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DEPARTMENT OF HEALTH

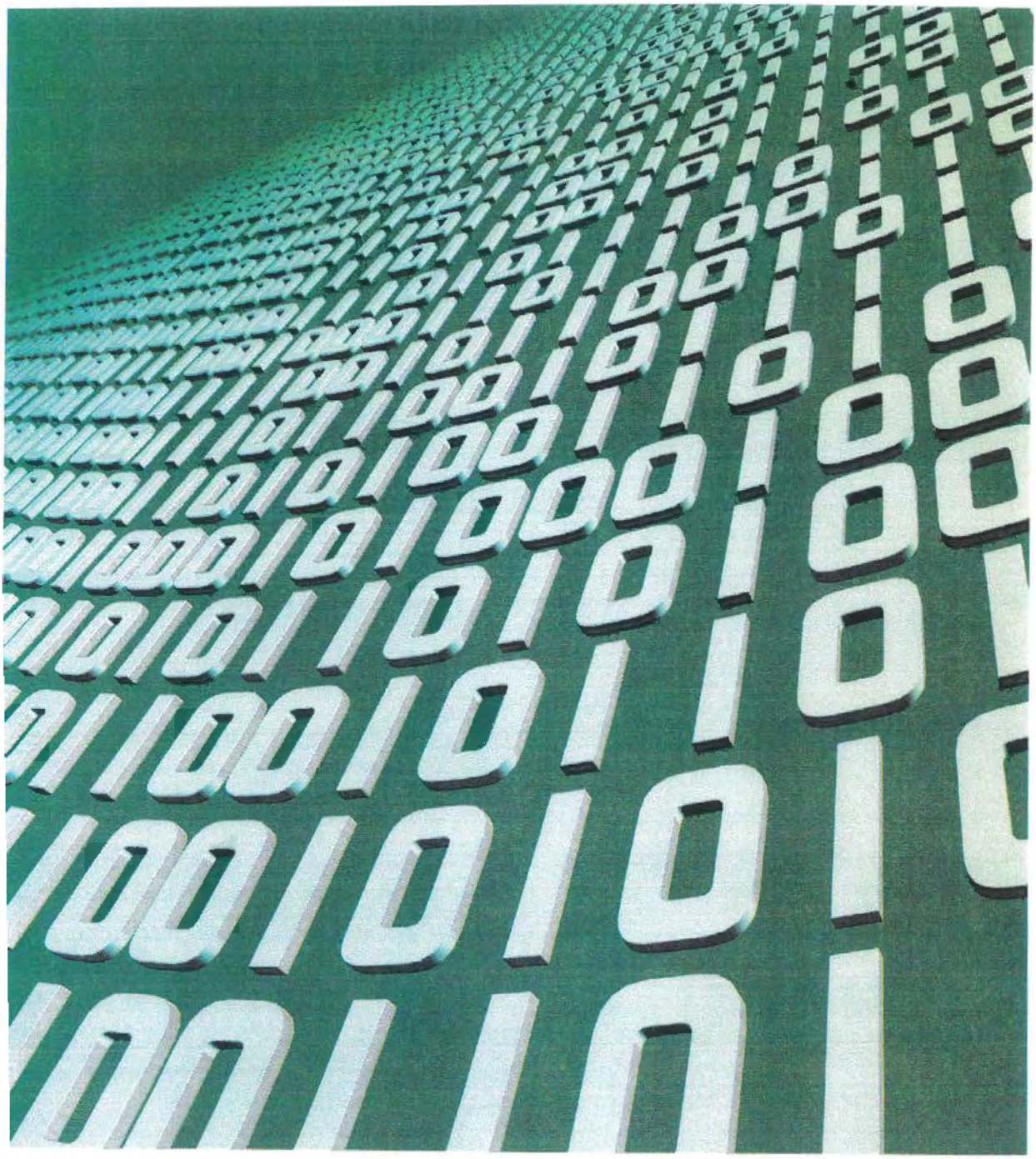
NO. 2667 **21 October 2022**

NATIONAL HEALTH ACT, 2003 (ACT NO 61 OF 2003)
NATIONAL 2021 NORMATIVE STANDARDS FRAMEWORK FOR INTEROPERABILITY IN DIGITAL HEALTH

I, Dr S.S.S Buthelezi, the Director-General: Health hereby, in terms of Section 74 (1) of the National Health Act, 2003 (Act No. 61 of 2003), publish the 2021 National Health Normative Standards Framework for Interoperability in Digital Health to facilitate and co-ordinate the establishment, implementation and maintenance by provincial departments, district health councils, municipalities and the private health sector of health information systems at national, provincial and local levels in order to create a comprehensive national health information system.

2021 National Health Normative Standards Framework for Interoperability in Digital Health is also available on www.health.gov.za

DR S.S.S BUTHELEZI
DIRECTOR-GENERAL: HEALTH
DATE: 05/09/2022



2021 HEALTH NORMATIVE STANDARDS FRAMEWORK

FOR DIGITAL HEALTH INTEROPERABILITY IN SOUTH AFRICA

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2021 HEALTH NORMATIVE STANDARDS FRAMEWORK

FOR DIGITAL HEALTH INTEROPERABILITY IN SOUTH AFRICA: 2021 HNSF

NDoH (2021), National Health Normative Standards Framework for Interoperability in Digital Health in South Africa. Pretoria, South Africa.

ISBN: 978-0-7988-5645-4

This version, 2021 HNSF, supersedes all previous versions.

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LIST OF ACRONYMS

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ATNA	Audit Trail and Node Authentication
CCOW	Clinical Context Object Workgroup (a context management specification)
CCD	Continuity of Care Document
CCR	Continuity of Care Record
CDA	Clinical Document Architecture
CEN	European Committee for Standardization
CHC	Community Health Centre
COBIT	Control Objectives for Information and Related Technologies
CSIR	Council for Scientific and Industrial Research
CT	Consistent Time
DICOM	Digital Imaging and Communications in Medicine
DSUB	Document Metadata Subscription
EA	Enterprise Architecture
edXML	Electronic Business using eXtensible Markup Language
EMR	Electronic Medical Record
EUA	Enterprise User Authentication
EU	European Union
FHIR	Fast Healthcare Interoperability Resources
HIMSS	Health Information and Management Systems Society
HIS	Health Information System
HL7	Health Level Seven
HNSF	Health Normative Standards Framework for Interoperability in Digital Health in South Africa
ICD-10	International Statistical Classification of Diseases, 10th Revision
ICT	Information and Communications Technology
ID	Identifier
IHE	Integrating the Healthcare Enterprise
ISO	International Organization for Standardization
IT	Information Technology
ITI	Information Technology Infrastructure
ITU	International Telecommunication Union
IUA	Internet User Authorisation
mACM	Mobile Alert Communication Management
mCSD	Mobile Care Services Discovery
MHD	Mobile access to Health Documents
MIOS	Minimum Interoperability Standard
MPQ	Multi-Patient Queries
NDoH	National Department of Health
NHI	National Health Insurance
NPFSm	Non-patient File Sharing
OASIS	Organisation for the Advancement of Structured Information Standards
PAM	Patient Administration Management
PDF	Portable Document Format
PDQ	Patient Demographics Query
PHC	Presidential Health Compact
PIX	Patient Identifier Cross-referencing
PIXm	Patient Identifier Cross-reference for Mobile
PIXv3	Patient Identifier Cross-referencing for HL7v3
PLT	Patient Location Tracking
PWP	Personnel White Pages
RID	Retrieve Information for Display
RIM	Reference Information Model
REST	Representational State Transfer
RFD	Retrieve Form for Data Capture
RMD	Remove Metadata and Documents
SA NHIS	South African National Health Information System
SeR	Secure Retrieve
SVS	Sharing Value Sets

WHO	World Health Organization
XAD-PID	XDS Affinity Domain Patient ID
XCA	Cross-Community Access
XCDR	Cross-Community Document Reliable Interchange
XCPD	Cross-Community Patient Discovery
XDM	Cross-Enterprise Document Media Interchange
XDS	Cross-Enterprise Document Sharing
XDS-MS	Cross-Enterprise Sharing of Medical Summaries
XML	Extensible Markup Language
XPID	XAD-PID Change Management
XUA	Cross-Enterprise User Assertion

FOREWORD

The 2018 Presidential Health Compact (PHC) of 2018, Pillar 9, articulates the role of an information system that will guide health system policies, strategies and investments. Information Systems are an essential element of achieving the portability of health services in South Africa because they provide healthcare workers with secure access to patient information to support quality services to all, and the systems place the patient at the centre of their own care.

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The Health Normative Standards Framework (HNSF) for Digital Health Interoperability in South Africa forms the basis for establishing interoperable solutions and platforms for data security, data sharing and storage of all information in the health system.

The 2021 HNSF aligns to the National Digital Health Strategy for South Africa 2019–2024 in pursuit of a unified health system and supersedes the 2014 HNSF.

The publication of this document is a testament to the interest and support of many stakeholders and is the culmination of an inspiring domain collaboration. The National Department of Health acknowledges all the institutions, entities and individuals that have been willing to engage in the process and have helped to shape and refine the final document.

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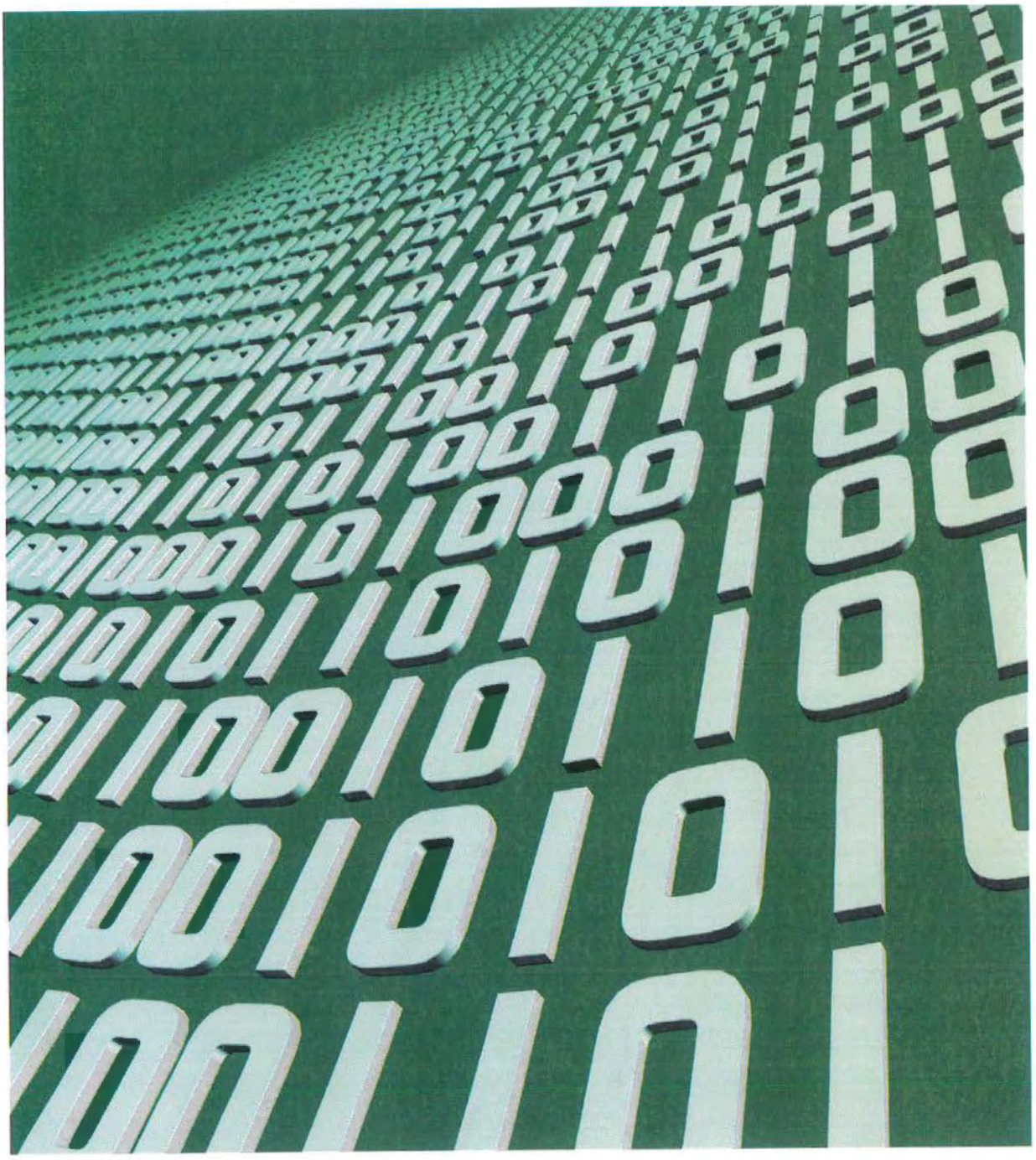
The CSIR project team, under the leadership of Matthew Chetty, Impact Area Manager: e-Government and Thomas Fogwill, has been collaborating since the publication of the 2014 HNSF and their efforts are acknowledged. The insights and efforts of Prof Adele Botha, JP Tolmay, Dr George Sibiya, Riaan Roos, Akhona Sampson, Dr Laticha Walters, Bahle Mkhize; and Prof Marlien Herselman have been vital to the conceptualisation and presentation of the 2021 HNSF.

As this document is published and its content realised, special recognition is given to the implementers, programmers and individuals to whom the task will fall to operationalise the content and as such become co-creators of a fully interoperable Health Information System for South Africa.

DR SSS BUTHELEZI
DIRECTOR GENERAL HEALTH
DATE : 01/09/2022



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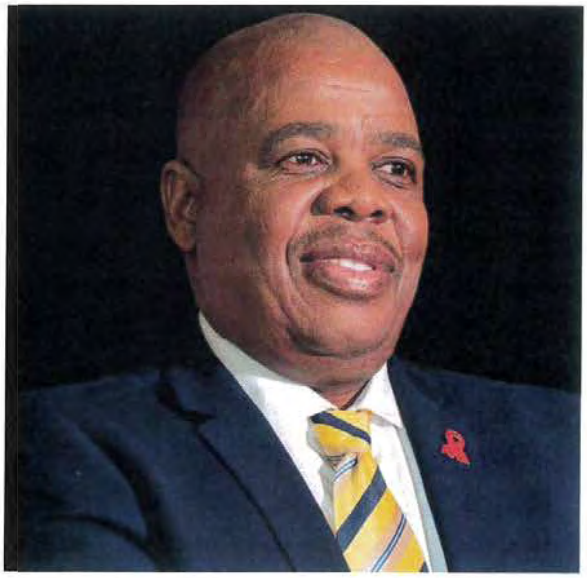

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DR SSS BUTHELEZI
DIRECTOR GENERAL HEALTH
DATE : 01/09/2022

EXECUTIVE SUMMARY

The 2021 Health Normative Standards Framework for Digital Health Interoperability in South Africa (2021 HNSF) follows on the 2014 HNSF, which set the foundational basis for interoperability as articulated in the eHealth Strategy for South Africa 2012–2017[1]. This strategy was replaced by the National Digital Health Strategy for South Africa 2019–2024[2], with its vision of a "better health for all South Africans enabled by person-centred Digital Health". The strategy proposes several strategic interventions that should be achieved by 2024, one of which is to "establish an integrated information architecture for interoperability and effective, safe sharing of health information across health systems and services" in South Africa. This is a key point that can be enabled by the HNSF.

The 2014 HNSF set the foundational basis for interoperability in Digital Health with the selection of:

- The family of standards based on the HL7 v3 Reference Information Model (RIM)[3];
- The standards based on the ISO 13606 Parts 1–5 / OpenEHR Reference Model (RM)[4]; and
- The interoperability standards-based profiles developed by the global organisation, Integrating the Health Enterprise (IHE)[5].

The 2014 publication of the HNSF is acknowledged as laying a foundation for national interoperability. Within this context, the National Digital Health Strategy for South Africa 2019–2024[6] acknowledges the contribution of the "strategic interventions for standards and interoperability" and speaks to a goal of national health information system interoperability towards "better health for all South Africans enabled by person-centred Digital Health". The strategy document proposes several interventions that should be achieved by 2024. One of these is to "establish an integrated information architecture for interoperability and effective, safe sharing of health information across health systems and services". A key enabler is the development of the HNSF to guide the realisation of a fully interoperable South African digital healthcare environment. In line with the vision of the National Digital Health Strategy for South Africa 2019–2024, this document outlines the progression of the HNSF and supersedes the 2014 HNSF version.

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[1] NDoH. (2012). eHealth Strategy for South Africa 2012-2017. Pretoria: South African National Department of Health

[2] NDoH. 2019. National Digital Health Strategy for South Africa, 2019–2024. South Africa

[3] Health Level Seven International. (2013e). HL7 Version 3 Product Suite, from http://www.hl7.org/implement/standards/product_brief.cfm?product_id=186

[4] EN 13606 Association. (2012). The CEN/ISO EN13606 standard, from http://www.en13606.org/the-ceniso-en13606-standard

[5] IHE International. (2012). IHE Changing the way in which healthcare connects, from http://www.ihe.net/

[6] NDoH. (2019). National Digital Health Strategy for South Africa, 2019–2024. South Africa

PURPOSE

The purpose of the HNSF is to enable the efficient and safe flow of healthcare-related person-centred information across institutional and provincial boundaries. The 2021 HNSF views interoperability as the ability of disparate and diverse organizations to interact towards mutually beneficial and agreed common goals. It extends to include the sharing of information and knowledge between organizations, through the business processes that they support, using the exchange of data between their respective ICT systems[7].

Health system efficiency remains a central concern in all health systems, and especially so within the South African resource constrained context. The efficient flow of healthcare-related information across institutional and provincial boundaries is considered a key enabler, which rests in system-wide interoperability. The HNSF is seen as taking the role of enabling interoperability within a fully interoperable South African healthcare environment. 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.

INTENDED AUDIENCE

This document is intended for use by policymakers, health domain decision makers, strategic planners, clinical information experts, business analysts, interoperability architects, enterprise architects, software developers and solution architects to guide and structure present and future Health Information System (HIS) planning and execution. Additionally, it is intended to guide decision makers when designing, developing and deploying digital health systems in South Africa.

SCOPE

The HNSF deals with the ability of health information systems to communicate with each other and to use each other's capabilities within an interoperable South African healthcare environment. From this perspective, the following are relevant:

- The HNSF is primarily concerned with interoperability with regards to patient-centric interactions within a fully interoperable South African digital healthcare environment;
- The HNSF does not address the internal system data flow or structure. However, if systems interact with, use data from, or upload data to a shared National Health Information System, infrastructure or shared EHR system, the HNSF will apply;
- IHE Profiles available for public comment were not included, as these were considered to still be in draft form. Selected exceptions are made in the case of FHIR[8];
- Dependencies among IHE Profiles are implied and need to be considered[9];
- The HNSF currently only refers to *value sets*[10]. The required use of specific sets relevant for local implementation will be published in Implementation Guides as National

[7] https://ec.europa.eu/isa2/eif_en

[8] This version of the HNSF incorporates relevant IHE ITI domain profiles that are in Final Text and Fast Healthcare Interoperability Resources (FHIR)-related profiles, despite being in Trial Implementation. This exception was made to balance the domain needs and the need for a stable set of profiles and standards. The ITI profiles, Healthcare Provider Directory, Advanced Patient Privacy Consents and Care Services Discovery are exceptions, as these were considered of imminent importance. More information is available at: https://wiki.ihe.net

[9] For example, the Patient Identifier Cross-referencing (PIX); each actor implimenting PIX should be grouped with the Time Client (TM). This is done to manage and resolve conflicts in multiple updates.

[10] Value sets are seen as specific sets of data relevant for local implementation.

Specification in due time; accordingly, semantic interoperability will remain an ongoing national undertaking; and

- This current version of the HNSF does not extensively address issues associated with the legal and regulatory, policy or care process interoperability, but acknowledges their importance in a fully interoperable healthcare environment[11].

The narrative in this document assumes a working knowledge of the standard landscape and the South African healthcare environment; hence, associated concepts are not extensively reviewed. Although a certain level of technical proficiency would be advisable, a concerted effort has been made to improve the readability for a non-technical audience. Some terms and concepts are outlined in the footnotes to avoid ambiguity.

APPROACH

The 2021 HNSF is presented as *useful* and not necessarily *optimal* or *perfect*, as the criteria for these concepts would change over time and may represent moving targets[12]. The 2021 HNSF applied a robust but pragmatic approach to its presentation and revision. The methodology recognised the rapidly changing information system environment, including the temporary nature of the domain and evolving stakeholder requirements. The guiding principles for the 2021 HNSF are outlined in Table 1.

A draft version of the 2021 HNSF was submitted to a rigorous domain evaluation and consultation process. The process included a workshop, domain feedback and the publication of the draft document for comment. Feedback and comments from various stakeholders were noted and addressed where relevant (Appendix A).

GUIDING PRINCIPLES

The guiding principles for the 2021 HNSF implementation towards a fully interoperable South African healthcare environment are outlined in Table 1.

TABLE 1: INTEROPERABILITY DEVELOPMENT PRINCIPLES

Principle Name	Principle Statement
Incremental approach	Take an incremental approach towards the development of a fully interoperable South African digital healthcare environment.
Manage initiatives through governed evolution	The NDoH is to assess all interoperability initiatives extensively for alignment to the HNSF.
National coordination and collaboration	Establish and maintain a national digital health and interoperability community to improve the adoption and development of a fully interoperable South African digital healthcare environment. Adopt a governance approach that includes the digital health community in decision-making and management implementation.
Security, confidentiality and patient privacy	Protect information security, confidentiality and patient privacy at all times.
Open source	Consider available open-source solutions for cost-effectiveness, and use internationally accepted standards that promote interoperability for data, workflows and technology.
Intellectual property	Ensure that the intellectual property ownership of public sector eHealth initiatives is vested in the government.

[11] https://ec.europa.eu/isa2/elf_en

[12] Nickerson, R., Muntermann, J., Varshney, U., & Isaac, H. (2009). *Taxonomy development in information systems: Developing a taxonomy of mobile applications.* Paper presented at the European Conference in Information Systems.

Principle Name	Principle Statement
Data availability	Ensure that data is available to digital health information systems (within the bounds of confidentiality).
Policy and governance adherence	Follow established national policies, as well as specific governance policies defined by the South African Government.
Data quality and integrity	Follow the accepted data standards and create measures to uphold the integrity and reliability of data, processed or stored.
Patient centricity	Patient journeys are at the core of health system interoperability and should be represented in all aspects of the digital health information system.

POLICY AND REGULATORY CONTEXT

The 2021 HNSF acknowledges the policy and regulatory environment as stated in the South African National Digital Health Strategy[13]. The legislation, regulation and policies affecting the interoperability of South Africa digital health systems are considered critical in the implementation of the HNSF to ensure strict compliance.

The 2021 HNSF acknowledges all the relevant regulatory bodies, authorities, legislative and policy frameworks that support the NDHS, as these monitor practitioners, locums and facilities; provide the necessary information and changes within the industry; ensure compliance and quality service standards; and promote safety and professionalism in industry[14].

The 2021 HNSF is aligned to an agreed level of interoperability of functionalities, as stated in the NHI Bill[15]. According to the NHI Bill[16], an information platform will enable informed decision-making on population health needs assessment, financing, purchasing, patient registration, service provider contracting and reimbursement, utilisation patterns, performance management, setting the parameters for the procurement of health goods, and fraud and risk management. Further detail on the policy and regulatory context is presented in Appendix B.

OUTLINE

The remainder of this document comprises the following sections:

- Health System-Level Interoperability.
- 2021 HNSF Implementation; and
- Conclusion

A number of Annexures highlight and provide additional detail on the feedback from the consultation process, the policy and regulatory context and IHE core components, and unpacks the National Interoperability Use Cases in greater detail.

[13] World Health Organization (WHO). 2012. National eHealth Strategy Toolkit. Retrieved October 2019 from https://www.itu.int/dms_pub/itu-d/opb/str/D-STR-E_HEALTH.05-2012-PDF-E.pdf.

[14] National Department of Health. 2020. Retrieved March 2020 from: https://www.gov.za/about-sa/health.

[15] National Health Insurance Bill. Retrieved March 2020 from https://www.gov.za/sites/default/files/gcis_document/201908/national-health-insurance-bill-b-11-2019.pdf

HEALTH SYSTEM-LEVEL INTEROPERABILITY

FEDERATED HEALTH INFORMATION ARCHITECTURE

The 2021 HNSF is approached from a health system-level interoperability view, in other words, information exchange between systems (and is therefore not concerned with the architecture of the individual systems). The conceptual model[16] for enabling system-level interoperability is a Federated Health Information Architecture, as conceptually presented in Figure 1. This conceptual view of the Interoperability Architecture is a hybrid between locally stored and centralised data.

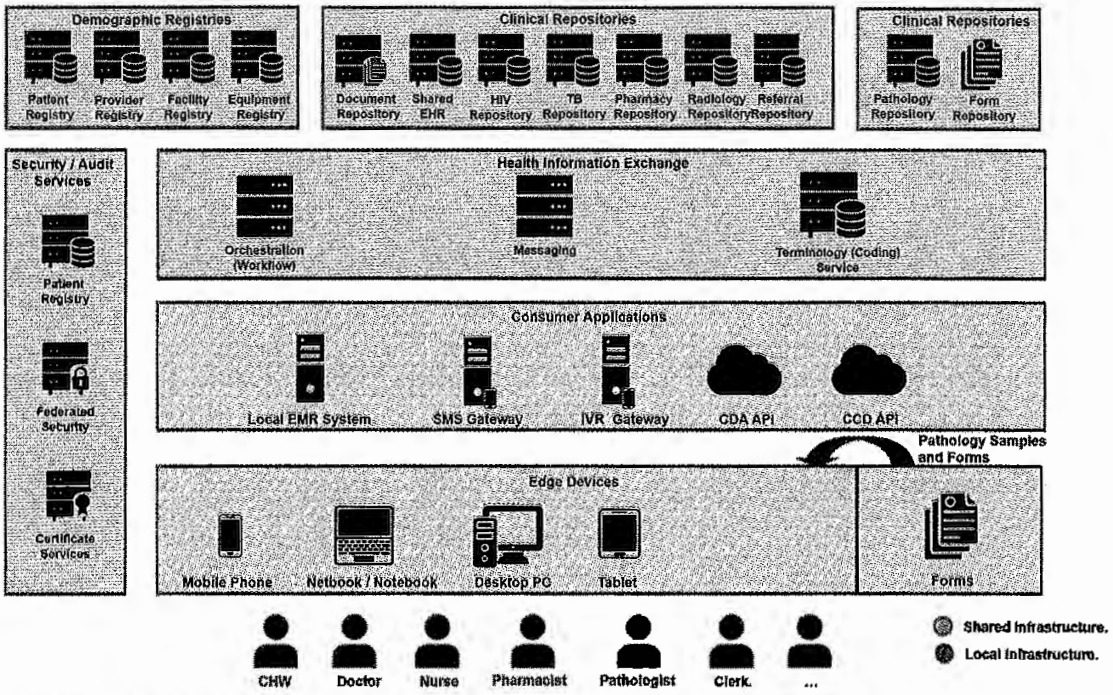

FIGURE 1: CONCEPTUAL VIEW OF THE INTEROPERABILITY ARCHITECTURE

A fully interoperable South African healthcare environment will make use of shared as well as local infrastructure. It will be characterised by:

- Clinical repositories that are shared across healthcare services and facilities, hospitals, and districts, within a province or nationally
  - A central patient registry exists, which is shared across all healthcare facilities served by the shared infrastructure (the patient will have the same identifier across all the healthcare services and facilities);

[16] A conceptual model is a representation of a system, made of the composition of concepts that are used to help people know, understand or simulate a subject that the model represents. It is also a set of concepts. Merriam-Webster Dictionary. https://unabridged.merriam-webster.com

  - 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; and
  - Centrally shared value sets exist, which are shared across all healthcare facilities served by the shared infrastructure.
- Shared clinical repositories that are accessed and updated by authorised users at all the healthcare facilities served by the shared infrastructure;
- A National Health Information Exchange (HIE) that will manages the data flow and activities, such as messaging, within in the shared infrastructure;
- Security and audit services that are in place to facilitate authentication across the shared infrastructure;
- Specialised consumer applications that can exist at the local healthcare facility level to manage the various edge devices (computers, mobile phones, etc.) that are used to access and record the information that is kept in the shared repositories and registries; and
- Some paper-based transactions that persist with the shared infrastructure.

2021 HNSF

The 2021 HNSF profiles are presented in Tables 2 and 3. In Table 2, each relevant IHE profile's abbreviation and description is provided for ease of reference[17,18], while Table 3 maintains backwards compatibility.

TABLE 2: 2021 HEALTH NORMATIVE STANDARDS FRAMEWORK FOR DIGITAL HEALTH INTEROPERABILITY IN SOUTH AFRICA

IHE Profile	IHE Profile Description	Referenced Standards
Advanced Patient Privacy Consents	The Advanced Patient Privacy Consents Profile defines a structural representation of a privacy consent policy. The definition allows for privacy consent policies that can include individualised parts, based on the patient's choices or other circumstances. This profile is intended to allow an unspecified enforcement mechanism, potentially within an existing access control system, to use the structured policy representation to automatically determine and enforce those policies.	XACML Core 2.0 HL7v3 Abstract Data Type Specification
Audit Trail and Node Authentication (ATNA) **Add RESTful Query to ATNA** **(Note Trial Implementation)**	Audit Trail and Node Authentication basic security through (a) functional access controls; (b) defined security audit logging; and (c) secure network communications. Note Trial Implementation addition of FHIR support in Add RESTful Query and Feed to ATNA.	DICOM: PS3.15 IETF: RFC2246, RFC7525, RFC3851 ITU-T: Recommendation X.509 (03/00) RFC5424 RFC5425 RFC5426 RFC7525 DICOM ASTM E2147-01

[17]IHE Technical Framework, vol. I: Integration Profiles, Revision 5.5. *Integrating the Healthcare Enterprise*: HIMSS/RSNA.

[18]IHE Technical Framework, vol. II: Transactions, Revision 5.5. *Integrating the Healthcare Enterprise*: HIMSS/RSNA.

IHE Profile	IHE Profile Description	Referenced Standards
		NIST SP 800-92 W3C XML 1.0 REST/HTTP(S), FHIR RFC2616 RFC4627 RFC6585 RFC5424 RFC3339 HL7 FHIR
Basic Patient Privacy Consent	Consent records a patient's privacy consent acknowledgement (for enforcing privacy appropriate to use).	HL7 CDA R2 ISO 2260 PDF RFC3778 PDF/A ISO 19005-1b. HL7 CDA Release 2.0 RFC5646 HL7 CDA R2 ISO 2260 PDF RFC3778 PDF/A ISO 19005-1b. HL7 CDA Release 2.0 RFC5646 HL7 CDA R2 ISO 2260 PDF RFC3778 PDF/A ISO 19005-1b. HL7 CDA Release 2.0 RFC5646
Care Services Discovery	Care Services Discovery queries directories containing data about organisations, facilities, services and providers.	
Consistent Time (CT)	Consistent Time synchronises system clocks and time stamps of computers in a network (median error less than 1 second).	NTP RFC1305 SNTP Simple Network Time Protocol (SNTP) RFC4330
Cross-Enterprise Document Workflow	Coordinates human and application-mediated workflows across multiple organisations.	OASIS Web Services – Human Task (WS-HumanTask) Specification Version 1.1 HL7 CDA Release 2.0 and Reference Information Model
Cross-Community Access (XCA)	Cross-Community Access queries and retrieves patient electronic health records held by other communities.	SOAP/HTTP(S) ebXML ebRIM ebRS
Cross-Community Document Reliable Interchange (XCDR)	Cross-Community Document Reliable Interchange pushes documents to systems in another community.	ebRIM OASIS/ebXML Registry Information Model v3.0 ebRS OASIS/ebXML Registry Services Specifications v3.0 ebMS OASIS/ebXML Messaging Services Specifications v3.0
Cross-Community Patient Discovery (XCPD)	Cross-Community Patient Discovery locates communities with electronic health records for a patient and translates patient identifiers across communities.	HL7 Version 3 SOAP/HTTP(S)
Cross-Enterprise Document Media Interchange (XDM)	Cross-Enterprise Document Media Interchange transfers documents and metadata using CDs, USB memory or email attachments.	ITI TF-3 DICOM PS3.10 DICOM PS3.12 XHTML™ 1.0

IHE Profile	IHE Profile Description	Referenced Standards
		W3C XHTML™ Basic RFC3798.
Cross-Enterprise Document Reliable Interchange	This profile is concerned with the exchanges of health documents between health enterprises using a web-service-based point-to-point push network communication.	ebMS OASIS/ebXML Messaging Services Specifications v3.0 ebRIM OASIS/ebXML Registry Information Model v3.0 ebRS OASIS/ebXML Registry Services Specifications v3.0
Cross-Enterprise Document Sharing (XDS)	Cross-Enterprise Document Sharing shares and discovers electronic health record documents between healthcare enterprises, physician offices, clinics, acute care in-patient facilities and personal health records.	SOAP/HTTP(S) ebXML ebRIM ebRS
Cross-Enterprise Sharing of Scanned Documents	This profile shares unstructured electronic documents, including scanned legacy paper and film.	PDF RFC 3778, The application/pdf Media Type (informative) PDF/A ISO 19005-1b. Document management - Electronic document file format for long-term preservation - Part 1: Use of PDF (PDF/A) HL7 CDA Release 2.0 (denoted HL7 CDA R2, or just CDA, in subsequent text) RFC 3066, Tags for the identification of languages
Cross-Enterprise User Assertion (XUA)	Cross-Enterprise User Assertion communicates claims about the identity of an authenticated principal (user, application, system...) across enterprise boundaries – Federated Identity.	SOAP/HTTP(S) ebXML ebRIM ebRS
Document Digital Signature specifies digital signatures for documents	This content profile specifies the use of digital signatures for documents that are shared between organisations.	XML Advanced Electronic Signatures XAdES http://www.w3.org/TR/XAdES/ -- aka. ETSI TS 101 903 XML-Signature Syntax and Processing. W3C Recommendation. Donald Eastlake, Joseph Reagle, David Solo. February 2002. http://www.w3.org/TR/2002/REC-xmldsig-core-20020212/ ASTM E1762-95(2013) – Standard Guide for the Authentication of Health Care Information http://www.astm.org/cgi-bin/SoftCart.exe/STORE/filtrexx40.cgi?U+mystore+odvl4256+-L+ASTM:E1762+/usr6/htdocs/astm.org/DATABASE.CART/REDLINE_PAGES/E1762.htm
Document Metadata Subscription (DSUB)	Document Metadata Subscription subscribes for metadata-triggered notifications within an XDS Affinity Domain and across communities.	OASIS Web Services Notification Family of Standards WS-Base Notification 1.3 OASIS Standard WS-Brokered Notification 1.3 OASIS Standard WS-Topics 1.3 OASIS Standard ITI TF-2b: 3.43.4.2.2 ITI TF-2x: Appendix V

IHE Profile	IHE Profile Description	Referenced Standards
		OASIS Web Services Notification Family of Standards WS-Base Notification 1.3 OASIS Standard WS-Brokered Notification 1.3 OASIS Standard 620 WS-Topics 1.3 OASIS Standard OASIS Web Services Notification Family of Standards WS-Base Notification 1.3 OASIS Standard WS-Brokered Notification 1.3 OASIS Standard 620 WS-Topics 1.3 OASIS Standard
Enterprise User Authentication (EUA)	Enterprise User Authentication enables single sign-on inside an enterprise by facilitating one name per user for participating devices and software.	HL7 Context Management 'CCOW' Standard, Version 1.4: Technology and Subject Independent Architecture, Component Technology Mapping: ActiveX, Component Technology Mapping: Web. Subject Data Definitions RFC1510 The Kerberos Network Authentication Service (V5) HL7 Context Management 'CCOW' Standard, Version 1.4: Technology and Subject Independent Architecture, Component Technology Mapping: ActiveX, Component Technology Mapping: Web. Subject Data Definitions
Healthcare Provider Directory	Healthcare Provider Directory supports discovery and management of healthcare provider information, both individual and organisational, in a directory structure.	DSMLv2 SOAP/HTTP(S)
Internet User Authorisation (IUA)	Internet User Authorisation provides user authorisation for RESTful interfaces.	
Mobile access to Health Documents (MHD)	Mobile access to Health Documents provides a RESTful interface to Document Sharing including XDS.	REST/HTTP(S), FHIR
Mobile Alert Communication Management (mACM)	Mobile Alert Communication Management provides a RESTful interface to an alert infrastructure.	REST/HTTP(S), FHIR HL7 FHIR HL7 Version 2.6 ISO/IEEE 11073-10201 ISO/IEEE 11073-10101 Nomenclature World Geodetic System WGS-84 IETF RFC7159 - JSON XML HTTP 1.1 XML Schema 1.1
Mobile Care Services Discovery (mCSD)	Mobile Care Services Discovery provides a RESTful interface to discover Care Services: Organisation, Location, Practitioner, and Health Services.	HL7 FHIR JSON – IETF RFC7159 XML HTTP 1.1

CONTINUES ON PAGE 130 OF BOOK 2

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IHE Profile	IHE Profile Description	Referenced Standards
Mobile Cross-Enterprise Document Data Element Extraction	Mobile Cross-Enterprise Document Data Element Extraction accesses data elements extracted from shared structured documents.	
Multi-Patient Queries (MPQ)	Multi-Patient Queries aggregates queries to a Document Registry for data analysis such as provider accreditation, clinical research trial data collection or population health monitoring.	ITI TF-2X: Appendix V Web Services for IHE Transactions. ebRIM OASIS ebXML Registry Information Model v3.0 ebRS OASIS ebXML Registry Services Specifications v3.0 ITI TF-2a: 3.18 Registry Stored Query [ITI-18] ITI TF-3: 4 Metadata used in Document Sharing profiles
Non-patient File Sharing (NPFSm)	Non-patient File Sharing defines how to enable the sharing of non-patient files. Those files can be created, consumed and updated by many different systems involved in a wide variety of data sharing workflows (clinical workflow definition, domain policies sharing, stylesheets management, etc.).	HL7 FHIR RFC2616 RFC7540 RFC3986 RFC6585
Patient Administration Management (PAM)	Patient Administration Management establishes the continuity and integrity of patient data in and across acute care settings, as well as among ambulatory caregivers.	XML V1.0 (MIOS) HL7 Version 2.5 ISO/TR 20514:2005 ISO 18308:2011
Patient Demographics Query (PDQ)	Patient Demographics Query queries patient identity by patient demographics from a central patient information server.	HL7 2.5
Patient Demographics Query for Mobile	Patient Demographics Query for Mobile provides a RESTful interface to a patient demographics supplier.	REST/HTTP(S), FHIR
Patient Identifier Cross-reference for Mobile (PIXm)	Patient Identifier Cross-Reference for Mobile provides a RESTful interface to patient identifier cross-references.	REST/HTTP(S), FHIR
Patient Identifier Cross-referencing (PIX)	Patient Identifier Cross Referencing queries for patient identity cross-references between hospitals, sites, health information exchange networks, etc.	HL7 Version 2.5 HL7 Version 2.3.1 HL7 2.5
Patient Identifier Cross-referencing for HL7v3 (PIXv3)	Patient Identifier Cross-Reference HL7v3 extends the Patient Identifier Cross-Reference profile leveraging HL7 version 3.	HL7 Version 3 SOAP/HTTP(S)
Patient Location Tracking (PLT)	Patient Location Tracking tracks the location of a patient within a facility.	
Patient Master Identity Registry	This profile provides a RESTful patient identity management.	HL7 FHIR R4
Patient Synchronised Application	Allows cooperating applications on a workstation to synchronise to selected patient context.	HL7 Context Management "CCOW" Standard, Version 1.4: Technology and Subject Independent Architecture

IHE Profile	IHE Profile Description	Referenced Standards
		Component Technology Mapping: ActiveX Component Technology Mapping: Web Subject Data Definitions
Personnel White Pages (PWP)	Personnel White Pages provides basic directory information on human workforce members within an organisation.	RFC2181; RFC2219; RFC2782 DICOM RFC2181; RFC1766; RFC2251; RFC2252; RFC2253; RFC2256 RFC2798; RFC2829; RFC2830 RFC3377; ISO/TS 17090; ITU-T: E.123; CRU; HL7 Version 2.5
Remove Metadata and Documents (RMD)	Remove Metadata and Documents removes documents and related metadata.	SOAP/HTTP(S), ebXML SOAP/HTTP(S) ebXML ebRIM ebRS
Retrieve Form for Data Capture (RFD)	Retrieve Form for Data Capture requests forms from clinical trial sponsors and public health reporting.	ITI TF-2x: Appendix V RFC1738 RFC2616 XML V1.0 (MIOS) XHTML™ 1.0 W3C XHTML™ Basic RFC1738 RFC2616 XML V1.0 (MIOS) ITI TF-2x XForms 1.1
Retrieve Information for Display (RID)	Retrieve Information for Display provides simple (browser-based) read-only access to clinical information (e.g., allergies or lab results).	RFC1738, RFC2616 W3C XHTML™ 1.0 XHTML™ Basic. RFC2616 W3C XML (XML V1.0 (MIOS) W3C WSDL
Secure Retrieve (SeR)	Secure Retrieve defines a model for Access Control for XDS environments that have a centralised Access Control Decision, with Document Repository enforcement.	OASIS SOAP v1.2 OASIS Security Assertion Markup Language (SAML) v2.0 OASIS eXtensible Access Control Markup Language (XACML) v2.0 OASIS Multiple resource profile of XACML v2.0 OASIS SAML 2.0 profile for XACML v2.0 OASIS Cross-Enterprise Security and Privacy Authorization (XSPA) Profile of SAML v2.0 for Healthcare Version 2.0 (not normative)
SeR & XDS	Secure Retrieve defines a model for Access Control for XDS environments that have a centralised Access Control Decision, with Document Repository enforcement. Cross-Enterprise Document Sharing shares and discovers electronic health record documents between healthcare enterprises, physician offices, clinics, acute care in-patient facilities and personal health records.	ebRIM ebRS

IHE Profile	IHE Profile Description	Referenced Standards
Sharing Value Sets (SVS)	Sharing Value Sets distributes centrally-managed, common, uniform nomenclatures.	HL7 Version 3 SOAP/HTTP(S) DSMLv2 SOAP/HTTP(S)
XDS Affinity Domain Patient ID (XAD-PID) Change Management (XPID)	Change Management updates the relationship between XDS Affinity Domain patient identifiers and other patient identifiers.	MLLP(S), HL7 v2.5
XDS Metadata Update		HL7 Version 3 SOAP/HTTP(S)

To ensure backwards compatibility, the following have been included. These are not part of the IHE ITI profiles.

TABLE 3: 2014 HNSF BACKWARDS COMPATIBILITY

Function Group	Function	IHE profile in HNSF 2014	Compatibility in HNSF 2021	Referenced standards
Identification, authentication and authorisation	Identify patient	None	XUA	-
	Authenticate patient	None	XUA	-
	Authenticate provider	None	XUA	-
	Authorise provider roles and permissions	None		ANSI INCITS 359-2004 ISO/TS 22600:1-3
Retrieve patient record	Display only	RID	-	RFC1738 XML WSDL XHTML
Update patient record	Add, query and update medical history	Cross-Enterprise Sharing of Medical Summaries (XDS-MS)	XDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS
	Add, query and update clinical observations	XDS-MS	XDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS
	Add, query and update interventions	XDS-MS	XDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS
	Add and query referrals	XDS-MS Referral Summary	XDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS

Function Group	Function	IHE profile in HNSF 2014	Compatibility in HNSF 2021	Referenced standards
	Add and query pharmacy orders	XDS-PRE	XDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS
	Add and query drugs dispensed	XDS-DIS	XDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS
	Add and query laboratory test results	XD-LAB	-	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS
	Add and query radiology test results	SINR	-	DICOM 2011, [ISO/IEC 12052]) (MIOS)
		XDS-I.b	XDS	DICOM 2011, [ISO/IEC 12052]) (MIOS)
	Add, update and query discharge summary	XDS-MDS	XDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS
	Add, query, and update antenatal care events	XDS-APS	XDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS
	Add and query birth details	XDS-LDS	XDS	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS
	Add, query and update care plan	PPOC	-	XML V1.0 (MIOS) RFC 2616 (MIOS) ISO/IEC 9075 (MIOS) ebMS ebRIM ebRS

Function Group	Function	IHE profile in HNSF 2014	Compatibility in HNSF 2021	Referenced standards
Scheduling	Schedule appointment	none	ECAS profile in the Eye Care Domain	
	Send reminders	none	-	
Emergency medical services peripheral	Contact ambulance	None	ETS profile in Patient Care Coordination domain	
	Dispatch ambulance	None	ETS profile in Patient Care Coordination domain	
	Route ambulance	none	ETS profile in Patient Care Coordination domain	
Supply chain management peripheral	Update and manage pharmacy stock	none	-	
Create billing account	Add, query and update bills	None	CHG in the Eye Care domain	XML V1.0 (MIOS)
	Submit medical bills for payment	None	CHG in the Eye Care domain	UN/EDIFACT
Generate metrics	Aggregate query	MQL	-	ebRIM ebRS
	Add, query and update health indicator	none	-	SDMX-HD

The 2021 HNSF, endeavours, within the IHE framework, to be backwards compatible with the HNSF 2014 version. The IHE profiles in *Final Text*[19] are maintained in a backward compatible manner. In this regard, the IHE does not guarantee, but makes every possible effort to maintain backward compatibility between *Trial Implementation* versions, or when profiles move from *Trial Implementation* to *Final Text* status. It is recommended that current maturity levels of the profiles are noted as profiles marked for *Trial Implementation*, although not subject to change for the duration of the profiles' *trial use*, are likely to change before the publication of the *Final Text*.

[19] IHE profiles are maintained by the IHE technical committees through the identification and correction of errata, utilising the IHE Change Proposal Process. They progress through various rigorous iterations from Draft Supplement (not yet ready for Public Comment); Public Comment (a new profile published for public comment, [not implementation]); Public Comment (a Trial Implementation profile republished for Public Comment); Trial Implementation not subject to change during trial use (however, changes will be permitted prior to Final Text); and Final Text (stable). https://www.ihe.net/resources/technical_frameworks/

2021 HNSF AND FHIR

With regards to FHIR, it should be noted that the IHE profiles are purposefully based on established and stable underlying standards. However, FHIR has shown a significantly high rate of industry adoption and offers some noteworthy benefits for established use cases. As such, IHE profiles based on FHIR have been incorporated and are subject to IHE updates and republishing as the underlying standard evolves. Deployments utilising these profiles would need to evolve alongside their updates to remain interoperable and conformant with an updated IHE profile[20].

[20] For example, at the time of writing this document, the profile Mobile Care Services Discovery (mCSD20) specifies in the IHE IT Infrastructure Technical Framework Supplement20, dated 6 March 2019, referenced HL7 FHIR standard Release 4, whereas the profile Patient Identifier Cross-reference for Mobile (PIXm20) specifies in IHE IT Infrastructure Technical Framework Supplement PIXm dated 24 July 2018, referenced HL7 FHIR standard Release 3. As such, the IHE profiles guide the selection of the underlying standard, as well as the specific version of the standard that needs to be adhered to. Considering the rate of evolution of the FHIR standards, it was thought prudent to exclude an explicit reference to a specific FHIR version in this document. HL7 describes FHIR Change Management and Versioning at https://www.hl7.org/fhir/versions.html.

2021 HNSF IMPLEMENTATION

NATIONAL INTEROPERABILITY USE CASES

South Africa's approach to Health Information System interoperability is based on an agreed set of standards. The HNSF takes up the role of communicating the set of standards to all stakeholders in the South African digital health domain, and so enables digital health interoperability for a fully interoperable South African digital healthcare environment. The IHE profiles and the associated data exchange standards are then critical building blocks for achieving digital health interoperability in South Africa.

However, the selected profiles need to be relevant and useful for the South African digital healthcare domain stakeholders. This is set to be achieved through a process of *localisation* of the selected IHE profiles. Localisation firstly entails the identification of National Interoperability Use Cases. From these cases, experts will draft detailed National Interoperability Specifications that will act as Implementation Guides.

The National Interoperability Specifications include Business Instances and Implementation Outlines that are relevant to the National Interoperability Use Cases[21]. From these high level Business Instances and Implementation Outlines, detailed specifications for the flow of information among the different health information systems are provided through the articulation of *extensions* to the established standards in order to cater for the local South African environment. It is these detailed specifications, described in implementation guides, that need to be implemented by industry and other stakeholders, and that are assessed for conformance to the HNSF. Amongst other things, the National Interoperability Specifications will detail specific local value sets and will prescribe their use for implementation in South Africa.

The digital health domain stakeholders are supported in their uptake and use of the HNSF and National Interoperability Specifications through Connectathons (conformity assessments marathons), Projectathons (interoperability assessment marathons) and informal conformity assessments to standards.

Gaps in the 2021 HNSF and future HNSF iterations are identified, prioritised and addressed as part of the localisation process. Future iterations of the HNSF is envisaged to address specific health domains and to cater for health innovations. Implementation Guides for the National Interoperability Specifications are published as extensions to the HNSF and are prescriptive in nature.

The process of identifying and prioritising National Interoperability Use Cases is depicted in Figure 2.

[21] See Annexure 4

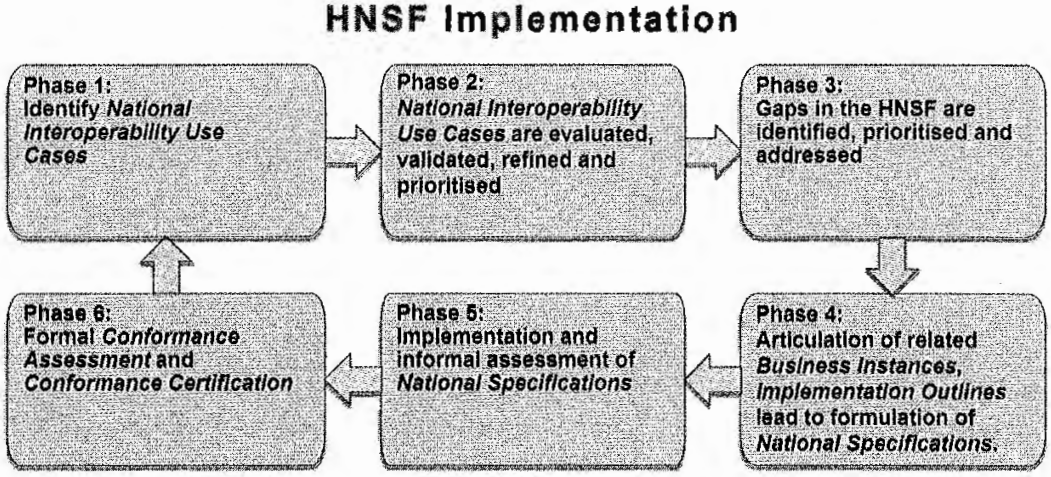

FIGURE 2: HNSF IMPLEMENTATION

The selection of National Interoperability Use Cases, articulation of ensuing National Interoperability Specifications, and the eventual Conformance Assessment and Conformance Certification consist of six phases, as described in Table 4.

TABLE 4: HNSF IMPLIMENTATION

Phase #	Description	Participants	Approach	Deliverable
1	Identify National Interoperability Use Cases	• NDoH (lead) • CSIR • IHE	• Digital health community feedback • Workshops • Secondary research	• 3 – 5 National Interoperability Use Cases
2	National Interoperability Use Cases are evaluated, validated, refined and prioritised	• NDoH (lead) • CSIR • IHE • Digital health community	• Digital health community feedback (e.g., surveys, questionnaires) • Workshops • Secondary research	• Consultation process feedback • Refined National Interoperability Use Cases. • Prioritised National Interoperability Use Cases.
3	Identify gaps in the HNSF and address them	• NDoH • CSIR • Digital health community	• Domain Innovation • Consultation process • Approval process (Document, review, gazette and publish) • Dissemination	• Draft HNSF • Consultation feedback • Updated HNSF
4	Articulation of related National Interoperability Specifications.	• NDoH • CSIR • IHE • Digital health community	• Workshops • Working Groups • Consolidation work • Publication of National Interoperability Specifications • Populating Shared Value Sets	• National Interoperability Specifications Document • Updated Shared Value Sets
5	Implementation and informal assessment	• CSIR • IHE	• Various software development	• Connectathon (conformity assessments marathons)

Phase #	Description	Participants	Approach	Deliverable
	of National Interoperability Specifications	• Digital health community	methods and systems development lifecycles. • Support Digital Health Community • Document, review and publish • Local tests • Conformance lab assessments • Connectathons • Projectathons • Digital health community feedback	• Projectathons (interoperability assessment marathons) • Informal conformity assessment to standards • Acknowledgement of vendor and supplier attendance to Connectathon and/or Projectathons
6	Formal conformance assessment and conformance certification	• NDoH • Relevant certification authority • IHE • CSIR • Digital health community	• Certification Authority to be appointed • Certification process, infrastructure and mandate to be put in place	• Conformance Certification

The phases outlined in Table 4 are repeated iteratively to continually align the health interoperability landscape, as depicted in Figure 3.

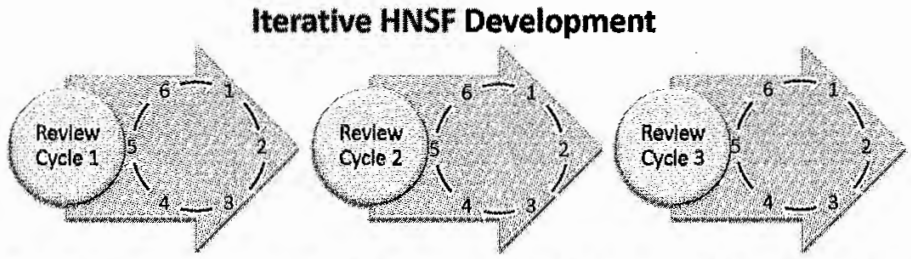

FIGURE 3: ITERATIVE HNSF DEVELOPMENT AND IMPLEMENTATION CYCLES

Details with regards to *National Interoperability Use Cases*, the resulting *Business Instance*, their *Implementation Outline* and *Technical Use Cases* can be found in Annexure 4, where it is unpacked in greater detail.

IMPLEMENTATION OF NATIONAL INTEROPERABILITY USE CASES

A federated architectural pattern will be followed to enable interoperability within a fully interoperable South African healthcare environment. In other words, some health information systems (such as clinical registries) are managed by local and provincial government departments, while others (such as demographic registries) are managed by the NDoH. In addition, some health information systems are privately owned and developed by third parties. As the private health sector forms part of a fully interoperable South African healthcare environment, it will need to share data with the national registries, as prescribed in the NHI

Bill. This information sharing will be based on the standards defined within the most current version of the HNSF.

The National Interoperability Use Case selection, prioritisation and implementation plan needs to be aligned with the system implementation of the various federated registries, as the maturity of underlying systems will pose a constraint to their selection. Consequently, the following general pattern will be followed, once the National Interoperability Use Cases have been identified and prioritised:

- Step 1: Implement a National Repository (and constraint on National Interoperability Use Case selection);
- Step 2: Develop HIS to comply with the latest version of the HNSF[22] (various HIS);
- Step 3: Developers, vendors and suppliers test their HIS for compliance with the latest version of the HNSF;
- Step 4: Developers, vendors and suppliers attend a Connectathon (conformity assessments marathon) to test their systems for compliance with the HNSF (based on use case and profiles used) by connecting to other Health Information Systems and the various national repositories. Attendance of vendors and suppliers are acknowledged;
- Step 5: Conformance testing of HIS for compliance to the HNSF (based on use case and profiles used) is undertaken. This is done at an NDoH-approved conformance testing lab. Attestation of HNSF compliance is issued; and
- Step 6: Integration into the shared SA National Health Information System takes place, subject to the vendor/suppliers' acceptance of certain terms and conditions, as stipulated by the NDoH. The NDoH provides approval on a case-by-case basis.

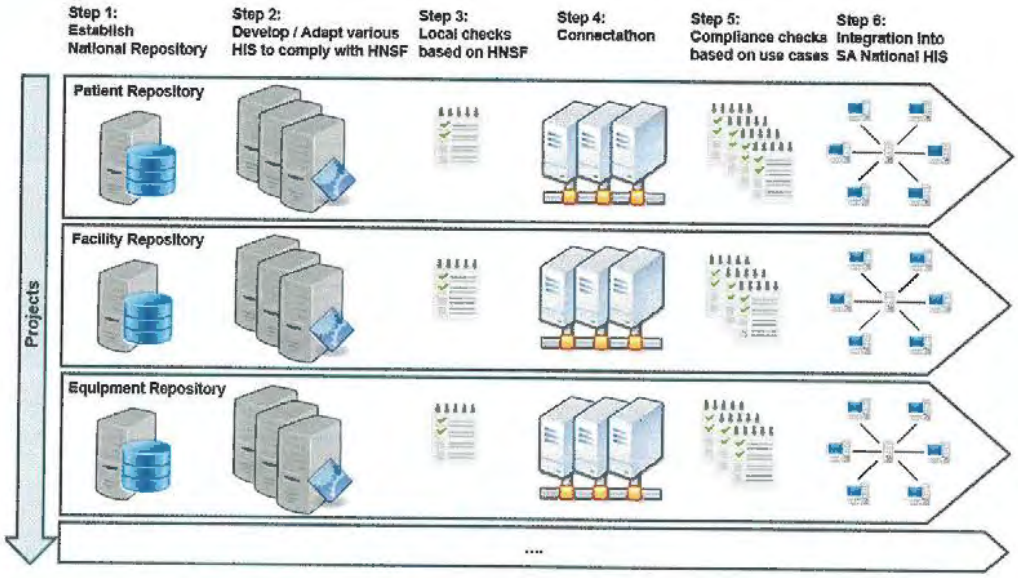

FIGURE 4: USE CASE CONSTRAINT BASED ON NATIONAL RESPOSITORY IMPLEMENTATIONS

[22] Implies the latest version of the HNSF and its implimentation guides.Currently it is the 2020 HNSF

Another constraint on the implementation plan is the scope of interoperability. The scope is currently limited to the IHE infrastructure domain (profiles). This scope will be expanded with future iterations of the HNSF. The expansion of the scope is prioritised in the plan presented in Figure 5.

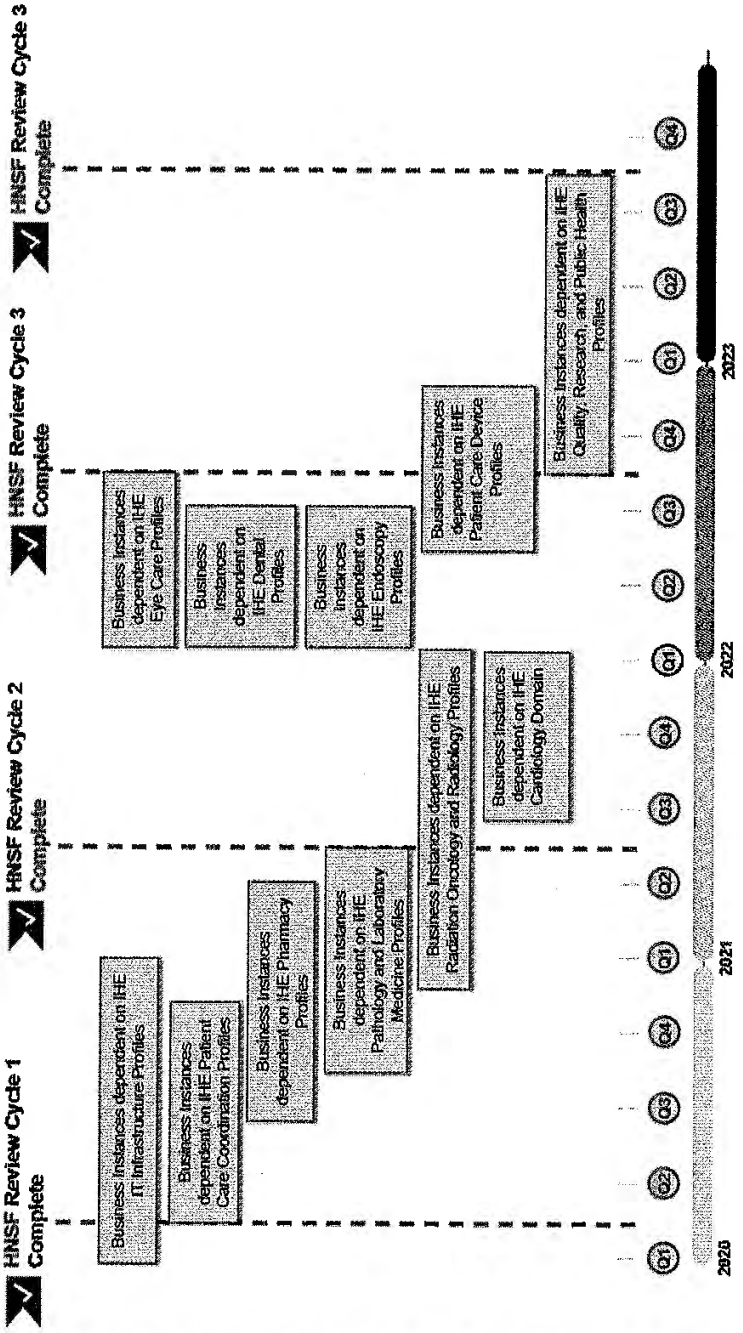

FIGURE 5: BUSINESS INSTANCE IMPLEMENTATION PLAN

CONCLUSION

The essential role of interoperability in Health Information Systems deployed in the South African healthcare system has been alluded to in the 2018 Presidential Health Compact (PHC), Pillar 9, and articulated in the National Digital Health Strategy for South Africa 2019–2024. The Health Normative Standards Framework (HNSF) forms the cornerstone of the South African interoperability efforts and supersedes the 2014 HNSF version. The purpose of the HNSF is to act as a key enabler of the efficient and safe flow of healthcare-related person-centred information across institutional and provincial boundaries. This will facilitate a systems-wide fully interoperable South African healthcare environment. The 2021 HNSF outlines a domain collaboration for a national consensus by applying an agreed set of standards that are aligned, integrated, flexible, reusable and portable and has a reduced time to market.

ANNEXURES

ANNEXURE 1: POLICY AND REGULATORY CONTEXT

The policy and regulatory context that frames the HNSF is linked to the components of a National eHealth Strategy, as described by the National eHealth Strategy Toolkit[23] of the WHO.

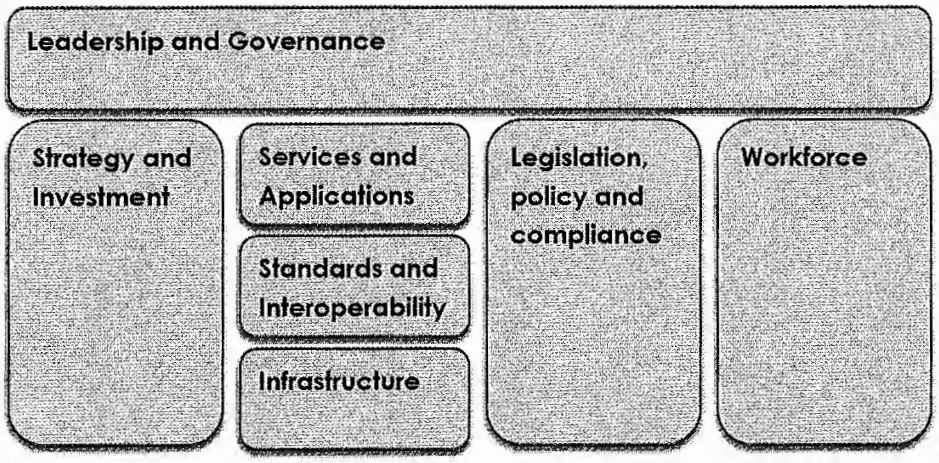

FIGURE A.1 THE COMPONENTS OF A NATIONAL EHEALTH STRATEGY STIPULATED BY THE EHEALTH STRATEGY TOOLKIT

The *eHealth European Interoperability Framework*[24] refers to the legislation, policy and compliance component of the WHO, in three dimensions:

- *Legal and regulatory* involves compatible legislation and regulatory guidelines that define the boundaries for interoperability across borders, but also within a country. The purpose of regulations is the safety of the person.
- *Policy* is the mechanism by which information exchange and collaboration agreements between organisations must be made. The purpose and value of the collaboration must be set. Trust and responsibilities between the organisations are formalised at the policy level. Governance documents anchor the governance of collaboration.
- *Care processes* is the dimension where specific care processes are analysed and aligned, resulting in integrated care pathways and shared workflows that prescribe the information that is needed to deliver integrated care. This includes compliance to standards, as illustrated in Figure A.1.

The WHO does not refer to the care processes, but explains that the legislation, policy and compliance component includes an adoption to national policies and legislation in priority areas; reviews sectoral policies for alignment and comprehensiveness; and establishes regular policy reviews. The aforementioned dimensions create a legal and enforcement

[23] World Health Organization (WHO). 2012. National eHealth Strategy Toolkit. Retrieved October 2019. Retrieved from https://www.itu.int/dms_pub/itu-d/opb/str/D-STR-E_HEALTH.05-2012-PDF-E.pdf.

[24] Joint Action supporting the eHealth Network (JAseHN). 201). eHealth Network: Refined eHealth European Interoperability Framework. Retrieved March 2020. Retrieved from https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_co03_en.pdf

environment within which to establish trust and protection for consumers and industry in eHealth practice and systems. The WHO also stresses under the standards and interoperability component (Figure A.1) that standards should be introduced that enable consistent and accurate collection and exchange of health information across health systems and services.

These dimensions are found under interoperability governance that, according to the WHO, ensures that strategic policy frameworks exist and are combined with effective oversight, coalition building, regulation, attention to system-design and accountability. Hence, governance can be seen as policy-centric, and includes consideration of all actors involved.

Under regulatory authorities, one also has to consider the following legislative and policy frameworks that frame any implementation of the HNSF:

- National Health Insurance Bill, 2018;
- National Health Act, Act 61 of 2003;
- National Digital Health Strategy 2019;
- State Information Technology Agency Act, Act 88 of 1998;
- The Minimum Information Interoperability Standards (MIOS);
- The Minimum Information Security Standard;
- The National Archives and Record Service of South Africa Act, Act 43 of 1996;
- The Policy of Free and Open Source Software Use for South African Government;
- Spatial Data Infrastructure Act, Act 54 of 2003;
- Electronic Communications and Transactions Act, Act 25 of 2002;
- Promotion of Access to Information Act, Act 2 of 2000;
- Statistics Act, Act 6 of 1999;
- Regulation about the Control of Private Hospitals, Regulation 158 of 1996;
- Protection of Personal Information Act 2013; and
- National e-Government Strategy and Roadmap 2017.

The HNSF's purpose is to advance the importance of developing an interoperable SA NHIS. The same development was echoed by the Presidential Health Compact (PHC) of 2018, especially Pillar 9, which deals with the development of an information system that will guide the health system policies, strategies and investments. Hence, the HNSF is advancing the PHC Pillar 9 through this section of the document.

The HNSF also aligns to the National Digital Health Strategy for South Africa 2019–2024[25], with its vision of a "better health for all South Africans enabled by person-centred Digital Health". The strategy proposes several strategic interventions that should be achieved by 2024, one of which is to "establish an integrated information architecture for interoperability and effective, safe sharing of health information across health systems and services" in South Africa. This is a key point that can be enabled by the HNSF.

The HNSF is aligned to an agreed level of interoperability of functionalities of the NHI Bill[26]. The NHI aims to provide for the sustainability of funding for healthcare services, and to make

[25] NDoH. 2019. National Digital Health Strategy for South Africa, *2019–2024*. South Africa.

[26] National Health Insurance Bill. Retrieved March 2020 from https://www.gov.za/sites/default/files/gcis_document/201908/national-health-insurance-bill-b-11-2019.pdf

provision for equity and efficiency in funding by pooling funds and strategic purchasing of healthcare services, medicines, health goods and products from accredited and contracted healthcare service providers. According to the NHI Bill[27], an information platform will enable informed decision-making on population health needs assessment, financing, purchasing, patient registration, service provider contracting and reimbursement, utilisation patterns, performance management, setting the parameters for the procurement of health goods, and fraud and risk management.

The exchange of healthcare-related information is then facilitated by the interoperability standards articulated in the HNSF. For the NHI Fund to operate effectively and efficiently, it has to contribute to the development and maintenance of a national health information system as contemplated in Section 74 of the National Health Act, , and subject to the provisions of the National Archives and Record Services of South Africa, 1996 (Act No. 43 of 1996), the Protection of Personal Information Act, 2013 (Act No. 4 of 2013), and the Promotion of Access to Information Act (Act No. 2 of 2000), which state that accurate and accessible data should be available to the NDoH and the NHI Fund, or any other stakeholder legally entitled to such information. This relates to security and privacy of personal information and is important for data governance. Under interoperability governance, data governance is also necessary because it encompasses the people, processes and information technology that are required to create consistent and proper handling of an organisation's data across the business enterprise.

COBIT[28] is the proposed governance model that was accepted in 2012 by the South African Government[29] (section 5:3), and that is informed by the approved Corporate Governance of ICT Policy Framework (CGICTPF), the Governance of ICT Framework (GICTF) and COBIT[30]. Governance in all government departments should align with the CGICTPF and GICTF. COBIT 2019 involves compatible legislation and regulatory guidelines that define the boundaries for interoperability across borders, but also within South Africa.

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[27] National Health Insurance Bill, Retrieved March 2020. Retrieved from https://www.gov.za/sites/default/files/gcis_document/201908/national-health-insurance-bill-b-11-2019.pdf

[28] COBIT (Control Objectives for Information and Related Technologies) 2019. www.isaca.org

[29] South Africa Public Service and Administration. 2012. *Public Service Corporate Governance of Information and Communication Technology Policy Framework*. Retrieved from https://www.gov.za/sites/default/files/gcis_document/201409/cgictpolicyframework.pdf

[30] South Africa Department of Justice and Constitutional Development. (2012). Corporate Governance of ICT: Policy Framework and Charter. Pretoria: Department of Justice and Constitutional Development.

ANNEXURE 2: IHE CORE COMPONENTS

Consistent with the arguments put forward in the 2014 version of the HNSF, the 2021 HNSF includes the IHE IT Infrastructure (ITI) domain profiles, as these establish a foundation for the sharing of healthcare information, and were deemed the most appropriate to articulate towards national interoperability. The IT Infrastructure Profiles represent common IT functions (e.g., Maintain Time) that are used as building blocks for a variety of health-related Business Instances.

The standards-based IHE profiles coordinate several base standards to ensure the outcome of a health domain-related function. The notion of the IHE core components (Profile, Actor and Transaction), as depicted in Figure A.2, is further clarified in Table A.5. The Open Systems Interconnection seven-layer model explains an application layer as the user interface that is responsible for displaying received information to the user, and an integration layer as the location where the mechanics of data consolidation are outlined[31].

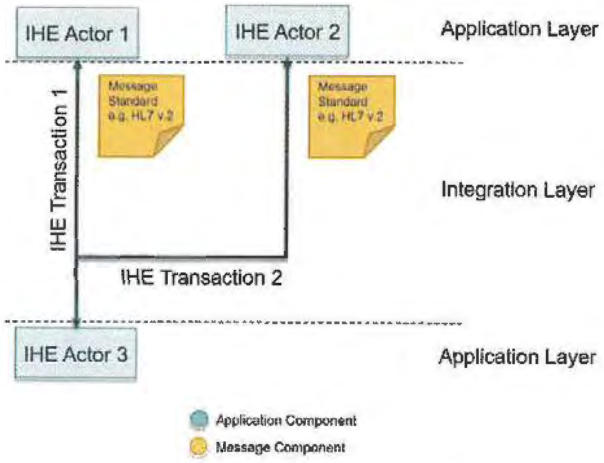

FIGURE A.2 IHE CORE COMPONENTS[32]

TABLE A.5 IHE CORE COMPONENTS

Components	IHE Definition (Technical Framework, Volume 1)	Description	Example
Profile	Each profile is a representation of a real-world capability, which is supported by a set of actors that interact through transactions.	A set of actors and transactions	Patient Identifier Cross-referencing (PIX) profile
Actor	Actors are Information Systems or components of Information Systems that produce, manage, or act on categories of information required by operational activities in the enterprise.	An application role in a distributed system	PIX Manager
Transaction	Transactions are interactions between actors that communicate the required information through standards-based messages.	A message exchange between actors	Patient Identity Feed between the Patient Identity Source and the PIX Manager (ITI-8)

[31] IEEE. (1990). *IEEE Standard Computer Dictionary: A Compilation of IEEE Standard Computer Glossaries*. www.ieee.org: Institute of Electrical and Electronics Engineers, 2018.

[32] https://oehf.github.io/ipf-docs/docs/ihe/

ANNEXURE3: NATIONAL INTEROPERABILITY USE CASES UNPACKED

The identification and formulation of National Interoperability Use Cases[33] would be the first step in implementing the HNSF. The NDoH identifies these based on national priorities. These National Interoperability Use Cases frame the articulation of the National Interoperability Specifications on the one hand and, on the other, the identification of gaps that would need to be addressed in future HNSF iterations.

The National Interoperability Use Cases, Business Instances, Implementation Outline, Technical Use Case and resulting integration profiles understanding and relationship are outlined below[34].

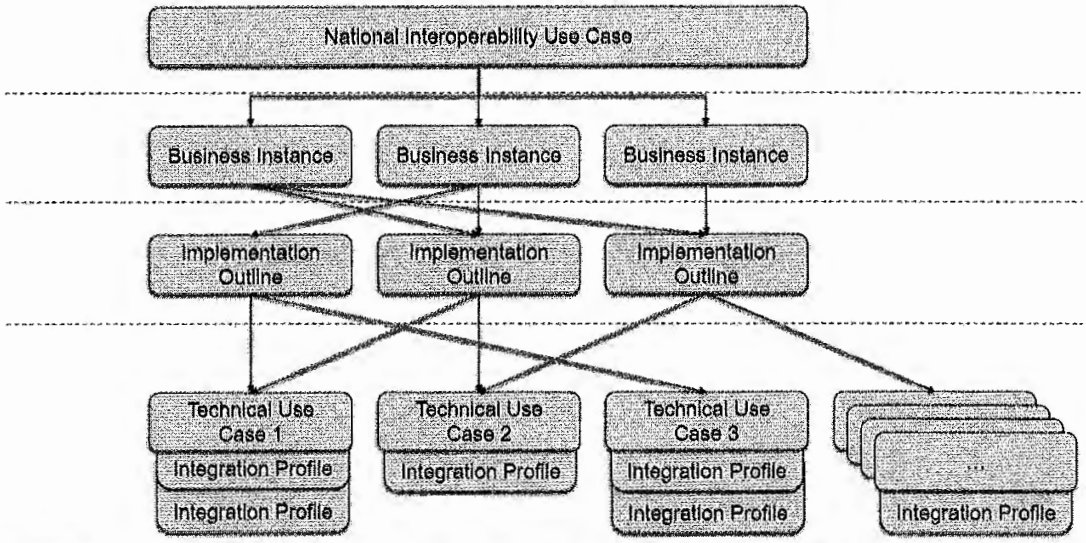

FIGURE A.3 GENERIC EXAMPLE OF THE RELATIONSHIP BETWEEN VARIOUS INTEROPERABILITY CONCEPTS[35]

- *National Interoperability Use Case*: A National Interoperability is seen as an overall description of a need for information sharing within, and across, healthcare organisations that use health information technology, often linked to the health objectives. It is written by users in a natural language and may include several healthcare-related *Business Instances*. A National Interoperability Use Case is developed by the users of the HIS, and the target audience is HIS decision makers. National Interoperability Use Cases are specific use cases within the context of a fully interoperable environment in South Africa, and ought to be prioritised to meet the needs of the South African health domain.
- *Business Instance*: A *Business Instance* is a description of a specific example of

[33] The term 'National Interoperability Use Case' refers to the use cases identified and prioritised at national level towards facilitating interoperability in the emerging SA NHIS.

[34] Bourquard, K., Orlova, A., & Parisot, C. (2017). Understanding User Needs for Interoperability: Defining Use Cases in eHealth. Journal of AHIMA, 88(6), 42.

[35] Orlova, Anna; Bourquard, Karima; Parisot, Charles. "Understanding User Needs for Interoperability: Standards for Business Cases in eHealth" Journal of AHIMA 88, no.7 (July 2017): 34–37.

Health Information System used for information sharing within the Use Case. Several Business Instances may derive from a single Use Case. Business Instances include a depiction of *business actors* (humans) and *technical actors* (systems), scope and workflows of tasks performed by healthcare professionals and associated data flows. It is written in a natural language and may include several *Implementation Outlines*. A Business Instance is developed by the users of the Health Information System, and the target audience is Health Information System healthcare professionals.

- *Implementation Outline*: An *Implementation Outline* is a description of a subset of workflow steps and data requirements within specific Business Instances from the business actors' perspectives, as well as specific transactions of technical actors (systems) to support workflow steps and data requirements. Examples of transactions include send–receive data, data query, and others. It is written in a natural language and may include several technical use cases for the selected transaction. It is described in Volume 1 of the IHE profile. Implementation Outlines are developed by users and IT specialists of the HIS, and the target audience is project managers, system architects, and implementers.
- *Technical Use Cases*: *Technical use cases* describe a need for a specific transaction between technical actors (systems, IHE actors) that supports the Implementation Outline. They are written in technical language and may include several implementation options enabled by individual standards selected for the transaction. They are described in Volume 2 of the IHE Technical Framework Documents. Technical use cases are developed by IT specialists, and the target audience is system architects and implementers.

In summary, the selection of National Interoperability Use Cases would enable the selection of profiles and underlying standards, as well as the verification and identification of gaps in the standards framework. This would lead to the selection of additional relevant standards and value sets through a localisation process.