FRAMEWORK FOR ELECTRONIC HEALTH RECORDS AND ELECTRONIC MEDICAL RECORDS STANDARDS IMPLEMENTATION IN THE HEALTH SECTOR OF ZIMBABWE

BY

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SUMMARY

Following the pronouncement of Zimbabwe's e-Health Strategy (2012-2017), coupled with the general emergence and benefits of health information technologies, the health sector of Zimbabwe has witnessed the mushrooming of Electronic Health Records (EHRs) and Electronic Medical Records (EMRs) systems. These systems are part of a health information system in a country and their role is to enable the capture, distribution and analysis of health information. However, such systems seem to be implemented in a haphazard manner and tend to be characterised by the dearth of standards. Although the then Ministry of Health and Child Welfare (MHCW), now the Ministry of Health and Child Care (MHCC), in its e-health strategy for Zimbabwe seems to acknowledge and appreciate the cardinal role played by EHRs standards, there seems to be no commensurate action plan with respect to the implementation of standards for EHRs and EMRs. Against this backdrop, the study sought to explore the EHRs and EMRs standards atmosphere in the health sector in Zimbabwe and propose a framework that may guide the implementation of standards for EHRs in the health sector of Zimbabwe. The methodology of the study was qualitative and a case study design was used. Using interviews and questionnaires, the study gathered data from five participants consisting of the Deputy Director in the Department of ICT, Deputy Director of the Department of Policy, Planning, Monitoring and Evaluation and the Deputy Director of Health Information in the Ministry of Health and Child Care and a Manager and the Director General at the Standards Association of Zimbabwe (SAZ). The study revealed that the state of standards implementation for EHRs was unfavourable, with the MHCC not knowing which and how many EHRs systems were in existence in the health sector. There was not yet meaningful interoperability between the disparate EHRs systems in use in the health sector. It emerged that SAZ and the MCHH had standing MoUs for standards, but none for EHRs and there was generally a low priority given to standards for such systems. The study further established that there were no policies and sound legislation specific to the implementation of standards for EHRs and EMRs in the country. The study proposed a framework that may inform the implementation of standards for EHRs and EMRs in Zimbabwe.

Key terms: Electronic Health Records (EHR), Electronic Medical Records (EMR), Health, Standards, Standards Association of Zimbabwe (SAZ), Ministry of Health and Child Care (MHCC)

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DEDICATION

I dedicate this work to my wife Sibusiso Eric, daughter Awakhiwe, aunt Similo, late mother and father Fildah and Headman.

Student number: **55785107**

DECLARATION

I declare that **FRAMEWORK FOR ELECTRONIC HEALTH RECORDS AND ELECTRONIC MEDICAL RECORDS STANDARDS IMPLEMENTATION IN THE HEALTH SECTOR OF ZIMBABWE** is my own work and that all the sources that I have used or quoted have been indicated and acknowledged by means of complete references.

_____ _____ 30 October 2019_____

SIGNATURE DATE

(MR M. MASUKU)

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LIST OF ABBREVIATIONS AND ACRONYMS

ACT	Anatomic Therapeutic Chemical Classification of Drugs
AIPPA	Access to Information and Protection of Privacy Act
ASTM	American Society for Testing and Materials
BOBS	Botswana Bureau of Standards
CCR	Continuity of Care Record
CDA	Clinical Document Architecture
CEN	Comite European de Normalisation
CPSBC	College of Physicians and Surgeons of British Columbia
CPT	Current Procedural Terminology
DICOM	Digital Imaging and Communications in Medicine
DSM-5	Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
ECISM	European Commission Information Society and Media
EHR	Electronic Health Record
EMR	Electronic Medical Record
EU	European Union
FICC	Federation of Indian Chamber of Commerce
HCPCS	Healthcare Common Procedure Coding System
HIE	Health Information Exchange
HIMSS	Health Information and Management Systems Society
HL7	Health Level Seven
ICD	International Classification of Diseases
ICD-10-CM	International Classification of Diseases, Tenth Revision-Clinical Modification
ICD-10-PCS	International Classification of Diseases, Tenth Revision, Procedural Coding System
ICHD	International Classification of Headache Disorders
IEC	International Electrotechnical Commission
ICTs	Information and Communication Technologies
ISO	International Organization for Standardisation
JCI	Joint Commission International
LOINC	Logical Observation Identifiers, Names and Codes
MHCC	Ministry of Health and Childcare (Zimbabwe)

MICSR	Merika Institute of the Council for Scientific Research
MOHCW	Ministry of Health and Child Welfare
NDC	National Drug Codes
NDH	National Department of Health (South Africa)
NIC	Nursing Intervention Classification
NOC	Nursing Outcomes Classification
SABS	South African Bureau of Standards
SAZ	Standards Association of Zimbabwe
SNOMED-CT	Systematic Nomenclature of Medicine- Clinical Terms
UNIDO	United Nations Industrial Development Organization
USAID	United States Agency for International Development
WHO	World Health Organization
ZABS	Zambia Bureau of Standards

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CHAPTER ONE
INTRODUCTION AND ORIENTATION OF THE STUDY

"Could you imagine the national road system without standards for width, signage, stop lights, and exits? Similarly, how about the railways without standard gauges for railway tracks? It is these standards that make systems work safely and effectively." (Brookstone 2012)

1.1 Introduction

The mushrooming of disparate health information systems such as electronic health records (EHRs) and electronic medical records (EMRs) that do not allow patient data to be shared has necessitated the standardisation of such systems so as to improve patient care and healthcare services and facilities in general. The need for the standardisation of EHRs and EMRs systems has been further strengthened by incessant demands for improved and coherent health information in the health sector. Electronic health information systems need to be rolled out in a manner which is consistent with the best practices in the form of standards so as to enable uniformity and coexistence between and among such technologies. In the context the present study, the afore-mentioned statement by Brookstone (2012) implies that standards are indispensable if order and effectiveness are to be achieved in the health sector. Thus, standards are the anchor of technological progress as they enable parts to fit together thereby ensuring consistency over time while facilitating communication (Ahmadi, Damanabi and Sodoughi (2014:118). Standards in the field of EHRs and EMRs systems play a critical role by acting as a "practice guide", stipulating the manner in which such systems should operate, exist in harmony and work towards common objectives. Thus, matters of interoperability as well as improved health communication are some of the most obvious benefits of standards for EHRs and EMRs. Additionally, standards are not only a matter of interoperability which is more technical, but are also a policy and economic issue. The International Telecommunication Union (2009:12) wrote:

> The Bridging the Standardization Gap initiative recognizes that ICT standards are not only the technical blueprints necessary for interoperability and connectivity within global information infrastructures. They are also tools with significant public policy and economic consequences. Exclusion from accessing, adopting, or developing standards can heighten economic inequalities in the context of ongoing information globalization.

This implies that a country or organisation which does not standardise its information technology systems will essentially be disconnected from the world, given the fact that standards-based information technologies are inevitably and increasingly playing a critical role in the collection, dissemination as well as sharing of information across all strands of an economy. For example, the dearth of health information systems may result in increased costs of rendering healthcare as the same information may be required to be captured multiple times, coupled with the preclusion of the sharing of patient data among healthcare players such as hospitals, primary health physicians, pharmacists as well as other healthcare providers (International Telecommunication Union 2009:15). In the context of health, such technologies have come in the form of EHRs and EMRs whose standards are inevitable if their adoption is to be meaningful. Against this background, the present study sought to understand the status quo concerning standards for EHRs and EMRs systems in the health sector of Zimbabwe, amid indications that there was a sporadic deployment of such systems, thereby culminating in the growth of silos of health information to the detriment of patients and healthcare efforts in the country.

1.2 Background to the study

Standards for EHRs and EMRs are important if such electronic systems are to yield their intended benefits such as interoperability and best practices including the preservation of patient privacy and confidentiality, as well as archiving of EHRs content for meeting administrative, legal and informational needs. Standards tend to be either de facto (informal) or formal (de jure). On one hand, de facto standards arise from an uncoordinated market-based approach whereby market forces and mechanisms such as competition culminate in the formation of the standard without any explicit or formal expression or commitment (Brunswicker, Rodriguez and Wareham 2014:4; Henson 2006:5). According to Henson (2006:5), "when a particular set of products or specifications gains market share such that it acquires authority or influence, the set of specifications is then considered a de facto standard." On the other hand, formal standards tend to be products of formal standards development organisations that are sponsored by government agencies (Brunswicker, Rodriguez and Wareham 2014:4).

In the present study, both formal standards and informal standards were covered in the study as the purpose of standards is generally the same and there is collaboration between formal

and informal standards bodies resulting in even sounder hybrid standards. For example, collaboration in the field of software technology between the International Organisation for Standardisation (ISO), which is a formal standards body, and the International Electrotechnical Commission (IEC) has been witnessed (Brunswicker, Rodriguez and Wareham 2014:4). A good example of this is the ISO/IEC 29100:2011- Information technology- security techniques- privacy framework, which is a health informatics standard in which ISO and the IEC are players.

Healthcare systems around the world are now characterised by different EHRs and EMRs systems that are meant to facilitate quick and timely access to patient information. The ability of healthcare information systems to share and exchange patient information, that is, interoperability, is important in facilitating the quality and effectiveness of healthcare services (Adebesin, Foster, Kotze and Greunen 2013), especially in light of the fact that health systems do not only use a number of information technology systems, but are also very complex and fragmented (Federation of Indian Chambers of Commerce Health Services India 2013:5). As stated by Standards Australia (2010), healthcare is becoming increasingly integrated and complex, and it is essential that health information in EHRs can be shared between and among members of a multi-speciality and multi-disciplinary healthcare. This has seen the emergence of various EHRs and EMRs systems for adoption by healthcare facilities. Thus, EHRs are designed in a manner which allows the sharing of health information among healthcare providers and organisations, including laboratories, specialists, medical imaging facilities, pharmacies, emergency facilities, schools as well as workplace clinics (Office of the National Coordinator for Health Information Technology 2012).

As observed by Kalra (2006:137), single-disease approaches are no longer adequate to underpin sound health, resulting in the emergence of different systems for managing health information for different diseases and such systems need to be linked to each other across healthcare industries in different countries to improve healthcare. This, Standards Australia (2010) observed, is only achievable through the standardisation of EHRs and EMRs systems that are necessary for interoperability, especially the structure, broad content of the record as well as processes and technologies that are used to manage and exchange EHRs. A standard, according to the International Organisation for Standardisation/ International Electrotechnical Commission (ISO/IEC) (2005:2) is a

> Document, established by consensus and approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their result, aimed at the achievement of the optimum degree of order in a given context.

Standards are particularly important in light of the fact that healthcare facilities all over the world are adopting information and communication technologies (ICTs) as information management tools. Approaching the development of Information Technology (IT) systems from an agreed set of standards offers a number of advantages, including alignment, integration, flexibility, reusability, portability and reduced time to market (Merika Institute of the Council for Scientific Research and the National Department of Health 2014:23). Standards for EHRs and EMRs are the pillars of interoperability and their development, as observed by Dumortier and Verhenneman (2011), is increasingly quickly with different approaches to their development being possible. Standards, as seen in the very definition of a standard by ISO (1999), are key in the imposition of order on ways of doing things in certain contexts. EHRs and EMRs, because of their fluidity and manipulability, particularly present very complex challenges such that standards to govern such systems are inevitable. Explaining the indispensability of orderly and consistent ways of implementing EHRs and EMRs systems, Armijo, McDonnell and Werner (2009:2) stated that how well such systems serve amid the complexity of care environments is actually a direct result of an interface that is meant to collect, organise and display patient information in such a way that is meaningful to clinicians at the point where care is rendered, consistent and aligned to cognitive workflows.

The application of ICTs in the healthcare industry is not new. Their use in the healthcare has become a major global issue that has triggered a lot of research (Sood et al 2008:6). As early as the 1970s, the United States of America implemented electronic personal records (EPR) (Berg 2004). In fact, as early as 1963, discussions were already underway regarding the potential of EHRs and EMRs to improve healthcare (Berg 2004) and in recent years, Boonstra, Versluis and Vos (2014:23) noted, an ever increasing number of hospitals around the world have been implementing EHRs. Thus, although the concepts of EHRs and EMRs appear to be relatively new, especially in countries such as Zimbabwe, various efforts have been put around the globe to enhance the application of ITCs in this regard.

The rationale for implementing such systems is the ability of healthcare institutions and health ministries to facilitate the seamless sharing of patient information to improve patient

care (Berg 2004). This calls for the existence of sound standards that are inter-operable. Zimbabwe has joined the rest of the world in adopting EHRs and EMRs at various levels in both public and private sectors but such systems are hardly compatible with each other, neither are there any standards that guide the implementation of such systems so as to reap the intended and maximum benefits from them. In the *Zimbabwe e-Health Strategy 2012-2017*, the Ministry of Health and Child Welfare (MOHCW) (n.d:9) stated that currently, "there is no clear well-coordinated mechanism in place where e-health implementations are organised" in the country. The fact that EHRs and EMRs are part of the broad e-health means that they are also negatively affected by such lack of coordination.

Limited attention has been given to standards that govern the implementation of such EHRs and EMRs in the country as also revealed by the MOHCW (n.d). A number of systems have been rolled out in both the public and private sectors, and they will continue to emerge as the country's healthcare industry adopts ICTs to better manage health information. For example, the Ministry of Health and Child Care (MHCC), formally the MOHCW, adopted various EMRs systems such as the Laboratory Information Management System (LabIMS), the Inpatient Morbidity and Mortality Information System (IMMIS), the Human Immunodeficiency Virus (HIV) Information Management System (IMS), Electronic Patient Management System (ePMS), the District Health Information Software (DHIS) and the Rapid Disease Notification System (RDNS). These systems seem not to be based on interoperable standards that enable their contents to be shared by authorised medical practitioners throughout the country as indicated by the MOHCW in its e-Health Strategy 2012-2017.

In its e-Health Strategy 2012-2017, the MOHCW lamented the dearth of national and international standards on which EHRs and EMRs are based, despite these systems mushrooming in Zimbabwe. Marlon-Ralp (2016), indirectly highlighting the importance of standards in the consolidation of health information, suggested that as a way of preventing data silos as well as blind spots that emanate from the private sector in Zimbabwe's health delivery system, all EHRs systems should preferably be able to feed to DHIS-2 of the MHCC. This was said in relation to the existing independent pockets of health information that were generated and continue to be generated by disparate EHR and other e-health information systems that were already in use in the Ministry and Zimbabwe's health sector in its entirety. In fact, Halamka (2010:2) stated "a health care system that uses electronic health records sporadically and also has no common software standards, can be compared to a tower

of Babel." Indeed, competing Electronic Health Information Systems (EHIS) have the potential of undermining the standardisation of systems (Moucheraud, Schwitters, Boudreaux, Giles, Kilmarx, Ntolo, Bangani, Louis and Bossert 2017:5).

The challenges posed by EHRs systems are not peculiar to Zimbabwe but a ubiquitous phenomenon throughout the world. Digitisation has given birth to changes in the use of clinical information, ranging from billing to taxation, even in the ancient Babylon, and such digitised EHRs have enabled standardisation, knowledge extraction and composition, decision making, action support and many more (Motoc 2017:243). Thus, from the information stored and managed in such digital formats, EHRs have become an enabling action capability (Motoc 2017:243). However, Motoc (2017:243) lamented the implementation of such systems without due or sufficient planning in the following words "unfortunately, this transformation occurs more impromptu than panned." Such a situation is bound to give rise to a situation in which countries experience a hype of EHRs and EMRs systems that are littered with serious challenges, one of them being a boom in non-standardised systems and in some cases, such challenges may prove not only costly, but insurmountable to tackle. This perhaps is the predicament that Zimbabwe's health sector finds itself in as witnessed by the emergence of EHRs and EMRs systems that are not hinged on clearly defined standards framework, resulting in the failure by such systems to yield maximum benefits, including the ability to share patient records and improved health information management practices.

Without standards for EHRs and EMRs systems in place, the actual benefits of IT adoption will not be realised. As stated by Fraser et al (2005:88), standardisation enables "…data to be exported in standard formats for analytic and statistical packages, third party software…" Thus, in order to move beyond successful prototypes to widespread use, EHRs and EMRs systems should be developed with standards and sharable components (Fraser et al 2005:88). This, Fraser et al (2005:88) further observed, will enable the linkage of a wide range of technological platforms and make collaboration between projects easy. Standards are therefore, important to enable EHRs and EMRs systems to share health information and for systems to talk to each other such that there is collaboration between and among those systems and projects. As stated by Kalra (2006:143) "the need is now urgent for standards to enable EHRs information to be shared." However, Berg and Bergen (2004:90) warned that

standardisation of healthcare systems is necessary but only where it enhances competencies and quality.

Zimbabwe, being characterised by systems that seem to lack standards, may find itself not realising the full benefits of ICTs application in the health sector. This demonstrates that standards are one of the important elements when rolling out such systems, implying that Zimbabwe, which is already characterised by systems that are not coordinated, needs to tackle the issue of the dearth of standards with a sense of urgency. Lamenting the predicament that EHRs and EMRs systems find themselves in in the developing countries, Sood et al (2008:6) wrote "these systems are fragmented and isolated- thus forming islands of users disconnected from each other", a situation that Zimbabwe finds itself in today. The existence of isolated and fragmented systems is also buttressed by the MOHCW in its e-Health Strategy 2012-2017 as it observed that the systems that are being developed and rolled out in the healthcare system in Zimbabwe are not aligned to any national or international standards, thereby increasing the risk of developing silos of data that are characterised by a lack of or limited interoperability. This remains the case despite the International Organisation for Standardisation (ISO), to which Zimbabwe, through the Standards Association of Zimbabwe (SAZ), is a member, having developed a number of EHRs and health information standards through its ISO/TC 215 Secretariat.

Furthermore, there seemed to be limited efforts to develop and promote health information management standards by SAZ, an institution that is mandated to facilitate the development and use of standards in Zimbabwe in order to promote the country's competiveness on the international market. It therefore, remains to be established through this study, the extent to which SAZ and the MHCC have collaborated in the area of standards for EHRs and EMRs.

SAZ, being a standards accrediting institution in Zimbabwe, is expected to adopt international standards on records management such as those developed by ISO, and localise them to Zimbabwe as per the needs of the country or develop some and encourage their implementation by various government departments, but this does not seem to be the case. EHRs standards such as those of ISO are flexible such that they can be adapted and localised to the countries that are members of ISO. As stated by Berg and Bergen (2004:91), standards are characterised by flexibility, implying that the standard can easily be revised and adapted to local needs or to new scientific insights. Thus, the conspicuous dearth of collaboration

between SAZ and the MHCC to foster the adoption of health records management standards has witnessed the subsequent burgeoning of EHRs and EMRs systems that are not based on any standards in the healthcare system of Zimbabwe, a development which triggered this study.

Despite standardisation being considered key in addressing healthcare information systems, e-health standardisation can be difficult for many reasons, one of them being making sense of the e-health interoperability standards landscape (Adebesin et al 2013). It therefore, remains to be established through this study, what the challenges that the health sector was facing are in Zimbabwe.

Healthcare facilities in Zimbabwe are in a predicament where there exists EMRs systems that have different functionalities and lack interoperable standards, a situation that is similar to that of Kenya before 2010 when the Ministry of Medical Services and the Ministry of Public Health and Sanitation (2010) of that country drafted a document to standardise EMRs systems in an effort to ensure that various systems talked to each other and enabled the sharing of health information. Before the production of such a document, the Ministry of Medical Services and the Ministry of Public Health and Sanitation (2010:6-7) reported that the development of EMRs in Kenya had not been properly coordinated, resulting in multiple EMRs systems that were characterised by varying objectives and functionalities, and lacked the ability to share patient information with other systems, programmes as well as the government. Such situations result in the health care industry being littered with systems that do not yield meaningful benefits to the health system and confusion in the long run.

Health information management continues to gather attention from a number of stakeholders including the government, healthcare professionals, patients, legal experts and politicians. As rightfully observed by Berge (2004:2) "at the beginning of the twenty-first century the field of information management has fundamentally changed and this has seen information becoming a more strategic resource." This has seen health information management gaining support from different stakeholders such as private players and governments. For example, in Europe, government bodies have been the major drivers behind the development and implementation of EHRs, and this resulted in many European countries establishing new legal frameworks simultaneously with the rollout of government initiated electronic health structures (Dumortier and Verhenneman 2011). In the United States of America, the major drivers were private companies, insurance and healthcare organisations (Dumortier and

Verhenneman 2011). However, the issue of standards has remained an issue of concern to the healthcare industry the world over. Thus, in light of all these developments in the healthcare area around the world, coupled with imminent losses of benefits on the part of healthcare facilities that do not implement coordinated health EHRs and EMRs systems in a standardised manner, it becomes necessary for this researcher to conduct a study which aimed at establishing the status quo concerning standards for EHRs and EMRs and suggest a framework within which such standards can be implemented and monitored over time.

It would seem the adoption of standards in many sectors, including the health sector, has been largely been optional in Zimbabwe and many organisations have not had their operations guided by standards. This has resulted in healthcare facilities rolling out EHRs and EMRs that are not standards based. However, for standards to be effective, there is a need for standardisation to be hinged on clear policies and legislations. The MHCC, in its e-health strategy (2012-2017) acknowledged the role played by clear policies and legislation in supporting standardised EHRs and EMRs systems and noted that there is a need to enact supportive legislative instruments that support e-health implementation and policies that ensure compliance with agreed protocols and standards. This study, therefore, further sought to find out about the existence of supportive legislative and policy frameworks for EHRs and EMRs in the health sector of Zimbabwe.

1.2.1 Brief history of the application of ICTs in the health sector of Zimbabwe

Literature shows that the application of ICTs in the health sector of Zimbabwe is not a new phenomenon. As early as 1985, the MOHCW, in response to emerging calls for increased availability of data to enable planning, implementation as well as monitoring health programmes, piloted a National Health Information and Surveillance (NHIS) system, which was fully rolled out on a national scale in 1988 (MOHCW 2012:5). In 1999, the MOHCW in conjunction with the World Health Organisation (WHO), conducted an evaluation of the system where a number of challenges relating to data collection, analysis, reporting and uniformity were identified and recommendations were made to improve the system (MOHCW 2012:5). In fact, the NHIS of Zimbabwe received a trophy from the Southern African Development Community (SADC) for being the best surveillance system in the region in 2004, although since then, the system has been characterised by a plethora of challenges that affected the health delivery system of the country, resulting in the national

health information unit struggling to ensure timely production of complete and reliable information for improved health services (MOHCW 2012:5). However, despite the noble efforts by the MOHCW, the aspect of EHRs and EMRs and their standards have not been given due attention and remain a cause for concern to a number of stakeholders, including the MOHCW and the medical practitioners.

The application of ICTs in the health sector of Zimbabwe has continued to gather support since the 1980s, although the success rates of the various ICT projects is something that is yet to be evaluated. In 2014, the Ministry of Health and Child Care (MHCC), through its Health Information and Software Unit (HISU) was using a number of electronic systems such as the Laboratory Information Management System (LabIMS), the Inpatient Morbidity and Mortality Information System (IMMIS), the HIV IMS, ePMS, the District Health Information Software (DHIS) and the Rapid Disease Notification System (RDNS).

LabIMS enables the management of laboratory test results, feedback and distribution of results (MHCC 2014). For example, the National TB Reference Laboratory had managed to install a complete LabMIS and the Mpilo Hospital Laboratory and had some sections that were utilising LabMIS as well as the National Microbiography Reference Laboratory that used the same system for Early Infants Diagnosis (MHCC 2014). The IMMIS was being utilised by all admitting hospitals and it enabled the capture of patient information (MHCC 2014). This system, according to the Health Information and Surveillance Unit in MHCC (2014), helps the MHCC to calculate the usage of hospitals, diseases burden, types of diseases and causes of morbidity and mortality and to date, admitting hospitals, that is, district, rural and mission hospitals were issued with laptops and trained in using the system, whose coding was also based on the International Classification of Diseases (ICD) 10 standard codes. The HIV IMS was a specialised programme that enabled the capturing of HIV Monthly Return Form, but as of October 2013, all the reporting had been shifted to DHIS2, implying that the HIV IMS was set to cease functioning once the legacy data had been transferred to DHIS2 (MHCC 2014).

DHIS2 was a tool for collecting, validating, analysing and presenting aggregate and transactional data that was tailored for integrated health information management activities (MHCC 2014). This system, according to the MHCC (2014), integrated various programmes so that there was a central repository of data. The Electronic Patient Monitoring System (ePMS) was another specialised patient level information system that was being developed

and used as a learning process towards implementing the Zimbabwe Health Record (MHCC 2014). According to the United Nations Development Programme (UNDP) (n.d:5), the MoHCW, together with the its partners, agreed to set up an electronic system to collect and manage data relating to HIV and TB at the patient level, with the aim of ultimately eliminating paper registers throughout Zimbabwe. In rolling out the project, a working group, consisting of the MoHCC, UNDP, the World Health Organisation (WHO), the Joint United Nations Programme on HIV/AIDS (UNIAIDS) the Centre for Disease Control and Prevention (CDC), the National Aids Council (NAC) and the Research Triangle Institute (RTI) took a cue from similar projects that had been rolled out in other African countries such as Zambia, Tanzania and Namibia to roll out the e-PMS system that was dedicated to the management of (1) common patient registrations; (2) demographic details; (3) past medical history; (4) patient follow up visits; (5) laboratory investigations; and (6) prescription and dispensation of drugs (UNDP n.d:5).

Finally, the RDNS, which was alternatively known as the Weekly Disease Surveillance System (WDSS) was a mobile based information system that was implemented using the FrontlineSMS (MHCC 2014). In this system, all health facilities were required to report selected diseases of public threat on a weekly basis (MHCC 2014). The system used a mobile based form that was being completed by nurses at a health facility and then submitted to a server, which translated such information into a database that was linked to DHIS2 (MHCC 2014). Thus, looking at these systems and others that are yet to be developed and rolled out in the health sector of Zimbabwe, a lack of standards will continue to be a serious hindrance to effective utilisation of EHRs and EMRs systems, resulting in the country failing to reap maximum benefits of technology in health information management.

1.2.2 Structure of the healthcare delivery system in Zimbabwe

In order to have a better appreciation of the importance of standards for EHR and EMR, it is important for one to understand the structure of the healthcare delivery system in Zimbabwe. The healthcare delivery system in Zimbabwe is arranged into four tiers or levels, which are primary, secondary, tertiary and quaternary or central levels (MOHCW 2012:2; United States Agency for International Development [USAID] 2010:11). The primary level the lowest in the hierarchy and renders less sophisticated care to patients. It consists of village health work, community-based distributors and small clinics that patients usually first visit, particularly in

the rural areas of the country (USAID 2011:14). According to USAID (2011:14), as far as the public sector healthcare is concerned, primary health care consists of one thousand one hundred and eighteen (1118) rural clinics, rural hospitals and urban polyclinics and these account for 78% of all the healthcare facilities in Zimbabwe. Care at this level includes maternal and child services; health education, nutrition education, communicable diseases, essential drugs programme, communicable diseases as well as the provision of basic and essential preventive and curative services (MOHCW 2012:5) and health issues that are beyond the scope of the primary healthcare facilities are referred to the next level, which is the secondary level comprising of district hospitals (USAID 2011:14).

Secondary healthcare consists of facilities that receive patients from the primary tier. Secondary care consists of forty-six (46) district hospitals and five (5) mission hospitals which have been given the district hospitals statuses and they represent about 3.6% of all the healthcare facilities in the health system (USAID 2011:14). The third tier is into tertiary care and receives patients from district hospitals. This tier consists of seven (7) provincial hospitals which are found in all the provinces of Zimbabwe, with the exception of Bulawayo and Harare where there are central hospitals that receive patients from other healthcare facilities (USAID 2011:14). This tier is also characterised by specialists who deal with more complicated health issues and they receive support and administration from the provincial government (USAID 2011:14). The final and highest tier is into quaternary or central care which consists of six (6) central hospitals in Bulawayo, Harare and Chitungwiza and have the most advanced and specialised equipment, staff as well as pharmaceuticals for dealing with the most severe cases (USAID 2011:15). Healthcare facilities in this tier report directly to the MOHCW (USAID 2011:15).

The healthcare system of Zimbabwe is also characterised by players from the public and private players. According to the MOHCW (2012:5), the majority of health services in the country are rendered by the public sector, which consists of the MOHCW, local government and to a limited extent, the Ministries of Education, Defence, Home Affairs and Prison Services, both in rural and urban settings. The private sector complements the public sector and it consists of private for profit, (for example, industrial clinics, private hospitals, maternity homes and general practitioners), and not-for profit private sector such as mission clinics and hospitals and Non-Governmental Organisations healthcare facilities (MOHCW 2012:5). Another healthcare sector is the traditional medicine sector that has become

pervasive and is also gaining momentum in Zimbabwe (USAID 2011:11). However, for the purposes of this study, this traditional medicine sector will not be considered.

Given the organisation of the healthcare system in Zimbabwe, it is possible to have a patient moving from one tier to the next, in a linear fashion or non-linear fashion, implying that a patient can move between and among all the four tiers for the same or different diseases. For example, a patient may visit a clinic which falls under the primary tier and move directly to a central hospital which falls under the fourth tier. This requires that the patient's health and medical information has to be readily available and accessible at each and every tier that the patient visits to facilitate smooth healthcare and minimise casualties as a result of a lack of adequate information. This calls for sound standards for EHRs and EMRs systems to enable ubiquitous and instantaneous availability of patient health information which seems to be currently lacking in the health delivery system of Zimbabwe. As lamented by the MOHCW (2009) cited in USAID (2011:99), there is a dearth of a central repository or data ware house for integrating health information systems data sources at the national level, a situation that is likely to limit analytical capacity.

1.2.3 Difference between Electronic Health Records and Electronic Medical Records

The phrases EHRs and EMRs are often, in a loose sense, used interchangeably. Whilst these two concepts are indisputably intertwined and closely related, it is worth noting that they mean two different things and such differences cannot be ignored in a study of this nature and magnitude. In light of the inherent differences between the two concepts, this section is dedicated to the explanation of the said differences.

An EHR on one hand, according to the College of Physicians and Surgeons of British Columbia (CPSBC) (2007:i) is a patient centred document containing information from a number of providers beyond family physicians, including medical specialists, social workers, dieticians, physiotherapists and many more and may, according to Boonstra, Versluis and Vos (2014:23), take various forms as the term may refer to a wide range of electronic information systems that are used in healthcare facilities. An EHR generally contains sharable patient information such as cumulative patient profiles with current prescriptions, allergies as well as immunisation history (CPSBC 2007:1). Buttressing the foregoing statement, Gonzalez, Blobel and Lopez (2011:694) viewed an EHR as one with the ability to

combine information sourced from a number of distributed health actors who intervene in the same or chained process of healthcare provision, at the same time exchanging information but not necessarily collaborating. Thus, an EHR can be seen as a repository of electronically maintained information about the patient's lifetime health status and healthcare, stored in such that it serves multiple legitimate users of the record (European Commission Information Society and Media 2008:17).

An EHR ideally contains integrated information that is related to the in-patient and outpatient encounters with the healthcare facility (CPSBC 2007:i) and may include information such as observations, laboratory tests, diagnostic imaging reports, treatments, therapies, drugs administered, patient identifying information, legal permissions as well as allergies (European Commission Information Society and Media 2008:17). As noted by the Federation of Indian Chambers of Commerce (FICCI) Health Services India (2013:5), EHRs are a summary of different EMR that are generated as clinical staff has encounters with patients.

Whilst the definitions of EHRs abound in the literature, the European Commission Information Society and Media (2008:17) observed that such definitions and concepts are rather idealistic and most probable have not yet been brought to real life in many parts of the world. This, the European Commission Information Society and Media (2008: 17) opined, is because systems that are commensurate with the existing definitions of EHRs can only be found in rather confined local or regional setups and for persons who may have been born only recently such that indeed their complete lifetime data are available.

An EMR on the other hand, refers to medical or physician specific information and its configurations are such that it reflects the needs of individual physicians or groups of physicians who are caring for a patient (CPSBC 2007:i). Thus, an EMR is configured in such a way that it is provider centric (CPSBC 2007:i) as opposed to being patient centred. EMRs generally allow healthcare providers to record detailed information per an encounter with every patient, some of which may be sensitive and not appropriate to share with other providers (CPSBC 2007:i). Because an EMR is provider centred, it is, broadly speaking, a specific recording or episode detailing an encounter *[of a patient with a clinician]*, and is specific to a case or purpose compared to an EHR that is an aggregation of EMRs and usually life-long (FICCI Health Services India 2013:10). Thus, EHRs and EMRs are closely related and linked patient health information systems that are all aimed at enabling the flow of information between and amongst healthcare practitioners.

The major difference is that EMRs are narrower and specific to medical conditions and the resultant records therefore, are considered medical whilst EHRs are broader than just medical details of a patient in the sense that they contain more details about a patient's health and encounters with different healthcare providers. However, it can be noted from this comparison that the difference is so subtle and it is not unusual for an EHR to contain all the information that is ideally found in an EMR. According to Garets and Davis (2006), an EHRs can only be possible in the presence of functional EMRs and EMRs will never attain their full potential in the absence of interoperable EHRs. Following this kind of reasoning, it can be observed that the difference between EHRs and EMRs lies in the granularity of the systems, with EMRs focusing on the lowest level of capturing patient medical data and being typically found in a healthcare facility whilst EHRs take a broader approach as they are an amalgamation of various EMRs systems and also allow patient health records to be shared beyond one healthcare facility. The researcher was alive to the differences between EHRs and EMRs throughout this study at the same time appreciating the complementary nature of the two concepts.

In terms of importance, EHRs and EMRs play what Armijo, McDonnell and Werner (2009:2) referred to as the evolving role, supporting clinical practice which can be organised around four primary functions that underpin the achievement of potential and related efficiency gains in health. The four roles include the memory aid, computational aid, decision support and collaboration aid functions (Armijo, McDonnell and Werner 2009:2). The memory aid function implies that EHRs and EMRs systems reduce the need to rely on memory alone for information that is needed to complete a task, whilst the computational aid function lessens the burden of mentally grouping, comparing and analysing health information as EHRs and EMRs systems have such functions embedded in them (Armijo, McDonnell and Werner 2009:2). Thus, EHRs and EMRs systems act as mnemonic devices allowing healthcare practitioners to interrogate them for histories of patients and related information, at the same time allowing for information relating to every aspect of health to be collected and collated with great ease and efficiency.

With regards to the decision support function, EHRs and EMRs aid evidence-based decisions by sourcing information from an array of sources, with the ability to integrate such information in a manner that allows for quick and informed decisions in healthcare organisations (Armijo, McDonnell and Werner 2009:2). The major advantage of this function is that decisions are not only based on evidence, but are made faster, something that is

necessary in today's fast, ever-changing and competitive health environment. Finally, the strand of collaborative aid talks to the enhancement of the ability of such EHRs and EMRs systems to communicate information as well as findings to other healthcare providers and patients (Armijo, McDonnell and Werner 2009:2). This particularly refers to the ability of EHRs and EMRs to share information through interoperable systems based on standardised terminologies and messaging platforms.

1.3 Statement of the problem

Standards for EHRs and EMRs play an indispensible role in facilitating the interoperability of EHRs and EMRs and improving healthcare through the provision of timely information to healthcare facilities and practitioners across the health sector in a country. According to the International Telecommunication Union (2009:7) "standards have a central technical objective of making pragmatic decisions that enable compatibility between telecommunications infrastructure, network equipment, data formats, and software interfaces." Marlon-Ralp (2016) explained that for silos of health data and information as well as blind sports emerging from the private sector health facilities to be eliminated, it is imperative that all EHRs be able to feed to DHIS-2 of the MHCC. This directly underscores the importance of and need for standardised EHRs and EMRs systems across the health sector of Zimbabwe so as to enable a seamless flow of health data and information for improved healthcare provision by all stakeholders.

However, it would seem the health sector of Zimbabwe is characterised by electronic systems that are rolled out at departmental and institutional levels throughout the country to generate and store both health and medical records of patients yet such systems are not coordinated and standardised to facilitate meaningful sharing of health information among healthcare facilities in the country. Neither are these systems compatible with each other, owing to a dearth of standards, a situation that leads to the country's healthcare industry failing to realise full benefits of such electronic systems. As a result, a gamut of technologies that are introduced in the health care sector of Zimbabwe tend to be customised to each hospital and lack communication abilities to each other (Furusa and Coleman 2018). As stated by the Ministry of Health and Child Welfare in its 2012-2017 e-Health Strategy

> The systems being developed and deployed do not use any national or international standards increasing the risk of developing vertical silos of data and limited information exchange across the health care divide.

Failure to share such electronic information of patients not only defies the logic behind the implementation of such systems, but also significantly disadvantages the patient as this means that their health and medical records will remain tied and fixed to the institutions from which they would have received care. Patients are mobile and they visit different healthcare facilities for various medical and health conditions and at times for the same conditions, for example, chronic disease, yet their records are not easily shareable especially when they visit more than one healthcare facility.

Furthermore, such a lack of standardisation is happening in the presence of SAZ, a standards body in Zimbabwe which is also affiliated to ISO. This leaves one with a question as to why there are no standards for EHRs and EMRs for the health sector in the country when SAZ is a member of ISO which, through its ISO/TC215 Secretariat, has produced a number of standards for EHRs. Such a lack of standards for EHRs and EMRs also implies that there may be no universal definition, scope and structure of what constitutes an EHR and EMR in Zimbabwe, a situation that compromises the quality of health information.

The predicament that health information finds itself in amid such a dearth of standards is exacerbated by the fact that the country's health industry is accelerating its efforts to utilise ICTs. Literature confirming the emergence of EHRs systems in the health sector of Zimbabwe abounds. Studies conducted in Zimbabwe have focused on other aspects of EHRs, leaving the aspect of standards for such systems under researched. For example, a study conducted by Furusa and Coleman (2018) focused on the factors that influenced e-health implementation by medical doctors in public hospitals in Zimbabwe; a study by Mutekiwa (2016) examined the institutionalisation of e-health in Zimbabwe with the evolution of DHIS in Marondera as the case in point whilst another study that was conducted by Moucheraud, Schwitters, Boudreaux, Giles, Kilmarx, Ntolo, Bangani, Luis and Bossert (2017) focused on the sustainability of Electronic Health Information Systems (EHIS) in Malawi, Zambia and Zimbabwe, thereby confirming the present researcher's observation that EHRs and EMRs standards are under researched. Corroborating and lamenting this observation on a larger scale, Adebesin, Foster, Kotze and van Greunen (2013:65) wrote "it should be noted that the level of e-health standards adoption is currently under-researched in Africa; with little or no published research available." Thus, the present study was a

necessary step towards understanding standards for EHRs and EMRs in Zimbabwe, amid the seemingly imminent multiplication of such systems in the country's health sector.

1.4 Research purpose

The purpose, which is the broad aim of the study, ought to be clearly stated as a way of showing the goal of one's research. As observed by Leedy and Ormorod (2010:3), research requires that one articulates the goal of his or her study. To Creswell (2009:111), a purpose statement "…sets the objectives, the intent, or the major idea of a proposal or a study." The study was an investigation of EHRs and EMRs standards implementation in Zimbabwe, with the aim of developing a framework within which such standards may be implemented.

1.5 Research objectives

The specific objectives guiding the study are to:

i. Analyse the existing standards for EHRs and EMRs for the health sector in Zimbabwe;
ii. Find out the extent of inter-operability of the EHRs and EMRs systems that are in use in the health sector of Zimbabwe;
iii. Ascertain the role of the Standards Association of Zimbabwe in the determination and promotion of EHRs and EMRs standards in Zimbabwe;
iv. Determine policies and legislation governing the development, implementation and monitoring of EHRs and EMRs standards in the health sector of Zimbabwe;
v. Determine the level of preparedness for the support and sustainability of EHRs and EMRs standards in Zimbabwe; and
vi. Develop a framework for EHRs and EMRs standards implementation in the health sector of Zimbabwe.

The research objectives captured above gave rise to the research questions and sources of information as shown in Appendix P.

1.6 Justification of the study

It is important for one to give rationale for their research. Research justification refers to the rationale for the research or the reason for which the study is being conducted, including the design and methods employed in the study (Ballinger 2008). Thus, Ballinger (2008) further stated:

> To explain the overall purpose, aims and objectives of the study, a rationale is constructed and may illustrate how the research endeavour addresses gaps in existing knowledge base, or generates theory about a phenomenon that has not been explored.

Literature shows that there is a need for inter-operable health information systems in the form of EHRs and EMRs if ICT applications are to yield meaningful benefits to the healthcare industry regarding health information management. As Kalra (2006:136) stated, clinical care increasingly requires different professionals in the healthcare industry to gain access to patient records or information that may be distributed across multiple sites. Other countries such as the United States of America, through HL7 standards, Australia through the IT-014-09 EHR Interoperability Subcommittee have made great strides towards the establishment of EHRs standards for possible adoption by their healthcare industries. On an international scale, ISO, through its ISO/TC 215 Secretariat and the CEN/TC 251 have also come up with a number of standards to guide EHRs. However, there seems to be a lack of research and literature on standards for EHRs and EMRs, not only in Zimbabwe, but in Africa as a continent. As observed by Adebesin et al (2013) "currently, e-health interoperability and standardisation, as well as their level of adoption in Africa is under-researched, with little or no published research available."

The researcher was aware of some standardisation efforts in Africa, including the EHR and EMR evaluation exercise that was employed by the Merika Institute of the Council for Scientific Research (MICSR) and the National Department of Health (NDH) (2014) in South Africa, a report by the Ministry of Medical Services and the Ministry of Public Health and Sanitation (2010) on the standardisation of EMRs in Kenya, a review of interoperability standards in e-health and imperatives for their adoption in Africa by Adebesin, Foster, Kotze and van Greunen (2013:66). At an international level, the researcher was aware of the works of e-Health Ontario (2013) whose thrust was a standards evaluation framework in its standards selection guide for EHR and EMR guidelines, the standardisation of EHRs and EMRs by the Government of India, Ministry of Health and Family Welfare (2016), reports by

May (2018) and another one by Monegain (2018) which all pointed out the challenge of lack of interoperable EHRs among hospitals in the USA, efforts of Standards Australia in partnership with the Department of Health and Ageing (DoHA) towards the development of health informatics standards which includes EHRs and EMRs.

Other previous studies that are related to the present study include the following: standardisation of medical record components in a correctional setting (Frye 2011), measuring quality performance in healthcare: the effects of Joint Commission International standards on quality performance (Hassan), a security framework for DICOM images in Health Information Systems (Kallepalli 2003), a review of healthcare indicators in South African district Health Information Systems for planning, monitoring and evaluation (Bhana 2010) among others. It should be noted there are many other studies that covered issues of implementation of EHRs and EMRs systems, indirectly touching on aspects of standards for such systems as well and this list is not exhaustive.

In Zimbabwe, there seems to be a gap of both literature and practical studies on the implementation of standardised EHRs and EMRs and such systems seem not to be guided by any local or international standards. This gap was also lamented by the MOHCW in its 2012-2017 e-Health Strategy when it stated that EHRs and EMRs systems that are being deployed in the health sector of Zimbabwe do not follow any national or international standards, a situation that increases the risk of developing vertical silos of data and limited information exchange across the healthcare divide. In light of this challenge, a study of this nature was necessary to explore the issue of EHRs and EMRs standards in the health sector of Zimbabwe. The study was set to generate literature that is specific to Zimbabwe as far as the subject of EHRs and EMRs standards is concerned, and suggest solutions that are tailor made for the country's healthcare delivery system.

The dearth of inter-operability in health information management in Zimbabwe was also lamented by health informatics institutions, a situation that necessitates a study of this nature. In a seminar that was held by the Computer Society of Zimbabwe in 2013, a speaker from the Health Informatics Training and Research Advancement Centre (HITRAC), Department of Community Medicine in the College of Health Sciences at the University of Zimbabwe stated that there was a need for centralised databases and interconnecting information so that there are real time updates and synchronised database to aid both the practitioners and patients at various institutes and observed the need for developing common standards where systems

must talk to each other, given the fact that standards enable systems to share meaningful health information (Rutsito 2013).

The speaker further gave an example of pharmacies in Zimbabwe that are characterised by independent computer systems that create verticalised data, resulting in locked bases that do not allow pharmacies to track history patterns of patients, a situation that results in unnecessary redundancy as well as drug abuse (Rutsito 2013). Thus, whilst there has been a gradual application of Information and Communication Technologies (ICTs) to create, manage and access health information in Zimbabwe, very little has been done to draft and implement standards that will enable the interoperability and hence sharing of health information by healthcare facilities in Zimbabwe. The present study comes in handy as it focuses on understanding the status quo concerning standards for EHRs and EMRs, with a view of proposing a framework within which standards for such systems may be implemented

1.7 Originality of the study

Originality of the study is one key aspect in research, especially at higher levels such as PhD as it avoids re-inventing the wheel by researchers. Originality is usually a prerequisite for research projects, especially those undertaken at degree levels, implying that a certain degree of originality is expected from those carrying out research at that level (Blaxter, Hughes and Tight 2001:13). According to Gill and Dolan (2015:11), originality in research is essential for a number of reasons, but chief among them is the production of new knowledge and indeed, according to the University of Sydney (2019), originality is one of the major criteria in the compilation of a successful thesis and should make a significant contribution to the accumulation of the knowledge pool in one's discipline, thus, it must proffer something new. According to Murray (2006:58), a thesis ought to show that one's work is original in some way and such originality differs from one level to the other. As the University of Melbourne (n.d) wrote, "as with depth and complexity of information, the extent of originality will also be determined by the level of your degree." Thus, at a PhD level, the approach to originality tends to be speculative and the academic goal is "creative originality" where new approaches are used or new knowledge is created (University of Melbourne n.d).

The term originality, as used in research, has a number of different interpretations and each thesis may employ a different definition (Murray 2006:58) and is not free from complexity,

resulting, in some cases, in frustration and challenges as to what exactly originality is among some students (Gill and Dolan 2014:13). As a way of indirectly defining originality, whilst explaining the confusion that bedevils PhD students concerning the meaning of the term, Gill and Dolan (2014:13) wrote "while this can be challenging and frustrating for many doctoral students, particularly those who wonder, 'Is this really a PhD?', determining the ways in which work is original is precisely what a PhD is about."

Whilst conceptualising and figuring out originality may be a mammoth and at times ambiguous exercise, the concept seems to have so many dimensions which somehow simplify its conceptualisation. For example, The University of Sydney (2019) lists eleven forms of originality in research which are easy to understand. Whilst "there are no absolute criteria, prescriptive principles or definitive solutions to follow" (Gill and Dolan 2015:13), originality in this study came in two main forms, which are part of Murray's (2006:59) list of originality and these include:

i. Synthesising things that have not been put together before; and
ii. Doing something in the country that has only been done elsewhere.

First, regarding the aspect of synthesising things that have not been put together before, the study will build and propose a framework for managing EHRs for the health sector of Zimbabwe, something that seemingly has never been done before as far as the reviewed literature revealed. As stated in the statement of the problem and background to the study, the country's health sector is characterised by EHRs systems that are not guided by interoperable standards that enable health information to be shareable by various healthcare providers at all the four health tiers that the health sector is divided into. The simplified framework that the study proposed was influenced by the prevailing situation in the health sector of Zimbabwe, thereby allowing for a context-specific framework for the country. According to the European Commission Information Society and Media (ECISM) (2008:30), "experience has shown that realising interoperability satisfactorily requires focusing on a concrete application context, which requires much more than implementing specific standards." This demonstrates the importance of understanding and appreciating the context within which standards are to be implemented or adopted so that the full benefits of EHRs that are based on interoperability and standards can be realised.

Second, regarding doing something in the country that has only been done elsewhere, the study, in developing the framework, took a cue from similar projects that have been rolled out in other countries towards tackling the challenge posed by the dearth of interoperable standards for EHRs, notably Kenya and South Africa. This is what Phillips and Pugh (1994) cited in the University of Melbourne (n.d) meant when they stated that originality in a study can come in the form of applying existing ideas to new areas, producing a critical analysis of something not previously done and conducting a study on a previously unsearched area or topic. Thus, the present study was not necessarily a new adventure in the world, but in Zimbabwe's health information management field, given that the literature shows that there appears to be a dearth of studies that have focused on establishing EHRs standards for the country's health sector. To the knowledge of the researcher, there seems to be scanty literature, if any, on the implementation of standards for EHRs and EMRs in Zimbabwe that is based on the present study's objectives.

The researcher demonstrated the originality of the study within the afore-mentioned scope, bearing in mind the warning that The University of Sydney (2019), and Blaxter, Hughes and Tight (2001:14) gave about originality that makes one's study sound over ambitious, scattered and unmanageable, given the fact that the contribution from a single study is relatively small in relation to the body of knowledge in a particular discipline and the scanty likelihood of one's research being very novel. Thus, "the element of originality in your own research is, realistically, likely to be very small." Highly original research is very unusual, and you are setting your sights far too high if you try aiming for it (Blaxter, Hughes and Tight 2001:14). Concurring with the afore-cited authors is The University of Sydney (2019) in the following words "while your thesis will be a big step for you, in most cases, your contribution will be a relatively small step for your field of study as a whole." This serves as advice against overemphasising the need for originality in one's research (The University of Sydney 2019). The present researcher remained alive to this warning by bearing in mind the fact that this study was located within the already existing literature on EHRs standards as some countries have already made great strides in the aspect currently under investigation.

1.8 Significance of the study

It is important for any researcher, at whatever level, to demonstrate the importance of their study to those stakeholders who stand to benefit and how they will benefit from such a study. To Creswell (2009:107), significance of the study serves to explain the importance of the problem for different groups that may profit from reading and using the study. By including this section, the researcher creates a clear rationale for the importance of their study (Creswell 2009:107). According to Bless, Higson-Smith and Kagee (2006:23), a viable research problem should, among other concerns, be timely, relate to a practical problem, relate to a wide population and have implications for a wider range of practical problems. Thus, a researcher should bear in mind the above-mentioned characteristics of a sound research problem and explain how ones' research addresses these as a way of demonstrating significance of one's study.

With the emergence of EHRs and EMRs that are not guided by any standards, the healthcare industry in Zimbabwe may adapt and adopt the recommendations of this study. This study may offer an insight into the status quo of standards for EHRs and EMRs in the health sector of Zimbabwe that the MOHCW may make reference to in its endeavour to fulfil the provisions of its e-health strategy (2012-2017). The Ministry recognises the importance of standards and interoperability and actually identifies this as one of the pre-requisites for an effective e-health programme. According to the MOHCW (2012), "there is need therefore for the country to come up with a common vision on e-Health." E-health encompasses EHRs and EMRs, which should be guided by sound and clear standards. Thus, the findings of the study, as well as its recommendations and the framework developed by the researcher may be adopted and adapted for the benefit of the healthcare industry in the country. The framework for EHRs and EMRs may further support and strengthen the health information system of Zimbabwe. As observed by the MOHCW (2012:5) "a robust health information system should support the delivery healthcare by providing information that is required for measuring the performance of service delivery at each health facility in the country." In light of the observation by the MOHCW (2012:5), it suffices to say that a sound health information system is one that is hinged on interoperable standards to enable health information sharing, and hence the importance of this study.

Furthermore, the standardisation of EHRs and EMRs will not only benefit the MOHCW, but a number of stakeholders, including patients and health practitioners. With standardised

EHRs and EMRs, patients can access their health information from anywhere in the country and even abroad and may easily be reminded about important activities such as review dates as these may easily be incorporated into the system. Health practitioners can also benefit by gaining up-to-date information about their patients, some of whom may have been referred to them by other health institutions. For example, given the organisation of the health delivery system in Zimbabwe where a patient may move between the four tiers for one or more diseases, it is important for health practitioners to gain authorised real-time access to such a patient's health information or history so as to expedite treatment and avoid casualties that may arise from a lack of adequate patient health history. Thus, all this may be possible through the use of EHRs and EMRs that are based on interoperable standards. Standards for these records will also improve the quality of health information in the country.

Additionally, a study of this nature helps with the generation of knowledge regarding the status quo of EHRs and EMRs standards development and implementation in Zimbabwe. Such literature also complements efforts of other scholars and practitioners, thereby enabling allowing the enunciation of knowledge regarding EHRs and EMRs standards through research. Lau, Bartle-Clar, Bliss, Borycki, Courtney and Kuo (2017:2) observed that in order to effectively implement ICTs applications such EHRs and EMRs, "there must be strong scientific, research, industrial and governmental supports in place in order to transform healthcare and build capacity at the regional, national and international level." An exploration of standards for EHRs and EMRs in the context of Zimbabwe goes a long way in contributing towards the scientific and research strand, as part of the many requirements for a successful implementation of such systems. This is particularly important in the light of the observation by Boonstra, Verluis and Vos (2014) that "although EHR systems are anticipated as having positive efforts on the performance of hospitals, their implementation is a complex undertaking." The present study proposes a simplified framework within which EHRs can be implemented in the context of the health sector in Zimbabwe whilst remaining alive to the fact that the framework is subject to improvements or modifications.

1.9 Definition of terms

Defining terms used in research helps readers understand such terms in the context of the study, given the fact that the same word may mean different things when used in certain

contexts. Thus, defining key terms in a study also helps determine the conceptual definitions of one's study.

1.9.1 Electronic health record

According to the Health Information Management Systems Society (HIMSS) cited in McLean (2006:1), an EHR is

> A longitudinal electronic record of a patient health information generated by one or more encounters in any care delivery setting. Included in this definition are patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data, and radiology reports.

EHRs are broader than EMRs as they stretch beyond a single organisation and are reliant on functional EMRs.

1.9.2 Electronic medical record

An electronic medical record was defined by Garets and Davies (2006:2) as:

> An application environment composed of the clinical data repository, clinical decision support, controlled medical vocabulary, order entry, computerised provider order entry, pharmacy, and clinical documentation applications. This environment supports the patient's electronic medical record across inpatient and outpatient environments, and is used by healthcare practitioners to document, monitor, and manage healthcare delivery within a care delivery organisation.

EMRs, in comparison to EHRs, are at a lower level and meant to capture clinical and medical data in a healthcare facility. EHRs therefore, act as building blocks for EHRs.

1.9.3 Framework

A framework is "a basic conceptual structure (as of ideas); a skeletal, openwork, or structural" (Merriam-Webster Thesaurus 2020).

1.9.4 Healthcare institution

A healthcare institution refers to “any hospital, convalescent hospital, health maintenance organization, health clinic, nursing home, extended care facility, or other institution devoted to the care of sick, infirm, or aged person” (The 'Lectric Law Library 1995-2020).

1.9.5 Health delivery system

A health system can be taken to “include all the activities whose primary purpose is to promote, restore or maintain health” (World Health Organisation 2000:5).

1.9.6 Standard

A standard was defined by the European Commission for Standadisation (CEN) (2020) as “a technical document designed to be used as a rule, guideline or definition. It is a consensus-built, repeatable way of doing something.”

1.10 Ethical considerations

Scientific research requires that researchers abide by research ethics. According to the University of Minnesota Center for Boiethics (2003:6) “research is a public trust that must be ethically conducted, trustworthy, and socially responsible if the results are to be valuable.” Thus, all parts of a research project, right from the design stage to submission of results for peer review have to be upstanding in order for the study to be considered ethical (University of Minnesota Center for Bioethics 2003:6-7). In this study, a number of ethical issues were observed, including avoiding plagiarism and sticking to the principle of informed consent regarding the respondents. Permission to gather data from both the MHCC and SAZ was sought, with the assistance of the Registrar of the National University of Science and Technology (NUST) who wrote to the two institutions, asking for permission on behalf of the researcher. The two institutions and respondents were fully informed of the objectives of the study, including the benefits that may be realised from the study. The researcher also declared any conflicts of interest that might arise in the course of the study and avoided misrepresenting facts during data presentation in order to protect the integrity of the study. Furthermore, the researcher had the proposal cleared by the Higher Degrees Committee in the

College of Human Sciences at the University of South Africa (UNISA) after ensuring that the study conformed to the ethical requirements of the Policy on Research Ethics (2016) on UNISA.

1.11 Scope of the study

Geographically, the study was limited to Zimbabwe. Conceptually, the study was limited to the country's health information management, with a special focus on EHRs and EMRs which were the focus of the study. The study drew its informants from the MHCC and SAZ.

1.12 Limitations of the study

The limitation of the study was the fact that the study did not have a practical flair since it was conducted from a theoretical point of view without the input of practitioners. Given the fact that the intention was to come up with a framework that could guide the implementation of standards for EHRs and EMRs, it would have been best to make the study a collaborative effort between the researcher and the practitioners so as to incorporate as much practical experiences as possible, which, unfortunately, was not possible in the present study. However, the researcher made efforts to ground the framework in the conclusions of the study which were arrived at after analyses of data gathered from the field, complemented by literature on international projects.

1.13 Conceptual framework

A conceptual framework is "an interconnected set of ideas (theories) about how a particular phenomenon functions or is related to its parts (Svinicki 2010:5). A conceptual framework therefore, "offers a logical structure of connected concepts that help provide a picture or visual display of how ideas in a study relate to one another within the theoretical framework (Grant and Osanloo 2014:17). It is on this basis that Grant and Osanloo (2014:17) warn that such a framework is not just a string of concepts but a representation of concepts and their interrelatedness, allowing the researcher to construct and communicate his/her epistemological and ontological paradigm and approach to his/her study. Thus, through a conceptual framework, the reader is able to identify the actors and factors that shape or mould

the phenomenon under investigation and logically bring out their relationship and their constitution of and contribution to the phenomenon.

In light of the fact that the present researcher was not aware of any theory that explains and guides the aspect of standards for EHRs and EMRs, literature on the subject matter was relied on to come up with a conceptual framework (see Figure 2.1). As observed by Ngulube, Mathipa and Gumbo (2015:62), some studies, especially exploratory ones may not necessarily require an explicit theoretical framework. This is especially the case with those areas of research that do not have well developed theories (Ngulube, Mathipa and Gumbo 2015:62). In such cases, "literature reviews may serve as conceptual frameworks." Thus, the above-mentioned statements by Ngulube, Mathipa and Gumbo (2015) are true for the present study as there seems not to be a theoretical framework on which the study may be hinged. This also allowed the researcher to formulate his conceptual framework in which the researcher demonstrated his conceptualisation of the problem as it manifested itself on the ground by giving an explanation of the possible factors at play that could help better understand the problem.

Moreover, the study was located in the interpretivist paradigm, relying on the relativist ontology and was more of an exploration of the situation on the ground concerning standards for EHRs and EMRs in the health sector of Zimbabwe, thereby allowing the use of literature on the subject matter as a conceptual framework. Thus, the study did not intend to prove or refute a theory but intended to explore and explain the status quo concerning EHRs and EMRs standards and their utilisation in the health sector of Zimbabwe, and developing a framework of standards for such, thereby permitting the use of literature on the subject matter as a conceptual framework. This is in tandem with Ngulube's (2018:9) assertion that a conceptual framework allows the researcher to map concepts that they explored in a research project and is inductively developed by the researcher drawing from a gamut of components of theories, concepts that exist in the form of literature, diverse theories and sources as well as experience. The conceptual framework of the study is discussed in detail in Chapter Two of the study.

1.14 Research methodology

This study employed a qualitative approach in the form of a qualitative case study. Regarding the design, the study utilised a qualitative case study design where respondents were purposively chosen and qualitative questions asked. The study informants consisted of the Director – Finance and Administration, Director- Epidemiology and Disease Control, Director- Policy Planning, Deputy Director- ICT, Deputy Director- Policy Planning and Deputy Director- Health Information in the MHCC and the Director General and a Manager at SAZ. As argued by Tellis (1997:1), "Case study research is not sampling research; that is a fact asserted by all the major researchers in the field, including Yin, Stake, Feagin and others", the respondents who constituted the population of the study also served as the sample of the study.

The study relied on questionnaires and interviews as its primary data gathering instruments. Owing to circumstances that were beyond the control of the researcher, the present study saw only one interview being conducted with the Director General-SAZ, and three questionnaires being successfully administered to three Deputy Directors in the MHCC and one being administered to the Deputy Director-SAZ. Because of the qualitative nature of the study, data was analysed and presented as in a textual format with verbatim quotations where necessary, thereby allowing the voices of the respondents to come out so as to enhance the richness of the data in the data presentation phase.

1.15 Thesis outline

Chapter One introduces the study by giving background information to the study and problematizing the issues of EHRs and EMRs standards in the form of background to the study and problem statement. The chapter also outlines the research objectives, research questions, purpose of the study, significance of the study, justification of the study and ethical issues. The chapter concludes with a summary.

Chapter Two of the study focuses on the conceptual framework of the study, explaining how the conceptual framework of the study informed the study. This chapter also focuses on reviewing literature that is related to the study. It consists of literature on EHRs and EMRs standards. Empirical studies on this are also be reviewed and juxtaposed with the prevailing

situation in Zimbabwe so as to further place the study in a context and reveal the gaps regarding EHRs and EMRs implementation in the country in comparison to the international community.

Chapter Three is made up the research paradigm and methodology. The researcher explains and justifies the paradigm under which the study falls. Issues of the research design, study population, study, data gathering tools and sampling are also explained in the chapter, with justification for their use and relevance. Chapter Four consists of data analysis and presentation, thus, presenting and analysing data that was gathered through the instruments that were used in the study.

Chapter Five focuses on data interpretation whereby the researcher makes meaning and sense out of the data gathered. This entails interpreting and understanding the data in the context of the problem under investigation as well as the objectives of the study. Findings of the present study are also juxtaposed and collated with those of related studies in an endeavour to bring to the fore any similarities and gaps between what was obtaining in Zimbabwe's health sector and what was happening around the globe.

Chapter Six consists of the summary of the study, findings and conclusions of the study. The chapter also proffers recommendations to the concerned stakeholders, based on the findings of the study. The proposed framework of standards implementation with regards to EHRs and EMRs is also given and explained in this chapter.

1.16 Summary

The chapter provided background to the study concerning standards for EHRs and EMRs in the context of Zimbabwe. As part of the background to the study, the organisation of the health delivery system, including the key classification of healthcare institutions into the four tiers and private and public sectors in Zimbabwe was described. This enabled the researcher to contextualise the study to Zimbabwe and problematize the issue of standards for EHRs and EMRs systems that are gradually emerging without standards. The statement of the problem was also given, clearly explaining how problematic the aspect of standards for EHRs systems is for the health sector of Zimbabwe. The problem statement was also accompanied by the purpose, objectives and questions of the study that acted as the pillars of the study. Furthermore, the significance, justification and originality of the study were highlighted in this chapter. Because research also requires one to abide by research ethics, a section was

dedicated to the explanation of the ethical aspects that were observed in the conduct of the study. The chapter further indicated the geographical and conceptual coverage of the study, thereby helping demarcate the scope of the study. Finally, the chapter gave an outline of the chapters that constituted the thesis, thereby showing how the study is structured. The next chapter presents the conceptual framework of the study and reviews literature regarding EHRs and EMRs standards and their implementation.

CHAPTER TWO
CONCEPTUAL FRAMEWORK AND REVIEW OF LITERATURE ON ELECTRONIC HEALTH RECORDS AND ELECTRONIC MEDICAL RECORDS STANDARDS

2.1 Introduction

With the previous chapter giving background information and the problem under investigation, the present chapter presents the conceptual framework and literature review for the study. The research terrain is typified by ever changing and cumulative discourses that call upon researchers to conduct literature reviews within certain conceptual or theoretical frameworks in order to place their studies within intelligible and progressive contexts. A conceptual framework and a literature review are both complementary and desiderata in academic research and their importance needs not be overemphasised.

The field of EHRs and EMRs is a relatively nascent but fast developing one, owing to the importance and evolution of health in general and the auxiliary nature of EHRs and EMRs to healthcare delivery systems throughout the world. Thus, a literature review that is guided by a relevant and vivid conceptual framework becomes indispensable to the present study. The quintessence of this chapter therefore, is to explain the conceptual framework of the study, showing the lanes within which the study and the literature were viewed and interrogated, respectively. Because a conceptual framework informs the literature review process and in a way reflects the edifice of the literature review process, this chapter starts off with explaining the conceptual framework that underpinned the study and then reviews the literature on EHRs and EMRs standards as they relate to the study's objectives.

2.2 Defining a conceptual framework

A conceptual framework helps the researcher depict his or her thought process throughout the study and helps one to demarcate the conceptual boundaries of the study. In a way, "conceptual frameworks have grown out of the traditional theoretical frameworks that may already exist and be taken to underpin a doctoral study" (Berman 2013:2). Sitko (2013:5) viewed a conceptual framework as the researcher's own theory, explaining what the researcher thinks is happening, that is, something that the researcher builds and it is not

found. In fact, according to Svinicki (2010:5), every human being is endowed with this talent of conceptualising the reality around them. Thus, "everyone has a conceptual framework about how reality works that allows him or her to make predictions about how A is related to B and what will happen when the two intersect" (Svinicki 2010:5). Based on this understanding, the researcher is able to construct their own understanding of concepts and perceived outcomes of the interplay of variables presumably involved in the phenomenon under study, thereby approaching the world from a particular perspective.

In coming up with a conceptual framework, the researcher is challenged to figure out what is useful and what is not, what is missing, and how can they fill the gap that they have since identified (Sitko 2013:5). To further understand the meaning of a conceptual framework in research, Sitko (2013:7) further implores researchers to pose the following series of cardinal questions to themselves:

i. What does one think is going on with the issues, setting or people they plan to study? It is this that then becomes the researcher's own theory;
ii. What established theories, beliefs, and prior research findings inform one's current understanding of what is going on?; and
iii. What literature, preliminary studies, and personal experiences will one draw on in their research and why?

In light of Sitko (2005)'s foregoing position, a conceptual framework, as opposed to a theoretical framework, is a body of carefully selected body of literature, concepts, theories, research findings on a subject that the researcher amalgamates with his or her own beliefs and expertise in a subject that helps him or her to explain, without necessarily adducing hard evidence, what they think is happening in the real world and the issue under study. Sitko (2005)'s views also resonate well with those of Jabareen (2009:50) who considered a conceptual frameworks as "…products of qualitative processes of theorization."-a network or a plane consisting of interlinked concepts that when digested together, provide the researcher with a comprehensive understanding of a phenomenon (Jabareen 2009:51). To Solomon and Solomon (n.d:6), a conceptual framework is a model which depicts an existing reality, that is, the status quo of a reality.

The views of Solomon and Solomon (n.d:6) are in sync with that of Sitko (20013:7) in viewing a conceptual framework as an expression and denotation of what the researcher

thinks is happening to the setup or phenomenon that is under investigation. It is that which Solomon and Solomon (n.d:6) refer to as the "existing reality-the status quo" about one's study which Sitko (2013:7) calls the researcher's own "theory." It is worth hinting that the researcher's own "theory" in this case refers to something that the researcher comes up with as their conceptual framework as opposed to a theoretical framework or predefined theories propounded by other scholars.

Further shedding light on how one may build an appropriate conceptual framework for their study is Lechissa (2017:2) who cited one's background, identity, technical knowledge, research knowledge and experiential knowledge as all potential and valid sources of conceptual frameworks. This is also in tandem with Miles and Huberman (1994:18) who characterised a conceptual framework as being, rudimentary or elaborate, theory driven or commonsensical, descriptive or causal. Thus, researchers are equipped with a plethora of building blocks for conceptual frameworks, that however, they need to meticulously digest and structure in a manner which helps them enunciate their conceptual positions regarding their studies.

Goertz (2005:4) defined a conceptual framework from a view that has philosophical implications by first unpacking the very term "concepts", which to him means "…theories about ontology: they are theories about the fundamental constitutive elements of a phenomenon." He argues for concepts that are reflective and representative of the phenomena that are being described by moving away from concepts that employ nominalism and semantics at the expense of realism. According to Goertz (2005:3), concepts that are based on nominalism and semantic definitions are arbitrary and

> If the concept is not intimately related to the empirical analysis of a phenomenon, then there is nothing to which one can anchor the concept, and everything becomes a matter of who is in charge of the definition.

Thus, an essentially semantic analysis of concepts, words and their definitions does not suffice as conceptualisation and concepts need to be defined from an ontological point of view so that they focus on what constitutes a phenomenon (Goertz 2005:4-5). It can be noted that the views of Goertz (2005) are indicative of a more rigorous way of conceptualising issues under investigation in which the researcher needs to define concepts in terms of their inherent attributes or characteristics, which is more scientific and clear. Whilst this is a plausible approach to conceptualisation, it is worth noting that the very act of "conceptulising" itself is an inherently fluid thought process whose meaning is always

constructed by the conceptualist. However, it is necessary for one to have a clear and logical conceptualisation process which is denoted by a conceptual framework when conducting research.

2.2.1 Utility of a conceptual framework in research

In light of what a conceptual framework is, its utility and indispensability in research are unquestionable. Ngulube (2018:11) makes it clear that a conceptual framework is a desideratum in research by stating that "…conceptual tools are not just a nice thing to have in a research project: they assist in ordering and operationalizing the research design." Having a conceptual or theoretical framework in a study goes a long way in terms of informing one's research methodology. Goertz (2005:2) laments the conspicuous dearth of conceptual or theoretical frameworks in most studies and maintains that theory should be in the forefront in informing our research methodologies. Thus, "while we all pay a lip service to the mantra that theory should guide methodology, it is often the case that the cart is leading the horse."

In the words of Solomon and Solomon (n.d:6), a conceptual framework has the ability of helping researchers identify inadequacies within the status quo and allows foresight to be applied to such inadequacies. This, Solomon and Solomon (n.d:7) further observed, facilitates sensible and academic debates in terms of the taxonomy, relationship between variables, propositions as well as models, to take place, at the same time, allowing clarity to be sought through such debates, resulting in problems being solved in a concise manner. This way, policy recommendations which may flow or arise from one's conceptual framework may also be fully debated in a coherent fashion (Solomon and Solomon n.d:7). Miles and Huberman (1994:18) stated that a conceptual framework may either graphically or narratively explain the form, the main things to be studied-the key factors, constructs or variables- and the presumed relationship among them. This implies that conceptual frameworks, although not based on empirical knowledge, may be used by researchers to explain the presumed interaction and interrelatedness of the factors under investigation and how they affect or may shape the phenomenon under study.

2.2.2 Why a conceptual framework in this study

In light of the seemingly narrow but methodologically significant differences between theoretical and conceptual frameworks, it is generally advisable for researchers to give rationale for using either a theoretical or conceptual framework in their studies. To cite Ngulube (2018:11), a researcher should give a clear rationale behind the employment of a conceptual framework instead of a theoretical framework. It should be equally appealing to the researcher to justify the utilisation of a theoretical framework instead of a conceptual framework. On that note, this section is dedicated to the justification of the use of a conceptual framework in this study.

To start off with, the present study was qualitative in nature and examined an issue that was not fixed and could be conceptualised in different ways and this allowed the use of a conceptual framework. The study was concerned with examining the status quo of EHRs and EMRs standards implementation in the health sector of Zimbabwe, with the view of developing one. The existence of EHRs and EMRs systems without an accompanying framework of standards to enable the health sector to reap maximum benefits from such systems was seen as a qualitative problem that required the researcher to employ a qualitative methodology of solving it.

As stated by Jabareen (2009:50), "conceptual frameworks are products of qualitative processes of theorization." Thus, the study objectives, which also act as the study's variables were not based on any theory but were developed by the researcher as factors that need to be understood or explored so as to understand the operations of EHRs and EMRs systems, as well the roles, responsibilities and duties of different stakeholders such as SAZ and the MHCC in the development and implementation of standards for such systems. Thus, the researcher took these as important players in the field of EHRs and EMRs standardisation and sought to understand the roles and contributions or lack of such, in the standardisation of such systems. All these aspects, when analysed together help conceptualise the process or framework of standards for EHRs and EMRs.

The study also employed a conceptual framework because of the contemporary nature of the issue under investigation. EHRs and EMRs, let alone their standardisation, are relatively nascent issues in the field of health and records management and the researcher is not aware of any existing theoretical framework that explains the development and or implementation

of a framework of standards for EHRs and EMRs. It was this researcher's view that the standardisation of EHRs and EMRs in the health sector of Zimbabwe is a social and relatively fluid phenomenon that is affected by a plethora of factors such as the government through the MHCC, SAZ, the presence or absence of clearly policies, legislation and monitoring mechanisms as well as the level of preparedness for the support and sustainability of EHRs and EMRs standards. This therefore, rendered the study wanting in terms of any theoretical framework to underpin it, with the result of a conceptual framework being employed. Thus, the study's research objectives denoted issues and factors that the researcher considered to be cardinal and rudimentary in understanding the terrain of EHRs and EMRs standardisation and rolling out a standards implementation framework for such systems, for which no theoretical framework was found to be in existence and of utility for the study. It is against this background that a conceptual framework was preferred to a theoretical framework.

2.2.3 Conceptual framework of the study

The following section is dedicated to demonstrating and explaining the conceptual framework that the study utilised. According to Miles and Huberman (1994:18), a conceptual framework may be presented in a graphical or narrative form and may be derived from common sense. This study depicts, both graphically and narratively, the factors that the researcher considered to be the most proximal ones and acted as determinants and enablers of standardisation of EHRs and EMRs and needed to be understood by the researcher. It is such factors, although not necessarily exhaustive, that the study considered as the desiderata for an appreciation of the standardisation of patient's health and medical records existing in electronic formats. Figure 2.1 shows the study's conceptual framework.

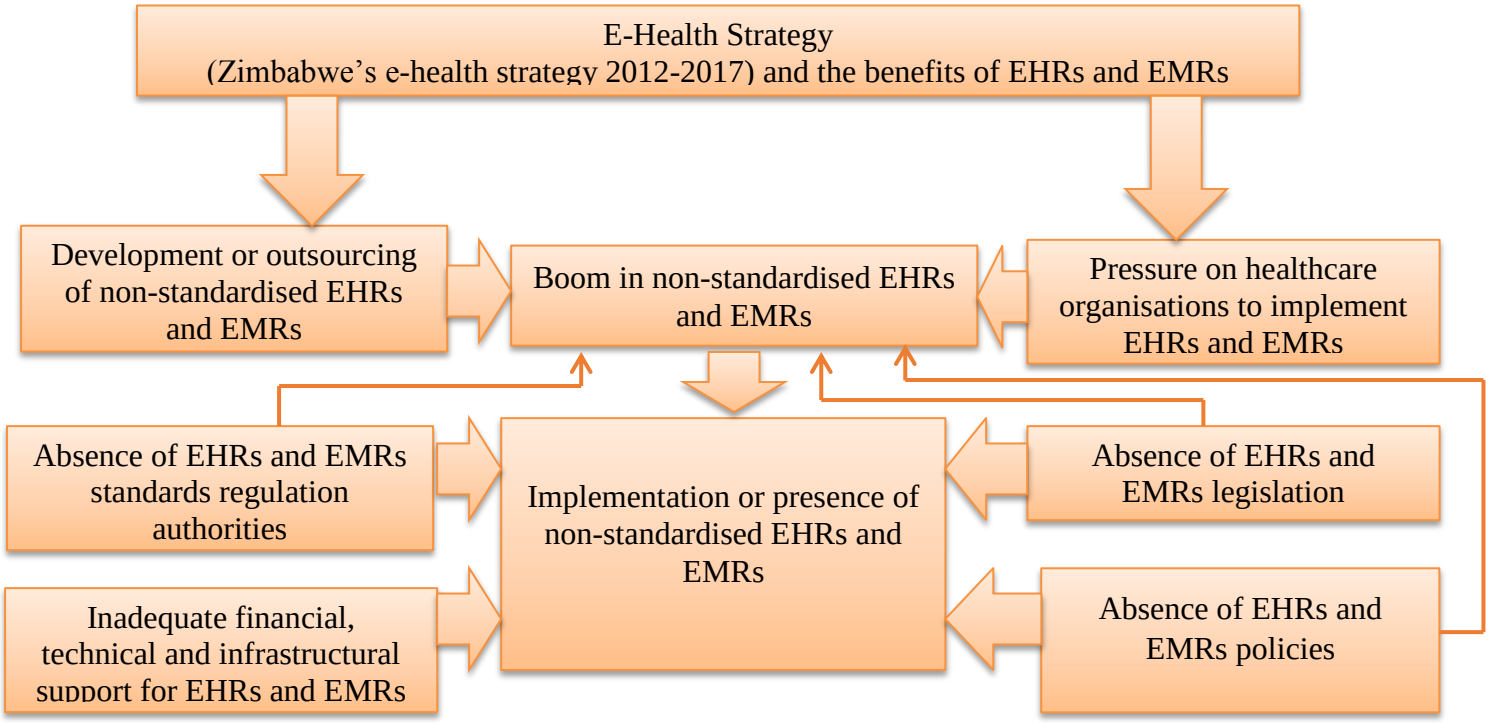

Figure 2.1: Conceptual framework of the study

Source: Constructed by the researcher

As shown in Figure 2.1, the conceptual framework of the study has nine factors that the researcher assumed were at play and partly responsible for the status quo regarding EHRs and EMRs standardisation. The starting off point is the pronouncement of the e-health strategy by the MHCC (Zimbabwe's e-health strategy 2012-2017) coupled with the benefits presented by EHRs and EMRs, which exerted pressure on healthcare organisations in the health sector to embrace ICTs and take advantage of them to improve health care in general. Health records were not spared from such calls, a situation that may have resulted in a good number of healthcare facilities rolling out EHRs and EMRs that, however, are not based on any standards. The rapid and unregulated adoption of ICTs in the health sector following the pronouncement of Zimbabwe's e-health strategy, may have seen healthcare organisations roll out EHRs and EMRs whose focus or concern is just the capturing of patient records in a non-standardised manner. As demand for EHRs and EMRs grew in healthcare facilities, there emerged EHRs and EMRs development initiatives as well as wide scale purchasing of such records systems that seemingly, are also not based on standards.

A combination of pressure on healthcare organisations to implement EHRs and EMRs, together with other ICT uses in healthcare facilities and the development of such systems presumably resulted in the emergence and booming of non-standardised EHRs and EMRs in healthcare facilities in Zimbabwe. As such systems boomed, healthcare facilities became "spoilt of choice" as they had a variety of both local and international markets from which the systems can be purchased. These factors had the net effect of directly impacting how such systems are rolled out. In this case, it implies that the healthcare facilities in the country became characterised by the implementation of EHRs and EMRs that were not based or governed by standards and therefore, do not allow for the realisation of maximum benefits of ICT, with regards to the management of patient health records.

Also contributing to the existence of non-standardised EHRs and EMRs are, as discerned in Figure 2.1 could be the death of clear legislation and policies that anchor the standardisation process of such systems. This presumably resulted in a weak and even non-existence of an EHRs and EMRs standards implementation framework, a challenge that characterises the healthcare delivery system today. Without legislation and policies that directly detect the legal provisions for standardisation, there is nothing that compels healthcare facilities to standardise their EHRs and EMRs. This leaves standardisation as a matter of choice instead of it being a requirement. In fact, sound, clear and progressive legislation and policies should be construed as indispensability to an EHRs and EMRs implementation framework, which, however, is conspicuously missing in the healthcare system of Zimbabwe. Thus, such dearth of sound and clear legislative and provisions for the standardisation of such records systems, the healthcare delivery system of Zimbabwe will continue to witness the booming of systems that compartmentalise patient health information, with the effect of realising limited benefits of ICT application in health information management.

Coupled with the above mentioned and having the same effect of promoting the emergence of EHRs and EMRs that are not standardised is the absence or lack of bodies that are dedicated to the development, or customisation of imported standards, evaluation and monitoring compliance with standards for such systems. As shown in Figure 2.1, where there is a drive towards the adoption of ICTs in healthcare without commensurate efforts of developing, embedding and promoting the adoption of standards for EHRs and EMRs, let alone a situation where there are no standards bodies for such systems, the mushrooming of non-standardised systems does not only have a very high likelihood, but an inevitability.

The other seemingly obvious culprit in the emergence of a weak and unclear EHRs and EMRs implementation framework and non-standardised systems is lack of resources that take the forms of finance, technical expertise and infrastructure. When these resources are missing, especially finance, the entire efforts of standardising EHRs and EMRs remains a nightmare.

Using the conceptual framework that is depicted in Figure 2.1, the researcher was able to conceptualise the problem under investigation which is the existence of EHRs and EMRs that are not guided by standards as well as the dearth of clearly outlined standardisation framework for such systems. Because conceptual frameworks are not ready made, but deliberately built by the researcher (Ngulube 2018:9), they offer a number of advantages such as flexibility, provision for modification, and perhaps more importantly, their emphasis on understanding rather than prediction (Jabareen 2009:49), the researcher managed to demonstrate his understanding of the possible factors that could be at play in the health sector of Zimbabwe and are presumably responsible for the dearth of an EHRs and EMRs standards framework.

It is worth mentioning that the conceptual framework that the researcher built is never exhaustive and is malleable. The researcher would also like to indicate that the framework is not purely causal in nature, but more commonsensical as it reflected the researcher's thought process about the problem under investigation and was informed by literature and the researcher's own understanding of how the phenomenon of non-standardised EHRs and EMRs could be understood. Thus, the framework was meant to demonstrate the understanding of the matter under investigation in a simplified non-causal manner.

2.3 Literature review

A literature review is one key ingredient of research work irrespective of one's discipline and its indispensability needs not be overemphasised. According to Maggio, Sewell and Artino (2016), a literature review allows the researcher to "join the conversation" through providing a context of their study, informing methodology, identifying innovation, avoiding duplicative efforts and upholding professional standards. To Mathipa (2015:70) a literature review "…is particularly important because scientifically sound and accurate research must be informed by existing literature…"

A literature review also helps clarify one's research question and show how the problem under investigation is embedded within the already available facts and theories (Bless, Higson-Smith and Kagee 2006:25). Harping on the same point is the Western Sydney University Library (2017) which characterised a literature review as an exercise meant to enable the researcher to gain an understanding of the already existing research and debates that relate to one's area of study. Thus, a literature review provides the reader with an opportunity to catch up with scholarly debates, discourses and discoveries that have been made by others and be able to situate their study in the vast and rich literature in a complementary fashion. In light of the above, the subsequent sections are dedicated to the literature review of the present study.

Although the reasons for conducting a literature review are undisputable and clear, Bless, Higson-Smith and Kagee (2006:25) warn researchers against being taken away by the existing literature to the extent of losing the original thrust of their own research and being influenced by the findings of previous studies. This implies that when conducting a literature review, one has to be careful and do this with extra caution by maintaining his or her own voice such that there is originality in one's study. The literature review in this study was conducted with this warning in mind and the researcher used the already existing literature on standards to identify, demonstrate and buttress the gap that exists in the health sector of Zimbabwe regarding EHRs and EMRs standards and to familiarise the reader with what has been happening on an international scale versus the status quo in Zimbabwe, thereby demonstrating and maintaining originality.

2.3.1 How literature was reviewed in this study

There are various types of literature reviews including chronological, thematic, argumentative, historical, methodical, systematic-meta-synthesis, meta-analysis and narrative. The choice of a type is contingent on the type of research that one is conducting and how best it advances their study. In the present study, a thematic review was employed in which the study objectives served as major themes for the review. This enabled the review to flow in logical fashion at the same time helping in ensuring that each research objective was adequately discussed.

2.3.2 Standards for EHRs and EMRs

Standards for EHRs and EMRs come in two broad types, namely interoperability standards and administrative standards that are commonly known as administrative safeguards standards. Interoperability standards in the context of EHRs and EMRs may be loosely defined as the messaging, content and terminology standards that render support to the exchange of data between points of service facilities and the registries, repositories as well as applications that constitute EHRs (FICCI Health Services India 2013:3). This category of standards focuses more on technical and structural protocols and content of EHRs and EMRs in a bid to allow such systems to share health information.

Administrative safeguards standards, according to the FICCI Health Services India (2013:45), "…require healthcare providers to develop and implement a security management process that includes policies and procedures that address the full range of their security vulnerabilities." Thus, standards of this type are meant to complement their technical counterparts by enabling healthcare organisations to safeguard patient information that the systems generate, store, rearrange, share and preserve in a bid to protect and preserve the integrity, privacy and confidentiality of patients. It therefore, implies that this type of standards will cover a spectrum of administrative aspects of EHRs and EMRs adoption, uses and management. Essentially, standards of this type will talk to issues of patient confidentiality, privacy, security of patient information, and other issues that are related to the upholding of patients' integrity. It is worth noting that both of these standard types are a necessity if EHRs and EMRs systems are to achieve full standardisation and interoperability.

2.3.2.1 Interoperability standards for EHRs and EMRs

One of the major benefits to be realised from EHRs and EMRs is interoperability. Indeed, many countries are advancing the use of EHR, personal electronic health records (PEHR) as well as patient portals (Cornet 2017:70). Commenting on its Health Information System of 2009-2014, the MoHCW (n.d:20), also noted that patient health information may be shared among healthcare providers dealing with the same client in various departments, and such requires networks and connections that support the sharing of such information from different levels of healthcare. According to the European Commission Information Society and Media (2008:17), ensuring interoperability of EHRs *[and EMRs]*, will contribute to effective and

efficient patient care by enabling the retrieval as well as processing of clinical information about a patient from different sites.

In the words of Bisbal and Berry (2009:5), the quintessence of EHRs systems development which has attracted so much attention is interoperability. This comes out of a realisation by Bisbal and Berry (2009:6) that despite the emergence of such EHRs, many of such systems have paid limited attention to interoperability, largely because such systems have been developed in a manner that they only satisfy the immediate requirements of their healthcare facilities as well as making decisions about other dimensions of the systems whilst interoperability has been overlooked. This results in pockets of isolated systems that do not allow healthcare facilities and patients to realise maximum benefits regarding health information sharing and accessibility.

Lamenting the challenge of the dearth of interoperability between EHRs and EMRs systems, Abid, Keshavjee, Karim and Guergachi (2017:2) observed that such technologies in healthcare facilities such as hospitals and clinics tend to function independently from each other such that data are maintained in silos. Making the situation worse is the fact that they tend to maintain data entry screens as well as templates in offline silos (Abid et al 2014:2). This would seem true for EHRs and EMRs systems of the developing countries, Zimbabwe included, where such systems are nascent and have just been rolled out or are still being rolled out. The FICCI Health Services India (2013) also categorised interoperability standards for EHRs and EMRs into three, namely vocabulary standards, content standards and clinical standards.

For EHRs and EMRs systems to be able to share health information, there should exist a standardised terminology which will see such systems talk the same language and such vocabulary is referred to as vocabulary or terminology standards. The latest EHRs hype and the deployment of such systems have given birth to terminology standards and their adoption by clinical practitioners (Bodenreider, Cornet and Vreeman 2018). Vocabulary standards are "standardised nomenclatures and codes, e.t.c used to describe clinical problems and procedures, medications, allergies" (FICCI Health Services India 2013:14).

According to Gonzalez, Blobel and Lopez (2011:694), the goal of semantic interoperability is for systems to be able to recognise and process semantically equivalent information, even in cases where instances are heterogeneously represented, that is, if they are differently structured, and/or using different terminology systems and/or using different natural

languages. Examples of vocabulary standards include the Logical Observations Identifiers Names and Codes (LOINC); International Classification of Diseases (ICD), Systematised Nomenclature of Medicine-Clinical Terms (SNOMED-CT) (e-Health Ontario 2013; FICCI Health Services India 2013:14), the Current Procedural Terminology, 4th Edition (CPT4), RxNorm, Anatomic Therapeutic Chemical Classification of Drugs (ACT) (FICCI Health Services India 2013:15). Thus, for EHRs and EMRs systems to be terminologically interoperable, any of the above mentioned standards may be adopted. It is worth mentioning that the list of vocabulary standards above is not in any way exhaustive but consists of mere examples. In actuality, there is an overlap between the different interoperability standards especially content and terminology standards as a standard in these categories can fit under both descriptions.

2.3.2.1.1Messaging standards and other technical standards

Messaging standards, according to WHO (2012:48), messaging refers to "the electronic communication of health from the point of collection or storage to a point of use." A health message in the context of EHRs and EMRs refers to health data that is communicated in a standardised vocabulary (WHO 2012:48) and thus, messaging standards define protocols for communicating data (WHO 2020:43). This includes archetype specifications and other communication protocols such as those defined by HL7 standards.

2.3.2.1.1.1 European Committee for Standardazation CEN 251 standards

CEN is a regional standards body that specialises in health informatics standards in Europe. The scope of CEN is standardisation in the field of ICTs so as to achieve compatibility and interoperability between systems that operate independently ans also allow for modularity (CEN 2020). It also includes placing requirements on health information structure in support of clinical as well as administrative procedures, technical methods that support interoperable systems and requirements to do with safety, security and quality (CEN 2020). This health informatics committee has more than 212 standards covering issues of device interoperability, case safety reports, audit and trails, security of EHRs, access, EHRs archetypes and many other essential standards for EHRs interoperability. The standards are

too many for discussion in this section. However, a list of the latest CEN 251 standards on the interoperability of EHRs is given below.

Table 2.1: Selected CEN/TC interoperability standards for EHRs

Standard	Scope
EN ISO 11073-20701:2020- Health informatics - Device interoperability - Part 20701: Point-of-care medical device communication - Service oriented medical device exchange architecture and protocol binding (ISO/IEEE 11073-20701:2020)	-Service-oriented medical device architecture and communication protocol specification for distributed system of Point-of-Care (PoC) medical devices and medical IT systems that need to exchange data or safely control networked PoC medical devices. -It identifies the functional components, their communication relationships as well as the binding of the components and communication relationships to protocol specifications.
EN ISO 13606-3:2019-Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists (ISO 13606-3:2019)	-Specifies a means for communicating part or all of the electronic health record (EHR) of one or more identified subjects of care between EHR systems, or between EHR systems and a centralised EHR data repository. -It can also be used for EHR communication between an EHR system or repository and clinical applications or middleware components (such as decision support components), or personal health applications and devices, that need to access or provide EHR data, or as the representation of EHR data within a distributed (federated) record system. -Lists that each specify the set of values for the particular attributes of the Reference Model defined in ISO 13606-1. -Defines normative and informative Reference Archetypes that enable frequently-occurring instances of EHR data to be represented within a consistent structure when communicated using this document.
EN 17269:2019- Health informatics - The International Patient Summary	- Formalises the dataset required to share information about the medical background and history of a patient from the patient's country of affiliation with a healthcare professional in another country where unscheduled treatment is required. - The dataset is minimal and non-exhaustive, providing a robust, well-defined set of items that are specialty-agnostic, condition-independent and usable by all clinicians for the unscheduled care of a person
EN ISO 13606-4:2019- Health informatics - Electronic health record communication - Part 4: Security (ISO 13606-4:2019)	- describes a methodology for specifying the privileges necessary to access EHR data. This methodology forms part of the overall EHR communications architecture defined in ISO 13606-1. -This document seeks to address those requirements uniquely pertaining to EHR communications and to represent and communicate EHR-specific information that will inform an access decision. -It also refers to general security requirements that apply to EHR communications and points at technical solutions and standards that specify details on services meeting these security needs.
EN ISO 13606-2:2019- Health informatics - Electronic health record communication - Part 2: Archetype interchange specification (ISO 13606-2:2019)	- Document specifies a means for communicating part or all of the electronic health record (EHR) of one or more identified subjects of care between EHR systems, or between EHR systems and a centralised EHR data repository - Used for EHR communication between an EHR system or repository and clinical applications or middleware components (such as decision support components) that need to access or provide EHR data, or as the representation of EHR data within a distributed (federated) record system. - Defines an Archetype Model to be used to represent Archetypes when communicated between repositories, and between archetype services.

	- Defines an optional serialised representation, which may be used as an exchange format for communicating individual archetypes. Such communication might, for example, be between archetype libraries or between an archetype service and an EHR persistence or validation service.

Source: iTeh Inc (n.d)

A comprehensive list of the CEN 251 standards can be accessed on: https://standards.cen.eu/dyn/www/f?p=204:32:0::::FSP_ORG_ID,FSP_LANG_ID:6232,25&cs=1FFF281A84075B985DD039F95A2CAB820. CEN is also using standards of other health informatics standards such as ISO, DICOM, IEEE and HL7.

2.3.2.1.1.2 International Organisation for Standardization ISO 215 standards

ISO is a prominent international standards body with a total of three hundred and twenty nine technical committees (TCs) that are responsible for the development and management of various standards that cut across the economy as of July 2020. Of all these TCs, there are four that are related to records, information and management, namely (i) ISO/TC-Information and documentation, (ii) ISO/TC 171-Document management applications, (iii) ISO/IEC JTC 1-Information Technology and (iv) ISO/TC 215-Health Informatics. According to ISO (n.d), ISO/TC- Information and documentation was created in 1947, with a mandate of standardising all practices that relate to libraries, documentation, information centres, publishing, archives, records management, museum, documentation, indexing and abstracting services. ISO/TC 171-Document management applications was established in 1978, with a mandate of standardising technologies as well as processes that involve the capture, indexing, storage, retrieval, distribution and communication, preservation, migration, exchange, preservation, integrity maintenance and disposal in the field of document management applications (ISO n.d). The standard excludes records management policies and procedures that that fall under the scope of TC 46 in order to avoid a clash. ISO/IEC JTC 1-Information Technology was founded in 1987 and its scope is standardisation in the field of information technology. Finally, ISO/TC 215-Health informatics which was created in 1998 has the "standardisation in the field of health informatics to facilitate capture, interchange and use of health-related data, information and knowledge to support and enable all aspects of the health system" (ISO n.d). Because the thrust of this study was specifically standards for EHRs and EMRs, the ISO/TC 215 Secretariat was of particular relevance to this study.

2.3.2.1.1.2.1 ISO/TC 215 health informatics standards

ISO/TC 215 has produced a number of standards that guide organisations that create, use and manage EHRs. The standards are too many to be discussed one by one in the present study. A comprehensive list of the ISO/TC 215 standards can be found on the ISO website: https://www.iso.org/committee/54960/x/catalogue/p/1/u/0/w/0/d/0#projects. Some of the latest ISO/TC standards relating to EHRs interoperability are discussed in this section below.

ISO/TR 21835:2020-Health informatics - Personal health data generated on a daily basis, has its thrust being the environmental scan of common data elements that are captured through various modalities such as cell phones, smart phones, mobile applications and remote monitoring devices that are combined with EHRs, patient portals and PHR systems which can ultimately be applicable to a variety of healthcare service environments; ISO/IEEE 11073-10201:2020-Health informatics - Device interoperability whose focus is the definition a general object-oriented information model that may be used to structure information and identify services used in point-of-care (POC) medical device communications (iTech Inc n.d). ISO 215 is also adopting standards of other established standards organisations such as the IEEE, HL7, DICOM, IEG and IHE where ISO standards remain the main standards. This demonstrates interoperability between the standards themselves.

Other earlier standards by ISO/TC 215 include ISO/TS 18308:2011- Health informatics-Requirements for an electronic health record architecture, ISO 27799:2008-Health informatics-Information security management in health using ISO/IEC 27002, ISO/TR 18307:2001(en)-Health informatics-Interoperability in messaging and communication standards-key characteristics, ISO 13606-5:2010-Health informatics-Electronic health record communication-Part 5:Interface specification and ISO 17090-1:2013(en)-Health informatics-Public key infrastructure-Part 1:Overview of digital certificates services.

ISO/TS 18308:2011-Health informatics-Requirements for an electronic health record architecture defines the requirements for the architecture of a system that processes, manages and communicates EHR information, that is, an EHR architecture (ISO 2011). The requirements, according to ISO (2011), serve to ensure that EHRs created and managed by such systems are faithful to the needs of health care delivery, are clinically sound, meet the prevailing legal requirements, support good clinical practice and facilitate data analysis for a multitude of purposes. Although this standard does not specify the full set of requirements

that an EHR system for direct patient care should meet, it contributes, largely, to the governance of EHRs information within such systems (ISO 2011).

ISO 27799:2008-Health informatics-Information security management in health using ISO/IEC 27002 talks to guidelines that support the interpretation and implementation of ISO/IEC 27002 in health informatics and is a companion to that standard (ISO 2008). This standard works by specifying a set of detailed controls for managing health information security best practice guidelines (ISO 2008). The implementation of this international standard enables health care organisations as well as other custodians of health information to ensure a minimum requisite level of security that is appropriate to their organisations' circumstances and further enables the confidentiality, integrity and availability of personal health information (ISO 2008). One of the advantages of ISO 27799:2008 is its versatility as ISO (2008) observed that the standard applies to health information in all its aspects and forms, be in it words, numbers, sound recordings, videos and images, irrespective of the means used to store it, including paper and electronic storage as well and is independent of the means used to transmit it, ranging from fax, hand to computer networks as the information must always be protected (ISO 2008).

ISO/TR 18307:2001(en)-Health informatics-Interoperability in messaging and communication standards-key characteristics describes a set of characteristics that are necessary to achieve interoperability and compatibility in trusted health information interchange between communicant application systems (ISO 2001). ISO 13606-5:2010-Health informatics-Electronic health record communication-Part 5: Interface specifications provides specifications for the information architecture that is required for interoperable communications between systems and services that need or provide EHR data (ISO 2010).

ISO 17090-1:2013(en)-Health informatics-Public key infrastructure-Part 1:Overview of digital certificates services provides basic definitions of the basic concepts regarding the use of digital certificates in healthcare and provides a scheme of interoperability requirements to establish a digital certificate-enabled secure communication of health information (ISO 2013). This standard also indicates the major stakeholders who are communicating health-related information, together with the main security services required for health communication where digital certificates may be required (ISO 2013).

2.3.2.1.1.3 Other EHRs and EMRs standards organisations

Other health standards organisations that produce and maintain EHRs and EMRs interoperability standards include the Integrating the Healthcare Environment (IHE), HL7 and the OpenEHR Foundation. The IHE is an industry sponsored organisation whose objective is to promote interoperability between systems that exist within specialist departments such as radiology, as well as conventional hospital systems that are used to order investigations and review imaging study reports (Kalra 2006:142). The IHE works with other standards bodies including CEN as well as HL7, for example its Cross-Documentation Sharing (XDS) which defines registry and repository services which works as a centralised or distributed warehouse for clinical documents to support HL7 CDA documents without supporting full EHRs (Kalra 2006:142). HL7 is a US based standards development body that is accredited by the US American National Standards Institute (Hovenga 2003:36). It focuses on the production of messaging standards so as to enable interoperability (Hovenga 2003:36) by specifying the interfaces for electronic data exchange between computer applications from different vendors for use in healthcare settings (Kalra 2006:142). The OpenEHR Foundation is an independent non-profit making organisation that came as an initiative of the University College London and the Ocean Informatics in the year 2000 (Kalra 2006:142). Its focus, according to Kalra (2006:142), is to facilitate the creation and sharing of health records by various stakeholders such as consumers and clinicians through open source standards-based initiatives. The distinctive feature of this initiative is its non-proprietary nature as witnessed by its advocacy for open source packages. Its implementations include the Ocean Health Systems in Australia in 2012, Better in Brazil in 2015, Switzerland in 2019, Germany in 2015 and 2029, Finland in 2029 and Fluance AG in Switzerland in 2020.

2.3.2.1.2 Vocabulary standards

Vocabulary standards, alternatively known as terminology standards, work by defining terms that describe different medical conditions and events (WHO 2012: 47). According to Gentul (2017:171), a nomenclature is a way of naming things and it is important in the sense that it facilitates communication in medical care. These standards focus on the nomenclature for medical conditions. Such standards also come in the form of classification systems that describe and name medical conditions according to body parts as well as those that allow the use of natural languages.

2.3.2.1.2.1 Logical Observation Identifiers Names and Codes (LOINC)

As a vocabulary standard, LOINC functions by allowing health information such as clinical results or clinical care, outcomes management, as well as research to be pooled and exchanged by systems through a set of universal codes and names that enable the identification of laboratory and other clinical observations (FICCI Health Services India 2013:14;). Thus, LOINC allows the identification of health measurements, observations as well as documents (Bodenreider, Cornet and Vreeman 2018). The purpose of LOINC is to identify clinical observations in electronic communications such as HL7 messages so as to enable healthcare facilities such as hospitals, pharmaceutical manufacturers, researchers as well as public health units to automatically file the results in their appropriate slots of their medical records, research and public healthcare facilities as and when they receive such messages from various sources (McDonald, Huff, Suico, Leavelle, Aller, Forrey, Mercer, DeMoor, Hook, Williams, Case and Maloney 2003:624).

Historically, LOINC is a product of the Regenstrief Institute, which is a not for profit medical research organisation associated with the Indiana University (Bodenreider, Cornet and Vreeman 2018) and is still being maintained by the same institution to date (FICCI Health Services India 2013:14). This Institute maintains the LOINC database and renders supporting documentation (FICCI Health Services India 2013:14). As early as 1994, a number of electronic systems were sending clinical information as separate results based on standards such as HL7, or the American Society for Testing and Materials (ASTM) (Bodenreider, Cornet and Vreeman 2018). Such messages had weakness of using local and idiosyncratic names and codes to identify the tests that were being communicated and this proved problematic for data exchange as well as the aggregation, owing to the large resources it takes to map codes between the various participating systems (Bodenreider, Cornet and Vreeman 2018). This saw the LOINC Committee embarking on the creation of a vocabulary that possesses an appropriate level of granularity for the definition of the names of observations used in laboratories and clinical systems (Bodenreider, Cornet and Vreeman 2018). In the LOINC database "for each observation, the database includes a code, a long formal name a short 30-character name and synonyms" (McDonald et al 2003:624).

2.3.2.1.2.2 International Classification of Diseases (ICD)

This standard comes in volumes, with the latest one being the ICD 11 and primary users of this standard include physicians, nurses, different health workers, researchers, health information practitioners, policy makers in the field of health, insurers, as well as those in charge of national health programmes (WHO 2019). The ICD standard is a diagnostic classification standard for all general epidemiological, management and clinical cases that is used internationally (FICCI Health Services India 2013:14). According to the International Headache Society (2003:12), classification refers to the act of deciding on which kinds of diagnostic entities should be recognised and how to order them in a meaningful fashion. The ICD standard allows the identification of trends in health as well as the production of health statistics around the world by defining the "universe of diseases, disorders, injuries and other related health conditions (WHO 2019). As an international standard that facilitates the definition and reporting on diseases and health conditions, the ICD standard enables players in the health sector to compare and share health information based on a common language (WHO 2019). As further indicated by WHO (2019), by allowing the organisation of health information into standard groupings of diseases, the ICD standard enables:

i. The easy storage, retrieval as well as analysis of health information to facilitate evidence based decision-making;
ii. Hospitals, regional settings as well as countries to share and compare health information between and among each other; and
iii. The comparison of health data in the same location over different time frames.

The ICD has remained flexible allowing diseases classificationists to append additional class codes to it in order to improve the specificity of the diseases. The International Classification of Diseases, Tenth Revision-Clinical Modification (ICD-10-CM) and the International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS) are typical examples of such appendages to the ICD.

2.3.2.1.2.2.1 International Classification of Diseases, Tenth Revision-Clinical Modification (ICD-10-CM)

This standard is characterised by clinical modifications to allow for more elaboration of diseases based on the basic ICD. According to Gentul (2017:172), ICD-10-CM is published by the Government of the US and has the International Statistical Classification of Diseases and Related Health Problems, Tenth Revision as its or ICD-10, published by the WHO as its foundation. Clinical modification expands the number of codes for diagnoses (Medical Billing and Coding Certificate n.d:19). It contains features that were absent in the previous version of the clinical modification of the ICD and its structure is such that is allows for considerable malleability thereby enabling the addition of new and specific codes as needed whilst preserving the general code structure (Gentul 2017:172). It specifically consists of:

i. The Index to Diseases, and Injuries (the main index)
ii. Neoplasm Table, Table of Drugs and Chemicals
iii. Index to Extenal Causes
iv. Tabular List of Diseases and Injuries (Gentul 2027:175).

2.3.2.1.2.2.2 International Classification of Diseases, Tenth Revision-Procedural Coding System (ICD-10-PCS)

Gentul (2017:175) reported that this set of codes was developed by 3M after being awarded a

contract by CMS to replace ICD-9-CM, Volume III detailing inpatient procedures only. ICD-10-PCS allows for more precise and stable definitions of all procedures performed in cases where ICD-9 procedure codes were based on out-dated technology and lacked current, accepted definitions (Ferguson 2019). For example, when ICD-10-PCS was introduced in 2015, the number available Procedure Coding Systems enormously increased from three thousand to above seventy thousand, thereby demonstrating the high level of specificity with which procedures can be coded (Ferguson 2019). It consists of seventeen sections (Gentul 2017) as shown in the table below.

Table 2.2: Sections of ICD-10-PCS

0	Medical and Surgical
1	Obstetrics
2	Placement
3	Administration
4	Measurement and Monitoring
5	Extracorporeal or Systemic Assistance and Performance
6	Extracorporeal or Systemic Therapies
7	Osteopathic
8	Other Procedures
9	Chiropractic
B	Imaging
C	Nuclear Medicine
D	Radiation
F	Physical Rehabilitation and Dignostic Audiology
G	Mental Health
H	Substance Abuse Treatment
X	New Technology

Source: ICD-10Data.com (n.d)

Because the Medical and Surgical Section contains the most procedure codes, it is further split based on the Body System (Gentul 2017:175), for example, 00-Central Nervous System; 07-Lymphatic and Hemic System e.t.c. For procedures that fall under the Medical and Surgical Section, the characters are arranged in the following order: Section; Body System, Root Operation, Body Part, Approach, Device, Qualifier. This is diagrammatically expressed in the figure below.

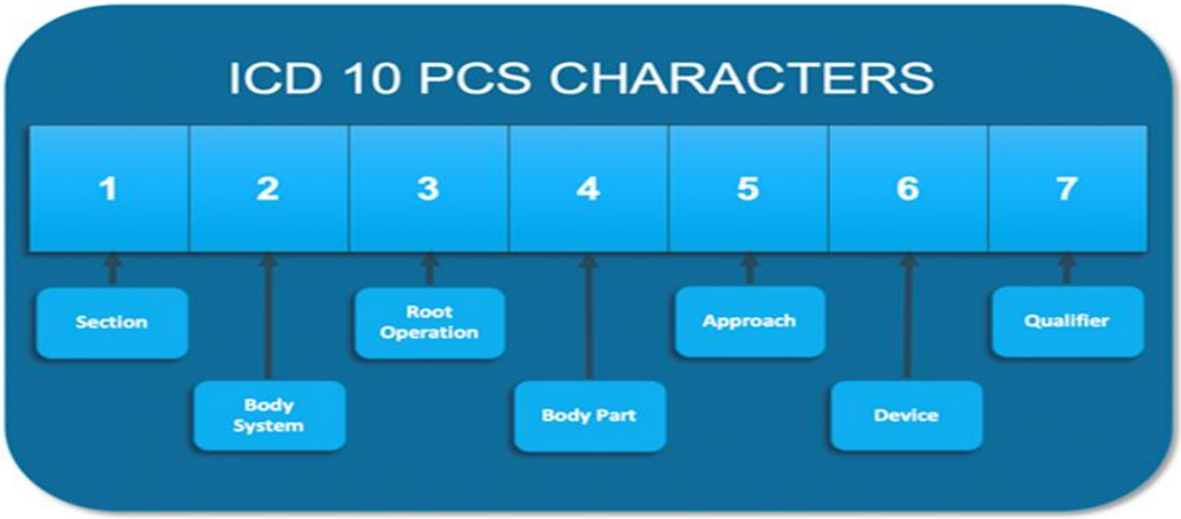

Figure 2.2: Structure of ICD-10-PCS showing a detailed description of the Medical and Surgery Section. **Source:** Ferguson (2019)

As an example given by Gentul (2017:176), colonoscopy can be coded as 0DJD8ZZ using the ICD-10-PCS which can be unpacked as follows:

0- Section: Medical and Surgical, character value 0
D- Body System: Gastrointestinal, character value D
J- Root Operation: Inspection, character value J
D- Body Part: Lower Intestinal Tract, character value D
8- Approach: Via Natural or Artificial Opening, character value 8
Z- Approach: No device, no device left inside the body after completion of the procedure, character value Z
Z- Qualifier: No Qualifier (No unique information specific to the procedure), character value Z

2.3.2.1.2.3 Systematized Nomenclature of Medicine- Clinical Terms (SNOMED-CT)

SNOMED-CT is a comprehensive clinical terminology which was originally developed by the College of American Pathologists (CAP) (FICCI Health Services India 3013:14). According to the International Health Terminology Standards Development Organisation (2017:5) SNOMED-CT enables the development and incorporation of EHRs content which is of high quality and comprehensive. SNOMED-CT based clinical information offers a number of benefits to various stakeholders in healthcare, including individual patients, clinicians and populations and is a basis of evidence based care (International Health Terminology Standards Development Organisation 2017:6). As a nomenclature standard, SNOMED-CT provides consists of over one million medical concepts and attributes that are arranged hierarchically and serves as a standardised core terminology for EHRs which enables better communication (Gentul 2017:177). SNOMED-CT can be incorporated into EHRs, thereby improving communication and availability of relevant health information as it will be stored in a manner which enables meaning-based retrieval (International Health Terminology Standards Development Organisation 2017:6). The uses and benefits of SNOMED-CT to the afore-mentioned stakeholders, as summarised by the International Health Terminology Standards Development Organisation (2017:6-7) are presented in Table 2.3.

Table 2.3: Uses and benefits of the SNOMED-CT standard in EHRs

SNOMED CT enabled health Records benefits to individuals	**SNOMED CT enabled health records benefits to populations**	**SNOMED CT enabled health records support evidence-based healthcare**
SNOMED CT enabled clinical health records benefit individuals by: • *Enabling relevant clinical information to be recorded using consistent, common representations during a consultation.* • *Enabling guideline and decision support systems to check the record and provide real-time advice, for example, through clinical alerts.* • *Supporting the sharing of appropriate information with others involved in delivering care to a patient through data capture that allows understanding and interpretation of the information in a common way by all providers.* • *Allowing accurate and comprehensive searches that identify patients who require follow-up or changes of treatment based on revised guidelines.* • *Removing language barriers (SNOMED CT enables multilingual use)*	SNOMED-CT enabled clinical health records benefit populations by: • *Facilitating early identification of emerging health issues, monitoring of population health and responses to changing clinical practices.* • *Enabling accurate and targeted access to relevant information, reducing costly duplications and errors.* • *Enabling the delivery of relevant data to support clinical research and contribute evidence for future improvements in treatment.* • *Enhancing audits of care delivery with options for detailed analysis of clinical records to investigate outliers and exceptions.*	SNOMED CT enabled health records inform evidence based health care decisions by: • *Enabling links between clinical records and enhanced clinical guidelines and protocols.* • *Enhancing the quality of care experienced by individuals.* • *Reducing costs of inappropriate and duplicative testing and treatment.* • *Limiting the frequency and impact of adverse healthcare events.* • *Raising the cost-effectiveness and quality of care delivered to populations.*

Source: International Health Terminology Standards Development Organisation 2017

SNOMED is owned, maintained and distributed by the International Health Terminology Standards Development Organisation, which is a non-profit association based in Denmark (FICCI Health Services India 2013:14). According to (Bodenreider, Cornet and Vreeman 2018), since the time of the Structured Nomenclature of Pathology (SNOP) as early as 1965, marking the origins of SNOMED-CT, a number of versions of SNOMED have come up, in terms of both content and representation.

Following the transfer of the ownership of SNOMED-CT to the newly formed International Health Terminology Standards Development Organisation which was also named SNOMED International in 2007, the standards organisation consists of a total of nine countries, totalling approximately 500 million in terms of population ((Bodenreider, Cornet and Vreeman 2018). SNOMED International, as of 2018, had expanded to cover 32 countries, with a total population of above 12 billion and available in a number of languages (Bodenreider, Cornet and Vreeman 2018). Thus, the standard has gained international recognition and continues to gather momentum as it also becomes available in an increasing number of languages. Because SNOMED contains codes for diseases and procedures together with relational terms, it allows for natural language to be translated into a classification scheme such as ICD-10 (Gentul 2017:177). Thus SNOMED-CT is easily compatible with other standards and also malleable as it allows the use of concepts in their natural form and in a number different of languages.

2.3.2.1.2.4 Healthcare Common Procedure Coding System (HCPCS)

HPSCI came into existence as a coding standard used for claim processing and is therefore important for billing (Gentul 2017:176). It works at two levels, namely Level I and Level II (Centres for Medicare and Medicaid Services 2020: Gentul 2017:176). Basically, Level I consists of the Current Procedural Terminology (CPT-4) whilst Level II consists of those standards that are not part of CPT-4.

2.3.2.1.2.4.1 Healthcare Common Procedure Coding System Level I (HCPCS Level I)

Level 1 of HCPCS consists of CPT-4 (Centre for Medicare and Medicaid Services 2020; Gentul 2017:176) and is used to "document the majority of medical procedures performed in a physician's office" (Medical Billing and Coding n.d:20). This is a uniform coding system

which is comprised of descriptive terms and identifying codes that are essentially used to identify medical services and procedures conducted by physicians and other healthcare professionals (FICCI Health Services India 2013:14). CPT-4 is a set of standardized numerical codes used by various healthcare practitioners, to describe the services as well as medical procedures performed on patients (Ritchie, Yang, Quinn, Ernst, Guttormsen, Simionov and Maniar 2018:1542; Centres for Medicare and Medicaid Services 2020). Thus, CPT-4 codes allow the reporting of procedures and services for the purposes of enabling reimbursement for the services rendered (Academy of Professional Coders 2019). Created by the American Medical Association (AMA) in 1996, CPT-4 codes work by standardising the reporting of medical, surgical as well as diagnostic services rendered to both inpatient and outpatients, with each code denoting a written description or a procedure or service such that any subjective interpretation of the service rendered or procedure performed on a patient is eliminated (Academy of Professional Coders 2019). Healthcare professionals use CPT-4 to identify services as well as procedures for which private and public health insurers will be billed based on the services rendered, including ambulatory surgery centres, emergency departments, clinics and rehabilitation centres (Centres for Medicare and Medicaid Services 2020; Gentul 2017:176). CPT-4 specifically excludes codes needed to separately bill items that are not rendered by physicians (Centres for Medicare and Medicaid Services 2020). Specifically, CPT-4 consists of three categories of codes, viz; (i) Category 1: Common Medical Services; (ii) Category 2: Performance Measures and (iii) New and Emerging Technologies (Medical Billing and Coding n.d:20; Gentul 2017:176).

2.3.2.1.2.4.2 Healthcare Common Procedure Coding System Level II (HCPCS Level II)

HCPCS Level II codes are meant to enable the reporting and claiming for products, supplies and services not catered for in CPT-4 such as durable equipment and ambulatory services, orthotics, prosthetics, rides and certain drugs and medicines (Medical Billing and Coding n.d: 21; Gentul 2017:177; Centres for Medicare and Medicaid Services 2020). Thus, HCPCS Level II codes are suitable for making claims for non-physician services and products in the USA and are acceptable in the private and public sectors.

2.3.2.1..2.5 RxNORM

RnNorm is a standardised nomenclature for medications in the United States of America (Bennette 2012). The impetus behind the development of RxNorm, according to Bennette (2012) was to have a consistent and standardised way of identifying and capturing important information about prescriptions. This was further meant to allow for the creation of EHRs in a manner that enables patient information to be shared across healthcare providers, that is, interoperability, the development of clinical decision support systems, fostering quality improvements as well as supporting other research efforts (Bennette 2012). This is possible as RxNORM works by harvesting information about the medication name, including generic and brand names, dosage, route of administration, ingredients, and fully-specified common dose forms (Nelson, Zeng, Kilbourne, Powel and Moore 2011, cited in Bennette 2012). As a product of the National Library of Medicine (NLM), this standard provides normalised names for clinical drugs (FICCI Health Services India 2013:15).

The standard also works by linking its names to many other drug vocabularies that are commonly used in areas such as pharmacy management and drug interaction software, including those of other terminologies such as the First Databank, Micromedex, Medi Span, Gold Standard Alchemy and Multum (FICCI Health Services India 2013:15). The ability of providing links to and between these vocabularies implies that, RxNORM mediates messages between systems that do not use the same software and vocabulary (FICCI Health Services India 2013:15). Thus, RxNORM plays a dual role of providing standardised clinical nomenclature and allowing systems that use different software and terminologies to interface.

2.3.2.1.2.6 Anatomic Therapeutic Chemical Classification of Drugs (ATC)

First published in 1976, this standard is used for the classification of drugs (FICCI Health Services India 2013:15). In terms of management, ATC is controlled by the World Health Organisation (WHO) Collaborating Centre for Drug Statistics Methodology (FICCI Health Services India 2013:15). This standard works by dividing drugs into groups based on the organs or system on which they act and or their therapeutic and chemical characteristics of the drugs (FICCI Health Services India 2013:15).

2.3.2.1.2.7 National Drug Codes (NDC)

NDCs are a system of identifying drugs so that they can be associated with their manufacturers. According to Gentul (2017:182), NDCs are available in the National Code Directly which is run by the US Food & Drugs Administration (FDA) by maintaining a list of identifiers or codes on its website. Thus, drug products are identified and reported using codes that are structured in three parts which serve as universal product identifiers for drugs (US Food & Drug Administration 2019; Washmuth 2003-2020).

The three segments that constitute an NDC are: the labeler (manufacturer or distributor of the drug) assigned by the FDA, product code (indicating the strength, dose and formulation of the specific drug) and the packaging code) showing the package size and type of the drug) which are partly assigned by the labeler (Gentul 2017:182: Washmuth 2003-2020). A labeler may be conceived as the manufacturer or distributor of the drug (Gentul 2017: 182). The NDC is therefore, a 10-digit number for all over-the-counter (OTC) medication and prescription medications packages or inserts, with a combination of the three segments of the NDC code identifying or describing different characteristics of each medication (Washmuth 2003-2020). NDCs are also important from a commercial perspective (Gentul 2027:182) as they provide important information about the source of the drug. NDCs may also be employed by healthcare facilities that want to fulfil the requirement of **Standard GLD.7.1-** *Hospital leadership seeks and uses data and information on the safety of the supply chain for drugs, medical technology and supplies to protect patients and staff from contaminated, fake and diverted products*, an administrative standard of the Joint Commission International.

2.3.2.1.2.8 International Classification of Headache Disorders (ICHD-3)

The ICHD allows for the classification of all known types of headaches, with a provision for "others" whose classification may not be ascertained. The International Headache Society (2003:11) stated that through the ICHD, all headaches are divided into major groups, with each group being further divided into one, two or three times into headache types, subtypes and sub-forms. The International Headache Society (2019) presented the structure of the ICHD-3 as follows.

Table 2.4: International Classification of Headache Disorders (ICHD-3)

Part I: The Primary headaches

1. Migraine
2. Tension-type headache (TTH)
3. Trigeminal autonomic cephalagias (TACs)
4. Other primary headache disorders

Part II: The secondary headaches

5. Headache attributed to trauma or injury to the head and/neck
6. Headache attributed to cranial or cervical vascular disorder
7. Headache attributed to non-vascular intracranial disorder
8. Headache attributed to a substance or its withdrawal
9. Headache attributed to infection
10. Headache attributed to disorder of homoeostasis
11. Headache or facial pain attributed to disorder of the cranium, neck, eyes, ears, nose, sinuses, teeth, mouth or other facial or cervical structure
12. Headache attributed to psychiatric disorder

Part III: Neuropathies & Facial Pains and other headaches

13. Painful lasions of the cranial nerves and other facial pain
14. Other headaches disorders

Part IV: Appendix

Source: International Headache Society Classification ICHD-3 (2019)

The ICHD-3 structure depicted above shows the basic structure of the classification scheme with four major sections that are then split into sub-groups. Each subgroup can further be divided into specific groups, demonstrating its subordination to the major group and section. An example given by the International Headache Society (2003:11) shows this using a migraine headache was split into its subtypes and sub-forms.

Table 2.5: Classification of a migraine headache using the ICHD

1- Migraine
1.2 - Migraine with aura
1.2.1 -Typical aura with migraine headache

2.3.2.1.2.9 Diagnostic and Statistical Manual of Mental Disorders (DSM)

Published by the American Psychological Association (APA), the Diagnostic and Statistical Manual of Mental Health Disorders (DSM) is a guide that is used by clinicians and psychiatrists to diagnose psychiatric disorders in the US (Cherry 2019). DMS has been updated seven times from 1952, the year in which it was published for the first time, with the latest update dating back to 2013 (Cherry 2019). DMS used to come as DSM-IV, which

stands for Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, and DSM-IV-TR which stands for Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision, both of which have been replaced by the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) (Gentul 2017:181).

DSM-5 works by providing clinicians with pathways to allocating ICD-10-CM codes that exist as text for each disorder in the manual and because of that, DSM-5 should not be considered as a distinct coding classification system but a mere classification scheme for disorders (Gentul 2017:182). In DSM, all metal categories of mental health disorders for adults and children are covered (Cherry 2019). Thus, DSM presents descriptions, symptoms as well as other criteria that are used for diagnosing mental health conditions (Cherry 2019). DSM-5 relies on an explicit criteria for disorders which collectively constitute a nomenclature of mental conditions accompanied by fully referenced explanatory text for the first time in the electronic version of DSM (Regier, Kuhl and Kupfer 2013:93). The statistical aspect of DSM is meant to provide statistics pertaining to which gender is more susceptible to a particular mental disorder, typical of onset, effects of treatment and common treatment approaches (Cherry 2019).

2.3.2.1.3 Content standards

Having terminology or vocabulary standards only as a way of achieving interoperability of EHRs and EMRs is not ample as there is a need for the actual content or material to be communicated to be standardised as well. Thus, content standards are the other prerequisite for interoperable EHRs and EMRs systems. Content standards are "… standards used to share clinical information such as clinical summaries, prescriptions, and structured electronic documents" (FICCI Health Services India 2013:15). Examples of such standards include the Health Level Seven Document Architecture (HL7 CDA), Continuity of Care Record (CCR), Digital Imaging and Communications on Medicine (DICOM) (e-Health Ontario 2013:3; FICCI Health Services India 2013:16-17). Content standards are different from vocabulary standards in the sense that their focus is on the actual content, in terms of both the structure and the fields that should ideally be captured in the standardised record. Content standards complement both the vocabulary/terminology standards and clinical/context standards in the sense that health practitioners are able to compile health information such as patient

summaries, discharge cards and other health documents in a standardised fashion that healthcare professionals and systems can understand and process with ease.

2.3.2.1.3.1 Health Level Seven Clinical Document Architecture (HL7 CDA)

This standard is a product of the Health Level Seven Inc, a voluntary non-profit making organisation in the United States of America (Natsuki (2008:79). CDA "is a document mark-up standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange between healthcare providers and patients" (HL7 2007-2020). Shabo (2018) added that "is a document mark-up standard that specifies the structure and semantics of clinical documents for the purpose of exchange and share of patient data". The standard operates on an XML-based mark-up standard that is meant to specify the encoding, structure and semantics of clinical documents for exchange (FICCI Health Services India 2013:16). Thus, as the name suggests, this standard spells out the architecture or layout on which clinical documents should be shared between and among EHRs and EMRs systems. The Clinical Document Architecture (CDA) is also applied to EHRs projects where it serves as a standard format for entering, retrieving and storing health information (FICCI Health Services India 2013:16). HL7 developed CDA serves the purpose of defining a standardised structure of a signed clinical document to enable Health Information Exchange (HIE) between EHRs and EMRs systems (Park and Atalag 2015). Thus, operating on this standard, health practitioners can systematically capture, store and retrieve health information.

CDA, according to Abrams, Learmonth and Gibson (2017:96) works by identifying the following six characteristics of all clinical documents.

i. Persistence- the clinical document continues to exist in an unaltered state for a period of time as defined by legislation;
ii. Stewardship- requiring that the clinical document be maintained by a person or organisation who has been entrusted with its care;
iii. Authentication- requiring that the author of the clinical document can be verified and validated which leads to the credibility of content;
iv. Context- implying that the documented "story" describing the care provided to the patient, with details such as the name of the clinical document, its author(s) and the

patient name must be included. Context may further be specified in this case under the clinical data content heading;

v. Wholeness- this places the need for the completeness of the story and the clinical documents as well as the ability to reference clinical statements back to their original source and;
vi. Human readability- requiring that the clinical document can be easily read and understood. Reliability entails legibility of the document whether in paper form or scanned. For example, there are a number of tools to ensure reliability including the application of technology, templates, forms and views design as well as data and content standards.

CDA has two editions: CDA R1 which was approved in 2000 and CDA R2 which was approved in 2005 (Shabo 2018). The two releases are part of the HL7 new generation of standards (V3), all hinged on a core reference information model (RIM) thereby facilitating semantic consistency across the various standards that pertain to health including laboratory, medications, care provision and so forth (Shabo 2028). The standard, however, leaves room for healthcare facilities to decide on what exactly constitutes a clinical document, whilst providing minimum requirements.

2.3.2.1.3.2 Health Level Seven 2.5.1 (HL7 2.5.1)

This standard, which is operating on textual and non XML encoding syntax that is based on delimiters, works by defining a series of electronic messages in support of a number of functions or activities such as administrative, logistical, financial and clinical (FICCI Health Services India 2013:16). The HL7 standard also allows interfacing with the other systems, enabling such systems to share information in a structured manner as specified in the delimiters of the standard. For example, HL7 v2.x already facilitates interoperability between electronic patient administrations, electronic patient management (EPM) systems, laboratory information systems (LIS), dietary, pharmacy and billing systems and EMRs and EHRs systems (FICCI Health Services India 2013:16). HIEs based on HL7 version 2.x messaging standard have been in existence and use for a reasonably long time in various areas of health such as lab results, summaries of discharge, medical records in primary care as well as referrals (Park and Atalag 2015).

2.3.2.1.3.3 Continuity of Care Record (CCR)

CCR is a standard which acts as a core data set of what is considered as the most relevant administrative, demographic as well as clinical information facts pertaining to a patient's healthcare, covering one or more healthcare encounters (FICCI Health Services India 2013:16-17). Consisting of three components, namely the CCR Header, the CCR Body and the CCR Footer, CCR enables a healthcare practitioner, healthcare system or setting to aggregate all the important data about a patient and forward it to another practitioner, system or setting to support continuity of care (FICCI Health Services India 2013:16-17)., and hence the name continuity of care record. According to the FICCI Health Services India 2013:16-17), "the primary use case for the CCR is to provide a snapshot in time containing the pertinent clinical, demographic, and administrative data for a specific patient."

Because this standard has to ensure interoperability, that is, the interchange ability of electronic CCR, it specifies the XMC coding that is necessary during the creation of CCR in a structured electronic format (FICCI Health Services India 2013:16-17). Security and privacy issues in EHRs and EMRs require maximum attention and need to be embedded in systems right from the onset. In CCR, security and privacy conditions should be established in a manner which allows only authorised personnel to gain access to the CCR document instance or its elements (FICCI Health Services India 2013:16-17).

In terms of development, the CCR standard is a product of a number of vendors working jointly, including the ASTM International, the Massachusetts Medical Society (MMS), the Healthcare Information and Management Systems Society (HIMSS), the American Academy of Family Physicians (AAFP), the American Academy of Paediatrics (AAP) and other health information vendors (FICCI Health Services India 2013:16-17).

2.3.2.1.3.4 Digital Imaging and Communications in Medicine (DICOM)

According to the National Electronic Manufacturers Association (NEMA) (2019), DICOM "is the standard for the communication and management of medical imaging information and related data." The focus of this standards body, through its DICOM Standards Committee, is the development and maintenance of international standards for the communication of biomedical diagnostic and therapeutic information in disciplines that tend to use digital

images and associated data (FICCI Health Services India 2013:17). The aims of DICOM include the achievement of compatibility and improve workflow efficiency between and among imaging systems as well as other health information systems healthcare environments throughout the world (FICCI Health Services India2013:17).

As a standard, DICOM currently works by defining an upper layer protocol (ULP) which is used over TCP/IP (independent of the physical network), messages services, information objects as well as any other relevant negotiation mechanisms (FICCI Health Services India 2013:17). The essence of the definitions is to see to it that any two implementations of a compatible set of services as well as information objects can effectively exchange information (FICCI Health Services India 2013:17). This standard, thus, ensures that health information that exists or is generated in digital images is shared or exchanged by and between healthcare systems or environments. As further indicated by NEMA (2019), DICOM enables interoperability between medical imaging technologies by specifying the following:

i. A set of protocols that devices that claim to be subscribing to the standard should follow in a networked environment;
ii. The syntax and semantics of commands, including associated information that may be exchanged on the basis of such protocols;
iii. A set of media storage requirements (for media communications) for devices that subscribe to the standard, together with the file formats and a medical dictionary structure to enable access to the stored images and related information; and
iv. The implementation information that is to be supplied during an implementation exercise.

DICOM, as a standard, has become uncontested regarding the exchange and management of medical images, given its prominence following the emergence of multi-vendor Picture Archiving and Communication Systems (PACS) and their successful integration with Hospital Information Systems and well as Radiology Information Systems (Gibaud 2008). It can be seen as having support for a number of levels, including support for image exchange for message senders and recipients, the underlying information model and services for information management (Oosterwijk 2004).

2.3.2.1.3.5 ISO/TC 215 Health informatics standards

ISO, through its ISO/TC 215 Committee has also come up with content standards for EHRs. Examples of these include ISO/TS 22220:2011-Health informatics-Identification of subjects of health care and ISO/TR 20514:2005-Health informatics-Electronic health record-definition, scope and context, ISO/TS 22220:2011-Health informatics-Identification of subjects of healthcare indicates the data elements and structure that are suitable for accurate and procedurally appropriate and sensitive identification of individuals in healthcare, either in a face-to-face setting supported by computer technology or through interactions between computer systems (ISO 2011). This standard, ISO (2011) further explained, provides guidelines for improving the positive identification of subjects of care within and between healthcare organisations. ISO/TR20514-Health informatics-Electronic health record-definition, scope and context describes the pragmatic classification of EHR and also provides simple definitions for the main categories (ISO 2005). This standard also indicates supporting descriptions of the characteristics of EHRs and record systems (ISO 2005). A comprehensive and a comprehensive list of the ISO/TC 2015 Secretariat can be found on the ISO website.

2.3.2.1.4 Clinical standards

The third type of interoperability standards are clinical standards. These are health information standards that capture patients' health information in a more coherent manner (FICCI Health Services India 2013:17). Because the aim of this standard is to capture patient information in a more comprehensive and coherent manner, the FICCI Health Services India (2013:17), observed that the standard may include all or part of the following elements of an EHR and EMR as is seen necessary:

i. The illness or ailment that a patient is suffering from;
ii. The observations made by physicians on patients;
iii. The diagnostic tests that need to be conducted on a patient in order to determine the ailment and its cause that a patient is suffering from and to enable the physician to render better treatment;
iv. The results of diagnostic tests;
v. The treatment regime that has to be rendered to the patient; and
vi. The way in which the treatment should be administered.

2.3.2.1.4.1 Nursing Interventions Classification (NIC) and Nursing Outcomes Classification (NOC)

The Nursing Interventions Classification (NIC) and the Nursing Outcomes Classification (NOC) are the most prominent standards that facilitate documentation at the same time allowing for a representation of the nursing activities and processes. The NIC came into existence in 1987 (Othman, Shatnawi, Alrajabi and Alshaideh 2019:19; Hovenga 2003:28) and is a standardised language of both direct and indirect nurse initiated interventions (Othman, Shatnawi, Alrajabi and Alshaideh 2019:19). This classification system was the first proprietary standards language of both doctor and nurse initiated treatments (Hovenga 2003:28). The NOC was developed later in 1991 as a comprehensive standard for classifying patient as well as clients outcomes (Othman, Shatnawi, Alrajabi and Alshaideh 2019:20; Hovenga 2003:28) and its chief objective is to evaluate the effects of nursing interventions (Hovenga 2003:28).

Both classification schemes are versatile by allowing their use in all healthcare settings and by all healthcare settings (Hovenga 2003:28). To allow for computerisation, each nursing intervention in the case of the NIC is denoted by a unique identifier, a definition, as well as a set of activities describing what the nurse does in the implementation of the intervention whilst in the NOC each nursing outcome is denoted by a unique identifier, a definition and a list of indicators users can use to evaluate the status of a patient using a five-point Likert scale (Othman, Shatnawi, Alrajabi and Alshaideh 2019:20; Hovenga 2003:28). The NIC contains 565 interventions which are arranged into 30 classes under 7 domains (Othman, Shatnawi, Alrajabi and Alshaideh 2019:18) whilst the NOC has 540 nursing outcomes that are arranged in an alphabetical order, grouped into 43 classes under 7 domains (Moorhead, Johnson, Maas and Swanson 2028 in Othman, Shatnawi, Alrajabi and Alshaideh 2019:20). The NIC, owing to its versatility, has been officially incorporated into HL7 as a terminology standard (Hovenga 2003:28).

2.3.2.1.4.2 Other clinical classification standards and codes

The type and thrust of clinical standards have increased over time, owing to new discoveries and improvements on those that already exist. Furthermore, the number of producers of such standards has also increased with some producers coming from outside the USA which had

the largest number of such producers. Table 2.6 below summarises some of the nursing classification systems used in clinical practice.

Table 2.6: Other nursing classifications used in clinical practice

Standard	Focus/use	Developer
Patient Care Data Set	-Set of standard terms to represent and capture clinical data for inclusion in patient care information systems -Consists of pre-coordinated phrases representing statement of patient problems, patient care and patient care sections. -Terms classified derived from 29 standards of care, 76 care protocols and 30 patient education plans -Fourth version incorporates characteristics better suited for use in HL7messages and software development (Hovenga 2003:28-29)	University Health Systems Consortium (1994-1995) (Hovenga 2003:28)
International Classification for Nursing Practice (ICNP)	-ICNP classifies patient data and clinical activity in the domain of nursing and can be used for decision-making and policy development aimed at improving health status and health care delivery (WHO 2017). -ICNP has a formal foundation that is used to compose and represent diagnoses, interventions, and outcomes in a polyhierarchy (WHO 2017)	International Council of Nurses (ICN) (1989) (Hovenga 2003:30)
Peri-operative Nursing Data Set	-Standardised nursing vocabulary (Hovenga 2003:29). -- -The PNDS enables nursing care to be documented in a standardized manner and allows the collection of reliable and valid comparable clinical data to evaluate the effectiveness of nurse-sensitive interventions and the relationship between these interventions and patient outcomes (Association of Peri-operative Registered Nurses [AORN] 2012-2020). -PNDS concepts are mapped to the clinical content within the AORN Syntegrity® perioperative documentation solution for the electronic health record (AORN 2012-2020). -Combination of nursing diagnoses, nursing interventions and nurse sensitive patient outcomes allows for the description of peri-operative patient experience from pre-admission to discharge (Hovenga 2003:29).	Association of Per-operative Registered Nurses (AORN) (Hovenga 2003:29)

Swedish VIPS	-A conceptual model based on four key concepts: wellbeing, integrity, prevention and safety (Ehnfors, Angermo, Berring, Ehrenberg, Lindhardt, Rotegard and Thorell-Ekstrand 2006:402). -Guidelines and criteria for nursing documentation in patient records with key words with explanations (Hovenga 2003:30). -It focuses on the creation of content that is relevant for the nursing recording as well as on patient's functioning in the activities of daily life (Ehnfors, Angermo, Berring, Ehrenberg, Lindhardt, Rotegard and Thorell-Ekstrand 2006:402). -The structure of the VIPS model enables nurses to use, save, retrieve and reuse information (Darmer, Ankersen, Nielsen, Landberger, Lippert and Egerod 2005:526). -Modifications for different nursing care practice area have been accoodated, including primary care, psychiatric care and operating room nursing (Hovenga 2003:30). -Transaltions for other Nordic languages, some Baltic languages as well as some African languages have been made (Hovenga 2003:30).	Ehnfors et al. (Darmer, Ankersen, Nielsen, Landberger, Lippert and Egerod (2005:526).
Danish Nursing Interventions Classifications	-Aimed at coming up with a common health care classification system in Denmark (Hovenga 2003:30). -Consists of efforts to combine all the existing official classifications into a joint hierarchical structure (Hovenga 2003:30).	Danish National Board of Health (Hovenga 2003:30).

The list above is not exhaustive. Other standards come in the form of data sets that are also cardinal to the documentation of standardised EHRs and EMRs.

2.3.2.2 Administrative standards

Administrative standards are complementary to interoperability standards and they operate by focusing on administrative issues that ensure compliance which is why they are sometimes referred to the administrative safeguards. The Joint Commission International (JCI) provides standards that are largely concerned with the administration of healthcare facilities by stipulating, item by item, specific requirements that healthcare administrators need to ensure in their healthcare facilities.

2.3.2.2.1 JCI standards

The JCI standards come in four major sections shown in Table 2.7.

Table 2.7: Joint Commission International Accreditation Standards for Hospitals, 5th Edition

Section I: Accreditation Participating Requirements
- Accreditation participation Requirements (APR)

Section II: Patient-Centred Standards
- International Patient Safety Goals (IPSG)
- Access to Care and Continuity of Care (ACC)
- Patient and Family Rights (PFR)
- Assessment of Patients (AOP)
- Anesthesia and Surgical Care (ASC)
- Medication Management and Use (MMU)
- Patient and Family Education (PFE)

Section III: Health Care Organisation Management Standards
- Quality Improvement Standards (QPS)
- Prevention and Control of Infections (PCI)
- Governance, Leadership, and Direction (GLD)
- Facility Management and Safety (FMS)
- Staff Qualifications and Education (SQE)
- Management of Information (MOI)

Section IV: Academic Medical Centre Hospital Standards
- Medical Professional Education (MPE)
- Human Subjects Research (HRP)

Source: JCI (2013)

As seen in Table 2.7, JCI standards provide for the entire management of a healthcare facility. Although JCI provides a broader standard framework for the management of a typical hospital, Section III: Health Care Organisation Management Standards has two sub sections that stipulate administrative standards that are of relevance to the present study; viz: Governance, Leadership and Direction (GLD) and Management of Information (MOI). The subsection on GLD is further divided into eleven sections with the subsection on Governance of the Hospital and Hospital Leadership for Resource Decision being of particular relevance to the present study.

2.3.2.2.1.1 Standard GLD.1- Governance structure and authority are described by laws, policies and procedures, or similar documents

This standard spells out what is expected of the hospital management in terms of leadership. The availability of clearly laid down laws, policies and procedures are highlighted by the standard. In the context of standards for EHRs and EMRs, this implies that healthcare facilities should be guided by clearly defined laws, policies and procedures in the implementation of e-health systems, including the adoption of EHRs and EMRs standards. This brought to the fore, the major question as to whether there were laws, policies and procedures guiding the implementation of standards for EHRs and EMRs systems in the health sector of Zimbabwe.

2.3.2.4.2 Standard GLD.7.1- Hospital leadership seeks and uses data and information on the safety of the supply chain for drugs, medical technology and supplies to protect patients and staff from contaminated, fake and diverted products

The standard talks to the standardisation of the hospital pharmacy department by ensuring that its pharmaceutical supplies are standard based in an effort to offer maximum protection to patients and staff from substances that are contaminated, not genuine or diverted. EHRs and EMRs contain pharmaceutical information about the drug name, supplier as well as instructions on the administration of the drug, thus, such information feeds into other standards such as the National Drug Codes (NDC) which constitute the transaction code under HIPAA in the United States of America. For example, NDCs "are also tied to a facility's pharmaceutical system and can therefore be traced to dispensing of medication at the patient level (Gentul 2017:182).This therefore, implies that the hospital management, through GLD.7.1 has to ensure the capture of full and accurate information pertaining to the origins of drugs and medical supplies in a hospital and this is possible with the implementation of standardised EHRs and EMRs systems that are linked to standardised pharmacy information systems.

The subsection on MOI is further split into three sections namely (i) Information Management with standards that range from Standard MOI.1 to Standard MOI.8; (ii) Management and Implementation of Documents which ranges from Standard MOI.9 to

Standard MOI.9.1 and (iii) Patient Clinical Record which ranges from Standard MOI.10 to Standard MOI.12. Of particular relevance to the present study are the following standards.

2.3.2.1.1.3 Standard MOI.2- Information Privacy, Confidentiality and Security- including data integrity- are maintained

This standard requires that hospitals strictly maintain and observe patient privacy, confidentiality and security in a manner that also ensures the integrity of patient data and information. This is a direct requirement for EHRs and EMRs systems as they capture patient data and thus, stand guided by the afore-mentioned standard requirements.

2.3.2.1.1.4 Standard MOI.4- The hospital uses standardised codes, procedures, symbols, abbreviations, and definitions

According to this standard, a hospital is required to roll out clearly defined codes, procedures and terminologies. This also directly requires hospitals to roll out standards based EHRs and EMRs systems. Thus, the hospital in such a case has the leeway of choosing from a range of content, messaging, technical and terminology standards that exist in the case of EHRs and EMRs.

2.3.2.1.1.5 Standard MOI.6- Health information technology systems are assessed and tested prior to implementation within the hospital and evaluated for quality and patient safety following implementation

This standard is placing a direct demand on the hospital management to ensure that the information technology systems that are rolled out are pre-tested prior to full implementation. This includes EHRs and EMRs systems and their standards. The standard further requires timely evaluation of the implemented systems so as to determine their utility versus the tasks at hand. Thus, EHRs and EMRs systems need to be evaluated for compliance for their fitness for purpose, implying that they should be performing according to set standards.

2.3.2.1.1.6 Standard MOI.7- Records and information are protected from loss, destruction, tampering and unauthorised access

EHRs and EMRs are highly susceptible to manipulation and authorised access and Standard MOI.7 requires that the hospital ensures maximum protection of such records. This administrative standard is very important, given the sensitive nature of health data which happens to be highly sought after by pharmaceutical companies as well as epidemiologists who use it for drug manufacture and morbidity rates in communities. EHRs and EMRs also find themselves passing through broader chains and circles of trust, a situation that increases their susceptibility to tampering and theft and hence the importance of the MOI.7 standard.

2.3.2.1.1.7 Standard MOI.10- The hospital initiates and maintains a standardised clinical record for every patient assessed or treated and determine the record's content, format, and location of entries

The importance of content standards needs not be emphasised. Standardising the content of a health record as well as data definition allows for the collection, aggregation, transferability, reproducibility and meaningful use of data across the jurisdiction (Abrams, Learmonth and Gibson 2017:98). Thus, Standard MOI.10 therefore makes it an administrative requirement for a hospital to maintain a standardised patient record. In the context of EHRs and EMRs, a number of standards have been developed to generate and maintain standardised patient records and hospitals have a wide pool of standards to choose from.

It should be noted that the afore-mentioned standards by JCI are administrative in the sense that they place administrative requirements on hospitals to put in place standards that ensure the smooth administration of healthcare facilities without necessarily directing them on which standards to implement. Thus, the question of which set of standards a hospital should implement is a matter of choice from the hospital leadership.

2.3.3 Planning for e-health interoperability, EHRs and EMRs

EHRs and EMRs cannot be achieved if they are implemented in isolation and as standalone projects. Instead, they need to be implemented within a country's e-health framework at the

very planning stage. This is because EHRs and EMRs and their standards are part of the broader e-health strategy and they can only exist following the pronunciation of an e-health strategy. The SemanticHealth (2006) cited in the European Commission Information Society and Media (2008:30) observed that the realisation of e-health interoperability across a given healthcare domain requires that there be policy implementation actions at four generic levels, namely (1) health policy, (2) organisation or healthcare provider, (3) semantic and (4) technical functionality levels. Table 2.8 broadly depicts the key and indispensable aspects of interoperability in e-health.

Table 2.8: e-Health interoperability levels and related issues

1. Health policy: *cooperation*	• Vision & strategies • Processes & measures, incentives • Socio-economic (sustainable), legal framework • Accreditation and certification
2. Health service providers (Organisational level): *collaboration*	• Organisational structures and culture • Intra & inter-jurisdictional service processes • Change management, behavioural change • Systems thinking, business process re-engineering
3. Semantic *interoperation*	• Terminologies, classifications • Translation • Data • Structures
4. Technical / functional *interoperation*	• Technical standards • Hardware and software connectivity • Security • User interfaces

Source: SemanticHEALTH (2006) in the European Commission Information Society and Media (2000:30)

Items 1 and 2 in Table 2.8 partly talk to the administrative issues of EHRs and EMRs standards, whilst items 3 and 4 emphasise the necessity of interoperability aspects that are all desiderata in the standardisation of health information systems. Thus, the e-health policy (item 1) which, as shown in Table 2.8, will pronounce the country's vision and strategies, processes, measures and incentives that are necessary to ensure cooperation among players in the healthcare sector (SemanticHEALTH 2006 in the European Commission Information Society and Media 2000:30).

The strand of policy, as part of the e-health framework, will also pronounce the socio-economic and the legislative framework of the e-health strategy, together with aspects of certification and accreditation (SemanticHEALTH 2006 in the European Commission Information Society and Media 2000:30). Zeroing in on EHRs and EMRs standards, this strand talks to administrative standards whereby issues such as the privacy, confidentiality and security of patient health information which are specifications that should be pronounced by clear policies and legislation that supports e-health.

Because it is equally important for EHRs and EMRs to operate and rely on credible systems that will ensure the security, confidentiality and privacy of patients' health information, issues of certification and accreditation of the systems and their providers also have to be addressed by this strand of the e-health strategy. It is important to note that the issue of security of patient health information that is generated, held, stored and shared by EHRs and EMRs systems is two pronged. On one hand, it is a policy and legislative issue in the sense that security measures and the associated consequences for security breaches first have to be specified and provided for both policy wise and legislatively and hence its discussion under the administrative standards strand. On the other hand, it is considered a technical issue in the sense that regarding implementation, security is technically achieved through a raft of technical measures, ranging from the use of passwords, biometrics, audit trails and many more.

The second strand (item 2) on health services providers at the organisational level specifies the necessities for collaboration in an e-health project. Included in this category are organisational structures and culture, intra and inter-jurisdictional service processes, change management, behavioural change and systems thinking, business process re-engineering (SemanticHEALTH 2006 in the European Commission Information Society and Media 2000:30). In light of EHRs and EMRs standards, this strand of the e-health interoperability strategy talks to the administrative or managerial aspects of standardisation processes in which the implementers are called upon to establish organisational structures, influence cultural changes that are supportive of the e-health strategy, which may also include encouragements to adopt EHRs and EMRs standards. This strand also extends to the aspects of business process re-engineering whereby organisational managers and all participants are being urged to rethink their operations model in a manner that is progressive by adopting standardised EHRs and EMRs systems.

The third element of e-health interoperability covers semantics (item 3), meant to achieve interoperation at a vocabulary level. The focus of this strand includes terminologies, classifications, translation, data, and structures (SemanticHEALTH 2006 in the European Commission Information Society and Media 2000:30). Issues of concern here include the development and use of structured and uniform terminologies or vocabularies in healthcare. This is what has seen the emergence of terminology or vocabulary standards that were discussed earlier on in this chapter. Thus, this strand of e-health directly talks to the interoperability EHRs and EMRs standards. The importance of semantic interoperability can also be seen in the AORTA infrastructure of the Dutch which was weak with regards to this aspect and had, in 2007, to join the newly formed International Health Terminology Standards Development Organisation (IHTSDO) (Cornet 2017:71). Thus, the AORTA infrastructure was technically strong, but semantically weak, thereby enabling the exchange of limited free text data set such that human interpretation was required (Cornet 2017:71). This witnessed the Dutch National Release Centre Nictiz introducing courses in SNOMED-CT in an effort to realise capacity building and to bring people up to speed (Cornet 2017:72).

The final strand of e-health interoperability (item 4) is about technical or functional interoperation. According to the SemanticHEALTH (2006), cited in the European Commission Information Society and Media (2000:30), technical or functional interoperability includes the following aspects: technical standards, hardware and software connectivity, security, user interfaces. As seen above, implementers at this stage should be preoccupied with purely technical issues that enable information to be shared over networks. This touches on issues of connectivity, use of standard codes as well as the physical infrastructural specifications that collectively act as conduits for patient health information transfer and sharing. For example, the AORTA infrastructure in the Netherlands consists of a national switch point which is based on a messaging mechanism using HL7 version 3 (Cornet 20017:71). Essentially, the switch point does not hold any clinical patient data, but contains references to systems that do, and facilitates the retrieval of patient data from such systems (Cornet 2017:71).

In the context of Zimbabwe, it would seem Zimbabwe's e-health strategy 2012-2017 provided a clear pronouncement of the country's vision regarding e-health, thereby partly meeting the specifications of policy in item 1 of Table 2.8, but may be found wanting with regards to the rest of the requirements for an interoperable health framework, especially the aspect of a framework of standards for EHRs and EMRs, which is the thrust of the present

study. Revealing the weakness of the Zimbabwe's e-health strategy 2012-2017, the MHCC (2012-2017:9) lamented

> The systems being developed and deployed do not use any national or international standards, increasing the risk of developing vertical silos of data and limited information exchange across the e-health care divide.

The importance of standards for EHRs and EMRs standards was not unknown to the MHCC as it vividly acknowledged the need for such standards in the Zimbabwe's e-health strategy 2012-2017. After lamenting the conspicuous dearth of EHRs and EMRs standards and the challenges that are associated with such a situation, the MHCC (2012-2017:12), in the following words, expressed the need to have standards for such systems: "standards will allow disparate systems to share information across the same national e-health infrastructure and applications platform." Thus, the MHCC was very aware of the need to complement its e-health strategy by interoperable EHRs and EMRs (items 3 and 4) in Table 2.8, but there seemed not to exist any roadmap or strategy of developing and implementing such standards. It therefore, remained the concern of this study to establish the strides, if any, that the MHCC has achieved so far in this regard.

Regarding administrative standards, the MHCC (2012-2017:18) also realised that its e-health strategy could only be successfully rolled out in the presence of an enabling policy and legislative atmosphere as well as a standards monitoring body. Thus, "there should be an enabling legal environment which will support the implementation and sustenance of the e-health framework" (MHCC 2012-2017:18). The MHCC (2012-2017:17), further explicated

> In addition to central governance, there should be sector level governance and sector standards compliance bodies, these self-governing structures are especially important as they will have all the locale specific information needed for controlling and monitoring of their members.

It therefore, remains once more, to be established how much ground the MHCC has covered in terms of setting up such bodies in an endeavour to achieve and enhance EHRs and EMRs standards.

2.3.4 EHRs and EMRs evaluation and implementation

The hype and boom of health information technologies have revolutionised and streamlined healthcare and their uptake is significantly rising (Lau, Bartle-Clar, Bliss, Borycki, Courtney

and Kuo 2017). This, in turn, has witnessed the birth of a variety of systems and applications, further resulting in increasing demands for the implementation of IT solutions in healthcare facilities such as hospitals, clinic, homes and virtual spaces of m-health (Lau et al 2017). In the same vain, the implementation of interoperability standards tends to be hindered by a plethora of factors, one of them being the numerousness of such standards such that organisations are faced with the challenge of making choices. As observed by e-Health Ontario (2013:3), the challenge that the implementers of interoperability standards face is the existence of numerous such standards that facilitate data exchange between healthcare facilities such that making a choice for the right one becomes a complicated task. Lamenting a similar challenge is the FICCI Health Services India (2013:5) in the following:

> With vendors incorporating different standards for similar or same systems, it is little wonder that all-round inefficiency, waste and errors in healthcare information and delivery management are all too commonplace an occurrence. Consequently, a patient's medical information often gets trapped in silos of legacy systems unable to be shared with members of the health community.

Whilst organisations are faced with the challenge of selecting appropriate interoperability standards for EHRs and EMRs, the adoption of appropriate standards does not remain an option but a desideratum. As observed by e-Health Ontario (2013:3), the adoption of an incorrect standard has far much reaching consequences that range from increased costs of maintaining the standards to the inability of an institution to adopt as well as sustain the use of the standard to support effective health services to patients. Further complicating the situation is the fact that there is an assortment of approaches to extending as well as constraining baseline standards for implementation in particular situations (e-Health Ontarion 2013:3). As an example, e-Health Ontario (2013:3) cited the HL7 CDA, which is used to define the structure as well content of clinical documents which may be taken as a baseline standard for an electronic hospital discharge summary document whilst there are many different implementation approaches that could be adopted for re-use.

The evaluation of the various approaches to the implementation of interoperable EHRs and EMRs calls upon the implementers to have clear criteria and supporting methodologies (e-Health Ontario 2013:3). Such criteria and supporting methodologies also require the consideration and involvement of information from different sources that affect the manner in which the standards will be implemented and maintained, including the assessment of the existing infrastructure, business requirements and other related standards (e-Health Ontario 2013:3). It is in the light of the aforementioned that e-Health Ontario (2013:3) recommends

the involvement of a standards analyst. Such a standards specialist, according to e-Health Ontario (2013:3), using best-practice tools and methodologies, will work directly with clients and help them with the selection of the most effective interoperability standards. The work of such a standard analyst will continue to a point where he or she collaborates with clients during the subsequent phases of the standards implementation in which the analyst will help his or her clients to either constrain or extend the standards to tailor them to specific implementation contexts (e-Health Ontario 2013:3).

In light of the afore-mentioned challenges surrounding the selection of EHRs and EMRs standards for adoption or implementation, the screening of such systems may be done based on initial screening criteria consisting of three principal categories namely: fit for purpose; stewardship and standards quality (e-Health Ontario 2013:3). Table 2.9 summarises the EHRs standards selection regime that was adopted by the e-Health Ontario (2013).

Table 2.9: Initial screening criteria for EHR standards

Criterion	Focus
Fit for purpose	• Aligns to Ontario EHR Blueprint • Constrained/extended from existing Interoperability Standards • Supports Business Requirements • Supports Technical Requirements • Adoption Likelihood • Supports coded data vs. free text
Stewardship criteria	• Cost of Implementation • Governance Structure • Intellectual Property and Licensing Costs • Defined Maintenance Process
Standard quality criteria	• Provides Implementation Support and Education • Enables Interoperability • Implementation and Maintenance Tools • Conformance Testing Methodologies and Tools • Proven Stability • Adaptable and customizable

Source: e-Health Ontario (2013:7)

2.3.5 Fitness for purpose

This criterion focuses on the evaluation of the "…appropriateness of the standard for the intended business, clinical and technical context" (e-Health Ontario 2013:6). In the context of Ontario's e-health strategy, this criterion included the following considerations:

i. Alignment to Ontario's e-Health Blueprint;
ii. Ability to be constrained or extended from existing interoperability standards;
iii. Ability to support business requirements;
iv. Likelihood to be adopted; and
v. Support for coded versus free text

This criterion is so cardinal in the standards selection process in the sense that it acts as the primary determinant, given that it talks to the very rudimentary or core business aspects to be standardised (business requirements). Without the standard meeting this criterion, it ceases to be of utility and attractive to the implementers, irrespective of how easily it meets the criteria of stewardship and quality.

2.3.6 Stewardship criteria

Stewardship, as a screening criterion, allows for comparisons of the stewardship of the standard in respect of its governance structure, licencing and intellectual property rights as well as clearly defined processes of their maintenance (e-Health Ontario 2013:6). Thus, this criterion, the e-Health Ontario (2013:6) further explained, also provided an insight into the sustainability of the standards. The importance of this criterion is embedded in the need for the standard to have a clear governance regime, including aspects of licencing and intellectual property rights to the standard. For example, overarching issues such as the continuity of the standard, its ability to support trust-worthy EHRs and EMRs systems, and its compliance with other legislative requirements such as privacy and confidentiality are all directly contingent on this criterion. Thus, failure to give due attention to this criterion may dearly cost the organisation in the form of security, confidentiality, privacy, copyright, and intellectual property violations as well as dearth of continuity of the standard. The very concept of interoperability also partly depends on the use of standards that are credible and have clearly defined regimes of maintenance.

2.3.7 Standard quality criteria

The thrusts of this strand of the screening criterion are to determine the overall calibre of the standard and are not related to context of the standard (e-Health Ontario 2013:6). This

requires the standard to enable interoperability, adaptability and stability (-Health Ontario 2013:6). Coupled with the afore-mentioned areas of consideration in the standard are the requirements of implementation resources such as relevant training, implementation guides as well as software to support development (e-Health Ontario 2013:6). Under this criterion of assessment, the standard should meet the conformance tests and maintenance requirements (e-Health 2013:6). Thus, the "standard quality criteria" as screening tools consist of a plethora of both managerial and technical considerations. For example, the requirement to make implementation resources such as the training of staff available is a managerial consideration whilst those to do with adaptability, stability, conformance testing and maintenance are more technical requirements. The importance of the "standard quality criteria" manifests itself by being able to bring the entire standards project exercise to a halt if it is not given due attention. For example, without the necessary resources being availed in support of the standard, there is no implementation to envisage, and without the standard being adaptable, stable, meeting the conformance tests and the maintenance requirements, the implementation of the project will become a white elephant for the organisation.

However, despite the suggested criterion for the selection of interoperable EHRs standards, e-Health Ontario (2013:5) hinted that prior to the standards selection process, there are certain preconditions that should be observed, which include the establishment of a project team, definitions of all business requirements and of course, the presence of a standards analyst. Above all, the overarching criteria to assess here are that the chosen standard renders support *[to the business endeavour]*, is adaptable and customizable (e-Health Ontario 2013:7). Thus, the process of selecting EHRs and EMRs standards is not an easy one and requires a vivid plan of action if interoperability is to be achieved. Most countries, including Zimbabwe, have immature EHRs and EMRs systems that are not based on any deliberately adopted standards.

Whilst e-Health Ontario (2013) proposed the afore-mentioned standards evaluation framework in its standards selection guide for EHRs and EMRs guidelines, a pragmatic EHRs and EMRs evaluation exercise that was employed by the Meraka Institute of the Council for Scientific Research (MICSR) and the National Department of Health (NDH) (2014) in South Africa followed a slightly different and expanded approach. The approach, the MICSR and NDH (2014:18) reported, "tied in with the interoperability focus and mitigated implementation risks." The evaluation criterion, as stated by the MICSR and NDH (2014:18) identified three stacks of standards, which are as follows:

i. The group of standards that are based on the HL7 v3 Reference Information Model (RIM) (Health Level Seven International, 2013e);

ii. The standards that operate on the 13606 Part 1-5/Open EHR -Reference Model (RM) (The En 13606 Association); and

iii. The interoperability standards-based profits developments by the Global Organisation, Integrating the Health Enterprise (IHE) (IHE International, 2012).

The standards assessment template that was used by the MICSR and NDH (2014:19) is shown in Table 2.10.

Table 2.10: EHR standards "stacks" evaluation matrix

Criteria	HL7 v3	ISO 13606	IHE
Scalability	x	x	x
Implementability			x
Conformance testable			x
Market acceptance			x
Economically feasible	x	x	x
Technical capacity			x
Maturity	x		x
Extensibility and flexibility	x	x	x
Support clinical and healthcare initiatives	x	x	x

Source: MICSR and NDH (2014:19)

As seen in Table 2.10, the standards selection matrix consisted of nine elements, including scalability, ability of the standard to be implemented, conformance testability, market acceptance, economic feasibility, technical capacity, maturity level, extensibility and flexibility as well as the abilities of the standards to support clinical and healthcare initiatives. The results of the evaluation exercise indicated that of all the three families of standards, the family of the IHE standards met all the nine assessment elements, with HL7 standards meeting only five elements, namely scalability, economic feasibility, maturity, extensibility and flexibility and the ability to support both clinical and healthcare initiatives. Ranking last in the assessment was the ISO 13606 family which met just four, namely scalability, economic feasibility, extensibility and flexibility as well as the ability to support clinical and healthcare initiatives, which was below half of the nine assessment strands. Shedding more light on the importance of flexibility and modifiability of a standard, the FICCI Health

Services India (2013:14) stated that it has to be borne in mind that standards should be flexible and modifiable so as to adapt to both the demographic and resource variance that may be observed in a country.

2.3.8 EHR standards selection

Another inevitable pre-standards implementation exercise is standard selection. This entails making an informed choice of a standard or set of standards. According to e-Health Ontario (2013:5) in its standards selection guide, the process of selecting EHR standards selection can be thought of as involving the stages that are summarised and depicted in Figure 2.3.

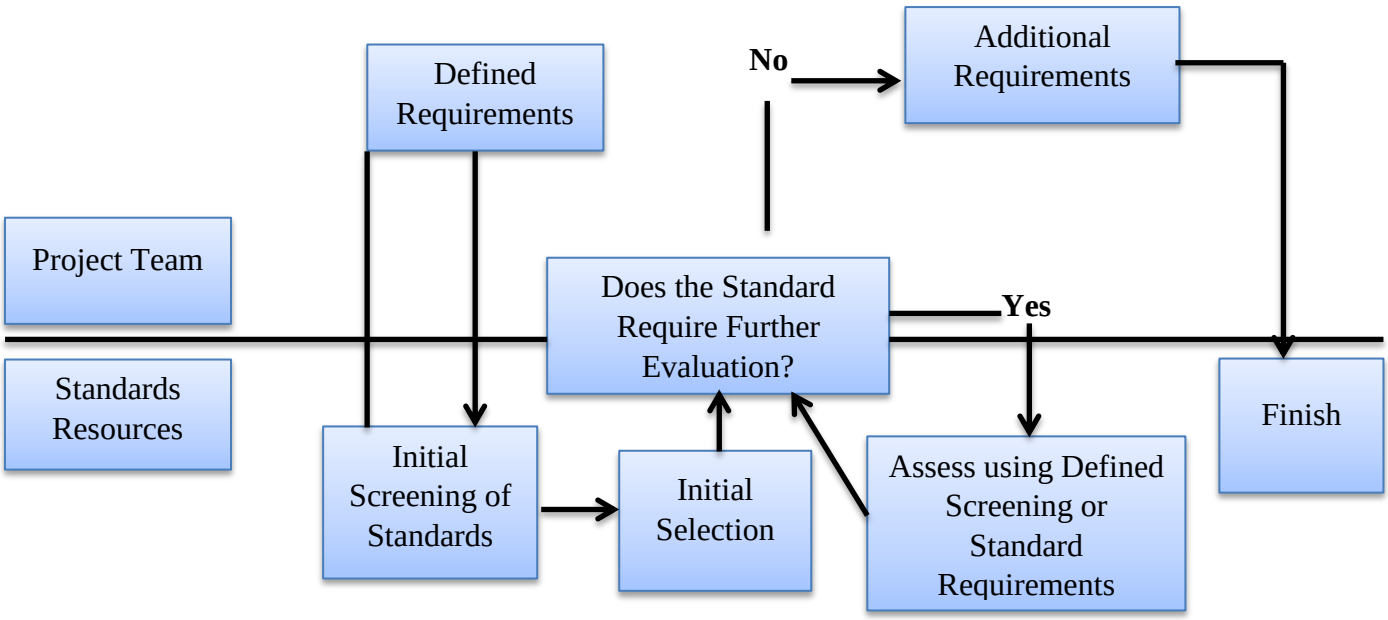

Figure 2.3: EHR standards selection process

Source: e-Health Ontario (2013:5)

As shown in Figure 2.3, it can be noted that the entire process starts off by availing the standards resources and putting together a standards project team. Once these have been made available, the next procedure involves a check as to whether the standards meet the defined requirements of the system or not. This will see the standards being subjected to the initial screening process that was explained using the fit for purposes, stewardship and standard quality criteria as the screening measures.

In the case of the standards surviving the initial screening process, the standards are selected for the first time. Following the initial selection, the standards project team will have to

subject the selected standards to the question: do the standards require a further evaluation? Should the team find out that the standards require further evaluation, the standards are further subjected to a second round of screening based on clearly defined screening criteria or standard requirements, after which, the standards team asks itself the same question of whether the standards require further evaluation. Should the standards be found to be in need of a further evaluation, the standards are subjected to further requirements (where there are any). It is after this that the selection process may be considered over and the standard can be implemented. The process of standards selection is one that has to be undertaken meticulously to avoid the waste of resources, let alone making a mistake of selecting and rolling out standards that do not meet the business requirements of the healthcare facility.

Given the three main families of standards for EHRs standards which are terminology standards, messaging standards and content standards, the e-Health Ontario (2013:7-8), further outlined the main factors to consider when selecting standards for each family of standards. For terminology standards, certain essential technical criteria need to be met, including concept orientation, concept permanence, unambiguous concept meanings and explicit versions identifiers, although other none essential criteria including meaningless identifiers, multi-hierarchies, source information/terminology model, use of synonyms and level of granularity are desirable (e-Health Ontario 2013:7-8). With regards to the messaging standards and content standards, attention should be paid to the implementation completeness, flexibility of the standards and market trends (e-Health Ontario 2013:8).

The selection and eventual implementation of the three principal families of standards, that is, terminology standards, messaging standards and content standards, there are three layers of standards that should also be taken into consideration, namely base standards; standards based profiles and interoperability specifications. This is in tandem with the observation by the FICCI Health Services India (2013:14), which stated that interoperability and standardisation may occur at many different levels.

2.3.9 Base standards

Bases standards, according to the MICSR and NDH (2014:23) "…are used to set a baseline for healthcare system development, whether electronic or manual." In essence, base standards define aspects such as terminologies or vocabularies, data structures and protocols that are necessary to achieve interoperability and are required to achieve consistency (MICSR and

NDH 2014:41). Thus, baseline standards are the first phase of ensuring that there is uniformity in defining and describing cases and terms in the healthcare and are desiderata for achieving the standardisation of expressions in healthcare, irrespective of whether the health system is electronic or manual. In terms of scope, base standards are flexible as they may be applicable to a specific healthcare field or area of specialisation, or may be applied across a wide array of industries in health to achieve fundamental ICT or security management (MICSR and NDH 2014:47). The malleability of the standards in this layer therefore, offers one of the greatest advantages in the form of flexibility.

This layer of standards possesses the fundamentality of acting as a foundation that facilitates the creation of elementary services, messages as well as documentation that supports any possible use domain (MICSR and NDH 2014:41). Characteristically, base line standards are generic and either (a) broad in scope and range of use cases that they are able to support such that in reality, only a subset of the provisions of the standard is generally used; or (b) very specific and require to be combined with other baseline standards to meet the requirements of any implementation requirement in the real-world (MICSR and NDH 2014:41). It can therefore, be said that this layer of standards is one that is so rudimentary and every other standardisation process relies on them. Thus, this layer can be considered as the primary tier of the standardisation process for EHRs and EMRs.

2.3.10 Standards-based profiles

By definition, "a standards-based profile is an agreed set of guideline building blocks that define how the base standards will be applied, in a coordinated way, to address a specific technical use case within a specific healthcare domain or setting" (MICSR and NDH 2014:41). This, ideally, should come after the selection of baseline standards to guide the standards project team on how to address certain specific cases in a particular health setting.

These standards are particularly needed for the specificity of interoperability desiderata which actually considered as interoperability serving blocks that can be re-used in more than one project (MICSR and NDH 2014:41). CEN/TC 251 of ISO (2009a) observed that such standards-based guidelines act as the glue or binding agent in the sense that they provide specifications that combine and refine the use or application of a set of baseline standards that address a specific technical use case. For example, a profile for the sharing of patient medical

summaries between and among healthcare providers and facilities will clearly outline which standards are applicable and the procedures of implementing them (MICSR and NDH 2014:42).

In terms of scope, standards-based profiles are also malleable and flexible as they cover an assortment of interoperability aspects, including security, privacy, patient identification, sharing of health records, provision of access to such records, content for care coordination records, specialty record content, home monitoring, referral as well as consultation workflows (MICSR and NDH 2014:42). It is imperative to define such e-health profiles so as to ensure relative independence as well as allowing organisations and standards project teams to employ different approaches to their standards implementation standards, for example, allowing a country to address its specific security and privacy policies (MICSR and NDH 2014:42). In summary, standards-based policies may be considered as "manuals", spelling out the step by step procedures that standard projects team members should follow in order to ensure the interoperability of standards and dealing with specific cases of standardisation activities.

2.3.11 Interoperability specifications

Sometimes known as interface specifications, implementation specifications, project specifications, interoperability specifications refer to a layer at the apex that is directly related to the business use cases they aim to support (MICSR and NDH 2014:42). In any e-health projects, the aim is to deliver a clear set of specifications that dictate the way of interfacing systems that are used for healthcare with a shared IT infrastructure supported by a district, provincial or national health information network (MICSR and NDH 2014:42). Such interoperability requirements or specifications, according to the MICSR and NDH (2014:42-44), anchor implementability by:

i. Specifying the standards-based profiles to use, as well as their underlying norms and standards;
ii. Combining the right set of standards-based profiles to address the business-level use case, and would therefore, be specific to a project, be it national, provincial, district or local to an institution;

iii. Enabling the expedition of implementation, reuse of software and test tools, and easier understanding of the customisation required by each project that is engaged in leveraging standards-based interoperability because of their construction being based, largely on standards-based profiles.

iv. Addressing the specifications that are related to the "interfacing" of healthcare record related management information systems to a home or point of care, district, provincial, national infrastructure but not the internal design specifications of all aspects of any such networks, or that of any IT system that is connected to it;

v. Offering a specification on how to exchange information, not a piece of software, thereby ensuring technological independence to support various systems, operating system environment, hardware architectures as well as business models; and

vi. Being written into procurement documents when e-health systems are required or developed.

Thus, the three levels of the standardisation process, that are the base standards, standards-based profiles as well as the interoperability specifications/requirements are all necessary in building e-health systems that are coordinated, flexible and adaptive, let alone the primary rationale for the standardisation of EHRs and EMRs, including the ability of such systems to share patient information. Taking care of the aforementioned procedures of EHRs and EMRs systems also enhances the chances of success for such systems as the standardisation process will be undertaken procedurally and systematically. The MICSR and NDH 2014:23) indicated that "the advantages of approaching the development of IT systems based on an agreed set of standards include alignment, integration, flexibility, reusability, portability and reduced time to market." Vividly, had the Zimbabwe's e-health strategy (2012-2017) taken the aforementioned path right at its conception stage, chances of witnessing EHRs and EMRs that are not interoperable and not based on any standard would not be witnessed today.

2.3.12 Legislation and policies for EHRs and EMRs

Health information, Gonzalez, Blobel and Lopez (2011:694) observed, is "…data intensive, complex, changing, life-long, sensible and policy regulated." This, in a way is an acknowledgement of the importance of having clearly defined policies to handle voluminous

amounts of information that characterise the healthcare industry. The adoption of EHRs presents a lot of new issues that call for a much more sophisticated and nuanced approach (EU Health Programme 2008-2013: 2014:14), and "the use of EMRs and development of shared medical records as integral communication channels within the health system represents an evolving and fundamental change to the practice environment" (College of Physicians and Surgeons of Alberta 2015:2).

Indeed, the application of ICTs in health information management has placed new and complex strains on the legislative and policy frameworks of countries that have embraced e-health, thereby compelling governments and health related stakeholders to revisit their health information management legislations and policies. To use the words of the CPSBC (2007:1), the traditional model of managing information is evolving, owing to a myriad of factors, including health information systems reforms, health information legislation, patient expectations as well as many IT factors.

Further harping on the unavoidable need for the re-alignment of health information legislation and policies in the of the information management complexities that are posed by EHRs and EMRs systems, the CPSBC (2007:1), wrote "given these impacts on the practice environment, as well as the evolving expectations of patients and society in general, physicians should periodically evaluate the practice's data stewardship framework to review and update policies and guidelines." Such policies and guidelines, the CPSBC (2007:1), may include the following:

i. The policies and processes involved in the collection, use and disclosure of health information within the medical practice;
ii. The availability and use of external medical records;
iii. Ensuring information protocols operate within the legislative framework, support a physician's ethical obligations, and follow best practices for information management and sharing within and external to the practice;
iv. Ensuring contractual agreements are in place for group practices that define the ownership and on-going management of medical records.

EHRs and EMRs allow healthcare practitioners to generate, use, store, retrieve and in some cases, preserve patient health information and health related data and the need, not only to have sound legislative and policy frameworks to guide and regulate healthcare stakeholders

on issues of access, privacy, confidentiality and security of patient health information and data but to adhere to such provisions as well become needless to mention. Indeed, EHRs allow simultaneous viewing by many stakeholders, and make use of a host of ICT tools (Harman, Flight and Bond 2012). According to Mann, Savulescu and Sahakian (2016), EHRs are easy to manipulate, aggregate and share, thereby allowing *[and necessitating]* access issues to be discussed and expert opinions to be sought and provided globally. Thus, the discourse of EHRs and EMRs cannot be successfully explored without paying due attention to legislative and policy issues that go hand in glove with the complexities of ICTs, coupled with an increasingly alert populace with regards to patient privacy, confidentiality and security of its health information. EMRs, have become so pervasive and their support has drastically been enhanced of late, with the result of increased adoption (CPSBC 2007:16). Such developments have come with security demands, given the fluidity and easy manipulability of such records.

CPSBC (2007:17) observed that EHRs [*and EMRs]* allow for additional uses, access, electronic communication as well as additional obligations for security management. Buttressing the indispensability of standards and the subsequent need for the implementation of legislative and policy frameworks for information handing in healthcare, the MHCW (n.d:16) in its 2009-2014 health information systems observed:

> Standards are critical to enable information to be shared effectively between all users and consumers of health services. Standards are required in the process of information gathering, storage, processing, communication/transmission, dissemination, infrastructure development, security and upholding of privacy, confidentiality and other ethical considerations for the national health information system and its sub-systems.

Thus, the importance of standards in health information management needs not be overemphasised. Harping on the importance of standards in light of the seemingly unavoidable and imminent EHRs and EMRs hype, is Kalra and Ingram (n.d) who said that the need to establish standards by which patient health records can be shared between healthcare providers has gained momentum internationally. However, such standards should be hinged on sound legislative and policy provisions. In fact, for the derivation of maximum benefits from any standard, especially in so far as matters of privacy, confidentiality as well the security of patient health information and records are concerned, there is a need for a vivid pronouncement of a legal and policy infrastructure upon which such matters will be anchored. It is against this background that one of the objectives of the present study was

dedicated to the exploration of legislative and policy issues surrounding the standardisation of EHRs and EMRs in Zimbabwe's e-health sector. The scope of this objective was not only limited to issues of privacy, confidentiality and security of EHRs and EMRs in a standardised manner, but was extended to explore the administrative or governance aspects of standardisation for such systems.

The MoHCW (n.d:17), in its Zimbabwe's e-health strategy (2012-2017) recognised the importance of the governance of EHRs that will oversee and enforce issues of policy for EHRs standards by stating that such a governance body should be responsible for encouraging the "market to develop quality e-health solutions which are scalable, aligned with national policies and use predefined standards for storing, transmitting and receiving messages." This is also in sync with the advice of the MICSR and NDH (2014:44) which stated that the process as well as governance aspect of EHRs standardisation should be in the hands of a relevant e-health standards authority that is specifically mandated to address health information systems issues. Such an authority, the MICSR and NDH (2014:44) further advised, should be comprised not only of standard experts, but of members of different and necessary backgrounds and expertise who are able to render expert advice on all issues that relate to e-health, including ICT infrastructure and the enabling environment. Thus, for the purposes of appreciating the indispensability of the governance for EHRs systems to achieve standardisation and interoperability, ECISM (2008:30) stated that experience has shown that on top of implementing concrete and context specific standards, legal and regulatory compliance is an additional requirement.

Failure to enact sound legislation and policies for the standardisation of EHR infrastructure may result in the implemented systems not performing up to their expectations or such systems being white elephants. A good example of this is the AORTA infrastructure project in the Netherlands that was conceptualised in 2002 whose objective was to establish a national infrastructure for the exchange of data between healthcare providers. According to Cornet (2017:71), whereas there were a number of technical challenges in that project, the main barriers for the implementation of the project were non-technical, with the first barrier being the use of a unique patient identifier. Upon rolling the project out, a decision to use social fiscal numbers for patients that had been in use since 1988 was taken, only for a legislation to be passed in the year 2007 to use the then called citizen service number for nothing other than fiscal purposes and in 2008, it was allowed to use such numbers in healthcare (Smith 2013 cited in Cornet 2017). Late 2008, the infrastructure was officially

adopted, in anticipation that legislation pertaining to the use of the citizen service number for electronic exchange of health information was going to be enacted (Smith 2013 cited in Cornet 2017).

However, this legislation did not see light, a situation that witnessed the Dutch Government arriving at a decision that the national infrastructure needed to be discontinued (Smith 2013 cited in Cornet 2017). Eventually, the national infrastructure was handed over to the Association of Healthcare Providers for Care Communications, whose mandate was to facilitate continuation of the infrastructure in a regionalised manner and without compulsory participation by care providers (Smith 2013 in Cornet 2017:71). Thus, the importance of taking into account, legislative, policy and political aspects for EMRs and EMRs, preferably prior to rolling out such systems cannot be overemphasised and need to be taken into consideration prior to rolling out health information systems to avoid such projects that will turn out to be white elephants.

2.3.12.1 Privacy issues and standards in health information management

The shift from paper to electronic platforms brings to the fore issues relating to the privacy and security of data for patients (Furusa and Coleman 2018). Privacy, in the context of health information management, particularly becomes a critical consideration for both the clinicians and non-clinical staff that provide auxiliary services to clinicians. In fact, patients, by virtue of being human beings, are entitled to privacy, implying that they are entitled to private spaces before they even interact with physicians and every other player in healthcare. However, due to various ailments that patients suffer from, they open up to their physicians and other healthcare providers in an effort to help healthcare providers to better understand their conditions and offer appropriate diagnoses and therapies to them. Basically, this is the stage at which patients' privacy is "legally, officially and ethically" invaded, and patients disclose to physicians and other healthcare givers on condition that the information that is extracted by such healthcare providers is material to understanding their ailments.

Health information for patients, in most cases, is collected in the context of confidence and trust between the patient and the healthcare provider and such information may be needed even ages after the purpose for which it was elicited from the patient has lapsed (MHCW n.d:17). Shedding more light on the importance of privacy, which usually goes with security

in healthcare, the MHCW (n.d:17) in its 2009-2014 health information system stated that "privacy and security are cornerstone principles of the use and collection of personal health information that should be protected in the laws of a country." Health records, according to Mann, Savulescu and Sahakian (20016), may contain sensitive information that patients may not be willing let second and third parties to know and thus, privacy therefore, prevents information about individual patients from being disseminated in contexts that are inappropriate.

The College of Physicians and Surgeons of Alberta (CPSA) (2015), harping on the need for the attention that has to be given to the privacy issues in light of shared EMRs *[and EHRs]*, systematic disclosure of information for primary and secondary uses, coupled with the growing accessibility of information for secondary uses, stated that the use of such systems, consistency, regarding the application of rules across professions as well as organisational boundaries is essential. This is also in tandem with the statement by the CPSBC (2007:10) which harped on the invaluable importance of privacy legislation in healthcare by stating that privacy legislation "…also provides for protection against invasion of personal privacy by prohibiting unauthorised collection, use or disclosure of personal information…" by those in healthcare. In Zimbabwe, matters of privacy in health are stipulated in the Health Professions Act Chapter 27:19 of 2000 (MHCW n.d:17).

Issues of privacy for health information in Zimbabwe are also covered by other legislative and policy tools such as the Constitution of Zimbabwe of 2013, the Zimbabwe Patients Charter and the Access to Information and Protection of Privacy Act (AIPPA) of 2002. The Constitution of Zimbabwe (2013:30), for example, in Section 57, Items (d) and (c), respectively, states that every person has the right to privacy, including the right not to have " the privacy of their communications infringed" and "their health condition disclosed." The Zimbabwe Patients Charter (2013) also provides for the privacy of patients by stipulating that patients are entitled to privacy and should consult healthcare providers in facilities that ensure such privacy. AIPPA, Chapter 10:27 (Act no 5 of 2002), which was amended in 2007, also protects the privacy of individuals by barring public institutions or bodies from releasing personal information of any individual that such public institutions or bodies may be in custody of without a request put in writing to the directors of such public institutions or bodies. The Act gives directors of public institutions or bodies the powers to act on requests for personal information or records in their custody within two weeks of receiving requests, in which case access may either be granted or declined. Thus, this legislation also affects

public hospitals as they are public institutions that may be taking custody of patient health information/records. Thus, great strides have been made in Zimbabwe regarding the provisions for patient privacy.

However, the emergence of EHRs and EMRs, which are essentially delicate and easily manipulated, presents new challenges for the existing legislation. According to the EU Health Programme of 2008-2013 (2014:14), "the issue of privacy of health data gained a whole new dimension with the development of e-Health." It therefore, became imperative for the present study to explore the sufficiency or insufficiency of the legislative and policy tools for the support of EHRs and EMRs standards in Zimbabwe. For example, taking a cue from the EU Health Programme of 2008-2013, patients' rights in the context of privacy in EHRs and EMRs may include:

i. The right to access information;
ii. Right to download;
iii. Right to know who accessed their EHRs and EMRs; and
iv. Right to modify/erase data from their EHRs and EMRs

Privacy and security of health information have become even more important not only from the perspectives of ethics and legal matters, but in a business sense as well. Health information has become "gold" to those who illegally sell it as they realise huge profits from such unscrupulous acts. For example, Peel (2010:2), cites Anderson (2009) who reported that annual revenues realised from health stealth data mining and sales are twice or thrice more, and estimates for one small EHRs company which realises revenue of $100 million per year from selling software indicate that it could earn an additional $25 million per year by selling patient data. This indicates how lucrative the sale of patient data is, a situation that calls for uncompromised security and privacy provisions and requirements for EHRs and EMRs platforms.

Countries that have implemented EHRs and EMRs systems have understood and appreciated the need to have policies that govern privacy and security issues in healthcare. Canada is one good example where a policy on the privacy and security of patient health records is documented. Canada has a policy titled "Electronic Health Record (EHR) Privacy and Security Requirements", which identifies and documents the privacy and security requirements that interoperable EHRs are expected to meet so as to fully protect the privacy

of patients (Canada Health Inforway 2005) this is also meant to maintain the confidentiality, integrity as well as availability of patient data (Canada Health Inforway 2005). Canada appreciated that an understanding of the privacy and security desiderata will facilitate the future identification of the privacy and security services that are necessary to support Canada's EHR Blueprint (Canada Health Inforway 2005).

2.3.12.2 Confidentiality issues and standards in health information management

Closely linked to privacy is the concept of confidentiality. According to the Department of Health/Royal College of General Practitioners/British Medical Association (2011:38), the confidential relationship between patients and healthcare providers is underpinned by trust and this is not replaceable by any other system of accountability, including electronic systems. Typically, confidentiality comes after privacy in the sense that the patient would have already allowed the healthcare provider to gain access to their personal or private space by disclosing their health status and other details that are otherwise private or personal under normal circumstances. The principle of trust therefore, calls upon healthcare providers and those who may not necessarily be in clinical practice but have legally and officially gained access to patients' health or medical record to keep such information to themselves.

A number of stakeholders in health are affected by this principle, including clinical practitioners, health insurance providers as well as health information practitioners. Thus, "deciding what information might and might not be disclosed in a shared record depends fundamentally on the relationships between patients and their health professionals" (Department of Health/Royal College of General Practitioners/British Medical Association 2011:38). Indeed, IT is rapidly impacting and changing medical care such that enhanced access to information as well as information sharing may have huge implications on the quality and continuity of care, and ultimately in patient safety (CPSBC 2007:3).

From the above mentioned statements, it can be discerned that confidentiality is another cardinal principle in healthcare provision, including those who offer auxiliary services to health, such as health information managers and systems administrators. It therefore, becomes imperative for everyone who either elicits health information from patients, or processes such information in a different capacity to uphold the principle of confidentiality in order to perpetuate trust among patients. Confidentiality, just like privacy, is a double

pronged principle in the sense that in some contexts, it is seen as an ethical issue, while it is considered a legal issue in contexts where legal provisions have been provided for it.

2.3.12.3 Chain of trust

The principle of confidentiality gives birth to the concepts that CPSBC (2007:5) referred to as a "chain of trust" and "circle of trust." A chain of trust is defined as "the concept of propagating the privacy and security attributes of a piece of information from one source to the next when it is shared (CPSBC 2007:5). This implies that whenever disclosure is being made, it should be taken as an extension of the patient's privacy by those who are sharing such information. This is so because as soon as a patient discloses their personal or private information in the process of seeking health, they would have indirectly allowed the recipients of such information to "officially and legally" gain access to their private space, but on condition that such information will not be disclosed to any other party under illegal, unofficial and unethical conditions. At such a stage, the patient has no means of preventing their information from being shared and is only banking on the concerned stakeholders to share his/her health information in a legal, official and ethical manner which preserves the integrity of the patient.

2.3.12.4 Circle of trust

The circle of trust was defined by CPSBC (2007:50) as "a network of professionals involved in a patient's care who see the patient's information in the medical record or through a disclosure by the information custodian." Such information, CPSBC (2007:5) further explained, is sharable on the basis of either a custodial or affiliate arrangement. Thus, more often than not, more than one person will gain access to the patient information gathered in such a manner, including other clinicians, health insurance providers, pharmacists, health information managers as well as ICT technicians. This is not unusual in healthcare, given the fact that the provision of health, in most instances is not a one man's show, but something that involves a number of players, with each stakeholder playing a critical role and having to gain access to the patient's information in order for them to render the best service to the patient. EHRs and EMRs have created a natural stress for physicians, owing to the ever changing nature of the circle of trust (CPSBC 2007:19). Essentially, EHRs and EMRs by

design have had an expanded circle of trust (CPSBC 2007:19). In the light of this challenge, it becomes imperative and apparent that commensurably robust and clearly documented legislation and policies are a desideratum in the process of rolling out and standardisation of EHRs and EMRs.

2.3.12.5 Stewardship of patient health data

The concept of disclosure has also given birth to information stewardship. As CPSBC (2007:19) opined, the decision to disclose patient information collected by physicians to EHRs needs to be a thoughtful act. This calls upon whoever is to disclose such information to adhere to the stipulated guidelines and policies to avoid the violation of disclosure principles. Data stewardship policies and guidelines are information protocols that fall within the legislative framework, rendering support to their ethical obligations, following best practices for information management as well as sharing within and outside of the practice (CPSBC 2007:21). This implies that stewardship policies and guidelines should be within the realm of, and subordinate to the general legislative framework for health in a country. Because physicians are seen as the stewards of sensitive patient health information, they are being implored to take care in the levels of disclosures as well as the potential implications of such disclosures (CPSBC 2007:21).

To avoid a casual approach to disclosure, which may have far reaching consequences on both the patient and the physician, CPSBC (2007:19), advised physicians to carefully evaluate each decision to disclose in the case of EHRs in order to understand the benefits as well as the risks to the wishes of the patient in the management of his/her health information, also bearing in mind the rules and processes which govern the actions of information service providers. Thus, the aspect of patient data stewardship in health is equally important as it is directly related to the enforcement of legal, official and ethical disclosures. The aspect of patient data stewardship is particularly important in light of EHRs and EMRs where physicians are not physically in control of their patients' data, but the ICT service providers are. This also implies that patient data stewardship is no longer a one man's show again, but one where there are a number of other players whose actions impact data stewardship.

2.3.12.6 Consent

Because the principles of confidentiality and privacy essentially have a bearing on disclosure, they become inherently linked to the principle of consent. According to the Department of Health/ Royal College of General Practitioners/British Medical Association (2011:41), patient consent is usually required if confidential data is to be elicited for other purposes beyond or outside the provision of health care. Consent refers to "the autonomous authorization of an information access or disclosure by individual patients. Consent has three components: disclosure, capacity and voluntariness" (CPSBC 2007:5). This implies that consent, in the context of healthcare, requires a patient to agree to a request by both the second and third parties to gather or disclose their health information, and the patient in question should have the capacity to give consent and that should happen on a voluntary basis.

The second party in such a case is considered to mean the physician or anyone else who elicits information from a patient in the process of rendering health and health related care to a patient. The third party is taken to mean any other person, be they another physician or any other person who requests to gain access to the collected patient information in order for them to render health or health related service to a patient or for other secondary uses such as research. When implemented properly, informed consent does not in any way impede data flow, instead, it assures data liquidity and integrity and further helps stakeholders in the health sector to cut down on costs that arise from cumbersome and complex legal arrangements for health data sharing in HIE (Peel 2010:21).

Further shedding light on what consent entails, Wilson (2012), cited in the EC Health Programme 2008-2013 (2014:31) concurred with CPSBC (2007:5) that the concept of informed consent is directly linked to the principle of autonomy of patients, and got to understand why most legislation governing EHRs carried clauses that stipulated the requirement to seek a patient's consent prior to the collection, during the processing or sharing health related information so as to ensure that the right of privacy of health data is respected. Consent is further split into two types, namely express consent and implied consent (Department of Health/Royal College of General Practitioners/British Medical Association 2011:41-42; CPSBC 2007:5).

2.3.12.6.1 Express consent

Express consent, according to CPSBC (2007:5), is one that is "signified by the willing agreement by the individual for the collection, use and disclosure of defined information for defined purposes." This type of consent can be given either verbally or in writing (CPSBC 2007:5; O'Neil 2007 cited in the Department of Health/Royal College of General Practitioners/British Medical Association 2011:41). Thus, express consent is chiefly characterised by the explicit expression of the patient to allow healthcare providers in their different capacities to gather data from them on condition that such healthcare providers make explicit to the patient, the purpose for which such data is elicited from them.

According to the Department of Health/Royal College of General Practitioners/British Medical Association 2011: 41), express consent or dissent should, ideally, be recorded in the record of a patient. In cases where such consent or dissent exists in the form of a signed consent form or letter, it should be stored in the patient's record, and in cases of EHRs and EMRs, it should be scanned and attached to the electronic record (Department of Health/Royal College of General Practitioners/British Medical Association 2011:41).

2.3.12.6.2 Implied consent

This type of consent may also be referred to as "inferred consent", and is one that involves the disclosure or sharing of a patient's health information by all healthcare providing individuals and institutions involved in the process of rendering health to the patient, including administrative personnel and is used for clinical audits by a team of healthcare givers rendering health to the patient (British Medical Association 2007 in the Department of Health/Royal College of General Practitioners/British Medical Association 2011:42). To CPSBC (2007:5), express consent is "…signified by the acceptance (by a reasonable person) by the individual for the collection, use and disclosure of information for the obvious purposes." In such cases, the use and disclosure of such information are not a requirement (CPSBC 2007:5).

Consent of this type becomes inferred consent in cases where the patient is expected to understand and appreciate that the disclosures of their health information is for the purposes of rendering healthcare to them, understands the extent of such disclosures and they *[patient]*

have the right to opt out, but have not objected to the disclosures (Department of Health/Royal College of General Practitioners/British Medical Association 2011:42).

Many countries, including South Africa and Zimbabwe, have come up with provisions for privacy, confidentiality and consent. In the case of South Africa, such provisions are provided for in the Patients' Rights Charter of 2007 and in Zimbabwe, such matters are further provided for in the Patients Charter of 2013.

2.3.12.6.3 Security issues and standards in health information

Security issues for EHRs and EMRs are equally important and need to be given the attention that they deserve. To cite Almutairi (2011:148), the maintenance of privacy and confidentiality is essential and thus, security standards are a necessity in order to ensure that the patient enjoys protection from unauthorised or mistaken disclosure, alteration or destruction. In fact, without security standards and requirements for EHRs and EMRs platforms, achieving privacy and confidentiality protection remains a mere tantalizing promise and a dream that will never come true for all the concerned stakeholders, owing to the sensitivity of health information. Accordingly, the EU Health Programme (2008-2013) (2014:8) remarked "considering the very sensitive nature of health data and the vulnerability and dissemination of information on electronic format, special attention should be paid to the security of data from EHRs."

The Australian Government, through the Department of Health (2015:15) established what it termed the PCEHR system operator, with rules that require all registered healthcare providers or organisations to establish and implement policies that address certain PCEHR issues such as security measures they will take as well as the training that they will offer to their staff. This serves to demonstrate the importance and value that should be attached to security issues as far as EHRs and EMRs technologies are concerned. Security issues in EHRs and EMRs arise mainly from the need by third parties to gain access to patients' records for use for secondary sources, and this need, in most cases is achieved through anonymisation of patients' EHRs and EMRs. For example, the PCEHR system operator of Australia was authorised to prepare as well as provide de-identified information in the PCEHR systems for research and other public uses of such health information (Australian Government, Department of Health 2015:15).

Vividly, by virtue of being able to be used to generate, store, share, retrieve, amend and preserve patient records, EHRs and EMRs and their standards need to be rolled out on the basis of sound and sensitive legislative and policy frameworks in order for them to act as a panacea to the challenges of traditional paper records. Given the existence of an array of healthcare facilities in terms of type and size, coupled with the commensurate complexities of healthcare itself, the need for standardised EHRs and EMRs that are hinged on sound and contextual legislation and policies needs not be overemphasised. Failure to have sound and policies on which to anchor EHRs and EMRs standardisation may results in the emergence of countless EHRs and EMRs systems that can only further complicate the already complicated field of health information management and care in general as cardinal principles of privacy, confidentiality and security of patient records will remain at risk. Thus, having a vivid legislative and policy framework for the support of EHRs and EMRs standardisation will not only encourage, but also compel systems developers and vendors to develop systems that are grounded in standards and interoperable.

2.3.13 Legislation and policies on EHRs and EMRs: a case of European countries

EHRs and EMRs standards legislation and policies may come in different forms, including specification of a number of issues ranging from the content of such systems, the standards (terminology, content and clinical standards) to be adopted by healthcare providers, minimum requirements on destruction, archiving, specific authorisation, health records auditing, privacy, confidentiality, updating, patient rights to their data, and security of EHRs and EMRs, as is the case with European countries, including those that are members of the European Union (EU) and those that are not members of the Union. The EU was used as a unique case study here due to the advancements the continent has made in the area of EHRs and EMRs implementation and the associated legislation and policies within which such systems may operate. The diversity of the legislative and policy provisions for EHRs and EMRs among the European countries also acted as rich cases studies for the present study. In 2014, the EU published results of a comprehensive study entitled "EU Health Programme (2008-2013)" whose aim was to determine the extent of adoption of EHRs systems, extent of standardisation of such systems as well as the extent to which European countries have enacted supporting legislation and policies for such systems, including standards. Owing to

the scarcity of literature specific to EHRs and EMRs standards in general, the ensuing sections relied, to a large extent, on the EU Health Programme study of 2014.

2.3.13.1 Development stages of EHRs in Europe

The EU Health Programme (2014:22) established that EHRs were in use in all the European countries, although there were notable disparities between these countries regarding the deployment of such systems. The report noted the following findings:

Table 2.11: EHRs development stages in Europe

Stage	**Policy initiation to develop shared EHRs systems**	**Pilot testing EHRs systems**	**Deploying EHRs system**	**Fully rolled out EHRs systems**
Country	Czech Republic, Germany, Ireland and Slovania	Croatia, Greece, Latvia, Norway, and Romania	Austria, Belgium, Cyprus, France, Italy, Lithuania, Luxembourg, Netherlands, Poland, Portugal, Slovakia	Bulgaria, Denmark, Hungary, Estonia, Finland, Malta, Netherlands, Sweden and the UK

Source: EU Health Programme (2014:22)

2.3.13.2 Legal approaches

Some differences were realised with regards to the legal frameworks that governed the operations of EHRs across Europe. The EU Health Programme (2014:22) reported that fourteen (14) countries, namely: Austria, Belgium, Croatia, Estonia, Luxembourg, Lithuania, Finland, France, Portugal, Poland, Norway, Slovakia, Spain, Sweden had already enacted specific legal requirements on shared EHRs, whilst a number of other countries that were still at the stage of coming up with policy initiatives for the development of EHRs systems had not adopted any specific rules on such systems. Other countries, including Croatia, Italy, Luxembourg, Latvia, Ireland and Romania were in the process of preparing legal frameworks for the regulation of their EHRs systems (EU Health Programme 2014:22).

The act of rolling out EHRs systems without sound legislation to support their operations, it would seem, is not only typical of Zimbabwe which has gone on to roll out EHRs without accompanying legislation to support such systems, but typical of a number of European countries as well. Although it is practical to enact and implement legislation and policies to regulate EHRs systems ex post facto, it tends to be costly and causes considerable inconveniences on the part of all the stakeholders in healthcare, including clinical and non-clinical practitioners, health information management practitioners, governments and the patients themselves.

The report of the EU Health Programme (2014:26-27) revealed the following as far as the legislation for EHRs in Europe is concerned:

1. Although all the countries had adopted terminology and clinical coding systems such as SNOMED Clinical Terms, NOMESCO, ICD-10, less than half of the countries, references to the use of common terminology and clinical coding of systems that enabled the definition and categorisation of health information from one country to the other;
2. Fourteen (14) countries had set up a legal requirement allowing them to use common health terminology or specific clinical coding standards;

For example, the Austrian EHRs legislation conferred the Minister of Health with the powers to define and publish, on the website of such a Ministry, health terminology to be used, and the use of such terminology standard was compulsory (EU Health Programme 2014:27). The legislation of Bulgaria required that the health data system must use established national codes as well as nomenclatures for the registration and reporting activities in healthcare while Italian draft legislation required that EHRs information shall be codified and classified in a manner that ensures interoperability at regional, national and European levels (EU Health Programme 2014:27).

In Latvia, the draft law required that surgical entries should be consistent with the NOMESCO classification standard whilst for diseases, disorders and disabilities, healthcare facilities should use the ICD-10 (SSK-10) (EU Health Programme 2014:27). In Portugal, legal coding systems and standards, including the International Classification for Nursing Practice, ICD and the National list of medicine and health products of the National Authority

of Medicines and Health Products, National List of Support Products of the National Institute of Rehabilitation were recommended (EU Health Programme 2014:27).

In Slovakia, it was required that in the compilation of patient summaries, diseases should be classified in accordance with the codes of diseases that are defined in the ICD with its detailed specification for disease of the patient in the past six months (EU Health Programme 2014:27). The Polish legislation required that healthcare facilities use the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems for the names and statistical numbers of diagnosed diseases, whilst in the UK, common terminology and code systems based on the SNOMED Clinical Terms was adopted (EU Health Programme 2014:27).

Thus, it can be observed that most European countries had enacted legislation that clearly outlined EHRs and EMRs standards that healthcare facilities were expected to comply with. Having clearly defined legislation and policies upon which EHRs and EMRs standards should be anchored offers an added advantage of making such standards not optional or voluntary but compulsory at law. Needless to say, the adoption of standards used to be a purely voluntary procedure that producers and service providers would adopt at their discretions, not only in health but in the commercial sector as well and thus, the provision for EHRs and EMRs standards in a country's legislation is particularly a great step towards fully standardised systems. This makes standards monitoring and evaluation an easy task.

2.3.13.2 Requirements on institutions hosting and managing EHRs and EMRs

The fact that EHRs and EMRs are shared by various healthcare players either for the purposes of directly rendering healthcare to patients or for secondary purposes such as research and archival or preservation purposes, they tend to be ubiquitous and fluid, implying that such records tend to find themselves in the hands and systems of a number players. This necessitates the need for legislative and policy frameworks within which EHRs and EMRs should be managed. This should see EHRs and EMRs being protected from a number of potential threats, including premature or illegal destruction, disclosure, access and other threats. In light of such fluidity and vulnerability of EHRs and EMRs, the EU Health Programme (2014:27) came up with recommendations that institutions that host and manage EHRs should abide by, including the following:

i. Institutions to roll out appropriate technical and organisational measures that protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, especially in cases where the processing of such data involves the transmission of data over a network, as well as against all other forms of unlawful data processing;

ii. Such measures should be a certain level of security that matches the risk that is presented by the processing as well as the nature of the data to be protected. In doing so, account should be taken regarding the state of the art and the cost of their implementation.

Thus, the sensitivity of health data will always require that institutions hosting and processing EHRs should ensure high levels of security (EU Health Programme 2014:27). The study of the EU Health Programme (2014) focused on legislation and policy aspects for EHRs standards that include the following critical aspects:

2.3.13.3 Specific rules on hosting and processing EHRs

Regarding the availability of specific rules on hosting and processing EHRs, the EU Health Programme (2014:28) observed that although all the European countries had data protection rules that would be applicable to institutions that hosted and processed such records, just above half the number of the European countries, that is, fifteen (15) had come up with specific rules, and in most instances, such rules were a direct result of laws that saw the establishment of the respective EHRs systems.

2.3.13.4. Specific authorisation

This aspect talks to specific authorisation requirements for those institutions that host and process EHRs (EU Health Programme 2014:28). With regards to this requirement, the EU Health Programme (2014:28) found out that France had adopted very detailed requirements to govern institutions that were hosting EHRs data. Such requirements specified that applicants to provide extensive information showing that their hosting system is secure and sophisticated enough to facilitate the upholding of EHRs rules such as consent, access and confidentiality as well as seeing to it that health data is amply protected, especially in light of the risks involved (EU Health Programme 2014:28). In Slovakia, the EU Health (2014:28),

observed, the legislation provided just general principles as the legal basis for implementation whilst legislation for the definition of standards for medical IT information systems was yet to be adopted.

In Finland, it was a legal requirement that data systems of institutions hosting and processing health data be consistent with the essential interoperability requirements (EU Health Programme 2014:28). Such systems were further required by law, to be certified and a certificate of conformity would be issued by the information security inspection body (EU Health Programme 2014:28). In Latvia, such hosting institutions were required by the draft legislation of that country to obtain prior authorisation by concluding a written agreement with the National Health Services as well as demonstrate compliance with security, connectivity and confidentiality desiderata of the internal systems (EU Health Programme 2014:28). As for the UK (England), the EU Health Programme (2014:28) further reported, hosting institutions were required to produce a standard service contract signed by a contractor rendering medical services to the National Health Service, containing provisions for keeping electronic records. Adherence to specific information governance requirements was also an additional requirement for institutions hosting EHRs in the UK (England) (EU Health Programme 2014:28).

2.3.13.5 Legal requirements for encrypted data

Given the sensitivity of health data and information, especially when shared over networks, legislation and policies that address the encryption of such data as part of security procedures becomes a necessity. The EU Health Programme (2014:28) stated that "encryption of data is one of the most common ways to ensure data security." It typically involves the translation of data into a secret code in such a manner that to decrypt such data, a password or key is needed (EU Health Programme 2014:28). A study of the European countries by the EU Health Programme (2014:28) revealed that just a handful of countries had established legal obligations that were specific to the encryption of health data held and shared on HER platforms. It was observed that in Austria, it was a requirement for health data that is stored in cloud computing environments to be encrypted and the transfer of health data was only permissible on closed networks or in an encrypted form, although there was no general obligation to store health information in an encrypted form (EU Health Programme 2014:29).

In Norway, there was a requirement that health data which allows the direct identification of a person be encrypted, although this requirement was not applicable to the national database for electronic prescriptions, whilst in Poland, healthcare providers were supposed to ensure that data were encrypted (EU Health Programme 2014:29). The dearth of explicit legal and policy provisions for the encryption of health data in most of the European countries, and indeed any other country implies that health data of individuals is at risk and patient privacy and confidentiality were compromised.

2.3.13.6 Specific auditing requirement

Practically speaking, merely enacting legislation and policies that make the adoption of EHRs standards without commensurate auditing and follow up activities would prove to be inadequate as a measure of preserving patient privacy and confidentiality. Thus, a standardisation framework for EHRs and EMRs should vividly pronounce the auditing requirements and procedures to be met by the organisations that handle health records and information. The EU Health Programme (2014:29) also sought to establish the extent to which the European countries had provisions for specific auditing requirements for EHRs systems. It was observed that in Estonia, security systems were legally auditable, independently, after every two years (EU Health Programme 2014:29). In France, when a licence for hosting EHRs expired, the hosting institution would ask for a renewal which will see the institution being subjected to external audits in an effort to make the institution attest to the implementation of privacy and security policy (EH Health Programme 2014:29).

In Sweden, healthcare providers were called upon to put in place measures that keep logs on access to patients' records, verify such logs on a regular basis and in a systematic fashion, at the same time documenting and properly storing such logs for a minimum period of a decade (EU Health Programme 2014:29). The Norwegian legislation that was adopted in 2013 pronounced a series of rules on the internal control for institutions that host and process EHRs (EU Health Programme 2014:29). In the UK (England) contractors were required to sign a standard services contract that enabled them to render medical services to the National Health Service and such a standard service contract mandated that the auditing functions of computerised systems must be enabled (EU Health Programme 2014:29). In the case of Finland, the external auditing of data systems of institutions that host and process EHRs as well as continuous self-auditing for users of data systems such as healthcare providers and

pharmacies were requirements, whilst in Italy, plans to establish specific requirements on operators tracking and audit were underway (EU Health Programme 2014:30).

2.3.13.7 Patient consent

Patient consent, as part of upholding the principle of confidentiality in health information management is important.. The EU Health Programme (2014:31) revealed that a few countries in Europe had specific legal rules guiding patient consent in the context of EHRs. One key aspect of patient consent in the context of EHRs includes rules on patients' consent in sharing health data. As discussed elsewhere in this chapter, consent can either be express or implied. A study by the EU Health Programme (2014:33-34) revealed that only fourteen (14) European countries had specific regulations on matters of patient consent.

Of those fourteen (14) countries, only eleven (11), that is, Croatia, Denmark, Estonia, Finland, France, Germany, Luxembourg, the Netherlands, Norway, Sweden and the UK (England) though to a certain extent, required that explicit consent be sought before patients EHRs could be shared, whilst in Austria, Estonia and France, consent was always implied (EU Health Programme 2014:33-34). In the cases of those countries where express consent was a prerequisite, it was noted though, that such a type of consent was not necessary when sharing data among healthcare providers that had a therapeutic relationship with the data subjects (EU Health Programme 2014:33-34). It can also be noted that the aspect of patient consent for EHRs was not yet provided for in a number of European countries.

2.3.13.8 Creation, access and update of EHRs and EMRs

The creation, access and update of EHRs is present their own complexities, again being compounded by the number of different players involved in these processes such as the health professionals and those who render auxiliary services to health, including health information management and health information systems personnel. Stakeholders in health may include citizens, healthcare providers, insurance companies, education, research institutions, investigators, government departments and institutions, including law enforcers and courts of law, public health agencies and NGOs, pharmaceutical industry and medical device makers, telemedicine institutions and software and hardware vendors (FICCI Health Services India

2013:5). It is worth noting that this list is not exhaustive and is likely to increase commensurately with the advancements in healthcare and ICTs.

As observed by the EU Health Programme (2014:36), "the question of access to EHRs by health professionals is quite a complex one." This is so in the sense that it is possible that not all health professionals enjoy the same rights in terms of both access and creation or updating of patient's EHRs, thereby making it possible, for instance, for a specialist to gain access to more information as compared to a general practitioner, who in turn, will have access to more information than a nurse or pharmacist (EU Health Programme 2014:36).

In some cases, it is possible, on one hand, that some professionals who also work in the health sector are denied access to certain health information, owing to possible conflicts of interest and on the other hand, access requirements may not be so strict in cases of emergency (EU Health 2014:36). Given the complexities that characterise the creation, access and update of EHRs, it the EU Health Programme (2014:36) recommended that legislation and policies need to be clear about the following aspects:

i. Rules for the identification and authentication of health professionals;
ii. Creation of EHRs;
iii. Different categories of access for different health professionals;
iv. Explicit prohibitions;
v. Exception to access requirements in emergency situations;
vi. Legal obligations for health professional to update EHRs;
vii. Rules on patient specific identification number for e-health purposes;
viii. Rights to access, indicating whether patients have the right to access their health information;
ix. Clauses as to whether patient have the right to download their health information from EHRs systems;
x. Right of patients to know who downloaded or accessed their EHRs; and
xi. Statement as to whether patients may modify or erase their data from EHRs.

The above-mentioned issues call upon all the concerned stakeholders to have access and security standards for EHRs and such standards should be hinged on sound legislation and policies.

In light of the complexities surrounding issues of creation, access and updating of EHRs, the EU Health Programme (2014:36) recommended that the legislation and policies be clear on the liabilities of health professionals with regard to such systems. The EU Health Programme (2014:39) further recommended that there be laws that address the secondary uses of health data, including those that are foreseen in law. Because secondary uses of EHRs affect their archiving, the EU Health Programme also advised that specific rules for the archiving of such records was necessary and should be legally provided for.

2.3.14 Related EHRs and EMRs projects in Africa

In order to gain a better appreciation of standards for EHRs and EMRs as well as their significance, it may be helpful to understand developments regarding the same phenomenon in Africa. Thus, this section is meant to give a few examples of developments that have taken place around Africa in the area of standards for EHRs and EMRs.

A number of countries in Africa have rolled out various EHRs and EMRs systems, including South Africa, Malawi, Kenya, Tanzania, Zambia, Botswana and Uganda to mention just a few. In almost all the countries that have rolled out such systems, standards that enable interoperability have become an issue of concern. In South Africa, provincial health facilities were also using different EHRs and EMRs systems such as Medicom in Kwazulu-Natal, Gauteng and the Limpopo Provinces, Nootropics in the Northern Cape Province, Clinicom in the Western Cape Province, Meditech KwaZulu-Natal and the Free State Province, Unicare in the Eastern and Western Cape Provinces and PADS in the Free State Province (Department of Health, Republic of South Africa 2008). These systems were working independently and were not able to share information as they had different functionalities, thereby prompting discussions over the issue of standardisation to facilitate health information sharing. The Department of Health, Republic of South Africa (2008) resolved that there be a national EHRs system than provincial ones, a situation that talks to standardisation and interoperability.

In Kenya, various EMRs systems that were based on non-interoperable standards were also witnessed prior to the intervention of the Ministry of Medical Services and the Ministry of Public Health and Sanitation in 2010. These Ministries reported that EMRs systems were being increasingly adopted in Kenya to improve the management of medical records and the

quality of patient care, but the greatest challenge was lack of interoperability between and among those systems. For example, three assessments were commissioned by the National AIDS and STI Control Programme (NASCOP) and the Division of Health Information Systems (HIS) with the aim of describing the functionality of existing EMRs systems in Kenya (Ministry of Medical Services and Ministry of Public Health and Sanitation 2010:7) and the assessments revealed that the existing systems had a number of different functionalities, including patient management software, hospital HMIS software, data collection and reporting software, administration or management software and external systems such as the MSH tool for stock control and supplies chain management (Ministry of Medical Services and Ministry of Public Health and Sanitation 2010:7).

The assessments revealed more problems that pointed to the dearth of interoperable standards. These include variable levels of functionality and data security, unpredictable vendor or technical support, issues with long-term sustainability, variable reporting functionality, limited feedback of data in EMRs systems for patient care and limited ability to exchange information between systems (Ministry of Medical Services and Ministry of Public Health and Sanitation 2010:7). Thus, literature shows that the aspect of standards for EHRs and EMRs is a topical one. Interestingly, whilst the Department of Health (2008) in South agreed on having one national EHRs system, the Ministry of Medical Services and the Ministry of Public Health and Sanitation (2010) in Kenya agreed that the EHRs systems that were already in existence in the country be allowed to exist, but were supposed to be governed by interoperable standards to enable health information sharing. In Zimbabwe, the aspect has not been exploited so much as shown by the scantiness of literature concerning the phenomenon of EHRs and EMRs, thereby revealing a chasm that the proposed study intends to fill. Examples of other EHRs around the world include the Healthconnect in Australia, ELGA in Austria, EHRS Blueprint in Canada, MedCom in Denmark, Spine in England, eHR Infrastructure in Hong Kong, China, AORTA in the Netherlands, EMRX in Singapore and the National Patient Summary (NPO) in Sweden (FICCI Health Services India 2013:10).

2.4 Summary

The chapter presented the conceptual framework that guided the present study. The framework was meant to explain the factors that the researcher presumed to be at play with regards to the problem of unstandardized EHRs and EMRs that characterised the health

sector of Zimbabwe. The chapter further explored and summarised literature pertaining to EHRs and EMRs standards and associated issues from around the world. It emerged from the literature that a number of standards for EHRs and EMRs existed and were being implemented in some countries, but literature on the implementation strategies was still scanty. From the review, it was observed that there was a chasm in literature regarding a clear implementation framework for EHRs and EMRs in the health sector of Zimbabwe. The literature review also revealed that a number of standards organisations have emerged, giving rise to a plethora of standards, thereby further complicating the challenges of EHRs and EMRs in healthcare facilities as such healthcare facilities have to be able to appraise and choose best standards from the ever-increasing pool of them. It was also observed, through the literature review that most countries tend to roll out EHRs and EMRs systems without accompanying standards, supporting legislation and policies at the inception stages or at the planning stages, giving birth to the problem of systems that lack interoperability and general standards for such systems. As a reaction to this, it further emerged from the literature that most governments, including those of the developed countries, have tended to enact, ex post facto, legislation and policies that require EHRs and EMRs systems to be standardised, an approach which presents more problems than solutions. The next chapter discusses the paradigm within which the study was conducted and the subsequent methodology applied.

CHAPTER THREE
RESEARCH PARADIGM AND METHODOLOGY

3.1 Introduction

The previous chapter explored literature on EHRs and EMRs standards as a way of catching up, as well as demonstrating the researcher's acquaintance with the trends and developments in that area. The thrust of this chapter is to expound the paradigm within which the research was conducted and the methodology that was employed in the study, together with the cogency of these in light of the issue under investigation.

A research paradigm and a research methodology are two closely related and complementary aspects in research. The way in which one views the world (paradigm) may have a huge impact on their methodology. Kivunja and Kuyini (2017:36) have it that a very important relationship exists between a research paradigm and research methodology in the sense that the methodological implications of the researcher's paradigmatic choice permeate his or her research questions, respondents' selection, data gathering instruments and collection procedures as well as data analysis. Indeed, every research paradigm is characterised by its own ontological and epistemological assumptions that have a bearing on its methodology and methods (Elshafie 2013:5). To Krauss (2005:759), "philosophical assumptions or a theoretical paradigm about the nature of reality are crucial to understanding the overall perspective from which the study is designed and carried out." Thus, a research paradigm and a research methodology are two inseparable and intertwined aspects of research that enunciate the understanding of the researcher's conceptualisation of reality and the ways and methods of inquiry into such a reality which subsequently have a bearing on the interpretation and implications of the researcher's findings.

Against this backdrop, this chapter, therefore, is dedicated to the research paradigm and methodology that the study employed. Precisely, the chapter explains the study's ontological and epistemological standpoints of the researcher, which are relativism and authoritative knowledge, respectively, given that the study was situated in the paradigm of interpretivism. In this chapter, the researcher proceeds to explain the methodology of the study, including the design, population, data gathering instruments and, data analysis procedures of the study. A

diagrammatical explanation of the paradigm and methodology of the study is shown in Figure 3.1.

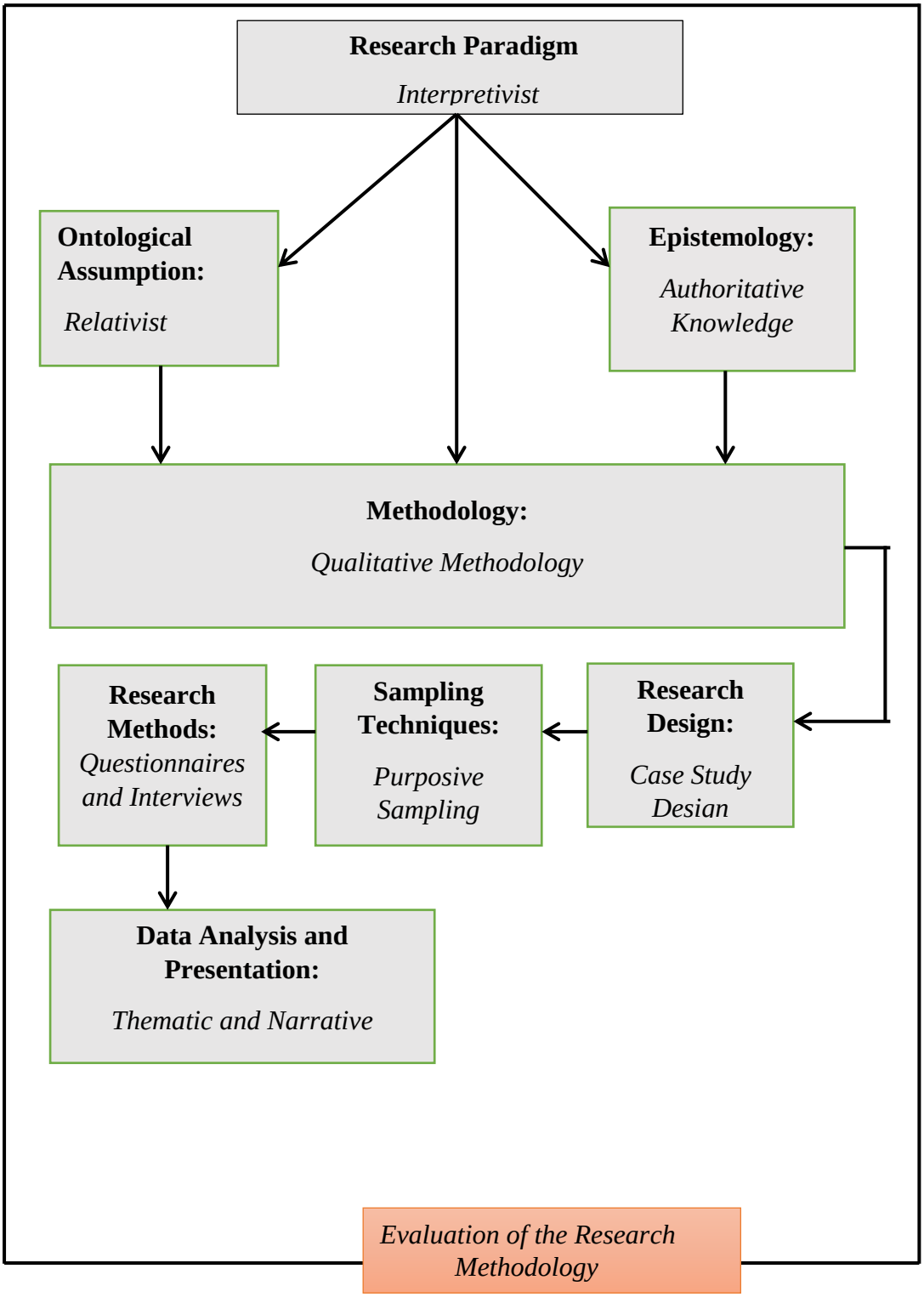

Figure 3.1 Methodology map of the study

3.2 Research paradigm

A research paradigm is key to research and it is important for one to be clear about this. To Ngulube (2019:89), paradigms may be taken as theoretical lenses through which social scientists view reality in their investigation of social phenomena and such paradigms are embedded in the philosophical foundations. In explaining the indispensability of a paradigm in research, Patterson and Williams (1998:280), posited that one's approach to research is hinged on the philosophical standpoint underpinning our approach to science as researchers.

To cite Elshafie (2013:5), "understanding the research paradigms is the first and most crucial step in any researcher's journey", yet the concept of a research paradigm is one that a good number of higher degrees research students and novice researchers find elusive to articulate and even apply in their research work (Kivunja and Kuyini 2017:26). In fact, engaging in any form of research without committing, although implicitly in many times, to ontological and epistemological positions by researchers is an impossibility (Scotland 2012:10). This is because a paradigm, in research, basically functions as the lens through which a researcher gleans into the world and defines the philosophical orientation of the researcher (Kivunja and Kuyini 2017:26).

A research paradigm, thus, has a huge bearing on the decisions that researchers in a particular discipline take in the research process, including the choice of what should be studied, the methodology and methods as well as how results of the studies should be interpreted (Kivunji and Kuyini 2017:26). This demonstrates the indispensability of one's paradigmatic position in research, irrespective of the magnitude and type of the research being conducted. Historically, the concept can be attributed to the American Philosopher Thomas Kuhn, who first used it in 1962 to refer to a philosophical way of thinking, whilst the term has its aetiology in Greek where it was used to refer to a pattern (Kivunja and Kuyini 2017:26; Patterson and Williams 1998:283).

A research paradigm is a world view that is, "a perspective, or thinking, or school of thought, or set of shared beliefs, that informs the meaning or interpretation of research data" (Kivunja and Kuyini 2017:26). Thus, a paradigm is a set of abstract assumptions concerning one's views about the nature of reality and ways of knowing that have a bearing on how one examines the problem under investigation, including data gathering, data processing, interpretation and communication of research findings. Indeed, a paradigm simply constitutes abstract beliefs as well as principles that shape the researcher's view of the world

and how the researcher interprets and acts in that world (Kivunja and Kuyini 2017:26). Because a paradigm consists of assumptions which are conjectures, it is impossible to empirically prove or disprove the philosophical underpinnings of a paradigm (Scotland 2012:9), irrespective of how well they may be argued (Guba and Lincoln 1994:107).

The term paradigm is wide-ranging, referring to the combination of a number of other philosophical aspects that constitute it. Expounding the concept of a research paradigm, Guba and Lincoln (1994:107) opined that a paradigm may be taken to mean a set of basic beliefs, alternatively known as metaphysics that focuses on dealing with the ultimate or first principles. It consists of the following elements: ontology, epistemology, methodology and methods (Scotland 2012:9; Elshafie 2013:5). Indeed, as Scotland (2012:10) also posited, "research methods can be traced back, through methodology and epistemology, to an ontological position." Thus, ontology, epistemology, methodology and methods are all different strands of a research paradigm that researchers need to be clear about, with ample justification regarding their appropriateness and role in their studies. The calling for this compliance is more pressing to erudite researchers.

Giving a warning against the complacence and temptation of dismissing differences between paradigmatic standpoints as mere philosophical differences manifesting themselves either implicitly or explicitly (Guba and Lincoln 1994:113), these scholars averred that actually, such positions have significant implications on the actual conduct of research, including how the study findings will be interpreted. In the present study, a paradigm was therefore, viewed as a way of conceptualising the phenomenon under investigation by way of explaining its nature of existence and the basis on which the researcher explores such a phenomenon so as to claim knowledge about it. It is this paradigm that guides the researcher in determining the methodology that is most appropriate for their study.

The present study was located in the interpretivist paradigm, which is sometimes known as interpretive research. Interpretive research arose as an opposite force against positivism and was popularised by the likes of Max Weber, Wilhem Dilthey, George Herbert Mead, Herbert Blumer, and Edmund Husserl, among others (Elshafie 2013:7). According to Ngulube (2019:89) interpretivism, which is antithetical to positivism, propounds that social reality is a subjective and socially constructed and co-constructed phenomenon and goes against the claim that truth is singular and can be objectively measured without being dependent on the researcher.

Interpretive research is based on an assumption that the social world is not singular or objective, *[as is the case with positivism]* but rather, it is shaped by human experiences and social context, which is its ontology, and can be best studied within its socio-historic context by reconciling the subjective interpretations of its various participants, which is seen as its epistemology (Bhattacherjee 2012:103). This paradigm thrives to comprehend the phenomenon under investigation from the point of view of the participants involved in the study and research in this paradigm tends to be inductive and emergent and does not have generalisation as its intention, given that it is context-bound (Elshafie 2013:7). Thus, because interpretive researchers consider the "social reality as being embedded within and impossible to abstract from their social settings, they interpret the reality through a sense-making process rather than a hypothesis testing process" (Bhattacherjee 2012:103). This implies that researchers who are investigating phenomena whose understanding is dependent on data gathered from participants and whose understanding is dependent on human experiences have their paradigmatic orientation lying in interpretivism. In the present study, interpretivism was taken to mean that reality is a subjective phenomenon whose interpretation and truthfulness is plural and dependent on how one experiences or interacts with such a reality.

Regarding the relevance and applicability of the interpretivist paradigm in the present study, this paradigm allowed the researcher to explore the aspect of EHRs and EMRs standards for the health sector in Zimbabwe, appreciating the fact that the context within which EHRs and EMRs systems and their standards was itself a social space that is dependent on the experiences and activities of different players in the health care delivery system of Zimbabwe, including the MHCC, SAZ, ISO, HL7 and many other health records and information management standards at the institutional level and different professionals such as the medical practitioners, ICT specialist, health information and records specialists, legal practitioners and administrators at the individual levels. Thus, the interactions between and among all these institutions and professionals on issues to do with the design or implementation of EHRs and EMRs systems and their standards is a social phenomenon that the researcher could best understand through interpretisvism. For example, the very concept of what constitutes EHRs and EMRs, their definitions, the concept of standardisation of EHRs and EMRs systems are all dependent on the understanding and actions of different players in Zimbabwe's healthcare delivery system.

Despite the literature on the importance of standards for EHRs and EMRs which abounds, the meaning of standardisation, the approaches to standardisation and the standards to adopt all

remain issues that depend on the understanding and eventually at the discretion of the different stakeholders who are involved in the health industry. Such issues of EHRs and EMRs standards attract different attention in terms of their importance, definition, approaches, including the policies and laws that support standardisation.

Furthermore, the framework of standards that the study indented to propose was also directly contingent on the views and activities of the various players such as the MHCC, SAZ and the different professionals who have roles to play in the standardisation of EHRs and EMRs in Zimbabwe. Thus, interpretivism was the closest paradigm that the researcher could employ in understanding the aspect of standardisation for EHRs and EMRs for the health sector in Zimbabwe. As Bhattacherjee (2012:103) hinted, the decision as to whether one pursues interpretive or positivist research depends on their paradigmatic considerations regarding the nature of the phenomenon under investigation and the best way of examining it. Indeed, that which we hold true of our paradigms tends to be of the analyses that we make of our research findings- thus, all that we are going to say eventually is just a construction of humans, that is, ours (Guba and Lincoln 1994:109).

3.2.1 Ontological foundation of the study

Articulating one's research paradigm without explaining their commensurate ontological position does not suffice. This section, therefore, is dedicated to the ontological position of the research in the conduct of the present study.

Ontology talks to the assumptions regarding the way in which we see the world, for example, do we believe that the world is made up of social order and is constantly evolving? (Bhattacherjee 2012:18). To Kivunja and Kuyini (2017:27), ontology is about the study of the very "nature of existence or reality, of being or becoming, as well as the basic categories of things that exist and their relationship." Scotland (2012:9) viewed ontology as assumptions that are concerned with knowing what constitutes reality- that is, *what is* –and researchers need to be clear about their positions regarding their perceptions about "how things really are and how things really work" whilst Elshafie (2013:5) defined ontology as simply "the nature of reality." To Guba and Lincoln (1994:108), addressing the question of ontology in research involves focus on the form as well as the nature of reality, and thus, the researcher asks themselves the question: what exists that the knower can know about that reality?, whilst

Patterson and Williams (1998:287) viewed ontology as simply concerned about the normative commitments that the researcher assumes about the being of reality, human nature and the being of the experiences of humans. Thus, all the afore-mentioned scholars are in agreement that ontology is primarily concerned about the nature of reality or universe which researchers thrive to understand and classify through research. In other words, researchers need to ask themselves the question: what is it and nature or outlook of that which constitutes the universe or reality?

Kivanju and Kuyini (2017:27) shed more light on the meaning of ontology in research by noting that ontology examines one's underlying system of belief as a researcher, about the "nature of being and existence." Therefore, ontology essentially talks to the assumptions that researchers make so as to believe that something makes sense or is actually real or exists or the very nature or essence about phenomena that are under investigation (Kivanju and Kuyini 2017:27). It is discernible that ontology is also a set of assumptions that researchers make about the "being or existence" of things- those things being reality. This can be considered, so far, as the highest order of research philosophy upon which everything else rests because for one to be able to dedicate their time to researching something, they need to first be convinced that that thing exists, the characteristics of such a thing as well as its elements and its relationships should be made vivid. In terms of importance and implications of ontology in research, Kivanju and Kuyini (2017:27) postulated that philosophical assumptions about the nature of reality are crucial to understanding how one makes meaning of the data that they gather.

The present study was located in the relativism ontological paradigm. As stated by Scotland (2012:10), "the ontological position of interpretivism is relativism." Given the fact that the current study focused on the implementation of standards for EHRs and EMRs in the health sector of Zimbabwe, the researcher assumed that these systems (EHRs and EMRs) themselves as well as standardisation itself exist as fluid concepts that can be understood and enhanced through conceptualising them in the social context in which they are being rolled out. Thus, the conceptualisation of the problem of the, the factors responsible for lack of a standards framework for EHRs and EMRs, existence of non-standardised systems and the conceptualisation of EHRs and EMRs themselves (see Figure 2.1: Conceptual framework of the study and differences between EHRs and EMRs were all relative, being influenced by scholarly literature on these concepts and players in the healthcare delivery system of Zimbabwe in general. This implies that the nature of EHRs and EMRs as well as lack of

standardisation for such systems was relative to the researcher, players and activities involved largely as a result of the literature on the subject matter and the background of the researcher. Thus, the nature of EHRs and EMRs and the standardisations of such systems were conceptualised by authors and literature from different backgrounds such as IT, medicine, information science (the subject discipline of the present researcher), standards specialists and other related disciplines and hence relativism.

3.2.2 Epistemological assumption of the study

The other important philosophical strand of a research paradigm is epistemology. Aetiologically, this concept is rooted in Greek where the term episteme means knowledge (Kivunja and Kuyini 2017:27). By definition, epistemology is "the theory of knowledge" (Elshafie 2013:5), or "put simply, in research, epistemology is used to describe how we come to know something; how we know the truth or reality." (Kivunja and Kuyini 2017:27). Willig (2013:39) explained that epistemology as a concept is a branch of philosophy whose concern is the theory of knowledge and tries to answer the questions how and what can be known. To Guba and Lincoln (1994:108), the question of epistemology focuses on the nature of the relationship between the inquirer, knower or would-be knower and that which can be known whilst Patterson and Williams (1998:289) perceived epistemology as the methods, limits as well as the very nature of knowing, that is, knowledge itself.

Given the location of the present study in the interpretive paradigm, epistemologically, the study relied on factual data from the participants- and such data was gathered through interviews and questionnaires from participants who were involved in the administration of policies and implementation of technologies in the health sector, including EHRs and EMR and their standards in the MHCC and SAZ. Thus, the present study was epistemologically located in the realm of authoritative knowledge.

This position is also buttressed by Kivunji and Kuyini (2017:27) who stated that when one, in conducting a study, relies on data that was gathered from those who are in the know, leaders in organisations or documented in books, then their epistemological position rests on authoritative knowledge. In the present study, the questionnaire and interview samples were participants who held leadership positions in the MHCC and SAZ. For example, questionnaires were intended for the Deputy Director- Policy Planning, Deputy Director- Health Information, Deputy Director- Information and Communication Technologies (ICT) in the MHCC and the Deputy Director- SAZ whilst interviews were scheduled for the

Director- Finance, Director- Policy Planning, Director- Epidemiology and Disease Control in the MHCC and the Director General- SAZ. Thus, by virtue of holding such leadership positions in those organisations, those participants were considered to be in the know and thus, were able to provide factual knowledge about EHRs and EMRs standards and policy and legislative issues that were obtaining in the MHCC and SAZ. This rendered authoritative knowledge as the most plausible epistemological grounding for the present study, that is, it was epistemologically assumed by the researcher that the purposefully selected participants, being insiders, were the best people who were intimate with the truth or facts regarding the issues that the study explored.

3.2.3 Weakness and defence of the interpretivist paradigm in this study

Research has been characterised by academic paradigmatic vituperations, primarily between the two main research paradigms, namely positivism and interpretivism. Such paradigmatic wars are far from being resolved, and it may not even be prudent for them to be abolished so as to preserve the healthiness of academia and pragmatic research. As far as interpretive research is concerned, because this approach relies heavily on interpretive analyses, which are considered subjective and dependent on the experiences of the researcher, it is often seen as possessing no rigour by those who air from the positivist paradigm (Bhattacherjee 2012:110). This criticism stems from the very ontological assumption of this paradigm, which is relativism- a philosophical position that subscribes to the standpoint of viewing reality, and the subsequent knowledge (epistemology) as fluid and constantly changing, depending on those who are involved in the construction of such a reality and knowledge. This paradigm tends to subscribe to the view that realities are multiple, apprehendable and sometimes contradictory as products of intellects of humans and are susceptible to change as their constructors advance in terms of information and sophistication (Guba and Lincoln 1994:111).

Indeed, the present researcher, by subscribing to the doctrines of this paradigm, acknowledged the fluidity of the very nature, definitions and conceptualisation of EHRs and EMRs and their standards as well as the fact that by relying on qualitative data gathering instruments such as questionnaires and interviews, the nature of knowledge gathered, and eventually the conclusions that were drawn about the objectives of the study were all a constructed reality, that is, the reality constructed by the axiological baggage of the

researcher and the participants and thus, the conclusions may not be objectively factual. This is something that qualitative researchers can barely avoid. Trifonas (1995:91), succinctly explained this inherent biasness of the researchers who are operating in the interpretive paradigm across by stating that an etymological examination of the lexical denotative meanings of the family of words that possess the root signifier "interpret", for example interpret, misinterpret, interpose, interpellate and so forth, seemingly indicates that that which is not "true-to-the-facts" is, surely, a product of personally significant translations of the subjective differences that arise between perception and experience.

Notwithstanding such unconcealed weaknesses of the interpretive paradigm of the present study, rigour in this worldview abounds. Needless to mention is the glaring fact that the means of judging the rigour of interpretive research is not, as Bhattachacherjee (2012:110) observed, based on reliability, internal validity and generalizability, as is the case with the positivist paradigm. Trifonas (1995:91) propounded that in the interpretive paradigmatic view, the act of knowing (epistemology), is in fact a transactional act simply because of the overall inner and outer states of the phenomenon that are irreversibly altered in the process of experiencing that which is received through the senses at the conscious, unconscious or subconscious levels. Thus, "the subjective qualities of perception are shaped through past encounter(s) and the present purpose(s) or value(s) is resolved in reflexion upon the being of experience" (Trifonas 1995:91). Thus, there is a general consensus among interpretive researchers that the very fact that there is no researcher who does not have any axiological baggage, owing to their background, and thus, what the knower discovers is influenced by what they have previously known cannot be avoided. Therefore, the ability of the interpretive researcher to admit that there is no absolute reality, instead, reality is what his mind, experiences, combined with those of his or her surrounding shape reality is important.

The aspect of EHRs and EMRs and their standardisation, by conceptualisation, definition, design and understanding are context specific, and thus, relativism and interpretivism were ontologically and paradigmatically appropriate for the study, respectively. Furthermore, given the location of the present study in the relativist interpretive paradigm, the ability of the study to gather experiential knowledge from the "insiders", who were also holders of leadership positions, was seen as the best method by which the phenomenon of EHRs and EMRs standards in the health sector of Zimbabwe could be understood. As explained in the population of the study in this chapter, the study had four (4) Directors, three (3) Deputy Directors and one (1) Manager who were directly or indirectly involved in policy, ICT and

health information management in the MHCC and the Director and a Manager at SAZ as its potential respondents, thereby being able to extract insider specific and authoritative knowledge about EHRs and EMRs standardisation. Thus, in this case, the interpretive paradigm was viable.

To cater for the weaknesses of interpretivism as a paradigm, Lincoln and Guba (1985), cited in Bhattacherjee (2012:110-111), proffered a criterion for determining the rigour of data that is generated through this paradigm, which are dependability; credibility, confirmability and transferability.

Dependability, which is equivalent to reliability in positivism, requires that two or more researchers conducting the same study using the same evidence reach similar conclusions (Bhattacherjee 2012:110) and the inferences and interpretations of a researcher are dependable because the researcher has the ability as well as skills to ensure that the findings of the study are drawn from the gathered data and analysed in the right context of the study (Kivunja and Kuyini 2017:34). In the present study, the researcher satisfied this requirement by strictly drawing conclusions of the study from the data that was gathered in the conduct of the study.

Credibility, which Bhattacherjee (2012:110) noted is concerned with the question of whether readers find the inferences of the researcher believable or not, is another strand of rigour in the interpretive paradigm. It is akin to the criterion of internal validity in the positivist paradigm (Bhattacherjee 2012:110; Kivunja and Kuyini 2017:34). In terms of addressing this strand of the rigour criterion, Bhattacherjee (2012:110) suggested a number of means, including adducing evidence of the researcher's lengthy stay in the field, triangulation of data, strict data management, analytic procedures, including the citation and transcription of interview respondents verbatim, maintenance of accurate records of contacts as well as interviews, maintenance of clear documentation relating to the theoretical and methodical steps in a manner that allows an independent audit of data gathering and analysis.

In the present research, credibility was safeguarded by data triangulation in which questionnaire and interview data were used in the study; sound research data management in which the interview recordings and scripts and populated questionnaires were maintained. Data analysis and presentation also included verbatim statements from the respondents as seen in Chapter four of the study and a clear research methodology of the study, including its population, sampling and data gathering techniques were all vividly explained.

Confirmability, the equivalent of objectivity in positivism (Bhattacherjee 2012:111), as a rigour criterion talks to the "extent to which the findings reported in interpretive research can be independently confirmed by others (typically, participants) (Bhattacherjee 2012:110), and its goal is see to it that the researchers biases are kept minimum and eliminated if possible so as to avoid the contamination of the findings (Kivunji and Kuyini 2017:34). In upholding this requirement, the present researcher was integral in the process of data gathering, analysis and processing and the data gathering instruments were as objective and rigorous as they could be. Thus, although the participants in the MHCC and SAZ may not necessarily be asked to confirm the findings of the study, the researcher vouches for the trueness and freeness of the data from his biasness.

The fourth rigour criterion, that is, transferability, which is akin to external validity in positivism, talks to the question of the level to which the findings of a study are generalisable to other settings (Bhattacherjee 2012:111), was not applicable to this study. This is due to the context-specificity of the findings of the study, that is, standards for EHRs and EMRs, although a common phenomenon worldwide today, were studied in the context of the healthcare delivery systems, policy and legislative issues affecting these were all influenced by the government administrative and technical contexts prevailing in Zimbabwe. For example, the stages and approaches to the standardisation of the EHRs and EMRs in Zimbabwe were only true for this country and the findings were not exportable to other settings outside the context of Zimbabwe. This best explains the use of case study as the study design for the present study.

3.3 Research methodology

A research methodology is key to research as it has a bearing on the credibility of one's research findings. Guba and Lincoln (1994:109) succinctly stated that the methodological question, as part of a paradigm, is primarily about how the researcher goes about finding out that which he/she believes is knowable. To Jonker and Pennink (2010:31), a "methodology is first and foremost associated with conducting research." It is a systematic way to solve a problem and is a science of studying how research is to be carried out (Rajasekar, Philominathan and Chinnathambi 2013:5; Khothari 2004:8). Essentially, a research methodology talks to the procedures by which a researcher goes about his or her work,

describing, explaining and predicting a phenomenon (Rajasekar, Philominathan and Chinnathambi 2013:5).

According to Jonker and Pennick (2010:31), "The etymological and traceable meaning of methodology (deduced from Greek methods= meta hodos is 'the way along which', in other words aimed at following a certain route." In the context of research, the term therefore, refers to "the way (or route) the researcher will need to take in order to achieve a certain result (knowledge, insight, design, intervention, solution" (Jonker and Pennick 2010:31). Thus, a research methodology becomes a roadmap for the researcher, vividly showing how the researcher went or will go about conducting the study. In other words, it is seen to be answering the 'HOW" question of one's research, in which the researcher makes clear the nature of the data the study will generate, design, population, data gathering techniques and data analysis procedures of his/her study.

According to Kreeves (1997), a research methodology is made up of a research design, methods, approaches as well as procedures that a researcher employs in an investigation. In terms of utility in research, a methodology helps facilitate the transparency of the approach that the researcher employed, not only to himself, but to others, including academia and business (Jonker and Pennink 2010:33). In this way, a research methodology serves as a "compass, a beacon, a set of principles and global instructions" (Jonker and Pennink 2010:33).

Other than the afore-mentioned utility of a research methodology in research, the term, according to Jonker and Pennink (2010:31), puts extra demands to the researcher in the sense that anyone who conducts what these two scholars refer to as "good" research, will, at one point, be called upon to justify their methodology choices to their supervisors, clients, people in the organisation and many more. Such justification may focus on the reasons for settling for a certain methodology and the criteria that the researcher employed in making their choices, thus, by doing so, the researcher will be making his or actions transparent and subsequently comprehensible (Jonker and Pennink 2010:31). Being able to do this is directly contingent on the researcher being aware of the choices that the researcher has made and how those choices have been reasoned, Jonker and Pennink (2010:31) hinted. The long and short of Jonker and Pennink's (2010:31) statements is that researchers should dedicate time and effort to the justification of their methodologies to an array of stakeholders who may have

interests in their research. Thus, the present researcher was able to justify each aspect of the methodology of his study.

The methodology employed by the researcher is directly dictated by the phenomenon under investigation. As indicated by Krauss (2005:761), the methodology employed must match the phenomenon that is of interest to the researcher. At the stage of methodology, one has to think of the phenomenon under investigation and design a methodology that helps him or her gather meaningful data pertaining to that particular phenomenon.

3.3.1 Qualitative methodology and its applicability to the present study

A research methodology can fall under one or two of the three methodologies which are quantitative, qualitative and mixed methods. This study employed a qualitative methodology which was hinged on the interpretive paradigm and relativist ontology. As Scotland (2012:9) observed, the researcher's ontological and epistemological views, that is, their paradigm, are reflected in their methodology. According to Thorne (2000:68), a study becomes qualitative when it relies on inductive reasoning processes in the meaning making (interpretation) exercise, something that the present study relied upon in the data presentation phase. Thus, qualitative researchers tend to be preoccupied with meanings, quality and texture of experience as opposed to cause and effect relationships in phenomena (Willig 2013:51-52).

By conceptualisation, qualitative research may include an array of methodologies that are, in their rights, completely different, but qualitative research (1) typically entails focus on phenomena that take place in their natural settings, that is, the real world, and (2) entails focusing on the complexity of such phenomena (Leedy and Ormrod 2015:269). The statement immediately above by Leedy and Ormrod (2015:269) was spot on for the present study in as far the employment of a qualitative methodology is concerned because the problem of existence of EHRs and EMRs that were not operating on clearly defined standards, owing to the dearth of a framework within which such systems could be standardised in the health sector of Zimbabwe, was a reality that existed in a natural setting. Thus, the health sector of Zimbabwe, which had its own setting in terms of EHRs and EMRs implementation, associated with the policies that gave birth to such systems all presented a complex situation that the present researcher intended to understand, and hence the appropriateness of a qualitative methodology.

Willig (2013:52) noted that the natural settings in which phenomena are studied in their natural setting is appropriate for qualitative studies as "these *[naturally occurring settings]* are open systems where conditions continuously develop and interact with one another to give rise to a process of on-going change." Standards for EHRs and EMRs that were in use in the health sector of Zimbabwe were studied in the natural settings of the institutions that were considered to be strategic and information-rich for such a phenomenon, that is, the MHCC and SAZ, and the data gathering exercise witnessed the researcher being involved with the participants in their natural working environments, without the manipulation of the surrounding.

In the present study, a qualitative methodology was also employed because the phenomenon under investigation, that is, EHRs and EMRs standards framework that the researcher intended to develop (in the absence of one) was contingent on the organisational activities and processes in the MHCC and the information pertaining to such activities was qualitative in nature and resided with the participants.

Furthermore, the adoption and the subsequent standardisation of EHRs and EMRs were directly dependent on policies and legislation governing such systems in the context of the healthcare delivery system in Zimbabwe. Again, the information pertaining to such, which was one of the objectives of the study, was qualitative in nature and resided with the participants in the MHCC as the custodian of health policies. This rendered the qualitative methodology the most convenient one to extract relevant data for the study objectives. This explains the use of interviews as one of the data gathering instruments in the study. As Doney (2012:38) stated, qualitative research basically entails talking to participants. The subsequent sections shed light on the sub-sets of the methodology that was employed in this study, including the research design, population of the study, sampling methods, data gathering instruments and data analysis procedures.

3.3.2 Weakness and justification of the qualitative methodology in this study

Qualitative research, just like the interpretive paradigm under which it usually falls, has been touted, Donely (2012:38) observed, as having limited rigour. Donely (2012:38) observed, "qualitative research is sometimes criticized for not being scientific or objective. It can be both." Actually, it is true that qualitative studies actually fail to produce results that are

statistically insignificant and lack geneneralisability to larger groups of interest (Donely (2012:38). The bulk of criticism of qualitative research emanates from the fact that this type of research falls short when it comes to validity and reliability.

However, when used in appropriate contexts, qualitative research actually possesses rigour that suffices in the social science realm. In defence of qualitative research, Leedy and Ormrod (2015:278) put it to the critics of this type of research that qualitative researchers do not intend to measure things in the numerical meaning of the term measure. Qualitative research, instead, possesses the ability to proffer a deeper understanding *[and appreciation]* of a phenomenon in the social world, and hence its ability to illuminate the social sphere in a manner that quantitative research is not able to (Donely 2012:38).

The arguments for qualitative research put forward by Leedy and Ormrod (2015:278) and Donely (2012:38) resonated well with the present researcher in the sense that the intention of his study was not to measure anything in statistical means, rather, the study aimed at understanding, in detail, the manner in which EHRs and EMRs had been rolled out and standardised in the health sector of Zimbabwe. This was seen as a social phenomenon that could be best explored and understood through qualitative lens, and hence the suitability and applicability of a qualitative methodology. Thus, the intention was to gain a detailed understanding of who were the players, in different capacities, in the rolling out and standardisation of EHRs and EMRs systems, with the intention of developing a framework for such systems. It was not the intention of the researcher to generalise or export the findings of the study to other settings as the data collected was specific and contextual to the health sector of Zimbabwe, thereby further justifying the appropriateness of a qualitative methodology for this study.

Leedy and Ormrod (2015:271), succinctly outlined three main cardinal benefits that are associated with qualitative research as follows, though it should be borne in mind that the list is not in any way prescriptive or conclusive:

i. Exploration: In the case of exploration, qualitative research enables the researcher to gain initial insights into an area or topic that has previously been studied to a limited extent (Leedy and Ormrod 2015:271). Indeed, in the present study, this benefit was realised as the researcher was able to explore the area of standards for EHRs and EMRs in the health sector of Zimbabwe, an area that seemingly has

been studied to a limited extent. As indicated in the justification of the study in Chapter one, there is a dearth of studies and literature on this subject.

ii. Multifaceted description: This talks to the ability of qualitative research to allow the researcher to reveal and delve into the complexities of the phenomenon under investigation in its natural setting, revealing the multi-layered setups, relationships and people (Leedy and Ormrod 2015:271). In the context of the present study, this benefit was realised by the ability of the researcher to explore the complexities of EHRs and EMRs standards in the MHCC, thereby allowing the researcher to understand the roles, duties, responsibilities and relationships between the MHCC and SAZ as far as the development, rolling out and monitoring of standards for such systems is concerned, including the policy and legal mandates of each one of those institutions. The roles, duties, capabilities and incapability of the Department of Policy and Planning, Department of ICTs and the Department of Health Information in the MHCC as far as EHRs and EMRs standards are concerned were also explored in detail through qualitative lens. All this is witnessed by the detailed qualitative questionnaires and in-depth interviews that were used as data gathering instruments in the present study.

iii. Problem identification: Leedy and Ormrod (2015:271) noted that as far as problem identification is concerned, qualitative research enables the researcher to unearth major problems or barriers or enigmas that the phenomenon under investigation is faced with. In the context of the present study, going qualitative yielded these benefits by enabling the researcher to identify and appreciate the challenges that characterised the EHRs and EMRs systems and their standardisation in the health sector of Zimbabwe. Thus, the challenges that were faced by the MHCC as the overseer of all programmes in the health sector of Zimbabwe, including the rolling out and performance of EHRs and EMRs in Zimbabwe as well as SAZ as the sole standards body authority in Zimbabwe were identified and appreciated through qualitative means. Understanding such fine details and challenges was indispensible, and indeed culminated in the designing of an EHR and EMR standards framework that is context specific and sensitive to the prevailing challenges in Zimbabwe.

Despite Leedy and Ormrod (2015:278) vehemently defending qualitative research, they warned qualitative researchers against complacence and challenged them to remain heedful of the significance of the two cardinal rigour assessment tests, that is, validity and reliability with regards to the data that they collect. In order to achieve what would be equivalent to validity and reliability of quantitative research, qualitative researchers should ensure that in particular, (1) the data that they gather are accurate by being reflective of the dynamics and features that characterise the phenomena under investigation (validity), and (2) the data that they collect possess consistency with regards to those dynamics and patterns that they display (reliability) (Leedy and Ormrod 2015:278). In the present study, the researcher ensured that the data gathered was elicited from the appropriate respondents and the data was processed immediately after its gathering to preserve its currency. By so doing, the data was reflective of the status quo of things as far as EHRs and EMRs and their standards were concerned. The array of steps explained in this section (section 3.3.2) in defence of the study's qualitative methodology may be read and appreciated in together with those that were raised in defence of the study's interpretive paradigm (see section 3.2.3).

3.4 Research design

Strongly linked to the research methodology is a research design, which again, a researcher has to be clear about, for, as Kothari (2004:31) hinted, the dearth of meticulousness in the preparation of a research design may upset the project in its entirety. A research design is usually confused with research methods, which, according to Denscombe (2007) includes specific methods of eliciting data and includes such techniques as interviews, questionnaires, observations and experiments. By the way, the research design has serious implications regarding the reliability of the study findings, and thus, constitutes the firm foundation on which the entire edifice of the study rests (Khothari 2004:31). Put in the words of Rajasekar, Philominathan and Chinnathambi (2013:22), for scientific research, it is important for one to prepare a research design. Yin (1994:19) offered a somewhat seminal definition of a research design as follows:

> In the most elementary sense, the design is the logical sequence that connects the empirical data to a study's initial research question and, ultimately, to its conclusions. Colloquially, a research design is an action plan for getting from here to there, where here may be defined as the initial set of questions to be answered, and there is some set

> of conclusions (answers) about these questions. Between "here" and "there" may be found a number of major steps, including the collection and analysis of relevant data.

The long and short of the rich definition by Yin (1994:19) is that a design is essentially about coming up with a strategy of obtaining data that helps the researcher get answers to his or her study questions. It therefore, goes without saying that the researcher should stand guided by the research questions of his or her study and design a strategy that is bound by such questions. Typically, such a design should be able to influence the methods of gathering data as well as the potential custodians or possessors of such data. This is tandem with sentiments by Kothari (2004:31), that a research design is some form of planning, in advance, the methods of gathering data, bearing in mind the objectives of the study and other crucial factors such as money, time and the availability of staff. So succinctly, a design typically displays the relationship between the problem under investigation, which should be vividly explained, data gathering techniques and procedures, the study population as well as data analysis procedures.

Research work, therefore, calls for a specific plan, showing how one will proceed during the course of their study (Leedy and Ormorod 2010:3). Infact, Leedy and Ormorod (2010:3) equated research to a carefully planned itinerary that one intends to take in order to reach their destination. Thus, a researcher plans his or her overall research design as well as the specific research methods to be employed in a purposeful fashion so as to acquire data that is relevant to his or her research problem (Leedy and Ormorod 2010:3). Khothari (2004:31) noted "decisions regarding what, where, when, how much, by what means concerning an inquiry or a research study constitute a research design."

What is emerging from the array of definitions proffered by the scholars cited above is that a research design is that part of a research methodology that calls upon the researcher to project the shape or outlook that their study will display. At the point of coming up with the design of their study, the researcher is still strategizing the form that their study will assume, paying particular attention to the principles that go with each design versus the nature of the phenomenon under investigation. Thus, at this stage, the key question that needs to be asked is: is the study going to be a survey, case study, experiment? Answers to this question will prompt the researcher to state their research design. The present study employed the case study design to understand EHRs and EMRs and their standards in the health sector of Zimbabwe. The following section explains the case study design as applied in the present study, with justification for its employment.

3.4.1 The case study design and its applicability in the study

Despite the seemingly obvious fact that literature on case studies abounds, defining a case study remains a nightmare to scholars. Indeed, a case study, according to Hammond and Wellington (2013:16), fails to render itself to a clear definition in light of its being associated with different things that researchers often hold implicitly. Cohen, Manion and Morrison (2018:375), while also admitting that agreeing on a single definition of a case study is an elusive wish, they averred that doing so is actually unnecessary. Whilst the position of Cohen, Manon and Morrison (2018:375) that thriving for a universal definition of a case study may not be necessary may sound pleasant in the ears of academic enthusiasts; it may sound frustrating and mysterious to novice researchers who are keen to gain accurate meanings of the term.

However, the beauty about it is that in the middle of the controversy surrounding the definition of a case study research, researchers can convincingly employ case study designs whilst the discourse on what exactly it is rages on. A number of scholars have made attempts to define or at least give descriptions of what may constitute case study research. Actually, the amount of literature attempting to define a case study abounds to a point where scholars and researchers may find themselves in a state of confusion in trying to unpack the meaning of a case study. This observation was made by Harrison, Birks, Franklin and Mills (2017) who stated that "there are a number of definitions and descriptions presented across the literature, which create confusion when attempting to understand case study research."

To start off with, Hammond and Wellington (2013:16), considered a case to literally refer to "an example of something- a unit of analysis- in which the something could be a school, person, a political system, type of management and so on, depending on the particular interest of the researcher and the field in which he or she works." Crowe, Cresswell, Robertson, Huby, Avery and Sheikh (2017) viewed a case study as a research approach that researchers employ in the generation of in-depth and multifaceted comprehensions of complex phenomena in their real-life atmosphere and, a design that has been utilised by researchers in an array of disciplines. A close examination of this case study description by Crowe et al (2017) already reveals and corroborates the confusion that Harrison et al (2017) already highlighted, in this case, the very classification of a case study either as an approach or design.

Crowe et al (2017), although offering a very insightful thinking into how a case study may be defined, the simultaneous characterisation of a case study as a "research approach" and a "research design" vividly presents the perplexities that are associated with a case study. Viewing a case study as a research approach in its own right was also Cohen, Manion and Morrison (2018:375), thus, Crowe et al (2017) are not alone in this camp. Further complicating the definition of a case study, Hammond, and Wellington (2013:18) opined that case studies, in most instances, have been conceived as "methodologies in their own right, and even epistemologies." This confusion is further fuelled by the dearth of a consensus on what exactly constitutes or is a "case" in a case study.

However, it was not the intention of the present study to delve into the hot debates of what exactly a case is and whether a case study is a design, a method, a methodology, an approach or what. The essence of this section is to offer very basic descriptions of a case study which the researcher referred to as the "working definitions" of a case study.

Thus, a case study was taken to refer to a design and the "case" in this study was taken to mean EHRs and EMRs in the health sector that the researcher sought to understand as enunciated in chapter one of the study. On that note, the definition of a case by Yin (1994:22) as either an event or entity which may not be so clearly defined as compared to a single individual informed the present study. This allowed the researcher to consider EHRs and EMRs standards in the health sector of Zimbabwe as an entity that had its own boundaries that enabled the researcher to understand how EHRs and EMRs systems were rolled out and how standards for such systems were implemented (if any) in the health sector of Zimbabwe. This is in tandem with the views of one of the case study gurus, Yin (1994:22) who declared that indeed, case studies have been conducted on decisions, the performance of programmes, implementation processes as well as organisational changes.

Furthermore, a case study is suitable where the researcher focuses on small scale, has detailed prior knowledge of the context of the study and is driven by curiosity to find out what exactly is happening in that particular context (Hammond and Wellington 2013:18; Zainal 2007:1-2). The need for a contextual understanding of the status of EHRs and EMRs standards in the health sector of Zimbabwe weighed in on the appropriateness of a case study design method which, according to Stjelja (n.d:5) allows for an in-depth analysis of unique context or setting. This way, the researcher engages real people in real-life situations, thereby allowing

readers to appreciate issues more clearly as compared to simply presenting them with mere abstracts or principles (Cohen, Manion and Morrisn 2018:376).

A case study is particularly suitable for exploring a phenomenon that is characterised by poor or little understanding (Leedy and Ormrod 2015:272), in which the phenomenon is studied in-depth rather than in-breadth (Kothari 2004:102). All this proves the aptness of the case study for this study, given the need for the researcher to understand, in detail, the circumstances, including policy and legislative issues, surrounding the implementation of EHRs and EMRs systems and their standards, an issue which has been explored to a limited extent in Zimbabwe, so far. The case study enabled the researcher to understand this by eliciting contextual information from the participants who were involved in the implementation, use and management of the EHRs and EMRs through interviews and questionnaires.

The implementation of EHRs and EMRs and their standards was considered a social phenomenon that solicited a deeper and contextual understanding as it was taking place in the social world that was affected by a number of other social factors such as expertise and resource availability and policies and legislation governing their implementation and management and hence the application of a case study. This is commensurate and in tandem with observations made by a number of scholars that case studies are typically employed in the interpretive paradigm (Starman 2013:30), in social science research (Harrison et al 2017; Heale and Twycross 2017; Starman 2013:29).

Case studies are known to be more qualitative than quantitative, albeit, not always as they can be quantitative, qualitative or a combination of both (Starman 2013:30). This perhaps explains the warning to case study researchers by Hammond and Wellington (2013:18) that although case studies have largely been associated with the interpretive paradigm, the epistemological assumptions behind case studies need not be taken for granted, particularly in view of the fact that case studies tend to be used as "catch all", resulting in researchers not coming out clean and clearly about paradigmatic divisions. However, the present researcher vividly explained his research paradigm and how it tallies with the qualitative methodology and the case study.

There are different types of case studies, chief among them being explanatory, exploratory and descriptive case studies. Of the three case studies, the present study adopted an exploratory case study which Stjelta (n.d:4) considered suitable for studying situations that do

not give clear or single sets of outcomes. This was true for the present study explored the state of standards implementation for EHRs and EMRs in the health sector of Zimbabwe, a phenomenon whose status the researcher had limited information about. Because the MHCC was the highest body regulating health policies and projects, including e-health projects such EHRs and EMRs standards whilst SAZ was the only standards authority in Zimbabwe, the study employed a case study series enabled the researcher to understand the role and progress of each of the aforementioned institutions regarding the standards for EHRs and EMRs.

3.5 Population of the study

The study population ought to be clear, relevant and representative by identifying and listing all the relevant and accurate respondents or subjects of interest to the researcher. The term population in the context of research refers to all the people or items, generally known as a unit of analysis, possessing the characteristics that the researcher intends to study (Bhattacherjee 2012:65). A unit of analysis (Bhattacherjee 2012:65-66) went on to expound, may be a person, a group of persons, country, object, or any other complete entity that the researcher intends to draw scientific inferences about. Concurring with the above-cited scholar on the definition of a population, Donely (2012:92), described a population as a complete list of items from which a sample will be drawn. This implies that a study population is basically a universe, containing all the subjects of interest to the researcher.

The criterion of determining this universe is relevance to the subject or phenomenon under investigation. It therefore, suffices to say that all the subjects or elements of research that potentially possess the information that is of interest to the researcher are considered a population. Thus, a population refers to all the items or people that a researcher intends to understand (Rahl 2017:3).

The target population of the present study consisted of the Director- Finance, Director- Policy Planning, Principal Director- Epidemiology and Disease Control, Deputy Director- Health Information, Deputy Director- ICT, Deputy Director- Policy Planning. The MHCC was chosen as the site for the present study because of its role as the overseer of all health policies, including the adoption, implementation and monitoring of compliance with policy. Thus, because the study focused on matters that were policy oriented, the Ministerial Headquarters was chosen for the study so that the researcher gets responses from the highest

office in charge of the health sector in Zimbabwe. As far as the MHCC is concerned, the Headquarters was particularly chosen because policy matter pertaining to eHealth and other projects are overseen by the MHCC itself.

The study targeted three (3) Units in the MHCC that were deemed relevant and involved, directly or indirectly, in EHRs and EMRs systems and their standards, that is, the ICT Unit, the Health Information Unit and the Policy Planning Unit. The Directorate of Finance housed the ICT Unit which the study targeted as it dealt with IT related issues of the study, and hence its relevance to the study, whilst the Directorate of Epidemiology and Disease Control housed the Health Information Unit, which the study also targeted in order to address health records and information standards and hence its relevance to the study. The Deputy Director- Policy Planning was responsible for policy and monitoring affairs in the MHCC and hence the relevance to the study. Data from the ICT and Health Information units were used to address issues relating to EHRs and EMRs, funding, technical standards, ICT infrastructure, and preparedness for standardisation whilst the Directorate of Policy Planning, Monitoring and Evaluation was responsible for the policy, legislative, planning and preparedness issues that related to EHRs and EMRs standards in the health sector of Zimbabwe.

The study also extended to cover SAZ where the Director and a Manager at SAZ were part of the study population. The inclusion of SAZ in the study was necessitated by the objective on the role of SAZ in health information management standards in Zimbabwe. SAZ, being a standards association in Zimbabwe, plays a pivotal role in standards development and promoting in the country, and the researcher found it useful to find out the status quo and the position of SAZ concerning health information management standards. Thus, some of the study's respondents were drawn from SAZ as this is the national standards body in the country. Thus, the study consisted of a target population of eight (8) participants. Table 3.1 shows the population of the study.

Table 3.1: Population of the study

Designation of participant	**Institution**	**Data collection method**
Director- Finance	MHCC	Interview
Director- Policy, Planning, Monitoring and Evaluation	MHCC	Interview

Principal Director- Epidemiology and Disease Control	MHCC	Interview
Deputy Director- Policy Planning	MHCC	Questionnaire
Deputy Director- ICT	MHCC	Questionnaire
Deputy Director- Health Information	MHCC	Questionnaire
Director General	SAZ	Interview
Manager	SAZ	Questionnaire

3.6 Sample frame

A sample frame is a list of all the subjects or items in the population of a study (Donely 2012:92). A sampling frame helps one come up with a representative sample, ensuring that all the relevant and key respondents are included in the study. The importance of a sound sample frame was underscored by Ngulube (2005:133) when he stated that "…having a sample frame is fundamental to sample design" and "researchers should evaluate the sample frame for comprehensiveness…" Thus, a sample frame enables one to come up with a representative sample and researchers should be able to point out the composition of their samples. Because this study involved a careful selection of participants who were considered to be information rich, the sample frame consisted of the target participants based on their roles in the MHCC and SAZ. This implies that there was no ready-made list of participants but the researcher specifically selected participants in the departments that were directly or indirectly involved in standards for EHRs and EMRs.

Descombe (2007:21) stated that a good sampling frame in research is characterised by (1) relevance, implying that it should contain subjects/objects that that are directly linked to the study; (2) completeness, which implies that it should cover all the relevant items of the study; (3) precision, meaning that it should, at all cost, exclude all the subjects or items that are irrelevant to the study; and (4) up-to-dateness, implying that it should incorporate latest

additions and changes and be cleansed of all redundant items. Thus, a sampling frame has to bear the afore-mentioned characteristics and it is up to the researcher to ensure that his or her sampling frame conforms to these characteristics as failure to do so may render the findings of a study questionable when it comes to the representativeness and relevance of the study population and sampling. Donely (2012:93) argued that the accuracy of a sample is dependent on the completeness of the sample frame, failure to which the sample will be biased.

For the present study, relevance, completeness, precision and currency of the sample frame were achieved by relying on the officially designated positions and the respective office bearers in the MHCC and SAZ, implying that data was gathered from true and relevant respondents. The informants who constituted the sample of the present study and were chosen on purpose and the administrative structures that were in existence at the time of applying for permission to gather data at the MHCC and SAZ were still existent at the actual time of collecting that data, thereby buttressing the relevance and currency of the sample frame.

3.6.1 Sampling procedures

Given the fact that conclusions of studies are primarily drawn from samples, stating and justifying one's sampling methods are a desideratum. Non-probability sampling was employed in the present study. Non-probability sampling, according to Taherdoost (2016:22), often goes with case study and qualitative research. Thus, this sampling method was in tandem with the design of the present study which was qualitative in nature and assumed a case study design. In this type of sampling, the sample needs not to be representative but simply give a clear rationale regarding the inclusion of participants in a study (Taherdoost 2016:22). This implies that, as opposed to probability or statistical sampling techniques where focus is on coming up with representative samples, the focus of non-probability sampling techniques is on coming up with relevant samples.

Non-probability sampling may take the form of purposive sampling, convenience sampling and snowball sampling. The present study employed purposive sampling. Purposive sampling involves the researcher including participants in the sample on the belief that they warrant inclusion (Taherdoost 2016:23). Purposive sampling is also known as judgemental sampling,

which Rahl (2017:3) defined as a situation whereby the researcher employs his or her own discretion to choose participants who are considered knowledgeable about the phenomenon under investigation. Essentially, this sampling technique is called purposive sampling because it involves choosing participants based on a particular purpose (Rahl 2017:3). This implies that in this technique of sampling, the chosen participants need to possess particular unique characteristics that are of interest to the researcher. Such characteristics therefore, distinguish such participants from other potential participants and they are considered information rich participants or cases.

In the present study, the Director of Policy, Planning, Monitoring and Evaluation, Director of Finance and Administration, Principal Director of Epidemiology and Disease Control, Deputy Director of Policy, Planning, Monitoring and Evaluation, Deputy Director of ICT, Deputy Director of Health Information in the MHCC and the Director and a Manager at of SAZ were specifically chosen on an understanding that they were the most senior and knowledgeable informants about issues of EHRs and EMRs standards, which is what the study was concerned with.

The study aimed at understanding the manner in which EHRs and EMRs standards had been rolled out in the health sector of Zimbabwe and the afore-mentioned participants, given their positions, had the best knowledge about the issue under investigation, and hence purposive sampling. The MHCC was responsible for overseeing all the policy, legislative and technical issues surrounding EHRs and EMRs standards that were under consideration in the study, and hence the purposive selection of heads of departments in the Ministry. The Director and a Manager at SAZ, the only standards body in Zimbabwe, were specifically targeted because of their deep knowledge concerning the development, deployment and promotion of standards in Zimbabwe, and the position and efforts of SAZ with regards to standards for EHRs and EMRs were of interest to the researcher, and hence purposive sampling. Thus, the study intended to elicit detailed information from the apex offices in the MHCC and SAZ so as to draw informed conclusions about the status quo concerning standards for EHRs and EMRs in the health sector of Zimbabwe.

In total, the study had a sample of eight (8) informants. Of the eight (8) informants, a total of five (5) participated in the study, with the other three (3) not participating due to work commitments. The informants who participated constituted of three (3) questionnaire

participants from the MHCC, one (1) questionnaire participant from SAZ and one (1) interview participant from SAZ.

3.7 Data collection methods

When one has vividly outlined their population and sampling procedures, the next step is to explain how data will be gathered. This talks to the data gathering techniques. Methods, which more often than not, are confusingly referred to as methodologies in many textbooks, actually refer to the step by step approaches or actions or phases that the researcher takes in a particular and eventually stringent order in the conduct of research (Jonker and Pennink 2010:33). Thus, preceding data analysis is the consideration of the most effective way of gathering data (Jonker and Pennink 2010:33).

In fact, conclusions of a study are drawn on the basis of the data gathered during the study, thereby placing a compelling and unavoidable request on the researcher for clear and justifiable methods in which data was gathered in their study. This is especially pressing to qualitative researchers, given the fact that qualitative research, Jonker and Pennink (2010:38) noted, tends to be regarded as being messy, vague, and unscientific and does not adhere to structured plans. Against this backdrop, the present researcher, having employed a qualitative approach, was left with no option but explain the data gathering methods that the study employed. The methods employed in the data gathering exercise are determined, to a large extent, by the questions as well as the objectives of the study (Canals 2017:3). The questionnaires and interview guides used in the present study were also drafted in a manner which enabled the researcher to elicit data that addressed the study objectives.

The present study utilised semi-structured questionnaires and semi-structured interviews which are explained below, through data source triangulation. Triangulation, according to Ngulube (2015:137) is important and is a way of boosting the trustworthiness and rigour of one's findings in qualitative research.

3.7.1 Questionnaires

Kothari (2004:100) characterised a questionnaire as consisting of a list of questions that are either typed or printed in a definite order or form or even set of forms. The questionnaire is a

favourite data gathering tool for many researchers and provides a cheaper means of collecting structured and easy-to-manage data (Wilkinson and Birmingham 2003:7). A total of four semi-structured questionnaires were designed and administered in the present study.

The first three questionnaires were administered to the Deputy Director of Policy, Planning, Monitoring and Evaluation, Deputy Director of ICTs and the Deputy Director of Health Information in the MHCC. These questionnaires had unique content as they addressed different aspects of the study. For example, the questionnaire for the Deputy Director of Policy, Planning, Monitoring and Evaluation was meant to elicit data pertaining to matters of policy, legislation, implementation, monitoring and preparedness for EHRs and EMRs standards, the one for the Deputy Director of ICT was meant to gather data about the standards themselves, technical issues surrounding the standards for EHRs and EMRs as well as the preparedness of the MHCC to implement and monitor standards for such systems whilst the one for the Deputy Director of Health Information was meant to elicit data pertaining to the EHRs and EMRs themselves and their standards.

The fourth questionnaire was issued to a Manager at SAZ so as to address one of the objectives of the study whose aim was to understand the role of SAZ in the design or adoption, implementation, promotion and monitoring of standards for EHRs and EMRs. In drafting questions for the data gathering exercise, the researcher partly borrowed from a study that was conducted by the EU Health Programme (2008-13) which was published in 2014.

3.7.1.1 Questionnaire design

Designing questionnaires, which Cohen, Manion and Morrison (2018:472) alternatively referred to as operationalization, involves the statement of the general purpose of the questionnaire and translating that purpose into an aim or set of aims that are specific and concrete. With regards to the present study, each questionnaire had a cover page in the form of an introductory letter in which the researcher introduced himself, the purpose of the study and the intended benefits of the study to the MHCC and SAZ.

Having satisfied the questionnaire operationalization process, the next step involves the formulation of the actual research questions that need to be answered (Cohen, Manion and Morrison 2018:472). At this stage, Kothari (2004:102) hinted, for the questionnaires to be effective, thereby giving quality responses, the researcher needs to ensure logic in the

sequence of the questions in the preparation of the questionnaire. One way of achieving this is to ensure clarity and smoothness in the questionnaire, implying that the relationship between questions needs to be easily discernible and sensible to the respondents (Kothari 2004:102).

As far as the present study is concerned, the questionnaires were designed in such a way that all the possible questions that related or addressed each and every objective of the study were presented under each objective. Furthermore, in cases of questions that were directly related to each other, the researcher would bring those immediately after the other, starting off with the general questions, moving to the more specific ones in a logical fashion. Thus, the questions were ordered in a thematic fashion, with each objective serving as a thematic area around which all the relevant questions were centred. In succinct, the researcher observed all the steps that were proposed by Cohen, Manion and Morrison (2018:472) as shown in Figure 3.2.

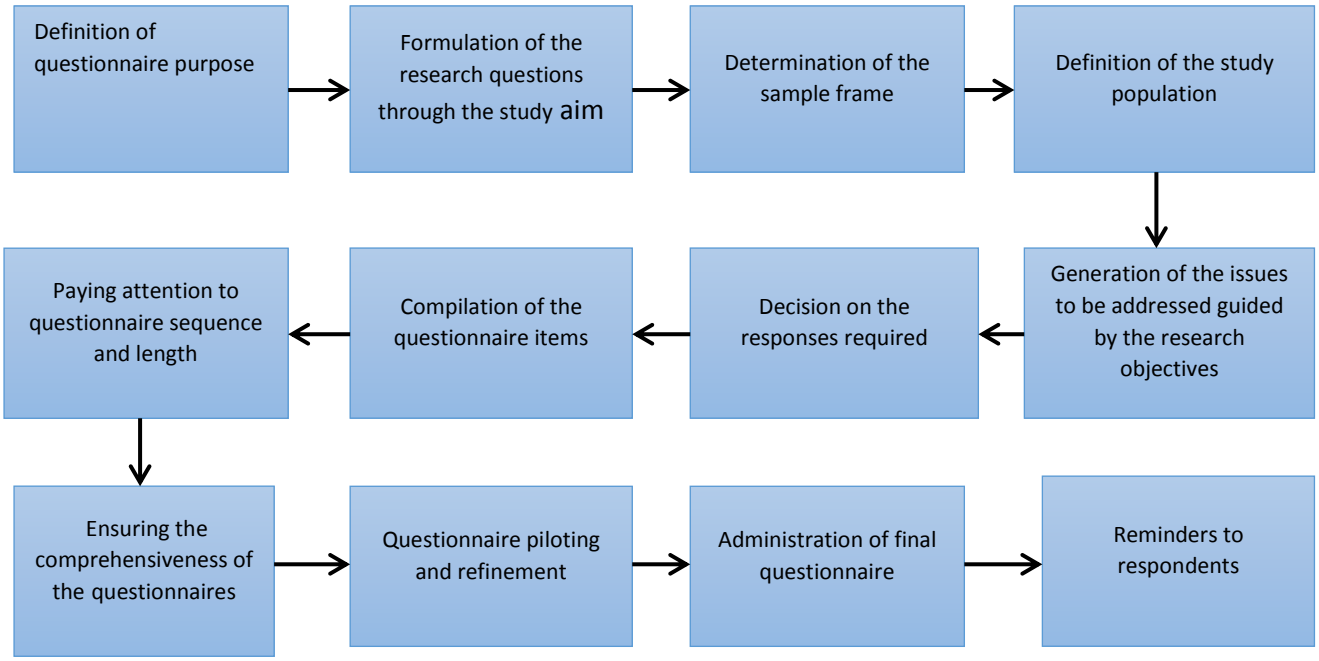

Figure 3.2: Questionnaire operationalization for the study

Thus, all the four questionnaires were operationalized through the same process in an effort to improve the quality of the questionnaires in all regards, including length, question sequence, relevance and expression. The operationalization of the questionnaires therefore, allowed the researcher to design questionnaires that were consistent with the prescription by Denscombe (2007:153) who pointed out that for questionnaires to suffice as research

instruments, they need to (1) be designed in a manner that allows them to collect data that is material to the subsequent analysis; (2) consist of a written list of questions, and (3) elicit data by posing questions that are directly linked to the study.

The questionnaires were sent earlier by post and collected in person during the time of conducting interviews. Albeit the shortcomings of questionnaires as data gathering instruments, they were particularly suitable for the present study as they allowed the Deputy Directors who had busy schedules to complete them at their own time.

3.7.2 Interviews

Interviews still render themselves attractive data gathering instruments to researchers (Denscombe 2007:173) and were employed in the present study. Interviews involve a presentation of "oral-verbal stimuli and reply in terms of oral-verbal responses" (Kothari 2004:97). Using interviews in a study usually indicates the importance that is attached to the issue under investigation (Wilkinson and Birmingham 2003:44). In the present study, interviews targeted the Directors in the MHCC and SAZ due to their seniority and knowledge in their respective institutions.

Semi-structured interviews were used in this study. In semi-structured interviews, the researcher still has a predetermined list of questions and issues to be tackled by the interviewee, but in this case, the researcher is flexible with regards to the order of issues to be asked and may allow the interviewee to come up with new ideas and go at length about the issues being pursued by the researcher (Denscombe 2007:176: Wilkinson and Birmingham 2003:43). Thus, there is limited flexibility in structured interviews as the researcher directs the interview process quite closely (Wilkinson and Birmingham 2003:43). The responses tend to be open ended and emphasis may be put on the interviewee to shed more light on the areas of interest (Denscombe 2007:176).

One-to-one interviews were scheduled to be conducted with the Director of Finance and Administration and the Director of Policy, Planning, Monitoring and Evaluation and the Principal Director of Epidemiology and Disease Control in the MHCC and the Director General of SAZ. However, only one interview was successfully conducted with the Director General- SAZ, whilst efforts the other three did not take place due to circumstances beyond the control of the researcher.

One-to-one interviews, according to Denscombe (2007:177), are the most common form of interview involving a meeting between one researcher and one respondent. This form of interview tends to be advantageous over other forms of interviews in the sense that the data that is gathered this way comes from one source (interviewee), thereby making it relatively straightforward for easy for the interviewer to associate specific responses with interviewees (Denscombe 2007:177). Thus, the researcher conducted one-to-one interviews with the interviewee at their office and was easy for the responses to be associated with certain respondents. An audio recorder was used to capture the proceedings of the interview. Interviews were particularly scheduled to be conducted with Directors at both the MHCC and SAZ as they were senior members of staff and were responsible for overseeing the portfolios that the researcher was interested in. Thus, key questions, especially those that pertained to policy issues needed the corroboration by the most senior members in the MHCC and SAZ.

Overall, the use of questionnaires and interviews, which was a form of data gathering triangulation, was meant to enrich the data that was gathered by the research. As observed by Denscombe (2007:112), combining the two methods (semi-structured questionnaires and semi-structured interviews) gives the researcher room for him/her to escape potential criticism that emanates from either the relatively small sample size that is typical of interviews or the somehow superficial data that that is collected through questionnaires. However, due to the failure by the researcher to conduct three out the four scheduled interviews, the intended corroboration was not possible in the case of data from the MHCC, resulting in the study relying on questionnaire data only. However, at SAZ, the intended interview with the Director General was successfully conducted.

3.8 Data analysis and presentation methods

The study was qualitative in nature and both questionnaire and interview data was analysed and presented in the form of textual narratives, with some key responses being captured verbatim. The population and sample of the study were reasonably small and each questionnaire and interview guide was directed at specific individuals who were considered best knowledgeable and the responses were specifically for each objective and the relevance and utility of software were not justifiable. Instead, data presentation involved significant chunks of statements that were cited verbatim from the participants so as to enrich data presentation and analysis. Some of the data was presented in a tabular form, not in a

statistical fashion, but in a manner that allowed the reader to have a feel of the direct responses from the informants as is usually the case with qualitative studies.

3.9 Evaluation of the research methodology

There is no research methodology that is without faults, no matter how justified it is as a single research problem may render itself exploitable by different researchers using more than one research methods. This necessitates evaluations of research methodologies that researchers may have employed in their studies. In light of this fact, the researcher felt compelled to briefly evaluate the methodology that the present employed. This was done after the data collection exercise, thereby allowing the researcher to bring to the fore, unforeseen hiccups that characterised the methods and process of gathering data.

As explained in the earlier sections of this chapter, the study was situated in the interpretivism paradigm, informed by the relativist ontology and authoritative knowledge as its epistemological position, which were all adequately justified in the relevant sections of the chapter, together with the methodology, research design, population, sampling techniques and the data gathering methods employed in the study. Thus, this section focuses of the experiences of the researcher during the gathering exercise.

First, the data gathering exercise was conducted in an ethical manner after the researcher was cleared by both the MHCC and SAZ to officially use these institutions as the research sites. As explained earlier on in the chapter, data was gathered through questionnaires and interviews. In all the cases, the researcher experienced maximum cooperation and willingness from both the questionnaire and interview respondents, despite some interviewees in the MHCC not being able to accommodate the researcher on the days of the interviews due to work commitments. The time at which data was gathered, among other factors, could have been material to the failure to achieve the maximum response rate. As Meltzoff (1998:12) observed, "principles of research design transcend content", implying that designing the methodology of a study goes beyond just the content of the data gathering instruments to cover other non-content factors, including the timing of the data gathering exercise. Data was collected in the month of December, a busy time of the year, according to the respondents, as some of them were preoccupied with their end year reports. Thus, the data gathering exercise

could have yielded maximum responses, had the researcher made arrangements for any other time other than the end of the year.

The qualitative outlook of the study, coupled with the detailed nature of the data gathering instruments (questionnaires and interviews) also seemingly affected the willingness and ability of some of the respondents to participate in the study. This was witnessed by the researcher as one of the questionnaire respondents invited the researcher to his office for a discussion prior to him/her populating the questionnaire and revealed that he/she preferred a quantitative questionnaire to a qualitative one. The preference of a quantitative questionnaire to a qualitative one by the respondents also manifested itself through laconic answers that the respondents gave whenever they were asked to explain as well as the failure/reluctance at all in some cases to give explanations. The researcher had to explain the nature of the study and why the questionnaires were qualitative in design, to the respondent who, however, cooperated and participated.

One of the interview respondents also indicated that the interview questions were too many and preferred an off the cuff discussion of the issues under investigation with the researcher. The researcher had to respect the will of the respondent by identifying and asking the broad thematic questions, which, fortunately, saw the respondent opening up during the interview and allowing the researcher to ask even finer questions pertaining to the study. The interview was successful and fruitful.

The completed questionnaires were also characterised by a shortcoming of respondents not tackling some questions as seen in Chapter four (data presentation and analysis) of the study. This was the case, despite the questionnaires containing a clause which advised respondents to attempt all the questions. The researcher could not get the reason for the failure by respondents to tackle all the questions. Perhaps, this is a weakness that is typical of questionnaires. However, the questionnaires were very much useful for the study and many of the major questions were answered, thereby allowing the researcher to arrive at meaningful conclusions of the study. Thus, overall, the methodology yielded data that was ample for the researcher to tackle the research problem by talking to the set out research objectives.

Because the study sought to investigate standards for EHRs and EMRs systems that are in use in the health sector of Zimbabwe, it was going to be wise for the researcher to also interact with such systems as one of the data gathering methods. However, this was not possible in light of privacy and confidentiality restrictions governing health and medical records. Such

systems contain health and medical records and only restricted and authorised users could interface with them. This left the researcher with in-depth interviews and questionnaires as the data gathering instruments. These two instruments enabled the researcher to gather sufficient data for the purposes of drawing sound conclusions regarding EHRs and EMRs standards in the health sector of Zimbabwe. This was achieved by targeting key departments in the MHCC, which is the overseer of all healthcare activities in Zimbabwe, as well as SAZ, the only standards body in Zimbabwe, to get a clear picture as to the existence and implementation of EHRs and EMRs standards in the country's health sector.

3.10 Summary

The chapter presented the paradigm and methodology of the study. Starting off with an introduction, the chapter proceeded to explain, with justification, the paradigm of the study, including the ontological and epistemological paradigmatic standings of the research. Specifically, the study was situated in the relativist ontology and interpretivist paradigm, given the fact that the issues that were under investigation were seen as being relative by definition and conceptualisation. Epistemologically, the study elicited data from respondents who were involved in EHRs and EMRs and their standards, and thus, were considered knowledgeable about the problem under investigation and thus, the study was grounded on authoritative knowledge.

In this chapter, the researcher proceeded to elucidate the methodology and design of the study which were qualitative and case study, respectively. Given the fact that the phenomenon under investigation was located in the ontology of relativism and was social in nature, data was gathered from respondents who were considered knowledgeable about the issues that were of interest to the researcher. The chapter proceeded to explain the population of the study, together with the sample frame and sampling techniques that were employed in order to gather relevant data. The chapter further outlined and justified the data gathering instruments which consisted of semi-structured questionnaires and semi-structured interviews, again given the qualitative nature of the study. An explanation of how the data gathering instruments were developed and administered was also made, with justification. Because no methodology is without weaknesses, the chapter contains an evaluation of the study'' methodology, highlighting the major success and pitfalls of the methodology. The next chapter analyses and presents the data obtained via questionnaires and interview.

CHAPTER FOUR
DATA ANALYSIS AND PRESENTATION

4.1 Introduction

The previous chapter presented the methodology that was employed in the study whilst the present study focuses on the analysis and presentation of data. Data analysis, is one of the many activities in a research process, and it comes after data has been collected (Flick 2013:9-10). Data analysis, Thorne (2000:68) explained, "unquestionably … is the most complex and mysterious of all the phases of a qualitative project…" yet it is one central step in the conduct of qualitative research (Flick 2013:3). The essence of this chapter is to present and analyse the data that was gathered for the study, which was qualitative in nature, owing to the thrust of the study which was to explore standards for EHRs and EMRs in the health sector of Zimbabwe. According to Flick (2013:5), "qualitative data analysis is the classification and interpretation of linguistic (or visual) material to make statements about implicit and explicit dimensions and structures of meaning-making in the material and what is represented in it". Citing Bohm (1983), Dey (1993:31) gave an etymological perspective of the term analysis, which he said was derived from the prefix "ana", which means "above", and the Greek root "lysis", meaning "to break up or dissolve".

To shed more light on the term, Dey (1993:31), used the following metaphorical expression: "you can't make an omelette without breaking eggs. And—to extend the aphorism—you can't make an omelette without beating the eggs together. 'Analysis' too involves breaking data down into bits, and then 'beating' the bits together." In the context of research, therefore, data analysis entails the act of resolving data into its constituent parts in an effort to bring out its qualities and structure (Dey 1993:31).

The result of a data analysis process gives a narrative in the form of findings, which is the construction of the researcher. Thus, in the figurative words of Dey (1993:31) "like the omelette, the result of this process of breaking down and beating together is something quite different from what we started with." This should, however, not come as a bolt from the blue, given the fact that after all, the quintessence is not to merely describe our research data, but to characterise the objects or events that our data denotes, and such descriptions constitute the core of any science (Dey 1993:31). In light of the afore-mentioned conceptualisation of the

term analysis, it was imperative for the researcher to dedicate this chapter to data presentation and analysis after his data gathering exercise.

4.2 Importance of data analysis and legitimacy of qualitative data analyses

Data analysis is not only important but also an unavoidable desideratum in any scientific research, for it is what enables the processing of raw data into meaningful statements that can be deciphered by the broader research community and all the other stakeholders in academia and outside. Thus, data analysis is imperative in the research process in light of the fact that data, as Young and Hren (n.d) declared "does not come out of ether" since it is obtained within contexts by participants who are also situated and come from specific contexts (Young and Hren nd). Thus, the analysis of qualitative data becomes even more demanding so as to bring out and appreciate the contexts in which data was gathered so as to negotiate the chasm between one's ontology and epistemology as encapsulated in their data. This entails the researcher coming up with qualitative descriptive themes. Constas (1992:254), in the following words, took the explanation to a higher level:

> "meaningfulness" of a given study does not reside "in the data." Contrary to what some have claimed, categories do not simply "emerge" from the data. In actuality, categories are created, and meanings are attributed by researchers who, wittingly or unwittingly, embrace a particular configuration of analytical preferences.

This implies that the exercise of data analysis becomes more inevitable as data on its own does not talk for itself. Instead, the researcher is the one to engage the data in an effort to give it a voice. Indeed, Thorne (2000:68) asserted, in an endeavour to generate findings that engage raw data to new knowledge, qualitative researchers need to engage in an analytic process which is active and demanding. In agreement with Thorne (2000:68) on the indispensability of data analysis in qualitative research is Flick (2013:3) who stated that irrespective of what the data is, it is its analysis, in a meticulous manner, that actually gives birth to the findings or outcomes of the research. Thus, without data analysis, reliance will be placed on the impressions and intuitions about the gathered data in its entirety (Dey 1993:31). Whilst it is a given that our impressions and intuitions indisputably have their role on data analysis, additional benefits can be derived from more robust and logical procedures of data analysis (Dey 1993:31). This goes to demonstrate the centrality of data analysis in research.

Regarding legitimacy, qualitative researchers almost feel compelled to elucidate and justify their data analysis methods, just like their data collection methods, despite some scholars arguing that the paradigmatic wars are no longer necessary. This comes against, not only against the backdrop of the thickness of the data and the complexities associated with the social world, but the ever hanging ruminants of the paradigmatic wars between qualitative and quantitative research approaches, with proponents and supporters of the latter waging an argument that qualitative research is characterised by the dearth of scientific rigour whose results are tantamount to mere chimera. Lamenting the predicament that qualitative research data and findings find themselves in, with the intention of coming to the defence of this type of research and the legitimacy of its findings, Atkinson and Heath (1991:161), concisely tackled the issue in the following words:

> Reservations about qualitative research often centre around contentions that since qualitative methods are also subjective and uncontrollable, the results of qualitative research are not valid and reliable. While, many qualitative researchers…have attempted to improve the trustworthiness of their results by making their methods more systematic, we argue that qualitative researchers cannot establish the trustworthiness of their findings, regardless of the methods they use. Rather, the legitimization of knowledge requires the judgement of an entire community of stakeholders. In the absence of certainty, knowledge is an ethical matter, one which the judgement of each stakeholder must count.

This implies that qualitative researchers need to get comfort in the nature of the data that they obtain using rigorous data gathering instruments that are at their disposal, given the fact that they cannot, and indeed, it is not their responsibility to vouch for the trustworthiness of their data, owing to the fluidity of the social world that qualitative research subscribes to. Thus, the present researcher made efforts to use all the rigorous data collection instruments and collected his data from credible sources, with justification; he cannot vouch for the trustworthiness of the study findings. In such cases, Atkinson and Heath (1993:163-164), urged qualitative researchers to get delight in their methods for knowledge ligitimization. They wrote:

> Rather than regretting that our methods for knowledge legitimization are unlike those of other older, more established disciplines, we could embrace our uniqueness and openly endorse the kind of communal legitimization process that has made our discipline strong

Thus, the judgement on the legitimacy of data and findings gathered from qualitative studies, as was the case with the present study, should be by those who have an appreciation of the principles of the relativist interpretivist paradigm that the present study was situated in, given

the fact that the intention of the study was not to count or measure things, but merely to gain a deeper understanding and appreciation of EHRs and EMRs and their standards. On that note, the qualitative data analysis was warranted.

4.3 Analysis of data in the present study

There is no single way of analysing qualitative data as qualitative researchers have a number of approaches at their disposal to doing this (Lacey and Luff 2007:9). Thus, the assorted nature of qualitative data, including videos, audio recordings, pictures, documents and field notes, qualitative researchers have a gamut of ways of presenting their data. The present study used a thematic approach to the analysis of data whereby the data was presented following the objectives of the study, owing to the qualitative nature of the data. That is, the research objectives gave rise to the themes under which the data was presented. This is in tandem with the sentiments of Lacey and Luff (2007:9) that "much qualitative analysis falls under the general heading of thematic analysis." In doing so, questionnaire and interview data was analysed and presented simultaneously in a complementary fashion. That is, questionnaire and interview data that related to the same objective or issues was analysed and presented concurrently in a corroborative manner where this was the case and to highlight areas of disagreements where such inconsistencies were noted in the data.

Data for objectives 1, 2, 4 and 5 was sought from three Departments in the MHCC. These are the Department of Policy Planning, Department of Health Information and the Department of ICT, whilst data for objective 3 was sought from SAZ. It is important to note that, owing to the purposive sampling method that was used in the study, each respondent in each Department was issued with a questionnaire that was specific to his/her Department, based on their relevance to the study.

As a reminder, the study was conducted against the backdrop of the proliferation of EHRs and EMRs that were seemingly, not hinged on standards, resulting in a plethora of real and potential challenges such as lack of interoperability between such systems as well as potential security, confidentiality and archival risks to health records stored and managed on such platforms. The purpose of the study was to analysis EHRs and EMRs systems and standards in Zimbabwe, with the aim of developing a framework for standards that may be employed in

the implementation of EHR and EMR standards. The study was hinged on the following objectives:

i. To analyse the existing standards for EHRs and EMRs for the health sector in Zimbabwe;
ii. To find out the extent of inter-operability of the EHRs and EMRs systems that are in use in the health sector of Zimbabwe;
iii. To ascertain the role of the Standards Association of Zimbabwe in the determination and promotion of health records standards in Zimbabwe;
iv. To determine which policies and legislation are currently governing the development, implementation and monitoring of EHRs and EMRs standards in the health sector of Zimbabwe;
v. To determine the level of preparedness for the support and sustainability of EHRs and EMRs standards in Zimbabwe; and
vi. To develop a framework for EHRs and EMRs standards implementation in the health sector of Zimbabwe.

4.3.1 Existing EHRs and EMRs and standards

The first objective of the study was to get a general stock of standards for EHRs and EMRs systems and standards that are in use in the health sector of Zimbabwe.

4.3.1.1 EHRs and EMRs for the health sector in Zimbabwe

Regarding the availability of EHRs and EMRs systems, all the three (3) questionnaire respondents revealed the availability of these and indicated that these systems were already in use in the health sector of Zimbabwe. When asked to name the systems that were in use, the following systems were listed: EHR (this was the name of the system), Epms, oPenEMR, and ePOC. This suggests that there were different EHRs and EMRs systems in Zimbabwe, a situation that buttresses and further necessitates the need for sound standards for such systems to enhance health information management.

Respondents were also asked whether the MHCC, as the only office responsible authority regarding policy matters in the health sector of Zimbabwe, was auditing the EHRs and EMRs systems that were already in use, and it emerged that there were no audits of the systems, but efforts were underway to propose a multi-sectorial approach to auditing such systems, courtesy of the MHCC. In response to this question, one of the participants gave the following response: "*No framework to facilitate that but multi sectorial [sic] approach is being proposed led by MoHCC*." This is indicative of the fact that the EHRs and EMRs systems were being rolled out without the MHCC knowing which and how many such systems had been rolled out in both the public and private sector healthcare facilities at the time the present study was conducted.

In terms of deployment, it emerged that the MHCC was involved, with its role being that of coordinating the development of standards for EHRs and EMRs. The study also sought to find out whether the standards that were in use were developed locally or internationally and the only respondent who was asked this question indicated that they were not certain about that. However, a closer look at all the standards that the respondent cited indicated that the standards were internationally developed and none of them had been developed in Zimbabwe, implying that there was no active standards development for EHRs and EMRs in Zimbabwe but mere adoption of standards from outside the country.

It further emerged that there was a proposal in the MHCC to work towards establishing a Health Information Exchange (HIE). Thus, one of the respondents wrote "*Currently proposing to work towards HIE (sic).*" An HIE is the transfer of patient data and health information between disparate health care facilities using electronic means (Maryland Health Care Commission 2018; Esmaeilzadeh and Sambasivan 2016:75). Typically, the information that is available through an HIE includes "laboratory results, radiology reports, discharge summaries, consultation notes, history and physical notes, operative notes, and secure clinical messaging and referrals" (Maryland Health Care Commission 2018).

When asked about funding for the EHRs and EMRs systems that were in existence in the health sector, it emerged that in the public sector, funding came from donors, whilst there was no mention of the private sector. This indicates that the pace at which standards for EHRs and EMRs were implemented, especially in public healthcare facilities was largely dependent on donors. The greatest disadvantage of reliance on donors is that the continuity of projects is bound to suffer when donors withdraw from the arrangement, resulting in the systems in use

suffering from a plethora of challenges such as lack of technical support. Donors tend to be political at times in their activities such that they abandon their projects whenever they are no longer in good books with the governments of the countries in which they are operating.

4.3.1.2 Existing standards for EHRs and EMRs in the health sector of Zimbabwe

Following the revelation that EHRs and EMRs systems were already in use in the health sector of Zimbabwe, respondents were asked whether such systems were based on any standards regarding the content, messaging, and security of EHRs and EMRs. Responses to this question were varied and somehow contradictory. Whilst one of the three (3) respondents was not asked this question as it was not relevant to his/her Department, one (1) respondent indicated that the EHRs and EMRs systems that were already in use were not reliant on standards at all, whilst the other one indicated that there were no standards for the content of such systems but there were standards for the security and messaging of such records.

The respondent who indicated that EHRs and EMRs standards existed mentioned the International Classification of Diseases (ICD) 10 (see chapter two of the study for the definition of the ICD standard) and the Integrated Care Pathway (ICPCZ). The ICP standard is defined by the National Health Services (NHS) Quality Improvement Scotland (2007:107) as "an explicit agreement by a local group of staff and workers, both multidisciplinary and multi-agency, to provide a comprehensive service to a clinical or care group on the basis of current views of good practice and available evidence or guideline." It is imperative, the NHS Quality Improvement Scotland (2007:107), continued "that the group agree *[sic]* on communication, recordkeeping and audit."

The respondent further revealed that there were no standards for the security of patient information held in EHRs and EMRs and the messaging of such records. Regarding the security and privacy of EHRs and EMRs, the same respondent was quoted as saying that despite the absence of a clearly defined standard, there was *"just encryption and de-identification of records."* This implies that the privacy of patient records was protected and ensured. However, the other respondent indicated that the MHCC once implemented the ISO 27001 standard. This could indicate that an information management security standard had been implemented and there could have been a lack of coordination regarding the standardisation of EHRs and EMRs systems in the organisation. The ISO/IEC 27001:2005(en) Information Technology- security techniques- information security

management systems-Requirements is part of a family of information security systems known as the ISO/IEC 20000 (ISO n.d).

The standard works by specifying the "requirements for establishing, implementing, operating, monitoring, reviewing, maintaining and improving a documented ISMS *[information security management system]* within the context of the organization's overall business risks" (ISO n.d). This is achieved through specifying "requirements for the implementation of security controls customized to the needs of individual organizations or parts thereof" (ISO n.d). The role of an ISM is to "ensure the selection of adequate and proportionate security controls that protect information assets and give confidence to interested parties" (ISO n.d).

In an effort to gain a fuller picture of status quo concerning standards for EHRs and EMRs, respondents were asked whether the MHCC was involved in the selection or appraisal and recommendation of such standards. The respondent who was asked this question indicated that the MHCC was involved in these processes. The respondent was cited as saying *"As the Unit that oversees the Health Information Sys [Systems] in Zimbabwe we advise technically and ensure the solution is able to communicate with other systems."* This implies that the MHCC was playing a supervisory role with regards to the selection and recommendations of standards for EHRs and EMRs. The respondent, for example, revealed that compliance with the ICD10, HL7, DICOM and ICPC standards and the OpenHIE were complied with.

Given the fact the MHCC is the sole authority with the responsibility of pronouncing policies that regulate the operations of all stakeholders throughout the health care delivery system in Zimbabwe, a question was asked whether the MHCC was also responsible for the recommendations on the EHRs and EMRs systems and standards in the private sector as well, and it emerged that the MHCC was not involved doing that. In response to this question, the respondent who was asked this question wrote *"No platform to facilitate engagement."* This implies that there was no coordination of EHRs and EMRs standards between the policy authority (MHCC) and the private sector, and the authority did not take stock of which systems had been rolled out in the Zimbabwe's private health sector.

4.4. Interoperability of EHRs and EMRs systems in Zimbabwe's healthcare facilities

The second objective was to find out the extent of inter-operability of the EHRs and EMRs systems that were in use in the health sector of Zimbabwe. Interoperability, according to Miller and Johns (2018:37) is the ability of various systems to exchange communication. In the context of health information management, to use the words of the Health Information and Management Systems Society (HIMSS) Electronic Health Record Association (2016), which cited the Medical Access and CHIP Reauthorization Act (2015) of the United States of America, is "the ability of two or more disparate technologies to exchange clinical information, and to use that information under a standard set of guidelines to coordinate patient care, ultimately improving patient outcome."

When asked the general question of whether the EHRs and EMRs in existence in the health sector were interoperable or not, all the three (3) questionnaire respondents indicated that the systems were not interoperable.

When asked whether EHRs and EMRs in use in the health sector of Zimbabwe were interoperable or not, with regards to the messaging and communication, EHRs interface specifications, EHRs scope and context and the EHRs and EMRs infrastructure or architecture, the respondent who was specifically asked the above questions indicated that there was no interoperability between and among the systems. The responses of the respondent are presented in Table 4.1.

Table 4.1: Interoperability of EHRs and EMRs in the health sector of Zimbabwe

Question	**Response**	
Do you have standards that govern the following aspects of EHR and EMR?	*YES*	*NO*
i. EHR and EMR infrastructure?		x
ii. Interoperability in messaging and communication?		x
iii. EHR and EMR definition, scope and context		x
iv. EHR interface specifications?		x

As seen in the table above, data pointed to lack of key aspects of interoperability for EHRs and EMRs. One (1) of the respondents, however, went on to explain that although the EHRs

and EMRs that had been rolled out were not operating on standards, efforts were under way to implement standards and such an exercise was at its infancy stage. The respondent revealed this in the following words in response to the question of whether such EHRs and EMRs were hinged on standards *"Not yet there but the drive is towards achieving that. Currently on its test phase."* Thus, although it was noted the same respondent earlier on cited the ICD10 and the ICPCZ as some of the standards that had been implemented to standardise the content of EHRs and EMRs, such systems did not facilitate interoperability.

In response to the question of who was/were the developers of the standards, the same respondent indicated that the area of standards development was a weak one and considerations were under way in the MHCC, not only to use standards for EHRs and EMRs systems, but to initiate standards development on a local scale. This was revealed by the respondents in the following words *"weak on stds [standards] but looking forward to use and develop our own."* The fact that Zimbabwe was not yet subscribing to interoperability standards for EHRs and EMRs was commensurate with its inability to develop local EHRs and EMRs systems themselves, as revealed by the data. This implies that both the EHRs and EMRs systems and the few standards that could have been implemented were outsourced from international developers.

In light of the existence of SAZ, the only standards development authority in Zimbabwe, one of the respondents in the in the Department that was responsible for policy planning in the MHCC was asked whether the MHCC had any relationship between SAZ with regards to standards for EHRs and EMRs and it emerged that there was not relationship between the two institutions as far as standards for these systems were concerned. Figure 4.1 shows the questions that were asked and the responses that the participant gave.

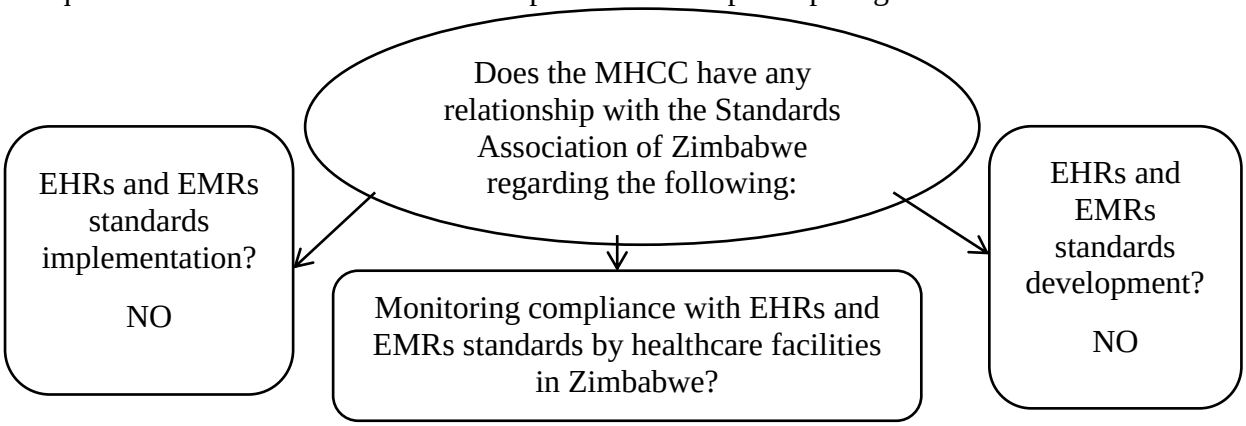

Figure 4.1: Relationship between the MHCC and SAZ regarding standards for EHRs and EMRs

The data presented in Figure 4.1 above reveals that there are still weaker policies for the development, implementation and monitoring of compliance with standards for EHRs and EMRs. However, some inconsistencies were noted with regards to responses to this question as the respondent, elsewhere, indicated that the MHCC was working with SAZ in the areas of standards development, implementation and compliance monitoring. His or her responses were juxtaposed with those of his/her two colleagues from the MHCC who indicated that the Ministry was not working with SAZ in those areas. Both the questionnaire and interview respondents from SAZ also revealed that SAZ had not worked with the MHCC with regards to standards development, implementation and compliance monitoring as far as EHRs and EMRs were concerned.

As shown later on in this chapter, SAZ and the MHCC had an MoU for other health standards, but they had not collaborated or partnered each other in the area of standards for EHRs and EMRs. The same questionnaire respondent from the MHCC who gave contradicting positions about the relationship between SAZ and the MHCC, also gave contradictory data when asked whether the existing EHRs and EMRs systems in Zimbabwe were based on any standards or not where he/she first indicated that the systems were not based on any standards, and later on indicated that such systems were based on standards from SAZ and other standards bodies. It was, however, noted, through data from the other three (3) respondents from the MHCC and SAZ that no standards from SAZ had been implemented. Respondents from SAZ further indicated that SAZ had not developed any standards for EHRs and EMRs, neither was it able to review international standards for adoption by healthcare facilities in Zimbabwe.

4.5 Role of SAZ in the determination and promotion of EHRs and EMRs standards

The study had its third objective being to ascertain the role of SAZ in the determination and promotion of health records standards in Zimbabwe. Data for this objective was gathered from SAZ where one questionnaire was issued to a Manager whilst an interview was successfully conducted with the Director General of that institution.

4.5.1 Involvement of SAZ in the generation/development of standards for EHRs and EMRs

Through a questionnaire, the respondent at SAZ was asked whether SAZ was involved in the generation or development of standards for EHRs and EMRs. The respondent indicated that SAZ was involved in this activity. However, when further asked to name the EHRs and EMRs standards that SAZ had generated, the respondent revealed that SAZ had not generated any standards of its own, rather, it was a member of ISO TC 215 and was participating in the standards development process at ISO. The respondent, in the following words, explained that SAZ was technically incapacitated to review and customise the ISO standards for EHRs and EMRs for adoption by Zimbabwean healthcare facilities. The respondent revealed this in in the following words *"We are observer member [sic] of the International Organisation for Standardization (ISO) Technical Committee TC 215: Health Informatics but do not have an active national mirror TC to review the international standards for national adoption."* To cite the International Organisation for Standardisation (ISO) Technical Committee, Health Informatics (TC) (2017:3), is one of the many ISO secretariats whose purpose

> is standardization in the field of health informatics to facilitate the secure and coherent capture, interchange and use of health-related data, information and knowledge to support and enable all aspects of eHealth. ISO/TC 215 develops standards for information and communications technology (ICT) and health information management (HIM) practices in eHealth to support healthcare delivery and public health; ensure secure interoperability between ICT products and integrity of health information and data; and assure the patient safety when using ICT products in healthcare.

However, in the interview that was conducted with the Director General of SAZ, it was noted that SAZ was actually a "P" member (participating) and not an "O" member (observing). This was also corroborated by the minutes of the ISO Committee on Consumer Policy (COPOLCO) 40th meeting that was held in Bali, Indonesia on the 10th of May 2018 in which Zimbabwe, through SAZ, was listed and participated in the meeting as a "P" member. Thus, although the questionnaire respondent indicated that SAZ did *"…not have an active national mirror TC to review the national standards for national adoption",* SAZ was now a "P' member of ISO.

The researcher further learnt that although SAZ was a "P" member of ISO and was able to buy EHRs and EMRs standards from ISO, it had not technically customised any of such standards. The interview respondent further revealed that although SAZ was able to acquire

such standards from ISO and customise them, at the moment, it was just purchasing them and reselling them without any customisation. In the case of the standard being adopted with customisation/amendments, the standard carries the code "ZWS ISO", whilst the one that is developed in Zimbabwe, although certain section of it may be based on international standards, carries the code "ZWS", the interview respondent explained. It emerged that as for customised EHRs and EMRs were concerned, there were no "ZWS" standards, thereby buttressing the absence of an active local committee for the review of international standards for customisation to the context of health in Zimbabwe.

A further question was posed to the questionnaire respondent with the intention of finding out whether the development of standards for EHRs and EMRs was the responsibility of SAZ or not. In response to this question, the respondent indicated that indeed, SAZ was responsible for the development of standards for a gamut of sectors of the Zimbabwean economy, including the health sector. The respondent stated: *"Yes. SAZ, as the national body has a mandate to develop national standards to meet national needs in liaison with stakeholders. Stakeholders have to express interest and submit proposals for the required needs. We work with policy makers and regulators."* Corroborating this, the interview respondent at SAZ indicated that *"our key role is to facilitate the development of national standards to support all sectors of the Zimbabwean economy…To date, we have developed over 2 400 standards."* This was against the background history of SAZ, which, according to the interview respondent, is a *"national standards body in Zimbabwe established in 1956, incorporated in 1960."* Thus, it is evident that SAZ is mature enough to tackle issues of standards in all the sectors of the economy.

The interview respondent further revealed that in 2017, SAZ rolled out the Zimbabwe National Standardisation Strategy, a national project on standardisation across the various sectors of the Zimbabwean economy. According to the interviewee, *"In 2017, we launched the Zimbabwe National Standardisation Strategy with the goal to develop 133 projects (standards) for various sectors."* Upon further asking the respondent whether there were any EHRs and EMRs standards among those projects, it emerged that these were not part of the strategy.

The respondent further revealed that the process of standards development was market driven, implying that if SAZ does not receive requests for standards development from the stakeholders, it cannot just develop standards for the sake of it. Given the fact that there was

no relationship between SAZ and the MHCC regarding the development of standards for EHRs and EMRs, one can infer that the health sector, which has rolled out such systems that are not guided by any standards, has been reluctant and reticent in engaging SAZ for the development of standards for those systems. This becomes remiss, given the fact that the MHCC vividly lamented the dearth of standards for EHRs and EMRs in the Zimbabwe's E-Health Strategy (2012-2017).

Regrettably, the questionnaire respondent revealed that SAZ once made an attempt to constitute a national mirror committee so as to facilitate the reviewing of the ISO 215 TC standards, but the effort did not receive stakeholder interest, resulting in it dying a natural death. The questionnaire respondent was cited as saying *"Some years back we initiated work to review for national adoption ISO TC 215 [sic] international standards but abandoned the work due to lack of stakeholder commitment."* This is indicative of limited willingness on the part of the stakeholders in the health sector to develop local or customise international standards for EHRs and EMRs. This observation makes more sense in light of the revelations of the interview respondent who emphasised that *"standards are voluntary documents which contain specific requirements."*

4.5.2 Legal mandate of SAZ to develop, implement and monitor EHRs and EMRs standards

The study also sought to understand if SAZ had any legal mandate to develop, implement and monitor standards for EHRs and EMRs in the health sector of Zimbabwe. Questions around these issues were posed on both the questionnaire and interview respondents at SAZ and their responses were consistent in indicating that SAZ did not have any legal mandate to develop, implement and monitor standards for such systems in Zimbabwe. The interview respondent was quoted as saying *"We are not established through an Act of Parliament. We are established in terms of the Companies Act of Zimbabwe".* The questionnaire respondent also buttressed that by stating that there is *"No standardisation Act in place, but SAZ has an MoU with the Government of Zimbabwe."* This shows that SAZ did not have a legal mandate to develop, implement and monitor standards in organisations across the economy of Zimbabwe, but had a document, in the form of an MoU, with the Government of Zimbabwe, that both parties could leverage on regarding standardisation. Thus, SAZ was operating on a not for profit basis as revealed by the interviewee at SAZ.

The interview respondent further explained that instead, the duties of SAZ included the development of standards in liaison with stakeholders, training people on standards, and certification of both products and systems. The questionnaire respondent corroborated this position in the following words *"SAZ offers some certification services for products and services and can be equipped as necessary to offer such services",* implying that SAZ had the material and expertise to play a supervisory role, but it was legally handicapped as that was outside its legal mandate. The interview respondent further explained that although they are the standards body, the implementation and monitoring of standards was the responsibility of the regulating bodies and SAZ was not involved in those activities.

4.5.3 Capacity of SAZ to develop standards for EHRs and EMRs

Given the fact that the intention of the study was to eventually develop a framework for the implementation of standards for EHRs and EMRs in the health sector of Zimbabwe, the researcher was keen to find out whether SAZ was capacitated to develop standards for such systems. This question was posed on the questionnaire respondent. In his/her response, the respondent indicated that technically and financially, the organisation was able to do that. The only handicap that the respondent cited was the legal mandate which the organisation did not have. The responses of the respondent are summarised in Table 4.2.

Table 4.2: Capacity of SAZ to develop standards for EHRs and EMRs

Question: Does SAZ have the capacity in the following areas to develop EHRs and EMRs standards for possible implementation by healthcare organisations in Zimbabwe?	**Response**	**Explanation of the response**
i. Technical expertise? Give reasons for your answer.	*"Yes"*	*"SAZ depends on national experts and expect stakeholders to provide the expertise for the areas they have requested standards. SAZ provides Secretariatship to manage the standards development processes."*
ii. Financial resources? Give reasons for your answer.	*"Yes"*	*"Standards development is funded by the Standards Development Levy fund set up by Government through an Act of Parliament."*

iii. Legal mandate? Give reasons for your answer.	*"No"*	*"No Standardization Act in place but SAZ has a MoU with the Government of Zimbabwe."*

It can be noted from the data in the table above that SAZ had the expertise and financial resources to develop EHRs and EMRs standards but did not have the legal mandate to do so as it was established according to an Act of Parliament.

4.5.4 Relationship of SAZ with the MHCC regarding EHRs and EMRs standards

In light of the fact that SAZ was the sole standards body in Zimbabwe, the researcher was keen to understand whether there was any collaborative or partnership work between SAZ and the MHCC in the areas of EHRs and EMRs standards development, implementation and compliance monitoring by healthcare facilities in Zimbabwe. The researcher learnt, through both the questionnaire and interview respondents that, there was no collaboration between the two organisations with regards to standards for EHRs and EMRs in Zimbabwe. However, it was gathered that although there was no collaboration between SAZ and the MHCC, there was an MoU that was signed by the two parties for other types of standards in the field health care other than health information management.

The researcher, in an effort to enhance his understanding of the operations of SAZ with regards to standards for EHRs and EMRs, further sought to find out the other regional and international bodies that SAZ was a member of or was collaborating with for standards development. It emerged that SAZ was affiliated to a number of standards development organisations that are both international and regional in terms of outlook and scope. When asked to mention those organisations, the interview respondent named ISO, the International Electrotechnical Commission (IEC), the South African Bureau of Standards (SABS), the Botswana Bureau of Standards (BOBS), the African Organisation for Standardisation (ARSO) to which the Director General of SAZ was the President, and the ASTM in Canada with which it had a standing MoU. Thus, SAZ was well connected and exposed to regional and international practices regarding standardisation. However, the collaborations and affiliations to other standards bodies that SAZ enjoyed were not on standards for EHRs and EMRs, but other various areas.

Given the existence of key and active international standards development bodies that have dedicated their efforts to the development of standards for health information, the researcher identified and listed some of the common health information standards bodies in the questionnaire so as to determine if there was collaboration between SAZ and those standards bodies. They included the Comite Europeen de Normalisation (CEN/TC 25), Health Level Seven Inc (HL7), Digital Imaging and Communications in Medicine (DICOM) Standards Committee, the Japanese Association of Healthcare Information Systems Industry (JAHIS) and the Medical Information System Development Centre (MEDIS-DC). It should be noted that the list of such bodies is not exhaustive and the respondent were given an opportunity to state any other EHRs and EMRs body that SAZ was in collaboration with in the questionnaire. The responses of the respondent are depicted in Table 4.3.

Table 4.3: Collaboration between SAZ and health information standards bodies on EHRs and EMRs standards

Question: Has SAZ ever collaborated with any of the following standards bodies with regards to EHRs and EMRs standards?

Standards Organisation	Yes	No
Comite Europeen de Normalisation (CEN/TC 251)		x
Health Level Seven Inc (HL7)		x
Digital Imaging and Communications in Medicine (DICOM) Standards Committee		x
Japanese Association of Healthcare Information Systems Industry (JAHIS)		x
Medical Information System Development Centre (MEDIS-DC)		x

It can be noted from the data presented that SAZ did not have any relationship with any of the afore-mentioned health information management bodies, save for ISO. This implies that SAZ was not that preoccupied with standards for EHRs and EMRs, not by design but simply because of lack of interest in the concerned stakeholders, including the MHCC, which, however, had standards for EHRs and EMRs featuring quite conspicuously as a prerequisite in the Zimbabwe's E-Health Strategy (2012-2017).

When asked why SAZ was not in collaboration or affiliated to any or adopted standards from any of the afore-mentioned standards bodies, the questionnaire respondent revealed that no interest was shown by stakeholders to warrant so much attention to such collaborations or affiliations. To cite the questionnaire respondent: *"No interest expressed by national stakeholders."* This was indicative of the reluctance and reticence of the entire healthcare sector in Zimbabwe to invest in standards for EHRs and EMRs, yet the same sector was so keen to implement such systems, with the potential of having Zimbabwe's healthcare delivery system being littered with systems that are weak on standardisation, a situation which comes with far much reaching ramifications with regards to a gamut of health records and information management aspects, including the security, privacy, interoperability, content and structure of EHRs and EMRs. Actually, the questionnaire respondent indicated that *"these standards might not be a priority at the moment."*

4.5.5 Promotion of EHRs and EMRs standards by SAZ

The researcher also intended to understand whether SAZ had made efforts to promote the implementation of, and adherence to standards for EHRs and EMRs by healthcare facilities in Zimbabwe, and what those efforts were, if any. In response to that question, the questionnaire respondent revealed that there were no efforts from SAZ. However, the respondent indicated, SAZ was willing to engage various players in the healthcare delivery system to partner them in the adoption of standards for EHRs and EMRs, but there was no commensurate interest from such stakeholders. To use the words of the respondent, *"SAZ is willing to partner with the relevant stakeholders to adopt those standards that are market relevant and implementable in ZW [Zimbabwe]."*

When asked to give an opinion as to why the concerned stakeholders were not adopting standards for EHRs and EMRs, the respondent mentioned three things that he/she thought were the chief reasons behind such reluctance, namely lack of resources, lack of requisite competencies and lack of priority at the moment. The respondent stated that *"No standards have been adopted yet, lack of resources and the required competencies, these standards might not be a priority at the moment."*

The view of the respondent about such standards not being a priority for now is corroborative of the explanation that he/she earlier on gave in his/her responses to the questionnaire and that which was given by the interview respondent where it was indicated that standards were

voluntary and market driven such that when stakeholders do not show interest in a standard(s), SAZ will not work on them. Indeed, stakeholder willingness and participation were cardinal in the adoption of these standards as the questionnaire respondent elsewhere in the questionnaire indicated that *"adoption only done in consultation with stakeholders. Previous efforts to adopt failed to take off due to lack of stakeholder interest. SAZ is willing to resuscitate this work as long as there is interest and commitment from stakeholders."* The respondent revealed an important factor that perhaps determines the willingness or lack it, to participate in the standards adoption process, that of whether the standards are relevant and whether they will be of utility to the organisation. The respondent, in the following words, hinted *"Also critical is that the adopted standards are relevant and will be used."*

In response to the question of whether SAZ as the only standards body in Zimbabwe, was satisfied with the rate of adoption of EHRs and EMRs standards by health care facilities in Zimbabwe, the responded expressed dissatisfaction at the seemingly non adoption of such standards.

When asked about the key challenges that SAZ had encountered with regards to the promotion of the uptake of EHRs and EMRs standards by healthcare facilities in Zimbabwe, the questionnaire respondent who was asked this question harped on the dearth of willingness on the part of the stakeholders, as well as the potential lack of the requisite competencies on the part of the same stakeholders despite SAZ making efforts to engage them. In response to this question, the respondent cited the challenges as *"stakeholder apathy, and probably low levels of competencies in this area."* In light of the revelation by the respondent that SAZ once made efforts to bring together the concerned stakeholders with the intention of reviewing EHRs and EMRs standards but in vain, the respondent, in the following words, indicated that SAZ was still well disposed towards such stakeholders and was willing to resuscitate those efforts *"If currently, there is interest and competencies we are willing to resuscitate the work."*

The same respondent was asked to make a suggestion as to what could be done to promote the adoption of EHRs and EMRs and he/she cited four critical points, namely: (i) the resuscitation of the standards review and adoption project that suffocated due to lack of stakeholder participation; (ii) capacitation of the participants with regards to their competencies; (iii) provision of resources at all levels and (iv) the linking of standards with any related policies. To cite the respondent there was need to *"resuscitate the initial efforts to*

adopt the standards, built up [sic] competencies to enable implementation, resource provision at all levels. Link standards with any related policies." Thus, SAZ was not only keen to witness the adoption of EHRs and EMRs standards by healthcare facilities in Zimbabwe, but was willing to partner the concerned stakeholders in such endeavours, but only on condition that the exercise is hinged on adequate expertise, resources and related policies.

4.6 Policies and legislation governing EHRs and EMRs systems and standards

The study had its fourth objective being to get a better understanding of the policies and legislations that were governing the development, implementation and monitoring of EHRs and EMRs standards in the health sector of Zimbabwe. Data for this objective was successfully gathered from the three (3) questionnaire respondents in the Department of Policy Planning, Department of ICT and the Department of Health Information.

A wide range of questions focusing on policy and legislative issues were asked under this objective, with each participant being asked about things that were seen to be most relevant to his/her Department. Thus, the questions varied from one respondent to the other. However, some questions would overlap in some instances and the responses of all the respondents would be taken into consideration in such cases.

4.6.1 Health data to be included in EHRs and EMRs

Data concerning what constitutes EHRs and EMRs was also sought from the questionnaire respondent. Typically, in this section, the respondent was asked about the availability and content of documented rules defining the content of EHRs and EMRs, the availability of a legal definition of EHRs and EMRs as well as the existence and contents of a policy or law specifying the common terminology and clinical coding systems that should be used by healthcare facilities in Zimbabwe. It was learnt, through the responses that none of those existed. This could imply that healthcare facilities were left to come up with their own conceptualisation of EHRs and EMRs in terms of content, meaning and terminology.

4.6.2 Requirements on institutions hosting and managing EHRs and EMRs

Given that EHRs and EMRs are shareable between many service providers in the health industry, including medical insurance providers, IT technicians, pharmacies, and many others, the study also sought to find out whether there were any documented requirements governing institutions that were hosting and processing EHRs and EMRs. The respondent who was asked this question indicated that there were specific rules for this. When asked to name the document containing such rules, the respondent sounded somehow uncertain and cited the Information Technology (IT) Policy. Precisely, the respondent wrote *"IT policy I think."* A closer look at the IT Policy for Zimbabwe by the researcher indicated that the policy was a general one, without anything specific to the EHRs and EMRs. Zimbabwe launched its 2016-2020 ICT policy entitled "Zimbabwe National Policy for Information and Communication Technology (ICT) 2016-2020" on 14 March 2018 (Machivenyika 2018). The latest policy comes as a revision of the Zimbabwe National Policy for Information and Communication Technology (ICT) of 2015. It was noted that the policy was found to be limited in terms of serving as a document spelling out the requirements for such systems. The policy did not have any specific mention of health records, let alone EHRs and EMRs.

The same respondent was further asked about the existence of a legal/policy requirement for the encryption of data generated and contained in EHRs and EMRs and whether there were any auditing requirements for such systems and it emerged that there was no such a policy on encryption, but was *"not sure"* whether there was a requirement for the auditing of such systems. The responses of the participant are summarised in Table 4.4.

Table 4.4: Requirements on institutions hosting and managing EHRs and EMRs

Question	Response
1. Are there specific rules governing institutions on hosting and processing EHRs and EMRs? If yes to question 1, name the rules….	*"Yes"* *"IT policy I think"*
2. Is there a legal/policy requirement for the encryption of data generated and contained in EHRs and EMRs systems? If yes to question 2, name the law/policy…	*"No"*
3. Are there auditing requirements for	*"Not sure"*

EHRs and EMRs? If yes to question 3, name the document containing such a requirement	

From the data presented in the table above, it can be noted that although there were rules regulating institutions that handled and processed EHRs and EMRs, policy requirements for encryption and auditing patient data help in such systems were not clearly pronounced.

4.6.3 Patient consent

In light of the technological volatility of EHRs and EMRs, coupled with the sensitivity of health records in general, the researcher asked a couple of questions relating to this aspect. The researcher intended to find out whether patients were made aware of the creation of their records electronically as this had implications on their shareability, security, privacy and confidentiality. Under this theme, the Zimbabwe Patient Charter was cited as the policy document that specifically addressed issues of patient consent. When asked whether such a policy specified the conditions under which the patient can consent in terms of the creation of their record in electronic means, the respondent indicated that the policy did not provide for this, whilst the same respondent indicated that they did not know any other policy/law that addressed the question.

It further emerged, from the respondent, that there were no policies specifically talking to the conditions under which EHRs and EMRs were shareable and a policy on the conditions under which such records were to be shared did not exist. Table 4.6 summarises the responses. From the responses, it is discernible that there was no specific policy that spoke to issues of patient consent as far as the creation and sharing of EHRs and EMRs are concerned. The Patient Charter that the respondent cited was only specific about consent in relation to the medical procedures that may need to be conducted on a patient and nothing specific was said about consenting to the creation and sharing of EHRs and EMRs.

Table 4.5: Patient consent

Question	Response
1. Are there specific legal/policy rules on patients' consent for EHRs and EMRs in Zimbabwe? If yes to question 1, name the legislation/policy rule	*"Yes"* *"Patient Charter"*
2. If yes to question 1, does the legislation/policy specify the conditions under which EHRs and EMRs should be created? If yes to question 2, name the legislation/policy and briefly state its provisions	*"No"*
3. If no to question 2, what governs the creation of EHRs and EMRs in Zimbabwe?	*"I don't know"*
4. If yes to question 1, does the legislation/policy specify how and under what conditions should EHRs and EMRs be shared in Zimbabwe? If yes to question 4, name the legislation/policy and briefly explain its provisions	*"No"*
5. If no to question 4, what governs the sharing of EHRs and EMRs in Zimbabwe?	The was no response to this question
6. When a patient opts-in or opts-out, which legislation/policy governs the conditions under which that can happen?	There was to response to this question
7. If yes to question 6, what does the law/policy say?	There was no response to this question
8. Is the law/policy specific on whether consent must be given in writing or not?	*"No"*

As shown in Table 4.5, three questions did not receive responses from the participant. From the responses given above, it can be noted that the policy and legislation governing issues of consent regarding the creation and sharing of EHRs and EMRs were seemingly absent and the healthcare facilities were reliant on the policies and laws that govern traditional paper environment.

4.6.4 Creation, access and update of EHRs and EMRs

EHRs and EMRs are not products of the activities of one person but many players and are not created in a linear fashion. Furthermore, these records have potential of being modified or updated by almost everyone who lays their hands on them. This necessitated an understanding of the framework within which these records were being created, accessed and updated or modified by those involved in the chain of their creation and management. A question pertaining to the existence and contents of a policy/legal instrument spelling out who creates, uses and shares patient information contained in EHRs and EMRs was asked, to which the participant responded by indicating that there was no such a policy/legislation. Other related questions related to the creation, access and updating of EHRs and EMRs were also asked and the responses are summarised in Table 4.6.

Table 4.6: Creation, access and updating of EHRs and EMRs

Question	Response
1. Are there rules governing the identification and authentication of health professionals who create, use and share patients' health records/information on EHRs and EMRs platforms?	There was no response to this question.
2. If yes to question 1, are such rules legally provided for? If yes to question 2, name the Act which specifies such rules.	*"No"*
3. Are there legal provisions or rules/policies which govern the creation of EHRs and EMRs in Zimbabwe? If yes to question 3, name the rules/policies and briefly explain their provisions…	*"Not sure"*
4. Is there a policy/legal document/rule(s) that specifies the	*"Yes"*

categories of access to health information that is held/created on EHR and EMR? If yes to question 4, name the policy/legislation/rule(s) and briefly explain its provisions…	*"Check with IT"*
5. If yes to question 4, does the policy/legislation/rule(s) contain any specific prohibitions on access to patient information held/generated on EHRs and EMRs? If yes to question 5, name the policy/legislation/rule(s) and briefly explain its provisions	There was no response to this question There was no response to this request.
6. If yes to question 4, is the policy/legislation/rule(s) explicit on exceptions to access requirements in emergency situations? If yes to question 6, name the policy/legislation/rule(s) and briefly explain its provisions.	There was no response to this question There was no response to this request
7. Is there a legal obligation for health professionals to update EHRs and EMRs in Zimbabwe? If yes to question 7, name the legislation/policy and briefly explain its provisions	*"No"*
8. Is there a policy/rule(s) on the rights of patients to their data that is held on EHRs and EMRs systems? If yes to question 8, name the policy/rule(s) and briefly explain its provisions.	*"Yes"* *"Charter"*
9. If yes to question 8, is the policy/rule(s) clear on any restrictions that patients have? If yes to question 9, name the policy and briefly explain its provisions	*"Yes"* There was no response to this request
10. If yes to question 8, is the	There was no response to this question

policy/rule(s) clear on the right of patients to download their health records or data from EHRs and EMRs platforms? If yes to question 10, briefly explain its provisions.	There was no response to this request
11. If yes to question 8, is the policy/rule(s) clear about the right of patients know who accessed their health records/information that is generated or held on EHRs and EMRs platforms? If yes to question 11, name the policy/rule(s) and briefly explain its provisions	*"No"* There was no response to this request
12. If yes to question 8, does the policy/rule(s) grant patients the right to modify or erase data from EHRs and EMRs?	*"No"*
13. Are there specific rules on patient specific identification number for e-health purposes? If to question 9, name the rules and briefly explain their provisions	*"No"*

As shown in Table 4.6, some questions did not receive responses. As for those that received responses, the informant singled out the Patient Charter as being the applicable document specifying the rights of patients to their own data that is held in EHRs and EMRs systems. However, a closer examination of the Charter revealed that it did not contain anything specific to access to information by patient, let alone on EHRs and EMRs platforms.

4.6.5 Rules on EHRs and EMRs standards

EHRs and EMRs standards need to be supported by relevant rules to enhance compliance. Two (2) out of three (3) respondents, on the basis of relevance, were asked a couple of questions pertaining to this aspect. When asked about the availability of such policies, both respondents indicated that such policies existed. When asked to name such policies, one (1)

respondent did not mention the policies. Of the two (2) informants who responded to further questions about this, one (1) of them named the MoHCC ICT Policy as the document that governed the use of standards whilst one (1) mentioned that there were no policies that were specific to the MHCC, but there was reliance on general ICT policies such as the Cyber Security Act, the Government's ICT Policy and others.

The researcher could not gain access to the MoHCC ITC Policy as it was not yet on the public domain. When further asked whether there were supporting policies on the monitoring and compliance with EHRs and EMRs, the respondent who mentioned the MHCC ICT Policy continued to cite the MoHCC ICT Policy and the *"Responsible Use Policy"* and cited the *"Employee Code of Conduct",* which are internal documents that the researcher was not privy to and thus, was not in a position to scrutinise those for the purposes of understanding their contents and coverage of standards for EHRs and EMRs systems.

The other respondent who cited the Cyber Security Act and the Government ICT Policy, noted that however, there were no policies or legislation that was specific to the MHCC and although efforts were being made to come up with Ministry specific policies. The respondent, in response to the question of the availability of policies/legislation on EHRs and EMRs rules, was cited as saying *"In the process of developing MoHCC specific policies. None specific [to] the MoHCC but build on Cyber Security Act, Gvt [Government] ICT Policy, e.t.c. Still a dark area and work towards establishing that is underway."*

Given the fact that standards are voluntary, save for those that have been referenced at law, a further question to establish whether there were any mechanisms of subjecting the existing EHRs and EMRs systems to any scrutiny as a way of enhancing compliance was asked. The respondent indicated that the systems were subjected to such checks by the e-PWS TWG. It, however, emerged that no quality assurance body had a legal mandate, including the MHCC, to enforce compliance with EHRs and EMRs standards.

4.6.6 Archival standards for EHRs and EMRs

It is very common for archival issues to be given last minute considerations at best and reactive attention at worst in electronic information management systems. The study sought to understand the archival standards for EHRs and EMRs. The respondent who was asked this question revealed that there were no archival standards as yet and that backup systems

were being used for archival purposes. The respondent, when asked to name the archival standards that the EHRs and EMRs were operating on, revealed that this was *"an area that needed further work"* and that there was *"no policy to support"* the archiving of EHRs and EMRs for now. The respondent continued to reveal that the *"archival Act was pronounced way b4 [before] independence"*, comments that point to the weakness of the existing National Archival of Zimbabwe Act of 1986 with regards to the archiving of electronic records in general.

4.6.7 Application of EHRs and EMRs standards, policies and laws in private healthcare facilities in Zimbabwe

In light of the mushrooming of EHRs and EMRs in both the public and private sectors and the fact that the MHCC was the responsible for policy pronouncement in the healthcare industry, the researcher sought to establish whether the Ministry was enforcing and directing standardisation efforts in the private sector of Zimbabwe. One (1) questionnaire respondent from a Department that was deemed the most relevant was engaged on this. When asked whether the MHCC, as the policy custodian, was aware of the use of EHRs and EMRs systems by healthcare facilities in the private sector, the respondent did not respond.

A further question was asked whether there were any policies/laws/regulations for private healthcare facilities to use or comply with any standards for EHRs and EMRs, to which the informant responded by indicating that such policies/laws/regulations did not exist. However, the respondent, when asked whether healthcare facilities were allowed to roll out EHRs and EMRs systems that were not defined or approved by the MHCC, the respondent indicated that that was not permissible. When asked to explain their response or name the document which prohibited healthcare facilities from doing so, the participant did not respond.

Other related questions were asked and the respondent indicated that the MHCC had intentions of fostering standards for EHRs and EMRs in the private sector, and that the use of common standards was preferable in both the private and public sectors, given the fact that medical conditions are basically the same in both sectors. The respondent further indicated that the MHCC was better positioned with regards to the monitoring of the implementation and compliance of such standards, citing the availability of policies and expertise as some of the reasons for such a position. Questions and responses relating to the application and

regulation of EHRs and EMRs standards in the private sector of Zimbabwe are presented in Table 4.7.

Table 4.7: Application and regulation of EHRs and EMRs standards

Question	Response
1. Are private healthcare facilities already using EHRs and EMRs systems?	There was no response to this question.
2. Are private healthcare facilities in Zimbabwe compelled/guided by any regulations/policy/law to use any standards in the implementation of any EHRs and EMRs systems? If yes, name the regulations/policy/law and briefly explain their provisions	*"No"* There was response to this request.
3. Are private healthcare facilities allowed to use EHRs and EMRs that are not defined by the MHCC?	*"No"*
4. If no to question 2, does the MHCC intend to pronounce and common standards for EHRs and EMRs for both the public and private healthcare facilities? If yes to question 3, name the document that contains such the policy on that and briefly explain its provisions……	*"Yes"* There was no response to this request.
5. If no to question 3, how does the MHCC intend to foster EHRs and EMRs standards adoption by private healthcare facilities?	*"Through training, through regulations. The private sector is in business and don't [sic]have time"*
6. Do you think that it is feasible for both private and public healthcare facilities to use common EHRs and EMRs standards? Give reasons for your answer.	*"Yes"* *Health conditions are the same and gvt [Government] can take the lead."*
7. Do you think that the Ministry has the capacity to monitor the	*"Yes"*

implementation and compliance with EHRs and EMRs standards by private healthcare facilities? Give reasons for your answer.	*"There are policies and experts plus more."*

It can be noted that the MHCC felt that it was better positioned in terms of regulating the application or use of EHRs and EMRs in the private sector as well, although the data indicated that by the time this study was conducted, the Ministry was not aware of which and how many such systems had been rolled out across the healthcare delivery systems and whether such systems were standardised or not in the private sector. This implies that healthcare facilities were left to roll out EHRs and EMRs systems with the MHCC not taking stock of such systems, let alone which ones were standardised and which ones were not and which standards were being adopted, if any. It would seem the regulation of the application and standardisation of such systems was not yet a priority. In fact, one (1) questionnaire respondent from the MHCC, when asked about the foreseen barriers regarding the adoption of standards for EHRs and EMRs, he/she cited lack of legislation to make the private sector conform to standards. The respondent, citing the foreseen barriers, was quoted as saying *"legislation to push private [sector] to conform to stds [standards]."*

4.7 Support and sustainability of EHRs and EMRs standards

Because the study aimed at developing a framework of standard for the implementation of EHRs and EMRs standards in the health sector of Zimbabwe, the study further sought to understand whether the MHCC, being the policy maker and custodian in the field of health, was prepared to support and sustain standards for such systems. Data for this section was gathered from all the three questionnaire respondents who were asked different but related questions about this objective.

When asked whether the MHCC was in a position to implement and monitor the adoption and compliance with EHRs and EMRs standards, the three questionnaire responses gave different positions, with the first one indicating that the Ministry was not prepared, the second one saying that the Ministry was capacitated, with the third one saying that the Ministry was not capacitated. The first respondent indicated that the Ministry was not read, indicating that there was no *"capacity to do so & the lack of the STD [standard] tools to facilitate that."*

The second respondent indicated that the Ministry was prepared and had the capacity to develop, roll out and monitor standards in Zimbabwe whilst the other one indicated that the Ministry was partly capacitated. This respondent, when asked to justify his/her response, indicated that the Ministry would leverage on *"a pool of software engineers and the ICT Policy/Health financing policy",* whilst the third respondent indicated that the MHCC was partly capable to undertake this project, although he/she did not cite the reasons for his/her response.

When asked whether it was part of the MHCC to roll out standards for EHRs and EMRs, all the three (3) respondents agreed that the Ministry intended to roll out such standards. The two (2) respondents who indicated that the MHCC was fully and partly capacitated to develop, implement and monitor standards for EHRs and EMRs in Zimbabwe, however, singled out limited funding as the constraint to support and sustain the development, implementation and monitoring such standards. When asked about the financial capacity of the MHCC to support such a project, the respondent who indicated that the Ministry was capacitated to undertake such projects, was quoted as saying *"little resources are allocated from Treasury"* whilst the one who indicated that the Ministry was partly capacitated revealed that that the budget for such standards existed *"though not adequate."* It was, however, noted that the Government of Zimbabwe had already established a standards development levy fund through an Act of Parliament, to specifically fund the standards development activities in Zimbabwe, as revealed by the respondents at SAZ.

When asked about the ability of the MHCC to play its role with regards to the development, implementation and monitoring compliance with standards for EHRs and EMRs, one respondent indicated that the Ministry may not be able to play its role due to *"political interference from within the organisation, political interference by other departments & donors."*

4.7.1 Relationship of the MHCC with international EHRs and EMRs standards bodies

The study further sought to understand the relationship that the MHCC had with standards bodies regarding standards for EHRs and EMRs. To address this question, the researcher identified major international developers of standards for such systems and other health information management standards and asked the respondents to indicate the ones to which the Ministry had affiliations or collaborated with and explain the nature of the relationship.

Of the two (2) respondents who were asked about this relationship, one (1) indicated that he/she was not sure whether the Ministry had any relationship with any of those standards developers, whilst one (1) respondent indicated that the Ministry had a relationship with the Health Level Seven Inc (HL7) in the areas of EHRs and EMRs standards. Table 4.8 summarises the responses of this participant.

Table 4.8: Relationship between the MHCC and international health information and records standards developers

Question: Does the MHCC have any relationship/arrangement with any of the following standards organisation regarding the development, implementation or monitoring compliance with EHRs and EMRs?

Standards Organisation	Yes	No
Comite Europeen de Normalisation (CEN/TC 25)		x
Health Level Seven Inc (HL7)	x	
Digital Imaging and Communications in Medicine (DICOM) Standards Committee		x
Japanese Association of Healthcare Information Systems Industry (JAHIS)		x
Medical Information System Development Centre (MEDIS-DC)		x

When further asked whether there was a standards selection, implementation and monitoring committee, the respondent indicated that such a committee existed and was known as the *"Electronic Patient Monitoring Systems Technical Working Group."*

The last objective was to develop a framework for EHRs and EMRs standards implementation in the health sector of Zimbabwe. This objective was addressed in Chapter Six of the study.

4.8 Key findings of the study

It is necessary and beneficial for the reader, after immersing himself/herself in his data analysis and presentation, to provide the readers with "take homes", in the form of major findings. Such major findings are seen as a synthesised statement of the outcome of the data analysis exercise in light of the research problem and objectives. The following section, therefore, presents key findings of the study.

- Various EHRs and EMRs were in the process of being rolled out in the health sector of Zimbabwe and there was no stock of which systems have been rolled out and the extent to which such systems had been rolled out.
- The various EHRs and EMRs that had been rolled out across the health sector of Zimbabwe were not yet standardised and there still existed silos of health information between the public and private health sectors and between facilities in each sector as such systems were not yet interoperable. Limited standardisation was reported within the MHCC, albeit without a clearly defined framework.
- There was limited coordination and interaction between the private healthcare facilities and the MHCC with regards to the coordination and standardisation of EHRs and EMRs systems.
- The only standards body in Zimbabwe, SAZ, had not yet developed standards for EHRs and EMRs, owing to a lack of stakeholder cooperation. SAZ was a full member of ISO and was able to adopt standards, including those for EHRs and EMRs, but was not yet able to review and customise them due to the dearth of stakeholder cooperation.
- There was no relationship between SAZ and the MHCC with regards to the development, implementation, and compliance monitoring of standards for EHRs and EMRs, although there was a standing MoU between the two entities which have been used to standardise other areas of health.
- SAZ was established through the Companies Act, and not an Act of Parliament, and therefore, did not have the legal mandate to compel organisations to comply with standards.
- There were no specific policies and legal stipulations on the standardisation of EHRs and EMRs. The MHCC relied on different policies to augment the standardisation of its EHRs and EMRs systems and other health information systems.
- The MHCC was the body with regulatory powers regarding which standards for EHRs and EMRs to adopt across the healthcare delivery system in Zimbabwe, but the Ministry was not yet regulating the application of standards, especially in the private sector.
- The MHCC was policy wise and technically prepared to support the standardisation of EHRs and EMRs across the health sector of Zimbabwe, but cited financial constraints

as a potential challenge. The MHCC intended to have all the EHRs and EMRs systems across the healthcare standardised.

- The whole process of standardisation for EHRs and EMRs was not coordinated and there was no step by step documentation on how to go about it and the terrain for the standardisation of such platforms was generally weak.

4.9 Summary

The thrust of this chapter was the presentation and analysis of data that was gathered from five (5) participants who participated in the study. The chapter consists of an introduction in which the researcher explained what data analysis entails and why it was necessary, especially in light of the qualitative nature of the present study. In that section, the nature and legitimacy of qualitative data analysis were given. Owing to the qualitative nature of the study, the data presentation and analysis sections were characterised by themes that emanated from the research objectives. The sections are also typified by directed quotations, either as part of the text or in tabular formats. Thus, the voices of the respondents were prominent throughout the data presentation and analysis process. The chapter ends with a synthesis of the analyses by giving key findings that emerged from the analysed data. Because the impetus of the data presentation and analysis section is logical and sequential statement of one's research findings without interpretation (University of Southern California 2018), the following chapter was dedicated to the interpretation of data.

CHAPTER FIVE
DATA INTERPRETATION AND DISCUSSION

5.1 Introduction

With the previous chapter having analysed and presented the study data, the thrust of this chapter is data interpretation. Data interpretation in research is inevitable, given the fact that data needs to be given meaning in the context of the problem and research objectives of the study. The interpretation of data was also done within the realm of the conceptual framework which the researcher developed to conceptualise the problem. Because data analysis is about finding meaning in something, it demands that one engages with something, for example, text or image in a manner which enables them to make kind of sense of it (Willig 2013:136).

Essentially, the interpreter plays the role of bringing to light, those aspects or dimensions of the phenomenon which are not so obvious, yet important to allow whoever is studying it to gain a better understanding of what it may be (Willig 2013:136). Data interpretation usually, if not always, comes after data analysis, an indication of the complementary nature of the two activities. Thus, the previous chapter was on data analysis and acted as the basis of the present chapter. Data analysis, on one hand, involves the manipulation of data whilst interpretation, on the other hand, has its thrust being making sense of data via more abstract conceptualisations (Spiggle 1994:497).

A historical glimpse of the term interpretation reveals that the term was originally used to imply the act of making sense of those documents that were particularly difficult to understand or obscure documents that had been revered and kept sacred for lengthy periods of time, examples of which include mythical or religious writings (Willig 2017:277). In such cases, interpretation became an indispensible activity, given the fact that such ancient documents did not carry obvious sense to contemporary audiences (Willig 2017:277). Etymologically, the term interpretation, which, in some circles is used synonymously with hermeneutics, later expanded in meaning to include any act whose outcome is the elucidation of meanings of written texts across disciplines (Willig 2017:277). This implies that the term is no longer restricted, in meaning and application, to ancient or medieval and sacred dossiers whose meaning was hidden from the general and modern readers, but now applies to any act of sense-making across disciplines.

In the context of research, the term analysis is used to refer to the act of deriving meaning from data that has been gathered by the researcher. From the etymology of the term, it can be discerned that the term and act of interpretation was primarily associated with qualitative phenomena, that is, texts or documents, which makes it more applicable to qualitative research, although quantitative researchers have also embraced the concept in their research. Data interpretation is at the core of qualitative research in the sense that qualitative research is essentially about meaning and meaning construction (Willig 2017:276). This is particularly so in light of the fact that qualitative studies tend to yield complex data whose meaning is hidden as it is always context-dependent, thereby making analysis a cumbersome exercise, which, however, requires the researcher to immerse himself or herself in the data at hand, with undiluted meticulousness.

As observed by Spiggle (1994:497), the fact that qualitative data is inherently intuitive, subjective, particularistic in nature, the subsequent interpretation of such data tends not to render itself to model or linear interpretation. Rather, interpretation tends to be done as a "gestalt shift and represents a synthetic holistic, and illuminating grasp of meaning as in deciphering a code" (Spiggle 497). The present study was also located in the interpretivist paradigm, thereby generating qualitative data, which is presented in the subsequent sections of this chapter. In doing so, the researcher was enlightened and aided by related literature in the form of best practices as well as related studies to make sense of the data under consideration.

5.2 Existing standards for EHRs and EMRs in the health sector of Zimbabwe

Data revealed that a few standards were in use in the public sector, whilst the Ministry did not know what was happening in the private sector. The standards that were reportedly in use include the ICD 10 and the Integrated Care Pathway (ICPCZ), with the only security standard or measure being encryption. The ICD 10 is a vocabulary standard whilst the ICPCZ is a quality standard. The use of these standards was plausible as this meant that there was standardised content through the use of the ICD 10 standard and improved and coordinated quality assurance regarding the delivery of health through the ICPCZ standard. The use of encryption also meant that confidentiality and confidentiality was upheld.

However, it can be noted that very few and inadequate standards were in use in the EHRs and EMRs systems. This implies that such systems were partially standardised and major standards requirements were still missing in the systems. Thus, the adoption of EHRs and EMRs standards in the health sector was no satisfactory in comparison to other countries. For example, the Government of India, through its Ministry of Health and Family Welfare has detailed and clearly defined standards for EHRs, EMRs and other health information systems that are in use in its health sector and when compared to Zimbabwe, it implies that the following key categories of standards were missing in the country's EHRs and EMRs systems, which shows how much Zimbabwe was missing.

Table 5.1: Health information standards in use in India

Category of standard	Importance	Examples
Identification and demographic data about patients	*"Demographic information including a unique identifier is necessary in a health record system in order to capture identifying information as well as identifiers for linking other medical artefacts logically as well as physically"*	ISO/TS 22220:2011 Health Informatics – Identification of Subjects of Health Care
Architectural requirements and functional specifications	*"A health record system must meet architectural requirements and functional specifications to remain faithful to the needs of service delivery, be clinically valid and reliable, meet legal and ethical requirements, and support good medical practices"*	***1.*** ISO 18308:2011 Health Informatics – Requirements for an Electronic Health Record Architecture ***2.*** ISO/HL7 10781:2015 Health Informatics - HL7 Electronic Health Records-System Functional Model Release 2 (EHR FM)
Logical information reference model and structural composition	*"A health record system must accumulate observable data and information for all clinically relevant events and encounters. For this purpose, it is important to have common semantic and syntactic logical information model and structural composition for captured artefacts. Unless the data being captured is standardized, its communication and understanding may not be same across systems"*	***1.*** ISO 13940 Health Informatics - System of Concepts to Support Continuity of Care ***2.*** ISO 13606 Health Informatics - Electronic Health Record Communication (Part 1 through 3) ***3.*** OpenEHR Foundation Models Release 1.0.2 3.1 Required Model Specifications: Base Model, Reference Model, Archetype Model 3.2 Optional Model Specifications: Service Model, Querying, Clinical Decision Support
Data standards for image, multimedia, waveform, document	*"A health record system stores data records and files of various types in support of clinical functions. These data elements serve the purpose of documentary records of various diagnostic and prescriptive data or information generated"*	***1.*** NEMA Digital Imaging and Communications in Medicine (DICOM) PS3.0-2015 ***2.*** Scanned or Captured Records: ***i*** Image: JPEG lossy (or lossless) with size and resolution not less than 1024px x 768px at 300dpi 2.2

		ii Audio/Video: ISO/IEC 14496 - Coding of Audio-Visual Objects 2.3 Scanned Documents: ISO 19005-2 Document Management - Electronic Document File Format for Long-Term Preservation - Part 2: Use of ISO 32000-1
Data exchange standards	*"A health record system has to operate in a larger ecosystem of other components with which it must share or communicate data in order to capture and provide as comprehensible medical information as is practical"*	***1.*** Event/Message Exchange: ANSI/HL7 V2.8.2-2015 HL7 Standard Version 2.8.2 - An Application Protocol for Electronic Data Exchange in Healthcare Environments ***2.*** Summary Records Exchange: ASTM/HL7 CCD Release 1 (basis standard ISO/HL7 27932:2009) ***3.*** EHR Archetypes: ISO 13606-5:2010 Health informatics - Electronic Health Record Communication - Part 5: Interface Specification ***4.*** Imaging/Waveform Exchange: NEMA DICOM PS3.0-2015 (using DIMSE services & Part-10 media/files)

Source: Government of India, Ministry of Health and Family Welfare (2016:10-14)

The absence of architectural requirements as well as functional specifications and identification and demographic patient data standards implies that there is no coordinated manner of designing systems for EHRs and EMRs and basic identification details for patients as well as their demographic details, respectively. The absence of logical and structural standards in the systems meant that the patient information and related health data captured in the systems in use could not be communicated in a logical comprehensible manner to support healthcare, while the absence of data exchange standards meant that health data could not be exchanged. A combination of the afore-mentioned factors tends to greatly limit the realisation of the benefits of EHRs and EMRs as the absence of just one standard requirement may have a domino effect on the intended benefits of such systems.

5.2.1 EHRs and EMRs in the health sector of Zimbabwe

Data indicated that the health sector of Zimbabwe has rolled out EHRs and EMRs systems as revealed by respondents in the MHCC Head Office. Examples of such systems include the EHR (name of the system), Epms, OpenEMR and ePOC. This implies that Zimbabwe's health sector was on the same page with the rest of the world as far as the implementation of such systems is concerned. For example, as early as 2005, a number of EHRs and EMRs systems had been rolled out in Africa and elsewhere in the world. Fraser, Biondich, Moodley, Choi, Mamlin and Szolovitis (2005:85-87), in their study, reported on a number of such systems, including the Mosoriot Medical Record System in Kenya, the Partners In Health Electronic Medical Record (PIH-EMR) in Peru, the HIV Electronic Medical Record system (HIV-EMR) in Haiti, Careware in Uganda, Lilongwe EMR in Malawi, the Computerized System for the Control of Drug Logistics (SILOCOM) in Brazil.

In Zambia, the Daily Nation (2018) reported on the implementation of SMARTCARE, which is said to be a fully integrated EHR meant to replace paper records in that country. Zambia first adopted the smart card systems in 2005 as part of its e-health strategy, and by 2010, the smart card system was already in use in 552 healthcare facilities in that country (Association of Chartered Certified Accountants 2013:25). Thus, Zimbabwe has managed to keep pace with international developments in terms of improving healthcare through the use of EHRs and EMRs.

Given the revelation that there were no audits of the existing EHRs and EMRs in Zimbabwe's health sector, it implies that the MHCC, as the regulatory authority, did not have accurate statistics of how many such systems had been rolled out or were in use in the health sector. This also implies that the MHCC did not know how such systems were fairing in every regard. This further meant that the MHCC was not able to measure the amount of progress that the health sector had made in terms of the dicta of the Zimbabwe's e-health Strategy (2012-2017), a brainchild of the same Ministry. According to the Ministry of Medical Services and the Ministry of Public Health and Sanitation in Kenya (2010), the success of healthcare is contingent on the coordination of the development, deployment, implementation as well as maintenance of EHRs and EMRs systems.

Although data from the Head Office of the MHCC revealed that efforts were being put to come up with a multi sectorial approach to the deployment and monitoring of EHRs and their

standards, the status quo at the time of conducting research which was characterised by a dearth of audits for EHRs and EMRs and lack of statistics regarding the number and types of such systems in use in the health sector spelt potential problems for the health sector. For example, the fact that the MHCC, as the overseer of health matters in the country, including health records and information, implies that the Ministry did not know which systems were in place in the private sector and whether such systems were compliant with the privacy and confidentiality issues or not. Thus, the deployment and use of EHRs and EMRs systems were not coordinated.

This situation also had great potential of causing serious challenges when it comes to enforcing interoperability in EHRs and EMRs systems in Zimbabwe as incorporating interoperability in retrospect is a great challenge. A good lesson can be drawn from Kenya where the Ministry of Medical Services and the Ministry of Public Health and Sanitation (2010:6-7) in Kenya reported that the health sector of that country witnessed an uncoordinated adoption of EHRs and EMRs systems, resulting in multiple systems with varying objectives and functionalities. This created confusion, prompting the afore-mentioned ministries in that country coming up with "Standards and Guidelines for Electronic Record Systems in Kenya" in an endeavour to ensure that such systems were able to share patients' information. In another cases, Katurura and Cilliers (2018:2) also reported that the health sector of South Africa was in a predicament of EHRs systems that often failed to communicate to each other and share information as a consequence of rolling out disparate systems developed by different vendors with different database architectures.

Literature shows that the challenge of having many disparate EHRs and EMRs systems being rolled out, without the authorities knowing how many or which systems are deployed in the health sector was also typical of the developed world, including the USA. May (2018), quoted the HIMSS Analytics Executive Vice President, Blain Newton lamenting this challenge in the following words "a big problem is exactly how many EHR companies are out there and, more specifically, the average number of platforms hospitals are running today." Thus, the coordination of the development and deployment of EHRs and EMRs was still a serious challenge in healthcare, not only in Zimbabwe as revealed by the present study, but the world over.

Data also revealed that funding for EHRs and EMRs in the public sector was largely dependent on donations, whilst the Ministry did not know what was happening in the private

sector. Such dependence on donor funding by the MHCC regarding funding for EHRs and EMRs systems was not typical of Zimbabwe only, but systems in Africa. This was lamented by Anon (2010), cited in Adebesin, Foster, Kotze and van Greunen (2013:65), who observed that that in general, the implementation of health information systems projects in Africa tends to lack coordination, particularly at national levels, in which case, with the majority of such implementation projects being driven by donor-funded vertical programmes for specific cases such as HIV/AIDS and TB, monitoring and evaluation. Dependence on donor funding for such projects serves to demonstrate how costly EHRs and EMRs can be for the developing world to which Zimbabwe belongs.

A study that was conducted by Moucheraud, Schwitters, Boudreaux, Giles, Kilmarx, Ntolo, Bangani, Louis and Bossert (2017:5) covering Malawi, Zambia and Zimbabwe revealed that the maintenance of the Electronic Health Information Systems (EHIS) in the three countries was associated with high costs, coupled with relatively low priority for the system within national budgets and that the systems were donor funded As Silvestre (2018:16) explained, the development, implementation and sustainability of a national EHR is greatly contingent on health funding such that even in instances where there is donor funding for health information systems, there are always direct and indirect costs which come in the form of hardware, software, routine maintenance as well as security enhancements.

Additional costs also include human resources expenses such as training costs, change management expenses as well as logistics expenses (Silvestre 2018:16). Reliance on donor funding carried with it, one greatest disadvantage, which is manipulation by the donor, a predicament that financially ill-resourced e-health projects, especially in the developing countries face (Moucheraud et al 2017:4). For example, Moucheraud et al (2017:4) in their study on the sustainability of EHIS in Malawi, Zambia and Zimbabwe, reported that while external funding comes with indisputable benefits, it comes with deliverables and some of their study respondents revealed concerns over donors using their influence to determine both the content as well as the deployment of EHIS so that they meet their own priorities and time lines. In the context of the present study, one (1) respondent from the MHCC revealed that there was political and donor influence regarding finding for health. This implies that the systems that the Ministry was deploying were also at a risk of being held at ransom by donors.

It would seem EHRs and EMRs projects in Zimbabwe did not enjoy much of Government support, financially, resulting in the relatively slow rate of adoption, seemingly in a less coordinated fashion. This finding seemed to tally with findings of a study that was conducted by Furusa and Coleman (2018) in which they found out that the health sector of Zimbabwe was poorly funded, a situation that culminated in failure by Government to channel adequate funds towards the acquisition of ICT resources that are needed in the sector.

The challenge of under-funding for such projects was not only typical of Zimbabwe's e-health system but many African countries. Akanbi, Ocheke, Agaba, Daniyam, Agaba, Okeke and Ukoli (2012), in their study titled *"Use of Electronic Health Records in sub-Saharan Africa: Progress and challenges"*, registered high costs of setting up and maintaining EHRs as the most documented challenge bedevilling African countries when it comes to the implementation of EHRs systems, resulting in African countries adopting open source systems, including South Africa, Tanzania and Uganda. Paton and Muinga (2018) also reported that the Government of Kenya was left with no option but to adopt the OpenMRS open source system in HIV and TB clinics due to high costs of proprietary systems.

The picture obtaining in low-income countries where there was limited funding for EHR and EMR projects was antithetical to that in high-income countries where the governments of the respective countries were financially supportive of such projects. For example, governments of the USA, Canada and Britain are financially supportive of such projects. The Office of the Auditor General of Canada (2010), reported that the Government of Canada granted $1.6 billion towards EHRs in the fourteen provinces of Canada. Thus, lack of government financial support towards a coordinated approach to the deployment of EHRs and EMRs in Zimbabwe is likely to result, not only in a disorderly isolated implementation, but very limited success rates as well.

Literature also shows that healthcare facilities were motivated, both financially and non-financially to adopt and implement e-health systems, something that developing countries, let alone ailing economies such as that of Zimbabwe could not afford. Taylor, Fischer, Gracner, Tejeda, Kim, Chavez-Herrerias and de la Guardia (2016:34) suggested that incentivising healthcare facilities to implement health IT projects is another means of encouraging the adoption of such technologies. In their study on the roadmap for the development of health information technology in Chile, Taylor et al (2016:31) recommended that healthcare

facilities be incentivised for the adoption of e-health technologies through the following methods:

i. Financial incentives whereby bonuses or per-service incentives are paid, particularly to those facilities which are still at their nascent stages of adoption of such technologies. Financial incentives were also common in other countries across the globe, including the USA and Australia (Taylor et al 2016:31).

ii. Non-financial incentives that may come in the form of free training for the medical and auxiliary personnel during at the infancy stages of telemedicine project implementation.

5.2.2 Pronouncement of EHRs and EMRs standards framework by the MHCC

Data further revealed that the MHCC had not yet clearly pronounced the use of EHRs and EMRs standards in the health sector save for the willingness and intention to implement standards for EHRs standards in the Zimbabwe's e-health strategy 2012-2017. A study by Furusa and Coleman (2018) also revealed a similar situation in which it emerged that the Government of Zimbabwe lacked clearly defined policies that are in support of the use of e-health systems in the public sector. Furusa and Coleman (2018), in their study, further observed "although the country has an e-health strategy (2012-2017), the policy needed to guide e-health development and technological diffusion in public hospitals is limited."

In the strategy, the MHCC (n.d:) acknowledges the importance of standards in addressing a number of pertinent aspects of e-health, including the security of patient health information, identification of patients across domains, common terminology lexicon as well as health information exchange. Thus, the Ministry is very much aware and appreciative of the need for health information management standards as one of the many critical components of a successful e-health strategy, although no noticeable steps had been taken by the Ministry in making this vision a dream come true.

Findings of the present study are also similar to those of a study by Moucheraud et al (2017:7) where it emerged that there were no "project champions" for massive and complex projects such as Electronic Health Information System (EHIS) in Zimbabwe, Malawi and Zambia. Moucheraud et al (2017:7) indicated that their study respondents explained that

projects of such magnitude needed engagement and commitment of highest level, yet it was missing amongst the authorities in the afore-mentioned countries. Thus, the dearth of project champions in EHIS could be directly linked to the absence of the same for standards for EHRs and EMRs systems in Zimbabwe's health sector where EHRs and EMRs were rolled out without a clear vision guided by designated and known champions.

Furthermore, the Ministry had not yet specified the exact standards to be used by healthcare facilities. This is different from what is usually the norm in other countries where the ministries of health have clearly pronounced standard frameworks for EHRs and EMRs for their health sectors. For example, in South Africa, the National Department of Health commissioned a report on the development of a standards policy on EHRs titled "National Health Normative Standards Framework for Interoperability of e-Health in South Africa", whose objective is to establish the basis for interoperability of healthcare systems as pronounced in the e-Health Strategy South Africa 2012-2016 (CSIR and NDoH 2013:17).

In Kenya, the Ministry of Medical Services and the Ministry of Public Health and Sanitation (2010:6-7) also came up with a document titled "Standards and Guidelines for Electronic Record Systems in Kenya" which also guides the implementation of standards for EMRs. The guidelines, according to the Ministry of Medical Services and the Ministry of Public Health and Sanitation (2010) were meant to complement the health information and strategic plan (2009-2014), which was developed by the Division of Health Information System (HIS) and the International Training & Education Centre for Health (I-TECH). A similar situation was obtaining in India as well where the Ministry of Health and Family Welfare (2016) came up with a document titled "Electronic Health Record (EHR) Standards for India-2016" containing standard specifications that the implementation of EHRs should comply with. Thus, the MHCC in Zimbabwe was yet to come up with sound EHRs and EMRs standards.

5.3 Interoperability of EHRs and EMRs systems in the healthcare system of Zimbabwe

With data indicating that there was no interoperability among the EHRs and EMRs systems in the health sector of Zimbabwe, it can be said that such systems were still not able to share health information, implying that silos of health information and data were still in existence in the sector. The dearth of interoperability implies that patients' health information existed as standalone records, a situation that had potential of delaying patient care. Interoperability

is defined by Ministry of Health of the Republic of Kenya (2016) as the ability of electronic systems to communicate and exchange data in a manner which guarantees and preserves accuracy, reliability and meaningfulness. The MHCC, as the data revealed, was on track regarding the appreciation of interoperability of EHRs and EMRs systems in the health sector and was in the process of putting the systems to test regarding standardisation and interoperability, albeit at a slower pace.

The Zimbabwe's e-Health Strategy (2012-2017) also appreciates the interoperability between EHRs systems. However, at the time of conducting the study, it was noted that the systems that were in place in the sector were still independent and disparate, resulting in isolated information stores, a situation that polarises the essence of EHRs and EMRs systems and the potential and expected benefits to be drawn from such systems. As Adebesin, Foster, Kotze and van Greunen (2013:57-58) observed, interoperability specifications should constitute an integral part of any e-health endeavour which is expected to register success, given the fact that return on investment is, to a great extent, contingent on the timely availability of health information from wherever it may be stored in support of healthcare.

The dearth of interoperability among the EHRs and EMRs systems in healthcare was not a challenge to the health sector of Zimbabwe, but a number of healthcare delivery systems, including the USA and South Africa. May (2018), in the following words, highlighted the challenge of interoperability of EHRs systems "the thorny matter of interoperability in healthcare, as it is or has historically been in other industries, is almost all-consuming among technology vendors and their clients."

May (2018) further reported that according to the HIMSS Analytics Executive Vice President, Blain Newton, in the USA, an average hospital uses 16 disparate EMRs vendors in different practices. This translated to 16 district EHRs platforms, statistics of the HIMSS Analytics drawn from its Logic database showing a 571 045 providers who were affiliated to 4 023 hospitals (May 2018). Monegain (2018) in his article titled "EHR interoperability, connectivity a big challenge around globe new study finds", reported that in the USA, a whopping 90% of his survey respondents confessed to being confused about what exactly makes a highly interoperable EHR. He further reported that Black Book Research surveyed 11 838 doctors, healthcare administrators, technology managers and clinical leaders around the world and the study revealed that 72% of them preferred linking their disparate EHRs systems through messaging, APIS, web services as well as clinic portals. The study further

revealed that just 7% of them described their regional Health Information System as having meaningful connectivity with other providers (Monegain 2018).

In Africa, the presence of healthcare systems that lack interoperability is closely linked to low levels of adoption of e-health standards, particularly at national levels (Adebesin, Foster, Kotze and van Greunen (2013:66. On top of this, Adebesin, Foster, Kotze and van Greunen (2013:66) further observed, the developing countries also face a myriad of challenges regarding the implementation of EHRs and EMRs systems standards, including the following:

i. Limited participation in the processes of standards developments;
ii. Human incapacitation with regards to standards development;
iii. Unavailability of appropriate experience regarding the application of standards;
iv. Limited understanding of the important role played by standards at national levels;
v. Dearth of key infrastructure; and
vi. Dearth of standards for implementation.

The afore-mentioned factors were seemingly largely true for the health sector of Zimbabwe, save for the appreciation of the roles and importance of standards for EHRs and EMRs systems, which are clearly captured in the Zimbabwe's e-Health Strategy (2012-2017). The limitedness of the participation of the only standards development body in Zimbabwe, SAZ, and the complete invisibility of the MHCC itself in the standards development and implementation of EHRs and EMRs standards, the lamentation of a lack of inability of the customisation of ISO developed or adopted standards to the Zimbabwean setup by SAZ respondents were some of the realities that match the factors that are generally faced by the developing world as far as the development and implementation of interoperable EHRs and EMRs systems are concerned. This was so despite indications by one of the MHCC respondents who said that the Ministry had a pool of expertise on which to leverage for the development of EHRs and EMRs standards.

The observations of Adebesin, Foster, Kotze and van Greunen (2013:66) are corroborative of those of the International Telecommunication Union (2009:5) which indicated that the inequalities in terms of national standards capabilities continue to account for the incessant divide between the developed and developing words, thereby thwarting any opportunities for economic and technological innovation.

Although literature indicates that developing and rolling out interoperable EHRs and EMRs systems was still a global challenge, including the developed world, literature shows that future systems are set to eliminate this challenge. For example, a 2018 report on the state of the global EHRs industry predicted a shift from independent EHRs` systems producing silos of health information towards systems that can share information even on a regional scale in Europe, the Middle East and South Asia (Monegain 2018). Participants in the Black Book Research survey were reportedly anticipating a shift towards EHR systems that facilitate data exchange and care coordination facilities that resemble the ones that the US vendors are offering by 2023 (Monegain 2018). In South Africa, Chowles (2016) reported that the NDoH in South Africa developed the its e-Health Strategy in 2012, which recognised the need for interoperability standards for the improvement of efficiency in clinical care, production of data needed by management and facilitation of patient morbidity. It is that strategy that culminated in the production of the National Health Normative Standards Framework Standards (HNSF) by the NDoH and CSIR (Chowles 2016).

Still in South Africa, Katuu (2017:242) reported that in the year 2000, South Africa had a plan to develop a National Electronic Health Record known as eHR.ZA whose objective was to integrate patient data in the public and private sectors. In 2009, wide consultations were done between provincial ministries and the Minister of Health resulting in a resolution that there should not be further acquisition of software that was not interoperable pending the finalisation of the eHealth Strategy South Africa (2020-2017) after realising that South Africa had about 42 disparate health information systems dotted around its provinces (Department of Health, South Africa 2014 cited in Katuu 20217). This further demonstrates the problem of rolling out EHRs and EMRs systems that are not based on interoperability standards.

In the USA, the Office of the National Coordinator for Health Information Technology also developed a document titled “A Shared Nationwide Interoperability Roadmap Draft Version 1.0” whose objective was to guide EHRs and EMRs, especially with regards to their interoperability. In New Zealand, Park and Atalag (2015) reported, the government-run Health Information Standards Organisation (HISO), in 2011, brought together a group of experts who authored an interoperability standard titled “Interoperability Reference Architecture” whose essential sections were standardised into the Health Information Exchange Building Blocks and were later on ratified as an interim standard by HISO. The standard, according to Park and Atalag (2015) is composed of three pillars which are as follows:

i. HISO 10040.1 whose focus is on clinical data repositories and how they interface with each other. This strand of the standard prescribes the requirements for a particular set of services that share documents using the HIE XDS integration profile. XDS offers definitions of methods of storage, location and retrieval of data from multiple sources of repositories whose scope may stretch up to regional and national levels. All this is made possible by the existence of a registry which provides a consolidated index over the entire contents across the ecosystem.

ii. HISO 1004.2 whose thrust is the "establishment of a single content model for supporting the semantics of information exchange. It is based on CCR specification and prescribes a set of detailed clinical models expressed as openEHR archetypes."

iii. HISO 10040.3 which stipulates the use of documents that are structured using HL7 CDA as the common means of exchange.

In Canada, interoperability of EHRs is fostered through a national interoperability document known as the Canada Health Inforway's EHRS Blueprint Version 2 of 2006 which serves as a framework for pan-Canadian Electronic Healthcare Records interoperability (Lennon 2014:71). The blueprint provides an architectural framework called the EHR Infrastructures that are deployable at provincial-territorial levels (Lennon 2014:71). The EHRs infrastructures are essentially constructed around key repositories, that is, copies of original data such as laboratory information, prescription information, diagnostic imaging information as well as shared health records and these are made accessible via a dedicated portal referred to as the EHR viewer, or indirectly through information systems which are referred to as Point of Service (POS) systems (Lennon 2014:71).

Another good example of interoperability effort is in the Netherlands where interoperability is facilitated by a national infrastructure called AORTA, enabling data to be stored in separate host systems that are connected to AORTA, allowing them to be accessed and assembled only when required (Lennon 2014:65-66). Basically, the data architecture denotes a decentralised arrangement in which health data is retained by source systems and only assembled as per need through a central switch point known as the LSP whose role is to provide reference indexing to patient data, authentication, authorisation as well as audit (Lennon 2014:65-66).

In light of these indications, it is obvious that other countries are taking the challenge of EHRs and EMRs interoperability head on. Thus, should the health sector of Zimbabwe procrastinate in tacking the challenge of interoperability earlier, it will not only continue to have isolated EHRs and EMRs systems but will also face a mammoth and costly task of recalibrating legacy systems and make them interoperable whenever interoperability issues will be addressed in Zimbabwe's health sector. As observed by the International Telecommunication Union (2009:15), interoperability challenges arising from failure to adopt universal standards or the adoption of standards that are characterised by incompatibility have the potential of pushing up the costs of daily business, government as well as customer activities. In the case of the health sector of Zimbabwe, this consequence may have far much reaching ramifications on the already financially strained healthcare delivery system.

5.4 SAZ and standards for EHRs and EMRs

Local standards bodies play a pivotal role in cultivating a healthy atmosphere for standards in a country. Given that SAZ was the only national standards body in Zimbabwe which produces and promotes standards across the economy of Zimbabwe, the researcher was behoved to discuss its role as far as standards for EHRs and EMRs are concerned.

5.4.1 Legal mandate of SAZ in the development, implementation and monitoring of EHRs and EMRs standards

Local standards development bodies play a crucial role in the determination and promotion of standards, not only in the health sector, but across the spectrum of industry. In the words of ISO and the United Nations Industrial Development Organisation (UNIDO) (n.d:7), a national standards organisation has its primary objective being to meet the needs of its country. Data revealed that SAZ was not legally responsible for the development, implementation and monitoring of EHRs and EMRs, neither was it responsible for their enforcement. However, SAZ had adopted some EHRs and EMRs standards from ISO, to which it was a member. This shows that the only standards body in Zimbabwe was not producing EHRs standards. The fact that SAZ was not legally mandated to serve as a national standards body left it with no mandate of developing, implementing and monitoring EHRs and EMRs for both the public and private sectors in Zimbabwe.

The fact that SAZ was constituted according to the Companies Act of Zimbabwe implies that it did not have any legal mandate to oversee standards, including those for EHRs and EMRs. As Marunda (2011:1) explained, SAZ is the national standards organisation of Zimbabwe which was formed in 1957 and incorporated three years later under the Zimbabwe's Companies Act with Articles and Memorandum of Association as a non-governmental and not for profit organisation. SAZ functions under the governance of a General Council consisting of 56 representatives of government, local authorities, professional and academic institutions, as well as industry and commerce, which oversees the affairs of the organisation (Marunda 2011:1). Its mandate, as a national standards body in Zimbabwe, is to facilitate the development of national standards, a function which is undertaken in consultation with relevant stakeholders.

The manner in which SAZ was operating was slightly different from the way in which other standards bodies in the African continent were operating, including Botswana, Malawi, Zambia and South Africa. Its counterparts were established according to Acts of Parliament and were therefore, directly falling under government and have legal mandates to develop, enforce and promote standards and their adoption. Standards are set by public institutions, especially regulatory agencies and where compliance is a legal obligation tend to be known as mandatory or regulatory standards (Henson 2006:5). For example, in Botswana, the Botswana Bureau of Standards (BOBS) was formed on the basis of the Standards Act by Parliament in 1995, and in April of 1997, BOBS transformed into a parastatal as provided for in the Act (BOBS 2018). In terms of mandate, BOBS has the primary responsibility of formulating standards for Botswana and co-ordinating quality assurance in Botswana (BOBS 2018). To buttress its legal mandate, BOBS is operating under the Government of Botswana under the leadership of a 12 member Standards Council, appointed by the Minister of Investment, Trade and Industry, and its portfolio is responsible for all matters that pertain to standardisation and quality assurance in Botswana (BOBS 2018).

In Malawi, the Malawi Bureau of Standards exists and operates as a statutory organisation which was established by an Act of Parliament (Cap 51:02) of the laws of Malawi in 1972, which Act was amended as Act No 14 of 2012 (Malawi Bureau of Standards 2019). Its mandate, according to the Malawi Bureau of Standards (2019), is "to promote metrology, standardisation and quality assurance of commodities and of the manufacture, production, processing or treatment thereof; and further to provide for matters incidental to, or connected with standardisation." In Zambia, the Zambia Bureau of Standards (ZABS) also exists and

operates as a statutory body housed in the Ministry of Commerce, Trade and Industry (ZABS 2017). Established in 1982 by an Act of Parliament, which was later on repealed by CAP of 1994, the Zambia Bureau of Standards implements the Standards Act No 4 of 2017 of the laws of Zambia (ZABS 2017). In South Africa, the South African Bureau of Standards (SABS) also exists and functions as a statutory organisation which was established by the Standards Act, 1945 (Act No 24 of 1945) and continues to derive its mandate from the revised and latest edition of the Standards Act, 2008 (Act No 8 of 2008) (SABS 2018). Its specific mandate includes:

i. The development, promotion and maintenance of South African National Standards (SANS);
ii. Promotion of quality with regards to commodities, products and services; and
iii. Offering conformity assessment services and rendering assistance in matters connected therewith.

In New Zealand, Government institutions are directly involved in healthcare ICT standards by coming up with clear guidelines as well as procedures governing the standardisation of health ICTs, right from the stage of conceptualisation stage up to the final stage or decommissioning of the standards (Park and Atalag 2015). In fact, the Government of New Zealand runs the Health Information Standards Organisation (HISO), specialising in standards for health information standards (Park and Atalag 2015). Furthermore, the Government of New Zealand, as reported by Park and Atlag (2015), has established government run Health Information Technology (HIT) organisations that are responsible for the development and updating of various HIT standards in that country.

It can be noted that SAZ, in comparison to its counterparts in the afore-mentioned countries, did not have the legal mandate to develop, implement and superintend over matters of standards, including EHRs and EMRs in the health sector of Zimbabwe. However, this does not mean that SAZ was operating in an unconventional manner as it is very common to have non-governmental and not for profit standards organisations in other countries not being responsible for legally overseeing standards development, implementation or monitoring in a country. Examples of this abound. In Australia, the USA and the UK standards development is done by independent private standards bodies (Park and Atalag 2015). For example, Standards Australia exists and operates as a non-governmental and not for profit national standards organisation in Australia (Standards Australia 2019). Actually, Henson (2006:5)

observed that in general, ISO, national and regional standards organisations tend to operate on the basis of voluntary consensus. In the USA, HL7 and the American National Standard Institute (ANSI) are responsible for standards development, whilst in the UK, standards development are the responsibility of the British Standards Institute (Park and Atalag 2015).

This implies that EHRs and EMRs remained optional in the health sector of Zimbabwe, given the fact that there was still no organisation which ensured their implementation, including the MHCC which had seemingly had a clear appreciation of standards in the Zimbabwe's e-Health Strategy (2012-2017). One would say that at the time of conducting the study, there was no stewardship for EHRs and EMRs standards development, implementation and promotion. However, data revealed that despite SAZ not operating as a statutory body established by an Act of Parliament, it had a healthy relationship with the Government of Zimbabwe, which the MHCC can leverage on to engage SAZ to produce or customise EHRs and EMRs for implementation by the healthcare sector of Zimbabwe. As Marunda (2011:5) revealed, SAZ has signed some MoUs with the Government of Zimbabwe, and other public and non-government organisations for matters relating to standards.

5.4.2 Capacity of SAZ to develop EHRs and EMRs standards

Data indicated that SAZ was in a position to develop standards for EHRs and EMRs but there seemingly was no commensurate willingness as yet from the relevant stakeholders and the MHCC itself was not actually developing any standards for such systems. It should be noted that the development of standards was a concerted effort by SAZ and the relevant stakeholders and this was on a voluntary basis. This implies that SAZ was not yet developing any standards for EHRs and EMRs for the Zimbabwean market, although it was adopting and selling ISO EHRs standards. Whilst adopting the already existing standards may be an added advantage as it eliminates the development and testing costs, the International Telecommunication Union (2009) hinted on the greatest disadvantage of this by stating that those countries that are not involved in the development of standards for various reasons, should be prepared to accept the design preferences as well as the associated policy implications of dominant standards, a situation that may result in the adoption of costly products that are not suitable for domestic use.

The present study also revealed that SAZ has made several attempts to bring together different stakeholders in Zimbabwe for the purposes of developing or adopting EHRs and EMRs standards but in vain, a revelation which corroborates the lack of willingness or interest in such standards. Such willingness was indicative of the fact that standards for EHRs and EMRs were not yet a pressing issue in the healthcare sector of Zimbabwe, despite the MHCC, through the Zimbabwe's e-Health Strategy (2012-2017) expressing a sound understanding and appreciation of standards for such systems. It is also indicative of the fact that standards for EHRs and EMRs were not yet appealing to the health sector of Zimbabwe. This view was also expressed by one of the respondents at SAZ who indicated that for as long as the industry or stakeholders do not see value of standards for a certain product or service, their attention, let alone cooperation will be absent at worst and minimum at best, given that standards development was a market driven exercise in Zimbabwe.

This status quo also meant that the adoption of standards for EHRs and EMRs were still voluntary and a matter of consensus in the health sector of Zimbabwe, despite the MHCC envisaging systems that are standards dependent. Henson (2006:5) observed that voluntary standards manifest themselves as a process in which participants formally come together in a coordinated fashion *[to either set or implement]* with or without the participation of government. This also implies that e-Health systems interoperability through HIE, EHRs and EMRs in the health sector of Zimbabwe was still far from being a dream come true as interoperability is directly contingent on the availability and implementation of systems that can talk to each other.

Data further revealed that technically and financially, SAZ was capable of developing EHRs and EMRs for the health sector of Zimbabwe, such that it was prepared to welcome proposals and collaborations from any sector, including health. For example, the institution indicated that it was receiving some funds through the Standards Development Funds and had the expertise to drive the development or customisation of standards for the health sector of Zimbabwe, but only if it received proposals for such.

Thus, lack of proposals for EHRs and EMRs standards from stakeholders in the health sector could imply that such standards were not yet a priority or matter of urgency, and such standards were not yet part of the culture of the health sector of Zimbabwe. As pointed out by ISO and UNIDO (n.d:14-15), the widespread use of standards is a good indicator of the culture of quality in societies and as a result, the number of standards that are developed

nationally or based on regional/international standards is often used as an indicator of that. This is particularly so because, as ISO and UNIDO (n.d:14) noted, the development of standards takes place through a transparent, open and consensus-based process whereby stakeholders with a keen interest in that standards define good practice in the case of services as well as processes.

Generally, it can be noticed that standards for services tends to be less prioritised in comparison to those for tangible goods. In the case of standards for EHRs and EMRs, this procrastination may need not to come as a surprise, given the relatively newness of these systems. Thus, the MHCC stands to see how much work lies ahead in terms of convincing the health sector of the importance of standards for EHRs and EMRs systems that are seemingly mushrooming in Zimbabwe.

5.4.3 Relationship of SAZ with the MHCC regarding standards for EHRs and EMRs

Findings of the study indicated that there was no collaboration between SAZ and the MHCC in the area of standards for EHRs and EMRs, although there was a healthy relationship between these two institutions in the form of MoUs for other types of standards in healthcare other than those for the afore-mentioned systems. It was surprising to learn that there was no pact between the MHCC and SAZ concerning the development of standards for EHRs and EMRs yet such systems were already being rolled out in the health sector. This again, implies that standards for EHRs and EMRs were not yet under consideration by the MHCC, yet in the Zimbabwe's e-Health Strategy (2012-2017), such standards were underscored.

It is worth noting that for a national body such as SAZ to develop, adopt or play an active role in the standardisation of any services or goods, stakeholders should make the gesture to it, giving a start and some impetus to the process. In the case of EHRs and EMRs standards, the MHCC can be seen as the major stakeholder, both logically and from a policy standpoint, given that the Ministry is the biggest regulator of healthcare services. On that note, the laxity or procrastination by the MHCC to initiate the process of the development of EHRs and EMRs standards or any other standards participation and initiation for such systems was likely to commensurately procrastinate the appreciation and application of standards by the healthcare sector in general.

The net effect of this is the continued mushrooming of EHRs and EMRs systems that are not standards based, thereby lacking interoperability and not reflective of best practice, a situation that runs tangentially to the aspirations of the MHCC of having interoperable systems, as encapsulated in the Zimbabwe's e-Health Strategy (2012-2017). Thus, it is ideal for the MHCC to take the initiative of engaging SAZ for the development of EHRs and EMRs, leveraging on the healthy relationship between itself and SAZ. According to the World Health Organisation (WHO) (2013:2), member states are encouraged to consider collaboration with relevant stakeholders such as national authorities, relevant ministries, healthcare facilities as well as academicians so as to be able to map out ways of implementing health data standards at both national and sub-national levels.

On the other hand, SAZ could take the initiative to partner the MHCC regarding the development of standards for EHRs and EMRs, given the fact that it is more up to date about standards in every discipline. ISO and UNIDO (n.d:39), stated that a national standards body has a duty to establish and maintain relations with its own national regulators and with its national standards bodies so as to encourage and coordinate sound regulatory practices. Despite this being the ideal and the obtaining relationship with regards to MoUs between the MHCC and SAZ for standards pertaining to other aspects of health, collaboration of such nature on EHRs and EMRs was still something which still begged for attention.

From the study data, it emerged that SAZ made an attempt sometime to bring interested stakeholders together to customise ISO 18489, but in vain as there was no cooperation by such stakeholders, resulting in the project dying a natural death, a situation which could be taken to mean that standards for EHRs and EMRs were not yet appealing to the stakeholders and could not have been a priority as yet. Data from SAZ further revealed that in 2017, SAZ launched the Zimbabwe National Standardisation Strategy, whose goal was to develop 133 projects (standards) for various sectors, but none of these were for EHRs and EMRs. A look at the Zimbabwe's e-Health Strategy (2012-2017) reveals that the strategy ran for half a decade and by the year in which it expired, the Ministry still did not have any pact or MoU with SAZ or any other standards body to support its e-health strategy. This in a way, points to lack priority for EHRs and EMRs which were already in use and those that are yet to be rolled out.

The conspicuous dearth of collaboration between SAZ and the MHCC was indicative of the tall order that still awaited the MHCC if it were to deliver on its vision of having

interoperable EHRs systems as envisaged in the Zimbabwe's e-Health Strategy given that international practices have shown that governments, especially ministries or departments of health, tend to play a pro-active role in order for interoperability and other benefits that are associated with such systems to be realised by collaborating with national standards bodies. For example, in Australia, Rowlands (n.d) reported that Standards Australia had a partnership arrangement with the Department of Health and Ageing (DoHA) whose objective was the acceleration of the development of health informatics, targeting national interests in health. Standards Australia did this by supplying funding towards the development of international standards as well as the dissemination of such standards (Rowlands n.d).

The Ministry of Health of the Republic of Kenya is another case in point where the Ministry, in its e-health policy titled "Kenya National eHealth Policy 2016-2030", appreciated that in order for it to realise full integration and interoperability of its eHealth systems, the Government of the Republic of Kenya will have to collaborate with standards development bodies so as to develop or identify standards that are appropriate for secure communication, networking as well as the processing of clinical dossiers (Ministry of Health, Kenya n.d:19). Thus, the MHCC may take a leaf from these cases and enter into an MoU with SAZ with regards to the development and general matters of standards for EHRs and EMRs for the health sector as part of the enunciation of the Zimbabwe's e-Health Strategy (2012-2017).

5.4.4 Relationship between SAZ and other standards bodies

A national standards body needs to be affiliated to other national, sub-national, regional and international standards bodies in order for it to keep track of the latest developments in the field of standardisation which is ever changing, owing to the twin effects of the services and goods for which standards are being promulgated and advancements in IT. Data from the present study indicated that SAZ enjoyed a healthy relationship with regional and international standards bodies such as the African Organisation for Standardisation (ARSO) to which the Director General of SAZ was the President at the time conducting the study, ISO where it had a "P" membership status, IEC to which it was affiliated and the ASTM with which it had an MoU. This implies that SAZ was on track as far as far as its relations with other standards bodies were concerned as its counterparts such as BOBS, SABS and ZABS that were members of ISO and other regional and international standards groupings. This was expected of SAZ, given its national standing as the only standards authority in Zimbabwe.

According to ISO and UNIDO (n.d:40), it is advisable for a national standards body to hold memberships in international, regional, sub regional standards organisations and to actively participate in their activities. This meant that SAZ was in a position to adopt and adapt standards from other organisations, thereby saving on the expenses of developing new national standards for services and goods that were seemingly international. For example, ISO and UNIDO (n.d:65) observed that it is becoming an increasingly rare phenomenon for national standards bodies to develop purely national standards nowadays as such bodies are now fond of adopting standards that are prepared by regional and or international standards bodies or another country's national standards that have global currency, of course in such cases, with permission from the respective countries (ISO and UNIDO n.d:65). This was also true for SAZ as data indicated that it had purchased some ISO standards for resell to the Zimbabwean market.

Adopting standards of other bodies, with its advantage being allowing for convenience and savings, may come with a huge disadvantage as customisation may not be the best option in certain contexts. As lamented by Adibesin, Foster, Kotze and van Greunen (2013:67), the adoption of internationally developed e-health standards, *[which EHRs and EMRs are part of]*, usually requires significant localization or customization for them to meet specific needs of the adopting country. In light of the already limited capacity and participation, largely due to lack of capacity and participation emanating from resource constraints, the African context is not factored in, resulting in a chasm between the standards and what specific healthcare facilities in Africa need, thereby giving birth to even more difficult and more expensive localization efforts (Adibesin, Foster, Kotze and van Greunen 2013:67). This, therefore, comes as a piece of advice to the standards bodies and regulators to make informed and justified decisions regarding the adoption versus development equation.

Despite SAZ being affiliated to both regional and international standards groupings, it was quite interesting to note that the institution had adopted just a handful of standards for EHRs and EMRs, which further buttressed the dearth of visibility and prioritisation of such standards by the health sector of Zimbabwe. For example, ISO, to which SAZ was a full member, had produced so many standards for EHRs and electronic health information through its ISO/TR 215 Secretariat, but just a handful of them had been adopted by SAZ, yet none of them had been adapted at all.

5.5 Policies and legislation governing EHRs and EMRs systems and standards

Whilst it is fully understood and appreciated that standards are optional or voluntary in Zimbabwe, it is clear that if the Zimbabwe's e-Health Strategy (2012-2017) is anything whose objectives are to be achieved, the adoption of standards for EHRs and EMRs needs to be made mandatory and appropriate policies and legislation enacted to support this. It should be known that projects of huge magnitudes as EHRs projects require sound leadership (Waters n.d:12) and such leadership can only be sound enough if it rests on sound policies and legislations. In fact, government visibility, in the form of appropriate and progressive policies and legislations, is cardinal and inevitable in such cases.

Data for the present study indicated that whilst there were general policies that governed the operations of healthcare facilities in Zimbabwe, specific policies and legislation to support or address the pronouncements of the Zimbabwe's e-Health Strategy (2012-2017) with regards to the deployment and subsequent standardisation of EHRs and EMRs were conspicuously missing. For example, data indicated that general policies such as the Patient Charter, the Constitution of Zimbabwe, the ICT Policy for Zimbabwe were the ones cited for the governing of EHRs and EMRs, a situation that reveals the predicament that such systems find themselves in. Findings of the present study were in tandem with those of a study by Furusa and Coleman (2018) in which the researchers lamented the inadequacy and in some cases, absence of sound legislation and policies on which e-health strategies should rest, resulting in the impediment of e-health systems. It was somehow surprising to note that there were still weak policies and legislation to guide the implementation of EHRs and EMRs standards in the health sector of Zimbabwe yet the e-health policy (2012-2017) which demonstrated an ambitious appetite to roll out standards based EHRs, was close to a decade old.

Thus, "an absence or inadequacy of legislation and policies and liability concerns may hamper the implementation of e-health systems at the organisational and health professional level." In most cases, where legislation and policies are lacking, e-health systems are rolled out without ample checks and balances with regards to important considerations such as interoperability, privacy, confidentiality, security and archiving of patient health information, usually compelling authorities and stakeholders to implement policies ex post facto. Synchronising legislations and policies with the already existing legacy systems is not only cumbersome but expensive as well.

Lack of specific EHRs and EMRs policies and legislation, such as what was obtaining in Zimbabwe at the time of conducting the study implies that the implementation of such systems, let alone their regulation, monitoring, evaluation or assessments remained uncoordinated at best and absent at worst. As also reported by Marlon-Ralp (2016), the healthcare sector in Zimbabwe is yet to have e-health standards enforced by legislature, a situation that corroborates the absence and weakness of the country's legislative and policy atmosphere for the envisaged and much coveted e-health services in the country.

The absence of specific policies for EHRs and EMRs perhaps explains the uncoordinated mushrooming of a myriad of such systems in the health sector of Zimbabwe, with the MHCC not knowing not only which systems are in use in the private sector, but what their features and functionalities are and whether they were in sync with the aspirations of the Zimbabwe's e-Health Strategy or not. This further complicated the picture concerning the state and progress of the implementation of EHRs and EMRs systems and whether there were any cost savings or not and whether the intended benefits of such systems, including interoperability, which is primarily meant to harmonize the country's fragmented health information systems, were being realised or not. According to WHO (2013:2), member states are advised to come up with appropriate policies and legislative mechanisms that talk to their overall e-health strategies in order to ensure compliance regarding the adoption of health data standards by all concerned stakeholders, including both public and private healthcare players and donors in a manner which ensures the privacy of personal clinical data. Corroborating the words of WHO (2013:2), Adebesin, Foster, Kotze and van Greunen (2013:68) stated that policies that govern the acquisition of e-health solutions at a national level are inevitable. Thus, an e-health strategy that is not hinged on sound and vivid policies and legislation will remain feeble, with its intended benefits remaining a nightmare.

Zeroing in on standards, the International Telecommunication Union (2009:13-14) outlines six different ways in which countries or organisations may participate in standardisation, including:

i. Developing standards;
ii. Influencing the design of standards;
iii. Adopting standards;
iv. Using products based on standards;
v. Regulating standards; and

vi. Providing standards education.

Of particular interest amongst the afore-mentioned ways of participating in standardisation is the one on the regulation of standards, which the International Telecommunication Union (2009:14) observed, may call upon governments to establish policies pertaining to the procurement of technical standards to be used on government infrastructure, develop national standards strategies and enact policies and laws that govern various aspects of standardisation. This shows that governments play a pivotal role in the creation of a conducive and progressive environment for the standardisation of services and goods.

The fact that data for the present study indicated that there were no clear standards policies for EHRs and EMRs as yet for the health sector of Zimbabwe implies that it was nearly impossible to discern order as well as interoperability among the e-health systems that were already in existence and those that were yet to be rolled out unless by happenstance. The state of affairs in the health sector of Zimbabwe concerning the policies and standards for EHRs and EMRs standards could be characteristic of the early stages of EHRs and EMRs systems implementation that is market rather than policy driven.

Literature reveals that the afore-mentioned state of affairs is what was once prevailing in a fair number of other countries in the world, whilst some countries already had sound standards laws and policies as early as over a decade of years ago. A study that was conducted by the International Communication Union (2009) Mongolia, through its Mongolian Agency for Standardization and Metrology (MASM), which is a government body has a law on "Standardization and Conformity Assessment" adopted in 2003 provides a legal basis for standardisation and conformity assessment in Mongolia and regulates the manner in which the government, citizens and business organisations that are involved in standardisation relate to each other (International Communication Union 2009:22). Czech, through the Czech Office for Standards, Metrology and Testing (COSMT), the country's national standards body was responsible for the development, publishing and distributing Czech standards (International Communication Union 2009:22). Thailand was reported to have a national standards body, that is, the Thai Industrial Standards Institute and Mali which was reported not to have a clearly defined standards body did not have clearly defined laws and policies specially talking to standardisation. Thus, findings of the present study indicate that Zimbabwe needs to move with speed in terms of enacting supporting policies and laws

for EHRs and EMRs as it means that it could be a way behind other countries as far as the prioritisation of standards legislation is concerned.

5.5.1 Health data to be included in EHRs and EMRs

The standardisation of EHRs and EMRs requires that there be specifications regarding what exactly should be captured and what should not be captured in such systems. This speaks to what exactly constitutes EHRs and EMRs. According to Olenik, founder of the Olenik Consulting Group in Kansas City, USA, EMRs have the capability to capture patient information in various formats than their paper counterparts, thereby making it difficult to determine what exactly constitutes an EMR (Dimick 2008). Further highlighting the challenges associated with determining the content of EMRs, Olenik, cited in Dimick (2008), continued to note that "I think that is the big unknown, and that is why the content question is not as simple as what used to be in the paper record". Data from the present study revealed that there was no document that had been written or offered a comprehensive definition of what constituted EHRs and EMRs by the MHCC or any other recognised healthcare player in the health sector of Zimbabwe, neither were there any legal definitions of what constituted EHRs and EMRs in the context of Zimbabwe's health care delivery system. Thus, healthcare facilities that were rolling out EHRs and EMRs systems were doing so without clear definitions or conceptualisation of such systems.

Having a clear conceptualisation of such systems is important as it enables the selection of systems that meet the criterion of standard EHRs and EMRs systems, as agreed on by the authorities or practitioners in a given country. As the HIMSS (2011) stated, the EHRs selection should ensure the chosen EHRs is designed appropriately and ensures adherence to laws, institutional requirements as well as any additional certification standards that may be applicable to the adopting institution. Such a conceptualisation of EHRs and EMRs should be in terms of the data that ideally constitutes such records, the basis on which such records are legally conceptualised as well.

The importance of having a clear conceptualisation of such systems needs not be overemphasised in light of vendor driven markets for EHRs and EMRs systems. This implies that healthcare facilities are bound to fall prey to some of the well marketed systems that purport to be EHRs and EMRs systems, yet their functionalities do not meet the criterion of

such systems. As HIMSS (2011) hinted "don't assume that a given EHR will meet your requirements for a legal record." Of course, as the EHRs marketplace's becomes more aware of the legal requirements for legal EHRs, its products will improve (HIMSS 2011), but the onus to ensure compliance lies with the healthcare facility implementing the system. This simply underscores the importance of standard legal definitions of EHRs and EMRs to guide both system designers and implementers regarding the functionalities and characteristics of such systems.

Thus, the fact that there were no clear definitions of EHRs and EMRs for the healthcare sector of Zimbabwe put the entire concept of health records and information management at risk whereby healthcare facilities find themselves with systems that fail to meet the basic or legal definitions of a health or medical record or systems that capture information that violates the privacy of patients. This risk was further exacerbated by the revelation that there were no mechanisms of auditing the EHRs and EMRs systems that were being rolled out in the health sector of Zimbabwe whereby the MHCC did not even have statistics as to how many systems were in existence and use, which characteristics or functionalities did they possess, let alone checking whether the data they captured met the basic standard of EHRs and EMRs.

The implications of not having clearly defined EHRs and EMRs in terms of content and other basic records management issues also has far much reaching legal ramifications. This is because health or medical records just need to be legally compliant in terms of what exactly constitutes such records. In the words of the HIMSS (2011), it is a given and common knowledge that a healthcare facility must have a health record, which should comply with all the statutory, regulatory as well as professional requirements for clinical and business uses. As Gamble (2012) observed, despite technology having been in use for about thirty years, physicians who are in the process of adopting EMRs may be faced with some challenges, particularly those relating to legal implications. Gamble (2012) further observed that EMRs present the courts and the industry with issues that were previously unaddressed in the era of paper records, with the major question being what exactly constitutes a legal medical record. This is because in the case of paper records, a medical record just conceived as a folder which contains a stack of papers that a physician uses in making clinical decisions (Gamble 2012).

The absence of legal definitions of EHRs and EMRs as well as clear standards that detail what constitutes such records in Zimbabwe was typical of the observations by Olenik, in

Dimink (2008) who stated that the realities of the healthcare industry are such that government regulations often do not resemble what they look like and there is no one neat list of what has to be captured in an electronic legal record. This implies that in most cases, there is dependence on legacy laws and regulations that seemingly cater for EHRs and EMRs and their systems, only to realise, usually as a result of legal challenges, that such laws are insufficient at best and inapplicable at worst to electronic health and medical record contexts.

The afore-mentioned, seemingly, was the predicament that EHRs and EMRs and their standards were facing in Zimbabwe as data from the present study indicated that there were no legal and policy statement that were dedicated to such systems and reliance was placed on auxiliary laws and policies that were promulgated prior to the implementation or even mooting of EHRs and EMRs systems. This spelt possible complications for the health sector of Zimbabwe when litigation cases arising from EHRs and EMRs arise and demand that the legal definition and contents of those forms of records be interrogated. Thus, a standard pertaining to what constitutes EHRs and EMRs is just inevitable and unavoidable for the health sector of Zimbabwe. In Kenya, the Ministry of Health (n.d), in that country has resolved to come up with EHRs standards, detailing how to capture data from patients, which it vowed to prioritise in its Kenya National e-Health Policy 2016-2030.

The US standards body for health records and information, Health Level Seven (HL7) International (2017-2019), through its standard titled "HL7 Electronic Health Record-System (EHR-S) Functional Model, Release 1" provide guidance on some major characteristics and functionalities a typical EHR system should contain. The standard provides about 1000 criteria for conformance for a total of 130 functions, including aspects of medication history, problem lists, orders, clinical decision support as well as those that support the privacy and security of patient information (HL7 International 2017-2019). The advantage of this standard, according to HL7 International (2017-2019), is that the functions of the standard are designed from the perspective of the user, and also allow for consistency in the expression of the EHRs system functionality, with the conformance criteria working as reference tools for entities that are considering the purchasing of EHRs systems as well as vendors as they develop EHRs software.

HL7 International (2017-2019) also reported on the existence of another standard governing the EHR titled "HL7 EHR Records Management and Evidentiary Support Functional Model, Release 1" abbreviated RM-ES FP, which provides functions that can assist an organisation

maintain a legal record for business and legal disclosure, lessen the provider's administrative burden as well as bring down costs and inefficiencies arising from redundant paper and electronic recordkeeping. This important standard, according to the HL7 International (2017-2019), typically offers the following functions:

i. Assistance in the identification of the functionality as well as conformance criteria supporting the collection of content for the health record that is required; and
ii. The ability of being married to a particular care setting so as to maintain legally sound health records.

Thus, it is discernible that the afore-mentioned standards serve to demonstrate the importance of not only having EHRs and EMRs capture clear, complete and economically sound contents, but maintaining EHRs and EMRs systems that are business and legally sound and compliant, as well as care contextual, something that the health sector of Zimbabwe may leverage its efforts on as early as possible, given indications that its EHRs and EMRs landscape is very nascent.

5.5.2 Access, update and sharing of EHRs and EMRs

Issues of access to EHRs and EMRs and their updating are intertwined and their separation is more of an idealistic and academic then pragmatic exercise. These issues are important in the context of EHRs and EMRs in the sense that they directly impact privacy, confidentiality and security of patients' health information, one of the most important considerations in health, given the sensitivity of health information. As such, access to and updating of EHRs and EMRs should be guided by well-defined standards and principles so as to protect the privacy and integrity of patients' health data and information. As observed by Ozair, Jamshed, Sharma and Aggarwal (2015), failure to identify standardised best practice methods to execute the duties in EHRs environments, users are left to struggle. Thus, clinics are expected to map and standardise their workflow processes even prior to the selection of EHRs systems (Ozair et al. 2015).

With the results of the present study indicating that there were no clear regulations explicitly outlining the roles and responsibilities of the various stakeholders involved in the creation and updating of EHRs and EMRs, patient's health information on such systems could be jeopardised in terms of privacy, confidentiality and privacy. What it means is that where

EHRs and EMRs systems were being used, the creation and updating of patient data on such systems was following the same rules as those governing paper records.

Whilst it is true that the duties of both the healthcare staff such as physicians, nurses, and those who provide auxiliary services such as records and information management, IT support services and medical aid insurance companies remain the same in both traditional and EHRs and EMRs environments, it is worth noting that it is the fluidity and ease of manipulation of information in EHRs and EMRs that calls for clarity and stringent regulations for various players in the healthcare provision chain. Indeed, "personal health information is being used and shared in ways patients never imagined." (Peel 2010:2). As the US Office of the National Coordinator for Health Information Technology (2018) observed, one of the key features of an EHRs is the ability of health information to be created and managed by authorised providers in electronic formats that allow information sharing with other providers across more than one healthcare provider.

Despite EHRs and EMRs systems offering such interesting benefits and conveniences, Furusa and Coleman (2018) observed that stakeholder expectations regarding the security of health information in such systems remain the same as those of traditional paper records. This therefore, behoves all the concerned stakeholders, especially regulatory authorities including governments, to articulate vivid standardised frameworks to govern matters of creation, access and updating of EHRs and EMRs. To cite Almutairi (2011:148), health information standards are particularly important given the fact that EHRs are programed in such a way that they deliberately enable access to health information by many users located in many different places as well.

As a means of minimising and possibly eliminating cases of breach of privacy and confidentiality of patients' information provisions, Almutairi (2011:162) suggests the use of roll-based access controls in which each member of staff amongst the stakeholders throughout the healthcare facility is assigned a specific role which determines the access levels to patients' information. This approach is particularly important in the sense that electronic systems tend to come up with new and redefined roles for each and every member of staff, including both medical and non-medical in healthcare facilities and beyond. It is such roles that then cause confusion in terms of demarcating boundaries for the various players who may lay their hands, one way or the other, on patients' health information for various reasons, be they legitimate or not, and hence the indispensability of access controls. This is in

tandem with the statement by Yu, Wijesekera and Costa (2015:25) that the aim of the healthcare industry is to map out quality improvement strategies so as to render standardised, safer and efficient services to patients, including the preservation of patient data privacy and security.

Access to EHRs and EMRs is the most important aspect of health information management. Access to health information is a sensitivity issue and thus, standards are a prerequisite so as to strike a balance between patients' rights to privacy and the legitimate needs of healthcare practitioners, healthcare facilities, researchers as well as other concerned stakeholders (Almutairi 2011:158). In fact, it has been suggested that the major threat to patients' information in EHRs and EMRs environments comes emanates from secondary uses of patients' identifiable health data and information (Almutairi 2011:162). The question of standards on how to share patients' health information is unavoidable and attention to it is inevitable if EHRs and EMRs systems are to yield their intended benefits. Butterfield (2012), writing in the context of the US, observed that with standards come policy and both are needed (standards and policy) in place so as to facilitate complete EHRs adoption. Thus, "we need to know how to technically share information, and we need policy in place to tell us how to formalize the who, where, when, why and how of sharing clinical information in order to ensure compliance." (Butterfield 2012).

Access also stretches beyond that by those rendering services to patients, directly and indirectly, to include patients being granted access to their health data and information. The present study revealed that the Patient Charter in Zimbabwe allows patients to gain access to their health information, which is a good sign towards the realisation and enunciation of the patient's right to their health information. EHRs and EMRs have tended to ignore the fact that patients have access to their health and medical records, resulting in this provision being taken for granted. This is so despite being common place that patients need to have access to their health records.

However, data for the present study revealed that the EHRs systems currently rolled out were not explicitly programmed to enable patients to access their records. This implies that the EHRs systems were provider-centred and needed to be enhanced to provide patients with access to their health records and information in such systems. Writing in the context of the health delivery system of Zimbabwe, Marlon-Ralp (2016) revealed that patients have the right to gain access to their health information, including treatment at any time. In light of

this fact and right, EHR systems need to facilitate such access by having a specific portal (Marlon-Ralp 2016). Thus, it would be plausible to go a step further by designing and implementing an Electronic Patient Health Record (EPHR) which enables the patient to longitudinally track their treatment (Marlon-Ralp 2016).

The afore-mentioned recommendations by Marlon-Ralp (2016) are in tandem with international practices literature which shows that it is a general rule that EHRs and EMRs be designed in such a manner that enables patients to gain access to their health information in a standardised manner. In the USA, Kushner, Lindell and Verma (2019) reported that patients should be granted access to their health information in a standardised electronic format, detailing their complete medical histories which are aggregated from their various healthcare providers. In 2018, the Centres for Medicare and Medical Services in the US took a first step towards the advancement of Blue Button 2.0 AIP, a new programme allowing Medicare beneficiaries to share data pertaining to their health claims with other applications and services that enable them to manage their health (Kushner, Lindell and Verma 2019).

Still under access to and updating of EHRs, the study sought to find out if there were standard provisions for patients to make inputs or edit their records on such systems and it emerged that there were no provisions for such as yet in Zimbabwe. This implies that the EHRs and EMRs systems that had been rolled out were still not yet offering maximum benefits to both the patient and the healthcare providers due to them being physician centred. The inability of the EHRs systems to enable patients to edit or update their records was not only a technical or system related issue, but a policy issue whereby policy makers and system designers have not factored in the value that is derived from patients being allowed to update and even share their records for maximum health benefits. As Peel (2010:2) observed, if patients do not control their personal health information stored in EHRs, their trust in health IT systems or data exchange systems will be significantly reduced, and will avoid them. This may reduce the intended benefits of EHRs systems in Zimbabwe compared to those countries that have clearly defined standard principles allowing patients not only to access their EHRs, but to edit or update and even correct them where necessary.

For example, Hosek and Straus (2013:xii) reported that the privacy protection and information security framework for the Department of Health and Human Services (DHHS) that governs health information institutions in the US has provisions not for patients to access their personal health information through simple and timeous means only, but rights to

"dispute the accuracy or integrity of their information and correct it or have their dispute recorded and the need for transparency about policies, procedures, and technologies that affect patients or their PHI *[personal health information]*."

The US, which is one country which has registered the highest numbers of meaningful use and adoption of EHRs and EMRs, through its Health Insurance Portability and Accountability Act (HIPAA) of 1996, made provisions for patients to have control over their health records in such systems. For example, the National Centre for Medical Records (NCMR) (2019) reported that HIPAA, whilst seeking to protect personal health information for patients from privacy and confidentiality breaches, the Act also grants patients more control over their health information. The US continues to enhance this provision in an effort to maximise the benefits of EHRs. As Kushner, Lindell and Verma (2019) revealed, the Centre for Medicare Medical Services (CMS) offers financial incentives to healthcare providers so as to encourage them to give patients more and better access to their health data, albeit maintaining high levels of protection of patient information in terms of privacy and security.

Additionally, another new rule is being proposed by CMS whereby health insurance sellers, including Medicare Advantage plans, Medicaid, the Children's Health Insurance Program and health plans that are on sale on the federal exchanges to share with their enrolees, health information pertaining to their medical claims and other health information via electronic systems by 2010 (Kushner, Lindell and Verma 2019). Should the current proposal be given green light without amendments, the US will see an additional whopping 85 million patients having access to their health information in a standardised digital format, on top of about 40 million Medicare enrolees who already have access to their health information via Blue Button 2.0 (Kushner, Lindell and Verma 2019). Thus, giving patients access to their records in EHRs systems enables patients to share their health information with their doctors, and researchers working on cures for diseases (Kushner, Lindell and Verma (2019). Thus, it can be said that whilst rolling out EHRs and EMRs in the health sector of Zimbabwe was a noble idea, the present systems needed to be hinged on progressive policies on aspects of access to, and editing or updating of patients' health information in a standardised manner so as to leverage such systems and propel them to greater heights to derive maximum benefits from them.

5.5.3 Patient consent

Closely tied to the aspects of access and sharing of health information is the aspect of patient consent. Whilst many standards and policies have focused on consent in which the patient is asked to make a decision pertaining to whether they are agreeing or disagreeing to undergo a medical procedure, patient consent in the context of health information management goes beyond that straightforward question to include aspects of the patient having a say in how, with who, by who, for what purposes should their health data be shared. The complexity of this aspect of patient consent requires that there be explicit standards governing consent issues. As such, the present study further sought to find out about the consent standards or framework for the EHRs and EMRs in the health sector of Zimbabwe.

Findings of the study revealed that patient consent was being guided by the Zimbabwe Patient Charter of 2013, which guarantees patients privacy during consultation, examination right through treatment and guarantees patients of keeping their health information and the circumstances surrounding their illness confidential and used only for the purposes of rendering them treatment, with disclosure only done when a court of law issues a subpoena to a healthcare provider. Thus, Zimbabwe was on the same page with its counterparts, for example, South Africa, which also guarantees patients confidentiality, privacy and informed consent through the Patients' Rights Charter, SA since 2007.

Whilst this is a plausible provision and step towards enhancing patient consent, it was not enough in the context of patient consent in information management. The present study revealed that there were no standards or mechanisms as yet, giving patients permission to know whether their health information has been shared to start off with, and if so, who accessed their health information, who shared their health information, with who, for what purposes, when and so on, a revelation pointing to the weaknesses of the present EHRs and EMRs systems. This remains an issue requiring attention given the fact that in reality, patient information is shared with a number of other stakeholders without the patient knowing, let alone consenting, whether for legitimate and illegitimate reasons. As noted by Peel (2010:2),

> However, once these details are shared to receive treatment, that personal information is used in many other ways, passed on and shared with other strangers in companies and government agencies that have no direct relationship with the patient; and this is secondary use of personal health information.

Thus, patients have not been informed of the secondary uses of their health data (Peel 2010:2). The afore-mentioned concern was particularly significant and pressing in the case of Zimbabwe, given revelations that MHCC was considering rolling out Health Information Exchange (HIE), yet there seemingly were no clear patient consent principles regarding the sharing of patient information in EHRs which are very fluid and porous by design. According to Hosek and Straus (2013:viii), there is widespread consensus on the principles on which HIE, including the importance of patient consent and of course, patient consent or authorisation in HIE is key to matters of privacy, yet its meaning as well as the ways of obtaining it are surrounded by ambiguity, something that could be adding to the prevalence of systems that are not able to enhance consent.

Literature reveals that the issue of informed consent in the context of health information management despite the enforcement of informed consent in systems is generally problematic and most EHRs systems lack basic informed consent provisions. For example, Yu, Wijesekera and Costa (2015:26), observed that "advanced automated features such as consistent enforcement of informed consent pursuant to statutes, regulations and guidelines are missing." Lamenting the same, Peel (2010:4) wrote "today, the majority of providers, insurers and major corporations fail to offer even basic electronic consent tools." Studies on the enforcement of informed consent in existing EMRs systems indicate that no such systems supported dynamically obtaining and automatically enforcing patient consent when medical processes are being implemented (Yu, Wijesekera and Costa 2015:26). This signifies the importance of embedding consent standards in the EHRs and EMRs right at the point of implementation of such systems.

However, despite such technical challenges characterising most EHRs and EMRs platforms, the question of informed consent seems to be principally talking to the strand of policy. As Yu, Wijesekera and Costa (2015:26) noted, for informed consent to be valid, there is need for it to be compliant with the laws and regulations that govern the sub disciplines of medicine. With regards to consent policies and laws, some countries have made great strides. A study by Asghar, Baig, Russello, Lee, Ullah and Dobbie (2017) revealed that in the UK, there were laws that explicitly required patient consent in cases where their health data was being passed onto any third party who is not directly involved in the care for the patient. Surprisingly, despite this positive observation, there was no process which enabled the obtaining of patient consent or even issuing patients whose data was being used or shared with notices to that effect (Asghar, Baig, Russello, Lee, Ullah and Dobbie).

However, the same study concluded that New Zealand had a fragmented EHRs landscape which typically lacked consent management processes as well as protocols. Canada was proactive in the case of informed consent by enacting relevant legislation prior to the implementation of EHRs (Lennon 2014:77). Thus, in Canada, such legislation requires that the EHRs be designated according to the Act as an information network, whereby there is a requirement for the publication of designation documents, explaining the adoption or use of EHRs, accompanied by data sources, statements on who the data will be shared with as well as the access control tools that will be embedded in the EHRs system (Lennon 2014:77). To ensure accountability and enforce the protection of patient data, the legislation requires that any changes to the EHRs, including the addition of new data sources result in the revision of the EHRs designation dossiers, which should be signed at a ministerial level (Lennon 2014:77). However, in some places such as the New Brunswick, Lennon (2014:76) reported, although healthcare practitioners were only allowed to gain access to patients' records on a need to know basis, patient consent was not a prerequisite for this.

Thus, it can be discerned that the aspect of informed consent can be said to need a robust standardised control mechanism that is hinged on vivid and sound mechanisms in the case of EHRs and EMRs systems. Such control mechanisms need to be policy and legally supported for them to hold water. As such, Peel (2010:21) urged the concerned stakeholders such as decision makers, legislators as well as policy makers to ensure that national healthcare systems speak to what patients want, what they need, and what they expect at every level of care. This is a message worth pondering on by the various stakeholders in the healthcare delivery chain in Zimbabwe, especially in light of the findings of the present study in which it emerged that EHRs and EMRs systems were already in existence and continued to be rolled out whilst matters of standards and protocols for patients were still hazy.

5.5.4 Archival standards for EHRs and EMRs

Standards for the archiving of EHRs are indispensable, given the need for comprehensive patient medical histories throughout their lives and beyond. Thus, it behoved the present researcher to find out about the archival standards for the EHRs and EMRs that were emerging in the healthcare delivery system of Zimbabwe. According to HL7 International (2017-2019), an EHR should be designed in such a manner which facilitates the creation,

receipt, maintenance, use, as well as the management of the disposition of records for evidentiary matters as they relate to the activities and transactions of an organisation.

The archiving of health data existing in EHRs and EMRs in today's e-Discovery environments needs not be over-emphasised. According to the Galen Healthcare Solutions (2016:3) "proper data archiving is needed to uphold and maintain e-Discovery requirements." By definition, e-Discovery is intertwined with archiving, but specifically talks to the ability of an agency to make electronic information available during investigations or in cases of litigation. According to the Galen Healthcare Solutions (2016:3), e-Discovery refers to "the electronic aspect of identifying, collecting, and producing electronically stored information in response to a request for production in a lawsuit or investigation." Cases of litigation are common place in the healthcare, a situation that stresses the need for dependable archival systems for electronic records for e-Discovery environments. Without doubt, trust and authenticity of EHRs and EMRs are only guaranteed where systems are standards sensitive and compliant.

Data from the present study revealed that the archiving of EHRs and EMRs was not yet guided by any archival standards and was something that needed further work. It further emerged that that there were no clear archival policies for EHRs and EMRs systems as yet, although respondents were aware of the NAZ Act of 1986 as being the outstanding archival legislation in Zimbabwe. The absence of archival standards for EHRs and EMRs, coupled with a clear archival plan for such systems implied that the long term availability of such records was not guaranteed as their preservation depends on their preservation. Thus, the implementation of EHRs and EMRs needs to have archiving functionalities embedded in them as a way of ensuring their preservation.

In the context of health, failure to archive health records may have a domino effect, not only on the patients concerned when their information is needed for the purposes of rendering medical help, but on the health delivery system itself where medical practitioners may not be able render timely care as well as retarded clinical or medical research which all hinge on the availability of health information. In fact, medical records are a special class of records that may need to be available throughout the life time of a patient, implying that their archiving needs to be robust and consistent so as to avoid unnecessary casualties arising from lack of patient information for clinical care. As ISO (2010) observed, "unlike other electronic documents, patient records must be available throughout their entire lifecycle (potentially

reaching 100+ years) regardless of time and place." Archival standards for EHRs and EMRs systems are inevitable, given the voluminous nature of health data. According to the Galen Healthcare Solutions (2016:2), the healthcare sector has come out as the fastest growing segment of the digital universe producing highest volumes of data, with statistics showing that its data grows at 48% per an annum in comparison to other types of data that is growing at just 40% per year. This demonstrates the indispensability of sound archiving methodologies that are guided by standards.

Because archiving is essentially about ensuring the long term availability of information for as long as the security and legal requirements prescribe, the absence of archival standards for EHRs and EMRs implies that healthcare facilities using such systems in the health care facilities in Zimbabwe may find themselves unable to meet the security and legal and business compliance requirements.

ISO, through its 254 Secretariat, has come up with a number of standards, including the ISO/TS 21547:2010- Health Informatics- Security Requirements for Archiving of Electronic Health Records. This standard defines the basic principles that are required for the secure preservation of health records that exist in any format (ISO 2010). According to this standard, the concept of archiving is seen in its widest form, stretching beyond just the permanent preservation of selected records (ISO 2010). Specifically, ISO/TS 21547:2010 defines security requirements that are architecture and technology-independent for the long term preservation of EHRs that have fixed content, however, the practical models as well as the associated technology for the security requirements are outside the concept of this particular technical specification (ISO 2010). ISO/TS 21547:2010 comes with additional complementary reports to the standard, and offer guidance to the agencies on how to implement the standard (ISO 2010). These are:

i. The Technical Report ISO 218, whose focus is on the security requirements covering aspects of the record integrity, confidentiality, availability and accountability that are key in ensuring that health information for patients is protected in long term digital preservation. This also implies that through this specification, issues of privacy protection are addressed for the EHRs itself and e-archiving systems that are employed in a healthcare environment (ISO 2010).
ii. The ISO/TR 21548:2010- Health Informatics- Security requirements for the archiving of electronic health records- Guidelines. Through ISO/TR 21548:2010,

agencies are provided with further guidance regarding the implementation of ISO/TS 21547 (ISO 2010).

Thus, from the provisions of ISO/TS 21547:2010, it can be discerned that the archiving of EHRs entails technical aspects in which the record's availability over lengthy periods of time is a prerequisite, given the need for the patient's complete history throughout their lifetime and even afterwards, and such aspects are inseparable from security, privacy and confidentiality concerns. This implies that in situations where there are no standards to guide the archival activities of EHRs and EMRs, the guarantee of the long term availability of patients' health information may remain a nightmare, given revelations by ISO (2010) that patients may live for more than 100 years.

Archival standards for EHRs and EMRs in Zimbabwe are even more important, given the fact that the current archival requirements detect that medical records be preserved or retained indefinitely as is the case with the National Archives of Zimbabwe with the traditional paper medical records. For example, Masuku and Ngulube (2019:8) revealed that medical records at NAZ still carried the "P" (preservation status) whereby such records preserved or retained indefinitely. If such a requirement is translated or applied to the EHRs EMRs, it implies that the systems that contain such records should be able to preserve patients' health information, not only for very long periods of time, but literally indefinitely, and the role of archival standards in such cases needs not be overemphasized. Therefore, findings of the present study in which it emerged that there were standards as yet to guide and aide the archiving of EHRs and EMRs are an indirect indication of the possibility of the inability of such systems to guarantee indefinite retention of EHRs and EMRs as is the case with their paper counterparts and in accordance with the standing instructions governing the retention of medical records in Zimbabwe.

5.6 Preparedness for the support of EHRs and EMRs standards

After understanding the status quo of standards for EHRs and EMRs, it was imperative for the researcher to find out how sustainable were such systems from the perspective of MHCC and SAZ in Zimbabwe. It is common that programmes are given attention at the time of inception and then lose momentum afterwards. According to Moucheraud et al (2017:2), sustainability is cardinal to the life cycle of a programme. It particularly talks to the question

"do activities and benefits continue after original support ends, and what aspects of a programme's design and activities help ensure longevity?" (Moucheraud et al 2017:2). In the context of standards for EHRs and EMRs, sustainability plays a critical role in ensuring dependable health information systems that maintain patient data and information intact for prolonged periods of time, given the fact that health records may have a life span which is in excess of 100 years as observed by ISO (2010).

Findings of the present study revealed that the MHCC had limited financial resources and may not be able to sustain standards. This is in tandem with the findings of Furusa and Coleman (2018) who reported that the Ministry of Health in Zimbabwe is faced with the challenge of inadequate funding for modern technologies due to little budgetary allocations to the health sector by the Ministry of Finance, resulting in limited ICT budgets for hospitals. Findings of Furusa and Coleman's (2018) study also match and corroborate what another study by Moucheraud et al (2017:4) revealed where funding for Electronic Health Information Systems (EHIS) was reportedly a challenge in Malawi, Zambia and Zimbabwe. This had a net effect of driving e-health projects to the "donor-dependence" status, with very poor sustainability rates post donor funding. For example, Moucheraud et al (2017:4) reported that almost all the respondents who participated in their study harped on the dependence of EHIS on contributions from external sources and that there was a general feeling that the systems would not last without substantial external funding.

However, data from the MHCC indicated that the Ministry had adequate expertise to support and maintain standards for EHRs and EMRs since it had a good pool of software engineers who can design and sustain such standards. SAZ also indicated that it was financially and technically able to render support and sustain EHRs and EMRs standards, provided there was cooperation from other concerned stakeholders. This implies that there was room for the sustainability of standards for EHRs and EMRs if SAZ and the MHCC were to have a coordinated and concerted effort towards such a project.

5.7 Summary

The chapter discussed the study's findings by comparing them to the general literature and related studies in an effort to give the findings meaning. When juxtaposed with the literature and related studies, findings of the present study point to an unfavourable status quo for EHRs and EMRs in the health sector of Zimbabwe, with no clearly defined and coordinated

effort towards standardisation projects, although the MHCC had a brilliant and promising e-Health Strategy for Zimbabwe that demonstrates sound appreciation of standards and their role as a key aspect of EHRs that are inevitable and indispensable in the Zimbabwe's e-Health Strategy (2012-2017). Thus, a comparison of literature proposals and best practices with findings of the present study shows that the health sector of Zimbabwe still has a long way to go in terms of cultivating key aspects of standards for EHRs and EMRs and their implementation, especially when it comes to issues of policy and collaboration with SAZ and other stakeholders.

The discussion indicated that for projects of national magnitude such as the standardisation of EHRs and EMRs to materialise, there is need for sound leadership, coupled with clear and robust policies and legal instruments that foster and enhance standards, something which was seemingly lacking in the health sector of Zimbabwe so as far as EHRs and EMRs standards are concerned. It further emerged that the aspect of implementation, monitoring and evaluation was still not yet ripe as it was characterised by comprehensive studies. This may point to the nascence of the area of standards in this area, owing to the infancy of the concepts of EHRs and EMRs themselves. The next chapter summarises the study in general and presents key findings of the study. Conclusions as are also presented in the next chapter as well as the recommendations of the study.

CHAPTER SIX
SUMMARY, FINDINGS, CONCLUSIONS AND RECOMMENDATIONS

6.1 Summary

After interpreting and discussing the study data in the previous chapter, the study proceeds by way of making bold statements about the study's objectives. The focus of this last chapter is three pronged, that is, summarising the study in general and the key findings, drawing conclusions of the study and making recommendations. The first chapter introduced the issues that were under consideration. In this chapter, the researcher managed to set the scene of the study by giving background information surrounding standards for EHRs and EMRs in the context of the health sector of Zimbabwe. Here, the researcher lamented the dearth of standards to guide EHRs and EMRs yet there was evidence of such systems being employed in the health sector of Zimbabwe. This was followed by the problem statement in which the researcher highlighted the predicament that the health information system found itself in, including the existence of silos of health information that is generated, stored and used by disparate systems, resulting in the health sector of Zimbabwe not benefiting from the deployment of EHRs and EMRs platforms, including instant and remote access to patient data by various healthcare facilities in the country.

The dearth of standards for such systems also had a domino effect on the health sector as it presented a myriad of other potential challenges for the health sector of Zimbabwe, including potential health information security breaches, improper archiving of electronic patient health records, grey areas regarding patient consent as far as sharing or accessing their health details by third parties is concerned as well as failure to reap the economic value from the deployed EHRs and EMRs systems, for example, through HIE, amid the deployment of health information systems that are not standardised. Against this backdrop, the study had sought to find out the state of affairs concerning the standardisation of EHRs and EMRs systems in Zimbabwe, an idea which is captured in the e-Health strategy of Zimbabwe (2012-2017).

The chapter presented the objectives which guided the study as well as the problem under investigation. The researcher proceeded to explain how the study was going to benefit the MHCC and the entire healthcare sector. The scantiness of meaningful and empirical studies on the standardisation of EHRs and EMRs that were being deployed, and continued to be

deployed as per the e-Health strategy of Zimbabwe, served as justification of the study. Because the study intended to gather data from participants at the MHCC and SAZ and because writing on its own requires sound ethical disposition, the key ethical considerations that the researcher observed during the data gathering exercise and compilation of the thesis were explained in this chapter.

Chapter Two was dedicated to the conceptual framework of the study and literature review. Thus, the first strand of the chapter presented the conceptual framework that the researcher developed. The framework was contextual to the variables that were presumably at play in the health sector of Zimbabwe, but was not in any way exhaustive or prescriptive. The second strand of Chapter Two was essentially a review of literature which is related to the study in an effort to further enlighten the reader of the importance of standards for EHRs and EMRs, showcase what has been done by various concerned stakeholders, pragmatically and theoretically concerning standards and standardisation of such systems, thereby indirectly demonstrating the indispensability of rolling out standards-based health information systems. Through reviewing literature, the study indirectly brought to the fore, the chasm that characterised the health sector of Zimbabwe with regards to the standardisation of EHRs and EMRs systems.

The third chapter presented the research paradigm and methodology that were employed in the study. Owing to the fluidity of the very concept of standards for EHRs and EMRs and these systems as well, the study employed an interpretivist paradigm and a qualitative methodology. The subsequent research design, study population, sampling methods and data gathering methods as well as the data presentation techniques that were deemed appropriate for the study were explained and justified in this chapter.

The fourth chapter was dedicated to data analysis and presentation in which the researcher immersed himself in the data so as to synthesize it and present it meaningfully and in a manner that brings out its significance in relation to the problem under investigation and the study objectives. Again, owing to the perception that the researcher carried about the concept of standards and standardisation and EHRs and EMRs, whereby these were being seen as relative and socially constructed and hence interpretivism, the analysis and presentation of data were done qualitatively through the use of words.

Chapter Five of the study was purely intended for data interpretation and discussion in which the researcher throve to make sense of the data and attach meaning to it in terms of its

implications to the health sector of Zimbabwe. Through this, the researcher was also able to juxtapose findings of the present study with those of other studies in an effort to enunciate the interpretation and present a fair comparison of how the status quo of EHRs and EMRs standardisation was like in comparison to the other healthcare facilities around the globe.

In Chapter Six, the study findings are summarised and conclusions as per the study objectives are drawn. In this chapter, the researcher proffers recommendations towards the improvement of standardisation for EHRs and EMRs. To fulfil the intention of the researcher, that is, to develop a proposed framework of EHRs and EMRs standards implementation, the researcher presents the proposed framework as an extension of the recommendations.

6.2 Major findings of the study

This section recaptures the salient findings of the study prior to drawing conclusions. A summary of findings in research is taken to mean key findings of the study that are drawn from the presented data and may include extracts of the data. Thus, when presenting the summary of findings which is essentially an iterative process, the researcher moves back and forth between his or her data presentation section and his or her summary of findings section. The study revealed the following key findings.

6.2.1 Existing standards for EHRs and EMRs for the health sector in Zimbabwe

The study sought to find out whether there were any standards governing the EHRs and EMRs in the health sector of Zimbabwe, amid the existence of such systems in the country's health sector.

6.2.2 Existence of EHRs and EMRs

It emerged through the study that there were a number of EHRs and EMRs systems that were being used in the health sector of Zimbabwe, including the EHR (name of the system), Epms, oPenEMR, DHIS2, and ePOC which were being used in Government hospitals. Thus, findings show that there was more than one system deployed in the health sector of Zimbabwe and more systems were yet to be deployed. The study further revealed that the

MHCC was planning to implement an HIE as part of the e-Health strategy (2012-2017) for Zimbabwe.

6.2.3 Existing standards for EHRs and EMRs in the health sector of Zimbabwe

Findings of the study revealed that ICD 10, HL7, DICOM and the Integrated Care Pathway (ICPCZ) were the standards that were mentioned as the ones in use by the respondents. However, it was not clear as to which family of HL7 standards were in use. It further emerged that the MHCC once implemented the ISO 27001 standard, but it would seem there was no proper follow up or sustainability of the standard. Encryptions as well as de-identification of personally identifiable health data were other means that were reportedly in use so as to protect the privacy of patients in EHRs systems. It was established through the study that despite the MHCC having the Department of ICT which is responsible for overseeing activities that relate to health information systems in Zimbabwe, there was no sharing of notes between the public sector and the private sector with regards to standards for EHRs and EMRs as well as the deployment, monitoring and evaluation of such systems. One respondent in the ICT Unit of the MHCC revealed that there was no platform for sharing notes between the two sectors.

6.3 Inter-operability of the EHRs and EMRs systems in use in the health sector of Zimbabwe

Findings of the study revealed that the systems that had been rolled out so far were not yet interoperable, but efforts were underway to achieve interoperability. Data pertaining to this objective further revealed that tests for system interoperability were at their infancy. Overall, data indicated that the MHCC was very much aware of the importance of standards for EHRs and EMRs in facilitating and enhancing interoperability and health information flow. This was commensurate with the pronouncements of the deployment and standardisation of EHRs in the e-Health strategy (2012-2017) for Zimbabwe.

6.4 Role of the Standards Association of Zimbabwe in the determination and promotion of health records standards in Zimbabwe

In light of the existence of SAZ, a national standards authority in Zimbabwe, it behoved the researcher to find out its role and ability regarding the development, deployment and possible monitoring of standards for EHRs and EMRs in the health sector of Zimbabwe.

6.4.1 Involvement of SAZ in the generation/development of standards for EHRs and EMRs

The study data revealed that SAZ was not involved in the generation or development of standards for EHRs as yet but had the potential of doing so. SAZ indicated that it had never generated any standard for EHRs and EMRs for use or implementation by the health sector of Zimbabwe. It was further learnt that SAZ was actually a full participating member of ISO, an international standards organisation that had a unit (ISO/TC 215 Secretariat on Health Informatics) that was responsible for the development of standards for health information and records. SAZ would adopt health information and records standards from ISO and sell them to the local market. However, SAZ indicated that it did not have a vibrant national mirror which should customise international standards for contextual use in Zimbabwe.

It was further learnt through the study that SAZ was willing and made efforts to bring together the concerned stakeholders for the customisation of ISO standards health informatics standards, including standards for EHRs and EMRs, but in vain and this constrained its efforts of doing so.

It was also learnt that because SAZ was registered and operated in accordance with the Companies Act of Zimbabwe, it developed standards in response to requests from stakeholders who would have expressed interest in having standards for application in their areas of operation. As for standards for EHRs and EMRs, data revealed that SAZ had not yet received requests for the development of standards for such systems and that its efforts to develop them were thwarted by lack of cooperation from stakeholders in the health sector to the extent of abandoning such a project. The dearth of cooperation from stakeholders regarding standards for EHRs and EMRs was a sign of lack of priority that standards were given, especially in light of the fact that standards were voluntary and market driven.

6.4.2 Legal mandate of SAZ to develop, implement and monitor EHRs and EMRs standards

Findings of the study revealed that SAZ did not have a legal mandate to develop or oversee or monitor the implementation or compliance with EHRs and EMRs standards by any healthcare facility in Zimbabwe since it was operating under the Companies Act. The fact that it was operating under this Act meant that it was not formed and given a mandate according to an Act of Parliament.

It was further learnt that although SAZ was not established according to an Act of Parliament, it did have MoUs with the Government ministries and department regarding the development of standards for the other sectors of the economy, with the health sector included, but not with regards to standards for EHRs and EMRs systems. It further emerged that SAZ was a not for profit entity which survived on revenues realised from standards development projects, but was also receiving funding from the Government of Zimbabwe through the Standards Development Fund. The Standards Development Fund requires all organisations to contribute to the fund through a mandatory standards tax.

Through the study, it was also established that other than developing standards, SAZ rendered advice on standardisation, offered training and guidance on standardisation as well as certification of products, services and systems. These services were open to any organisation or entity or individuals who approached SAZ in need of such, from both the private and public sectors, again on the basis that standards were voluntary and market driven. Data further revealed that SAZ was comfortable in not being involved in the regulation of standards so as to maintain objectivity amid the absence of a standards regulatory body for EHRs and EMRs in Zimbabwe, although it did not mind being equipped to do that.

6.4.3 Capacity of SAZ to develop standards for EHRs and EMRs

The study findings indicated that SAZ was technically and financially capacitated to develop standards but was not legally mandated to do so. It was learnt, from the study findings that financially, SAZ enjoyed double streams of revenue, that is, revenue realised from its standards projects and cash injection that was coming through the Standards Development

Fund and therefore, the financial capacity of the Association to develop standards of any type and for EHRs and EMRs was there. Technically, SAZ indicated that it had enough laboratories and expertise to develop and test standards for the afore-mentioned systems.

6.4.4 Relationship between the MHCC and SAZ regarding standards for EHRs and EMRs

Given the existence of SAZ and the seemingly high interest in the deployment of standardised EHRs and EMRs systems in the health sector of Zimbabwe as encapsulated in the Zimbabwe's e-Health Strategy (2012-2017), one would anticipate close cooperation between SAZ and the MHCC. However, the study revealed that there was no relationship or collaboration or standing MoU between the MHCC and SAZ as far as standards for EHRs and EMRs were concerned.

6.4.5 Relationship between the MHCC and other standards bodies regarding for EHRs and EMRs

The researcher also sought to understand whether MHCC was affiliated to any other standards bodies for the purposes of the development or collaboration in the area of standards for EHRs and EMRs, given the fact that such systems were already being deployed to the health sector of Zimbabwe. Findings of the study indicated that the Ministry was not affiliated or held membership of any health information development organisation.

6.4.6 Relationship of SAZ with the MHCC regarding EHRs and EMRs standards

The study data revealed that SAZ was in collaboration with and affiliated to a good number of regional and international standards organisations including ISO, the International Electrotechnical Commission (IEC), the South African Bureau of Standards (SABS), the Botswana Bureau of Standards (BOBS), the African Organisation for Standardisation (ARSO), and the ASTM in Canada. However, none of all the afore-mentioned standards bodies, save for ISO, dealt with standards from EHRs and EMRs. It further emerged that SAZ was not affiliated to or in collaboration with other prominent standards bodies such as the Comite Europeen de Normalisation (CEN/TC 25), Health Level Seven Inc (HL7), Digital Imaging and Communications in Medicine (DICOM) Standards Committee, the Japanese

Association of Healthcare Information Systems Industry (JAHIS) and the Medical Information System Development Centre (MEDIS-DC) whose areas of specialisation are health information standards, including EHRs and EMRs, demonstrating the peripheral nature of EHRs and EMRs at SAZ, owing to the dearth of interest in such standards by stakeholders in the health sector of Zimbabwe as revealed by the study data.

6.4.7 Promotion of EHRs and EMRs standards by SAZ

The study data pointed towards willingness by SAZ to promote standards for EHRs and EMRs in the health sector of Zimbabwe, but lamented the dearth of cooperation by the healthcare players. A respondent from SAZ hinted that since participation in standards development and implementation were determined by the market, the witnessed dearth of cooperation in the area of standards for EHRs and EMRs in Zimbabwe was a sign that such standards were not yet considered important or a priority.

6.5 Policies and legislation governing the development, implementation and monitoring of EHRs and EMRs standards in the health sector of Zimbabwe

For any project of the magnitude of EHRs and EMRs standardisation on a national scale to carry weight and yield intended fruits, it needs to be hinged on sound policies and legislation. Against this backdrop, the study sought to understand the policy and legislative framework that guided the implementation of standards for the afore-mentioned systems.

6.5.1 Health data to be included in EHRs and EMRs

Data revealed that there was no specific policy and legally binding definition of EHRs and EMRs, including their scope in terms of what constitutes these records, given the fluidity of these systems and the obvious disparities between these forms of records and their tradition paper counterparts with regards to both scope and contents. It was learnt that the Zimbabwe's e-Health Strategy (2012-2017) was the terms of reference for EHRs and EMRs that were being rolled out. This pointed to a need for a clear policy and legislative framework governing the scope (conceptualisation) of such systems by way of defining their contents and how they should be captured.

6.5.2 Requirements for institutions hosting and managing EHRs and EMRs

It was learnt from the study data that there were not yet specific requirements placed or dictated to institutions rolling out or hosting and managing EHRs and EMRs in terms of auditing of such systems, patients' security information, using and processing and sharing patient data. This included both medical and auxiliary personnel and organisations in their different categories. The study further revealed that the Zimbabwe ICT national policy was being used as the default policy to guide healthcare facilities in terms of hosting and managing patient health information.

6.5.3 Patient consent

In the context of health information management, patient consent requires that the patient be informed of the entity that requires access to their health or medical data and information and this is tied to patient confidentiality, privacy and security of their information. Data from the study revealed that there were not yet any rules or regulations or platforms allowing patients to know who wants to gain access to their information stored in EHRs and EMRs systems. The Patient Charter of Zimbabwe was cited as the main instrument addressing patient consent. However, the Charter was only good at addressing informed consent as far as eliciting rendering treatment to patients is concerned and was lacking in the aspect of informed consent in terms of the management, use and sharing of patient health information and data by healthcare facilities such as pharmacies, medical aid societies e.t.c and professionals including physicians, nurses, health and medical records and information managers, ICT personnel, researchers and many others who, one way or the other, may need to gain access to patients' data and information generated and stored in EHRs and EMRs platforms.

6.5.4 Updating of EHRs and EMRs

It further emerged that there were no standards as yet detecting who was responsible for updating patient records in EHRs and EMRs systems, but was assumed that the Patient Charter was adequate for this. The study data suggested that this concept was an elusive one and that the provisions for this were not clear and standardised.

6.5.5 Rules on EHRs and EMRs standards

Data revealed that there were no specific standard rules spelling out whether standards for EHR and EMR were compulsory or not, and how such standards were to be used or adhered to by healthcare facilities in Zimbabwe. Data indicated that there was no policy that was specific to the MHCC as yet but reliance was made on other instruments that were relevant. Reference was made to the "Responsible Use Policy", the "Employee Code of Conduct", the Cyber Security Act and the ICT Policy for Zimbabwe. Findings of the study indicated that whilst no specific rules and standards were in place, efforts were being made by the MHCC to come up with such.

6.5.6 Archival standards for EHRs and EMRs

Data from the study revealed that there were no archival standards for EHRs and EMRs and acknowledged this area as one that needs due attention. Data suggested that the respondents were aware of the NAZ Act (1986) when it comes to the archiving of health records, but lamented its inadequacy for EHRs and EMRs.

6.5.7 Application of EHRs and EMRs standards and their policies and laws in private healthcare facilities in Zimbabwe

It was learnt that there was no policy as yet that addressed issues of standards for EHRs and EMRs in the private sector, ranging from their application, adherence, maintenance as well as the deployment of such systems themselves. Respondents from the MHCC indicated that there was no platform for such as yet as the private sector was in business and did not have time, but the Ministry intended to look into that. One respondent cited the absence of legislation that will enable the Ministry to regulate private sector healthcare facilities with regards to standards for EHRs and EMRs.

6.5.8 Existence of a Health Information Standards Regulatory Body in the health sector of Zimbabwe

The study indicated that there was no health information standards regulatory body to deal with the standardisation of EHRs and EMRs in the health sector of Zimbabwe. As a result, healthcare facilities were rolling out such systems without paying due attention to their

standardisation as witnessed by systems that were still lacked interoperability and were found wanting in a number of standardisation aspects in comparison to their counterparts in other countries across the globe. A health information standards regulatory body would spell out the requirements and prerequisites for standards-based EHRs and EMRs platforms prior to implementation, promote and enhance compliance with such standards, thereby contributing to the enunciation of Zimbabwe's e-Health Strategy (2012-2017).

6.6 Preparedness for the support and sustainability of EHRs and EMRs standards in Zimbabwe

The study established that the potential to technically support and sustain standards for EHRs and EMRs existed at SAZ and the MHCC due to the existence of pools of expertise in both of these organisations. However, when it comes to financial preparedness to support and sustain standards for EHRs and EMRs, SAZ expressed confidence in rendering support for this endeavour if approached to do this by the relevant stakeholders, whilst the MHCC expressed inabilities, owing to financial constraints. Overall, the study indicated that sustainability and support for the afore-mentioned systems was possible if SAZ and the MHCC synergised their efforts, guided by a clear standardisation framework, which unfortunately, was missing at the time of conducting the study.

6.7 Conclusions of the study

According to the University of Southern California (2019), a conclusion serves the purpose of helping the reader appreciate why one's research should matter to them after reading it. Because a research conclusion is a synthesised statement of a study, the University of California (2019) further hinted that this should not be a mere summary of the major aspects that the study covered, neither should it be a mere re-statement of one's research problem, but a synthesised list of key points, and where possible, a conclusion should be accompanied by recommendations for further research. Thus, a conclusion is a meticulously written statement in which the researcher confidently makes sound statements about the status quo of the issues that were under consideration during the research process (problem under investigation and study objectives) and should be grounded in the findings of the study. In other words, a conclusion is the "takeaway" of a study.

6.7.1 Existing standards for EHRs and EMRs for the health sector in Zimbabwe

It can be concluded that there was just a handful of standards for EHRs and EMRs standards and such standards were not rolled out in a clear and coordinated fashion. They included ICD 10, DICOM, the Integrated Care Pathway (ICPCZ). This meant that healthcare facilities in Zimbabwe were deploying EHRs and EMRs that were not guided by sound and adequate standards. This left the healthcare sector of Zimbabwe being littered with unstandardized health information systems whose functionalities were not the same or synergised, with far much reaching ramifications to the health sector when efforts will be made in future to standardise such a myriad of legacy systems that will be characteristic of the sector in the coming medium to long term. The fact that there was no coordination of standards as yet for the ever increasing number and types of health information technologies in the health sector spelt potential setbacks for the Zimbabwe's e-Health Strategy (2012-2017) as one of the aims of the strategy is to achieve the standardisation of EHRs.

The number of existing standards for EHRs and EMRs systems reportedly in existence was not commensurate with the types and complexities of health information systems that were in use in the country's health sector, implying that that there was mushrooming of such systems at an unregulated rate coupled with the absence of a health information standards body in Zimbabwe. Healthcare facilities were likely to keep rolling out vendor driven systems at the expense of standardised systems, resulting in silos of inaccessible silos of health data and information between successive generations of health information packages. The ramifications again are far much reaching here where health information and data is locked up in idiosyncratic systems that are eventually dumped by vendors and healthcare facilities.

The presence of non-standardised EHRs and EMRs systems in the health sector, yet the MHCC and SAZ had a pool of expertise including software engineers points to low priority that was given to the standardisation of various health information systems that were however, seemingly becoming commonplace in the health sector of Zimbabwe. This implies that despite standards for EHRs and EMRs playing a cardinal role of the realisation of the vision of the MHCC as encapsulated in its e-Health Strategy (2012-2017), they were not yet given due attention.

6.7.2 Inter-operability of the EHRs and EMRs systems that were in use in the health sector of Zimbabwe

Based on the findings of the study in which it emerged that the EHRs and EMRs systems that had been rolled out were not interoperable, it can be concluded that the health information system of Zimbabwe was still fragmented and there were still pockets of grey areas in terms of health information, especially at the level of the Ministry where decisions need to be made based on complete and accurate information about the status quo of the country's health delivery system. In this vein, it can be discerned that the country will continue to suffer from the challenges of poor and incomplete health information that were typical of the traditional paper environment, something which is antithetical to the basis on which EHRs an EMRs systems were deployed.

Furthermore, the presence of disparate health information systems that were not talking to each other meant that the healthcare industry was deploying these systems for their internal use to solve elementary problems of health information/records management such as storage and filing, and that such systems were not yet liberalised. Furthermore, the primary beneficiary of such systems, who is the patient, will still have to retell their medical history each time they visited a different healthcare facility.

The dearth of interoperability of the deployed EHRs and EMRs systems in the health sector of Zimbabwe also implies that the plans of the MHCC to roll out a national HIE programme will face serious setbacks as the very concept of an HIE is contingent, among other things, on interoperable systems. Thus, if the Ministry was to roll out an HIE, there was need for it to be pro-active by ensuring the interoperability between all the systems that generate and store health information across the health sector in its entirety, including private and public care. This is particularly important given the fact that patients are mobile and seek medical interventions from institutions of their choices across the health sector, implying that if their information is to be shared for the purposes of improving care, there has to be swift exchange of information between and among the various EHRs and EMRs systems, something that was still a dream to come true for the health sector of Zimbabwe, looking at the lack of interoperability and synergism between the private and public health information systems.

6.7.3 The role of the Standards Association of Zimbabwe in the determination and promotion of health records standards in Zimbabwe

Given the revelation that SAZ was not very active in the area of standards for EHRs and EMRs across the health sector of Zimbabwe, coupled with the dearth of interest among stakeholders in the health sector of Zimbabwe, it can be concluded that the aspect of standardisation of health information systems such as EHRs and EMRs systems was not yet a priority in the sector, yet such systems continued to be rolled out throughout the sector.

Furthermore, the fact that SAZ was willing to work with any stakeholder in the area of standards for EHRs and EMRs systems and had actually made efforts in the past to cultivate the idea of standardising such system but in vain, owing to the dearth of commensurate cooperation from the healthcare players in Zimbabwe further buttresses the extremely low spirits amongst the stakeholders to deploy standardised health information systems and the consequences will be far much reaching, especially in light of the e-Health strategy (2012-2017) that was envisioned by the MHCC given that the interoperability of health information systems was set out as one of the intended objectives and facilitators of the strategy.

The fact that the MHCC had an MoU with SAZ regarding standards for other aspects of healthcare, yet no MoU existed between the two entities for EHRs standards, especially in view of the grand vision of the MHCC with regards to EHRs in its e-Health strategy (2012-2017) where the role of standards was clearly understood and explained, was further confirmation of the slow pace at which the aspect of standardisation for such systems was moving in the country. The fact that the e-Health Strategy had a five-year life span, which has come and passed, without any sound action or any engagements with SAZ on the part of the MHCC regarding the standardisation of EHRs, either meant that the MHCC was going to have a separate unit on the standardisation of health information systems or the standards were not yet in the list of its priorities.

The fact that SAZ was already an authority in the aspect of standardisation and had expertise and all the other resources, including finance and testing infrastructure, and was affiliated to one of the international and renewed standards body, ISO, which had a specific Secretariat dedicated to health informatics, placed it at an added advantage in terms of championing the development and promotion of standards for EHRs and EMRs, something that the MHCC

could ride on if its e-Health strategy (2012-2017) is to be realised regarding the aspect of EHRs and EMRs, their standardisation as well as its envisaged HIE.

6.7.4 Policies and legislation governing the development, implementation and monitoring of EHRs and EMRs standards in the health sector of Zimbabwe

Based on the study findings, it can be concluded that standards for EHRs and EMRs were likely to remain peripheral as there were no specific policies governing the development, implementation and monitoring of such standards. This meant that the implementation of standardised systems was not only going to remain a matter of choice among healthcare facilities, but in the case of those that opted to have standardised systems, they will have to do that in a haphazard manner. Thus, it is commonplace that where things remain optional without any policy or legislative enforcement, institutions remain reluctant to implement them, especially something that commitments that are financially and technically demanding such as standards.

It can as well be concluded that there was no sound leadership in the aspect of standards for EHRs and EMRs as there was no institution or body that advocated for and regulated standards for such systems, yet their importance in improving the quality of care is indisputable. This meant that for as long as the prevailing status quo continued the prospects of having standardised EHRs and EMRs systems as envisaged in the e–Health Strategy of Zimbabwe (2012-2017) will remain in limbo. The effect of the twin factors of the absence of polices and legislation for health information standards and the absence of a standards regulatory body presented a double blow to the health sector of Zimbabwe as it means that standards for such systems were not a desideratum and for those institutions that cared to standardise their systems, there was no framework within which to measure their compliance.

6.7.5 Preparedness for the support and sustainability of EHRs and EMRs standards in Zimbabwe

Against the backdrop of the study findings, the researcher can conclude that the potential to support and sustain standards for EHRs and EMRs in Zimbabwe was present, but only on condition that the MHCC and SAZ entered into a clear MoU which enunciates the cause of standardisation. This conclusion is premised on the fact that both of these organisations had

an indisputable appreciation of standards for EHRs and EMRs and they both had a good pool of expertise, and whilst the MHCC was suffering from financial constraints, SAZ was well financed to support and sustain standards for EHRs and EMRs in Zimbabwe. Thus, the MHCC was yet to exploit the opportunity that arose from its MoU with SAZ.

6.8 Recommendations of the study

Because the present study was problem driven, it was compelling and important for the researcher to suggest ways in which the standardisation of EHRs and EMRs could be improved in the health sector of Zimbabwe. Against that backdrop, the researcher proffers recommendations which were informed by the study findings and conclusions. The recommendations proffered are objective specific.

6.8.1 Existing standards for EHRs and EMRs for the health sector in Zimbabwe

Given indications that the standards for EHRs and EMRs that existed so far were insufficient and the EHRs and EMRs systems continued to emerge, it is recommended that the MHCC, in conjunction with the Ministry of Information and Communication Technology and Courier Services (MICTCS) conduct an audit of the existing EHRs, EMRs and other health information systems that are in use in the health sector of Zimbabwe so as to understand the extent and character of those systems and implement a clear and robust standardisation strategy for such systems.

It is also recommended that the MHCC plays a monitoring role regarding the deployment of EHRs and EMRs systems by healthcare facilities of any type in Zimbabwe's health sector and set minimum standards that such facilities should adhere to. This will not only improve the standardisation of such systems as envisaged in the Zimbabwe's e-Health Strategy (2012-2017), but will also curb the mushrooming of EHRs and EMRs systems that are idiosyncratic, vendor driven and less useful in terms of the improvement of the country's health delivery system. This will also save the country huge sums of money that is, expenses arising from the cumbersome and costly process of standardising legacy systems in retrospect. This recommendation comes against the backdrop that the MHCC was seemingly not regulating the deployment of health information systems, especially in the private sector and did not

even know what types of systems, with what functionalities, guided by which standards were in existence in the private sector. This implies that there was need to also synergise efforts between the MHCC and the private sector regarding the deployment of standards based EHRs and EMRs systems since the Ministry needed to interface with all healthcare facilities in the country.

6.8.2 Extent of inter-operability of the EHRs and EMRs systems that are in use in the health sector of Zimbabwe

As the study findings reflected, there was limited interoperability between the deployed EHRs and EMRs systems in the country's health sector, meaning that the deployed systems could not share health information and silos of health data continued to exist and expand commensurately with the continued deployment of such systems. In light of this finding, it is recommended that the MHCC, through its ICT, Policy Planning and Health Information Units, comes together with all the concerned stakeholders in the health sector and agree on a specific and pragmatic interoperability roadmap that should guide all healthcare facilities in the country, irrespective of the sector or level of care. Such an interoperability framework should be made mandatory and compliance must be ensured by the MHCC. The interoperability framework should be modelled along the lines of the already existing health information flow in the health sector, with the MHCC being able to interface with any healthcare facility in terms of information sharing. This recommendation also comes in handy for the MHCC as it was learnt through the study that an HIE was in the pipeline and interoperability is a desideratum if such a concept is to yield meaningful fruits.

It is further recommended that the Government of Zimbabwe, through the MHCC comes up with a framework which spells out the "good use" of EHRs and EMRs systems by healthcare facilities in Zimbabwe and rewards those facilities that are found to be compliant with the "good use" framework as a way of incentivising them. In such a framework, standards for EHRs and EMRs should then be made compulsory by being part of the "good use". This model was propounded by the USA where the Government of that country came up with the idea of "meaningful use of EHRs" and incentivised healthcare facilities to comply with the meaningful use framework by rewarding those that were found to be compliant with the framework. Given the financial challenges that the MHCC and Government in general were facing, incentives in the form of training for the medical and non-medical staff in EHRs and EMRs may be the starting point in Zimbabwe.

6.8.3 Role of the Standards Association of Zimbabwe in the determination and promotion of health records standards in Zimbabwe

Given the findings of the study in which it was learnt that SAZ was willing and had the capacity to develop standards for EHRs and EMRs for the health sector of Zimbabwe, but there was no request or expression of interest from such a sector to develop or promote such standards, it is recommended that the MHCC engages SAZ on the development and promotion of standards and stirs interest in such standards in the health sector through workshops and training of members of staff. The fact that the Ministry had a standing MoU with SAZ and was the overseer and policy maker in the field of health puts it at an advantage in terms of mobilising healthcare facilities and stakeholders towards developing interest in the deployment of standards for both the existing system and those that are yet to be deployed.

Given the fact that SAZ was a full member of ISO, an international standards organisation with health informatics standards that include standards for EHRs, and was adopting ISO health informatics standards, coupled with a good pool of expertise, it is recommended that the Ministry of health collaborates with SAZ and adopt such ISO standards. The fact that SAZ relies on the local market for expertise to form a national TC mirror and there was no cooperation from the health sector in Zimbabwe and that SAZ once made efforts to customise ISO standards but there was no commensurate support and willingness implies that there was no priority given to EHRs and EMRs standards so far in Zimbabwe.

It is further recommended that SAZ steps up its efforts on the promotion of standards and initiates a deliberate process of marketing and certifying healthcare facilities that deployed standards based EHRs and EMRs. Should SAZ initiate such a process, the MHCC should complement it by incentivising those healthcare facilities that adopt such standards and rolling out such standards in all of its healthcare facilities as a way of leading by example, riding on its e-Health Strategy (2012-2017) in which the adoption of standardised EHRs was pronounced.

The use of SAZ ISO adopted standards by healthcare facilities will help them serve on costs of buying the standards directly from ISO as SAZ was sourcing them through its membership to ISO and customising or selling them at a subsidised price to the local market. It is appreciated that internationally developed standards such as those of ISO have the advantage of being the best ones in most cases, given their international flair. However, they are usually

pitched at the apex in terms of their requirements in the case of implementation and maintenance, and it is appreciated that this may strain the ailing Zimbabwean healthcare sector. Thus, it is recommended that where such high profile standards are being adopted, they are customised and contextualised to the Zimbabwean needs and abilities through a national TC mirror that unfortunately, was reportedly missing, thereby necessitating its formation.

6.8.4 Policies and legislation governing the development, implementation and monitoring of EHRs and EMRs standards in the health sector of Zimbabwe

With the study the study revealing that there were no standards specific policies for EHRs and EMRs outlining the "dos and donts" for healthcare facilities, it is recommended that the MHCC, in conjunction with the MICTCS and all other relevant stakeholders in the health sector come to the table and set out a policy and a monitoring and evaluation framework that will guide healthcare facilities of all types in terms of standardising their EHRs and EMRs systems. Such a policy should have specific time lines for compliance and monitoring and evaluation mechanisms for all EHRs and EMRs systems in use in the health sector of Zimbabwe. Legislation should prescribe mandatory standards, especially in aspects of privacy, patient consent and archiving.

The MHCC should also lobby the Government of Zimbabwe for the enactment of clear, sound and relevant legislation for EHRs and EMRs, ranging from their conceptualisation/definition right through their deployment and minimum standards on a number of issues including the following:

i. Creation, access and updating of EHRs and EMRs;
ii. Sharing of patient health information generated, captured and stored in EHRs and EMRs systems, including patient consent. Regarding patient consent, it is necessary to strike a balance between access for healthcare and access for secondary uses such as use by third parties, for which patient consent has to be sought and protected;
iii. Privacy and confidentiality, together with associated security and privacy breach consequences on both healthcare givers and third parties in their different categories; and
iv. Archiving of EHRs and EMRs.

The afore-mentioned recommendation is in tandem with practices in some progressive countries in the areas of health and health information management, including the US, Canada, Australia and many European countries where there are sound policy and legislative frameworks that detect the minimum standards requirements for the above-mentioned important aspects.

It is further recommended that there be national health information standards body formed and comprises of representatives of various stakeholders in the health sector and beyond. For example, the body may be comprised of members from the MHCC in their different capacities and this Ministry should assume a leadership role, members from the MICTCS, information and health records managers, archivists from the National Archives of Zimbabwe and members from SAZ. Such a body should have powers to detect standards for EHRs and EMRs as well as every other electronic health information systems that healthcare facilities should use and be given a statutory and policy mandate to make binding pronouncements regarding standards for such systems including evaluation, monitoring compliance and promotion of standardised systems upon deployment.

It is further recommended that the MHCC has full control over the deployment of EHRs and EMRs as well as other health information systems in the private sector as well as NGOs that render health services in Zimbabwe and ensure that they deploy and maintain standardised systems. This recommendation comes against the study findings where it emerged that the MHCC had no control over systems that were deployed in private health sector facilities and did not know how many systems had been deployed by private healthcare facilities, with what functionalities and whether they were operating on any standards or not. The health information standards body, if formed should, among other things, be responsible for conducting EHRs and EMRs systems audits to determine their compliance levels and advise the healthcare facilities accordingly. This would expedite and complement Zimbabwe's e-Health Strategy (2012-2017) towards becoming a reality.

6.8.5 Preparedness for the support and sustainability of EHRs and EMRs standards in Zimbabwe

Given the revelations of the study that SAZ had a pool of standards expertise and was in a position to sustain EHRs and EMRs in terms of technical support and advice, it is

recommended that the MHCC, which was reportedly financially constrained regarding funding for standards, takes advantage of its cordial relationship with SAZ to engage it in the aspect of the standardisation exercise. Thus, the two institutions should join hands and come up with a clear health information systems standards roadmap. The fact that SAZ is already a member of ISO and other standards bodies means that it was better placed as far as the development of standards is concerned.

6.9 Proposed framework for EHRs and EMRs standards implementation in the health sector of Zimbabwe

Figure 6.1 is the proposed framework, giving a simplified conceptualisation of standards implementation in the health sector of Zimbabwe. The framework was developed by the researcher under the influence of the study findings as well as literature and best practices around the world.

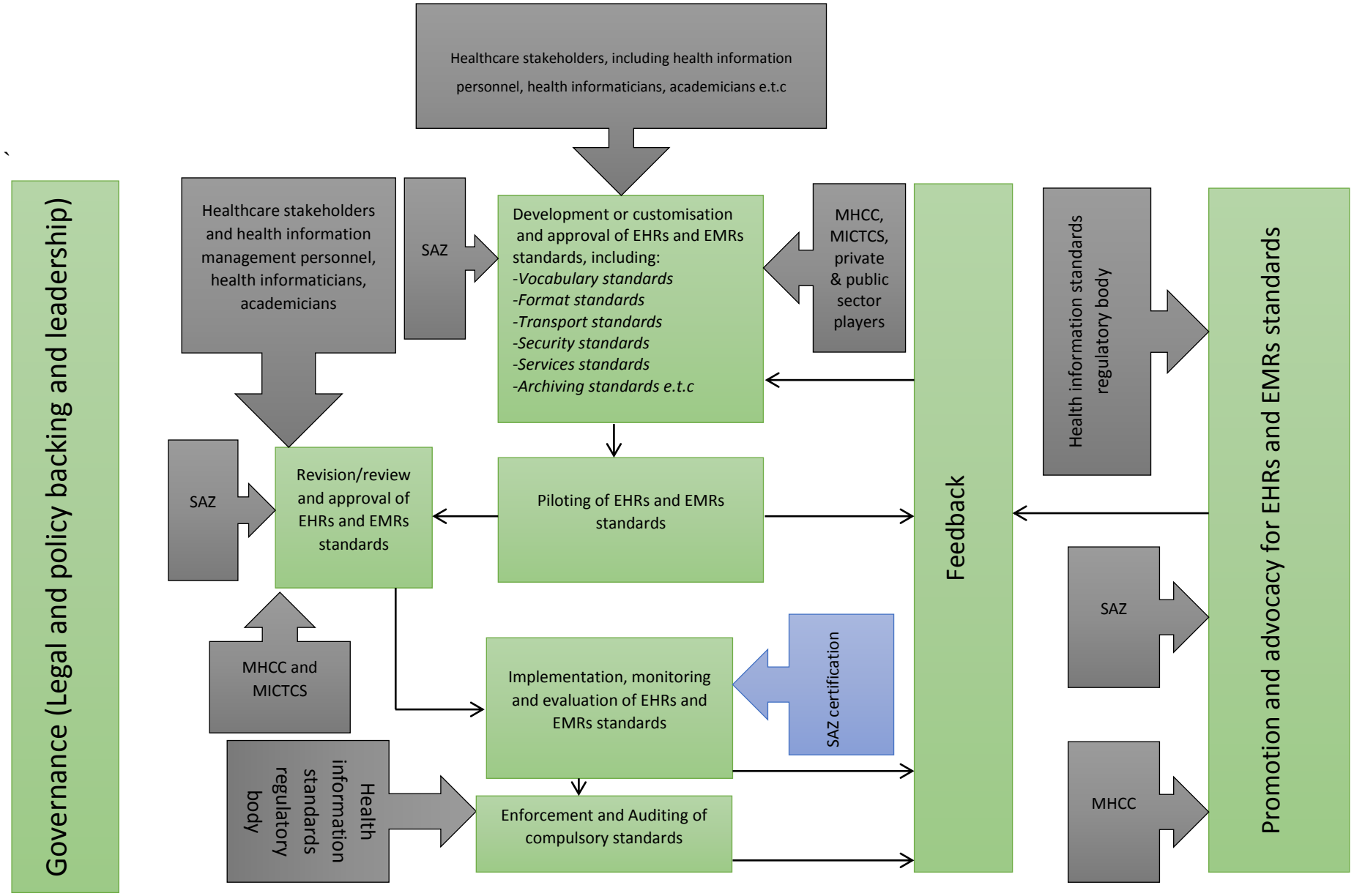

Figure 6.1: Proposed framework for EHRs and EMRs standards implementation in Zimbabwe's health sector

6.9. 1 Explanation of the framework

A framework can be seen as "a structure for supporting or enclosing something else, especially a skeletal support used as the basis for something being constructed (The American Heritage Dictionary of the English Language 2016) and "a supporting structure around which something can be built…a system of rules, ideas, or beliefs that is used to plan or decide (Cambridge Dictionary n.d). The framework consists of eight key activities within which standards for EHRs and EMRs could be implemented in the context of the healthcare delivery system of Zimbabwe. The framework takes into consideration data gathered from the study, the literature on best practices regarding standards for EHRs and EMRs as well as the contextual setting in Zimbabwe. The framework also tapes from project management as essentially the process of standards implementation is a project or a series of projects if each activity is to be treated as a project. The framework consists of the following strands which are presented and discussed seriatim.

6.9.2 Development, adoption, adaptation and approval of EHRs and EMRs standards

This is the first stage of the framework, whose thrust is to come up with the desired standards for EHRs and EMRs that should be used in the health sector of Zimbabwe by all healthcare facilities in the country. The determination of such standards may take three forms, that is, development in the case of standards that do not exist or adoption of already existing standards in the case of the already existing standards being found to be adequate and suitable for use in the health delivery system of Zimbabwe or adaptation whereby already existing standards can be customised to fit the local context. Standards that are developed or adopted or adapted should be comprehensive and cover all categories, including vocabulary standards, content standards, clinical standards, information management standards, privacy and security standards. It is always best for healthcare facilities to adopt international standards from international standards bodies such as ISO, HL7, DICOM, CEN, ICD and many more or customise them to local settings through SAZ. The development of fresh standards should be done only when necessary and when the adoption of international standards is impossible. This is because the adoption of already existing standards is cheaper as most of them would have been tried and tested in e-health implementations. However, where international standards are impossible to adopt or implement

for different reasons, local standards should developed as this allows for the development of low costs standards that are sensitive to local settings.

The framework proposes that at the stage of development of adoption of EHRs and EMRs, the MHCC, SAZ, MICTCS, healthcare stakeholders from various types of healthcare facilities and health information management professionals come together and form a standards adoption committee that should be tasked with the responsibility of selecting best standards for adoption or advising on the specifications of the new standards to be developed. This is particularly important, given the fact that standards are best practices and those are best determined through concerted efforts from all the relevant stakeholders.

Once the standards have been adopted or developed, the same committee should approve the standards for piloting and possible implementation by healthcare facilities, irrespective of type and size. Healthcare facilities of all types should be encouraged to use approved standards so that the MHCC is in a position to vouch for the functionalities of the different EHRs and EMRs systems that are in use in the health sector at any given point in time, and interoperability will be made less cumbersome. This approach will help curb the deployment of EHRs and EMRs systems that are disparate, not standardised and responsible for the fragmentation of health information, as was currently the case with the health information flow in the country's health sector. Thus, in the development or adoption or adaptation of standards at this stage, due attention should be given to the already existent EHRs and EMRs systems as well as any other legacy systems to enable their standardisation ex post facto, where possible.

6.9.3 Piloting

According to The Association for Project Management (2019), piloting may be considered as the first small-scale implementation of a project whose aim is to address the viability and scalability question of the project by allowing the proposed project to be tested. The afore-mentioned view is in tandem with that of Bassi (2010:6) who explained that "piloting of an ICT project is defined as the implementation of an ICT technology, software, or related project on a small scale to allow for its full impact, benefits and weaknesses to be evaluated before implementation on a regional or nationwide scale basis." The piloting stage of the proposed framework involves the implementation of the approved standards in a few healthcare facilities and will be meant to

determine how the standards meet the country's health information requirements or solve the current challenge of disparate health information systems in Zimbabwe's health sector.

Piloting the approved standards will give room for the standards' weaknesses and strengths to be identified and addressed prior to rolling the standards out on a full scale. This should give rise to the revision of the standards after being rolled out on a large scale. This should result in detailed and contextual piloting reports with recommendations on the areas that need improvements. This is possible because in essence, piloting is for the purposes of learning in an effort to adjust the initial assumptions about the project and take appropriate and informed decisions in terms of rolling out the project on a large scale (Bassi 2010:7). Thus, piloting enables an organisation to undertake risk management in a new project and identify the weaknesses of the project prior to committing substantial amounts of resources to such a project. This will help the standards development stakeholders to make informed reviews of the EHRs and EMRs standards objectively before scaling the project to healthcare facilities in Zimbabwe. After the identification of the strengths and weaknesses of the approved standards, the revision process should follow.

6.9.4 Revision

This stage should be necessitated and informed by findings of the piloting stage. The thrust at this stage is to improve the standards by eliminating or minimising the challenges that they present. This is important and almost inevitable whether the standards were newly developed in Zimbabwe or adopted from a renowned international standards body. In the case of the newly developed standards, by virtue of being new and not having been tried elsewhere, the standards are likely to create complications and will need to be revised so as to polish them up as per the recommendations from the piloting exercise.

In the case of international standards being adopted, the likelihood of the standards being either too complicated for the local market or being too expensive to fully implement is also very high, especially for the health sector of Zimbabwe which is currently ailing, owing to the decade + years of economic slide in the country. This then necessitates the revision of the standards so as to keep them within achievable and implementable levels in the health sector of Zimbabwe. At this stage, the MHCC, MICTCS, SAZ, health sector stakeholders and health information

management personnel come in to share ideas on how best to address the challenges that would have arisen from the piloting and evaluation stage. This will see the amendment of the standards accordingly. This stage should also give feedback to the development and approval stage of the standard.

6.9.5 Implementation and monitoring

Implementation talks to rolling out the standards on a large scale in the health sector of Zimbabwe. The stage of implementation should be accompanied by extensive promotion and advocacy activities so as to encourage as many healthcare facilities as possible to implement the standards. For example, promotion may come in the form of partial funding or awarding of bonuses to institutions rolling out the standards and non-financial incentives such as free training to staff of the institutions that are implementing the standards. The stage of monitoring and evaluation should also be accompanied by solid and clear policies and legislations to guide the process of implementation so as to ensure that healthcare facilities that roll out the proposed standards are aware of what is expected of them in terms of policy and legislation. At this stage, SAZ, as the national standards body in Zimbabwe may play a critical role of certifying all the EHRs and EMRs systems in terms of them meeting to set standards. Such certification should be made a requirement and not an option for all healthcare facilities in Zimbabwe and that should include both the already existing and the new EHRs and EMRs platforms, supported by policy and legislation.

Closely tied to implementation is monitoring and evaluation, twin activities that are usually treated as one and the same thing due to their being intertwined and complementary nature, yet they are distinct. Following the implementation of the approved standards, the next critical stages are those of monitoring and evaluation. Monitoring, as a basis for evaluation and learning, is a function that aims at furnishing those in charge of a project, such as managers and stakeholders with early information pertaining to the progress or lack of it, thereby enabling organisations to track their achievements and facilitates timely decision making, accountability (Sera and Beaudry 2007:1). Monitoring thus, indicates “whether things are going to plan and helps project managers to identify and solve problems quickly. It keeps track of project inputs and outputs such as activities, reporting and documentation, finances and budgets and supplies and equipment” (WHO 2019). Thus, the thrust of monitoring is to collect information pertaining to

the performance of a project and using such information by management to determine the effect of the project, including its intentional and unintentional impacts, thereby assisting the management know whether the project is meeting its objectives (Otieno n.d).

In the context the proposed framework, monitoring involves a continuous process of collecting information about the performance of the implemented EHRs and EMRs systems and appraising such information in relation to the objectives of standardisation. Such monitoring information should be gathered on the EHRs and EMRs standards themselves, as well as the associated governance structure so as to determine their sufficiency and suitability in terms of underpinning the standards implementation project or framework. The monitoring exercise should address the key objectives of standardisation such as interoperability, creation, access and updating of EHRs and EMRs, sharing of patient health information, privacy, confidentiality, security and archiving of patient health information on EHRs and EMRs systems. This process should be conducted by an "all stakeholder" monitoring committee consisting of representatives from all healthcare facilities in Zimbabwe, with the MHCC taking the lead. The monitoring stage should be followed by the evaluation exercise.

6.9.6 Evaluation

Evaluation talks to a systematic and objective process of a project, programme or policy, either complete or still running, including aspects of its design, implementation and outcomes (Sera and Beaudry 2007:1). According to Hughes and Nieuwenhuis (2005:13), evaluation, metaphorically speaking, has a dichotomous purpose, which is the "stick" and "torch" strands. The first strand is about accountability in which evaluation serves as a measuring stick, that is, justifying the very existence of a project in the first instance, its activities and its continuation in which case the ethos is inspectorial and judgemental and focus is on value for money, quality standards, thus, the "stick" strand effectively serves as a licence for practice in the eyes of the sponsors (Hughes and Nieuwenhuis 2005:13). The second strand, the "torch" function is about project improvement and has its ethos being diagnostic and interpretive where the thrust is collective learning (Hughes and Nieuwenhuis 2005:13). On that note, this strand can be viewed as a development process, that is, a torch facilitating in the illumination of problems and acknowledges good practice (Hughes and Nieuwenhuis 2005:13). Thus, the evaluation stage talks to the fundamentals of the project and determining whether these are being met or not,

thereby justifying the project's continued existence or suspension. Both formative and summative evaluations are imperative for the success of the standardisation of EHRs and EMRs systems in Zimbabwe. Formative evaluations will be necessitated by the fact that this is a project that may be implemented from scratch and whilst summative evaluations will be dedicated to the progress and continuous improvements of the project.

In the context of the framework, the implemented EHRs and EMRs standards should be evaluated against the objectives of the standards project at the stage of development. The evaluation process should determine whether the standards are compatible with the health sector of Zimbabwe and whether the governance structure is in sync with the standards objectives by rendering relevant policy and legislative support. The evaluation process should be a participatory process in which all the stakeholders in the healthcare sector participate, with the MHCC taking a lead. The standardisation process for EHRs and EMRs systems should meet the objectives of Zimbabwe's e-Health Strategy (2012-2017) as pronounced by the MHCC, and hence the need for the Ministry to take a lead in the evaluation process. Where the implemented standards are found to be in sync with the objectives of the standards implementation process, the project should continue. However, where the evaluation process points to undesired results and impact, the stakeholders involved in the project may need to revisit the project, especially the standards themselves under the guidance of the e-Health Strategy (2012-2017).

6.9.7 Enforcement and auditing

The study findings revealed a dearth of a standards enforcement and auditing structure in the health sector of Zimbabwe, resulting in the emergence of EHRs and EMRs systems whose functionalities are not known. It also emerged that the absence of enforcement emanated from the fact that standards for EHRs and EMRs were still considered voluntary in Zimbabwe in comparison to other standards which were made compulsory by regulatory authorities. The study further revealed that there was no standards auditing and compliance structure and this saw the MHCC being in darkness as to how many systems, with what characteristics, and what standards were in existence in the country's health sector, especially in the private sector. Such findings posed a serious threat to the Ministry's e-Health Strategy (2012-2017) in which standardised EHRs systems were envisaged to play a significant role towards the achievement of such goals.

In light of such findings, the proposed framework proposes that certain standards for EHRs and EMRs be made mandatory and there be enforcement of such standards in Zimbabwe's health sector, irrespective of the sector. According to Henson (2006:5), mandatory or regulatory standards are those standards that are set by public institutions, especially regulatory bodies with which compliance is a legal requirement. Thus, the proposed health information standards regulatory body should be legally empowered to enforce mandatory standards in the healthcare facilities, irrespective of the sector. Mandatory standards should include the following:

i. Privacy, confidentiality and information security standards;
ii. Access and patient consent standards;
iii. EHRs and EMRs archiving standards; and
iv. Requirements on institutions that host and manage health information.

Enforcement and auditing should be undertaken by an independent health information standards regulatory body and should be guided by the objectives of the standardisation project for EHRs and EMRs. The health information standards regulatory body needs to operate within clear guidelines regarding the enforcement and auditing process and should be guided by clear legal and policy guidelines. Such a body should also be empowered to make recommendations that are legally binding to healthcare facilities. The enforcement and auditing body should comprise of experts with both technical and standardisation knowledge and should ideally be headed by an EHRs standards specialist.

6.9.8 Governance

Governance in the context of the proposed framework talks to the provision of leadership as well as legal and policy atmosphere that is conducive for the project. The governance strand will cut across all the fundamental project activities and should be specific to standards for EHRs and EMRs. Literature has shown that where a project does not have sound governance, it tends to collapse and this may have been the case in the context of EHRs and EMRs standards framework in Zimbabwe where clear governance for such standards was missing, resulting in a boom of such systems that do not operate on standards and clear governance. The policy and legislative atmosphere should be realistic and sensitive to the Zimbabwean context, with compulsory standards identified in "Enforcement and Auditing" section being legally provided for, whilst the

policies that guide the other processes of implementation should be encouraging and aligned to international practice.

6.9.9 Promotion and advocacy

It emerged from the study that there were not any promotion and advocacy for standards for EHRs and EMRs standards in the health sector of Zimbabwe and that there was reluctance and very limited interest in such standards from stakeholders, coupled with standards being voluntary in the country. Against this background, the framework provides for the promotion and advocacy which should cut across all the activities, including the pre-implementation and post-implementation stages. According to the International Council on Archives (ICA) (2016) "In practice advocacy activities generally target specific audiences the association may wish to influence, whereas, promotion is about taking a broad message to the widest audience possible." The promotion and advocacy for standards for EHRs and EMRs should target both public and private healthcare facilities. At this stage, the MHCC should take a lead given its vision about the standardisation of EHRs systems as envisaged in its e-Health Strategy (2012-2017) and collaborate with other stakeholders such as SAZ, the proposed national health information standards body as well as representatives from the private sector. It is important to include the private sector in such activities as a way of gaining "buy in" from the sector, which is usually operating outside some government policies.

6.10 Theoretical, policy and methodological implications

It is commonplace that the researcher explains how their proposed framework will impact theory, policy and methodology, which is the thrust of this section. This should not be confused with the significance of the study. Whilst significance of the study talks to the benefits of the findings of the study in its entirety to the various stakeholders, this section is specifically dedicated to the implications of the proposed framework whereby the researcher appraises the proposed framework in the context of theory, policy and methodology, given the fact that the framework impacts those key aspects.

Theoretically, the framework offers a synthesised conceptual lens of some EHRs and EMR standards implementation fundamentals. The proposed framework gives a basic idea regarding the standardisation process for EHRs and EMRs, something that takes into consideration the possible roles of specific stakeholders in the context of Zimbabwe. As acknowledged earlier on, the framework is not in any way exhaustive or conclusive in terms of the fundamentals and is open for constructive criticism and modification. In particular, the framework was designed by the researcher from a purely theoretical perspective and the researcher has not practiced or participated in EHRs or EMRs projects or their standardisation. Thus, the researcher acknowledges that the framework may need a practical flare to complement the researcher's ideas.

In terms of policy, the proposed framework may influence policy making and implementation as it calls for improved and clearly defined policies between and among stakeholders in the health sector of Zimbabwe. In particular, the framework calls for the MHCC, MICTCS, SAZ and other stakeholders to come to the table and roll out an EHRs and EMRs standards implementation blue print that should unite the entire health sector towards the standardisation of its health information systems. Thus, the stakeholders may have to move away from their comfort zones and have new and redefined roles if the standards for EHRs and EMRs are to be a reality in Zimbabwe. The framework further affects policy by suggesting the establishment of a new player in the implementation of standards for EHRs and EMRs, that is, a national health information standards body, whose primary role is the enforcement and auditing of EHRs and EMRs systems for compliance with mandatory standards and such a body should be interfacing with other stakeholders in the sector.

Regarding methodology, the framework proposes a more pragmatic approach which is rolled out in a scientific manner in which the implementation of standards for EHRs and EMRs is guided by some elements of project management, thereby allowing for checks and balances to be done to the project. This framework is cognisant of the failure by most government pronouncements that are not accompanied by commensurate deliberate action plans as was seemingly the case with the standards for EHRs that were encapsulated in Zimbabwe's e-Health Strategy (2012-2017) where there was a detailed understanding and appreciation of such standards without a clear plan of action regarding implementation. However, the researcher admits that the

framework is still abstract and a lot of other complementary activities and actual plans of action need to be drafted to complement the framework for improvement.

6.11 Overall conclusion of the study

The study sought to explore the terrain of standards for EHRs and EMRs in Zimbabwe so as to understand the progress which the MHCC has made in terms of enunciating the standardisation of health information systems following its pronouncement of the Zimbabwe's e-Health Strategy (2012-2017). From the study findings, it can be concluded that the concept of standards for EHRs and EMRs in Zimbabwe was at its nascent stage as witnessed by inadequate standards, EHRs and EMRs systems that were not interoperable, absence of standards specific policies and legislation and the absence of a health information standards regulatory body.

It can be further concluded that standards for EHRs and EMRs were still enjoying very low priority among the stakeholders, and thus, more and more disparate systems were being rolled out in the country's health sector and the MHCC was not keeping track of the systems that were being rolled out across the country's health sector. This implies that in the medium to long run, the health sector of Zimbabwe is going to be faced with a mammoth, cumbersome and costly task of standardising such systems in retrospect. Thus, given the prevailing status quo, Zimbabwe was not yet reaping maximum benefits from the deployment of EHRs and EMRs, and the prevailing state of affairs regarding standardisation was set to retard the realisation of the maximum benefits from the country's e-Health Strategy (2012-2017). Despite this observation, the researcher noted that Zimbabwe had a good starting point for rolling out a viable EHRs and EMRs standards framework, including a sound and up-to-date ICT policy and the Zimbabwe's e-Health Strategy (2012-2017).

6.12 Recommendations for further research

The researcher recommends the use of a different methodology that will use the actual healthcare facilities as the study population. The present study drew its respondents from the Head Office of the MHCC in which the Deputy Director of Health Information, Deputy Director of Policy and Planning and the Deputy Director of ICT as well as the Director General of SAZ and the

Manager of one the Departments at SAZ. A different study may zero in on the healthcare facilities on the ground and use them as the study population.

The study further recommends quantitative evaluative studies for the existing EHRs and EMRs in terms of their standardisation in which the researchers will gain access to the systems and physically interact with the systems at the healthcare facilities, preferably in collaboration with those who are in practice. This was impossible as e-health implementation was a prerogative of the MHCC and the present study was not designed to be a practice based qualification. The present study was purely theoretical and relied on the data that was provided by the respondents and did not have access to the actual EHRs and EMRs systems due to privacy, confidentiality and security concerns, given the fact that the systems held patient information and data. Thus, a study based on systems analyses is recommended.

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Appendix A: Ethical Clearance from UNISA

UNISA university of south africa

Department of Information Science
College of Human Sciences

Date: 30 October 2014

Proposed title: **Framework for electronic health records and electronic medical records standards implementation in the health sector of Zimbabwe**

Principal investigator: Mehluli Masuku

Student number: 55785107

Reviewed and processed as: Class approval (see paragraph 10.7 of the UNISA. Guidelines for Ethics Review)

Approval status recommended by reviewers: Approved

The Research Ethics Committee of the Department of Information Science in the College of Human Sciences at the University of South Africa has reviewed the proposal and considers the methodological, technical and ethical aspects of the proposal to be appropriate to the tasks proposed. Approval is hereby granted for M Masuku, (55785107) to proceed with the study in strict accordance with the approved proposal and the ethics policy of the University of South Africa.

In addition, the candidate should heed the following guidelines:

- To only start this research study after obtaining informed consent from the interviewees.
- To carry out the research according to good research practice and in an ethical manner.
- To maintain the confidentiality of all data collected from or about research participants, and maintain security procedures for the protection of privacy.
- To notify the committee in writing immediately if any adverse event occurs.

Kind regards

Mr SC Ndwandwe
Chair: Research Ethics Committee
Department of Information Science
Tel + 2712 429 6037

University of South Africa
Preller Street, Muckleneuk Ridge, City of Tshwane
PO Box 392 UNISA 0003 South Africa
Telephone: +27 12 429 3111 Facsmile: +27 429 12 429 4150
www.unisa.ac.za

Appendix B: Introductory letter from Supervisor (MHCC)

University of South Africa
School of Interdisciplinary Research and Postgraduate Studies
P. O. Box 392
UNISA
0003
UNISA - Campus
Preller Street
Theo van Wijk Building - Room 04-02
Tel: +27 12 429 2832

20 April 2018

The Permanent Secretary
Ministry of Health and Child Care
P. O Box CY 1122
Causeway
Harare

RE: REQUEST FOR PERMISSION TO GATHER RESEARCH DATA-MR MEHLULI MASUKU

This is to confirm that Mr Mehluli Masuku is a Doctor of Litt et Phil (Information Science) candidate (Student Number 55785107) in the Department of Information Science at the University of South Africa (UNISA) and is conducting a research project titled **"Framework of Standards for Electronic Health Records and Electronic Medical Records for the Health Sector in Zimbabwe**" in partial fulfilment of the requirements of a doctor of philosophy. He is working under the supervision of Professor Patrick Ngulube and Professor Mpho Ngoepe. His study requires that he gathers data from potential respondents in the Ministry of Health and Child Care. On that note, you are being kindly requested to assist him with permission to gather the necessary data from your Ministry.

Mr Masuku would like to gather data from informants in the Department of Policy and Planning, Department of Health Information and the Department of Information and Communication Technologies in the Head Office, Ministry of Health and Child Care. Please note that Mr Masuku's study requires him to conduct interviews and issue questionnaires to potential respondents in the afore-mentioned departments in the Ministry and he does not intend to and will not gain access or peruse through any patient files.

The study is intended to generate useful knowledge on electronic health records and electronic medical records standard framework that may be of use to the health sector in Zimbabwe. The study's findings will be shared with your organisation and the recommendations that the study will make may be adopted and adapted by your institution. Kindly note that all the data that will be gathered from your institution will be used for research purposes and strict confidentiality will be upheld.

Your cooperation and assistance will be greatly appreciated.

For further questions or queries, you may contact the undersigned on the following contact details: Email: ngulup@unisa.ac.za; Cell: +27 828527612.

Yours faithfully

Prof Patrick Ngulube
Supervisor

Appendix C: Introductory letter from Supervisor (SAZ)

University of South Africa
School of Interdisciplinary Research and Postgraduate Studies
P. O. Box 392
UNISA
0003
UNISA - Campus
Preller Street
Theo van Wijk Building - Room 04-02
Tel: +27 12 429 2832

20 April 2018

The Director General
Standards Association of Zimbabwe
Head Office
Northend Close
Northridge Park, Borrowdale
P. O. Box 2259
Harare

RE: REQUEST FOR PERMISSION TO GATHER RESEARCH DATA-MR MEHLULI MASUKU

This is to confirm that Mr Mehluli Masuku is a Doctor of Litt et Phil (Information Science) candidate (Student Number 55785107) in the Department of Information Science at the University of South Africa (UNISA) and is conducting a research project titled **"Framework of Standards for Electronic Health Records and Electronic Medical Records for the Health Sector in Zimbabwe**" in partial fulfilment of the requirements of a Doctor of Philosophy Degree. He is working under the supervision of Professor Patrick Ngulube and Professor Mpho Ngoepe. His study requires that he gathers data from potential respondents at the Standards Association of Zimbabwe. On that note, you are being kindly requested to assist him with permission to gather the necessary data from your organisation.

Mr Masuku would like to conduct interviews and issue questionnaires to potential respondents in your organisation so as to understand the standards development, implementation and monitoring processes of the Standards Association of Zimbabwe and how the Association relates to the Ministry of Child and Care concerning electronic health

records and electronic medical records standards.

The study is intended to generate useful knowledge on electronic health records and electronic medical records standard framework that may be of use to your organisation and the health sector in Zimbabwe. The study's findings will be shared with your organisation and the recommendations that the study will make may be adopted and adapted by your institution.

Kindly note that all the data that will be gathered from your institution will be used for research purposes only and strict confidentiality will be upheld.

Your cooperation and assistance will be greatly appreciated.

For further questions or queries, you may contact the undersigned on the following contact details: Email: ngulup@unisa.ac.za; Cell: +27 828527612.

Yours faithfully

Prof Patrick Ngulube
Supervisor

Appendix D: Letter for seeking permission to gather data in the MHCC

National University of Science and Technology
P.O. Box AC 939 Ascot . Bulawayo, Zimbabwe
Cnr. Gwanda Road/Cecil Avenue
Telephone: 263-9-282842/288413/39/58
Fax: 263-9-286803

REGISTRAR

01 June 2018

The Permanent Secretary
Ministry of Health and Child Care
P. O Box CY 1122, Causeway
Harare

Dear Sir/Madam

RE: REQUEST FOR PERMISSION TO GATHER RESEARCH DATA-MR MEHLULI MASUKU

Mr Mehluli Masuku, a Lecturer in the Department of Records and Archives Management at the National University of Science and Technology (NUST), is a DLitt et Phil (Information Science) candidate (Student Number 55785107) in the Department of Information Science at the University of South Africa (UNISA) and is conducting research titled **"Framework of Standards for Electronic Health Records and Electronic Medical Records for the Health Sector in Zimbabwe."** He is working under the supervision of Professor Patrick Ngulube and Professor Mpho Ngoepe of UNISA. Find attached, a letter confirming Mr Masuku's candidature at UNISA from one of his supervisors, Professor Patrick Ngulube. His study requires that he gathers data from potential respondents in the Ministry of Health and Child Care. On that note, you are being kindly requested to assist him with permission to gather the necessary data from your Ministry.

Mr Masuku would like to gather data from informants in the Department of Policy and Planning, Department of Health Information and the Department of Information and Communication Technologies in the Head Office, Ministry of Health and Child Care. Please note that Mr Masuku's study requires him to conduct interviews and issue questionnaires to potential respondents in the afore-mentioned departments in the Ministry and he does not intend to and will not gain access or peruse through any patients' files.

The study is intended to generate useful knowledge on an electronic health records and electronic medical records standard framework that may be of use to the health sector in Zimbabwe. The study's findings will be shared with your organisation and the recommendations that the study will make may be adopted and adapted by your institution.

Kindly note that all the data that will be gathered from your institution will be used for research purposes only and that strict confidentiality will be upheld.

Your response to this request may be sent to NUST using the address given above.

Your cooperation and assistance will be greatly appreciated.

Yours faithfully

F Mhlanga (Mr)
Registrar

Appendix E: Letter for seeking permission to gather data at SAZ

National University of Science and Technology
P.O. Box AC 939 Ascot . Bulawayo, Zimbabwe
Cnr. Gwanda Road/Cecil Avenue
Telephone: 263-9-282842/288413/39/58
Fax: 263-9-286803

REGISTRAR

01 June 2018

The Director General
Standards Association of Zimbabwe
Head Office
Northend Close, Northridge Park, Borrowdale
P. O. Box 2259
Harare

Dear Sir/Madam

RE: REQUEST FOR PERMISSION TO CONDUCT RESEARCH-MR MEHLULI MASUKU

Mr Mehluli Masuku, a Lecturer in the Department of Records and Archives Management at the National University of Science and Technology (NUST) is a DLitt et Phil (Information Science) candidate (Student Number 55785107) in the Department of Information Science at the University of South Africa (UNISA) and is conducting research titled **"Framework of Standards for Electronic Health Records and Electronic Medical Records for the Health Sector in Zimbabwe**." He is working under the supervision of Professor Patrick Ngulube and Professor Mpho Ngoepe. Find attached, a letter confirming Mr Masuku's candidature at UNISA from one of his supervisors, Professor Patrick Ngulube. His study requires that he gathers data from potential respondents at the Standards Association of Zimbabwe. On that note, you are being kindly requested to assist him with permission to gather the necessary data from your organisation.

Mr Masuku would like to conduct interviews and issue questionnaires to potential respondents in your organisation so as to understand the standards development, implementation and monitoring processes of the Standards Association of Zimbabwe and how the Association relates to the Ministry of Child and Care concerning electronic health records and electronic medical records standards.

The study is intended to generate useful knowledge on an electronic health records and electronic medical records standard framework that may be of use to your organisation and the health sector in Zimbabwe. The study's findings will be shared with your organisation

and the recommendations that the study will make may be adopted and adapted by your institution.

Kindly note that all the data that will be gathered from your institution will be used for research purposes only and that strict confidentiality will be upheld.

Your response to this request may be sent to NUST using the address provided above.

Your cooperation and assistance will be greatly appreciated.

Yours faithfully

F Mhlanga (Mr)
Registrar

Appendix F: Permission to gather data in the MHCC

Telephone: +263-4-798537-80

All correspondences should be Addressed to the Permanent Secretary for Health and Child Care

ZIMBABWE

Reference: A|12|101

Ministry of Health and Child Care
P.O. Box CY1122
Causeway
Zimbabwe

29 June 2018

The Registrar
National University of Science and Technology
P.O. Box AC 939
Ascot
Bulawayo

Attention: Mr F. Mhlanga

Re: Request for Permission to Gather Research Data: Mr Mehluli Masuku

Your request on the above refers.

Ministry of Health and Child Care has no objection on your request for permission to gather research data in the Departments of Policy and Planning, Health Information and Information and Communication Technologies at the Ministry's Head Office.

You are therefore requested to submit soft and hard copies of the final report.

Thanking you.

SECRETARY FOR HEALTH & C.C.
PRINCIPAL DIRECTOR-Policy
Planning, Monitoring & Evaluation
29 JUN 2018
P.O. BOX CY 1122, CAUSEWAY
ZIMBABWE

Dr R. F. Mudyiradima
Principal Director, Policy, Planning, Monitoring and Evaluation
FOR: SECRETARY FOR HEALTH AND CHILD CARE

/pm

Appendix G: Permission to gather data at SAZ

Authorisation is granted
Director General SAZ

Dr. Eve C. Gadzikwa
Gadzikwa 2018/10/24

The Director General
Standards Association of Zimbabwe
Head Office
Northend Close, Northridge Park, Borrowdale
P. O. Box 2259
Harare

08 September 2018

National University of Science and Technology
Department of Records and Archives Management
P. O Box AC 939 Ascot
Bulawayo

RE: REQUEST FOR PERMISSION TO CONDUCT RESEARCH-MR MEHLULI MASUKU

I am a Lecturer in the Department of Records and Archives Management at the National University of Science and Technology (NUST) and a DLitt et Phil (Information Science) candidate (Student Number 55785107) in the Department of Information Science at the University of South Africa (UNISA). I am conducting research titled **"Framework of Standards for Electronic Health Records and Electronic Medical Records for the Health Sector in Zimbabwe**." I am working under the supervision of Professor Patrick Ngulube and Professor Mpho Ngoepe. Find attached, a letter confirming my candidature at UNISA from one of his supervisors, Professor Patrick Ngulube. My study requires that I gather data from potential respondents at the Standards Association of Zimbabwe. On that note, I am asking for permission to gather data at your organisation.

I would like to conduct interviews and issue questionnaires to potential respondents in your organisation so as to understand the standards development, implementation and monitoring processes of the Standards Association of Zimbabwe and how the Association relates to the Ministry of Child and Care concerning electronic health records and electronic medical records standards.

The study is intended to generate useful knowledge on an electronic health records and electronic medical records standard framework that may be of use to your organisation and the health sector in Zimbabwe. The study's findings will be shared with your organisation and the recommendations that the study will make may be adopted and adapted by your institution.

Kindly note that all the data that will be gathered from your institution will be used for research purposes and strict confidentiality will be upheld.

Your cooperation and assistance will be greatly appreciated.

For further questions or queries, you may contact the undersigned on the following contact details:

e-mail: mehluli.masuku@nust.ac.zw or mehlulimasuku1@gmail.com

STANDARDS ASSOCIATION OF ZIMBABWE
24 OCT 2018
P.O. BOX 2259, HARARE

Cell: 0775 338 062

Yours Faithfully

Mehluli Masuku

Appendix H: Interview guide for the Director of Finance, MHCC

INTERVIEW GUIDE TO GATHER DATA FOR THE STUDY ENTITLED "FRAMEWORK FOR ELECTRONIC HEALTH RECORDS AND ELECTRONIC MEDICAL RECORDS IMPLEMENTATION FOR THE HEALTH SECTOR IN ZIMBABWE"

INTERVIEW GUIDE FOR THE DIRECTOR OF FINANCE IN THE MINISTRY OF HEALTH AND CHILD CARE

Date of the Interview:_____

Time of the Interview:_____

Venue of theInterview:_____

1. Is your Department aware of the EHRs and EMRs systems that exist in the health sector of Zimbabwe?

2. Are the existing systems guided by any standards with regards to, the contents of the record, security of the record and messaging of EHRs and EMRs?

3. Does your Department, through its ICT Unit, take part in the deployment/recommendation of EHRs and EMRs standards in the health sector of Zimbabwe?

4. Are the existing EHRs and EMRs guided by any standards on interoperability?

5. Has your Department, through the ICT Unit, ever adopted EHRs and EMRs standards from the Standards Association of Zimbabwe (SAZ) or the International Organisation for standardisation (ISO)?

6. If no to question 5, what are the barriers?

7. Are there any clear and specific policies/legislation that guide your Department with regards to EHRs and EMRs standards development, implementation and monitoring compliance? What is the name of the policy/legislation and what does it say?

8. Do you think that your Department, through your ICT Unit, is capable to develop, implement or monitor compliance with EHRs and EMRs standards by healthcare organisations in Zimbabwe? Explain your answer

9. Does your Department have any plans to develop and implement EHRs and EMRs standards?

10. Is your Department responsible or involved in the archiving of patient records/information that is stored in EHRs and EMRs systems?

11. Are such archival activities based on any standard? Name those standards.

12. Is there a clearly documented policy on archiving patient information/data that is stored in EHRs and EMRs systems?

THE END

Appendix I: Interview guide for the Director of Policy and Planning, MHCC

INTERVIEW GUIDE TO GATHER DATA FOR THE STUDY ENTITLED "FRAMEWORK FOR ELECTRONIC HEALTH RECORDS AND ELECTRONIC MEDICAL RECORDS IMPLEMENTATION FOR THE HEALTH SECTOR IN ZIMBABWE"

INTERVIEW GUIDE FOR THE DIRECTOR OF POLICY AND PLANNING IN THE MINISTRY OF HEALTH AND CHILD CARE

Date of the Interview:_____

Time of the Interview:_____

Venue of the Interview:_____

1. Does the health sector of Zimbabwe have Electronic Health Records (EHRs) and Electronic Medical Records (EMRs) in use?

2. If yes, are these in use in both the private and public healthcare facilities?

3. Are such systems based on any standards? If so, what are the standards on?

4. Are such standards specific on issues to do with the security, content and messaging of EHRs and EMRs?

5. Are such systems interoperable?

6. Are the EHRs and EMRs systems that are deployed uniform?

7. Are healthcare facilities in both the private and public sector allowed to roll out their EHRs and EMRs systems without approval from the Ministry of Health and Child Care?

8. Is it mandatory for such systems to be interoperable?

9. Does the Ministry of Health and Child Care have clearly documented policies/legislations to support the development, acquisition and monitoring of EHRs and EMRs standards in both the public and private healthcare facilities?

10. Does the Ministry of Health and Child Care conduct audits of EHRs and EMRs systems in Zimbabwe? How often?

11. In your assessment, how widespread are EHRs and EMRs systems in healthcare facilities in Zimbabwe?

12. Is there an intention by the Ministry of Health and Child Care to standardise EHRs and EMRs in the health sector of Zimbabwe? How does the Ministry intend to go about it?

13. Has the Ministry of Health and Child Care adopted/intends to adopt any EHRs and EMRs standards from the Standards Association of Zimbabwe (SAZ)? If so, which ones and when?

14. Is there a committee that is responsible for the EHRs and EMRs standards? If so, name it. Who sits on the committee?

15. Does the Ministry of Health and Childcare have the capacity to roll out EHRs and EMRs standards and monitor compliance in the health sector of Zimbabwe? Give reasons for your answer.

16. Is the health sector of Zimbabwe prepared for nationwide implementation of standards for EHRs and EMRs? Explain your answer.

17. Do you think that the Ministry of Health and Child Care has adequate laws and policies to support EHRs and EMRs standards in Zimbabwe?

18. Do you think that the Ministry of Health and Child Care has enough financial resources and technical expertise to implement, monitor and support EHRs and EMRs standards?

19. Are there any standards for the archiving of EHRs and EMRs?

20. Is the Ministry of Health and Child Care responsible for overseeing the deployment of EHRs and EMRs standards to healthcare facilities in Zimbabwe?

THE END

Appendix J: Interview guide for the Principal Director of Epidemiology and Disease Control, MHCC

INTERVIEW GUIDE TO GATHER DATA FOR THE STUDY ENTITLED "FRAMEWORK FOR ELECTRONIC HEALTH RECORDS AND ELECTRONIC MEDICAL RECORDS IMPLEMENTATION FOR THE HEALTH SECTOR IN ZIMBABWE"

INTERVIEW GUIDE FOR THE PRINCIPAL DIRECTOR OF EPIDEMIOLOGY AND DISEASE CONTROL IN THE MINISTRY OF HEALTH AND CHILDCARE

Date of the Interview:_____

Time of the Interview:_____

Venue of the Interview:_____

1. Is your Department, through the Health Information Unit, involved in the deployment or implementation of EHRs and EMRs systems in Zimbabwe?

2. How wide spread are EHRs and EMRs in healthcare facilities in Zimbabwe?

3. Who are the stakeholders in the development and implementation of EHRs and EMRs in Zimbabwe and what are their roles?

4. Are such systems based on standards? If yes, name them.

5. Is your Department, or the Health Information Unit involved in the selection/appraisal/recommendation of EHRs and EMRs standards?

6. Are there any policies/legislations that support the standardisation of EHRs and EMRs? Name them.

7. How are EHRs and EMRs archived in public healthcare facilities?

8. Are such archival practices based on any standards? Name them.

9. In your opinion, who should foster the adoption, promotion and monitor compliance with EHRs and EMRs standards in Zimbabwe?

10. Do you think that your Department is capable of recommending and monitoring compliance with EHRs and EMRs standards by healthcare facilities in Zimbabwe?

11. Does your Department have any plans to recommend EHRs and EMRs standards for adoption/implementation by the health sector in Zimbabwe?

12. What do you think are the barriers to the adoption/implementation of EHRs and EMRs by healthcare facilities in Zimbabwe?

13. In your opinion, how do you think EHRs and EMRs and compliance with them can be promoted in healthcare facilities in Zimbabwe?

THE END

Appendix K: Interview guide for the Director General, SAZ

INTERVIEW GUIDE TO GATHER DATA FOR THE STUDY ENTITLED "FRAMEWORK FOR ELECTRONIC HEALTH RECORDS AND ELECTRONIC MEDICAL RECORDS IMPLEMENTATION FOR THE HEALTH SECTOR IN ZIMBABWE"

INTERVIEW GUIDE FOR THE DIRECOR GENERAL OF THE STANDARDS ASSOCIATION OF ZIMBABWE (SAZ)

Date of the Interview:_____

Time of the Interview:_____

Venue of the Interview:_____

1. What is the legal mandate of SAZ?

2. What is the scope of the legal mandate of SAZ (which sectors are legally catered for by SAZ?

3. Which health records/information standards is SAZ involved in?

4. Does SAZ have the capacity to develop standards for EHRs and EMRs for implementation in the healthcare facilities in Zimbabwe?

5. Does SAZ have plans to develop EHRs and EMRs for the health sector in Zimbabwe?

6. Does SAZ have any relationship with the healthcare facilities in Zimbabwe with regards to EHRs and EMRs standards implementation/adoption? If yes, what is the role of SAZ in such an arrangement?

7. If yes, how successful has such an arrangement been and with what challenges?

8. Is SAZ a participating or observing member of ISO?

9. If an observing member, why is it not a participating member of ISO? Has SAZ adopted any EHRs and EMRs standards from the International Organisation for Standardisation (ISO)?

10. Does SAZ have a legal mandate to monitor the implementation of and compliance with EHRs and EMRs standards in both private and public healthcare facilities?

11. If yes, how has SAZ been doing this and with what challenges?

12. Does SAZ have the financial and technical capacity to foster and monitor compliance with EHRs and EMRs standards by healthcare facilities in Zimbabwe?

13. Has SAZ adopted any other EHRs and EMRs standards or health information standards from other organisations other than ISO? If yes, name the standards and their developers. If not, why?

14. Does SAZ have measures or plans in place to promote the adoption, implementation and compliance with EHRs and EMRs standards by the health sector of Zimbabwe? If so, explain your response.

15. What challenges has SAZ encountered on its efforts to promote the adoption, implementation and compliance with EHRs and EMRs standards by healthcare facilities in Zimbabwe?

16. What do you think should be done to promote/foster the development, adoption, implementation and compliance with EHRs and EMRs standards by healthcare facilities in Zimbabwe?

THE END

Appendix L: Questionnaire for the Deputy Director, Department of Policy and Planning, MHCC

National University of Science and Technology
P. O Box AC 939 Ascot
Bulawayo

The Deputy Director
Department of Policy, Planning, Monitoring and Evaluation
Ministry of Health and Child Care
P. O Box CY 1122, Causeway
Harare

08 September 2018

RE: DATA GATHERING-MR MEHLULI MASUKU

My name is Mehluli Masuku, a Lecturer in the Department of Records and Archives Management at the National University of Science and Technology (NUST). I am a DLitt et Phil (Information Science) candidate (Student Number 55785107) in the Department of Information Science at the University of South Africa (UNISA) conducting research titled **"Framework of Standards for Electronic Health Records and Electronic Medical Records for the Health Sector in Zimbabwe**." My study requires that I gather data from the Department of Policy and Planning in the Ministry of Health and Child Care. Because of your senior position and knowledge about the operations of your Department and the Ministry, you have been identified as a suitable informant for this study.

I am kindly asking you to fill in the attached questionnaire and send it to the Secretary of your Department by **18 October 2018**. The study is intended to generate knowledge that may inform an electronic health records and electronic medical records standards framework that may be of use to the health sector in Zimbabwe. The study's findings will be shared with your organisation and the recommendations that the study will make may be adopted and adapted by your institution.

Kindly note that all the permission to gather data from your Department was sought and granted by the Office of the Permanent Secretary in the Ministry of Health and Child Care and the data that will be gathered from your institution will be used for research purposes and strict confidentiality will be upheld.

Your cooperation and assistance will be greatly appreciated.

Yours Faithfully

Mehluli Masuku

QUESTIONNAIRE TO GATHER DATA FOR THE STUDY ENTITLED "FRAMEWORK FOR ELECTRONIC HEALTH RECORDS AND ELECTRONIC MEDICAL RECORDS IMPLEMENTATION FOR THE HEALTH SECTOR IN ZIMBABWE"

QUESTIONNAIRE FOR THE DEPARTMENT OF POLICY, PLANNING, MONITORING AND EVALUATION IN THE MINISTRY OF HEALTH AND CHILDCARE

Instructions

1. Please answer all the questions. Do not leave any spaces bank. Where the question does not apply to you or your Department or when you do not know the answer, indicate by N/A and "Do not know" respectively.
2. Kindly avoid the use of abbreviations and acronyms without first expanding them. Where abbreviations and acronyms are to be used, kindly expand them first, for example "National University of Science and Technology (NUST)".
3. Where technical jargon is used, kindly simplify in brackets, for example, "Interoperable (ability of systems to share information or data on a network based on standards)".
4. Where the spaces provided are not enough for your response, feel free to use additional paper, number your response accordingly and attach to the questionnaire.
5. Kindly write legibly.

EXISTING STANDARDS FOR ELECTRONIC HEALTH RECORDS AND ELECTRONIC MEDICAL RECORDS

1. Do healthcare facilities in Zimbabwe use Electronic Health Records and Electronic Health (EHRs) Medical Records (EMRs)? Yes No
2. If yes, name the EHRs and EMRs systems that are in use in the healthcare facilities in Zimbabwe.
   _____
   _____
   _____
3. If yes to question 1, are such EHRs and EMRs systems using open source software or proprietary software? Open source software Yes Proprietary software Yes
4. Are the systems in use developed and maintained by local developers or they are sourced from out of Zimbabwe? Locally developed and run Yes Imported and run by developers outside Zimbabwe Yes
5. If the EHRs and EMRs systems in use were developed and maintained in Zimbabwe, which organisation(s) is responsible for that?_____
6. If the systems are imported, what is the name of the developer of those systems?_____
7. Who is responsible for the funding or sponsoring the development or purchasing and maintenance of the EHR and EMR systems that are in use in Zimbabwe? Government Donors Other (specify)_____
8. What specific challenges has the Ministry of Health and Child Care (MHCC) experienced with regards to the following:
   i. Development of EHRs and EMRs systems?_____

ii. Implementation of those systems?_____

iii. Maintenance of the systems?_____

9. Are the systems based on any standards for the following aspects of EHRs and EMRs?
   i. Content of the EHRs and EMRs? Yes No
      If yes, please name the standard(s)_____
   ii. Terminology used in EHRs and EMRs? Yes No
      If yes, please name the standard(s)_____
   iii. Messaging of EHRs and EMRs? Yes No
      If yes, please name the standard(s)_____
   iv. Security of EHRs EMRs? Yes No
      If yes, please name the standard(s)_____
   v. Privacy and confidentiality? Yes No
      If yes, please name the standard(s)_____
10. Other than standards relating to the afore-mentioned (question 9), which other EHRs and EMRs standards are in use in the health sector of Zimbabwe?_____
    _____
    _____
11. Do you think that the existing policy and legislative framework is adequate for the successful and sustainable implementation of EHRs and EMRs standards is adequate for the following aspects of EHRs and EMRs?
    i. Privacy and confidentiality of patient records/information held in EHRs and EMRs? Yes No
       Please give reasons for your answer_____
       _____
       _____
    ii. Content and structure of EHRs and EMRs? Yes No Please give reasons for your answer_____
       _____
       _____
    iii. Security of EHRs and EMRs? Yes No Please give reasons for your answer
       _____
       _____
       _____
    iv. Monitoring compliance with EHRs and EMRs standards? Yes No
       Please give reasons for your answer_____
       _____
       _____

INTEROPERABILITY OF EHRs AND EMRs AND STANDARDS

1. Are the EHRs and EMRs systems that are in place interoperable (i.e, are they able to communicate with each other for information/records sharing)? Yes No
2. If yes to question 1, name the interoperability standards that are being used by the systems to facilitate information sharing._____
   _____
3. Are such interoperability standards developed locally (in Zimbabwe)? Yes No
4. If yes to question 3, name the developers of such interoperability standards.

_____

_____

5. If no to question 3, where are the standards being sourced from?_____

_____

6. Do you have standards that govern the following aspects of EHRs and EMRs:
   i. EHRs and EMRs architecture? Yes No
      If yes to question 6, please name the standard(s)_____
   ii. Patient records/information held in EHRs and EMRs systems? Yes No

      _____
   iii. Interoperability in messaging and communication? Yes No

      _____
   iv. EHRs and EMRs definition, scope and context? Yes No

      _____
   v. EHRs interface specifications? Yes No

      _____
   vi. EHRs and EMRs infrastructure? Yes No

      _____
7. Does the MHCC have any relationship with the Standards Association of Zimbabwe (SAZ) regarding the following:
   i. EHRs and EMRs standards development? Yes No
   ii. EHRs and EMRs standards implementation? Yes No
   iii. Monitoring compliance with EHRs and EMRs standards by healthcare facilities on Zimbabwe? Yes No
8. If no to question 7, which other standards body or bodies is the MHCC affiliated to regarding EHRs and EMRs standards?_____

_____

POLICIES AND LEGISLATION GOVERNING THE DEVELOPMENT, IMPLEMENTATION AND MONITORING OF EHRs AND EMRs SYSTEMS AND STANDARDS

SECTION A: HELATH DATA TO BE INCLUDED IN EHRs and EMRs

1. Are there documented rules defining the content of EHR and EMR? Yes No
   If yes, name the rules_____

   _____
2. Are there legal definitions of EHRs and EMRs? Yes No
   If yes to question 2, name the legislation of legislation or policy which provides legal documentations of EHRs and EMRs?_____

   _____
3. Is there a law(s) or policy that specifies common terminology and clinical coding systems that healthcare facilities should use for EHRs and EMRs? Yes No
   If yes to question 3, please name the law(s) and policies which provides such.

SECTION B: REQUIREMENTS ON INSTITUTIONS HOSTING AND MANAGING EHRs AND EMRs

1. Are there specific rules governing institutions on hosting and processing EHRs and EMRs? Yes No
   If yes to question 1, name the rules_____

   _____

2. Is there a legal/policy requirement for the encryption of data generated and contained in EHRs and EMRs systems? Yes No
   If yes to question 2, name the law/policy_____
   _____
3. Are there auditing requirements for EHRs and EMRs? Yes No
   If yes to question 3, name the document containing such requirement_____
   _____
   _____

SECTION C: PATIENT CONSENT

1. Are there specific legal/policy rules on patients' consent for EHRs and EMRs in Zimbabwe? Yes No

   If yes to question 1, name the legislation/policy rule_____
   _____
2. If yes to question 1, does the legislation/policy specify the conditions under which EHRs and EMRs should be created? Yes No

   If yes to question 2, name the legislation/policy and briefly state its provisions_____
   _____
   _____
3. If no to question 2, what governs the creation of EHRs and EMRs in Zimbabwe?_____
   _____
4. If yes to question 1, does the legislation/policy specify how and under what conditions should EHRs and EMRs be shared in Zimbabwe? Yes No
   If yes to question 4, name the legislation/policy and briefly explain its provisions_____
   _____
   _____
5. If no to question 4, what governs the sharing of EHRs and EMRs in Zimbabwe?
6. When a patient opts-in or opts-out, which legislation/policy governs the conditions under which that can happen?_____
   _____
7. If yes to question 6, what does the law/policy say?_____
   _____
8. Is the law/policy specific on whether consent must be given in writing or not? Yes No

SECTION D: CREATION, ACCESS AND UPDATE OF EHRs AND EMRs

1. Are there rules governing the identification and authentication of health professionals who create, use and share patients' health records/information on EHRs and EMRs platforms?

   Yes No
2. If yes to question 1, are such rules legally provided for? Yes No

   If yes to question 2, name the Act which specifies such rules_____
   _____
3. Are there legal provisions or rules/policies which govern the creation of EHRs and EMRs in Zimbabwe? Yes No

If yes to question 3, name the rules/policies and briefly explain its provisions_____
_____
_____
_____

4. Is there a policy/legal document/rule(s) that specifies the categories of access to health information that is held/created on EHRs and EMRs? Yes No
   If yes to question 4, name the policy/legislation/rule(s) and briefly explain its provisions____
   _____
   _____
5. If yes to question 4, does the policy/legislation/rule(s) contain any specific prohibitions on access to patient information held/generated on EHRs and EMRs? Yes No
   If yes to question 5, name the policy/legislation/rule(s) and briefly explain its provisions.
6. If yes to question 4, is the policy/legislation/rule(s) explicit on exceptions to access requirements in emergency situations? Yes No
   If yes to question 6, name the policy/legislation/rule(s) and briefly explain its provisions.
7. Is there a legal obligation for health professionals to update EHRs and EMRs in Zimbabwe? Yes No
   If yes to question 7, name the legislation/policy and briefly explain its provisions_____
   _____
   _____
8. Is there a policy/rule(s) on the rights of patients to their data that is held on EHRs and EMRs systems? Yes No
   If yes to question 8, name the policy/rule(s) and briefly explain its provisions_____
   _____
   _____
9. If yes to question 8, is the policy/rule(s) clear on any restrictions that patients have? Yes No
   If yes to question 9, name the policy and briefly explain its provisions_____
   _____
   _____
10. If yes to question 8, is the policy/rule(s) clear on the right of patients to download their health records or data from EHRs and EMRs platforms?
    If yes to question 10, briefly explain its provisions _____
    _____
    _____
11. If yes to question 8, is the policy/rule(s) clear about the right of patients know who accessed their health records/information that is generated or held on EHRs and EMRs platforms? Yes No
    If yes to question 11, name the policy/rule(s) and briefly explain its provisions_____
    _____
    _____
12. If yes to question 8, does the policy/rule(s) grant patients the right to modify or erase data from EHRs and EMRs? Yes No
13. Are there specific rules on patient specific identification number for e-health purposes? Yes No
    If yes to question 9, name the rules and briefly explain their provisions_____
    _____
    _____

SECTION E: SECONDARY USE OF HEALTH DATA

1. Is the law or policy of EHRs and EMRs clear about the secondary use of patient health information held such platforms? Yes No
   If yes to question 1, name the law/policy and briefly explain its provisions_____
   _____
   _____
2. If yes to question 1, is the information anonymised before use for secondary purposes? Yes No
3. If no to question 2, what measures are in place to safeguard patient privacy and confidentiality when their information is used by third parties?_____
   _____
4. If yes to question 4, does the law specify the types of secondary use of patient information held in EHRs and EMRs systems? Yes No
   If yes to question 4, please name the secondary uses of patient information that are legally permissible_____
   _____
   _____
5. Does the law specify the types of patient health records/information that is held on EHRs and EMRs platforms? Yes No
   If yes to question 5, please list the secondary uses of patient health records/information that are permissible by law_____
   _____
6. Is the law on whether patient consent should be sought for secondary use of patient health records/information? Yes No
   If yes to question 6, please name the law that provides for such and briefly explain its provisions
   _____
   _____
7. If yes to question 7, is the law specific about the consequences/penalties associated with the breach of provisions for secondary use? Yes No
   If yes, name the law that provides for that and briefly explain its provisions_____
   _____
   _____
8. If no to question 7, how does the Ministry handle cases of access to patient health records/information by third parties or for secondary use?_____
   _____

SECTION F: ARCHIVING OF EHRs

1. Are there specific rules/requirements for archiving EHRs and EMRs data? Yes No
   If yes to question 1, name the rules/requirements and briefly explain their provisions_____
   _____

SECTION G: INYTEROPERABILITY OF EHRs AND EMRs SYSTEMS

1. Is there a policy/rule(s) on the interoperability of EHRs and EMRs systems between and within healthcare organisations in Zimbabwe? Yes No
   If yes to question 1, please name the policy/rule(s) and briefly explain its provisions_____
   _____
   _____

2. Are EHRs and EMRs systems required to be interoperable with other e-health solutions, for example e-prescriptions, medical insurance providers e.t.c? Yes No
3. Are EHRs and EMRs systems linked or connected to similar systems outside of Zimbabwe in the case of those patients who receive healthcare outside of Zimbabwe? Yes No
   If yes, is the law clear about the ownership, management, access and use of Zimbabwean patients' health information held in e-health systems outside Zimbabwe? Yes No
   If yes to question 3, name the law/policy that provides for such and briefly explain its provisions_____
   _____

SECTION H: RULES AND STANDARDS ON EHRs AND EMRs INTEROPERABILITY

1. Are the available EHRs and EMRs systems governed by any interoperability rules/standards? Yes No
   If yes, name the rules/standards and briefly explain their provisions_____
   _____
2. Does the Ministry of Health and Child Care (MHCC) have a policy on the use of EHRs and EMRs standards? Yes No
   If yes to question 2, please name the policy and briefly explain its provisions_____
   _____
3. Does the MHCC have any relationship with the Standards Association of Zimbabwe (SAZ) regarding the development, implementation and monitoring of EHRs and EMRs standards? Yes No
4. If yes to question 3, has the MHCC implemented EHRs and EMRs standards from SAZ? Yes No
   If yes to question 4, please name the EHRs and EMRs that SAZ has implemented from NAZ
   _____
5. If no to question 4, what are the reasons for not utilising or implementing EHRs and EMRs standards from SAZ?_____
   _____
6. Does the MHCC have a relationship with the International Organisation for Standardisation (ISO) regarding EHRs and EMRs standards? Yes No
   If yes to question 7, please specify the nature of the relationship:
   i. EHRs/EMRs standards development Yes No
   ii. EHRs/EMRs implementation Yes No
   iii. EHRs/EMRs implementation compliance monitoring Yes No
7. If yes to question 6, has the MHCC adopted any ISO standards on EHRs and EMRs? Yes No
   If yes to question 7, name the standard and briefly explain its provisions_____
   _____
8. If no to question 7, what is the reason(s) for failure to adopt the standards?_____
   _____
9. Does the MHCC have any legal mandate to enforce and monitor compliance with EHRs and EMRs standards? Yes No
   If yes, name the policy or legislation that mandates the MHCC to do that and briefly provide its provisions_____

_____

10. If no to question 6, does the MHCC have any intentions/plans to use ISO standards on EHRs and EMRs standards? Yes No
    If yes, when does the MHCC intend to do so?_____

SECTION I: APPLICATION OF EHRs/EMRs STANDARDS, POLICIES AND LAWS IN PRIVATE HEALTHCARE FACILITIES

1. Are private healthcare facilities already using EHRs and EMRs systems? Yes No
2. Are private healthcare facilities in Zimbabwe compelled/guided by any regulations/policy/law to use any standards in the implementation of any EHRs and EMRs systems? Yes No

If yes, name the regulations/policy/law and briefly explain their provisions_____
_____

3. Are private healthcare facilities allowed to use EHRs and EMRs that are not defined by the MHCC? Yes No
4. If no to question 2, does the MHCC intend to pronounce and common standards for EHRs and EMRs for both the public and private healthcare facilities? Yes No

If yes to question 3, name the document that contains such the policy on that and briefly explain its provisions_____
_____

5. If no to question 3, how does the MHCC intend to foster EHRs and EMRs standards adoption by private healthcare facilities?_____
_____

6. Do you think that it is feasible for both the private and public healthcare facilities to use common EHRs and EMRs standards? Yes No

Give reasons for your answer_____
_____

7. Do you think that the Ministry has the capacity to monitor the implementation and compliance with EHRs and EMRs standards by private healthcare facilities? Yes No

Give reasons for your answer_____
_____

SECTION J: MANAGEMENT AND DEPLOYMENT OF EHRs AND EMRs

1. Which office is responsible for the deployment and management of EHRs and EMRs systems in Zimbabwe?_____
2. Does such an office conduct audits of which and how many EHRs and EMRs systems are in use in the healthcare facilities in Zimbabwe? Yes No
3. If yes to question 2, how often are such audits conducted?_____
4. If yes to question 2, when was the last audit conducted?_____
5. If yes to question 2, how many EHRs and EMRs systems are in place to date?_____
6. Which office is responsible for the compliance with EHRs and EMRs standards if any?
   _____

7. Are healthcare facilities in both the private and public healthcare allowed to source and roll out their own EHRs and EMRs systems without seeking approval from the MHCC?
   Yes No
8. If approval has to be sought from the MHCC, does the Ministry specify the standards that such systems should run on with regards to the following aspects:
   i. Security of patient health records/information? Yes No
   If yes to question 8i, name the standard and briefly explain its provisions_____
   _____
   ii. Content of the EHRs and EMRs? Yes No
   If yes to question 8ii, name the standard and briefly explain its provisions_____
   _____
   iii. Messaging of EHRs and EMRs? Yes No
   If yes to question 8iii, name the standard and briefly explain its provisions_____
   _____

PREPARDNESS FOR THE SUPPORT AND SUSTANINABILITY OF EHRs AND EMRs STANDARDS

1. Is the adoption of EHRs and EMRs standards part of the MHCC's strategic plan?
   Yes No
   If yes to question 1, does the MHCC have a specific budget for the purchasing, implementation and monitoring of EHRs and EMRs standards? Yes No
2. Does the MHCC have the capacity to implement SAZ or ISO standards on EHRs and EMRs?
   Yes No
   If yes to question 2, give reasons for your answer_____
   _____
3. If no to question 2, in what area is the MHCC incapacitated to do that?
   i. Funding inadequate? Yes No
   ii. Technical expertise not available/enough? Yes No
   iii. Infrastructure not available/sufficient? Yes No
   iv. Laws/policies on EHRs and EMRs not clear? Yes No
   v. Standards on EHRs and EMRs too complicated ?
   vi. Other(specify)_____
4. Is the MHCC capacitated to develop and implement its own EHRs and EMRs standards?
   Yes No
   If yes to question 4, give reasons for your answer_____
   _____
5. If yes, has the MHCC ever developed such standards? Yes No
   If yes to question 5, name the standard(s) and briefly explain its provisions_____
   _____
   _____
   If no to question 4, briefly outline the barriers to such an exercise_____
   _____
6. Is there any form of collaboration between the MHCC and any of the following standards organisations in the area of EHRs and EMRs? (Please tick the applicable)

Standards Organisation	**Yes**	**No**
Comite Europeen de Normalisation (CEN/TC 25)		

Health Level Seven Inc (HL7)		
Digital Imaging and Communications in Medicine (DICOM) Standards Committee		
Japanese Association of Healthcare Information Systems Industry (JAHIS)		
Medical Information System Development Centre (MEDIS-DC)		

7. If yes to question 6, explain the nature of the collaboration, e.g standards development, standards implementation, standards monitoring_____
   _____
8. Has the MHCC ever implemented EHRs and EMRs standards from any of the standards bodies listed in question 6? Yes No
   If yes to question 8, name the standard_____
   _____

9. Has the MHCC ever collaborated with any other standards body other than ISO and the ones stated in question 6 with regards to EHRs and EMRs? Yes No
   If yes to question 9, name the standards body and the nature of the collaboration_____
   _____
10. Has the MHCC ever implemented any standard or adopted any EHRs and EMRs from any other standards organisation other than ISO and the ones identified in question 6? Yes No
    If yes, name the body and the standard_____
    _____

THE END

Appendix M: Questionnaire for the Deputy Director, Department of Health Information, MHCC

National University of Science and Technology
P. O Box AC 939 Ascot
Bulawayo

The Deputy Director
Department of Health Information
Ministry of Health and Child Care
P. O Box CY 1122, Causeway
Harare

08 October 2018

RE: DATA GATHERING-MR MEHLULI MASUKU

My name is Mehluli Masuku, a Lecturer in the Department of Records and Archives Management at the National University of Science and Technology (NUST). I am a DLitt et Phil (Information Science) candidate (Student Number 55785107) in the Department of Information Science at the University of South Africa (UNISA) conducting research titled **"Framework of Standards for Electronic Health Records and Electronic Medical Records for the Health Sector in Zimbabwe."** My study requires that I gather data from the Department of Health Information in the Ministry of Health and Child Care. Because of your senior position and knowledge about the operations of your Department and the Ministry, you have been identified as a suitable informant for this study.

I am kindly asking you to fill in the attached questionnaire and send it to the Secretary of your Department by **18 October 2018**. The study is intended to generate knowledge that may inform an electronic health records and electronic medical records standards framework that may be of use to the health sector in Zimbabwe. The study's findings will be shared with your organisation and the recommendations that the study will make may be adopted and adapted by your institution.

Kindly note that all the permission to gather data from your Department was sought and granted by the Office of the Permanent Secretary in the Ministry of Health and Child Care and the data that will be gathered from your institution will be used for research purposes and strict confidentiality will be upheld.

Your cooperation and assistance will be greatly appreciated.

Yours Faithfully

QUESTIONNAIRE TO GATHER DATA FOR THE STUDY ENTITLED "FRAMEWORK FOR ELECTRONIC HEALTH RECORDS AND ELECTRONIC MEDICAL RECORDS IMPLEMENTATION FOR THE HEALTH SECTOR IN ZIMBABWE"

QUESTIONNAIRE FOR THE HEALTH INFORMATION DEPARTMENT IN THE MINISTRY OF HEALTH AND CHILD CARE

Instructions

1. Please answer all the questions. Do not leave any spaces bank. Where the question does not apply to you or your Department or when you do not know the answer, indicate by N/A and "Do not know" respectively.
2. Kindly avoid the use of abbreviations and acronyms without first expanding them. Where abbreviations and acronyms are to be used, kindly expand them first, for example "National University of Science and Technology (NUST)".
3. Where technical jargon is used, kindly simplify it in brackets, for example, "Interoperable (ability of systems to share information or data on a network based on standards)".
4. Where the spaces provided are not enough for your response, feel free to use additional paper, number your response accordingly and attach to the questionnaire.
5. Kindly write legibly.

AVAILABILITY, DEPLOYMENT OF ELECTRONIC HEALTH RECORDS (EHRs), ELECTRONIC MEDICAL RECORDS (EMRs) AND THEIR STANDARDS

SECTION A: AVAILABILITY OF EHRs AND EMRs SYSTEMS

1. Are there Electronic Health Records (EHRs) and Electronic Medical Records (EMRs) systems that your Department is aware of? Yes No
   If yes to question 1, name them_____
   _____
2. Does your office conduct audits of which and how many EHRs and EMRs systems are in use in the health sector of Zimbabwe? Yes No
   If yes to question 2, how many EHRs and EMRs systems are in use in the healthcare facilities in Zimbabwe?_____
3. If yes to question 2, how often are such audits conducted?_____

SECTION B: DEVELOPMENT AND DEPLOYMENT OF EHRs AND EMRs STANDARDS

1. Is your Department involved in the development of EHRs and EMRs standards? Yes No
   If yes to question 1, what is the role of your Department in the development of such standards?_____
   _____
2. Is your Department involved in the selection/appraisal/recommendation of EHRs and EMRs standards for adoption by the healthcare facilities in Zimbabwe? Yes No
   If yes to question 2, specify the role of your Department_____
   _____
3. If yes to question 2, which EHRs and EMRs standards has your Department selected/appraised/recommended for implementation by healthcare facilities in Zimbabwe?

_____

_____

Give reasons for settling or recommending or selecting those particular standards_____

_____

_____

4. If no to question 2, who is responsible for the selection/appraisal/recommendation of EHRs and EMRs standards?_____
5. Is your Department responsible for the deployment of EHRs and EMRs systems in healthcare facilities? Yes No
   If yes to question 4, does your Department prescribe the EHRs and EMRs systems and standards that private healthcare facilities should roll out? Yes No
6. If yes to question 5, is one type of a system deployed or healthcare institutions use any systems of their choices?_____
7. If no to question 2, which office is responsible for the selection/appraisal/recommendation of EHRs and EMRs systems?_____
8. Are the EHRs and EMRs systems that are deployed operating on standards with regards to the following aspects:
   i. Content of EHRs and EMRs? Yes No
      If yes, name the standard_____
   ii. Security of patient information held in EHRs and EMRs systems? Yes No
      If yes, name the standard_____
   iii. Messaging of EHRs and EMRs? Yes No
      If yes, name the standard_____

SECTION C: ARCHIVING STANDARDS FOR EHRs AND EMRs

1. Is your Department involved in the archival of EHRs and EMRs and electronic data for patients? Yes No
   If yes, which standards are your systems using?_____
   _____
2. Is there a clearly defined policy/plan for the archiving of patient health records/information generated and held by EHRs and EMRs systems? Yes No
   If yes, name the policy and briefly explain its provisions_____
   _____

INTEROPERABILITY OF EHRs AND EMRs SYSTEMS

1. Are the existing EHRs and EMRs systems in use interoperable (ability to share patient health information/data)? Yes No
   If yes, name the standard(s) that facilitate such interoperability?_____
   _____
   _____
2. Who is the developer of the standards that you mentioned in question 1?_____
   _____

POLICIES AND LEGISLATION FOR EHRs AND EMRs

1. Is there a policy/legislation that governs your office and other health information departments on EHRs and EMRs in Zimbabwe? Yes No
   If yes to question 1, name the policy/legislation and briefly explain its provisions_____
   _____
2. If yes to question 1, which office is responsible in overseeing the implementation and compliance with the policy/legislation?_____
3. Does your office play any role in overseeing the implementation and compliance with the stipulations of the policy/legislation? Yes No
   If yes to question 3, briefly explain the role of your department_____
   _____

PRAPAREDNESS TO SUPPORT AND SUSTAIN EHRs AND EMRs STANDARDS

1. Do you think that your Department id capable to recommend, implement and monitor the adoption of EHRs and EMRs standards? Yes No
   Give reasons for your answer_____
   _____
2. Does your Department have plans to ensure that EHRs and EMRs are compliant with standards? Yes No
   If yes to question 1, briefly explain the plans and how your department intends to execute that plan_____
   _____
3. Are you foreseeing any barriers in your organisation regarding the adoption and compliance with EHRs and EMRs standards? Yes No
   Give reasons for your answer_____
   _____

THE END

Appendix N: Questionnaire for the Deputy Director, Department of ITC, MHCC

National University of Science and Technology
P. O Box AC 939 Ascot
Bulawayo

The Deputy Director
Department of Information and Communication Technologies
Ministry of Health and Child Care
P. O Box CY 1122, Causeway
Harare

08 October 2018

RE: DATA GATHERING-MR MEHLULI MASUKU

My name is Mehluli Masuku, a Lecturer in the Department of Records and Archives Management at the National University of Science and Technology (NUST). I am a DLitt et Phil (Information Science) candidate (Student Number 55785107) in the Department of Information Science at the University of South Africa (UNISA) conducting research titled **"Framework of Standards for Electronic Health Records and Electronic Medical Records for the Health Sector in Zimbabwe."** My study requires that I gather data from the Department of Information and Communication Technologies in the Ministry of Health and Child Care. Because of your senior position and knowledge about the operations of your Department and the Ministry, you have been identified as a suitable informant for this study.

I am kindly asking you to fill in the attached questionnaire and send it to the Secretary of your Department by **18 October 2018**. The study is intended to generate knowledge that may inform an electronic health records and electronic medical records standards framework that may be of use to the health sector in Zimbabwe. The study's findings will be shared with your organisation and the recommendations that the study will make may be adopted and adapted by your institution.

Kindly note that all the permission to gather data from your Department was sought and granted by the Office of the Permanent Secretary in the Ministry of Health and Child Care and the data that will be gathered from your institution will be used for research purposes and strict confidentiality will be upheld.

Your cooperation and assistance will be greatly appreciated.

Yours Faithfully

Mehluli Masuku

QUESTIONNAIRE TO GATHER DATA FOR THE STUDY ENTITLED "FRAMEWORK FOR ELECTRONIC HEALTH RECORDS AND ELECTRONIC MEDICAL RECORDS IMPLEMENTATION FOR THE HEALTH SECTOR IN ZIMBABWE"

FOR THE ICT DEPARTMENT IN THE MINISTRY OF HEALTH AND CHILD CARE

Instructions

1. Please answer all the questions. Do not leave any spaces bank. Where the question does not apply to you or your Department or when you do not know the answer, indicate by N/A and "Do not know" respectively.
2. Kindly avoid the use of abbreviations and acronyms without first expanding them. Where abbreviations and acronyms are to be used, kindly expand them first, for example "National University of Science and Technology (NUST)".
3. Where technical jargon is used, kindly simplify in brackets, for example, "Interoperable (ability of systems to share information or data on a network based on standards)".
4. Where the spaces provided are not enough for your response, feel free to use additional paper, number your response accordingly and attach to the questionnaire.
5. Kindly write legibly.

STANDARDS FOR ELECTRONIC HEALTH RECORDS (EHRs) AND ELECTRONIC MEDICAL RECORDS (EMRs)

1. List the EHRs and EMRs that are in use in healthcare facilities in Zimbabwe_____
   _____
2. Are the EHRs and EMRs that you identified in question 1 operating on any standards?
   Yes No
   If yes to question 2, name the standards_____
3. If yes to question 1, are the standards specific on the following aspects of EHRs and EMRs:
   i. Privacy and confidentiality of patient records/information held on EHRs and EMRs systems? Yes No
      If yes to question 3i, name the standard_____
   ii. Content of EHRs and EMRs? Yes No
      If yes, name the standard_____
   iii. Messaging or communication of EHRs and EMRs? Yes No
      If yes, name the standard_____
   iv. Security of EHRs and EMRs? Yes No
      If yes, name the standard_____
4. If yes to question 2, were the standards developed in Zimbabwe? Yes No
   If yes to question 4, were the standards developed by the Standards Association of Zimbabwe (SAZ)? Yes No
   If yes, name the standard(s)_____
   _____
5. If the standards were not developed in Zimbabwe, were they developed by the International Organisation for Standardisation (ISO)? Yes No
   If yes, name the standards_____
   _____
6. If no to question 6 and 7, name the developer(s) of the standards and the actual standards.___

_____

_____

INTEROPERABILITY OF EHRs AND EMRs

1. Are the available EHR and EMR in use in healthcare facilities in Zimbabwe interoperable (ability to share patient health information/data on a network between healthcare facilities)? Yes No
   If yes to question 1, name the standard(s) being used to enable interoperability_____
   _____
2. Do patient have unique identifiers for use when they visit healthcare facilities? Yes No
   If no, how are patients identified by EHR and EMR?_____
   _____

POLICIES AND LEGISLATION FOR EHRs AND EMRs

1. Is there a specific policy/legislation that spells out issues that relate to standards for EHRs and EMRs in Zimbabwe? Yes No
   If yes to question 1, name the policy/legislation and briefly explain its provisions_____
   _____
2. If no to question 2, what are the terms of reference for EHRs and EMRs standards that govern the activities of healthcare facilities in Zimbabwe?_____
   _____
3. If the policy/legislation exists for EHRs and EMRs standards, is it specific about the following:
   i. Standard definition of EHR and EMR? Yes No
      If yes to question 2i, name the policy/legislation which provides such definitions____
      _____
   ii. Standard for the content(s) of EHRs and EMRs? Yes No
      If yes to question 3i, name the document which specifies the content(s) of such records_____
      _____
   iii. Security standards for EHRs and EMRs? Yes No
      If yes to question 3i, name the policy/legislation_____
      _____
   iv. Archiving standards for EHRs and EMRs? Yes No
      If yes to question 3iv, name the policy/legislation_____
      _____
4. Are there mechanisms of monitoring compliance with the stipulated EHRs and EMRs standards in the Ministry of Health and Child Care (MHCC)? Yes No
   If yes to question 4, state the mechanism_____
   _____
5. If yes to question 4, is such a mechanism(s) legally documented or written down as policies? Yes No
   If yes to 4, name the document/policy/legislation in which they are documented_____
   _____
6. Are EHRs and EMRs systems in the MHCC legally subjected to external scrutiny as a way of monitoring compliance, for example by the Standards Association of Zimbabwe or any other standards body? Yes No

7. If yes to question 7, name the body that is legally mandated to do that_____
_____

PRAPAREDNESS FOR THE SUPPORT AND SUSTAINABILITY OF EHRs AND EMRs STANDARDS

1. Does the MHCC have the capacity to develop EHRs and EMRs standards with regards to the following aspects:
   i. Financial resources? Yes No
   Give reasons for your answer_____
   _____
   ii. Technical expertise? Yes No
   Give reasons for your answer_____
   _____
   iii. Legal/policy mandate? Yes No
   Give reasons for your answer_____
   _____

2. Does the MHCC have the capacity to implement EHRs and EMRs standards with regards to the following:
   i. Financial resources? Yes No
   Give reasons for your answer_____
   _____
   ii. Technical expertise? Yes No
   Give reasons for your answer_____
   _____
   iii. Legal/policy mandate? Yes No
   Give reasons for your answer_____
   _____
3. Does the MHCC have the capacity to monitor compliance with EHRs and EMRs standards by healthcare facilities with regards to the following:
   i. Financial resources? Yes No
   Give reasons for your answer_____
   _____
   ii. Technical expertise? Yes No
   Give reasons for your answer_____
   _____
   iii. Legal/policy mandate? Yes No
   Give reasons for your answer_____
   _____
4. Does the MHCC have any relationship/arrangement with the Standards Association of Zimbabwe (SAZ) regarding the development, implantation and monitoring of standards for EHRs and EMRs? Yes No
   If yes to question 4, name the document which contains such an arrangement_____
   _____
5. If yes to question 4, select the aspects that are enshrined in the arrangement:

i. EHRs and EMRs standards development
ii. EHRs and EMRs Standards implementation
iii. Compliance with EHRs and EMRs standards

6. If yes to question 4, what are the duties/role of your Department or institution regarding the aspect(s) that you selected in question 5?_____
_____
7. If yes to question 4, do you think that your organisation has the capacity to adequately play its role in the agreement/arrangement? Yes No
Give reasons for your answer_____
_____
8. If no to question 7, what barriers are preventing it from playing its role satisfactorily?_____
_____
_____
9. Has your Department or the MHCC ever implemented any EHRs and EMRs standards from the Standards Association of Zimbabwe (SAZ)? Yes No
If yes to question 9, name the standard(s)_____
_____
10. Does the MHCC or your Department have any relationship with the International Organisation for Standardisation (ISO) regarding the development, implementation or monitoring compliance with EHRs and EMRs standards? Yes No
If yes to question 10, select the applicable area of collaboration:
i. EHRs and EMRs standards development
ii. EHRs and EMRs standards implementation
iii. Monitoring compliance with EHRs and EMRs standards by healthcare organisations
11. Has the MHCC ever implemented any ISO standards for EHRs and EMRs? Yes No
If yes to question 11, name the standard(s)_____
_____
12. Does the MHCC have any relationship/arrangement with any of the following standards organisation regarding the development, implementation or monitoring compliance with EHRs and EMRs?

Standards Organisation	**Yes**	**No**
Comite Europeen de Normalisation (CEN/TC 25)		
Health Level Seven Inc (HL7)		
Digital Imaging and Communications in Medicine (DICOM) Standards Committee		
Japanese Association of Healthcare Information Systems Industry (JAHIS)		
Medical Information System Development Centre (MEDIS-DC)		

13. Has your Department/organisation ever implemented EHRs and EMRs standards from other standards organisations other than the one stated above and ISO? Yes No
If yes to question 13, name the standard and organisation responsible for the development of the standard_____
14. Is there a committee/office responsible for EHRs and EMRs standards selection, implementation and monitoring in the MHCC? Yes No
If yes to question 14, name the Committee/office_____
_____

15. If no to question 14, who is responsible for EHRs and EMRs standards selection, implementation and monitoring?_____
_____
16. If yes to question 14, is the committee/office that is responsible for EHRs and EMRs selection and monitoring responsible being guided by any documented policy? Yes No
If yes to question 16, name the policy and briefly provide its provisions_____
_____
17. Are there clearly defined penalties or consequences of failure to comply with EHRs and EMRs standards policy? Yes No

THE END

Appendix O: Questionnaire for the Deputy Director, SAZ

National University of Science and Technology
P. O Box AC 939 Ascot
Bulawayo

The Manager
Standards Association of Zimbabwe
Head Office
Northend Close, Northridge Park, Borrowdale
P. O. Box 2259
Harare

08 October 2018

RE: DATA GATHERING-MR MEHLULI MASUKU

My name is Mehluli Masuku, a Lecturer in the Department of Records and Archives Management at the National University of Science and Technology (NUST). I am a DLitt et Phil (Information Science) candidate (Student Number 55785107) in the Department of Information Science at the University of South Africa (UNISA) conducting research titled **"Framework of Standards for Electronic Health Records and Electronic Medical Records for the Health Sector in Zimbabwe."** My study requires that I gather data from the Standards Association of Zimbabwe. Because of your senior position and knowledge about the operations of your Department and the Standards Association of Zimbabwe, you have been identified as a suitable informant for this study.

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Kindly note that all the permission to gather data from your Department was sought and granted by the Office of the Director General of your organisation and the data that will be gathered from your institution will be used for research purposes and strict confidentiality will be upheld.

Your cooperation and assistance will be greatly appreciated.

Yours Faithfully

Mehluli Masuku

QUESTIONNAIRE TO GATHER DATA FOR THE STUDY ENTITLED "FRAMEWORK FOR ELECTRONIC HEALTH RECORDS AND ELECTRONIC MEDICAL RECORDS IMPLEMENTATION FOR THE HEALTH SECTOR IN ZIMBABWE"

QUESTIONNAIRE FOR THE STANDARDS ASSOCIATION OF ZIMBABWE

Instructions

1. Please answer all the questions. Do not leave any spaces bank. Where the question does not apply to you or your Department or when you do not know the answer, indicate by N/A and "Do not know" respectively.
2. Kindly avoid the use of abbreviations and acronyms without first expanding them. Where abbreviations and acronyms are to be used, kindly expand them first, for example "National University of Science and Technology (NUST)".
3. Where technical jargon is used, kindly simplify in brackets, for example, "Interoperable (ability of systems to share information or data on a network based on standards)".
4. Where the spaces provided are not enough for your response, feel free to use additional paper, number your response accordingly and attach to the questionnaire.
5. Kindly write legibly.

ROLE OF THE STANDARDS ASSOCIATION OF ZIMBABWE IN THE DETERMINATION AND PROMOTION OF HEALTH STANDARDS IN ZIMBABWE

1. Is the Standards Association of Zimbabwe (SAZ) involved in the generation of health records standards? Yes No
   If yes to question 1, name the standard(s) that your organisation has developed_____
   _____
2. If no to question 1, please give reasons for not developing health records standards_____
   _____
3. Is SAZ responsible for the development of EHRs and EMRs standards? Yes No
   If yes to question 3, name the standard(s)_____
   _____
4. If no to question 3, why is your SAZ not doing that_____
   _____
5. Is SAZ mandated by law to generate health records standards? Yes No
   If yes, name the law_____
6. Does SAZ have the capacity in the following areas to develop EHRs and EMRs standards for possible implementation by healthcare organisations in Zimbabwe?
   i. Technical expertise? Yes No
      Give reasons for your answer_____
   ii. Financial resources? Yes No
      Give reasons for your answer_____
   iii. Legal mandate? Yes No
      Give reasons for your answer_____
   iv. Other (specify)_____
7. Does SAZ have a legal mandate to monitor and enforce compliance of healthcare organisations with EHRs and EMRs standards in Zimbabwe? Yes No
   If yes to question 7, name the Act/legislation_____
8. If no to question 7, do you think that SAZ has the capacity to monitor the implementation and compliance with EHRs and EMRs standards by healthcare organisations in Zimbabwe? Yes No

Give reasons for your answer_____
_____

9. Does SAZ have an affiliation to the International Organisation for Standardisation with regards to EHRs and EMRs standards? Yes No
   If yes to question 9, what is the nature of the affiliation?
   i. Member. Yes No
   ii. Partner. Yes No
   iii. Other (specify)_____
10. If a member, what is the nature of membership?
    i. Participating member. Yes No
    ii. Observing member. Yes No
    iii. Other (specify)_____
11. If not a participating member, explain the reasons for such membership_____
    _____
12. If a member of ISO, does SAZ customise EHRs and EMRs standards that ISO produces? Yes No
    If yes to question 12, name the EHRs and EMRs standards that SAZ has adopted from ISO.
    _____
13. If no to question 12, what barriers does SAZ face in adopting ISO produced standards on EHRs and EMRs?_____
    _____
14. If SAZ is an observing member of ISO, briefly outline the reason for being an observing member._____
    _____
15. When did SAZ become a member of ISO?_____
16. If SAZ is currently an observing member, does it have plans to become a participating member? Yes No
    If yes to question 16, indicate the year in which it intends to become a participating member_
    _____
17. Does SAZ have a relationship with the Ministry of Health and Child Care (MHCC) with regards to the following aspects of EHRs and EMRs standards:
    i. EHRs and EMRs standards development? Yes No
       If yes to question 17i, state the role of SAZ_____
    ii. EHRs and EMRs standards implementation? Yes No
       If yes to question 17ii, state the role of SAZ_____
    iii. Monitoring of compliance with EHRs and EMRs standards?
       If yes to question 17iii, state the role of SAZ_____
18. Do you think that SAZ has the capacity to undertake the following activities?
    i. Monitor the implementation of EHRs and EMRs standards by the MHCC and healthcare facilities in Zimbabwe? Yes No
       Give reasons for your answer_____
    ii. Monitor compliance with EHRs and EMRs standards by the MHCC and healthcare facilities in Zimbabwe? Yes No
       Give reasons for your answer_____
19. Has SAZ ever collaborated with any of the following standards bodies with regards to EHRs and EMRs standards?

	Standards Organisation	Yes	No
	Comite Europeen de Normalisation (CEN/TC 25)		
	Health Level Seven Inc (HL7)		
	Digital Imaging and Communications in Medicine (DICOM) Standards Committee		
	Japanese Association of Healthcare Information Systems Industry (JAHIS)		
	Medical Information System Development Centre (MEDIS-DC)		

If yes, name the standards body that SAZ has collaborated with and select the area of collaboration from the list below:

Name of standards body_____

Area of collaboration:

i. EHRs/EMRs standards development. Yes No

ii. EHRs/EMRs standards implementation. Yes No

iii. Compliance with EHRs/EMRs standards. Yes No

20. If no to question 19, what is the reason for not collaborating or not adopting EHRs and EMRs standards from any of the standards bodies listed in question 19?_____
_____

21. Has SAZ ever collaborated or adopted EHRs and EMRs that were developed by any other organisation other than ISO and the ones mentioned in question 19? Yes No
If yes to question 21, name the standard and the organisation that is responsible for its development_____
If yes to question 21, give reasons for such a collaboration or adoption_____
_____

22. Are there any measures that SAZ has implemented or intends to implement in an effort to promote the adoption and adherence to EHRs and EMRs standards by healthcare facilities in Zimbabwe? Yes No
If yes to question 22, briefly explain those_____
_____

23. What challenges has SAZ encountered in terms of promoting the uptake or adoption of EHRs and EMRs standards by healthcare facilities in Zimbabwe?_____
_____

24. In your evaluation/opinion, is SAZ satisfied with the rate and level of adoption for EHRs and EMRs by healthcare organisations in Zimbabwe? Yes No
Give reasons for your answer_____
_____

25. if no to question 24, what do you think could be the reason healthcare facilities are not adopting or implementing EHRs and EMRs standards?_____
_____

26. What do you think could be done to promote the adoption and compliance with EHRs and EMRs by healthcare facilities in Zimbabwe_____
_____

THE END

Appendix P: Relationship between the research objectives, research questions and sources of data

Question	Which standards are in existence for EHRs and EMRs in the health sector of Zimbabwe?	To what extent are the existing EHRs and EMRs systems in the health sector of Zimbabwe interoperable?	What is the role of the Standards Association of Zimbabwe in the determination and promotion of EHRs and EMRs standards in Zimbabwe?	Which policies govern the implementation and monitoring of EHRs and EMRs standards in the health sector of Zimbabwe?	What is the level of preparedness for the support and sustainability of EHRs and EMRs standards in the health sector of Zimbabwe?	What framework of standards can be developed for the implementation of EHRs and EMRs standards in the health sector of Zimbabwe?
Did this question require empirical evidence?	Yes	Yes	No	Yes	No	No
What research methods were used?	Questionnaires and Interviews	Questionnaires and Interviews	Questionnaires and Interviews	Questionnaires and Interviews	Questionnaires and Interviews	Study data, Interviews, Questionnaires and literature
Justify method and instruments. Why was/were this method(s) the most suitable for answering this question?	Questionnaires enabled respondents to explain the standards that their EHRs and EMRs systems use and the standards on which such systems were operating. The study informants were operating on busy schedules and questionnaires allowed them to respond to the questions during their spare time. Interviews allowed for the verification of the questionnaire data as they were conducted after the questionnaire data.	Questionnaires allowed respondents who had busy work schedules to respond to the study questions during their spare time and allowed for detailed responses to be provided. Interviews allowed for the verification of the questionnaire data as they were conducted after the questionnaire data.	Questionnaires and interviews enabled officials at SAZ to explain their role and extent of involvement in the drafting, implementation or monitoring of the processes and activities relating to the implementation of EHRs and EMRs standards in Zimbabwe, and how it interacts with ISO and the MHCC regarding the adoption of standards for those systems. Interviews will help verify or corroborate or clarity some issues that would been raised by the respondents as a way of triangulating.	Questionnaires and interviews enabled the informants in the MHCC to give detailed responses regarding issues of policy for EHRs and EMRs and their standards. interviews allowed for the verification of questionnaire data.	Questionnaires and interviews enabled officials at the MHCC and SAZ to explain the extent to which prepared to support the standardisation of EHRs and EMRs.	Questionnaires and interviews enabled the researcher to gather contributions from respondents at SAZ and the MHCC regarding the status quo for standards for EHRs and EMRs and the factors that were impeding the implementation of standardised EHRs and EMRs systems in the health sector. Such data was taken into consideration in the development of the proposed framework for EHR and EMR implementation. Literature allowed the researcher to learn from those countries/institutions that have successfully developed and or rolled out EHRs and EMRs standards. Data from the questionnaires and interviews enabled the researcher to understand the contextual setting and the operations of healthcare delivery systems in Zimbabwe, SAZ and the MHCC regarding standards for EHRs and EMRs. This understanding enabled the researcher to develop a framework for EHRs and EMRs implementation that is sensitive

						and context specific for Zimbabwe.
Where was data obtained?	MHCC	MHCC	SAZ	MHCC	MHCC, SAZ	Study data and literature
What sample was used for this question?	Deputy Director- Policy Planning, MHCC; Deputy Director- Health Information, MHCC and Deputy Director- ICT, MHCC	Deputy Director- Policy Planning, MHCC; Deputy Director- Health Information, MHCC and Deputy Director- ICT, MHCC	Director General, SAZ and Deputy Director, SAZ	Principal Director- Epidemiology and Disease Control, MHCC; Director- Policy and Planning, MHCC, Deputy Director- Policy Planning, MHCC; Deputy Director- Health Information, MHCC and Deputy Director- ICT, MHCC	Director- Finance, MHCC, Principal Director-Epidemiology and Disease Control, MHCC; Director- Policy and Planning, MHCC, Deputy Director- Policy Planning, MHCC; Deputy Director- Health Information, MHCC and Deputy Director- ICT, MHCC	Non-applicable
How many respondents in the sample?	Three (3)	Three (3)	Two (2)	Three (3)	Five (5)	Non-applicable
How many times was data collected in order to answer this question?	Once	Once	Once	Once	Once	Non-applicable