total number antenatal client eligible for HAART
17. Total number of babies initiated on HAART (under 18 months)
18. Total number of babies eligible for HAART
19. Total number of antenatal client on HAART at 1st visit
20. Total number of antenatal client who were re-tested for HIV at 32 weeks or later
21. Total number of antenatal client re-tested at 32 weeks or later with positive HIV result
22. Total number of antenatal client on AZT before labour
23. Total number of antenatal client Nevirapine taken during labour
24. Total live births to HIV positive women
25. Total number of babies given Nevirapine within 72 hours after birth
26. Total number of babies initiated on Co-Trimoxazole around 6 weeks
27. Total number of babies who had PCR test done around 6 weeks
28. Total number of babies whose PCR test was positive around 6 weeks
29. Total number of babies who had HIV antibody test done at 18 months
30. Total number of antenatal client who are known to be HIV positive but NOT on HAART at 1st visit
31. Total number of babies whose HIV antibody test was positive at 18 months
32. Total number of antenatal client who had the 1st HIV test done
33. Total number of antenatal client whose 1st HIV test was positive
34. Total number of antenatal client who had 1st CD4 test done
35. Number of patients with a CD4 count below 100 at baseline
36. Total number of antenatal client initiated on AZT
37. Total number of antenatal client initiated on HAART
38. Total number of caesarean sections in facility
39. Total number of delivery in facility under 18 years
40. Total number of delivery in facility 35 years and older

41. Total number of delivery in facility
42. Total number of inpatient death - early neonatal
43. Total live birth in facility under 2500g
44. Total live birth in facility
45. Total number of inpatient death - late neonatal
46. Total number of maternal death in facility
47. Total number of normal delivery in facility
48. Total still birth in facility
49. Total births in facility
50. Number of babies who received postnatal care within 6 days after birth
51. Number of mothers who received postnatal care within 6 days after delivery
52. Total birth defects case - mother 35 years and older
53. Total birth defects case - mother under 18 years
54. Total number of children with common priority Birth Defects
55. Total number of adults that started treatment this month
56. Total patients still on treatment at the end of the month
57. Total children (under 15) that started treatment this month
58. Total children (under 15) were still on treatment at the end of the month
59. Number of patients on TB treatment when they started ART
60. Number of adults who started treatment 3 months ago
61. Number of children (under 15) started treatment 3 months ago
62. Number of patients who died at 3 months
63. Number of adults who started treatment 6 months ago
64. Number of adults still on the first line regimen after 6 months
65. Number of children (under 15) who started treatment 6 months ago
66. Number of children (under 15) still on the first line regimen after 6 months
67. Number of adults on a second line regimen after 6 months
68. Number of children (under 15) on a second line regimen after 6 months
69. Number of patients who had their CD4 counts tested at 6 months
70. Number of patients with CD4 count above 200 at 6 months
71. Number of patients who had their Viral Load tested at 6 months
72. Number of patients with a Viral Load below 400 at 6 months
73. Number of patients who died between 3 and 6 months of treatment
74. Number of patients that were lost to follow up between 3 and 6 months of treatment
75. Number of adults who started treatment 12 months ago
76. Number of adults still on the first line regimen after 12 months
77. Number of children (under 15) who started treatment 12 months ago
78. Number of children (under 15) still on the first line regimen after 12 months
79. Number of adults on a second line regimen after 12 months
80. Number of children (under 15) on a second line regimen after 12 months
81. Number of patients who had their CD4 counts tested at 12 months
82. Number of patients who had a CD4 count above 200 at 12months
83. Number of patients who had their Viral Load tested at 12 months

84. Number of patients who had a Viral Load below 400 at 12 months
85. Number of patient that were lost to follow up between 6 and 12 months of treatment
86. Number of adults who started treatment 24 months ago
87. Number of adults still on the first line regimen after 24 months
88. Number of children (under 15) that started treatment 24 months ago
89. Number of children (under 15) were still on the first line regimen after 24 months
90. Number of adults on a second line regimen after 24 months
91. Number of children (under 15) on a second line regimen after 24 months
92. Number of patients who had their CD4 counts tested at 24 months
93. Number of patients with a CD4 count above 200 at 24 months
94. Number of patients who had their Viral Load tested at 24 months
95. Number of patients with a Viral Load below 400 at 24 months
96. Number of patient lost to follow up between 12 and 24 months of treatment
97. Number of children under 5 years that were weighed
98. Number of children under 1 year that had the 1st dose of BCG
99. Number of children that had the 1st dose of DTaP-IPV/Hib
100. Number of children that had the 3rd dose of DTaP-IPV/Hib
101. Number of children that had the 4th dose of DTaP-IPV/Hib
102. Number of children that had the 1st dose of DTP-Hib
103. Number of children that had the 3rd dose of DTP-Hib
104. Number of children that had the 1st dose of HepB
105. Number of children that had the 3rd dose of HepB
106. Number of children under 1 year that were fully Immunised
107. Number of children under 1 year that had the 1st dose Measles
108. Number of children that had the 2nd dose of Measles
109. Number of children that had the 1st dose of OPV
110. Number of children that had the 3rd dose of OPV
111. Number of children that had the 1st dose of PCV7
112. Number of children that had the 3rd dose of PCV7
113. Number of children that had the 1st dose of RV
114. Number of children that had the 2nd dose of RV
115. Number of people that had Td at 6 years
116. Number of people that had Td at 12 years
117. Number of children aged 6-11 months that had Vitamin A supplement
118. Number of children aged 12-59 months that had Vitamin A supplement

I.5 ACTIVITIES

I.5.1 Typical use case

I.5.2 At the CHC

- Patient comes for antenatal care
- Clerk searches for patient folder
- If patient has been to this centre previously, clerk retrieves patient's folder
- If this is patient's first visit to the centre, clerk manually creates a new folder and small clinic card for patient
- All women who came for antenatal care are given health education (each day's topic varies)
- Patient is seen by nurse
- Nurse obtains and records past medical history
- Nurse carries out various clinical observations (e.g. weight, blood pressure, temperature, fundal height, Pinkie's heart rate, and the baby's heart rate)and records in the standard maternity case record
- Nurse counsels patient about HIV testing and discusses the PMTCT program with patient
- Patient agrees to have HIV test and sign consent form
- Patient is tested with finger prick test
- Finger prick test kit gives test result
- If result is positive, test is repeated using test kit from another manufacturer
- Finger prick test kit gives test result
- If result is positive, nurse do post-test counselling
- Patient is screened for TB, WHO clinical staging is derived
- Nurse takes blood for various tests (full blood count, CD4 count, Alamine Aminotransferase)
- Nurse initiates patient on prophylactic ART (Zidovudine)
- Nurse completes order form for blood tests, label the blood samples and send to laboratory via a courier
- Blood results is returned to the centre by the courier and filed in patient's file
- Patient is given one week appointment to be seen by doctor at the centre and for blood result
- A day prior to appointment date, clerk pulls the files of all patients that have appointments for the following day to reduce waiting time
- Patient returns to the centre for the scheduled appointment
- Clerk confirms appointment and gets patient's file
- Patient is seen and examined by doctor
- Doctor records his findings in patient's file
- Patient continues to receive ante natal care at the CHC until she is due to have her baby
- When patient is in labour, she is admitted to the MOU section of the centre
- Midwife monitors patient while in labour
- Midwife administers intra-partum ART to patient according to NDoH PMTCT guideline

- Midwife delivers baby
- After delivery, midwife administers post-partum ART to patient according to NDoH PMTCT guideline
- Midwife administers prophylactic nevirapine, first doses of BCG and oral polio vaccines according to the PMTCT and childhood immunisation guidelines
- Midwife records delivery in the delivery detail in the 'delivery summary' section of the 'maternity case record' booklet
- Midwife examines mother and baby for fitness for discharge
- Midwife discharge mother and baby and completes the 'discharge summary' section of the 'maternity case record' booklet. A copy of the discharge summary is kept in patient's file
- Mother and baby are given appointment to come for check-up after two days
- Mother and baby are seen and examined by doctor
- Doctor recommends that baby continues with nevirapine for six weeks
- Mother and baby are given appointment to come for check-up after six weeks

I.5.3 After Six Weeks

- Patient returns with her baby
- Mother and baby are seen by the doctor
- Mother and baby are examined by the doctor
- Doctor orders blood for CD4 count,
- Blood is sent to the lab via courier
- Doctor records clinical observation and WHO clinical stage
- Doctor screens patient for TB
- Make appointment to come back for test results
- Write appointment date and time on patient card
- Laboratory results sent back
- Results filed in patient's file
- If Patient's CD4 count is more than 350 cells/mm^3, she is referred for wellness services and family planning
- If Patient's CD4 count is below 350 cells/mm^3 and/or WHO clinical stage is 3 or 4, patient is initiated on lifelong ART

I.6 EXCEPTIONAL USE CASE

I.6.1 At the CHC

- Patient comes for antenatal care
- Clerk searches for patient folder
- If patient has been to this clinic previously, clerk retrieves patient's folder

- If this is patient's first visit to the clinic, clerk manually creates a new folder and small clinic card for patient
- All women who came for antenatal care are given health education (each day's topic varies)
- Patient is seen by nurse
- Nurse obtains and records past medical history
- Nurse carries out various clinical observations (e.g. weight, blood pressure, temperature, urine analysis, fundal height, Pinkie's heart rate, and the baby's heart rate)and records in the standard maternity case record
- Patient's blood pressure is high, her feet are swollen, and the urine test shows presence of protein
- Nurse counsels patient about HIV testing and discusses the PMTCT program with patient
- Patient agrees to have HIV test and sign consent form
- Patient is tested with finger prick test
- Finger prick test kit gives test result
- If result is positive, test is repeated using test kit from another manufacturer
- Finger prick test kit gives test result
- If result is positive, nurse do post-test counselling
- Because the doctor does not visit the centre on the day, nurse decides to refer patient to the district hospital
- Nurse fills the standard referral letter

I.6.2 At the district hospital

- Patient presents the referral letter to the clerk
- Clerk searches for patient file
- If patient has been to this clinic previously, clerk retrieves patient's file
- If this is patient's first visit to the clinic, clerk manually creates a new file and small registration card for patient
- Patient is seen by doctor
- Doctor reads referral letter, obtains and records past medical history
- Doctor carries out various clinical observations (e.g. weight, blood pressure, temperature, fundal height, Pinkie's heart rate, and the baby's heart rate)and records WHO clinical staging
- Doctor makes a diagnosis of pre-ecplamsia
- Doctor orders blood for Full blood count, CD4 count Alamine Aminotransferase and liver function test
- Doctor placed patient on bed rest at home
- Doctor prescribes medicines for high blood pressure and prophylactic ART medicines (Zidovudine) and routine iron + folate
- Blood is sent to the laboratory
- Make appointment to come back for test results
- Write appointment date and time on patient card
- Pharmacist dispenses medicines and prescribed

- Pharmacist records dispensing
- Laboratory results sent back
- Results filed in patient's folder

I.6.3 Return Visit for blood results

- Patient returns for appointment
- Patient goes to the clerk, who updates any change in patient's demographic information
- Patient is seen by doctor
- Doctor repeats clinical observations (e.g. weight, blood pressure, temperature, fundal height, Pinkie's heart rate, and the baby's heart rate)and records WHO clinical staging
- Doctor reviews blood results
- Doctor repeats prescriptions for high blood pressure and prophylactic ART medicine (Zidovudine) and routine iron + folate
- Doctor advises patient to continue with bed rest at home
- Doctor counsels patient about breast and formula feeding
- Make appointment
- Write appointment date and time on patient card
- Pharmacist dispenses medicines and prescribed
- Pharmacist records dispensing

I.6.4 Follow-up antenatal care (the following activities are repeated at each visit)

- Patient returns for appointment
- Patient goes to the clerk, who updates any change in patient's demographic information
- Patient is seen by doctor
- Doctor repeats clinical observations (e.g. weight, blood pressure, temperature, urine analysis, fundal height, Pinkie's heart rate, and the baby's heart rate)and records WHO clinical staging
- Doctor records clinical observation and WHO clinical stage
- Make appointment for follow-up antenatal visit
- Write appointment date and time on patient card
- Pharmacist dispenses medicines and prescribed
- Pharmacist records dispensing

I.6.5 Labour and Delivery

- Patient suspects she is in labour
- Patient goes to district hospital
- Patient is seen by the doctor
- Doctor examines patient
- Doctor admits patient to labour ward

- Doctor prescribes ARVs (intra-partum: single-dose Nevirapine, single dose of Truvada and 3 hourly Zidovudine; post-partum: single dose of Tenofovir and Emtracitabine)
- Midwife receives patient in the labour ward
- Midwife assigns patient to available bed
- Midwife measures and records vital signs (temperature, heart rate, blood pressure, fetal heart rate, frequency and intensity of abdominal contraction, cervical dilatation, etc.)
- Midwife records patient's detail in ward admission book
- Midwife draws a care plan for patient
- Midwife sends patient's prescription to pharmacy for collection of ARV
- Midwife administers intra-partum ART as prescribes
- Midwife continues to monitor patient's progress while in labour
- Midwife delivers baby
- Midwife records birth details in delivery register
- If any complication arises or labour does not progress well, necessary procedure (e.g. forceps delivery, vacuum extraction or caesarean section) is carried out by doctor
- After delivery, midwife administers post-partum ART to patient according to NDoH PMTCT guideline
- Midwife administers prophylactic nevirapine, first doses of BCG and oral polio vaccines according to the PMTCT and childhood immunisation guidelines
- Midwife records delivery in the delivery detail in the 'delivery summary' section of the 'maternity case record' booklet
- Baby is started on exclusive formula feed as per mother's decision
- Mother and baby are seen and examined by doctor
- Doctor recommends that baby continues with nevirapine for six weeks
- Mother and baby are given appointment to come for check-up after six weeks
- If all is well, mother and baby are discharged, to come back for follow-up visit after two days
- Make appointment for follow-up post natal visit
- Write appointment date and time on patient card
- Nurse records date of discharge against patient's name in the ward admission book

I.6.6 Postpartum Visits

- Patient returns with her baby after two days
- Mother and baby are seen by the doctor
- Mother and baby are examined by the doctor
- Doctor prescribes more Nevirapine for baby (for six weeks)
- Make appointment for follow-up postnatal visit after six week
- Write appointment date and time on patient card
- Pharmacist dispenses Nevirapine
- Pharmacist records dispensing

I.6.7 After Six Weeks

- Patient returns with her baby
- Mother and baby are seen by the doctor
- Mother and baby are examined by the doctor
- Doctor orders blood for CD4 count,
- Blood is sent to the lab via courier
- Doctor records clinical observation and WHO clinical stage
- Doctor screens patient for TB
- Make appointment to come back for test results
- Write appointment date and time on patient card
- Laboratory results sent back
- Results filed in patient's file
- If Patient's CD4 count is more than 350 cells/mm^3, she is referred for wellness services and family planning
- If Patient's CD4 count is below 350 cells/mm^3 and/or WHO clinical stage is 3 or 4, patient is initiated on lifelong ART

I.6.8 Follow-Up care for Baby

- Follow-up care basically follows the childhood immunisation schedule
- First visit within three days after birth
- Ten days after birth
- Six weeks after birth
- At six weeks of age, baby's blood is drawn for HIV and Polymerase Chain Reaction (PCR)
- Baby discontinues prophylactic Nevirapine
- Doctor prescribes cotrimoxazole for baby
- Baby will continue exclusive formula feeding
- PCR is repeated six weeks after the mother stops breast feeding
- If both HIV and PCR are negative, doctor discontinues cotrimoxazole
- Another HIV test is done when baby is 18 months
- If PCR is positive, baby will continue with cotrimoxazole; confirmatory HIV test and viral load will be done (for initiation on ART)

J APPENDIX - ANTENATAL AND POSTNATAL CARE AND MANAGEMENT: LEVEL 2 - SCENARIO

This scenario has been described in two use cases:

1. A typical use case, where antenatal care is received at the community health centre (CHC) and delivery takes place at the centre's maternal obstetric unit (MOU). Being HIV positive is not an indication for referral to hospital for antenatal care and delivery.
2. An exceptional use case, where other maternal and/or fetal condition(s) necessitate referral to hospital for antenatal care and delivery.

J.1 CHARACTERS

- Pinkie – pregnant mum
- Sarah – local community health centre (CHC) registration clerk
- Mary – general nurse at the CHC
- Dr White – physician at CHC (visits the centre twice per week between 08:00 AM and 4:00 PM)
- Bongi – pharmacy assistant at the CHC
- Beatrice – midwife at CHC maternal obstetric unit (MOU)
- Thando – lab technician at the district hospital lab
- Busi – district hospital registration clerk
- Dr. Naidoo – physician at the district hospital
- Precious – pharmacist
- Dr Mandla – doctor on duty at district hospital
- Linah – midwife at district hospital labour ward

J.2 TYPICAL USE CASE (ANTENATAL CARE AND DELIVERY TAKES PLACE AT THE CHC)

J.2.1 Antenatal care

Pinkie is a 19 year old single mother of one, Bridget who is 10 month old. Pinkie is unemployed. She lives in a two-room shack with her grandmother, Naledi, and two siblings, Piladi (15 years) and Banda (10 years).

Pinkie is 5 months pregnant with her 2nd child. Pinkie has decided to go to the local community health centre (CHC) to register for ante natal care.

On arrival at the CHC, Pinkie reported at the registration clerk's (Sarah) desk. She told Sarah she is pregnant and would like to see the nurse or doctor.

Sarah asked Pinkie if she has been to the centre before. Pinkie replied no. Nevertheless, Sarah still went ahead and searched the centre's stand-alone patient management system (PMS), first using Pinkie's ID number and then a combination of her demographics data (name, surname, date of birth, etc.); to make sure Pinkie is not registered on the system. No record matching Pinkie's detail was found.

Hence, Sarah created a new record for Pinkie on the local system using information provided by Pinkie, as well as that in her ID book. The system generates a unique identifier for Pinkie, using her national ID number. Sarah also printed some labels with Pinkie's name and registration number and stuck one on a new file and another on a small clinic card. She then placed the remaining inside Pinkie's folder for later use.

Sarah then asked Pinkie to wait in the waiting area.

After a while, Mary the centre nurse came to the waiting area and collected all the files of those who have come for ante-natal care from the clerk's window and called all the pregnant women to follow her to a room for the day's health talk. The focus of the talk was on the importance of getting tested for HIV and breastfeeding.

After the talk each of the pregnant women was called in to the consulting room for one-on-one consultation.

When her turn came, Pinkie went in to see Mary. Mary noted that this is Pinkie's first ante-natal care visit. Mary asked Pinkie questions about her health history (number of children, previous pregnancies, her last menstrual period, previous conditions, with dates and outcomes). She also carried out a number of clinical observations (Pinkie's weight, blood pressure, temperature, urine analysis, fundal height, Pinkie's heart rate, and the baby's heart rate). Mary records the information and the readings in the appropriate section of the standard 'Maternity case record' booklet supplied by the department of health.

Thereafter, Mary again discussed the importance of getting tested for HIV with Pinkie. She explained to her that the result of the test would be confidential, and that disclosing the result to her family member would be Pinkie's choice.

After the counselling, Pinkie agreed to do the HIV test. Mary asked Pinkie to sign a standard HIV consent form, so that her consent is documented.

Mary cleaned Pinkie's finger with an alcohol swab and did a finger prick HIV test. She asked Pinkie to wait outside for the result. After 20 minutes Mary called Pinkie to the consulting room; she told Pinkie the test was positive, but they would need to do another one to be sure. Mary did a second finger prick HIV test using a test kit from another manufacturer.

About half an hour later, Mary called Pinkie in again. She was very sorry, she said, but the second test was also positive. Pinkie was understandably distraught and began to cry. Mary comforted Pinkie and carried out a post-test counselling.

Mary discussed Government's prevention of mother to child transmission (PMTCT) program with Pinkie and explained that people with HIV could live normal, healthy lives, and that the PMTCT program will reduce the risk of her unborn baby being infected with HIV. Mary also told Pinkie that she needs to do more blood tests, so they could put her on appropriate treatment. She then took blood for Full blood count, CD4 count and Alamine Aminotransferase. Pinkie was also screened for tuberculosis (TB) and the WHO clinical staging was derived. Mary asked Pinkie specific questions regarding symptoms of TB and whether she has been previously treated for TB The blood samples were labelled and sent to the laboratory via a courier.

Mary initiated Pinkie on prophylactic antiretroviral treatment (ART) with Zidovudine and iron + folate supplements as per the NDoH PMTCT clinical guidelines. She asked Pinkie to return after one

week, so she could be seen by the doctor and her blood results reviewed. At the end of the care event, Mary recorded all actions performed on, and treatment given to Pinkie in the appropriate section of the standard 'Maternity case record' booklet.

Pinkie stopped at the centre's pharmacy to collect her medicines. She gave her file to Bongi, the pharmacy assistant. Bongi dispensed one week supply of the medicines as prescribed and labelled the medicine containers with dosage instructions.

Pinkie returned to Sarah, who scheduled the appointment on the local PMS, and wrote the appointment's date on Pinkie's small card.

A day before Pinkie's appointment, Sarah prompts the local PMS to generate a 'picking list for the files of all patients who have appointments the following day. She then pulled out the files in the list to reduce the waiting time.

Pinkie's blood results have since been brought back from the lab by the courier and filed in Pinkie's file.

On her appointment date, Pinkie was at the centre. Sarah confirmed the appointment and brought out Pinkie's file.

Pinkie was later seen by Dr White, who reviewed the information in Pinkie's 'Maternity case record' booklet, including the blood results. Dr White asked Pinkie how she was doing; he carried out and recorded Pinkie's clinical observations. He assured Pinkie that she and her baby were doing well, and recommend that she continue with the prophylactic ART, which was initiated by the nurse during her last visit. Dr White then wrote a repeat prescription of Zidovudine, iron and folate supplements for Pinkie.

Dr White also discussed breast and formula feeding with Pinkie; and the implications of the various options. He told her she still has to decide whether or not to breastfeed her baby after birth. Pinkie promised to think about it.

Pinkie continues to receive ante natal care at the CHC until she is due to have her baby.

J.2.2 Labour and delivery

As soon as Pinkie suspects that she is in labour, she went to the CHC as advised. She reported at the registration clerk who searched for and retrieved her file.

Pinkie was seen by Mary (it was not Dr White's visiting day); she asked Pinkie when the pain started and the frequencies. She also examined her and confirmed that she is in labour. Mary then admits Pinkie to the maternal obstetric unit (MOU) of the CHC.

Pinkie was received by Beatrice, a midwife at the MOU. Beatrice measured and recorded Pinkie's vital observation e.g. temperature, heart rate, blood pressure, fetal heart rate, frequency and intensity of abdominal contraction, cervical dilatation, urine analysis etc.) in the appropriate section of the 'Maternity case record' booklet . She also draws a care plan for Pinkie according to the NDoH PMTCT guidelines on intra-partum care of HIV+ women in labour. Beatrice administered a single-dose of Nevirapine, single dose of Truvada , and 3hourly Zidovudine to Pinkie, according to the NDoH PMTCT guidelines. After the admission 'routine', Beatrice recorded Pinkie's detail in the MOU 'admission' book.

Beatrice continues to monitor Pinkie throughout labour and recorded her progress in the appropriate section of the 'Maternity case record' booklet, until she delivered her baby.

After delivery, Pinkie is given post-partum ARV medicines (single dose of Tenofovir and Emtracitabine).

Beatrice carried out a physical examination on baby Pinkie and recorded her findings in the appropriate section of the 'Maternity case record' booklet. The baby also received the first doses of BCG and oral polio vaccines according to the childhood immunisation guideline, as well as prophylactic nevirapine according to the NDoH PMTCT guidelines. Details of the vaccination were recorded in a new 'Road to health' card.

Beatrice records the birth in the MOU's delivery book and completes the 'summary of labour' section of the 'Maternity case record' booklet.

Pinkie has decided not to breast feed her baby; hence the baby was started on formula feed at the centre.

Since Pinkie's delivery process was uneventful; she and her baby were discharged the same day (patients are admitted in MOUs for six hours). Pinkie was given an appointment to come back with her baby for post-natal check-up after two days. Beatrice completed the standard 'discharge summary' section of the 'Maternity case record' booklet. A copy of the discharge summary was filed in Pinkie's file.

Post-natal care

After two days, Pinkie came back to the centre with her baby for post-natal check-up. Since it was the doctor's visiting day to the centre, Pinkie and her baby were seen and examined by Dr White.

Dr White decides that Pinkie's baby should continue taking nevirapine for six weeks according to the NDoH PMTCT guidelines.

Pinkie is given appointment to come for check-up within six weeks of delivery. Another appointment was scheduled accordingly.

On the date of her appointment, Pinkie was back at the CHC. During this visit, blood was drawn for CD4 count and clinical staging of HIV is done. Pinkie was also screened for TB.

Pinkie is given one week appointment to come for the results of blood tests.

If Pinkie's CD4 count is more than 350 cells/mm^3, she will be referred for wellness services and family planning.

(NB: Wellness service is follow-up program of HIV-infected individuals not yet on ART and includes: provision of TB screening, INH prophylaxis, cortrimoxazole prophylaxis, nutritional and psychosocial support, cervical cancer screening, monitoring of CD4 count, clinical staging and preparedness for ART).

If Pinkie's CD4 count is below 350 cells/mm^3 or in she is in clinical stage 3 or 4, she will be initiated on lifelong ART.

Follow-up care for baby Pinkie, according to the according to the NDoH PMTCT guidelines is as follows:

- Follow-up care basically follows the childhood immunisation schedule
- First visit within three days after birth
- Ten days after birth
- Six weeks after birth
- At six weeks of age, baby's blood is drawn for HIV and Polymerase Chain Reaction (PCR)
- Baby discontinues prophylactic Nevirapine
- Doctor prescribes cotrimoxazole for baby
- Baby will continue exclusive formula feeding
- PCR is repeated six weeks after the mother stops breast feeding
- If both HIV and PCR are negative, doctor discontinues cotrimoxazole
- Another HIV test is done when baby is 18 months
- If PCR is positive, baby will continue with cotrimoxazole; confirmatory HIV test and viral load will be done (for initiation on ART)

J.3 EXCEPTIONAL USE CASE (REFERRAL TO HOSPITAL FOR ANTENATAL CARE AND DELIVERY)

Pinkie is a 19 year old single mother of one, Bridget who is 10 month old. Pinkie is unemployed. She lives in a two-room shack with her grandmother, Naledi, and two siblings, Piladi (15 years) and Banda (10 years).

Pinkie is 5 months pregnant with her 2nd child. Pinkie has decided to go to the local community health centre (CHC) to register for ante natal care.

On arrival at the CHC, Pinkie reported at the registration clerk's (Sarah) desk. She told Sarah she is pregnant and would like to see the nurse or doctor.

Sarah asked Pinkie if she has been to the centre before. Pinkie replied no. Nevertheless, Sarah still went ahead and searched the centre's stand-alone patient management system (PMS), first using Pinkie's ID number and then a combination of her demographics data (name, surname, date of birth, etc.), to make sure Pinkie is not registered on the system. No record matching Pinkie's detail was found.

Hence, Sarah created a new record for Pinkie on the local system using information provided by Pinkie, as well as that in her ID book. The system generates a unique identifier for Pinkie, using her national ID number. Sarah also printed some labels with Pinkie's name and registration number and stuck one on a new file and another on a small clinic card. She then placed the remaining inside Pinkie's folder for later use.

Sarah then asked Pinkie to wait in the waiting area.

After a while, Mary the centre nurse came to the waiting area and collected all the files of those who have come for ante-natal care from the clerk's window and called all the pregnant women to follow her to a room for the day's health talk. The focus of the talk was on the importance of getting tested for HIV and breastfeeding.

After the talk each of the pregnant women was called in to the consulting room for one-on-one consultation.

When her turn came, Pinkie went in to see Mary. Mary noted that this is Pinkie's first ante-natal care visit. Mary asked Pinkie questions about her health history (number of children, previous pregnancies, her last menstrual period, previous conditions, with dates and outcomes). She also carried out a number of clinical observations (Pinkie's weight, blood pressure, temperature, urine analysis, fundal height, Pinkie's heart rate, and the baby's heart rate).

Mary notes that Pinkie's blood pressure was slightly elevated and both feet are swollen; her urine dipstick test also tested positive for protein. She records the information obtained from Pinkie and the clinical readings in the appropriate section of the standard 'Maternity case record' booklet supplied by the department of health.

Thereafter, Mary again discussed the importance of getting tested for HIV with Pinkie. She explained to her that the result of the test would be confidential, and that disclosing the result to her family member would be Pinkie's choice.

After the counselling, Pinkie agreed to do the HIV test. Mary asked Pinkie to sign a standard HIV consent form, so that her consent is documented. Pinkie signed the consent form as requested. The signed form was filed in her file.

Mary cleaned Pinkie's finger with an alcohol swab and did a finger prick HIV test. She asked Pinkie to wait outside for the result. After 20 minutes Mary called Pinkie to the consulting room; she told Pinkie the test was positive, but they would need to do another one to be sure. Mary did a second finger prick HIV test using a test kit from another manufacturer.

About half an hour later, Mary called Pinkie in again. She was very sorry, she said, but the second test was also positive. Pinkie was understandably distraught and began to cry. Mary comforted Pinkie and carried out a post-test counselling.

Because the doctor does not come to the centre that day, Mary explained to Pinkie that she will be referring her to the district hospital due the high blood and swollen feet, so she could be reviewed by a doctor.

Mary filled the standard referral form and asked Pinkie to go to the district hospital, preferably the same day since the hospital is not far from the centre. She also gave Pinkie her 'maternity case record' booklet to take along to the hospital.

Pinkie left the CHC and immediately went to the district hospital.

She showed the referral letter to the hospital registration clerk. Busi (the registration clerk) asked Pinkie if she has been to the hospital before. Pinkie replied no. Just to make sure that Pinkie is not on the hospital's system, Busi searched the hospital's stand-alone PMS, first using Pinkie's ID number and then a combination of her demographics data (name, surname, date of birth, etc.), but no record matching Pinkie's detail was found.

Busi then created a new record for Pinkie on the local system using information provided by Pinkie, as well as that in her ID book. The system generates a unique identifier for Pinkie, using her national ID number. Busi also printed some labels with Pinkie's name and registration number and stuck one

on a new file and another on a small clinic card. She then placed the remaining inside Pinkie's folder for later use.

Pinkie was seen by the doctor on duty, Dr Naidoo. Dr Naidoo read the referral letter and asked Pinkie how she was doing. He asked her questions about her previous pregnancy and birth, as well as specific questions about TB. For example has she ever had TB? Is she coughing at present? The information was recorded in Pinkie's folder.

Thereafter, Dr Naidoo carried out detail physical examination on Pinkie (weight, height, blood pressure, temperature, fundal height, Pinkie's heart rate, and the baby's heart rate, and the swollen feet). He also derived the WHO clinical, using history and his clinical observations.

Dr Naidoo explained to Pinkie that he needs to draw some blood for testing (Full blood count, CD4 count Alamine Aminotransferase, and liver function test), so that Pinkie could be started on appropriate treatment. The blood samples were labelled, the order form was filled and the blood was sent to the hospital laboratory.

Dr Naidoo made a diagnosis of pre-eclampsia; he then explained to Pinkie that he would place her on bed rest (at home) and prescribe medicines for the high blood pressure. He also told Pinkie that he would start her on prophylactic antiretroviral treatment (ART) as per the NDoH PMTCT clinical guidelines.

Dr Naidoo then wrote prescriptions for high blood pressure medicine and ART, as well as routine iron and folate supplements. He asked Pinkie to come back after one week.

Pinkie went back to Busi, who scheduled the appointment on the local system, and wrote the appointment's date on Pinkie's small card.

Thereafter, Pinkie went to the pharmacy where the pharmacist (Precious) dispensed the medicines according to the doctor's prescription; she wrote the dosage instructions on their containers.

On the date of her appointment, Pinkie went back to the district hospital. She gave her registration card to Busi, who confirmed the appointment and retrieved Pinkie's file. Busi asked Pinkie if any of her demographic detail has changed. Pinkie answered no.

Pinkie was seen by Dr Naidoo, who repeated the physical and clinical observations and recorded the WHO clinical staging. The blood result is now available and has been filed in Pinkie's folder. Pinkie's blood results has since been returned and filed in her file. Dr Naidoo noted that the CD4 count is above 350 cells/mm^3 and the WHO clinical staging is stage 2. He also noted that Pinkie's blood pressure is reducing gradually and the swollen feet are subsiding. Thus, he decides Pinkie should continue with the anti-hypertensive medicines and prophylactic Zidovudine, as well as the routine iron and folate supplements.

Dr Naidoo also discussed breast and formula feeding with Pinkie and implications of the various options. He told her she still has to decide whether or not to breastfeed her baby after birth. Pinkie promised to think about it.

Dr Naidoo informed Pinkie that she would be seen every two weeks during her pregnancy, but advised her to come to the hospital if there is any problem in-between her appointments.

Pinkie continues to receive antenatal care at the district hospital. At each visit, a full physical and clinical observation (weight, blood pressure, heart rate, fetal heart rate, fundal height, urine analysis

etc.) is carried out by the doctor and recorded in her file. She also continued with the prophylactic ART and antihypertensive medicines.

J.3.1 Labour and delivery

As soon as Pinkie suspects that she is in labour, she went to the district hospital as advised. She reported at the registration clerk who retrieved her file.

She was seen by the doctor on duty (Dr Mandla), who examined Pinkie and confirmed that she is in labour. Dr Mandla ordered that Pinkie be admitted to the labour ward.

Dr Mandla initiated Pinkie on intra-partum ARV (single-dose Nevirapine, single dose of Truvada and 3 hourly Zidovudine) according to the NDoH PMTCT guidelines.

Pinkie was received by Linah, a midwife in the labour ward. Linah measured and recorded Pinkie's vital observation (e.g. temperature, heart rate, blood pressure, fetal heart rate, urine analysis, frequency and intensity of abdominal contraction, cervical dilatation, etc.) in the appropriate section of the 'Maternity case record' booklet . She also draws a care plan for Pinkie according to the NDoH PMTCT guidelines on intra-partum care of HIV+ women in labour. Linah administered a single-dose of Nevirapine, single dose of Truvada , and 3hourly Zidovudine to Pinkie, according to the NDoH PMTCT guidelines. She also recorded Pinkie's detail, as well as the ART administered in the delivery book.

Linah continues to monitor Pinkie throughout labour and recorded her progress in the appropriate section of the 'Maternity case record' booklet, until she delivered her baby.

If the condition of Pinkie and/or her baby necessitates that a procedure be carried out (e.g. forceps delivery, vacuum extraction or caesarean section, the appropriate procedure would be carried out by the doctor.

After delivery, Pinkie is given post-partum ARV medicines (single dose of Tenofovir and Emtracitabine) and the baby also receives prophylactic nevirapine according to the NDoH PMTCT guidelines. Linah also completes the 'summary of labour' section of the 'Maternity case record' booklet.

Linah records the birth in the delivery book, and the baby's detail in a new 'Road to health' card. The baby received the first doses of BCG and oral polio vaccines according to the childhood immunisation guideline. Details of the vaccination were recorded in the appropriate section of the 'Road to health' card. Pinkie has decided not to breast feed her baby; hence the baby was started on formula feed soon after birth in the ward.

Pinkie's delivery process was uneventful. Pinkie and her baby were examined by Dr Mandla, who noted that mother and baby are well; hence Pinkie and her baby were discharged a day after delivery. Linah completes the 'discharge summary' section of the 'maternity case record' booklet and kept a copy in Pinkie's hospital file.

Pinkie is asked to come to back to the hospital for check-up with her baby two days after discharge.

Linah sent the hospital attendant to the OPD to schedule an appointment for Pinkie. She also recorded the date Pinkie's was discharged against her detail in the ward's admission book.

J.3.2 Post-natal care

Two days after discharge, Pinkie came back to the hospital's OPD with her baby as per the scheduled appointment. She showed her registration card to the clerk, who confirmed the appointment in the appointment book and pulled out Pinkie's file.

Pinkie and her baby were seen by Dr Mandla. He asked how she and her baby were doing, whether the baby is feeding well, and if she has anything the report. Pinkie answered that there was no problem with her and the baby. Dr Mandla examined mother and baby and recorded his observations in Pinkie's file. Dr Mandla decides that Pinkie's baby should continue taking nevirapine for six weeks according to the NDoH PMTCT guidelines.

Pinkie is given appointment to come for check-up within six weeks of delivery. Another appointment was scheduled accordingly.

On the date of her appointment, Pinkie was back at the hospital. During this visit, blood is drawn for CD4 count and clinical staging of HIV is done. Pinkie is also screened for TB.

Pinkie is given one week appointment to come for the results of blood tests.

If Pinkie's CD4 count is more than 350 cells/mm^3, she will be referred for wellness services and family planning.

(NB: Wellness service is follow-up program of HIV-infected individuals not yet on ART and includes: provision of TB screening, INH prophylaxis, cortrimoxazole prophylaxis, nutritional and psychosocial support, cervical cancer screening, monitoring of CD4 count, clinical staging and preparedness for ART).

If Pinkie's CD4 count is below 350 cells/mm^3 or in she is in clinical stage 3 or 4, she will be initiated on lifelong ART.

Follow-up care for baby Pinkie, according to the according to the NDoH PMTCT guidelines is as follows:

- Follow-up care basically follows the childhood immunisation schedule
- First visit within three days after birth
- Ten days after birth
- Six weeks after birth
- At six weeks of age, baby's blood is drawn for HIV and Polymerase Chain Reaction (PCR)
- Baby discontinues prophylactic Nevirapine
- Doctor prescribes cotrimoxazole for baby
- Baby will continue exclusive formula feeding
- PCR is repeated six weeks after the mother stops breast feeding
- If both HIV and PCR are negative, doctor discontinues cotrimoxazole
- Another HIV test is done when baby is 18 months
- If PCR is positive, baby will continue with cotrimoxazole; confirmatory HIV test and viral load will be done (for initiation on ART)

J.3.3 The following health indicators are associated with this scenario

1. How many people 5 years and older were seen at the clinic
2. How many children under 5 years were seen at the clinic
3. Inpatient days – total
4. Inpatient deaths - total
5. Inpatient discharges – total
6. Inpatient transfers out - total
7. OPD headcount - follow-up visit
8. How many cases were seen by a Professional Nurse
9. How many women were given vitamin A supplement within 8 weeks after delivery
10. Total number of antenatal 1st visit
11. Total number of antenatal follow-up visit
12. Total number of antenatal 1st visit at 20 weeks or later
13. Total number of antenatal 1st visit before 20 weeks
14. Total number of pregnant women who received 2nd/Booster dose of Tetanus Toxoid
15. Total number of antenatal client on HAART at delivery
16. Total number antenatal client eligible for HAART
17. Total number of babies initiated on HAART (under 18 months)
18. Total number of babies eligible for HAART
19. Total number of antenatal client on HAART at 1st visit
20. Total number of antenatal client who were re-tested for HIV at 32 weeks or later
21. Total number of antenatal client re-tested at 32 weeks or later with positive HIV result
22. Total number of antenatal client on AZT before labour
23. Total number of antenatal client Nevirapine taken during labour
24. Total live births to HIV positive women
25. Total number of babies given Nevirapine within 72 hours after birth
26. Total number of babies initiated on Co-Trimoxazole around 6 weeks
27. Total number of babies who had PCR test done around 6 weeks
28. Total number of babies whose PCR test was positive around 6 weeks
29. Total number of babies who had HIV antibody test done at 18 months
30. Total number of antenatal client who are known to be HIV positive but NOT on HAART at 1st visit
31. Total number of babies whose HIV antibody test was positive at 18 months
32. Total number of antenatal client who had the 1st HIV test done
33. Total number of antenatal client whose 1st HIV test was positive
34. Total number of antenatal client who had 1st CD4 test done
35. Number of patients with a CD4 count below 100 at baseline
36. Total number of antenatal client initiated on AZT
37. Total number of antenatal client initiated on HAART
38. Total number of caesarean sections in facility
39. Total number of delivery in facility under 18 years
40. Total number of delivery in facility 35 years and older
41. Total number of delivery in facility

42. Total number of inpatient death - early neonatal
43. Total live birth in facility under 2500g
44. Total live birth in facility
45. Total number of inpatient death - late neonatal
46. Total number of maternal death in facility
47. Total number of normal delivery in facility
48. Total still birth in facility
49. Total births in facility
50. Number of babies who received postnatal care within 6 days after birth
51. Number of mothers who received postnatal care within 6 days after delivery
52. Total birth defects case - mother 35 years and older
53. Total birth defects case - mother under 18 years
54. Total number of children with common priority Birth Defects
55. Total number of adults that started treatment this month
56. Total patients still on treatment at the end of the month
57. Total children (under 15) that started treatment this month
58. Total children (under 15) were still on treatment at the end of the month
59. Number of patients on TB treatment when they started ART
60. Number of adults who started treatment 3 months ago
61. Number of children (under 15) started treatment 3 months ago
62. Number of patients who died at 3 months
63. Number of adults who started treatment 6 months ago
64. Number of adults still on the first line regimen after 6 months
65. Number of children (under 15) who started treatment 6 months ago
66. Number of children (under 15) still on the first line regimen after 6 months
67. Number of adults on a second line regimen after 6 months
68. Number of children (under 15) on a second line regimen after 6 months
69. Number of patients who had their CD4 counts tested at 6 months
70. Number of patients with CD4 count above 200 at 6 months
71. Number of patients who had their Viral Load tested at 6 months
72. Number of patients with a Viral Load below 400 at 6 months
73. Number of patients who died between 3 and 6 months of treatment
74. Number of patients that were lost to follow up between 3 and 6 months of treatment
75. Number of adults who started treatment 12 months ago
76. Number of adults still on the first line regimen after 12 months
77. Number of children (under 15) who started treatment 12 months ago
78. Number of children (under 15) still on the first line regimen after 12 months
79. Number of adults on a second line regimen after 12 months
80. Number of children (under 15) on a second line regimen after 12 months
81. Number of patients who had their CD4 counts tested at 12 months
82. Number of patients who had a CD4 count above 200 at 12months
83. Number of patients who had their Viral Load tested at 12 months
84. Number of patients who had a Viral Load below 400 at 12 months

85. Number of patient that were lost to follow up between 6 and 12 months of treatment
86. Number of adults who started treatment 24 months ago
87. Number of adults still on the first line regimen after 24 months
88. Number of children (under 15) that started treatment 24 months ago
89. Number of children (under 15) were still on the first line regimen after 24 months
90. Number of adults on a second line regimen after 24 months
91. Number of children (under 15) on a second line regimen after 24 months
92. Number of patients who had their CD4 counts tested at 24 months
93. Number of patients with a CD4 count above 200 at 24 months
94. Number of patients who had their Viral Load tested at 24 months
95. Number of patients with a Viral Load below 400 at 24 months
96. Number of patient lost to follow up between 12 and 24 months of treatment
97. Number of children under 5 years that were weighed
98. Number of children under 1 year that had the 1st dose of BCG
99. Number of children that had the 1st dose of DTaP-IPV/Hib
100. Number of children that had the 3rd dose of DTaP-IPV/Hib
101. Number of children that had the 4th dose of DTaP-IPV/Hib
102. Number of children that had the 1st dose of DTP-Hib
103. Number of children that had the 3rd dose of DTP-Hib
104. Number of children that had the 1st dose of HepB
105. Number of children that had the 3rd dose of HepB
106. Number of children under 1 year that were fully Immunised
107. Number of children under 1 year that had the 1st dose Measles
108. Number of children that had the 2nd dose of Measles
109. Number of children that had the 1st dose of OPV
110. Number of children that had the 3rd dose of OPV
111. Number of children that had the 1st dose of PCV7
112. Number of children that had the 3rd dose of PCV7
113. Number of children that had the 1st dose of RV
114. Number of children that had the 2nd dose of RV
115. Number of people that had Td at 6 years
116. Number of people that had Td at 12 years
117. Number of children aged 6-11 months that had Vitamin A supplement
118. Number of children aged 12-59 months that had Vitamin A supplement

J.4 ACTIVITIES

J.4.1 At the CHC (typical use case)

- Patient comes for antenatal care
- Clerk searches for patient folder
- If patient has been to this centre previously, clerk retrieves patient's folder

- If this is patient's first visit to the centre, clerk manually creates a new folder and small clinic card for patient
- All women who came for antenatal care are given health education (each day's topic varies)
- Patient is seen by nurse
- Nurse obtains and records past medical history
- Nurse carries out various clinical observations (e.g. weight, blood pressure, temperature, fundal height, Pinkie's heart rate, and the baby's heart rate)and records in the standard maternity case record
- Nurse counsels patient about HIV testing and discusses the PMTCT program with patient
- Patient agrees to have HIV test and sign consent form
- Patient is tested with finger prick test
- Finger prick test kit gives test result
- If result is positive, test is repeated using test kit from another manufacturer
- Finger prick test kit gives test result
- If result is positive, nurse do post-test counselling
- Patient is screened for TB, WHO clinical staging is derived
- Nurse takes blood for various tests (full blood count, CD4 count, Alamine Aminotransferase)
- Nurse initiates patient on prophylactic ART (Zidovudine)
- Nurse completes order form for blood tests, label the blood samples and send to laboratory via a courier
- Blood results is returned to the centre by the courier and filed in patient's file
- Patient is given one week appointment to be seen by doctor at the centre and for blood result
- A day prior to appointment date, clerk pulls the files of all patients that have appointments for the following day to reduce waiting time
- Patient returns to the centre for the scheduled appointment
- Clerk confirms appointment and gets patient's file
- Patient is seen and examined by doctor
- Doctor records his findings in patient's file
- Patient continues to receive ante natal care at the CHC until she is due to have her baby
- When patient is in labour, she is admitted to the MOU section of the centre
- Midwife monitors patient while in labour
- Midwife administers intra-partum ART to patient according to NDoH PMTCT guideline
- Midwife delivers baby
- After delivery, midwife administers post-partum ART to patient according to NDoH PMTCT guideline
- Midwife administers prophylactic nevirapine, first doses of BCG and oral polio vaccines according to the PMTCT and childhood immunisation guidelines
- Midwife records delivery in the delivery detail in the 'delivery summary' section of the 'maternity case record' booklet
- Midwife examines mother and baby for fitness for discharge

- Midwife discharge mother and baby and completes the 'discharge summary' section of the 'maternity case record' booklet. A copy of the discharge summary is kept in patient's file
- Mother and baby are given appointment to come for check-up after two days
- Mother and baby are seen and examined by doctor
- Doctor recommends that baby continues with nevirapine for six weeks
- Mother and baby are given appointment to come for check-up after six weeks

J.4.2 After Six Weeks

- Patient returns with her baby
- Mother and baby are seen by the doctor
- Mother and baby are examined by the doctor
- Doctor orders blood for CD4 count,
- Blood is sent to the lab via courier
- Doctor records clinical observation and WHO clinical stage
- Doctor screens patient for TB
- Make appointment to come back for test results
- Write appointment date and time on patient card
- Laboratory results sent back
- Results filed in patient's file
- If Patient's CD4 count is more than 350 cells/mm^3, she is referred for wellness services and family planning
- If Patient's CD4 count is below 350 cells/mm^3 and/or WHO clinical stage is 3 or 4, patient is initiated on lifelong ART

J.5 EXCEPTIONAL USE CASE

J.5.1 At the CHC

- Patient comes for antenatal care
- Clerk searches for patient folder
- If patient has been to this clinic previously, clerk retrieves patient's folder
- If this is patient's first visit to the clinic, clerk manually creates a new folder and small clinic card for patient
- All women who came for antenatal care are given health education (each day's topic varies)
- Patient is seen by nurse
- Nurse obtains and records past medical history
- Nurse carries out various clinical observations (e.g. weight, blood pressure, temperature, urine analysis, fundal height, Pinkie's heart rate, and the baby's heart rate)and records in the standard maternity case record

- Patient's blood pressure is high, her feet are swollen, and the urine test shows presence of protein
- Nurse counsels patient about HIV testing and discusses the PMTCT program with patient
- Patient agrees to have HIV test and sign consent form
- Patient is tested with finger prick test
- Finger prick test kit gives test result
- If result is positive, test is repeated using test kit from another manufacturer
- Finger prick test kit gives test result
- If result is positive, nurse do post-test counselling
- Because the doctor does not visit the centre on the day, nurse decides to refer patient to the district hospital
- Nurse fills the standard referral letter

J.5.2 At the district hospital

- Patient presents the referral letter to the clerk
- Clerk searches for patient file
- If patient has been to this clinic previously, clerk retrieves patient's file
- If this is patient's first visit to the clinic, clerk manually creates a new file and small registration card for patient
- Patient is seen by doctor
- Doctor reads referral letter, obtains and records past medical history
- Doctor carries out various clinical observations (e.g. weight, blood pressure, temperature, fundal height, Pinkie's heart rate, and the baby's heart rate)and records WHO clinical staging
- Doctor makes a diagnosis of pre-ecplamsia
- Doctor orders blood for Full blood count, CD4 count Alamine Aminotransferase and liver function test
- Doctor placed patient on bed rest at home
- Doctor prescribes medicines for high blood pressure and prophylactic ART medicines (Zidovudine) and routine iron + folate
- Blood is sent to the laboratory
- Make appointment to come back for test results
- Write appointment date and time on patient card
- Pharmacist dispenses medicines and prescribed
- Pharmacist records dispensing
- Laboratory results sent back
- Results filed in patient's folder

J.5.3 Return Visit for blood results

- Patient returns for appointment
- Patient goes to the clerk, who updates any change in patient's demographic information
- Patient is seen by doctor

- Doctor repeats clinical observations (e.g. weight, blood pressure, temperature, fundal height, Pinkie's heart rate, and the baby's heart rate)and records WHO clinical staging
- Doctor reviews blood results
- Doctor repeats prescriptions for high blood pressure and prophylactic ART medicine (Zidovudine) and routine iron + folate
- Doctor advises patient to continue with bed rest at home
- Doctor counsels patient about breast and formula feeding
- Make appointment
- Write appointment date and time on patient card
- Pharmacist dispenses medicines and prescribed
- Pharmacist records dispensing

J.5.4 Follow-up antenatal care (the following activities are repeated at each visit)

- Patient returns for appointment
- Patient goes to the clerk, who updates any change in patient's demographic information
- Patient is seen by doctor
- Doctor repeats clinical observations (e.g. weight, blood pressure, temperature, urine analysis, fundal height, Pinkie's heart rate, and the baby's heart rate)and records WHO clinical staging
- Doctor records clinical observation and WHO clinical stage
- Make appointment for follow-up antenatal visit
- Write appointment date and time on patient card
- Pharmacist dispenses medicines and prescribed
- Pharmacist records dispensing

J.5.5 Labour and Delivery

- Patient suspects she is in labour
- Patient goes to district hospital
- Patient is seen by the doctor
- Doctor examines patient
- Doctor admits patient to labour ward
- Doctor prescribes ARVs (intra-partum: single-dose Nevirapine, single dose of Truvada and 3 hourly Zidovudine; post-partum: single dose of Tenofovir and Emtracitabine)
- Midwife receives patient in the labour ward
- Midwife assigns patient to available bed
- Midwife measures and records vital signs (temperature, heart rate, blood pressure, fetal heart rate, frequency and intensity of abdominal contraction, cervical dilatation, etc.)
- Midwife records patient's detail in ward admission book
- Midwife draws a care plan for patient
- Midwife sends patient's prescription to pharmacy for collection of ARV
- Midwife administers intra-partum ART as prescribes

- Midwife continues to monitor patient's progress while in labour
- Midwife delivers baby
- Midwife records birth details in delivery register
- If any complication arises or labour does not progress well, necessary procedure (e.g. forceps delivery, vacuum extraction or caesarean section) is carried out by doctor
- After delivery, midwife administers post-partum ART to patient according to NDoH PMTCT guideline
- Midwife administers prophylactic nevirapine, first doses of BCG and oral polio vaccines according to the PMTCT and childhood immunisation guidelines
- Midwife records delivery in the delivery detail in the 'delivery summary' section of the 'maternity case record' booklet
- Baby is started on exclusive formula feed as per mother's decision
- Mother and baby are seen and examined by doctor
- Doctor recommends that baby continues with nevirapine for six weeks
- Mother and baby are given appointment to come for check-up after six weeks
- If all is well, mother and baby are discharged, to come back for follow-up visit after two days
- Make appointment for follow-up post natal visit
- Write appointment date and time on patient card
- Nurse records date of discharge against patient's name in the ward admission book

J.5.6 Postpartum Visits

- Patient returns with her baby after two days
- Mother and baby are seen by the doctor
- Mother and baby are examined by the doctor
- Doctor prescribes more Nevirapine for baby (for six weeks)
- Make appointment for follow-up postnatal visit after six week
- Write appointment date and time on patient card
- Pharmacist dispenses Nevirapine
- Pharmacist records dispensing

J.5.7 After Six Weeks

- Patient returns with her baby
- Mother and baby are seen by the doctor
- Mother and baby are examined by the doctor
- Doctor orders blood for CD4 count,
- Blood is sent to the lab via courier
- Doctor records clinical observation and WHO clinical stage
- Doctor screens patient for TB
- Make appointment to come back for test results
- Write appointment date and time on patient card

- Laboratory results sent back
- Results filed in patient's file
- If Patient's CD4 count is more than 350 cells/mm^3, she is referred for wellness services and family planning
- If Patient's CD4 count is below 350 cells/mm^3 and/or WHO clinical stage is 3 or 4, patient is initiated on lifelong ART

J.5.8 Follow-Up care for Baby

- Follow-up care basically follows the childhood immunisation schedule
- First visit within three days after birth
- Ten days after birth
- Six weeks after birth
- At six weeks of age, baby's blood is drawn for HIV and Polymerase Chain Reaction (PCR)
- Baby discontinues prophylactic Nevirapine
- Doctor prescribes cotrimoxazole for baby
- Baby will continue exclusive formula feeding
- PCR is repeated six weeks after the mother stops breast feeding
- If both HIV and PCR are negative, doctor discontinues cotrimoxazole
- Another HIV test is done when baby is 18 months
- If PCR is positive, baby will continue with cotrimoxazole; confirmatory HIV test and viral load will be done (for initiation on ART)

K APPENDIX - ANTENATAL AND POSTNATAL CARE AND MANAGEMENT: LEVEL 3 - SCENARIO

This scenario has been described in two use cases:

1. A typical use case, where antenatal care is received at the community health centre (CHC) and delivery takes place at the centre's maternal obstetric unit (MOU). Being HIV positive is not an indication for referral to hospital for antenatal care and delivery.
3. An exceptional use case, where other maternal and/or fetal condition(s) necessitate referral to hospital for antenatal care and delivery.

K.1 CHARACTERS

- Pinkie – pregnant mum
- Sarah – local community health centre (CHC) registration clerk
- Mary – general nurse at the CHC
- Dr White – physician at CHC (visits the centre twice per week between 08:00 AM and 4:00 PM)
- Bongi – pharmacy assistant at the CHC
- Beatrice – midwife at CHC maternal obstetric unit (MOU)
- Thando – lab technician at the district hospital lab
- Busi – district hospital registration clerk
- Dr. Naidoo – physician at the district hospital
- Precious – pharmacist
- Dr Mandla – doctor on duty at district hospital
- Linah – midwife at district hospital labour ward
- Patience – data capturer at provincial hospital

K.2 TYPICAL USE CASE (ANTENATAL CARE AND DELIVERY TAKES PLACE AT THE CHC)

K.2.1 Antenatal care

Pinkie is a 19 year old single mother of one, Bridget who is 10 month old. Pinkie is unemployed. She lives in a two-room shack with her grandmother, Naledi, and two siblings, Piladi (15 years) and Banda (10 years).

Pinkie is 5 months pregnant with her 2nd child. Pinkie has decided to go to the community health centre (CHC) to register for ante natal care.

On arrival at the CHC, Pinkie reported at the registration clerk's (Sarah) desk. She told Sarah she is pregnant and would like to see the nurse or doctor.

Sarah asked Pinkie if she has been to the centre before. Pinkie replied no. Nevertheless, Sarah still went ahead and searched the centre's patient management system (PMS), which is linked to the provincial shared health record system, first using Pinkie's ID number and then a combination of her demographics data (name, surname, date of birth, etc.); to make sure Pinkie is not registered on the system. No record matching Pinkie's detail was found.

Hence, Sarah created a new record for Pinkie using information provided by Pinkie, as well as that in her ID book. A unique identification number was generated for Pinkie by the central patient master index (PMI) responsible for allocating patient identifiers. Sarah also printed some labels which have Pinkie's name and registration number and stuck one on a new folder. She then placed the remaining inside Pinkie's folder for later use. Sarah also gave Pinkie a small CHC card on which she stuck one of the labels.

Sarah then asked Pinkie to wait in the waiting area.

After a while, Mary the centre nurse came to the waiting area and collected all the files of those who came for ante-natal care from the clerk; she then called all the pregnant women to follow her to a room for the day's health talk. The focus of the talk was on the importance of getting tested for HIV and breastfeeding.

After the talk each of the pregnant women were called in to the consulting room for one-on-one consultation.

When her turn came, Pinkie went in to see Mary. Mary noted that this is Pinkie's first ante-natal care visit. Mary asked Pinkie questions about her health history (number of children, previous pregnancies, previous conditions, with dates and outcomes). She also carried out a number of clinical observations (Pinkie's weight, blood pressure, temperature, urine analysis, fundal height, Pinkie's heart rate, and the baby's heart rate). Mary records the information and the readings in the appropriate section of the standard 'Maternity case record' booklet supplied by the department of health.

Thereafter, Mary again discussed the importance of getting tested for HIV with Pinkie. She explained to her that the result of the test would be confidential, and that disclosing the result to her family member would be Pinkie's choice.

After the counselling, Pinkie agreed to do the HIV test. Mary asked Pinkie to sign a standard HIV consent form, so that her consent is documented. Pinkie signed the consent form as requested. The signed form was filed in her file.

Mary cleaned Pinkie's finger with an alcohol swab and did a finger prick HIV test. She asked Pinkie to wait outside for the result. After 20 minutes Mary called Pinkie to the consulting room; she told Pinkie the test was positive, but they would need to do another one to be sure. Mary did a second finger prick HIV test using a test kit from another manufacturer.

About half an hour later, Mary called Pinkie in again. She was very sorry, she said, but the second test was also positive. Pinkie was understandably devastated and began to cry. Mary comforted Pinkie and carried out a post-test counselling.

Mary discussed Government's prevention of mother to child transmission (PMTCT) program with Pinkie and explained that people with HIV could live normal, healthy life, and that the PMTCT program will reduce the risk of her unborn baby being infected with HIV. Mary also told Pinkie that she needs to do more blood tests, so they could put her on appropriate treatment. She then took blood for Full blood count, CD4 count and Alamine Aminotransferase. Pinkie was also screened for tuberculosis (TB) and the WHO clinical staging was derived. Mary asked Pinkie specific questions

regarding symptoms of TB and whether she has been previously treated for TB The blood samples were labelled and sent to the laboratory via a courier.

Mary initiated Pinkie on prophylactic antiretroviral treatment (ART) with Zidovudine and iron + folate supplements as per the NDoH PMTCT clinical guidelines. She asked Pinkie to return after one week, so she could be seen by the doctor and her blood results reviewed. At the end of the care event, Mary recorded all actions performed on, and treatment given to Pinkie in the appropriate section of the standard 'Maternity case record' booklet.

Pinkie stopped at the centre's pharmacy to collect her medicines. She gave her file to Bongi, the pharmacy assistant. Bongi dispensed one week supply of the medicines as prescribed and labelled the medicine containers with dosage instructions.

Pinkie returned to Sarah, who scheduled the appointment on the centre's PMS, and wrote the appointment's date on Pinkie's small card.

A day before Pinkie's appointment, Sarah prompts the centre's PMS to generate a 'picking list for the files of all patients who have appointments the following day. She then pulled out the files in the list to reduce the waiting time.

Pinkie's blood tests have since been completed, and the results brought back from the lab by the courier and filed in Pinkie's file.

On her appointment date, Pinkie was at the centre. Sarah confirmed the appointment and brought out Pinkie's file.

Pinkie was later seen by Dr White, who reviewed the information in Pinkie's 'Maternity case record' booklet, including the blood results. Dr White asked Pinkie how she was doing; he carried out and recorded Pinkie's clinical observations. He assured Pinkie that she and her baby were doing well, and recommend that she continue with the prophylactic ART, which was initiated by the nurse during her last visit. Dr White then wrote a repeat prescription of Zidovudine, iron and folate supplements for Pinkie.

Dr White also discussed breast and formula feeding with Pinkie; and the implications of the various options. He told her she still has to decide whether or not to breastfeed her baby after birth. Pinkie promised to think about it.

Pinkie continues to receive ante natal care at the CHC until she is due to have her baby.

K.2.2 Labour and delivery

As soon as Pinkie suspects that she is in labour, she went to the CHC as advised. She reported at the registration clerk who searched for and retrieved her file.

Pinkie was seen by Mary (it was not Dr White's visiting day); she asked Pinkie when the pain started and the frequencies. She also examined her and confirmed that she is in labour. Mary then admits Pinkie to the maternal obstetric unit (MOU) of the CHC.

Pinkie was received by Beatrice, a midwife at the MOU. Beatrice measured and recorded Pinkie's vital observation e.g. temperature, heart rate, blood pressure, fetal heart rate, frequency and intensity of abdominal contraction, cervical dilatation, urine analysis etc.), in the appropriate section

of the 'Maternity case record' booklet . She also draws a care plan for Pinkie according to the NDoH PMTCT guidelines on intra-partum care of HIV+ women in labour. Beatrice administered a single-dose of Nevirapine, single dose of Truvada , and 3hourly Zidovudine to Pinkie, according to the NDoH PMTCT guidelines. After the admission 'routine', Beatrice recorded Pinkie's detail in the MOU's 'admission' book.

Beatrice continues to monitor Pinkie throughout labour and recorded her progress in the appropriate section of the 'Maternity case record' booklet, until she delivered her baby.

After delivery, Pinkie is given post-partum ARV medicines (single dose of Tenofovir and Emtracitabine).

Beatrice carried out a physical examination on baby Pinkie and recorded her findings in the appropriate section of the 'Maternity case record' booklet. The baby also received the first doses of BCG and oral polio vaccines according to the childhood immunisation guideline, as well as prophylactic nevirapine according to the NDoH PMTCT guidelines. Details of the vaccination were recorded in a new 'Road to health' card.

Beatrice records the birth in the MOU's delivery book and completes the 'summary of labour' section of the 'Maternity case record' booklet.

Pinkie has decided not to breast feed her baby; hence the baby was started on formula feed at the centre.

Since Pinkie's delivery process was uneventful; she and her baby were discharged the same day (patients are admitted in MOUs for six hours). Pinkie was given an appointment to come back with her baby for post-natal check-up after two days. Beatrice completed the standard 'discharge summary' section of the 'Maternity case record' booklet. A copy of the discharge summary was filed in Pinkie's file.

K.2.3 Post-natal care

After two days, Pinkie came back to the centre with her baby for post-natal check-up. Since it was the doctor's visiting day to the centre, Pinkie and her baby were seen and examined by Dr White.

Dr White decides that Pinkie's baby should continue taking nevirapine for six weeks according to the NDoH PMTCT guidelines.

Pinkie is given appointment to come for check-up within six weeks of delivery. Another appointment was scheduled accordingly.

On the date of her appointment, Pinkie was back at the CHC. During this visit, blood was drawn for CD4 count and clinical staging of HIV is done. Pinkie was also screened for TB.

Pinkie is given one week appointment to come for the results of blood tests.

If Pinkie's CD4 count is more than 350 cells/mm^3, she will be referred for wellness services and family planning.

(NB: Wellness service is follow-up program of HIV-infected individuals not yet on ART and includes: provision of TB screening, INH prophylaxis, cortrimoxazole prophylaxis, nutritional and psychosocial

support, cervical cancer screening, monitoring of CD4 count, clinical staging and preparedness for ART).

If Pinkie's CD4 count is below 350 cells/mm^3 or she is in clinical stage 3 or 4, she will be initiated on lifelong ART.

Follow-up care for baby Pinkie, according to the according to the NDoH PMTCT guidelines is as follows:

- Follow-up care basically follows the childhood immunisation schedule
- First visit within three days after birth
- Ten days after birth
- Six weeks after birth
- At six weeks of age, baby's blood is drawn for HIV and Polymerase Chain Reaction (PCR)
- Baby discontinues prophylactic Nevirapine
- Doctor prescribes cotrimoxazole for baby
- Baby will continue exclusive formula feeding
- PCR is repeated six weeks after the mother stops breast feeding
- If both HIV and PCR are negative, doctor discontinues cotrimoxazole
- Another HIV test is done when baby is 18 months
- If PCR is positive, baby will continue with cotrimoxazole; confirmatory HIV test and viral load will be done (for initiation on ART)

K.3 EXCEPTIONAL USE CASE (REFERRAL TO HOSPITAL FOR ANTENATAL CARE AND DELIVERY)

K.3.1 At CHC

Pinkie is a 19 year old single mother of one, Bridget who is 10 month old. Pinkie is unemployed. She lives in a two-room shack with her grandmother, Naledi, and two siblings, Piladi (15 years) and Banda (10 years).

Pinkie is 5 months pregnant with her 2nd child. Pinkie has decided to go to the local community health centre (CHC) to register for ante natal care.

On arrival at the CHC, Pinkie reported at the registration clerk's (Sarah) desk. She told Sarah she is pregnant and would like to see the nurse or doctor.

Sarah asked Pinkie if she has been to the centre before. Pinkie replied no. Nevertheless, Sarah still went ahead and searched the centre's patient management system (PMS), which is linked to the central provincial electronic health record EHR system, first using Pinkie's ID number and then a combination of her demographics data (name, surname, date of birth, etc.); to make sure Pinkie is not registered on the system. No record matching Pinkie's detail was found.

Hence, Sarah created a new record for Pinkie using information provided by Pinkie, as well as that in her ID book. A unique identification number was generated for Pinkie by the central patient master

index (PMI) responsible for allocating patient identifiers. Sarah also printed some labels which have Pinkie's name and registration number and stuck one on a new folder. She then placed the remaining inside Pinkie's folder for later use. Sarah also gave Pinkie a small CHC card on which she stuck one of the labels.

Sarah then asked Pinkie to wait in the waiting area.

After a while, Mary the centre nurse came to the waiting area and collected all the files of those who came for ante-natal care from the clerk; she then called all the pregnant women to follow her to a room for the day's health talk. The focus of the talk was on the importance of getting tested for HIV and breastfeeding.

After the talk each of the pregnant women were called in to the consulting room for one-on-one consultation.

When her turn came, Pinkie went in to see Mary. Mary noted that this is Pinkie's first ante-natal care visit. Mary asked Pinkie questions about her health history (number of children, previous pregnancies, previous conditions, with dates and outcomes).

She also carried out a number of clinical observations (Pinkie's weight, blood pressure, temperature, urine analysis, fundal height, Pinkie's heart rate, and the baby's heart rate).

Mary notes that Pinkie's blood pressure was slightly elevated and both feet are swollen; her urine dipstick test also tested positive for protein. She records the information obtained from Pinkie and the clinical readings in the appropriate section of the standard 'Maternity case record' booklet supplied by the department of health.

Thereafter, Mary again discussed the importance of getting tested for HIV with Pinkie. She explained to her that the result of the test would be confidential, and that disclosing the result to her family member would be Pinkie's choice.

After the counselling, Pinkie agreed to do the HIV test. Mary asked Pinkie to sign a standard HIV consent form, so that her consent is documented.

Mary cleaned Pinkie's finger with an alcohol swab and did a finger prick HIV test. She asked Pinkie to wait outside for the result. After 20 minutes Mary called Pinkie to the consulting room; she told Pinkie the test was positive, but they would need to do another one to be sure. Mary did a second finger prick HIV test using a test kit from another manufacturer.

About half an hour later, Mary called Pinkie in again. She was very sorry, she said, but the second test was also positive. Pinkie was understandably distraught and began to cry. Mary comforted Pinkie and carried out a post-test counselling.

Because the doctor does not come to the centre that day, Mary explained to Pinkie that she needs to refer her to the district hospital due the high blood and swollen feet, so she could be reviewed by a doctor.

Mary filled the standard referral form and asked Pinkie to go to the district hospital, preferably the same day since the hospital is not far from the centre. She also gave Pinkie her 'maternity case record' to take along to the hospital.

Pinkie left the CHC and immediately went to the district hospital.

Pinkie told Busi, the district hospital registration clerk, that she has been referred from the CHC and showed her the referral letter.

Busi asked Pinkie if she has previously been to the hospital, and she replied no. Busi searched the hospital's centralised patient administration system to see whether Pinkie is already registered on the system, first using Pinkie's ID number and then a combination of her demographics data (name, surname, date of birth, etc.). Because this is Pinkie's first visit to the hospital, Busi could not find any record matching her detail. She then registered Pinkie on the hospital system, using the same identifier that was generated for Pinke at the CHC.

Busi also printed some labels with Pinkie's name and registration number and stuck one on a new file and placed the remaining inside Pinkie's folder for later use.

Pinkie was seen by the doctor on duty, Dr Naidoo. Dr Naidoo read the referral letter and asked Pinkie how she was doing. He asked her questions about her previous pregnancy and birth, as well as specific questions about TB. For example has she ever had TB? Is she coughing at present? The information was recorded in Pinkie's folder. Thereafter, Dr Naidoo carried out detail physical examination on Pinkie (weight, height, blood pressure, temperature, fundal height, Pinkie's heart rate, and the baby's heart rate, and the swollen feet). He also derived the WHO clinical, using history and his clinical observations.

Dr Naidoo explained to Pinkie that he needs to draw some blood for testing (Full blood count, CD4 count Alamine Aminotransferase, and liver function test), so that Pinkie could be started on appropriate treatment. The blood samples were labelled, the order form was filled and the blood was sent to the hospital laboratory.

Dr Naidoo made a diagnosis of pre-eclampsia; he then explained to Pinkie that he would place her on bed rest (at home) and prescribe medicines for the high blood pressure. He also told Pinkie that he would start her on prophylactic antiretroviral treatment (ART) as per the NDoH PMTCT clinical guidelines.

Dr Naidoo then wrote prescriptions for high blood pressure medicine and ART, as well as routine iron and folate supplements. He asked Pinkie to come back after one week.

Pinkie went back to Busi, who scheduled the appointment on the hospital's system, and wrote the appointment's date on Pinkie's small card.

Thereafter, Pinkie went to the pharmacy where the pharmacist (Precious) dispensed the medicines according to the doctor's prescription; she wrote the dosage instructions on their containers. Precious updated the pharmacy system with details of the dispensed medicines.

On the date of her appointment, Pinkie went back to the district hospital. She gave her registration card to Busi, who confirmed the appointment and retrieved Pinkie's file. Busi asked Pinkie if any of her demographic detail has changed. Pinkie answered that her cell phone number has changed and Busi updated the hospital's system with the new number.

Pinkie was seen by Dr Naidoo, who repeated the physical and clinical observations and recorded the WHO clinical staging. The blood result is now available and has been filed in Pinkie's folder. Pinkie's blood results has since been returned and filed in her file. Dr Naidoo noted that the CD4 count is above 350 cells/mm^3 and the WHO clinical staging is stage 2. He also noted that Pinkie's blood pressure is reducing gradually and the swollen feet are subsiding. Thus, he decides Pinkie should

continue with the anti-hypertensive medicines and prophylactic Zidovudine, as well as the routine iron and folate supplements.

Dr Naidoo also discussed breast and formula feeding with Pinkie and implications of the various options. He told her she still has to decide whether or not to breastfeed her baby after birth. Pinkie promised to think about it.

Dr Naidoo informed Pinkie that she would be seen every two weeks during her pregnancy, but advised her to come to the hospital if there is any problem in-between her appointments.

Pinkie continues to receive antenatal care at the district hospital. At each visit, a full clinical observation (weight, blood pressure, heart rate, fetal heart rate, fundal height, urine analysis etc.) is carried out by the doctor and recorded in her file. She also continued with the prophylactic ART and antihypertensive medicines.

K.3.2 Labour and delivery

As soon as Pinkie suspects that she is in labour, she went to the district hospital as advised. She reported at the registration clerk who retrieved her file.

She was seen by the doctor on duty (Dr Mandla), who examined Pinkie and confirmed that she is in labour. Dr Mandla ordered that Pinkie be admitted to the labour ward.

Dr Mandla initiated Pinkie on intra-partum ARV (single-dose Nevirapine, single dose of Truvada and 3 hourly Zidovudine) according to the NDoH PMTCT guidelines.

Pinkie was received by Linah, a midwife in the labour ward. Linah measured and recorded Pinkie's vital observation (e.g. temperature, heart rate, blood pressure, fetal heart rate, urine analysis, frequency and intensity of abdominal contraction, cervical dilatation, etc.) in the appropriate section of the 'Maternity case record' booklet . She also draws a care plan for Pinkie according to the NDoH PMTCT guidelines on intra-partum care of HIV+ women in labour. Linah administered a single-dose of Nevirapine, single dose of Truvada , and 3hourly Zidovudine to Pinkie, according to the NDoH PMTCT guidelines. She also recorded Pinkie's detail, as well as the ART administered in the delivery book.

Linah continues to monitor Pinkie throughout labour and recorded her progress in the appropriate section of the 'Maternity case record' booklet, until she delivered her baby.

If the condition of Pinkie and/or her baby necessitates that a procedure be carried out (e.g. forceps delivery, vacuum extraction or caesarean section, the appropriate procedure would be carried out by the doctor.

After delivery, Pinkie is given post-partum ARV medicines (single dose of Tenofovir and Emtracitabine) as prescribed by Dr Mandla.

Linah carried out a physical examination on baby Pinkie and recorded her findings in the appropriate section of the 'Maternity case record' booklet. The baby also received the first doses of BCG and oral polio vaccines according to the childhood immunisation guideline, as well as prophylactic nevirapine according to the NDoH PMTCT guidelines. Details of the vaccination were recorded in a new 'Road to health' card.

Linah records the birth in the labour ward's delivery book and completes the 'summary of labour' section of the 'Maternity case record' booklet.

Pinkie has decided not to breast feed her baby; hence the baby was started on formula feed soon after birth in the ward.

Pinkie's delivery process was uneventful. Pinkie and her baby were examined by Dr Mandla, who noted that mother and baby are well; hence Pinkie and her baby were discharged a day after delivery. Linah completes the 'discharge summary' section of the 'maternity case record' booklet and kept a copy in Pinkie's hospital file.

Pinkie is asked to come to back to the hospital for check-up with her baby two days after discharge.

Linah sent the hospital attendant to the OPD to schedule an appointment for Pinkie. She also recorded the date Pinkie's was discharged against her detail in the ward's admission book.

K.3.3 Post-natal care

Two days after discharge, Pinkie came back to the hospital's OPD with her baby as per the scheduled appointment. She showed her registration card to the clerk, who confirmed the appointment in the appointment book and pulled out Pinkie's file.

Pinkie and her baby were seen by Dr Mandla. He asked how she and her baby were doing, whether the baby is feeding well, and if she has anything the report. Pinkie answered that there was no problem with her and the baby. Dr Mandla examined mother and baby and recorded his observations in Pinkie's file. Dr Mandla decides that Pinkie's baby should continue taking nevirapine for six weeks according to the NDoH PMTCT guidelines.

Pinkie is given appointment to come for check-up within six weeks of delivery. Another appointment was scheduled accordingly.

On the date of her appointment, Pinkie was back at the hospital. During this visit, blood is drawn for CD4 count and clinical staging of HIV is done. Pinkie is also screened for TB.

Pinkie is given one week appointment to come for the results of blood tests.

If Pinkie's CD4 count is more than 350 cells/mm^3, she will be referred for wellness services and family planning.

(NB: Wellness service is follow-up program of HIV-infected individuals not yet on ART and includes: provision of TB screening, INH prophylaxis, cortrimoxazole prophylaxis, nutritional and psychosocial support, cervical cancer screening, monitoring of CD4 count, clinical staging and preparedness for ART).

If Pinkie's CD4 count is below 350 cells/mm^3 or she is in clinical stage 3 or 4, she will be initiated on lifelong ART.

Follow-up care for baby Pinkie, according to the according to the NDoH PMTCT guidelines is as follows:

- Follow-up care basically follows the childhood immunisation schedule

- First visit within three days after birth
- Ten days after birth
- Six weeks after birth
- At six weeks of age, baby's blood is drawn for HIV and Polymerase Chain Reaction (PCR)
- Baby discontinues prophylactic Nevirapine
- Doctor prescribes cotrimoxazole for baby
- Baby will continue exclusive formula feeding
- PCR is repeated six weeks after the mother stops breast feeding
- If both HIV and PCR are negative, doctor discontinues cotrimoxazole
- Another HIV test is done when baby is 18 months
- If PCR is positive, baby will continue with cotrimoxazole; confirmatory HIV test and viral load will be done (for initiation on ART)

K.3.4 The following health indicators are associated with this scenario

1. How many people 5 years and older were seen at the clinic
2. How many children under 5 years were seen at the clinic
3. Inpatient days – total
4. Inpatient deaths - total
5. Inpatient discharges – total
6. Inpatient transfers out - total
7. OPD headcount - follow-up visit
8. How many cases were seen by a Professional Nurse
9. How many women were given vitamin A supplement within 8 weeks after delivery
10. Total number of antenatal 1st visit
11. Total number of antenatal follow-up visit
12. Total number of antenatal 1st visit at 20 weeks or later
13. Total number of antenatal 1st visit before 20 weeks
14. Total number of pregnant women who received 2nd/Booster dose of Tetanus Toxoid
15. Total number of antenatal client on HAART at delivery
16. Total number antenatal client eligible for HAART
17. Total number of babies initiated on HAART (under 18 months)
18. Total number of babies eligible for HAART
19. Total number of antenatal client on HAART at 1st visit
20. Total number of antenatal client who were re-tested for HIV at 32 weeks or later
21. Total number of antenatal client re-tested at 32 weeks or later with positive HIV result
22. Total number of antenatal client on AZT before labour
23. Total number of antenatal client Nevirapine taken during labour
24. Total live births to HIV positive women
25. Total number of babies given Nevirapine within 72 hours after birth
26. Total number of babies initiated on Co-Trimoxazole around 6 weeks
27. Total number of babies who had PCR test done around 6 weeks
28. Total number of babies whose PCR test was positive around 6 weeks

29. Total number of babies who had HIV antibody test done at 18 months
30. Total number of antenatal client who are known to be HIV positive but NOT on HAART at 1st visit
31. Total number of babies whose HIV antibody test was positive at 18 months
32. Total number of antenatal client who had the 1st HIV test done
33. Total number of antenatal client whose 1st HIV test was positive
34. Total number of antenatal client who had 1st CD4 test done
35. Number of patients with a CD4 count below 100 at baseline
36. Total number of antenatal client initiated on AZT
37. Total number of antenatal client initiated on HAART
38. Total number of caesarean sections in facility
39. Total number of delivery in facility under 18 years
40. Total number of delivery in facility 35 years and older
41. Total number of delivery in facility
42. Total number of inpatient death - early neonatal
43. Total live birth in facility under 2500g
44. Total live birth in facility
45. Total number of inpatient death - late neonatal
46. Total number of maternal death in facility
47. Total number of normal delivery in facility
48. Total still birth in facility
49. Total births in facility
50. Number of babies who received postnatal care within 6 days after birth
51. Number of mothers who received postnatal care within 6 days after delivery
52. Total birth defects case - mother 35 years and older
53. Total birth defects case - mother under 18 years
54. Total number of children with common priority Birth Defects
55. Total number of adults that started treatment this month
56. Total patients still on treatment at the end of the month
57. Total children (under 15) that started treatment this month
58. Total children (under 15) were still on treatment at the end of the month
59. Number of patients on TB treatment when they started ART
60. Number of adults who started treatment 3 months ago
61. Number of children (under 15) started treatment 3 months ago
62. Number of patients who died at 3 months
63. Number of adults who started treatment 6 months ago
64. Number of adults still on the first line regimen after 6 months
65. Number of children (under 15) who started treatment 6 months ago
66. Number of children (under 15) still on the first line regimen after 6 months
67. Number of adults on a second line regimen after 6 months
68. Number of children (under 15) on a second line regimen after 6 months
69. Number of patients who had their CD4 counts tested at 6 months
70. Number of patients with CD4 count above 200 at 6 months

71. Number of patients who had their Viral Load tested at 6 months
72. Number of patients with a Viral Load below 400 at 6 months
73. Number of patients who died between 3 and 6 months of treatment
74. Number of patients that were lost to follow up between 3 and 6 months of treatment
75. Number of adults who started treatment 12 months ago
76. Number of adults still on the first line regimen after 12 months
77. Number of children (under 15) who started treatment 12 months ago
78. Number of children (under 15) still on the first line regimen after 12 months
79. Number of adults on a second line regimen after 12 months
80. Number of children (under 15) on a second line regimen after 12 months
81. Number of patients who had their CD4 counts tested at 12 months
82. Number of patients who had a CD4 count above 200 at 12months
83. Number of patients who had their Viral Load tested at 12 months
84. Number of patients who had a Viral Load below 400 at 12 months
85. Number of patient that were lost to follow up between 6 and 12 months of treatment
86. Number of adults who started treatment 24 months ago
87. Number of adults still on the first line regimen after 24 months
88. Number of children (under 15) that started treatment 24 months ago
89. Number of children (under 15) were still on the first line regimen after 24 months
90. Number of adults on a second line regimen after 24 months
91. Number of children (under 15) on a second line regimen after 24 months
92. Number of patients who had their CD4 counts tested at 24 months
93. Number of patients with a CD4 count above 200 at 24 months
94. Number of patients who had their Viral Load tested at 24 months
95. Number of patients with a Viral Load below 400 at 24 months
96. Number of patient lost to follow up between 12 and 24 months of treatment
97. Number of children under 5 years that were weighed
98. Number of children under 1 year that had the 1st dose of BCG
99. Number of children that had the 1st dose of DTaP-IPV/Hib
100. Number of children that had the 3rd dose of DTaP-IPV/Hib
101. Number of children that had the 4th dose of DTaP-IPV/Hib
102. Number of children that had the 1st dose of DTP-Hib
103. Number of children that had the 3rd dose of DTP-Hib
104. Number of children that had the 1st dose of HepB
105. Number of children that had the 3rd dose of HepB
106. Number of children under 1 year that were fully Immunised
107. Number of children under 1 year that had the 1st dose Measles
108. Number of children that had the 2nd dose of Measles
109. Number of children that had the 1st dose of OPV
110. Number of children that had the 3rd dose of OPV
111. Number of children that had the 1st dose of PCV7
112. Number of children that had the 3rd dose of PCV7
113. Number of children that had the 1st dose of RV

114. Number of children that had the 2nd dose of RV
115. Number of people that had Td at 6 years
116. Number of people that had Td at 12 years
117. Number of children aged 6-11 months that had Vitamin A supplement
118. Number of children aged 12-59 months that had Vitamin A supplement

K.4 ACTIVITIES Typical use case

K.4.1 At the CHC

- Patient comes for antenatal care
- Clerk searches for patient folder
- If patient has been to this centre previously, clerk retrieves patient's folder
- If this is patient's first visit to the centre, clerk manually creates a new folder and small clinic card for patient
- All women who came for antenatal care are given health education (each day's topic varies)
- Patient is seen by nurse
- Nurse obtains and records past medical history
- Nurse carries out various clinical observations (e.g. weight, blood pressure, temperature, fundal height, Pinkie's heart rate, and the baby's heart rate)and records in the standard maternity case record
- Nurse counsels patient about HIV testing and discusses the PMTCT program with patient
- Patient agrees to have HIV test and sign consent form
- Patient is tested with finger prick test
- Finger prick test kit gives test result
- If result is positive, test is repeated using test kit from another manufacturer
- Finger prick test kit gives test result
- If result is positive, nurse do post-test counselling
- Patient is screened for TB, WHO clinical staging is derived
- Nurse takes blood for various tests (full blood count, CD4 count, Alamine Aminotransferase)
- Nurse initiates patient on prophylactic ART (Zidovudine)
- Nurse completes order form for blood tests, label the blood samples and send to laboratory via a courier
- Blood results is returned to the centre by the courier and filed in patient's file
- Patient is given one week appointment to be seen by doctor at the centre and for blood result
- A day prior to appointment date, clerk pulls the files of all patients that have appointments for the following day to reduce waiting time
- Patient returns to the centre for the scheduled appointment
- Clerk confirms appointment and gets patient's file
- Patient is seen and examined by doctor

- Doctor records his findings in patient's file
- Patient continues to receive ante natal care at the CHC until she is due to have her baby
- When patient is in labour, she is admitted to the MOU section of the centre
- Midwife monitors patient while in labour
- Midwife administers intra-partum ART to patient according to NDoH PMTCT guideline
- Midwife delivers baby
- After delivery, midwife administers post-partum ART to patient according to NDoH PMTCT guideline
- Midwife administers prophylactic nevirapine, first doses of BCG and oral polio vaccines according to the PMTCT and childhood immunisation guidelines
- Midwife records delivery in the delivery detail in the 'delivery summary' section of the 'maternity case record' booklet
- Midwife examines mother and baby for fitness for discharge
- Midwife discharge mother and baby and completes the 'discharge summary' section of the 'maternity case record' booklet. A copy of the discharge summary is kept in patient's file
- Mother and baby are given appointment to come for check-up after two days
- Mother and baby are seen and examined by doctor
- Doctor recommends that baby continues with nevirapine for six weeks
- Mother and baby are given appointment to come for check-up after six weeks

K.4.2 After Six Weeks

- Patient returns with her baby
- Mother and baby are seen by the doctor
- Mother and baby are examined by the doctor
- Doctor orders blood for CD4 count,
- Blood is sent to the lab via courier
- Doctor records clinical observation and WHO clinical stage
- Doctor screens patient for TB
- Make appointment to come back for test results
- Write appointment date and time on patient card
- Laboratory results sent back
- Results filed in patient's file
- If Patient's CD4 count is more than 350 cells/mm^3, she is referred for wellness services and family planning
- If Patient's CD4 count is below 350 cells/mm^3 and/or WHO clinical stage is 3 or 4, patient is initiated on lifelong ART

K.5 ACTIVITIES Exceptional use case

K.5.1 At the CHC

- Patient comes for antenatal care
- Clerk searches for patient folder
- If patient has been to this clinic previously, clerk retrieves patient's folder
- If this is patient's first visit to the clinic, clerk manually creates a new folder and small clinic card for patient
- All women who came for antenatal care are given health education (each day's topic varies)
- Patient is seen by nurse
- Nurse obtains and records past medical history
- Nurse carries out various clinical observations (e.g. weight, blood pressure, temperature, urine analysis, fundal height, Pinkie's heart rate, and the baby's heart rate)and records in the standard maternity case record
- Patient's blood pressure is high, her feet are swollen, and the urine test shows presence of protein
- Nurse counsels patient about HIV testing and discusses the PMTCT program with patient
- Patient agrees to have HIV test and sign consent form
- Patient is tested with finger prick test
- Finger prick test kit gives test result
- If result is positive, test is repeated using test kit from another manufacturer
- Finger prick test kit gives test result
- If result is positive, nurse do post-test counselling
- Because the doctor does not visit the centre on the day, nurse decides to refer patient to the district hospital
- Nurse fills the standard referral letter

K.5.2 At the district hospital

- Patient presents the referral letter to the clerk
- Clerk searches for patient file
- If patient has been to this clinic previously, clerk retrieves patient's file
- If this is patient's first visit to the clinic, clerk manually creates a new file and small registration card for patient
- Patient is seen by doctor
- Doctor reads referral letter, obtains and records past medical history
- Doctor carries out various clinical observations (e.g. weight, blood pressure, temperature, fundal height, Pinkie's heart rate, and the baby's heart rate)and records WHO clinical staging
- Doctor makes a diagnosis of pre-ecplamsia
- Doctor orders blood for Full blood count, CD4 count Alamine Aminotransferase and liver function test
- Doctor placed patient on bed rest at home

- Doctor prescribes medicines for high blood pressure and prophylactic ART medicines (Zidovudine) and routine iron + folate
- Blood is sent to the laboratory
- Make appointment to come back for test results
- Write appointment date and time on patient card
- Pharmacist dispenses medicines and prescribed
- Pharmacist records dispensing
- Laboratory results sent back
- Results filed in patient's folder

K.5.3 Return Visit for blood results

- Patient returns for appointment
- Patient goes to the clerk, who updates any change in patient's demographic information
- Patient is seen by doctor
- Doctor repeats clinical observations (e.g. weight, blood pressure, temperature, fundal height, Pinkie's heart rate, and the baby's heart rate)and records WHO clinical staging
- Doctor reviews blood results
- Doctor repeats prescriptions for high blood pressure and prophylactic ART medicine (Zidovudine) and routine iron + folate
- Doctor advises patient to continue with bed rest at home
- Doctor counsels patient about breast and formula feeding
- Make appointment
- Write appointment date and time on patient card
- Pharmacist dispenses medicines and prescribed
- Pharmacist records dispensing

K.5.4 Follow-up antenatal care (the following activities are repeated at each visit)

- Patient returns for appointment
- Patient goes to the clerk, who updates any change in patient's demographic information
- Patient is seen by doctor
- Doctor repeats clinical observations (e.g. weight, blood pressure, temperature, urine analysis, fundal height, Pinkie's heart rate, and the baby's heart rate)and records WHO clinical staging
- Doctor records clinical observation and WHO clinical stage
- Make appointment for follow-up antenatal visit
- Write appointment date and time on patient card
- Pharmacist dispenses medicines and prescribed
- Pharmacist records dispensing

K.5.5 Labour and Delivery

- Patient suspects she is in labour
- Patient goes to district hospital
- Patient is seen by the doctor
- Doctor examines patient
- Doctor admits patient to labour ward
- Doctor prescribes ARVs (intra-partum: single-dose Nevirapine, single dose of Truvada and 3 hourly Zidovudine; post-partum: single dose of Tenofovir and Emtracitabine)
- Midwife receives patient in the labour ward
- Midwife assigns patient to available bed
- Midwife measures and records vital signs (temperature, heart rate, blood pressure, fetal heart rate, frequency and intensity of abdominal contraction, cervical dilatation, etc.)
- Midwife records patient's detail in ward admission book
- Midwife draws a care plan for patient
- Midwife sends patient's prescription to pharmacy for collection of ARV
- Midwife administers intra-partum ART as prescribes
- Midwife continues to monitor patient's progress while in labour
- Midwife delivers baby
- Midwife records birth details in delivery register
- If any complication arises or labour does not progress well, necessary procedure (e.g. forceps delivery, vacuum extraction or caesarean section) is carried out by doctor
- After delivery, midwife administers post-partum ART to patient according to NDoH PMTCT guideline
- Midwife administers prophylactic nevirapine, first doses of BCG and oral polio vaccines according to the PMTCT and childhood immunisation guidelines
- Midwife records delivery in the delivery detail in the 'delivery summary' section of the 'maternity case record' booklet
- Baby is started on exclusive formula feed as per mother's decision
- Mother and baby are seen and examined by doctor
- Doctor recommends that baby continues with nevirapine for six weeks
- Mother and baby are given appointment to come for check-up after six weeks
- If all is well, mother and baby are discharged, to come back for follow-up visit after two days
- Make appointment for follow-up post natal visit
- Write appointment date and time on patient card
- Nurse records date of discharge against patient's name in the ward admission book

K.5.6 Postpartum Visits

- Patient returns with her baby after two days
- Mother and baby are seen by the doctor
- Mother and baby are examined by the doctor
- Doctor prescribes more Nevirapine for baby (for six weeks)

- Make appointment for follow-up postnatal visit after six week
- Write appointment date and time on patient card
- Pharmacist dispenses Nevirapine
- Pharmacist records dispensing

K.5.7 After Six Weeks

- Patient returns with her baby
- Mother and baby are seen by the doctor
- Mother and baby are examined by the doctor
- Doctor orders blood for CD4 count,
- Blood is sent to the lab via courier
- Doctor records clinical observation and WHO clinical stage
- Doctor screens patient for TB
- Make appointment to come back for test results
- Write appointment date and time on patient card
- Laboratory results sent back
- Results filed in patient's file
- If Patient's CD4 count is more than 350 cells/mm^3, she is referred for wellness services and family planning
- If Patient's CD4 count is below 350 cells/mm^3 and/or WHO clinical stage is 3 or 4, patient is initiated on lifelong ART

K.5.8 Follow-Up care for Baby

- Follow-up care basically follows the childhood immunisation schedule
- First visit within three days after birth
- Ten days after birth
- Six weeks after birth
- At six weeks of age, baby's blood is drawn for HIV and Polymerase Chain Reaction (PCR)
- Baby discontinues prophylactic Nevirapine
- Doctor prescribes cotrimoxazole for baby
- Baby will continue exclusive formula feeding
- PCR is repeated six weeks after the mother stops breast feeding
- If both HIV and PCR are negative, doctor discontinues cotrimoxazole
- Another HIV test is done when baby is 18 months
- If PCR is positive, baby will continue with cotrimoxazole; confirmatory HIV test and viral load will be done (for initiation on ART)

L APPENDIX - ANTENATAL AND POSTNATAL CARE AND MANAGEMENT: LEVEL 4 - SCENARIO

This scenario has been described in two use cases:

1. A typical use case, where antenatal care is received at the community health centre (CHC) and delivery takes place at the centre's maternal obstetric unit (MOU). Being HIV positive is not an indication for referral to hospital for antenatal care and delivery.
4. An exceptional use case, where other maternal and/or fetal condition(s) necessitate referral to hospital for antenatal care and delivery.

L.1 CHARACTERS

- Pinkie – pregnant mum
- Sarah – local community health centre (CHC) registration clerk
- Mary – general nurse at the CHC
- Dr White – physician at CHC (visits the centre twice per week between 08:00 AM and 4:00 PM)
- Bongi – pharmacy assistant at the CHC
- Beatrice – midwife at CHC maternal obstetric unit (MOU)
- Thando – lab technician at the district hospital lab
- Busi – district hospital registration clerk
- Dr. Naidoo – physician at the district hospital
- Precious – pharmacist
- Dr Mandla – doctor on duty at district hospital
- Linah – midwife at district hospital labour ward

L.2 TYPICAL USE CASE (ANTENATAL CARE AND DELIVERY TAKES PLACE AT THE CHC)

L.2.1 Antenatal care

Pinkie is a 19 year old single mother of one, Bridget who is 10 month old. Pinkie is unemployed. She lives in a two-room shack with her grandmother, Naledi, and two siblings, Piladi (15 years) and Banda (10 years).

Pinkie is 5 months pregnant with her 2nd child. Pinkie has decided to go to the community health centre (CHC) to register for ante natal care.

On arrival at the CHC, Pinkie reported at the registration clerk's (Sarah) desk. She told Sarah she is pregnant and would like to see the nurse or doctor.

Sarah asked Pinkie if she has been to the centre before. Pinkie replied no. Nevertheless, Sarah still went ahead and searched the centre's electronic medical record (EMR) system, which is linked to the provincial shared health record system, first using Pinkie's ID number and then a combination of her demographics data (name, surname, date of birth, etc.); to make sure Pinkie is not registered on the system. No record matching Pinkie's detail was found.

Sarah then created a new EMR for Pinkie using the demographic information she has provided. A unique identification number was generated for Pinkie by the provincial central patient master index (PMI) responsible for allocation patient identifiers.

Sarah also produced a plastic bar-coded small card, with Pinkie's demographic data, as part of the registration process. Sarah then asked Pinkie to wait in the waiting area.

After a while, Mary the clinic nurse, came to the waiting area and called all the pregnant women to follow her to a room for the day's health talk. The focus of the talk was on the importance of getting tested for HIV and breastfeeding.

After the talk each of the pregnant women were called in to the consulting room for one-on-one consultation.

When her turn came, Pinkie went in to see Mary, who scanned the bar-coded card to retrieve Pinkie's EMR. She noted that this is Pinkie's first ante-natal care visit. Mary asked Pinkie questions about her health history (number of children, previous pregnancies, previous conditions, with dates and outcomes). She also carried out a number of clinical observations (Pinkie's weight, blood pressure, temperature, urine analysis, fundal height, Pinkie's heart rate, and the baby's heart rate). Mary then recorded the information obtained from Pinkie, as well as clinical observation data in Pinkie's EMR.

Thereafter, Mary again discussed the importance of getting tested for HIV with Pinkie. She explained to her that the result of the test would be confidential, and that disclosing the result to her family member would be Pinkie's choice.

After the counselling, Pinkie agreed to do the HIV test. Mary asked Pinkie to sign a standard HIV consent form, so that her consent is documented. Pinkie signed the consent form as requested. The signed form was later scanned and uploaded to Pinkie's EMR.

Mary cleaned Pinkie's finger with an alcohol swab and did a finger prick HIV test. She asked Pinkie to wait outside for the result. After 20 minutes Mary called Pinkie to the consulting room; she told Pinkie the test was positive, but they would need to do another one to be sure. Mary did a second finger prick HIV test using a test kit from another manufacturer.

About half an hour later, Mary called Pinkie in again. She was very sorry, she said, but the second test was also positive. Pinkie was understandably devastated and began to cry. Mary comforted her and her and carried out a post-test counselling.

Mary discussed Government's prevention of mother to child transmission (PMTCT) program with Pinkie and explained that people with HIV could live normal, healthy lives. She also explained that the PMTCT program will reduce the risk of her unborn baby being infected with HIV. Mary also told Pinkie that she needs to do more blood tests, so they could put her on appropriate treatment. She then took blood for Full blood count, CD4 count and Alamine Aminotransferase. Pinkie was also screened for tuberculosis (TB) and the WHO clinical staging was derived. Mary asked Pinkie specific questions regarding symptoms of TB and whether she has been previously treated for TB.

An electronic order form for the blood tests was completed by Mary and sent directly to the laboratory system, which is linked to the CHC system. The blood samples were labelled and taken to the laboratory by a courier service.

Mary initiated Pinkie on prophylactic antiretroviral treatment (ART) with Zidovudine and iron + folate supplements as per the NDoH PMTCT clinical guidelines. She asked Pinkie to come back to the CHC after one week, so she could be seen by the doctor and her blood results reviewed.

At the end of the care event, Mary updated Pinkie's EMR and uploaded a summary of the care event to the provincial shared health record.

Pinkie stopped at the centre's pharmacy to collect her medicines. She gave her plastic card to Bongi, the pharmacy assistant. Bongi scanned the card to retrieve Pinkie's EMR; she then dispensed one week supply of ART and iron supplements as prescribed and labelled the medicine containers with dosage instructions. Bongi also update the pharmacy system with details of the dispensed medicines.

Pinkie returned to Sarah, who scheduled the appointment on the centre's PMS. Pinkie also received a text message on her phone detailing the date of the appointment.

A day before the scheduled appointment, Pinkie received a text message on the phone reminding her about the appointment for the next day.

Pinkie's blood tests have since been completed, and the results were sent directly to her EMR at the CHC.

On the date of her appointment, Pinkie went back to the CHC. She gave her plastic card to Sarah, who scanned the card to confirm Pinkie's appointment.

Pinkie was later seen by Dr White. Dr White scanned Pinkie's plastic card to retrieve her EMR. He reviewed the previous week's encounter, as well as the blood results. Dr White asked Pinkie how she was doing and carried out clinical observations. He assured Pinkie that she and her baby were doing well, and recommend that she continue with the prophylactic ART, which was initiated by the nurse during her last visit. Dr White then completes an electronic prescription for Zidovudine, iron and folate. He also recorded the day's encounter in Pinkie's EMR.

Dr White discussed breast and formula feeding with Pinkie; and the implications of the various options. He told her she still has to decide whether or not to breastfeed her baby after birth. Pinkie promised to think about it.

Pinkie continues to receive ante natal care at the CHC until she is due to have her baby.

L.2.2 Labour and delivery

As soon as Pinkie suspects that she is in labour, she went to the CHC as advised. She reported at the registration clerk who scanned her bar-coded plastic card to retrieve her EMR.

Pinkie was seen by Mary (it was not Dr White's visiting day); she asked Pinkie when the pain started and the frequencies. She also examined her and confirmed that she is in labour. Mary then admits Pinkie to the maternal obstetric unit (MOU) of the CHC.

Pinkie was received by Beatrice, a midwife at the MOU. Beatrice measured and recorded Pinkie's vital observation e.g. temperature, heart rate, blood pressure, fetal heart rate, frequency and intensity of abdominal contraction, cervical dilatation, urine analysis etc.). She also draws a care plan for Pinkie according to the NDoH PMTCT guidelines on intra-partum care of HIV+ women in labour.

Beatrice administered a single-dose of Nevirapine, single dose of Truvada , and 3hourly Zidovudine to Pinkie, according to the NDoH PMTCT guidelines.

Beatrice continues to monitor Pinkie throughout labour and recorded her progress until she delivered her baby.

After delivery, Pinkie is given post-partum ARV medicines (single dose of Tenofovir and Emtracitabine).

An EMR was created for the baby and linked to Pinkie's EMR. Beatrice carried out a physical examination on baby Pinkie and recorded her findings in his EMR. The baby also received the first doses of BCG and oral polio vaccines according to the childhood immunisation guideline, as well as prophylactic nevirapine, according to the NDoH PMTCT guidelines. Details of the vaccination and prophylactic nevirapine were recorded in the baby's EMR.

Beatrice also updated Pinkie's EMR with the delivery data, and a delivery summary was uploaded to the shared health record.

Pinkie has decided not to breast feed her baby; hence the baby was started on formula feed at the centre.

Since Pinkie's delivery process was uneventful; she and her baby were discharged the same day (patients are admitted in MOUs for six hours).

Pinkie was given an appointment to come back with her baby for post-natal check-up after two days.

L.2.3 Post-natal care

After two days, Pinkie came back to the centre with her baby for post-natal check-up. Since it was the doctor's visiting day to the centre, Pinkie and her baby were seen and examined by Dr White.

Dr White decides that Pinkie's baby should continue taking nevirapine for six weeks according to the NDoH PMTCT guidelines. An electronic prescription was completed by Dr White and the medicine dispensed by Bongi, the pharmacy assistant.

Pinkie is given appointment to come for check-up within six weeks of delivery. Another appointment was scheduled accordingly.

On the date of her appointment, Pinkie was back at the CHC. During this visit, blood was drawn for CD4 count, and an electronic laboratory order was completed accordingly. Pinkie was also screened for TB and clinical staging of HIV was done.

Pinkie was given one week appointment to come for the results of blood tests.

If Pinkie's CD4 count is more than 350 cells/mm^3, she will be referred for wellness services and family planning.

(NB: Wellness service is follow-up program of HIV-infected individuals not yet on ART and includes: provision of TB screening, INH prophylaxis, cortrimoxazole prophylaxis, nutritional and psychosocial support, cervical cancer screening, monitoring of CD4 count, clinical staging and preparedness for ART).

If Pinkie's CD4 count is below 350 cells/mm^3 or she is in clinical stage 3 or 4, she will be initiated on lifelong ART.

Follow-up care for baby Pinkie, according to the according to the NDoH PMTCT guidelines is as follows:

- Follow-up care basically follows the childhood immunisation schedule
- First visit within three days after birth
- Ten days after birth
- Six weeks after birth
- At six weeks of age, baby's blood is drawn for HIV and Polymerase Chain Reaction (PCR)
- Baby discontinues prophylactic Nevirapine
- Doctor prescribes cotrimoxazole for baby
- Baby will continue exclusive formula feeding
- PCR is repeated six weeks after the mother stops breast feeding
- If both HIV and PCR are negative, doctor discontinues cotrimoxazole
- Another HIV test is done when baby is 18 months
- If PCR is positive, baby will continue with cotrimoxazole; confirmatory HIV test and viral load will be done (for initiation on ART)

L.3 EXCEPTIONAL USE CASE (REFERRAL TO HOSPITAL FOR ANTENATAL CARE AND DELIVERY)

L.3.1 At CHC

Pinkie is a 19 year old single mother of one, Bridget who is 10 month old. Pinkie is unemployed. She lives in a two-room shack with her grandmother, Naledi, and two siblings, Piladi (15 years) and Banda (10 years).

Pinkie is 5 months pregnant with her 2nd child. Pinkie has decided to go to the community health centre (CHC) to register for ante natal care.

On arrival at the CHC, Pinkie went to Sarah, the registration clerk. She told Sarah she is pregnant and would like to see the nurse or doctor.

Sarah asked Pinkie if she has been to the centre before. Pinkie replied no. Nevertheless, Sarah still searched the centre's electronic medical record (EMR) system, which is linked to the provincial shared health record system, first using Pinkie's ID number and then a combination of her demographics data (name, surname, date of birth, etc.); to make sure Pinkie is not registered on the system. No record matching Pinkie's detail was found.

Sarah then created a new EMR for Pinkie using the demographic information she has provided. A unique identification number was generated for Pinkie by the provincial central patient master index (PMI) responsible for allocation patient identifiers.

Sarah also produced a plastic bar-coded small card, with Pinkie's demographic data, as part of the registration process. Sarah then asked Pinkie to wait in the waiting area.

After a while, Mary the clinic nurse, came to the waiting area and called all the pregnant women to follow her to a room for the day's health talk. The focus of the talk was on the importance of getting tested for HIV and breastfeeding.

After the talk each of the pregnant women were called in to the consulting room for one-on-one consultation.

When her turn came, Pinkie went in to see Mary, who scanned the bar-coded card to retrieve Pinkie's EMR. She noted that this is Pinkie's first ante-natal care visit. Mary asked Pinkie questions about her health history (number of children, previous pregnancies, previous conditions, with dates and outcomes). She also carried out a number of clinical observations (Pinkie's weight, blood pressure, temperature, urine analysis, fundal height, Pinkie's heart rate, and the baby's heart rate).

Thereafter, Mary again discussed the importance of getting tested for HIV with Pinkie. She explained to her that the result of the test would be confidential, and that disclosing the result to her family member would be Pinkie's choice.

After the counselling, Pinkie agreed to do the HIV test. Mary asked Pinkie to sign a standard HIV consent form, so that her consent is documented. Pinkie signed the consent form as requested. The signed form was later scanned and uploaded to Pinkie's EMR.

Mary cleaned Pinkie's finger with an alcohol swab and did a finger prick HIV test. She asked Pinkie to wait outside for the result. After 20 minutes Mary called Pinkie to the consulting room; she told Pinkie the test was positive, but they would need to do another one to be sure. Mary did a second finger prick HIV test using a test kit from another manufacturer.

About half an hour later, Mary called Pinkie in again. She was very sorry, she said, but the second test was also positive. Pinkie was understandably devastated and began to cry. Mary comforted her and her and carried out a post-test counselling.

Mary updates Pinkie's EMR with readings of the clinical observations, as well as the HIV test results. Mary notes that Pinkie's blood pressure was slightly elevated and both feet are swollen; her urine dipstick test also tested positive for protein.

Because the doctor does not come to the centre that day, Mary explained to Pinkie that she will be referring her to the district hospital because of the high blood and swollen feet, so she could be reviewed by a doctor. She asked Pinkie to go to the district hospital, preferably that day since it is not far from the CHC.

Mary completed and electronic referral form and uploaded this to the provincial shared health record. The shared health record was also updated with a summary of the encounter with Pinkie.

Pinkie left the CHC and immediately went to the district hospital.

Pinkie told Busi, the district hospital registration clerk, that she has been referred from the CHC and showed her the bar-coded plastic card from the centre. Busi scanned the card to retrieve the referral letter from the CHC, which is stored in the shared health record.

Busi asked Pinkie if she has been to the district hospital previously, and she replied no. Busi then went through the routine of searching for Pinkie's record on the hospital's EMR system, just to make sure she is not on the system.

When no record matching Pinkie's detail was found, Busi created a new EMR for Pinkie on the hospital's system using the same registration number as that on her CHC record (NB: registration number is centrally managed and allocated by the provincial PMI).

Pinkie was seen by one of the doctors on duty. Dr Naidoo retrieved Pinkie's EHR and the referral letter by scanning her plastic card. He read the referral letter and asked Pinkie how she was doing. He then queried the shared health record for Pinkie's past medical and birth histories.

Dr Naidoo repeated the clinical examinations on Pinkie (weight, height, blood pressure, temperature, fundal height, Pinkie's heart rate, and the baby's heart rate). Pinkie's BMI was calculated using the weight and height readings. He then derived a WHO clinical staging of stage 2 for Pinkie, using history and his clinical observations.

He explained to Pinkie that he needs to draw some blood for testing (Full blood count, CD4 count and Alamine Aminotransferase), so that Pinkie could be started on appropriate treatment. He then filled an electronic order for laboratory investigation, indicating the required tests.

Dr Naidoo reassured Pinkie that people with HIV could live normal, healthy life. He discussed prevention of mother to child transmission (PMTCT) program with Pinkie and explained that would reduce the risk of her unborn baby being infected with HIV.

Dr Naidoo made a diagnosis of pre-eclampsia; he then explained to Pinkie that he would place her on bed rest (at home) and prescribe medicines for the high blood pressure. He also told Pinkie that he would start her on prophylactic antiretroviral treatment (ART) as per the NDoH PMTCT clinical guidelines.

Dr Naidoo filled an electronic prescription for high blood pressure medicine and ART, as well as routine iron and folate supplements. He asked Pinkie to come back after one week.

Pinkie's hospital EMR was then updated with details of the encounter with Dr Naidoo.

Pinkie went back to Busi, who scheduled Pinkie's appointment on the hospital's system. An automatic text message about the date of the appointment was immediately sent to Pinkie's phone immediately after the appointment has been scheduled on the system.

Thereafter, Pinkie went to the pharmacy to collect her medicines. Precious, the pharmacist retrieved the e-prescription by scanning Pinkie's plastic card. She then dispensed the medicines according to the prescription. Precious updated the pharmacy system with details of the dispensed medicines.

Thando, the laboratory technician receives Pinkie's blood sample, he retrieves the order form which indicates the type of tests required. The blood test was completed and the results sent directly to Pinkie's EMR. Dr Naidoo also received notification of the test results.

A day before the scheduled appointment, Pinkie received a text message on the phone reminding her about the appointment for the next day.

On the date of her appointment, Pinkie went back to the district hospital. She gave her plastic card to Busi, who scanned it to confirm Pinkie's appointment. Pinkie was asked her if any of her demographic detail has changed. Pinkie answered that her cell phone number has changed and Busi updated the hospital's system with the new number.

Pinkie was seen by Dr Naidoo, who repeated the physical and clinical observations and recorded the WHO clinical staging.

Dr Naidoo retrieves and reviews Pinkie's blood test results and noted that the CD4 count is above 350 cells/mm^3. He also derived WHO clinical staging (stage 2). He also noted that Pinkie's blood pressure is reducing gradually and the swollen feet are subsiding. Thus, he decides Pinkie should continue with the anti-hypertensive medicines and prophylactic Zidovudine, as well as the routine iron and folate supplements.

Dr Naidoo also discussed breast and formula feeding with Pinkie and implications of the various options. He told her she still has to decide whether or not to breastfeed her baby after birth. Pinkie promised to think about it.

Dr Naidoo informed Pinkie that she would be seen every two weeks during her pregnancy, but advised her to come to the hospital if there is any problem in-between her appointments.

Every time when an appointment is scheduled for her, she receives a text message relating to the appointment. She also receives reminders on her phone a day before her appointment.

Pinkie continues to receive antenatal care at the district hospital. At each visit, a full clinical observation (weight, blood pressure, heart rate, fetal heart rate, fundal height, urine analysis etc.) is carried out by the doctor and her EMR is updated accordingly. She also continued with the prophylactic ART and antihypertensive medicines.

L.3.2 Labour and delivery

As soon as Pinkie suspects that she is in labour, she went to the district hospital as advised. She reported at the registration clerk who searched for Pinkie's record using her plastic card.

She was seen by the doctor on duty (Dr Mandla), who examined Pinkie and confirmed that she is in labour. Dr Mandla ordered that Pinkie be admitted to the labour ward.

Dr Mandla prescribed ARVs for Pinkie (intra-partum: single-dose Nevirapine, single dose of Truvada and 3 hourly Zidovudine; post-partum: single dose of Tenofovir and Emtracitabine) according to the NDoH PMTCT guidelines.

Pinkie was received at the labour ward by Linah, the midwife, who assigned Pinkie to the available bed. Linah measured Pinkie's vital observations (e.g. temperature, heart rate, blood pressure, fetal heart rate, frequency and intensity of abdominal contraction, cervical dilatation, etc.) and recorded this in. Pinkie's EMR.

Linah draws care plan for Pinkie according to the NDoH PMTCT guidelines on intrapartum care of HIV+ women in labour and administered a single-dose of Nevirapine, single dose of Truvada , and

3hourly Zidovudine to Pinkie, according to the NDoH PMTCT guidelines and as per Dr Mandla's prescription.

Linah continues to monitor Pinkie throughout labour and recorded her progress, until she delivered her baby.

If the condition of Pinkie and/or her baby necessitates that a procedure be carried out (e.g. forceps delivery, vacuum extraction or caesarean section, the appropriate procedure would be carried out by the doctor.

Pinkie received post-partum ARV medicines (single dose of Tenofovir and Emtracitabine) as prescribed by Dr Mandla.

An EMR was created for the baby and linked to Pinkie's EMR. Linah carried out a physical examination on baby Pinkie and recorded her findings in his EMR. The baby also received the first doses of BCG and oral polio vaccines according to the childhood immunisation guideline, as well as prophylactic nevirapine, according to the NDoH PMTCT guidelines. Details of the vaccination and prophylactic nevirapine were recorded in the baby's EMR.

Linah also updated Pinkie's EMR with the delivery data, and a delivery summary was uploaded to the shared health record.

Pinkie has decided not to breast feed her baby; hence the baby was started on formula feed while still in the ward.

Pinkie's delivery process was uneventful. Pinkie and her baby were examined by Dr Mandla who noted that mother and baby are well, hence Pinkie and her baby were discharged a day after delivery. Pinkie is asked to come to the hospital for check-up with her baby two days after discharge. Dr Mandla also made an e-prescription for Nevirapine for baby Pinkie, as well as discharge medicines for Pinkie. The medicines were dispensed by the pharmacist as ordered.

An appointment was scheduled for Pinkie to come back for check-up.

L.3.3 Postpartum

Two days after discharge, Pinkie came back to the hospital's OPD with her baby as per the scheduled appointment. She showed her card to the clerk, who confirmed the appointment

Pinkie and her baby were seen by Dr Mandla. He asked how she and her baby were doing, whether the baby is feeding well, and if she has anything the report. Pinkie answered that there was no problem with her and the baby. Dr Mandla examined mother and baby and updated the two EHRs accordingly. Dr Mandla decides that Pinkie's baby should continue taking nevirapine for six weeks according to the NDoH PMTCT guidelines, and completed an e-prescription accordingly.

The medicine was dispensed by Precious according to the e-prescription created by Dr mandla.

Pinkie is given appointment to come for check-up within six weeks of delivery. Another appointment was scheduled system accordingly.

On the date of her appointment, Pinkie was back at the OPD. During this visit, blood is drawn for CD4 count and clinical staging of HIV is done. Pinkie is also screened for TB.

Pinkie is given a two-week appointment to come for the results of blood tests.

If Pinkie's CD4 count is more than 200 cells/mm^3, she will be referred for wellness services and family planning, and an electronic referral note will be created accordingly.

(NB: Wellness service is follow-up program of HIV-infected individuals not yet on ART and includes: provision of TB screening, INH prophylaxis, cortrimoxazole prophylaxis, nutritional and psychosocial support, cervical cancer screening, monitoring of CD4 count, clinical staging and preparedness for ART).

If Pinkie's CD4 count is below than 200 cells/mm^3 or she is in clinical stage 3 or 4, she will be initiated on lifelong ART.

Follow-up care for baby Pinkie, according to the according to the NDoH PMTCT guidelines is as follows:

- Follow-up care basically follows the childhood immunisation schedule
- First visit within three days after birth
- Ten days after birth
- Six weeks after birth
- At six weeks of age, baby's blood is drawn for HIV and Polymerase Chain Reaction (PCR)
- Baby discontinues prophylactic Nevirapine
- Doctor prescribes cotrimoxazole for baby
- Baby will continue exclusive formula feeding
- PCR is repeated six weeks after the mother stops breast feeding
- If both HIV and PCR are negative, doctor discontinues cotrimoxazole
- Another HIV test is done when baby is 18 months
- If PCR is positive, baby will continue with cotrimoxazole; confirmatory HIV test and viral load will be done (for initiation on ART)

L.3.4 The following health indicators are associated with this scenario

1. How many people 5 years and older were seen at the clinic
2. How many children under 5 years were seen at the clinic
3. Inpatient days – total
4. Inpatient deaths - total
5. Inpatient discharges – total
6. Inpatient transfers out - total
7. OPD headcount - follow-up visit
8. How many cases were seen by a Professional Nurse
9. How many women were given vitamin A supplement within 8 weeks after delivery
10. Total number of antenatal 1^{st} visit
11. Total number of antenatal follow-up visit
12. Total number of antenatal 1^{st} visit at 20 weeks or later
13. Total number of antenatal 1^{st} visit before 20 weeks
14. Total number of pregnant women who received 2^{nd}/Booster dose of Tetanus Toxoid

15. Total number of antenatal client on HAART at delivery
16. Total number antenatal client eligible for HAART
17. Total number of babies initiated on HAART (under 18 months)
18. Total number of babies eligible for HAART
19. Total number of antenatal client on HAART at 1st visit
20. Total number of antenatal client who were re-tested for HIV at 32 weeks or later
21. Total number of antenatal client re-tested at 32 weeks or later with positive HIV result
22. Total number of antenatal client on AZT before labour
23. Total number of antenatal client Nevirapine taken during labour
24. Total live births to HIV positive women
25. Total number of babies given Nevirapine within 72 hours after birth
26. Total number of babies initiated on Co-Trimoxazole around 6 weeks
27. Total number of babies who had PCR test done around 6 weeks
28. Total number of babies whose PCR test was positive around 6 weeks
29. Total number of babies who had HIV antibody test done at 18 months
30. Total number of antenatal client who are known to be HIV positive but NOT on HAART at 1st visit
31. Total number of babies whose HIV antibody test was positive at 18 months
32. Total number of antenatal client who had the 1st HIV test done
33. Total number of antenatal client whose 1st HIV test was positive
34. Total number of antenatal client who had 1st CD4 test done
35. Number of patients with a CD4 count below 100 at baseline
36. Total number of antenatal client initiated on AZT
37. Total number of antenatal client initiated on HAART
38. Total number of caesarean sections in facility
39. Total number of delivery in facility under 18 years
40. Total number of delivery in facility 35 years and older
41. Total number of delivery in facility
42. Total number of inpatient death - early neonatal
43. Total live birth in facility under 2500g
44. Total live birth in facility
45. Total number of inpatient death - late neonatal
46. Total number of maternal death in facility
47. Total number of normal delivery in facility
48. Total still birth in facility
49. Total births in facility
50. Number of babies who received postnatal care within 6 days after birth
51. Number of mothers who received postnatal care within 6 days after delivery
52. Total birth defects case - mother 35 years and older
53. Total birth defects case - mother under 18 years
54. Total number of children with common priority Birth Defects
55. Total number of adults that started treatment this month
56. Total patients still on treatment at the end of the month

57. Total children (under 15) that started treatment this month
58. Total children (under 15) were still on treatment at the end of the month
59. Number of patients on TB treatment when they started ART
60. Number of adults who started treatment 3 months ago
61. Number of children (under 15) started treatment 3 months ago
62. Number of patients who died at 3 months
63. Number of adults who started treatment 6 months ago
64. Number of adults still on the first line regimen after 6 months
65. Number of children (under 15) who started treatment 6 months ago
66. Number of children (under 15) still on the first line regimen after 6 months
67. Number of adults on a second line regimen after 6 months
68. Number of children (under 15) on a second line regimen after 6 months
69. Number of patients who had their CD4 counts tested at 6 months
70. Number of patients with CD4 count above 200 at 6 months
71. Number of patients who had their Viral Load tested at 6 months
72. Number of patients with a Viral Load below 400 at 6 months
73. Number of patients who died between 3 and 6 months of treatment
74. Number of patients that were lost to follow up between 3 and 6 months of treatment
75. Number of adults who started treatment 12 months ago
76. Number of adults still on the first line regimen after 12 months
77. Number of children (under 15) who started treatment 12 months ago
78. Number of children (under 15) still on the first line regimen after 12 months
79. Number of adults on a second line regimen after 12 months
80. Number of children (under 15) on a second line regimen after 12 months
81. Number of patients who had their CD4 counts tested at 12 months
82. Number of patients who had a CD4 count above 200 at 12months
83. Number of patients who had their Viral Load tested at 12 months
84. Number of patients who had a Viral Load below 400 at 12 months
85. Number of patient that were lost to follow up between 6 and 12 months of treatment
86. Number of adults who started treatment 24 months ago
87. Number of adults still on the first line regimen after 24 months
88. Number of children (under 15) that started treatment 24 months ago
89. Number of children (under 15) were still on the first line regimen after 24 months
90. Number of adults on a second line regimen after 24 months
91. Number of children (under 15) on a second line regimen after 24 months
92. Number of patients who had their CD4 counts tested at 24 months
93. Number of patients with a CD4 count above 200 at 24 months
94. Number of patients who had their Viral Load tested at 24 months
95. Number of patients with a Viral Load below 400 at 24 months
96. Number of patient lost to follow up between 12 and 24 months of treatment
97. Number of children under 5 years that were weighed
98. Number of children under 1 year that had the 1st dose of BCG
99. Number of children that had the 1st dose of DTaP-IPV/Hib

100. Number of children that had the 3rd dose of DTaP-IPV/Hib
101. Number of children that had the 4th dose of DTaP-IPV/Hib
102. Number of children that had the 1st dose of DTP-Hib
103. Number of children that had the 3rd dose of DTP-Hib
104. Number of children that had the 1st dose of HepB
105. Number of children that had the 3rd dose of HepB
106. Number of children under 1 year that were fully Immunised
107. Number of children under 1 year that had the 1st dose Measles
108. Number of children that had the 2nd dose of Measles
109. Number of children that had the 1st dose of OPV
110. Number of children that had the 3rd dose of OPV
111. Number of children that had the 1st dose of PCV7
112. Number of children that had the 3rd dose of PCV7
113. Number of children that had the 1st dose of RV
114. Number of children that had the 2nd dose of RV
115. Number of people that had Td at 6 years
116. Number of people that had Td at 12 years
117. Number of children aged 6-11 months that had Vitamin A supplement
118. Number of children aged 12-59 months that had Vitamin A supplement

L.4 ACTIVITIES At the CHC (typical use case)

L.4.1 At the CHC

- Patient comes for antenatal care
- Clerk searches for patient folder
- If patient has been to this centre previously, clerk retrieves patient's folder
- If this is patient's first visit to the centre, clerk manually creates a new folder and small clinic card for patient
- All women who came for antenatal care are given health education (each day's topic varies)
- Patient is seen by nurse
- Nurse obtains and records past medical history
- Nurse carries out various clinical observations (e.g. weight, blood pressure, temperature, fundal height, Pinkie's heart rate, and the baby's heart rate)and records in the standard maternity case record
- Nurse counsels patient about HIV testing and discusses the PMTCT program with patient
- Patient agrees to have HIV test and sign consent form
- Patient is tested with finger prick test
- Finger prick test kit gives test result
- If result is positive, test is repeated using test kit from another manufacturer
- Finger prick test kit gives test result
- If result is positive, nurse do post-test counselling
- Patient is screened for TB, WHO clinical staging is derived

- Nurse takes blood for various tests (full blood count, CD4 count, Alamine Aminotransferase)
- Nurse initiates patient on prophylactic ART (Zidovudine)
- Nurse completes order form for blood tests, label the blood samples and send to laboratory via a courier
- Blood results is returned to the centre by the courier and filed in patient's file
- Patient is given one week appointment to be seen by doctor at the centre and for blood result
- A day prior to appointment date, clerk pulls the files of all patients that have appointments for the following day to reduce waiting time
- Patient returns to the centre for the scheduled appointment
- Clerk confirms appointment and gets patient's file
- Patient is seen and examined by doctor
- Doctor records his findings in patient's file
- Patient continues to receive ante natal care at the CHC until she is due to have her baby
- When patient is in labour, she is admitted to the MOU section of the centre
- Midwife monitors patient while in labour
- Midwife administers intra-partum ART to patient according to NDoH PMTCT guideline
- Midwife delivers baby
- After delivery, midwife administers post-partum ART to patient according to NDoH PMTCT guideline
- Midwife administers prophylactic nevirapine, first doses of BCG and oral polio vaccines according to the PMTCT and childhood immunisation guidelines
- Midwife records delivery in the delivery detail in the 'delivery summary' section of the 'maternity case record' booklet
- Midwife examines mother and baby for fitness for discharge
- Midwife discharge mother and baby and completes the 'discharge summary' section of the 'maternity case record' booklet. A copy of the discharge summary is kept in patient's file
- Mother and baby are given appointment to come for check-up after two days
- Mother and baby are seen and examined by doctor
- Doctor recommends that baby continues with nevirapine for six weeks
- Mother and baby are given appointment to come for check-up after six weeks

L.4.2 After Six Weeks

- Patient returns with her baby
- Mother and baby are seen by the doctor
- Mother and baby are examined by the doctor
- Doctor orders blood for CD4 count,
- Blood is sent to the lab via courier
- Doctor records clinical observation and WHO clinical stage
- Doctor screens patient for TB

- Make appointment to come back for test results
- Write appointment date and time on patient card
- Laboratory results sent back
- Results filed in patient's file
- If Patient's CD4 count is more than 350 cells/mm^3, she is referred for wellness services and family planning
- If Patient's CD4 count is below 350 cells/mm^3 and/or WHO clinical stage is 3 or 4, patient is initiated on lifelong ART

L.5 ACTIVITIES Exceptional use case

L.5.1 At the CHC

- Patient comes for antenatal care
- Clerk searches for patient folder
- If patient has been to this clinic previously, clerk retrieves patient's folder
- If this is patient's first visit to the clinic, clerk manually creates a new folder and small clinic card for patient
- All women who came for antenatal care are given health education (each day's topic varies)
- Patient is seen by nurse
- Nurse obtains and records past medical history
- Nurse carries out various clinical observations (e.g. weight, blood pressure, temperature, urine analysis, fundal height, Pinkie's heart rate, and the baby's heart rate)and records in the standard maternity case record
- Patient's blood pressure is high, her feet are swollen, and the urine test shows presence of protein
- Nurse counsels patient about HIV testing and discusses the PMTCT program with patient
- Patient agrees to have HIV test and sign consent form
- Patient is tested with finger prick test
- Finger prick test kit gives test result
- If result is positive, test is repeated using test kit from another manufacturer
- Finger prick test kit gives test result
- If result is positive, nurse do post-test counselling
- Because the doctor does not visit the centre on the day, nurse decides to refer patient to the district hospital
- Nurse fills the standard referral letter

L.5.2 At the district hospital

- Patient presents the referral letter to the clerk
- Clerk searches for patient file
- If patient has been to this clinic previously, clerk retrieves patient's file

- If this is patient's first visit to the clinic, clerk manually creates a new file and small registration card for patient
- Patient is seen by doctor
- Doctor reads referral letter, obtains and records past medical history
- Doctor carries out various clinical observations (e.g. weight, blood pressure, temperature, fundal height, Pinkie's heart rate, and the baby's heart rate)and records WHO clinical staging
- Doctor makes a diagnosis of pre-ecplamsia
- Doctor orders blood for Full blood count, CD4 count Alamine Aminotransferase and liver function test
- Doctor placed patient on bed rest at home
- Doctor prescribes medicines for high blood pressure and prophylactic ART medicines (Zidovudine) and routine iron + folate
- Blood is sent to the laboratory
- Make appointment to come back for test results
- Write appointment date and time on patient card
- Pharmacist dispenses medicines and prescribed
- Pharmacist records dispensing
- Laboratory results sent back
- Results filed in patient's folder

L.5.3 Return Visit for blood results

- Patient returns for appointment
- Patient goes to the clerk, who updates any change in patient's demographic information
- Patient is seen by doctor
- Doctor repeats clinical observations (e.g. weight, blood pressure, temperature, fundal height, Pinkie's heart rate, and the baby's heart rate)and records WHO clinical staging
- Doctor reviews blood results
- Doctor repeats prescriptions for high blood pressure and prophylactic ART medicine (Zidovudine) and routine iron + folate
- Doctor advises patient to continue with bed rest at home
- Doctor counsels patient about breast and formula feeding
- Make appointment
- Write appointment date and time on patient card
- Pharmacist dispenses medicines and prescribed
- Pharmacist records dispensing

L.5.4 Follow-up antenatal care (the following activities are repeated at each visit)

- Patient returns for appointment
- Patient goes to the clerk, who updates any change in patient's demographic information
- Patient is seen by doctor

- Doctor repeats clinical observations (e.g. weight, blood pressure, temperature, urine analysis, fundal height, Pinkie's heart rate, and the baby's heart rate)and records WHO clinical staging
- Doctor records clinical observation and WHO clinical stage
- Make appointment for follow-up antenatal visit
- Write appointment date and time on patient card
- Pharmacist dispenses medicines and prescribed
- Pharmacist records dispensing

L.5.5 Labour and Delivery

- Patient suspects she is in labour
- Patient goes to district hospital
- Patient is seen by the doctor
- Doctor examines patient
- Doctor admits patient to labour ward
- Doctor prescribes ARVs (intra-partum: single-dose Nevirapine, single dose of Truvada and 3 hourly Zidovudine; post-partum: single dose of Tenofovir and Emtracitabine)
- Midwife receives patient in the labour ward
- Midwife assigns patient to available bed
- Midwife measures and records vital signs (temperature, heart rate, blood pressure, fetal heart rate, frequency and intensity of abdominal contraction, cervical dilatation, etc.)
- Midwife records patient's detail in ward admission book
- Midwife draws a care plan for patient
- Midwife sends patient's prescription to pharmacy for collection of ARV
- Midwife administers intra-partum ART as prescribes
- Midwife continues to monitor patient's progress while in labour
- Midwife delivers baby
- Midwife records birth details in delivery register
- If any complication arises or labour does not progress well, necessary procedure (e.g. forceps delivery, vacuum extraction or caesarean section) is carried out by doctor
- After delivery, midwife administers post-partum ART to patient according to NDoH PMTCT guideline
- Midwife administers prophylactic nevirapine, first doses of BCG and oral polio vaccines according to the PMTCT and childhood immunisation guidelines
- Midwife records delivery in the delivery detail in the 'delivery summary' section of the 'maternity case record' booklet
- Baby is started on exclusive formula feed as per mother's decision
- Mother and baby are seen and examined by doctor
- Doctor recommends that baby continues with nevirapine for six weeks
- Mother and baby are given appointment to come for check-up after six weeks
- If all is well, mother and baby are discharged, to come back for follow-up visit after two days

- Make appointment for follow-up post natal visit
- Write appointment date and time on patient card
- Nurse records date of discharge against patient's name in the ward admission book

L.5.6 Postpartum Visits

- Patient returns with her baby after two days
- Mother and baby are seen by the doctor
- Mother and baby are examined by the doctor
- Doctor prescribes more Nevirapine for baby (for six weeks)
- Make appointment for follow-up postnatal visit after six week
- Write appointment date and time on patient card
- Pharmacist dispenses Nevirapine
- Pharmacist records dispensing

L.5.7 After Six Weeks

- Patient returns with her baby
- Mother and baby are seen by the doctor
- Mother and baby are examined by the doctor
- Doctor orders blood for CD4 count,
- Blood is sent to the lab via courier
- Doctor records clinical observation and WHO clinical stage
- Doctor screens patient for TB
- Make appointment to come back for test results
- Write appointment date and time on patient card
- Laboratory results sent back
- Results filed in patient's file
- If Patient's CD4 count is more than 350 cells/mm^3, she is referred for wellness services and family planning
- If Patient's CD4 count is below 350 cells/mm^3 and/or WHO clinical stage is 3 or 4, patient is initiated on lifelong ART

L.5.8 Follow-Up care for Baby

- Follow-up care basically follows the childhood immunisation schedule
- First visit within three days after birth
- Ten days after birth
- Six weeks after birth
- At six weeks of age, baby's blood is drawn for HIV and Polymerase Chain Reaction (PCR)
- Baby discontinues prophylactic Nevirapine
- Doctor prescribes cotrimoxazole for baby
- Baby will continue exclusive formula feeding

- PCR is repeated six weeks after the mother stops breast feeding
- If both HIV and PCR are negative, doctor discontinues cotrimoxazole
- Another HIV test is done when baby is 18 months
- If PCR is positive, baby will continue with cotrimoxazole; confirmatory HIV test and viral load will be done (for initiation on ART)