Exploring the Role of Procurement in the Sustained Adoption of Medical Devices in Low-Resource Healthcare Systems

Evidence from Malawi

TU Delft

Exploring the Role of Procurement in the Sustained Adoption of Medical Devices in Low-Resource Healthcare Systems:

Evidence from Malawi

By

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Executive Summary

Universal Health Coverage (UHC) aims to ensure that all individuals have access to essential healthcare services without facing financial hardship. Achieving UHC requires not only the availability of healthcare services but also the delivery of high-quality care, supported by essential technologies such as medical devices. Medical devices enhance healthcare delivery by enabling timely and accurate medical interventions, yet ensuring that these devices contribute to healthcare outcomes requires more than making them available. In many low- and middle-income countries (LMICs), the functionality and integration of medical devices into healthcare delivery remain a persistent challenge. Devices that are not properly maintained, adapted to local contexts, or aligned with clinical needs often end up unused or broken. Therefore, procurement plays a crucial role in ensuring that medical devices are appropriately selected, acquired, and maintained to meet healthcare needs and remain functional over time.

This research explores how government-led procurement can be structured to support the sustained adoption of high-cost medical devices in LMICs, focusing on Malawi as a case study. A qualitative research design was adopted, using semi-structured interviews with key informants directly involved in the public procurement of medical devices in Malawi. These interviews provided insights into procurement practices, decision-making structures, and broader institutional dynamics. To guide the analysis, this research applies the Adaptability, Scalability, and Sustainability (ASaS) model, a decision-oriented framework designed to assess whether health interventions can be adapted, scaled, and sustained over time. The ASaS model is used as an evaluative tool to assess how well Malawi's procurement practices align with key determinants of sustained adoption and to identify opportunities for improvement.

The findings show that public procurement of high-cost medical devices in Malawi is organised through a multi-layered system operating across national, institutional, and operational levels. Procurement processes are centrally governed to ensure regulatory oversight and financial accountability, with institutions such as the Internal Procurement and Disposal Committee (IPDC), the Public Procurement and Disposal of Assets Authority (PPDA), and the Ministry of Justice overseeing compliance with national priorities under the PPDA Act of 2017. These formal structures define clear steps for procurement, including needs assessments, technical specifications, supplier selection, tendering, contract negotiation, and quality assurance to ensure procured devices meet required standards. However, while procurement structures define formal decision-making processes, procurement practices encompass the broader systemic and institutional conditions that shape how these processes function in practice and influence procurement outcomes.

Procurement practices in Malawi face challenges that affect the sustained adoption of high-cost medical devices. Externally, fragmented procurement between donor-driven and government-led acquisitions leads to the introduction of devices without government oversight, limiting central tracking and complicating procurement and maintenance planning. Funding constraints further restrict the ability to acquire and sustain essential devices. Although regulatory frameworks promote transparency, they often result in a proliferation of device types that are difficult to manage over time. Internally, poor coordination between procurement and planning departments leads to delays and misalignment with facility readiness. In addition, weak monitoring and evaluation systems hinder follow-up on device functionality and prevent evidence-based decision-making. Finally, procurement outcomes are shaped by device-specific factors, including maintenance needs, spare parts availability,

and alignment with clinical workflows, which are not consistently addressed in procurement processes, increasing the risk that devices will become underutilised or non-functional.

Based on these findings, the research concludes that supporting the sustained adoption of high-cost medical devices in Malawi requires shifting from cost-driven acquisition models to more strategic procurement processes that incorporate the Total Cost of Ownership (TCO). Procurement decisions should account for long-term costs such as maintenance, spare parts, operation, and supplier service commitments. Additionally, establishing a centralised national inventory and tracking system for medical devices would improve oversight, support more accurate needs assessments, and enhance future procurement planning. Moving toward evidence-based procurement will require the development of monitoring and evaluation systems to track device functionality and usage over time, ensuring that medical devices remain operational and integrated into healthcare delivery.

Beyond procurement processes, institutional design also influences procurement outcomes. A better balance is needed between centralised technical expertise and local facility input to improve the alignment of procurement decisions with clinical needs and usability. Integration of usability assessments at the need identification stage could help ensure that selected medical devices are both clinically essential and aligned with existing workflows. At the same time, navigating the trade-offs between transparency, competition, and standardisation is essential. While open competition remains important for fairness, moving toward a more standardised selection of device types could simplify maintenance, training, and spare parts sourcing, thereby supporting long-term usability and integration into clinical workflows.

In conclusion, this research underscores that the sustained adoption of high-cost medical devices in Malawi requires rethinking both procurement processes and the broader institutional frameworks in which they are embedded. Aligning procurement with healthcare system capacities requires moving beyond cost-driven acquisitions toward approaches that account for long-term usability, maintenance, and operation. Embedding these elements into procurement planning, alongside the development of monitoring and reporting mechanisms, would help ensure that procurement decisions are aligned with real needs and capacities within healthcare facilities. Equally important is addressing institutional design to ensure that procurement processes are supported by governance structures capable of integrating clinical, technical, and operational perspectives. By aligning procurement with the realities of healthcare system capacities and embedding long-term considerations, Malawi can move from acquiring medical devices to ensuring their sustained use. These insights are critical for policymakers and practitioners seeking to strengthen healthcare systems and promote sustainable outcomes from medical device investments.

List of Abbreviations

ASaS	Adaptability, Scalability and Sustainability
CHAM	Christian Health Association of Malawi
CoSEM	Complex, Systems Engineering and Management
HBP	Health Benefit Package
HIC	High-Income Country
HSPA	Health System Performance Assessment
HSSP	Health Sector Strategic Plan
HTSS	Health Technical Support Services
IPDC	Internal Procurement and Disposal Committee
LMIC	Low- and Middle-Income Countries
MoH	Ministry of Health
NGO	Non-Governmental Organization
PAM	Physical Asset Management
PBF	Performance-Based Financing
PPDA	Public Procurement & Disposal of Assets
SDG	Sustainable Development Goal
SEL	Standard Equipment List
SMT	Senior Management Team
SSA	sub-Saharan Africa
TAM	Technology Acceptance Model
THE	Total Health Expenditure
TCO	Total Cost of Ownership
THE	Total Health Expenditure
UHC	Universal Health Coverage
UTAUT	Unified Theory of Acceptance and Use of Technology
WHO	World Health Organization

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1. Introduction

The aim of this chapter is to provide an overview of the research by outlining its background, research problem, objective, and structure. It establishes the foundation for the research by discussing the main areas of focus and the approach taken to address them.

Section 1.1 presents the research background, introducing the broader context and key themes relevant to the study. **Section 1.2** defines the research problem, explaining why the topic requires attention. **Section 1.2.1** outlines the research objective, while **Section 1.2.2** explains the research approach**. Section 1.2.3** introduces the main research question and sub-questions that guide the study. **Section 1.2.4** provides definitions of core concepts to ensure clarity in terminology and scope. **Section 1.3** discusses the relevance of the research, linking it to its academic and practical significance. Finally, **Section 1.4** serves as a reading guide, outlining the structure of the research and providing an overview of the upcoming chapters.

1.1 Research Background

Universal Health Coverage (UHC) aims to ensure equitable access to healthcare services without financial hardship. UHC is particularly vital for improving health outcomes in low- and middle-income countries (LMICs), where disparities in healthcare access and quality continue to undermine health equity. Achieving UHC requires both access to and delivery of high-quality care. The Lancet Global Health Commission estimates that about nine million preventable deaths occur each year in LMICs due to substandard healthcare (Kruk et al., 2018). Addressing this crisis necessitates system-wide improvements, including ensuring the availability and functionality of medical devices. Medical devices are essential components of healthcare systems, supporting disease prevention, diagnosis, treatment, and patient rehabilitation (WHO, 2011). Their effective utilisation enhances healthcare delivery by enabling timely and accurate medical interventions.

A well-functioning healthcare system is fundamental for ensuring that medical devices contribute to improved health outcomes. The World Health Organization (WHO)'s Health System Performance Assessment (HSPA) for UHC provides a structured approach to understanding health systems. The HSPA Framework for UHC defines four essential health system functions: *governance*, *financing*, *resource generation*, and *service delivery*. These functions are interconnected, with governance playing a central role, functioning at both the system level and within the other health system components (Papanicolas et al., 2022).

As illustrated in Figure 1, resource generation is a crucial construct that ensures the provision of essential inputs, including *health workforce*, *pharmaceuticals*, and *medical devices*. The governance of resource generation encompasses various activities such as planning, procurement, and management of these essential inputs (Papanicolas et al., 2022). Among these activities, procurement is critical in ensuring that healthcare facilities receive appropriate medical devices.

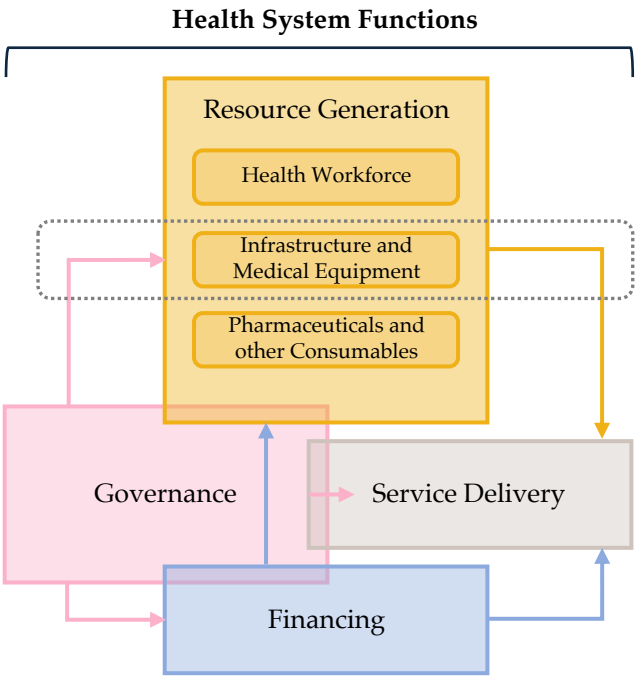

Figure 1. HSPA Framework for UHC (Adapted from Papanicolas et al., 2022)

However, ensuring that medical devices contribute to healthcare outcomes requires more than making them available. Their impact also depends on how these devices are integrated and maintained within health systems. Beyond acquisition, procurement practices influence the functionality and long-term implementation of medical devices. When procurement is inefficient, devices may remain idle or underutilised, leading to unnecessary financial burdens and reduced system efficiency (Papanicolas et al., 2022). Additionally, mismatches between procured devices and actual healthcare needs prevent these resources from serving their intended purpose. Thus, procurement operates at the intersection of governance and service delivery, guiding both the selection and sustained use of medical devices.

Due to financial constraints and limited healthcare budgets, LMICs depend heavily on donated equipment. According to the WHO (2011), approximately 95 percent of medical equipment in LMICs is imported, with around 80 percent funded by international donors or high-income countries (HICs) (Williams et al., 2020). In the case of sub-Saharan Africa (SSA), around 70 percent of their medical equipment is acquired through donations (Marks et al., 2019), while the remainder is imported from HICs through public procurement structures.

In this context, public procurement serves as an essential mechanism for governments to complement donated equipment and address gaps in healthcare delivery. Public procurement involves the acquisition of goods and services essential for public service delivery. It plays a pivotal role in government operations and socio-economic development by ensuring value for money, promoting fair competition among suppliers, and contributing to sustainable economic growth (Hassan et al., 2024). However, achieving these objectives requires a robust procurement framework guided by *transparency*, *accountability*, and *efficiency*.

Globally, evidence shows that LMICs face systemic challenges in optimising scarce resources within their health sectors (Mfutso-Bengo et al., 2023). These challenges undermine service delivery and hinder the provision of equitable, high-quality healthcare. Given the limited availability of public

funds, governments must invest strategically to maximise the impact of healthcare spending and establish procurement systems that foster the timely acquisition, maintenance, and usability of medical devices aligned with local healthcare needs.

WHO (2011) proposes a standardised procurement procedure for medical equipment. This framework, presented in Figure 2, provides structured methodologies covering needs assessment, acquisition, and post-procurement evaluation. Procurement encompasses all actions, from planning and need identification to the awarding of contracts, as represented by the dashed lines in the figure. However, how this framework is practically implemented and adapted to the realities of LMICs remains underexplored.

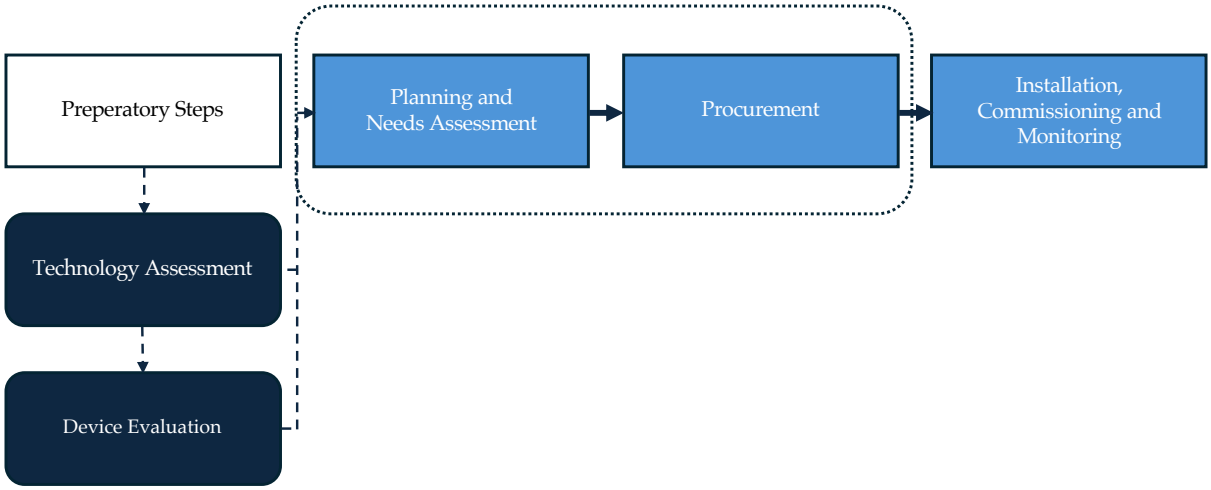

Figure 2. Flow Chart of Standard Procurement Procedures (Adapted from WHO, 2011)

1.2 Problem Definition

The availability and functionality of medical devices remain a persistent challenge in LMICs, where an estimated 40 to 70 percent of devices are broken, unused, or unfit for purpose (Diaconu et al., 2017). Many of these devices are unsuitable for local conditions, lack maintenance protocols, and often become inoperable shortly after acquisition (Asma et al., 2023). These failures have led to so-called '*medical equipment graveyards,*' where both donated or procured devices remain idle or unusable. A critical contributor to this problem lies in procurement structures that prioritise low-cost purchases while overlooking essential factors such as maintenance, training, and long-term usability (Hinrichs-Krapels et al., 2022). Additionally, vital components such as consumables, spare parts, and user support are frequently excluded from procurement decisions, further compromising the sustained use of medical devices (Hinrichs-Krapels et al., 2022). These issues underscore the need for procurement approaches that go beyond acquisition to ensure usability, durability, and alignment with contextual needs (Diaconu et al., 2017). However, there remains an important gap in understanding how procurement practices facilitate or hinder the continued integration of medical devices into resource-constrained healthcare systems. Addressing this gap requires a deeper examination of procurement practices to ensure that medical devices are not only acquired but also sustained in use over time.

1.2.1 Research Objective

This research aims to explore how public procurement can be structured to support the sustained adoption of medical devices in LMICs. Through an in-depth analysis of governance structures, decision-making frameworks, and stakeholder interactions, this study seeks to identify shortcomings within procurement systems and uncover institutional barriers that hinder the long-term integration of medical devices. By addressing these critical gaps, the research contributes to better understanding the public procurement landscape in resource-constrained healthcare systems. Furthermore, the study aims to offer insights into improving procurement outcomes, supporting the use and maintenance of medical devices beyond their initial acquisition.

1.2.2 Case Study: Malawi

To explore how public procurement practices influence the sustained adoption of medical devices in resource-constrained settings, this research adopts a case study approach focused on Malawi. The Malawian healthcare system is characterised by limited financial resources, chronic shortages of qualified healthcare workers, and widespread gaps in essential equipment and consumables, relying heavily on international funding for medical equipment (Mfutso-Bengo et al., 2023). Per capita health spending is low, underscoring the need for more effective resource allocation. In such contexts, sub-optimal procurement decisions carry significant opportunity costs and hinder efforts to improve population health outcomes (Mfutso-Bengo et al., 2023).

By focusing on Malawi, this case study offers a valuable opportunity to examine the real-world dynamics of medical device procurement and the challenges of sustained adoption. While grounded in Malawi's national context, the study's findings are expected to generate broader insights relevant to other LMICs facing similar procurement challenges and resource constraints.

1.2.3 Definitions of Core Concepts

This section sets out the definitions of the fundamental concepts of *medical devices and equipment*, *procurement*, *sustained adoption*, and *low-resource setting*s. These definitions form the foundational understanding of the core concepts addressed in this study.

- ***Medical Devices and Equipment***

The WHO (2011) defines medical devices and equipment as follows:

Medical Device: 'An article, instrument, apparatus, or machine used in the prevention, diagnosis, or treatment of illness or disease, or for detecting, measuring, restoring, correcting, or modifying the structure or function of the body for a health-related purpose. Notably, the function of a medical device is not achieved through pharmacological, immunological, or metabolic means (WHO, 2011)'

Medical Equipment: 'A subset of medical devices that require calibration, maintenance, repair, user training, and decommissioning. These activities are typically overseen by clinical engineers. Medical equipment is specifically used for the purposes of diagnosis, treatment, or rehabilitation following disease or injury. It can be used alone or in conjunction with accessories, consumables, or other equipment. Excluded from this definition are implantable, disposable, or single-use medical devices (WHO, 2011)'

For the purposes of this research, the terms ‘medical devices’ and ‘medical equipment’ are collectively referred to under the umbrella term ‘medical devices.’

This research focuses specifically on high-cost medical devices, which require significant financial investment and often involve complex procurement, maintenance, and operational challenges.

- ***Procurement***

The WHO (2011) defines procurement as ‘*The acquisition of property, plant and/or equipment, goods, works, or services through purchase, hire, lease, rental, or exchange” is taken to include “all actions from planning and forecasting, identification of needs, sourcing and solicitation of offers, evaluation of offers, review and award of contracts, contracting, and all phases of contract administration until delivery of the goods, the end of a contract, or the useful life of an asset*’

This research distinguishes between procurement structures and procurement practices:

- **Procurement structures** refer to how stakeholders interact and make decisions throughout the procurement process. These structures define the step-by-step procedures for acquiring medical devices.
- **Procurement practices** encompass the broader conditions that influence procurement decision-making and outcomes. These include regulatory frameworks, institutional arrangements, financial considerations, and external forces that shape procurement outcomes. Procurement practices set the context within which procurement structures operate, affecting how procurement is planned, executed, and sustained.

While **procurement structures** focus on the operational and procedural aspects of procurement, **procurement practices** define the overarching conditions that shape procurement decisions and their outcomes.

- ***Sustained Adoption***

This research defines sustained adoption as the continuous integration of medical devices into healthcare systems, ensuring their long-term functionality and impact.

- ***Low-Resource Settings***

The World Bank defines *low-income economies* as follows:

‘Economies with a GNI per capita of $1,145 or less in 2023 (World Bank, n.d.).’

and defines *lower middle-income economies* as follows:

‘Economies with a GNI per capita between $1,146 and $4,515 in 2023 (World Bank, n.d.).’

In this research, the term low-resource setting is used interchangeably with the term LMIC, while both refer to low-income **and** lower-middle-income economies.

1.2.4 Research Questions and Scope

The main research question guiding this study is:

How can the public procurement process of medical devices in Malawi be structured to support sustained adoption?

To address this overarching question, two sub-questions are explored. These sub-questions provide a structured approach to understanding procurement practices and their implications for the functionality and long-term implementation of medical devices. The flow of these sub-questions and the research methodologies used to answer them are further elaborated in **Chapter 3**.

SQ1. *How are high-cost medical devices procured through public procurement structures in Malawi?*

This sub-question aims to map the procurement landscape by identifying the stakeholders involved in the public procurement of medical devices in Malawi. It will examine their roles, relationships, and interactions in the procurement process. Additionally, it will investigate the steps and procedures followed in procurement, highlighting key decision points that influence the selection and acquisition of medical devices.

SQ2. *To what extent do procurement practices in Malawi support the sustained adoption of medical devices?*

The second sub-question evaluates whether current procurement practices facilitate or hinder the long-term adoption of medical devices. This will be done by assessing how theoretical conditions identified as critical for sustained adoption are reflected in, and influence, procurement practices and outcomes in Malawi.

1.3 Relevance to COSEM Study Program

This research explores public procurement within a complex sociotechnical system. Healthcare systems in LMICs are characterised by intricate interdependencies among stakeholders, constrained resources, and multi-level governance structures. Public procurement demands a multidisciplinary approach, integrating management and policy perspectives. By analysing procurement processes in the healthcare sector, it applies process management and institutional design to a critical public service domain. Moreover, it contributes to CoSEM's objective of developing innovative, sustainable solutions for complex environments. This makes the study both academically and practically relevant in addressing real-world procurement and governance challenges.

1.4 Reading Guide

This thesis is structured to provide a comprehensive understanding of the public procurement of medical devices in Malawi and its relationship to sustained adoption. This chapter introduces the research background, defines the scope of the problem, and outlines the research objective along with the key questions that guide the research. This chapter establishes the boundaries of the study and lays the foundation for the subsequent analysis. Following this, **Chapter 2** identifies the knowledge gap in the field of medical device procurement by systematically reviewing existing literature. To establish a robust research framework, **Chapter 3** details the methodology, explaining the research flow and

approach used in this study. It describes the research methods applied to each sub-question. The theoretical foundation for understanding sustained adoption is presented in **Chapter 4**, which reviews adoption frameworks for medical devices in low-resource settings. Before analysing procurement systems, **Chapter 5** provides background on Malawi, offering insights into the socioeconomic context and healthcare system. This chapter outlines health system governance, financing structures, and service delivery organisation, ensuring a deeper understanding of the environment in which medical device procurement takes place. With this contextual knowledge, **Chapter 6** examines the public procurement structure of medical devices in Malawi. It identifies the key stakeholders involved and analyses the public procurement process. Additionally, the decision-making processes in public procurement are explored in detail. The study then shifts focus to **Chapter 7**, which investigates procurement practices in Malawi and its relation to sustained adoption of medical devices. This leads to **Chapter 8**, which extends the discussion beyond procurement, exploring broader determinants of sustained adoption. **Chapter 9** presents a detailed discussion of the research findings, linking them to existing theories and assessing their contributions to the field. It also reflects on the study's limitations and its relevance to the CoSEM program. Finally, **Chapter 10** concludes the thesis by answering the main research question, summarising the implications for policy and practice, and suggesting directions for future research.

2. Identification of Knowledge Gap

The aim of this chapter is to provide a comprehensive overview of the available literature on medical device procurement in SSA and to identify the knowledge gap that this research seeks to address. This chapter reviews studies on procurement practices and methods, assessing their relevance to the research focus.

Section 2.1 details the search strategy and selection criteria used to identify relevant literature. **Section 2.2** presents an analysis of existing research. The final **section, 2.3**, synthesises these findings, illuminating gaps in the literature and explaining the need for further research on public procurement practices for high-cost medical devices in resource-constrained healthcare systems.

2.1 Search Description and Selection Criteria

This section aims to identify relevant literature that enhances the understanding of the problem domain and helps define the knowledge gap. The literature search was structured around key concepts central to this research, with carefully selected keywords and their synonyms to ensure comprehensive coverage, as shown in Table 1. Searches were conducted in Scopus and PubMed, two databases widely recognised for their extensive and reliable coverage of healthcare-related research.

Table 1. Main Keywords Used in Literature Search

Concepts: Combine with AND				
Synonyms: Combine with OR	Concept 1	Concept 2	Concept 3	Concept 4
	Medical Devices Health Technology Medical Equipment	Sub-Saharan Africa	Public	Procurement Acquisition Purchase

The search terms were combined using **'AND'** and **'OR'** operators to refine and broaden the results. The **'AND'** operator was used to narrow the search by linking specific terms, ensuring that all included studies addressed the key concepts of the research topic. Meanwhile, the **'OR'** operator was applied to include related or synonymous terms, increasing the comprehensiveness of the search results. Several iterations of search strings were tested, with details on the concepts, search strings, results, and reasons for exclusion provided in **Appendix A**. To ensure relevance, only articles published between 2015 and 2024 were included.

The final search string used was the following:
TITLE-ABS-KEY: (("diagnostic*" OR ("med*" AND ("device*" OR “equipment” OR "technol*" OR “innovation*”)) OR ("health*" AND ("device*" OR “equipment” OR "technol*" OR “innovation*”))) **AND** ("Sub-Saharan Africa" OR "SSA" OR "Africa South of the Sahara" OR "West Africa" OR "East Africa" OR "Southern Africa" OR "Central Africa" OR "Kenya" OR "Uganda" OR "Malawi" OR "Nigeria" OR "Ethiopia" OR "Tanzania" OR "Ghana" OR "South Africa" OR "Zambia" OR "Senegal" OR "Mali" OR "Sudan" OR "Democratic Republic of Congo" OR "Burundi" OR "Zimbabwe" OR "Mozambique" OR "Rwanda" OR "Niger" OR "Botswana" OR "Lesotho" OR "Swaziland" OR "Namibia" OR "Sierra Leone" OR "Liberia" OR "Chad" OR "Cameroon" OR "Burkina Faso") **AND** (“procurement*” OR “purchase*” OR “acquisition*”) **AND** “public”

The search initially identified 568 records from Scopus and 165 records from PubMed. After removing duplicates, 382 unique documents remained for further analysis. These records were then screened based on titles, abstracts, and full texts to assess their relevance and eligibility for final selection. The final selection was limited to articles with an overall focus on procurement practices. Studies pertaining to specific technologies or clinical research were excluded to ensure the relevance of the findings to this study’s focus on procurement frameworks. This process resulted in 7 articles being considered relevant to the study. Additionally, 2 more articles were incorporated through snowballing, bringing the total number of included studies to 9. The selection process is outlined and visualised in the PRISMA flow diagram presented in Figure 3.

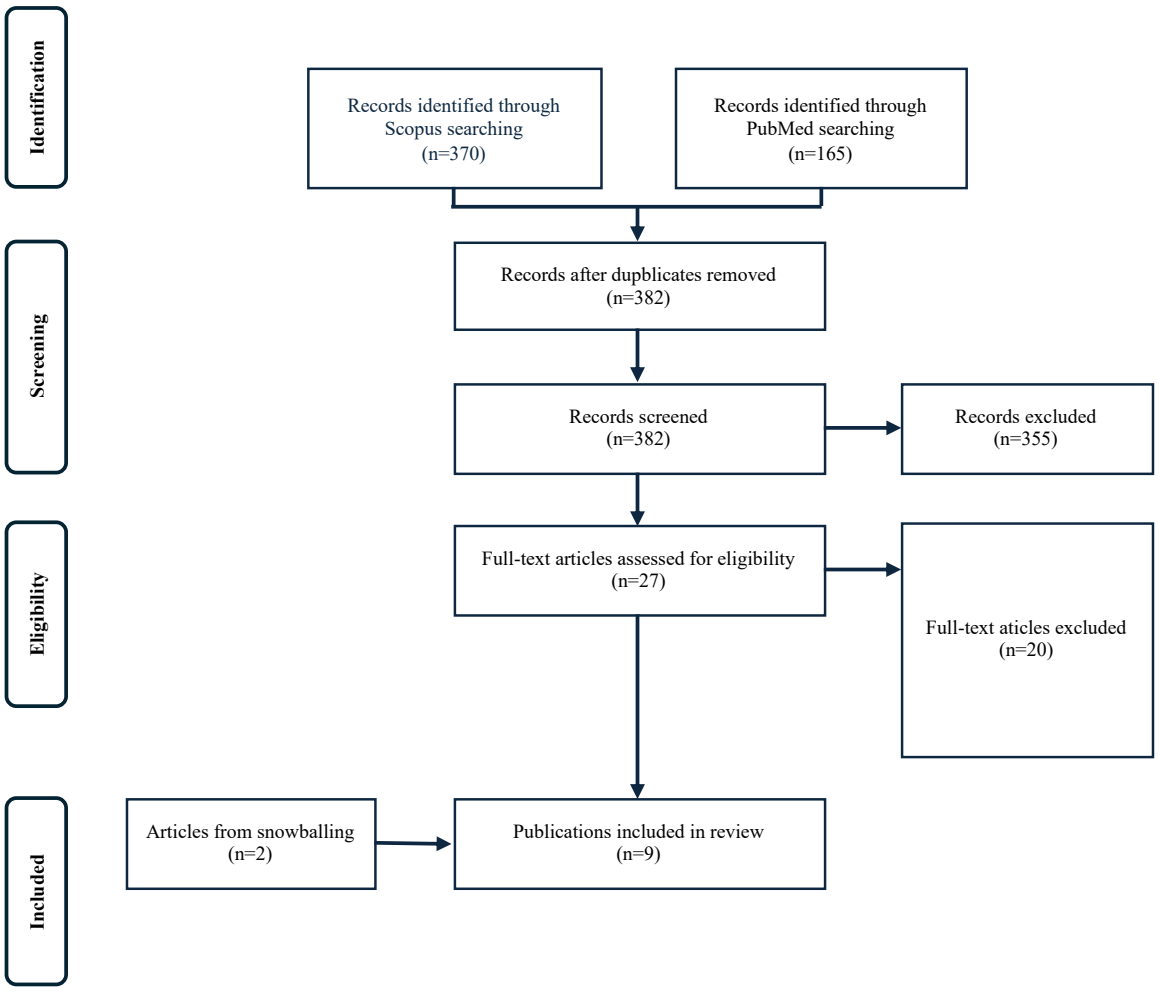

Figure 3. PRISMA Flow Diagram of Literature Search

Table 2 presents an overview of the selected articles used for the qualitative synthesis.

Table 2. Overview of Articles Used to Identify the Knowledge Gap

No.	Article	Purpose
1.	Asma et al. (2023)	To establish and implement a systematic evaluation process to identify medical devices that meet Target Product Profiles (TPPs) for use in low-resource settings.
2.	Diacuno et al. (2017)	To conduct a systematic review of the existing literature on medical device and equipment procurement in LMICs.
3.	Gamessa et al. (2022)	To evaluate the planning, budgeting, and procurement practices for medical devices in Ethiopian public hospitals.
4.	Mackintosh et al. (2018)	To analyse the procurement of essential medicines and supplies in Tanzania and Kenya as a governance process within health systems and its connections to local and international industrial development.
5.	Masembe et al. (2016)	To analyse how strategic planning affects the procurement of medical supplies in Uganda's Regional Referral Hospitals (RRHs).
6.	Mfutso-Bengo et al. (2023)	To assess the feasibility of institutionalising Health Technology Assessment (HTA) in Malawi and explore the necessary steps to establish a formalised HTA system that enhances decision-making in health technology prioritisation and adoption.
7.	Sakala et al. (2022)	To explore strategies for integrating vertical and horizontal health programs in Malawi to improve reproductive, maternal, newborn, child, and adolescent health (RMNCAH) services.
8.	Tafera & Anbessa (2024)	To assess the procurement, storage, after-procurement services, and monitoring & evaluation practices in public health facilities.
9.	Yemeke et al. (2023)	To analyse the impact of the COVID-19 pandemic on the procurement and supply chain of medical products in Zimbabwe.

The studies reviewed are consistent with the research focus, addressing the procurement of medical devices in SSA. Consequently, the studies are situated in SSA countries, including Malawi, Kenya, Tanzania, Ethiopia, Nigeria, Uganda, and Zimbabwe. The studies vary in their methodological approaches, with a balance between qualitative and quantitative designs. Several studies employed quantitative designs to assess the impact of procurement methods, such as Asma et al. (2023), Gamessa et al. (2022), and Masembe et al. (2016). These studies focus on measurable outcomes like availability of equipment, procurement planning, and financing models. In contrast, other studies adopted qualitative methodologies to explore more in-depth governance and institutional dynamics, including Mackintosh et al. (2018), Mfutso-Bengo et al. (2023), and Yemeke et al. (2023). These qualitative studies provide insights into the experiences and perceptions of actors involved in procurement processes. Regarding publication outlets, studies appeared in a range of peer-reviewed journals, demonstrating the growing recognition of procurement as an important topic in health system development. The years of publication range from 2016 to 2024, reflecting a recent but increasing academic focus on procurement practices and their impact on healthcare delivery.

2.2 Knowledge Gap

The available literature provides an overview of public procurement practices in resource-constrained healthcare systems. The reviewed studies can be categorised into three key areas: (1) *challenges in procurement of medical devices*, (2) *procurement of medical supplies*, and (3) *procurement methods*.

2.2.1 Challenges in Procurement of Medical Devices

The literature underscores a combination of structural, operational, and technical challenges that hinder the effective procurement of medical devices in LMICs. Budget constraints, weak monitoring mechanisms, and inadequate planning undermine procurement outcomes, as identified by Tafera and Anbessa (2024). Masembe et al. (2016) similarly emphasise that in public hospitals in Uganda, the availability of funding is a primary condition influencing procurement outcomes. In addition, misalignment between donor-driven and government-led procurement processes complicates efforts to ensure appropriate device selection. According to Sakala et al. (2022), donor-funded procurement often overlooks national health priorities, resulting in the acquisition of medical devices that may not match healthcare needs. This concern is reinforced by Mackintosh et al. (2017), who show that donor-driven procurement in Tanzania and Kenya tends to prioritise low-cost international sourcing. As a result, local industries are undermined, and the responsiveness to local healthcare needs is reduced. Furthermore, technical capacity gaps also impede procurement. Gamessa et al. (2022) emphasise the limited involvement of biomedical engineers and the frequent absence of clear technical specifications, both of which contribute to the procurement of unsuitable or non-functional medical devices.

2.2.2 Procurement of Medical Supplies

Next to medical devices, medicines and consumables are essential in maintaining the functionality of healthcare systems. The literature also outlines challenges in the procurement of these supplies. Inefficiencies in supply chains, weak regulations, and poor procurement planning contribute to stock shortages, inflated costs, and widespread wastage. Yemeke et al. (2023) examined the impact of the COVID-19 pandemic on medical supply chains in Zimbabwe and found substantial price increases, shortages, and disruptions in logistics. However, while their analysis focuses on pandemic-related disruptions, it does not fully address the broader structural inefficiencies that persist in routine procurement processes. Although this research offers important insights, it is essential to distinguish between the procurement of medical supplies and that of medical devices. Medicines and consumables generally follow shorter procurement cycles, involve lower costs, and are characterised by more predictable demand patterns. In contrast, medical device procurement requires longer lead times, higher costs, and more complex maintenance and lifecycle planning.

2.2.3 Procurement Methods

Some studies explore methods to improve procurement decisions and outcomes for medical devices. Mfutso-Bengo et al. (2023) examine the potential for institutionalising Health Technology Assessment (HTA) in Malawi, arguing that integrating HTA into procurement processes could enhance procurement outcomes and cost-effectiveness by ensuring evidence-based evaluation of medical devices. Similarly, Asma et al. (2023) developed an evidence-based technology review process to identify medical devices suitable for small and sick newborn care in low-resource hospitals. Their study concludes that an evidence-based device selection process can contribute to the procurement of devices tailored to the needs of resource-constrained settings. Together, these studies

underscore the importance of adopting structured, evidence-informed approaches to improve the selection and procurement of appropriate medical technologies in LMICs.

2.2.4 Conclusion

The available literature addresses challenges in the procurement of medical devices. However, gaps remain in understanding how procurement structures and decision-making processes can support the sustained adoption of medical devices in resource-constrained healthcare systems. The current research focuses on identifying contextual barriers or on exploring procurement methods that inform device selection. Among the reviewed studies, Diaconu et al. (2017) provide the only analysis of procurement structures for medical devices in LMICs, yet their work does not examine how these structures could be optimised to support sustained adoption. This research addresses this gap by focusing specifically on public procurement structures for high-cost medical devices in Malawi. By analysing how procurement decisions are made, this study aims to deepen the understanding of how procurement frameworks can be adapted to promote sustained adoption. In doing so, this research moves beyond examining procurement methods to focus on the structural and institutional organisation of procurement processes, contributing novel insights into how public procurement can move from short-term acquisition towards supporting the long-term integration of medical devices into healthcare systems.

3 Methodology

The aim of this chapter is to provide a structured and detailed overview of the research methodology used in this study. It explains the rationale behind the chosen approach, how it aligns with the research objectives, and the methods employed to answer the research questions. This chapter also establishes the interconnectedness between the research approach, data collection techniques, and analytical methods to ensure a systematic and coherent research process.

Section 3.1 presents an overview of the research approach, outlining the rationale for adopting an exploratory qualitative study. **Section 3.2** details the research methods employed for each research sub-question, including a literature review and semi-structured interviews, and describes how data collection and analysis were conducted. **Section 3.3** discusses the role of AI tools in supporting aspects of the research process.

3.1 Research Flow and Approach

The study adopts an exploratory research approach, which is well-suited for examining complex and under-researched phenomena (Sekaran & Bougie, 2016). Given the limited research on medical device procurement in resource-constrained settings, this approach allows for an in-depth evaluation of the institutional and systemic conditions influencing procurement outcomes. Exploratory research is particularly effective for addressing ‘what,’ ‘why,’ and ‘how’ questions (Saunders et al., 2023), making it suitable for investigating procurement decision-making structures. One of the key advantages of this approach is its ability to capture nuances and contextual factors that more structured methodologies might overlook (Sekaran & Bougie, 2016). This flexibility is especially important in resource-limited environments, where procurement processes are shaped by unique and often complex dynamics.

The research is structured through a detailed research flow, outlining key methods, activities, and their alignment with each research sub-question. Figure 4 provides a schematic representation of this research process, illustrating how different methodological components interconnect to ensure a systematic investigation.

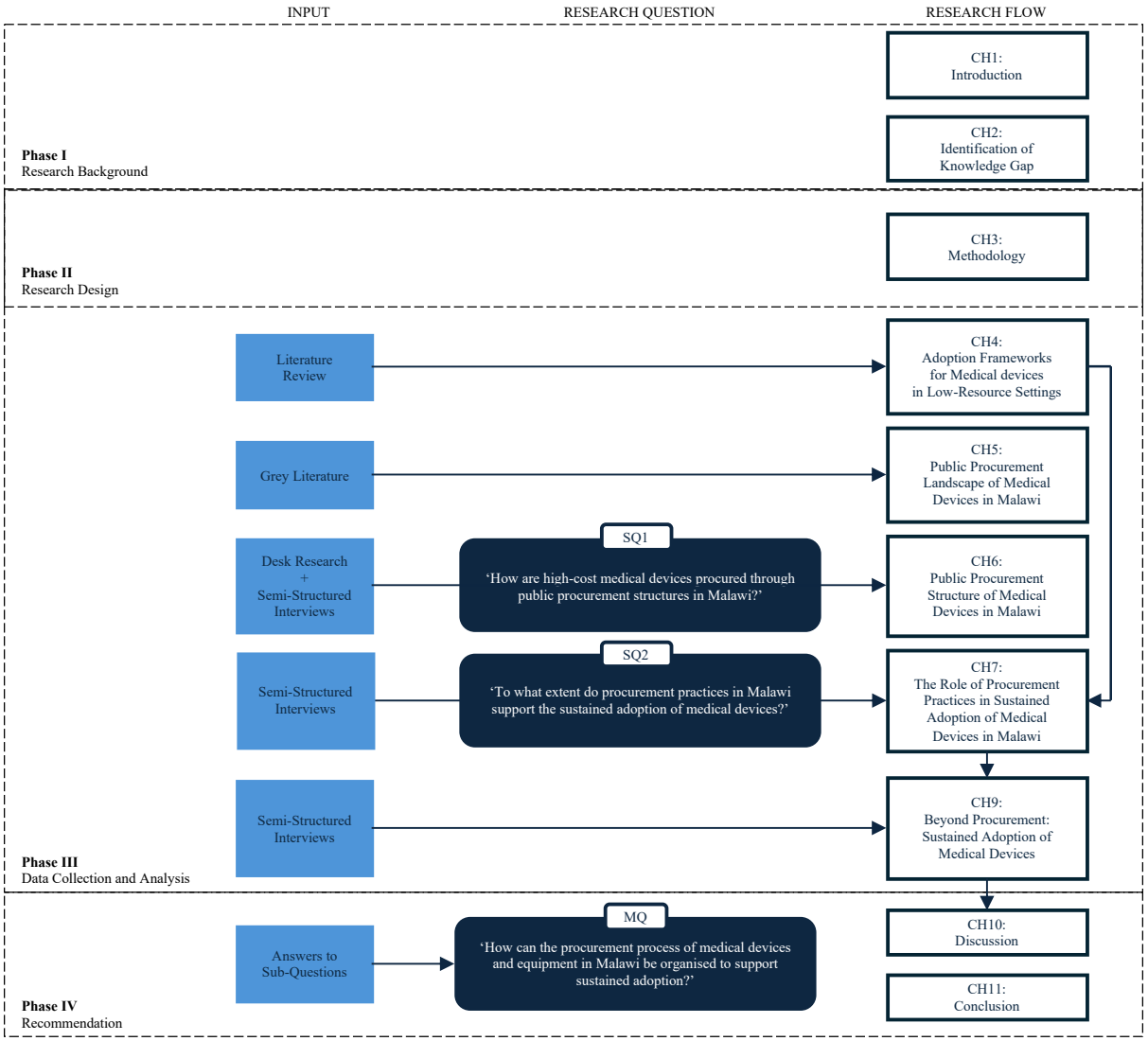

Figure 4. Research Flow Diagram

3.2 Research Methods in Sub-Questions

This section outlines the research methods used in this study, explaining their purpose and contribution to addressing the research objective. Exploratory research often relies on qualitative approaches such as informal discussions, interviews, focus groups, and case studies to investigate complex and context-dependent phenomena (Sekaran & Bougie, 2016). Qualitative research enables the collection of rich, detailed, and descriptive data (Saunders et al., 2023).

To gain a comprehensive understanding of medical device procurement and its relation to sustained adoption, this study combines desk research and semi-structured interviews. The desk research involved a literature review of adoption frameworks, providing a theoretical foundation for identifying determinants that influence the sustained adoption of medical devices. In addition, semi-structured interviews were conducted with key informants directly involved in the public procurement of medical devices in Malawi. These interviews provided essential insights into procurement practices and decision-making structures.

Figure 5 presents an overview of the research methods and illustrates how data is analysed and synthesised throughout the study.

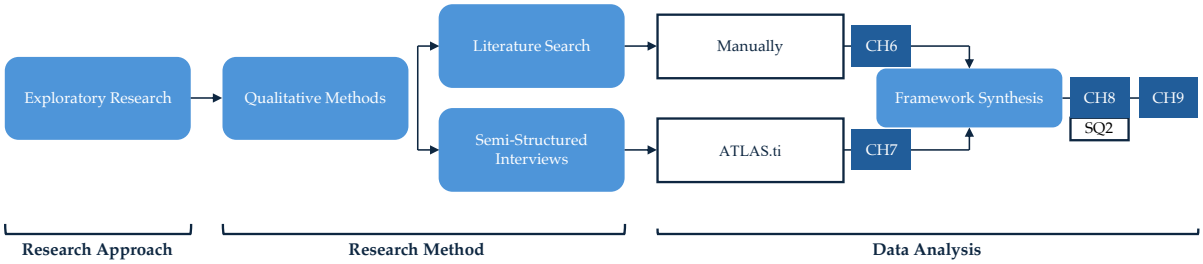

Figure 5. Research Design

3.2.1 Literature Review

The literature review in this research was conducted in multiple phases, each designed to address specific research objectives. The first phase involved a systematic review of available literature on the procurement of medical devices in the SSA region, as detailed in **Chapter 2**. This phase aimed to develop a foundational understanding of procurement practices in resource-constrained settings. The second phase of the literature review focused on grey literature, particularly policy documents, to examine the institutional environment governing medical device procurement in Malawi. This phase aimed to understand the governance structures and regulatory frameworks shaping public procurement in the country. The third phase concentrated on adoption models relevant to low-resource settings. This phase aimed to evaluate existing theoretical frameworks on the adoption of health technologies. By synthesising insights from these models, the study established a theoretical foundation for assessing adoption dynamics in healthcare systems.

3.2.2 Semi-Structured Interviews

Semi-structured interviews were conducted as the primary qualitative method to explore the public procurement structure for high-cost medical devices in Malawi. These interviews aimed to address both research sub-questions. The first focused on roles and decision-making structures, while the second examined the contextual conditions shaping procurement outcomes.

Semi-structured interviews are well-suited for collecting rich, in-depth data, as they combine open-ended questions with the flexibility to probe deeper into participants' responses (Gill et al., 2018). This approach enables researchers to capture nuanced insights and firsthand experiences of stakeholders involved in public procurement. In healthcare research, such interviews are widely recognised for their effectiveness in uncovering professional practices, challenges, and emerging themes, particularly in under-explored areas (DiCicco-Bloom & Crabtree, 2006; Gill et al., 2008).

A structured interview guide was developed, including open-ended questions that encouraged participants to reflect on their experiences, procurement practices, and challenges encountered in their roles. The full questionnaire is provided in **Appendix C**.

Participants were selected from key stakeholder groups directly involved in the public procurement of medical devices in Malawi. These included biomedical engineers from the Ministry of Health (MoH) and representatives from external development partners. Table 3 provides an overview of the interviewees and their respective roles.

Table 3. Overview of Interviewees and Their Roles

Interviewee No. / Code	Organisation	Occupation
GOV-1	MoH	Biomedical Engineer
GOV-2	MoH	Biomedical Engineer
GOV-3	MoH	Biomedical Engineer
NGO-1	NGO	Supply Division

The participants were selected through referrals from the study's external advisor, M. Madzivire, and via snowball sampling. They were approached via email. In total, four of them agreed to participate. All interviews were conducted online via Microsoft Teams between December 23, 2024, and January 29, 2025. Each session lasted between 45 and 60 minutes and was both recorded and transcribed for analysis. The online format enabled efficient scheduling within a limited timeframe.

In addition to these four semi-structured interviews, an explorative open conversation was held at the beginning of the research with a key informant who formerly worked at the MoH in Malawi. This conversation served to gain preliminary insights into the broader environment in which procurement takes place and to better understand the structure and functioning of the Malawian healthcare system. These initial insights helped to refine the interview focus and provided essential context for interpreting subsequent data.

Although the number of participants in this study is limited, the sample consists of key informants with direct, first-hand experience in the public procurement of medical devices in Malawi. Given the limited number of stakeholders involved in these processes, their insights offer a concentrated and relevant source of knowledge. Moreover, as this research aims to explore institutional dynamics and governance structures, the in-depth perspectives gathered from these interviews provide information that may not be accessible through broader surveys.

3.2.2.1 Ethical Considerations

Ensuring ethical compliance was a fundamental aspect of this research, given the involvement of human participants in data collection. The research was designed to minimise potential risks, prevent undue harm, and uphold the rights and well-being of all participants.

To achieve this, a comprehensive risk assessment and mitigation plan was developed in consultation with the Data Steward at TU Delft. This plan guided the ethical protocols throughout the research process, including the development of an informed consent form and a data management plan. Prior to data collection, the Human Resource and Ethics Committee (HREC) reviewed and approved these research protocols, ensuring compliance with the institutional ethical guidelines and research integrity standards.

To foster transparency and trust, participants were provided with the informed consent form outlining the purpose of the study, the anonymisation process, and the intended use of collected data, as detailed in **Appendix B**. This procedure ensured that all participants were fully aware of how their data would be handled and had the opportunity to ask questions before providing consent.

To protect participant privacy, all interviewees were assigned pseudonyms or coded identifiers, and any identifying details were either omitted or generalised in the final analysis. The anonymisation measures helped safeguard sensitive information while maintaining the integrity of the research findings.

Finally, participation in the study was entirely voluntary, with no financial or other incentives provided to interviewees. This approach ensured that responses were free from external influence, allowing participants to engage based solely on their expertise and professional experiences.

3.2.2.2 Data Analysis

The qualitative data from semi-structured interviews were analysed using ATLAS.ti to systematically identify key themes and patterns relevant to the research sub-questions. Interview transcripts were downloaded from Microsoft Teams in .docx format, imported into ATLAS.ti, and thoroughly reviewed for accuracy and completeness. Following verification, relevant text segments were coded, facilitating the identification of recurrent patterns and enhancing analytical clarity. A deductive thematic analysis was conducted, with predefined themes based on a selected adoption framework, ensuring consistency in interpretation and alignment with the study's conceptual model. To maintain a structured analytical approach, participants were not consulted for feedback post-analysis, preserving the integrity of the adopted thematic framework and focusing on the study's core research objectives. For a comprehensive explanation of the coding approach, see **Appendix E**.

3.3 Reflection on the Use of AI Tools

This study utilised AI tools, specifically ChatGPT and QuillBot, to enhance writing quality and coherence. ChatGPT was used to provide feedback on text clarity and structure, while QuillBot refined sentence construction and ensured grammatical accuracy. However, all academic content, analysis, and arguments were independently developed by the researcher, with AI tools serving solely as writing aids to improve readability and presentation.

4. Adoption Frameworks for Medical Devices in Low-Resource Settings

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The aim of this chapter is to examine the theoretical determinants influencing the sustained adoption of medical devices in resource-constrained healthcare systems. This chapter provides an analysis of relevant adoption theories, introduces the Adaptability, Scalability, and Sustainability (ASaS) model, and applies it to the research context.

Section 4.1 reviews technology adoption frameworks and underscores their relevance and limitations in low-resource settings. **Section 4.2** introduces the ASaS model. **Section 4.3** explains how this model is used to evaluate procurement practices and sustained adoption of medical devices in Malawi.

4.1 Adoption Theories in Low-Resource Settings

Theoretical frameworks are valuable tools for analysing the components and interconnections that influence technology adoption. These frameworks provide insights into how users interact with new technologies and how these innovations can be integrated into existing systems. Adoption frameworks have been applied across multiple disciplines, including healthcare, behavioural sciences, transportation, and information science, to design, implement, and evaluate interventions (Taherdoost, 2018; Sun et al., 2024). By explaining causal mechanisms and contextual influences, these frameworks support the development of strategies that promote sustained adoption. Furthermore, these tools enable researchers and practitioners to identify barriers and facilitators to technology uptake, thereby improving both initial adoption and long-term implementation.

A variety of models and frameworks have been developed to examine the uptake of new technologies, many of which focus on assessing the users' intention to use, such as the Technology Acceptance Model (TAM) and the Unified Theory of Acceptance and Use of Technology (UTAUT) (Campbell et al., 2017; Taherdoost, 2018). Intention to use refers to an individual's or organisation's willingness and likelihood to adopt a technology (Campbell et al., 2017). These models mainly focus on factors such as perceived usefulness and ease of use. However, most existing adoption frameworks have been developed for high-income contexts, limiting their applicability to low-resource settings. In these contexts, broader systemic challenges, such as limited infrastructure, resource constraints, and sociocultural factors, significantly influence adoption (Adlung et al., 2025). Conventional models often overlook such complexities. As a result, the literature on the implementation of health technologies in resource-constrained settings remains sparse. This gap highlights the need for tailored, context-specific models that better reflect the realities of healthcare delivery in resource-constrained environments (Adlung et al., 2025).

Recognising these gaps, Sun et al. (2024) introduced the Adaptability, Scalability, and Sustainability (ASAS) model, which integrates elements from existing frameworks while addressing the contextual complexities of resource-constrained settings. The ASaS model captures the dynamics of interaction between technological, institutional, and environmental factors, providing a more holistic approach to technology adoption. By emphasising adaptability to local conditions, scalability within resource-constrained healthcare systems, and long-term sustainability, ASaS provides a practical lens through which to analyse and support the adoption of health technologies in resource-constrained settings.

4.2 The Adaptability, Scalability, and Sustainability (ASaS) model

The ASaS model builds on established frameworks such as EPIS (Exploration, Preparation, Implementation, Sustainment), CFIR (Consolidated Framework for Implementation Research), NASSS (Non-adoption, Abandonment, Scale-up, Spread, and Sustainability), and DSF (Dynamic Sustainability Framework). Although these models offer valuable insights into implementation, they often lack the flexibility to account for the unique challenges of low-resource settings (Sun et al., 2024). The ASaS model responds to this limitation by integrating and adapting elements from these frameworks to reflect the realities of resource-constrained contexts.

Designed as a systematic and decision-oriented framework, the ASaS model is intended to support stakeholders in evaluating whether health interventions can be adapted to local conditions, scaled to broader populations, and sustained over time. By explicitly accounting for contextual dynamics, the model seeks to guide the design, implementation, and long-term integration of interventions in complex healthcare environments. It is intended to serve a diverse range of stakeholders, including policymakers, healthcare practitioners, non-governmental organisations (NGOs), researchers, and donors, ensuring that interventions are not only context-appropriate but also capable of delivering lasting impact.

The ASaS model conceptualises the sustained adoption of medical devices through four key dimensions: *outer context*, *inner context*, *intervention characteristics*, and *bridging* factors.

First, the external context captures the broader environment in which medical devices are introduced. It encompasses sociopolitical factors, including regulatory frameworks, institutional arrangements, and cultural considerations that influence the adoption process. Supportive policies and well-defined regulations can facilitate adoption, whereas regulatory gaps or inconsistencies can present barriers. Additionally, funding mechanisms determine the feasibility of procurement and maintenance of medical devices. Interorganisational networks foster collaboration, information exchange, and resource sharing. Together, these determinants from the external construct of the ASaS model, hightlight the importance of aligning adoption strategies with the broader sociopolitical and economic context.

Second, the inner context addresses the readiness of healthcare institutions to adopt and sustain new technologies. Organisational readiness refers to the ability of institutions to absorb and operationalise innovations, which is influenced by leadership and institutional culture. An enabling work environment is essential to ensure that medical devices are used and maintained appropriately. Furthermore, the attitudes and skills of individual adopters influence whether medical devices are effectively integrated into daily clinical practice. These elements constitute the internal construct of the ASaS model, focusing on how organisational structures shape technology adoption.

Third, device-specific characteristics affect the likelihood of sustained adoption. According to Sun et al. (2024), factors such as the cost of the device, availability of spare parts, and ongoing maintenance requirements are critical determinants of successful integration. Devices that are expensive to maintain, or for which spare parts are unavailable, are unlikely to remain functional over time. These considerations are grouped under the device-specific construct.

Finally, bridging factors serve as the link between the external and internal contexts. Community engagement fosters end-user acceptability and ongoing support, strengthening the alignment between device functionality and clinical realities. By facilitating coordination across multiple system levels,

bridging factors enhance the likelihood that medical devices will be integrated and sustained within healthcare systems. Within the ASaS model, these elements are conceptualised as bridging constructs, reinforcing the interplay between external influences and internal adoption processes.

A detailed description of these constructs, their associated determinants, and definitions is provided in **Appendix D**, with an overview presented in Table 4.

Table 4. The Factors Influencing Sustained Adoption of Medical Devices (Sun et al., 2024)

Outer Context	**Inner Context**
Sociopolitical Context	Organisational Characteristics
Interorganisational networks	Leadership
Funding	Individual Adopter or Provider Characteristics
Client Advocacy	Monitoring and Evaluation
Leadership	Staffing
Intervention Characteristics	**Bridging Factors**
	Community Function
	Purveyors/Intermediaries

4.3 Application of ASaS Model for Sustained Adoption of Medical Devices in Malawi

This research employs the ASaS model to identify theoretical determinants influencing the sustained adoption of medical technologies. Rather than guiding procurement decisions directly, the model serves as an evaluative framework to assess whether the current public procurement process in Malawi adequately consider these determinants. By doing so, the study examines how well procurement practices align with the conditions for sustained adoption and identifies opportunities for improvement.

5. Public Procurement Landscape of Medical Devices in Malawi

The aim of this chapter is to provide a contextual foundation on the socioeconomic and health system structures that influence healthcare service delivery and procurement processes in Malawi. It examines key demographic, economic, governance, and financing structures, offering insight into the broader environment in which procurement decisions are made.

Section 5.1 explores Malawi's socioeconomic context, including demographic trends, economic conditions, and key development challenges that impact healthcare access and resource allocation. **Section 5.2** examines Malawi's healthcare system, focusing on health system governance and financing, as procurement takes place at the intersection of these two domains. The discussion is based on key policy documents, including the Health Sector Strategic Plan (HSSP) III (2023–2030) and the National Health Financing Strategy (2023–2030), from which the information on governance structures, financing mechanisms, and strategic health priorities is derived. **Section 5.4** provides an overview of the main insights from this chapter, providing an understanding of the procurement landscape in Malawi.

5.1 Socioeconomic Context of Malawi

Before presenting the research findings, it is essential to contextualise Malawi's broader socio-economic landscape. Malawi is a landlocked country in Southern Africa, bordered by Mozambique, Zambia, and Tanzania. As of 2022, its population was estimated at 19.4 million, with 41 percent under the age of 15 and 15 percent between the ages of 5 and 15 (MoH, 2023a). The population has been growing at an average annual rate of 2.69 percent and is projected to reach 23.1 million by 2030.

Despite implementing economic and structural reforms aimed at fostering growth, Malawi remains one of the poorest countries in the world (World Bank, 2024). Between 2016 and 2020, economic growth averaged 3.2 percent per year, far below the 6 percent annual growth rate required for sustainable poverty reduction (MoH, 2023b). The economy remains heavily dependent on agriculture, which employs over 80 percent of the population and is highly vulnerable to external shocks, particularly climatic disruptions (World Bank, 2024).

Despite these economic challenges, Malawi has made notable progress in population health and service delivery outcomes over the past decade. Between 2010 and 2020, life expectancy increased from 55.6 to 64.7 years, primarily due to significant reductions in maternal and neonatal mortality rates (MoH, 2023a). However, persistent underinvestment in essential health system components poses a major challenge to sustaining these gains. Achieving Sustainable Development Goals (SDGs), particularly SDG 3, which aims to ensure healthy lives and promote well-being for all, requires accelerated efforts and systemic reforms.

5.2 Healthcare System of Malawi

5.2.1 Health System Governance

Governance in health systems determines how decisions are made, resources are allocated, and regulations are enforced. According to the WHO (2010), governance is assessed through rules-based indicators, which examine the presence of formal policies, legal frameworks, and strategic plans.

Malawi's health governance is structured around several national policies and strategic plans that establish regulatory mechanisms, healthcare priorities, and financial structures for the health sector. These documents define the institutional and regulatory landscape that governs Malawi's health system. The following section outlines Malawi's main *national health policies and strategic plans*, which provide the foundation for governance in the health sector.

- ***National Health Policy (2018)***

The National Health Policy serves as the cornerstone of Malawi's health governance, providing a structured framework for policy implementation and decision-making. It establishes clear guidelines for healthcare delivery, equitable resource distribution, and improved service accessibility. The policy defines the roles of government institutions, private sector stakeholders, and international donors in strengthening the health system while aligning with legal frameworks such as the Public Health Act (1948) and the Public Procurement Act (2003) to enhance transparency, accountability, and efficiency.

- ***Health Sector Strategic Plan III (2023–2030)***

The Health Sector Strategic Plan (HSSP) III operationalises the National Health Policy by outlining concrete objectives, financing models, and governance strategies to accelerate progress toward UHC. It delineates sector-wide priorities, including workforce capacity building and infrastructure development. HSSP III also aligns national health priorities with international commitments, ensuring coordinated efforts between government agencies, NGOs, and international health partners through a "One Plan, One Budget, One Report" approach.

- ***National Decentralization Policy (1998)***

The National Decentralisation Policy provides a governance framework that transfers decision-making authority to local health structures. It establishes decentralised governance structures at both national and district levels, allowing for localised healthcare management. This policy ensures that district health offices and local governments have the authority to manage resources, oversee service delivery, and make procurement decisions tailored to their specific healthcare needs.

- ***Malawi Vision 2063***

Malawi Vision 2063 serves as the country's long-term national development plan, incorporating health system priorities within its human capital development agenda. It provides a strategic framework that aligns health governance with broader socioeconomic development goals, emphasising long-term investments in medical infrastructure, workforce development, and technology acquisition.

Malawi's health governance is also influenced by *international frameworks* and commitments, which provide global health priorities and financing mechanisms. These policies guide national health strategies and promote alignment with international development goals.

- ***Sustainable Development Goals (SDG 3)***

SDG 3 provides a global governance framework that ensures Malawi's health sector aligns with international health standards and development priorities. It emphasises reducing maternal and neonatal mortality, strengthening healthcare systems, and improving access to essential medicines and medical equipment. SDG 3 influences national policies by guiding investment in key health initiatives and promoting equitable access to high-quality healthcare.

- ***Paris Declaration on Aid Effectiveness (2005)***

Malawi's health governance is further shaped by the Paris Declaration on Aid Effectiveness, which establishes principles for improving international aid coordination and financial management. This framework influences how donor funds are allocated within the health sector.

Malawi's health system is structured around a comprehensive set of national policies and international frameworks, which serve as rules-based governance indicators. These documents establish regulatory oversight, resource allocation mechanisms, and accountability structures for the health sector. While the rules-based governance indicators confirm the existence of structured policies and strategies, this research does not assess their impact in practice. The presence of these policies provides a formal governance foundation for Malawi's health system.

5.2.2 Health System Financing

Health system financing is an essential pillar of any health system, playing a crucial role in the procurement of medical devices and the overall delivery of quality healthcare services. However, Malawi faces significant financial constraints, with a total health expenditure (THE) per capita of $39.9, which is far below the recommended $86 for low-income countries (MoH, 2023a). This deficit hinders the country's ability to meet regional and international health financing benchmarks. For instance, the health sector accounts for only 9.2 percent of total government expenditure, falling well below the Abuja Declaration target of 15 percent. Furthermore, health spending constitutes only 2.9 percent of the GDP, significantly lower than the 5 percent threshold set by the Southern African Development Community (SADC).

Malawi's healthcare financing model is heavily reliant on external funding, with donor contributions comprising 54.5 percent of THE, compared to 24.1 percent from government sources, 9.1 percent from private insurance, and 11.9 percent from out-of-pocket payments (MoH, 2023a). As a result, Malawi has adopted a hybrid financing model that integrates domestic resources with international aid. However, of the pooled health sector funds, only 40.3 percent are part of a formal government scheme, and just 39.4 percent of THE is directly managed by the government (MoH, 2023b). This financing structure is visually presented in Figure 6, providing a clear breakdown of the funding distribution.

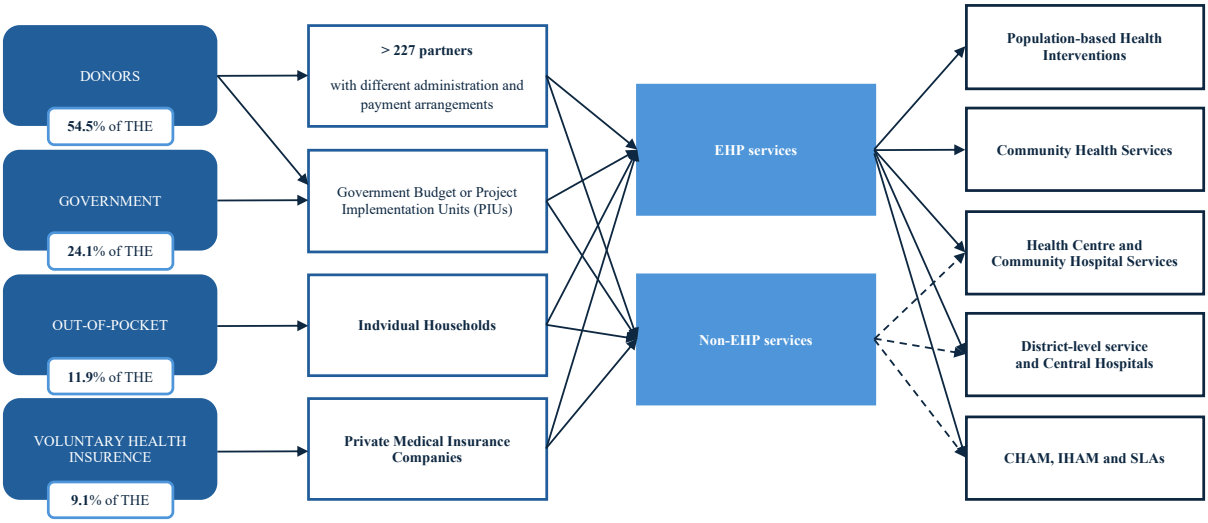

Figure 6. Health Financing Architecture (Adapted from MoH, 2023b)

While external assistance plays a critical role in sustaining healthcare service delivery, funding specifically allocated for medical devices remains poorly documented. Estimates suggest that transnational funders contribute up to 80 percent of medical device procurement costs in resource-constrained settings (Williams et al., 2020).

The Health Benefit Package (HBP) is a key financing mechanism that ensures free healthcare services at public facilities and select private institutions, including those under the Christian Health Association of Malawi (CHAM) and the Islamic Health Association of Malawi. However, the absence of user fees for non-HBP services complicates enforcement, increasing financial strain on healthcare providers and leading to informal payments.

Malawi employs a mixed-provider payment system, with private facilities operating under service-level agreements (SLAs) generally demonstrating greater efficiency in service delivery compared to public facilities, which rely on input-based financing (MoH, 2023b). Studies suggest that performance-based financing (PBF) could significantly improve health outcomes by incentivising quality care, pro-poor service delivery, and efficiency (Brenner et al., 2017). Although PBF has been approved as a policy direction, implementation has yet to take place.

5.2.3 Organisation of Service Delivery

The organisation of healthcare delivery in Malawi is shaped by operational frameworks that define the hierarchical structure of the health system and influence service provision. The Malawian healthcare system operates at three levels—primary, secondary, and tertiary—which are interconnected through a structured referral system to facilitate patient care coordination (MoH, 2023a).
Healthcare services are delivered through a diverse network of public institutions, NGOs, private nonprofit entities, and private for-profit providers. Among these, government-owned facilities comprise the majority, followed by institutions managed by private actors and the CHAM. To provide a clearer overview of the distribution of health facilities by type and ownership, Table 5 presents the composition of Malawi's healthcare infrastructure.

Table 5. Distribution of Health Facilities by Type and Ownership (MoH, 2023)

Facility Type	Facility Owner					Total
	Government	Private for Profit	CHAM	Private non-Profit	NGO	
Clinic	20	233	7	46	46	**352**
Dispensary	49	2	2	8	1	**62**
Health Centre	364	4	109	7	5	**489**
Health Post	89	-	5	-	1	**95**
Hospital	49	9	41	1	-	**100**
Total	**571**	**248**	**164**	**62**	**53**	**1098**

CHAM is the largest non-governmental healthcare provider in Malawi, accounting for approximately 37 percent of all healthcare services, while government-run facilities deliver over 60 percent of care (MoH, 2023a). CHAM predominantly serves rural and underserved populations, playing a complementary role to public healthcare institutions. Its service delivery is facilitated through a Memorandum of Understanding (MOU) with the government, which ensures that CHAM facilities located more than 8 kilometres from public healthcare institutions receive prioritised support. This collaborative framework aims to enhance service accessibility, minimise duplication of services, and optimise healthcare delivery, particularly in remote and underserved areas (MoH, 2023a). Through this public-private collaboration, CHAM contributes to bridging healthcare access gaps, particularly in areas where government infrastructure remains limited.

5.3 Conclusion

This chapter has provided a comprehensive overview of the socioeconomic and healthcare system context in Malawi. As a resource-constrained country, Malawi faces substantial challenges stemming from fragile economy and underfunded health system. Persistent underinvestment and heavy reliance on external funding continue to hinder healthcare delivery. While governance structures offer a formal framework to guide procurement decisions, their implementation depends on the capacity of Malawi's institutions. Healthcare delivery in Malawi is organised through a diverse network of public, private, and faith-based providers. Together, these insights lay the foundation for analysing how these contextual conditions influence procurement outcomes and the sustained adoption of medical devices.

6. Public Procurement Structure of Medical Devices in Malawi

The aim of this chapter is to provide a structured analysis of the public procurement structure for high-cost medical devices in Malawi. It examines stakeholders and decision-making mechanisms that influence procurement outcomes within the healthcare system.

Section 6.1 identifies the key stakeholders involved in procurement, categorising them into macro, meso, and micro levels to analyse their roles and interactions. **Section 6.2** outlines the procedural steps in procurement, detailing how medical device needs are assessed, prioritised, and translated into acquisitions. **Section 6.3** presents a swimlane diagram that visually maps the procurement decision-making process, illustrating stakeholder responsibilities and key decision points. **Section 6.4** concludes the chapter by synthesising the findings and answering sub-question 1, examining how high-cost medical devices are procured through public procurement structures in Malawi.

6.1 Stakeholders Involved in Public Procurement of Medical Devices in Malawi

This section identifies and analyses the diverse stakeholder groups involved in the public procurement of high-cost medical devices in Malawi, categorising them based on the level at which they operate within the health system: *macro*, *meso*, and *micro* levels. This layered framework, adapted from Diacuno et al. (2017) and presented in Figure 7, provides a systematic approach to understand the roles, responsibilities, and interactions of these stakeholders. It offers a comprehensive view of their contributions to the procurement process within the Malawian context.

At the macro level, international donor organisations and national government bodies collaborate to shape overarching procurement policies and allocate resources. These actors play a strategic role in developing the regulatory and financial frameworks that govern procurement processes. At the meso level, the MoH and their subunits are responsible for translating national policies into actionable procurement strategies. Their responsibilities include planning, coordinating, and implementing procurement activities that address local needs. At the micro level, healthcare facilities use the medical devices, acting as the link between procurement decisions and service delivery.

By classifying stakeholders according to their operational levels, the framework provides insight into the dynamics between international donor partnerships, national health system planning, and health facilities. Furthermore, this classification also highlights the interdependencies that exist within the health system.

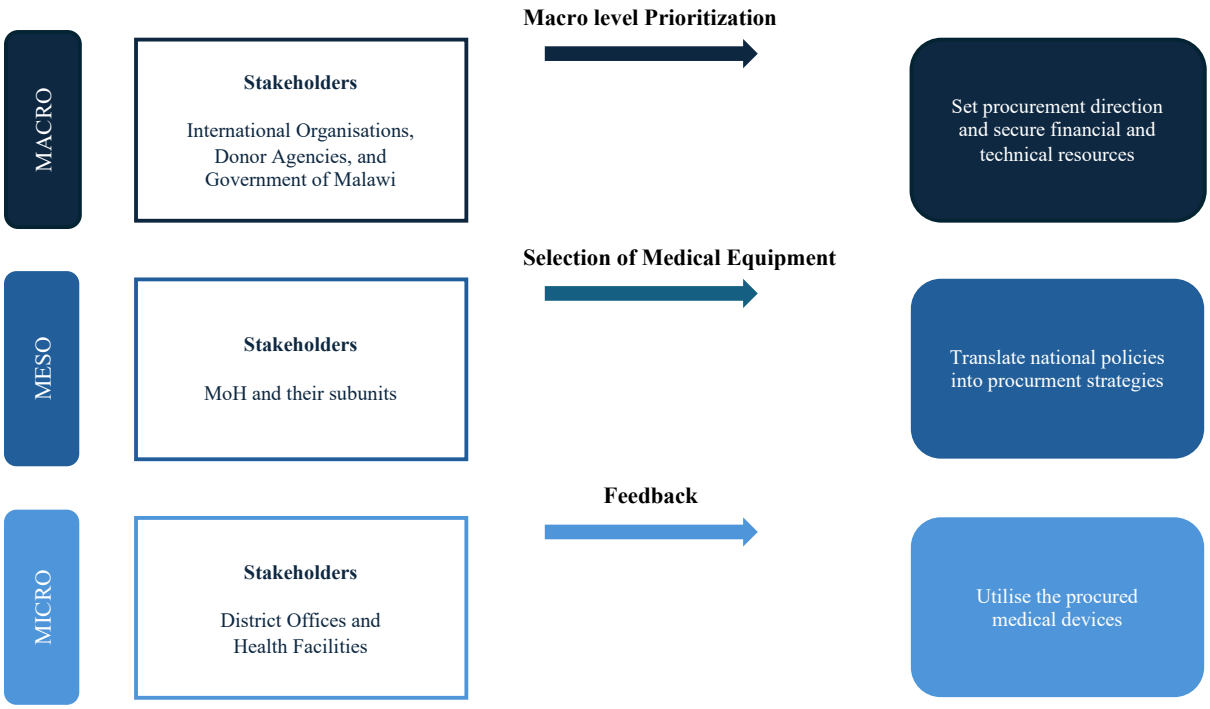

Figure 7. Layered Framework of Stakeholders Dynamics in Public Procurement (Adapted from Diacuno et al., 2017)

6.1.1 Stakeholders at Macro Level

Macro-level stakeholders in Malawi play an essential role in determining the strategic direction, policies, and resource allocation frameworks that guide the procurement of medical devices. Operating across governmental, international, and multilateral domains, these stakeholders establish the foundational parameters that influence procurement practices and resource security.

- **International Organisations and Donor Agencies**

International organisations and donor agencies are pivotal in supporting Malawi's healthcare system. Their contributions encompass the provision of financial resources, technical expertise, and strategic guidance, ensuring the implementation of national healthcare initiatives. Organisations like the WHO and UNICEF support countries by setting procurement guidelines, offering strategic advice to strengthen health systems, and funding essential health programs. Donor agencies often partner with the government to fund large-scale procurement projects, particularly for high-priority health interventions.

Collaboration among donors and stakeholders is facilitated through platforms like the Health Donor Group (HDG) (MoH, 2023a), which aids in the formulation of health sector reforms and finance strategies under Malawi's HSSP III. Technical partners, such as the Clinton Health Access Initiative (CHAI), contribute to health financing and human resources, ensuring that procurement processes are informed and provide equitable access to essential medical devices. Other organisations, including OXFAM and the United Nations Development Programme (UNDP), offer additional financial and technical assistance to advance the country's health goals.

The Health Services Joint Fund (HSJF) functions as an essential pooled funding mechanism, enabling donors to consolidate their contributions and improve resource allocation efficiency (MoH, 2023b). The HSJF operates independently of Malawi's Public Financial Management system. This fund demonstrates the shared funding approach adopted by Malawi's health sector donors, facilitating coordinated financial support to achieve strategic health objectives (MoH, 2023b). Through these combined efforts, international organisations and donor agencies help ensure the procurement of essential medical devices.

- **Government of Malawi**

The national government of Malawi plays a central role in the procurement of high-cost medical devices by defining policies and ensuring their alignment with national health strategies. Government bodies are responsible for setting procurement priorities and coordinating with international donors to harmonise efforts with the broader health objectives. Additionally, the government oversees compliance with procurement guidelines, ensuring transparency and adherence to national and international practices.

6.1.2 Stakeholders at Meso Level

Stakeholders at the meso level serve as intermediaries between national policy directives and facility-level implementation, ensuring that procurement strategies align with overarching health system priorities while addressing localised needs. At this level, MoH and its sub-units play a critical role in operationalising procurement, ensuring that medical technologies and supplies are acquired and distributed to meet national health objectives.

- **Ministry of Health and Its Sub-Units**

As a central stakeholder at the meso level, the MoH is responsible for coordinating and overseeing the implementation of national health policies and procurement decisions. Its mandate encompasses strategic planning, resource allocation, and monitoring and evaluation. Within the MoH, specialised sub-units—such as the Health Technical Support Services (HTSS) Directorate, the Physical Assets Management (PAM) Division, and the Administration Directorate—are directly involved in the procurement of high-cost medical devices.

Figure 8 presents the organisational structure of the MoH in Malawi. While the MoH operates through fourteen directorates, the figure only presents those that play an essential role in the procurement of medical devices. The governance of these directorates falls under the Senior Management Team (SMT), comprising the Secretary for Health, the Chief of Health Services, Directors and Deputy Directors of MoH Headquarters, and Directors of the five Central Hospitals (Mfutso-Bengo et al., 2023).

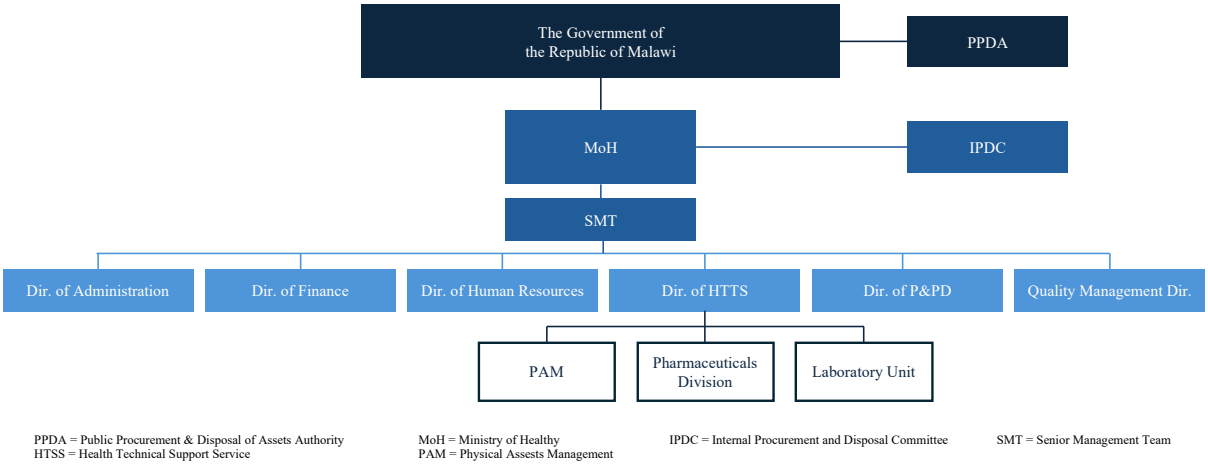

Figure 8. Organisation Structure of MoH

Among these directorates, the HTSS Directorate is the primary unit involved throughout the entire procurement process. It consists of three key divisions (Mfutso-Bengo et al., 2023): (1) PAM Unit, which coordinates the procurement of medical devices and health technologies; (2) Pharmaceutical Division, which oversees the procurement of medicines and medical supplies; and (3) Laboratory Unit, which manages the procurement of laboratory supplies and reagents.

In addition to the MoH's directorates, two independent entities play a crucial role in regulating public procurement at the national level. These bodies ensure that procurement activities across public institutions in Malawi adhere to established legal and regulatory frameworks. At the central level, the Public Procurement & Disposal of Assets (PPDA) Authority functions as the regulatory body, overseeing procurement policies, monitoring compliance with procurement regulations, and ensuring transparency across all public institutions. Within the MoH, the Internal Procurement and Disposal Committee (IPDC) executes procurement and disposal activities in accordance with PPDA guidelines, ensuring all acquisitions align with the PPDA Act of 2017.

6.1.3 Stakeholders at Micro Level

At the micro level, stakeholders within healthcare facilities implement and utilise medical devices. They are essential in ensuring the use of procured equipment and maintaining a critical connection between service delivery and higher-level procurement decisions. This level represents the stage where procurement processes transition into tangible healthcare outcomes, as stakeholders help ensure the adoption and sustained use of medical devices.

- **Regional and District Health Offices**

Regional and district health offices are responsible for identifying and consolidating the equipment needs of healthcare facilities within their jurisdiction. Their position as intermediaries between health facilities and MoH enables them to bridge the communication gap between the national and facility levels, ensuring that procurement decisions are informed by ground-level realities. Their role in decision-making is limited and more involved in the implementation of medical devices.

- **Clinical and Technical Staff**

Healthcare professionals, including doctors, nurses, and technicians, are the primary users of medical devices. Biomedical engineers and technicians within districts are responsible for the maintenance and repair of medical devices, ensuring their functionality.

6.2 Public Procurement Process of Medical Devices in Malawi

The procurement of medical devices occurs at the meso level. This process encompasses a series of interconnected activities. To provide a structured understanding of this process, this section examines the main stages of Malawi's public procurement of high-cost medical devices, focusing on the two primary steps of the WHO flowchart for procurement of medical equipment: (1) Planning and Needs Assessment and (2) Procurement.

6.2.1 Planning and Needs Assessment

The planning and needs assessment phase is a fundamental component of the medical device procurement process, serving as the link between healthcare delivery requirements and actionable procurement plans. This phase encompasses two core activities: (1) conducting a needs assessment to identify gaps in service provision and (2) translating healthcare service delivery needs into procurement requirements.

National health policies provide overarching guidance for procurement planning, ensuring alignment with overarching healthcare priorities (WHO, 2011). However, in Malawi, procurement decisions are further influenced by external development plans and donor strategies. Diacuno et al. (2017) identify two primary approaches to medical equipment planning: *experience-based planning* and *need-based planning*. Experience-based planning relies on historical procurement and consumption patterns to inform decisions. In contrast, need-based planning prioritises health objectives, service delivery targets, and context-specific epidemiological data to guide procurement choices. In recent years, Malawi has increasingly embraced need-based planning to align procurement efforts with the HBP, supporting integrated care standards across all levels of service delivery (MoH, 2023a).

In Malawi, the planning phase begins with a comprehensive needs assessment aimed at quantifying gaps in healthcare service provision. This process is aligned with the HSSP III and prioritises the procurement based on the Standard Equipment List (SEL). The SEL serves as a baseline for determining facility-specific requirements. As described by a government official (GOV-1), "*You have a standard equipment list that will tell you, at this facility level, you need this much of particular equipment*." However, due to resource constraints, not all facilities can be equipped simultaneously. Prioritisation becomes necessary to determine which facilities receive new medical devices. A recent example of Liquid Oxygen Systems (LOS) illustrates how prioritisation is conducted: "*So then we come up with a priority list. And then we could also look at the population of that district. We would look at the staffing level of the districts. If we were to bring this massive operating program of liquid oxygen, would they be able to manage it? What capabilities do they have so that they can manage these projects? [...] So you'll see that criteria will be listed down as well. So the one will be a higher tier than the other.*" [GOV-1].

After the needs assessment is completed, the procurement requirements are defined through the generation of technical specifications for the devices. These specifications provide a clear framework for vendors, ensuring that procured devices meet quality and functionality standards. According to GOV-2, the specifications generated by the PPDA Act are generally broad,*" The specifications that need to be generated by the procurement act are general. For example, for the oxygen generator, the voltage should be this. And the power setting should be something like that. The output should be this."* Technical specifications serve as the foundation for key procurement documents.

The culmination of the planning phase is the development of an acquisition plan, which outlines the product types, quantities, and locations (WHO, 2011). This plan serves as the foundation for subsequent procurement activities.

6.2.2 Procurement

Procurement is the operational phase that transforms planned healthcare requirements into tangible acquisitions, ensuring that identified needs are met through a structured acquisition process. It serves as the link between planning and implementation, involving a series of strategic and administrative activities. During this phase, the equipment requirements established in the planning and needs assessment stages are translated into concrete procurement actions. Key activities include identifying suppliers, issuing tenders, evaluating bids, negotiating contracts, and purchasing medical equipment, all of which must adhere to the PPDA Act of 2017. This legal framework is designed to uphold transparency and accountability.

First, suppliers are solicited, and procurement needs are communicated through tendering or quotation mechanisms. These procurement documents based on the technical specifications ensure that suppliers receive clear and standardised requirements. During the tendering process, the MoH, through its procurement unit, advertises tenders and invites qualified bidders to submit proposals that align with the specified technical requirements and contractual terms. In accordance with the PPDA Act of 2017, the selection process prioritises the lowest evaluated bid that meets all specified requirements. While cost remains a primary consideration, additional non-price factors—such as delivery timelines, warranty provisions, and after-sales service—may also be evaluated if explicitly included in the bidding documents. The PPDA Act outlines the principles guiding bid selection in Section 44(7):

"*A successful bid shall be the lowest evaluated bidder subject to any margin of preference provided in the bidding documents. Alternatively, if so stipulated in the bidding documents, the successful bid shall be the lowest evaluated on the basis of price and subject to any margin of preference and non-price criteria specified in the bidding documents.*"
(Government of Malawi, 2017)

Once the winning bidder is identified, the contract negotiation phase begins. This step is critical for finalising the terms, conditions, and responsibilities associated with the procurement. To complete the procurement process, the medical equipment undergoes evaluation to verify their alignment with contractual requirements. This quality assurance step ensures that procured equipment meets performance standards, safety regulations, and operational specifications before integration into healthcare facilities.

6.3 Decision-Making in Public Procurement of Medical Devices in Malawi

This section examines the decision-making process followed during the procurement of high-cost medical devices in Malawi, focusing on stakeholder interactions and the sequence of critical decision points. To provide a structured representation of these interactions, a swimlane diagram has been developed. This diagram categorises the core activities, responsibilities, and decision-making steps within the procurement process, offering a clear mapping of coordination and accountability mechanisms that guide procurement decisions.

A swimlane diagram is a specialised process flowchart that organises activities and decision points across multiple stakeholders or departments. Each 'swimlane' represents a specific entity involved in the procurement process, visually distinguishing their respective roles and interactions. To facilitate interpretation, the swimlane diagram employs various symbols, similar to those used in traditional flowcharts, to represent different process components. Each symbol conveys a specific function within the procurement process, and their corresponding meanings are outlined in Table 6.

Table 6. Explanation of Symbols Used in Swimlane Diagram

Symbol	Label	Description
	Start Loop	Indicates the beginning of a loop.
	End Loop	Indicates the point at which the loop ends.
	Start/End	Indicates the process's start or end points.
	Process	Indicates a proces, action, or operation.
	Conditional	Indicates a question.
	Document	Indicates a document or report that is involved in the process.

Following this structured approach, the decision-making process in the procurement of high-cost medical devices involves six primary stakeholders, each with a distinct role and responsibility. These stakeholders are represented in separate lanes within the swimlane diagram, ensuring a clear delineation of responsibilities throughout the procurement process. The key stakeholders include:

1) **PAM**—Coordinates the procurement of medical devices and ensures alignment with national health infrastructure needs.
2) **Directorate of Administration of MoH**—Oversees administrative procedures and ensures compliance with procurement policies.
3) **IPDC of MoH**—Evaluates procurement requests, assesses supplier bids, and ensures adherence to procurement guidelines.
4) **SMT of MoH**—Provides strategic oversight and final approvals for procurement decisions within the Ministry of Health.
5) **PPDA**—Regulates and monitors procurement processes, ensuring transparency and compliance with national procurement laws.

6) **Ministry of Justice**—Reviews procurement contracts and ensures legal compliance in all agreements and transactions.

To visually represent the interactions among these stakeholders, a swimlane diagram of the decision-making process in public procurement of high-cost medical devices is presented in Figure 10. This diagram focuses specifically on the planning and needs assessment, as well as the procurement phases, which constitute the initial stages of the procurement lifecycle. Consequently, the process begins with the identification of a medical equipment need and concludes with the awarding of the contract to the selected supplier. The diagram does not cover subsequent phases such as installation, commissioning, and monitoring.

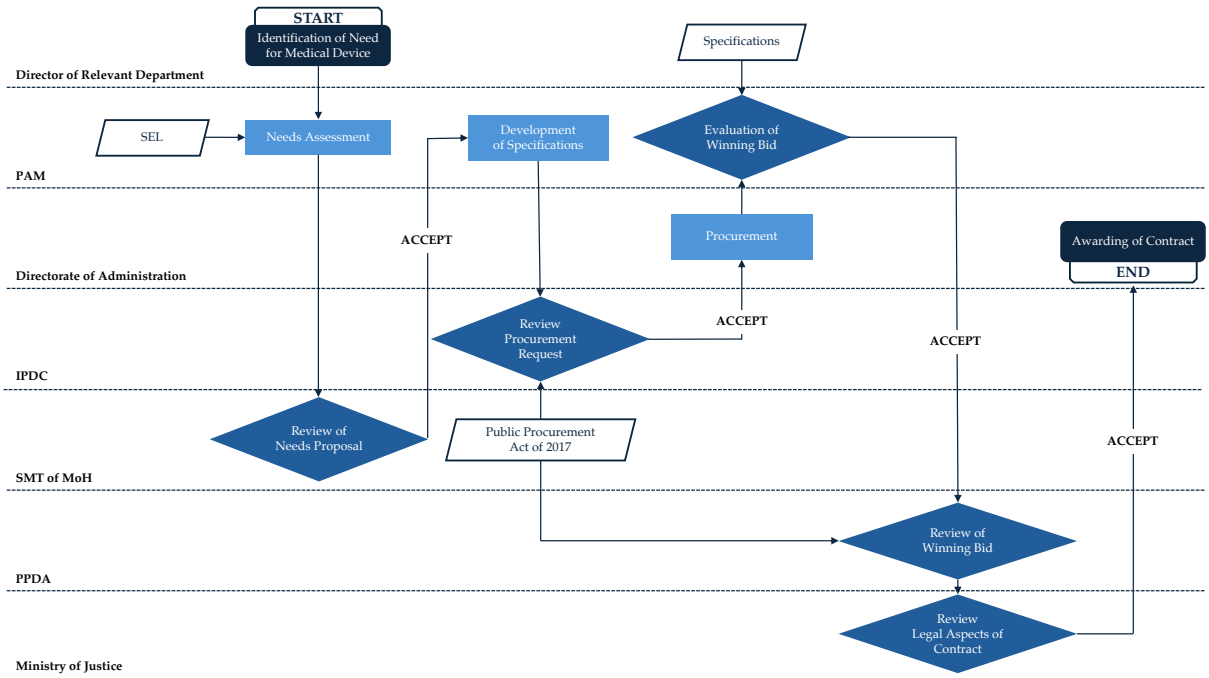

Figure 9. Swimlane Diagram of Public Procurement Decision-Making for Medical Devices

The process begins with the identification of medical equipment needs by a relevant department. The PAM unit, often with the support of biomedical engineers at the district level, then conducts a needs assessment to determine whether existing medical devices meet healthcare demands. This assessment is informed by the SEL and involves collecting data on current equipment availability and quality. Based on this data, a priority list is developed, ensuring that procurement practices address critical shortages and align with budgetary constraints.

Following this assessment, a procurement request is formally submitted to the SMT of MoH for review. The SMT has the authority to accept or reject the procurement proposal based on recommendations provided by PAM. If the SMT approves the procurement request, the process advances to the development of technical and functional specifications by PAM. Once the specifications are finalised, PAM initiates a formal procurement request, which is then reviewed by the IPDC.

With the IPDC's approval, the Directorate of Administration takes responsibility for executing the procurement process. This phase involves actions such as advertising tenders, sourcing quotations, and creating procurement documents. Once bids are received, an evaluation process is conducted to select the winning bidder based on technical compliance, cost-effectiveness, and adherence to the specifications developed earlier. At this stage, PAM plays a critical verification role, ensuring that the selected supplier's submission aligns with the predefined technical requirements. Subsequently, PPDA assesses the procurement process to verify compliance with the PPDA Act of 2017.

Before finalising the procurement, the Ministry of Justice conducts a legal review of the contract, ensuring that all terms comply with government procurement regulations. Once the Ministry of Justice approves the contract, the procurement process concludes with the official awarding of the contract to the winning bidder. This marks the final decision-making stage, after which the supplier is formally engaged to deliver the medical devices according to the agreed specifications and timelines.

6.4 Conclusion

The public procurement of high-cost medical devices in Malawi is governed by a multi-layered structure that operates across macro, meso, and micro levels. Procurement decisions are embedded within a centralised framework aimed at ensuring regulatory oversight and financial accountability. Key actors involved in this process include the SMT of MoH, the IPDC, the PPDA, and the Ministry of Justice, all of which are responsible for overseeing regulatory compliance and alignment with national priorities.

Procurement decisions strictly adhere to the PPDA Act of 2017, which mandates transparency and accountability throughout each phase of the procurement process. The process begins with comprehensive needs assessments to identify gaps in healthcare service delivery, guided by national health policies and the SEL, followed by the development of technical specifications. The subsequent procurement phase includes supplier identification, tendering, bid evaluation, contract negotiation, and quality assurance to ensure that procured devices meet required standards.

7 The Role of Procurement Practices in Sustained Adoption of Medical Devices in Malawi

This chapter synthesises insights from the literature and interviews to examine how procurement practices influence the adoption of medical devices in Malawi. The analysis focuses on the determinants of sustained adoption within the ASaS model, as explicitly considered by the interviewees. The coding approach underpinning these findings is detailed in **Appendix E**. By assessing procurement practices through the lens of the ASaS model, this chapter explores how practices either hinder or facilitate the long-term integration and use of medical devices in the healthcare system.

This chapter is structured according to the constructs of the ASaS model. **Section 7.1** explores external factors, assessing how broader contextual influences impact procurement outcomes and the long-term functionality of medical devices. **Section 7.2** examines organisational factors, focusing on how institutional capacity affects sustained adoption. **Section 7.3** analyses device-specific characteristics and their role in procurement decisions. **Section 7.4** concludes the chapter by synthesising the findings and answering sub-question 2, assessing to what extent procurement practices in Malawi support the sustained adoption of medical devices.

7.1 Outer Context

7.1.1 Sociopolitical Context

The Malawian healthcare system is characterised by a strong reliance on donor funding, with medical devices procured through two primary pathways: *government-funded procurement* and *donor-driven procurement*. Each of these pathways operates under a distinct framework, influencing the sustained adoption and integration of medical devices in the healthcare system.

The government-funded pathway operates under a structured framework, guided by the Procurement Act. GOV-1 explained, *"When it comes to procurement, we use the Procurement Act,"* affirming the regulatory framework governing public procurement. GOV-3 further confirmed this by explaining, *"You just have to follow the procurement guidelines as registered by law and PPDA."* This regulatory approach aims to ensure transparency through standardised selection criteria based on generic specifications. While this structured process ensures compliance, in practice, these generic specifications have led to significant variability in the types and brands of medical equipment across and within health facilities. One interviewee illustrated this issue, stating, *"Currently, at Queen Elizabeth Central Hospital, we have more than 32 brands of oxygen concentrators."* This lack of standardisation complicates the training of healthcare workers and hinders the procurement of spare parts, all of which present challenges for long-term maintenance and usage.

In contrast to government-funded procurement, donor-driven procurement often bypasses national regulatory frameworks, granting donors considerable autonomy in selecting and acquiring medical devices. As NGO-1 explained, "*Procurement for the products didn't have to go through them, which meant that you could purchase whatever product you wanted instead of having to tender for a set of specifications.*" Although some donors engage with government authorities prior to introducing new

medical equipment. NGO-1 noted, "*In theory, if you're doing it right, we would still speak to the Ministry of Health, talk to them about the products that we were interested in bringing in, and give them the opportunity to give comments on the products.*" However, such consultations are neither mandatory nor consistently applied.

As a result, the government is often unaware of which medical devices are delivered directly to healthcare facilities. This limits government oversight and control over the types and standards of devices integrated into the system. Moreover, without centralised oversight and tracking mechanisms, the government lacks comprehensive data on donated equipment, hindering its ability to manage inventory and plan for maintenance.

Overall, the procurement of medical devices in Malawi operates through two distinct but interdependent pathways, each presenting advantages and challenges for sustained adoption. While government-funded procurement adheres to regulatory frameworks that promote transparency and compliance, it is hindered by limited standardisation of device types. On the other hand, donor-driven procurement allows for greater flexibility but lacks formal coordination with national systems, leading to fragmented device integration and limited government oversight. Together, these parallel pathways create a fragmented procurement landscape that undermines the consistent and sustainable use of medical devices.

7.1.2 Interorganisational Networks

Interorganisational networks play a vital role in structuring procurement policies and healthcare system guidelines. NGO-1 highlighted how organisations such as WHO and UNICEF influence procurement processes by setting clinical guidance and international standards: *"UNICEF looks to WHO as the sort of clinical guidance for what to do. [...] And then governments typically will take the standards that are provided by the WHO and adapt them to their own context."* This illustrates a structured flow of information, where international organisations set standards that national governments modify to fit local healthcare needs. Additionally, these networks function as reciprocal channels rather than top-down structures. NGO-1 emphasised the role of government feedback in influencing global health recommendations: *"If a bunch of governments say this doesn't work, then they can provide feedback to the WHO. [...] So there is an opportunity for people typically to be able to provide some sort of input into what is developed."*

7.1.3 Funding

Budget constraints influence procurement decisions, limiting the health system's ability to acquire and sustain medical devices. GOV-1 described resource limitations as a major barrier, stating, "*The selection you are adjusting because we have no option."* This indicates that procurement decisions are often driven by financial constraints rather than an optimal selection of medical devices based on need. Similarly, GOV-3 emphasised funding shortages as a persistent challenge, noting, "*The main challenge is funding for the procurement."* This highlights the broader issue of budgetary constraints that restrict access to essential medical devices.

Financial limitations extend beyond initial acquisition, impacting ongoing maintenance, repair services, and technical training. Insufficient budgetary provisions often result in medical devices falling into disrepair. Without sustained financial support, even well-intended procurement efforts may fail to ensure the long-term functionality of medical devices.

In addition to funding constraints, the role of external funders further complicates procurement decisions. Donor funding, while essential for filling resource gaps, often comes with predefined priorities that may not align with national healthcare needs. As NGO-1 pointed out, "*Funders have their own priorities, and sometimes those priorities don't make sense*." This reflects how donor-driven procurement can introduce equipment that may not be the best fit for the local context. Moreover, governments often lack the leverage to negotiate or adjust these priorities, as NGO-1 noted: "*Most governments don't have the power to talk back to the funders like that*." This dynamic highlights the asymmetry of influence in donor-dependent procurement processes, where external actors can shape national procurement priorities.

Altogether, both limited national funding and donor-driven priorities constrain procurement outcomes, influencing not only what devices are acquired but also how well they can be integrated, maintained, and used over time.

7.1.4 Leadership

Leadership structures influence decision-making, coordination, and engagement in the procurement process. At the national level, GOV-1 described the challenges of securing approval from SMT within the MoH, stating, *"We had to convince the senior management of the MoH, including politicians. That is not that easy because people have different perspectives, [...] And you have to work so hard to convince them. And you don't convince all of them."* This statement underscores the complexities of leadership in decision-making, as different stakeholders within the government may have conflicting views on resource allocation and procurement priorities.

Moreover, the expertise and background of decision-makers influence procurement outcomes. NGO-1 raised concerns about the expertise of those setting clinical standards, remarking, *"The standards are set by people that do not clinically practice anymore."* This gap can result in procurement decisions that overlook practical usability and integration into clinical workflows. Devices selected without input from active healthcare practitioners may fail to meet day-to-day needs. As NGO-1 emphasised,*"It is important to make sure that the usability side of these things is at the forefront, and I feel like it's often not."* This disconnect between decision-makers and clinical realities can result in the selection of medical devices that are not user-friendly, ultimately hindering their integration into clinical workflows.

7.2 Inner Context

The sustained adoption of high-cost medical devices in Malawi is influenced not only by external dynamics but also by the organisational characteristics of the healthcare system. A crucial determinant is the readiness of healthcare facilities to integrate new technologies, which depends on their internal capacity and organisational structures.

7.2.1 Organisational Characteristics

An aspect of public procurement involves assessing whether healthcare facilities have the necessary human resources and technical expertise to operate and maintain medical equipment. GOV-1 noted that these factors are evaluated when prioritising facilities for equipment allocation. This evaluation helps ensure that devices are assigned to locations with the capacity to support their long-term use.

Beyond facility-level considerations, procurement processes are often hindered by a lack of coordination between government departments. GOV-2 pointed out inefficiencies caused by the disconnect between PAM and the planning department, explaining: *"There is a gap between our department of physical asset management and the planning department. [...] So in planning, they're doing their own things. They built the hospital without involving the physical asset management. Then later they say there is this facility that needs to be furnished with medical equipment. Hence, the process of procurement of equipment will start late. So there's that delay."* This misalignment results in delayed procurement processes and a lack of coordination between infrastructure development and equipment needs. Poor interdepartmental communication means that essential infrastructure is sometimes not in place to support procured medical devices, further complicating implementation.

An example of this issue is illustrated by the case of medical washing machines, as described by GOV-2: *"In some facilities, these washing machines are not yet installed after four years or so. [...] At first, an assessment was done to identify where these machines would be installed, and facilities were told to bring in water and electricity. However, by the time procurement was completed, many facilities had not fulfilled these requirements, leading to some equipment being moved to other facilities."* This case illustrates how inadequate coordination can lead to delayed or failed implementation of medical devices, ultimately undermining their intended impact.

Addressing these coordination challenges is essential but ensuring that healthcare personnel are equipped with the necessary skills to operate and maintain the procured equipment is equally important. Knowledge-sharing mechanisms are integrated into the procurement process to support the implementation of acquired devices into clinical use. GOV-1 described an initiative aimed at building local technical expertise by training engineers who would then educate healthcare workers on system maintenance: *"So we have now a few engineers that have been trained. [...] They will be training the doctors and the nurses on how to maintain the system management in terms of repairs."* This approach to capacity-building helps ensure that newly procured devices can be maintained beyond the initial implementation phase.

7.2.2 Leadership

Leadership structures within the Malawian healthcare system also influence procurement processes. Efforts toward decentralising procurement in Malawi have been initiated, granting district-level authorities increased responsibilities for acquiring small medical equipment. However, the lack of specialised expertise at the local level limits the extent to which decentralisation can be effectively implemented.

GOV-1 explained that district councils, under the leadership of district commissioners, now have the authority to procure small types of medical equipment. However, for high-cost or complex medical technologies, procurement remains centralised due to budget limitations, as GOV-2 noted: *"Other technologies cannot be procured at the facility level. They are supposed to be procured at the central level. I think due to budgeting constraints."* This restriction reinforces the reliance on centralised procurement for advanced medical devices.

Additionally, limitations in expertise further reduce the effectiveness of decentralised procurement. GOV-1 emphasised that some medical devices require specialised knowledge that district-level engineers may not possess: *"Some of this equipment is so complicated that you need people with a lot*

of experience so that they make better choices." This reliance on technical expertise underscores the need for centralised procurement for complex medical technologies.

7.2.3 Monitoring and evaluation

Monitoring and evaluation are essential for ensuring that medical devices remain functional and are effectively utilised. Monitoring systems facilitate data collection, tracking, and analysis, which support data-driven decision-making.

Interviewees highlighted various challenges and opportunities in the monitoring and evaluation of medical devices in Malawi. NGO-1 described efforts to establish structured monitoring mechanisms, stating, "*We specifically set up our equipment for weekly calls with focal points at each of the hospitals that we worked in, [...], so that we could make sure that the equipment was functional."* This indicates an attempt to implement systematic oversight to ensure devices remained operational.

Remote monitoring was mentioned as a potential solution for tracking medical device usage and functionality, reducing the need for physical site visits. However, they noted that while remote monitoring was a promising approach, it was not fully embedded into the MoH's systems, limiting its effectiveness. NGO-1 noted, "*Theoretically speaking, if we had been able to have the ministry sort of have their own dashboard that they could access all the time to see this, that would have been much easier to sort of keep track of the equipment and make sure that it was still sustained."* This suggests that integrating remote monitoring tools into government systems could enhance oversight and improve the long-term functionality of medical devices.

Additionally, NGO-1 emphasised the need for stronger institutional involvement, particularly from the MoH's Quality Improvement Department: *"Involvement of the quality improvement section of the MoH is needed for consistent planning."* This highlights the necessity of embedding monitoring and evaluation processes within existing healthcare structures to ensure systematic follow-up on device performance and maintenance.

In summary, while monitoring and evaluation are beneficial to the sustained adoption of medical devices, existing mechanisms in Malawi remain underdeveloped. Weak system-wide monitoring undermines the ability to track device performance and plan for maintenance.

7.3 Characteristics of Medical Devices

The characteristics of medical devices influence procurement decisions in Malawi, determining which devices are selected. These determinants also influence how these devices are maintained and integrated into the healthcare system. Procurement decisions must balance clinical necessity, resource availability, and supply chain considerations to help ensure that medical devices remain functional and adopted in resource-constrained environments.

An important consideration in procurement is whether a device is clinically essential and whether it supports healthcare providers in delivering care efficiently. As NGO-1 noted, "*I am only going to bring in products that I think are really clinically essential, or they decrease the work for the nurse or clinician that is going to have to use them."* This reflects how the medical relevance of a device influences purchasing decisions. Similarly, GOV-2 highlighted that technological advancements also guide procurement choices, citing the acquisition of an MRI machine to improve diagnostic capacity:

"*So it was based on the improvement of patient diagnosis. That's why we had to procure an MRI in the city."*

Beyond initial acquisition, the long-term adoption of medical devices depends on the healthcare system's capacity to maintain them. Therefore, procurement decisions must account for maintenance needs, spare parts availability, and operational costs. GOV-1 stressed this issue in the context of oxygen systems: "*You have to put in a lot of resources again in terms of training the technicians and the engineers for liquid oxygen systems."* Additionally, supply chain reliability is critical. As GOV-1 explained, "*The procurement of the liquid oxygen itself. So we have to manage the supply chain very well so that you don't have situations where you have a limited tank."*

A major barrier to sustained functionality is the limited availability of spare parts. GOV-3 observed, "*Most of the equipment is down because of the lack of spare parts."*, highlighting how devices without an assured supply of components are prone to rapid deterioration. While some procurement processes incorporate service and maintenance contracts to mitigate these risks, GOV-3 noted that challenges in supplier tracking and contract enforcement remain: "*The capital equipment usually comes with a maintenance contract."* […] *It is also difficult to track distributors."*

These issues point to the importance of early and coordinated stakeholder engagement in procurement planning. Involving relevant actors from the outset helps ensure that devices meet both clinical needs and operational realities. GOV-1 emphasised the need for proactive engagement, stating, "*We started having discussions with the relevant stakeholders about how we are going to sustain this project after the donor pulls out."* This suggests that procurement planning must extend beyond initial acquisition and consider long-term sustainability strategies. NGO-1 further underscored the necessity of government involvement to foster ownership and long-term commitment: "*I think it's super important. I mean, because the thing is that if you do things by yourself, then no one has any investment in them and therefore no reason to see them be sustained."*

Ultimately, while medical device characteristics such as clinical utility and technological advancement influence procurement outcomes, their long-term functionality also depends on practical considerations, including the ability to maintain and repair devices and secure necessary consumables. Without integrating these factors into procurement decisions, devices risk becoming underutilised or non-functional.

7.4 Conclusion

Public procurement practices in Malawi do not sufficiently support the sustained adoption of high-cost medical devices. While formal procurement structures and regulatory frameworks contribute to transparency and oversight, several systemic and organisational challenges hinder the long-term integration and use of medical devices. Fragmented procurement pathways undermine the standardisation of device types introduced to the healthcare system, complicating maintenance, training, and supply chain management. As a result, government control over device selection and monitoring remains limited. In addition, persistent funding constraints restrict both the acquisition and maintenance of essential medical devices. Donor-driven procurement is necessary to fill in gaps in resources, but it can bring in devices that are not well suited to local healthcare needs or operational capabilities. This makes them harder to use and integrate in the long term. Organisational factors further influence the sustained adoption of medical devices. Limited human resources, coordination challenges, and weak monitoring mechanisms affect how devices are integrated and maintained over time. Poor coordination between departments involved in procurement and planning often leads to

delays and misalignment between equipment needs and infrastructure readiness. Moreover, although monitoring and evaluation are recognised as critical, current systems remain underdeveloped, hindering regular follow-up on device functionality and maintenance. Practical considerations such as spare parts availability, maintenance needs, and operational expenses are not always adequately addressed in procurement decisions. Limited tracking of spare parts, especially for devices sourced from various suppliers, can impede sustained functionality. Although training and maintenance contracts are sometimes included to mitigate these risks, they are not consistently applied. In sum, while procurement decisions in Malawi consider device characteristics, they often overlook the broader systemic and organisational conditions essential for ensuring that medical devices remain functional and are integrated into routine healthcare delivery.

8. Beyond Procurement: Sustained Adoption of Medical Devices

The aim of this chapter is to examine factors critical to sustained adoption that are either not incorporated into procurement practices or not considered within the ASaS model. The analysis explores gaps in procurement decision-making and limitations of the ASaS model in capturing determinants of sustained adoption of medical devices.

Section 8.1 identifies determinants crucial to sustained adoption that remain outside the scope of procurement decisions but are accounted for in the ASaS model. **Section 8.2** evaluates factors influencing sustained adoption that are not accounted for within the ASaS model but are considered by the interviewees. By identifying these gaps, this chapter provides a broader perspective on sustained adoption, extending beyond procurement considerations. **Section 8.3** reflects on how the understanding of sustained adoption extends beyond procurement.

8.1 Determinants of Sustained Adoption within the ASaS model

The characteristics of individual healthcare providers influence the implementation and use of medical devices. Factors such as professional experience and workload affect how medical devices are integrated into clinical practice. NGO-1 highlighted how work culture and individual attitudes are shaped by overwhelming workloads in resource-constrained settings: *"So you either try and prioritise your triage. Or you say, My God, there's so much fire and you sit down and wait for the fire. Like, that's kind of the two attitudes that you have with this. And I would say it's 97% sit down and wait for the fire, because what can you do? And like 3% is, let's triage. Let's figure out how to approach this."* This statement reflects the pressures faced by healthcare providers in low-resource settings, where an excessive caseload forces them to focus on immediate crises rather than systematic problem-solving or proactive implementation of medical devices. As a result, there is a tendency to adopt a more reactive than proactive approach, where providers wait for issues to escalate instead of seeking early interventions.

While NGO-1 considered the characteristics of individual healthcare providers an important factor in medical device adoption, these characteristics cannot be directly linked to procurement decisions. Instead, they primarily influence how procured devices are used and maintained in clinical practice, rather than shaping the procurement process itself.

8.2 Determinants of Sustained Adoption Beyond the ASaS model

The ASaS model provides a structured framework for understanding the sustained adoption of medical devices. However, it does not explicitly account for systematic and infrastructure challenges, which were identified by interviewees as barriers to adoption. These fundamental constraints raise concerns about whether the model sufficiently captures the external environmental conditions that influence the functionality and long-term integration of medical devices.

One of the infrastructure challenges identified was the lack of a stable power supply, which directly affects the functionality and longevity of medical devices. NGO-1 underscored this issue, arguing that

without stable power infrastructure, sustainable medical device adoption is unattainable. Highlighting the broader implications of inadequate infrastructure, NGO-1 strongly advocated for prioritising power grid development over other forms of aid, stating, "*My favourite thing would be if everyone just stopped giving money to anything else and just rebuilt all the power grids in the world. Because there will be no economic development, there will be no sustainable economic growth until that's fixed."*

A concrete example of how infrastructure challenges disrupt healthcare operations was provided by an interviewee who described the impact of power failures on the government's current monitoring system: *"So we have to solve the power supply to restore the system. So previously we could do track hops of commodities in our facilities."*. This illustrates how power instability hinders essential healthcare functions, further demonstrating that medical device adoption is not solely contingent on procurement and financial mechanisms but is deeply interwoven with broader infrastructural conditions.

Beyond infrastructure, systemic challenges were also identified as significant barriers to sustained medical device adoption. NGO-1 highlighted that many of the challenges surrounding medical device implementation stem from broader systemic inefficiencies rather than isolated procurement or implementation failures. As an example, NGO-1 described a project focused on developing a robust oxygen concentrator equipped with a built-in voltage stabiliser to mitigate power fluctuations. During the development process, stakeholders debated whether additional components, such as a solar panel or backup battery, should be included. However, NGO-1 questioned the practicality of investing in isolated technological fixes rather than addressing underlying systemic issues: *"Why would you invest this much money into solar backup for one oxygen concentrator? Which will help one oxygen concentrator and maybe, let's say, if you're in a newborn care unit, possibly three to five patients. When you could do that for the entire hospital, or you could do that for the entire country? Like, it's not—it won't fix the symptoms, right? Fix the problem."* This example reinforces the argument that focusing on device-specific technological modifications does not address the underlying systemic deficiencies, such as inadequate power infrastructure. Without resolving these fundamental systemic challenges, investments in medical devices will remain unsustainable, as healthcare providers will continue to face operational limitations beyond the scope of individual technologies.

The ASaS model primarily conceptualises external factors through the lens of sociopolitical dynamics, interorganisational collaboration, and financial constraints. While infrastructure issues such as power supply might be viewed as a resource constraint, this framing does not fully capture the systemic nature of the problem. Instead, infrastructure represents an overarching issue that affects all components of the healthcare system, shaping how procurement, implementation, and long-term use unfold in practice. Given this gap, systematic and infrastructure challenges should be explicitly recognised as external factors distinct from those currently captured in the ASaS model.

8.3 Conclusion

Although procurement practices, as examined in **Chapter 7**, influence procurement outcomes, the determinants of sustained adoption extend beyond procurement decisions. The long-term use and integration of medical devices are determined not only by procurement decisions but also by broader conditions within the healthcare system, many of which are either difficult to address through procurement or are not typically considered. Among these, infrastructure considerations are critical for enhancing both procurement outcomes and sustained adoption. Thus, the findings underscore that sustained adoption requires aligning procurement decisions with broader health system strengthening

to ensure that medical devices remain functional and are effectively integrated into clinical care over time.

9. Discussion

The aim of this chapter is to interpret and reflect on the research findings by examining the institutional tensions and trade-offs that shape procurement decisions and outcomes.

Section 9.1 presents an interpretation of the research findings, discussing institutional tensions in public procurement of medical devices in Malawi. **Section 9.2** reflects on the applicability of the ASaS model, outlining its strengths and limitations in capturing the determinants of sustained adoption. **Section 9.3** outlines the research contributions to the field of medical device procurement and technology adoption. **Section 9.4** discusses limitations of the research. Finally, **Section 9.5** outlines implications for future research.

9.1 Interpretation of the Research Findings

The availability and functionality of essential medical technologies in Malawi depend not only on procurement decisions but also on broader institutional structures that shape their adoption. This section interprets the findings of this research by examining the institutional conflicts that affect procurement outcomes and the sustained adoption of medical devices. First, the findings reveal a persistent tension between *centralised* and *decentralised* procurement structures, as the system faces obstacles in balancing national-level technical oversight with responsiveness to local healthcare needs. Second, there is a conflict concerning *standardisation*, as regulatory frameworks that prioritise cost and rely on generic specifications have led to the procurement of diverse device types, complicating maintenance and integration. Third, the findings underscore fundamental challenges in *procurement approaches*, particularly regarding the role of monitoring and evaluation in evidence-based decision-making. This section will elaborate on these institutional tensions.

- ***Procurement of Medical Devices: Centralisation vs. Decentralisation***

The public procurement of high-cost medical devices in Malawi presents tensions between centralisation and decentralisation. The multi-tiered health system is structured to balance national governance with external funding influences, resulting in a procurement system that is highly centralised. While centralisation ensures regulatory oversight and compliance with national procurement policies, it also creates challenges in aligning procurement decisions with the practical needs and acceptance of end-users in healthcare facilities. This raises questions about the extent to which procurement decisions should be centralised or decentralised to optimise both technical precision and usability in clinical settings.

A critical aspect of this dilemma is the concentration of technical expertise at the national level. High-cost medical devices require specialised technological expertise, which is unavailable at lower levels. Centralised procurement enables biomedical engineers to define technical specifications and conduct evaluations, reducing the risk of suboptimal purchasing decisions. However, while this approach strengthens technical precision, it often neglects the usability and practical implementation of medical devices within healthcare workflows.

An important determinant of medical device adoption is perceived usefulness by healthcare workers, yet this factor is often overlooked in procurement decisions. The findings indicate that devices requiring minimal adaptation to existing workflows, or those deemed clinically essential, are more readily accepted by end-users. In contrast, devices that introduce additional steps or disrupt clinical procedures often face resistance. The knowledge about user acceptance is decentralised, residing primarily at the healthcare facility level, where clinicians and healthcare workers interact with equipment. The exclusion of the end-users from procurement can lead to a misalignment between technical specifications and practical implications.

In response to these challenges, steps have been taken to decentralise procurement authority by granting district health offices greater autonomy in decision-making. However, the decentralisation of high-cost medical device procurement remains limited due to the lack of technical expertise at these levels. Without adequate biomedical knowledge, decentralisation risks poor procurement decisions and suboptimal device selection. While greater autonomy at district levels could improve alignment with healthcare needs, it must be accompanied by sufficient technical capacity to prevent inefficiencies.

Addressing this imbalance requires an integrated approach that combines centralised oversight with decentralised usability considerations. One potential solution is the structured integration of usability assessments at the needs identification stage, ensuring that selected medical devices are both clinically essential and aligned with existing workflows. Currently, device selection is dictated by SEL, which outlines essential medical devices for health facilities. Refining this list by including only devices that are clinically essential or that simplify clinical workflows could enhance procurement outcomes. By doing so, procurement decisions would retain the technical rigour of centralised expertise while incorporating user acceptance, ultimately leading to the better integration of medical devices in resource-constrained healthcare systems.

- ***Standardisation of Medical Device Types***

The regulatory framework governing public procurement decisions is essential in ensuring transparency and compliance. However, they also introduce inefficiencies that hinder the long-term integration of medical devices into healthcare facilities. In Malawi, public procurement operates under a strict regulatory framework, notably the PPDA Act of 2017, which mandates supplier selection based on competitive bidding and cost efficiency. While this approach aims to ensure fairness and cost-effectiveness, it does not necessarily support the adoption and usability of medical devices in healthcare settings.

One of the main challenges arises from the cost-driven procurement approach outlined in the PPDA Act of 2017. This law prioritises low-cost supplier selection, leading to *brand proliferation*, where a wide range of brands and models of the same device type are procured. While this may reduce upfront costs, it significantly complicates training, maintenance, and spare parts management.

Limiting the number of brands per device category could mitigate these challenges. However, such an approach requires balancing regulatory compliance with practical usability considerations. The PPDA Act was introduced to promote fair competition in public procurement, and standardisation could create risks of reduced competition and potential corruption. Additionally, many LMICs, including Malawi, rely heavily on donated medical devices, which are often outside government control, further complicating efforts to standardise medical device types.

At the national level, excessive brand diversity undermines economies of scale for both procurement and maintenance contracts. To tackle maintenance complexities resulting from brand proliferation, one potential solution is to prioritise procurement contracts that include servicing agreements. However, this approach presents its own challenges. Since most high-cost medical devices in Malawi are imported from HICs, reliance on international suppliers for servicing can lead to delays in maintenance and repairs.

- ***Procurement Approaches***

Procurement decisions in Malawi are driven by cost-effectiveness, with contracts awarded to the lowest bidder. While this approach aims to ensure immediate affordability, it often comes at the expense of long-term functionality and integration of medical devices. Prioritising the lowest-cost bids may reduce upfront expenses but often leads to procurement inefficiencies. Critical factors such as maintenance requirements, spare parts availability, and supplier service commitments are frequently overlooked. A procurement approach that prioritises long-term adoption would incorporate Total Cost of Ownership (TCO), which evaluates the long-term costs associated with procurement decisions rather than just the initial purchase price. This approach accounts for operational expenses, including maintenance, spare parts, training, and extended service contracts.

In addition to considering the full lifespan costs of medical devices, Malawi lacks systematic oversight of both medical equipment availability and the functionality and use of procured devices. While government-led procurement operates under strict regulatory frameworks, donor-driven procurement often functions independently, bypassing formal government channels. As a result, the MoH lacks a centralised inventory system to track available devices and assess national needs. Without accurate data on what equipment is present across healthcare facilities, resource allocation becomes inefficient, leading to procurement decisions that do not necessarily reflect actual needs.

Beyond monitoring availability, there is also a significant gap in tracking the use and functionality of medical devices. The absence of a real-time monitoring system means that MoH cannot assess whether devices are actively being used, remain operational, or require maintenance. Without continuous oversight, essential equipment may be left unused because of minor technical faults or missing spare parts, accelerating obsolescence and weakening evidence-based procurement planning.

To address these challenges, monitoring systems are necessary. Implementing integrated digital tracking systems across healthcare facilities could enhance procurement decision-making by providing data on which devices are available, actively in use, or in need of repair. By embedding these structural reforms into procurement policies, Malawi can transition from a cost-driven procurement system to an evidence-based mechanism that supports sustained adoption of high-cost medical devices.

9.2 Reflection on Chosen Framework

The ASaS model provides a multi-dimensional framework to examine how contextual dynamics influence the adoption of medical devices in healthcare systems. However, its applicability in this research context has some limitations.

The ASaS model does not explicitly account for usability as determinant for sustained adoption. Although the model includes '*technical advancements*' and '*individual adopter*' determinants, Sun et

al. (2024) do not clearly define how these relate to usability. In contrast, well-established adoption models such as UTAUT and TAM emphasise that adoption depends not only on technical suitability but also on how easily users can interact with and accept new technologies. This suggests that the ASaS model lacks a behavioural perspective, limiting its ability to capture the role of user acceptance in the sustained adoption of medical devices.

Beyond procurement considerations, systemic inefficiencies and infrastructure limitations also pose significant barriers to sustained adoption, yet they are not adequately captured in the ASaS model. One of the most pressing infrastructure challenges identified in this study is the lack of a stable power supply, which directly affects the functionality and longevity of medical devices. NGO-1 strongly emphasised that without a stable energy infrastructure, the sustained adoption of medical devices remains unattainable. They argued that investments in power grid development should take precedence over fragmented aid initiatives. Power instability disrupts essential healthcare functions, such as government monitoring systems, which depend on continuous electricity to track medical commodity flows and ensure functional equipment.

While the ASaS model considers external factors such as sociopolitical conditions, interorganisational collaboration, and financial constraints, it does not sufficiently capture the systemic nature of infrastructure challenges. Power supply issues may be viewed as a resource limitation under the current framework, but this framing does not fully reflect the pervasive and structural impact of infrastructure deficits on medical device adoption. Instead of being treated as a secondary consideration, infrastructure should be recognised as a distinct external determinant that affects all stages of procurement, implementation, and long-term device use.

9.3 Contribution of the Research

This research contributes to understanding how public procurement practices influence the sustained adoption of medical devices in resource-constrained healthcare systems by focusing on the role of institutional design. While existing studies highlight contextual barriers and inefficiencies in medical device procurement (Gamessa et al., 2022; Tefera & Anbessa, 2024) and call for institutional change (Mackintosh et al., 2018), they do not examine how institutions can be shaped to support long-term device integration. This study addresses that gap by showing how institutional design affect procurement outcomes and the sustained functionality of medical devices. Moving beyond technical and procedural recommendations, it demonstrates that procurement effectiveness depends on the way institutions are designed to support device integration over time. Furthermore, by applying the ASaS model to evaluate procurement processes, this research offers a novel perspective on how adoption determinants are (or are not) embedded in procurement practices. While adoption models are commonly used to assess specific healthcare interventions (Taherdoost, 2018; Sun et al., 2024), this study extends their application to procurement, providing new insights into how procurement practices can either enable or hinder the long-term use and impact of medical devices.

9.4 Limitation to the Research

This study presents several methodological and contextual limitations that must be acknowledged. The research primarily relies on qualitative data collected through interviews, offering an in-depth understanding of procurement processes. However, the limited number of participants, particularly the dominance of biomedical engineers from the MoH, may have introduced a narrow perspective on procurement. While these participants provided crucial technical insights, procurement also involves stakeholders from other directorates, whose perspectives were under-represented in the study.

Therefore, the purchasing and tendering processes were not thoroughly captured. Additionally, the study included only one NGO representative. A more diverse sample of participants could have provided a more comprehensive understanding of procurement interactions across different stakeholder groups.

Another limitation concerns the study's reliance on secondary data, primarily drawn from policy documents and strategic plans issued by Malawian institutions. While these sources offer valuable insights into procurement frameworks, they also pose risks of bias, as official documents can reflect aspirational policies rather than actual implementation practices. Because of the lack of prior studies, the research had to rely heavily on data from the interviews. Moreover, the study's search strategy was limited to SSA due to the large number of results generated when using broader concepts, such as LMICs. Expanding the search string and including adoption-related keywords could have yielded more relevant articles, enhancing the study's theoretical foundation.

Beyond methodological constraints, the study is also context-specific, meaning its findings may not be directly transferable to other low-resource settings. Procurement systems are shaped by country-specific governance structures, regulatory environments, and funding mechanisms, which vary across LMICs.

9.5 Implications for Future Research

The findings of this research reveal institutional tensions within the public procurement system for high-cost medical devices in Malawi. Future research should investigate how procurement frameworks can be adapted to balance these institutional tensions while ensuring medical devices are to support sustained adoption of medical devices.

One area for future research is the impact of centralisation and decentralisation on procurement outcomes. Research should explore how different governance structures affect procurement outcomes by examining procurement models in different healthcare settings and assessing their implications for both technical oversight and practical usability. Additionally, research should explore mechanisms to improve communication and collaboration between national procurement agencies and healthcare facilities to better align procurement decisions with clinical needs.

Another critical area for research is the impact of the standardisation of medical device types in a healthcare system. Research should investigate how standardisation can be incorporated into public procurement structures while maintaining transparency and competition. A financial impact assessment of standardisation on procurement costs, maintenance budgets, and supply chain efficiency would provide empirical evidence on the trade-offs involved in greater standardisation. Furthermore, understanding how standardisation interacts with donor-driven procurement is essential, as many donated medical devices bypass government procurement regulations, leading to further fragmentation. Future studies should assess how national standardisation policies can be aligned with donor contributions to promote more sustainable medical device integration.

Beyond regulatory frameworks, research is needed to explore procurement approaches that promote long-term integration of medical devices. Future studies should investigate how procurement evaluation frameworks can transition from price-driven models to long-term value-based approaches, ensuring that procurement accounts for the full lifecycle costs of medical devices. A pilot study to test a TCO procurement approach in Malawi would provide practical insights into how TCO-based

models impact procurement outcomes and device adoption. This research would help develop procurement policies that consider not only acquisition costs but also maintenance, spare parts availability, and long-term usability.

A final area of research should focus on procurement monitoring and evaluation systems. The absence of real-time monitoring limits evidence-based procurement planning, resulting in underutilised and nonfunctional medical devices. Research should explore how digital inventory and real-time tracking systems can improve procurement decision-making. Case studies from other LMICs that have implemented monitoring systems could inform practices for Malawi. Evaluating the impact of remote tracking tools in healthcare facilities would provide insights into the feasibility of a nationwide procurement monitoring system that enhances medical device management and inform procurement.

Investigating these research areas will contribute to a deeper understanding of how institutional structures and monitoring mechanisms influence the sustained adoption of medical devices. Addressing institutional tensions in procurement governance will provide evidence-based recommendations to develop sustainable procurement frameworks, ensuring long-term usability and integration. Future research will be instrumental in guiding policymakers toward procurement reforms that enhance the adoption of medical devices through sustainable public procurement systems.

10. Conclusion

The aim of this chapter is to understand how procurement processes in Malawi can be structured to support the sustained adoption of medical devices. The discussion integrates key insights from the research to provide an analysis of procurement dynamics and institutional design necessary to long-term medical device integration.

Section 10.1 presents a comprehensive evaluation of the main research question, synthesising the findings on procurement structures, stakeholder interactions, and systemic barriers that influence sustained adoption. **Section 10.2** outlines the practical implications of the study.

10.1 Answer to the Main Research Question

To support the sustained adoption of high-cost medical devices in Malawi, procurement processes need to move beyond a narrow focus on initial acquisition costs toward a more comprehensive approach that considers the TCO. Incorporating TCO into procurement planning could help ensure that devices remain functional over time. However, making procurement decisions that align with actual needs also requires better information on what devices are already available in healthcare facilities. The absence of a central system to track medical devices limits the MoH's ability to assess what equipment is available, making needs assessments and resource allocation less effective. Strengthening procurement decision-making will require better alignment with actual facility needs and long-term use considerations, including supplier commitments for maintenance and training. Over time, building toward an evidence-based procurement system will require monitoring and evaluation mechanisms to track functionality and use. Without such systems, devices may remain unused or fall into disrepair due to minor faults or missing parts, undermining their value and long-term impact. Establishing monitoring and evaluation tracking systems could provide essential data for making informed procurement choices and for planning maintenance and training needs. By embedding these elements into procurement frameworks, Malawi can work toward an evidence-based system that supports the long-term adoption and functionality of high-cost medical devices.

Yet, sustained adoption of high-cost medical devices is shaped not only by procurement decisions but also by the broader institutional structures within which these decisions take place. While Malawi's centralised procurement system ensures regulatory compliance and technical oversight, it often limits responsiveness to local needs, revealing a tension between national expertise and healthcare facility input. Addressing this tension requires rethinking how procurement responsibilities are shared between national and district levels to balance technical precision with practical usability. Moreover, navigating the trade-offs between transparency and competition on the one hand, and standardisation on the other, will be essential. Although procurement regulations prioritise fairness and cost-efficiency, they have also led to the procurement of diverse brands and models, complicating maintenance, training, and spare parts management. Moving toward greater standardisation, while maintaining competition, could facilitate easier integration of medical devices into clinical care. Ultimately, ensuring sustained adoption will require not only improved procurement processes but also institutional structures that enable better alignment between procurement, healthcare delivery, and long-term system needs.

10.2 Implications for Practice

Despite the limitations of context-specific data, this research underscores two areas that policymakers should consider in order to support sustained adoption of medical devices. First, procurement processes could move beyond a focus on initial cost and more explicitly incorporate long-term sustainability considerations. This includes adopting TCO to account for factors such as operation, maintenance, spare parts, and supplier service support. By embedding these elements into procurement planning, decision-makers can help ensure that devices remain functional and integrated into healthcare delivery over time. Establishing monitoring and reporting mechanisms on device functionality and use would also allow procurement decisions to be better informed by real needs and existing capacities within healthcare facilities.

Second, sustained adoption depends not only on how procurement decisions are made but also on the institutional structures. Policymakers should consider how procurement processes are governed to ensure that devices are suitable for the contexts in which they are used. This includes balancing centralised technical expertise with input from healthcare workers on the ground and navigating the trade-offs between maintaining open competition and moving toward greater standardisation of device types to ease maintenance and training. Aligning procurement practices with institutional structures that enable sustained use could strengthen the long-term value and functionality of medical devices within resource-constrained healthcare systems.

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Appendix A. Overview Tested Search Strings

Search	Concepts	Search String	Results	Reason of exclusion
1	Medical Devices LMICs Procurement	TITLE-ABS-KEY (("diagnostic*" OR "med*" OR “clinic*” OR “health*”) AND ("device*" OR “equipment” OR "technol*" OR “innovation*”)) AND (("low- andmiddle-income countr*" OR "lmics" OR "low-income countr*" OR "developing countr*" OR "less developed countr*" OR "underdeveloped nation" OR "resource-poor countr*" OR "economically challenged countr*" OR "impoverished nation" OR "socioeconomically varied countr*" OR "mixed-income countr*"))) AND (“procurement*” OR “purchas*” OR “acqui*” OR “donation” OR “donor*” OR “donated” AND “public*”)	…	Too many results
2	Medical Devices Sub-Saharan Africa Procurement	TITLE-ABS-KEY (("diagnostic*" OR "med*" OR “clinic*” OR “health*”) AND ("device*" OR “equipment” OR "technol*" OR “innovation*”)) AND ("Sub-Saharan Africa" OR "SSA" OR "Africa South of the Sahara" OR "West Africa" OR "East Africa" OR "Southern Africa" OR "Central Africa" OR "Kenya" OR "Uganda" OR "Malawi" OR "Nigeria" OR "Ethiopia" OR "Tanzania" OR "Ghana" OR "South Africa" OR "Zambia" OR "Senegal" OR "Mali" OR "Sudan" OR "Democratic Republic of Congo" OR "Burundi" OR "Zimbabwe" OR "Mozambique" OR "Rwanda" OR "Niger" OR "Botswana" OR "Lesotho" OR "Swaziland" OR "Namibia" OR "Sierra Leone" OR "Liberia" OR "Chad" OR "Cameroon" OR "Burkina Faso")AND (“procurement*” OR “purchas*” OR “acqui*” OR “donation” OR “donor*” OR “donated” AND “public*”)	1.454	Too many results

3	Medical Devices Sub-Saharan Africa Procurement Neonatal	TITLE-ABS-KEY ((("diagnostic*" OR "med*" OR “clinic*” OR “health*”) AND ("device*" OR “equipment” OR "technol*" OR “innovation*”)) AND ("Sub-Saharan Africa" OR "SSA" OR "Africa South of the Sahara" OR "West Africa" OR "East Africa" OR "Southern Africa" OR "Central Africa" OR "Kenya" OR "Uganda" OR "Malawi" OR "Nigeria" OR "Ethiopia" OR "Tanzania" OR "Ghana" OR "South Africa" OR "Zambia" OR "Senegal" OR "Mali" OR "Sudan" OR "Democratic Republic of Congo" OR "Burundi" OR "Zimbabwe" OR "Mozambique" OR "Rwanda" OR "Niger" OR "Botswana" OR "Lesotho" OR "Swaziland" OR "Namibia" OR "Sierra Leone" OR "Liberia" OR "Chad" OR "Cameroon" OR "Burkina Faso")AND (“procurement*” OR “purchas*” OR “acqui*” OR “donation” OR “donor*” OR “donated” AND “public*”) AND (“newborn” OR “neonat*” OR “postnatal” OR “infant*” OR “baby*” OR “new-born” OR (“new*” AND “born”))	178	Not enough results
4	Medical Devices Sub-Saharan Africa Procurement Public	TITLE-ABS-KEY ((("diagnostic*" OR "med*" OR “clinic*” OR “health*”) AND ("device*" OR “equipment” OR "technol*" OR “innovation*”)) AND ("Sub-Saharan Africa" OR "SSA" OR "Africa South of the Sahara" OR "West Africa" OR "East Africa" OR "Southern Africa" OR "Central Africa" OR "Kenya" OR "Uganda" OR "Malawi" OR "Nigeria" OR "Ethiopia" OR "Tanzania" OR "Ghana" OR "South Africa" OR "Zambia" OR "Senegal" OR "Mali" OR "Sudan" OR "Democratic Republic of Congo" OR "Burundi" OR "Zimbabwe" OR "Mozambique" OR "Rwanda" OR "Niger" OR "Botswana" OR "Lesotho" OR "Swaziland" OR "Namibia" OR "Sierra Leone" OR "Liberia" OR "Chad" OR "Cameroon" OR "Burkina Faso")AND (“procurement*” OR “purchas*” OR “acqui*” OR “donation” OR “donor*” OR “donated” AND “public*”) AND (“public”)	382	**Chosen search string**

Appendix B. Informed Consent Form

Informed Consent Form

You are being invited to participate in a research study titled Evaluation of Public Procurement of Medical Devices and Equipment for Newborn Care in Malawi. This study is being conducted by Tosca van Oostrum from TU Delft.

The purpose of this research study is to gather insight in the current dilemmas during the procurement of medical devices and equipment for newborn care in Malawi. The interview will take approximately 45 minutes to complete. The findings will be used as part of a Master's thesis. During the interview, we will ask you questions related to your experiences and perspectives on the procurement processes for newborn care devices, including challenges faced and strategies used.

As with any online activity, there is always a risk of a data breach. However, to the best of our ability, your answers in this study will remain confidential.

In the course of this study, the following types of data will be *collected* and *stored*:

1) Data collected in the Informed Consent form (*names* and *signatures*)
2) Signed Informed Consent forms
3) Email addresses and/or other addresses for digital communication
4) Names
5) Demographic information: area of living (*region*)
6) Professional experience (*years*)
7) Organization (e.g., Hospital/NGO/Government)
8) Job description and domain of activity

In the course of this study, the following types of data will be *collected*:

1) Demographic information: area of living (*region*)
2) Professional experience (*years*).
3) Organization (e.g., Hospital/NGO/Government).
4) Job description and domain of activity

The research data, comprised of recordings and transcripts, will be stored on TU Delft's secure institutional storage and accessible only to the TUD Research team. All personal data will be handled in accordance with the European General Data Protection Regulation (GDPR). Personal data will be securely deleted 1 month after the completion of the project.

Your participation in this study is entirely voluntary. You are free to withdraw at any time without providing a reason. Additionally, you can choose to skip any question that you are uncomfortable answering. If you wish to withdraw your data after completing the interview, please contact us within one month of participation.

The results of this study will be published in a Master's thesis. Only aggregated data and anonymized quotes will be used in any publication to ensure that individual responses remain confidential.

I agree that my responses, views or other input can be quoted anonymously in research outputs.	Yes	No

By signing this informed consent form, you indicate that you have read and understood this information, and agree to participate in this study.

Signatures

_____	_____	_____
Name of participant [printed]	Signature	Date

For more information or if you have any questions about this research, please contact:

Tosca van Oostrum (Corresponding Researcher)

Saba Hinrichs-Krapels (Responsible Researcher)

Appendix C. Interview Outline

Introduction

- Explain the purpose of the interview and how the information will be used.
- Ask for informed consent and if the meeting can be recorded.

1) Can you tell me about your role in the procurement of medical devices and equipment?
2) Can you walk me through how the process of procuring medical devices typically happens?
   > Are there specific steps you always follow?
   > Who else is involved in this process?
   > Where in the process? Or in which step?
3) Could you share a recent example of a medical device that was procured?
   > How was the need for it identified?
   > How was the decision made about which device to buy?
4) What challenges do you face during the procurement process?
5) Are there differences in the process when the equipment is donated or funded by external development partners?
6) Are there any guidelines or frameworks that you use when planning procurement?
   > Do these guidelines align with what happens in practice?
7) What do you consider when you procure medical devices and equipment?
   > To what extend does long term adoption plays a role in these considerations?
   what do
8) How are funds allocated for purchasing medical devices?
   > How are these funds distributed across districts?
   > What happens with sales from private wings?
   > How are these earnings used? Are they used for the maintenance or procurement of medical devices?

Closing Question

1) Is there anything else you think is important for me to know about the procurement process?
2) Who else do you think I need to speak to?

Thank you for your time and insights!

Appendix D. Definitions of Determinants of AsAS Model

Table 7. Definitions of Determinants of ASaS Model (Sun et al., 2024)

External Context	
Sociopolitical context	Relating to or involving a combination of social and political factors. The political context focuses on the distribution of power, assets, and interests within a population, as well as the range of organisations involved, their interests, and the formal and informal rules that govern interactions between them. Also comprises the health care system and its accessibility (e.g., delivery of services, leadership and governance, health information, human resources, and financing).
Interorganizational networks	Includes the linkages and connections among organisations and other stakeholders that enable social support and flows of information within a community or healthcare system.
Funding	Fiscal support can target multiple levels (e.g., staff training, fidelity monitoring, provision of the innovation) involved in implementation and delivery/use of the innovation
Client Advocacy	Support/marketing for system change based on consumer needs, priorities, and/or demographics
Leadership	Characteristics and behaviors of key decision-makers pertinent at all levels who are necessary but not sufficient to facilitate or promote the implementation process and delivery/use of the innovation
Internal Context	
Organizational characteristics	Structures or processes that take place and/or exist in organizations that may influence the process of implementation
Leadership	Characteristics and behaviors of key decision-makers pertinent at all levels who are necessary but not sufficient to facilitate or promote the implementation process and delivery/use of the innovation
Individual adopter or provider characteristics	Shared or unique characteristics of individuals (e.g., provider, supervisor, director) that influence the process of implementation
Monitoring and evaluation	Processes or procedures undertaken to ensure adherence to the active delivery of the innovation/EBP and/or an implementation strategy.
Staffing	Processes or procedures in place at an organisation related to the hiring, review, and retention of staff involved in the active delivery of the innovation/EBP and/or its implementation.
Intervention Characteristics	
“”	Factors relating to the characteristics of the innovation to be implemented. Innovation factors can also relate to the relationships of various stakeholders with intervention developers and the flexibility or rigidity in the use of the innovation.
Bridging Factors	
Community engagement	Mobilising community resources, community-academic partnerships, and facilitated community support to meet the needs of patients
Purveyors/intermediaries	Individuals, groups, or communities who aim to facilitate the effective and

	sustainable implementation of CHIs. Intermediaries provide consultancy and training services to governments, organisations, etc., and also develop and implement different health-services and projects for them

Appendix E. Qualitative Coding Approach

This study employed a framework analysis approach, utilising the ASsS model to ensure a systematic and structured coding process. While the ASaS model provided a predefined framework for categorising data, an additional inductive review was conducted to capture emergent themes beyond the established structure. The qualitative data were analysed using a deductive thematic coding approach, structured around the four ASAS constructs, which provided a comprehensive framework for examining barriers and facilitators within procurement practices in Malawi. Importantly, these constructs were not introduced to participants during the interview process. Instead, open-ended questions encouraged unbiased and candid responses, which were later systematically categorised within the ASaS framework.

Before the coding process, an independent analysis was conducted to map the public procurement structure in Malawi and identify key stakeholders. While this analysis provided essential contextual understanding, it was not part of the coding process itself.

The coding process followed a three-step structured approach:

Step 1. Categorisation by ASAS Constructs
Relevant citations were systematically categorised under one of the four ASAS dimensions.

Step 2. Refinement of Constructs through Determinant Sub-Themes
Within each construct, determinants were introduced as sub-themes to further classify the data, as outlined in Table 8. This approach, based on the ASaS model presented by Sun et al. (2024), facilitated a structured classification of procurement-related barriers and facilitators.

Table 8. Coding Framework

Construct	**Determinant**
Outer Context	Sociopolitical Context
	Funding
	Interorganisational Networks
	Client Advocacy
	Leadership
Inner Context	Organisational Characteristics
	Leadership
	Individual Adopter
	Monitoring and Evaluation

	Staffing
Intervention Characteristics	
Bridging Factors	Community Engagement
	Purveyors

Step 3. Inductive Review to Identify Emerging Themes Beyond ASaS Constructs
Although the coding was primarily deductive, an inductive review was conducted to identify themes beyond the ASaS model that stakeholders deemed critical for sustained adoption. This approach ensured that significant emerging themes were not overlooked due to the predefined structure. Recurring themes outside the ASaS model were analysed separately to evaluate their relevance to procurement and determine whether the model comprehensively captured all relevant determinants of medical device adoption.

To maintain coding consistency, definitions from Sun et al. (2024) were used as reference points, as presented in **Appendix D**. Additionally, Table 9 presents the determinants of intervention characteristics that Sun et al. (2024) identified as relevant to adoption.

Table 9. Determinants of Intervention Characteristics (Sun et al., 2024)

Characteristics	**Definition**
Communication	Effectively communication among healthcare workers and participants.
Quality and fidelity monitoring/support	Continuous data collection plus collection across the sites to promote quality monitoring … costs and its consistency with the initial plan of the project. reflexive monitoring (formal and informal appraisal of the benefits and costs of the intervention).
Geographical	Circumstances associated with a physical location that affect humans living within a specific area.
Project champion	Individuals who dedicate themselves to supporting, marketing, and 'driving through an [implementation]'.
Resources	Resources dedicated for implementation and on-going operations, including money, training, education, physical space, and time; mobilising community resources.
Stakeholder involvement	-
Supervision	The action, process, or occupation of supervising especially: a critical watching and directing (as of activities or a course of action).
Support system or tool	Any hardware, software and other tools and/or utilities used to support complex health interventions. Example: information and

	communication systems facilitated rather than hindered the implementation and sustainability of a new CCM.
Technology advance or environment	-
Time-cost	-

The structured coding process resulted in the systematic representation of findings, which are presented in **Chapter 7**. Table 10 provides an overview of the frequency of sub-themes identified in the qualitative data.

Table 10. Frequency of Constructs and Determinants in Coded Data

Construct	**Determinant**	**Frequency**
Outer Context	Sociopolitical Context	15
	Funding	4
	Interorganisational Networks	3
	Client Advocacy	-
	Leadership	5
Inner Context	Organisational Characteristics	7
	Leadership	2
	Individual Adopter	3
	Monitoring and Evaluation	5
	Staffing	-
Intervention Characteristics		24
Bridging Factors	Community Engagement	-
	Purveyors	-