A MODEL TOWARDS DATA INTEGRITY IN HOSPITAL INFORMATION SYSTEMS FOR SOUTH AFRICA

by

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DECLARATION

I declare that **A MODEL TOWARDS DATA INTEGRITY IN HOSPITAL INFORMATION SYSTEMS FOR SOUTH AFRICA**, is my work and that all the sources that I have used or quoted have been indicated and acknowledged by means of complete references.

I further declare that I have not previously submitted this work, or part of it, for examination at UNISA for another qualification or at any other higher education institution.

TThulare _____ 09 May 2023 _____

SIGNATURE DATE

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ABSTRACT

Healthcare decision-making heavily relies on data. However, maintaining data integrity remains a challenge. Human error and malware threats continue to threaten patients' health information. Further, software or system malfunctions, or configuration issues with electronic data handling, can negatively impact healthcare data quality. Data integrity ensures that the data is accurate and has not been altered in any way. A Data Integrity Model for Hospital Information Systems was developed using the Delphi technique. An expert panel evaluated and validated the components of the model. The results of the study show the need for a Data Integrity Model for South Africa and the components needed to develop one. This study contributes to the body of knowledge in developing such a novel model. Additionally, the Data Integrity model is considered relevant and potentially applicable to the improvement of Hospital Information Systems and similar health systems.

Keywords: data integrity, hospital information systems, cyber threats, health information systems, data integrity components, data integrity risks, data integrity challenges, the Delphi technique

PUBLICATIONS

Peer Reviewed Conference Proceedings

The following three conference abstract notes were submitted, accepted, and presented during this MSc research:

Thulare, T., Herselman, M. & Botha, A. 2020. A scoping review on identifying aspects of data integrity in health information systems for South Africa. 2020 International Conference on Artificial Intelligence, Big Data, Computing and Data Communication Systems (icABCD):1-8. https://doi.org/10.1109/icABCD49160.2020.9183870.

Thulare, T., Herselman, M. & Botha, A. 2020. Data Integrity: Challenges in Health Information Systems in South Africa. International Journal of Computer and Information Engineering, 14(11):423-429. http://hdl.handle.net/10204/12012.

Thulare, T., Maremi, K. & Herselman, M. 2022. A Scoping Review of Applying the Delphi Method Based on the Impact of the COVID-19 Pandemic on Conducting Research. 2022 4th International Conference on Applied Research in Education (ARECONF). https://www.dpublication.com/abstract-of-4th-areconf/36-8115/.

Other publications:

Foko, T., Legare, L., Thulare, T. & Maremi, K. 2017. Addressing Service Delivery in Rural Areas through Deployment of Information and Communication Technology Platforms. Cunningham, P. & Cunningham, M. IST-Africa 2017 Conference Proceedings. Windhoek, Namibia. 30 May 2017 - 02 June 2017 https://doi.org/10.23919/ISTAFRICA.2017.8102341.

Foko, T., Thulare, T., Legare, L. & Maremi, K. 2017. Information and communication technology platforms deployment: Technology access reaches South African rural areas. Cunningham, P. & Cunningham, M. 2017 IST-Africa Week Conference Windhoek, Namibia. 30 May 2017 - 02 June 2017 https://doi.org/10.23919/ISTAFRICA.2017.8102300.

Maremi, K., Thulare, T. & Herselman, M. 2022. The Benefits of Digital Transformation addressing the Hindrances and Challenges of e-Government Services in South Africa:

A Scoping Review. Cunningham, M. & Cunningham, P. 2022 IST-Africa Conference. Ireland. 16-20 May 2022 https://doi.org/10.23919/IST-Africa56635.2022.9845641.

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List of Acronyms and Abberviations

ALCOA+	Attributable, Legible, Contemporaneous, Original and Accurate, Complete, Consistent Enduring (Indelible/Durable), and Available
CDA	Clinical Document Architecture
CDGs	Continua Design Guidelines
DICOM	Digital Imaging and Communications in Medicine
DHIS	District Health Information System
HER	Electronic Health Record
EMR	Electronic Medical Record
FHIR	Fast Healthcare Interoperability Resources
HIMSS	Healthcare Information and Management Systems Society
HIS	Hospital Information Systems
HIV/AIDS	Human Immunodeficiency Virus, Acquired Immunodeficiency Syndrome
HL7	Health Level Seven International
HNSF	National Health Normative Standards Framework
HPRS	Health Patient Registration System
ICT	Information and Communications Technology
IEEE	The Institute of Electrical and Electronics Engineers
IICC	IVD Industry Connectivity Consortium
IOTA	Information For Operational and Tactical Analysis
IT	Information Technology
IS	Information Systems
ISO	International Standards Organisation
LOINC	Logical Observation Identifiers Names and Codes
MAM	Masked Authenticated Messaging
NHI	National Health Insurance
NCPF	National Cybersecurity Policy Framework
POPI	Protection of Personal Information Act
QRM	Risk Management System
UCUM	The Unified Code for Units of Measure

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1 CHAPTER 1: INTRODUCTION

1.1 Introduction

The study developed a model that would serve as a basis for future data integrity interventions for Hospital Information Systems in South Africa. To this end, data integrity elements, data integrity issues, and data integrity practices were explored through a literature review to inform the development of a model that was evaluated and validated by expert review through an exploratory Delphi technique.

As part of its mandate, the National Department of Health (NDoH) establishes, implements, and coordinates Health Information Systems at all levels of government (national, provincial, and local) (NDoH, 2019a, 2019b). For South Africa, the Sustainable Development Goal (SDG) 3 aims to promote healthy living and well-being at all stages of life (NDoH, 2020). To achieve this, the development and implementation of a comprehensive, effective, efficient, and quality Health Information System is critical to guide health system policies, strategies, and investments (NDoH, 2019a; South African Government, 2019). Among the noteworthy systems is the District Health Management Information System, which compiles health statistics from different sources, and is used primarily in the public sector to track and document health services provided at all levels of government (NDoH, 2011). In healthcare institutions, Hospital Information Systems (HIS) are essential tools for managing administrative, financial, and clinical data (Ahmadian, Khajouei, Nejad, Ebrahimzadeh & Nikkar, 2014). Data about patients as well as medical data and its interpretation, which is used in several parts of the healthcare facilities, are gathered, stored, displayed, and retrieved in a Hospital Information System (Ismail, Abdullah & Shamsuddin, 2015).

It was first necessary to distinguish between Health Information Systems and Hospital Information Systems to ensure that the concepts are clearly understood and to avoid using the terms interchangeably. Health Information Systems integrate data collection, processing, reporting, and use of the information necessary for improving health service effectiveness and efficiency at all levels of healthcare (English, Masilela, Barron & Schonfeldt, 2011). It includes all health data sources, such as data from health facilities and communities, electronic health records for patients, information from population databases, human resources information, financial data, supply chain data, and surveillance data, as well as their use, storage, and communication. In

contrast, Hospital Information System (HIS) is a type of Health Information System widely used in healthcare settings. As a comprehensive and integrated information system, HIS handles healthcare institutions' administrative, financial, and clinical aspects (Esfahani, Ahmadi, Nilashi, Alizadeh, Bashiri, Farajzadeh, Shahmoradi, Nobakht & Rasouli, 2018; Mehdipour & Zerehkafi, 2013). Among the main elements of a HIS are registration, order entry, results reporting, medical documentation, scheduling, and patient billing (Mehdipour & Zerehkafi, 2013), HIS assesses primary care quality, monitors quality indicators, supports clinical care assessment studies, and conducts concurrent audits of ongoing care utilizing reminders and decision support tools. The goal is to provide immediate access to the patient full medical history, health information, and data that is difficult to find within traditional patient charts (Esfahani *et al.*, 2018; Jayawardena, 2014).

Essentially, HISs helps to improve all aspects of clinical, financial, and administrative operations in a hospital (NDoH, 2019b; Handayani, Hidayanto, Pinem, Sandhyaduhita & Budi, 2018; Nilashi, Ahamdi, Ibrahim & Almaee, 2015). The implementation of HIS has led to increased productivity; reduced financial impact and medical errors; improved data availability and sharing; promotion and facilitation of teamwork; and has ensured patient confidentiality and security of their data (Slight, Berner, Galanter, Huff, Lambert, Lannon, Lehmann, Mccourt, Mcnamara, Menachemi, Payne, Spooner, Schiff, Wang, Akincigil, Crystal, Fortmann & Bates, 2015; Ahmadian *et al.*, 2014). While HIS has numerous advantages in healthcare, its implementation must be evaluated and weighed against concerns regarding the protection of patient health records when transmitted over the internet, which raises the risk of data integrity being compromised, which in turn compromises patient privacy and security (Moreira, Guimarães, Duarte, Salazar & Santos, 2022). The concept of data integrity has been used in computer systems for many years to ensure the integrity of relational databases. Pearlman (2019) and Liu, Yu, Chen, Xu & Zhu (2017) define data integrity as the process of maintaining data throughout its life cycle and ensuring accuracy and consistency thereof the data. Data that is inherently reliable should be complete, accurate, and consistent (Barkow & Takahashi, 2017; Ansara, 2016; Schmitt, 2014; AHIMA Work Group, 2013; Dan Rode & Chps, 2012). Data integrity in HIS ensures that data is accurate and complete when retrieved so healthcare professionals can make informed decisions.

This chapter presented the purpose and focus of the study. In Section 1.2, the background of the study and problem statement were discussed. Section 1.3 explained the importance of the study. The objectives and research questions of the study were outlined in Sections 1.4 and 1.5. An overview of the scope of the study was given in Section 1.6, while Section 1.7 outlined the applied research approach. The ethical considerations were summarised in Section 1.8, and the dissertation structure is shown in Section 1.9.

1.2 Background

Healthcare is essential for every nation (Reedy & Ramu, 2016). According to the World Health Organisation (WHO, 2019a), healthcare is essential to human wellbeing, economic growth, and happiness. Sekgwelo & Nemutanzhela (2015) posit that the use of information and communications technology (ICT) may improve access to care, reduce system costs, and optimise operations in the healthcare sector. Thus, HIS are heavily invested in by healthcare institutions to increase efficiency and effectiveness (Gursel, Zayim, Gulkesen, Arifoglu & Saka, 2014). In today's competitive environment, organisations use data as a competitive strategy. Healthcare professionals use data to make informed decision and improve the quality of care. In accordance with the South African eHealth strategy, "patient-based information systems must be implemented at all healthcare facilities," and all indicator data must be derived from electronic data collected at the point of treatment (NDoH, 2019a:18). While academics have advocated the benefits of implementing an electronic Health Information System in South Africa, studies have identified challenges within the quality of healthcare system data (Thomas, 2016; Botha, 2015; Kleynhans, 2012; Ruxwana, Herselman & Conradie, 2010). As a result, South Africa is implementing the National Health Insurance (NHI) financing model through the development of a patient registration system that can be used along with an electronic health record (EHR) to improve health system initiatives, address healthcare financing challenges, and eliminate fragmentation. (NDoH, 2019b; Katurura & Cilliers, 2018; NDoH, 2017).

1.3 Problem Statement

The majority of South African clinics, community health clinics, and rural hospitals use paper-based information system, resulting in paper-based patient records and health statistics rather than being accessible through a centralised database (NDoH & CSIR, 2014; Cline & Luiz, 2013). One of the priorities of the South African National Digital

Health Strategy (NDoH, 2019a) and NHI Bill (NDoH, 2019b) is the development of a complete national EHR. Therefore, NDoH has implemented the Health Patient Registration System (HPRS) as part of the development of the patient EHR (NDoH, 2019a). HPRS is a patient and service provider registration system that uses the South African Identification Number and other legal person identification to provide a Patient Registry and Master Patient Index (NDOH, 2019a).

However, unauthorised manipulation or modification of data can cause damage to both paper-based and computer-based information systems (Thulare, Herselman & Botha, 2020). Several authors agree that data integrity issues adversely affect healthcare delivery, while also arguing that action must be taken to mitigate its impact (Maunu, 2019; Pearlman, 2019; Barkow & Takahashi, 2017; Kucharski, 2016; Vimalachandran, Wang, Zhang, Heyward & Whittaker, 2016). The concerns have heightened with the increased number of data breaches in healthcare facilities, due to internal attacks and the lack of access control mechanisms, which has resulted in several serious consequences and contributed to the security threat in health records systems (Pandey, Khan, Abushark, Alam, Agrawal, Kumar & Khan, 2020; Wanyonyi, Rodrigues, Abeka & Ogara, 2017). This was the case with Life Healthcare Group, whose data was compromised during the COVID-19 outbreak, hampering operations in terms of billing and submitting medical aid claims as well as in processing invoices from vendors and generating financial results (Mungadze, 2020).

In South Africa, there are a number of disparate systems operating in the nine provinces, posing problems related to interoperability (NDoH, 2019a). Some provinces have Health Information Systems that cannot communicate with each other, while others use paper-based systems. Consequently, information cannot be exchanged, which can lead to medical errors due to the fragmentation of patient health information (Tsegaye & Flowerday, 2021). Considering how sensitive patient health information is, it is crucial to ensure that it is protected from unauthorised access through the appropriate mechanisms.

While there has been work in the area of data integrity over the years, a standard definition for data integrity yet has to be developed, prior to the eventual acceptance of a Data Integrity Model (Ivan, 1991). South Africa is working towards becoming a digital health society. It becomes imperative to prevent, or at least detect, unauthorised

manipulations and disclosures of sensitive data contained within a HIS. According to Zarour *et al.* (2021), identifying and implementing the security and control processes and procedures ensures the data integrity of HIS at different levels of use in healthcare facilities. The latter need, in addition to security and control, well-established security policies to address data integrity. Furthermore, data integrity provides a way for health organisations to conduct accurate research and provide an accurate picture of the real world (Hartzband & Jacobs, 2016).

1.4 Research Questions

Based on the background and the problem statement, the researcher derived one main and three subsidiary research questions in conceptualising the final Data Integrity Model for HIS in South Africa. To address the main research question, three secondary questions are used to guide the study to answer the main research question.

1.4.1 Main Research Question (MRQ)

What constitute the components of the model towards achieving data integrity for Hospital Information Systems, such as the health patient registration system (HPRS), in South Africa?

The aim of the main research question (MRQ) was to identify the components of a Data Integrity Model for Hospital Information Systems in South Africa. The three secondary research questions served as a guide for developing a component-based model to support Hospital Information Systems.

1.4.1.1 Secondary Research Questions (SRQ)

The three secondary research questions are:

1.4.1.1.1 Secondary Research Question 1 (SRQ 1)

How should digital Health Information Systems align with interoperability practices?

This question examined the context of the various HISs in use across South Africa and demonstrated the value that can be derived from ensuring interoperability.

1.4.1.1.2 Secondary Research Question 2 (SRQ 2)

What role does data integrity play in Hospital Information Systems?

This question seeked to explore the data integrity risks, data integrity issues and provided insights to the data integrity mechanism implemented to ensure data integrity in healthcare information systems. To acquire this information, a complete literature review was conducted focusing on digital health, in healthcare.

1.4.1.1.3 Secondary Research Question 3

What elements constitute a Data Integrity Model to support Hospital Information Systems?

This question (SRQ3) seeked to examine the literature on key data integrity elements that can be positioned to support Hospital Information Systems from various existing models or frameworks.

1.5 Purpose and Objectives

The purpose of the study was to develop a model towards achieving data integrity in HIS for South Africa. Current implemented data integrity practices were evaluated within government healthcare facilities in South Africa. In response to the research problem, the study objectives were to:

- define data integrity as stated in the literature review.
- identify existing data integrity issues through a literature review.
- identify the necessary elements of a Data Integrity Model for Hospital Information Systems through a literature review and
- verify and elaborate on the components that constitute a Data Integrity Model through expert reviews.

1.6 Research Scope

The study was limited to include only expert reviews in the field of Information Systems (IS) and included only experts in South Africa. The study did not use quantitative methods to validate or ensure data integrity for the specific healthcare systems but created a basis for future interventions on data integrity. The findings were vital in the development of the Data Integrity Model. Digital Health interventions were aligned with health sector priorities. These interventions include, amongst others, a complete EHR, to improve patient management and the digitisation of health systems business processes, including various health systems to improve efficiency and quality at the institutional level for human resources, as well as medicine access (NDOH, 2019a).

The researcher assumed that, as it develops, the Data Integrity Model can be a tool used as a guide to support the National Digital Health Strategy (NDOH, 2019a).

1.7 Research Approach

The study employed an exploratory Delphi technique as its research approach. It provided a structured mechanism and an iterative process through which a collective group (panel) of individuals (usually experts) seeked to distil and correlate the views on a particular topic or problem (Alarabiat & Ramos, 2019). Using the Delphi technique of Dalkey & Helmer (1963), a Data Integrity Model that can support HIS in South Africa is developed as an outcome. In addition, an interpretive philosophy was used within the Delphi technique to refine and validate the model. Chapter 4 provides a more detailed discussion of the research methodology.

1.8 Expected Contribution of the Study

The model comprised a theoretical construction of components based on the literature. Therefore, investigation of currently existing models to adapted from the South African perspective were investigated. Methodologically, the model was developed by applying an exploratory Delphi technique as an approach where evaluation and validation was necessary. The application of the model in a specific context to observe its impact and obtain feedback from users, could become a conceptual framework that can be refined and contextualised for the health domain in South Africa. This represented both a practical and a methodological contribution, as such a model for South Africa has to date not been constructed by applying the Delphi technique.

The practical contribution stemmed in the first place from the potential future practical application of the model. Secondly, it stemmed from the development of a new model that constituted components that could be applied in other areas in South Africa with similar systems or in other developing contexts, as well as add value to realise the National Digital Health Strategy for South Africa (NDOH, 2019a). Theoretically, it contributed in terms of data integrity, health systems, interoperability, and digital health.

1.9 Ethical Considerations

Ethics is described as rules or morals that govern how people behave and ultimately make decisions (Castellano, 2014). In research, a code of ethics has been developed in several disciplines and countries to balance the relationship of researchers to the

participants and the intended field of study (Bos, 2020:p39-41). The study was conducted in accordance with the ethical guidelines established by the University of South's Research ethics policy (see Annexure A) and the National Department of Health (NDoH), South Africa, to protect the rights of all participants and ensure that quality ethical research is conducted. These included:

- The researcher conducting the research directly and openly.
- The participants had the right not to participate in the study.
- The participants could withdraw at any time during the study.
- Before the commencement of the study, an agreed informed consent was presented to the participants and
- The participant's information was treated confidentially.

Dissertation Layout

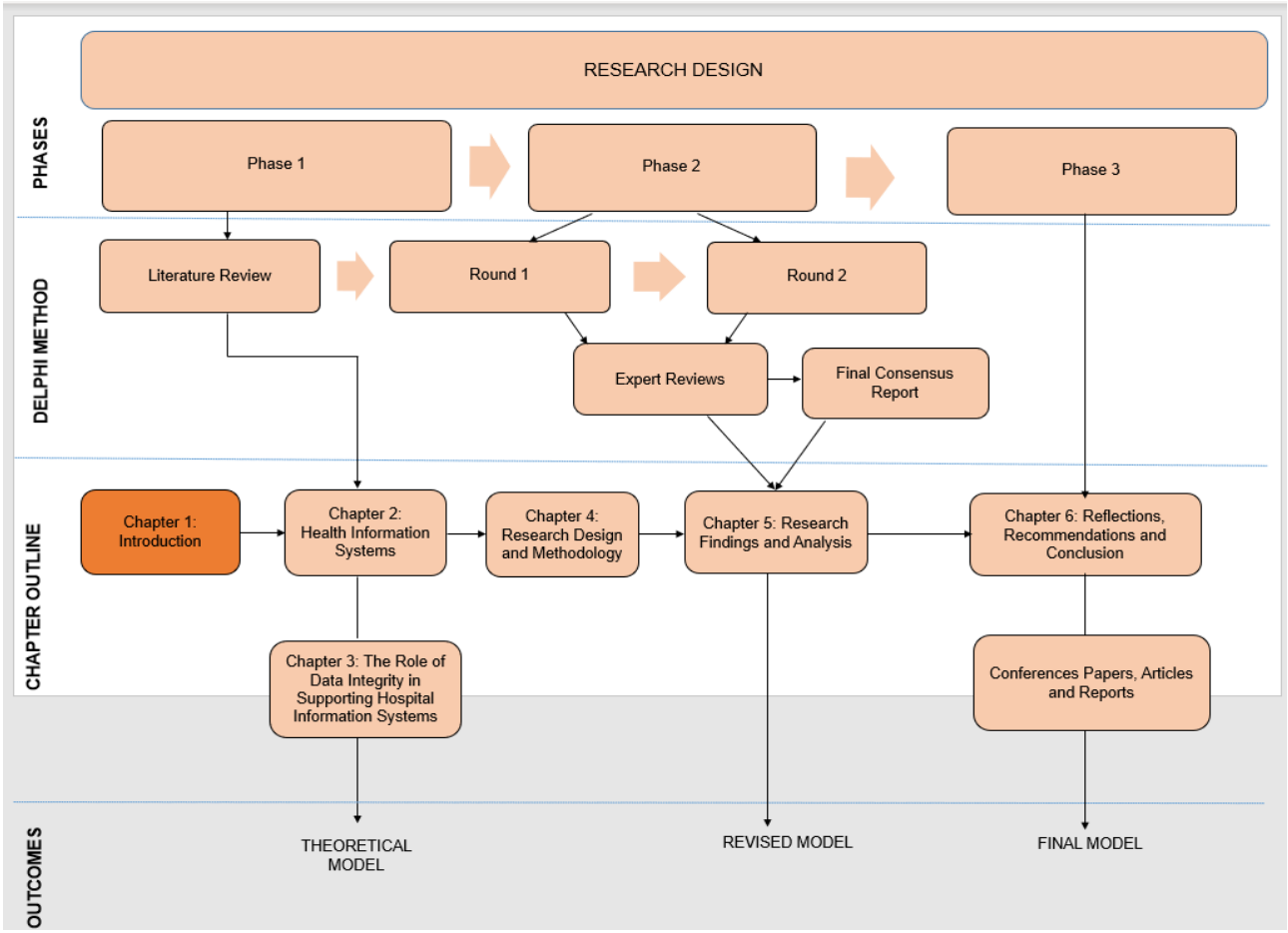


Figure 1:1: Chapter Layout of Research Study

The study is presented graphically in Figure 1.1, indicating the titles of the chapters. A summary of their content as follows:

Chapter 1: Provided context and motivation for the investigation. The research problem and significance of the research, along with the research questions and objectives.

Chapter 2: Presented insight into Health Information Systems worldwide. Before considering Health Information Systems in South Africa, their benefits, challenges, and importance, it was essential to first comprehend their context. The concluding part of the literature addressed SRQ 1, which identified and explored the constructs that form the Data Integrity Model to support HIS.

Chapter 3: The second part of the literature review provided insight into data integrity in Hospital Information Systems. This explored the data integrity risks in the healthcare

industry. Additionally, the chapter identified the elements (SRQ 2) that could comprise of the theoretical model. Lastly, the chapter also examined the data integrity considerations (SRQ 3) that needed to be considered when exploring data integrity endeavours. The constructs provided in this chapter informed the theoretical model.

***Chapter 4*:** Covered research methods, including the use of the research onion. The chapter addresses the rationale behind the study's methodology and techniques, as well as the research paradigms employed.

***Chapter 5*:** Presented a theoretical model within a qualitative Delphi technique for expert evaluations. The empirical evidence of the Delphi technique process, which was applied to explore the Delphi participants' perceptions, has been used to design the revised model and provide the final Data Integrity Model.

***Chapter 6*:** Presented the final discussions and model, a summary of the study recommendations, and a conclusion based on the findings of the research.

2 CHAPTER 2: HEALTH INFORMATION SYSTEMS

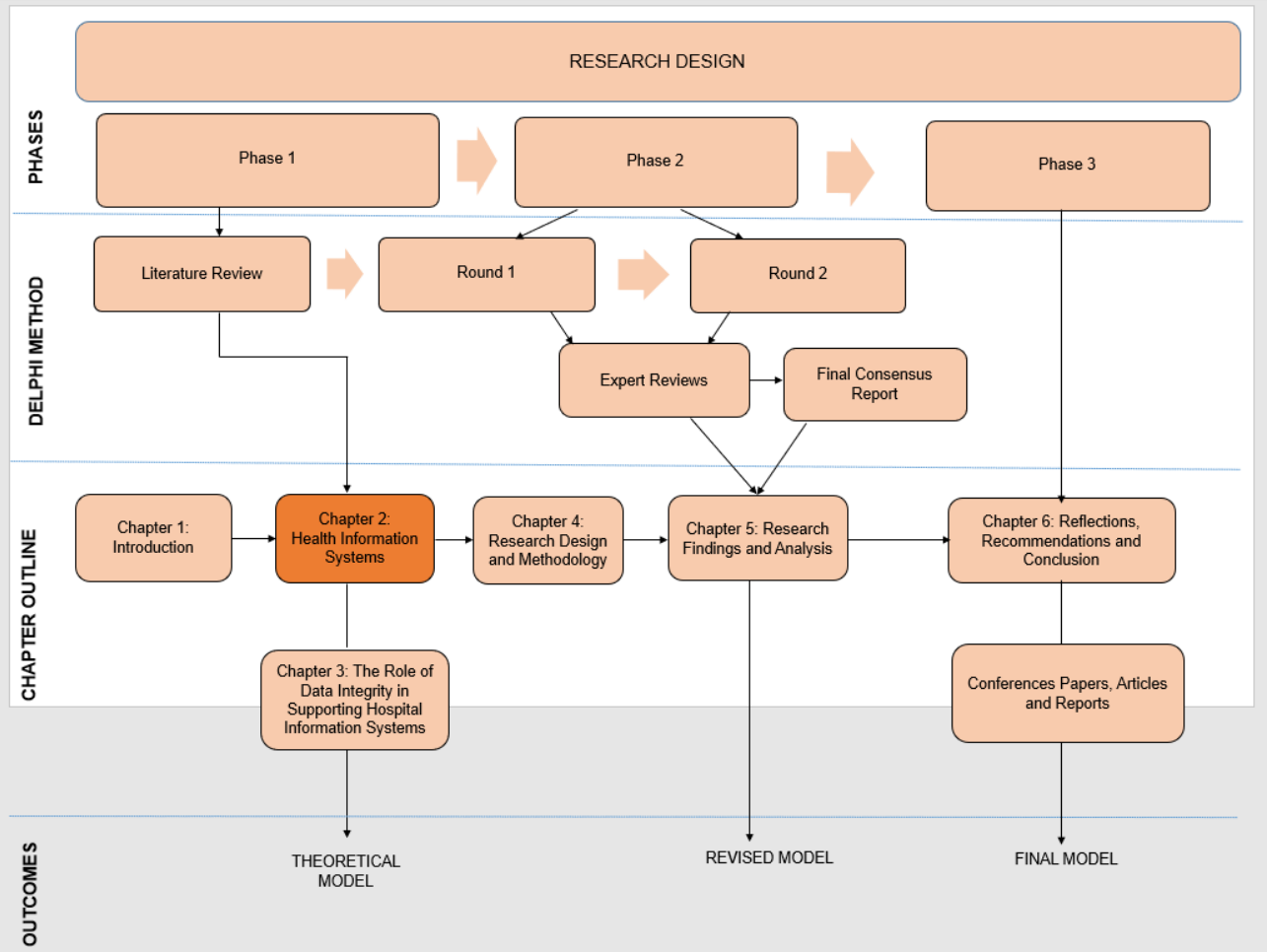


Figure 2.1: Chapter Layout of Research Study

2.1 Introduction

Healthcare provision is unquestionably a key priority for any government and society at large (Gabonewe, 2017). Healthcare is considered a human right worldwide, but many challenges still make that reality difficult for countries. Poor health systems and under-resourced facilities pose challenges for public healthcare systems in developing countries (Cline & Luiz, 2013). South Africa is no different with generous subsidies and highly skilled professionals in the private sector. Like most developing countries, 80% of public healthcare in South Africa is plagued by a quadruple burden of disease HIV/AIDS and tuberculosis; maternal and child mortality; non-communicable diseases; and violence and injury), weak healthcare systems, under-resourced provider networks, and low staff morale (Expatica, 2020; Marais, 2017; Masilela, Foster & Chetty, 2013). In most sections of the country, there exists a substantial difference between public and private healthcare services (Pillay & Motsoaledi, 2018).

In response to these challenges, there has been an increased usage of information communications and technologies (ICTs) by many public and private hospitals, and clinics to provide better patient care, reduce medical errors, and improve service delivery (Gabonewe, 2017). The advantages of using ICTs are evident in most world countries, but some countries have not taken advantage of this opportunity particularly when accessing health data and the provision of health services that are critical to health (Olu, Muneene, Bataringaya, Nahimana, Ba, Turgeon, Karamagi & Dovlo, 2019). Some countries lag behind because the automation of the healthcare system is misunderstood, as information technology (IT) investments are often compared to the costs of improving healthcare infrastructure, hiring additional resources for healthcare workers, or purchasing supplies to improve access to care (Cline & Luiz, 2013). However, it is becoming increasingly apparent that by using IT in healthcare in a highly constrained economy, frees up other valuable resources and can increase efficiency and productivity (Gabonewe, 2017). Given the many challenges facing the South African public health sector, the implementation of Hospital Information System may be the solution to some of the challenges associated with this (Alotaibi & Federico, 2017).

An assessment of the literature was conducted using a scoping review, aimed at mapping the literature on a particular topic or research area and identifying key concepts, research gaps, as well as sources of evidence to inform policymaking,

practice and research (Pham, Rajić, Greig, Sargeant, Papadopoulos & Mcewen, 2014). As a result, it provided an overview of the discipline's literature and offered a chance to explore broader perspectives (Peterson, Pearce, Ferguson & Langford, 2016; Colquhoun, Levac, O'Brien, Straus, Tricco, Perrier, Kastner & Moher, 2014). A comprehensive review cannot be achieved by selecting a literature review approach only, but a rationale for the chosen approach is required (Peterson *et al.*, 2016). The most common reasons researchers prefer scoping reviews, according to Arksey & O'Malley (2005) are:

- Research findings are not presented in depth, but rather the range of information is consolidated.
- The mapping of literature may form the basis of a full systematic review.
- Summarise research findings. This outlines the information obtained.
- Finding gaps in the literature where research is minimal or non-existent.

This study used the scoping review approach to synthesise and communicate the research outcomes. The objective was to identify what components constitute a Data Integrity Model for HISs. There is a paucity of studies on data integrity in HIS for South Africa (NDoH, 2019a). More research is needed to inform improvement across healthcare systems. Scoping reviews are valuable in fields where very few randomised controlled trials exists or important when no comprehensive review is available in specific domain (Peterson *et al.*, 2016; Levac, Colquhoun & O'Brien, 2010:p1).

2.1.1 Steps for Conducting Scoping Reviews

To conduct a complete evaluation that can be duplicated in future research, a detailed account of the process must be provided. Thus, for this research study, the framework developed by (Arksey & O'Malley, 2005) and modified by Levac *et al.* (2010) led the synthesis of the literature review.

2.1.1.1 Determine the research question to help focus the review process

Defining the scope of literature to be considered was accomplished through the development of research questions (see Section 1.4). Establishing research questions ensures that progress is made toward the research objectives. Therefore, this research was motivated by the MRQ mentioned in Section 1.4.1, *What constitutes the*

components necessary for achieving data integrity in Hospital Information Systems such as the Health Patient Registration System (HPRS) in South Africa? Chapters 2 and 3 mapped the literature, addressed the research phenomena and guided the theme extraction.

2.1.1.2 Identify relevant studies

This step involved identifying appropriate literature. To begin, a comprehensive literature search was conducted using Scopus, IEEE Xplore, Science Direct, and Google Scholar. Conference papers, journal articles, and books were considered. Additionally, strategic documents and newspapers were accessed through government websites, mainly the South African National Department of Health website.

2.1.1.3 Select relevant studies

Having determined where to source pertinent literature, eligibility criteria (inclusions and exclusions) had to be developed. The criteria included:

- Research studies written in English.
- Studies that use the terms Data Integrity, Health Information Systems, or Hospital Information Systems alone or in combination.
- Studies that go into detail on data integrity procedures.
- Health Information Systems studies in the healthcare sector.
- Health Information Systems in the context of South Africa.
- The literature review was limited to studies conducted between 2011 and 2021.

Data integrity is a broad term that can be applied in a variety of settings and fields, some of which were pertinent to this study. As a result, the search strategy was confined to considering the following areas to match the search term with the research purpose:

- Literature that refers to Data integrity across paper-based and electronic healthcare systems in public healthcare sectors.

- Literature studies of Hospital Information Systems in South Africa and developing countries alike.

Search terms such as "data integrity" and "healthcare" and "data integrity issues" and "Hospital Information Systems" and "challenges" and "data integrity requirements" and "Health Information Systems" along with "interoperability" and "South Africa" were used to find potential papers. Layers and healthcare together with "interoperability." Using the title, keywords, or phrases identified in the search terms combined, and the abstracts of each publication as well as citation ranking that is not less than 1.00, the search results were screened for appropriateness (Herculano Da Luz Júnior, Silva, Albuquerque, Medeiros & Lira, 2020). As a result of the initial screening process, 38 full-text papers met the research's eligibility criteria. Figure 2.2. summarises the process for selecting relevant studies.

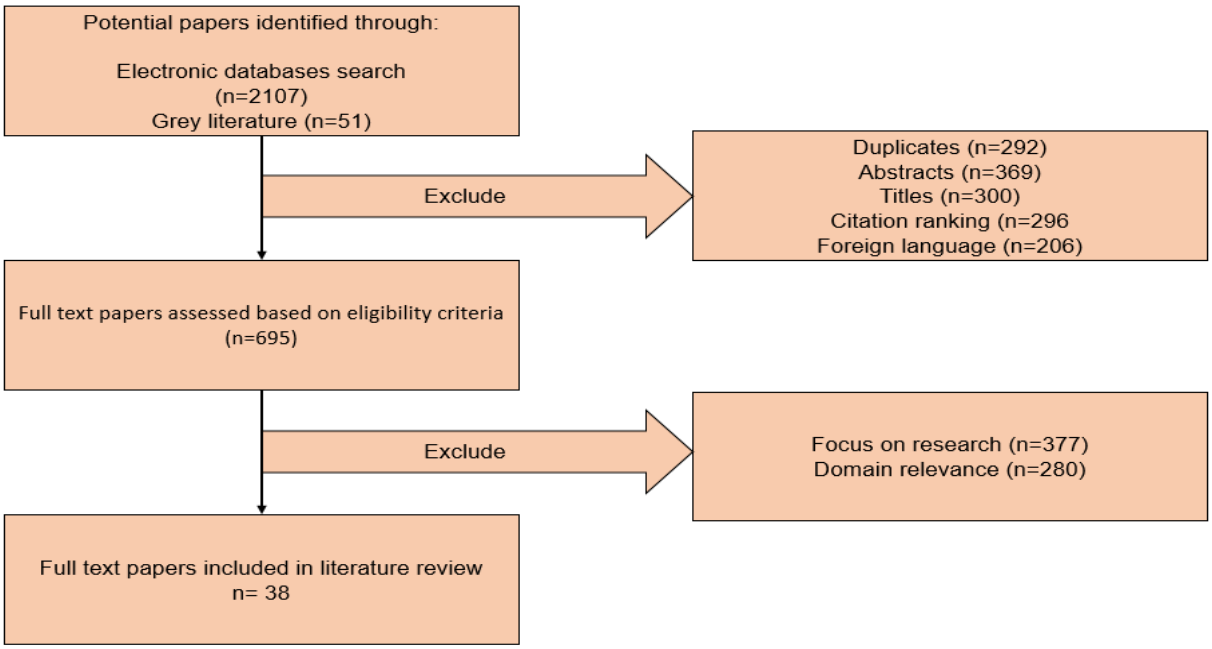


Figure 2.2: Summary of Selection Records

Munn, Peters, Stern, Tufanaru, Mcarthur & Aromataris (2018) argue that scoping reviews are more about mapping the literature than providing exhaustive explanations. The result is a variety of relevant studies that offer insight into a wide variety of phenomena. However, big numbers may compromise the study's quality during analysis (Saunders *et al.*, 2019:p111). Managing the study's outcomes ensured that it

stayed on course. Additionally, literature was purposefully sampled to evaluate the breadth of data integrity and HIS concepts, as well as their differences and similarities.

2.1.1.4 Chart data obtained from studies

Charting data involved synthesising crucial information from research studies. This was accomplished by documenting critical information across various themes that aided the research. The scope of the inquiry was narrowed using a combination of strings related to this study. Using Excel, this study charted the core literature: Author, Publication Year, Title, Key Findings, and Research Theme. Each research study was evaluated according to its key findings for eligibility and significance. Furthermore, each article considered had to be consistent with the larger research themes. As shown in Figure 2.3, a total of 23 key articles contributed to Phase 2 of the research study. Detailed information on the main articles is available in Annexure C.

2.1.1.5 Reporting and summarising findings attained

Arksey & O'Malley (2005) conclude their scoping review framework with the discussion of the results and findings. In this way, each publication's key findings could be determined. An analysis of the literature review was included in the findings.

In Chapter 4, the Delphi technique is discussed and its application to the research study. This chapter provides a literature review of key issues related to the research objectives of this study. Key concepts such as healthcare, Health Information Systems, Hospital Information Systems, and data integrity practices are discussed. Although the researcher attempted to use only the most recent entries, in some cases, the researcher had to rely on older sources because they were relevant publications on the subject under study.

Main Literature Review Papers					
Paper Number	Author	Publication Year	Title	Key Findings	Research Theme
1	Timmerman, R	2011	A Model for Creating and Maintaining Document Data Integrity In an Enterprise Electronic Health Record.	Methods of electronic document creation and document management as well as important considerations in developing policies and procedures surrounding document management requires guidelines describing how these are to be used and when it is appropriate to use each method	Data Integrity
2	Dan Rode, M.B.A. & Chps, F	2012	Data Integrity in an Era of EHRs, HIEs, and HIPAA: A Health Information Management Perspective	The use of standards is absolutely necessary to maintain integrity and make the data useful. Organisations (providers and others) must establish a data governance strategy and process to ensure data integrity and conformity as well as to facilitate confidentiality	Data Integrity
3	Mchunu, N.N.	2012	Adequacy of healthcare information systems to support data quality in the public healthcare sector, in the Western Cape, South Africa	The public healthcare administration must enhance their training programs to cater for the needs of all users, regardless of their background. It needs to improve user skills and boast their confidence in using electronic systems. Adherence to data handling procedures must be strictly enforced, with policies thoroughly communicated to the users for improved service delivery in the public healthcare sector in South Africa	Hospital Information Systems
4	Bowen, R. and Smith, A.R	2014	Developing an enterprisewide data strategy: data integrity is a critical concern for both the clinical and financial sides of the healthcare enterprise, ensuring both quality of care provided and accurate payment for services--and that also makes it a critical concern for the CFO.	The establishement of a information governance program in hosptials will ensure the quality and integrity of data.	Data Integrity
5	Botha, M., Botha, A. and Herselman, M	2014	Data quality challenges: A content analysis in the e-health domain	Provides a prioritised list of data quality challenges experienced by users of healthcare systems in South Africa, to guide future health data interventions and ensure future data quality in South Africa.	Hospital Information Systems
6	Masrom, M. and Rahimly, A.	2015	Overview of data security issues in hospital information systems.	Technical issues in Hospital Information System must have strong protection for the data and information derived from patient-specific health- elateddata that cover data acquisition, storage, retrieval and linkage activities, and analytic and reporting activities.	Hospital Information Systems

Figure 2.3: Summary of Main Literature for Review.

2.2 Health Information Systems

Over the last few decades, the transition from paper-based health records to EHRs has led to the widespread adoption of Health Information Systems to improve public healthcare services and reduce inefficiencies. The use of Health Information Systems improves disease surveillance, facilitates the use of information strategically, manage patients and programs, and improves service quality (Moucheraud, Schwitters, Boudreaux, Giles, Kilmarx, Ntolo, Bangani, St Louis & Bossert, 2017).

Healthcare institutions are divided into various organisational wards with different types of information processing disciplines and diverse professional healthcare personnel. The different levels of Health Information Systems enable the discernment of each system's functional state, allowing for better decision-making when determining the most appropriate course of action. It is imperative to understand the different digital health systems' maturity levels. Carvalho, Rocha, van De Wetering & Abreu (2019) developed a HIS maturity model with the unique ability to combine several important maturity-influencing factors and respective characteristics, allowing for both the assessment of an HIS's overall maturity as well as the individual maturity of each of its various dimensions. In health analytics maturity models identify the strengths and weaknesses of HIS information maturity and address HIS

implementation complexity (Carvalho, Rocha, Vasconcelos & Abreu, 2019). The maturity levels can assist in identifying areas for improvement and determining the most appropriate course of action that will facilitate a move to a higher level of maturity (Duncan, Eden, Woods, Wong & Sullivan, 2022; NDoH & CSIR, 2014). For South African Health Information Systems, NDoH & CSIR (2014) described the different levels of e-Health maturity that may exist as:

- **Complete paper-based system using standardised forms and stationery (maturity Level 1)** – The most basic form of patient data recording. This level records and stores health information manually. In paper-based repositories, the Patient Master Index cannot always interface with other healthcare providers. Duplicate files result from an unintegrated system.
- **Localised computer system for patient administration (maturity level 2)** – are paper-based with limited IT support. Using the IT system, authorised clerks process all administrative tasks. Medical records are maintained in a single location with no links to other repositories. The system collects demographic information about patients. Those with access to patient records could create patient cards using the patient identifier and demographics. Facilities also record interactions with patients. The system could also edit and update patient demographics. Further interoperability challenges arise due to IT limitations in these systems.
- **Centralised electronic patient record system (maturity Level 3)** – Is a hybrid of paper-based and electronic features. Medical records are first manually entered into the file of a patient. Once collected and captured in common clinical repositories, physicians, general practitioners, pharmacies, laboratories, and other medical facilities can access EHRs and medical data through local IT systems. Access to the shared clinical repository is available via IT systems for authorized healthcare facilities. Security and audit services would also make authentication across the centralized infrastructure easier. Health facilities could also control information stored on devices and controlled by specialized consumer apps.
- **A Fully integrated national shared electronic health record system (maturity Level 4)** – Keeps all patient information electronically at the healthcare facility in the local electronic medical record (EMR), and some or all

the information is stored centrally in the shared EHR. Furthermore, EMRs can be used to record patient-centred information in healthcare facilities. A shared EHR system can be centralised within a hospital complex, district, province, or even the nation. The following infrastructure is shared by the Health Information System:

- The Health Information System is mostly electronic for healthcare facility-based transactions, and healthcare professionals can enter and retrieve data at the point-of-care using edge devices.
- Information from EHRs and clinical repositories is shared among all healthcare facilities in a district, province, or nationally.
- Throughout the healthcare facilities served by the shared infrastructure, authorised users can access and update the shared clinical repositories.
- A health information exchange manages workflow and operations such as communications in the shared infrastructure.
- The shared infrastructure is protected by security and audit services that facilitate authentication across the network.
- Local healthcare facilities have specialised consumer apps to manage the different smart devices used to access and record data from shared repositories and registries.

Most Health Information Systems are paper-based systems (maturity Level 1) and designed to provide information for monitoring, evaluation, and public health programs. But more recently NDoH has made advances of maturity levels with a localised computer system for patient administration through the implementation of HPRS. While maturity Level 4 is the ultimate goal, most care settings may only be able to reach Level 3 in the current South African healthcare context (NDoH & CSIR, 2014). It is due to a lack of infrastructure, a dearth of skilled healthcare professionals, and the cost of purchasing ICT-based edge devices for all healthcare workers who will need to access the EHRs in the shared infrastructure (Katuu, 2018). Moreover, achieving Level 4 would require a very substantial investment in change management. In other words, all healthcare workers would need to change their work practices (Di Paola & Vale, 2019:p246).

2.3 The Purpose of Digital Health

In general, digital health refers to the use of various technologies that improve the health status of patients and the quality of their care. Katuu (2016) defines digital health as the provision of health information, the implementation of electronic methods, and the integration of information across different systems. Manteghinejad & Javanmard (2021) write that when health telematics emerged in the 1970s, the focus was on diagnosing and treating diseases. As desktop and personal computers, the Internet, mobile phones and smartphones became more widespread in the 21st century, the focus shifted from diseases to health. This change was achieved by using digital technologies to deliver healthcare services anywhere and anytime (Manteghinejad & Javanmard, 2021). Digital health aims to enhance all aspects of healthcare and the communication thereof by combining some or all the various types of digital health. The use of digital devices, such as smartphones, helps with communication, but these devices also offer a number of apps that can monitor blood pressure, and blood sugar levels, ensure medication compliance, and track physical activity levels (Ronquillo, Meyers & Korvek, 2017). Additionally, digital health has successfully been applied to the prevention of non-communicable diseases, such as cancer, maternal and child health, immunisation, HIV/AIDS management, and the supply chain management of essential medicines and medical products (Olu *et al.*, 2019).

The COVID-19 pandemic has exposed weaknesses in healthcare systems as well as global public health responses in low- and middle-income countries, despite the improvements in health outcomes over time in these countries. In light of this, healthcare information, delivery, and management platforms need to be more flexible and responsive (Al Knawy, Adil, Crooks, Rhee, Bates, Jokhdar, Klag, Lee, Mokdad, Schaper, Al Hazme, Al Khathaami & Abduljawad, 2020; Ronquillo *et al.*, 2017). Healthcare systems need to adapt to changing health needs by taking advantage of the opportunities offered by digital health to deliver and meet health needs as they arise (Kruk, Gage, Arsenault, Jordan, Leslie, Roder-Dewan, Adeyi, Barker, Daelmans, Doubova, English, García-Elorrio, Guanais, Gureje, Hirschhorn, Jiang, Kelley, Lemango, Liljestrand, Malata, Marchant, Matsoso, Meara, Mohanan, Ndiaye, Norheim, Reddy, Rowe, Salomon, Thapa, Twum-Danso & Pate, 2018). However, with these digital technologies arise concerns. Issues of concerns include ethical

considerations (Cummins & Schuller, 2020), digital health equity (Kaihlanen, Virtanen, Buchert, Safarov, Valkonen, Hietapakka, Hörhammer, Kujala, Kouvonen & Heponiemi, 2022), data security (Abernethy, Adams, Barrett, Bechtel, Brennan, Butte, Faulkner, Fontaine, Friedhoff & Halamka, 2022) and interoperable digital technology (Al Knawy *et al.*, 2020). The various applications of digital health have demonstrated promising results and the ability to scale up, and regardless the issues of concerns digital health can and should act as a force multiplier of the interventions to combat these issues (Abernethy *et al.*, 2022).

2.4 Interoperability and the Role of Standards in Digital Health

In recent years, interoperability has gained a lot of attention. Through interoperability, quality and outcomes can be improved while waste and costs can be reduced. The goal of interoperability is delivering the right information at the right time to the right place (Benson & Grieve, 2016). The term interoperability has different meanings depending on the perspective from which it is understood. This study will define interoperability in the context of healthcare. The Healthcare Information and Management Systems Society (HIMSS), defines it as the capability of different information systems, devices and applications to connect, exchange and cooperatively use data between stakeholders, within and across organisational boundaries to optimise the health of individuals and populations (HIMSS, 2019:p113). The complexity of healthcare systems is often seen as a result of their interrelated components (Han, Liu, Evans, Song & Ma, 2020a). The challenges associated with documentation, distribution, and follow-up of diagnostic test results across disparate entities were made evident, exposing an unfortunate fact regarding the interoperability of medical data in the healthcare system during the pandemic (Greene, Mcclintock & Durant, 2021). Additionally, different actors play different roles in providing healthcare and may require information that is relevant to their specific needs (Tsegaye & Flowerday, 2021). Until a clear outline is laid out of how each actor and system can communicate as a unit, interoperability in electronic health systems will remain a challenge (Reisman, 2017).

2.4.1 Layers of Interoperability

Several layers of interoperability have been developed to facilitate implementation. To optimise interoperability implementation, it is imperative to analyse these layers. According Kobusinge (2021), interoperability has quite a few facets, such as

pragmatic, conceptual, dynamic, operational, information and static interoperability. The fact that various terms are associated with interoperability adds to its complexity. In addition to the commonly known layers of organisational, technical, syntactical, and semantic interoperability, the European Union has incorporated legal interoperability (Kobusinge, 2021; Delgado, Calegari, González, Montarnal & Benaben, 2020). As such, the legal aspect relates to the exchange of data and is particularly crucial for the healthcare industry, where the sharing of information is a sensitive issue (European Commission, 2017).

- Legal interoperability

Legal interoperability involves aligning legislation so that exchanged data is given the appropriate legal weight. To accomplish this, legislation must be screened to identify any barriers to interoperability, and legislation must be screened to identify any obstacles to digital exchange, as well as assessing ICT impact on stakeholders and ensuring that it suits the physical and digital environment (European Commission, 2017).

- Organisational interoperability

This layer is aimed at achieving mutually beneficial goals by aligning and coordinating processes and expectations between organisations (European Commission, 2017). Additionally, it focuses on the organisations' ability to communicate and transfer meaningful information through various Information Systems (IS) (NDoH & CSIR, 2014). According to the European Commission (2017) organisational interoperability requires technical, syntactic, and semantic interoperability foundations in order to be successful.

- Technical interoperability

Technical interoperability, also called foundational interoperability (Tsegaye & Flowerday, 2021), allows for the transmission of data between Health Information Systems through a network (Benson & Grieve, 2016). To ensure uninterrupted information flow, the hardware and software of the systems are addressed as part of the layer. The disadvantage of this layer is that it only ensures that information is transmitted and does not say anything about its significance. Syntactic and semantic interoperability, however, addresses these constraints (Tsegaye & Flowerday, 2021).

- Syntactical interoperability

The layer utilises predefined messaging formats and data formats to facilitate the exchange of information. For data exchange to occur simultaneously across systems, there must be well-established syntax and encoding (European Commission, 2017). Even though the receiving system may recognize the message structure, interoperability is not guaranteed. The reason for this is that syntactic interoperability does not guarantee that the receiving system will interpret the content of the message (Tsegaye & Flowerday, 2021).

- Semantic interoperability

Semantic interoperability addresses the syntactical layer issue by ensuring that communication channels have a common understanding of certain terms and that consistent communication between them is maintained (European Commission, 2017). An agreement on the meaning and structure of information can be reached either by specifying possible statements or through a harmonisation process (Kobusinge, 2021; Benson & Grieve, 2016).

Leal, Guédria & Panetto (2019) argue that interoperability is not a one-time achievement. Rather, it can be continuously improved over time at different levels. Together, these layers of interoperability could ensure the accurate exchange, interpretation, and use of information between the different systems among the participating entities. Understanding how they can be optimised is essential for the successful implementation of Health Information Systems interoperability (Kobusinge, 2021). Standardisation is necessary to ensure semantic interoperability from both a foundational and syntactic standpoint. Interoperability and standards are examined in the next section.

2.4.2 Standards of Interoperability in Healthcare

Interoperability can be achieved in digital health systems through standardisation (NDoH & CSIR, 2014). Standards are agreed upon specifications that are established or maintained consistently (Han *et al.*, 2020a). For interoperability, there must be appropriate standards for linking computer systems and allowing the sharing of information in a way that safeguards security and privacy concerns, though this requires translation into and out of an interchange language (Benson & Grieve, 2016:p19). Information exchanged between different systems is semantically

interoperable with the help of standards (Kobusinge, 2021). Due to the wide variety of contexts, it is often difficult to implement consistent standards across the various systems. However, standardisation ensures that information is understood and interpreted consistently across those contexts (Bates & Samal, 2018; Oemig & Snelick, 2016:p75; Silsand & Ellingsen, 2016).

There has been a variety of communication standards developed in healthcare over the years, and their role in facilitating interoperability has been well documented (Alunyu & Nabukenya, 2018; Oemig & Snelick, 2016:p75; NDoH & CSIR, 2014). Despite the fact that standards are fundamental to enabling interoperability, the numerous digital health standards and lack of adequate infrastructure has led to the low adoption (Kobusinge, 2021; Tsegaye & Flowerday, 2021; Oemig & Snelick, 2016:p3; NDoH & CSIR, 2014; Adebesin, Kotzé, Van Greunen & Foster, 2013). Standards developed without considering what type of infrastructure is present can lead to inaccurate representations (Alunyu & Nabukenya, 2018). Therefore, standards should specify exactly what types of services are required to ensure all communication levels are covered.

The standards developing organisations have not always delivered standards at the rate and granularity that healthcare systems need (Gansel, 2021). Therefore, their landscape is comprised of semi-official as well as private organisations and initiatives, such as digital imaging and communications in medicine, health level seven international, IVD Industry Connectivity Consortium, integrating the healthcare enterprise, logical observation identifiers names and codes, unified code for units of measure, etc, (Gansel, 2021). An overview of the initiatives relevant to this study is provided below.

- Digital Imaging and Communications in Medicine (DICOM) is the international standard for medical images and related information. Radiology images were the first use case that generated interest in standardised health information sharing. The initial version of the standard was created and released in 1985 by a joint committee of the American College of Radiology and the United States National Electrical Manufacturers Association (DICOM, 2022). Currently, DICOM is managed by a secretariat of the National Electrical Manufacturers Association and the Medical Imaging & Technology Alliance (Gansel, 2021). This standard specifies

the formats, workflow support, and exchange mechanisms for medical images that meet the quality requirements for clinical use (NDoH & CSIR, 2014). In addition to systems that create medical images, it is also used in oncology, electrocardiography, laboratories, and endoscopes (Aiello, Esposito, Pagliari, Borrelli, Brancato & Salvatore, 2021; Gansel, 2021). DICOM is used in hospitals and healthcare facilities worldwide.

- Health Level Seven International (HL7) develops international standards for clinical and administrative data exchange. In the healthcare domain, HL7 is an international organisation that provides standards to enable interoperability (Tsegaye & Flowerday, 2021). It was founded in 1987 as a non-profit organisation in the United States to provide a framework for integrating, sharing, and retrieving electronic health information (Gansel, 2021; HL7 International, 2019). It is globally acknowledged that HL7 version 2 is the most widely used healthcare messaging standard and widely seen as a legacy technology today (Ahmadi, Foozonkhah, Shahmoradi & Mahmodabadi, 2016; Benson & Grieve, 2016; NDoH & CSIR, 2014). Version 3 of HL7 was a comprehensive, but complex meta-standard whose practical application was through the Clinical Document Architecture (CDA) (Gansel, 2021). As a result of the complexity of HL7 v3, Hosseini & Dixon (2016:p134) state healthcare organisations prefer to implement HL7 v2 over HL7 v3. The HL7 CDA standard, however, provides a common architecture, coding, semantic framework, and markup language for the creation of electronic clinical documents (Tsegaye & Flowerday, 2021; NDoH & CSIR, 2014). With the introduction of Fast Healthcare Interoperability Resources (FHIR) in 2013, HL7 intends to facilitate the exchange of healthcare information between healthcare providers, patients, caregivers, payers, researchers, and anyone else involved in the healthcare ecosystem (Saripalle, 2020). FHIR utilises a contemporary suite of Application Programming Interface technology, with a representational state transfer protocol based on hypertext transfer protocol, and a variety of data representation options (Gansel, 2021).
- The Logical Observation Identifiers Names and Codes (LOINC) standard enables semantic identification and interoperability of medical laboratory health measurements, observations, and documents (Yeh, Peng, Yang, Islam, Poly, Hsu, Huff, Chen & Lin, 2021). Developed in 1994, it is maintained by the Regenstrief

Institute, a United States non-profit medical research organisation (Gansel, 2021). LOINC was developed in response to the need for an electronic database for clinical care and management (Gansel, 2021; Yeh *et al.*, 2021). Additionally, the standard includes nursing diagnoses, nursing interventions, outcomes classification, and patient care data sets (Gansel, 2021).

- Integrating the Healthcare Enterprise (IHE) is a healthcare industry initiative to improve data exchange between Health Information Systems (Bittins, Kober, Margheri, Masi, Miladi & Sassone, 2021; NDoH & CSIR, 2014). Using IHE's process, healthcare IT systems can be interoperable in all aspects. To ensure interoperability between systems, the IHE coordinates the use of well-known standards known as Profiles (Gansel, 2021). But it does not necessarily define the standards to be applied (NDoH & CSIR, 2014). It is essential to use coordinated standards since some standards may not be compatible when used together. There are 14 IHE profiles, including those for Radiology, Pathology, Laboratory Medicine, Pharmacy, Laboratory, Devices, and IT Infrastructure (Gansel, 2021). IHE Profiles provide implementation guidelines that specify coordinated standards that can be used to ensure interoperability for a specific use case (Hosseini & Dixon, 2016:p129-130).
- The IVD Industry Connectivity Consortium (IICC) a global non-profit organisation, is dedicated to creating a unified connectivity standard for IVD (in vitro diagnostic) devices and healthcare informatics to reduce costs and variability of data exchange (IICC, 2020). The organisation aims to improve the efficiency of healthcare and the quality of care for patients. A collaborative effort between the IICC and several government organisations and business organisations led to the development of LOINC for IVD (LIVD), which allows IVD manufacturers to map LOINC codes and the IHE Laboratory Analytical Workflow profile (LIVD), a digital format for the publication of LOINC codes mapping by IVD manufacturers (Gansel, 2021).
- SNOMED-CT is a systematic, computer-processable collection of medical terms which comprises the world’s most comprehensive and precise, multilingual health terminology in the world (NIH, 2016). It was created in the United States as a "systematised nomenclature of medicine", only to be merged with a United Kingdom effort on clinical terms in 2002, which led to its current name, "SMOMED-CT" (Gansel, 2021). Currently, SNOMED-CT serves as a multinational and

multilingual terminology that continues to be developed collaboratively for the benefit of all medical professionals worldwide (NIH, 2016). By mapping SNOMED-CT to other coding systems, such as ICD-9 and ICD-10, it facilitates semantic interoperability of clinical health information (NIH, 2016). The SNOMED-CT membership program grants free access and usability to all healthcare stakeholders to SNOMED-CT (Gansel, 2021).

- The Unified Code for Units of Measure (UCUM) was developed for scientific, engineering, business, and business-related disciplines as a grammar/syntax for describing units of measure across disciplines (HL7 International, 2020). UCUM is a unit of measurement used in electronic communication like HL7 messages and documents (Gansel, 2021; HL7 International, 2020). Although it is most commonly associated with electronic data interchange protocols, it can also be applied to various forms of machine communication (HL7 International, 2020).
- As a professional association for electronics and electrical engineering, the Institute of Electrical and Electronics Engineers (IEEE) developed the IEEE 11073 series of standards, which have since become the industry standard for determining and communicating vital signs in hospitals and personal health devices (ISO/IEEE, 2020). IEEE defines data formats and communication protocols for this domain, distinguishing between Point of Care devices used in hospitals and Personal Health Devices used outside of hospitals (ISO/IEEE, 2020).
- International Standards Organisation (ISO) 13606 is a standard intended to address semantic interoperability by defining the information architecture for EHR communications (ISO, 2019). ISO 13606 was developed by the European Commission of Standardisation and comprises of five parts that support the standard's implementation (ISO, 2019).
- Continua Design Guidelines (CDGs) were first released in 2008 to improve the interoperability of Health Information Systems with personal health devices – both medical devices and consumer (“mHealth”) devices (Gansel, 2021). Moreover, they improve interoperability by clarifying specifications and standards, reducing options or adding missing features (Delgado-Gomes, Januário, Vilhena, Marques & Jardim-Gonçalves, 2019). For this purpose, CDG aligns with other healthcare standards organisation, such as IHE, HL7, ISO/IEEE and HIMSS (Gansel, 2021; Delgado-Gomes *et al.*, 2019).

It is imperative for developers of interoperability standards to understand the application requirements for systems that will be implementing the standards. Those standards then need to be developed in a way that meets these requirements. Additionally, vendors should provide the standards developers with information about the functionality of their applications. As a result of this collaboration, applications can be more designed to meet the requirements of end-users while supporting interoperable data exchange (Oemig & Snelick, 2016:p75).

2.5 Challenges with the Implementation of Health Information Systems

Since the advent of EHRs over paper-based health records over the past few decades, Health Information Systems have become widely used to improve public healthcare services and reduce inefficiencies (Wright, O'mahony & Cilliers, 2017; Evans, 2016; Kohli & Tan, 2016). Digital health technologies can be challenging to implement, and many initiatives never reach their full potential. This is because the healthcare industry is composed of numerous and diverse stakeholders and therefore crucial to understand how the various stakeholders act in relation to one another within the healthcare industry (Nilsen, Stendal & Gullslett, 2020). In South Africa, the lack of financial investment in the healthcare sector results in limited access to health information and knowledge and the high bureaucracy limits the implementation of information systems in the healthcare sector (Ngobeni, Breitenbach & Aye, 2020). Using digital health technologies, such as HIS, healthcare professionals are able to reduce medication and diagnostic errors, provide timely and up-to-date patient information, and improve patient efficiency (Ileri & Kaya, 2015). While insightful ways have been established for carefully planning and monitoring the implementation of HIS, several authors have suggested that technological, organisational, and human factors have a significant impact on the implementation of HIS (Svensson, 2020; Esfahani *et al.*, 2018; Ahmadi, Nilashi, Shahmoradi & Ibrahim, 2017; Handayani, Hidayanto, Pinem, Hapsari, Sandhyaduhita & Budi, 2017; Ahmadian *et al.*, 2014).

Ahmadian, Dorosti, Khajouei & Gohari (2017) identified *human factors and the human environment* as the most important challenges to using HIS Factors such as staff resistance, computer usage skills, ease of system use, user acceptance, etc., are some of the challenges with the successful implementation of such systems (Al-Rawajfah & Tubaishat, 2019; Ileri & Kaya, 2015). As healthcare professionals play an integral role in adopting and evaluating Health Information Systems, their acceptance

is essential for its successful adoption and implementation. Taylor, Fischer, Gracner, Tejeda, Kim, Chavez-Herrerias & De La Guardia (2016:p21) posit introducing incentives for end users to adopt and implement HIS. The more the end users are convinced of the usefulness of these information systems, the more they will try to learn and implement the system into their daily routines. According Al-Bashayreh, Almajali, Altamimi, Masa'deh & Al-Okaily (2022) perceived *usefulness* depends on perceived ease of use, compatibility, skills, and self-efficacy. *Organisational factors* such as stakeholder involvement, and funding are challenges hindering organisations from implementing Health Information Systems (Mohamadali & Zahari, 2017).

Implementing and adopting digital health initiatives requires organisational readiness. Therefore, organisations must be capable of adapting to change and dealing with its intended and unintended consequences when introducing and adopting digital health technology (Faber, van Geenhuizen & De Reuver, 2017). The role of organisations in ensuring that HISs are successfully adopted in hospitals and aligned with organisational goals is crucial (Mohamadali & Zahari, 2017). If hospital resources are not well planned, they might be misused when implementing HIS. Organisations, however, face high adoption costs, infrastructure issues, top management involvement, and security threats when implementing HISs (Keshvari, Yusefi, Homauni, Omidifar & Nobakht, 2018; Mohamadali & Zahari, 2017; Farzandipur, Jeddi & Azimi, 2016). Communication and coordination between healthcare professionals, hospital management and IT people, organisational commitment, strategic IT planning, and user involvement in HIS implementation are key organisational barriers to overcome (Ileri & Kaya, 2015).

HIS acceptance and successful implementation are significantly affected by *technological factors* such as data security, medical software integration, and IT support and infrastructure (Farzandipur *et al.*, 2016). There is a high level of concern about the security of HIS. Kruse, Smith, Vanderlinden & Nealand (2017) report inadequate security measures for patient records in HIS. There are no protocols or guidelines regarding the protection of patient privacy in these systems (Motti & Berkovsky, 2022:p203; Cline & Luiz, 2013). EHRs are often hindered by technological factors such as interoperability between systems and a lack of health data standards in facilities with poor Internet access (Modise, 2019; Malekzadeh, Hashemi, Sheikhtaheri & Hashemi, 2018). According to Moreira *et al.* (2022) the lack of

interoperability between disperse systems and the lack thereof interoperability standards adds a risk of comprising data integrity and the consequent security and privacy of patients as these EHRS are transmitted over the internet.

2.6 Evolution of Hospital Information Systems (HIS)

In the 1960s, when HIS were first introduced, the focus was primarily on the financial aspects of the business. This limitation was imposed not for lack of ingenuity, but simply due to the high investment cost of mainframe computing and lack of network capability (Venter, 2017). In the 1980s, the advent of local area networks and smaller personal computers triggered the first wave of change (Adeola & Evans, 2018). By connecting disparate internal systems, vendors could provide a more comprehensive perspective on the management of healthcare services within a facility (Venter, 2017). Through the Wide-Area Networks, hospitals were able to connect, enabling the sharing of digital data between them. As a result of technology, we are now equipped to send and receive data electronically.

2.6.1 HIS Implementation Outside South Africa

Worldwide, HIS systems are comprised of different modules that contain information that contributes to a patient's EHR. Tsegaye & Flowerday (2021) report that Canada and New Zealand were among the first countries to adopt HIS. While HIS are used and developed differently in different countries, their functionality remains the same with a few minor differences. Luz, Mussi, Dutra & Chaves (2021) posit that government objectives with these initiatives are to improve the effectiveness and efficiency of healthcare delivery, integrate information and health organisations, reduce costs, and streamline resources. A review of the HIS in Tanzania (Peltola, 2019), Angola (Sanjuluca, De Almeida & Cruz-Correia, 2022), Argentina (Yacubsohn, 2012), United States of America (Collen & Miller, 2015:p339), Malaysia (Ismail *et al.*, 2015), Pakistan (Sultan, Aziz, Khokhar, Qadri, Abbas, Mukhtar, Manzoor & Yusuf, 2014), Middle east countries (Bahrain, Oman, United Arab Emirates, Saudi Arabia and Iran) (Moghaddasi, Mohammadpour, Bouraghi, Azizi & Mazaherilaghab, 2018), Sri Lanka (Jayawardena, 2014), were conducted. These systems appeared to possess common functionality/modules between the various systems as illustrated in Figure 2.4.

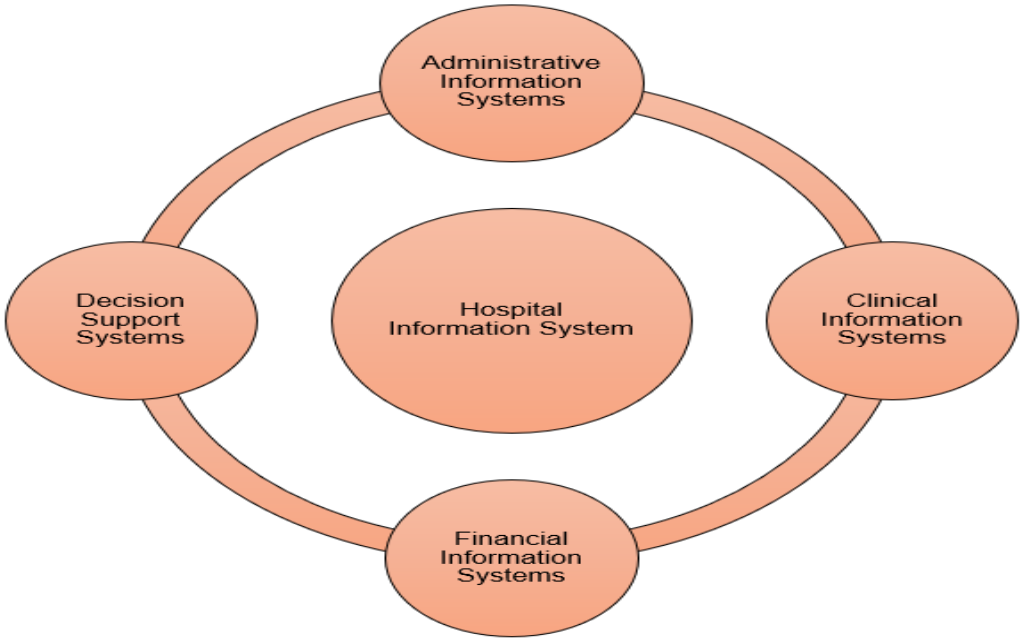


Figure 2.4: Summary of Common Modules Within a Hospital Information Systems

- Clinical Information System

This module facilitates direct patient care by providing immediate access to patient clinical data to support healthcare operational management. The data the information systems provides include, but not limited to medical history, laboratory reports, and images. The built-in error checking eliminates tedious manual activities. The result is improved communication, relevant data is available for clinical decision makers, quality improvement is encouraged, real-time, accurate data is available to aid in medical research and clinicians are provided with patient x-rays and scans more quickly (Islam, Poly & Li, 2018).

- Administrative Information System

This module supports patient care by tracking patient movement in the hospital, managing non-clinical patient information and demographic information, and providing reporting capabilities.

- Financial Information systems

The financial aspects of the healthcare facility are monitored and controlled by this module. This system stores financial data calculates healthcare costs and provides patient billing information (Ayatollahi, Nazemi & Haghani, 2016). Billing functions are an area where a hospital can obtain more immediate return on investments. Decision-makers can use this information to monitor performance and determine the most effective investments, strategies, and modifications for continued growth.

- Decision Support System

In this computer-based system, data is collected from a variety of sources (diagnoses, laboratory results, medication choices, or complex combinations of clinical data) and is then structured by various analytical models and visual tools to improve and facilitate the final outcome of nonroutine and nonrepetitive decision-making tasks (Sutton, Pincock, Baumgart, Sadowski, Fedorak & Kroeker, 2020), Decision Support Systems allow a hospital to organise the data collected by its information system into product lines. In this way, management can analyse the financial performance of a hospital much more thoroughly.

2.6.2 HIS Implementation in South Africa

A parallel system of private and public health exists in the South African healthcare sector. Healthcare is provided by a well-developed, resource-intensive, and highly specialised formal private health sector and a resource-constrained public health sector (Bantom, 2016). In much of the nation, there is a substantial disparity between public and private healthcare facilities due to significant money and access to highly skilled medical professionals in the private sector. The growth of the private healthcare sector has fundamentally altered the way healthcare is delivered. It is for this reason that an ecosystem of mutually reinforcing relationships has emerged among private insurers, private hospitals, and specialists despite the fact that a very small percentage of the population can afford it (Barber, Kumar, Roubal, Colombo & Lorenzoni, 2018). As with most developing countries, 80 percent of South African public healthcare is plagued by HIV/AIDS, tuberculosis, and malaria; weak healthcare systems; under-resourced provider networks; and low staff morale while 20% of the wealthiest opt for private healthcare (Expatica, 2020; Marais, 2017; Masilela *et al.*, 2013). Healthcare facilities are often located in remote areas with poor road networks and intermittent

access to water and electricity utilities. Since not all healthcare facilities in all provinces have computers and web-based versions of the District Health Information System (DHIS), the facilities are still reliant on paper-based processes for service delivery and administrative responsibilities. According to an assessment of the Health Information Systems of South Africa, surveillance reports generated at the national level are neither timely nor complete; raising concerns about the quality of routinely collected data in the South African healthcare system (Ogundaini, 2016). Additionally, clinical registries are managed by local and provincial health departments, while demographic registries are managed by the National Department of Health. Furthermore, some Health Information Systems are owned by private companies and developed by third parties (BusinessTech, 2022).

With disparate systems operating in each province without communication with other provinces and still paper-based prevents interoperability among systems and thus the exchange of information because patient information is fragmented (Amin, Sutrisman, Stiawan, Alzahrani & Budiarto, 2020; Wright *et al.*, 2017). Considering the challenges facing the South African healthcare system, NDoH has recognised the need to improve public health efficiency, with particular attention to ensuring that all citizens have an equal opportunity through the innovative use of ICT to have access to health services (NDoH, 2019a). It has led to the implementation of electronic Health Information Systems in public healthcare facilities, which includes HISs such as the patient care information system, picture archiving and communication system, DHIS etc, systems to improve healthcare system management and more recently HPRS (NDoH, 2019a; Ogundaini, 2016).

According to Wright *et al.* (2017) the NDoH and the Council for Scientific and Industrial Research (CSIR) conducted an information systems assessment that reported at least 42 different Health Information Systems all addressing various aspects of the health system in the public sector. The assessment showed that 14 of the 42 systems were independent systems that were interoperable and more than half did not comply with any national or international standard (Katuu, 2016). The National Health Normative Standards Framework (HNSF) for Interoperability in eHealth was developed to conduct compliance assessments of all healthcare facilities to be able to use the same Health Information Systems towards attaining Universal Health Coverage through the NHI programme (NDoH, 2019b). The HNSF's standards-based approach has since

set a precedent for interoperability in Health Information Systems. Through the defined specifications for the HNSF, it focuses on achieving network effects representing a desired complete healthcare environment. To align with the research theme, a Hospital Information Systems is defined as a comprehensive, integrated information system designed to manage the administrative, financial and clinical aspects of a hospital (Esfahani *et al.*, 2018). Table 2.1 shows some of the systems used in the provincial healthcare facilities from the various provinces.

Table 2.1: Hospital Information Systems Currently Deployed in Public Healthcare Facilities in South Africa adopted from (NDoH & CSIR, 2014; NDoH, 2012)

Province	Number of HIS identified	Examples of HIS used
Western Cape Province (WC)	18 systems	Clinicom; Delta 9; PHCIS, JAC Pharmacy
KwaZulu Natal Province (KZN)	16 systems	Medicom; Meditech; PALS; ProClin; ReMed
Gauteng Province (GP)	15 systems	Medicom; Soarian MedSuite; PharmAssist; PAAB
Free State Province (FS)	10 systems	Meditech; PADS
Mpumalanga Province (MP)	10 systems	PAAB
Eastern Cape Province (EC)	9 systems	Delta 9
North West Province (NW)	8 systems	PAAB
Northern Cape (NC)	8 systems	Nootroclin
Limpopo Province (LP)	7 systems	Medicom

Through the implementation of the NHI system, South Africa intends to address its interoperability challenges (Tsegaye & Flowerday, 2021). The system aims to improve access to health services for all South Africans and includes the construction of a nationwide interoperable EHR system (NDoH, 2019b). Currently, the South African government is building the foundation for the NHI system, which will allow health and medical data from the private sector to be shared across the country. Under the NHI Bill, which is based on HNSF standards, the private healthcare sector must share data with the national registry so that digital health systems can manage the sharing of medical information between the public and private healthcare sectors (BusinessTech, 2022). This will enable a fully interoperable South African healthcare environment for the national EHR system.

In conjunction to the NHI, NDoH can assess the different studies by scholars that proposes solutions to dealing with interoperability and challenges in the healthcare. In particular to the South African context, Tsegaye & Flowerday (2021) proposes a system architecture that addresses interoperability challenges by indicating how the interoperability of EMR systems would be possible at a South African national level. It is worth noting that the Western Cape has implemented the integration of systems, linking a unique patient identifier module with a master patient index that can be linked

(Wright *et al.*, 2017; Ogundaini, 2016). Inkosi Albert Luthuli Hospital Central Manor, a paperless hospital that has successfully implemented EHRs and entered a PPP for the provision of "state-of-the-art" non-clinical services (IALCH, 2017). Even though South Africa still needs to make a lot of progress before achieving a national EHR, there is evidence that HIS are successful and positively perceived (Faloye, Ndlanzi & Ajayi, 2021; Makeleni & Cilliers, 2021).

2.7 Chapter 2 Literature Constructs: Informs the Design of the Initial Data Integrity Model.

For resource-constrained countries such as South Africa to effectively detect epidemics, decision-makers must be able to access relevant health information from healthcare systems when it is needed (Alam, Nabyona-Orem, Mohammed, Malac, Nkengasong & Moeti, 2021). For this to be feasible, HIS must be built comprehensively. Table 2.2, which summarises the knowledge in Chapter 2, informs the designing of the initial Data Integrity Model. The table shows the most important construct(s) related to HIS considered relevant to the Data Integrity Model.

Table 2.2: Chapter 2 Constructs Towards the Design of the Data Integrity Model

	Constructs	Key focus areas
C	e-Health Maturity Levels	The focus area is on digital health. Different levels of maturity that HIS operate at, from paper-based local systems to semi-electronic systems that combine paper-based and electronic features to integrated national health systems.
	Interoperability Layers	Identifying the capabilities of existing hardware resources and software resources (semantic and syntactical use) before embarking on interoperability journeys is crucial to the readiness of a digital environment (legal interoperability).
	Standards of Interoperability	Standards play an important role in interoperability with the focus on using the HNSF for Interoperability in eHealth in South Africa and FHIR to guide interoperability.

2.8 Summary

To advance data integrity practices in HISs, an understanding of the South African Health Information System context was critical. In South Africa, there are significant inequalities in the healthcare sector, primarily due to inequities in finance and skills allocation between the public and private sectors. As a result, public hospitals face obstacles and inefficiencies in patient flow, affecting hospital processes, resources as well as patient and employee satisfaction. In this chapter, the researcher defined HIS and its associated implementation forms as well as pointed out the value they can provide to the beneficiaries. A subsequent analysis of the current state of healthcare transformation in South Africa. The chapter also discussed the various layers of interoperability in digital health to further understand how interoperability can be achieved. In this way, the researcher identified the most relevant areas to consider when addressing the HIS themes of this research study. Consequently, the components that would comprise the Data Integrity Model. In the next chapter, the research will discuss the role that data integrity plays in supporting HIS.

3 CHAPTER 3: THE ROLE OF DATA INTEGRITY IN SUPPORTING HOSPITAL INFORMATION SYSTEMS

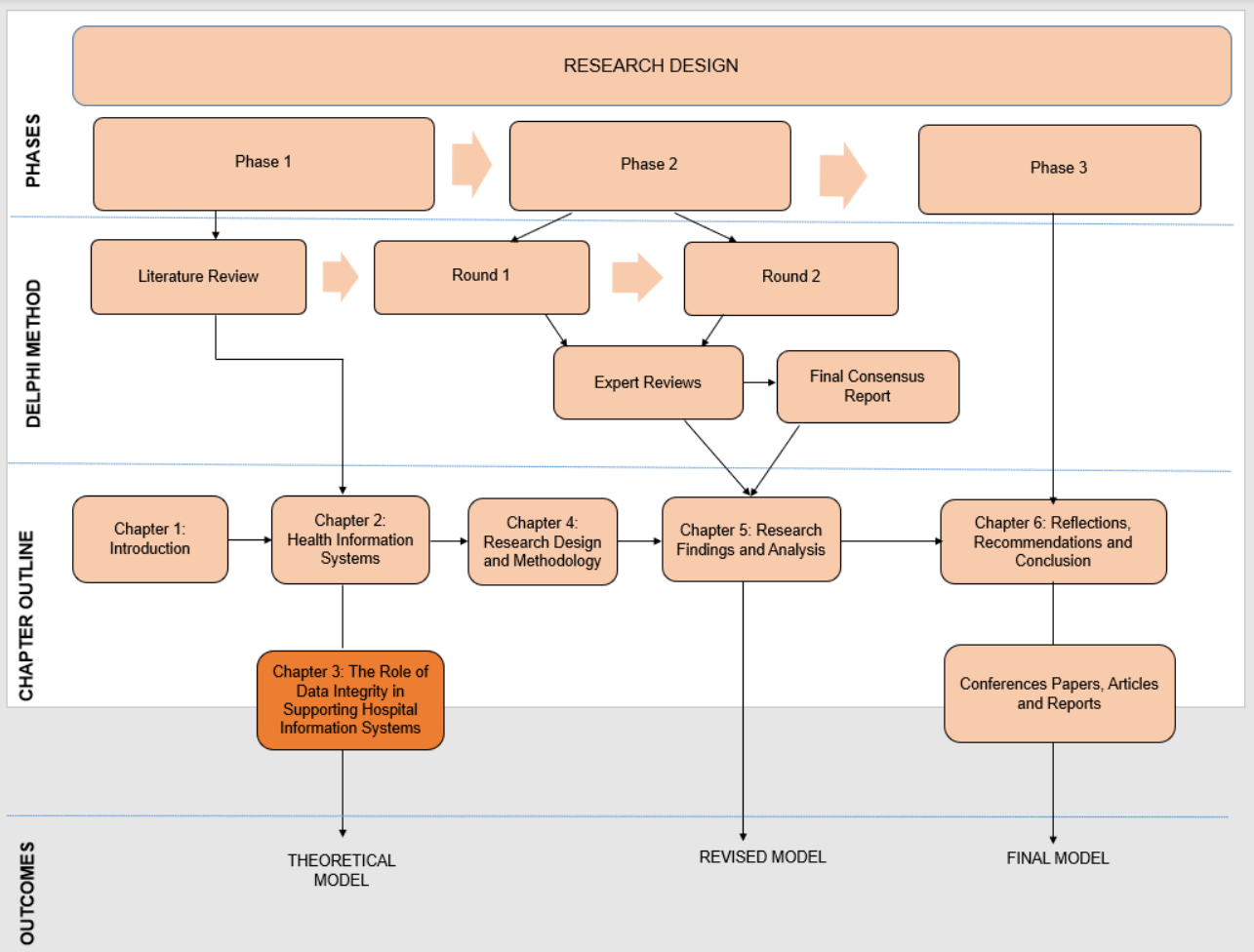


Figure 3.1: Chapter Layout of Research Study

3.1 Introduction

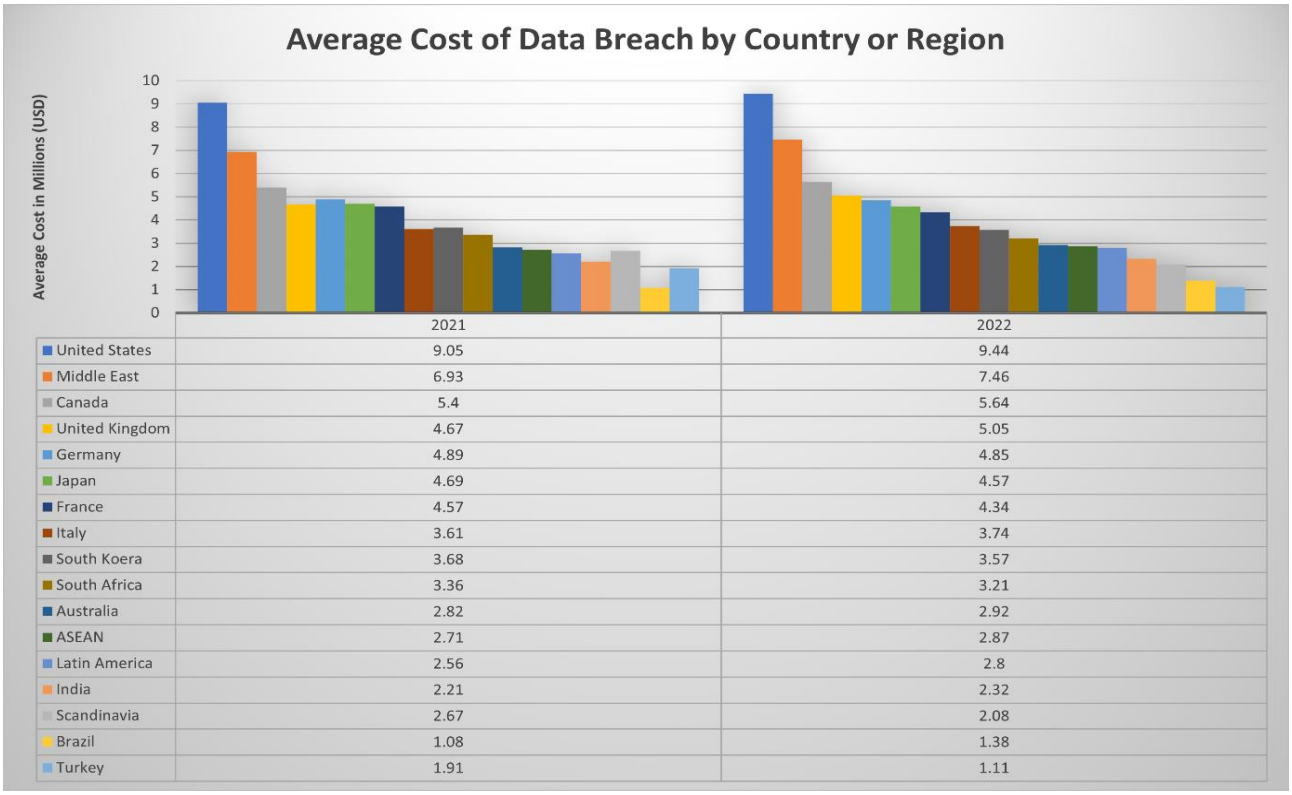
One of the most valuable assets of an organisation is its data. Globally, professionals in healthcare organisations interpret data to make informed decisions about various issues in the healthcare setting. (Bantom, 2016). Data Integrity is a concept that has no definitive definition, but many agree that it refers to data that is complete, accurate, and consistent (Barkow & Takahashi, 2017; Ansara, 2016; Schmitt, 2014; Dan Rode & Chps, 2012). Data integrity ensures that the data has not been tampered with or changed in any way, including patient health records, diagnostic reports, test results, and others. Managing data integrity remains a challenge for healthcare professionals and researchers. Cybercriminals manipulate health information. Consequently, healthcare organisations are most concerned with ensuring the integrity of their data (Zarour *et al.*, 2021). Health professionals and research scientists continue to be confronted with data integrity concerns, as data integrity management is a challenging task.

A breach of data integrity in healthcare facilities due to internal attacks and lack of access control mechanisms can have several potentially serious consequences and contribute to the security threats in health records (Pandey *et al.*, 2020; Wanyonyi *et al.*, 2017). Patients' health records and health information can be tampered with in a way that poses a life-threatening situation. Cyber threats to health records in HIS are regarded as one of the most serious threats (Ntsaluba, 2017). The numerous security breaches show that healthcare is lagging behind when it comes to protecting healthcare information (Pandey *et al.*, 2020). Maintaining data integrity and ensuring accuracy and consistency over the course of its life cycle is therefore imperative (Pearlman, 2019; Liu *et al.*, 2017). This chapter explores the current state of data integrity risk and data integrity practices for supporting HIS. Data integrity in HIS is defined and investigated. A discussion is provided on some of the most prioritised mechanisms that are being used to address data integrity issues in health care.

3.2 The Current State of Data Integrity Risk

The role of healthcare experts in managing data integrity is crucial. The numerous challenges associated with information management present many opportunities for attackers to exploit healthcare organisations (Zarour, 2021). As cyber threats evolve, cybercriminals have become increasingly adept at gaining access to organisation’s data and holding it for ransom (Ntsaluba, 2017). According to IBM’s Cost of a Data

Breach 2022 report, healthcare has the highest rate of data breaches. For 12 years in a row, it has been ranked as the highest-cost industry (Mansfield-Devine, 2022). Healthcare costs reached an all-time high of USD 4.35 million, a 2.6% increase over last year (Mansfield-Devine, 2022). In Figure 3.2, the average cost of a data breach in 2021 and 2022 is compared. From the survey, the United States placed first in terms of the average overall cost of a data breach, at USD 9.44 million. This represents a 4.3% increase of USD 0.39 million from USD 9.05 million in 2021. As was the case in 2020, the Middle East had the second highest average total cost for data breaches. In 2022, this rose from USD 6.93 million to USD 7.46 million. Canada ranked third with USD 5.64 million, an increase of USD 0.24 million or 4.4%. The United Kingdom advanced from seventh to fourth place. Breach costs in the United Kingdom averaged USD 5.05 million, up from USD 4.67 million. This is an increase of USD 0.38 million, or 8.1%, over two years. With a relative cost increase of USD 0.15 million, South Africa ranks 10th on the list. Some of the data breaches experienced in South Africa included e.g., Experian, a credit bureau working with major South African banks, that revealed the personal information of approximately 24 million South Africans (Timeslive, 2020). Additionally, Life Healthcare Group had its data breached during the COVID-19



	2021	2022
United States	9.05	9.44
Middle East	6.93	7.46
Canada	5.4	5.64
United Kingdom	4.67	5.05
Germany	4.89	4.85
Japan	4.69	4.57
France	4.57	4.34
Italy	3.61	3.74
South Koera	3.68	3.57
South Africa	3.36	3.21
Australia	2.82	2.92
ASEAN	2.71	2.87
Latin America	2.56	2.8
India	2.21	2.32
Scandinavia	2.67	2.08
Brazil	1.08	1.38
Turkey	1.91	1.11

Figure 3.2: Comparison of Average Cost of Data Breach as Adapted From (Mansfield-Devine, 2022)

outbreak, which affected operations in southern Africa during June and part of July 2020 in terms of billing, submitting medical aid claims, processing vendor invoices, and generating financial results (Mungadze, 2020).

The impact of data breaches is almost always the same, regardless of their type. IT failures were reported by IBM to be the most common breach experienced by companies. Attacks of this type are caused by interruptions or failures in an organisation's computer systems, followed by human errors and supply chain attacks resulting from business partners being compromised (Mansfield-Devine, 2022). Destructive attacks and ransomware attacks were identified as the least common types of breaches. Seh, Zarour, Alenezi, Sarkar, Agrawal, Kumar & Khan (2020), agree that Hacking/IT incidents are the leading cause of healthcare data breaches, followed by unauthorised internal disclosures. Hackers frequently target digital health data, making it highly vulnerable. It is evident that both data breaches and their costs will increase in the future given the current state of data integrity risk. Therefore, researchers, security experts, and healthcare organisations should prioritise preventive measures. To achieve data integrity, a variety of technical and human challenges must be overcome. As Precisely (2021), explains, there is a lack of resources and tools to effectively manage data, and also a lack of technology and services to facilitate data integration. Nonetheless, many enterprises have established a basic foundation for data-driven decision-making and automation in an effort to maintain data integrity at scale (Mansfield-Devine, 2022; Precisely, 2021).

3.3 Data integrity in Hospital Information Systems

As healthcare technologies advance, HIS have become an increasingly crucial component of efficient healthcare service delivery, as they simplify the exchange of information between different hospital wards and healthcare professionals (Najem, 2016). The lack of data integrity hinders the sharing, research, and reporting of health information. Due to inaccurate, inconsistent, or incomplete information, further data integrity issues will arise (Bani Issa, Al Akour, Ibrahim, Almarzouqi, Abbas, Hisham & Griffiths, 2020; Timmerman, 2011). If the integrity of external data is not ensured before incorporation into HIS, clinical data could be unfit for use. In the context of digital health, India has implemented a nationwide system for the management of digital identities for all citizens. Even though several state-based digital health applications have been developed in silos at the national level. Aadhaar is a unique

12-digit identification system designed to reduce inefficiencies and counter fraud when distributing targeted subsidies (WHO, 2020a). In contrast to similar systems in many countries, it captures biometric data such as fingerprints and iris scans, as well as demographic information about an individual. It maintains data integrity, identifies citizens accurately, and protects their privacy. Despite this, integration across the silos systems presents a challenge to the HIS in terms of providing seamless data exchange to facilitate comprehensive decision-making (WHO, 2020a). Similarly, NDoH has implemented HPRS nationally for the purpose of maintaining and cross-referencing identifiers, including the South African Identification Document and other legal identification documents, such as passport numbers, driving licenses, asylum permits, and refugee permits, as well as offering master patient index capabilities so as to help standardise compliance with electronic health applications (NDoH, 2019a). The HPRS is interoperable with other information systems, including TIER.net, which retains the information on antiretroviral therapy patients who are receiving HIV treatment (NDoH, 2021). It has improved the patient registration process, record-keeping, and patient experience at healthcare facilities. Even though countries have made some progress in this area, data integrity issues remain a major concern for the healthcare industry. In the following section, the data integrity issues are examined in more detail.

3.3.1 Data Integrity Issues

Data integrity issues are attributed to cyber threats, unclear incident reporting frameworks, and infrequent training on data breaches and cyberattacks (UN, 2020). WHO (2020b) describes these issues as a result of insufficient data management, inadequate computerised systems, and excessive trust placed in people. The most common causes of errors in HISs are human errors, hackers, missing documents, and software/hardware failures (Masrom & Rahimly, 2015). These attacks, according to Chapple, Stewart & Gibson (2021:p6) aim to violate integrity. In the paper "Data Integrity: Challenges in Health Information Systems in South Africa" (Thulare *et al.*, 2020), it is noted that human and computerised system challenges adversely affect the quality of data contained in healthcare records, thereby posing health risks and impairing data integrity. Both paper-based and electronic HISs are affected by these issues. Often, data integrity issues are difficult to detect, and they can be extremely risky. Unfortunately, data integrity issues cannot be solved but it is possible to

minimise and detect them more quickly to protect patients from their negative consequences and provide them with quality care.

3.3.1.1 Human Errors Challenges

A human error is described as a conscious decision made only after it has happened (Higham & Vincent, 2021:p29). The most common cause of human errors is negligence due to inattention, tiredness and distraction, as well as a lack of knowledge, experience and information (Creamer Media, 2022). Additionally, stress, instability in the work environment, a shortage of health workers, and excessive workload can all lead to human errors (Ebnehoseini, Ebrahimipour, Koohjani, Adel, Badiee Aval, Hoseini, Jamili, Vejdani, Hoseini & Deldar, 2022). The majority of unauthorised information modifications are caused by user errors, oversights, or unintentional actions (Chapple *et al.*, 2021:p6). Alternatively, decisions can be made with the intent of causing harm, such as deliberately sharing patients' personal information without permission or destroying health records (Wager, Lee & Glaser, 2017:p447). In this regard, the act of decision is considered a violation, usually caused by a lack of safety culture, as well as attitudes and motivations on the individual level (Higham & Vincent, 2021:p31; Sameera, Bindra & Rath, 2021). Ebnehoseini *et al.* (2022) found that healthcare professionals felt uncertain about working for referral hospitals during the early stages of the COVID-19 pandemic. The feelings of uncertainty arose when healthcare professionals compared the COVID-19 virus environment with other healthcare professionals in hospitals but felt they did not receive the proper incentives. The theft of patient medical records for litigation purposes is a common violation committed by healthcare professionals (Bantom, De La Harpe & Ruxwana, 2016).

Human errors have negatively impacted the provision of healthcare in South Africa. As a result of capturing data on a paper-based system, there has been a lack of continuity of care, as duplicate or missing records often lead to inaccurate reporting (Maphumulo & Bhengu, 2019). Despite being in the fourth industrial revolution, Dr Angelique Coetzee of the South African Medical Association argues that healthcare is still at the level of the first industrial revolution (Karrim, 2020). The integrity of health information provided by health institutions is further questioned in this statement, as COVID-19 information is shared across several platforms, mostly through the National Institute for Communicable Diseases and the current Ministry of Health, in order to

promote transparency among the public (Marivate & Combrink, 2020). Despite the fact that these sources are valuable, Marivate & Combrink (2020) note that they may not be as effective because there are so many platforms a person must navigate to access accurate data, and the format in which the data is presented isn't machine-readable. As a result, the University of Pretoria's Data Science for Social Impact research group has developed an open repository for the data integrity of South African COVID-19 cases (Marivate & Combrink, 2020).

When assessing data integrity, healthcare institutions must determine intent. Whether intentional or unintentional, understanding the dynamics that drive and enable the individual(s) to perform the actions is key to addressing human errors and preventing their recurrence. By understanding the underlying causes of human misbehaviour, healthcare institutions can avoid widespread actions that are not necessary, especially when considering the preventative data integrity measures already implemented (Johnson, 2016).

3.3.1.2 Computerised System Challenges

Collecting and analysing data from different sources of operations that take place in various locations is a complex, multi-stage process. It is often the case that computerised systems are faced with many technological challenges. Ebnehoseini *et al.* (2022), posit that these technology challenges include several non-interoperable Health Information Systems. In addition, there are no standards or transparent guidelines for the design, recording, and management of health information in HISs, resulting in inconsistent statistics. Furthermore, computerised systems are often challenged by the lack of suitable hardware and communication equipment and frequent interruptions of the Internet. Globally, the COVID-19 pandemic highlighted many technological challenges in many Health Information Systems (Ebnehoseini *et al.*, 2022; Marivate & Combrink, 2020).

In light of the fact that computer viruses are among the most common and malicious forms of intentional (violation) manipulating of computers including trojans, spyware, worms, and ransomware, they pose a serious threat to computerised patient data and healthcare applications (Wager *et al.*, 2017:p447-448). Data integrity management in computerised systems can be compromised by the absence of adequate system control (Chapple *et al.*, 2021). Software errors in HIS that contains hundreds, and

thousands of medical records can affect many patients. Medical records can be damaged, deleted, or placed in the incorrect location due to software errors (Chapple *et al.*, 2021; Bowman, 2013). Using these information systems can often be difficult due to their complexity (Bowman, 2013). The graphical user interface of some HISs is not user-friendly because it displays information in limited windows. Users who need to access patient notes, blood tests, or medications may find it tedious leading to mistakes (Salahuddin, Ismail, Hashim, Raja Ikram, Ismail & Naim@ Mohayat, 2018).

Researchers have documented the risks associated with copying and pasting. These include incorrect or outdated information, redundant information, trouble identifying the author of the document, the dissemination of false information, internal inconsistencies in progress notes, and billing errors that cost billions of dollars (Champagin, 2019; Bowman, 2013). IS that allow users to cut and paste or use drop-down menus can lead to poor data quality, which can result in health risks and liabilities (Barrett, 2020; Vimalachandran *et al.*, 2016). Healthcare facilities do not currently have a rigorous, real-time approach by which to regularly assess the safety of their Health Information Systems and identify integrity issues (Sittig, Wright, Coiera, Magrabi, Ratwani, Bates & Singh, 2018). If connected to an insecure network, these Health Information Systems are vulnerable to unauthorised employees or external parties who can access and falsify data. There is a link between data integrity issues and factors arising from policies, the environment, health workers, and a lack of awareness.

- Policy

Data integrity and data security are inextricably linked, with one critical to the success of the other. Data security involves preventing unauthorised access and corruption of data, which is necessary for data integrity. The desired outcome of data security is data integrity. However, the phrase data integrity relates to the authenticity and accuracy of data rather than its preservation. Data security is one of the techniques used to ensure data integrity because unauthorised access to sensitive data can result in modifications to health records and data loss. In general, policies serve to inform and guide the decisions and missions of an organisation. In a data security policy, procedures are defined to ensure that files, databases, and accounts on a network are protected (Harrington, 2020). Assigning responsibilities, defining roles, defining audit requirements, outlining enforcement processes, identifying compliance requirements,

and establishing acceptable risk levels are all part of the security policy (Chapple *et al.*, 2021:p24). Additionally, it explains how data security gaps are managed, by whom, and how security incidents are analysed to prevent further incidents (WHO, 2021). Healthcare institutions implement and adhere to a data security policy. It obligates healthcare institutions to safeguard their data and ensure that the information they disclose is appropriate (Masrom & Rahimly, 2015).

However, these healthcare institutions do not have a data integrity policy within their data security strategies. A data integrity policy explains what constitutes raw data, source data metadata, and a "complete data set", as well as how the validation process is conducted (WHO, 2020b; Babati, 2018). Data integrity policy outlines procedures and processes for collecting, analysing, reporting, and retaining information and data in a manner that accurately, truthfully, and completely reflects what actually occurred (PIC/S, 2021). Creating a usable set of raw data often entails gathering a significant amount of relevant data, documenting it, and then aggregating, stratifying, or categorizing it (AICPA, 2018). Moreover, a description of data is intended to provide context for users so they can understand the data and make appropriate decisions. The policy essentially ensures that data is protected from unauthorised access and that it is accessible when needed. In addition to a data security policy, HISs should implement a data integrity policy as it also serves as an important tool for ensuring the integrity of data in terms of regulatory compliance (Harmony University, 2018). The establishment and compliance with policies, such as data integrity policies, can help ensure the quality of healthcare information and its consistency across departments and institutions (Makeleni & Cilliers, 2021).

- Environment

Errors committed by healthcare workers are often influenced by the work environment The distraction of a healthcare worker may lead to data entry errors or inattention to the information presented by the HIS (Vimalachandran *et al.*, 2016). According to Walker (2018), stressful work environments are responsible for medical errors from nurses' perspectives. South African healthcare facilities are reported to struggle with poor waste management, poor sanitation, and poor equipment maintenance (Maphumulo & Bhengu, 2019). Consequently, healthcare workers in public hospitals experience psychological stress, job dissatisfaction, and burnout (Shisana, 2018;

Mokoena, 2017). A toxic working environment can negatively affect the safety of healthcare professionals and patients (Manyisa & Aswegen, 2017). Additionally, the physical environment plays a role in data integrity issues, but organisational culture can also lead to human errors. The likelihood of general errors is lower in an organisation that prioritises data integrity (Ahola, 2019; Salahuddin *et al.*, 2018).

Organisational culture has an instrumental role to play in solving environmental problems. Users generally know what should be done, but they do not act. There are probably easier ways to accomplish something, or they don't believe it's worth the effort. A persistent culture of non-use of data and poor data quality can lead to human error challenges (Lemma, Janson, Persson, Wickremasinghe & Källestål, 2020). Healthcare institutions needs to foster an open culture in which subordinates feel comfortable questioning the hierarchy and reporting systematic and individual errors (APIC, 2022). It is the leadership's responsibility to provide opportunities for active engagement of healthcare workers and capacity building to create a culture of data integrity in healthcare institutions (Kenneth, Yitambe, Nyamari & Koome, 2019).

- Health Workforce

The global shortage of healthcare workers is projected to reach 15 million by 2030, with the greatest deficit concentrated in Africa (Rispel, Blaauw, Ditlopo & White, 2018). Despite South Africa's consistent development of strategic plans for the health workforce at the national level over the past two decades, major challenges remain in terms of affordability, availability, distribution, and management of health workers (Van Ryneveld, Schneider & Lehmann, 2020; Barron & Padarath, 2017). The public health workforce is disproportionately distributed across rural and urban areas and within provinces, with rural areas having significantly fewer skilled workers, nurses, and community health workers than urban areas (Cleary & Low, 2020). A large share of South African healthcare workers are nurses, but more than half of them will retire over the next 15 years. The South African Nursing Council statistics show that 27% of registered nurses are over 50, while 26% are over 40, and only 21% are in their 30s (SANC, 2020). Furthermore, with the COVID-19 pandemic, healthcare workers have increasingly been overwhelmed in their ability to provide effective care (Cherisich, Gray, Fairlie, Eichbaum, Mayhew, Allwood, English, Scorgie, Luchters, Simpson, Haghighi, Pham & Rees, 2020; Nyasulu & Pandya, 2020).

In addition to providing primary care, community health workers must collect, capture, and verify patient data. It can affect health workers' ability to fulfil their caregiving responsibilities, the quality of services they provide, and ultimately, the reliability and accuracy of the data they collect themselves (Manyisa & Aswegen, 2017; Lubbe & Roets, 2014). Health workers already use and perceive the benefits of some digital tools and solutions in their work (Rochmah, Fakhruzzaman & Yustiawan, 2020; Alipour, Mehdipour & Karimi, 2019). Others, however, disagree with the value of digital technologies or believe that it interferes with their ability to do their jobs (Booth, Strudwick, Mcbride, O'Connor & Solano López, 2021). Many health workers report not having the opportunity to gain the necessary skills to fully utilise the technology, or that the legal, financial, and organizational aspects of work have not been properly redesigned so as to add value (Al-Shorbaji, 2021). Moreover, workers and patients demand appropriate safeguards to ensure that the use of digital tools does not have undesired side effects, including a lack of transparency or data security threats (Socha-Dietrich, 2021). Consequently, many nurses have relocated overseas for better wages and working conditions, including to the United Kingdom, Australia, New Zealand, Canada, and the United Arab Emirates (Nevhutalu, 2016).

- Lack of awareness

Often, human errors are caused by end-users simply not knowing what the right course of action is (Ahola, 2019). Meanwhile, health workers and patients have limited awareness of or knowledge about the actual security measures put in place or the quality of health data infrastructures (Socha-Dietrich, 2021). Thus, negative perceptions persist, regardless of whether actual security problems exist. Digital security awareness in healthcare organisations is the primary need because it is users who will be facilitated by secure technologies and approaches in a healthcare organisation (Pandey *et al.*, 2020). Garvey (2017) points out, the lack of awareness is an obstacle to reliable data and information and is one of the main obstacles to providing high-quality healthcare service delivery in South Africa (Maphumulo & Bhengu, 2019; Gray & Vawda, 2018; Shisana, 2018; Luthuli & Kalusopa, 2017; Botha, 2015; Mathebeni-Bokwe, 2015).

At all levels of health care, professionals must understand the importance of data integrity and how their actions can affect it. This includes awareness and knowledge

of cyber and information security procedures for storing, sharing, and retrieving healthcare data and other personal information, as well as behaviour to prevent unauthorised access to data and information (Socha-Dietrich, 2021). By ensuring that everyone understands and is properly trained on their roles and responsibilities, organisations can ensure the integrity of information (Anderson, Abiodun & Christoffels, 2020). Many data integrity issues arise as a result of limited knowledge of what functionalities digital health solutions actually offer, which, in turn, results from a haphazard introduction of many technologies that, in particular, fails to account for the time and training health workers require to master the technologies (Socha-Dietrich, 2021). Data integrity issues can be prevented through proper monitoring and control; such issues are related to individual behaviour or decision-making. The identified data integrity issues have established a guide for the identification of data integrity elements that will be discussed in Section 4.3.3.

3.3.2 Data Integrity Models

Unauthorised manipulation of or modifications to data can cause significant damage to computer-based information systems. Modification or manipulation of data can, in many cases, be more harmful than disclosure to an unauthorised user. This points to the fact that there needs to be a way to prevent, or at least detect, unauthorised manipulation and disclosure. Biba, Goguen and Meseguer, and Clark/Wilson are among the earliest integrity models documented in the literature, each of which provides a definition of data integrity and presents their own mechanisms for preserving integrity (Garnaut & Thompson, 2011; Ivan, 1991). The adoption of one of these models as a standard for data integrity will result in a comprehensive protection policy that addresses both security and integrity. As data becomes more vulnerable to malicious attacks, traditional approaches to protecting it are becoming obsolete. Conventional tactics are no longer sufficient against modern attackers (Kumar, Agrawal & Khan, 2020). In the healthcare sector, various data integrity mechanisms have been proposed to ensure data integrity in computer-based information systems. Unfortunately, in the actual world, there are still gaps in managing updated data integrity measures (Pandey *et al.*, 2020). Adapting more advanced approaches to data management and security is essential.

3.3.2.1 Data Integrity Mechanisms

A data integrity mechanism ensures that data is recorded exactly as intended. Furthermore, it ensures that, when the data is retrieved, it is identical to the original. For protection against data integrity attacks, strong defence mechanisms should monitor the system for any unauthorised data modifications (Kumar *et al.*, 2020). Zarour *et al.* (2021) and Pandey *et al.* (2020) posit that blockchain and masked authenticated messaging extensions are recent mechanisms used to manage data integrity in the healthcare sector. They both identified previous studies that focused on different aspects of the healthcare sector, and challenges and ethical issues were prominent among the identified studies.

3.3.2.1.1 Blockchain Approach

Blockchain technology uses decentralisation and de-trusting to establish a reliable database in a distributed environment (Chen, Mu, Liang & Gao, 2019). In any system, blockchain technology ensures data integrity and confidentiality. By incorporating blockchain technology into application layers, healthcare providers have an opportunity to ensure data integrity, privacy, and security (Gavrilov, Simov & Trajkovik, 2020). Blockchain technology is characterised by the ability to withstand tampering and de-trusting, so that data in the medical system can be protected through cryptography. A decentralised peer-to-peer transmission system can eliminate barriers to access and non-circulating information between medical institutions (Chen *et al.*, 2019). Blockchain technology has the capability to enhance patient care, financial transactions can be processed more securely, medicine can be distributed more widely, and medical records can be maintained and governed more efficiently. Using the technology, patients and caregivers can securely communicate patient identity and healthcare information across platforms (Manski, 2017). Thus, allowing patients to envision a future in which they are responsible for their own healthcare (Niyitunga, 2022). Different aspects/elements of blockchain are:

- Authentication – Password-based authentication is the current method of authentication. Using blockchain technologies, current mechanisms can be improved to reduce the vulnerability of health records to cyberattacks.
- Authorisation – Current role-based access control systems have been identified as a weak point, where blockchain technologies can provide a more fine-grained and dynamic authorisation system.

- Audit logs – Due to the lack of immutable audit logs stored in a centralised architecture, current audit logs do not assure data integrity. Blockchain technology provides tamper-proof and peer-to-peer data storage, which can ensure data integrity from creation to retrieval.
- Data storage - Traditional healthcare records are stored in a centralised architecture, such as a relational database, which is prone to failure. The decentralised, peer-to-peer, and tamper-proof nature of blockchain technology makes it ideal for electronic healthcare records. This storage model ensures data integrity from data creation to data retrieval, thus avoiding a single point of failure.
- Data transactions – Usually, healthcare organisations use three models when sharing electronic health records, namely the push model, the pull model, and the view model. The traditional models lack a standardised method for generating audit trails. As a result, data integrity cannot be ensured from the time data is created to the point it is retrieved and analysed. Through a secure peer-to-peer means of transferring information, data integrity can be ensured from data origin to data retrieval with the use of a tamper-proof audit log.

3.3.2.1.2 Masked Authenticated Messaging Extension

Masked authenticated messaging (MAM) is a data transmission protocol for publishing encrypted data streams. With MAM, users can send encrypted data streams through the Tangle that are a chain of messages or sensor data to information for operational and tactical analysis (IOTA) with zero cost (Gangwani, Perez-Pons, Bhardwaj, Upadhyay, Joshi & Lagos, 2021). With IOTA, you can securely transmit data between Internet-of-Things devices using a directed acrylic graph structure called Tangle (Gangwani *et al.*, 2021).

Using a masked identity verification message extension module, Brogan, Baskaran & Ramachandran (2018) improved the security of patient data in connected medical devices. In their paper, the authors explain how IOTA and masked authentication messaging extensions can work together to overcome the challenges facing wearable technology. The IOTA strategy was designed to be compact and flexible to provide data security and connectivity among Internet-of-Things systems. In contrast to conventional blockchain-based distributed ledger procedures, it specifically addresses

two major issues, namely, latency and costs. According to Zarour *et al.* (2021) and Pandey *et al.* (2020), researchers can benefit from the following methodologies:

- Secure-body sensor network (Gope & Hwang, 2016).
- Authentication (Vimalachandran, Wang, Zhang, Heyward & Zhao, 2017).
- Encryption (Elhoseny, Ramírez-González, Abu-Elnasr, Shawkat, Arunkumar & Farouk, 2018).
- Wolf-coding based secret sharing (Luo, Bhuiyan, Wang, Rahman, Wu & Atiquzzaman, 2018).
- Secure Cloud (Manogaran, Thota, Lopez & Sundarasekar, 2017) and
- Merkle Tree-based approach (Sharma, Sekharan & Zuo, 2018).

Using these data integrity mechanisms, health information is protected both from unauthorised and authorised users. Developing data monitoring systems to defend against security threats has become an urgent necessity to prevent data integrity breaches. A mechanism is needed for specifying, detecting, and responding to anomalous data and data accesses caused by users and applications. This will provide a deeper understanding of who, when, and where data is accessed and manipulated (Agrawal & Alharbe, 2019). The models alone are not sufficient, as the whole HIS must be built on a comprehensive Data Integrity Model. Figure 3.3 illustrates the hierarchy of integrity methods in different healthcare domains. The figure shows the priority of integrity methods in each sub-field of healthcare.

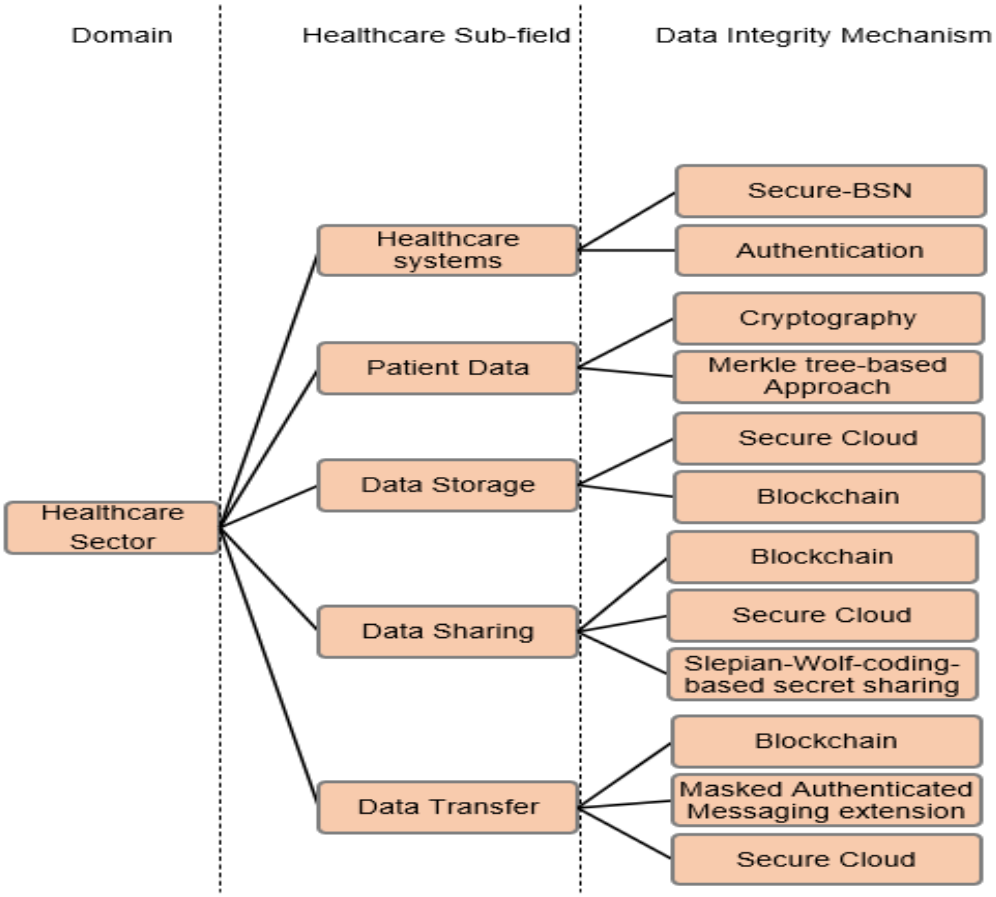


Figure 3.3: Hierarchy of Data Integrity Mechanisms Used in Different Sub-fields of Healthcare, Adapted From (Zarour, Alenezi, Ansari, Pandey, Ahmad, Agrawal, Kumar & Khan, 2021)

3.3.3 Data Integrity Elements

Health professionals, policymakers, data management applications, and the healthcare sector rely on the integrity of data for informed decisions. The process often depends more on business processes and rules than on technology (Pollard, Blankenship & Lyness, 2018). Organisational and technical controls should be implemented to promote a culture of quality (Babati, 2018; Acharya, 2010). A strong emphasis should be placed on an information management program meant to promote data integrity and involve user training, clear communication with suppliers, and strategies for achieving that integrity (IBM, 2019; Bowen & Smith, 2014; Timmerman, 2011). As part of this process, organisational employees at every level must participate and be committed (Bussiness.Com, 2019; Pérez, 2017). According to Mcdowall (2019) a Data Integrity Model depends on a foundation of *data governance*, *qualified*

analytical instruments, and validated software with properly developed and validated robust analytical procedures. Literature indicates that data integrity governance, data integrity training, and data integrity requirements, can all be positioned with data integrity to support HIS. The following section investigates each of these aspects.

3.3.3.1 Data integrity governance

An organisation's data governance involves managing the availability, usability, and integrity of its data, and ensuring its reliability and consistency (Techtarget, 2020). Throughout the data lifecycle, data integrity governance ensures that data, irrespective of format, is recorded, processed, retained, and used to ensure a complete, consistent, and accurate record (Mcdowall, 2018:p82). Data governance and data integrity are critical components in assuring the reliability of data and information collected from Hospital Information Systems (WHO, 2020b). According to Mcdowall (2018:p97), data integrity governance involves:

3.3.3.1.1 Management leadership

An effective data integrity strategy must be established and implemented by senior management. Leadership should drive a strategy that focuses on prevention, detection and response. This applies to paper and electronically generated data. Leadership must first accept that there have always been - and always will be – data integrity concerns on some level. Investigating and understanding the existing data integrity considerations within an organisation provides a strong foundation from which to begin the process of reducing such concerns by incorporating data integrity policies that cascade down to HIS and to staff who are being trained in data integrity on an ongoing basis (Gribbin, 2017). Mcdowall (2018:p96) describes data integrity as a work program in which senior management is actively involved to ensure that data integrity governance is firmly in place within the environment of a HIS.

3.3.3.1.2 Data integrity procedures and training

The biggest challenge that institutions face is that their employees don't know how to preserve data integrity. Data integrity principles, elements, and practices should be incorporated into HIS systems and procedures (Gribbin, 2017). Healthcare workers have been unable to understand data integrity procedures due to inadequate training (Vignesh & Ganesh, 2020). Providing training on how to enter and maintain data and entrusting them with the responsibility of preserving data integrity is a good start.

Training personnel in good documentation practices can prevent and detect data integrity issues. Specific training may be required in cases where computerised systems are used in the generation, processing, interpretation and reporting of data and where a risk assessment system has shown that this may be required. For example, such systems should assess the security of individual computerised systems, back-ups, configuration settings, and review the electronic data and metadata, such as audit trails and logs, used to generate, process and report data (WHO, 2020b). This will ensure everyone in the team puts effort into maintaining data integrity.

3.3.3.1.3 Involvement of all the staff in the organisation

Data is managed, handled, and used by many people within an organisation, with different requirements. Information and asset ownership are among the most important concepts here. Owners are primarily responsible for protecting data and assets. According to Chapple *et al.* (2021) the ultimate responsibility for identifying, classifying, and protecting data lies with the data owners. Data processing systems are owned by system owners. Process owners own the systems and ensure that they provide value to the organisation. The data controller determines what data to process. Often, data processors are third-party entities that work under the direction of data controllers to process data for an organisation. Administrators receive guidelines from data owners on how to access data. A user, or subject, accesses data while performing work tasks. Data custodians protect and store data on a daily basis (Chapple *et al.*, 2021). These roles ensure that data is obtained, secured, processed, and reported in line with established protocols and that anomalies are documented and examined.

3.3.3.1.4 Assessment and remediation of processes and systems

A quality risk management (QRM) system is typically used in the assessment and remediation of processes and systems. QRM are in responsible for ensuring that regulations, policies, and procedures are followed, along with conducting data integrity audits and investigations (Mcdowall, 2019). Data integrity risks should be examined, mitigated, reported, and reassessed at a frequency determined by the risk assessment process throughout the data life cycle (WHO, 2020b). Data integrity gaps must be thoroughly explored to understand the scope, root cause, and impact, as well as outline immediate, remedial, and preventive actions (Gribbin, 2017). Sandler (2018) argue that risk assessment should not only consider IT system functionality or

complexity thereof but also focus on business processes, evaluation of data flows and methods of generating data.

3.3.3.1.5 Open culture

Data integrity issues are generally thought to be caused by deliberate fraud. In most cases, data manipulation is caused by bad practices, poor organisational behaviour, and weak systems. A way to mitigate these data integrity issues is through culture. Culture includes the skills, knowledge, attitudes, values, and motives of a group (Kumar, Jain & Kumar, 2017). Data integrity issues can be raised and reported through a culture of responsible openness and constructive criticism (Sandler, 2018). Individuals should be able to raise and investigate concerns without fear of reprisal if the culture fosters transparency and rapid escalation of integrity gaps, incentives and amnesty for revealing potential gaps, and no-retaliation environments (Gribbin, 2017).

3.3.3.1.6 Technical controls for computerised systems and paper-based systems

All computerised systems should go through processes to verify that they are fit for their function. Validation of these computerised systems is required to ensure accuracy, reliability, and consistency. To maintain data integrity, computerised systems need security processes to prevent unauthorised access and data changes. Only authorised individuals should have access to the system and appropriate permissions. Authorisation records with detailed access levels must be maintained. User roles should be recorded, thereby access rights and permissions(European Medicines Agency, 2021). The design, security, and use of computer programs and the security of data files are controlled by a combination of hardware, software, and manual procedures that create an overall control environment. A summary of the types of general control (PIC/S, 2021) is:

- Software controls – Monitor system software usage and prevent unauthorized access to software, system software, and computer programs.
- Hardware controls – Check for equipment malfunctions and ensure that computer hardware is physically secure. Computer equipment should be safeguarded against natural and environmental risks, as well as unauthorised access to an organisation's information systems (Heath, 2016). This comprises controls over facility access, workstation use and security, and device and media management (Beckers, 2020).

- Administrative controls – Ensure that an organisation's general controls are properly implemented and enforced through standards, rules and procedures. CMS (2007a) Requires information systems to keep mechanisms in place for reviewing records of information system activity, such as audit logs, access reports, and security incident reports.
- Data security controls – Prevent unauthorised access, change, or destruction of valuable business data files on disk or tape.

According to Kruse *et al.* (2017) technical control in healthcare facilities can involve role-based access control, attribute-based access control, and identity-based access control. Furthermore, administrators could implement a logging and monitoring function that detects suspicious activities, and can satisfy this by reviewing user access logs regularly, thus further providing auditors with such reports (TIBCO, 2017). Moreover, integrated delivery networks must develop techniques for creating, transmitting, and enforcing standardised data integrity policies and procedures. Techniques for maintaining data integrity that can be used to validate data quality metrics in computerised healthcare systems involve: (i) performing risk-based validation; (ii) selecting the appropriate system and service providers; (iii) auditing your audit trails; (iv) change control; (v) using IT quality and validation systems; (vi) planning for business continuity; (vii) being accurate; and (viii) archiving regularly (Marley, 2020; Maunu, 2019; Kucharski, 2016). Most healthcare facilities have regulations that ensure that all employees sign confidentiality agreements when joining the facility (Bani Issa *et al.*, 2020). The integrity of paper records should be ensured by specific controls. Among them (WHO, 2020b) are:

- Ensuring control over loose paper sheets used for data recording.
- Using permanent and indelible ink.
- No pencils or erasers.
- Using single-line cross-outs to record changes with the identifiable person making the change, date and reason.
- No correction fluid or other obscuring of the original record.
- Notebooks that are bound and paginated.
- Blank forms are issued sequentially with authenticity controls and
- records are stored by authorised personnel in secure and controlled archives.

Key policies and measures have been put in place for data governance for South African healthcare facilities. The Standard Operating Procedures are implemented by all employees and external stakeholders when engaging with health information-related activities for Department of Health facilities (NDoH, 2011). Despite these policies and measures Fusheini, Eyles & Goudge (2017) observes the impact of ineffective governance in a public hospital and argues for management to be guided in practice by principles set out in the national policies. Similarly where good policies and measures existed Malakoane, Heunis, Chikobvu, Kigozi & Kruger (2020) found that poor implementation, poor prioritisation, and lack of governance structures led to a compromised level of patient care and service quality.

HIS must be managed and protected according to an appropriate data integrity governance framework. As no specific data integrity statute for electronic healthcare systems exists there is a need to strengthen the current policies and processes to adapt with the ever-increasing threat to health information. Adlam (2020) summarises the generic privacy and data protection regulations provided by the South African law, namely the National Health Act, Health Professional Council for South Africa and the Protection of Personal Information Act (POPI) to ascertain their implications and relevance to electronic healthcare systems (see Table 3.1).

Table 3.1: Summary of Privacy and Data Protection Regulations by the South African Law

Criteria	National Health Act	Health Professional Council of South Africa	The Protection of Personal Information Act
Authentication	No health records may be created, modified or destroyed without authority to do so.	The original entry of a health record must stay intact and never be removed. New or modified information should only be appended to the health record.	Personal information should only be stored if necessary. Personal information should be destroyed/ deleted/ de-identified as soon as reasonably possible. The data subject is permitted to request for their personal information to be destroyed.
Authorisation	Intuitions are required to set up suitable security measures to prevent unauthorised access to health records.	All computers used to store or process electronic health records in any form should only be accessed by authorised personnel with a login password.	Access to, and processing of, personal information should be restricted for authorised use only.

		No unauthorised person should be able gain access to health records.	
Audit logs	Patient consent needs to be dated and signed by the patient.	Changes made to health records should be signed and dated by the person making the changes. The reason for the change should also be stated.	
Data storage	Health records should be stored in a safe place with suitable security measures	Health records in electronic format should be safeguarded with security measures, e.g., encryption. The use of ROM technology, (e.g., CD-ROM) is permitted, if copies are made and stored in a different physical location for safety reasons.	Data handlers should identify all present or future risks to personal information from internal and external threats. These risks should be mitigated through the implementation of commonly accepted information security controls.
Data Transaction	Sharing of health records with any party is strictly prohibited unless the patient provides consent. Only a court order can trump this prohibition.	Any personal information shared electronically should be safeguarded by security measures, e.g., passwords, encryption, and/or any other reliable security.	Only a court order can authorise the sharing of personal information without the consent of the data subject. Data handlers are allowed to use de-identified personal information for statistical purposes. Only the statistical results may be disclosed freely.

Digital health technologies have enabled South Africa to realise the potential for improving the quality and coverage of healthcare services, improving access to services and skills, and improving health behavioural changes to prevent acute and chronic illnesses (NDoH, 2019a). However, digital health technologies pose new, complex, and costly risks such as cyberattacks. Due to these threats and attacks, the Ministry of State Security implemented the National Cybersecurity Policy Framework (NCPF) in 2015 (Sutherland, 2017) and more recently the POPI. South Africa has established a NCPF purposed to create a secure, dependable, reliable and trustworthy cyber environment that facilitates the protection of Critical Information Infrastructure

whilst strengthening shared human values and understanding of Cybersecurity in support of national security imperatives and the economy (Ntsaluba, 2017). However, the NCPF is not being adopted in a timely manner; it is complex and slow to implement due to a lack of risk assessment, lack of transparency, and difficulties in coordination between government, business, and society (Sutherland, 2017).

3.3.3.2 Data integrity requirements

Manual (paper) records and electronic data are equally subject to data integrity requirements. Paper records should be traceable, readable, contemporaneous, original and correct, complete, consistent, enduring (indelible/durable), and available (ALCOA+) throughout their lifespan (WHO, 2020b). ALCOA+ principles should be followed in validation systems and report writing to reduce data quality and integrity issues, to ensure events are accurately documented and data can be used for informed decision-making (Sandler, 2018). Table 3.2 provides a brief description of the ALCOA+ principles that data should comply with in both paper and electronic systems (PIC/S, 2021).

Table 3.2: ALCOA+ principles for paper and electronic systems

Data Integrity Requirement	Paper / Electronic Systems Considerations
Attributable	It should be possible to identify the individual or computerised system that performed a recorded task and when the task was performed. This also applies to any changes made to records, such as corrections, deletions, and changes where it is important to know who made a change, when, and why.
Legible/Permanent	All records should be legible – the information should be readable and unambiguous in order for it to be understandable and of use. This applies to all information that would be required to be considered Complete, including all original records or entries. Where the 'dynamic' nature of electronic data (the ability to search, query, trend, etc.) is important to the content and meaning of the record, the ability to interact with the data using a suitable application is important to the 'availability' of the record
Contemporaneous	The evidence of actions, events or decisions should be recorded as they take place. This documentation should serve as an accurate attestation of what was done, or what was decided and why, i.e., what influenced the decision at that time.
Original	The original record can be described as the first capture of information, whether recorded on paper (static) or electronically (usually dynamic, depending on the complexity of the system). Information that is originally captured in a dynamic state should remain available in that state.
Accurate	Records need to be a truthful representation of facts to be accurate. Ensuring records are accurate is achieved through many elements of a robust Pharmaceutical Quality System. This can be comprised of:

	□ equipment related factors such as qualification, calibration, maintenance and computer validation. □ policies and procedures to control actions and behaviours, including data review procedures to verify adherence to procedural requirements. □ deviation management including root cause analysis, impact assessments and corrective action and preventive action trained and qualified personnel who understand the importance of following established procedures and documenting their actions and decisions. Together, these elements aim to ensure the accuracy of information, including scientific data that is used to make critical decisions about the quality of products.
Complete	All information that would be critical to recreating an event is important when trying to understand the event. It is important that information is not lost or deleted. The level of detail required for an information set to be considered complete would depend on the criticality of the information. A complete record of data generated electronically includes relevant metadata.
Consistent	Information should be created, processed, and stored in a logical manner that has a defined consistency. This includes policies or procedures that help control or standardise data (e.g., chronological sequencing, date formats, units of measurement, approaches to rounding, significant digits, etc.).
Enduring	Records should be kept in a manner such that they exist for the entire period during which they might be needed. This means they need to remain intact and accessible as an indelible/durable record throughout the record retention period.
Available	Records should be available for review at any time during the required retention period, accessible in a readable format to all applicable personnel who are responsible for their review whether for routine release decisions, investigations, trending, annual reports, audits or inspections.

Data integrity requires quality and risk management systems, as well as solid scientific principles and strong documentation procedures (European Medicines Agency, 2021). Papers and data should be regularly reviewed for compliance in accordance with ALCOA+ standards. Those healthcare organizations with an effective risk management system will be able to increase performance and improve quality (Abor & Abor, 2021). The industry must modernise past control systems and adopt modern QRM and scientific standards for HIS.

3.3.3.3 Data integrity training

Training is teaching staff to perform their work tasks and to comply with policies implemented (Chapple *et al.*, 2021). Training usually begins with identifying the staff that needs development. It involves identifying the kind of training required, that is, operational, technical, or application related. In the South African public healthcare,

this is unfortunately not the case due to a shortage of healthcare workers. Furthermore, the lack of cybersecurity skills has contributed to the decline of government staff recruitment and retention (Maphumulo & Bhengu, 2019; Sutherland, 2017). Most clerks who handle health information lack basic computer skills, as stated previously. Consequently, many manual errors occur in system processes, resulting in data corruption and inaccurate patient records. This poses patient care as well as medico-legal risks (Mutshatshi, Mothiba, Mamogobo & Mbombi, 2018; Mathioudakis, Rousalova, Gagnat, Saad & Hardavella, 2016). Healthcare professionals lack an understanding of how to use HIS as a result of insufficient training and hasty implementation (Ogundaini, 2016). Public healthcare institutions deal with many patients every day; due to the lack of staff, it can hence be challenging to find the time to attend training and learn how to use HIS. Training ensures that healthcare professionals are competent, responsive, and adequately supported (WHO, 2019b). Thus, it is essential to create multiple training streams to provide different levels of training within the available sessions. The healthcare sector should implement mandatory skills development programs so that users can learn how to use existing systems, improve their skills, and gain confidence in using them (Luthuli & Kalusopa, 2017).

A data integrity training program should include educating staff on the relevance of data integrity principles, as well as creating an environment conducive to transparency and actively encouraging the reporting of errors, omissions, and undesirable outcomes (European Medicines Agency, 2021). The program should equip participants with the information and skills necessary to implement data integrity governance systems, processes, and programs (RSC, 2020). Staff should be qualified and trained for their respective roles, with proper job segregation, and the importance of strong documentation methods should be stressed. Computerised systems may require specific training when they are used in the generation, processing, interpretation, and reporting of data, and a risk assessment indicates that this is necessary. Training in this area should include, for example, examining system security, backups, configuration settings, and document examination. To assess the value of training, proof of the effectiveness of crucial procedure training, such as electronic data review, should be provided (WHO, 2020b) There should be evidence of the effectiveness of

training on critical procedures, such as electronic data review to measure the benefit of training . (PIC/S, 2021; Vignesh & Ganesh, 2020).

With the growing use of HIS and online services in healthcare institutions, advanced controls are critical. To meet the current demand for digital upskilling, more systematic support should be created that ensures upskilling for all categories of healthcare professionals, through more flexible (self) learning opportunities. An effective response to data breaches and cyberattacks requires awareness of cybersecurity concerns, clear incident reporting frameworks, and ongoing staff training (UN, 2020). The future strategy entails intensification of research on IT security, promotion of further training for personnel and dedication of more resources to tackle cyber threats.

3.4 Literature Constructs from Chapter 3: Informs the Design of the Data Integrity Model.

The results of the literature can be consolidated into a summary of the most important constructs to consider when developing a Data Integrity Model. Table 3.3 details the most prominent construct covered in this chapter.

Table 3.3: Literature Constructs from Chapter 3: Towards the Data Integrity Model

	Constructs	Key focus areas of construct
C1	Data integrity mechanism	By identifying and implementing the most effective technique of managing data integrity in the various HIS levels.
C2	Data integrity governance	The development and implementation of a data integrity governance system, facilitated through a mixture of appropriate rules of engagement; people and organisational bodies; and processes.
C3	Data integrity requirements	Adherence of paper-based and computerised systems to ALCOC+ principles. These alone are not sufficient without quality risk management systems, and adherence to sound scientific principles and good documentation practices to ensure compliance with regulation, policies, and procedures as well as performing data integrity audits and data integrity investigations.
C4	Data integrity training	This aspect stems from inadequate training. Training should provide the required understanding enable the implementation of the required data integrity governance systems, methodologies, and programs.
C5	Data safeguards	In the absence of data safeguards, there is a need for incorporating "data integrity standard" into the data security standard to ensure complete protection of data. The "data integrity standard" should include data integrity measures for people, networks, operating systems, data files, data, and database management systems, and should be implemented alongside a data security standard to preserve data integrity.
C6	Human error challenges	This aspect represents one of the most cited causes of data integrity concerns in the healthcare sector. Managing these challenges through awareness, training, policies, and processes is of utmost importance.
C7	Computerised systems challenges	These are also causes of data integrity concerns. As part of the call to move to electronic HIS and use digital technologies to streamline and deliver quality healthcare services, there is a need to mitigate these challenges as soon as possible.

3.5 Summary

In this chapter, the researcher showed how data integrity plays a role in supporting HIS. Data integrity plays a crucial part in the decision-making of health professions, policymakers, data management applications/services, and overall healthcare services. The researcher explored the current state of data integrity risks to provide insight to the severity of the risks in the healthcare industry. The researcher was able to identify the data integrity issues faced in the healthcare sector as human and computerised systems and showed how these issues can be reduced as well as how data integrity can be maintained. In addition, the research examined the factors contributing to these challenges, finding that they are related to policy, environment, health workforce, and lack of awareness. Through identification of data integrity issues, the research identified data integrity elements that the government, along with healthcare institutions and other stakeholders, need to include in an overall data integrity strategy to support health information interventions in the South African healthcare system. There is a rapid growth in health information threats and cybersecurity threats, despite the political commitment and strong policies for protecting health information. This requires an assessment of current policies and procedures and the development of new regulations, which should prioritise data protection. As South Africa fully engages in digital health activities, the data integrity mechanisms can form a guide as to how to further proceed when engaging in security for data protection in HIS. The methodology and techniques used to conduct the enquiry in the research study are presented Chapter 4.

4 CHAPTER 4: RESEARCH DESIGN AND METHODOLOGY

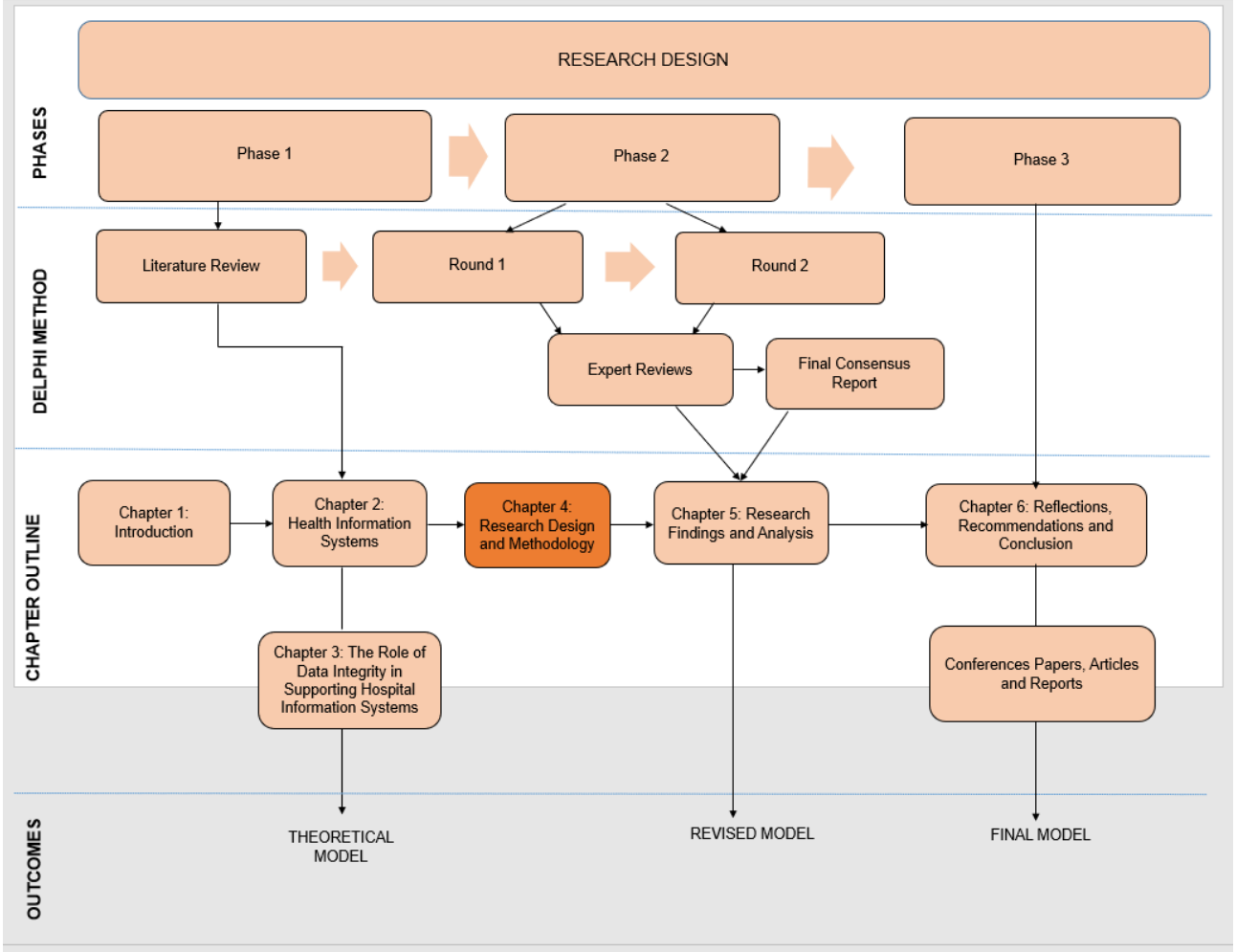


Figure 4:1: Chapter Layout of Research Study

4.1 Introduction

The previous chapter introduced the role that data integrity plays in supporting hospital information systems. This chapter provides an overview of the research methodology and design used to answer the research questions. Sileyew (2019) defined research methodology as a path that a researcher embarked on to formulate a research question and goals with the intention to present the findings based on the data obtained during the research. Hoftsee (2006) was of the view that a research methodology was an easy-to-understand diagram or roadmap that illustrated how researchers arrived at their conclusions. Research methodology provides structure to research, allowing new knowledge to be discovered and answers to research questions to be formulated (Saunders & Lewis, 2017). The next section of this chapter provides a detailed description of the research processes employed by the researcher as well as the methods of data collection, sampling, and analysis, including the reasons for their selection.

4.2 Research Methodology

Research design is considered a type of investigation in research methods that provides specific direction for procedures to ensure that research objectives are achieved through systematic implementation in a study (Saunders *et al.*, 2019:p173-174; Creswell & Creswell, 2018:p60). Sanders developed the onion as a guide for researchers to characterize research design. The onion model, which is applicable to research, consisted of philosophy, research approach, research decisions, strategy, time range and data collection methods. This model focused on data collection, however, it was essential that all other layers of the onion be considered and applied as decisions that were made in the outer layers influenced the inner layers (Saunders & Lewis, 2017). This chapter explains the selected research methodology based on the onion layers depicted in Figure 4.2.

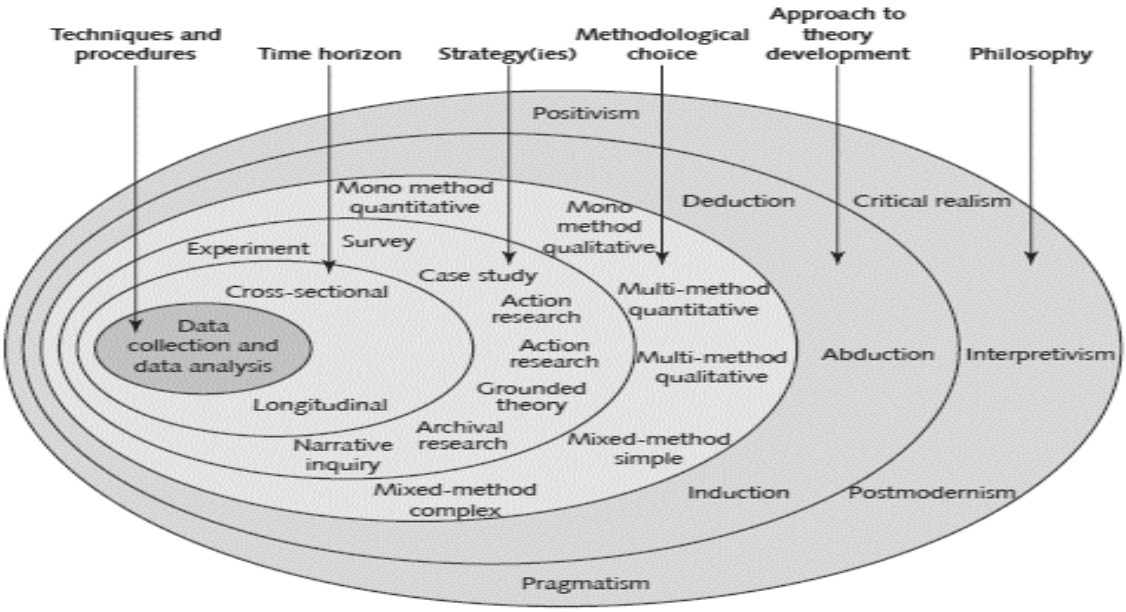


Figure 4.2: Research Onion (Saunders, Lewis & Thornhill, 2019:p174)

4.3 Research Philosophy

Philosophy is a fundamental concept for studying a particular field and has meaning on a methodological and theoretical level (Flick, 2013:p185). Creswell & Creswell (2018:p54) referred to the term worldview as a set of underlying views that, despite ongoing debates over the worldviews used by researchers, carried out individual actions that ultimately influenced how research was conducted. The definition above elaborates on the way a researcher conceptualises the world as well as the impact it has on research conduct. Each philosophy comprises of four key elements: axiology, ontology, epistemology, methodology (Kaushik & Walsh, 2019). These factors form the underlying assumptions, beliefs, norms, and values for each paradigm. The main philosophies of literature, as described by Creswell & Creswell (2018:p54), are:

- ***Post-positivism***. A post-positivist worldview, also known as positivist/post-positivist research, is scientific research that uses experimentation to explore and answer questions (Kivunja & Kuyini, 2017). Post-positivist scholars argued that worldviews and truths did not exist (Aliyu, Bello, Kasim & Martin, 2014), and suggested that we cannot positively evaluate knowledge claims when considering behaviour. and human behaviour (Wahyuni, 2012). Instead, they prefer to work with observable social reality, and research findings that can be

generalised and applied to similar situations elsewhere (Oates, Griffiths & Mclean, 2022:p294; Saunders *et al.*, 2019:p144). Experiments and questionnaires are typical quantitative data collected by post-positivist researchers.

- ***Constructive***. Constructivist worldview, also known as interpretivism, in its simplest form for human understanding. Interpretation is a model of humanistic research that aims to understand different cultures through human empathy and perception (Mabila, 2017). This means that researchers put themselves in the subject's shoes and look through their eyes. According to (Hussain, Elyas & Nasseef, 2013), constructivists do not acknowledge any truth but believe that understanding and knowledge are based on interpretation. This philosophy often employs qualitative research methods including case studies and action studies, where interviews and observations are applied to understand context (Oates *et al.*, 2022:p301-302; Hevner & Chatterjee, 2010).
- ***Critical***. Although critical research takes place in a context similar to that of interpretivism, this particular research challenges social, political, cultural, economic, and technological frameworks that will provoke change (Moon & Blackman, 2014). Moreover, critical research is premised on the belief that social, political, and cultural factors limit the ways people change their economic and social circumstances. Researchers conducting critical research can identify and seek to resolve social power imbalances that contribute to the inequality, injustice, and economic isolation of particular social groups (Taylor & Medina, 2013).
- ***Pragmatism***. Pragmatism as a worldview arose from the practical application of the most effective methods in a given situation (Creswell & Creswell, 2018:p58). The pragmatic researcher first highlight research questions and use a variety of methods to understand existence (Creswell & Creswell, 2018:p58; Wahyuni, 2012). Several authors define pragmatism as a philosophy that considers mixed paradigms, data collection methods, and data analysis techniques (Kaushik & Walsh, 2019; Maarouf, 2019; Creswell, 2014). Pragmatism is both subjective and objective because it allows for reality while allowing people to have multiple interpretations of that reality (Maarouf, 2019). Pragmatism claims that no two people have the same experience of their

worldview (Kaushik & Walsh, 2019). Maarouf (2019) suggests that to understand how social actors behave, we need to study their worldviews (perceptions).

Interpretivism was the paradigm of choice for the researcher. Interpretivism focuses on understanding how people create meaning from different ideas. According to Creswell & Creswell (2018:p320), the main objective of this research is to understand participants' perceptions of the problem situation. According to (Creswell & Poth, 2018:p15), researchers use well-defined philosophical assumptions and rationales based on their positions to influence how they interpret value and discover meaning. This means that philosophical assumptions influence the choice of research paradigm. The most common philosophical assumptions used in IS and IT research are ontology, epistemology and axiology. These are explained below.

- ***Ontology*** deals with the researcher's view of the nature of reality or state of being (Saunders *et al.*, 2019:p133). In qualitative research, the researcher embraces the idea of many realities. This essentially means that the researcher conducts research to account for multiple realities, i.e., different researchers grasp different realities, as do study participants and research readers. Thus, the evidence compiled by the researcher explains the different perspectives and experiences of the participants, including the use of multiple quotes based on the actual words of the different participants, and their point of view (Creswell, 2007). Based on Kivunja & Kuyini (2017), ontology refers to how we place our trust in something to be true or meaningful, furthermore allowing us to derive meaning from collected data.
- ***Epistemology*** is made up of assumptions about knowledge, what knowledge is valid and acceptable, and how knowledge can be communicated to others (Saunders *et al.*, 2019:p133). The focus is on the experience and knowledge that researchers can gain to broaden, broaden and deepen the knowledge in their field of study (Kivunja & Kuyini, 2017). Gray (2014) points out that epistemology is necessary because it can help clarify research design issues. Specifically, it deals with the general framework for research, including the types of evidence to collect, where to find it, and how to interpret it. The researcher can better identify operational designs (for specific purposes) by knowing the research philosophy.

- ***Methodology*** is defined as a set of tools for researchers to study a phenomenon (Wahyuni, 2012). It refers to the combination of processes, methods, and tools chosen by the researcher, and the underlying beliefs that guide that research method over other research methods (Saunders *et al.*, 2019:p57). Meyer (2017) asserts that the researcher structures the process and ensures that the research provides answers to the questions posed by defining the methodology.
- ***Axiology*** refers to the value in research and the position of the researcher in relation to the topic being studied (Hiller, 2016:p99). It examines the nature of values and the various values by which things and events determine basic and inferred human needs and how they satisfy or affect life (Biedenbac & Jacobsson, 2016). Wahyuni (2012) described these values as ethical, moral, religious, and aesthetic. Kivunja & Kuyini (2017) explained that the researcher must best demonstrate ethical behaviour by showing how well they understood good and bad amid as well as after the research process. This means that the researcher must explain how they will deal with the values of the participants at the beginning of the study. Table 4.1 illustrates the application and influence of the philosophical assumptions in this study.

Table 4.1: Summary of Philosophical Assumptions with Implications for the Study Adapted From (Saunders *et al.*, 2019:p144-145; Tracy, 2013:p260)

PHILOSOPHICAL ASSUMPTIONS	**Interpretive**	**Influence in the study**
ONTOLOGY (Nature of reality)	There are multiple realities, and they can be socially constructed.	The researcher will use participants' views to construct reality, in this case a model for data integrity in HIS.
Epistemology (nature of knowledge)	The research is subjective, as the researcher uses empathy to gain value and knowledge.	The researcher will use questionnaires to assess and understand the experts in IS on their knowledge and experience in data integrity practices.
METHODOLOGY (How to design an artefact)	-Value choice with ethical and political ramifications. -multiple methods show the contexts' layered and partial nature. -hermeneutical.	The study employs an inductive approach. After collecting data, the researcher will propose a specific model.

	-seeks an empathetic understanding of human behaviour.	
AXIOLOGY (Role of values)	Contextual understanding is important and descriptive.	In qualitative research, there is an element of subjectivity because of the nature of the research process and the research itself.

4.4 Approach to Theory Development (Research Approach)

According to Mack, Woodsong, Macqueen, Guest & Namey (2011:p1), qualitative research aims to understand a certain research problem or topic from the point of view of the relevant population. This includes understanding aspects that individuals or groups see as problems or social problems (Creswell & Creswell, 2018:p51). Quantitative research, on the other hand, involves measuring variables, analysing their correlations, and applying statistical procedures to test hypotheses (Creswell & Creswell, 2018:p51). A mixed research approach combines and analyses qualitative and quantitative data in a single study (Williams, 2007). The researchers then test their views or arguments. Three different questions are used in research methods, namely, deductive, inductive, and inductive.

- ***Deduction inquiry*** involves testing a theoretical proposition using a research strategy specifically designed to collect the data to be tested (Saunders & Lewis, 2017). Researchers evaluate their data from a topic perspective to determine if there is additional evidence that could support each topic or if they need to gather more information (Creswell & Creswell, 2018:p296).
- ***Induction research*** is the approach in which the researcher initially evaluates the information available to identify patterns that can best explain the data (Lune & Berg, 2017:p194). It is a bottom-up research approach in which researchers alternate between topics and databases until they have established a comprehensive set of topics (Azungah & Kasmad, 2020; Creswell & Creswell, 2018:p296).
- ***Adduction inquiry*** involves collecting data and bringing together topics to ascertain patterns, then create a new or modify an existing theory for later testing.

The research is mainly based on qualitative research method. Participants in this form of investigation favour an inductive research approach that focuses on the meaning

people attribute to events and the importance of calculating the complexity of events. situation (Creswell & Creswell, 2018:p51). An inductive investigative approach was adopted. The researcher begins by analysing the literature review, followed by developing a conceptual data integrity model to support hospital information systems. Then, using inductive reasoning, the components of data integrity were identified, and the data involved were carefully examined to develop a Data Integrity Model.

4.5 Research Methodological Choice

The choice of research method can be qualitative, quantitative or mixed. Although qualitative and quantitative approaches are often seen as contradictory, qualitative and quantitative approaches represent different endpoints on the continuum, whereas mixed methods are both quantitative and qualitative approaches. It is in the middle of this continuum because it incorporates elements of both quantitative and qualitative approaches (Creswell & Creswell, 2018:p51). Table 4.2 summarises the main characteristics of quantitative and qualitative research methods.

Table 4:2 Comparison of Quantitative and Qualitative Research

Basis of Comparison	Quantitative Research	Qualitative Research
Meaning	Is a research method that is used to generate numerical data and hard facts, by employing statistical, logical, and mathematical techniques.	Is a method of inquiry that develops an understanding of human and social sciences, to understand the way people think and feel.
Nature	Particularistic	Holistic
Approach	Objective	Subjective
Research type	Conclusive	Exploratory
Reasoning	Deductive	Inductive
Sampling		Purposive
Data	Measurable	Verbal
Inquiry	Result-orientated	Process-oriented
Hypothesis	Tested	Generated
Elements of analysis	Numerical data	Words, pictures, and objects
Objective	To examine cause and effect relationship between variables	To explore and discover ideas used in the ongoing process
Methods	Structured techniques such as surveys, questionnaires, and observations	Non-structured techniques such as in-depth interviews, group discussions
Result	Recommends final course of action	Develops initial understanding

Qualitative research was the research method of choice for this study. It has proven to be an advantageous method if the topic has never been raised to a particular group of people (Creswell & Creswell, 2018:p69). There is not any substantiating evidence in literature to suggest that HIS data integrity practices are being addressed by a panel of people, as was the case in this expert review study.

4.6 Research Strategy

A research strategy is a comprehensive research plan that helps researchers plan, conduct, and monitor research (Johannesson & Perjons, 2014:p39). Strategies typically determine the why, what, who, where, when and how data will be collected and analysed to solve a research question (Oates *et al.*, 2022:p117). According to Gray (2014), research questions in case studies ask "how" and "why", whereas in research approaches or archival records, research questions ask "what", "who", and "where". . "Figure 4.3 illustrates the different types of research strategies employed when using qualitative, quantitative, or mixed methods. Following are (Saunders *et al.*, 2019:p190-211):

Figure 4.3: Different Research Strategies, Adapted From (Saunders *et al.*, 2019:190)

- ***Case studies*** pursue research questions within a real-life context, using evidence (data) from various sources.
- An ***ethnographic*** research strategy describes and interprets the social world through first-hand fieldwork.
- An ***experiment*** is a research strategy that involves defining a hypothesis, selecting samples from known populations, assigning those samples to different experimental groups, changing and measuring some variables, and controlling others.
- ***Grounded theory*** uses an inductive inquiry approach to gather data from observations or interviews, and from there, theory is developed.
- ***Archival research*** analysis administrative records and documents as the principal source of data.
- A ***survey*** is a structured research strategy that collects data from a sizeable population via structured interviews or questionnaires.
- ***Action research*** is a strategy concerned with managing change and involves close collaboration between practitioners and researchers.
- **Narrative inquiry** is more than just telling a story or interpreting personal accounts. Attempts are made to preserve chronological connections and the sequence of events as told by the narrator (participant) to enhance understanding and aid analysis.

Among the various strategies used in qualitative research, Avella (2016) points to the Delphi method as gaining momentum among dissertation-pursuing student qualitative research researchers. Delphi methods are primarily qualitative and share some interpretivist traits, but may also include quantitative elements depending on the application(Avella, 2016).

The name Delphi derives from an oracle used to predict and seek the advice of the gods in ancient Greece, and the technique has been widely criticized for being unscientific due to its mystical origins (Avella, 2016; Yousuf, 2007).). In the early 1950s, the Rand Corporation developed the Delphi technique for use in military defence projects, which later developed into scientific research, education, and business (Fisher, Erasmus & Viljoen, 2020; Alarabiat & Ramos, 2019). Over time, this technique has been applied in a variety of ways and is now considered by researchers

to be a valuable method for uncovering data-driven problems or questions for which evidence is limited (Jaana, Tamim, Pare & Teitelbaum, 2011). Strasser (2019) described the Delphi technique as a way to build group communication, fostering the ability of diverse people to work together effectively to find solutions to complex problems. This technique is commonly used in subject-related research to measure comprehension, judgment, and mental cognition. Various authors describe the Delphi technique with these four characteristics (Fisher *et al.*, 2020; Hirschhorn, 2019; Strasser, 2017; Skinner, Nelson, Chin & Land, 2015; Rowe & Wright, 2011):

- ***Anonymity of participants***: The researcher(s) anonymise the responses from the questionnaires. The anonymity of the group facilitates individuals' expression of their views without feeling the pressure of dominant individuals. Additionally, anonymised responses can eliminate the negative influences caused by the personalities and statuses of respondents.
- ***Controlled feedback***: Each questionnaire iteration is followed by controlled feedback. The researcher informs each participant of the thoughts of their anonymous peers and discards all irrelevant information.
- **Iterative process**: The questionnaire consists of several iterations. In each iteration, participants can reflect on their judgments and change them using the information that they received from the other experts.
- **Statistical aggregation of group response**: All views contribute to form part of the answer after the final round. These answers can then be treated quantitatively and statistically.

Although originally intended as a predictive technique, its flexibility allowed researchers to adapt it to specific problems and goals. This has led to many variants of the technique, which are continuously being further developed (Hirschhorn, 2019). Variants differ greatly in the selection of participants, the types of questions used, how responses are evaluated, and the intended outcomes (Fisher *et al.*, 2020; Hirschhorn, 2019; Strasser, 2017; Kobus & Westner, 2016). Table 4.3 summarises the different variants of the Delphi technique.

Table 4.2: Different Variants of the Delphi Technique

Variants of Delphi Technique	Description
Classical Delphi	A group of experts is recruited to obtain reliable information on future trends on a specific topic or topics.
Modified Delphi	There are some modifications to the classical Delphi technique. This is a method by which the panel is provided with the initial alternatives that responded to the researcher's questions, based on careful selection.
Spatial Delphi	This is applicable when consultants and related decisions are concerned with spatial location issues. The experts' contributions are plotted on geographic maps, and the coincidence of their opinions is indicated using simple geometric shapes (circles or rectangles). In the course of subsequent iterations, the shapes gradually decrease, limiting a very small part of the territory, which represents the final solution to the research problem.
Policy Delphi	Based on experts' judgments, opinions, and experiences, it explores the most important pros and cons for each policy resolution.
Real-time Delphi	Expert judgments are fed back online in real time.
Argument Delphi	Places greater emphasis on the ongoing discussions and on finding relevant arguments, as opposed to focusing on the output.
Disaggregating Policy Delphi	It assumes that consensus is not achievable through expert communication, but rather evokes various views based on the alternative arguments that gain support.
Problem Solving Delphi	Participants' rankings or paired comparisons are collected for collaborative judgment.
The Fuzzy Delphi Method (FDM)	Information obtained is expressed as fuzzy numbers instead of a single value in traditional deterministic methods.
Ranking-type Delphi	The ranking-type Delphi technique is the most used Delphi technique in the IS field. It focuses on classical IS research topics such as identifying and ranking Critical Success Factors , identifying components of research frameworks, or prioritising selection criteria.

Conducted in three phases, this research study uses exploratory Delphi techniques to gather participants' perspectives and experiences on data integrity practices. According to Avella (2016), exploratory Delphi methods do not initially consult a panel of experts when generating answers to Round 1 questions. Instead, researchers use a literature review to gather initial responses and present them to the panel for consensus building. This differs from other designs such as her traditional Delphi and ranking Delphi methods that require questions to identify an expert and find or solve problems. The purpose of this study was to develop a model to serve as a basis for future data integrity measures for hospital information systems in South Africa. Based

on a theoretical model derived from a review of relevant literature, researchers compiled an initial list of responses and distributed them to an expert panel. An expert panel was asked to rank each item according to specific criteria provided by the researchers. Each type of Delphi technique has a similar process, but the purpose and objective of the research dictates which type you use. Delphi's methodological process typically involves groups (panellists) answering a series of focused questionnaires with multiple iterations of controlled feedback until consensus is reached (Alarabiat & Ramos, 2019; Strasser, 2019; Kobus & Westner, 2016; Skinner *et al.*, 2015). A key feature of this technique is the anonymity of each response, avoiding conflicts between experts. In this way, individuals do not have to defend wrong views and are not subject to strong arguments from others (Ju & Pawlowski, 2011). In a narrow sense, the Delphi method consists of two to three interviews, so-called iterations, each with a different focus (Fink-Hafner, Dagen, Doušak, Novak & Hafner-Fink, 2019). Rounds are repeated according to consensus among the participating experts. Avella (2016) points out that consensus does not imply 100% agreement when different perspectives and judgments are considered, but the Delphi method tends to reach consensus between 55% and 100%, while 70% is considered normal.

Choosing the right Delphi technique participants is one of the most challenging aspects of the process, as this will greatly influence the quality of the results (Veugelers, Gaakeer, Patka & Huijsman, 2020). The Delphi technique aims to explore minds rather than set out precise recommendations; the results are not intended to be generalised to all situations, but to provide in-depth insight into a complex problem (Alarabiat & Ramos, 2019). Therefore, choosing participants must not be random; rather, they must be carefully chosen. Several authors recommend that participants should have first-hand background knowledge and experience of the topic under investigation. They should also be willing to invest considerable time and effort because the Delphi technique can require multiple rounds of iteration after initial judgments. Furthermore, participants should be respected and well known in the relevant fields (Ahmad & Wong, 2019; Alarabiat & Ramos, 2019; Fink-Hafner *et al.*, 2019; Hohmann, Cote & Brand, 2018). The size of the overall panel should also be considered. A standard size for a panel does not exist, nor has it been determined what constitutes a large or a small panel. Panels comprising fewer than 10 or over 1000 participants are rare, and 10 – 100 member panels are most common (Avella,

2016). According to Alarabiat & Ramos (2019), 10-15 experts are sufficient if they have extensive experience; if a larger number of experts is needed, homogeneous expert panels should be defined to facilitate the consensus-finding process and to reduce the number of rounds thereafter. For the research study, experts specifically in the field of IS were selected. Ten experts in the fields of IS were selected, based on their knowledge and experience. More details on the experts are found in Chapter 6.

As with the size of the panel, there is no standard number of rounds for the Delphi technique process, but the recommendation is usually two or three (Alarabiat & Ramos, 2019). Studies from Vogel, Zwolinsky, Griffiths, Hobbs, Henderson & Wilkins (2019); Santaguida, Dolovich, Oliver, Lamarche, Gilsing, Griffith, Richardson, Mangin, Kastner & Raina (2018); Njuangang, Liyanage & Akintoye (2017) have shown that three rounds are needed to collect information for consensus, while Schmalz, Spinler & Ringbeck (2021) used just two rounds. The argument is that too many rounds can exhaust experts, resulting in them changing their opinions to hasten the study, thus bringing about a false consensus (Rowe & Wright, 2011; Yousuf, 2007). This research study employed an exploratory qualitative study with Delphi expert reviews to achieve consensus within two rounds (agreement ranges between 55 – 100%). In their study, Lange, Kopkow, Lützner, Günther, Gravius, Scharf, Stöve, Wagner & Schmitt (2020) point out that consensus also depends on the format of a rating scale and the consensus threshold.

Scaling techniques are used for Delphi ranking in many ways. For the most part, they have been used in exploratory studies to add rigour, and to assess the validity and reliability of the study's result (Alarabiat & Ramos, 2019). Scaling technique is a method by which respondents are placed on a continuum of gradual change in the pre-assigned values, symbols or numbers based on the features of a particular object, as per the defined rules (Prachi, 2019). Figure 4.4 illustrates the different types of scaling techniques.

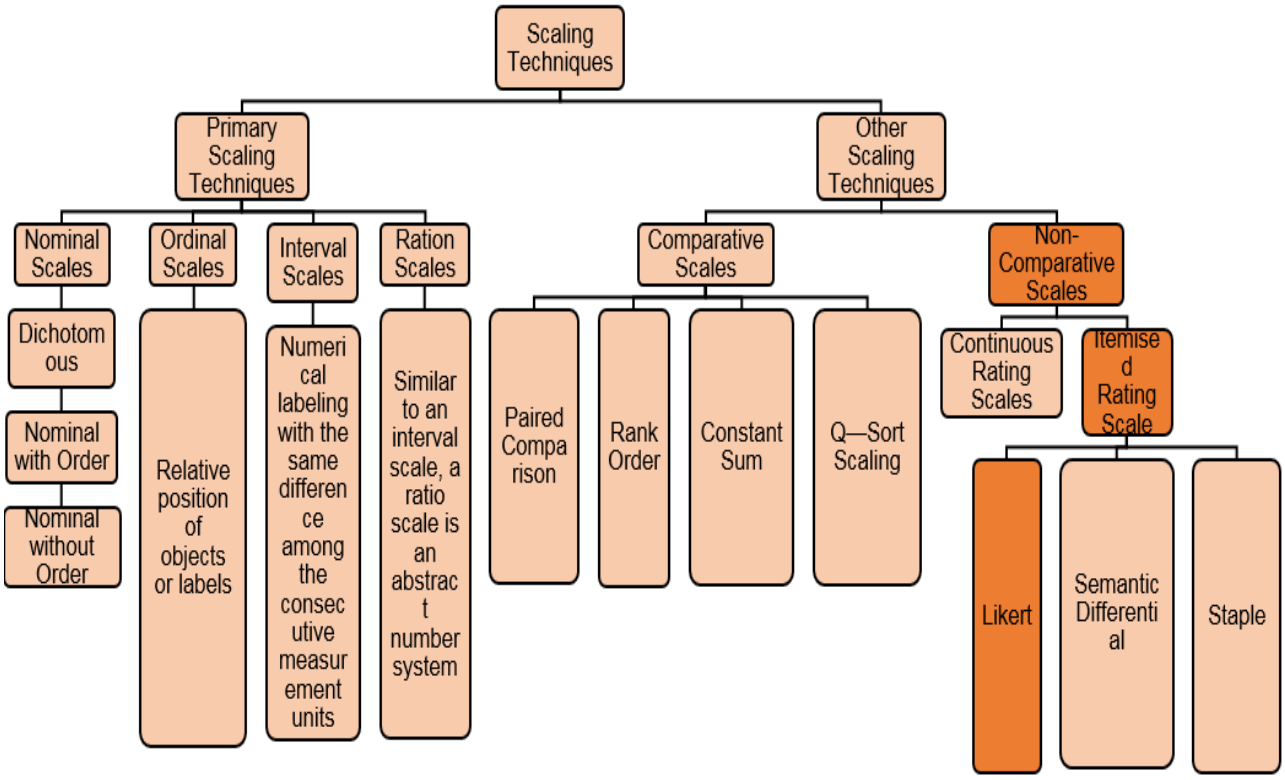


Figure 4.4: Different Types of Scaling Techniques

The study focused on non-comparative, itemised, Likert scales. Likert (1932) developed the technique to measure attitudes. Researchers use Likert scales to measure response levels of agreement or disagreement with statements, allowing respondents to choose from different options depending on their feelings about the statement (Prachi, 2019; Sullivan & Artino, 2013). By definition, it is the process of generating the continuum (a continuous sequence of values) upon which the measured objects are placed (Taherdoost, 2016a). Different types of Likert scales exist. However, the 5-point and 9-point scales are most used in Delphi technique (Lange *et al.*, 2020; Giannarou & Zervas, 2014). Likert scales are easy to construct, likely to produce a reliable scale, and easy for participants to read and complete; however, they may be biased in the sense that participants may avoid extreme response categories, and may agree with statements to please the researcher; validity may be difficult to demonstrate (Bertram, 2007). For identifying the constructs of the model, the study applies the 5-point scale, ranging from Scales 1 and 2 (“unimportant” and” moderately important”), Scale 3 (“neutral”), to Scales 4 and 5 (“Important” and

"Very Important"). Figure 4.5 illustrates how an exploratory Delphi technique is applied as a research strategy.

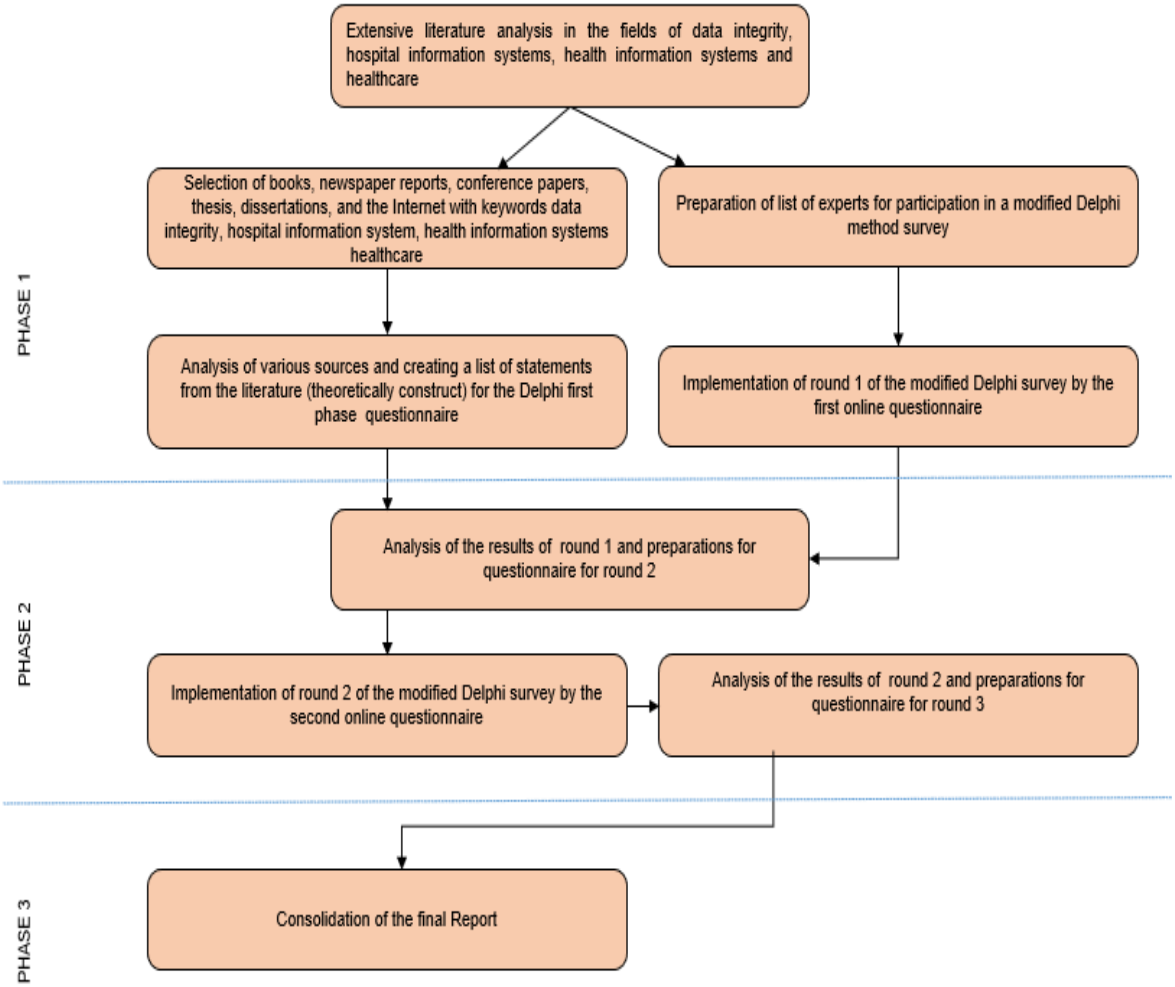


Figure 4.5: Exploratory Delphi Technique Phases and Steps

As described in the literature, there are many advantages to using the Delphi technique. However, like other research methods, it has disadvantages. To minimise the negative consequences of these drawbacks, it is important to identify them to be addressed and corrected (Alarabiat & Ramos, 2019). Table 4.4 lists the advantages and disadvantages of various authors (Alarabiat & Ramos, 2019; Fink-Hafner *et al.*, 2019; Skinner *et al.*, 2015).

Table 4.4: Advantages and Disadvantages of the Delphi Technique

Advantages	Disadvantages
• Ensures that responses are anonymous and confidential. • Avoids confrontation of experts with one another (encourages honest opinion, free from group pressure). • Ties together the collective wisdom of experts to contribute to the understanding and resolution of important problems. • The panellists drive content, which ensures a high degree of validity due to their own experiences. • Cost-effective and flexible/adaptable. • Experts are effectively used to establish the basis for future studies.	• Researchers may use money to entice experts to participate, thus leading to a risk of biased surveys. • There are no set criteria for selecting the panel, interpreting and analysing the results, or setting consensus criteria. • Feedback mechanisms may lead to conformity rather than consensus. • Concerns about the reliability of the technique. • It takes a long time to conduct several rounds; it requires participants to commit, to avoid the risk of dropping out.

4.7 Time Horizon

A cross-sectional study collects data at a single point in time, whereas a longitudinal study examines phenomena over a period of time (Gray, 2014). The researcher chose a cross-sectional survey since data was collected at a single point in time. A panel of experts was selected to share their knowledge and experiences on data integrity.

4.8 Techniques and Procedures

The techniques and procedures of the onion research process refer to the collection and analysis of data used in a study. This section discusses the data collection techniques, data analysis, and data verification as applied in this research.

4.8.1 Data Collection Techniques

Researchers use data collection techniques to collect data using qualitative or quantitative methods to answer research questions and gather valuable information to conduct their studies (Oates *et al.*, 2022:p122-123). This study collected its data through literature reviews, document analysis, and expert consultations. The different techniques are explained below.

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- Document analysis

Bowen (2009) defines document analysis as a qualitative research technique in which the researcher interprets documents to give meaning to a specific topic. This is usually done by coding content into themes, as is done the same way with focus groups and interviews (Bowen, 2009). Policy documents, strategic documents and reports were utilised to complement other data collection techniques and validate some responses to the interviews. In addition, exploring and examining the elements of the documents can provide insights into some aspects that are difficult to obtain from data sources such as interviews.

- Questionnaires

The questionnaire is used as technique to collect numerical information to identify the components of a Data Integrity Model to support HIS in South Africa. Both open-ended and closed-ended questionnaires were used. The closed-ended questionnaires were developed based on the analysis obtained from the literature review. The questions were aimed at evaluating and validating data integrity practices in HIS. The closed-ended questions were designed according to the five-point Likert scale, which is the most common method to assess participants' agreement and disagreement with given statements (Bertram, 2007). The interval scale used here is an ordinal scale which refers to a measurement scale that depicts the order of variables rather than the different between them.

- Literature reviews

A literature review synthesises and summarises past knowledge on a topic or area of interest. The literature review shares the results of other studies to evaluate and understand the topic under study as well as relates the study to a more extensive, ongoing dialogue in the literature that fills gaps and expands previous studies (Creswell & Creswell, 2018:p79). Phase one of the research study focused on the literature review, which enables the researcher to gather the information with a view on integrating and summarising what is known on the topic or domain. It also enables the researcher to identify some knowledge gaps (Rowe, 2014). Literature reviews examine and critically assess existing knowledge in a particular problem domain, as such forming a foundation for identifying weaknesses and poorly understood

phenomena, or enabling problematisation of assumptions and theoretical claims in the existing body of knowledge (Boell & Cecez-Kecmanovic, 2014).

The context, that is, data integrity and the location investigated in this study (South Africa), has not been investigated in previous studies.

Various sources were used to search for the literature, including books, newspaper reports, conference papers, theses, dissertations, and the Internet. All these sources were properly referenced in this research study. The literature review was done to answer the secondary research questions posed in Section 1.4.1.1. From the literature, data integrity elements, data integrity challenges and risks, as well as their contributing factors were identified. Understanding and examining data integrity and its practices were critical in developing the theoretical model. In the first phase of the modified Delphi technique, the researcher conducts an extensive literature review. Literature on data integrity, Hospital Information Systems, Health Information Systems, and healthcare is analysed, thus providing insights for the researcher to identify and approach potential experts and secure participant commitment based on the criteria (see Table 2.4). Simultaneously, questionnaire development is based on the analysis of the literature.

- Sampling

Sampling is the process of selecting a part of the population (or participants) for the research, studying the population in depth by assessing results provided through engagement with the sample, and interpreting the findings in the broader context of the research. Researchers use two major sampling techniques, namely, probability sampling and nonprobability sampling (see Figure 4.6).

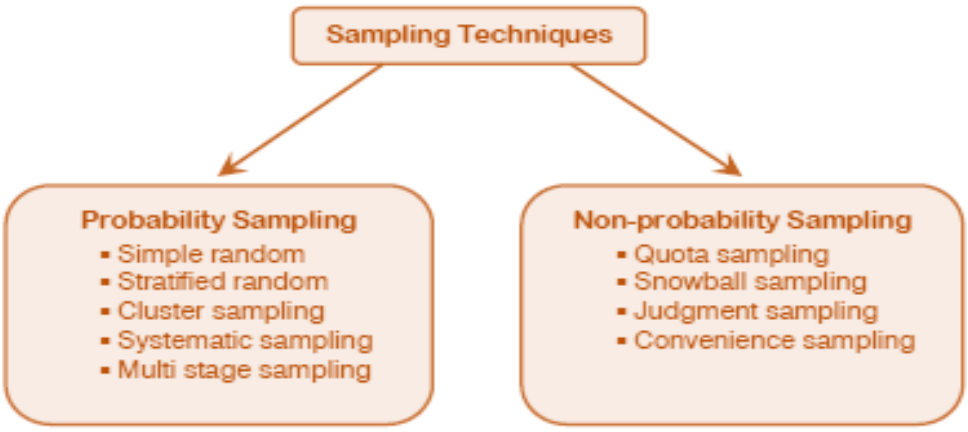

Figure 4.6: Sampling Techniques, Adapted From (Taherdoost, 2016b)

Probability sampling is a technique used by researchers to select a sample size that is known to the researcher and from which a generalisation can be made regarding the whole population (Adwok, 2015). In probability sampling, each item in a research sample from a research population has the same random chance of being selected or excluded (Taherdoost, 2016b). This technique is usually applied in quantitative research using surveys and experiments, as the findings can be generalised for each item to an entire research population (Saunders *et al.*, 2019:p297). Among the various types of probability sampling, there is simple random sampling, stratified random sampling, cluster sampling, systematic sampling, and multi-stage sampling (Turner, 2020; Taherdoost, 2016b). Below is a brief description of each.

- *Simple random sampling* means that every item of the population has an equal probability of being included in the sample.
- *Stratified random sampling* refers to the process of dividing the population into strata (or subgroups) of interest, and randomly selecting samples from each stratum.
- *Cluster sampling* involves dividing the whole population into groups or clusters for inclusion in the study, and then randomly sampling from the groups or clusters to represent the population.

- *Systematic sampling* involves listing all elements, selecting a random number as the starting point, and selecting every *yth* element after that number. The sampling interval, *y*, is calculated by dividing the population size by the desired sample size.
- *Multi-stage sampling* is a step-by-step process that moves from a broad to a narrow sample. In statistics, this process involves taking samples in stages using smaller and smaller sampling units at each stage.

The non-probability sampling technique is frequently used in qualitative research and is useful for exploratory purposes. There is no known or uniform probability of selection in the population, and samples are used to examine real-world phenomena rather than to make statistical inferences in relation to the larger population. A brief description of the different non-probability sampling techniques follows:

- *Quota sampling* is a process in which a target population is divided into groups; quotas for the unit structures in the sample are created, after which individuals are selected to fit within the quotas (Iiiyasu & Etikan, 2021).
- *Snowball sampling* is a technique used for obtaining samples whose characteristics are rare and difficult to identify (Kirchherr & Charles, 2018). The process is also known as chain-referral, because existing study participants recruit potential participants among their acquaintances; the sampling process continues until data saturation (Naderifar, Goli & Ghaljaei, 2017).
- *Convenience sampling* includes participants who are convenient to the study. In other words, the study includes participants of the target population who meet certain practical criteria such as simple access, geographical proximity, availability during a given time, or willingness to participate (Etikan, Musa & Alkassim, 2016).
- *Judgement or purposive sampling* is the selection of samples based on the researcher's knowledge of the population being sampled (Edgar & Manz, 2017:106). The researcher deliberately selects participants based on their qualities. Therefore, no underlying theories or a set of number of participants are required, since the researcher identifies what needs to be known and finds individuals who are willing to provide that information by virtue of knowledge and experience (Etikan *et al.*, 2016).

For this study, snowballing, convenience, and purposive sampling methods were applied. Snowball sampling was used to identify participants, while experts were selected from potential participants by convenience and purposeful sampling. Various sampling methods are used to collect purposive samples, such as maximum variation, homogenous, typical case, extreme/deviant case, critical case, total population, and expert sampling (Etikan *et al.*, 2016). Expert sampling entails selecting experts in certain fields to be the grounds of the purposive sampling. It is particularly useful when there is no observational evidence (Etikan *et al.*, 2016). This is consistent with the nature of the study, since no observational evidence was gathered; instead, experts participate in the Delphi technique to reach a consensus on the research question(s).

- Expert reviews

An expert review provides an opportunity to assess the potential usability of a model without involving the end-users (Carlsson, Henningsson, Hrastinski & Keller, 2011), and constitutes a recognised method to find the purpose, events, and understanding of experts (Moonen & Van Hillegersberg, 2011). Since experts are the primary source of data collection in the Delphi technique, the number of experts included in a study is crucial as it influences the results. As mentioned before, there is no standard requirement for the number of experts that forms a panel (see Section 2.6). However, it is advised that, for the validity, efficacy, and reliability of the results, the number of experts with extensive experience should range between 10-15 (Alarabiat & Ramos, 2019; Avella, 2016). Furthermore, using an appropriate pre-qualification criterion, a researcher builds a panel of informed participants who have experience in the area under study. Purposive sampling is usually applied in selecting experts, since they are specifically selected to apply their knowledge and expertise to a problem under investigation (Lune & Berg, 2017:p39; Ogbeifun, Agwa-Ejon, Mobohwa & Pretorius, 2016). The experts were selected based on their availability, and specifically for their expertise in the fields of IS in ICT projects. The focus of the literature review was on determining a perspective on data integrity practices, specifically in HIS. The experts consisted of people involved in developing HIS, Health Information Systems, systems engineers, and digital health (See Table 4.5), who participated in evaluating and validating the theoretical model that was conceptualised at the end of the literature analysis. This included correcting the use of language and assessing the applicability

and relevance of the model for HIS, and the appropriateness of the components of the model.

Table 4.5: Profile of Expert Reviewers

Field of expertise	Years of experience	Position	Number of expert(s)
Data integrity	15	Data integrity specialist - Industry expert responsible for data integrity in an organisation	3
Information Systems	12	IS specialist - Industry expert responsible for data integrity in an organisation	2
Hospital Information Systems	15	Consultant – Health informatics standards	1
Hospital Information Systems Development	10	Software developer - Industry expert in developing HIS	2
Information Systems Development	10	Software developer – Industry expert in developing IS	2

4.8.2 Data Analysis

According to Bordens & Abbott (2018:p397), data analysis examines data for potentially important patterns and relationships, especially simple graphical techniques and numerical summaries. Essentially, it is about organising and preparing the collected data, coding (identifying) themes and presenting them. Data analysis takes place after a research study has been concluded to facilitate an understanding of the findings. In this research, data analysis was conducted within the final round of the exploratory Delphi technique to ensure that the trends identified during the literature review are consistent with the results obtained from the experts.

Data analysis involved thematic analysis, which is a method for identifying emergent themes (Michelle & Varpio, 2020). Thematic analysis examines the perspectives of various research participants, identifies similarities and differences, and draws unexpected conclusions (Braun & Clarke, 2013). The following activities were part of

the data analysis process used to conduct thematic analysis (Creswell & Creswell, 2018:p308-310):

- *Data organisation* - The process involved categorising the literature into folders based on each paper's title and arranging them according to the research themes. The folders were created to represent the main areas of research or themes, such as data integrity and Hospital Information Systems.
- *Reading using memos* - Involved understanding the information presented in each paper by taking notes and noting key points.
- *Describe data into codes* - Provided a description for each code generated. Descriptions were aligned in accordance with the concepts covered in each chapter of the literature review (Chapters 2 and 3).
- *Classify data into codes* - Involved classifying the generated code. This was accomplished by grouping the code according to the descriptions provided.
- *Data visualisation* - Presented a consolidated view of the codes generated. This was illustrated by the word cloud shown in Section 5.3.

This step was important to allow the data to be more clearly interpreted and understood. To make the data more meaningful, we grouped the data from the experts into specific topics. Interpretivism has been used to apply hermeneutics to data analysis. Hermeneutics, as an interpretive technique, refers to rational human behaviour and the products of such behaviour, mainly problems that arise in contact with texts (Mantzavinos, 2016). It acknowledges social reality by interpreting the importance of social actors as a key theme against which theories revealed from empirical evidence can be built (Brannick & Coghlan, 2007).

Data was collected through a literature review and an online questionnaire. Researchers analysed the data using an open-source spreadsheet tool (Microsoft Excel) and software analysis tools such as Open Coding to guide the analysis phase using NVivo 12 (NVivo, 2021). According to Creswell & Poth (2018:p342), the development of code in primary documentation to improve data analysis. NVivo is a popular digital software for qualitative data analysis, enabling analytical tasks such as annotation, association, searching, coding, querying and visualization (NVivo, 2021:p349; Creswell & Poth, 2018). Chapter 5 provides detail of how the collected data was analysed.

4.8.3 Data Verification

In qualitative research, validation seeks to assess the accuracy of results based on analysis of participant responses as described by the researcher (Creswell & Creswell, 2018:p314). One technique for ensuring data accuracy and improving validity is known as triangulation. Triangulation combines different data collection methods within a study to better understand the validity of different data sources and a particular knowledge claim so that the research proposal is considered more authoritative (Abdalla, Oliveira, Azevedo & Gonzalez, 2018). Furthermore, we ensure that rigor, reliability, and superior quality are achieved during data collection procedures. In this study, triangulation between data sources enabled identification of model elements, and evaluation of new information based on already conceptualised models enabled further refinement. The forms of triangulation used in this study include:

- *Data triangulation*, where various sources within or external to the study are used to collect the same data. The study used primary data in the form of expert reviews through questionnaires, as well as secondary data sources such as document analysis and literature.
- *Methodological triangulation*, in which the study uses multiple data generation methods. The study used literature reviews (see Chapter 3), document analysis, and expert reviews to collect data.
- *Analysis triangulation*, which uses two or more techniques to analyse data. The use of hermeneutics, thematic analysis and applying NVivo software was employed for this study.

4.8.4 Ethical Considerations

Ethics describes the morals or rules that govern how people behave and ultimately make decisions (Castellano, 2014). This research complies with the ethical guidelines set by the SOC Ethics Committee of the University of South Africa's Faculty of Computing and the NDoH of South Africa to protect the rights of all participants and ensure good ethical research is compliant. Therefore, the researcher conducted the research directly and openly, and adhered to the following ethical considerations during the study:

- Formal permission: Permission granted by UNISA to conduct field research;

- Informed consent and voluntary participation: The participants were informed about why the research was being carried out. Their participation was voluntary, and participants were free to withdraw their participation in the research whenever they felt uncomfortable. Participants were asked to sign a consent form that they were participating voluntarily; and
- Confidentiality and privacy: The confidentiality of participants was protected during the data collection process, since the names of individuals were not revealed in this study.

4.8.5 Study Limitations

The limitation that exists within the research study included bias, as this was a qualitative Delphi study and was based on expert opinion only. However, it was useful for this setting, and it can be regarded for future studies.

4.9 Summary

This chapter described the research methodology of this study. The researcher discussed the research process, different philosophical paradigms, research strategies, data collection methods, and data analysis techniques. The study adopted Interpretivism as a philosophy, based on the principles of hermeneutics, and applied the exploratory Delphi technique as a research strategy. Qualitative data collection instruments such as a literature review and questionnaires were provided and discussed. The chapter also highlighted triangulation techniques as well as ethical considerations. Figure 4.7 summarises the research design and methodology as applied in this study. The next chapter presents the results of the expert evaluation of the Data Integrity Model developed for HIS.

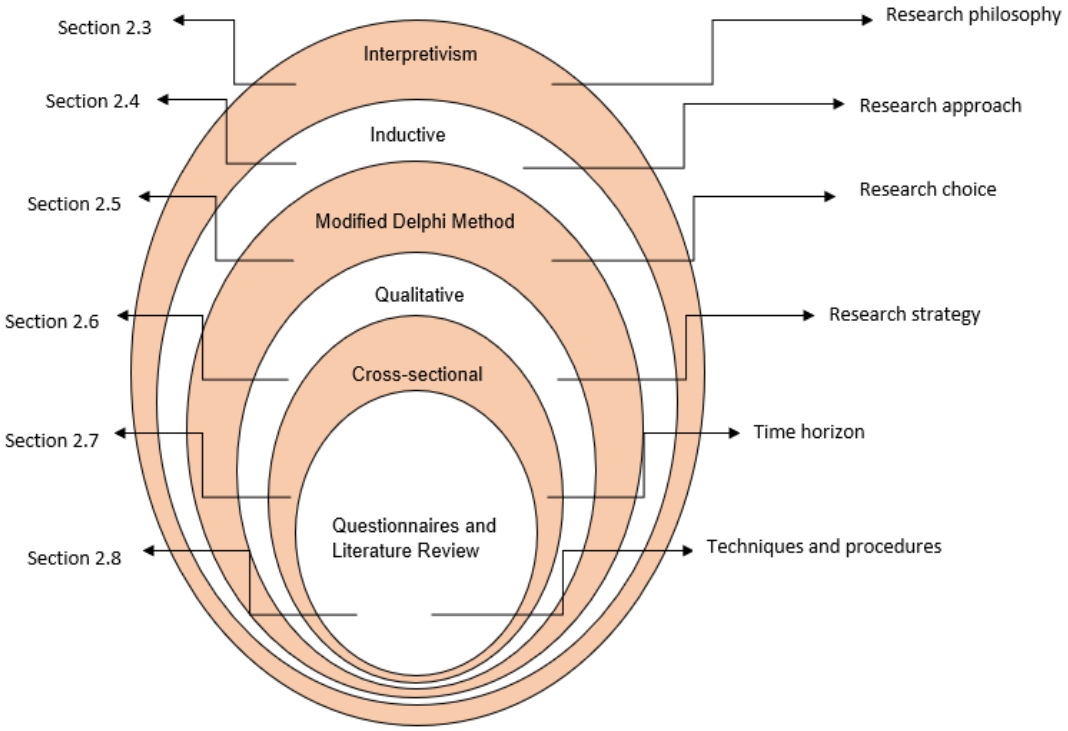

Figure 4.7: Applied Research Onion Process Adapted From (Saunders *et al.*, 2019:p174)

5 CHAPTER 5: RESEARCH FINDINGS AND ANALYSIS

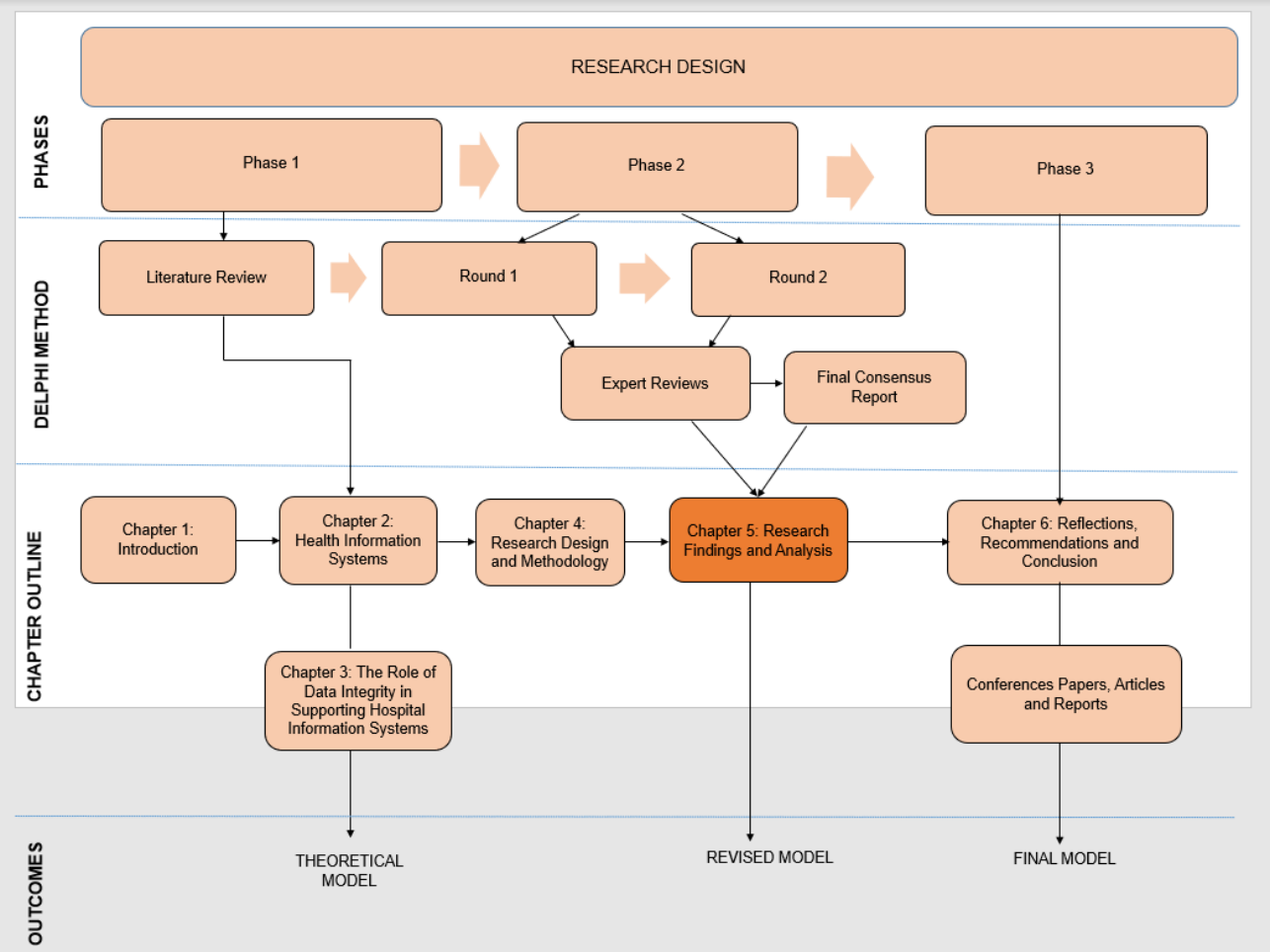

Figure 5.1: Chapter Layout of the Research Study

5.1 Introduction

In this chapter, the findings of the content analysis and expert review are presented, to form the basis of the proposed model. First, the content analysis sample were selected and analysed, followed by the results of the content analysis. A discussion of the expert review results followed, including a review of the proposed model and analysis of the expert review responses. As indicated earlier, this research aimed to develop a Data Integrity Model that can support HIS. The key research themes were discussed in chapters 2 and 3. Phase 1 of the research led to the design of the initial model based on the literature (see Figure 5.2). As the research was qualitative in nature, the chapter explained how the Scoping Reviews approach guided the development of the model's theoretical foundation.

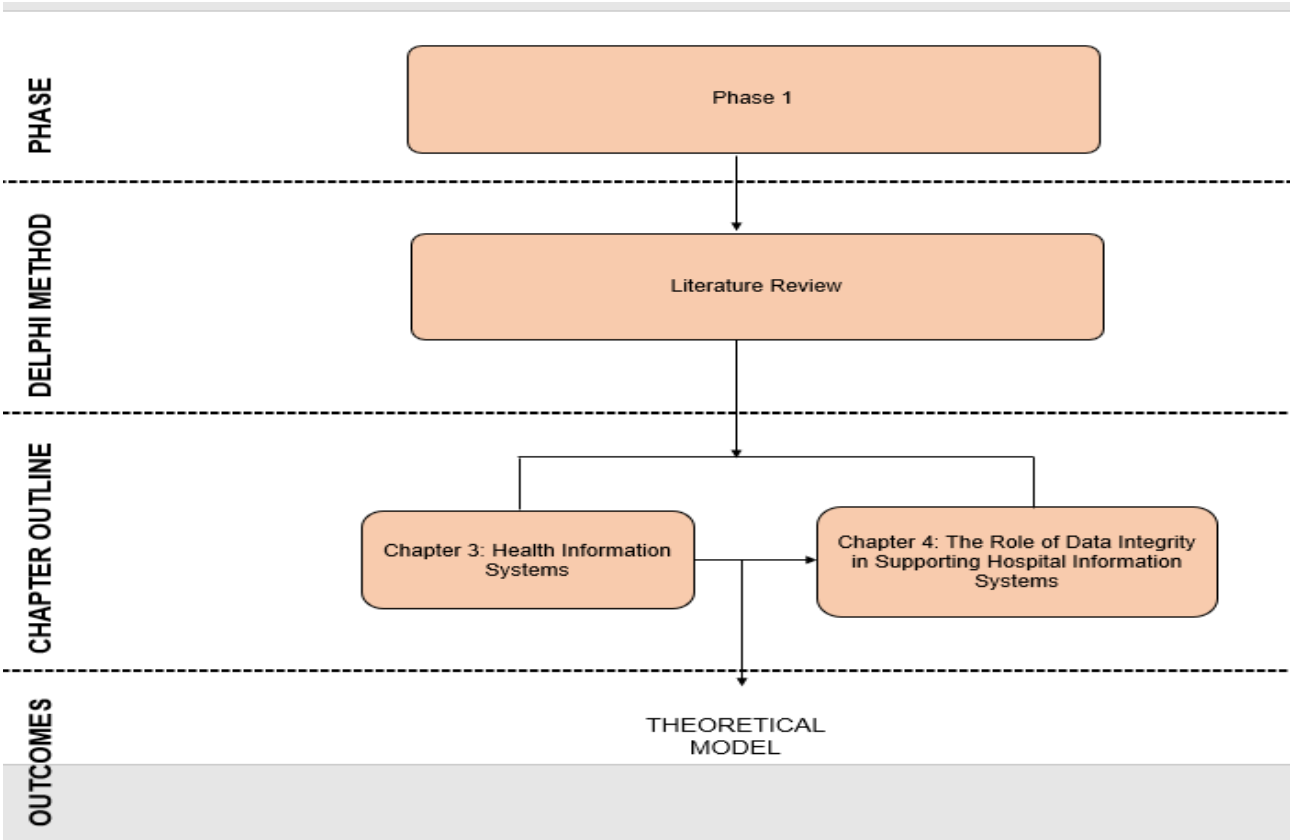

Figure 5.2: Phase 1 Research Design

5.2 Scoping Reviews Completed for Chapters 2 and 3

Scoping reviews of prior literature were outlined in Chapters 2 and 3. Two scoping reviews were conducted. Chapter 2 focused on Health Information Systems, while

Chapter 3 focused on Data Integrity and its role in Hospital Information Systems. The reason for bringing this back into context is that it is necessary to show the relevance of using these types of reviews in developing a model. The feedback by the experts during the two rounds was seen as a mechanism to evaluate and validate. As indicated in Chapter 4, Arksey & O'Malley (2005) discussed reasons why researchers would like to opt for using scoping reviews as an approach to finding information on various topics. Chapter 2 referred to a lack of research in South Africa on data integrity. It is an area that needs more work and for future improvements to be informed. Therefore, scoping reviews were seen as the most obvious choice because "the paucity of randomised controlled trials makes it difficult for researchers to undertake systematic reviews" (Levac *et al.*, 2010:p1); for this reason, this study did not use systematic reviews. Furthermore, scoping reviews are relevant for fields with no comprehensive review in a particular area (Peterson *et al.*, 2016) as is the case in this study, since it focused on data integrity in Hospital Information Systems for South Africa – an aspect that has to the researcher's knowledge not yet been done.

5.3 Thematic Analysis Results

Based on the literature search, 38 full-text papers were identified as input for the analysis. NVIVO was used to establish patterns across the papers and to validate the theoretical foundations outlined in Phase I (Chapters 2 and 3). An important component of qualitative inquiry is thematic analysis. This method is useful when searching data sets for possible patterns in the data (Saunders *et al.*, 2019:p112). Additionally, it is a practical approach to use when developing research themes and codes. Thematic analysis contributed to the constructs of the theoretical model in addition to the theoretical foundation (Chapters 2 and 3). This research study refers to Creswell & Poth (2018) data analysis as described in Section 2.8.2, and involves data organisation, data reading, description of the data using codes, classification of the data into categories, interpretation of the data, and presentation of the data. Literature was organised and classified according to research themes, including literature on data integrity and HISs, to facilitate the process of reviewing the papers. Following this, the literature was reviewed, and associated concepts were used. After the codes were identified, the most frequently occurring words in the literature review were examined. This process generated a word cloud (see Figure 5.3).

Using the theoretical groundwork, various concepts were created with the use of NVivo. In Figure 5.3, a word cloud is shown to illustrate the most used concepts. The concepts contributed to the research themes, and they were part of the theoretical model. Figure 5.3 illustrates the word cloud used in the research, which reflects the theoretical basis and the components of the research themes. These are indicated by concepts such as “data integrity”, “Hospital Information Systems”, “interoperability”, “standards,” and others. Nevertheless, it is important to note that the word cloud encompasses terms that go beyond the scope of this study. This is due primarily to the fact that the literature broadly discusses data integrity and HIS regardless of the context.

Figure 5.3: Most Frequently Used Words Across the Selected Literature

The constructs of the initial theoretical model were developed in accordance with studies conducted in the context of healthcare. Research constructs were defined in consideration of the research purpose, namely, to develop a Data Integrity Model for supporting HIS. Although new terms were introduced as part of the research, for them to be considered part of the initial model, they had to be aligned with the purpose of the research study. Excluded were those that had no effect on enhancing the model's design.

5.4 Data Integrity Model Constructs

Based on the scoping review process, Table 5.1 combined the constructs developed to inform the initial model (See Tables 2.7 and 3.3). In the table below, the researcher considered how each construct relates to the initial theoretical model in the research themes: data integrity and HIS. These constructs were used as input for the final design of the data integrity model.

5.5 Design of the Initial Data Integrity Model

The initial Data Integrity model is outlined below, built on the constructs described in Section 5.4. In the initial Data Integrity model, the focus is on data integrity in HISs by examining the e-Health maturity levels to understand the levels at which HIS operate in a healthcare setting. The different levels include local paper-based systems, local paper-based systems with limited IT support, a centralised electronic system that combines paper-based and electronic features, and a fully integrated shared national health system. As indicated in Section 3.3, data integrity applies to paper-based as well as electronic HISs. Thus, strategies for maintaining data integrity must be implemented for both, as shown in Figure 5.4

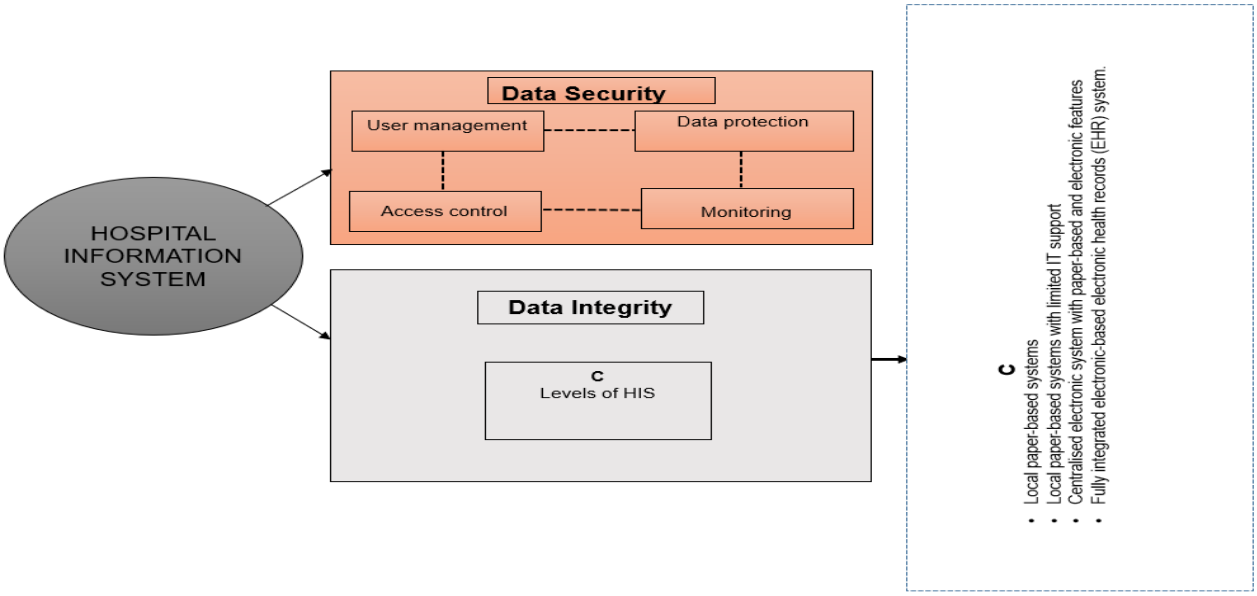

Figure 5.4: Data Integrity for the Different e-Health Maturity Levels

Additionally, data integrity can only be achieved by following best practices in handling data. The overall strategy for data integrity practices in HIS needs to be standardised rather than left to the discretion of individuals or teams. A holistic view on how the construct functions is presented, as such concluding Phase 1 of the Delphi technique. Based on the literature and theoretical foundations, Figure 5.5 summarises the initial Data Integrity Model. Visually, the model illustrates how the different concepts in each theme interact with each other. The constructs outlined and discussed in Table 5.1 align with Figure 5.5.

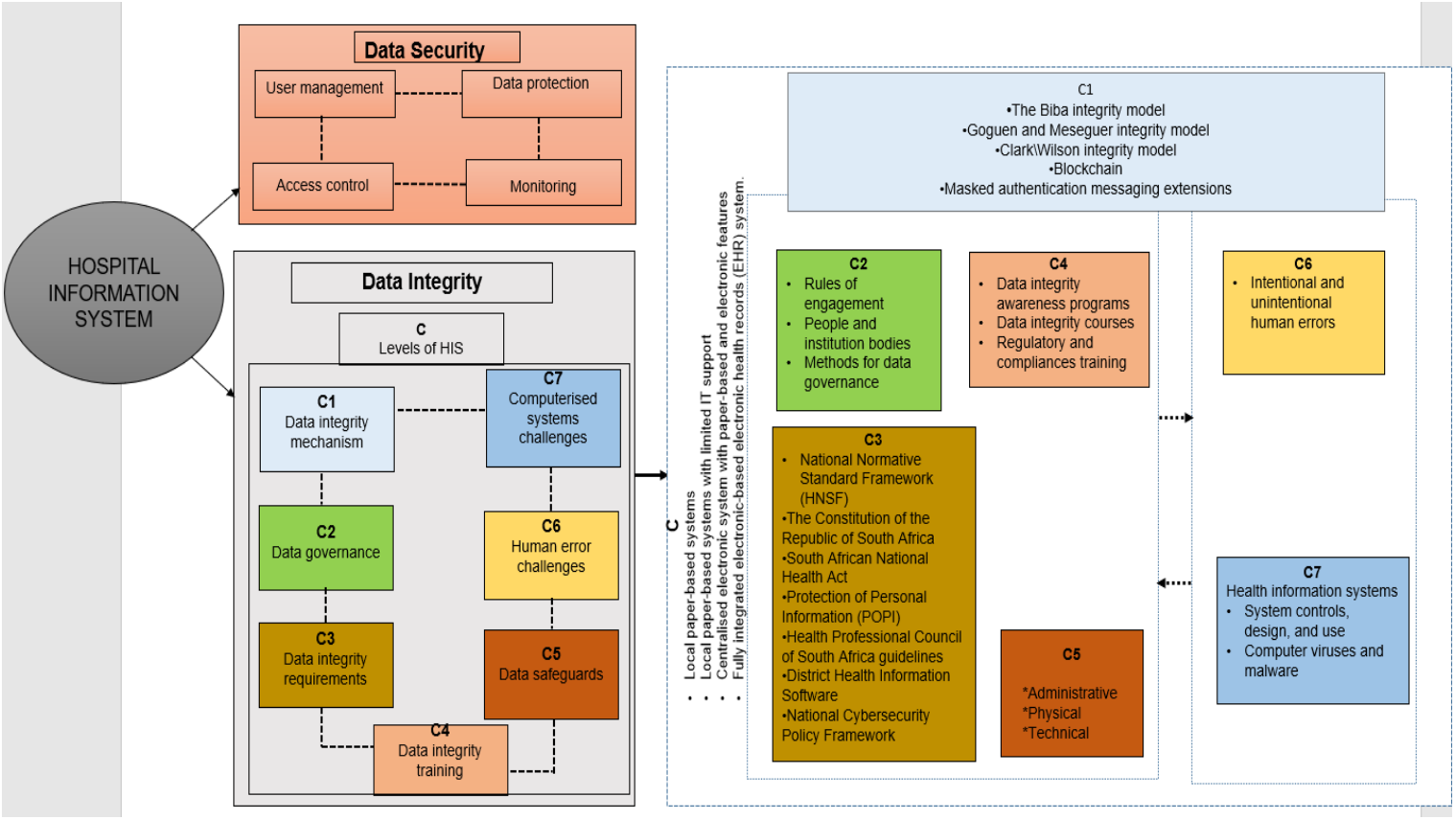

Figure 5.5: Initial Data Integrity Model

Table 5.1: Constructs for the Data Integrity Model

Construct	Description
C - e-Health Maturity Levels	E-health maturity levels imply that solutions need to be able to grow with time as they move from one place to another, from one level of the health system to another (from district to facility), and generally become more detailed and comprehensive over time (NDoH & CSIR, 2014).
Interoperability Layers	Interoperability in the context of health refers to how health information can be exchanged between healthcare professionals to enable knowledge-sharing networks (Payne, Lovis, Gutteridge, Pagliari, Natarajan, Yong & Zhao, 2019). The goal is to improve patient access to healthcare records and information to make better healthcare decisions (European Commission, 2017).
Interoperability standards	Standards are specifications that have been agreed upon to create or maintain consistently (Han, Liu, Evans, Song & Ma, 2020b). Both national and international regulations must be translated into healthcare operations on a daily basis through standards (Katuu, 2016).
C2 - Data Integrity Governance	Data integrity is a concept that has no singular definition, but many agree that it refers to data that is complete, accurate, and consistent (Barkow & Takahashi, 2017; Ansara, 2016; Schmitt, 2014; Dan Rode & Chps, 2012). This means maintaining the consistency, accuracy, and completeness of the data throughout its lifecycle. Data integrity mechanisms prevent unauthorised modification of information.
C3 - Data Integrity Requirements	Data integrity governance refers to the procedures in place to ensure that data, regardless of format, is recorded, processed, maintained, and used to ensure a complete, consistent, and accurate record throughout the data lifecycle (Mcdowall, 2018:p82).
C4 - Data Integrity Training	Both manual (paper) and electronic records must meet data integrity requirements throughout their entire life cycle. ALCOA+ must be maintained throughout the lifespan of the data (WHO, 2020b). ALCOA+ principles must be adhered to in validation systems and reports to address issues related to data quality and integrity. As a result, events will be accurately recorded and data can be used to make informed decisions (Sandler, 2018).
C5 - Data Safeguards	Training teaches staff to perform their tasks and comply with policies (Chapple *et al.*, 2021). It involves identifying the kind of training required, that is, operational, technical, or application related. Training ensures that healthcare professionals are competent, responsive, and adequately supported (WHO, 2019b). Data integrity training should include staff training in the importance of data integrity principles and the creation of a working environment that enables visibility and that actively encourages reporting of errors, omissions, and undesirable results (European Medicines Agency, 2021).
C6 - Human Error Challenges	Data safeguards are industrial-standard processes and procedures to protect data against theft, loss, misuse, destruction, and unauthorised alteration (Li, 2020).

C7 - Computerised Systems Challenges	Human error is an action that has negative consequences or fails to achieve the desired outcome (Kanki, 2018:p34).
C - e-Health Maturity Levels	Computerised system challenges are problems that occur unexpectedly and prevent a computer from functioning properly.

C - e-Health Maturity Levels - South African health systems span four levels of maturity (NDoH & CSIR, 2014):

- Level 1 – Local paper-based Health Information Systems.
- Level 2 – Local paper-based Health Information Systems with limited IT features.
- Level 3 – Centralised electronic system with hybrid features (both Level 1 and Level 2).
- Level 4 - Fully integrated electronic-based EHR system.

***Linkage in the Data Integrity Model*:** NDoH has implemented HPRS nationally for the purpose of maintaining and cross-referencing identifiers (South African Identification Document and other legal identification documents, i.e., passport numbers, driving licenses, asylum permits, and refugee permits), as well as offering master patient index capabilities so as to help standardise compliance with electronic health applications (NDoH, 2019a). The researcher proposes this construct for understanding the current state of health systems. A complete understanding of the maturity level at which health facilities operate is necessary to ensure the interoperability and data integrity of HIS systems. Furthermore, comprehension of the different maturity levels will enable the right decisions to be taken when implementing data integrity constructs C1 through to C7.

Interoperability Layers - South Africa has made an effort to use digital health through digitising patient health records to enhance healthcare delivery. However, many South African Health Information Systems lack interoperability, while others are still paper-based, making communication between these diverse systems difficult (NDoH, 2019a). Through the NHI system, South Africa intends to overcome its interoperability challenges, and will increase access to health services for all South Africans (Tsegaye

& Flowerday, 2021; NDoH, 2017). Interoperability can be achieved through five layers (Kobusinge (2021); (European Commission, 2017):

- Organisational interoperability - Aims to ensure that business goals, processes, and collaboration can be incorporated beyond the scope of one organisation.
- Technical interoperability - Ensures uninterrupted information flow, specifically protocols, interfaces, and related features that enable information exchange.
- Semantic interoperability - The goal is to ensure that communication channels have a common understanding of certain terms, and that continuous communication is maintained between them. Consistent coding standards are integral to semantic interoperability in eHealth.
- Syntactical interoperability - Involves using predefined messages and data formats to facilitate the exchange of information.
- Legal interoperability - Involves aligning the legislation of exchanged data so that it actively promotes interoperability through standardising privacy and security protections and preventing data blocking.

***Linkage in the Data Integrity Model*:** As part of the development towards a national EHR system, NDoH has implemented HPRS (NDoH, 2019a). A key feature of HPRS is its interoperability with other systems. Data in paper-based and older systems in healthcare facilities may be incompatible. As a result, patient health information would need to be moved to systems that allow interoperability, such as HPRS. The Data Integrity Model can support HPRS and guide the requirements for an interoperable national EHR system in South Africa.

Interoperability standards - Health Information Systems used in hospitals do not comply with interoperability standards, and some of those that do comply are unable to exchange health records because the hospital with which they are exchanging records uses a different HIS and does not comply with the standard used by other hospitals (NDoH & CSIR, 2014). The foundations for facilitating interoperability in healthcare are a clear understanding of the existing standards and how to use them to develop appropriate ones for facilitating effective HIE, creating coexisting operating environments and ensuring that systems are interoperable (Alunyu & Nabukenya, 2018). The HNSF provides practical insight into the implementation of interoperability

and plays a key role in the South African healthcare landscape. NDoH & CSIR (2014) review international eHealth standards and consider their applicability to South Africa, and develop use cases to illustrate how the specifications may be implemented (NDoH & CSIR, 2014).

Linkage in the Data Integrity Model: HNSF sets the standard for interoperability using a standards-based approach. The compliance of the Data Integrity Model in HIS with HNSF can solve the interoperability challenges that exist between heterogeneous systems when exchanging data, or when sharing health information (Ngwenya, 2018).

C1 - Data Integrity Mechanism - Data integrity mechanisms ensure that data is recorded exactly as intended. It ensures that, when the data is retrieved, it is identical to the original. For protection against data integrity attacks, strong defence mechanisms should monitor the system for any unauthorised data modifications (Kumar *et al.*, 2020). Zarour *et al.* (2021) and Pandey *et al.* (2020) posit that blockchain and masked authenticated messaging extensions are recent mechanisms used to manage the data integrity of different aspects of the healthcare sector, as well as challenges and ethical issues.

Linkage in the Data Integrity Model: This construct is based on the adoption of digital technologies and the awareness of cyberattacks by the government. To ensure the data integrity of health records in Hospital Information Systems, the researcher proposes adopting existing data integrity mechanisms. This can be accomplished by analysing existing Hospital Information Systems infrastructure, digital health services, and applications. Furthermore, it is proposed that data sharing agreements are obtained between NDoH and third-party IS to bring data into the national platform, while prioritising data from Hospital Information Systems (NDoH, 2019a).

C2 - Data Integrity Governance - Data integrity governance is important in ensuring the reliability of data and information obtained in Hospital Information Systems (WHO, 2020b). According to (Mcdowall, 2018:p97), data integrity governance involves: management; leadership; data integrity procedures and training; involvement of all the staff in the organisation; assessment and remediation of processes and systems; open culture and technical controls for computerised and paper-based systems.

Linkage in the Data Integrity Model: A data integrity governance framework for South Africa, comprising policies and regulations, data strategy and leadership, data

ecosystems, and invested data technologies to mitigate risks to government and society from poor data quality, data falsification, data obsolescence, and security threats (UN, 2020). The researcher proposes the review and alignment of current health governance policies, processes, and digital health governance structures.

C3 - Data Integrity Requirements - Adherence to sound scientific principles, adequate QRM systems and good documentation practices are required for ensuring data integrity (European Medicines Agency, 2021). QRM are responsible for ensuring compliance with regulations, policies, and procedures, as well as conducting data integrity audits and investigations (Mcdowall, 2019). A method for routinely checking documents and data for compliance with ALCOA+ principles should exist.

Linkage in the Data Integrity Model: Industry needs to modernise historical control strategies and apply modern quality risk management and sound scientific principles to HIS. To accomplish this, the researcher suggests reviewing existing regulations, policies, and procedures to enforce compliance and prioritise data integrity issues. The DHIS that has been implemented at healthcare facilities to ensure the quality of data Health Information Systems at district level serves as example (NDoH, 2011).

C4 - Data Integrity Training - Due to insufficient training and hasty implementation, healthcare professionals lack an understanding of how to use HIS (Ogundaini, 2016). To meet the current demand for digital upskilling, more systematic support should be created that ensures upskilling for all categories of healthcare professionals, through more flexible (self) learning opportunities. An effective response to data breaches and cyberattacks requires awareness of cybersecurity concerns, clear incident reporting frameworks, and ongoing staff training (UN, 2020). Data integrity training enables the implementation of data integrity governance systems, methodologies, and programs (RSC, 2020). Through data Integrity awareness programs, data Integrity courses, and regulatory and compliances training, data integrity training provides the knowledge and skills necessary to identify and avoid potential data integrity concerns.

Linkage in the Data Integrity Model: This construct is based on thereon that awareness among healthcare workers is severely lacking. Healthcare professionals lack an understanding of how to use HIS due to insufficient training and hasty implementation (Jinabhai, Onwubu, Sibiya & Thakur, 2021; Ogundaini, 2016). The future strategy entails intensifying research on IT security, promoting further training

for personnel, and dedicating more resources to address cyber threats. The researcher proposes the restructuring of existing training sessions into multiple streams, that is, a digital health workforce that caters to different levels of training needs. In addition, the need exists to implement mandatory skills development programs to allow users to improve their skills.

C5 - Data Safeguards - Implementation of a data integrity standard that includes industry-standard safeguards for measures for people, networks, operating systems, data files, data, and database management systems.

- Administrative safeguards - are measures that a facility employs to assess risk and incorporate appropriate mitigation plans (Bani Issa *et al.*, 2020). Measures such as these involve policies, practices, and procedures that continuously check for vulnerabilities and improve the level of security.

- Physical safeguards - are the measures, policies, and procedures that are in place to prevent natural and environmental hazards and unauthorised intrusion into an organisation's information systems (Heath, 2016). These safeguards are divided into facility access control; workstation use and security; and device and media controls (CMS, 2007b).

- Technical safeguards - are normally associated with computerised systems, usually over a network that stores electronic medical information. These safeguards include system protection such as antiviruses, firewalls, automatic logouts, and audit trails (Bani Issa *et al.*, 2020). Technical safeguards in healthcare facilities can involve role-based access control, attribute-based access control, and identity-based access control; unauthorised disclosure; or alteration of data (Kruse *et al.*, 2017).

Linkage in the Data Integrity Model: The construct is motivated by the need to improve data protection measures for healthcare information against cybersecurity threats and hacking. The researcher posits examination of current HIS infrastructure and connectivity to provide digital health broadband connectivity.

C6 - Human Error Challenges - These challenges have negatively affected the delivery of high-quality services in healthcare facilities (Maphumulo & Bhengu, 2019;

Gray & Vawda, 2018). Human errors include both unintentional and intentional challenges.

Linkage in the Data Integrity Model: This construct is based on the lack of computer skills and skilled personnel within healthcare institutions and the need to provide quality service delivery. There is a need to develop a digital health workforce plan. The researcher contends that this can be accomplished by integrating the first five constructs.

C7- Computerised Systems Challenges - These challenges are often attributed to poor or complete lack of system control, poor system use, inappropriate systems design, complex system features, computer virus, and malware (trojans, spyware, worms, and ransomware) (Wager *et al.*, 2017:p447-448).

Linkage in the Data Integrity Model: The construct draws upon existing HIS and calls for all healthcare institutions to fully utilise electronic IS. The researcher proposes the integration of the first five constructs to achieve this.

5.6 Research Findings

Based on the scoping review, the following results were elicited, including the literature constructs from Chapter 2 and Chapter 3. These constructs were combined and are presented in Table 5.1. Additionally, this section summarises the findings of the evaluation and final development through expert reviews. The data is represented using descriptive statistics, which are then interpreted to reveal their meaning.

5.6.1 The Exploratory Delphi Technique Process

A two-iteration Delphi technique was used to reach consensus on the components that should constitute a data integrity model to support HIS. This study was conducted over two sequential iterations, which were distributed to a panel of experts over a period of seven months from 12 January 2022 – 19 August 2022. The characteristics of this method included anonymity as well as the overall statistical feedback of results from previous iterations.

After ethical approval was gained (see Annexure A), an internet-based survey software and questionnaire tool was used to conduct the first survey. At this stage, potential participants were informed that they were voluntarily consenting to participate

in this study by completing the questionnaire. As anonymity was paramount in this inter-professional expert group, everyone was prompted at intervals to complete the study. Only the overall collated results were sent out to individuals between iterations. This approach ensured anonymity as only the primary researcher and the supervisor had access to the participant list. This inductive data collection process was conducted in two distinct phases to elicit the response of expert opinions. The flowchart in Figure 5.6 depicts the researcher's intent to address the experts' perceptions regarding data integrity and the methodology employed for this purpose.

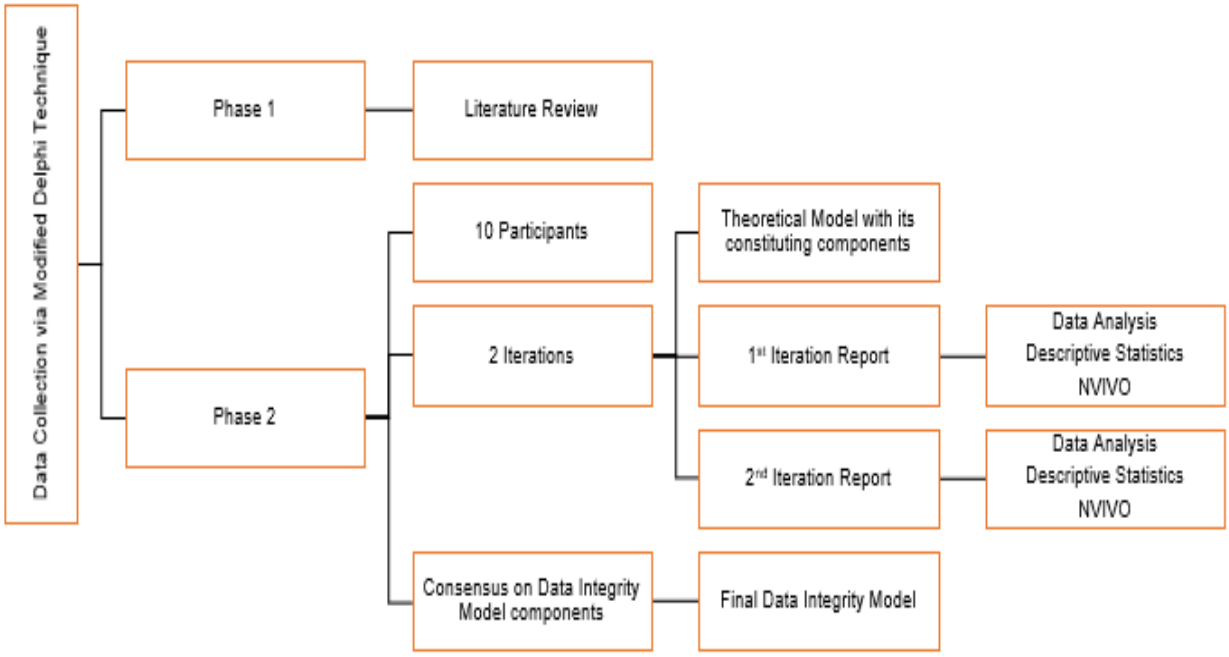

Figure 5.6: Flow Diagram of the Data Collection Process

This study was conducted in two phases, with analysis of participants' input at the end of each phase to assess for themes and to look for consensus and disagreements among participant responses. Iteration 1 and 2 each consisted of two sections, namely, the relevance of the model in the healthcare environment and the model's constructs. In the relevance section, the participants were asked to indicate agreement/disagreement with nine statements across the four categories, after which the constructs of the model were considered according to a 5-point Likert scale. The Likert scale included Unimportant, Moderately Important, Neutral, Important, and Very Important categories. When gathering expert opinions during qualitative research,

Likert scales are used to determine the importance of items (Habibi, Sarafrazi & Izadyar, 2014). The questionnaire presented in Annexure D was conducted in English and each expert was requested to rate the constructs according to what they felt was more or less important. In addition, the questionnaire included a strengths and weaknesses section of the model, as well as a comments section that allowed participants to add any appropriate suggestions regarding the Data Integrity Model.

5.6.2 Expert Review Results

5.6.2.1 Experts' Reviewer Information

Selected experts (n=10) with relevant experience in the disciplines of Health Information Systems and epidemiology; information systems; international Hospital Information Systems; digital health and IT governance; e-health and healthcare systems; interoperability; and systems engineering participated in this study. These experts included local persons who had been personally involved in previous deployments and in the design of IS projects for the purpose of healthcare service delivery. The experts were identified through the researcher field environment network and through recommendations from other participants. The expert review responses were analysed using narration. Most of the experts had the relevant years of experience to reflect that they are knowledgeable in their area of expertise. Thus, the experts were qualified to participate in the study. Table 5.2 presents a summary of the experts' information. In the next section, the researcher presents the results of the Delphi technique rounds.

Table 5.2: Expert Reviewers Information Summary

Field of expertise	Years of experience	Position	Number of expert(s)
Health Information Systems and Epidemiology	>30	Specialist that works directly with the safeguarding and release of health information	3
Information Systems	17	IS specialist - Industry expert responsible for data integrity in an organisation	1
Hospital Information Systems Internationally	20	Consultant – Health informatics standards	1
Digital Health and IT Governance	29	Specialist that works to support the design, implementation, and use of health technology within the industry, so as to provide quality healthcare	1
e-Health and Healthcare Systems and Interoperability	>8	Specialist responsible for handling technical support, customer service, process improvement, and project management for the eHealth Exchange health information network.	2
Systems Engineering	20	Software developer – Industry expert in IS development	2

5.6.2.2 Results of Two Delphi Technique Rounds

The consensus level of agreement was set at 60%. Model constructs that achieved less than 60% consensus were reviewed and adapted according to the experts' reviews. For both Iteration 1 and Iteration 2, the results were captured in a Microsoft Excel® spreadsheet. Once all iterations were completed, they were analysed, firstly, by assessing which items had achieved 100% consensus, and thereafter by assessing which items had achieved more than 60% consensus. The Delphi technique consensus tends to range between 55% and 100% (Avella, 2016). To quantify the level of agreement among the experts, the mean and standard deviations were calculated. The mean of a data set represents its central tendency. A measure of central tendency is a single value that attempts to describe a set of data by identifying the central position within that set of data (Chakrabarty, 2021). The standard deviation is a measure of how dispersed the data is compared with the mean. The low standard variation indicates that values are close to the mean or expected value for the set. By contrast, a high standard deviation indicates that the values are dispersed over a wider range (Hargrave, 2022). The descriptive analysis provided insight into participants'

perceptions based on the mean and standard deviation, after which those that fell into the same Likert-scale range were grouped together.

5.6.2.2.1 Result of Iteration 1

Phase 1 consisted of extensive literature analysis, developing the initial theoretical model, and creating a list of statements from the literature constructs for the Delphi techniques first round questionnaire. The Iteration 1 invitation was distributed to 10 potential participants during the second week of January 2022.

Relevance of the Model

To assess the rigour of the Data Integrity model and its constructs, expert opinions were sought on whether the model is relevant to the healthcare sector. Across all statements and model constructs, the mean for each category was 1.67. The validity category included four statements. The low standard deviation of two of the statements suggests that experts agree that the model is applicable to similar healthcare systems. However, the other two statements showed a high standard deviation. The higher the standard deviation, the more uneven the distribution is. In other words, 50% of experts agree and 50% disagree. The utility category consists of only two statements. In comparison to the validity distribution, the standard deviation of the utility distribution is extremely low, which suggests that experts agree with the model's utility. Furthermore, the low variance of the model's quality suggests that experts find the model easy to understand. Moreover, the experts agreed that the model was efficient, as is evidenced by a low variance. The results of Iteration 1 are shown in Figure 5.7.

Rating of the Model's Constructs

The background of each construct was provided, and the experts were asked to rate it on a Likert scale of 1 to 5. Using the following scale, experts were asked to indicate whether their responses with regards to the constructs are: Unimportant (1); Moderately Important (2); Neutral (3); Important (4); or Very Important (5). The results of rating the constructs within a South African context indicate that the standard deviation of the constructs for the initial Data Integrity Model (see Figure 5.8) is close to the mean, but that some are spread more widely than others.

There was a low standard deviation for the constructs *Level of HIS, Data Integrity Training, Data Integrity Requirements, Human Error Challenges,* and *Computerised Systems Challenges*. This suggests agreement on their appropriateness. The standard deviation of the constructs *Data Mechanism, Data Governance,* and *Data Safeguard* was higher, indicating a need to look further into the constructs. The experts' views are shown in Figure 5.8.

Relevance of the Model								
Valilty								
							Mean	stdDeve
Statement	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree	No Answer		
Does the model address a real problem/need?	0	0	0	6	4	0	1.67	2.66
Is it compatible with existing data integrity research or practices?	0	1	0	6	3	0	1.67	2.42
Is the application in the South African context?	1	1	1	2	5	0	1.67	1.75
Would the data integrity model be applicable in similar environments?	1	1	1	4	3	0	1.67	1.51
Utility								
Any missing elements or components?	1	4	0	4	1	0	1.67	1.70
Will the application of the model produce useful results if used in your context?	0	1	2	4	3	0	1.67	1.49
Quality								
Is the model easy to understand?	1	2	1	2	4	0	1.67	1.25
Efficiency								
Does it incorporate the components needed to develop a model?	0	1	2	3	4	0	1.67	1.49
Does it appropriately categorise the concepts included?	0	1	2	1	5	1	1.67	1.60

Figure 5.7: Relevance Results for Iteration 1

Constructs of the Model									
								Mean	stdDeve
	Constructs	1-Unimportant	2-Moderately Important	3-Neutral	4-Important	5-Very Important	No Answer		
Hosptial Information Systems Theme									
C	Levels of HIS	0	2	0	5	2	1	1.67	1.86
Data Integrity Theme									
C1	Data Integrity Mechanism	0	0	1	1	6	2	1.67	2.25
C2	Data Governance	0	0	0	1	7	2	1.67	2.73
C3	Data Integrity Training	0	0	2	2	4	2	1.67	1.51
C4	Data Integrity Requirements	0	0	2	1	5	2	1.67	1.86
C5	Data Safeguard	0	0	0	2	6	2	1.67	2.13
C6	Human Error Challenges	0	0	1	2	5	2	1.67	1.70
C7	Computerised System Challenges	0	0	1	2	5	2	1.67	1.70

Figure 5.8: Results of Constructs for Iteration 1

The experts agree that the Data Integrity Model is relevant but have not reached a consensus on the constructs. The latter form part of the development of a novel model and comprises components that can be applied in other areas of South Africa with similar systems or developing contexts. It is thus crucial to achieve a consensus on the constructs. Consequently, based on the experts' comments and suggestions, iteration 2 of the Delphi technique was needed.

5.6.2.2.2 Results of Iteration 2

In July 2022, the invitation for iteration 2 of Phase 2 was emailed to the same 10 participants. Multiple reminders were sent, and only one response had not been completed by the deadline set in August 2022. The same email invite included a summary report of the results of Iteration 1. The Iteration 2 questionnaire (see Annexure E) included all the comments of the experts' reviews that led to the revised Data Integrity Model as presented in Figure 5.9. The results from Iteration 2 were as follows. The revised model incorporated layers of interoperability and standards as they form part of digital health in healthcare systems. Furthermore, the Data Integrity Model with its components illustrates how together with data security can support HIS.

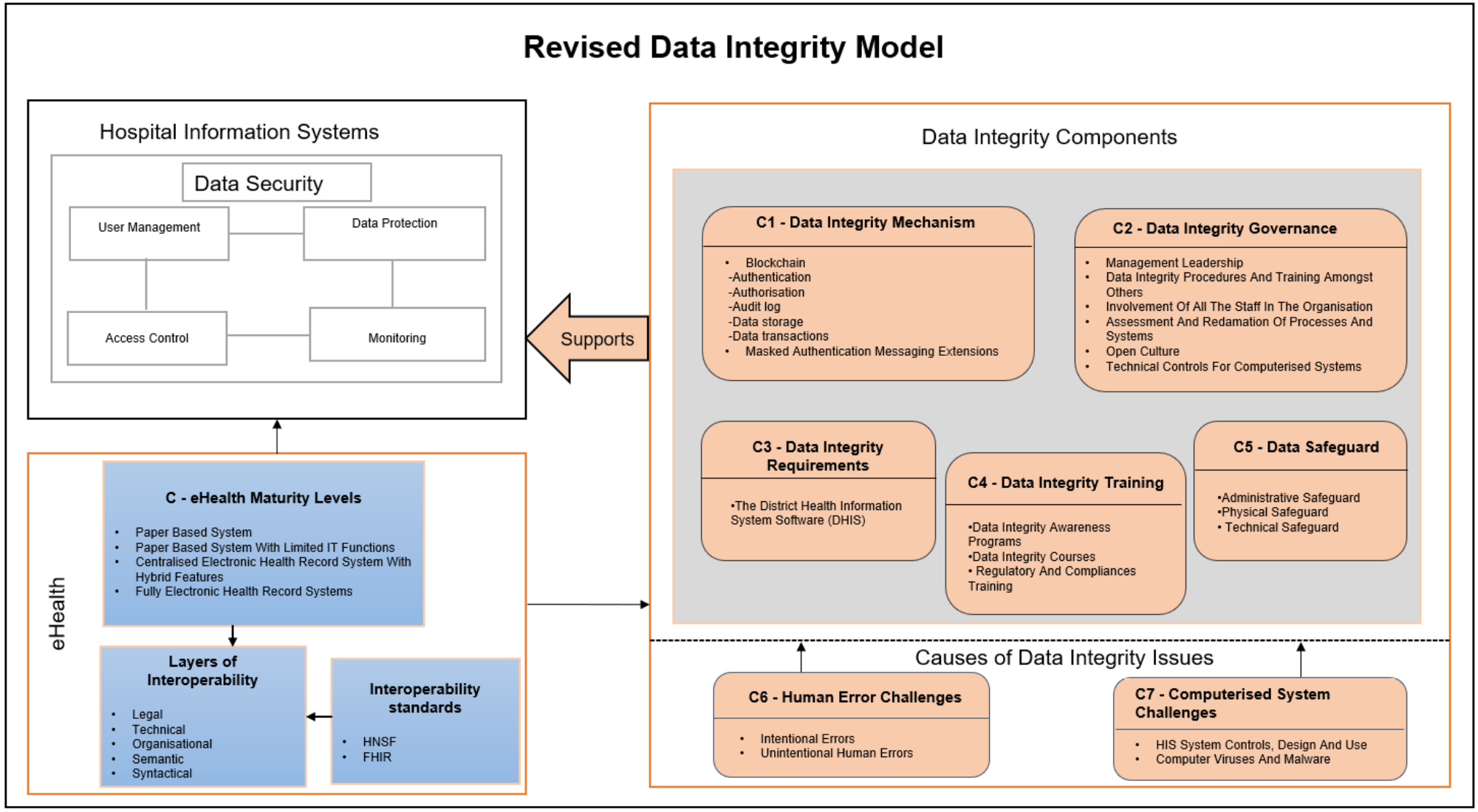

Figure 5.9: The Revised Data Integrity Model

Relevance of the Revised Model

In Iteration 2, the experts' responses differed slightly from those in Iteration 1. In this instance, the mean was constant across all statements and model constructs at 1.50. Three of the four validity statements had higher standard deviations. As compared to Iteration 1, the utility had varying opinions. The quality category did not change, as the low variance suggested that experts still find the model easy to understand. Lastly, the efficiency category had a higher variance as compared to Iteration 1. Figure 5.10 shows the results of iteration 2.

Relevance of the Revised Model

Valilty								
							Mean	stdDeve
Statement	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree	No Answer		
The model addresses a real need/problem	0	0	1	2	6	0	1.50	2.35
The model is adaptable to existing data integrity research or practices	0	0	1	3	5	0	1.50	2.07
The model applies to the health domain in South Africa	0	1	0	3	5	0	1.50	2.07
The model is applicable to similar healthcare systems	0	1	1	2	5	0	1.50	1.87
Utility								
Any missing elements or components?	4	1	2	1	1	0	1.50	1.26
The application of the model can improve the quality of healthcare data and service delivery	0	1	0	2	6	0	1.50	2.14
Quality								
The model is easy to understand	0	1	0	4	4	0	1.50	1.80
Efficiency								
The model incorporates the componets needed to develop the data integrity model	0	1	0	2	6	0	1.50	2.14
The model includes appropriately categorised concepts	0	1	0	1	7	0	1.50	2.50

Figure 5.10: Relevance Results for Iteration 2

Rating of the Models' Constructs

Most of the constructs in the revised Data Integrity Model had a higher standard deviation than those closer to the mean. *Data Integrity Requirements, Data Safeguards, and e-Health Maturity Levels* were close to the mean. In contrast, the new constructs *Interoperability Layers, Standards of Interoperability, and Data Governance, Data Integrity Requirements, Training in Data Integrity*, *Human Error Challenges*, and *Computerised Systems Challenges* had a high standard deviation. Figure 5.11 illustrates the results.

5.7 Data Integrity Model Evaluation Results

As previously indicated, the Strongly Agree and Agree results were combined and then labelled with the heading Agree to evaluate the results. The percentage agreements under the Disagree group and those under the Strongly Disagree group were combined and labelled with the heading Disagree. The neutral group remained unchanged. Based on validity, utility, quality, and efficiency, the proposed Data Integrity Model was developed and evaluated. To assist in evaluating whether the model would contribute to the healthcare environment in its current state, experts were

Constructs of the Revised Model									
								Mean	stdDeve
	Constructs	1-Unimportant	2-Moderately Important	3-Neutral	4-Important	5-Very Important	No Answer		
Hosptial Information Systems Theme									
C	e-Health Maturity Levels	0	0	0	4	4	1	1.50	1.97
	Interoperability Layers	0	0	2	0	7	0	1.50	2.81
	Interoperability Standards	0	0	1	1	7	0	1.50	2.74
Data Integrity Theme									
C1	Data Integrity Mechanism	0	0	2	2	5	0	1.50	1.97
C2	Data Integrity Governance	0	0	1	2	6	0	1.50	2.35
C3	Data Integrity Requirements	0	0	0	2	6	1	1.50	2.14
C4	Data Integrity Training	0	0	0	2	7	0	1.50	2.57
C5	Data Safeguard	0	0	1	5	3	0	1.50	1.89
C6	Human Error Challenges	0	0	1	0	8	0	1.50	2.93
C7	Computerised System Challenges	0	0	1	1	7	0	1.50	2.50

Figure 5.11: Results of Constructs for Iteration 2

asked to share their insights. The models' constructs were evaluated by the percentage of "important", particularly the "very important".

The participants agreed that the model's strength lies in the fact that it is based on existing literature. It focuses, incorporates, or acknowledges all the components that should be considered. One participant further stated that the model provides a straightforward guide for implementing data integrity in Hospital Information Systems.

Validity of Evaluation Results

Experts assessed the models' validity and determined whether it addressed a real healthcare need. One of the experts indicated that "There is indeed a need for a South African Data Integrity Model". The feedback suggested that the use of the model is appropriate in healthcare to address pressing healthcare needs. In addition to the experts' acknowledgement of the model's importance in the healthcare environment, another expert stated that the model "acknowledged other challenges, specifically the construct C4 - Data Integrity Training, which plays a valuable role in driving the entire model". The reason for this is that, in their interactions with healthcare workers, "it was evident that there was a need for more training to equip them with regard to IT processes as there is usually a misalignment between government objectives and what is deployed at lower levels".

Utility Evaluation Results

The Data Integrity Model needed to be evaluated for its utility in healthcare environments. Experts were divided as to whether the model would produce useful results. According to one expert, the model covers most of the important aspects, but it is very theoretical. As another expert pointed out, "the model is comprehensive and usable but has not been tested or implemented, so this is part of what makes it less useful".

Quality Evaluation Results

Experts were consulted to determine whether the constructs were easy to comprehend. The model was viewed as simple and easy to follow. It confirmed that the constructs were presented clearly, and that the model's purpose was clear.

Efficiency Evaluation Results

Lastly, experts were asked to provide their thoughts on the model's efficiency. This was to determine whether the model incorporates the components needed for developing the Data Integrity Model and whether it appropriately categorises the concepts. It was generally agreed among the experts that the model included the most appropriate components. An expert who supported this statement added that "the model incorporates all the necessary elements that need to be considered and how each link with one another to show dependence and importance". Figure 5.12 presents evaluation results for Iteration 1 and Figure 5.13 presents evaluation results for Iteration 2.

5.7.1 Hospital Information Systems Theme

This theme is informed by Chapter 3, which details Health Information Systems and describes the different levels of Health Information Systems and the importance of understanding the different e-Health systems' maturity levels.

Analysis of Relevance of the Model

Cut-off for consensues = 60%

Valilty					
Statement	Disagree	Undecided	Agree	No	Consensus
Does the model address a real problem/need?	0%	0%	100%	0%	Yes
Is it compatible with existing data integrity research or practices?	10%	0%	90%	0%	Yes
Is the application in the South African context?	20%	10%	70%	0%	Yes
Would the data integrity model be applicable in similar environments?	20%	10%	70%	0%	Yes
Utility					
Any missing elements or components?	50%	0%	50%	0%	No
Will the application of the model produce useful results if used in your context?	10%	20%	70%	0%	Yes
Quality					
Is the model easy to understand?	30%	10%	60%	0%	Yes
Efficiency					
Does it incorporate the components needed to develop a model?	10%	20%	70%	0%	Yes
Does it appropriately categorise the concepts included?	10%	20%	60%	10%	Yes

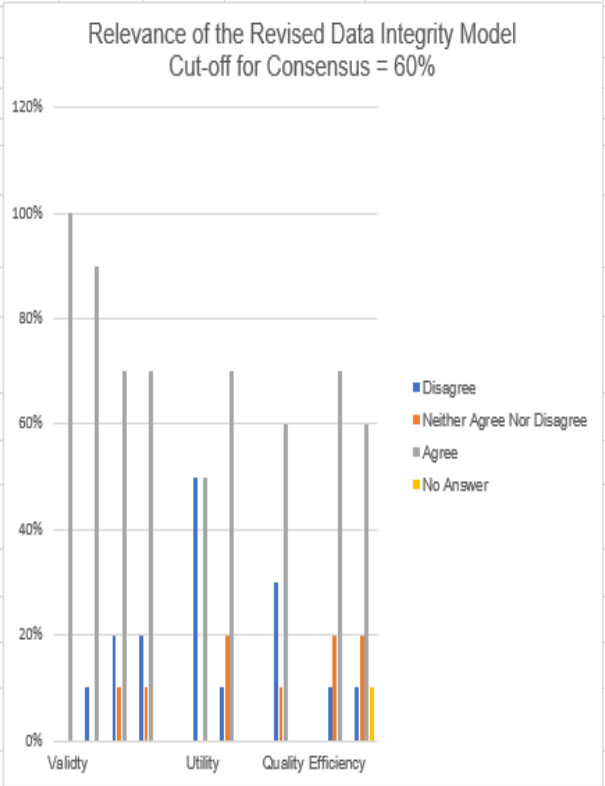

Figure 5.12: Analysis of the Results for Iteration 1

5.7.1.1 Level of HIS and e-Health Maturity Levels

The results in Iteration 1 revealed that 20% of the respondents felt that the Level of HIS construct is very important, as presented in Figure 5.14. The results indicated that there was a need to revisit the construct to define and align it with the objectives of the model. In Iteration 2, the results were slightly different. Construct C was defined as e-Health Maturity Levels. 40% of participants in this iteration believed that e-Health Maturity Levels were very important. Additionally, the construct included Interoperability Layers and Standards of Interoperability. The results reveal that 70% of respondents believe that Interoperability Layers are very important and 60% believe Standards of Interoperability are equally important, as illustrated in Figure 5.15.

Analysis of Relevancy of the Model					
Cut-off for Consensus = 60%					
Statement	**Disagree**	**Undecided**	**Agree**	**No Answer**	**Consensus**
Validy					
The model addresses a real need/problem	0%	10%	80%	0%	Yes
The model is adaptable to existing data integrity research or practices	0%	10%	80%	0%	Yes
The model applies to the health domain in South Africa	10%	0%	80%	0%	Yes
The model is applicable to similar healthcare systems	10%	10%	70%	0%	Yes
Utility					
Any missing elements or components?	50%	20%	20%	0%	No
The application of the mofel can improve the quality of healthcare data and service delivery	10%	0%	80%	0%	Yes
Quality					
The model is easy to understand	10%	0%	80%	0%	Yes
Efficiency					
The model incorporates the componets needed to develop the data integrity model	10%	0%	80%	0%	Yes
The model includes approprately categorsed concepts	10%	0%	80%	0%	Yes

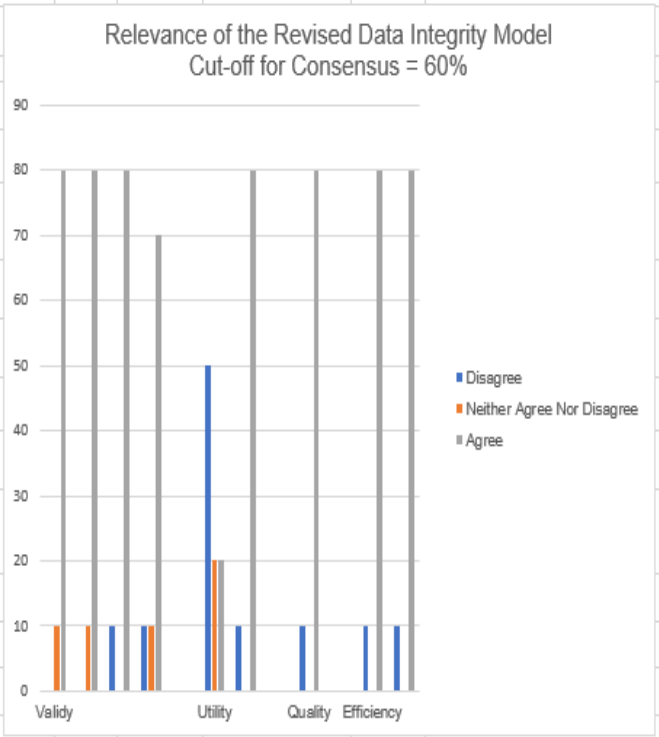

Figure 5.13: Analysis of Results for Iteration 2

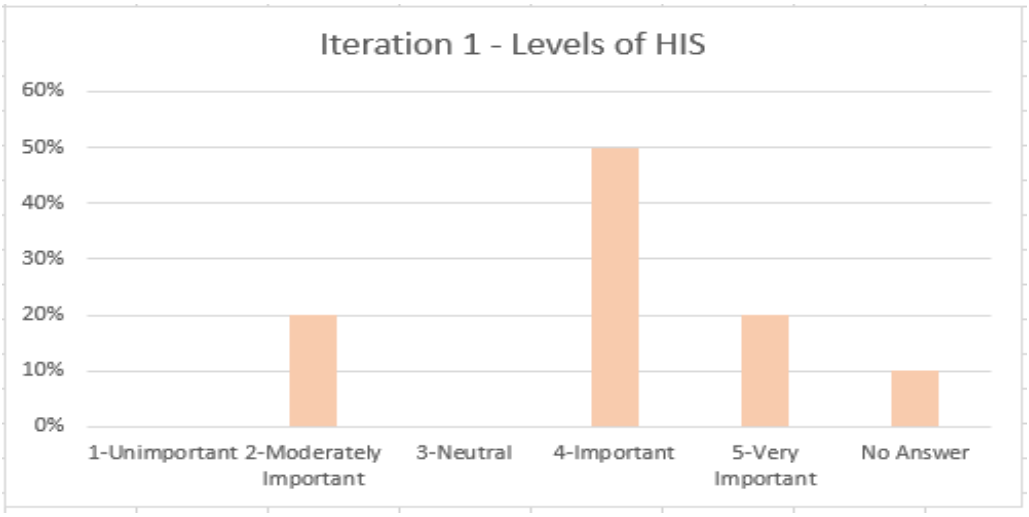

Figure 5:14: Evaluation Results of the Level of HIS Constructs in Iteration 1

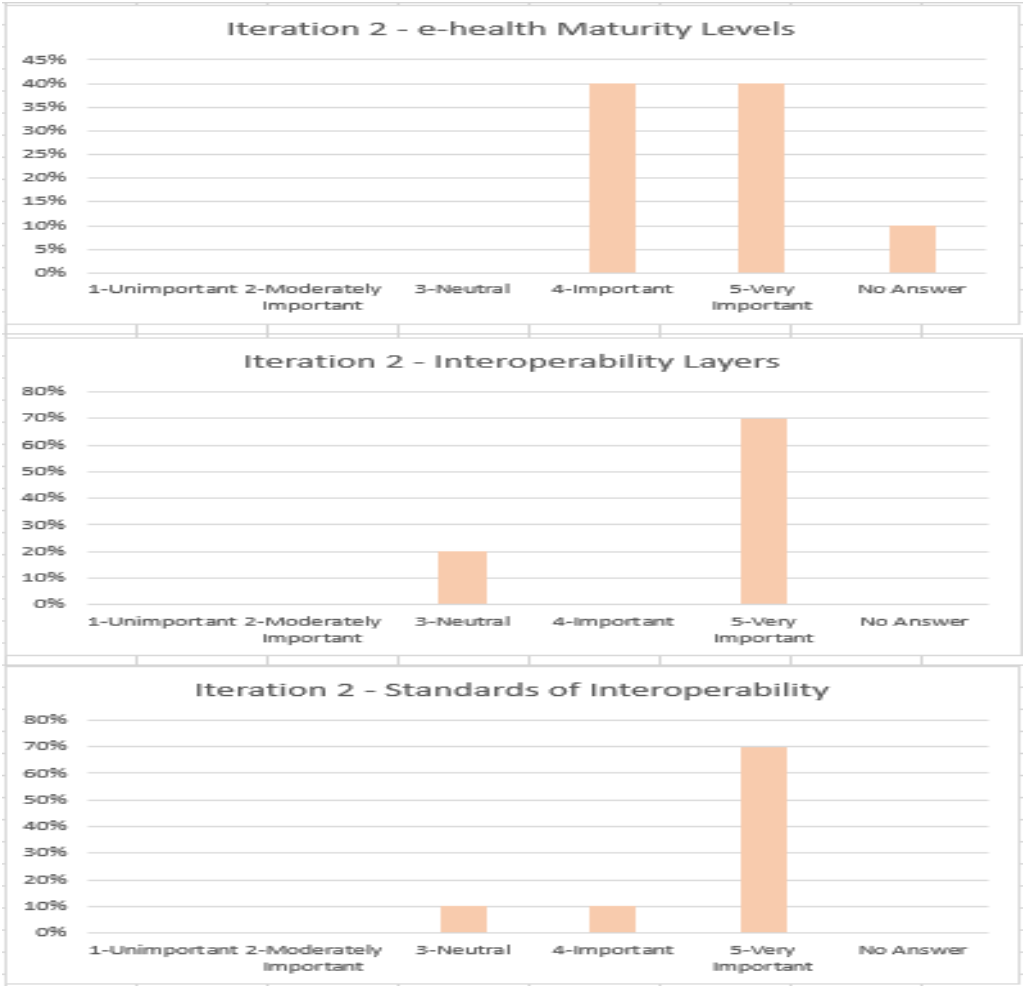

Figure 5:15: Evaluation Results of e-Health Maturity Levels, Interoperability Layers, and Standards of Interoperability

5.7.2 Data Integrity Theme

This theme is derived from Chapter 4, which discusses how data integrity supports Hospital Information Systems. The chapter discusses data integrity issues and the factors that contribute to them, namely, implementation of data integrity models at different healthcare levels and the elements that should be in such a model.

5.7.2.1 Data Integrity Mechanism

The response to the Data Integrity Mechanism construct revealed that, in Iteration 1, 60% of the participants felt that the construct was very important. In Iteration 2, 50% of the participants felt that it was very important, as depicted in Figure 5.16.

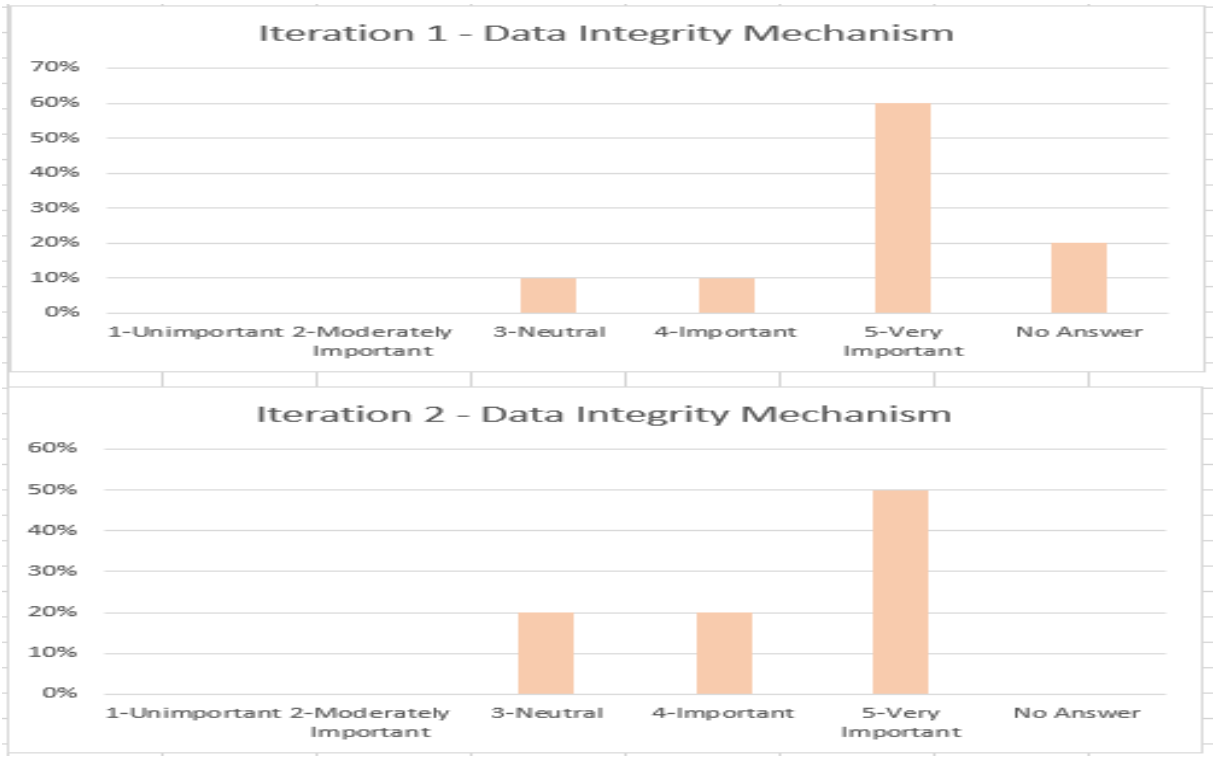

Figure 5.16: Evaluation Results of the Data Integrity Mechanism Construct

5.7.2.2 Data Integrity Governance

Figure 5.17 shows that 70% of participants felt the Data Integrity Governance construct was very important in Iteration 1. In Iteration 2, 60% of participants felt that it was very important.

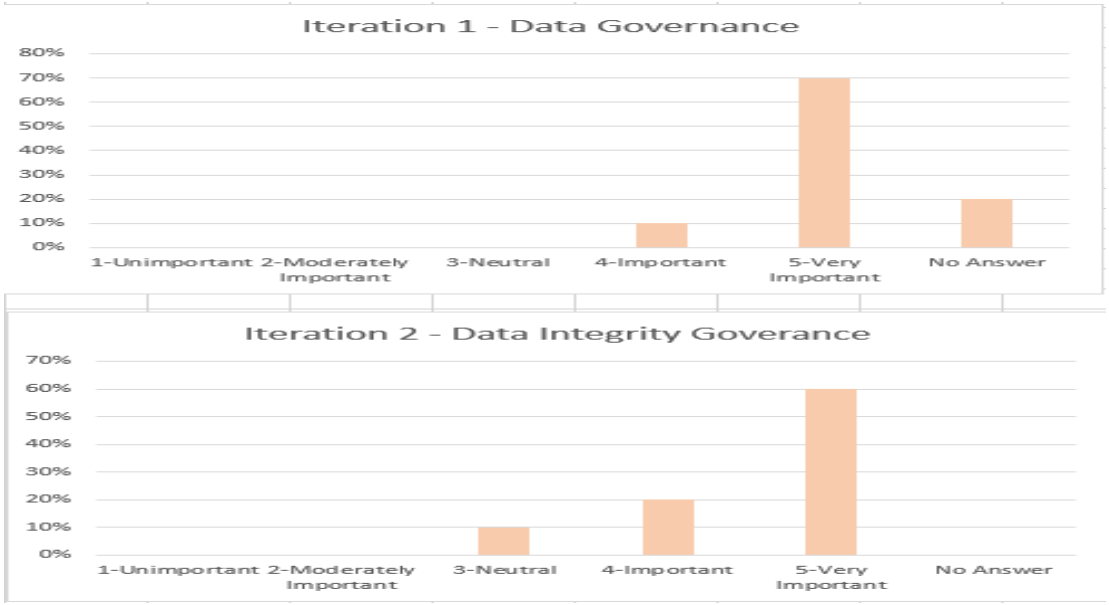

Figure 5.17: Evaluation Results for the Data Integrity Governance Construct

5.7.2.3 Data Integrity Requirements

The Data Integrity Requirements construct revealed that, in Iteration 1, 50% of the participants felt that the construct was very important. In Iteration 2, 60% of the participants felt that it was very important as presented in Figure 5.18.

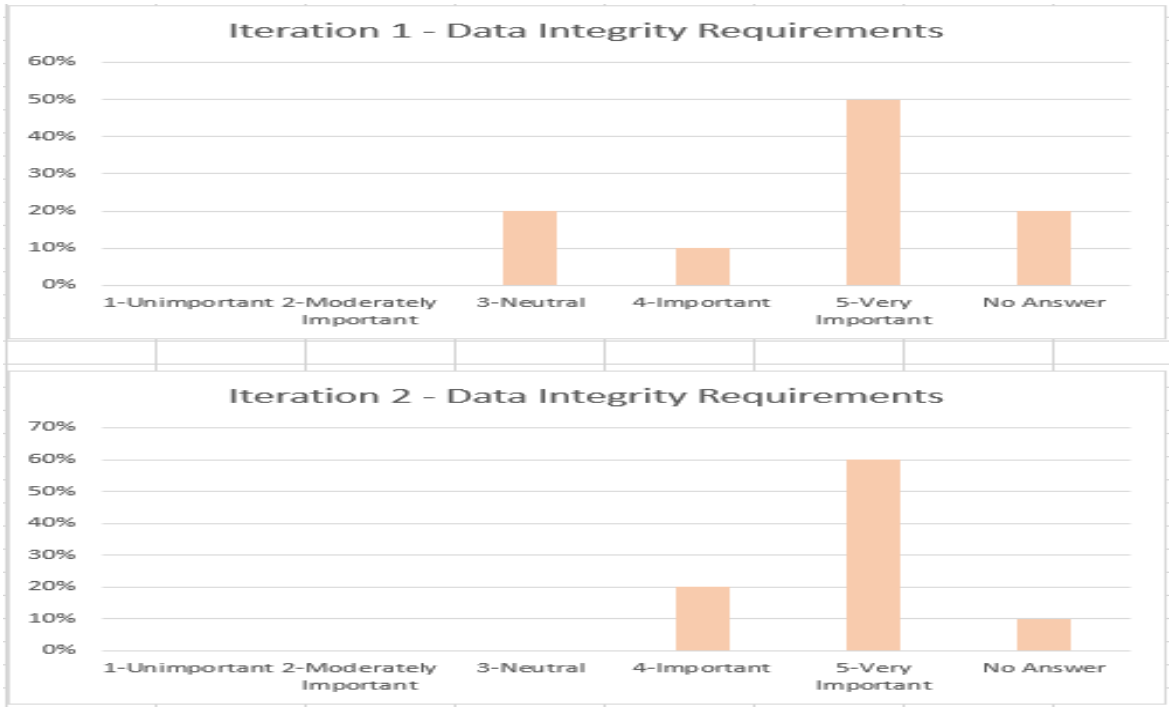

Figure 5.18: Evaluation Results for Data Integrity Requirements Construct

5.7.2.4 Data Integrity Training

The Data Integrity Training construct in Iteration 1 revealed 40% of the participants felt that the construct was very important. In Iteration 2, the response increased as 70% of the participants felt that it was very important as presented in Figure 5.19.

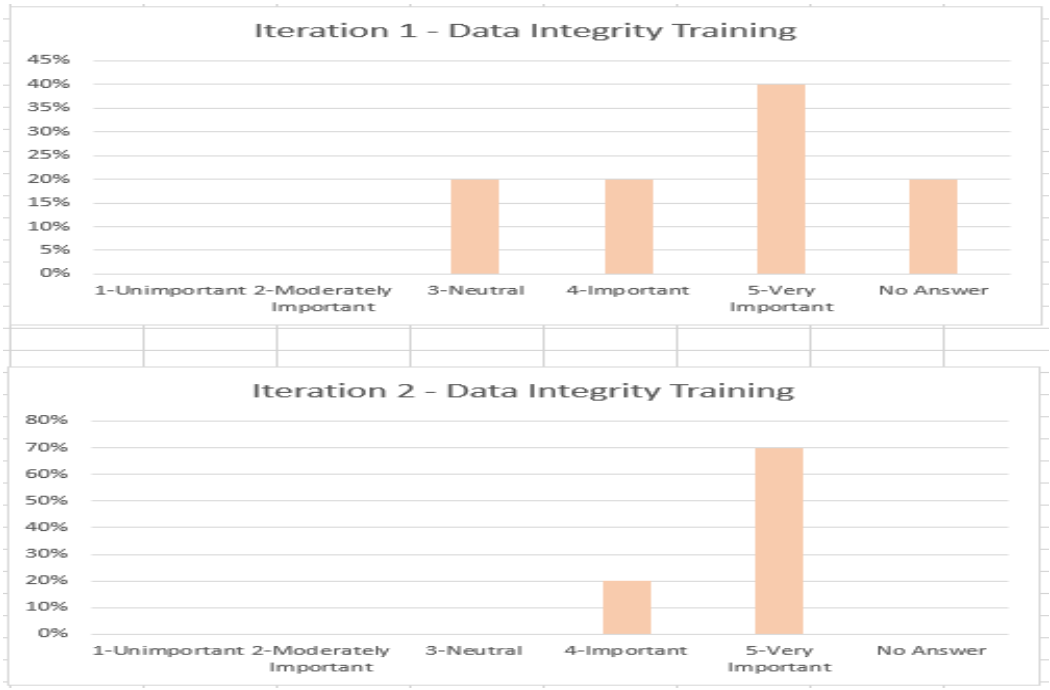

Figure 5.19: Evaluation Results for the Data Integrity Training Construct

5.7.2.5 Data Safeguard

The Data Safeguard construct in Iteration 1 revealed that 50% of the participants felt that the construct was very important. In Iteration 2, the response decreased as 30% of the participants felt that it was very important. This is represented in Figure 5.20.

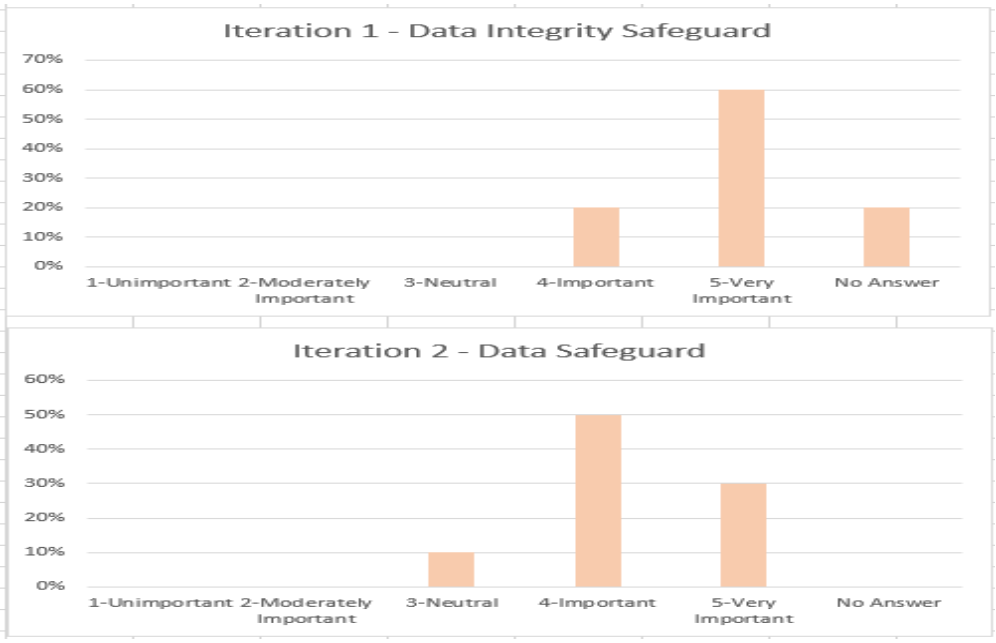

Figure 5.20: Evaluation Results for the Data Integrity Safeguard Construct

5.7.2.6 Human Error Challenges

Iteration 1 revealed that 50% of the participants felt that the Human Error Challenges construct was very important. In Iteration 2, the response increased as 80% of the participants felt that it was very important. The results are shown in Figure 5.21.

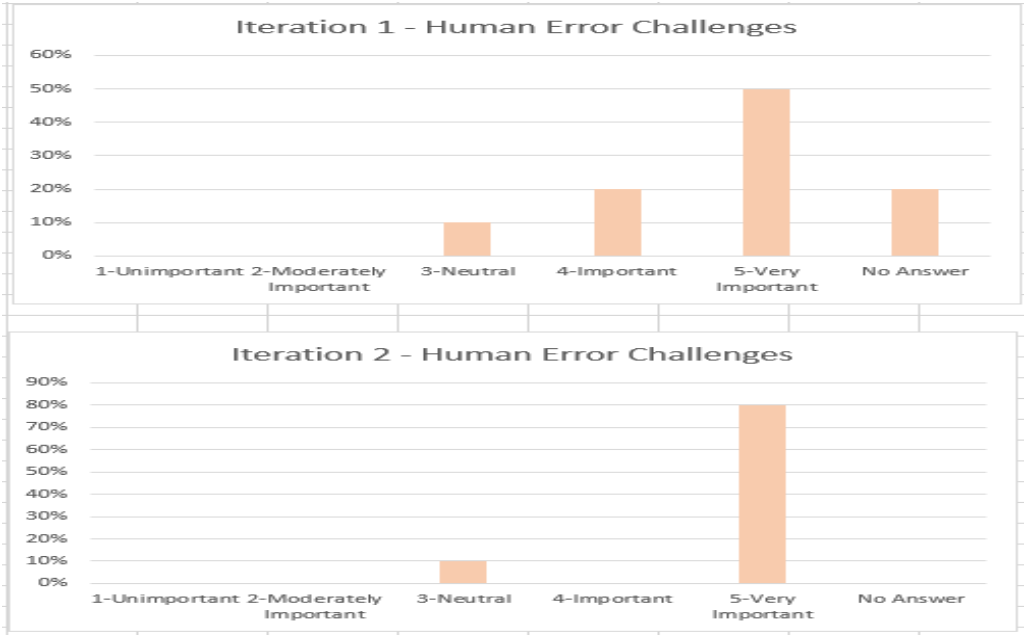

Figure 5.21: Evaluation Results for the Human Error Challenges Construct

5.7.2.7 Computerised System Challenges

Iteration 1 revealed that 50% of the participants felt that the Computerised System Challenges construct was very important. In Iteration 2, the response revealed that 70% of the participants felt that it was very important. Figure 5.22 presents the evaluation results.

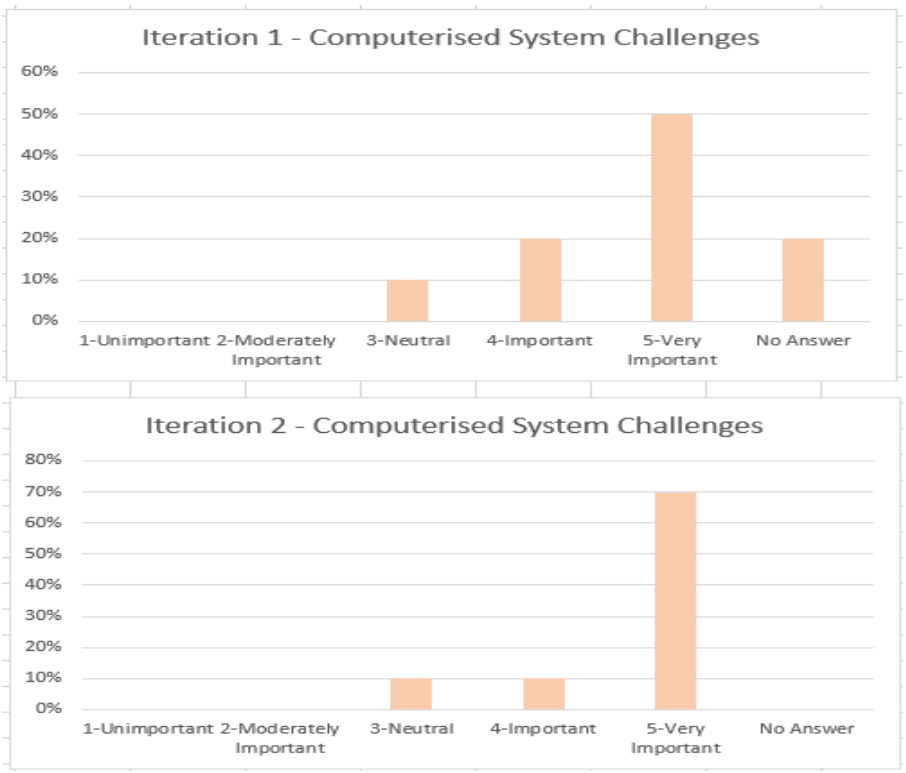

Figure 5.22: Evaluation Results for the Computerised System Challenges Construct

The constructs that achieved consensus after Iteration 1 included *Data Governance* (70%), *Data Integrity Mechanism* (60%), and *Data Safeguard* (60%) while those that did not achieve consensus with a percentage below 60% included *Level of HIS* (20%), *Data Integrity Training* (40%), *Data Integrity Requirements* (50%), *Human Error Challenges* (50%) and *Computerised Systems Challenges* (50%). Figure 5.23 shows the results.

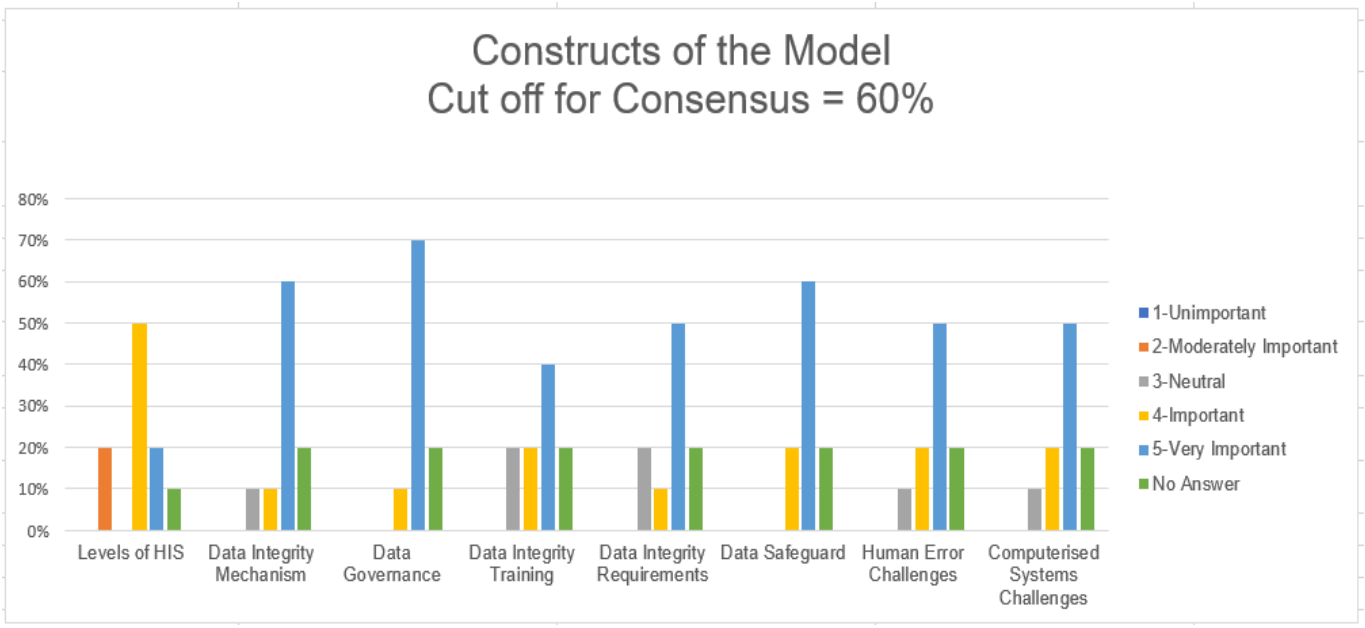

Figure 5.23: Consensus of the Constructs for the Initial Data Integrity Model

The constructs that achieved consensus after Iteration 2 included *Human Error Challenges* (80%), *Computerised Systems Challenge* (70%), *Interoperability Layers* (70%), *Standards of Interoperability* (70%), *Data Integrity Training* (70%), *Data Governance* (60%), and *Data Integrity Requirements* (60%), while those that did not achieve consensus with a percentage below 60% included *e-Health Maturity Levels* (40%), *Data Integrity Mechanism* (50%), and *Data Safeguard* (30). The results are summarised in Figure 5.24.

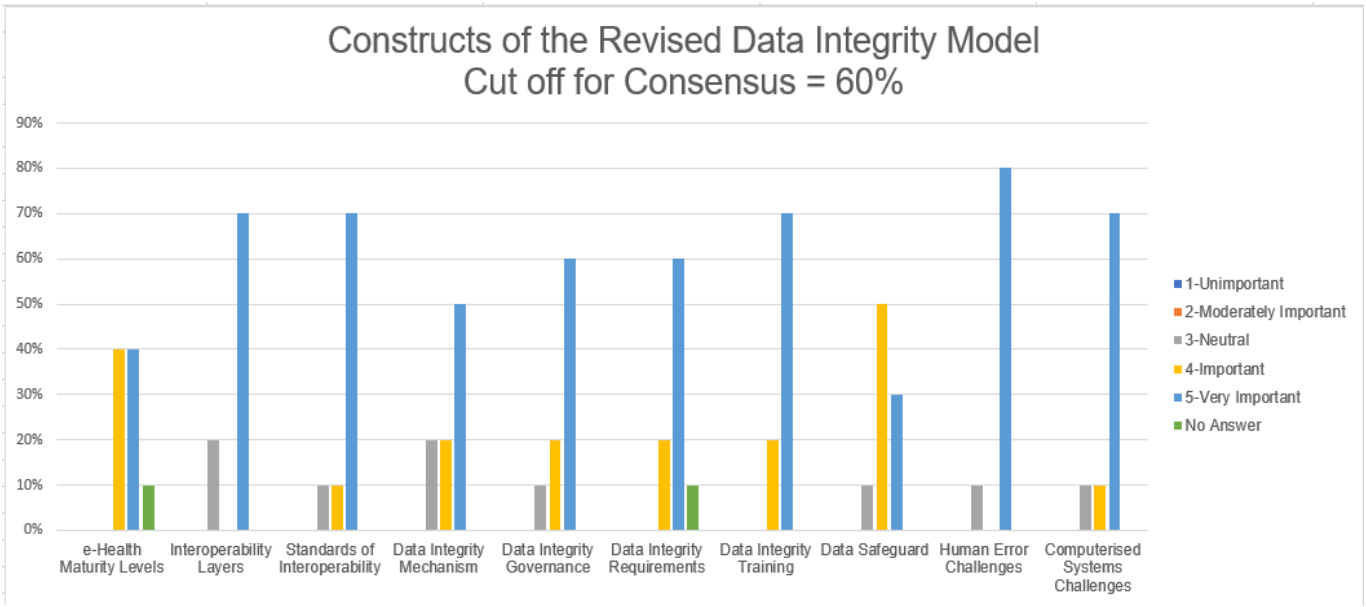

Figure 5.24: Consensus of the Constructs for the Revised Data Integrity Model

5.7.3 Data Integrity Model Development Based on Evaluation Results

The expert review process was conducted specifically to obtain feedback that would assist in the development and evaluation of the Data Integrity Model. The researcher reflected on the results obtained from the evaluation activity in this section. In turn, the results were discussed and incorporated into the final Data Integrity Model. Feedback documented in Sections 5.7.1 and 5.7.2 supported the expert's positive evaluation of the relevance of the Data Integrity Model. The proposed model was generally accepted by respondents. Experts assessed and deemed the constructs relevant. Using feedback on the constructs and how they were used, the model was revised and presented in a modified design as shown in Figure 5.9.

According to comments from Iteration 1, there was no obvious connection between Data Integrity and Data Security. Additionally, the model fails to recognise the importance of interoperability within border health systems, which is paramount to the selection and evaluation of the efficacy of HIS. For some experts, the construct C - *Level of HIS* was confusing and ambiguous. It was unclear whether the construct was part of an IT maturity model or if it refers to the different levels at which South African Health Information Systems operate. The construct was redefined and presented as C1 - *e-Health Maturity Levels* for Iteration 2. Construct C2 – *Data Governance* needed to be assessed in terms of regulations defined by governments as part of the law. Thus, the link to the Data Integrity Model was not immediately clear. Essentially, the constructs needed defining and refining based on the requirements to function and inter-relate with other constructs as per the initial model.

Comments from Iteration 2 were based on the refined model that incorporated feedback from Iteration 1. The experts deemed the revised model as easy to follow and understand. The model's strength lies therein that it addresses a real need in South Africa and incorporates all relevant aspects that such a model needs to be functional and appropriate. It was suggested to simplify the constructs as many of them overlap, such as construct C2 – *Data Governance*, which typically includes construct C1 - *Data Integrity Mechanisms* and construct C5 – *Data Safeguards*. *Interoperability Layers* are part of *Standards of Interoperability*, and construct C5 – *Human Error Challenges* and construct C6 – *Computerised Systems* are part of construct C4 – *Data Integrity Training*. In the end, constructs C - *e-Health Maturity*

Levels and C5 - *Data Safeguards* were removed as they did not meet the percentage consensus level.

The feedback provided was considered relevant for the research study and for the refinement of the Data Integrity Model. There was, however, consensus that the proposed model was purely theoretical and had not been tested or implemented. The application of the proposed model was not the focus of the research. However, the proposed model could be tested in the actual world by putting into practice a prototype based on it. Upon evaluation of the proposed model, the respondents concluded that it focused on significant phenomena. This was appropriate for its setting and provided the foundation for the Data Integrity Model shown in Figure 5.25.

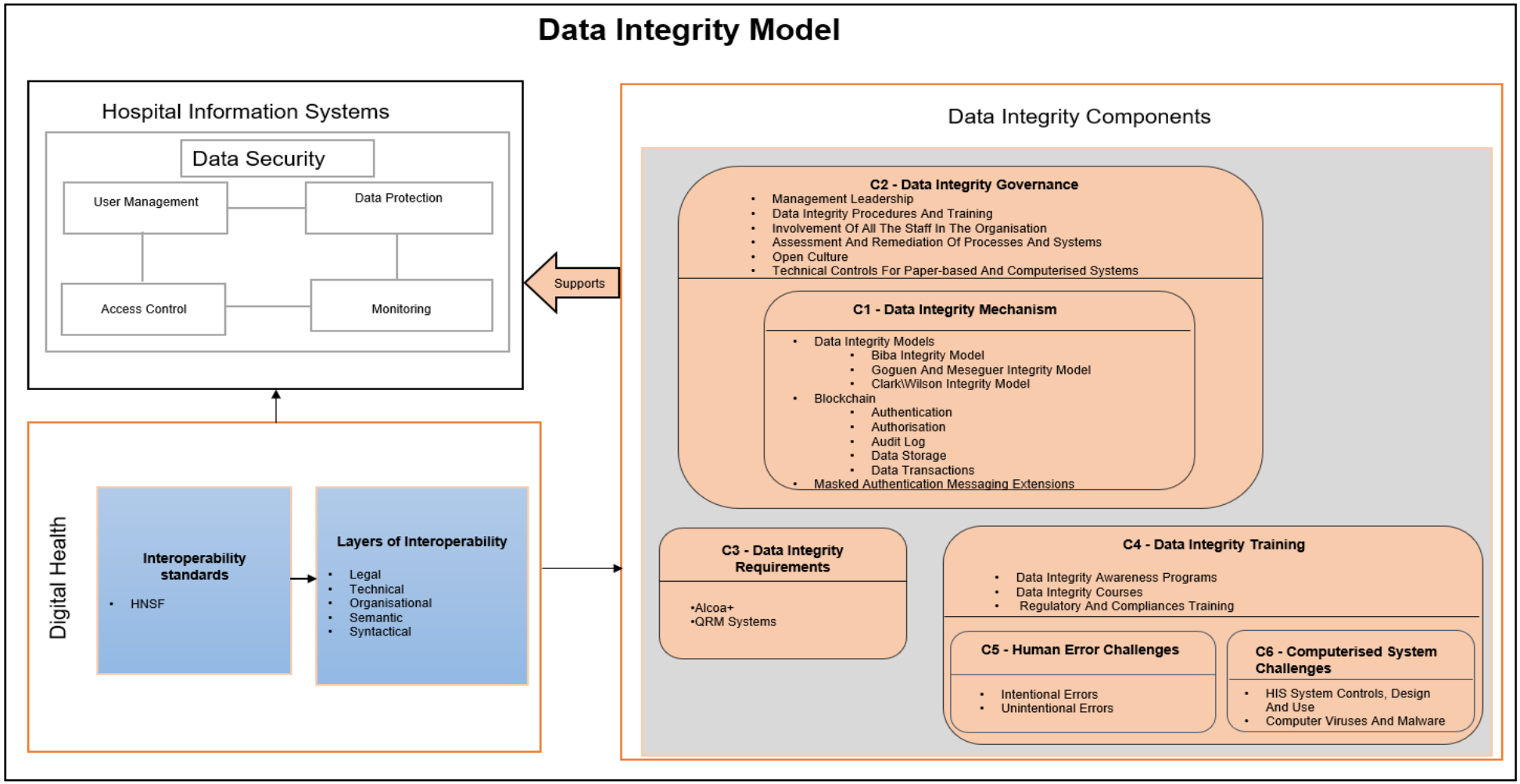

Figure 5.25: Data Integrity Model

5.8 Research Findings in the South African Healthcare Context

Based on assessments conducted by CSIR in 2015, several individual systems were developed to address different aspects of the health system, but a more integrated platform and architecture are needed to make them interoperable. Furthermore, cybersecurity and inadequate human resources were some of the key challenges identified during the previous eHealth Strategy review (NDoH, 2019a). Overall, the research results reveal alignment with some of the objectives outlined in the National Digital Health Strategy for South Africa, 2019-2024, which are to reinforce digital health governance structures and develop robust integrated platforms to support systems development (NDoH, 2019a).

The reinforcement of digital health standards and interoperability in HIS provide a platform for an integrated information architecture that allows for data sharing across health systems and services that is effective and safe. The findings demonstrate that constructs C5 - *Human Error Challenges* and C6 - *Computerised System Challenges* are largely addressed by construct C4 - *Data Integrity Training*. The literature suggests that skills development is necessary. Globally, digital health skills are in demand, and resources are scarce in South Africa's public and private sectors (NDoH, 2019a). The public service currently provides training in an ad hoc, fragmented, and uncoordinated manner, with little integration between training and business strategies. The development of digital health human capital and in-service digital health training for the health workforce will address the existing workforce while establishing new cadres of information health workers through the use of new tools and approaches (NDoH, 2019a).

In HIS, a data security policy should be adopted concurrently with data integrity governance. The results demonstrate that construct C2 - *Data Integrity Governance* addresses the risks associated with maintaining data integrity. Preventive measures (C1 - *Data Integrity Mechanism*) guard against harm to people and systems. In addition to addressing the risks associated with data security, cybersecurity, and cybercrime, a good data governance strategy should also ensure that a wide range of data will be used to the fullest extent possible in terms of both economic and societal benefit (Macmillan, 2020). South Africa has stringent regulations, notably the POPI

Act, which contains a sophisticated data protection statute. The development of a data governance framework for South Africa, however, necessitates a review and strengthening of governance and oversight processes (NDoH, 2019a).

5.9 Summary

This chapter focused on defining the process by which the initial model was developed. The theoretical foundation for this research was reflected in Chapters 2 and 3. A scoping review and a sample of the core literature were used to define the constructs of the initial model. To validate the concepts addressed in the literature that was reviewed for the theoretical foundation of the research, the researcher used NVivo during the scoping review process. Following the identification of the constructs, the researcher provided a synthesised view of the model and how it can be viewed holistically. Finally, the chapter concluded with a visual representation of the Data Integrity Model.

6 CHAPTER 6: REFLECTIONS, RECOMMENDATIONS AND CONCLUSION

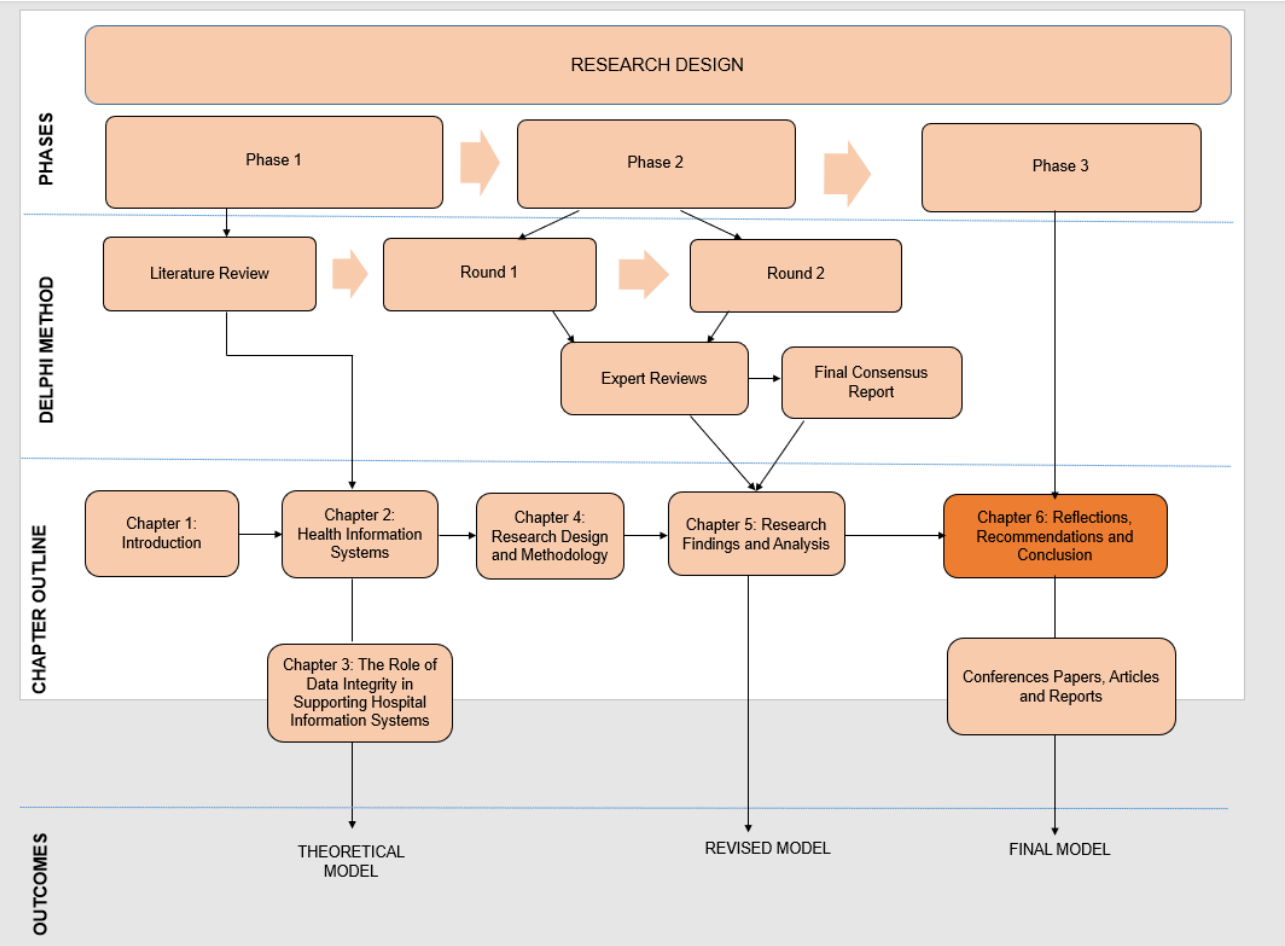

Figure 6.1: Chapter Layout of Research Study

6.1 Introduction

With changing health needs and risks to data integrity, Hospital Information Systems need to be improved to ensure efficient healthcare. An important aspect of data quality is data integrity. Since organisations rely on their data to make decisions, HIS must provide accurate data to decision-makers. This research study was conducted to develop a Data Integrity Model to assist in the development of the NHI in South Africa and address the need for improved healthcare. The Data Integrity Model supports Hospital Information Systems activities and ensures patient privacy.

Presented in Chapter 6 are reflections, recommendations, limitations, and conclusions based on the study objectives and study results. The chapter provided an overview of the research undertaken to design the model. The research study was guided by objectives and research questions. The remainder of the chapter discussed the method used to develop the Data Integrity Model. The limitations of the study were then presented, along with future study recommendations.

6.2 Overview of the Research

This exploratory Delphi study identified and evaluated the components that constitute a Data Integrity Model. The Data Integrity Model would serve as a basis for future data integrity interventions for Hospital Information Systems in South Africa. Using an exploratory Delphi technique provided a forum for discussing this phenomenon, which otherwise might not have been possible due to logistics, cost, and time constraints. As a result of the shared experience of this phenomenon, participants' perceptions were collected, analysed, and interpreted. This study is the first to employ an exploratory Delphi technique to solicit expert input in developing a Data Integrity Model.

6.2.1 Main Research Question (MRQ)

This study's main research question was: What constitutes the components of a model for achieving data integrity for Hospital Information Systems, such as the health patient registration system (HPRS), in South Africa? The following sub-research questions were formulated to further explore the main research question. These elements were addressed in Chapters 3 and 4, forming the theoretical basis for the Data Integrity Model.

- SRQ 1: How should digital Health Information Systems align with interoperability practices?

The purpose of this question, addressed in Chapter 2 of this thesis, examined the context of the various Health Information Systems in use across South Africa. The purpose advocated for the value that can be added by aligning interoperability. This was accomplished by defining the terms "Health Information Systems" and "Hospital Information Systems" within the context of this study. An investigation of the differences between the maturity levels at which interoperability can occur was presented, followed by a discussion of how digital health is implemented. A view of the evolution of Hospital Information Systems and fragmentation across different Health Information Systems in different provinces of South Africa was also presented.

- SRQ 2: What role does data integrity play in Hospital Information Systems?

This question explores the theme of data integrity in Chapter 3. Further addressing SRQ 1, this chapter examined how data integrity supports Hospital Information Systems. It examined the risk imposed by data integrity in the healthcare industry, the data integrity issues faced, and data integrity mechanisms. By identifying data integrity issues, the research identified data integrity elements that the government, health institutions, and other stakeholders need to include in an overall data integrity strategy. Consequently, current policies and procedures were reviewed and updated. It was this background that informed the construct "data integrity governance". Further recommendations were made by expert reviews, which were incorporated into the final Data Integrity model. This suggested the integration of the construct Data Integrity Mechanism, as it was a duplication that could be included in the Data Integrity Governance construct.

- SRQ 3: What elements constitute a Data Integrity Model to support Hospital Information Systems?

The purpose of this question (SRQ3) is to examine the literature regarding key data integrity elements that can be positioned to support Hospital Information Systems from various existing models or frameworks. In the chapter, the elements of the theoretical model were identified. Based on the experts' recommendations, the final components of the Data Integrity Model are Data Integrity Governance, Data Integrity Requirements, and Data Integrity Training.

These chapters analysed the various research themes to determine how data integrity can support Hospital Information Systems. These considerations informed the theoretical basis for the study.

6.3 Research Contribution

The purpose of this research was to develop a model to guide professionals in healthcare environments, academia, and government toward achieving data integrity in Hospital Information Systems.

6.3.1 Methodological / Theoretical Contribution

The theoretical contribution is quite novel and emerged as a result of the regulations related to the COVID-19 pandemic. At first, the researcher intended to develop the model using the Design Science Research Methodology (DSRM) but, due to the COVID-19 regulations, the researcher was unable to access health professionals in the various regions. Consequently, the researcher chose to use the Delphi technique, which was a new approach that the researcher had to learn. The research study combined the qualitative paradigm with the Delphi technique. Round 1 of the Delphi technique focused primarily on developing the construct of the initial model by reviewing literature related to Data Integrity and Hospital Information Systems (across Chapters 2 and 3. A design of the initial model was presented as part of the output. Round 2 focused primarily on developing the revised model in preparation for the final model, following the review and evaluation of expert feedback. In the end, it enabled the development of the final model without using another methodology. It was sufficient and had enough rigour and relevance to assist in developing the Data Integrity Model (Chapter 5).

6.3.2 Practical Contribution

The practical contribution of this work is in the first place rooted in the potential future practical application of this model. The model can be used to gain a deeper understanding of data integrity. There are well-defined health policies and regulations in South Africa, but implementation is still lagging. The research study suggests that policies already in existence should be furthered, as there is a need for improved implementation of their use. Health professionals, academics, practitioners, and NGOs can use the model to write their own data integrity policies in South Africa.

6.4 Limitations

This research study has the following limitations:

- As a qualitative exploratory Delphi study, the empirical contributions were based solely on expert opinions. The Delphi technique has inherent limitations and biases, particularly as participants move toward a common opinion with each subsequent iteration.
- There were only a few experts consulted on the subject matter, resulting in limited data sets.
- The initial sample of experts participated in each iteration but input from one expert was not obtained in the second iteration.
- The Delphi technique does not allow for in-depth analysis of opinions surrounding each item, and while informed conclusions are made about the reasons for or against their inclusion, the rationale, therefore, is only probed in a limited way.

6.5 Recommendations

Establish data integrity governance that includes policies and procedures related to the creation, editing, and removal of patient health information documents from paper-based and computer-based IS in healthcare facilities. The data integrity governance program should inform healthcare workers on how data integrity issues and risks can be identified proactively, eliminating medical safety issues and poor medical decision-making. Data integrity governance should also include policies and procedures that outline the implementation of data integrity mechanisms to enforce and ensure the data integrity of patient health information.

Healthcare worker training must be tailored to meet user needs, regardless of their background. It should strengthen users' confidence and skills when using electronic systems. Data management protocols must be strictly followed, and policies must be clearly communicated to users. Users must also be educated on data integrity, both in terms of what it entails and how its absence affects healthcare data. This will ensure that the South African public healthcare sector has access to systems and related policies, as well as the ability to fully leverage them for improved service delivery.

A QRM system should be in place to ensure compliance with data integrity principles. Healthcare workers should analyse, mitigate, and communicate data integrity risks in

accordance with QRM practices. The latter requires data to adhere to ALCOA+ to ensure the quality of patient health information in healthcare information systems.

6.6 Personal Reflections

My personal motivation to engage with the overall research theme is the work environment in which I currently work. The division in which I work focuses on health-related projects. As the stream lead for the Support and Maintenance of two national health projects, I have had the opportunity to interact with healthcare facilities that have implemented or are implementing hospital information systems. Human errors as well as computerised systems pose challenges to these healthcare facilities daily. A motivation arose from this to understand these challenges faced and how they can be addressed to assist healthcare workers and professionals in their daily tasks to improve the quality of healthcare.

This research has not been without challenges. To begin with, the study's initial methodology was to develop a model using the DRSM method. This changed when the COVID-19 pandemic imposed restrictions nationwide. Because of this, I was not able to access a number of healthcare facilities and could not gain greater insight into my research. Consequently, with the help of my supervisor, I had to adapt and think quickly. As agreed, the Delphi technique would become the primary method to collect qualitative data for this study, thereby changing the research methodology. To me, this was a completely different approach, and it was frustrating to have to start over. However, through the journey, I have learned the value of delving into the literature and thinking about each study and the implications of the methodology in the research. This expanded my thinking about the basis of what I'm developing to design the end product as a result. Being able to interact with and learn from experts expanded my understanding of healthcare. It also taught me to be resilient when facing obstacles.

Lastly, the discontinuation of my previous qualification caused sleepless nights and stress for both my supervisor and me, as she fought hard for the qualification (MTech: Information Technology) to be migrated to another qualification (MSc in Computing) to complete this research. I have also gained valuable experience through interacting with my two supervisors, who have shared a plethora of information from both industry and academia. My research and overall research progress were made possible by this

diverse skill set. As I reflect upon the study, the theoretical contribution made, the method used, and my personal development, I am satisfied.

6.7 Conclusion

Globally, healthcare organisations are required to maintain data integrity. Both paper-based and electronic data are equally vulnerable to data integrity risks. It can result from inadequate systematic control of data management systems owing to human error, or from deliberately concealed, or deceptive data. Senior management must promote a culture of quality and put in place the necessary organisational and technical controls to maintain data integrity. Additionally, health institutions require the involvement and commitment of all employees and stakeholders.

The research study aimed to develop a model that could be used to guide the development of data integrity practices in Hospital Information Systems. This was accomplished by using the Delphi technique and applied in the data collection process. The study was then carried out on two central themes: Data Integrity and Hospital Information Systems. A theoretical foundation for the model was developed from the themes that were identified in Phase 1. Ascertaining the constructs and evaluating the foundation of the model were also critical. Thus, expert reviews were conducted to identify potential areas of improvement and to determine if the model addressed a real need in the healthcare environment. Research insights led to the development of the final Data Integrity Model, which integrated the two research themes to facilitate future data integrity interventions. Chapter 6 provided a summary of the study and its findings. Here, the researcher explained the study's purpose and focus, and the conclusions reached after analysing the data and utilising the researchers' experience. Lastly, the researcher offered suggestions for future research.

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Annexure A – Ethical Approval

UNISA university of south africa

UNISA-CAES HEALTH RESEARCH ETHICS COMMITTEE

Date: 03/12/2021

Dear Ms Thulare

NHREC Registration # : REC-170616-051
REC Reference # : 2021/CAES_HREC/163
Name : Ms T Thulare
Student #: 43614000

Decision: Ethics Approval from 02/12/2021 to 30/11/2024

Researcher(s): Ms T Thulare
tthulare@csir.co.za; 012-842-7260

Supervisor (s): Prof M Herselman
mherselman@csir.co.za; 012-841-3081

Prof A Botha
abotha@csir.co.za; 012-841-3265

Working title of research:

A model towards achieving data integrity in hospital information systems for South Africa

Qualification: MTech Information Technology

Thank you for the application for research ethics clearance by the Unisa-CAES Health Research Ethics Committee for the above mentioned research. Ethics approval is granted for three years, **subject to further clarification, and submission of the relevant permission letter and yearly progress reports. Failure to submit the progress report will lead to withdrawal of the ethics clearance until the report has been submitted.**

The researcher is cautioned to adhere to the Unisa protocols for research during Covid-19.

Due date for progress report: 30 November 2022

The progress report is available on the college ethics webpage:
https://w2.unisa.ac.za/www.unisa.ac.za/sites/corporate/default/Colleges/Agriculture-%26-Environmental-Sciences/Research/Research-Ethics.html

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Annexure B – Informed Consent

UNISA university of south africa

Ethical clearance #: 2021/CAES_HREC/163

Research permission #:

COVER LETTER TO AN ONLINE ANONYMOUS WEB-BASED SURVEY

Dear Prospective participant,

You are invited to participate in a survey conducted by Tumiso Thulare under the supervision of Marlien Herselman, a Chief Researcher at CSIR and adjunct Professor in the Department of Science, Engineering and Technology (School of Computing) towards an MTech: Information Technologiae at the University of South Africa.

The survey you have received has been designed to study data integrity practices in hospital information systems. You were selected to participate in this survey because of your expertise and knowledge in either data integrity, hospital information systems, information systems and hospital information systems development. You will not be eligible to complete the survey if you have not participated in ICT projects in Information System field and do not have a minimum of 10 years experiences in either one of the special fields mentioned before. By completing this survey, you agree that the information you provide may be used for research purposes, including dissemination through peer-reviewed publications and conference proceedings.

It is anticipated that the information we gain from this survey will help us to identify the components that constitute a data integrity model. You are, however, under no obligation to complete the survey and you can withdraw from the study prior to submitting the survey. The survey is developed to be anonymous, meaning that we will have no way of connecting the information that you provide to you personally. If you choose to participate in this survey it will take up no more than 1 hour of each 3 Delphi method rounds. You will not benefit from your participation as an individual, however, it is envisioned that the findings of this study will create a basis for future interventions on data integrity. We do not foresee that you will experience any negative consequences by completing the survey. The researcher(s) undertake to keep any information provided herein confidential, not to let it out of our possession and to report on the

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findings from the perspective of the participating group and not from the perspective of an individual.

The records will be kept for five years for audit purposes where after it will be permanently destroyed. Hard copies will be shredded, and electronic versions will be permanently deleted from the hard drive of the computer. You will not be reimbursed or receive any incentives for your participation in the survey.

The research was reviewed and approved by the UNISA-CAES Health Research Ethics Committee. The primary researcher, Tumiso Thulare, can be contacted during office hours at TThulare@csir.co.za or 0128427260. The study leader, Prof Marlien Herselman, can be contacted during office hours at MHerselman@csir.co.za or 0128413081. Should you have any questions regarding the ethical aspects of the study, you can contact the chairperson of the Committee, Prof MA Antwi, at 011-670-9391 or antwima@unisa.ac.za . Alternatively, you can report any serious unethical behaviour at the University's Toll Free Hotline 0800 86 96 93.

You are making a decision whether or not to participate by continuing to the next page. You are free to withdraw from the study at any time prior to clicking the send button.

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Annexure C – Sample of Scoping Reviews for Analysis

Main Literature Review Papers					
Paper Number	Author	Publication Year	Title	Key Findings	Research Theme
1	Timmerman, R	2011	A Model for Creating and Maintaining Document Data Integrity In an Enterprise Electronic Health Record.	Methods of electronic document creation and document management as well as important considerations in developing policies and procedures surrounding document management requires guidelines describing how these are to be used and when it is appropriate to use each method	Data Integrity
2	Dan Rode, M.B.A. & Chps, F	2012	Data Integrity in an Era of EHRs, HIEs, and HIPAA: A Health Information Management Perspective	The use of standards is absolutely necessary to maintain integrity and make the data useful. Organisations (providers and others) must establish a data governance strategy and process to ensure data integrity and conformity as well as to facilitate confidentiality	Data Integrity
3	Mchunu, N.N.	2012	Adequacy of healthcare information systems to support data quality in the public healthcare sector, in the Western Cape, South Africa	The public healthcare administration must enhance their training programs to cater for the needs of all users, regardless of their background. It needs to improve user skills and boast their confidence in using electronic systems. Adherence to data handling procedures must be strictly enforced, with policies thoroughly communicated to the users for improved service delivery in the public healthcare sector in South Africa.	Hospital Information Systems
4	Bowen, R. and Smith, A.R	2014	Developing an enterprisewide data strategy: data integrity is a critical concern for both the clinical and financial sides of the healthcare enterprise, ensuring both quality of care provided and accurate payment for services--and that also makes it a critical concern for the CFO.	The establishement of a information governance program in hosptials will ensure the quality and integrity of data.	Data Integrity
5	Botha, M., Botha, A. and Herselman, M	2014	Data quality challenges: A content analysis in the e-health domain	Provides a prioritised list of data quality challenges experienced by users of healthcare systems in South Africa, to guide future health data interventions and ensure future data quality in South Africa.	Hospital Information Systems
6	Masrom, M. and Rahimly, A.	2015	Overview of data security issues in hospital information systems.	Technical issues in Hospital Information System must have strong protection for the data and information derived from patient-specific health- elateddata that cover data acquisition, storage, retrieval and linkage activities, and analytic and reporting activities.	Hospital Information Systems
7	Mathebeni-Bokwe, P.	2015	Management of medical records for healthcare service delivery at the Victoria Public Hospital in the Eastern Cape Province: South Africa	The adoption of an elecontronic records management system by Victoria Hospital to efficiently and effectively promote easy accessbility, retrival of patient medical records and allow easy communication among the healthcare service institutions and healthcare practitioners.	Hospital Information Systems
8	Bantom, S.A	2016	Accessibility to Patients' own Health Information: A Case in Rural Eastern Cape, South Africa	Healthcare service delivery can be impacted by the issues surrounding access to patient records across the entire community, as well as in other resource-restricted communities. A significant finding of the study states the necessity of providing seamless and secure healthcare records accessible to all communities, not just rural.	Hospital Information Systems
10	Mahlaola, T.B. & Van Dyk, B. 2016	2016	Reasons for Picture Archiving and Communication System (PACS) data security breaches: Intentional versus non-intentional breaches	The Picture Archiving and Communication System (PACS) has led to an increase in breached health records and violation of patient confidentiality. Clear organisational policy and improved awareness of guidelines through user education and training could help improve ethical attitudes to security issues.	Hospital Information Systems
11	Vimalachandran, P., Wang, H., Zhang, Y., Heyward, B. and Whittaker, F	2016	Ensuring data integrity in electronic health records: a quality health care implication.	The quality and safety of patient care can be adversely affected by electronic health record related issues and risks. A method is proposed to preserve data integrity and reduce the identified potential risks associated with electronic health record systems.	Data Integrity
12	Pérez, J.R	2017	Maintaining data integrity	Failure to manage data integrity appropriately applies to both paper and electronic data. Data bias can result from poor systematic control of data management systems, human error, or deliberately concealed, falsified, or misleading data. An important element of good documentation practices is data integrity, which is one of the pillars of any quality management system.	Data Integrity
13	Kim, M.O., Coiera, E. & Magrabi, F	2017	Problems with health information technology and their effects on care delivery and patient outcomes: a systematic review	Research on health IT problems continues to be qualitative, and many opportunities remain for systematically studying and quantifying risks and benefits. When combined with existing classifications for health IT safety problems, the information value chain can enhance measurement. Patient safety risks can be identified more easily this way.	Hospital Information Systems
15	Wright, G., O'mahony, D. & Cilliers, L	2017	Electronic health information systems for public health care in South Africa: a review of current operational systems.	Support for clinical care, such as radiology and pathology, as well as monitoring, evaluation, and administration are the most common roles of health information systems. There are some systems that capture limited clinical information, but few that support patient-centred clinical care. Health information systems should be expanded to support direct patient care and improve individual health outcomes.	Hospital Information Systems
16	Mutshatshi, T.E., Mothiba, T.M., Mamogobo, P.M. & Mbombi, M.O.	2018	Record-keeping: Challenges experienced by nurses in selected public hospitals	A variety of challenges confront nurses working in public hospitals, including limited time to complete records, increased patient admissions, and a shortage of recording materials, making record-keeping a challenging activity. A comprehensive record-keeping system remains essential to improving patient care in public hospitals.	Hospital Information Systems

17	Salahuddin, L., Ismail, Z., Hashim, U.R., Raja Ikram, R.R., Ismail, N.H. & Naim @ Mohayat, M.H.	2018	Sociotechnical factors influencing unsafe use of hospital information systems: A qualitative study in Malaysian government hospitals.	The factors influencing the unsafe use of a hospital information system originate from multidimensional sociotechnical aspects. Unsafe use of a hospital information system may lead to errors, posing a risk to patient safety. To shape high-quality hospital information system use, multiple interventions (such as technology systems and teamwork) are required.	Hospital Information Systems
18	Agrawal, A. & Alharbe, N.R	2019	Need and Importance of Healthcare Data Integrity	In the healthcare industry, data breaches pose a more unknown threat than simple data theft. In this way, attackers can alter anything on the record. It is often difficult to detect breaches of healthcare data integrity. Where this type of compromise has occurred, the real impact has yet to be determined. Technology cannot guarantee that a system is impenetrable. However, it is possible to significantly reduce the risk of attacks by implementing appropriate preventative measures, resulting in the most advantageous position to thwart any potential attacks. To achieve a much more secure position, the healthcare industry must develop a better understanding of the risks and develop methods for addressing pertinent challenges in preserving data integrity. Healthcare data must be protected from malicious alteration, ensuring its validity.	Data Integrity
19	World Health Organization	2019	Guideline on data integrity	Concerns have increased regarding the integrity of data documentation and record management practices. This may be caused by (i) inadequate human practices; (ii) poorly defined procedures; (iii) resource constraints; (iv) improper management and validation of computerized systems or inadequate compliance with regulatory requirements; (v) insufficient data flow (e.g. manual data transfers); and (vi) insufficient review and management of original data and records. Guidelines and recommendations are provided to facilitate compliance with regulatory requirements for DI documentation and record keeping.	Data Integrity
20	Sittig, D	2020	Current challenges in health information technology–related patient safety	A summary of nine short-term challenges for healthcare organizations, health information technology developers, researchers, policymakers, and funders is presented. Depending on the stage in the health information technology lifecycle at which they occur, these challenges relate to (1) developing models, methods, and tools that facilitate risk assessment; (2) creating standard user interface design functions and features; 3) ensuring software safety in an interfaced, networked clinical environment; 4) devising a method for identifying patients unambiguously (1-4 Design and Development stage); (5) improving safety by developing and implementing decision support; (6) developing a process for safely managing information technology system transitions (5 and 6 Implementation and Use stage); (7) developing real-time methods for automating the monitoring and surveillance of system performance; (8) creating a safe harbor for the sharing of information about hazards and adverse events; and 9) developing models and methods for consumers/patients to improve health information technology safety (7-9 Monitoring, Evaluation, and Optimization). Identifying and addressing these challenges represents the first step toward ensuring that health information technology-based systems are safe, reliable, and efficient.	Hospital Information Systems
21	Malakoane, B., Heunis, J.C., Chikobvu, P., Kigozi, N.G. and Kruger, W.H.	2020	Public health system challenges in the Free State, South Africa: a situation appraisal to inform health system strengthening	The major challenges of the public health system were fragmentation of services, staff shortages, and financial issues. To strengthen health systems, human and financial deficiencies need to be addressed.	Hospital Information Systems
22	Pandey, A.K., Khan, A.I., Abushark, Y.B., Alam, M.M., Agrawal, A., Kumar, R. and Khan, R.A.	2020	Key issues in healthcare data integrity: Analysis and recommendations	The findings show that a modern and safe data integrity strategy is needed in the healthcare sector. Data integrity techniques previously used in healthcare are assessed and ranked using the fuzzy-AHP technique, which provides a path for future data integrity researchers. Researchers and practitioners would benefit from such a compilation if they pursue both possible solutions to the problem of data integrity as well as a means to adopt the most prioritised technique for securing data in the healthcare industry.	Data Integrity
23	Wager, K.A., Lee, F.W. and Glaser, J.P	2021	Health care information systems: a practical approach for health care management	Healthcare information systems and information technology are explored in depth in order to support national quality initiatives, value-based payment, population health management, and precision health and quality reporting. Issues such as interoperability, the usability of electronic health records, and the safety of health IT are discussed. Data governance and analytics are discussed in relation to clinical decision-making and healthcare operations.	Hospital Information Systems

Annexure D - Expert Review Questionnaire Round

Expert Review Questionnaire

Questionnaire: Background and Instruction

This research is being conducted to obtain your input regarding health information systems, data integrity and its practices within hospital information systems as part of my Masters in Information Technology studies at the University of South Africa (UNISA). The purpose of my study is to develop a model for data integrity to support hospital information systems in South Africa. Your inputs will assist the researcher to validate and evaluate the components of the model as identified by the literature.

This questionnaire consists of four sections to be completed by the expert reviewer once the appropriate consent is given. Background information about the project and the Data Integrity Model should be reviewed before completing the given questionnaire. Participation is entirely voluntary. All participants will remain anonymous. Answers are used as part of the master's thesis for evaluating and improving the proposed model based on industry inputs.

Section A: Expert's Details

Field of expertise: _____

Years of experience: _____ **Date:** _____

Section B : Constructs from Literature

The following constructs were identified from two separate literature reviews. A description of each construct to ground its link to the Data Integrity Model is provided in the table below. Please take a moment to read the summary below, and then answer the questions. By answering the questions, you consent to participate in this research. Your identity will not be revealed.

Construct		Description	Linkage in the data integrity model
C	Levels of HIS	The different levels at which health information systems operate across South Africa. • Local paper-based systems • Local paper-based systems with limited IT support • Centralised electronic system with paper-based and electronic features, fully integrated national shared health system.	The construct is based on the decision that government needs to make when implementing the different types of health information systems. The government needs to provide the necessary resources to achieve their desired objectives of national healthcare systems with electronic health records.
C1	Data integrity mechanism	The adoption and implementation of existing data integrity mechanisms used by healthcare institutions • The Biba integrity model • Goguen and Meseguer integrity model • Clark\Wilson integrity model • Blockchain • Masked authentication messaging extensions Obtain data sharing agreements between the national Department of Health and third-party information systems to bring data into the national platform prioritising data from hospital information systems (NDOH, 2019).	This construct is based on the adoption of digital technologies and the awareness of cyberattacks by the government. In an effort to protect health information from unauthorised users, the researcher proposes the adoption of existing data integrity mechanisms. By analysing existing health information systems infrastructure, digital health services and applications, this can be accomplished.
C2	Data governance	A data governance framework for South Africa comprising policies and regulations, data strategy and leadership, data ecosystems and invested data technologies to mitigate risks to government and society from poor data quality, data falsification, data obsolescence, and security threats (UN, 2020)	The construct stems from the need to establish a digital health data governance. This can be achieved by reviewing and aligning current health governance and digital health governance structures.
C3	Data integrity requirements	Establish data integrity requirements through the development of policies and procedures. This is to ensure that data meets the stated integrity requirements and the quality of the data being shared. South Africa is known for its progressive constitution with strong protection of human rights, confidentiality, and privacy of all citizens. • National Normative Standard Framework (HNSF) • POPI Act • The Constitution of the Republic of South Africa of 1996 • South African National Health Act of 2003 • Protection of Personal Information (POPI) Act of 2019 • Health Professional Council of South Africa guidelines • District Health Information Software • National Cybersecurity Policy Framework	This construct is motivated by the need to tighten regulations pertaining to data protection, data sharing between private and public entities, and cybersecurity. To accomplish this, the researcher suggests new regulations should be developed, and mechanisms should be created to enforce compliance, prioritising data integrity issues.
C4	Data integrity training	Enables the implementation of data integrity governance systems, methodologies, and programs. Training should be structured into different streams and cater to different levels of training requirements. Healthcare professionals should implement mandatory skills acquisition programs to gain the skills and confidence to use existing tools and increase user confidence in working with health information systems.	This construct is based on the awareness that there is a severe lack of human resources and government funding for healthcare workers. The need to restructure existing training sessions into multiple streams i.e., digital health workforce that caters to different levels of training needs. In addition, the need to implement mandatory skills development

		• Data Integrity Awareness Programs • Data Integrity Courses • Regulatory and Compliances Training	programs to allow users to improve their skills.
C5	Data safeguards	Implementation of data integrity standard that includes measures for people, networks, operating systems, data files, data, and database management systems. Industry-standard safeguards for administrative safeguards involve data integrity policies that clearly define what constitutes raw data, source data, metadata and a "complete data set". Physical safeguards that involve measures such as shredding documents when disposing of them in terms of storage using a secured access filing mechanism for medical records and bills and controlled prescription pads. Technical safeguards measure normally associated with computerised systems, usually over a network that stores electronic medical information. These safeguards include system protection such as antiviruses, firewalls, automatic logouts, and audit trails. These are measures against the destruction, loss, misuse, unauthorized disclosure, or alteration of data (Li, 2020).	The construct is motivated by the need to improve data protection measures for healthcare information against cybersecurity threats and hacking. The researcher posits examining current health information systems infrastructure and connectivity to provide digital health broadband connectivity..
C6	Human error challenges	Human errors include both unintentional and intentional challenges. These challenges have negatively affected the delivery of high-quality services in healthcare facilities (Maphumulo & Bhengu, 2019; Vawda & Gray, 2018).	This construct is based on the lack of computer skills and skilled personnel within healthcare institutions and the need to provide quality service delivery. There is a need to develop a digital health workforce plan. The researcher contends this can be accomplished by integrating the first five constructs.
C7	Computerised systems challenges	These challenges are often attributed to poor or complete lack of system control, poor system use, inappropriate systems design, complex system features, computer virus and malware (trojans, spyware, worms, and ransomware).	The construct draws upon existing health information systems and the call for all healthcare institutions to utilise electronic information systems fully. The researcher proposes the integration of the first five constructs to achieve this.

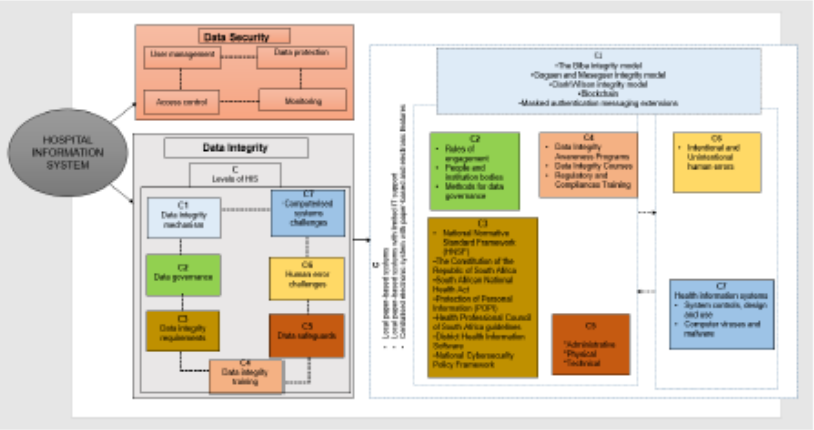

Figure 1: Data Integrity Model

Section C: Rating Level of Agreement

Based on your knowledge in your domain, please indicate your level of agreement to the following statements by crossing your selection with an "X"

Statements	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
Validity					
Does the model address a real problem/need?					
Is it compatible with existing data integrity research or practices?					
Is the application in the South African context					
Would the data integrity model be applicable in similar environments?					

Utility					
Any missing elements or components?					
Will the application of the model produce useful results if used in your context?					
Quality					
Is the model easy to understand?					
Efficiency					
Does it incorporate the components needed to develop a model (see Table above)?					
Does it appropriately categorise the concepts included?					

Please state the strengths and weaknesses of the model below.

Strengths: ----------

Weaknesses: ----------

Section D: Rate the Constructs from a South African perspective

Please rate the constructs below based on your field of expertise and based on your knowledge

	Constructs	1- Unimportant	2- Moderately Important	3- Neutral	4- Important	5-Very Important
C	Levels of HIS					
C1	Data integrity mechanism					
C2	Data governance					
C3	Data integrity training					
C4	Data integrity requirements					
C5	Data safeguard					
C6	Human error challenges					
C7	Computerised systems challenges					

Any additional comments on the constructs or the model that the researcher should consider to improve the model:

.....
.....
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.....
.....
.....

End of Questionnaire

Thank you for time and participation