



Describing healthcare technology management practices in the procurement of medical devices in the Dr Kenneth Kaunda District Municipality

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DECLARATION

I, P M Mogorosi, declare that the mini dissertation titled: “***Describing Healthcare Technology Management Practices in the Procurement of Medical Devices in the Dr Kenneth Kaunda District Municipality***” submitted to the North-West University Business School, under the Faculty of Economics and Management Sciences for the Master of Business Administration (MBA) has not been previously submitted for any other degree or any other university. I affirm that this work is my own and that proper credit has been attributed to any relevant individual(s) cited.

ACKNOWLEDGEMENTS

First and foremost, I hold the deepest reverence for the Almighty God. In moments of doubt and challenge, His gifts of resilience, wisdom, and strength upheld me. I am forever grateful for His guiding light and the invisible hand that has led me through this arduous journey with grace.

In the quietude of night, my thoughts often wander to my late parents, Pulane and Howard Mogorosi. Though they are no longer with us in the physical realm, their spirit and values continue to be a source of endless inspiration and strength. May their souls find eternal rest and peace.

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ABSTRACT

This study delves into Healthcare Technology Management (HTM) practices, with a focus on the procurement of medical devices within public healthcare facilities, particularly Community Healthcare Centres (CHCs), in the Dr Kenneth Kaunda District Municipality, North West Province, South Africa. It uncovers a prevalent procurement approach prioritising technology safety and clinical efficacy, often at the expense of cost-effectiveness. This focus, while guaranteeing quality and safety, tends to neglect efficient financial management in medical device procurement, a challenge acutely felt in low- and middle-income regions faced with financial limitations, scarce technical expertise, and a shortage of trained healthcare personnel.

The objective of this research is to describe and recommend augmentations to procurement practices by emphasising healthcare technology management principles. These principles encompass needs assessment, adherence to specifications and standards, technology assessment, cost analysis, and comprehensive life cycle management, offering insights for more balanced and efficient procurement strategies in resource-constrained settings.

Employing a qualitative research approach, this study gathered primary data through interviews with healthcare officials from the procurement and technical departments of the Dr Kenneth Kaunda District Municipality. A stratified sampling method provided insights from individuals involved in medical device procurement from strategic (managerial positions) and operational (supply chain officers, clinical engineering technicians/engineers) perspectives. Despite aiming for 13 participants, data saturation was achieved after the 5th interview, with 6 participants (46% of the target) solidifying the findings.

Analysis of the interview data across both strata resulted in 48 codes condensed into 8 comprehensive themes. These themes elucidate shared and distinct concerns between strategic and operational layers. The strategic layer uniquely focused on "Committees and Decision-Making" and "Guidance, Policy, and Standardisation in Procurement," indicating an emphasis on policy formulation and strategic oversight. In contrast, the operational layer uniquely or more prominently addressed "Service Delivery and Impact" and "Standard Operating Procedures," highlighting operational challenges in service delivery and procedural application. This detailed examination reveals the complex nature of HTM challenges, spanning strategic policy formulation to operational execution, and underscores the necessity for holistic and adaptable improvement strategies within the municipality.

The research identifies a significant disparity between the acknowledged importance of cost-effectiveness and its practical implementation, with a tendency to prioritise technological safety and efficacy over cost-efficiency. Furthermore, it emphasises the critical role of HTM principles in

refining procurement practices to enhance healthcare outcomes, particularly in low- and middle-income settings like South Africa's Dr Kenneth Kaunda District Municipality.

The study concludes that the Dr Kenneth Kaunda District Municipality partially applies HTM principles in its procurement processes but lacks full adherence, particularly in aspects like needs assessment, specification adherence, technology assessment, cost analysis, and life cycle management of medical devices. Budget constraints further complicate procurement planning, underscoring the absence of a dedicated committee for HTM concerns and a specific procurement policy for medical devices.

Keywords: *Cost-effectiveness, Dr Kenneth Kaunda District Municipality, Health Technology Assessment, Healthcare Technology Management, Low- and Middle-Income Countries, Medical Devices, Procurement.*

LIST OF ABBREVIATIONS

CHC	Community Healthcare Centre
HTA	Health Technology Assessment
HTM	Healthcare Technology Management
LCM	Life Cycle Management
NWU	North-West University
SOP	Standard Operating Procedure
WHO	World Health Organisation
INAHTA	International Network of Agencies for Healthcare Technology Management
POPIA	Protection of Personal Information Act

LIST OF DEFINITIONS

Healthcare Technology Management (HTM)	McCarthy <i>et al.</i> (2014:43) state that healthcare technology management describes the role that embraces scientific and technical support of electromedical devices and clinical information technologies, including their financial stewardship.
Healthcare Technology Assessment (HTA)	<p>WHO (2011) defines “HTA as a systematic evaluation of health technology’s properties, effects, and impacts to inform technology-related policy-making in health care and thus improve the uptake of cost-effective new technologies while preventing the uptake of technologies of dubious value to the health system.”</p> <p>The definition below was gazetted in 2020 by the International Network of Agencies for HTA (INAHTA) and Health Technology Assessment International (HTAI).</p> <p>According to the HTM Glossary (2020), HTA is a multidisciplinary process that uses explicit methods to determine the value of health technology at different points in its lifecycle. The purpose is to inform decision-making and promote an equitable, efficient, high-quality health system.</p>
Procurement	According to Young (2022), procurement is the purchase of goods or services, typically for business purposes.
Medical devices	According to WHO (2012), a medical device is an “instrument, apparatus, implement, machine, appliance, implant, reagent for invitro use, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination for medical purpose.”
Low- and middle-income countries	The World Bank (2003) defines low- and middle-income countries as those with a Gross National Product (GNP) per capita income between \$756 and \$2995.
Life Cycle Management (LCM)	Sonnemann <i>et al.</i> (2015) define Life Cycle Management (LCM) as a business management strategy widely used in both industrial and service sectors to enhance a business's sustainability performance while improving its products, services, and overall value chains.

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CHAPTER 1: INTRODUCTION

1.1 Introduction

This chapter provides an overview of the research problem, focusing on healthcare technology management (HTM) practices related to the procurement of medical devices in the Dr Kenneth Kaunda District Municipality, South Africa. It provides background, highlights the importance of the study, the field of study, geographical demarcation, industry under investigation, and outlines the research question and objectives. A concise review of the research methodology, data collection instruments, and an outline of the subsequent chapters are presented.

1.2 Background

Integral to healthcare technology, medical devices are central to planning, assessment, and budgeting processes (Anderson *et al.* 2020:2075). These devices have become indispensable in public and private healthcare facilities, particularly in patient care and within the scope of HTM. Gamessa *et al.* (2022:405) emphasise that effective planning and budgeting for medical devices enable healthcare institutions to allocate funds appropriately, ensuring the acquisition of efficient, high-quality medical devices, thereby enhancing healthcare delivery. However, there are prevalent concerns about the efficacy of medical device assessment techniques, leading to doubts about their sufficiency (Tarricone *et al.*, 2017:5).

Inadequate policies and management strategies for medical device procurement can compromise patient care quality and influence fund allocation (Anderson *et al.*, 2022:2075). For optimal management and utilisation of medical devices, it is imperative to establish sound policies, guidelines, and strategic documents at each healthcare delivery level (World Health Organisation, 2012). Effective HTM encompasses a thorough medical device procurement process, from identifying user needs to managing device delivery, installation, and eventual decommissioning. Policies and standard operating procedures (SOPs) are vital in setting guidelines to ensure safe, efficient, and high-quality healthcare services (Samsam *et al.*, 2021:1).

Borges (2018:148) notes that the legal enforcement of healthcare rights varies, from availing specific medicines or equipment to determining health service structures in certain areas. Drafting informed policies or SOPs necessitates understanding the need to prioritise medical devices based on a healthcare facility's demand and service standards. Newbrander (2007:5) argues that the lack of reliable and functional medical devices and equipment hinders health service provision, leading to adverse patient outcomes and significant challenges for the health system. Issakov and Poluta (2005:5) argue that technology generation, acquisition and utilisation demand substantial investment, and decisions in this area must ensure alignment between technology

supply and health system needs, the balance between capital and recurring costs, and the capability to manage technology throughout its lifespan. Hence, strategic planning and adept management are pivotal in healthcare technology, as decisions made during a technology lifecycle significantly influence patient care outcomes.

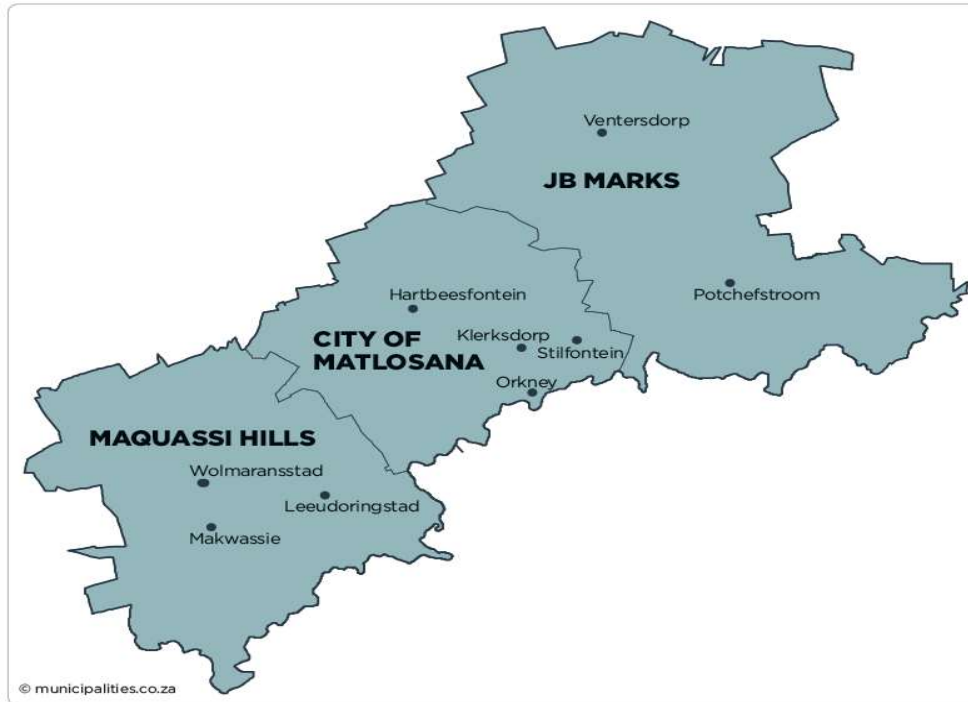
1.3 Scope of the Study

Achieving effective governance in healthcare, particularly within the domain of HTM, presents significant challenges in numerous low- and middle-income countries, often described as akin to 'moving a mountain' (Houngbo *et al.* 2017:2). These challenges encompass a range of issues from inappropriate procurement of medical devices, the prevalence of malfunctioning devices due to inadequate maintenance, disorganised healthcare technical services, to a pronounced shortage of skilled personnel (Issakov & Poluta, 2005:4). It is imperative for healthcare facilities to meticulously align their medical device demand plans with their service delivery standards to mitigate unexpected maintenance costs and ensure that priority plans for medical devices are effectively realised. The procurement of medical devices necessitates informed decision-making, where decisions should ideally be steered by safety and efficacy as well as demand plans to avoid mismatches.

This study describes the decision-making process in the procurement of medical devices within the public sector in the Dr Kenneth Kaunda District Municipality, South Africa, by studying whether procurement officers adhere to essential HTM principles. These principles include needs assessment, specification and standards adherence, technology assessment, cost analysis, and comprehensive life cycle management. By focusing on the procurement processes of medical devices, this research plunges into the strategies, policies, and procedures that underpin the acquisition of medical devices in healthcare settings. The study aims to provide a precise overview of the procurement of medical devices, outline the difficulties faced, and identify potential areas for enhancement in the use of HTM principles, specifically during the procurement phase. This phase is pivotal in ensuring medical devices' availability, reliability, and effectiveness, which are instrumental in delivering optimal patient care.

1.3.1 Geographical Demarcation

Holman and Wilholt (2022:212) argue that demarcation is the process of distinguishing between research that is influenced by appropriate setup and that which is affected by inappropriate ones. Given this notion, it is crucial to identify and separate the areas of research that are essential to ensure that geographical accuracy is maintained throughout. This study is focused on the Dr Kenneth Kaunda District Municipality in the North West Province of South Africa. The research aims to understand better the procurement of medical devices in the public sector of this geographical area, excluding the private sector and other municipalities/districts in South Africa.



Source: Municipality.co.za (2020)

Figure 1: Map of Dr Kenneth Kaunda District Municipality

1.3.2 Specific Industry Under Investigation

The study describes the challenges related to HTM practices, with a specific focus on the principals involved in the procurement of medical devices. The research methodology is tailored to address the needs and challenges of procuring medical devices within the Dr Kenneth Kaunda District Municipality, South Africa. The study focuses on the procurement of medical devices in the public healthcare sector, specifically CHCs. These healthcare facilities get instant privileges from the district's allocated budget for the procurement of medical devices. This study specifically excluded tertiary and district hospitals, which function autonomously and procure medical devices using their budget. The procurement of these medical devices is critical to ensuring the quality and safety of healthcare since they are fundamental to diagnosing, treating, and managing health conditions.

1.4 Problem Statement

The procurement of medical devices in low- and middle-income countries, including their prioritisation and management, presents unique challenges, which diverge significantly from practices observed in high-income countries (Diaconu *et al.*, 2014:1). Recent challenges in these countries have led to a critical gap in the availability of medical devices impeding healthcare facilities from meeting the service standards expected by their communities. These challenges

are compounded by the need to balance clinical and cost-effectiveness with equity and value-based considerations (Fricke & Dauben, 2009:21). Despite an emphasis on delivering quality care and value for money, an estimated 40% to 70% of medical devices in these settings are broken, unused, or unsuitable, leading to significant resource wastage and hindering patient services (Diaconu *et al.*, 2017:2).

The conventional method of purchasing medical equipment only considers pricing (Messori *et al.*, 2017:2). Cost containment and price remain essential considerations when purchasing medical devices in many countries, both developed and developing (Sorenson & Kanavos, 2011:44; Diaconu *et al.*, 2017:2). A shift from a purely price-focused approach to a more comprehensive one with the goal of including the patient outcomes will cause long term efficiencies and better health for patients (Prada, 2016:162). Research indicates that adopting a value-based strategy for purchasing medical equipment can improve patient outcomes and save costs for healthcare institutions (Trippoli, 2018:62; Messori *et al.*, 2017:3; Obremskey, 2012:1055). This approach is pivotal in ensuring that medical devices procured are aligned with the district service charter and the community healthcare centres in Dr Kenneth Kaunda District Municipality, South Africa.

Lenel *et al.* (2005:4) state, "*The life cycle of health technology, i.e., medical devices and drugs, consists of three main phases – provision, acquisition, and utilisation. Procurement is one of the critical steps in the acquisition phase. Ensuring that suitable health sector goods, e.g., medical devices and drugs, are available in appropriate places and in the required quantities is vital. Good procurement practices lead to savings in acquisition costs and facilitate downstream activities during the utilisation phase, especially maintenance for medical devices.*" It is crucial to assess healthcare facilities' gaps and challenges to establish a reliable medical device management system (Gamessa *et al.*, 2022:406). The acquisition of medical devices should adhere to effective governance approaches that leverage the public purse to formulate strategies for intervention and propose solutions.

This study describes the current procurement approaches regarding HTM principles in the public sector regarding medical devices in Dr Kenneth Kaunda District Municipality. A comprehensive literature review was conducted to delve into organisational concepts related to medical device procurement, including the empirical examination of medical devices' demand plan processes. This involved an exploration of grey literature, including policy guidelines, manuals, and articles, which were crucial for achieving the study's objectives and answering the research question. This approach provided an understanding of the specific environment, aiding in proposing informed strategies for medical device procurement in the Dr Kenneth Kaunda District Municipality, South Africa.

1.5 Research Objectives

The primary purpose of this research is to describe the HTM practices focusing on principles used by healthcare officials in the procurement and technical departments when planning for the procurement of medical devices within public healthcare facilities, specifically CHCs, in the Dr Kenneth Kaunda District Municipality, North West Province, South Africa.

1.5.1 Secondary Objectives

To achieve the primary objective, the following secondary objectives were established:

- To describe procurement strategies focusing on healthcare technology management principles, including needs assessment, specification and standards adherence, technology assessment, cost analysis, and comprehensive life cycle management of medical devices.
- To investigate the extent to which healthcare technology management principles are being utilised in procurement processes and how these principles can be better integrated to enhance healthcare outcomes, particularly in low—and middle-income settings.
- To pinpoint the discrepancy between the recognised importance of cost-effectiveness and its practical implementation in procurement practices within the Dr Kenneth Kaunda District Municipality.
- To propose methodologies for prioritising medical device procurement to strengthen healthcare systems by balancing cost-effectiveness with technological safety and efficacy.

1.6 Research Question

The guiding research question for this study is: *“How are healthcare technology management principles applied when purchasing medical devices for public sector healthcare facilities in Dr Kenneth Kaunda District Municipality, South Africa?”*

1.7 Research Design and Methodology

This section offers an overview of the study's research design, methodology, and framework, detailing the systematic data collection and analysis approach. It emphasises the recruitment process and informed consent.

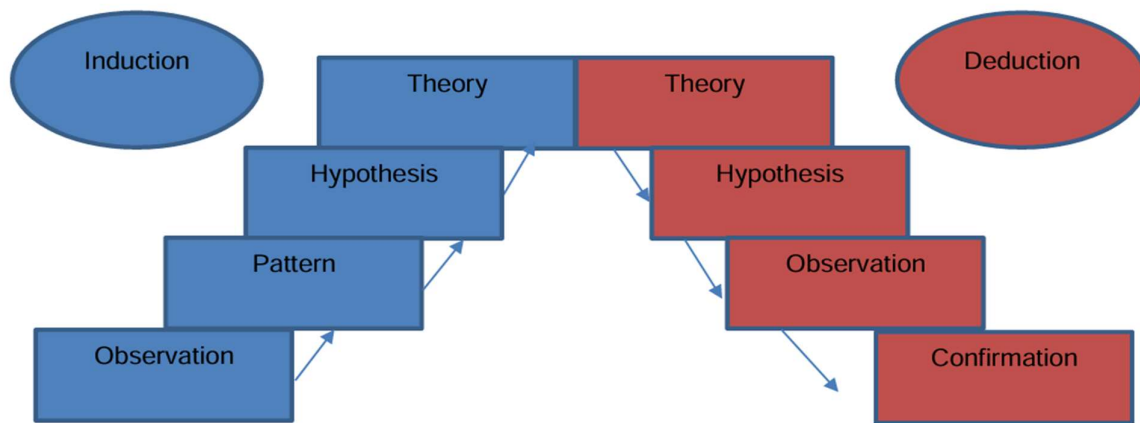
1.7.1 Empirical Investigation

Calfee and Chambliss (2005:43) define empirical research as a systematic method of answering questions by collecting data in well-defined, repeatable settings, encompassing qualitative and quantitative methodologies.

1.7.1.1 Research Approach

This study adopted an inductive approach aligned with the interpretive epistemology paradigm (Saunders *et al.*, 2016). As depicted in Figure 2, a researcher has two options for creating a new theory: deduction or induction (Trochim & Donnelly, 2008:22). In deductive reasoning, a hypothesis is the first step, and a research method is created to test that theory. This method is occasionally referred to as a top-down strategy (Trochim & Donnelly, 2008:23). The second strategy, known as inductive theory-building, begins with comprehensive research that finds patterns and correlations to formulate a hypothesis regarding a particular phenomenon; it is commonly known as the bottom-up strategy (Trochim & Donnelly, 2008:23). Interpretivism ideas were integrated into the analysis of textual data through the use of the inductive technique.

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Source: Trochim and Donnelly (2008:23)

Figure 2: Diagram illustrating Inductive and Deductive Reasoning

1.7.2 Methodological Choice

A qualitative research design was employed for this study. Wild and Diggins (2013:87) assert that a qualitative research approach is typically associated with the interpretivism research paradigm, focusing on a smaller sample of subjective views and beliefs. This approach is most appropriate for gathering descriptive information that can be assessed for trends, themes, and significance. A qualitative investigation is intended to examine phenomena in their genuine surroundings, aiming to interpret or construct meaning from the data obtained. Given this notion, it is pivotal for a researcher to explain the choice of methodology for their study. The below paragraph is dedicated to distinguishing the difference between qualitative and quantitative methodology.

The primary focus of qualitative research should be on five distinct acts (Bryman & Bell 2017:46). First and foremost, it is crucial to see events from the perspective of the participants, which is achieved by seeing under the surface (Bryman & Bell, 2017:46). To gain a more profound knowledge of each participant's experience with the purchase of medical devices in the Dr Kenneth Kaunda District Municipality, probing was used throughout the interviews for this study. Second, researchers who employ a qualitative methodology ought to elucidate the situation and underscore the significance of comprehending and illuminating social behaviour in the surrounding context (Bryman & Bell, 2017:46). Thirdly, processes and patterns must be explained, as well as how they develop over time, in qualitative research (Bryman & Bell, 2017:46). Fourth, the researcher should be transparent to the participants in the study and use a flexible approach instead of strict processes (Bryman & Bell, 2017:46). Inductive formulation of concepts and hypotheses is the final step (Bryman & Bell, 2017:46). Additionally, Bryman and Bell (2017:51) highlight that quantitative research uses numbers, statistics, and measurement to answer research questions, whereas qualitative research essentially uses language and description. The perspective of the participant is likewise a greater focus of qualitative research than of quantitative research. One characteristic that sets qualitative research apart is the inductive generation of concepts and hypotheses from the data gathered for this investigation (Bryman & Bell, 2017:48).

According to Stahl and King (2020:27), qualitative research is uniquely positioned to provide researchers with process-based, narrated, storied data more closely related to the human experience. Valuable insights can be gained by observing and absorbing the experiences of others, mainly through engaging narratives. However, the level of trust one has in the narrator significantly influences the level of confidence assigned to the story being told. Qualitative research studies yield similar results (Stahl & King, 2020:26).

Qualitative investigations are intended to be undertaken with a high level of rigour due to the inherent potential for subjectivity in this style of research (Cypress, 2017:254). Morse *et al.* (2002:14) argue that research lacking rigour is rendered worthless, resembling fiction, and loses its practical value. Davies and Dodd (2002:278) define rigour as the extent to which research is reliable and valid; they also note that rigour is inherently biased towards quantitative methods. Some scholars have contended that reliability and validity apply to quantitative research but are irrelevant to qualitative inquiry, as they align with the positivist perspective (Cypress, 2017:254). Rigour is an essential objective that must be achieved by incorporating various philosophical perspectives inherent in qualitative research and employing specific strategies for each methodological approach; this includes adhering to verification techniques throughout the research process. Refer to Chapter 3 for more information on the rigour of this study.

1.7.3 Study Population and Sampling

When a researcher plans to use probability sampling, a sample frame needs to be extracted. According to Collis and Hussey (2014), this is a record of the population from whom a sample was taken.

The researcher can select one of five non-probability sampling designs: purposeful, judgmental, expert, accidental, and snowball. With the following exceptions, they can be used in qualitative research even though their primary application is quantitative (Kumar, 2019:312).

- In quantitative research, information is obtained from a pre-specified population. When conducting qualitative research, the researcher gathers data until they believe a saturation point has been reached without considering the sample size.
- In quantitative research, the researcher's goal of selecting a random sample drives the study. In qualitative research, the investigator is directed by their assessment of which individuals would yield the most significant data.

This study used a purposive non-probability sampling methodology. As Lathan (2007) indicates, in purposive non-probability sampling, the researcher selects participants based on their knowledge of the identified characteristics.

It is crucial to note that a research project reaches its saturation point when it is clear that no new information becomes apparent during data analysis. At the end of saturation, the researcher concluded that the sample size was adequate and that no additional information from participants was needed to support any particular claims (Kumar, 2019).

1.7.4 Data Collection Instrument

An interview is defined by Kumar (2019) as a face-to-face or other interpersonal discussion between two or more people with a stated goal. The sample respondents were interviewed one-on-one to acquire the primary data for this study. The primary purpose of the interview was to learn about the respondent's perspectives, beliefs, past experiences, and understanding of reality (Wahyuni, 2012:73). Besides the grey literature, primary data was gathered through interviews lasting 30 to 45 minutes. A semi-structured approach was used, and open-ended questions were asked; see Annexure D.

1.7.5 Collection of Data

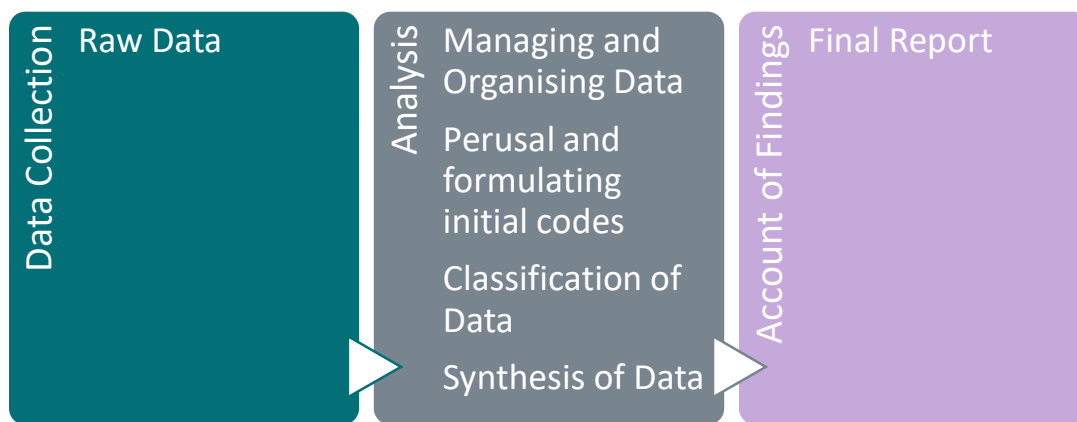
Cypress (2017:254) states that data collection involves using several methodologies, and regardless of the source, the researcher serves as the sole instrument of the study and the primary means of gathering information. All participants were asked to sign an informed consent form before the start of the interview. Following the consent form signatures from each participant,

the semi-structured interviews were conducted using the prearranged schedule. The researcher led the conversation by posing pre-planned questions on various subjects while allowing the participants to respond freely. Every interview was recorded on audio. The voice recordings were transcribed to classify and identify the various topics. The procedures were then repeated until the researcher believed saturation had been reached, as explained in Sections 1.7.2, 1.7.3 and Chapter 3. Interviews were conducted one-on-one with participants at their places of employment, and recording permission was acquired. Throughout the discussions, every COVID-19 safety procedure was followed.

1.7.6 Data Analysis

Content analysis is going over the information gathered from the notes and interviews and analysing it to identify the main themes that surface from the participant remarks (Kumar, 2019:402). The data analysis processes described by Cresswell (2013:183) are shown in Source: Adapted from Cresswell (2013:183)

Figure 3.



Source: Adapted from Cresswell (2013:183)

Figure 3: Data Analysis Diagram

Kumar (2019) outlines a content analysis method in four steps:

- Step 1: Identify the main themes. After identifying the meanings of each participant's descriptive response to a question, it is necessary to sift through them to create overarching themes that consider these meanings.
- Step 2: Give each of the significant themes a code. If the researcher wants to count the times a subject has come up during the interviews, assigning codes to the major topics will be helpful.

- Step 3: Sort the answers into groups based on the main themes. The interview responses were categorised into groups based on the main themes that emerged from the thematic analysis.
- Step 4: The main themes discovered during the content analysis phase are covered in the main body of the empirical study of the dissertation, along with theme integration.

It is essential to illustrate the data analysis process to the reader before they begin reading this mini-dissertation, as doing so will improve their understanding of the findings (Hofstee, 2018). It is imperative that data be reliable; as per Lincoln and Guba (1985:331), trustworthiness is a way to exhibit the reasonableness, legitimacy, and integrity of the qualitative research process. This study employed a narrative exploration strategy in the context of healthcare technology to gain a more profound knowledge of the procurement of medical devices and the examination of principles related to HTM. The approach involved subjectively interpreting events to provide a clearer understanding of the actual situation (Bryman & Bell, 2017:358).

Thematic analysis was used to assess and analyse the transcribed interviews; a more comprehensive analysis is provided in Chapter 3. According to Vaismoradi *et al.* (2013:398), thematic analysis aids in locating and interpreting participant-shared ideas. The data were manually organised and analysed.

1.8 Ethical Considerations

Arifin (2018:30) asserts that all research studies must protect human subjects by applying appropriate ethical principles. In this study, participant safety and privacy were of utmost importance. The anonymity of participants, including clinicians, supply chain management, and clinical engineering personnel, was preserved in all published documents using designations such as Participant 01 or Participant 02. The study adhered to all ethical standards, including compliance with the Protection of Personal Information Act (POPIA).

1.9 Recruitment Process and Informed Consent

After obtaining ethical clearance, data collection commenced in August 2023 and concluded in October 2023. The researcher collaborated with the Chief Director and all relevant stakeholders of Dr Kenneth Kaunda District Municipality to define the research objectives and develop an action plan. The researcher selected suitable participants for the study after determining the structure of the Dr Kenneth Kaunda District Municipality. Participants were informed about the objectives of the study, expectations, and the intended use of the collected data, and informed consent was obtained before commencing with the interviews. This ensured that participants fully understood the benefits of the research and their invaluable contribution to the knowledge domain. During the discussions, participants were consistently reminded of the confidentiality terms and their right to

withdraw at any time. Participants were provided with the contact details of the researcher, supervisor and ethics office for any queries or concerns. Table 3 on page 39 provides a detailed description of this process.

1.10 Contribution of the Study

Precisely aligning service standards with demand plans is crucial for informed healthcare decisions. This study explored the intricacies of the decision-making process during medical device procurement, explicitly focusing on the application of HTM principles. The research addressed a critical issue often observed in medical device procurement: the tendency to acquire devices outside a prioritised plan, leading to increased maintenance costs and inefficiencies.

Drawing on over sixteen years of experience as a clinical engineer, the researcher has witnessed first-hand how procurement decisions, influenced by budget constraints and clinician requests, can lead to the acquisition of non-priority medical devices. Such choices often result in mismatches between healthcare facilities' needs and the procured medical devices. This study specifically addressed these challenges within the geographical area of the Dr Kenneth Kaunda District Municipality in South Africa, aiming to align the priority list of medical devices with the available budget.

This research aimed to contribute new insights into optimising medical device procurement processes and bridge gaps in the existing literature. The findings are intended to inform and refine procurement practices, ensuring that decisions are cost-effective and aligned with the community's healthcare needs and service standards in the Dr Kenneth Kaunda District Municipality, South Africa.

1.11 Delimitations and Limitations of the Study

According to Theofanidis and Fountouki (2018:156), limitations of any particular study concern potential weaknesses that are usually out of the researcher's control and are closely associated with the chosen research design, funding constraints, or other factors. This research aims to describe the HTM practices focusing on the principles regarding the procurement of medical devices in healthcare facilities, particularly CHCs in the Dr Kenneth Kaunda District Municipality, South Africa. These facilities receive direct support from the district or sub-district for their medical device procurement budget. It is important to note that this study excluded tertiary and district hospitals, which have independent operations and procure medical devices from their allocated budgets. Theofanidis and Fountouki (2018) state that delimitations are boundaries that a researcher consciously creates to specify the parameters of their study and ensure that the aims and objectives of the research remain attainable. An inherent limitation of this study is that it does

not do a comparative analysis of healthcare providers, i.e., private and public sector, and other districts or municipalities in South Africa.

1.12 Document Structure

This mini dissertation is structured into five chapters, delineated as follows:

Chapter 1 introduces the critical gaps in medical device procurement in low- and middle-income countries, specifically focusing on Dr Kenneth Kaunda District Municipality. It aims to illuminate these gaps and underscore the necessity for all stakeholders to adhere to HTM principles recommended by the World Health Organisation (WHO). The chapter outlines the research aim, articulates the problem statement, and delineates the research objectives. It also provides an overview of the research methodology, data sources, and literature analysis approach.

Chapter 2 extends the discussion to integrating medical device procurement within the broader framework of healthcare policies and systems. It accentuates the pivotal role of government regulations and standards in ensuring the safety and efficacy of medical devices. The chapter underscores the necessity for a collaborative approach involving healthcare providers, technology vendors, and policymakers in enhancing the procurement process. This approach includes assessing healthcare needs, evaluating technological options, and making informed decisions regarding appropriate medical devices. This chapter emphasises the importance of considering the total lifecycle costs of medical devices, encompassing acquisition and disposal.

Chapter 3 details the research methodology, including the empirical investigations undertaken. It discusses the pivotal aspects of the research, methods, and inherent limitations, including the data collection tool. The chapter also elaborates on the sampling methods and provides an overview of the data analysis process.

Chapter 4 presents the research findings and the discussions, including coding. The data is analysed, evaluated, and presented in tables and figures to understand the findings better.

Chapter 5 synthesises the study, provides its strengths and limitations, and provides recommendations for future research. The chapter culminates with a concluding statement, assessing whether the study's objectives have been met and if the research question has been answered accordingly.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

This chapter reviews healthcare technology management (HTM) literature focusing on the procurement of medical devices in low- and middle-income countries. It plunges into various theories and frameworks related to medical device procurement, including vital principles such as needs assessments, defining specifications and standards, technology evaluation, device lifecycle management, and cost analysis. The chapter also examines healthcare technology procurement strategies, including medical device procurement. Although limited research has been published on this niche topic, the researcher conducted this study to gain a better understanding of HTM principles regarding medical devices.

2.2 Theoretical Framework for the Procurement of Medical Devices

According to the World Health Organisation (WHO) (2014), a medical device is any instrument, apparatus, machine, implant, appliance, reagent for in vitro use, software, material, or any other related article that is specifically intended by the manufacturer for use in human beings for specific medical purposes, either alone or in combination.

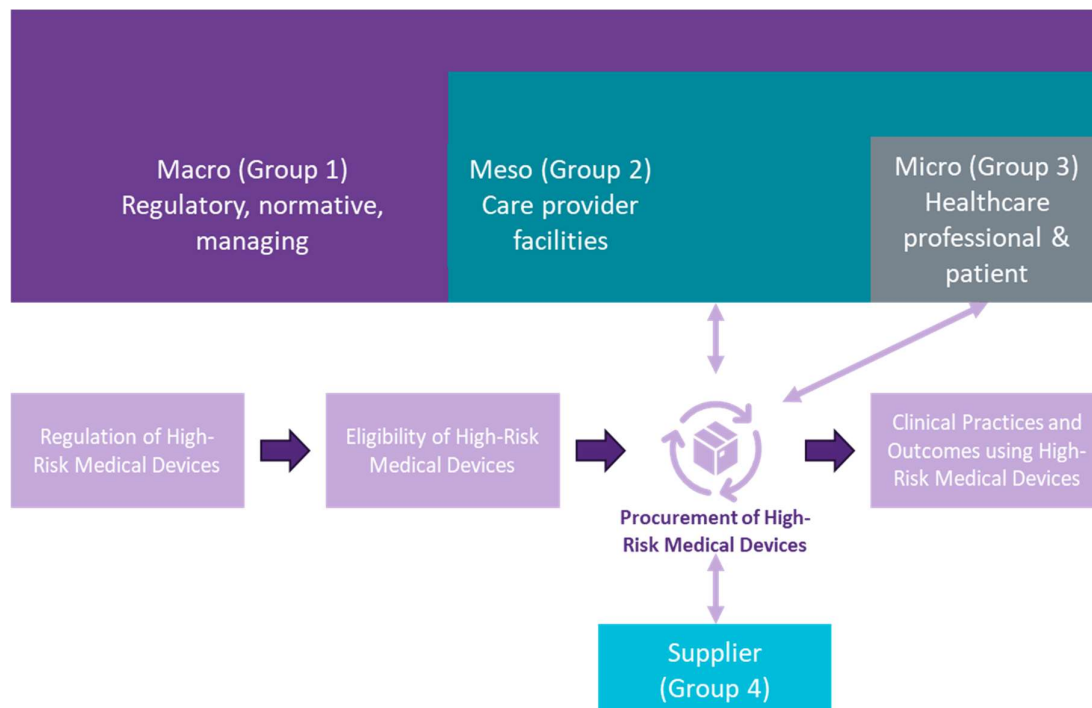
Analysts note that the widespread adoption of medical technology in healthcare systems often correlates with rising costs (Sorenson *et al.*, 2013:224). Therefore, understanding how financing methods influence the spread of medical technology is crucial. This understanding is vital for formulating appropriate financing policies for healthcare, considering the diffusion of medical technology at various administrative levels (Castro *et al.*, 2014:216). Enhancing the transfer of medical device technology can provide patients with innovative and efficient devices and foster economic growth in the healthcare sector. However, challenges related to transferring and commercialising technology for medical devices often remain underexplored (Páes-Avilés, 2015:26).

Resae *et al.* (2020:113) state that public procurement is a demand-driven technology policy and a vital economic facet that necessitates a thorough understanding of conditions and access to reliable information. Torbica and Cappellaro (2010:62) suggest that innovation in the medical industry is intrinsically linked to procurement policy. Roos (2012) argues that effective policy formulation requires a comprehensive understanding of the current conditions and access to dependable information, fostering a clear vision for future technological advancements. Lingg *et al.* (2016:1) note that in affluent countries, especially those with a national registry for medical devices, purchasing decisions are often influenced by long-term clinical outcomes.

Sanderson *et al.* (2015) state that, ideally, procurement decisions should be rooted in transparency and cost-effectiveness, encompassing selection and contracting, relationship management, demand management, and operational delivery (WHO, 2016). In certain procurement systems, the priority of reducing costs can take precedence over the input and expertise of healthcare professionals.

Kakwesi and Nyeko (2019:2) highlight that quality assurance initiatives are frequently absent in low- and middle-income countries, leading to a lacklustre focus on the procurement process. Research has explored the link between procurement and the risk of procuring subpar medical devices; however, comprehensive follow-up studies are still awaited (Lingg *et al.*, 2016:2). Often, healthcare stakeholders prioritise addressing more pressing healthcare challenges, such as universal healthcare access, before focusing on optimisation (Lingg *et al.*, 2016:2).

Lingg *et al.* (2016:3) propose a multi-faceted approach to healthcare delivery, considering how medical device regulations influence procurement (macro level), how procurement regulations align with clinical practice expectations (Meso level), and how procurement practices impact clinical outcomes (micro level). Figure 4, adapted from Lingg *et al.* (2016:3), illustrates this conceptual framework, designed for high-risk medical devices but can be tailored to the specific needs of any healthcare facility.



Source: Lingg *et al.* (2016:3)

Figure 4: Theoretical Conceptual Framework for the Procurement of Medical Devices

Adherence to stringent procurement restrictions may have a detrimental impact on healthcare delivery; hence, it is necessary to establish regulations that are in line with efficient procedures to provide optimal healthcare provision (Lingg *et al.*, 2016:8). Source: Lingg *et al* (2016:3)

Figure 4 summarises the recommended strategy managers and clinicians often use different methods to influence purchase decisions.

2.2.1 Procurement Model Related to Tendering

Governments and healthcare institutions globally are exploring strategies to curb the continued rise in healthcare expenses. One such strategy is tendering, which is employed in the procurement of medical devices. While tendering has bolstered the bargaining power of buyers and reduced procurement prices, it has not always translated into a reduction in overall healthcare expenditure (HBS Consulting, 2003; Hübner & Elmhorst, 2008). Robinson (2008:1524) points out that the intricacies of tendering systems can inadvertently inflate costs and pave the way for corruption. Graves (2011:102) warns that while tendering might seem a straightforward solution for securing favourable pricing for medical devices, the inherent variability in tendering programmes introduces potential risks and unforeseen outcomes.

Like previous healthcare reforms, value-based healthcare was adopted to address several healthcare system concerns, including rising prices and disparities in service quality (Porter & Teisberg, 2006; Gerecke, 2015). This idea focuses on health outcomes and associated expenditures, with value defined as health outcomes per dollar spent (3). Medical devices have the ability to drive value-based health care (Gerecke, 2015, Miller *et.al*, 2019:52), as they are at the centre of value creation and serve as a vehicle for value-based change in the health system. Graves (2011:104) emphasises that investment in initially more expensive, high-quality medical equipment can result in long-term cost savings. Conversely, opting for cheaper but inferior products may escalate long-term costs (United Kingdom Department of Trade and Industry (UKDTI), 2003).

Healthcare institutions should prioritise the quality and efficacy of medical devices to ensure optimal patient outcomes and cost savings. A comprehensive approach to procurement decisions is essential to avoid an undue focus on initially cheaper products and to ensure the selection of medical devices that offer long-term benefits (Graves, 2011:103). Sorenson (2008:4) observes that many tendering systems have adopted an "all-or-nothing" approach, often awarding contracts to a limited set of suppliers, granting them a significant market share.

2.2.2 Procurement Model and the Role of the Healthcare Technology Committee

Graves (2011:104) advocates for the involvement of professionals from diverse departments in product selection. Establishing a multidisciplinary committee, such as the Healthcare Technology Management Committee, can offer a holistic perspective on the entire care process, promoting

awareness of medical device's long-term clinical benefits and costs. Such a committee can evaluate various factors, including clinical benefits, economic impacts, value-added services, and product lifecycle costs (Milne & McGee, 2002:97).

2.3 Healthcare Technology Management

McCarthy *et al.* (2014:43) emphasise the importance of HTM, which provides scientific and technical support for medical devices and clinical information systems and promotes financial responsibility. Such leadership is essential for delivering top-tier, secure patient care, albeit at a significant investment (McFadden *et al.*, 2009:391). David and Jahnke (2004:73) note that healthcare facilities allocate substantial funds to manage capital assets, leading to the dual pressure of acquiring cutting-edge medical technology while managing older inventory. Beyond mere procurement, capital asset management now anticipates market demands and future facility needs (Beech, 2001:47).

Healthcare technologies have revolutionised medical capabilities, from prevention to diagnosis and treatment (Keller & Walker, 2005). However, their adoption hinges on physicians' priorities and adherence to established clinical practices. The STEEEP principles—Safety, Timeliness, Effectiveness, Efficiency, Equity, and Patient-centredness (Institute of Medicine, 2001)—serve as a benchmark for healthcare technology provision. Yet, many developing nations struggle with these principles due to limited access to such technologies. The WHO (2004) reports that 95% of healthcare technology in developing countries is imported, often resulting in mismatches, as technologies developed in affluent nations may not cater to local needs. Technology transfer disparities can affect cost and utility (Temple-Bird, 2005).

Consultants in HTM must guide the procurement of medical devices, refining demand plans, budget estimates, equipment effectiveness, and ownership costs (David & Jahnke, 2015:23). Despite substantial investments in medical device procurement, strategic management remains underemphasised (Houngbo *et al.*, 2017:447). Many primary and secondary healthcare facilities lack essential technologies, leading to equipment being unavailable, dysfunctional, misused, or unsuitable. Therefore, making informed capital decisions is paramount, especially considering the rising influence of clinical engineering insights and ownership costs (David *et al.*, 2003).

Technology is indispensable in healthcare systems; without medical devices, many procedures would be unfeasible (Dasanayaka, 2011:318). Effective technology management is vital for public hospitals, which allocate a significant portion of their budget to medical devices (Bodenheimer, 2005:937; Rabb, 2001). Numerous studies underscore the dearth of essential medical devices in low- and middle-income countries (Perry & Malkin, 2011:719). Diaconu *et al.* (2014:2) indicate a limited understanding of procurement processes for these devices, which might starkly differ from those in affluent nations. Howitt *et al.* (2012:507) stress the need for medical devices to be apt,

accessible, and affordable for healthcare facilities in such settings. Understanding medical device procurement in low- and middle-income countries remains limited, with significant variations from high-income countries (Diaconu *et al.*, 2014:2). The decision-making process for the procurement of medical devices involves multiple stakeholders, namely clinicians and administrators (Fricke & Dauben, 2009:23).

International health organisations have developed guidelines and tools to assist decision-makers in procuring medical devices for low- and middle-income countries. The WHO suggests 'availability matrices' for device procurement, focusing on clinical areas with the highest disease burdens (Diaconu *et al.*, 2014:2). Implementing this approach could enhance access to vital healthcare services in these nations.

Healthcare technology extends beyond medical devices to software, procedures, energy systems, supplies, infrastructure, organisational models, and medicines (Vilcahuaman *et al.*, 2017:252). Effective HTM is pivotal, especially concerning medical devices. It refines the procurement process, ensuring devices meet clinical and technical needs while offering value for money. Choosing suitable devices for healthcare facilities can be facilitated using proper terminology matching their specific applications.

Considering these factors, healthcare facilities should strategise and assess their medical device infrastructure, aligning it with their service standards. This might entail listing essential medical devices for healthcare service delivery in line with national or regional standards (Gamessa *et al.*, 2022:406). However, equipping facilities with advanced devices often requires a significant budget, necessitating a detailed costing model, especially initially (Kim, 2018:34). With dwindling profit margins in primary care, optimally allocating resources has become increasingly intricate (Willis, 2004:53). Figure 5 on page 18 adapted from Lenel *et al.* (2005:12), presents an ideal health system which can serve as a policy framework to ensure that patients receive appropriate and timely health services.



Figure 5: The Role of Healthcare Technology Management in the Health System.

2.4 Public Procurement of Medical Devices

Public procurement is integral to acquiring goods and services to meet governmental needs (Fourie, 2015:38). The Constitution of the Republic of South Africa (RSA, 1996) and the Public Finance Management Act (RSA, 1999) guide public procurement in South Africa, ensuring transparency and fairness. For effective HTM, transparent policies, technical guidance, and practical tools are crucial (Issakov and Poluta, 2005:5). Proactive health service asset management can address some challenges in low- and middle-income countries. Infrastructure, including buildings and technology, represents the health sector's most significant capital expenditure. Thus, it is financially prudent to manage these resources efficiently, ensuring appropriate selection and maximised capacity of healthcare technology.

According to Roos (2015), policy development hinges on understanding current circumstances and accurate information; furthermore, based on transparent and clear foresight, the technology path is constructed as a roadmap. Public procurement represents one side of the demand for technology policies (Clark & Guy, 1998:364), recognised as a strategy for creating a more sustainable community and economy (Elder *et al.*, 2011), and is governed by regulatory and policy frameworks in most countries (Kastanioti *et al.*, 2013:8). According to Resaee (2021:113), medical device technology stands as one of the nation's most critical technologies, with public procurement being a suitable approach for this technology.

Vilcahuaman *et al.* (2017:252) highlight an evolution in the models for managing and organising technology within hospitals. This evolution calls for a re-engineered model that prioritises clinical effectiveness, efficiency, safety, cost control, and quality to align with users' expectations of hospital technology. Global case studies have showcased successful and unsuccessful policy reforms (Hanushek, 2003:65). Resource constraints on employees often hamper policy implementation. This limitation can adversely impact the government's procurement of medical devices, exacerbating challenges in an already overburdened healthcare system. According to WHO (2010), many developed countries face inefficiencies and wastage in managing medical devices, as shown in Table 1 on page 19.

Table 1: Management of Medical Devices

Problem	Waste
Inability to correctly specify and foresee the total needs when tendering and procuring equipment	10-30% extra cost
Purchase of sophisticated equipment that remains unused due to lack of skill of the operating and technical staff	20-40% of the equipment
Extra modifications or additions to equipment and/or building unforeseen at the tendering stage due to lack of staff expertise	10-30% of the equipment
Maltreatment by operating and maintenance staff	30-80% of the equipment
Lack of standardisation	30-50% extra spare parts cost
Downtime due to inability to use or repair, or lack of spare parts and accessories	25-35% of the equipment

2.5 Impact of Procurement on the Medical Device Market

Resaee *et al.* (2020:113) observe that the United States dominates the global medical device trade, accounting for 45% of the \$302 billion market, with sales approximating \$136 billion in 2014. Mueller *et al.* (2014:326) estimated the South African medical device industry's worth to be between \$2.5 billion and \$3 billion in the same year. Over time, Europe and China have ascended the ranks, now holding second and third positions in the medical device market (Collins, 2015). Forecasts suggest that this industry could grow significantly, reaching \$800 billion by 2030, with a global annual growth rate of around 5% (Van den Heuvel *et al.*, 2018).

A recent study examining global patent application activity as a measure of innovation across twelve sectors found that medical devices were the most active, with the highest year-over-year growth (+27%) in the number of patents from 2014 to 2015 (Thomson Reuters, 2016). As governments try to strike an appropriate balance between patient access to modern care and healthcare systems' economic viability, they seek to select the most cost-effective technology at the lowest available pricing (Gallea *et al.*, 2017:89). Health Technology Assessment (HTA) and centralised procurement have played a growing role in regulating the introduction and diffusion of medical devices to strike the right balance between patient access to innovation and cost containment (Sorenson & Kanavos, 2011).

The global medical devices market is poised for substantial growth in the coming years, driven by the rising demand for advanced medical technologies in developed and developing countries. While many medical innovations promise significant benefits for patients and the healthcare sector, their widespread adoption can pose challenges, especially in resource-limited settings (Qerimi, 2014:7). Striking a balance between cost-effectiveness, efficiency, efficacy, and fostering innovation can be intricate, as these goals might conflict (Obwegster & Müller, 2018:3). However, the pivotal role of advancements in medical technology in enhancing human well-being is undeniable, and the medical device industry thrives on relentless innovation (Nexon, 2011).

Innovation is increasingly acknowledged as a crucial competitive and growth driver in the medical device industry. Renowned for its rapid innovation cycles, the industry often sees products being superseded by improved versions every 18-24 months (Commission UI, 2007). This relentless pace of innovation fosters intense competition within the medical device sector (Donahoe & King, 2009). In this context, 'innovation' includes developing new medical devices and continuously refining existing equipment and clinical protocols (WHO, 2010). Sorenson and Kanavos (2011:44) note that countries have adopted varied regulatory and policy-making strategies to oversee and manage procurement practices. These strategies range from regulating the procurement and operation of medical devices to modifying financial systems to counteract cost surges and enhance healthcare accessibility.

Despite governmental initiatives, particularly in low- and middle-income countries, universal access to affordable, high-quality healthcare remains elusive. The public procurement of medical devices can influence healthcare costs in two primary ways: (i) some innovations enhance performance, leading to cost savings, and (ii) others boost productivity, resulting in reduced expenses (Gurtner & Soyes, 2015).

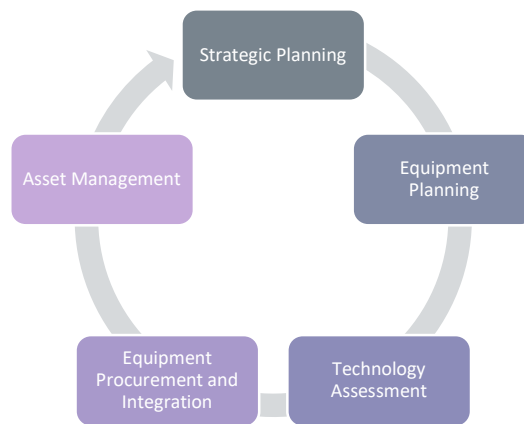
2.6 Comparative Analysis of Medical Device Procurement Strategies

In the 1980s, legislators and policymakers initiated significant initiatives to assess new medical technologies, aiming to enhance decision-making within healthcare (Berg *et al.*, 2004:36). This emphasis on evaluating novel medical technology persists today, with decision-makers recognising the importance of harmonising innovation with cost-effectiveness in healthcare. High-income countries with robust infrastructures have developed effective legislative frameworks to support medical device procurement. Such countries have adopted centralised procurement systems for medical devices, employing diverse strategies like the United Kingdom's Procurement and Supply Agency and National Health Service and the Collaborative Procurement Hubs in the United States of America (Brown *et al.*, 2008:243).

Willeme and Dumont (2015:1028) argue that medical technologies significantly influence healthcare costs, having a more pronounced impact on healthcare than any other factor within a nation. Hence, it is paramount, especially for low- and middle-income countries, to establish a proficient system for medical device procurement that ensures cost-effectiveness. Many nations employ regulatory and policy instruments to oversee public procurement practices, aiming for long-term sustainability (Edler, 2011). Such an approach can stimulate innovation and create market opportunities for sustainable products and services, notably medical devices. A comprehensive understanding of medical devices and the implementation of supervisory and planning systems can enable officials to make informed decisions at the grassroots level. The overarching objective is to foster long-term economic stability and elevate the standard of healthcare services for the populace (Collins, 2015).

2.6.1 Needs Assessment in Healthcare Technology Management

Healthcare establishments are overhauling their technology management frameworks, starting with strategic planning, to enhance the support extended to medical technology management (David & Jahnke, 2004:76). Central to this endeavour is a comprehensive needs assessment. This involves evaluating the current status of medical devices, identifying gaps in the facility's equipment repertoire, and understanding healthcare providers' and end-users' needs and preferences. As articulated by David and Jahnke (2004:76), this assessment is tailored to each institution, serving as a guide for subsequent planning related to medical devices. Implementing well-devised guidelines and consistent monitoring is crucial for the success of a strategy. Figure 6, sourced from David and Jahnke (2004:76), shows that the Texas Children's Hospital exemplifies a well-orchestrated approach. By emulating this model, a healthcare institution can ensure the success of its strategy. This blueprint leverages the collective acumen of a diverse team of professionals and integrates a consensus-driven policy.



Source: David and Jahnke (2004:76)

Figure 6: Texas Hospital Technology Management Process

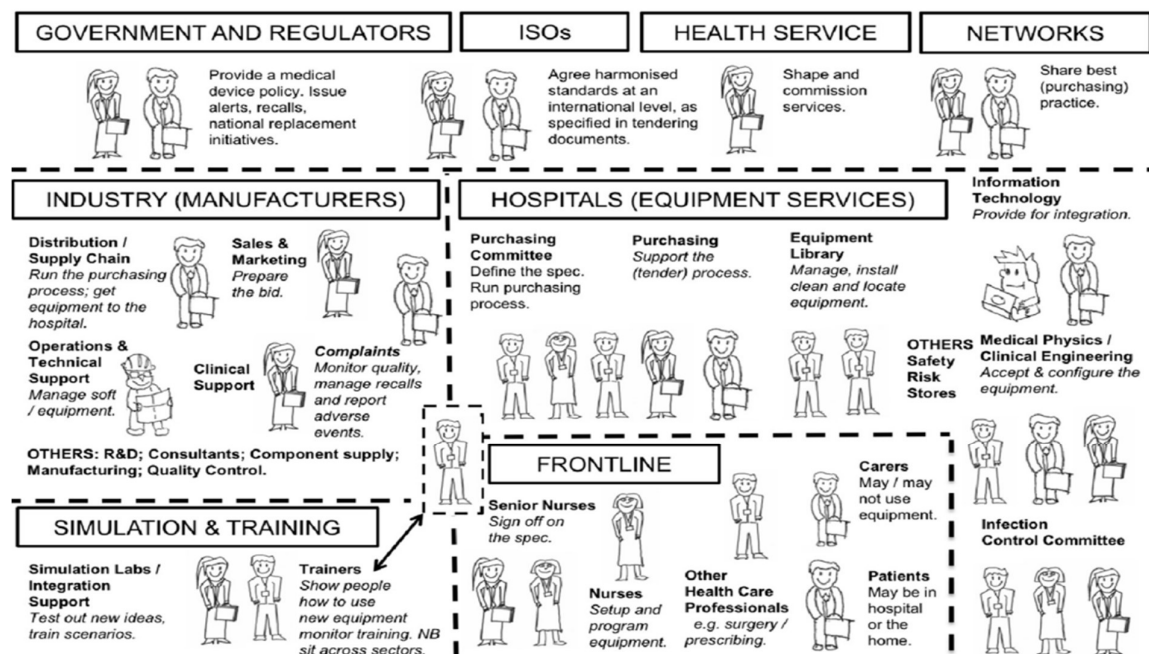
David and Jahnke (2004:76) emphasise that this synergistic team adopts a unified methodology to define medical technologies' precise requirements, scope, and objectives, especially medical devices. Their combined expertise and collaborative approach lay the foundation for effective technology deployment and enhanced healthcare delivery.

2.6.2 Specification and Standards in Medical Device Procurement

Vincent and Blandford (2016:114) underscore that several factors can influence the provision of medical devices that align with requisite usability standards, regulatory requirements, international benchmarks, and market expectations. Establishing clear specifications and standards becomes imperative during the acquisition of medical devices. This involves specifying desired functionalities, distinct attributes, and anticipated performance metrics. The procurement decision profoundly impacts the usability of medical devices, affecting both their direct and ancillary aspects (Vincent & Blandford, 2016:114).

Source: Vincent and Blandford (2016:114)

Figure 7, adapted from Vincent and Blandford (2016:114), illustrates the interplay between various stakeholders and outlines the optimal procedural trajectory, considering the specifications and standards of medical devices. According to the author, in the field of procurement, the coming together of different stakeholders to discuss specifications and standards is seen as a crucial point of intersection. The individuals involved in this process, ranging from those making internal decisions to external suppliers, navigate through a complex system of technicalities and conventions to shape the fundamental principles of quality, sustainability, and innovation.



Source: Vincent and Blandford (2016:114)

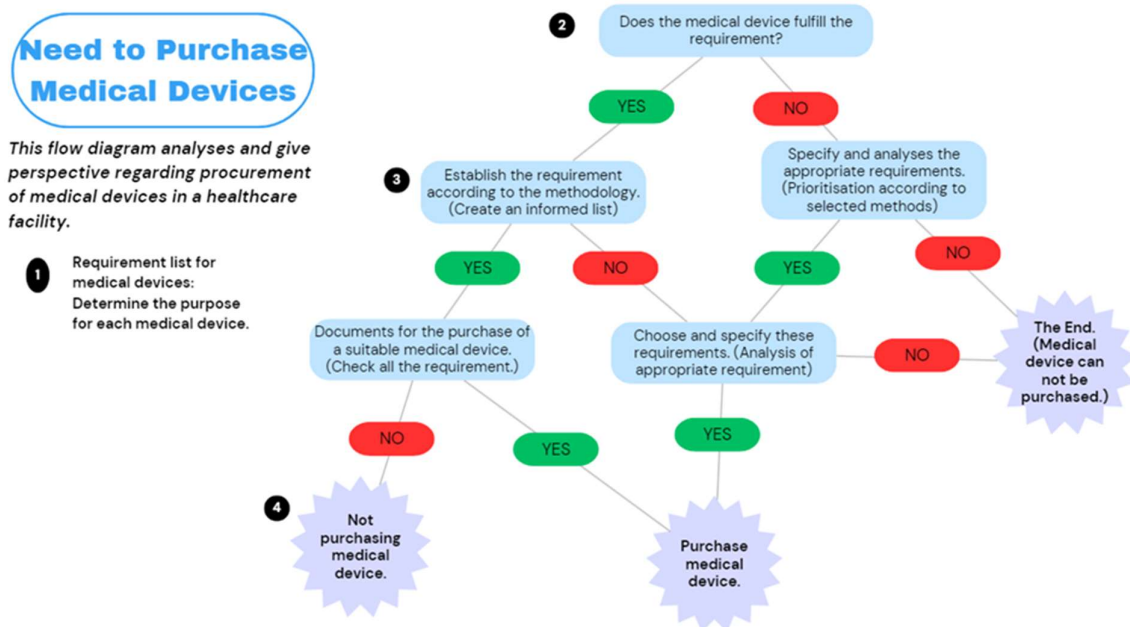
Figure 7: Procurement Stakeholders Regarding Specifications and Standards

The procurement process's interaction between requirements and standards is similar to creating custom clothing. Every stitch and cut is carefully considered to combine form and function, guaranteeing that the outcome meets the immediate requirement and serves as a monument to lasting worth.

2.6.3 Technology Assessment for Medical Devices Procurement

Evaluating various health technologies' efficacy, appropriateness, and costs is crucial in constrained resources and escalating healthcare expenses. This includes drugs, biologics, devices, equipment, supplies, medical and surgical procedures, support systems, and organisational and managerial frameworks (Goodman, 2014). Since the 1990s, health technology assessment has been crucial in drug reimbursement worldwide, as it compares the clinical outcomes with the costs of interventions (Goodman, 2014). Although this methodology has effectively assessed health technologies, managing and applying medical devices within healthcare technology remains challenging (Drummond *et al.*, 2009:403; Markiewics *et al.*, 2014:139). Source: Rosina *et al.* (2014:26)

Figure 8, adapted from Rosina *et al.* (2014:26), illustrates the management trajectory relevant to the technology assessment of medical devices.



Source: Rosina *et al.* (2014:26)

Figure 8: The Requirements Management Process Regarding Medical Devices

The figure shows the intricate and multifaceted decision-making process for managing medical device requirements. This procedure, crucial for ensuring that medical devices comply with regulatory and user requirements, requires precise attention to detail and thorough inspection at

every stage. The core of this endeavour is the creation of specifications, which involves converting user requirements into a clear set of instructions. This step is fundamental, establishing the framework for all subsequent actions and serving as a guiding principle for development initiatives.

2.6.4 Life-Cycle Management of Medical Devices

Ison and Miller (2000:454) highlight the importance of rigorous performance specifications and criteria before any medical device is approved for clinical use. In managing device replacement, it is crucial to consider spare parts availability, upgrade potential, and disposal mechanisms to minimise service interruptions. Ison and Miller (2000:454) identify two main factors influencing the choice of one product over another:

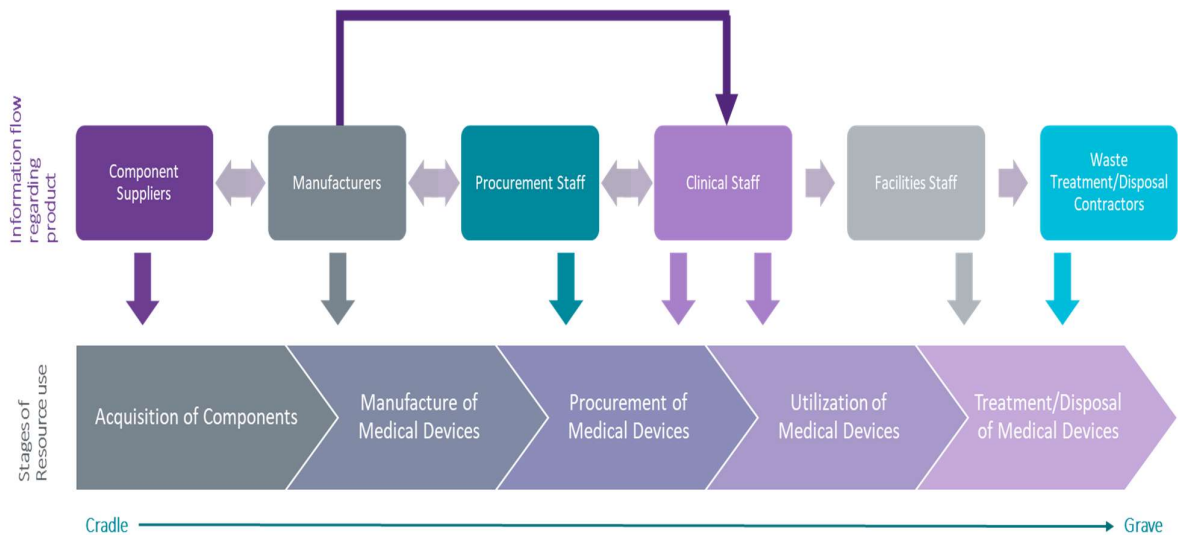
- Potential risks to patients and staff during device operation.
- The financial cost of procuring the device.

However, specific considerations often overlooked during the selection and acquisition of medical devices include:

- The financial implications of treating and disposing of the device post-use.
- The environmental impact of the device across its life stages.

While this research does not focus on the life-cycle evaluation of medical devices during procurement, it is essential to highlight aspects of their stewardship. Source: Adapted from Ison and Miller (2000)

Figure 9, adapted from Ison and Miller (2000), presents a life-cycle perspective encompassing all elements of a device's operation, disposal, and environmental impact.



Source: Adapted from Ison and Miller (2000)

Figure 9: The Utilisation and Management of Medical Devices - Healthcare Sector

Figure 9 on page 24 illustrates the utilisation and management of medical devices in the healthcare field, which involves a complete framework to optimise the effectiveness and safety of these equipment throughout their lifespan. This includes strategic measures ranging from acquiring and implementing to monitoring and eventually retiring, ensuring that each device is used to its fullest potential to improve patient care while complying with strict regulatory criteria. Managing these devices is an ongoing effort that involves consistent maintenance and calibration to maintain maximum performance. This stage is crucial for extending the longevity of the devices and ensuring their dependability and precision in diagnosis and therapy. Medical devices in healthcare must be ethically decommissioned according to environmental regulations and disposed of in a way that minimises harm to human health and the environment.

2.6.5 Cost Consideration in Medical Device Procurement

Opting for price as the sole determinant, with a focus on short-term cost curtailment, can inadvertently sideline patient requirements and the comprehensive costs associated with medical device acquisition (Gerecke *et al.*, 2015; Sorenson & Kanavos, 2011:45). Planning for device replacements in healthcare is essential, and overlooking this pivotal phase can have severe repercussions. However, it's imperative to recognise the pronounced disparities in medical device procurement procedures across nations (Trippoli *et al.*, 2018:63). These disparities are evident in fragmented organisational structures, misaligned incentives, underdeveloped information systems, and the inability of procurers to seek optimal value (Robinson, 2008:1523; Sorenson & Kanavos, 2011:45; Trippoli *et al.*, 2018:63).

Robinson (2008:1523) posits that the essence of value-based purchasing lies in an astute, financially savvy, and well-informed consumer leveraging their resources to choose services selectively within a technologically advanced environment. Physician preference items (PPIs) constitute a significant portion of total hospital supply costs and are rapidly becoming a notable expenditure. Most of these devices are used in orthopaedics, neurosurgery, cardiovascular surgery, and interventional cardiology, significantly boosting hospital revenues (Russo *et al.*, 2004). Consequently, they are under intense scrutiny by management. Medical device costs in hospitals can range from 30-80% of the reimbursements from public and private insurers. Therefore, adeptly managing device selection is crucial for the hospital's supply-chain efficiency and financial health (Medical Device Intensive, 2006).

2.7 Healthcare Technology Procurement Practices

In May 2007, the World Health Assembly WHA60.29 endorsed a resolution addressing various aspects, including health technologies and the pivotal role of robust health systems in addressing disease prevention, diagnosis, treatment, and patient rehabilitation. This resolution was designed to tackle challenges stemming from the unsuitable deployment and utilisation of health

technology. It emphasised the urgency of prioritising and managing health technologies, focusing on medical devices (WHO, 2011). Member State representatives highlighted the indispensable role of health technology in achieving health-related developmental objectives and fostering advancements in medical devices.

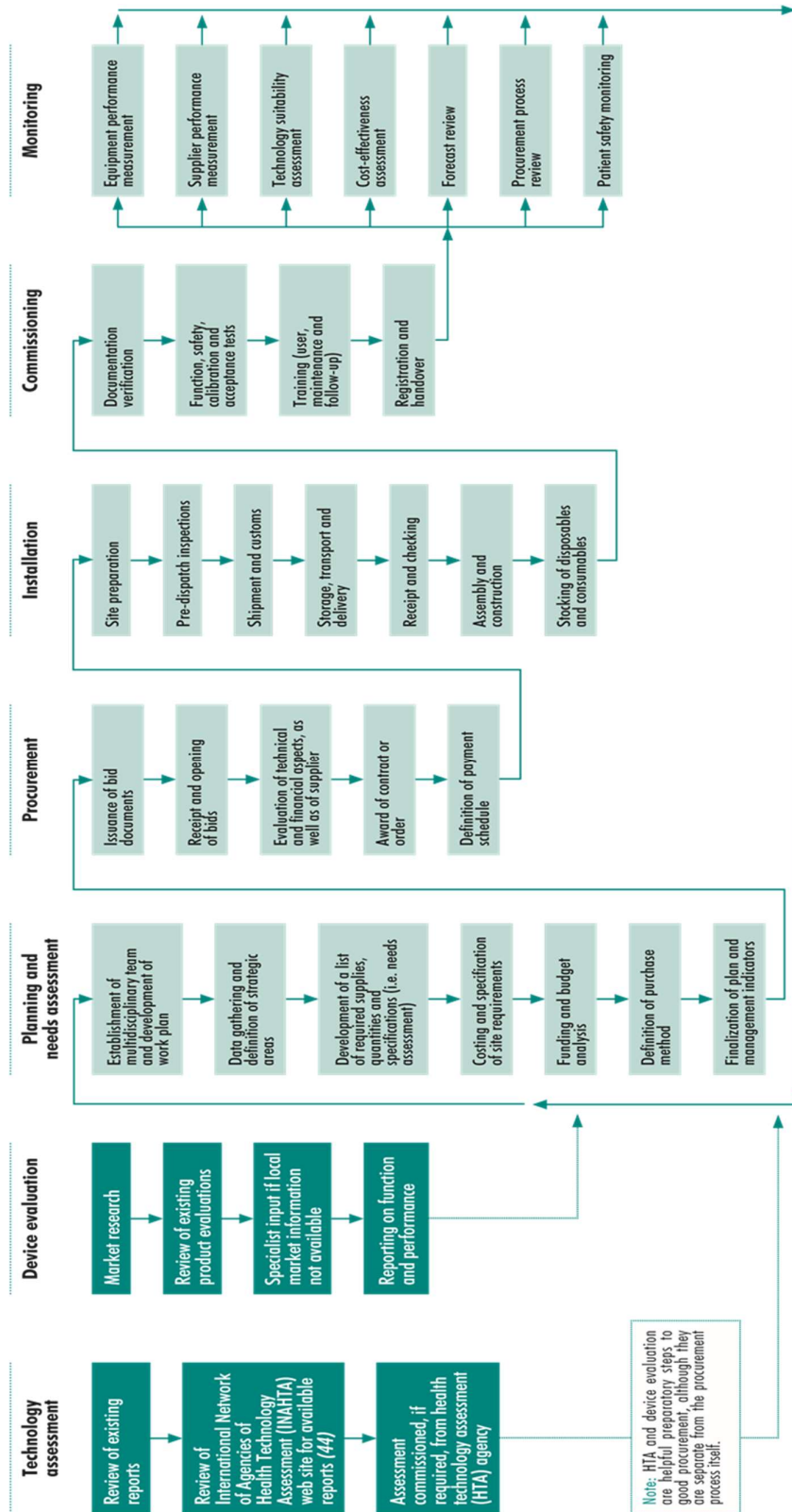
The WHO (2011) states that effective procurement of health technologies results in safe, equitable, and superior healthcare for all stakeholders. Transparent and accountable procurement practices benefit funders, medical professionals, and patients, leading to optimal healthcare outcomes. Procurement, a linchpin of equitable healthcare access, involves activities ranging from acquiring assets to planning and forecasting (WHO, 2011). It also encompasses the entire lifecycle of an asset, from need identification to contract administration and delivery (ENOPS, 2010). The Organisation for Economic Co-operation and Development (OECD, 2008) underscores that an effective procurement system rests on four foundational 'principles':

- Legislative framework
- Integrity and transparency
- Institutional and management capacity
- Operations and markets.

Following these fundamental principles ensures that a procurement system operates efficiently and responsibly manages public resources. Vital governance initiatives in public procurement can promote crucial values such as accountability, responsiveness, professionalism, transparency, competition, and the right to appeal (WHO, 2011).

Access to medical devices is crucial for healthcare delivery, especially in resource-constrained nations. Proficient procurement practices can ensure that medical devices are both available and accessible to healthcare establishments and patients in a timely and cost-effective manner. Given the intricacies of the procurement process, adhering to standard procurement protocols that align with public procurement reforms and sound procurement systems is essential (WHO, 2011). Source: WHO (2011)

Figure 10 on page 27 provides a concise flowchart delineating the standard procurement procedures, encapsulating everything from need identification to contract management and oversight.



Source: WHO (2011)

Figure 10: Summary Flowchart of the Standard Procurement Procedures

2.8 Healthcare Technology Assessment Defined

The International Network of Agencies for Healthcare Technology Assessment (INAHTA, 2020:188) defines healthcare technology assessment (HTA) as a multidisciplinary process that uses explicit methods to determine the value of health technology at different points in its lifecycle. This field examines the medical, social, ethical, and economic implications of the development, dissemination, and application of health technology (Gallea *et al.*, 2016:90). As Herndon *et al.* (2007:1293) observe, HTA initially emerged within federal agencies but has since evolved, becoming more decentralised with increased participation from the private sector. It involves a comprehensive evaluation of medical technologies, assessing their efficacy, safety, feasibility, cost, cost-effectiveness, and suitable indications for use (Bosic *et al.*, 2004:1306).

Healthcare technology management, combined with centralised procurement, has skilfully navigated the regulatory landscape of medical devices. It balances providing patients with access to innovative devices and realising cost savings (Sorenson & Kanavos, 2011:45). Herndon *et al.* (2007:1293) stress that the successful introduction of validated, safe, clinically effective, and cost-efficient new technologies requires synergy among physicians, institutions, and the industry. Robust pre-market clinical trials and rigorous post-market evaluations underpin this synergy.

Gallea *et al.* (2016:89) argue that while technological innovation in healthcare can improve health outcomes, it also leads to increased healthcare expenditure. Governments must balance patient access to treatments with the sustainability of the healthcare system. A holistic analysis of emerging technology should include its scientific, ethical, economic, and societal implications, including its potential impact on service quality and resource allocation (Herndon, 2007:1297). In the context of public procurement in low- and middle-income countries, HTA enables decision-makers to judiciously select medical devices based on their cost-effectiveness and prospective influence on patient outcomes. Herndon *et al.* (2007:1928) identify financial incentives for physicians and hospitals as primary factors influencing healthcare technology adoption.

Research indicates that national evaluations of HTA have incentivised the selection of cost-effective devices (Sechmeister & Schumacher, 2012:79) and have influenced the unit price of pioneering devices (Scottish Health Technologies Group, 2008). Numerous public and private organisations in the United States are leading HTM to meet specific regional or organisational needs (Herndon, 2007:1297). Healthcare technology management programmes are often viewed, especially by clinicians, as tools primarily designed to reduce device expenditure (Gagnon *et al.*, 2014:3). Integrating HTM into the procurement process can enhance the quality and availability of medical devices, leading to improved health outcomes in low- and middle-income countries.

Physicians play a crucial role in developing, adopting, utilising, and selecting new technologies (Bosic *et al.*, 2004:1307). This suggests that alternative HTM governance models, with varying degrees of engagement and integration, might coexist within a single jurisdiction. These models support decisions related to technology adoption, reimbursement policies, and pricing (Gallea *et al.*, 2016:91).

2.9 Chapter Summary

This chapter explored HTM, medical device procurement, and the critical components of a robust healthcare system. It highlighted the importance of meticulous assessment and planning for medical technology to ensure the seamless delivery of high-quality healthcare services. Healthcare facilities can identify gaps in their medical device inventory through a comprehensive needs assessment and gain insights into healthcare providers' and end-users' needs and preferences.

Selecting suitable medical devices is crucial for ensuring optimal patient care. However, it is equally important to consider the financial implications of these decisions. By balancing these aspects and adopting a multidisciplinary approach, healthcare facilities can optimise resource allocation, promote sustainability, and ensure equitable care for all stakeholders. Healthcare technology management plays a pivotal role in evaluating the trajectory of medical devices throughout their lifecycle, from providing safety to responsible disposal. By prioritising ethical and economic considerations, healthcare facilities can improve patient care while managing resources judiciously. A collaborative effort among physicians, institutions, and the industry is essential for successfully integrating new medical technologies into healthcare facilities. Chapter 3 will elaborate on the research design and methodology guiding the study.

CHAPTER 3: RESEARCH DESIGN AND METHODOLOGY

3.1 Introduction

Chapter 3 plunges deeper into the research design and methodology, building upon the overview provided in Chapter 1. This chapter details the systematic steps to gather, scrutinise, and interpret data, ensuring the research findings are valid and reliable. It outlines the qualitative research design adopted for the study and explains the data collection methods, emphasising their alignment with the research objectives. The chapter also elucidates the data analysis techniques employed, illustrating how they are particularly suited to addressing the research question. By establishing this foundation, the chapter provides a solid basis for subsequent research chapters while also addressing ethical considerations to ensure the integrity of the research process.

3.2 Empirical Investigation

Calfee and Chambliss (2005:43) define empirical research as a systematic method of answering specific questions by collecting evidence under precisely defined and replicable conditions. Both qualitative and quantitative methods are included in empirical research. Venter and Van Eck (2021:64) explain that the research design of an empirical investigation includes determining the research paradigm, methodological approach, choice, research strategy, time horizon, and data collection and analysis techniques.

3.2.1 Research Paradigm

Creswell and Clark (2017) assert that no research is value-free; hence, all studies contain assumptions about the world and knowledge that inform the inquiries. Collis and Hussey (2019) define a research paradigm as rooted in people's philosophies and assumptions about the world, which subsequently influence their research methods. This research followed an epistemological paradigm, allowing the researcher to probe into the reality of what is known and explore the scope, techniques, and distinction between belief and opinion related to the truth.

3.2.2 Research Approach

As Collis and Hussey (2019) describe, the research approach entails the process and logic used throughout the research. This study adopted an inductive approach, typically associated with the interpretive epistemology paradigm. The inductive method was chosen as it facilitates the achievement of interpretivism concepts through textual data, concluding the study's general ideas using bottom-up reasoning.

3.2.3 Methodological Choice

According to Allwood (2012:1417), the distinction between qualitative and quantitative research is often seen as unclear and of limited value, with its popularity potentially leading to unfortunate consequences. This critique highlights the importance of addressing the mismatch observed in some studies between the relevant details of the actual research process, such as how epistemic risks were balanced out in methodological decisions and the interpretation or understanding of these processes by the audience (Holman & Wilholt, 2022:213). This perspective underscores the complexity of broadly applying research outcomes and the need for a nuanced approach in evaluating research methodologies and their implications.

Densin and Lincoln (2005:2) state, *“Qualitative research is multimethod in focus, involving an interpretative, naturalistic approach to its subject matter. This means that qualitative researchers study things in their natural settings, attempting to make sense of or interpret phenomena in terms of the meanings people bring to them. Qualitative research involves using and collecting various empirical materials – case studies, personal experiences, introspective, life stories, interviews, observational, historical, interactional, and visual texts – that describe routine and problematic moments and meanings in individuals’ lives.”*

The study employed a qualitative research design because the researcher wanted to introspect the practices and principles used in the procurement of medical devices by interviewing knowledgeable participants in the procurement and clinical engineering field. According to (Saikia, 2024), qualitative research focuses on the subjective experiences of individuals, exploring deep-rooted issues and revealing the intricate interpretations that people assign to their experiences, interactions, and surroundings. Qualitative research is linked with the interpretivism research paradigm, which focuses more on a small sample’s subjective views and beliefs (Wild & Diggins, 2013:87). A qualitative method allows participants to share their subjective thoughts and views without prejudice while allowing the researcher to probe more without third-party influence. It enables the exploration and representation of the complexities and differences of the worlds under investigation (Philip, 1998:267). According to Sofaer (1999:1104), qualitative methods help construct or develop theories or conceptual frameworks and generate premises.

Reliability and validity are essential components of every research endeavour. Researchers contend that the rigour of qualitative research is commensurate with its reliability and validity, rendering these crucial components of quality (Cypress, 2017:254). Trustworthiness is the primary criterion used to evaluate the quality of qualitative investigations. For a more reflective knowledge of the significance of reliability, validity, trustworthiness, and rigour in qualitative research, refer to page 35 (3.3.1).

3.2.4 Research Strategy

Research design acts as a blueprint, connecting conceptual research dilemmas with actionable and tangible empirical insights (Van Wyk, 2012). A research method is a systematic approach that transitions from the foundational premises of the research design to the actual data collection (Myers, 2019). Mohajan (2020:73) describes research methodology as the rationale or procedure employed to develop a theory, framing the procedural context within which the research unfolds.

De Queiros Barbosa *et al.* (2014:242) state that research by design is a type of academic investigation through which innovation is explored as a method of inquiry. This involves the development of a project and exploring different materials through mapping. Once the research paradigm is chosen, the data collection technique, also known as the methodological strategy, must be selected (Bryman *et al.*, 2014:100). This ensures that the preferred method aligns with the system and the design while meeting the research objectives. The study utilised interviews as the primary data collection method. These interviews were conducted once for each participant, lasting 30 to 45 minutes. The interview method was chosen as it allowed participants to share their insights without external influence.

3.2.5 Time Horizon

Melnikovas (2018:34) explains that a time horizon refers to the period during which a study is conducted. This study took a cross-sectional approach. According to Wang and Cheng (2020:65), cross-sectional research involves collecting data at a single point in time to examine one or more variables within a particular population or setting. This approach can be applied in qualitative research to gather in-depth information, perspectives, experiences, or beliefs from participants through interviews. The data collection commenced in August 2023 and concluded in October 2023.

3.2.6 Study Population and Sampling

Burns and Grove (2005:40) define a population as all the elements (individuals, objects, or substances) that meet specific criteria for inclusion in a study. After consulting with the Chief Director of Dr Kenneth Kaunda District Municipality, it was agreed that 13 participants should be interviewed. These participants were chosen based on their key performance areas and relevance to the research objectives. Acharya *et al.* (2013:333) state that a 'sample' is a subset of the population selected to represent the larger group. Therefore, a researcher needs to identify a sample within the population that will appropriately influence their research. Given this population (13 participants), a sample size could not be extracted since the researcher anticipated reaching saturation from these participants. These samplings are categorised as 'probability' and 'non-probability' models. Determining which of these two sampling methods allows a researcher to estimate the study's cost, human resources, and focus area (Acharya *et al.*, 2013:333).

This study employed a purposive non-probability sampling methodology. This approach enabled the researcher to identify potential participants who could contribute meaningfully to the study. As Lathan (2007) indicates, in purposive non-probability sampling, the researcher chooses participants based on their knowledge of the identified characteristics.

3.2.6.1 Inclusion and Exclusion Criteria

This research focused on healthcare facilities, specifically CHCs supported by the district or sub-district, regarding medical device procurement in the Dr Kenneth Kaunda District Municipality, South Africa. These facilities directly benefit from the district's budget for medical device procurement. Notably, tertiary and district hospitals operating independently and procuring medical devices from their allocated budgets were excluded from this study.

Hornberger and Rangu (2020) state that inclusion and exclusion criteria set the stage for the potential participant pool and directly impact the feasibility of the study. A too-narrow criterion can lead to an insignificant sample size and data amount, while a broad criterion might introduce external factors negatively impacting the research objectives (Hornberger & Rangu, 2020).

Patino and Ferreira (2018:84) define inclusion criteria as the critical features of the target population that investigators will use to answer their research questions. These criteria typically include demographics, clinical, and geographic characteristics (Patino & Ferreira, 2018:84). According to Hornberger and Rangu (2020), exclusion criteria consist of qualities or external factors around a person that contradict or interfere with the study's goal. Patino and Ferreira (2018:84) note that exclusion criteria are features of potential study participants who meet the inclusion criteria but present additional characteristics that could interfere with the study's success or increase their risk for an unfavourable outcome.

The inclusion criteria were established to ensure that participants were relevant to the study's objectives:

- Employees in the public healthcare sector in the Department of Health of Dr Kenneth Kaunda District Municipality, South Africa, who are involved in medical device procurement processes as discussed with the Chief Director.
- Employees in the public healthcare sector in the Department of Health of Dr Kenneth Kaunda District who work in specific departments, such as clinicians in management positions, supply chain management or healthcare technology, and clinical engineering, which influence procurement processes, as discussed with the Chief Director.

The exclusion criteria were established to ensure the collected data was pertinent and not influenced by external factors:

- Clinicians (Drs or Nurses) who are not directly involved in the procurement process for medical devices in Dr Kenneth Kaunda District Municipality, South Africa, as discussed with the Chief Director.
- Private healthcare facilities, hospitals, surrounding districts and municipalities in South Africa.
- Participants without a minimum level 4 qualification (grade 12).
- Employees unable to read, write, and speak English.
- Employees with less than two years of experience in procurement or technical services related to medical device procurement.

Table 2 lists the potential population to be interviewed as discussed with the Chief Director, ensuring representation from various role players within the Dr Kenneth Kaunda District Municipality in South Africa. From the meeting with the Chief Director of Dr Kenneth Kaunda District Municipality, 13 participants were identified as the study population based on the district's structure. The sample size could not be ascertained, given this number. However, saturation was achieved after the fifth participant. Qualitative researchers use saturation as a criterion to stop collecting data (Saunders *et al.*, 2018:1894). Fusch and Ness (2015:1408) state that failure to reach saturation can impact research quality. Morse (1995:148) notes that saturation is often touted as a guarantee of qualitative rigour. Despite this, the researcher continued until the sixth participant. All participants willingly participated and provided valuable contributions. Neither the researcher nor the participants had prior knowledge of each other before the study.

Table 2: Population and Selected Number of Participants Interviewed to Reach Saturation

Role	Number of possible participants	Number of participants interviewed
Chief Director (District Office)	1	0
Sub-district Manager (one from each sub-district)	3	1
Supply Chain Management Personnel (one from each sub-district)	3	2
Clinicians (in management) (one from each sub-district)	4	1
Clinical Technician/Engineer (District Office)	2	2
Total	13	6

3.3 Data Collection Instrument

Kumar (2014:1717) suggests that a single study can employ various data collection methodologies, both primary and secondary. Given the qualitative nature of this research, both primary and secondary data were incorporated to fulfil the research objectives. Ajayi (2017:3) defines primary data as information directly obtained by the researcher through surveys, observations, questionnaires, and interviews. In comparison, secondary data is information collected by third parties for various purposes at different times. To enhance the reliability and validity, the researcher cross-referenced the information from the literature review with data from document analysis and semi-structured interviews.

Significant preparation is essential for structured interviews, including determining the type of questions in line with the broader research study (Newcomer *et al.*, 2015). Semi-structured interviews were conducted with participants, as indicated in Table 2 on page 35. As Adam (2013:493) describes, this method involves a conversational style with individual respondents, blending closed and open-ended questions, often followed by probing questions. The interviews were conducted in English and lasted 30 to 45 minutes to clarify the study's subject matter and avoid potential translation issues.

3.3.1 Validity and Reliability (Trustworthiness)

Qualitative research often faces criticism for lacking scientific rigour, with concerns that it may be merely a collection of personal opinions and susceptible to researcher bias (Noble & Smith, 2015:34). Scholars have debated the application of reliability and validity in qualitative research, traditionally associated with quantitative analysis, but its relevance in all research forms has become increasingly recognised (Golafshani, 2003:601). Stenbacka (2001:552) suggests that reliability might be misleading in qualitative research.

Golafshani (2003:601) notes that reliability and validity are essential criteria for quality in quantitative paradigms. However, qualitative studies focus on trustworthiness to ensure quality and credibility (Brink *et al.*, 2018:157). The researcher employed various techniques to manage and measure the research's reliability and dependability, thus guaranteeing the findings' trustworthiness. These included ensuring unbiasedness and confirmability, comparing similarities and differences in the transcript, maintaining meticulous record-keeping, and inviting participant validation for the interview transcripts (Brink *et al.*, 2018:157).

Unlike quantitative research, where statistical methods can establish and test validity and reliability, qualitative methods allow the researcher to incorporate strategies to ensure the trustworthiness of the findings. The researcher applied the following techniques to manage and measure the reliability and dependability of the research:

- Acknowledging biases in sampling and engaging in ongoing critical reflection of methods to ensure sufficient depth and relevance of data collection and analysis.
- Employing a precise, meticulous record-keeping method to demonstrate how decisions were made and ensure that data interpretation was consistent and transparent.
- Cases with similarities and differences were compared to ensure that different perspectives were represented; this included providing thick, verbatim descriptions of participants to support findings.
- Demonstrating clarity and thought process throughout the analysis of the findings to ensure that data is interpreted accurately without biases.
- Emphasising respondent validation, especially in interviews, where participants are invited to comment on the interview transcript and assess whether themes and concepts have adequately captured the phenomenon being investigated, given their responses.

According to Golafshani (2003), reliability, validity, trustworthiness, and rigour are crucial factors in distinguishing between good and bad research. Agar (1986) argued that terminology like reliability and validity are more applicable to quantitative research and may not accurately capture the nuances of qualitative research. Validity standards in qualitative research are also even more challenging because of the necessity to incorporate rigour and subjectivity, as well as creativity, into the scientific process (Johnson, 1999:67). The first issue concerns the ambiguity around the terms “rigour” and “trustworthiness”. Morse (2016) proposed the use of the vocabulary prevalent in mainstream social science, advocating for the usage of the term “rigour” instead of “trustworthiness.” There is an ongoing debate on the reasons why certain qualitative researchers choose not to use the notions of reliability and validity in their studies. Instead, they rely on Lincoln and Guba's (1985) criteria for trustworthiness, which include transferability, dependability, confirmability, and credibility.

Following Lincoln and Guba's (1985) standards for trustworthiness, the researcher asked, “*How can I proficiently convey the significance of my research findings to my audience and motivate them to consider them?*” The researcher described the four criteria (credibility, dependability, transferability, and confirmability) established by Lincoln and Guba (1985) as fundamental principles for ensuring the quality and integrity of qualitative research in their study. These criteria provide a robust framework for effectively and compellingly presenting research findings from the Dr Kenneth Kaund District Municipality, South Africa.

Credibility

Credibility refers to the degree of truthfulness of the findings in a qualitative theory-building investigation (Guba, 1981:76). It assesses the correctness and validity of the study's conclusions. Credibility, as defined by Lincoln and Guba (1985), refers to the extent to which research findings accurately reflect the participants' original data and correctly interpret their original perspectives. The findings presented in the chapter established credibility by employing rigorous methodological practices, such as conducting semi-structured interviews, addressing ethical considerations, and validating findings with participants. The study's strict commitment to stringent ethical standards and scientific precision, such as conducting interviews until data saturation was reached and maintaining participant comfort and secrecy, highlights the credibility of the findings. The researcher demonstrated the study's dependability and comprehensiveness by effectively conveying these methodologies.

Dependability

Dependability, as defined by Lincoln and Guba (1985), refers to the assessment made by participants regarding the validity of the study's findings, interpretations, and recommendations; this assessment is based on the data provided by the participants. Dependability pertains to the consistency and reliability of data over time. The study provides a comprehensive account of the qualitative approach, detailing the data analysis and topic exploration methods. The research's methodological choices, influenced by the extensive and adaptable nature of thematic analysis and inductive reasoning, established a solid basis for reliability in this study. The researcher emphasised the study's trustworthiness by demonstrating the systematic data gathering and analysis approach, highlighting its consistency and replicability.

Transferability

According to Lincoln and Cuba (1985), transferability refers to the extent to which qualitative research findings can be applied to different situations or settings with other participants. This refers to how the findings can be generalised to various contexts or environments. An in-depth analysis of the procurement procedures and the incorporation of HTM principles in Dr Kenneth Kaunda District Municipality provided a significant contextual insight that can benefit similar environments. The study's findings, based on the complicated and intricate nature of procurement processes in the real world, are presented in a manner that enables the identification of themes and tactics that may be relevant in different situations. Providing explicit details about the circumstances in which the findings were obtained and a thorough explanation of the research environment enables the audience to assess the applicability of the insights.

Confirmability

Lincoln and Guba (1985) define confirmability as the process of ensuring that the facts and interpretations of the findings are not subjective or imaginary but are based on the data itself. Confirmability refers to the degree to which the respondents shape the conclusions rather than being influenced by any prejudice, incentive, or personal interest on the researcher's side. The document detailed a meticulous procedure for participant validation and a dedication to maintaining ethical standards throughout the research process. This methodology guaranteed that the findings accurately reflect the participants' responses and viewpoints without any influence from the researcher's personal biases. The researcher enhanced the objectivity and impartiality of the study by publicly describing the measures taken to reduce potential biases and maintaining the anonymity of the participants.

Triangulation

Triangulation in qualitative research uses many methods or data sources to thoroughly understand phenomena (Patton, 1999). Triangulation, as described by Carter *et al.* (2014: 545), is considered a qualitative research approach that aims to assess validity by combining information from many sources. The researcher utilised triangulation to verify the correctness and comprehensiveness of information and interpretation through cross-referencing. The research incorporated primary responses from key actors (participants) engaged in the procurement process. The study examined the utilisation of HTM concepts in the acquisition of medical devices. It delved into strategic planning, operational efficiency, and stakeholder engagement. Because of the study's limitations, the researcher could not improve the study by including other stakeholders, such as medical device suppliers, patients, or healthcare officials, to obtain a more comprehensive understanding of the procurement landscape and the impact of health technology management principles. The inclusion of other perspectives would have ensured that the findings represent a comprehensive view of the procurement processes and are not influenced by a singular viewpoint. However, recommendations were made for future research in this regard.

3.3.2 Development of Data Collection Tool

This study required developing a bespoke set of interview questions to address the gap in literature and guidelines on healthcare technology management (HTM) principles specific to medical device procurement in the Dr Kenneth Kaunda District Municipality. These questions (Annexure D) were crafted based on guidelines from WHO documents concerning medical device procurement, ensuring alignment with the objectives and the central research question.

A preliminary test was conducted to validate these questions' relevance and applicability. Two technicians from the Klerksdorp medical workshop and one from Potchefstroom participated in this testing phase. Their feedback was instrumental in refining the questions and was overwhelmingly positive. All three technicians expressed their appreciation for the study, recognising its potential to address some of the existing shortcomings in the procurement of medical devices.

3.3.3 Recruitment Process and Informed Consent

Following ethical approval, recruitment for this research commenced in August 2023. The researcher engaged with the Chief Director and stakeholders at Dr Kenneth Kaunda District Municipality to discuss the study and its potential benefits. Potential participants were identified at the district level based on the inclusion criteria. Several key points were discussed during the recruitment meetings, as outlined in Table 3. The researcher emphasised the objectives and benefits of the study, ensuring that participants understood their contribution to the body of knowledge.

Table 3: Rules of Engagement

<p>Guidelines followed during the interviews:</p> <ol style="list-style-type: none">1. Review questionnaires and consent forms to ensure the correct participant was interviewed.2. Participants are required to sign and date the consent forms where necessary.3. Each interview was scheduled to last between 30-45 minutes.4. Encourage participants to speak freely and share their perspectives.5. The researcher's sensitivity to signs of distress from participants.6. Maintenance of respect and privacy by the researcher and participants throughout the interviews.7. Reminder to participants that there were no right or wrong answers.8. Attentive listening by the researcher without opposing participants' views.9. In cases where interviews were conducted at participants' workplaces, participants were allowed to answer their phones but were expected to rejoin the discussion promptly.
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These guidelines ensured that the recruitment process and interviews were conducted ethically and respectfully, maintaining the research process's integrity and the participants' well-being.

3.3.4 Data Collection Process

During the interviews for this study, the researcher strictly adhered to all COVID-19 protocols, particularly hand sanitisation and social distancing. Interviews were conducted individually at the participants' workplaces, and permission was sought to record the conversations. Participants were reminded of their right to withdraw from the interview at any time and were given ample opportunity to respond to questions. If any questions were unclear, participants were encouraged to ask for clarification.

Following each interview, the discussions were transcribed verbatim and sent back to the interviewees for verification. This process ensured the data's validity, reliability, and trustworthiness. Appointments for the interviews were scheduled via email within 24 hours of receiving the signed informed consent form. Those who missed the initial recruitment meeting were emailed the consent form to acquaint themselves with the research content. This approach allowed them ample time to read and understand the document before their interview. This careful and considerate approach to the data collection process was designed to respect participants' rights and ensure the accuracy and credibility of the collected data.

3.4 Data Analysis

A thematic analysis was chosen for its effectiveness in identifying, analysing, and reporting patterns within data (Braun & Clarke, 2012:58). Vaismoradi *et al.* (2013:398) note that thematic analysis can discern and interpret the common thoughts of participants.

A qualitative document analysis was also utilised to consistently interpret content, focusing on previous procurement plans for medical devices in the Dr Kenneth Kaunda District Municipality. This approach enhanced trustworthiness by informing questionnaires and primary research questions through semi-structured interviews.

The study was conducted inductively, with data coded without a predetermined structure (Nowell *et al.*, 2017). To maintain anonymity, each participant was assigned a code, such as participant 01 or participant 02, and interviews were transcribed verbatim. The data was then manually analysed.

The thematic analysis comprised six phases (Nowell *et al.*, 2017):

- Familiarising Yourself with Your Data: The researcher thoroughly engaged with the data, reading transcripts, studying fieldnotes, and listening to responses to ensure accurate transcription.
- Generating Initial Codes: Keywords were identified based on participants' responses and the study's objectives.
- Searching for Themes: The researcher identified similar codes supported by participant verbatim quotes. Related sub-themes were categorised, contributing to the main themes. These themes were organised based on participant responses.
- Reviewing Themes: Another meeting was held with the supervisor and co-supervisor to ensure the themes' appropriateness and methodological rigour.
- Defining and Naming Themes: Activities from Phase 3 were revisited. Codes were conceptualised and visualised using thematic tables.

- Producing the Report: A report was prepared according to the research objectives, and the results were presented in Chapter 4. This report was ultimately submitted as a mini-dissertation for the Master of Business Administration (MBA) degree.

3.5 Ethical Considerations

Protecting human subjects by adhering to ethical principles is crucial in all research studies (Arifin, 2018:30; Orb *et al.*, 2001:93). Ethical considerations include safeguarding participants' rights, obtaining informed consent, and ensuring institutional review processes (Klopper, 2008:71). Due to the in-depth nature of qualitative studies, ethical considerations are particularly significant (Arifin, 2018:33). This is especially true when interviewing vulnerable groups, where there is a risk of participants facing repercussions for sharing sensitive information. The researcher must protect the participants, ensuring their right to privacy, autonomy, confidentiality, fair treatment, and protection from harm (Klopper, 2008:71).

This study rigorously adhered to all necessary ethical considerations. Ethical approval was obtained from the Faculty of Economic Management Sciences at the NWU (reference: **NWU-00581-23-A4**, see Annexure B) and the Ethics Committee of the NWDoH (see Annexure A). Strict confidentiality protocols were followed in handling the interview questions (Annexure C), and the researcher exclusively managed the interview questions.

Data collected from participants were used solely for this study in accordance with the consent provided. Although no significant risks were anticipated, the study was designed to minimise potential issues. The information handled was neither personal nor sensitive, posing a low risk to participants. To further safeguard participant confidentiality, all personal information was anonymised. Participants were assigned a unique identifier, such as 'participant 01', to maintain their anonymity.

Interviews were conducted at the participants' workplaces for convenience, ensuring minimal schedule disruption. Throughout this process, the study upheld all relevant ethical standards, including compliance with the POPI Act, to ensure the integrity and ethical validity of the research. Following ethical approval, the participants were:

- Informed about the purpose and benefits of the study.
- Provided an informed consent form to sign at least 24 hours before the interview.
- Assured of their right to withdraw at any time.
- Guaranteed anonymity and confidentiality.
- Made aware of the voluntary nature of the study.
- Informed that data would be used strictly for academic purposes, with all records securely stored for five years.

3.6 Delimitations and Limitations of the Method

According to Theofanidis and Fountouki (2018:156), limitations of any particular study concern potential weaknesses that are usually out of the researcher's control and are closely associated with the chosen research design, funding constraints, or other factors. This study focused on primary healthcare facilities, specifically CHCs, within the Dr Kenneth Kaunda District Municipality, South Africa. The CHCs were selected as they provided more relevant information regarding medical device procurement and are directly funded by the district. Tertiary and District hospitals, which receive funding from the province, were excluded from this study. The selection of Dr Kenneth Kaunda District Municipality in South Africa was based on their shortcomings in procuring medical devices and their proximity to the researcher. This decision was made because the researcher is funding the research themselves.

Delimitations refer to the boundaries consciously established by researchers to define the scope of their study, ensuring the aims and objectives remain achievable (Theofanidis & Fountouki, 2018:156). These are self-imposed limitations concerning the decisions made by the researcher to delineate the extent of their work. In this study, representatives spanned various departments (clinician-management, technical, supply chain management, and procurement), intentionally omitting those from the finance department due to their limited role in the procurement of medical devices, though they make provision in terms of budget. This deliberate selection aimed to fulfil the study's objectives and address the research question. However, a sample size of Table 2 on page 33 is not a representation of quantitative research and may not pose challenges in achieving data saturation within qualitative research methods.

As Theofanidis and Fountouki (2018:156) allude, a limitation is considered an 'imposed' restriction, which is essentially beyond the researcher's control. One of the limitations of this study is that it does not compare healthcare providers, the private sector, and other districts or municipalities regarding the procurement of medical devices across South Africa.

3.7 Chapter Summary

Chapter 3 outlined the research design and methodology, establishing a framework for the study's investigation. The methodology, firmly rooted in a qualitative approach, was tailored to capture the complexities of medical device procurement within HTM. This approach was instrumental in collecting rich, detailed data pertinent to the research question and objectives.

Chapter 4 will present the findings and results derived from this research study. It aims to analyse the data in-depth, providing valuable insights that emerged from the qualitative inquiry. This analysis is crucial for a thorough understanding of the decision-making processes in medical device procurement, particularly in the context of the Dr Kenneth Kaunda District Municipality.

Chapter 4 will play a pivotal role in achieving the study's objectives by dissecting and interpreting the data. It aims to bridge the identified gaps in the literature and contribute to a more nuanced understanding of HTM practices, ultimately addressing the central research question.

CHAPTER 4: FINDINGS AND DISCUSSIONS

4.1 Introduction

This chapter explores the intricate processes underlying the procurement of medical devices within the public healthcare sector of Dr Kenneth Kaunda District Municipality, South Africa. It seeks to unveil the decision-making paradigms and define the roles of healthcare officers across procurement, clinical management, and clinical engineering departments. By navigating the complexities and hurdles within these processes, this research aims to illuminate the critical importance of incorporating healthcare technology management (HTM) principles to enhance procurement strategies and resource allocation.

Central to this exploration is the qualitative analysis of firsthand responses from key participants, complemented by the review of pertinent literature. This dual approach facilitates a comprehensive understanding of the procurement landscape, spotlighting the pivotal role of HTM principles in steering decisions that ultimately shape the efficacy and efficiency of healthcare delivery in the Dr Kenneth Kaunda District Municipality.

This chapter discusses how systematic implementation of HTM principles may transform procurement practices regarding medical devices. Through thorough analysis, the objective is to demonstrate how these principles can steer the procurement process towards sustainable and cost-effective outcomes while prioritising patients' needs and well-being. This study seeks to offer valuable insights into healthcare technology management principles and support potential developments in the procurement of medical devices in resource-limited countries such as South Africa, particularly in the Dr Kenneth Kaunda District Municipality.

Chapter 4 is presented in an article format to emphasise the background, methodology, setting, data analysis, and conclusions. The research's structure highlights the most significant elements and preserves a logical flow of information that aligns with the study's overall desired outcomes.

4.2 Background

In public healthcare, medical device procurement represents a critical juncture where quality of care intersects with fiscal responsibility. This study zeroes in on the procurement processes within Community Healthcare Centres (CHCs) of the Dr Kenneth Kaunda District Municipality, South Africa, highlighting the application of HTM principles as a cornerstone for informed decision-making.

This study's research question is: *“How are HTM principles applied in the procurement of medical devices for public healthcare facilities in Dr Kenneth Kaunda District Municipality?”* The primary purpose of this research is to describe the HTM practices focusing on principles used by

healthcare officials in the procurement and technical departments when planning for the procurement of medical devices within public healthcare facilities, specifically CHCs, in the Dr Kenneth Kaunda District Municipality, North West Province, South Africa.

To achieve the primary objective, the following secondary objectives were established:

- To describe existing procurement strategies focusing on healthcare technology management principles, including needs assessment, specification and standards adherence, technology assessment, cost analysis, and comprehensive life cycle management of medical devices.
- To investigate the extent to which healthcare technology management principles are being utilised in procurement processes and how these principles can be better integrated to enhance healthcare outcomes, particularly in low—and middle-income settings.
- To pinpoint the discrepancy between the recognised importance of cost-effectiveness and its practical implementation in procurement practices within the Dr Kenneth Kaunda District Municipality.
- To propose methodologies for prioritising medical device procurement to strengthen healthcare systems by balancing cost-effectiveness with technological safety and efficacy.

This study employed a qualitative analysis to study the application of HTM practices in this specific setting and the influence of these principles on procurement decisions related to medical devices in the public sector of the Dr Kenneth Kaunda District Municipality.

4.3 Methods

The following section delineates the qualitative approach adopted to investigate the application of HTM principles in the procurement of medical devices, highlighting the methodological rigour and ethical considerations guiding the study. The research employed semi-structured interviews, carefully constructed to balance the controlled inquiry and the flexibility to explore participants' viewpoints and firsthand knowledge in depth. This choice facilitated a deeper understanding of the procurement procedures, reflecting the complexity of decision-making regarding medical devices in healthcare settings.

The study purposefully conducted interviews beyond the point of saturation (5th participant) to ensure an in-depth and reliable analysis. By including the sixth subject, the researchers ensured that they had gathered enough data and were able to validate their findings thoroughly. Conducting a sixth interview further strengthened the detected patterns and observations, increasing the study's credibility.

Ethical rigour was paramount throughout the research process. Before conducting interviews, ethical approval was secured, adhering to stringent guidelines to protect participant welfare and data integrity. Participants were recruited based on their knowledge and experience to ensure the study was conducted with the relevant and qualified Dr Kenneth Kaunda District Municipality officers. The adherence to the principles of informed consent and the option to withdraw without any negative consequences ensured that participants had a favourable experience and that their contributions were highly appreciated. Interviews were conducted in settings that prioritised participant comfort and confidentiality, with measures in place to mitigate potential biases and uphold the study's anonymity by denoting participants as 01,02 up until 06. To bolster the trustworthiness of the findings, participant validation was sought for the verbatim transcriptions, establishing a solid foundation for the study's conclusions.

This study adhered to the high standards of qualitative research by integrating methodological rigour with ethical diligence. It ensured that the insights derived from the procurement practices in Dr Kenneth Kaunda District Municipality were credible and ethically grounded.

4.4 Setting

This study was conducted in the Dr Kenneth Kaunda District Municipality. The region is known for its thriving towns and abundant cultural legacy, with a strong focus on public health and welfare. The Department of Health, which plays a vital role in acquiring medical devices, is faced with aligning the demand for medical devices with service demands while dealing with budgetary constraints. This study, done between August and October 2023, assessed the existing procurement methods, explicitly emphasising the application of HTM principles in the procurement of medical devices for public healthcare facilities in the Dr Kenneth Kaunda District Municipality. This study aimed to gain insights into the decision-making processes and the application of HTM principles in the procurement of medical devices in Dr Kenneth Kaunda District Municipality. Officials were interviewed, and the literature was reviewed to gain more knowledge. The findings of this study offered valuable perspectives for enhancing the procurement process for medical devices in the Dr Kenneth Kaunda District Municipality.

4.5 Data Analysis

Data analysis in this study followed the thematic approach, with the process being inductively driven. Hargood *et al.* (2008:41) state that the thematic approach focuses on themes within a story to give narratives a sense of direction and purpose. Inductive coding is a ground-up approach where the researcher derives their codes from the data. According to Bingham and Witkowsky (2022:133), inductive analysis is a more emergent strategy, where the researcher reads through the data and allows codes to emerge/names concepts as they appear; it is more

of a “bottom-up” analytic strategy. Using an inductive approach, the researcher does not engage in preconceived notions but allows the narrative or theory to emerge from the raw data. This involved engaging with the data for accurate transcription, generating initial codes from participant responses, and categorising themes.

In this critical phase of the study, the researcher delves into the essence of HTM practices within the procurement of medical devices at the Dr Kenneth Kaunda District Municipality. Employing a thematic approach grounded in inductive reasoning assisted the researcher in uncovering the participants' nuanced perspectives and experiences. This methodological choice, inspired by the depth and flexibility it offered the researcher to derive themes directly from the data, ensures that the findings are firmly rooted in the complexities and intricacies of procurement processes.

The research commenced by carefully extracting codes from the narratives provided by six participants. The codes, representing a wide range of perspectives and knowledge on HTM activities, were the basis for the thematic investigation. By consolidating related codes and finding overarching themes, the researcher achieved a coherent and thorough understanding of HTM principles in medical device procurement. This understanding matched the overall research aims.

4.5.1 Making Meaning from the Data

The researcher initiated the inductive process by identifying and providing meaning to the data taken from the transcripts. This was accomplished by open coding, a traditional qualitative coding method in which the researcher peruses the data and creates and applies codes in real time to reflect the events documented in the data. The researcher developed and used codes, identified emergent themes and concepts, and reviewed the data in each category produced in the first round. Through this process, patterns within data sources were identified; this is referred to as "pattern coding." The researcher condensed data into fewer analytic concepts by developing codes during open coding.

4.5.2 Develop Themes and Findings

The emergence of themes from the data was guided by the goal of delving deep into the narratives to uncover recurring patterns that speak to the study's objectives. This step was crucial in bridging the gap between individual experiences and the broader research aims, allowing for a comprehensive understanding of the application of HTM principles in procurement.

4.5.3 Representative Data and Findings

Participant quotes were instrumental in the coding process, offering a direct window into the lived experiences and perspectives of those involved in medical device procurement. The running memos, enriched with participant comments and field notes, were vital in capturing the essence of the findings, facilitating a deeper engagement with the data.

4.5.4 Explaining Findings Using Interviews and Literature

The analysis interwove inductive and deductive coding, utilising theoretical frameworks and literature to provide context and depth to the findings. This approach reinforced the study's academic foundation and allowed for a nuanced understanding of HTM principles in action, aligning closely with the specific context of Dr Kenneth Kaunda District Municipality.

The analysis offered a dual perspective on HTM principles by categorising participants into strategic and operational groups, highlighting the distinct yet complementary roles within the procurement process. This segmentation underscored the multifaceted nature of HTM practices, from high-level decision-making to hands-on operational management, providing a rich tapestry of insights into the challenges and opportunities within medical device procurement.

The thematic analysis, supported by robust validation techniques and a comparative approach, emphasised the study's commitment to academic rigour and practical relevance. Through this meticulous process, the research contributed to the body of knowledge on HTM practices and offered actionable insights for enhancing procurement principles within the Dr Kenneth Kaunda District Municipality.

4.6 Observations from the strategic strata of HTM (Participants 01 to 03)

Within the strategic strata of HTM, participants 01 to 03 offer a profound insight into a comprehensive approach toward the procurement of medical devices, covering the spectrum from initial planning to post-procurement activities. This group, aged 22 to 55 and boasting a cumulative experience of 42 years across diverse educational backgrounds from National Diplomas to Postgraduate degrees, embodies the essence of a multidisciplinary approach in HTM practices. Their expertise combines technical knowledge with administrative prowess, advocating for a holistic and anticipatory method.

At the core of this strategic layer is a forward-looking perspective, where the complex requirements of healthcare providers are meticulously forecasted, and strategies are meticulously crafted to meet the present needs and anticipate future demands. This proactive stance is characterised by a blend of analytical depth and visionary thinking, aiming to align procurement decisions with the broader goals of operational efficiency, innovation, and exemplary patient care.

4.6.1 Themes and Codes Explored by Participants 01 to 03:

From the information provided by participants 01 to 03 in the strategic strata of Healthcare Technology Management (HTM) within the Dr Kenneth Kaunda District Municipality, 32 distinct codes emerged. These codes were organised into 8 overarching themes, offering a detailed framework alluding to the HTM practices, challenges, and recommendations. This organisation

of codes into themes provides a structured insight into the strategic layer's approach to medical device procurement and management.

Figure 11 presents a network diagram of themes derived from interviews with participants from the Strategic Strata. This visualisation aids in understanding the interconnectedness of various themes and their relevance to strategic decision-making in HTM.



Figure 11: Network Diagram of Themes gathered from the Strategic Strata

In interpreting Table 4 on page 50, it is essential to view these themes and codes as interconnected elements forming a comprehensive picture of the HTM practices landscape within the Dr Kenneth Kaunda District Municipality. Each theme contributes to a holistic understanding of the current practices, challenges, and areas for improvement, guiding strategic enhancements to optimise medical device procurement and management for improved healthcare delivery.

Table 4: Themes and Codes - Participants 01 to 03

Themes	Codes
Roles and Responsibilities in HTM	Medical Device Procurement Oversight; Technician Supervision; Medical Device Specification Drafting; Vendor Liaison; Post-Procurement Device Monitoring; Technical Advisory; Procurement Planning Collaboration; Commissioning Assistance; Clinician Training on New Devices; OEM Specification Maintenance.
Medical Device Adequacy and Need Assessment	Device Shortages; Unforeseen Events Impact; Need for Devices; Redundancy Importance; Needs Assessment; Facility Needs Assessment; Service Tailoring; Patient Volume Consideration; Health Professional Feedback.
Committees and Decision-Making	Absence of HTM Committee; Presence of Specification Committee; Demand Planning; Procurement Planning; Budget Analysis; Evaluation Committee Influence; District Management Consideration; Clinical Team Recommendations; Alignment with Health Strategy; Beyond Demand Plan; Clinical Need Consideration; Device Performance Review; Strategic Alignment.
Procurement Prioritisation and Process	Clinical Need-Based; Urgency of Demand; Budget Consideration; Device Lifespan; Technological Advancement; Specification Drafting; Quotation Sourcing; Evaluation Committee Review.
Device Life Cycle and Replacement	Presence of Replacement SOP; Device Age Criterion; Device Breakdown Frequency; Technological Obsolescence Consideration; Lack of Life-Cycle Strategy; Crisis Management Tendency.
Challenges and Impediments in Procurement	Reactive Procurement; Service Continuity Motivation; Budget Constraints; Supply Chain Delays; Rapid Technological Advancements; Lack of Trained Personnel; Patient Care Compromises; Care Quality with Outdated Tech Device Underutilisation.
Guidance, Policy, and Standardisation in Procurement	Lack of Acquisition Policy; Structured Process Adherence; Strategy Alignment Reviews; Absence of Standard Operating Procedure (SOP).
Recommendations and Improvements in Procurement	Development of Acquisition Policy; Process Adherence; Draft SOP.

4.6.1.1 Brief Synopsis for each Theme: Participant 01-03

Roles and Responsibilities in HTM: This theme encompasses the broad responsibilities essential for effective HTM practices, from oversight of medical device procurement to post-procurement monitoring. The codes under this theme, such as Medical Device Procurement Oversight and Clinician Training on New Devices, signify the diverse tasks that stakeholders engage in to ensure that medical devices are procured, deployed, and managed effectively, highlighting the need for a multidisciplinary team effort.

Medical Device Adequacy and Need Assessment: Here, the focus is on identifying and addressing the gap between the available medical devices and healthcare facilities' actual needs. Codes like Device Shortages and Needs Assessment illustrate the critical steps in understanding and responding to healthcare demands, emphasising the importance of aligning procurement with the specific requirements of patient care and facility operations.

Committees and Decision-Making: This theme reveals the structural and procedural aspects of decision-making in HTM, notably the presence or absence of committees that oversee various facets of procurement. For example, the absence of an HTM Committee and the presence of a Specification Committee point to the organisational frameworks within which procurement decisions are made, suggesting areas for structural enhancement.

Procurement Prioritisation and Process: It addresses the criteria and processes for selecting which medical devices to procure. The emphasis on Clinical Need-Based procurement and Technological Advancement reflects a strategic approach to procurement that seeks to balance clinical needs with the opportunities presented by new technologies.

Device Life Cycle and Replacement: This theme concentrates on the strategies for managing medical devices throughout their life cycle. A Replacement SOP and considerations like the Device Age Criterion indicate the need for systematic approaches to managing devices from acquisition to eventual replacement or disposal, underscoring the importance of planning for obsolescence and technological updates.

Challenges and Impediments in Procurement: This theme identifies the main obstacles faced in the procurement process, from Reactive Procurement to Supply Chain Delays. It highlights the external and internal factors that can hinder effective HTM and underscores the necessity for strategies that mitigate these challenges, ensuring continuity and quality of care.

Guidance, Policy, and Standardisation in Procurement: This theme discusses the lack of formal policies and standardised procedures and points to the need for clear, comprehensive guidelines to streamline procurement activities, enhance transparency, and ensure alignment with best practices.

Recommendations and Improvements in Procurement: Suggesting actionable steps forward, this theme encapsulates the strategies proposed to refine HTM practices, such as the Development of Acquisition Policy and Process Adherence.

4.6.2 Themes and Codes Explored by Participants 04 to 06

The operational perspective on HTM practices, as detailed by participants 04 to 06, spotlights the day-to-day intricacies involved in the procurement and management of medical devices. Representing the pragmatic side of HTM principles, this segment underscores critical aspects

such as asset management and maintaining quality assurance throughout the procurement cycle. The individuals in this group, whose ages range from 38 to 55, bring together experience totalling 47 years, backed by qualifications spanning from National Diplomas to a B-Tech degree.

The operational stratum's narrative is dedicated to achieving excellence despite the myriad operational challenges encountered. This dedication is evident in the adept navigation through the complexities of device lifecycle management, ensuring that each medical device operates optimally throughout its tenure in the healthcare setting.

Figure 12 depicts a network diagram combining themes from the Operational Strata. This diagram provides a comprehensive view of the procurement process's operational challenges and priorities, highlighting the interdependencies between thematic areas.

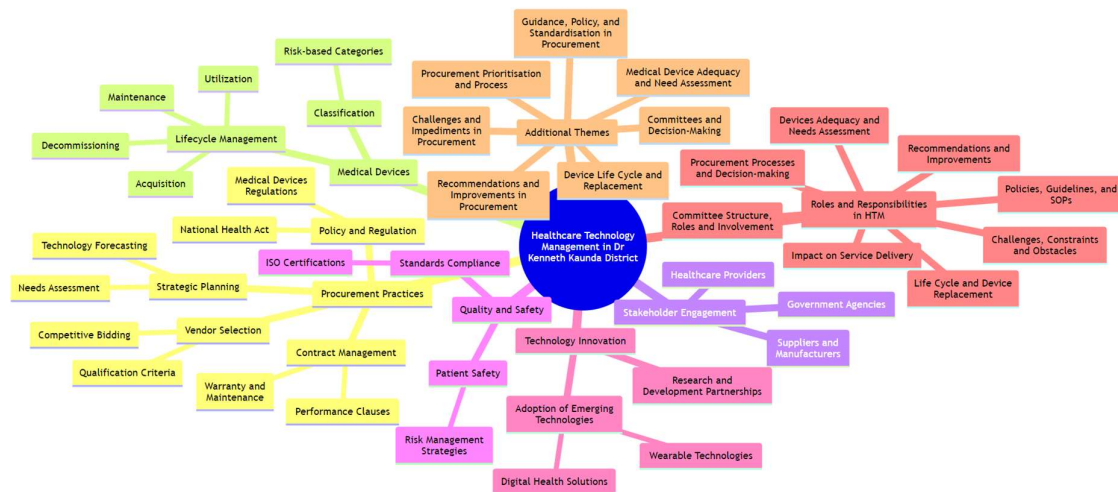


Figure 12: Network Diagram of Combined themes gathered from the Operational Strata

From the operational strata represented by participants 04 to 06 in the Dr Kenneth Kaunda District Municipality, a total of 25 distinct codes emerged. These codes were organised into 9 overarching themes, which provided a structured and comprehensive view of the operational aspects of HTM practices, challenges, and areas for improvement in the procurement and management of medical devices.

Table 5: Themes and Codes - Participants 04 to 06

Themes	Codes
Roles and Responsibilities in HTM	Asset Management; Procurement Oversight; Vendor Relations; Team Collaboration Quality Assurance.
Medical Devices and Adequacy and Assessment	Inadequate Equipment; Budget Limitations; Reprioritisation; Healthcare Facility Feedback.
Committee Structure and Roles	Past Committee; Holistic Approach Collaboration; Needs Evaluation; Guideline Adherence; Feedback Review.
Policy and Guidelines	Unverified Policy; Draft Stage; Uncertainty; Lack of Visibility.
Procurement and Decision-making	Essential Devices; Health Interventions; Historical Data; Healthcare Trends; Needs Assessment; Bids Evaluation; Committee Involvement; Order Commitment; Collaborative Decisions; Transparency; Demand Plan; Healthcare Needs; Professional Feedback.
Life Cycle Management and Replacement	Structured Plan; Lifecycle Consideration; Technological Updates; No Monitoring.
Challenges and Constraints	Rare Occasions; Equipment Failures; Donations; Budget Constraints; Delayed Deliveries; Adaptability.
Service Delivery and Impact	Equipment Downtime; Treatment Delays; Unnecessary Referrals.
Standard Operating Procedures	Draft SOP; Approval Pending.
Recommendations and Improvements	Committee Implementation; Needs Identification; Fast-tracked Process; Diverse Committee Composition.

Drawing upon the insights from participants 04 to 06, as outlined in Table 5: Themes and Codes - Participants 04 to 06, the operational strata on HTH practices within the Dr Kenneth Kaunda District Municipality reveal a pragmatic focus on navigating the day-to-day complexities of medical device procurement and management, emphasising the necessity of a collaborative, quality-centered approach to ensure optimal healthcare delivery.

4.6.2.1 Brief Synopsis for each Theme: Participant 04-06

Roles and Responsibilities in HTM: This theme highlights the essential functions of HTM practices from an operational standpoint, including asset management, procurement oversight, and fostering vendor relations. The emphasis on team collaboration and quality assurance is critical for ensuring that medical devices are procured, managed, and utilised effectively.

Medical Devices and Adequacy and Assessment: Focusing on managing inadequate equipment and budget limitations, this theme captures the operational efforts to prioritise and reprioritise medical device procurement. Including healthcare facility feedback is pivotal in aligning procurement practices with actual clinical needs.

Committee Structure and Roles: Reflecting on the structure and functionality of committees, this theme underscores the importance of a holistic approach, collaboration, and adherence to guidelines in the procurement process. The need for continuous evaluation and feedback integration is highlighted as essential for refining procurement strategies.

Policy and Guidelines: The absence of verified policies and the challenges posed by draft-stage SOPs are identified as significant hurdles, leading to uncertainty and a lack of visibility in procurement practices from an operational perspective.

Procurement and Decision-making: Detailing the decision-making process, this theme illustrates the reliance on essential devices, health interventions, and the analysis of historical data and healthcare trends. It advocates for a transparent, collaborative approach to decision-making, emphasising the significance of aligning procurement with healthcare needs.

Life Cycle Management and Replacement: This theme addresses the need for a structured approach to managing the life cycle of medical devices, highlighting the lack of monitoring systems as a gap in ensuring equipment's continuous relevance and functionality.

Challenges and Constraints: Operational challenges such as equipment failures, budget constraints, and delayed deliveries are identified, stressing the need for adaptability and proactive management to minimise their impact on service delivery.

Service Delivery and Impact: The direct impact of procurement challenges on service delivery, including equipment downtime and treatment delays, is spotlighted, underlining the operational imperative to enhance procurement efficiency.

Standard Operating Procedures: The ongoing development and approval of SOPs are crucial for standardising and streamlining operational HTM practices.

Recommendations and Improvements: Suggestions for improving operational HTM practices include implementing diverse committees, improving needs identification, and adopting fast-tracked processes to enhance efficiency and effectiveness.

Through the lens of the operational stratum, this exploration into HTM practices reveals a landscape marked by dedication to excellence, the navigation of operational challenges, and a clear vision for improvement. The insights garnered from participants 04 to 06 emphasise the critical need for structured policies, comprehensive planning, and collaborative efforts to advance

the procurement and management of medical devices, ultimately aiming to elevate healthcare delivery within the Dr Kenneth Kaunda District Municipality.

4.6.3 Intersecting Perspectives of the Strata: Collaborative Dynamics between Strategic and Operational Layers in HTM

The interface between operational excellence and strategic foresight represents a critical nexus in HTM practices, facilitating an intricate and pivotal collaborative dynamic. This interplay, where strategic planning informs and is informed by operational realities, embodies a reciprocal relationship essential for enhancing HTM practices in the Dr Kenneth Kaunda District Municipality. In this context, the strategic layer's proactive approach to selecting medical devices complements the operational layer's rigorous management of these medical devices. This symbiosis results in a comprehensive HTM framework that addresses current medical device procurement challenges while proactively anticipating and preparing for future developments. Such an approach ensures the sustainability and resilience of HTM practices in low- and middle-income countries.

The data from the strategic and operational strata within the Dr Kenneth Kaunda District Municipality reveals several shared opinions and common ground regarding Healthcare HTM practices, highlighting the intersection of strategic foresight and operational excellence.

Critical areas of consensus include:

- **The Importance of a Multidisciplinary Approach:** Both strata emphasise integrating diverse expertise in HTM, combining technical knowledge with administrative and clinical insights to enhance decision-making and implementation processes.
- **Quality Assurance and Standards Adherence:** There's a mutual understanding of the critical need for maintaining high standards in medical device procurement and management, ensuring that devices are safe, effective, and meet international and national standards.
- **Committee Involvement and Decision-Making:** Participants across both layers recognise the significance of committee structures in facilitating holistic and informed procurement decisions. The presence of or need for specific committees, like the HTM Committee, is acknowledged as crucial for strategic alignment and operational efficiency.
- **Challenges and Constraints in Procurement:** Shared concerns are expressed regarding the challenges faced in procurement, including budget constraints, device shortages, and the impact of rapid technological advancements. Both strata highlight the effects of these challenges on the ability to deliver quality patient care.
- **Need for Policy Development and Standardisation:** There is unanimous agreement that the absence of comprehensive policies and standardised procedures is a significant gap

in HTM practices. Developing and adhering to clear policies and SOPs are essential to improving procurement practices.

- **Life Cycle Management:** Both groups stress the importance of considering the entire life cycle of medical devices, from procurement to replacement, underscoring the need for structured strategies encompassing maintenance, obsolescence, and eventual disposal.
- **Training and Capacity Building:** The necessity for continuous training and development of personnel involved in HTM to keep pace with evolving technologies and best practices is a common theme, highlighting the need for skill enhancement to navigate the complexities of medical device management effectively.

These shared opinions between the strategic and operational layers underscored a collective recognition of the complexities involved in HTM practices regarding the procurement of medical devices. They also highlight a shared vision for enhancing healthcare delivery through improved HTM practices, emphasising the need for collaboration, comprehensive policies, and a proactive approach to address current and future challenges.

4.6.4 Differing Perspectives of the Strata

While participants from the strategic and operational strata within the Dr Kenneth Kaunda District Municipality shared common views on several aspects of HTM, their perspectives diverged in certain areas, reflecting the distinct nature of their roles and responsibilities. Here are the key aspects where they differed:

4.6.4.1 Focus on Strategic Planning vs. Operational Challenges

Strategic Strata (Participants 01 to 03): Emphasised the importance of strategic planning, policy formulation, and the anticipation of future healthcare needs. Their perspective leaned towards a broader, visionary approach, focusing on long-term goals, efficiency, innovation, and alignment with overarching health strategies.

Operational Strata (Participants 04 to 06): They concentrated on addressing immediate operational challenges, including managing the day-to-day complexities of medical device procurement and maintenance and ensuring quality assurance. They focused more on the practical aspects of HTM practices, such as asset management, dealing with equipment failures, and responding to urgent healthcare demands.

4.6.4.2 Committee Structure and Roles

Strategic Strata: This highlighted the need for strategic oversight through the formation or presence of committees, such as HTM Committees, to guide procurement processes and policy development. Their emphasis was on strategic alignment and decision-making at a higher level.

Operational Strata: While also recognising the importance of committees, the operational strata's concerns revolved around how committees facilitate or impede day-to-day procurement operations and their role in addressing immediate challenges, ensuring quality, and adhering to standards in procurement activities.

4.6.4.3 Policy Development and Standardisation

Strategic Strata: This approach entails creating and executing official policies and Standard Operating Procedures (SOPs), establishing explicit recommendations to standardise district municipal procurement processes, and enhancing related HTM practices concerning medical devices.

Operational Strata: This strategy focused on the impact of lacking or draft-stage policies and SOPs on operational efficiency and the ability to maintain standards in the procurement process. It emphasised the need for clear, actionable guidelines directly affecting the procurement cycle and device management.

4.6.4.4 Response to Technological Advancements

Strategic Strata: Viewed technological advancements as an opportunity to enhance healthcare delivery through strategic procurement of innovative medical devices, considering long-term benefits and alignment with health strategies.

Operational Strata: Focused on the challenges posed by rapid technological advancements, including the need for continuous training, device compatibility, and integrating new technologies within existing healthcare infrastructures.

These differences illuminate the unique perspectives and priorities of the strategic versus operational roles within HTM practices, highlighting the significance of integrating these distinct viewpoints to develop a cohesive and comprehensive approach to medical device procurement and management in the Dr Kenneth Kaunda District Municipality. Bridging these divergent aspects is crucial for creating a balanced HTM practice that addresses strategic ambitions and operational realities.

4.7 Exploration of Themes

This section examines each theme independently to highlight significant issues associated with the research question and the objectives of the study.

4.7.1 Theme: Medical Devices Adequacy and Need Assessment

This theme elucidates the complexities and pivotal considerations inherent in the procurement, availability, and sufficiency of medical devices across the Dr Kenneth Kaunda District Municipality

healthcare facilities. It accentuates the imperative for comprehensive facility need assessments and the critical role of adaptive demand planning within budgetary confines.

4.7.1.1 Identifying the Gap

The process of procuring medical devices that fulfil both suitability and sustainability criteria reveals the intricate nature of HTM practices. Discussions among participants shed light on the extensive efforts required to navigate these challenges effectively. For instance, Participant 01 underscored the commitment to sourcing devices that address immediate healthcare requirements and are sustainable long-term, necessitating a careful examination of various facets such as quality, cost-efficiency, usability, and maintenance demands. *“Our department is dedicated to sourcing medical devices that not only meet our immediate healthcare needs but are also viable in the long term. This goes beyond mere acquisition. We scrutinise every aspect, from the equipment's quality and cost-effectiveness to its user-friendliness and maintenance requirements. It's a complex balancing act to ensure we are making wise investments.”* This highlights the complexity of making prudent investments in medical technology.

Similarly, Participant 03 identified a recurrent challenge: the absence of a robust system for monitoring device performance, which complicates the upgrade or replacement decisions, potentially affecting patient care quality. This indicates a pressing need for a more systematic approach. *“Keeping our inventory up-to-date is a constant struggle, increased by the lack of a robust system for monitoring device performance. Ideally, decisions on upgrades or replacements should be data-driven, yet we often find ourselves relying on guesswork. This gap in our process can directly impact patient care, making it evident that a more systematic approach is desperately needed.”*

Moreover, Participant 04 pointed out the importance of regular device monitoring and the obstacles posed by inadequate tools for effective oversight, suggesting that a structured system for routine evaluations could markedly enhance device reliability and patient safety. *“Regular monitoring of our devices is crucial, yet we are hampered by insufficient tools for effective oversight. This shortfall can lead to unnoticed performance issues until they escalate, affecting patient safety. Implementing a structured system for routine checks could significantly improve our capability to maintain device reliability.”*

The conversations revealed concerns over the adequacy of medical devices. This situation calls for an urgent re-evaluation of priorities, with a focus on leveraging real-time feedback from healthcare professionals to bridge the gap between current HTM practices and the actual needs of healthcare facilities.

These dialogues underscore the urgency of re-evaluating priorities and incorporating real-time feedback from healthcare professionals to align HTM practices more closely with facilities' actual

needs. Incorporating frontline staff insights could significantly inform decisions on device features that genuinely improve patient care and spotlight issues with current equipment not immediately apparent from a managerial standpoint.

4.7.1.2 Challenges in Procurement

Participants 01-06 highlighted several procurement challenges, including bureaucratic delays and a need for more streamlined practices. The struggle to secure necessary medical devices is exacerbated by insufficient device availability and stringent budget constraints, necessitating a strategic reprioritisation of resources.

Participant 01 shares a poignant reflection: *“...We often struggle to get the medical devices we need. There is just not enough budget or the right equipment available, which significantly hampers our ability to provide care.”*

Echoing this sentiment, Participant 02 adds, *“The biggest issue we face is the sheer lack of proper equipment. This forces us to constantly re-evaluate and rethink how we allocate our limited resources to meet pressing needs.”*

From the perspective of Participant 03, *“It is challenging when we cannot access the right medical devices. We find ourselves heavily relying on feedback to help prioritise purchases, a process far from ideal.”*

Participant 04 observes the direct impact of financial constraints: *“I see firsthand how budget cuts affect our equipment availability. What we need is a procurement process that is more adaptable, one that truly accommodates our changing needs and constraints.”*

Participant 05 elaborates on the balancing act required in procurement: *“We are always juggling inadequate equipment and tight budgets. Striking a balance to meet the healthcare facility's needs is a constant struggle.”*

Participant 06 points out a critical aspect of supply chain management: *“Our main challenge lies in responding swiftly to changing demands. A more flexible approach in fund allocation and equipment acquisition is crucial.”*

These insights underline the critical need for a procurement process that is not only flexible but also responsive and capable of adapting to the evolving healthcare landscape and its constraints. Such reflections underscore the impact of financial limitations on equipment availability and the necessity for a procurement process that accommodates changing needs and constraints.

4.7.1.3 The Need for Systematic Monitoring

Insights from Participants 01, 03, and 06 reveal a significant gap in current HTM practices regarding the effective management of medical device life cycles. This deficiency highlights a

broader issue: the essential role of systematic monitoring in ensuring device adequacy throughout usage and informing decisions on upgrades or replacements.

Participant 01 stressed the holistic approach required in HTM practices, from procurement to supplier collaboration and comprehensive life cycle management. *“To succeed in healthcare technology management, we have to focus on everything—from buying the right equipment to working well with suppliers and ensuring everyone is on the same page.”*

Participant 03’s emphasis on quality and integrating procurement, asset management, and quality assurance processes underlines the importance of a seamless strategy to uphold service excellence. Meanwhile, Participant 03 highlighted the significance of effective vendor relationships and teamwork in navigating the complexities of HTM practices. *“In my experience, quality is key. It is about bringing together all parts of the process, like managing our assets and keeping a close eye on procurement, to ensure we deliver the best possible service.”*

Meanwhile, Participant 06 highlighted the significance of effective vendor relationships and teamwork in navigating HTM complexities. *“I have found that effective vendor relationships and teamwork are crucial. They are as important as managing our equipment properly to ensure we are getting the most out of our technology investments.”*

These discussions point towards a multifaceted strategy to bridge the identified gap in HTM practices, emphasising the need for diligent procurement, ongoing asset management, quality assurance, and collaborative vendor relations. This comprehensive approach aims to enhance the reliability and performance of medical devices, support informed decision-making regarding equipment management, and ultimately improve patient outcomes and operational efficiencies.

4.7.2 Theme: Committee and Decision Making

This theme delves into the collaborative decision-making model employed by committee members within the Dr Kenneth Kaunda District Municipality, specifically concerning the procurement of medical devices. This analysis underscores the criticality of comprehensive assessments, strict protocol adherence, and the essential contribution of healthcare professionals' input towards enhancing procurement procedures.

Participants 02, 03, 04, and 05 reveal the workings of a model that prioritises collective insight and rigorous evaluation within the framework of established procurement guidelines, emphasising feedback's crucial role in navigating judicious equipment selection.

Participant 02 articulates the committee's (bid-evaluation, adjudication and specification) commitment to a unified approach, leveraging pooled insights for well-informed equipment procurement decisions. This process embodies the essence of inclusive decision-making, wherein every stakeholder's voice is acknowledged and considered. *“We strive for a unified*

approach in our meetings. By pooling our insights—evaluating needs against the backdrop of established rules—we navigate towards more informed choices regarding equipment procurement. It's the essence of listening to every voice that steers us correctly.”

Echoing this sentiment, Participant 04 reflects on the committee's (bid-evaluation, adjudication and specification) diligent consideration of various factors before finalising equipment decisions. Despite the comprehensive evaluation process, budgetary limitations frequently necessitate compromises, underscoring a significant gap in service delivery that often results in patient referrals to higher-tier facilities. *“Our committee diligently weighs all factors before making equipment decisions. We navigate the necessities, absorb experiences from the ground, and navigate through established channels. However, budget constraints often curtail our ambitions, leading to compromises in acquiring the necessary medical devices. This shortfall necessitates patient referrals to higher-level care facilities, highlighting a critical gap in our service delivery.”*

Participant 03 emphasises the procurement process's foundation in teamwork and detailed assessment, highlighting the importance of aligning decisions with healthcare staff needs to ensure the procurement of truly beneficial equipment for the facility. *“The essence of our procurement process lies in teamwork and meticulous evaluation. While we anchor our decisions in guidelines, giving ear to the healthcare staff's needs ensures we procure equipment that truly complements our facility's capabilities.”*

These narratives collectively spotlight the committee's (bid evaluation, adjudication and specification) indispensable role in fostering a collaborative and inclusive decision-making environment. The described methodology incorporates a thorough evaluation of needs, strict adherence to procurement guidelines, and a receptive stance towards feedback, enabling prudent medical device management.

Further insights from Participants 02 and 04 illuminate the comprehensive nature of the committee's (bid-evaluation, adjudication and specification) deliberations, which extend beyond mere equipment selection to include a deep understanding of facility needs, regulatory compliance, and stakeholder feedback. Participant 05's observations reinforce this approach, underscoring the importance of a holistic evaluation encompassing ground realities, regulatory adherence, and collective insights to guide procurement decisions. *“Being an integral part of the committee has enlightened me on our crucial role. Our decisions extend beyond mere selection; they encompass a thorough assessment of needs, compliance with regulations, and responsiveness to feedback. This comprehensive stewardship aims to optimise our budget [P02].”; “In our committee deliberations, we adopt an encompassing perspective [P04].”; “Our committee's method is thorough. We don't isolate our decisions; we consider every angle, from*

ground realities to regulatory compliance, embracing the collective insights to guide our choices [P05]”.

This section offers a nuanced exploration of the complex dynamics influencing medical device procurement within the healthcare sector of the Dr Kenneth Kaunda District Municipality. It highlights the critical role of committees (bid evaluation, adjudication, and specification) in ensuring effective, responsive procurement strategies and the core of collaborative decision-making processes, where each decision significantly impacts patient care and healthcare outcomes.

Notably, the absence of a dedicated HTM committee within the Dr Kenneth Kaunda District Municipality responsible for overseeing the selection of appropriate medical devices and ensuring healthcare facilities are equipped by their service charter is acknowledged. All participants concurred on the non-existence of such a committee, indicating that current procurement practices are predominantly guided by the Public Finance Management Act (PFMA), led by supply chain processes. The utilisation of bid evaluation, adjudication, and specification committees, outlined in this section, guarantees the prudent allocation of funds in the procurement of medical devices in the Dr Kenneth Kaunda District Municipality, South Africa.

4.7.3 Theme: Procurement Prioritisation and Process

This theme examines the critical gaps identified by participants 01 to 03 from the strategic layer and participants 04 to 06 from the operational layer in the procurement prioritisation and process for medical devices within HTM. A central issue underscored by both groups is the absence of a formal HTM committee, pinpointed as a fundamental cause of inconsistencies and inefficiencies in medical device procurement. This deficiency suggests a lack of a dedicated entity to holistically oversee and incorporate HTM principles into the procurement strategy, neglecting crucial aspects such as needs assessment, adherence to specifications and standards, and comprehensive lifecycle management.

4.7.3.1 Strategic Layer Concerns (Participants 01 to 03)

Participant 01 highlighted the fragmentation in procurement approaches due to the absence of a formalised HTM committee, leading to often overlooked needs assessment and lifecycle management. *“The absence of a formalised HTM committee has led to a fragmented approach towards procurement, where needs assessment and lifecycle management are often sidelined.”*

Participant 02 reflected on the procurement process proceeding "without a compass" without a comprehensive HTM policy, culminating in selecting medical devices that might not fully meet technological or patient care standards. *“Without a comprehensive HTM policy, our procurement process navigates without a compass. This results in the selection of medical devices that may not fully meet our technological or patient care standards.”*

Participant 03 lamented the compromised strategic oversight essential for aligning procurement with healthcare objectives, proposing a multidisciplinary HTM committee to ensure technology assessment and cost analysis are integral to procurement strategies. *“The strategic oversight necessary for aligning procurement with healthcare objectives is significantly compromised. A multidisciplinary HTM committee could bridge this gap, ensuring technology assessment and cost analysis are integral to our procurement strategy.”*

4.7.3.2 Operational Layer Observations (Participants 04 to 06)

Participant 04 discussed the exacerbation of daily management challenges due to unclear HTM practices, impacting procured technology's maintenance and optimal utilisation. *“Day-to-day challenges in managing medical devices are exacerbated by the lack of clear HTM guidelines, affecting our ability to maintain and optimally use the technology we procure.”*

Participant 05 pointed out a significant disconnect between procured items and ground-level needs, indicating the absence of an operational feedback loop in the strategic procurement planning process. *“The disconnect between what is procured and what is needed at the ground level is stark. It indicates a clear absence of an operational feedback loop into the strategic procurement planning process.”*

Participant 06 called for urgently establishing an HTM policy or Standard Operating Procedures (SOPs) that guide procurement and comprehensive lifecycle management of devices to integrate technology effectively into healthcare delivery. *“We are in urgent need of an HTM policy or even an SOP that not only guides procurement but also informs the comprehensive lifecycle management of devices. This will ensure we are not just buying technology, but effectively integrating it into healthcare delivery.”*

The narratives collectively signal a pressing need for a structured HTM policy to mitigate operational inefficiencies and strategic misalignments. The proposed solutions include forming a cross-functional HTM committee, comprising members from both strategic and operational layers, to foster better communication and align procurement efforts with HTM objectives.

The absence of a well-defined HTM policy further exacerbates the situation, leaving the procurement process without a clear roadmap to ensure compliance with HTM principles. This gap has resulted in a procurement process that often fails to align with the actual needs of healthcare facilities, overlooks critical cost-analysis procedures, and neglects the importance of technology assessment in decision-making.

Participants 04 to 06, focusing on the operational aspects of HTM practices, have observed operational inefficiencies directly linked to the absence of an HTM committee and a well-articulated HTM policy. These inefficiencies manifest in delayed procurement cycles, misalignment between procured technology and healthcare needs, and challenges in adhering to

specified standards and regulations. The lack of HTM practices focused on the approach in the procurement process has led to suboptimal utilisation of medical devices, negatively impacting healthcare outcomes.

Incorporating HTM principles into daily management and procurement procedures is essential to reduce these operational inefficiencies. This can be accomplished by putting in place precise policies and processes supported by a firm HTM policy. Better communication and alignment of procurement efforts with HTM practices may be facilitated by creating a cross-functional team (HTM committee) with members from both the strategic and operational layers. Future procurement choices could be informed by implementing a continuous feedback mechanism to track and assess the efficacy of purchased medical devices, guaranteeing that these decisions are supported by data and aligned with healthcare delivery objectives.

4.7.4 Theme: Device Life Cycle and Replacement

This theme underscores the imperative for articulating life cycle management strategies and integrating technological advancements during acquisition as critical steps towards optimising medical devices' utility and operational efficiency. The investigation reveals a notable deficiency: the absence of robust systems for monitoring medical devices. This gap highlights a significant opportunity to enhance healthcare equipment's durability and functional efficacy.

Participant 01 emphasised the importance of a comprehensive management blueprint from device acquisition to obsolescence. The participant noted the proactive adoption of cutting-edge technologies at purchase yet acknowledged a decline in the vigilance for ongoing performance assessment. This oversight, the participant argued, compromises device longevity and functionality, underlining the necessity to address this gap to maintain high standards of patient care. *“The blueprint for managing our devices from acquisition to obsolescence is essential. While we proactively try to incorporate the latest technologies at purchase, our vigilance wanes. We overlook the continuous assessment of performance, a lapse that compromises longevity and functionality. It is imperative we bridge this gap to uphold the standards of patient care.”*

Participant 04 advocated for a systematic approach to managing the entire lifespan of medical devices. While acknowledging the municipality's progressive procurement strategies, the participant highlighted the lack of a comprehensive monitoring framework as a critical oversight. A move towards enhanced surveillance of device performance was proposed to extend their utility and efficiency significantly. *“Adopting a systematic approach to the entire lifespan of our medical apparatus is undeniably vital. We are halfway there with our forward-looking procurement strategies. However, our oversight in establishing a comprehensive monitoring framework is evident. A shift towards improved surveillance of device performance could significantly prolong their utility and efficiency.”*

Participant 06 recognised the foresight in lifecycle management, particularly against rapid technological advancements. However, the participant identified a glaring deficiency in monitoring mechanisms, stressing the importance of rectifying this issue to preserve the equipment's relevance and effectiveness over time. *“Our acknowledgement of the need for lifecycle foresight, especially given the brisk pace of technological evolution, is commendable. Nevertheless, the conspicuous shortfall in our monitoring mechanisms cannot be overlooked. Addressing this concern is crucial for maintaining our equipment's relevance and effectiveness, ensuring they serve our needs for the longest possible time.”*

The WHO (2022) study on a mid-sized Swedish hospital illustrates the tangible benefits of enhanced monitoring systems, including a 30% reduction in equipment downtime and a 25% increase in the average lifespan of devices. These findings offer a pragmatic benchmark for what the Dr Kenneth Kaunda District Municipality could achieve with focused effort and strategic planning.

4.7.5 Theme: Challenges and Impediments in Procurement

This theme explores the critical challenges faced by participants 01, 05, and 06 in navigating budget constraints while attempting to fulfil the urgent demand for essential medical devices in the healthcare facilities of Dr Kenneth Kaunda District. The discourse shows a gap between theoretical budget allocations and practical needs within healthcare settings. A strategic re-evaluation is needed, informed by real-time feedback from frontline patient care.

Participant 01 addresses the perennial challenge of aligning budgetary limitations with healthcare facilities' genuine medical equipment needs. The participant articulates that procurement decisions are often dictated by cost limitations rather than actual requirements, suggesting that a more engaged dialogue with healthcare facilities could lead to more informed budgetary allocations. *“Balancing the budget with the medical equipment needs of our healthcare facilities is a constant struggle. More often than not, procurement decisions are driven by cost constraints rather than the actual necessities. A richer dialogue with the facilities could pave the way for more sensible budgetary decisions.”*

Participant 05 adds depth to the conversation by highlighting the operational barriers encountered in the quest to deliver exemplary patient care due to the lack of essential medical equipment. This deficiency, the participant notes, affects operational efficiency and compromises healthcare service quality. A recalibration of budget priorities, steered by the experiences of healthcare providers and patient feedback, is proposed as a crucial step towards addressing this issue. *“In our quest to provide exemplary patient care, we frequently hit barriers due to the scarcity of essential medical equipment. This shortfall hampers our operational efficiency and compromises the quality of healthcare services we can deliver. A revisit of budget priorities, informed by our*

daily encounters and patient feedback, could significantly mitigate this challenge.” Here, the emphasis on direct experiences from healthcare delivery underscores the urgent need for a budgeting model that is responsive to the realities on the ground.

Participant 06 reflects on the dilemmas faced due to budgetary constraints, which often force difficult decisions regarding equipment procurement or repair, potentially misaligning with the facility's needs. This perspective emphasises the necessity for a budgeting framework that is both adaptive and focused on healthcare needs: *“Despite our utmost efforts, the constraints imposed by our budget often leave us in a dilemma over which equipment to purchase or repair, leading to choices that may not fully align with the needs of our healthcare facility.”*

Integrating broader viewpoints, including patient testimonials and analyses from healthcare policy experts, could enrich the understanding of the extensive implications of budgetary constraints. For instance, data from the Global Health Equipment Initiative (GHEI, 2023) indicates that approximately 30% of healthcare facilities operate with significant equipment shortages, detrimentally impacting patient care delivery. This challenge's severity and ubiquity highlight this challenge. This statistical evidence complements the qualitative feedback provided by participants, offering a comprehensive view of the procurement obstacles within the healthcare sector.

4.7.6 Theme: Guidance, Policy, and Standardisation in Procurement

The investigation into procurement practices within Dr Kenneth Kaunda District Municipality has uncovered a critical issue: the absence of fully verified policies or Standard Operating Procedures (SOPs), which currently exist only in draft form. This prevailing uncertainty and the lack of clarity in policy documentation significantly hamper efforts towards establishing standardised and transparent procurement practices.

Participant 01 articulates the practical challenges posed by the indeterminate status of policies, remarking on the difficulty of ensuring uniform practices across the board when policy guidelines remain ambiguous: *“We have got a policy that is still a draft, not finalised. It is tough to ensure we are all doing things the same way when the rules are unclear”*. This sentiment is reinforced by Participant 05, who underscores the impediments to maintaining consistent and transparent procurement practices without firmly established guidelines. *“The lack of verified policies and standard procedures is a real problem. Maintaining consistent and open procurement practices is hard when working with guidelines that are not set in stone yet.”*

A hypothetical scenario illustrates the real-world implications of such policy ambiguity: disparate interpretations of a draft policy by different departments lead to conflicting procurement decisions, thereby delaying the procurement of medical devices and exacerbating interdepartmental

tensions. This scenario highlights the tangible repercussions for the efficiency and harmony within Dr Kenneth Kaunda's District Municipality operations.

Participant 04 reflects on the complexities involved in policy finalisation, emphasising the necessity of balancing the demand for meticulousness and the pressures of daily operational needs. This perspective illuminates the nuanced challenges of policy development, advocating for a measured approach that avoids both hasty decisions and procedural stagnation. *“Finalising this policy involves balancing the need for thoroughness with the urgency of daily operations. It is a delicate act of ensuring we don’t rush to conclusions while also not paralysing our processes.”*

Cognisant of these challenges, Dr Kenneth Kaunda District Municipality has initiated efforts to prioritise verifying policies, involving stakeholders from diverse departments in a comprehensive review process. This nascent endeavour seeks to reconcile policy development with practical implementation, aiming to cultivate a culture of consistency and transparency in procurement activities. The preliminary steps taken by the district highlight the crucial recognition of the adverse effects of policy vagueness, including operational inefficiencies and a decline in team morale. These efforts represent a significant change towards clarifying policy ambiguities, paving the way for developing clear, actionable policies and unified procurement strategies.

It is imperative to acknowledge a notable observation regarding participant familiarity with the district's policies on medical device procurement and the associated HTM principles. Throughout this study, it emerged that certain participants were not fully aware of the existing policies or the specific HTM practices within the Dr Kenneth Kaunda District Municipality. This revelation is crucial for contextualising the insights and discussions presented in this research.

The variability in participant awareness concerning procurement policies and HTM practices necessitates a nuanced interpretation of the findings. It underscores the importance of considering the degree of policy dissemination and understanding among stakeholders to evaluate the effectiveness of procurement and HTM practices within Dr Kenneth Kaunda District Municipality. This aspect is particularly relevant in discussions about policy ambiguity, stakeholder engagement, and the implementation of standardised procedures.

4.8 Discussion of Observations

This study critically explores HTM principles about the procurement of medical devices within the Dr Kenneth Kaunda District Municipality. This section aims to contextualise the findings within the framework of previously identified themes and codes by synthesising insights from academic literature and empirical data from interviews. A brief overview of these themes elucidates the interplay between participant responses and their implications for procurement practices.

The interview data collected from participants within Dr Kenneth Kaunda District Municipality elucidates shared advocacy for a holistic and integrated approach to HTM procurement practices regarding medical devices. Several vital components characterise this envisioned approach:

- **Robust Asset Management:** Emphasising the importance of maintaining an accurate and up-to-date inventory of medical devices, ensuring their optimal functionality throughout their lifecycle.
- **Effective Vendor Relations:** This section highlights the necessity of cultivating positive relationships with suppliers and vendors to facilitate better terms of purchase, maintenance, and support for medical technologies.
- **Collaborative Decision-Making Process:** Advocating for a decision-making framework that leverages historical data, current healthcare trends, and comprehensive needs assessments to inform procurement strategies.

Despite these articulated strategies, a gap is identified in the absence of systematic monitoring practices. This gap signals a need for enhanced mechanisms for the ongoing evaluation of medical device efficacy and performance, ensuring they continue to meet the healthcare facility's needs and standards over time.

Interviewees reflected on the experiences and outcomes of past committee activities related to HTM practices and procurement, revealing a consensus preference for a holistic approach. This approach is distinguished by:

- **Collaboration:** Engaging multiple stakeholders, including clinicians, technicians, administrators, and suppliers, to gather various perspectives and expertise.
- **Thorough Needs Evaluation:** Conducting detailed assessments of the healthcare facility's current and future needs to guide procurement decisions.
- **Adherence to Guidelines:** Ensuring procurement processes comply with established policies, standards, and best practices to maintain transparency, fairness, and accountability.
- **Comprehensive Feedback Review:** Incorporating feedback from various sources, including end-users and technical staff, to continually refine and improve procurement practices.

The theme of "Committee Decision-Making" and the associated code of "Holistic Evaluation" emerged prominently, highlighting the value placed on comprehensive and inclusive approaches to decision-making. This approach facilitates more informed and effective procurement decisions and fosters a culture of collaboration and continuous improvement within the HTM domain. The interview insights underscore the critical importance of integrating a broad spectrum of considerations—from technological advancements and market trends to user feedback and

operational requirements—in shaping HTM and procurement strategies. This integrated approach is pivotal in ensuring that the procurement of medical devices aligns with the overarching goals of enhancing healthcare delivery, improving patient outcomes, and optimising resource utilisation within the Dr Kenneth Kaunda District Municipality.

4.9 Insights from Academic Literature on Medical Device Procurement

Exploring medical device procurement within the academic literature uncovers a significant dichotomy in decision-making approaches. Two distinct perspectives characterise this dichotomy:

- **Experience-Based Decision-Making:** Some decision-makers primarily draw upon their previous experiences in procurement. This approach is deeply rooted in familiarity and precedent, suggesting a reliance on established practices and historical outcomes to guide current procurement choices.
- **Needs-Driven Approach:** Alternatively, another group of decision-makers emphasises a needs-driven methodology. This approach prioritises managing and mitigating critical health conditions, underscoring a commitment to addressing the most pressing healthcare needs through strategic procurement.

A central theme in the decision-making process is the intricate balance between medical device cost implications and technical specifications. The alignment of these devices with the environmental conditions of their intended operational context is identified as a crucial factor. This highlights a sophisticated understanding of the operational necessities that influence procurement decisions, emphasising the importance of context-specific considerations.

Furthermore, the literature signals an increasing recognition of the value of health needs assessments. Despite this acknowledgement, there appears to be an inconsistent reference to an application of Health Technology Assessment (HTA) processes. This inconsistency suggests potential areas for improvement in decision-making frameworks, mainly through the more systematic application of HTA to ensure evidence-based procurement.

The procurement process involves a diverse array of stakeholders across various levels of the healthcare system. From grassroots needs identification to strategic decision-making at the upper echelons, it is depicted as a complex, multi-faceted endeavour. The involvement of such a wide range of stakeholders highlights the necessity for integrated approaches that effectively accommodate and synthesise the diverse inputs and perspectives of all parties involved in the procurement of medical devices.

4.10 Findings: Comprehensive HTM Approach

The study critically emphasises adopting a comprehensive approach in HTM practices, encompassing effective asset management, procurement oversight, vendor relations, and team collaboration. Quality assurance emerged as a critical aspect, emphasising the need to integrate various elements of HTM principles to achieve optimal performance (Themes: Roles and Responsibilities in HTM; Codes: Asset Management, Procurement Oversight).

4.10.1 Consolidated Themes

Through strategic and operational strata perspectives, the analysis of HTM practices within the Dr Kenneth Kaunda District Municipality has yielded a set of consolidated themes. These themes provide a holistic view of the principles guiding the procurement of medical devices, encapsulating shared viewpoints, divergent focuses, and the collaborative dynamics essential for enhancing healthcare delivery. Below are the consolidated themes with their associated descriptions:

Multidisciplinary Approach to HTM

This theme underscores the importance of integrating diverse expertise—combining technical, clinical, and administrative knowledge—to ensure effective decision-making and management of medical devices throughout their lifecycle.

Strategic Planning and Policy Development

Highlights the need for comprehensive strategic planning and the development of clear, actionable policies and SOPs. It emphasises a forward-looking approach that anticipates future healthcare needs and technological advancements, aiming to standardise procurement practices and align them with broader healthcare objectives.

Operational Efficiency and Quality Assurance

This theme focuses on the day-to-day operational challenges of managing medical devices, including procurement, maintenance, and ensuring adherence to quality standards. It advocates for processes that are efficient, transparent, and capable of delivering high-quality patient care.

Committee Involvement in Decision-Making

It reflects on the role of various committees in facilitating holistic and informed procurement decisions and suggests structures that enable strategic oversight, operational input, and stakeholder engagement in the HTM process.

Challenges in Procurement and Lifecycle Management

Identifies the key challenges faced in the procurement and management of medical devices, including budget constraints, rapid technological changes, and the necessity for structured life cycle management strategies to address obsolescence and ensure device functionality.

Integration of Technology and Innovation

This theme highlights the district's approach to integrating new technologies and innovations within the healthcare setting. It emphasises the importance of staying abreast of technological advancements to improve healthcare outcomes and operational practices.

Cost Analysis and Financial Management

Underscores the importance of conducting comprehensive cost-benefit analyses to ensure financial prudence in the procurement of medical devices. It advocates for decisions that consider long-term financial implications and the overall value to the healthcare system.

Stakeholder Engagement and Training

Focuses on the significance of engaging a broad range of stakeholders in the HTM process and the need for continuous training and capacity building among personnel involved in procurement and management of medical devices.

Sustainability and Environmental Considerations

Acknowledges the growing importance of environmental sustainability in medical device procurement, emphasising the need for practices that consider the environmental impact of medical devices throughout their life cycle.

These consolidated themes represent a comprehensive framework for understanding and improving HTM practices in the Dr Kenneth Kaunda District Municipality. They highlight the interconnectedness of strategic planning, operational efficiency, stakeholder engagement, and integrating new technologies as fundamental to achieving a resilient, efficient, and patient-centric healthcare technology management system.

This research highlights the vital need for implementing comprehensive HTM practices, specifically concerning the procurement of medical devices within the Dr Kenneth Kaunda District Municipality. These practices are delineated through a holistic strategy encompassing detailed procurement oversight, strategic vendor engagement, diligent asset management, and concerted team collaboration.

Quality assurance is paramount, emphasising integrating HTM practice's multifaceted components to ensure optimal and efficient healthcare delivery. This is achieved by:

- Regularly auditing technology utilisation and maintenance to ensure devices are used to their full potential and kept in excellent working condition.
- Adhering to standardised protocols throughout procurement processes to maintain consistency and transparency.
- Promoting interdepartmental teamwork, cultivating a culture of continuous improvement and shared responsibility.

By prioritising these strategic domains, the Dr Kenneth Kaunda District Municipality stands to elevate the quality of its healthcare services significantly. This approach serves as a practical illustration of the substantial benefits that a well-structured HTM strategy offers, demonstrating its effectiveness in enhancing healthcare outcomes in real-world contexts.

4.10.2 Comprehensive HTM Approach

A comprehensive approach to HTM practices ensures that medical devices and technologies are effectively managed throughout their lifecycle, enhancing healthcare delivery within the Dr Kenneth Kaunda District Municipality. This broad-based approach encompasses several key components, each contributing to the overall efficacy and efficiency of HTM practices:

- **Asset Management:** This involves meticulous tracking, maintenance, and utilisation of medical devices and technologies, ensuring they are fully operational and effectively meet the healthcare needs throughout their lifecycle. Asset management is pivotal for maximising the utility and lifespan of medical technologies, contributing significantly to healthcare quality and patient safety.
- **Procurement Oversight:** Rigorous oversight during the procurement process is essential to ensure alignment with healthcare needs and operational standards. This involves evaluating medical devices' necessity, efficiency, and cost-effectiveness before acquisition, ensuring that procurement decisions are informed, strategic, and in the best interest of healthcare outcomes.
- **Vendor Relations:** Establishing and nurturing positive relationships with vendors is key to securing favourable procurement, maintenance, and support terms. Constructive vendor relations enable smoother negotiations, better pricing, and more reliable support and maintenance services, ultimately benefiting the healthcare system's operational efficiency and cost management.
- **Team Collaboration:** Encouraging collaboration among healthcare professionals, technical staff, and administrative management is fundamental to successful HTM. Through teamwork, diverse expertise and perspectives are brought together to address challenges, innovate solutions, and ensure that medical technologies are used to their fullest potential in serving patient needs.

Quality assurance is identified as a critical pillar within this comprehensive HTM practice. It underscores the necessity of maintaining high standards in the procurement, deployment, and monitoring of medical technologies. By emphasising roles such as procurement oversight, technician supervision, and post-procurement device monitoring, quality assurance ensures that every step of the HTM principle contributes to delivering high-quality, efficient, and safe healthcare services.

This holistic HTM strategy, emphasising asset management, procurement oversight, vendor relations, team collaboration, and quality assurance, forms the backbone of effective HTM. Implementing this approach within the Dr Kenneth Kaunda District Municipality promises to significantly enhance healthcare delivery by ensuring that medical technologies are strategically procured, meticulously managed, and optimally utilised for patient care.

4.10.3 Device Adequacy and Needs Assessment

Addressing medical device inadequacy is pivotal in enhancing HTM within the Dr Kenneth Kaunda District Municipality. This situation highlights the essential need for a strategic alignment between the procurement of medical devices and healthcare facilities' actual requirements. Such alignment is predicated on implementing thorough needs assessment processes, which are crucial for identifying and understanding facilities' specific healthcare needs and operational demands.

A comprehensive needs assessment evaluates medical device inventory and usage patterns and anticipates future healthcare challenges and technological advancements. This approach ensures that procurement decisions are not made in isolation but are informed by a deep understanding of the healthcare ecosystem's evolving dynamics. Incorporating feedback from healthcare facilities plays a significant role in this process, offering real-world insights into existing medical devices' effectiveness, utility, and limitations.

Feedback mechanisms facilitate a dialogue between medical technology end-users (healthcare professionals) and those responsible for procurement and management. This exchange of information is vital for ensuring that procured devices meet the technical specifications and quality standards and align with healthcare providers' practical needs and preferences. By integrating such feedback into the procurement process, the municipality can make informed decisions that enhance the adequacy of medical devices, address shortages effectively, and ultimately improve healthcare delivery standards.

The emphasis on medical device adequacy and needs assessment underscores the necessity for proactive, informed, responsive HTM practices that are well informed. By aligning medical device procurement with healthcare facility requirements through robust needs evaluation and feedback incorporation, the Dr Kenneth Kaunda District Municipality can ensure that its

healthcare providers are equipped with the necessary tools to deliver high-quality patient care efficiently and effectively.

4.10.4 Committee Involvement in Procurement

The role of committees in the procurement process within the Dr Kenneth Kaunda District Municipality is instrumental in achieving a comprehensive and effective approach to HTM. These committees' structure and active participation ensure that procurement planning is holistic and inclusive, embodying a process that rigorously evaluates healthcare needs, adheres to established guidelines, and incorporates valuable stakeholder feedback.

Committees serve as a bridge, connecting diverse perspectives and expertise within the procurement framework. Their involvement facilitates a multidimensional analysis of procurement needs, ensuring decisions are based on a thorough understanding of healthcare facility requirements, technological advancements, and budgetary constraints. This collaborative approach enables a balanced consideration of various factors, from the technical specifications and cost-effectiveness of medical devices to their impact on patient care and healthcare delivery outcomes.

Furthermore, committees are pivotal in fostering a culture of transparency and accountability within the procurement process. By involving representatives from different sectors—clinical, technical, administrative, and sometimes even patient representatives—committees ensure that procurement decisions are made transparently and subject to scrutiny and validation by a broad spectrum of stakeholders. This openness contributes significantly to building trust within the healthcare community and the public, ensuring that procurement practices align with the municipality's commitment to delivering high-quality healthcare services.

The findings from this study, distilled into key themes and consolidated codes, provide a detailed understanding of the complexities and challenges faced in the procurement of medical devices in Dr Kenneth Kaunda District Municipality. They highlight the essential role of committee involvement in enhancing HTM practices, emphasising the need for a strategic, collaborative, and continuously improving approach to procurement. By adhering to these principles, the Dr Kenneth Kaunda District Municipality can navigate the intricacies of medical device procurement more effectively, ensuring that healthcare facilities are well-equipped to meet the needs of their patients and that HTM practices contribute positively to improving healthcare delivery.

4.11 Findings: Navigating Policy Formulation and Operational Complexities in HTM

This study revealed critical concerns and potential areas for improvement in medical device procurement processes. The findings underscore the multifaceted nature of HTM challenges and offer pathways towards more effective management and procurement practices.

4.11.1 Policy Formulation and SOPs

A significant issue identified is the prevalence of unverified policies and Standard Operating Procedures (SOPs) that remain in draft stages, leading to uncertainty and reduced transparency in HTM practices. This situation impedes the establishment of a cohesive HTM framework, which is crucial for the efficient procurement and management of medical assets. There's a pressing need for more robust policy formulation and the development of transparent, standardised operating procedures to ensure clarity and consistency in HTM practices.

4.11.2 Procurement Process Complexities

The procurement process is marked by its complexity, involving detailed decision-making that includes bid evaluation, committee involvement, and integrating historical data with current healthcare trends. However, challenges such as budget constraints and delayed deliveries present significant barriers, adversely impacting the efficiency of procurement processes and, consequently, the quality of healthcare service delivery. Incorporating HTM principles into everyday management and procurement procedures is advocated to streamline and enhance these processes.

4.11.3 Impact on Service Delivery

The adverse effects of procurement challenges on service delivery are profound, with equipment failures and treatment delays directly affecting patient care. The study highlights the need for efficient, responsive procurement processes to support high-quality healthcare provision and improve patient care outcomes.

4.11.4 Life Cycle Management

Recognising the importance of structured life cycle management plans is another key finding, particularly in addressing technological updates. However, the absence of comprehensive monitoring systems represents a significant oversight, indicating a vital need to adopt advanced monitoring technologies and methodologies. Innovations, such as using Internet of Things (IoT) technologies for real-time performance tracking and predictive maintenance, are suggested as transformative solutions that could significantly extend the functional lifespan of medical devices and optimise healthcare delivery.

4.11.5 Recommendations for Improvement

To address the gaps identified, the study proposes several recommendations, including the implementation of diverse committees, the enhancement of needs identification processes, the acceleration of process improvements, and the strengthening of inter-departmental communication. These recommendations aim to foster a more integrated and effective HTM framework, ensuring that procurement practices are closely aligned with the actual needs of

healthcare facilities and contribute towards the overarching objective of delivering high-quality patient care.

These findings and recommendations collectively provide a roadmap for navigating the policy formulation and operational complexities in HTM practices within the Dr Kenneth Kaunda District Municipality. The aim is to enhance the procurement and management of medical devices for improved healthcare outcomes.

4.12 Key Insights from the Study

The study unveils a nuanced procedural dichotomy characterising the procurement of medical devices within the Dr Kenneth Kaunda District Municipality, showcasing a strategic balancing act. This dichotomy encompasses leveraging Request for Tenders contracts for substantial procurements alongside sourcing quotations for less extensive needs, a methodology aimed at optimising budgetary resources while ensuring the procurement of high-quality, relevant medical devices.

Central to the procurement process are the specification, adjudication, and bid-evaluation committees. These bodies play a crucial role in guiding procurement decisions, ensuring they are cost-effective, prudent and aligned with the overarching goals of long-term healthcare delivery. Despite the theoretical foundation of HTM principles to optimise procurement practices, the study highlights a notable inconsistency in their application. Procurement practices occasionally tend to be demand-driven and budget-oriented, potentially sidelining the comprehensive, strategic considerations essential for effective HTM.

The insights derived suggest a pivotal opportunity for enhancing procurement strategies within the municipality through the integration of HTM principles. Emphasising strategic planning, forecasting, and a holistic approach to procurement could markedly refine the procurement process. By adopting a strategy that is deeply informed by HTM principles, the municipality can better navigate the delicate balance between meeting immediate healthcare needs and adhering to budgetary limitations, all while keeping an eye on long-term healthcare delivery objectives. This approach envisions a more strategic, principle-driven procurement methodology, heralding the potential for a sustainable, efficient healthcare technology ecosystem that effectively serves the district's healthcare needs.

4.13 Recommendations for Improvement in Healthcare Technology Management

To address the findings from this study and fortify the healthcare delivery infrastructure within the Dr Kenneth Kaunda District Municipality, several strategic recommendations are proposed. These recommendations aim to refine the procurement and management processes for medical devices, thus enhancing the overall quality and efficiency of healthcare services:

- **Formation of an HTM Committee:** Establish a multidisciplinary HTM committee comprising healthcare providers, technicians/engineers, and supply chain administrative staff. This committee should oversee the conduct of comprehensive assessments of healthcare facilities' needs to ensure procurement decisions are well-informed and clinically aligned.
- **Strategic Prioritisation of Medical Devices:** Adopt a prioritisation framework that evaluates medical devices based on the health burden they address, their impact on the population, and the effectiveness of the interventions they support. This strategy will ensure procurement efforts are in harmony with desired health outcomes.
- **Specification Development for Medical Devices:** Create clear and comprehensive specifications for each medical device, detailing technical requirements, performance characteristics, and safety standards. Such specifications will guide more informed and precise procurement decisions.
- **Cost-Effectiveness Analysis:** Perform thorough medical device cost-effectiveness analyses, considering initial purchase costs and ongoing operational expenses. These analyses underpin procurement decisions with a solid economic value and impact foundation.
- **Technology Assessment Process:** Implement a formalised technology assessment process to critically evaluate medical devices for safety, efficacy, and compatibility with existing healthcare infrastructure. This step is critical to ensure that newly introduced devices contribute effectively to the healthcare ecosystem.
- **Life Cycle Management Guidelines:** Develop and disseminate comprehensive guidelines for the life cycle management of medical devices, covering acquisition, usage, maintenance, and eventual disposal. Emphasise the total cost of ownership and environmental considerations to promote sustainability.
- **Standardisation of Procurement Processes:** Standardise procurement practices to ensure transparency, ethical conduct, and accountability, thereby fostering integrity and trust in the procurement of medical technologies.
- **Monitoring Systems for Medical Devices:** Establish robust monitoring systems to continuously track medical device performance and impact. This infrastructure is vital for making informed, evidence-based adjustments to procurement strategies.
- **Training and Educational Initiatives:** Invest in the ongoing professional development of procurement personnel, focusing on enhancing their understanding of HTM principles and sustainable procurement practices. Additionally, educational programs should be developed to raise awareness about the importance of sustainability in medical device procurement.

By embracing these recommendations, the Dr Kenneth Kaunda District Municipality can significantly elevate its HTM practices, leading to more efficient, effective, and sustainable healthcare delivery. The subsequent steps for implementing these recommendations will be further discussed in Chapter 5, representing a pivotal move towards advancing HTM practices within Dr Kenneth Kaunda District Municipality.

4.14 Chapter Summary

The comprehensive analysis conducted within the Dr Kenneth Kaunda District Municipality has illuminated the multifaceted challenges and opportunities that define the current state of HTM. Through a meticulous examination of strategic and operational perspectives, this study has unearthed critical insights into medical devices' procurement, revealing a landscape marked by procedural dichotomies, policy gaps, and complex operational realities.

The findings underscore the imperative for a holistic, strategic approach to HTM practices. This model encompasses rigorous policy formulation, effective life cycle management, and the integration of cutting-edge technologies. This approach is crucial for addressing the nuanced challenges of medical device procurement and ensuring that healthcare delivery infrastructure is responsive, resilient, and aligned with the evolving needs of the patient population.

Key recommendations have been proposed to bridge identified gaps, ranging from establishing a multidisciplinary HTM committee to implementing standardised procurement processes and technology assessment protocols. These recommendations serve as a roadmap in guiding efforts to refine HTM practices and enhance healthcare services' overall quality and sustainability.

This chapter laid the foundation for significant improvements in the procurement of medical devices within the Dr Kenneth Kaunda District Municipality. By embracing the proposed recommendations and fostering a culture of continuous learning and adaptation, the district municipality can advance towards a future where HTM practices effectively support delivering high-quality patient care.

CHAPTER 5: CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

This study aimed to describe Healthcare Technology Management (HTM) practices in public healthcare institutions, specifically Community Health Centres (CHCs), in the Dr Kenneth Kaunda District Municipality, located in the North West Province of South Africa. At its core, the study aimed to elucidate how healthcare officials in procurement and technical departments employ HTM principles during the procurement of medical devices. The research aimed to look at procurement strategies and assess the incorporation of HTM principles in these processes. This analysis aimed to enhance processes to improve healthcare outcomes in low- and middle-income settings, especially Dr Kenneth Kaunda District Municipality.

5.1.1 Objectives Achieved

Procurement Strategies and HTM Principles: The study successfully detailed procurement strategies encompassing needs assessment, specification and standards adherence, technology assessment, cost analysis, and comprehensive life cycle management. These components are crucial for ensuring that medical device procurement is aligned with healthcare facilities' actual needs and operational realities.

Utilisation of HTM Principles: Investigation revealed a varying degree of utilisation of HTM principles in procurement processes. While some practices align with these principles, gaps exist in their consistent application, highlighting opportunities for more integrated approaches to bolster healthcare outcomes.

Cost-effectiveness Discrepancy: The research pinpointed a notable gap between the acknowledged importance of cost-effectiveness in procurement practices and its practical implementation within the municipality. This discrepancy underscores the need for methodologies that evaluate cost and consider the safety and efficacy of medical technologies.

Prioritisation Methodologies: The study proposes methodologies for prioritising medical device procurement, emphasising the balance between cost-effectiveness and technological safety and efficacy. These methodologies strengthen healthcare systems by ensuring that procurement decisions are informed, strategic, and aligned with long-term healthcare objectives.

5.1.2 Research Question Addressed

This research describes integrating HTM principles within the procurement approaches for medical devices across public healthcare facilities in the Dr Kenneth Kaunda District Municipality, South Africa. The study aimed to enhance procurement strategies based on HTM principles, including needs assessment, adherence to specifications, technology evaluation, cost analysis,

and complete life cycle management through exploration. The inquiry was driven by a central question: *How are HTM principles applied when purchasing medical devices for public sector healthcare facilities in Dr Kenneth Kaunda District Municipality, South Africa?*

The findings elucidate an intricate scenario where HTM principles are acknowledged but not fully incorporated into procurement practices. A noticeable gap exists in the systematic application of these principles, with a tendency towards demand-driven and budget-conscious procurement overshadowing strategic HTM practices. This discrepancy underscores the need for a more integrated approach that harmonises immediate procurement needs with broader HTM practices, fostering a healthcare delivery system that is efficient, sustainable, and optimally responsive to community health needs.

5.1.3 Recommendations for Enhancing HTM Practices in Dr Kenneth Kaunda District Municipality

Based on the insights garnered, the following recommendations are posited to enhance HTM practices within the Dr Kenneth Kaunda District Municipality. These recommendations are derived from the comprehensive analysis conducted throughout this research, aiming to address the identified challenges and capitalise on opportunities for improvement. Implementing these strategies is anticipated to streamline HTM practices, ensuring they align with the overarching goals of enhancing healthcare delivery and outcomes.

Establish a Dedicated HTM Committee

- Action: Initiate a multidisciplinary HTM committee comprising members from diverse backgrounds, including healthcare providers, technical experts, and administrative personnel.
- Purpose: To oversee the broad range of HTM practices, ensuring a cohesive approach from policy formulation to the effective life cycle management of medical devices.

Enhance Strategic Planning and Policy Development

- Action: Formulate and enforce clear, comprehensive policies and SOPs deeply rooted in HTM principles.
- Purpose: To ensure procurement and management practices are systematically guided by HTM principles, thereby enhancing transparency, efficiency, and accountability in the management of medical technologies.

Strengthen Cost-Effectiveness Analyses

- Action: Implement detailed methodologies for conducting cost-effectiveness analyses of medical devices.

- Purpose: To guarantee that procurement decisions are financially sound and aligned with the objectives of delivering quality healthcare services, ensuring investments are justified by their impact and value.

Integrate Technology Assessment

- Action: Formalise a process for the comprehensive assessment of medical devices, evaluating their safety, efficacy, and compatibility with the existing healthcare infrastructure.
- Purpose: To facilitate the strategic adoption of medical technologies that positively contribute to healthcare outcomes and ensure that new devices fit the current and future needs of the healthcare ecosystem.

Foster Continuous Training and Capacity Building

- Action: Develop and support continuous education and training initiatives for healthcare officials and technical staff involved in HTM practices.
- Purpose: To enhance the expertise and capabilities of those at the forefront of HTM practices and foster a culture of continuous improvement and innovation within medical device management.

By adopting and effectively implementing these recommendations, the Dr Kenneth Kaunda District Municipality is set to make substantial advancements in HTM practices. Such enhancements will streamline the procurement and management of medical devices and are expected to yield significant improvements in healthcare outcomes for the community. This strategic approach to HTM promises a future where efficient, sustainable, and patient-focused technology management practices underpin healthcare delivery.

5.1.4 Limitations of the Study

This research focused on the public healthcare sector in the Dr Kenneth Kaunda District Municipality in the North West Province of South Africa. The study explored the intricate aspects of HTM practices, with a particular emphasis on the procurement of medical devices. While the study has provided valuable insights, it acknowledges certain constraints due to its focused scope, influencing the breadth of applicability and interpretation of the findings. These limitations are vital for contextualising the relevance of the research outcomes.

5.1.4.1 Scope Limitation

The investigation was exclusively targeted at Community Healthcare Centres (CHCs) within the Dr Kenneth Kaunda District Municipality, not encompassing tertiary and district hospitals, which may follow distinct procurement processes and strategies. Consequently, the findings may not fully represent the broader spectrum of procurement practices across different healthcare facility

types within the district. It was noted during the interviews that some of the questions listed in Annexure D were considered irrelevant. However, WHO deems these questions an essential part of determining HTM practices, especially regarding the principles related to the procurement of medical devices. Considering this limitation when interpreting the findings and discussions is crucial.

5.1.4.2 Reactive Procurement Analysis

The district's predominantly demand-driven procurement approach, especially highlighted during emergencies like the COVID-19 pandemic, suggests a focus on reactive procurement strategies within the study. This emphasis might downplay the critical role of proactive, strategic planning and forecasting in procurement decisions, potentially biasing the interpretation of findings towards immediate rather than long-term solutions.

5.1.4.3 Policy Absence

Before this research, the lack of a specific, comprehensive policy for medical device procurement in the district posed challenges for collecting and analysing consistent historical data. Variations in data quality and consistency stemming from the absence of standardised guidelines or procedures may affect the study's reliability to some extent.

5.1.4.4 External Influences

Procurement processes are subject to external influences, including political pressures, vendor relationships, and unexpected emergencies. These factors could add complexity and potential biases, complicating the assessment of the integration of HTM principles into procurement decisions.

5.1.4.5 Dynamic Healthcare Landscape

The rapidly evolving medical device industry and changing healthcare demands render the study's findings time-sensitive. Technological advancements or emerging healthcare challenges post-study might alter the relevance or accuracy of the results, highlighting the dynamic nature of the healthcare and procurement landscape.

5.2 Recommendations for Future Research

Building on the groundwork laid by this study, several areas for future research are recommended to deepen the understanding of HTM practices and their implications for healthcare delivery:

- Longitudinal Analysis of Policy Impact: Assessing the long-term effects of newly implemented procurement policies on efficiency, cost management, and healthcare outcomes.

- **Comparison with Other Districts:** Conduct comparative analyses with other districts within and outside the North West Province to identify best practices and innovative procurement strategies.
- **Technological Integration and Efficacy:** Investigating the district's adoption and assessment of new medical technologies to evaluate their impact on healthcare outcomes.
- **Cost-Benefit Analysis:** Undertaking detailed cost-benefit analyses of medical device procurements to weigh financial implications against patient care benefits.
- **Environmental and Sustainability Aspects:** This project explores the environmental impact of medical device procurement practices, focusing on the sustainable and responsible management of healthcare technologies.

These recommendations for further research are poised to support the Dr Kenneth Kaunda District Municipality's ongoing development, contributing to its recognition as a model of healthcare excellence. The proactive, strategic exploration of these areas will enable the municipality to navigate the evolving healthcare landscape, ensuring that HTM practices continue to support high-quality, sustainable healthcare delivery.

5.3 Conclusion

This research embarked on an empirical journey to unravel the intricacies of HTM practices within the public healthcare sector of the Dr Kenneth Kaunda District Municipality, focusing on the procurement of medical devices. Through the lens of HTM principles, this study aimed to illuminate the existing procurement strategies, assess their integration into current practices, and identify opportunities for enhancement, particularly within the context of CHCs.

The investigation revealed a complex landscape of HTM practices marked by commendable efforts and significant gaps. While strategic and needs-based procurement were observed, particularly in response to emergencies such as the COVID-19 pandemic, the study identified a notable discrepancy in the systematic application of HTM principles across the board. This gap underscores the potential for more holistic and integrated approaches to medical device procurement, which could significantly uplift healthcare outcomes in low- and middle-income settings like the Dr Kenneth Kaunda District Municipality.

While addressing the core research question, it became evident that the application of HTM principles in the procurement of medical devices is, at times, overshadowed by immediate needs and budget constraints. This situation highlights the necessity for a strategic realignment towards a more comprehensive driven approach to HTM principles. Such an approach would enhance the efficiency and effectiveness of healthcare delivery and ensure that procurement decisions are made with a long-term perspective on patient care and system sustainability.

This study made several recommendations to navigate these challenges and capitalise on opportunities for improvement. Establishing a dedicated HTM committee, enhancing strategic planning and policy development, strengthening cost-effectiveness analyses, integrating technology assessment, and fostering continuous training and capacity building were pivotal steps towards optimising HTM practices within the municipality. These recommendations aim to forge a path towards a more effective, efficient, and patient-centred healthcare technology management system, ultimately improving healthcare outcomes for the community it serves.

As this research concludes, it is clear that the journey towards integrating and enhancing HTM practices is both necessary and ongoing. The findings and recommendations presented herein serve as a foundation for future endeavours to advance healthcare delivery within the Dr Kenneth Kaunda District Municipality. Through the continuous exploration, adaptation, and implementation of HTM principles, the municipality can aspire to achieve excellence in healthcare provision, ensuring that medical technologies are managed strategically, sustainably, and with the utmost regard for patient welfare.

This study, while comprehensive, acknowledges its limitations and views them as avenues for future research. By embracing a proactive and strategic approach to HTM practices, the Dr Kenneth Kaunda District Municipality can navigate the complexities of the modern healthcare landscape, ensuring that its facilities are equipped to meet the evolving needs of its population with efficiency and compassion. The path forward is marked by the collaborative effort of all stakeholders, united in their commitment to elevating healthcare standards and fostering a future where the principles of HTM inform every decision. The researcher has drafted a policy (ANNEXURE E) to address and resolve the highlighted shortcomings of Dr Kenneth Kaunda District Municipality in this study.

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ANNEXURE A: APPROVAL LETTER – NW PROVINCE



health
Department:
Health
North West Provincial Government
REPUBLIC OF SOUTH AFRICA



1st Floor, Health Office Park
Private Bag X 2068
MMABATHO
2735

**RESEARCH, MONITORING &
EVALUATION**

Tel: +27 (18) 391 4501
Email: Mpu@doT@nwpg.gov.za
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Name of Researcher: Mr P.M. Mogorosi
North West University

Physical Address: Flat 22, Wilgen Street
(Work/ Institution) CURRO - KLERKLOPP

HEAD OF DEPARTMENT

2023-06-02

NORTH WEST DEPARTMENT OF HEALTH
PRIVATE BAG X 2068, MMABATHO, 2735

Subject: Research Approval Letter – Exploring healthcare technology management concepts regarding procurement and prioritisation of medical device: A case study of Dr Kenneth Kaunda District, South Africa.

This letter serves to inform the Researcher that permission to undertake the above mentioned study has been granted by the North West Department of Health. The Researcher must arrange in advance a courtesy meeting with the District Chief Director and the Chairperson of the District Health Research Committee (DHRC) (as per their details below), to introduce their research team/members on the proposed research to be undertaken. The researcher can thereafter proceed to the identified institution/s and/or facility and produce this letter to the Management as proof that the research was approved by the NWDoH.


This letter of permission should be signed and a copy returned to the department. By signing, the Researcher agrees, binds him/herself and undertakes to furnish the Department with an electronic copy of the final research report. Alternatively, the Researcher can also provide the Department with an electronic summary highlighting recommendations that will assist the Department in its planning to improve some of its services where possible. Through this, the Researcher will not only contribute to the academic body of knowledge but also contributes towards the bettering of health care services and thus the overall health of citizens in the North West Province.

Below are the contact details.

Office of the Chief Director: Dr Kenneth Kaunda District	Chairperson of the DHRC
Ms. Dineo Moromane	Dr. C. Cachet
Contact person: Mr. Calvin Mmisele	Contact person: Kutloano Mtimkulu
018 462 5744 CMmisele@nwpa.gov.za	018 294 9100 x9175/ 9170

Kindest regards,


 Dr. FRM Reichel
 Director: RM&E
 Date: 2/6/2023


 Researcher
 Date: 2023/06/02



ANNEXURE B: ETHICS CLEARANCE CERTIFICATE



Private Bag X1290, Potchefstroom
South Africa 2520

Tel: 018 299-1111/2222
Fax: 018 299-4910
Web: <http://www.nwu.ac.za>

Senate Committee for Research Ethics
Tel: 018 299-484
Feziwe.Mseleni@nwu.ac.za

28 February 2023

ETHICS APPROVAL LETTER OF STUDY

Based on approval by the **Economic and Management Sciences Research Ethics Committee (EMS-REC)** on 31/03/2023, the Economic and Management Sciences Research Ethics Committee hereby **approves** your study as indicated below. This implies that the North-West University Senate Committee for Research Ethics (NWU-REC) grants its permission that, provided the special conditions specified below are met and pending any other authorisation that may be necessary, the study may be initiated, using the ethics number below.

Study title: Healthcare technology management regarding the procurement of medical devices: A case study of Dr Kenneth Kaunda District, South Africa

Study Leader/Supervisor (Principal Investigator)/Researcher): Prof Leenta Grobler / Mrs M Vorster – MBA

Student: Mogorosi, PM (30006619)

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Institution Study Number Year Status

Status: S = Submission; R = Re-Submission; P = Provisional Authorisation; A = Authorisation

Application Type:

Commencement date: 1/4/2023

Expiry date: 1/5/2024

Risk:

Approval of the study is initially provided for a year, after which continuation of the study is dependent on receipt and review of the annual (or as otherwise stipulated) monitoring report and the concomitant issuing of a letter of continuation.

Special in process conditions of the research for approval (if applicable):

•

General conditions:

While this ethics approval is subject to all declarations, undertakings and agreements incorporated and signed in the application form, the following general terms and conditions will apply:

- *The study leader/supervisor (principle investigator)/researcher must report in the prescribed format to the EMS-REC:*
 - *annually (or as otherwise requested) on the monitoring of the study, whereby a letter of continuation will be provided, and upon completion of the study; and*
 - *without any delay in case of any adverse event or incident (or any matter that interrupts sound ethical principles) during the course of the study.*
- *The approval applies strictly to the proposal as stipulated in the application form. Should any amendments to the proposal be deemed necessary during the course of the study, the study leader/researcher must apply for approval of these amendments at the EMS-REC, prior to*

implementation. Should there be any deviations from the study proposal without the necessary approval of such amendments, the ethics approval is immediately and automatically forfeited.

- *Annually a number of studies may be randomly selected for an external audit.*
- *The date of approval indicates the first date that the study may be started.*
 - in the interest of ethical responsibility, the NWU-SCRE and EMS-REC reserves the right to:*
 - *request access to any information or data at any time during the course or after completion of the study;*
 - *to ask further questions, seek additional information, require further modification or monitor the conduct of your research or the informed consent process;*
 - *withdraw or postpone approval if:*
 - *any unethical principles or practices of the study are revealed or suspected;*
 - *it becomes apparent that any relevant information was withheld from the EMS-REC or that information has been false or misrepresented;*
 - *submission of the annual (or otherwise stipulated) monitoring report, the required amendments, or reporting of adverse events or incidents was not done in a timely manner and accurately; and / or*
 - *new institutional rules, national legislation or international conventions deem it necessary.*

The EMS-REC would like to remain at your service as scientist and researcher, and wishes you well with your study. Please do not hesitate to contact the EMS-REC or the NWU-SCRE for any further enquiries or requests for assistance.

Yours sincerely,

Mark
Rathbone

Digitally signed by Mark Rathbone
DN: cn=Mark Rathbone, o=North
West University, ou=Business
management,
email=mark.rathbone@nwu.ac.z
c=ZA
Date: 2023.04.19 11:01:53 +02'0

Prof Mark Rathbone
Chairperson: NWU Economic and Management Sciences Research Ethics Committee

ANNEXURE C: INFORMED CONSENT FORM

INFORMED CONSENT DOCUMENTATION FOR A CASE STUDY (MBA-Mini Dissertation) REGARDING UTILISATION OF HEALTHCARE TECHNOLOGY MANAGEMENT PRINCIPLES DURING THE PROCUREMENT OF MEDICAL DEVICE IN DR KENNETH KAUNDA DISTRICT MUNICIPALITY IN THE PUBLIC SECTOR, SOUTH AFRICA.

TITLE OF THE RESEARCH STUDY: **Describing healthcare technology management practices in the procurement of medical devices in the Dr Kenneth Kaunda District Municipality.**

ETHICS REFERENCE NUMBERS: **N W U - 0 0 5 8 1 - 2 3 - A 4**

PRINCIPAL INVESTIGATOR: **Prof Leenta Grobler**

POST GRADUATE STUDENT: **Mr Pule Matthews Mogorosi**

ADDRESS: **Flat 29, Campus@Home 1, Wilgen Street, Dassierand, Potchefstroom, 2532**

CONTACT NUMBER: **078 049 2058 or 074 578 4529**

You are invited to participate in a research study that forms part of my Master of Business Administration (MBA) qualification. Please take time to read the information presented here, which will explain the details of this study. Please ask the researcher questions about any part of this study you do not fully understand. It is imperative that you are fully satisfied and clearly understand what this research is about and how you might contribute to the study. Also, your participation is entirely voluntary, and you are free to say no to participating. You can also withdraw from the study at any point, even if you agree to participate now.

This study will be conducted according to the ethical guidelines and principles of Ethics in Health Research: Principles, Processes and Structures (DoH, 2015) and other international ethical guidelines applicable to this study. It might be necessary for the research ethics committee members or other relevant people to inspect the research records.

What is this research study all about?

- The study will evaluate whether healthcare technology management (HTM) principles are being utilised in the procurement of medical devices within the public sector of Dr Kenneth Kaunda District Municipality, South Africa.
- This study will be conducted in the Dr Kenneth Kaunda District Municipality in the public sector (inclusive of 3 sub-districts) in South Africa. This study will be conducted by an experienced clinical engineer (researcher) trained as a specialist in healthcare technology management. The study will be conducted from January 2023 to November 2023, and

participants can be assured anonymity during this study. The researcher will ensure that the interviews are conducted professionally and respectably at all material times in the comfort of the participant's working space.

Why have you been invited to participate?

- You are invited to be part of this research because your key performance areas at your workplace will contribute immensely to the study. You are purposively selected to be one of the participants for this study because the knowledge you have will contribute towards answering the question(s) and assist in achieving the study's objectives.
- Participants in this research share similar characteristics that positively impact the procurement process regarding medical devices in the Dr Kenneth Kaunda District Municipality, South Africa.
- You will unfortunately not be able to participate in this research if you do not work directly or influence the process of procuring medical devices in your department.

What will be expected of you?

- You will be expected to answer closed- and open-ended questions regarding the procurement of medical devices focusing on the HTM concept. Specific questions during the interview might sound unnecessary and irrelevant; however, as a participant, you must answer all the questions no matter how insignificant they are to the study. Each question serves to answer the question(s) at hand and realise the research objectives.
- Interviews will take 30 – 45 minutes and be conducted only once in the comfort of your workplace. The researcher will be conducting interviews during April and May 2023. During the interview, participants will be allowed to answer essential calls; however, you will be requested to return to the discussion room as soon as you are done. No follow-up interview will be conducted; hence, the time frame suggested (30-45 minutes) is to ensure that aspects of interest are addressed.

Will you gain anything from taking part in this research?

- Should you agree to participate in this study, the gains for you will be to contribute to the body of knowledge regarding the procurement of medical devices in your district or sub-district. Through your contribution as a participant, some of the challenges might be addressed due to the knowledge that will be shared during the interview(s). There will be no direct gains for you as a participant in the study, let alone monetary compensation. There will be no cost incurred from the participant(s) except that they must take their time contributing through an interview.

- The other gains of the study are to be realised when the case study is completed, whereby recommendations and solutions are given to the current shortcomings experienced by the district and sub-district regarding the procurement of medical devices. The researcher, as the main protagonist, will gain more knowledge regarding this study, which will assist in contributing more solutions to the challenges experienced concerning the HTM concept as far as the procurement of medical devices is concerned.

Are there risks involved in participating in this research, and what will be done to prevent them?

- The risks to you as a participant in this study are minimal to serious and manageable. No participant will be exposed to unnecessary risk, let alone danger, during the interview(s); hence, these conversations will be conducted at your workplace. Healthcare technology management concepts have forever improved due to the Industrial Revolution; the participant(s) stand an excellent chance to learn more during this case study. However, their procurement process knowledge regarding medical devices is critical to the study.
- There are more gains for you than risks when joining this study.

How will we protect your confidentiality, and who will see your findings?

- The anonymity of these findings from the study will be kept as such, and information gathered will be protected by ensuring that the names of the participants are withheld at all material times. Each participant will be assigned a code to monitor and categorise data accordingly. The findings gathered from this study will strictly be for academic purposes only. Your privacy will be respected by keeping the names of the participants anonymous and using codes. Results from this research will be kept confidential by the researcher and only shared with the district of Dr Kenneth Kaunda District Municipality through the Chief Director's office upon request. Only the researcher, supervisor and co-supervisor can view these findings before any academic submission. Results will be kept safe by locking hard copies in locked cupboards in the researcher's office, and electronic data will be password protected. (As soon as data has been transcribed, it will be deleted from the recorders). Data will be stored for five years.

What will happen with the findings or samples?

- The results of this study will only be used to attain a qualification, i.e., an MBA. Should a request be made to be used beyond scholarly purposes, participants will be made aware of such a request, and all parties involved will discuss whether or not to agree to the proposal.

How will you know about the results of this research?

- We will give you the research results when the researcher completes the study.
- You will be informed of any new relevant findings, and recommendations will be shared with everyone so they can mitigate their shortcomings where possible.

Will you be paid to participate in this study, and are there any costs for you?

- The study is self-funded by Mr. P M Mogorosi, a student at NWU.
- There will be no affiliation costs for participants in this study.
- Equally, no incentives will be paid to the participants involved.

Is there anything else that you should know or do?

- You can contact Mr P M Mogorosi at **078 049 2058** or **074 578 4529** if you have further questions or concerns regarding this case study.
- You can also contact Mrs Carolien van Syl at 018 299 1206 or carolien.vansyl@nwu.ac.za if you have any unanswered references to the research or have complaints about the study.
- You will receive a copy of this information and a consent form.

Declaration by participant

By signing below, I agree to take part in the research study titled: **Describing healthcare technology management practices in the procurement of medical devices in the Dr Kenneth Kaunda District Municipality.**

I declare that:

- I have read this information, which was explained to me by a trusted person in a language I am fluent and comfortable with.
- The research was clearly explained to me.
- I have had a chance to ask questions to both the person getting consent from me and the researcher, and all my questions have been answered.
- I understand that participating in this study is voluntary, and I have not been pressured to participate.
- I may choose to leave the study at any time, and I will not be treated negatively if I do so.
- I may be asked to leave the study before it has finished if the researcher feels it is in the best interest of the study.

.....

Signature of participant

Declaration by the person obtaining consent

I (full name and surname) declare that:

- I clearly and in detail explained the information in this document to
.....
- I did/did not use an interpreter.
- I encouraged participant(s) to ask questions and took adequate time to answer them.
- I am satisfied that the participant(s) adequately understand all aspects of the research, as discussed above
- I gave them time to discuss it with others if they wished.

Signed at (place) on (date) 20...

.....

Signature of the person obtaining consent

Declaration by researcher

I, ~~*Pule Matthews Mogerosi*~~, declare that:

- I explained the information in this document to to ensure that the question(s) is answered and the objectives of the research are achieved.
- I did/did not use an interpreter during the explanation of this document.
- I encourage the participant(s) to ask clarity-seeking questions and to take their time answering questions from the researcher during the interview.
- informed consent was obtained by the researcher since an independent person could not be appointed due to limited resources.
- I am satisfied that the participant(s) adequately understands all aspects of the research, as described above.
- I am satisfied that the participant(s) had time to discuss it with others if they wished.

Signed at (place) on (date) 20...

.....

Signature of researcher

ANNEXURE D: SEMI-STRUCTURED INTERVIEW QUESTIONS

Semi-structured Interview Questions

The researcher would like to put the following forward to ensure the participants understand their roles in this research. This interview aims to collect information for an academic dissertation and meet a requirement for a Master of Business Administration (MBA) degree from NWU. Participants' cooperation in answering these questions will contribute towards achieving the research objectives and answering the research question. This approach will lead to recommendations and possible solutions to the challenges the district/sub-district faces while procuring medical devices.

Section A: Biographical Information

Kindly complete the information below:

1. Age

18 – 24	
25 – 37	
38 – 46	
47 - 55	
56 - 65	
65 +	

2. Qualification Completed

Grade 12 (Standard 10)	
National Diploma (N6)	
Bachelor's Degree (B-Tech)	
Honour's Degree (Post-Grad: Diploma)	
Master's Degree	
PhD	
Other:	

3. Position (Job Title)

Technician/Engineer – HCT	
Admin Personnel – SCM	
Health Professional – Nurse/Dr	
Line Manager/District Manager	
Senior Manager (Deputy Director)	
Top Manager (Chief Director)	
Other:	

4. Name of your district or sub-district

Dr Kenneth Kaunda	
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5. Working Experience:

1 – 3 years	
4 – 7 years	
8 – 15 years	
16 – 20 years	
+ 21 years	

Section B: Classification and roles of the participant(s)

Participation Code:

1. Describe your **current role** in the Department of Health, e.g., daily duties.

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2. To your **knowledge**, does your healthcare facility (facilities) have adequate medical devices? Explain.

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3. Does the sub-district or district have a **Healthcare Technology Management Committee**? If yes, what is the composition of the committee?

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4. What is the **role** of this committee in your sub-district or district? Explain.

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5. Does your sub-district have an **Acquisition Policy** regarding the procurement of medical devices? If yes, when was it updated?

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6. Does it provide enough **guidance** as far as the procurement of medical devices is concerned? Explain.

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7. How do you **prioritise** procurement of medical devices in your sub-district, district or healthcare institution/facility, looking at your demand plan? Explain.

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8. What **processes** do you follow when procurement of medical devices is undertaken? Explain.

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9. Who makes the **final decision(s)** regarding the procurement of medical devices in your sub-district/district or healthcare facilities? Explain the process.

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10. Are these decisions based on the **demand plan**, i.e., a wish list? If not, what informs these decisions? Explain.

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11. Do you have a **replacement plan** for your medical devices? If yes, when was it updated? Explain.

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12. Tick the appropriate statement for your district/sub-district or facility.

- Our budget **is sufficient** for the procurement of medical devices.
- Our budget **is not sufficient** for the procurement of medical devices.

13. How do you ensure medical devices are **suitable (appropriate)** for each healthcare facility in your sub-district? Explain.

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14. How do you calculate the **life-cycle cost** (the total cost of ownership throughout its lifespan) of medical devices?

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15. Do you procure **unplanned** medical devices? If so, what prompted you as a subdistrict/district or health facility to do that? Explain.

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16. What **obstacles hinder** your acquisition plan regarding medical devices in your healthcare facility or sub-district/district?

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17. How are these challenges **influencing** service delivery, i.e., diagnoses, treatment and rehabilitation? Explain.

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18. How does the sub-district/district manage the procurement of medical devices for their healthcare facilities? Explain.

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19. Do the district/sub-district healthcare facilities have a **standard procurement process document**, e.g., SOP, for medical devices? If yes, is it efficient?

Explain

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20. In your **view**, what can be done to improve the procurement of medical devices in your sub-district/district? Explain.

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The End.

ANNEXURE E: POLICY BRIEF ON THE PROCUREMENT OF MEDICAL DEVICES

North West Province Department of Health *Dr Kenneth Kaunda District Municipality*

POLICY ON THE PROCUREMENT OF MEDICAL DEVICES

Document Ref: NWPDH/KKD-MDP/2023

1. INTRODUCTION

Recognising the urgent need for a structured, efficient, and transparent procurement process, the North West Province Department of Health, in partnership with the Dr Kenneth Kaunda District Municipality, presents this policy to govern the procurement of medical devices. Drawing inspiration and direction from Healthcare Technology Management (HTM) principles, this policy is a testament to our unwavering commitment to improving healthcare outcomes, ensuring fiscal responsibility, and adhering to the highest standards.

2. OBJECTIVES

This policy brief aims to:

- Streamline the medical device procurement process.
- Ensure acquisitions align with current healthcare demands and future predictions.
- Guarantee the procurement of safe, effective, and durable medical devices.
- Foster prudent financial management and optimal use of the district's resources.
- Uphold transparency, predictability, and consistency in all procurement endeavours.

3. POLICY STATEMENTS

3.1 Establishment of a Policy Steering Committee

A multidisciplinary committee comprising medical experts, financial analysts, patient representatives, and other key stakeholders will guide, review, and periodically update the procurement process.

3.2 Integration of HTM Principles

The HTM framework will steer all procurement activities to ensure a holistic, forward-thinking approach:

(a) Needs Assessment

A comprehensive analysis will be carried out to determine both immediate and long-term healthcare requirements. This assessment will evaluate the potential

patient load, diverse healthcare scenarios, and specific medical challenges the district might face.

(b) **Specification and Standards**

Detailed specifications for each device will be clearly outlined, ensuring alignment with global standards. This guarantees that devices are fit for purpose and adhere to the highest safety and quality benchmarks.

(c) **Technology Assessment**

Before any procurement activity, an in-depth assessment will be conducted to gauge potential medical devices' efficacy, relevance, and adaptability. This ensures the district remains abreast of technological advancements and procures devices that offer optimal patient outcomes.

(d) **Cost Analysis**

Beyond the initial procurement expenses, a detailed life cycle cost analysis will be incorporated into the decision-making process. This holistic view will consider maintenance, training, potential upgrades, and end-of-life management costs, ensuring the district achieves the best value for money.

(e) **Life Cycle Management**

A robust framework will be established, encompassing procurement, maintenance, upgrades, and the eventual decommissioning of devices. Regular reviews will ensure devices remain functional and offer optimal patient care throughout their operational life.

3.3 Transparent Tendering and Quotation Process

An open and competitive bidding process will be endorsed, ensuring transparency, fairness, and maximum value for money in all transactions.

3.4 Continuous Training and Skill Development

Continuous training provisions will be introduced to ensure procurement staff remain updated with the latest trends, technologies, and best practices in medical device acquisition.

3.5 Review and Feedback Mechanism

Periodic reviews, incorporating feedback from various stakeholders, will be carried out to ensure the policy remains adaptive and responsive to the evolving healthcare environment.

4. STANDARDS

All medical devices procured under this policy will:

- Adhere to relevant ISO (International Organisation for Standardisation) standards for medical devices.
- Align with the WHO's list of essential medical devices and guidelines.
- Comply with any other internationally recognised benchmarks pertinent to specific devices.

5. POLICY COMMENCEMENT AND REVIEW

5.1 Commencement Date: 1st January 2024

5.2 Review Date: Every two years from the commencement date, with the following scheduled review on 1st January 2026. However, ad hoc reviews may be initiated if significant changes in the medical device landscape or related standards occur.

6. CUSTODIANSHIP

The North West Province Department of Health, in collaboration with the Dr Kenneth Kaunda District Municipality, will remain the custodian of this policy, ensuring its proper execution, monitoring, and periodic review.

Approved/Not Approved

Signature:

Date:

This policy is ratified by the North West Province Department of Health leadership and the Dr Kenneth Kaunda District Municipality, South Africa administrative authorities.