Implementing medical devices in low- and middle-income countries

Enabling and hampering conditions for implementation – The case of Strokefinder MD100 in Western Cape, South Africa

Master's thesis in Quality and Operations Management

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Cover: The Strokefinder MD100 device used in the case study conducted in Western Cape, South Africa. A detailed description of the device is provided in Section 3.6.2

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Summary

Stroke is a leading cause of death and disability globally, with a particularly heavy burden falling on low- and middle-income countries (LMICs). Despite the existence of diagnostic innovations that could improve stroke care, a persistent implementation gap prevents many evidence-based technologies from reaching routine clinical use. This study examines the enabling and hampering conditions for implementing medical devices in stroke diagnostic processes in LMICs, using the Strokefinder MD100 in the Western Cape, South Africa as the empirical case.

The study is conducted prior to implementation and applies the Consolidated Framework for Implementation Research (CFIR) as its primary analytical lens, complemented by change management theory. Data is collected through a case study design, combining three qualitative methods: interviews, observation, and document study.

The findings show that the Western Cape healthcare system operates under significant structural strain, shaped by resource constraints, and a fragmented stroke pathway in which most patients fall outside the treatment window. Within this context, Strokefinder MD100 is identified as most applicable in the early stages of the pathway, where it could support faster triage and more targeted referral decisions. Twelve conditions are identified across CFIR's five domains as influencing implementation, each capable of functioning as either enabling or hampering depending on how it is managed.

Based on the findings, the study proposes a framework that differentiates implementation implications along two dimensions, enabling versus hampering, and static versus dynamic, where static conditions are fixed and must be designed around, while dynamic conditions can be actively influenced. This yields four categories, each carrying different implications for action. Furthermore, sustainability is identified as a cross-cutting condition not adequately captured within CFIR's existing domains, and is proposed as an additional construct of particular relevance in LMIC contexts.

Keywords: Change management, Implementation conditions, Implementation science, Low- and middle-income countries (LMICs), Medical device implementation, Resource-constrained settings, South Africa, Stroke diagnostic.

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Linn Andersson Pitkänen, Gothenburg, June 2026
Maja Quist, Gothenburg, June 2026

List of Acronyms

Below is the list of acronyms that have been used throughout this thesis listed in alphabetical order:

CFIR	Consolidated Framework for Implementation Research
CT	Computed Tomography
EMS	Emergency Medical Services
HIC(s)	High-Income Country/Countries
HTA	Health Technology Assessment
LMIC(s)	Low- and Middle-Income Country/Countries
MRI	Magnetic Resonance Imaging
SA	South Africa
SAHPRA	South African Health Products Regulatory Authority

Contents

List of Figures

List of Tables

1

Introduction

This chapter provides a background to the study, covering the global burden of stroke in low- and middle-income countries (LMICs), the implementation gap, and the role of implementation frameworks in bridging research and practice. The purpose and research questions are then presented, followed by the scope and limitations of the study.

1.1 Background

Stroke is a global disease and a major public health problem, as it is the second leading cause of mortality worldwide (Bersano & Gatti, 2023; Tribelhorn et al., 2021). The burden is greatest in LMICs, where the number of deaths is highest (Tribelhorn et al., 2021). In African countries specifically, many individuals have low awareness of their own health conditions and the risks associated with them, even for key risk factors of stroke such as hypertension and diabetes (Akinyemi et al., 2021; The Economist Intelligence Unit Limited, 2014). Consequently, preventive measures are less effectively implemented, contributing to the increasing burden of stroke in the region. HIV is also a known risk factor for stroke, where South Africa (SA), as an LMIC with the world's largest HIV-positive population, faces a particularly high stroke burden (Akinyemi et al., 2021; Tribelhorn et al., 2021; Zuma et al., 2022).

There are two types of strokes, ischemic and hemorrhagic (Bersano & Gatti, 2023), where there is a short time window for effective treatment and management (Saver, 2006). This aligns poorly with access to treatment in SA, as healthcare has clear deficiencies (Malakoane et al., 2020). Dysfunctional emergency care, staff shortages, lack of equipment, and long waiting times are the reality in SA and represent clear limitations to receiving the rapid, necessary care required in ischemic stroke. In addition, computer tomography (CT) and sometimes magnetic resonance imaging (MRI) are currently needed to diagnose stroke, which is often a time-consuming step even after the first contact with healthcare services (Persson et al., 2014). Stroke detection and diagnosis with a portable microwave helmet is under development and could be a solution to these healthcare system-related challenges in stroke care. Because it is portable, the helmet can be located where the patient is first encountered, for example in emergency rooms and ambulances, and thereby contribute to

the faster diagnosis and treatment required (Persson et al., 2014).

Despite being clinically proven effective, the existence of a medical technology alone does not constitute value. Instead, value depends on successful implementation in clinical practice, which is often limited by a gap between research and practice (Adam et al., 2013; Brailsford, 2023; Last et al., 2018). Innovations often take time to be fully adopted, and in some cases, they never make it into practice at all. This implementation gap leads to a situation where there is substantial potential for solutions and improvements in healthcare, but where implementation itself becomes a barrier to translating this potential into practice. The reasons for inadequate implementation vary and may include organizational, structural, as well as individual factors (Pitsillidou et al., 2021). Lack of time, insufficient support from top management, and resistance to change are some of the reasons that stand in the way of successful implementation (Lee et al., 2025). Moreover, innovations are particularly challenging in LMICs due to factors such as country-specific healthcare system constraints and demographic burdens (Dutta & Dhar, 2024).

As a response to the implementation gap, a range of theories, models, and frameworks have been developed to address the need to bridge this gap (Wang et al., 2023). These approaches have been shown to facilitate the development of a shared language and a common conceptual understanding. In addition, they can guide implementation planning and support the identification and analysis of critical factors for successful implementation. Through a clearer understanding of these factors, the likelihood of successful implementation increases (Nilsen, 2015). However, these types of implementation frameworks have been criticized for being weakly grounded in theory and therefore providing limited explanations of why or how an implementation succeeds or fails (Moullin et al., 2020; Nilsen, 2015). Without underpinning theories, it has been difficult to determine whether outcomes are due to chance, context, or other factors. In recent years, the use of frameworks in combination with additional theories, such as psychology and organizational theory, has therefore increased to enable a more in-depth understanding of the mechanisms and contextual factors that influence implementation outcomes (Nilsen, 2015).

Further criticism directed at existing implementation frameworks is the lack of connection to already existing processes within organizations (Breimaier et al., 2015). The frameworks do not sufficiently consider that healthcare innovations are implemented in environments with established routines, rather than in neutral environments. This lack of consideration risks leading to duplication of work, inefficient use of resources, and resistance from affected staff, as implementation does not build on the organization's actual starting point. This becomes particularly problematic where healthcare systems are often characterized by limited resources (Dutta & Dhar, 2024), making inefficiencies particularly costly.

In addition, implementation outcomes are highly influenced by contextual conditions such as infrastructure, staffing capacity, sociocultural norms, and access to training and technical support (Leonard et al., 2020; Nnaji et al., 2021). Failure to account

for these contextual factors may therefore limit the sustainability and long-term integration of medical devices within existing healthcare systems (Malkin, 2007). These limitations suggest that, although frameworks exist to guide implementation, there is still limited understanding of how medical devices are actually integrated into existing processes.

1.2 Purpose and research questions

To address these limitations, this study is conducted prior to implementation to examine how a medical innovation can be integrated into existing organizational processes within a new context. It aims to examine the enabling and hampering conditions for the implementation of medical devices in stroke diagnostic processes in LMICs. By identifying that, this study seeks to generate actionable insights to support in translating diagnostic innovations into clinical practice.

Based on the identified problem and the purpose of this study, three research questions have been formulated. To identify enabling and hampering conditions for the implementation of medical devices in stroke diagnostic processes in LMICs, it is necessary to first establish an understanding of the current context for implementation and how these conditions influence the implementation of the specific medical device. Accordingly, the first research question of this study is:

[1] What is the current implementation context for stroke diagnostic processes in the Western Cape, South Africa?

After the current implementation context for stroke diagnostic processes in LMICs have been established, it is necessary to identify which conditions that enable and hamper the implementation of medical devices in stroke diagnostic processes in LMICs. Consequently, the second research question is:

[2] Which are the enabling and hampering conditions for an implementation of medical devices in stroke diagnostic processes in LMICs?

By identifying enabling and hampering conditions for the implementation of medical devices in stroke diagnostic processes in LMICs, it becomes possible to determine implications for achieving a successful implementation. Accordingly, the third research question is:

[3] What are the implications for achieving a successful implementation of medical devices in stroke diagnostic processes in LMICs?

1.3 Scope and limitations

This study focused specifically on the implementation of the medical device Strokefinder MD100, despite the existence of several other new medical devices within stroke diagnostics. The scope of the study has therefore been limited to Strokefinder MD100, as this was commissioned by the project owner. However, as the study focused solely on implementation and not on factors such as technical performance, improved patient outcomes, or clinical effectiveness, the findings are assumed to be largely generalisable to the implementation of other medical devices, as the analysis is limited to implementation rather than device-specific clinical characteristics.

Furthermore, the study is based on the assumption that a successful clinical study of Strokefinder MD100 has already been conducted. A successful clinical study implies that the product has been investigated and demonstrated safety and/or efficacy (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, 2016). Accordingly, this study assumes that Strokefinder MD100 functions adequately from a clinical perspective, and therefore does not evaluate its medical performance, patient outcomes, or related clinical effectiveness aspects. While health economic evaluations are commonly used to assess clinical utility and value, such considerations were beyond the scope of this study and have therefore not been included in the analysis.

While this study does not constitute a full Health Technology Assessment (HTA), it addresses several of its core domains. HTAs typically encompass clinical efficacy, health economics, ethics, and organizational aspects. The present study contributes primarily to the organizational domain, examining the contextual and structural conditions for implementation within the Western Cape healthcare system. Cost and funding are addressed as implementation conditions, and regulatory requirements through SAHPRA are discussed, thereby touching on the economic and legal dimensions of HTA. However, clinical efficacy and formal health economic analysis, such as cost-effectiveness or QALY assessments, fall outside the scope of this study, as the clinical value of Strokefinder MD100 is assumed based on existing evidence. As such, this study can be understood as a pre-implementation complement to a full HTA, providing the organizational and contextual insights.

This study was conducted solely in the Western Cape in SA, and did not include other LMIC contexts. The study has therefore been delimited to the Western Cape only. This may have had an impact on the generalisability of the findings to other LMIC, as only the Western Cape was studied. However, SA is a LMIC and, like other LMICs, has a high stroke burden, resource constraints, demographic burdens, as well as other characteristics typical of LMIC settings, which suggests that the findings still provide relevant insights for similar contexts.

In addition, the scope of this study has been limited to the public healthcare sector in the Western Cape. The private healthcare sector has therefore been excluded, as an implementation of Strokefinder MD100 was not considered relevant in that

context. Unlike the public sector, private hospitals in the Western Cape are already equipped with CT scanners, meaning that patients suspected of stroke already have rapid access to CT imaging. Consequently, implementing Strokefinder MD100 in the private setting would not alter the existing stroke pathway, as CT scanning would still be required upon hospital arrival to confirm the type of stroke. Therefore, Strokefinder MD100 was not considered suitable for implementation within the private healthcare sector, and is consequently not further analyzed in this study.

2

Theoretical background

This chapter presents the theoretical background of the study. The theoretical background consists of two main parts: implementation science and change management. First, an introduction to implementation science is presented, followed by an overview of implementation frameworks and a more detailed examination of the Consolidated Framework for Implementation Research (CFIR), before implementation within LMICs is addressed. The chapter subsequently introduces change management as a complementary theoretical perspective, covering the concepts planned and emergent change, resistance to change, and readiness for change, before concluding by situating change management within a healthcare context.

2.1 Implementation science

Implementation science concerns how new innovations can be brought into practical, routine use in healthcare (Bauer et al., 2015; Bauer & Kirchner, 2020). Within healthcare, the actual effect and benefit of an innovation are crucial, but in addition to this, implementation focuses on how the innovation is taken up and used in practice. Without successful implementation, a clinically useful innovation has little real-world value (Adam et al., 2013). In medical research, the terms efficacy and effectiveness are often employed, where the former refers to how an innovation performs under ideal conditions and the latter to how it functions in real-world clinical settings (Bauer & Kirchner, 2020). However, these two aspects alone do not appear to be sufficient to ensure the routine use of an innovation. This is where implementation science becomes relevant, as it addresses the question of how innovations can be put into practice. The focus thus shifts from function to use.

The main reason for the need for implementation science is the gap between research and practice (Last et al., 2018). Studies have often estimated that it takes approximately 17 years for innovations to reach routine clinical use, and that effective innovations achieve clinical usage in fewer than 50% of cases (Balas & Boren, 2000; Morris et al., 2011). Implementation gap therefore refers to the gap between an innovation being developed and it being used in practice and producing real benefit (Brailsford, 2023). To achieve higher-quality care, there is therefore great potential in starting to use already evidence-based solutions instead of discovering something

new (Last et al., 2018). However, studies from many countries still indicate that a substantial number of patients receive care that is not grounded in evidence (Grol, 2001). In addition, the implementation gap may be even larger in LMICs, where approximately 70% of medical devices developed in high-income countries (HICs) fail to be successfully implemented or used effectively in these contexts (Malkin, 2007).

The implementation gap has several consequences, with patient benefit at its core. Evidence-based solutions that could improve care quality are often not implemented in practice and therefore do not achieve the best possible patient outcomes (Last et al., 2018). In addition to affecting quality of care, the slow or absent use of innovations leads to a waste of resources. Due to multiple factors, it is estimated that over 80% of medical research funding is inefficiently used because it does not translate into practical value (Chalmers & Glasziou, 2009). This also means that society's investments in medical research do not generate the return they could if innovations were implemented in practice (Bauer & Kirchner, 2020).

2.1.1 Implementation frameworks

There are many theories about why implementation gaps arise and what should be done to avoid them (Wang et al., 2023). Theories, models, and frameworks are used within implementation science to understand and analyze implementation. Common purposes include identifying barriers and facilitators, specifying the implementation process, and evaluating implementation outcomes (Moullin et al., 2020; Nilsen, 2015; Wang et al., 2023). Failing to use the existing theories and frameworks may lead to a waste of resources and incorrect conclusions, where, for example, contextual factors risk being misunderstood (Proctor et al., 2012). Frameworks can be used before an implementation, during the implementation process, and afterwards as an evaluation tool (Moullin et al., 2015). The most common practice is to use frameworks during the implementation phase, even though it is also important to apply them earlier in the process.

The three main purposes of theories, models, and frameworks; identifying barriers and facilitators, specifying the implementation process, and evaluating implementation outcomes, can be further divided into additional categories (Nilsen, 2015). The first category describes how implementation should be carried out by outlining a series of stages and providing practical guidance. These are referred to as process models. However, they rarely identify the specific factors that influence outcomes and risk portraying implementation as more linear than it actually is (Nilsen, 2015). The second category is determinant frameworks, and unlike process models, these do not explain how change should be implemented. Instead, they help identify barriers and facilitators, and what influences change. They can be seen as a structured mapping of influencing factors and often include multiple levels, such as the individual level and the organizational level. One of the most widely used determinant frameworks is Consolidated Framework for Implementation Research (CFIR), which has integrated many different theories and organized them into domains (Nilsen, 2015).

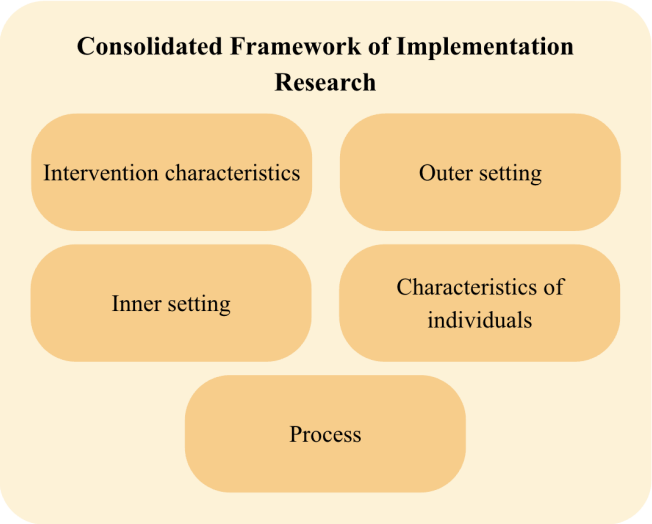
Additional categories aimed at understanding and explaining factors that influence implementation are classic theories and implementation theories (Nilsen, 2015). Classic theories originate from other fields, such as organizational theory and psychology. They can contribute to a deeper understanding of behaviors and mechanisms involved in change. Insights into organizational climate, culture, and leadership can help explain the implementation process through organizational influencing factors. Implementation theories focus on understanding implementation climate and readiness, also providing a deeper comprehension of factors contributing to implementation success.

The final category is evaluation frameworks, which are used to evaluate the implementation. These frameworks offer a structured approach for assessing the interventions undertaken during the implementation process. These different categories should not be used merely to label activities, but rather to recognize that different theories, models, and frameworks serve different purposes. They differ in what they analyze and the outcomes they produce, and understanding the intended purpose of the investigation is necessary for choosing the appropriate framework or method (Nilsen, 2015).

2.1.2 Consolidated Framework for Implementation Research

CFIR is the most widely used determinant framework (Nilsen, 2015), and will therefore be further outlined. It has combined multiple existing theories and helps evaluate factors influencing implementation and its success (Damschroder et al., 2009). The framework helps identify facilitators and barriers and systematically guides implementation across different contexts by highlighting the factors that influence its success. The framework is divided into five domains to capture the complex factors that affect implementation; intervention characteristics, outer setting, inner setting, characteristics of individuals and process, as illustrated in Figure 1. Below, each domain and its content are described.

Figure 1
Consolidated Framework for Implementation Research domains.



Note. Own illustration based on Damschroder et al. (2009).

2.1.2.1 Intervention characteristics

Intervention characteristics include the factors that have influenced the development of the intervention as well as its defining attributes that shape how it can be implemented (Damschroder et al., 2009). First, the source of the intervention is evaluated. It may have emerged internally as a solution or been developed in a more top-down manner by researchers or vendors. Depending on the source and its credibility, this can affect implementation. The intervention should also demonstrate high quality and have proven benefits. In the case of a medical device, this involves conducting a successful clinical investigation to establish safety and efficacy. The adaptability of the intervention is also highly important (Damschroder et al., 2009). It should be able to adapt to local needs and contexts without compromising the core idea of the intervention. Certain components or system supports should be flexible if required in the specific context.

Furthermore, the possibility to piloting the intervention on a small scale can facilitate learning and refinement during implementation as it provides opportunities for experience and reflection (Damschroder et al., 2009). The complexity of the intervention plays a critical role in this learning process as staff must be able to understand and adopt the new approach, where more complicated interventions can hinder learning and slow adoption. The complexity may also arise from the number of individuals, teams, or departments involved. When the intervention is evaluated, it will be compared with alternative solutions, making its relative value an important consideration. Finally, the costs associated with the intervention and its implementation are crucial for success, and the available resources in the context will determine whether these costs can be managed effectively (Damschroder et al., 2009).

2.1.2.2 Outer setting

The outer setting refers to the external context surrounding an organization that influences implementation (Damschroder et al., 2009). Patients are a major part of the outer setting, and their needs should be prioritized first. All forms of interventions in health care should have a positive impact on patients' well-being, and organizations that focus on this are more likely to succeed with implementation. The organization's networks and collaboration with external actors can also influence implementation, as strong relationships outside the organization make it easier to introduce new interventions. Competitive pressure from competitors can drive implementation, especially for late adopters who may have a high need for change in such situations. Finally, the outer setting includes external policies and incentives. In health care, there are regulations governing what can be implemented and how it should be done to ensure safety for staff and patients. Government regulations influence how implementations are conducted, which can result in contextual variations depending on the geographic location of the implementation (Damschroder et al., 2009).

2.1.2.3 Inner setting

The inner setting encompasses the internal organizational context in which implementation takes place (Damschroder et al., 2009). The inner setting is complex, and there are challenges in understanding how the different parts and levels of the organization influence one another. The organization's structural characteristics can affect implementation. These include the number of units and departments, the relationship between managers and staff, whether decisions are made centrally, as well as the organization's size and maturity. The networks and communication within the organization, where relationships and team cohesion play a key role, are also crucial for effective implementation. Successful implementation requires clear communication of the mission and goals, an open feedback culture, and high-quality informal communication. By achieving these elements, implementation is more likely to succeed (Damschroder et al., 2009). One reason implementation initiatives often fail is that the visible, tangible aspects of the organization are mapped, while assumptions, ways of thinking, and culture are not taken into account. People are often unaware of the culture, yet it plays a crucial role in the success of an implementation.

An additional aspect of the inner setting is the implementation climate (Damschroder et al., 2009). The perceived need for change, the extent to which stakeholders recognize and value the change, plays a crucial role in shaping this climate. Implementation climate is also influenced by the degree of compatibility between the intervention and the existing organizational culture, structures, and workflows. For successful implementation, the intervention must align not only with formal procedures but also with individuals' norms, values, and everyday practices. The greater the perceived alignment between stakeholders' own views on the need for change and the way the change is communicated and introduced, the more likely the implementation process is to succeed. Furthermore, a positive implementation climate requires a psychologically safe environment that encourages reflection and learning,

as well as a setting in which individuals feel valued and respected. Clear goal setting, effective communication, and ongoing feedback are also essential components (Damschroder et al., 2009).

The final construct within the inner setting is readiness for implementation (Damschroder et al., 2009). Leadership commitment is a central determinant of implementation readiness, as leaders at all levels need to be actively engaged in and supportive of the implementation process. Their involvement signals priority and fosters motivation throughout the organization. The availability of resources, such as funding, education, and sufficient time, also strongly influences the level of readiness. Without adequate resources, even well-supported initiatives may struggle to be effectively integrated into practice. Another key component of readiness is access to information and knowledge. This includes having experienced staff, access to experts, appropriate training opportunities, and supportive systems that enable staff to understand and apply the intervention (Damschroder et al., 2009).

2.1.2.4 Characteristics of individuals

The individuals involved in and affected by the implementation also play a crucial role in determining its success (Damschroder et al., 2009). Their characteristics are highly influential on the implementation's outcomes. An individual's attitude toward the implementation is a key factor, largely shaped by their knowledge and beliefs about the intervention. Positive experiences and perceived benefits enhance motivation, while negative experiences can generate resistance. Confidence in the ability to carry out the change is also critical, as higher self-efficacy increases the likelihood of accepting the intervention. Moreover, individuals may be at different stages of change, which can influence the outcomes. These stages can include awareness of the innovation, understanding, acceptance, implementation, and maintenance, with different types of barriers potentially emerging at each stage (Grol, 2001).

An individual's perception of the organization significantly influences both their motivation and capacity to enact change (Damschroder et al., 2009). The quality of the relationship with the organization shapes the willingness to invest the additional effort that successful implementation may require. Without a sense of identification or connection to the organization, engagement in the change process is unlikely. Furthermore, implementation outcomes are affected by personal attributes, including competence, motivation, and innovativeness (Damschroder et al., 2009).

2.1.2.5 Process

The implementation process consists of four key activities: planning, engaging, executing, and evaluating (Damschroder et al., 2009). Planning involves establishing a clear method for implementation and ensuring its quality. The goal of this phase is to design an action plan and build the capacity needed for successful implementation. Plans will vary depending on the context and target group. Engaging focuses on actively involving and motivating people to support the intervention. Of-

ten underestimated, this step is crucial for success. Early engaged users can foster a positive climate around the intervention and help spread it to others. Engagement can take several forms. Opinion leaders influence colleagues' attitudes and behaviours through authority or credibility. Formally appointed internal leaders, such as project leaders, are responsible for driving the implementation. Champions actively support and promote the intervention, sometimes risking their status. Finally, consultants, researchers, or external experts provide formal influence and specialized support (Damschroder et al., 2009).

The execution phase follows the planned approach, keeping to the established timeline while actively involving the relevant individuals (Damschroder et al., 2009). Throughout implementation, continuous reflection and evaluation help generate insights and support learning. This can take the form of formal assessments or personal reflection. By doing so, the process can be adjusted as needed, improving effectiveness and ensuring that the intended goals are achieved (Damschroder et al., 2009).

2.1.2.6 Criticism and research

CFIR is an established framework and one of the most widely used implementation frameworks (Damschroder et al., 2022). Several studies have examined the framework in which it has both been applied and evaluated. It has been described that by using the domains within CFIR, relationships among different factors can be systematically identified (Breimaier et al., 2015). The framework is characterized as helpful and logically structured (Damschroder et al., 2022), and when CFIR is incorporated early in the process, there is a greater likelihood of successful implementation (Kirk et al., 2016). It is recommended that the framework should be applied proactively prior to implementation in order to identify potential barriers and thereby mitigate them. However, despite this, it is most commonly used post-implementation (Means et al., 2020). Research on CFIR, which has primarily been conducted in HICs, indicates that the most influential domains are process, inner setting, and characteristics of innovation, with particular emphasis on the process domain, especially in relation to fostering engagement (Schmitt et al., 2025). These domains appear to have the greatest influence on successful implementation outcomes.

While CFIR is described as helpful and logically structured, criticism has also been directed toward the framework (Damschroder et al., 2022). It has, for example, been characterized as overly complex to fully comprehend and apply in its entirety. Given the broad range of constructs it encompasses, addressing all domains within CFIR may be perceived as overwhelming in an implementation process. Determinant frameworks such as CFIR are also primarily descriptive rather than explanatory, which may be considered a limitation in terms of providing deeper causal understanding (Nilsen, 2015). Additional classical theories, such as those derived from psychology and organizational theory, may therefore be necessary to develop a more comprehensive understanding. By integrating such underpinning theories, the applications of CFIR can become more valuable. Another limitation that has been

identified concerns the insufficient involvement of frontline staff (Breimaier et al., 2015). Engaged frontline staff are critical to successful implementation. Consequently, it has been recommended that stakeholder engagement be more explicitly incorporated as an aspect within the process domain.

One reason identified for why implementation initiatives often fail despite careful execution relates to contextual factors (Damschroder et al., 2022). Implementation never occurs within a neutral environment; therefore, pre-existing structures, conditions, and events must be taken into account during the introduction of an intervention (Breimaier et al., 2015). It has consequently been argued that CFIR should be complemented with elements within its domains that more explicitly address the existing context, given its substantial influence on outcomes. Contextual factors are described not merely as baseline conditions, but as dynamic elements that continuously shape the implementation process, both positively and negatively (Damschroder et al., 2022; May et al., 2016). Implementation is an interaction between the intervention and the context, where the two interact dynamically (May et al., 2016). Whether the implementation succeeds will depend on how flexible the context is and whether it can make room for the intervention, as well as how adaptable the intervention is and whether it can be adjusted to fit the context.

When using implementation frameworks, context is described at different levels (Nilsen & Bernhardsson, 2019). The micro level relates to patients and their expectations, attitudes, and needs. The meso level refers to the organizational context, including structures, culture, climate, and readiness for change. The macro level encompasses the wider environment, such as policies, research findings, and legislation. However, relatively few frameworks address this broader aspect of context in depth. In addition, there are multi-level dimensions that span several contextual levels, such as leadership, time constraints, and financial resources. All of these levels may be important in implementation processes, and context therefore needs to be understood holistically to create the best possible conditions for successful implementation (Nilsen & Bernhardsson, 2019). At the same time, although context plays a central role, there is limited representation of LMICs in the applications of CFIR. As a result, much of the knowledge generated through the framework is largely based on HIC settings, and may therefore be insufficiently adapted to LMIC contexts (Damschroder et al., 2022).

In LMICs, contextual factors often manifest as staff shortages, lack of equipment, and unstable funding for implementation (Damschroder et al., 2022). These types of contextual conditions are decisive in determining whether an implementation effort succeeds or fails and are therefore critical to consider. When applying CFIR in LMICs, certain components of the framework have been subject to criticism (Means et al., 2020). Due to hierarchical structures, there is a more top-down culture, and patients' needs have less influence on decision-making processes. This makes the CFIR construct patient needs and resources difficult to operationalize in these settings. For similar reasons, capturing individuals' individual stages of change may also be challenging, as individual readiness tends to be less relevant in LMICs

compared to HICs.

Given the more top-down organization of many LMIC health systems, system-level characteristics become increasingly important. Consequently, characteristics of systems has been proposed as a potential additional domain within CFIR when applied in LMIC contexts (Means et al., 2020). In such settings, it becomes particularly important to understand how the health system is organized, how funding mechanisms operate, how the innovation aligns with existing policies, and whether there is long-term availability of resources. The CFIR domains intervention characteristics and outer setting have been identified as presenting the greatest barriers (Means et al., 2020). This contrasts with similar investigations in HICs, where the outer setting is not considered as critical (Schmitt et al., 2025). These differences indicate that implementation determinants may operate differently depending on context.

2.1.3 Enabling and hampering factors for implementation in low- and middle-income countries

Hampering conditions to implementation can arise at multiple levels within an organization, including the individual, team, organizational, and broader societal levels, all of which may hinder successful implementation (Ayoubian et al., 2020; Grol & Grimshaw, 2003). At the individual level, obstacles may relate to negative attitudes, limited time, or insufficient knowledge. At the team and organizational levels, barriers can instead involve weak leadership or a lack of administrative support. More broadly, at the societal level, insufficient policy support and decision-makers who do not prioritize implementation may further impede progress, where collaboration between research, policy, and practice could function poorly (Ayoubian et al., 2020; Grol & Grimshaw, 2003).

The challenges that arise during implementation in LMICs are primarily related to structural and contextual factors (Meshkovska et al., 2023). Political support and policies are a major part of this aspect, where political commitment and financing play an important role in successful implementation (Leonard et al., 2020; Nnaji et al., 2021). Effective governance can function as a bridge between local initiatives and broader system-level change, enabling real change (Kosiol et al., 2024). Conversely, a lack of political engagement and regulatory frameworks that work against rather than support implementation can also act as significant hampering conditions. Financing involves not only securing funding for the initial implementation but also ensuring that it is sustainable over time (Leonard et al., 2020). Without long-term funding, implementation efforts risk failing, and the financial resource constraints in LMICs therefore represent a major hampering conditino to successful implementation. It has been shown that the purchase price is not usually the primary financial barrier (Malkin, 2007). Instead, challenges related to operation, maintenance, and consumables often limit sustained use. Access to spare parts and consumables is frequently restricted and sometimes prohibitively expensive.

To ensure successful implementation, the intervention must be functional and there

must be sufficient knowledge about it, which is achieved through training and adequate support (Nnaji et al., 2021). It also needs to be user-friendly and adapted to the local needs of the context (Leonard et al., 2020). A common misconception is that medical equipment must be simple to succeed in LMICs (Malkin, 2007). In reality, failures are rarely due to an inability to learn how to use the equipment, however, training must be continuous. LMICs often experience high staff turnover, which means that training on equipment needs to be recurring and easily accessible so that new staff can gain the same knowledge as more experienced staff (Leonard et al., 2020). Moreover, technical expertise, tools, and service manuals are often lacking, making repairs difficult even when spare parts are available (Malkin, 2007). A lack of these resources is another example of situations where implementation may initially succeed but fails to remain sustained over time.

The most common factor that hamper implementation is the lack of resources, both human and material (Leonard et al., 2020; Nnaji et al., 2021). Regardless of how effective an intervention is, it cannot succeed if there are insufficient resources to support and manage it (Leonard et al., 2020). Human resource constraints include overburdened staff and therefore limited planning capacity prior to implementation. In addition, staff shortages lead to time constraints, resulting in limited opportunities for training and the introduction of new practices. This means that there is often insufficient time to introduce a new intervention, and when staff are already working near their capacity limits, new interventions may be perceived as an additional burden (Nnaji et al., 2021). There is also a lack of physical resources, which represents another common barrier in LMICs (Leonard et al., 2020). Unreliable power supply, unstable internet connectivity, and a lack of ambulances are examples of factors that frequently hinder implementation, particularly when interventions are designed in HICs where such infrastructure is assumed to be readily available (Leonard et al., 2020).

An explanation for why interventions developed in HICs often fail to fit the conditions in LMICs is the lack of designing for dissemination (Last et al., 2018). This means that when developing any form of innovation or intervention in healthcare, it is important to consider how it will be used in practice. Instead of trying to force something that doesn't fit a system, the needs, resources, and timeframes of those who will use it are taken into account already in the design process. This approach creates greater and better opportunities for a successful implementation (Last et al., 2018). Specific adaptations are required not only in the design phase but also in the implementation, where implementation context plays a major role (Adlung et al., 2025). The use of simple models does not always capture the complexity that certain contexts entail, and therefore consideration of the context prior to an implementation is of great importance (Last et al., 2018). Especially in LMICs, challenges often depend on the local context (Adlung et al., 2025).

It has been noted that the use of implementation frameworks often fails to adequately consider the local context (Damschroder et al., 2022). Contextual factors that may act as both facilitators and barriers include the political system, economic

conditions, and infrastructural circumstances (Leonard et al., 2020). In addition, the sociocultural context may act as a barrier, where social norms, cultural and religious beliefs, and lack of community acceptance can hinder successful implementation (Leonard et al., 2020; Nnaji et al., 2021). Geographic factors may also function as contextual enabling or hampering conditions, as distances to healthcare services, transportation options, and the characteristics of the landscape can influence several practical aspects of implementation (Leonard et al., 2020).

Leadership can also act as an enabler in implementation (Nnaji et al., 2021). Strong and supportive leadership is an important factor in contributing to actual change, staff motivation, and the stability of the implementation. Authentic leadership has been described as important for inspiring others and building trust (Kosiol et al., 2024). A key facilitator related to leadership is the presence of a champion, a person who drives the innovation forward and engages others in the process (Leonard et al., 2020). Different roles within an organization may take on the role of champion and help address challenges during implementation. However, leadership in LMICs often takes the form of more hierarchical structures (Means et al., 2020), which can hamper implementation (Kosiol et al., 2024; Nnaji et al., 2021). This can result in decisions being made far from those working in practice, limited opportunities for staff to express their ideas, and reduced collaboration. Instead, implementation tends to benefit from open communication, collaboration, and opportunities to share ideas (Kosiol et al., 2024).

In addition to leadership, organizational culture is another factor that influences whether an implementation succeeds or not (Kosiol et al., 2024; Leonard et al., 2020). Attitudes toward change within the organization, staff norms, motivation, and values are all elements that can affect the implementation process (Leonard et al., 2020). A culture that is supportive of innovation encourages experimentation and learning from mistakes as part of ongoing development (Kosiol et al., 2024). If these aspects are lacking, resistance to change may arise, both at the organizational level and among staff, which can instead become a barrier to implementation. However, at the individual level in LMICs, factors were more often enablers rather than barriers (Meshkovska et al., 2023), suggesting that organizational culture may play a more significant role.

Successful implementation requires the involvement of multiple actors, and collaboration between them is crucial for the outcome of the implementation (Leonard et al., 2020). Strong relationships are needed between stakeholders such as researchers, healthcare professionals, and policymakers. These actors also need to have shared perceived goals in order to reduce conflicts over priorities and minimize resistance (Nnaji et al., 2021). To enable effective collaboration between these different actors, careful and well-functioning information sharing is necessary to ensure that communication reaches all parties involved (Kosiol et al., 2024). Challenges such as language barriers and a lack of trust between stakeholders are not uncommon. Poor coordination among actors within the health system can instead become a hampering factor to implementation (Leonard et al., 2020).

Achieving successful implementation requires identifying and addressing both enabling and hampering conditions (Leonard et al., 2020). Particularly prominent in LMICs is the lack of resources, including shortages of staff, limited financing, and insufficient physical infrastructure. Clear and supportive leadership, adequate training, and a well-adapted intervention are key components for enabling successful implementation. Overall, efforts should focus both on reducing structural barriers and on strengthening the factors within the system that facilitate the adoption of new practices (Leonard et al., 2020).

2.2 Bridging implementation science and change management

As highlighted in the critique above, CFIR is a structured and well-established framework for identifying factors that influence implementation; however, the framework itself is descriptive rather than explanatory (Nilsen, 2015). To understand the mechanisms that drive or hinder change, complementary theories are required. Implementation frameworks such as CFIR therefore need to be grounded in established theories from fields such as organizational theory and psychology in order to provide a deeper understanding of the identified factors (Nilsen, 2015).

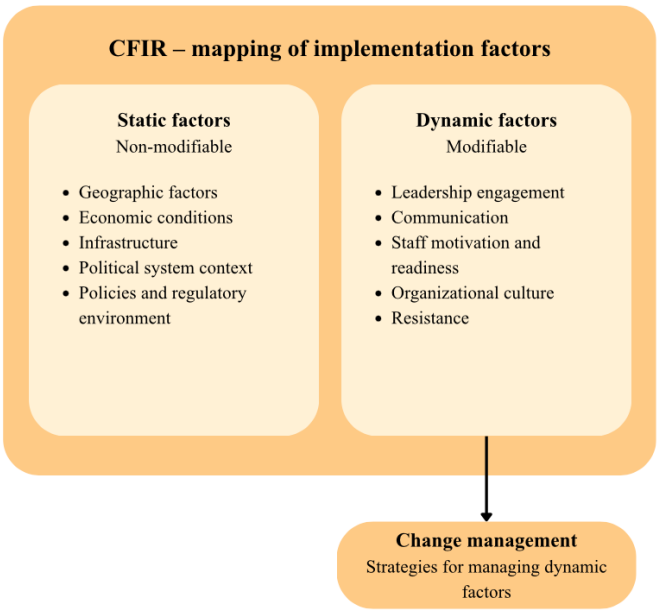
A central distinction within CFIR concerns the degree to which implementation factors can be modified. Damschroder et al. (2009) differentiate between non-modifiable and modifiable factors. Non-modifiable factors include contextual elements such as geographic conditions, economic constraints, infrastructure, and political or regulatory environments, which shape implementation but cannot be directly changed through implementation efforts. Modifiable factors, in contrast, include elements such as leadership engagement, communication, staff motivation and readiness, organizational culture, and resistance to change, which can be influenced and actively addressed during implementation (Damschroder et al., 2009; Leonard et al., 2020).

This distinction provides an important foundation for understanding implementation conditions not only in terms of their presence, but also in terms of their responsiveness to change processes. On this basis, factors that are largely non-modifiable can be understood as relatively static in nature, whereas modifiable factors are more dynamic, as they may both influence implementation and be influenced by it as implementation unfolds.

These modifiable factors are what constitute the focus of change management. While CFIR provides a systematic mapping of what influences implementation, change management offers the tools and strategies for how these factors can be actively managed and shaped (Todnem By, 2005). Change management can therefore be understood as the practical and process-oriented complement to CFIR's analytical framework, and as the additional theoretical perspective needed to help explain the mechanisms underlying implementation (Nilsen, 2015). Together, they enable a more complete understanding. The distinction between static and dynamic factors,

as well as the role of change management in influencing dynamic factors, is illustrated in figure Figure 2.

Figure 2
Bridging implementation science and change management.



Note. Own illustration inspired by Damschroder et al. (2009).

2.3 Change management

Change management concerns the process through which an organization reaches its desired future state (Lorenzi & Riley, 2000). Thus, change management supports and facilitates the organization in achieving its desired condition. However, change is not viewed as a temporary state, rather, it is a continuous condition and process that must be regularly reviewed (Todnem By, 2005). Consequently, change management can be seen as a constant process of reviewing an organization's direction, structure, and capabilities in order to continually meet changing internal and external demands. Therefore, to assist organizations and employees during change, change management encompasses a range of models and strategies (Phillips & Klein, 2023).

A common distinction in the change management literature is between planned and emergent change, which represent different approaches to how organisational change unfolds (Todnem By, 2005). Planned change is typically characterised by a top-down logic where change is initiated and directed by management, with the aim of moving the organisation from a current to a desired future state in a controlled manner. However, this approach has been criticised for assuming relatively stable conditions and for being less suitable in fast-changing environments where change cannot easily follow predefined stages (Todnem By, 2005).

In contrast, emergent change is viewed as a more continuous and adaptive process that develops in response to internal and external conditions rather than following a fixed plan. It is often more bottom-up in nature, involving contributions from different levels of the organisation and making use of tacit knowledge that may not be visible in planned approaches (Mladenova, 2022). When applied effectively, this bottom-up involvement can increase the likelihood of successful change, as more employees feel engaged and understand the purpose of the change (Hastings, 2025). At the same time, emergent change can be less focused and more diffuse due to its open-ended nature, making it particularly suitable for operational or implementation-level changes rather than large-scale strategic transformations (Mladenova, 2022).

A well-known model for how change should be implemented is the eight-step model for transforming an organization developed by Kotter (1995). Kotter's model consists of eight steps that an organization should go through when undergoing change: establishing a sense of urgency, forming a guiding coalition, creating a vision, communicating the vision, empowering others to act on the vision, planning for and creating short-term wins, consolidating improvements, and finally institutionalizing new approaches. Accordingly, the model provides a clear structure for how change can be driven step by step. However, it assumes that change occurs sequentially and linearly, even though change is often iterative and parallel, especially in situations characterized by rapid and continuous change (Carreño Sepúlveda, 2025). Therefore, Kotter's model remains a strong strategic framework for managing change, but it should be adapted with more flexible approaches such as lean, agile, or other methodologies.

2.3.1 Resistance and reaction to change

Resistance to change has long been viewed as an obstacle to change and as something inherently negative (Piderit, 2000). In such cases, resistance has, for example, been explained by self-interest, meaning that the individual may fear losing status, power, or other advantages. It may also stem from factors such as misunderstanding the change, lack of trust in the person initiating the change, differing evaluations of the situation affected by the change, or a low ability to adapt (Kotter & Schlesinger, 2008).

However, the view of resistance has become more nuanced over time (Kotter & Schlesinger, 2008). Instead of seeing resistance as something purely negative, it can be seen as a signal that there may be problems in the change process that need improvement. Resistance can also function as constructive criticism and as a way to enhance the change process (Khaw et al., 2022). This implies that resistance should no longer be viewed as an obstacle, but rather as feedback and a valuable resource (Ford & Ford, 2010). In other words, resistance itself should not be seen as the problem in change processes; rather, it is management's way of interpreting and handling reactions that may turn it into obstacles. Managers should therefore stop labeling objections solely as resistance and instead listen to what the reactions actually signal. For example, asking many questions may be interpreted as engage-

ment from one perspective, but as push-back from another. Resistance should thus be regarded as a resource that can be used to clarify the purpose of the change, increase participation, clarify strategy, and improve the change process itself (Ford & Ford, 2010).

Therefore, instead of viewing reactions to change as purely opposition, a more multidimensional perspective has been proposed (Piderit, 2000). According to this perspective, an individual's reaction to change can be understood through three dimensions. The first is the cognitive dimension, which represents what the person thinks and believes about the change. The second is the emotional dimension, which reflects what the individual feels about the change. The third is the intentional dimension, which represents how the person intends to act in response to the change, for example, whether they will oppose it, support it, or take other actions. By understanding individuals' reactions through these three dimensions, it becomes evident that a person may hold mixed feelings and evaluations. For instance, an individual may have negative emotions toward the change, believe that it could be beneficial, yet still act against it (Oreg, 2006; Piderit, 2000).

The structure of the three-dimensional model of reaction is explained by personality and context (Oreg, 2006). These factors determine how reaction is made up and help explain why reaction differs between individuals. In this context, personality refers to an individual's general predisposition to resist change in general and primarily influences the emotional dimension, and partly the intentional dimension. Contextual factors can be divided into two aspects: the expected outcomes of the change and the way the change is implemented. The expected outcomes concern what the change will lead to and may affect factors such as power, employment, autonomy, and similar aspects. These outcomes primarily influence the cognitive and emotional dimensions. The implementation of the change involves factors such as whether employees receive sufficient information about the change, trust in management, and related aspects, which primarily influence the intentional dimension (Oreg, 2006).

Another way to explain the causes of reactions, according to the three-dimensional model of reaction, is through the two components: pre-change antecedents and change antecedents (Oreg et al., 2011). Pre-change antecedents consist of two parts that influence the individual's reaction: the characteristics of the change recipient and the internal context. The characteristics of the change recipient refer to aspects such as personality traits, demographics, needs, and similar factors that affect the individual's perceptions. The internal context, on the other hand, concerns the environment in which the change takes place and includes aspects such as whether there is a supportive environment, the organizational culture, and organization commitment, all of which also influence the individual's reaction. The second component that explains reactions, change antecedents, instead concerns factors that are directly linked to the change itself, namely, what the change process looks like, how the individual perceives the effects of the change, and what the change actually entails. However, how the change is implemented and communicated is, in many

cases, more significant for the individual's reaction than the content of the change itself (Oreg et al., 2011).

Importantly, individuals' reactions are decisive for whether a change initiative ultimately succeeds (Oreg et al., 2011). The interaction between the cognitive, emotional, and intentional dimensions of reaction, together with leadership style and communication among employees, determines how the outcome unfolds and may result in one or more of four possible individual responses: voice, exit, neglect, and loyalty behaviors (Khaw et al., 2022). For example, an individual may initially attempt to influence the situation (voice), subsequently shift toward neglect, and in some cases ultimately choose exit.

2.3.2 Readiness for change

To reduce the risk of resistance to change, employees need to be ready for the change, as employees who are not ready for change are more likely to resist it (Holt et al., 2007). Readiness for change can be defined through two main components: change commitment, appropriateness, and change efficacy (Ellis et al., 2023; Weiner, 2009). Change commitment, appropriateness, refers to the extent to which employees are willing to implement the change and perceive it as necessary. This perceived necessity is closely linked to the idea of discrepancy, meaning the extent to which employees perceive a gap between the current state and the desired future state (Armenakis et al., 1993). Change efficacy, on the other hand, refers to the extent to which employees' belief in their capability to successfully carry out the change. Consequently, a high level of readiness for change implies that employees both want to implement the change and believe they have the ability to do so (Armenakis et al., 1993; Ellis et al., 2023; Weiner, 2009).

Several factors contribute to the development of readiness for change. Firstly, the message surrounding the change is crucial (Armenakis et al., 1993)]. Employees need to understand that the change is necessary and recognize that the organization cannot continue in its current state. In addition, employees must believe that both they and the organization have the ability to carry out the change (Armenakis et al., 1993). This belief in the organization and employees' ability to implement the change is influenced by factors such as task demand and resource availability (Weiner, 2009). Task demand refers to what is required to carry out the change, including aspects such as the complexity of the change, the knowledge and skills required, and how the related activities should be organized. Resource availability, on the other hand, concerns whether the organization has sufficient resources to implement the change, such as time, money, and staff (Weiner, 2009).

Readiness for change is also created and influenced by interpersonal and social dynamics within the organization. This firstly includes the social influence of colleagues, managers, and other organizational members and their attitudes toward the change (Armenakis et al., 1993). Individual differences among employees also play a role, as some individuals are generally more open to change while others tend

to be more cautious. Furthermore, organizational culture can influence employees' readiness, as norms, motivation, and shared values shape how employees perceive and respond to change (Armenakis et al., 1993). For example, a strong teamwork culture characterized by collaboration and openness can contribute to employees feeling more informed and included in the change process (Ellis et al., 2023). When employees feel informed, their readiness for change tends to increase. Therefore, a positive team culture and effective communication can enhance employees' readiness for change. This also suggests that the change should ideally be communicated through multiple channels to increase readiness, such as informal conversations, emails, and dedicated newsletters about the change (Ellis et al., 2023).

Additional organizational factors that may influence the level of readiness include the timeframe allocated for the change, the level of organizational support, the presence of conflicts within the organization, and the priority given to the change within the organization (Weiner, 2009). Contextual factors may also influence readiness for change. These include external conditions such as competition, economic conditions, and regulations, all of which can influence an organization's readiness for change (Armenakis et al., 1993).

Another factor influencing and creating the level of readiness for change concerns how the change message is communicated, referred to as influence strategies (Armenakis et al., 1993). There are three main strategies for communicating change in ways that create readiness. The first is persuasive communication, which involves convincing employees of the purpose and urgency of the change in order to create acceptance and motivation among employees. The second strategy is active participation, which involves actively engaging employees in processes that allow them to discover and recognize the need for change themselves. The third strategy involves the use of external sources, such as media, consultants, and literature, to reinforce the message and highlight the need for the change (Armenakis et al., 1993).

2.3.3 Change management in healthcare

Healthcare systems face several challenges in meeting patient needs (Harrison et al., 2021). Quality, efficiency, safety, and accessibility are some of the key requirements that must be addressed, and change is necessary to achieve this. However, healthcare systems are complex, and it is not uncommon for change initiatives to fail despite the use of change management approaches. Strong clinical leadership, staff engagement, and a clear focus on patient benefit are factors that have positively influenced change initiatives in healthcare. Early involvement of relevant stakeholders, as well as effective collaboration between them, can also contribute to the success of change efforts. It is equally important to sustain the change over time in order to ensure long-term sustainability. Maintaining momentum and integrating the change into daily routines are therefore crucial for lasting success (Harrison et al., 2021).

While system barriers are identified as a major challenge in LMICs (Schmitt et al., 2025), this does not necessarily imply more rigid internal organizational structures

as in HICs. Instead, organizational structures in LMICs may in some cases enable change efforts more easily due to less regulation and fewer established complex structures (Silvola et al., 2024). With fewer regulatory barriers and requirements, change initiatives in healthcare in LMICs may be easier to implement, particularly when staff are engaged. Due to this flexibility, there is significant potential for working with change initiatives in this context (Silvola et al., 2024).

Despite flexible organizational structures, other barriers to change initiatives in healthcare remain (Ellis et al., 2023). Change can create uncertainty among staff, lead to resistance, and increase stress and the risk of burnout. Resistance has been shown to come from individuals with long professional experience as well as from those in leadership positions, which may be related to their level of responsibility and the risks that change processes can involve (Silvola et al., 2024). Resistance is also common among nurses and may arise due to several factors (Cheraghi et al., 2023). At the individual level, nurses may experience uncertainty, fear, or a lack of motivation when faced with new ways of working, particularly if they perceive the change as threatening their professional role or sense of security. At the same time, their attitudes may be influenced if information about the change is unclear, or if colleagues express negative attitudes, which can further reinforce resistance. Organizational factors also play an important role, such as how leadership communicates the change, whether staff are involved in decision-making, and whether sufficient resources and support are available (Cheraghi et al., 2023).

To successfully implement change initiatives in healthcare, these challenges need to be addressed early in order to avoid them (Cheraghi et al., 2023). It is also important that those affected by the change are involved throughout the entire process, highlighting the importance of participation and staff involvement (Silvola et al., 2024). Staff also need to be engaged through communication, information, and training in order to create motivation and understanding of the change. By understanding the importance and benefits of the change, it is more likely to be implemented successfully (Silvola et al., 2024). Despite the importance of creating motivation and understanding, these emotional aspects of change are often overlooked (Harrison et al., 2022). One aspect that is often missing in change initiatives is that organizations rarely work systematically to strengthen staff members' perception that the change has real value for them. It is therefore important that organizations involve staff in change processes so that they feel motivated to support the change, rather than simply complying with requirements.

3

Methodology

This chapter presents the methodology of the study. The chapter begins by outlining the research strategy and research design, followed by a description of the sampling of participants and the data collection methods employed, namely observation, interviews, and document study. An overview of the context of the study is then provided, including stroke, stroke in SA, and the Strokefinder MD100. The chapter subsequently presents the data analysis approach before concluding with a discussion of research quality and ethical considerations.

3.1 Research strategy

The study adopted an interpretive and constructionist approach, as individuals' interpretations, experiences, and contextual conditions were considered essential for addressing the purpose of the study and for identifying the conditions for successful implementation (Bell et al., 2022). This was particularly important in this research, as it was conducted in a LMIC, which differs substantially from many other contexts, such as those in the Western world. Consequently, contextual factors were of central importance. Accordingly, data were collected using qualitative methods in order to capture actors' perspectives, opinions, reflections, and lived experiences, rather than focusing on quantification (Bell et al., 2022). To conduct and structure the qualitative methods and to address the research questions of the study, an abductive research logic was applied. This was done by not departing exclusively from either theory or empirical data, instead, it involved a continuous interplay between theory and empirical data, in which theory informed what was examined in the empirical data, while the empirical data simultaneously shaped and refined the understanding of theory (Bell et al., 2022).

The CFIR framework as described in Section 2.1.2 was used to structure and guide both the research process and the data collection. As the framework is not originally developed for use in LMIC contexts, it was applied as a guiding point of departure for identifying relevant analytical domains and structuring the data collection, while also allowing the empirical findings to contribute new perspectives and insights to the framework (Means et al., 2020). In addition, change management theory was employed to provide complementary theoretical perspectives, which were subsequently

compared with the empirical findings.

3.2 Research design

Despite growing interest in medical devices for stroke diagnostics, there is limited research on the enabling and hampering conditions for the implementation of medical devices in stroke diagnostic processes in LMICs, particularly in the context of the Western Cape. Therefore, a case study is an appropriate choice of research design, as it enables the study of less explored areas and allows for an exploratory approach (Säfsten & Gustavsson, 2019). Furthermore, the study requires the study to be conducted in the actual setting where the implementation is intended to take place in order to gain an understanding of the conditions associated with the implementation. This necessitates examining the phenomenon within its real-world context, which can be achieved through a case study approach (Yin, 2018). In addition, the study requires a deep understanding of the local stroke diagnostic process and its related components, which a case study enables through in-depth analysis of the case.

In this study, the case is explicitly defined as the implementation of a medical diagnostic device within stroke diagnostic processes in Western Cape. Thus, the unit of analysis is the implementation in stroke diagnostic processes itself as it occurs within the Western Cape context. The study is therefore designed as a single-case study, meaning that only one unit of analysis, the implementation of a medical device in stroke diagnostics in Western Cape, is examined (Säfsten & Gustavsson, 2019). Although data were collected from multiple different participants, representing diverse professional roles and areas of expertise, these participants do not constitute separate analytical cases. Rather, each interview contributed complementary perspectives on the same overarching case. Therefore, the purpose is not to compare individual respondents or organizations, but to develop a comprehensive understanding of the implementation a medical device within the Western Cape context. Consequently, multiple data collection points were used to illuminate different dimensions of one single case within the same contextual setting.

3.2.1 Sampling of participants

As the study follows a qualitative research approach, purposive sampling was used for the selection of participants in combination with snowball sampling. Purposive sampling is the most commonly applied sampling strategy in qualitative research and is based on the deliberate selection of cases that are considered most suitable for addressing the research question and fulfilling the purpose of the study (Bell et al., 2022). Therefore, purposive sampling is a strategic selection of participants based on a set of predefined selection criteria, while snowball sampling is an approach in which the initial sample of participants is asked to suggest other individuals whom they believe to be appropriate for inclusion in the study (Bell et al., 2022).

Accordingly, participant selection began with purposive sampling based on a set of predefined criteria, ensuring that all chosen participants were considered appropriate

for the purpose of the study. To be included, participants were required to hold expertise in at least one of the following criteria:

- Technical expertise related to the StrokeFinder MD100
- Implementation of new medical devices in the South African context
- The Western Cape healthcare systems
- Clinical workflows related to stroke diagnostic processes
- Regulatory frameworks governing medical devices in South Africa
- Market access of new medical devices in South Africa

Technical expertise related to the Strokefinder MD100 was included to ensure access to in-depth knowledge about the device´s functionality, design, and operational requirements, which are important considerations for implementation. Implementation of new medical devices in the South African context was considered essential, as the study focuses on implementation and participants with experience of introducing medical devices in SA could provide insights into enablers, challenges and contextual factors specific to the setting. The Western Cape healthcare system was included as a criteria given that the study is geographically bounded to this area. Knowledge of the Western Cape's specific healthcare infrastructure, resource allocation, and organizational structures is necessary for assessing the implementation within this particular context.

Clinical workflows related to stroke diagnostic processes were considered relevant as the Strokefinder MD100 is intended for use within existing stroke care pathways. Understanding how stroke patients currently move through the healthcare system is critical for identifying where and how the device could be integrated. Regulatory frameworks governing medical devices in SA were considered a relevant criteria, as regulations influence the implementation of new medical devices. Market access for new medical devices in SA was included to capture the commercial dimensions of implementation, including aspects such as distribution channels and pathways for introducing new technologies into healthcare.

Following each data collection session with participants selected through purposive sampling, they were asked whether they could suggest other individuals whom they believed would be suitable participants for the study. If the researchers also assessed these suggested individuals as appropriate for inclusion, they were subsequently contacted and data collection was conducted with them as well.

However, access to participants constituted a separate practical constraint for the sampling. Access to participants within the healthcare sector in the Western Cape, is institutionally restricted, meaning that private external actors are generally unable to obtain access to contacts within healthcare systems. As a result, the study was dependent on existing professional networks to in some cases being able to facilitate access to participants. Consequently, this meant that the sample of participants to some extent reflected a form of fixed purposive sampling, as the sample to some extent determined in advance due to prior knowledge of which participants the study

would be able to access and which it would not (Bell et al., 2022). Nevertheless, there remained flexibility in the sampling process, as it was possible both to exclude certain participants and to seek access to additional ones.

3.3 Data collection

The case study employed three qualitative data collection methods: observation, interviews, and document study, in order to fulfill the purpose of the study. By combining these methods, triangulation was achieved, enabling both cross-verification of data and the identification of patterns across different data sources (Bell et al., 2022). Triangulation also ensured that the breadth of data necessary to address the research questions and fulfill the purpose of the study could be collected.

Data collection was carried out across multiple times, as the necessary conditions for collection all data simultaneously were not available at a single point in time. Certain types of data needed to be collected prior to others, and some stages of data collection led to additional data collection points that were not foreseeable at the outset, as a result of snowball sampling.

3.3.1 Observation

To address the first research question, an observation of the current conditions in one of the facilities involved in the diagnostic process was conducted in order to gain an understanding of some of the existing conditions within the stroke pathway. Observation enables the study to identify aspects that are typically difficult to capture through interviews which makes it a suitable method to include in the study (Bell et al., 2022).

The observation took place at one of the tertiary hospitals in the Western Cape, more specifically at the department where a CT scanner is located. Conducting the observation in the natural work environment enabled the study to capture real-time conditions as they occur (Säfsten & Gustavsson, 2019). The purpose of the observation was to gain insight into how work is carried out in practice in relation to the CT scanner and the associated queues, as the CT scanner represents an important node in the stroke pathway. The CT scanner is a critical part of the process, as it determines whether a stroke is hemorrhagic or ischemic, which subsequently determines the treatment that the patient should receive.

Furthermore, the observation was carried out using a passive participant approach, meaning that the observers were present but did not engage to any significant extent in the observed activities (Säfsten & Gustavsson, 2019). Through passive participation, the observers' influence on the observed situation was minimized, thereby supporting a more accurate representation of reality, which is essential for the purpose of this study.

3.3.2 Interviews

To address all three research questions of the study, interviews were conducted. Experiences, perceptions and information regarding the Western Cape healthcare system, its stroke diagnostic processes, and the conditions for implementation medical devices in this setting were required to answer the research questions. Therefore, interviews constituted an appropriate data collection method, as interviews are suitable when perceptions and experiences need to be collected, as well as for understanding actual conditions (Säfsten & Gustavsson, 2019).

The interviews were conducted using a semi-structured format, meaning that predefined questions were developed but only used primarily as a guide, allowing for additional specifying and follow-up questions to be asked (Bell et al., 2022). The predefined interview questions were designed based on the CFIR framework and its respective domains. This approach ensured that the interviews covered the areas of the framework relevant, while also allowing flexibility to ask follow-up questions in order to obtain more in-depth responses, clarifications, and explanations. Furthermore, it allowed participants to raise aspects beyond the CFIR domains, ensuring that the study was not limited to the framework alone, as additional important factors may exist outside the predefined structure.

The predefined interview questions differed between respondents, as their areas of knowledge and experience varied. In total, 17 interviews were conducted, involving participants with both similar and diverse professional roles and areas of expertise, as summarized in Table 1. Consequently, the specific focus of each interview was adapted to the respondent´s expertise, meaning that individual interviews addressed different aspects of the research topic. The interviews covered six main perspectives namely the technical expertise, implementation context, health systems, regulatory framework, procurement process, clinical workflow, and market access. As several respondents held expertise across multiple areas, some interviews addressed more than one perspective, as reflected in Table 1. To ensure anonymity, respondents are referred to by their professional role rather than by name. In cases where a specific role or organization could make a respondent identifiable, a more general role description has been used instead.

All interviews were audio-recorded and transcribed with the informed consent of each participant, in order to ensure the accuracy and completeness of the collected data. Transcription was conducted using TurboScribe, after which all transcripts were manually reviewed to verify transcription correctness.

Table 1
Summary of interviews

Interview number	Date	Respondent	Perspective	Duration	Location
1	18/2-2026	Representative from Medfeild Diagnostics	Technical expertise	75 min	Online
2	25/2-2026	PhD Student in Industrial Engineering, Stellenbosch University	Implementation context & health systems	60 min	Online
3	25/2-2026	PhD Student in Industrial Engineering, Stellenbosch University	Implementation context & health systems	65 min	Online
4	26/2-2026	PhD Student in Industrial Engineering, Stellenbosch University	Implementation context & regulatory framework	60 min	In person
5	3/3-2026	Health Technology Director at Southern Right HTM Consulting	Health systems & regulatory framework	90 min	Online
6	4/3-2026	Head of division of Emergency Medicine at Tygerberg Hospital	Clinical workflow & implementation context	90 min	In person
7	5/3-2026	Researcher with the Stroke group at the Neuroscience Institute and Emergency Medicine doctor at Groote Schuur Hospital	Clinical workflow & implementation context	90 min	In person
8	9/3-2026	Director of University of Cape Town MedTech Lab	Implementation context & regulatory framework	55 min	In person
9	9/3-2026	Operational Head of the Trauma Unit at Tygerberg Hospital and Division of Emergency Medicine	Clinical workflow & implementation context	60 min	In person
10	10/3-2026	Executive Head of the Department of Family and Emergency Medicine and Head of the Divison of Family Medicine and Primary Care, Stellenbosch University	Implementation context & health systems	60 min	Online
11	10/3-2026	Product Manager, Medical innovation company	Market access	30 min	Online
12	10/3-2026	Director Public Health and Commercial Excellence, Medical diagnostics company	Market access	60 min	Online

Interview number	Date	Respondent	Perspective	Duration	Location
13	12/3-2026	Chief Medical Officer at private health organization	Implementation context & health systems	75 min	In person
14	11/3-2026	Associate Professor of Emergency Medicine at University of Cape Town and Deputy Director at WHO Collaborating Centre for Integrated clinical care	Implementation context & health systems	90 min	Online
15	13/3-2026	Doctor at Groote Schuur Hospital	Clinical workflow & implementation context	30 min	In person
16	13/3-2026	Doctor at Groote Schuur Hospital	Clinical workflow & implementation context	30 min	In person
17	27/3-2026	Professor Biomedical Engineering, Stellenbosch University	Implementation context	65 min	Online

3.3.3 Document study

To gain an understanding of the current conditions, more specifically the legal conditions for the implementation of medical devices in stroke diagnostic processes, a document study was conducted. A document study is a data collection method in which secondary data are used as the primary source of information (Säfsten & Gustavsson, 2019).

This study included an analysis of public documents in the form of regulations, more specifically the regulations issued by the South African Health Products Regulatory Authority (SAHPRA). SAHPRA is the national regulatory body responsible for ensuring that medical devices on the South African market meet acceptable standards of safety, quality, and performance and therefore are the ones issuing all the regulations, guidelines and licenses (South African Health Products Regulatory Authority, n.d.).

The purpose of the document study was therefore to obtain knowledge regarding the regulatory requirements governing the implementation of medical devices in the Western Cape healthcare system. Consequently, the documents constituted data that already existed and were not originally produced for the specific purpose of this study.

3.4 Data analysis

The data collected through interviews, observation, and document study were analyzed using thematic analysis. Thematic analysis is a fundamental analytical approach in qualitative research and is used to systematically identify and analyze themes and patterns within the empirical data (Säfsten & Gustavsson, 2019). This approach was considered suitable for the study, as the empirical data encompassed both contextual descriptions of the current conditions and multiple conditions for successful implementation, both of which required structuring into coherent themes through the identification of overarching themes and patterns.

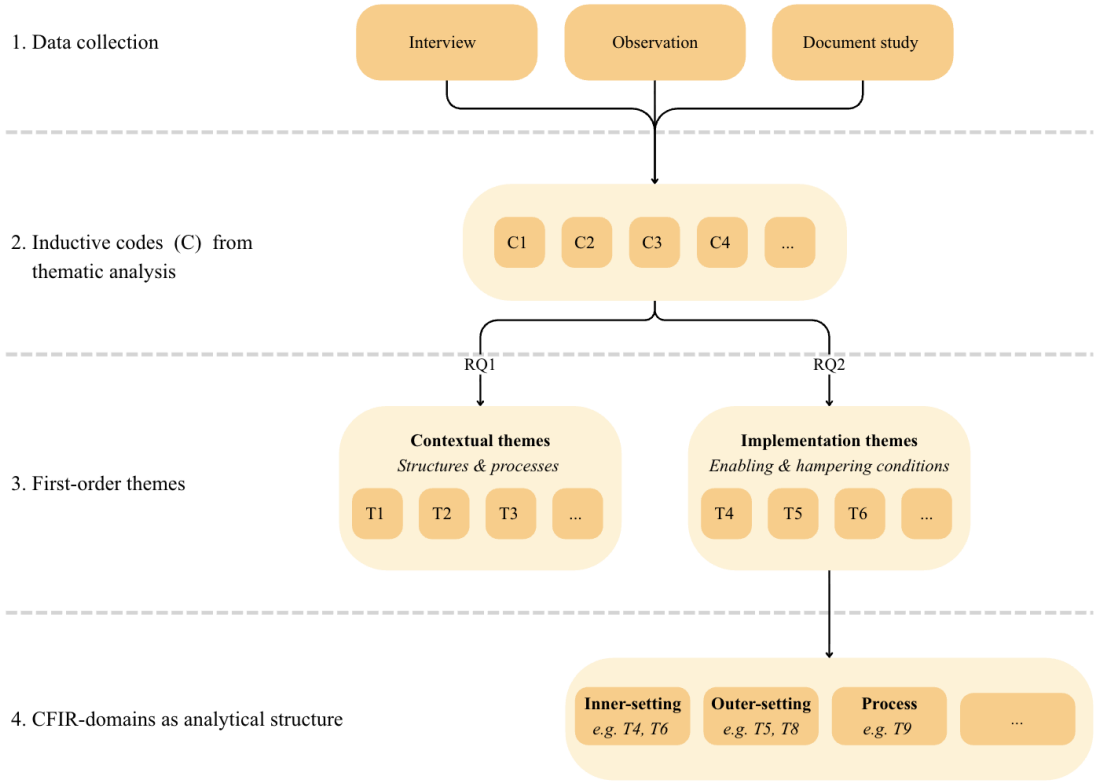
The analytical process followed the established steps of thematic analysis, including familiarization with the data, generation of initial codes, searching for and collating codes into themes, refinement and definition of themes, and subsequently interpreting these themes in relation to theory and context (Bell et al., 2022). The data collected during the case study were initially coded inductively in order to capture empirically derived codes. These codes therefore emerged solely from the data, without reference to existing theoretical frameworks, and were formulated using short explanatory descriptions.

Once the initial coding was completed, the codes were structured along two analytical paths corresponding to the first and second research questions respectively. The first path addressed the first research question by grouping codes that described the current context into first-order contextual themes. These themes capture the existing structures, processes, and circumstances that characterize the Western Cape healthcare system and its stroke diagnostic processes.

The second path addressed the second research question by grouping codes that represented enabling and hampering conditions into first-order themes. Each theme encompasses several related codes and represents a condition that can either facilitate or hinder a successful implementation of medical devices in stroke diagnostic processes.

Subsequently, in order to further structure the themes identified along the second path and examine their relationship to the CFIR framework, the themes were mapped onto the respective CFIR domains. This approach enabled an assessment of the extent to which the CFIR framework captures, or does not capture, the conditions identified as necessary for an implementation. The process of the data analysis is illustrated in Figure 3.

Figure 3
Summary of the data analysis.



Note. Own illustration.

The third research question was addressed through an integration of the findings derived from the first and second analytical paths. Rather than introducing a separate analytical procedure, the analysis for this question was conducted by applying the conditions identified in response to the second research question onto the context established through the first research question. In other words, the enabling and hampering conditions captured in implementation themes were examined in relation to the specific structures, processes, and circumstances characterizing the Western Cape healthcare system and its stroke diagnostic processes. This allowed for an assessment of how the identified contextual factors interact with, reinforce, or constrain the conditions necessary for a successful implementation of medical devices in stroke diagnostic processes in LMICs. By integrating the two analytical paths, the analysis moved beyond describing conditions in isolation and instead considered their implications within the specific healthcare context.

3.5 Data quality and ethics

Research quality in this study was ensured through several measures to ensure the trustworthiness. Trustworthiness consists of four criteria namely, credibility, transferability, dependability, and confirmability (Bell et al., 2022). These criteria were

considered throughout the research process in order to strengthen the quality of the study.

Credibility concerns the extent to which the findings accurately represent the social reality studied (Bell et al., 2022). This study ensured credibility as data were collected through triangulation across three complementary data collection methods interviews, observation, and document study which allowed for cross-verification and identification of consistent patterns in the empirical data. The 17 interviews involved participants with diverse professional roles and expertise, capturing a breadth of perspectives that contributed to a richer and more complete picture of the empirical data.

The in-person observation at one of the healthcare facilities in the Western Cape enabled firsthand insight into existing processes beyond what interviews alone could provide, which would have been difficult to capture through interviews alone and therefore strengthen the creditability. While the observation was limited to a single site, it served to confirm and contextualize findings from the interview data rather than to stand as evidence in isolation.

Transferability concerns the extent to which findings from one context can be applied to other settings (Bell et al., 2022). The study was conducted exclusively within the Western Cape, and findings are therefore most directly applicable to this specific context. However, SA shares several characteristics with other LMICs, including significant resource constraints, a dual public-private healthcare system, and high disease burdens. As the characteristics are similar, the findings are likely to hold a broader relevance beyond this particular context. Although the Western Cape is considered a relatively urbanized and comparatively well-resourced LMIC context, the healthcare system itself does not reflect this relative advantage. Several respondents explicitly noted the significant insufficiencies within the Western Cape healthcare system, including infrastructure limitations, staff shortages, and resource constraints. This indicates that, despite the region's relative prosperity, the healthcare conditions are more representative of typical LMIC settings than the regional context alone might suggest, thereby strengthening the transferability of the findings to other LMICs.

Dependability concerns whether the research process has been conducted in a transparent and systematic manner that would enable it to be audited (Bell et al., 2022). All interviews were audio-recorded and subsequently transcribed, which reduces the risk of human errors and enables verification of how empirical material was interpreted. The use of recordings also allowed for revisiting responses during analysis and confirm that interpretations were grounded in what was actually said. In addition, the research process has been clearly described in this study, including the participant selection, the data collection methods, and the analytical procedures, making it possible to follow how the study was conducted and how the results were produced.

Confirmability concerns the extent to which the findings reflect the data rather than the research's personal values or preferences (Bell et al., 2022). The analytical process taken in this study supported confirmability by beginning with inductive coding directly from the empirical material, prior to any mapping onto theoretical frameworks. This sequencing ensured that the conditions identified emerged from the data rather than being imposed by the CFIR structure from the outset. Only after the inductive coding was complete were the themes mapped onto CFIR domains, allowing the framework to serve as a lens rather than a predetermined template. While the CFIR framework also informed the development of the interview guide, its role was to ensure broad coverage of relevant domains in line with the study's purpose, rather than to direct respondents toward particular answers.

Ethical considerations were integrated throughout the research process. Prior to data collection, all participants were informed about the purpose of the study and how the data contributing with would be used. Participation was voluntary, and informed consent was obtained from each respondent before interviews were conducted, including consent for audio-recording and transcription. To preserve anonymity, respondents are referred to by their professional role rather than by personnel name.

3.5.1 Use of artificial intelligence

Throughout this study, artificial intelligence (AI) has been used as a supportive tool in two main areas. AI-based tools were employed during the transcription of interviews, as well as to improve the linguistic quality of the text by refining grammar, sentence structure, and terminology. All AI-generated output was thoroughly reviewed and assessed by the authors to ensure that the content accurately reflected the empirical material and remained consistent with the study's findings.

3.6 The context of the study

This study aims to investigate the implementation of a portable diagnostic microwave helmet for stroke within Western Cape health care system. The following section provides the context for the study, outlining stroke and the portable diagnostic microwave helmet, Strokefinder MD100. The SA's health care system is instead outlined in the empirical data.

3.6.1 Stroke

Stroke is a global disease and a major public health problem, as it is the second leading cause of mortality worldwide (Bersano & Gatti, 2023; Tribelhorn et al., 2021). It is a condition characterized by sudden, localized neurological problems caused by damage to blood vessels, either due to blocked blood flow (infarction) or bleeding (hemorrhagic stroke) (Murphy & Werring, 2023). Most strokes, 85%, are caused by infarction, called ischaemic strokes. Stroke is considered a result of the interaction between genetic, environmental, and lifestyle factors, meaning

that not only hereditary aspects play a role, but also socio-economic circumstances and personal habits (Bersano & Gatti, 2023). Risk factors beyond heredity include hypertension, diabetes, smoking, alcohol consumption, and physical inactivity.

In the case of stroke, every second counts for treatment. In ischemic stroke, it is crucial to rapidly recanalize the blocked blood flow, since brain tissue is rapidly damaged as the condition progresses (Saver, 2006). Every minute, 1.9 million neurons are lost, highlighting the importance of prompt treatment. Even in hemorrhagic stroke, time to treatment is critical, as the bleeding can continue for several hours and cause neurological worsening if not stopped (Mayer, 2003). By stopping the bleeding and reducing the pressure caused by the accumulated blood, the number of neurons lost can be limited, thereby improving prognosis and functional outcomes after stroke (Lv et al., 2024).

3.6.1.1 Stroke in South Africa

The burden of stroke is greatest in LMICs, where the number of deaths is highest (Tribelhorn et al., 2021). In SA, the incidence of stroke is increasing, driven by socioeconomic and epidemiological changes that have led to a higher burden of non-communicable diseases and an ageing population. One factor contributing to SAs high stroke rates is HIV infection (Tribelhorn et al., 2021). The country bears the world's largest HIV burden, with an estimated prevalence of about 20% (Zuma et al., 2022). The widespread HIV epidemic has no single explanation and is driven by a complex interplay of socio-behavioral and structural factors, contributing to the high burden of stroke in the country.

One of the main drivers of stroke is hypertension, and it remains a major health challenge in SA. The continent of Africa carries the highest burden of high blood pressure, yet preventive measures in SA are still limited, even though proper management could help control and monitor the condition (Tribelhorn et al., 2021). The healthcare system is inadequate and does not provide this type of health screening. It is characterized by low quality of care, as well as insufficient and outdated infrastructure (Malakoane et al., 2020). These characteristics also contribute to long waiting times, patients being transferred between different healthcare facilities, and in some cases being denied care, which can have serious consequences (Maphumulo & Bhengu, 2019). As mentioned, time to treatment in stroke is critical (Mayer, 2003; Saver, 2006), yet SA's health care lacks an organized system to ensure patients receive rapid assessment and treatment, which can significantly worsen outcomes.

3.6.1.2 Stroke diagnosis and treatments

In stroke care, rapid treatment is essential because of the limited time window for intervention (Mayer, 2003; Saver, 2006), yet treatment depends on first obtaining a diagnosis (Patil et al., 2022). First, clinical symptoms and triage are used to establish suspicion of stroke. Common symptoms include numbness, speech difficulties, and visual loss. In hemorrhagic stroke, there are also symptoms such as vomiting and seizures (McDermott et al., 2025). In case of suspected stroke, there are stroke

scales, which is a tool that, with the help of scoring, allows for an acute assessment (Patil et al., 2022). This type of scale is often used in prehospital and emergency care but has insufficient sensitivity and specificity to definitively confirm stroke. To subsequently confirm suspicion of stroke, some type of brain and neurovascular imaging is needed. Techniques used today include computer tomography (CT) and magnetic resonance imaging (MRI) to ensure stroke and the type of stroke (Patil et al., 2022). CT is most often used due to the time required for MRI.

It is essential to distinguish between different types of strokes, as they require different treatment approaches (McDermott et al., 2025). Ischemic stroke requires reperfusion therapies, such as thrombolysis and thrombectomy, to dissolve the obstructing blood clot. In contrast, hemorrhagic stroke is caused by bleeding, and thrombolysis in this context would be life-threatening. Instead, treatment must focus on controlling and stopping the hemorrhage (Patel & Mody, 1999). Therefore, accurate diagnostics is crucial to reliably determine the type of stroke that has occurred in order to ensure that the correct treatment can be provided.

Even though CT and MRI are currently necessary to reliably establish a diagnosis of stroke (Patil et al., 2022), access to these instruments is limited. Especially in economically poor regions, there is a lower level of access, as CT and MRI scanners are associated with high costs. This leads to many stroke cases remaining undiagnosed and untreated in these areas. Several portable and more cost-effective medical devices are under development to be used for diagnostic purposes in acute care units. These could be used as a complement to CT and MRI where availability is limited. These portable, more accessible devices could achieve widespread use, allowing more patients to receive appropriate care, and shorten the time to diagnosis if they prove to be clinically useful (Patil et al., 2022).

3.6.2 Strokefinder MD100

Microwave imaging and sensing are considered potential alternatives to CT and MRI. The technology emerged in the medical field during the 1980s and gained increasing research interest, along with early clinical investigations, in the early 2000s (Origlia et al., 2024). During this period, the use of microwaves in diagnostic and therapeutic medicine gained significant attention due to their considerable advantages over existing imaging modalities. One of the primary benefits is that microwave-based techniques do not rely on ionizing radiation, unlike imaging methods such as CT. In addition, microwave systems are generally more cost-effective.

The Strokefinder MD100, see Figure 4, has been developed by Medfield Diagnostics AB as a diagnostic method for stroke identification (Tsiftsis et al., 2024). It is designed as a helmet equipped with eight antennas arranged in four pairs, intended to be placed around the patient's head. Using microwave signals and an AI-based algorithm, Strokefinder MD100 can distinguish between patients with stroke and those without stroke (Persson et al., 2014). The device was originally designed for use in HICs. The purpose is to utilize the advantages of microwave technology in

prehospital care and emergency departments to enable faster stroke identification.

Figure 4
Strokefinder MD100.

Note. Reprinted from Persson et al. (2014).

The current version of the system is CE-marked for identifying the presence of stroke. In clinical evaluations, this version has demonstrated a sensitivity of approximately 97%, indicating a high ability to detect patients with stroke (Tsiftsis et al., 2024). The specificity is relatively low, around 48%, meaning that the system generates a considerable number of false-positive results. This design reflects a deliberate prioritization of sensitivity to minimize the risk of missing stroke cases.

The system is battery-powered and operated via a tablet-based interface. The device is equipped with two rechargeable batteries, allowing continuous operation by using one battery while the other is charged and available for replacement when depleted. All components are contained in a backpack, and the total weight of the system is approximately 6 kg. The device is considered safe for both patients and healthcare staff. It uses low-power microwave signals, with radiation levels lower than those emitted by a standard mobile phone. A study conducted on the Strokefinder MD100 demonstrated good feasibility, and is described as easy to use and transport, and fast in providing results (Tsiftsis et al., 2024). The device required 12 hours of training to operate and generated a response within 45 seconds. According to the existing study, it cannot replace CT, but it could improve early triage and support decision-making regarding the priority of imaging.

Future development aims to expand the system's capabilities beyond simple stroke detection. Additional algorithms are under development to differentiate between ischemic stroke, hemorrhagic stroke, and traumatic brain injury. These advanced functions are currently investigational and are not CE-marked.

4

Empirical data

This chapter presents the empirical data collected through the study and is structured in accordance with two of the research questions. The chapter begins by addressing the first research question through an overview of the implementation context in the Western Cape healthcare system. The chapter subsequently addresses the second research question by presenting twelve enabling and hampering conditions identified as influencing the implementation of medical devices in stroke diagnostic processes, before concluding with an overview of these conditions.

4.1 Implementation context in the Western Cape healthcare system

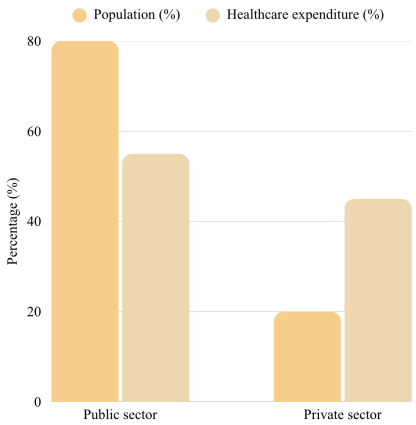
This section is divided into two sections: the current state of the healthcare system, covering the healthcare system, emergency medical services, the South African Health Products Regulatory Authority, and the stroke pathway and its associated delays, followed by an examination of the prospective implementation of Strokefinder MD100 within the stroke pathway in order to understand the context in which the device is most suitable.

4.1.1 Current state of the Western Cape healthcare system

The healthcare system in SA is characterized by a pluralist structure, consisting of both public and private healthcare sectors operating in parallel. According to the respondents, approximately 15-20% of the population utilizes the private sector while the remaining 80-85% depends on the public healthcare system. Despite this distribution, the respondents described healthcare expenditure as more evenly divided between the two sectors, where around 45% of total expenditure is attributed to the private sector while the remaining 55% comes from the public sector. It is therefore a common perception among the respondents that this results in a significant imbalance, where a smaller proportion of the population utilities a share of the healthcare expenditure nearly equivalent to that consumed by the majority of the population, this is visualized in Figure 5

Figure 5

Distribution of population and healthcare expenditure between the public and private healthcare sectors in South Africa.



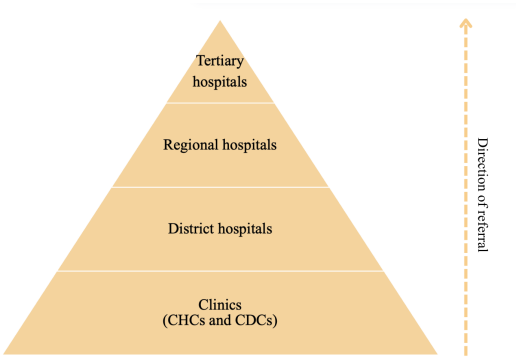
Note. Own illustration based on empirical data.

Due to this imbalance, the availability and speed of care differ significantly between the sectors. One respondent exemplified this by describing, " If you have two hospitals right next to each other, one is a private hospital with neurosurgery or interventional radiology, you will get excellent care, and right next door, you will probably get no care because you're waiting for a secondary transfer by ambulance to go get a CT scan at another hospital". Respondents therefore described the healthcare system as highly dependent on individual's financial resources, which determine which sector the patient enters.

The public healthcare system in the Western Cape was consistently described as operating under considerable pressure, with demand for healthcare services frequently exceeding the available supply of resources such as staff, diagnostic services, and treatment capacity. Within this context, the public healthcare system is structured according to a referral-based model consisting of multiple levels of care. These include clinics, which in turn include Community Health Centres (CHCs) and Community Day Centres (CDCs), district hospitals, regional hospitals, and tertiary hospitals. Each facility type is defined by the services it can provide. Patients initially seek care at the clinics and are then referred to district hospitals, followed by regional hospitals, and finally to tertiary hospitals when specialized services are required. This referral pathway is visualized in Figure 6.

Figure 6

General referral pathway within the Western Cape public healthcare system.

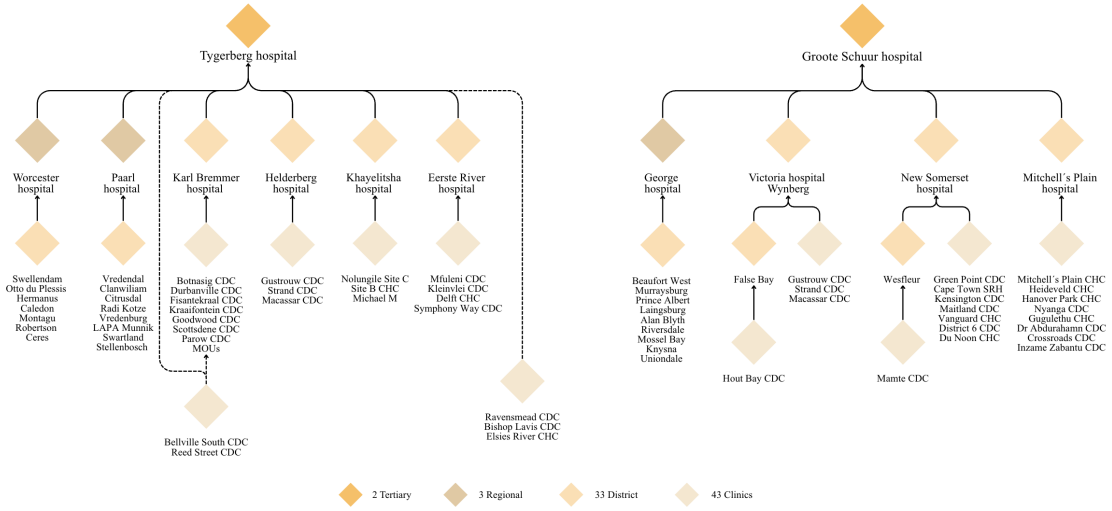


Note. Own illustration based on empirical data.

However, policies exist that allow critically ill patients to bypass lower-level facilities in order to receive care faster. However, respondents explained that this is rarely feasible in practice, as it would risk overloading the tertiary hospitals, and therefore this is rarely done in practice. Instead, patients are typically referred sequentially through the system. Figure 7 illustrates the current general referral pathways in the Western Cape from lower-level facilities to the two tertiary facilities, Tygerberg hospital and Groote Schuur hospital.

Figure 7

Referral pathway within the Western Cape public healthcare system.



Note. Own illustration based on empirical data.

Healthcare access and service quality within the public system were described as highly dependent on geographic location and socio-economic conditions, and therefore hospitals within the public sector differ significantly. Urban hospitals, particularly those located in Cape Town, were reported to be better resourced and capable of providing more advanced services. In contrast, facilities in rural areas were described

as having more resource constraints, shortages of staff, and additional challenges. One respondent expressed "We have a phenomenal public hospital here in Cape Town, but then if you go into rural areas, they're mismanaged". Additionally, in some regions within the Western Cape, patients may need to travel long distances to reach the hospitals, and in particular to access specialized care at tertiary hospitals, as there are only two such facilities and they are located in the urban areas. One respondent expressed "So, you may have to travel 2,000-3,000 kilometers sometimes to get to the nearest functional tertiary hospital".

Emergency care services are available across all facility types. However, the type of services provided varies between facilities and locations, and access to diagnostic services, in particular CT scanning, varies significantly across facilities. It was consistently described that some healthcare facilities provide CT scanning continuously, meaning 24 hours per day, 7 days per week, while other facilities only provide during weekday office hours, and some facilities have no CT scanning services at all. It is described by respondents that based on their CT imaging availability, each facility corresponds to a CT imagining level, this is described in Table 2.

Table 2
Definition of CT imaging levels based on availability of CT imaging services.

CT Imaging Level	**CT Imaging Availability**
Level 1	No CT imaging services available
Level 2	Limited CT imaging available, typically during weekday office hours (e.g., 07:00-16:00)
Level 3	Continuous CT imaging available (24 hours per day, 7 days per week)

Respondents described that there is no clear distinction between each healthcare facility type and corresponding CT imaging level. However, general guidelines were described regarding which CT imaging level different healthcare facility types typically have, as presented in Table 3.

Table 3
Healthcare facility types and corresponding CT imaging levels.

Healthcare Facility Type	**CT Imaging Level**
CHC	Level 1
District hospital	Level 1-2

Healthcare Facility Type	CT Imaging Level
Regional hospital	Level 2-3
Tertiary hospital	Level 3

When diagnostic services are not available at the presenting facility, patients requiring imaging must be transferred to higher-level hospitals to receive the required services. Respondents described that in some of these cases, patients may need to skip one of the facilities in their general pathway (Figure 6), as the facility does not have the required imagining capacity, and instead be referred directly to a higher-level facility. Respondents explained this referral a frequent occurrence, given that only a limited proportion of hospital facilities have access to CT scanning services. Respondents therefore described that there can be long waiting times for receiving CT scan due to transfer times, as well as delays at receiving hospitals where multiple patients are referred for imaging.

4.1.1.1 Emergency medical services

Emergency medical services (EMS) in the Western Cape include both public and private providers. Public EMS services are responsible for the majority of emergency services within the public healthcare sector. However, respondents explained that private ambulance services may be used when public services are unavailable or delayed, and in these cases the private ambulances may still transport patients to the public hospitals.

Respondents consistently described significant capacity constraints, in terms of ambulances, within the public EMS system. The number of emergency calls often exceeds the available ambulance resources, resulting in prolonged response times and delays in patient transport. One of the respondents expressed "They're not even close to meeting the demand. Not even close". The availability of receiving public EMS is also expressed to be dependent of the patient's geographical location, where they live, as the availability of ambulance differ a lot between locations. One of the respondents described "It's often like a rural sub-district where they only have two ambulances, two or three ambulances, and they're dealing with everything".

Therefore, even if a patient is diagnosed with a specific illness and they need acute care, it is not always possible for a patient to receive EMS due to the limited number of ambulances available. One of the respondents expressed "Even if, for example, you get diagnosed with an ischemic stroke your chances to get a treatment unless you are, like, down the road are very few because we don't have control of the ambulances and what happens with them". It was further described that in some areas and situations it can take the ambulance 12 hours to arrive at the hospital from the initial call.

Due to the delays in ambulance response time, respondents emphasized that patients are often transported to hospitals by family members or private transport, such as ride-hailing services (e.g., Uber), instead of waiting for ambulance. Respondents reported limited trust in public EMS in many areas, leading patients to seek alternative transport. It was expressed in the interviews that "Sometimes they'll say that instead of waiting, we'll just go ourselves".

4.1.1.2 South African Health Products Regulatory Authority

The South African Health Products Regulatory Authority (SAHPRA) is the national regulatory body responsible for ensuring that medical devices on the South African market meet acceptable standards of safety, quality, and performance (South African Health Products Regulatory Authority, n.d.). Based on the empirical data, two main SAHPRA regulatory processes were identified as relevant for the introduction of Strokefinder MD100 in the Western Cape; product registration and establishment licensing.

The registration process for medical devices, the product registration, is still under development and therefore, the exact steps and timelines for registration are not fully defined at present (South African Health Products Regulatory Authority, n.d.). However, the first step in the regulatory process, regardless of the final registration requirements, is device classification. In this step, the device is assigned to a risk class based on its intended use, which in turn determines the level of further documentation and review required for the application (South African Health Products Regulatory Authority, 2025). In addition, SAHPRA has established a reliance-based regulatory pathway. This means that if a device already holds approval from a recognized reference jurisdiction, such as CE marking, required for sale within the EU (European Commission, n.d.), or FDA approval, the authorization needed in the United States (U.S. Food and Drug Administration, n.d.), SAHPRA can base its evaluation on the existing approval rather than conducting a full independent assessment from the beginning (South African Health Products Regulatory Authority, 2026). Since Strokefinder MD100 already holds CE marking, this pathway may be applicable and could therefore facilitate the future registration process of the device (Tsiftsis et al., 2024).

Beyond the approval of the device itself, any company that intends to import or distribute medical devices in SA must obtain a medical device establishment license from SAHPRA, and no import or distribution can take place without this valid licence (South African Health Products Regulatory Authority, n.d.). SAHPRA issues three different types of establishment licenses depending on the nature of the activities to be performed (South African Health Products Regulatory Authority, 2023). The three types of establishment licenses include manufacturer license, distributor license and wholesaler license (South African Health Products Regulatory Authority, 2023). Applications for establishment licenses are submitted electronically using the format provided by SAHPRA and must include information such as contact details, risk classification as well as additional classifications of the device. Each application

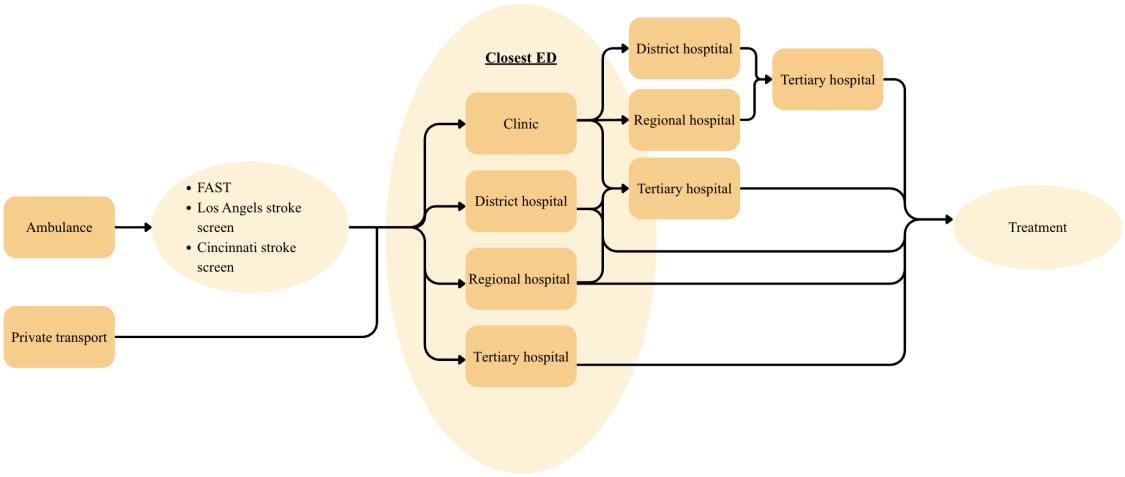
must also have an authorised representative who is physically based in SA and responsible for ensuring compliance with applicable laws, regulations, and guidelines on behalf of the organization (South African Health Products Regulatory Authority, 2023; South African Health Products Regulatory Authority, n.d.).

4.1.1.3 The stroke pathway and associated delays

The empirical material shows that the stroke pathway in the Western Cape public healthcare system is neither linear nor uniform, this is illustrated in Figure 8. Respondents consistently described a pathway in which patients may enter the system through different routes, move across several levels of care, and encounter delays at multiple points along the way.

Figure 8

Stroke pathway within the Western Cape public healthcare system.

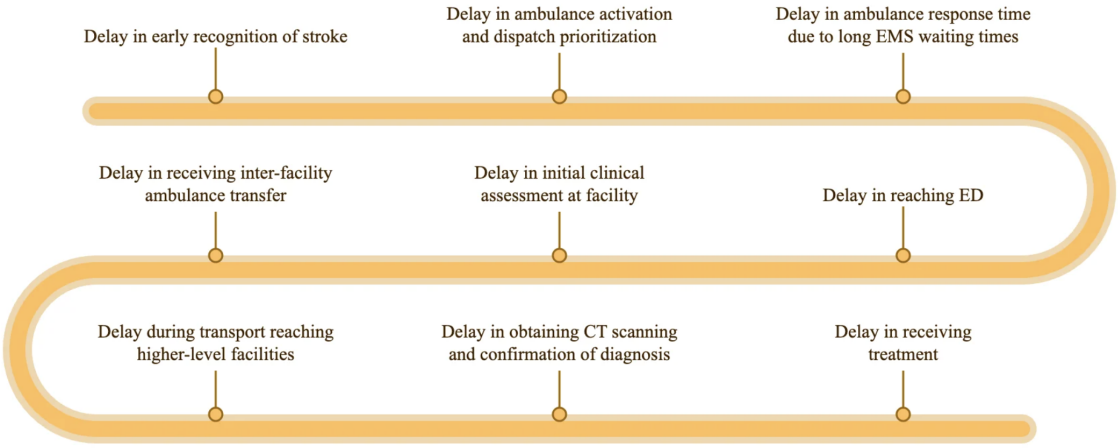


Note. Own illustration based on empirical data.

Several delays were identified by respondents throughout the stroke pathway, which together contribute to patients not receiving treatment in time, as shown in Figure 9. A first recurring theme in the interviews was that the stroke pathway often begins with delay already at the point of symptom onset, because of delayed recognition of stroke symptoms. Respondents described so-called wake-up strokes, in which the event occurs during sleep and is only identified the following morning, as well as cases in which patients or relatives do not immediately recognize symptoms such as slurred speech, weakness, or facial asymmetry as signs of stroke. Respondents therefore suggested that the stroke pathway often begins with a significant delay before contact with the healthcare system has even been established.

Figure 9

Delays within the stroke pathway in the Western Cape public healthcare system.



Note. Own illustration based on empirical data.

Once symptoms are recognized, patients may either arrange private transport or enter the system through EMS. Respondents repeatedly emphasized that private transport is common, largely because of long ambulance response times, as explained in Section 4.1.1.1. Respondents noted that when patients do seek care through EMS, call-center staff are generally not medically trained and do not receive stroke-specific training beyond basic scripts or intuitive judgment. This was described as a challenge in the pathway, since the ability to identify a stroke during the emergency call affects whether the case is prioritized early, with failure to do so resulting in a potential delay in ambulance activation. As one respondent explained, "Another challenge is identifying it at the time of the emergency call and being able to then set a priority response". Following this, another potential delay in the pathway concerns the long waiting times for EMS arrival, which further delays the ambulance response.

Once EMS is activated, pre-hospital providers assess the patient on scene by applying stroke screening tools, such as FAST, the Los Angeles Prehospital Stroke Screen or the Cincinnati Prehospital Stroke Screen. These assessments inform the transport decision, but the empirical material suggests that the destination is not determined only by stroke suspicion. Instead, EMS staff transport patients to the closest emergency department, regardless of facility type or whether it has CT capacity or stroke treatment capability. Respondents described this as a key feature of the public stroke pathway, patients are commonly taken to the nearest point of entry rather than directly to the most appropriate stroke-capable facility. Respondents consistently emphasized, however, that geographical distances are in many cases considerable, thereby introducing an additional potential delay in reaching the emergency department.

The first receiving facility may therefore be a clinic, a district hospital, a regional hospital, or, less commonly, a tertiary hospital. As respondents commonly described the pathway as strongly shaped by geography, clinics and level 1 district hospitals

are often the first point of entry, as they are more numerous and more locally distributed. This means that many patients begin their pathway at facilities that do not themselves have CT scanning or stroke treatment capacity. As one respondent put it, "There's not very much that one can do in primary care if somebody is having a stroke, other than recognize that it is a stroke and refer them usually to the hospital." In other words, lower-level facilities often function primarily as points of recognition and referral rather than treatment. Respondents commonly noted that high patient volumes at lower-level facilities mean that it can take considerable time before a patient is seen by healthcare staff, resulting in delays in receiving an initial clinical assessment.

When a patient presents to a clinic and stroke is suspected, the next critical step is CT imaging. Respondents consistently identified CT scanning as the decisive diagnostic step in the pathway, as it is needed to distinguish ischemic stroke from hemorrhagic stroke and thereby determine the appropriate treatment. However, because clinics do not have CT imaging capacity, the patient must be referred onward by ambulance to a higher-level facility. At this stage, another delay may occur due to inter-facility ambulance transfer, as respondents repeatedly pointed to ambulance shortages and long waiting times for transfer vehicles. One respondent described this by saying "I mean, you might be sitting there for hours before you get transferred.". Thus, even after stroke has been recognized at clinic level, the patient may still spend considerable time waiting for transport to the next point of care. When the ambulance arrives, the destination is determined by time of day: during office hours, the patient is taken to a level 2 district or regional hospital, whereas after hours, the patient is taken to a tertiary hospital.

If a district or regional hospital is the closest emergency department, the patient is taken there first and assessed. If stroke is suspected by the hospital staff, the same logic applies and the next step is CT imaging. Depending on the level of the hospital, the time of day, and local capacity, the patient will either undergo a CT scan at the current hospital or be transferred to a tertiary hospital. Respondents explained that some level 2 district or regional hospitals are also able to perform thrombolysis, the treatment for ischemic stroke, meaning that patients presenting during daytime hours may also receive treatment there. However, only a small proportion of district and regional hospitals have access to CT imaging, meaning that most patients are transferred to tertiary hospitals. As one respondent noted, "In most cases, you're probably not going to get imaging, actually, because you'd have to refer the person to the higher-level hospital for that". Respondents consistently noted that considerable geographical distances between facilities introduce further potential delays during transportation to higher-level facilities.

There are also cases in which patients are brought directly to tertiary hospitals by EMS, but respondents stressed that this is uncommon and would occur only if the tertiary hospital happens to be the closest emergency department. If a stroke is suspected at tertiary level, CT can be performed there without the need for an additional transfer, which shortens the pathway considerably.

Once a patient reaches a tertiary hospital or a level 2 district or regional hospital with CT access, the CT scan must still be booked. Respondents described another important source of delay at this stage: prolonged waiting times for CT scanning. Stroke patients compete with other emergency cases, and prioritization depends partly on available resources and partly on whether the patient remains within the treatment window. Several respondents referred to the thrombolysis window, the treatment window for ischemic stroke, as approximately four to six hours from symptom onset. Respondents explained that if a patient is already outside the thrombolysis window, the case may no longer be prioritized in the same way, and CT scanning may simply be performed when capacity allows. Conversely, if the patient is within the time window, they are prioritized. However, this was described as unusual and one respondent expressed this by "unless by some miracle, you end up at somewhere like Tygerberg Hospital, within the window of opportunity when treatment would still be possible". Another respondent illustrated this by explaining that if it already takes two hours to obtain an ambulance, the patient arrives three to four hours after onset, and another hour and a half is spent obtaining CT, then by the time CT scanning is done the patient will be outside the time window.

If CT scanning is completed, the findings then determine the next stage of the pathway. If imaging confirms a stroke and the patient remains within the time window, treatment may be administered. Some level 2 district and regional hospitals were described as being able to provide treatment, often in liaison with radiologists or neurologists at tertiary level, while tertiary hospitals provide more comprehensive acute stroke care as well as thrombolysis. However, respondents noted that even once imaging confirms a stroke, a further delay may occur before treatment is actually received, as it may depend on the availability of the relevant healthcare staff or coordination with another facility.

Respondents therefore repeatedly emphasized that the cumulative delays mean that many patients fall outside the treatment window before diagnosis is completed, such that only a small proportion proceed from diagnosis to treatment. Instead, patients are typically stabilized, followed by rehabilitation and assessment of underlying risk factors.

4.1.2 Prospective implementation of Strokefinder MD100 within the stroke pathway

The empirical material indicated that the potential role of Strokefinder MD100 within the stroke pathway is highly dependent on where in the public healthcare system it is implemented. Respondents did not consistently describe one single implementation site as the most optimal. Instead, respondents emphasized that the usefulness and consequences of the device would differ depending on where it is implemented. However, respondents consistently described that the potential role of Strokefinder MD100, as a tool appropriate for earlier triage, referral support, and simplification of prioritization decisions.

Respondents therefore explained that Strokefinder MD100 is therefore not seen as a solution to all the challenges and delays of the stroke pathway described in Section 4.1.1.3, but rather as a device that could potentially improve specific parts of the pathway. One respondent expressed this by stating, "You could say that MD100 don't provide the solution but rather can help a little by improving the processes for those who have had a stroke, by identifying stroke earlier, directing patients to the right level of care, and potentially reducing downstream consequences such as rehabilitation burden".

4.1.2.1 Implementation of Strokefinder MD100 in ambulances

The ambulance setting was described as a suitable site for Strokefinder MD100 to be implemented in. Respondents described this phase of the pathway as particularly important since the patient's condition remains unknown at this point, and where an earlier indication of stroke could influence the decision regarding which facility type to take the patient to. Respondents suggested that Strokefinder MD100 could support earlier detection and help to immediately direct patients to a facility where CT scanning is available, thereby bypassing the lower-level facilities. One respondent explained this by saying, "What it would do is if it says yes, stroke, the destination triage could take the patient to a place where a CT scan is currently available, so let's go to a place that can scan them quickly". In turn, this could potentially shorten the time to appropriate CT scanning and accelerate movement into a stroke-capable pathway.

However, respondents also emphasized that bypassing lower-level facilities could shift the pressure further up the pathway rather than remove delays altogether. One respondent explained this by saying," if you bypass the district and the regional hospitals, you're only overloading the tertiary with patients. So, there'll still be delays at the tertiary hospital". Respondents therefore noted that high specificity is important in order to not transfer too many unnecessary patients to the tertiary hospitals.

4.1.2.2 Implementation of Strokefinder MD100 at lower-level facilities

Respondents identified lower-level facilities, including clinics and district hospitals, as potential implementation sites for Strokefinder MD100. Especially, respondents emphasized facilities that are geographically distant from higher-level facilities with CT availability. In this part of the stroke pathway, similar to the ambulance implementation, respondents suggested that the device could be function as an early triage or pre-screening tool to identify likely stroke cases and support faster escalation for CT scanning, enabling patients to bypass lower-level facilities and move directly to higher-level facilities.

Despite this potential, respondents questioned whether the added value at lower-level facilities would be sufficient, given that they cannot provide stroke treatment. While earlier identification of a likely stroke may improve recognition and prioritization, it does not alter the subsequent steps in the pathway, the patient must still

be transferred by ambulance onward for CT scanning and treatment. Respondents therefore described its usefulness in lower-level as conditional on whether earlier indication of stroke actually accelerates transfer to the next level of care. Given the ambulance shortages described in Section 4.1.1.1, delays in transfer may persist regardless of earlier identification, limiting the device's overall impact on the pathway. Implementation at lower-level facilities could therefore improve recognition and prioritization, but its effect on the overall pathway would remain dependent on available ambulances.

Furthermore, respondents argued that lower-level facilities capture a large proportion of patients within the public healthcare system and thereby making it a suitable location for Strokefinder MD100. Respondents pointed out that many self-referred patients present first at these facilities, and district hospitals in particular serve as central nodes in the referral structure, receiving patients referred from clinics before any further onward referral. As a result, district hospitals were described as frequently experiencing significant patient queues. Respondents therefore described that Strokefinder MD100 could manage queues and support the prioritization of patients by helping to distinguish patients requiring escalation from those who do not require immediate CT scanning. One respondent expressed this by stating, "the district hospitals, there is a greater potential there in saving time and also resources because they get overloaded, and being able to send away some of the patients that actually don't need the CT and only escalating patients who really need the CT would be really good".

Nevertheless, concerns were also raised by respondents regarding unintended consequences stemming from the current low specificity of Strokefinder MD100. If the device generates a high rate of positive identifications, this could result in an increased number of more patients being referred and sent onward for CT scanning, thereby intensifying the overload at tertiary hospitals that already exists. The empirical material therefore suggested that the implementation at lower-level facilities are highly dependent on the diagnostic accuracy of Strokefinder MD100. In addition, there are concerns regarding the cost aspect of implementation in lower-level facilities. As shown in Figure 7, lower-level facilities are significantly more numerous than higher-level facilities, which means that a larger number of devices would be required. This, in turn, leads to increased costs.

4.1.2.3 Implementation of Strokefinder MD100 at higher-level facilities

Higher-level facilities, tertiary hospitals and level 2 district and regional hospitals, were not identified by respondents as suitable implementation sites for Strokefinder MD100 within the stroke pathway. Respondents explained that regional hospitals already have access to CT scanning during office hours, while tertiary hospitals have CT capacity available 24 hours a day. As such, respondents did not perceive these levels of care as the most relevant locations for introducing the device. Instead, respondents consistently emphasized that the implementation should be focused on earlier stages in the stroke pathway as a triage tool.

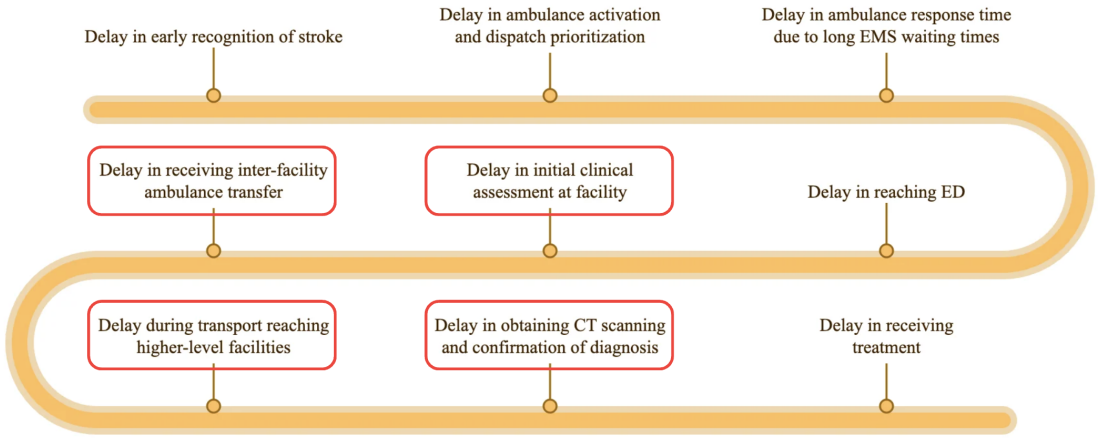
4.1.2.4 Impact of Strokefinder MD100 on stroke pathway delays

The empirical material suggested that Strokefinder MD100 had the greatest potential impact during the early stages of the stroke pathway, particularly in ambulances and at lower-level facilities such as clinics and district hospitals. These parts of the pathway were described as particularly important because they often represent the patient's first contact with the healthcare system, while also lacking CT scanning and stroke treatment capacity. As a result, patients frequently experience delays before being identified, prioritized, and referred onward to higher-level hospitals.

Respondents described Strokefinder MD100 primarily as an early triage and prioritization tool. By providing an earlier indication of stroke, the device could help healthcare staff identify time-critical patients more quickly and prioritize them for onward referral. This was considered particularly important both in ambulances, where earlier identification could support destination decisions, and at lower-level facilities, where long waiting times may delay clinical assessment and referral decisions.

Respondents suggested that implementation of Strokefinder MD100 in ambulances and at lower-level facilities could reduce several delays within the stroke pathway. Earlier and more reliable identification of stroke could potentially shorten delays related to initial clinical assessment and access to CT imaging, as it may enable faster prioritization of suspected time-critical cases. It could also reduce delays associated with inter-facility transfers and reaching definitive care by enabling paramedics to bypass lower-level facilities and transport patients directly to hospitals with CT capacity, thereby avoiding unnecessary transport steps. However, a substantial set of challenges would remain unaffected. Figure 10 illustrates how Strokefinder MD100 could influence delays across the pathway, with potential reductions in the highlighted stages and no observable effect in others.

Figure 10
Impact of Strokefinder MD100 on delays within the stroke pathway in the Western Cape public healthcare system.



Note. Own illustration based on empirical data.

The empirical material showed that limited public awareness of stroke symptoms means that patients continue to present late, regardless of what happens downstream in the pathway. Ambulance shortages, geographical distances between facilities, and the difficulty call dispatchers face in prioritizing stroke cases without clinical competence were also described as systemic problems that the device cannot resolve. At the tertiary level, resource constraints and competing priorities among seriously ill patients were similarly described as persistent challenges. The empirical material therefore suggested that Strokefinder MD100 could reduce delays in specific parts of the pathway, while other delays would remain unaffected.

4.2 Enabling and hampering conditions

Based on the empirical material, twelve conditions influencing the implementation of the intervention were identified. Each condition can function as either an enabling or hampering factor depending on how it is addressed in practice. Table 4 provides an overview of the identified conditions and their potential enabling and hampering characteristics. The identified conditions are presented in detail in the following sections.

Table 4
Description of characteristics of identified enabling and hampering conditions for implementation

Condition	Description of the condition	Potential role in implementation
Contextual fit	The degree to which the technology is aligned with clearly defined local needs, problems, and contextual conditions within the healthcare system.	Enabling: The contextual fit is achieved when the intervention is selected based on clearly identified needs and adapted to the local context, increasing relevance and acceptance among users. Hampering: The contextual fit is limited when technologies are introduced without sufficient understanding of the local context or problem, leading to low relevance, skepticism, and reduced adoption.
Cost and funding	The cost of the intervention and the availability of financial resources required to procure and implement it within a resource-constrained healthcare system.	Enabling: The cost and funding of the intervention are aligned with available budgets, and a strong business case clearly demonstrates patient benefit and value, increasing the likelihood of securing financial support. Hampering: The cost and funding requirements exceed available resources, and competing priorities within limited budgets lead to difficult trade-offs, resulting in denied implementation.
Regulatory and market access requirements	Regulatory and market access requirements that must be fulfilled before and during implementation of the intervention.	Enabling: Regulatory processes are clear and manageable, allowing timely approval and implementation. Hampering: Regulatory requirements are complex or include mandatory approvals or certifications that can delay, restrict, or outright prevent implementation.

Condition	Description of the condition	Potential role in implementation
Local representation	The presence of a local representative or organization responsible for managing customer contact, sales, and after-sales support within the target market.	Enabling: A trusted local representative or distributor is available, providing responsiveness, and credibility in interactions with hospitals. Hampering: The absence of local representation reduces trust, limits accessibility, and makes it more difficult to establish relationships with potential customers.
Identify a champion	The presence of a committed medical practitioner who actively promotes, supports, and takes ownership of the intervention, and who serves as a key link between clinical practice, decision-makers, and funding processes.	Enabling: The champion is a trusted medical practitioner who is engaged in the clinical area, advocates for the innovation, and takes ownership of the implementation process, creating support among colleagues and facilitating progress toward adoption. Hampering: The champion role is difficult to assign or sustain due to unclear processes for identifying the right individual, limited time, or competing responsibilities, reducing engagement and weakening the momentum needed for successful implementation.
System-wide alignment	The extent to which organizational processes, workflows, and stakeholders across the system are prepared and aligned to support the implementation of the intervention.	Enabling: Relevant stakeholders are informed, processes are adjusted, and the organization is aligned to support the change across the entire system. Hampering: Processes are not coordinated across units, stakeholders are insufficiently informed, and lack of alignment limits the effectiveness and sustainability of the intervention.

Condition	Description of the condition	Potential role in implementation
Training and support	The initial and ongoing training and technical support required to ensure that staff and maintenance personnel can competently use and sustain the intervention over time, including routines for maintenance.	Enabling: Relevant stakeholders are informed, processes are adjusted, and the organization is aligned to support the change across the entire system. Hampering: Processes are not coordinated across units, stakeholders are insufficiently informed, and lack of alignment limits the effectiveness and sustainability of the intervention.
Feasibility	Practical and operational conditions that must be in place for the intervention to be used and integrated into routine practice.	Enabling: Practical conditions that support routine use of the technology, including adequate infrastructure, usability, reliability, and compatibility with existing workflows. Hampering: Practical constraints such as insufficient infrastructure, limited time, complexity, or lack of compatibility that make the technology difficult to use in everyday practice.
Perceived impact on workload and workflow	The extent to which the intervention is perceived to affect staff workload and existing workflows, including whether it adds tasks, changes routines, or improves efficiency in daily practice.	Enabling: The intervention is perceived to streamline workflows, reduce workload, or improve efficiency, and its value in making daily work easier is clearly communicated to staff. Hampering: The intervention is perceived to add tasks, increase workload, or disrupt established routines, leading to resistance to change.

Condition	Description of the condition	Potential role in implementation
Perceived value and evidence	The extent to which the intervention is perceived to provide meaningful benefits for patients and is supported by clear and credible evidence demonstrating its effectiveness and reliability.	Enabling: The intervention is supported by clear evidence demonstrating patient benefit, and its value is effectively communicated to staff, increasing trust and willingness to adopt the intervention. Hampering: The value of the intervention is unclear, poorly communicated, or not supported by credible evidence, leading to skepticism and resistance to adoption.
Organizational culture	The shared norms, routines, and perceptions within the organization that influence openness to change, including attitudes toward innovation, adherence to established ways of working, and the level of engagement and ownership among staff.	Enabling: The organizational culture supports engagement, learning, and openness to change, where staff understand the purpose of the intervention and recognize its value in addressing existing challenges. Hampering: The organizational culture emphasizes maintaining established routines, following rules, and avoiding risk, and staff feel insufficiently engaged or informed about the purpose of the change, leading to resistance to new interventions.

Condition	Description of the condition	Potential role in implementation
Sustainability	The ability to maintain the intervention over time through reliable long-term planning for maintenance, consumables, technical support, and financial resources required to keep the intervention operational.	Enabling: The sustainability of the intervention is supported by clear long-term plans for maintenance and consumables, accessible technical support, and sufficient resources to keep the intervention operational. Hampering: The sustainability of the intervention is undermined by a lack of long-term planning, limited access to maintenance or consumables, or high costs, leading to the intervention becoming nonfunctional over time.

4.2.1 Contextual fit

To succeed with implementation, it is repeatedly mentioned in the interviews that a clear understanding of the problem is essential. Before considering potential solutions, the context must be carefully examined in order to understand what the actual problem is. Without a clear definition of the problem, attempts to develop solutions lack purpose and direction. Change should only be pursued in areas where current practices are not functioning adequately, and without a clear definition of the problem, it is not possible to assess whether a need for change is present. One respondent stated "So I think first off is being very clear with defining what the problem is. Then you find a solution that supports that problem to be solved".

The interviews describe numerous situations in which technologies and innovations from HICs have been introduced into a specific context without sufficient understanding of that context. One example that is highlighted involves bicycles being donated to enable children to travel to school. However, the broader circumstances were not taken into consideration, and the bicycles were instead sold in order to generate income. It was described "If we do give everyone a bicycle, they will sell it because their hunger is more important than the actual school". In this case, an innovation that functions effectively in one context was assumed to work equally well in another, without a proper understanding of local conditions. The same principle is described as applicable within healthcare systems. The concept of technology push is discussed as an approach that is often ineffective, where a technology is developed and then introduced into a context regardless of local needs. Instead, respondents emphasize the importance of demand pull, where identified needs should guide the selection and implementation of technologies.

It is also described that, due to multiple previous technology push initiatives, a degree of skepticism exists when new technologies are introduced. Consequently, new technologies must be communicated carefully and introduced in an appropriate manner in order to increase the likelihood of acceptance. It was described that "If you say that I have got a technology, I want to test it, people won't listen to you. But if you instead say, I want to understand what your problem is and see where we can find a solution, people are more receptive to it".

Another clear theme emerging from the interviews is the perception that the context itself cannot be expected to adapt. Healthcare is described as a complex system that cannot be fundamentally changed simply because a new technology is introduced, "You need to get your tech into the context, not the context into your tech. So context is fixed. Tech should always fit into the context.". This further reinforces the importance of ensuring that technology is adapted to the context in order to be sustainable and successfully implemented.

4.2.2 Cost and funding

In a resource-constrained setting, the cost of implementation is a critical consideration. The context is widely described as facing significant resource limitations and as being underfunded, a respondent described "There's always budget constraints in the public sector because it's very much underfunded, under-resourced. So, there's always that issue". As a result, the pricing of new innovations needs to be carefully aligned with the financial realities of the healthcare system and the resources available, respondents highlighted that "pricing an innovation to make it affordable in the Stockholm region is very different from considering what it would look like here". The higher the cost of an innovation, the more difficult it will be to secure approval for procurement, as the ability to pay becomes a decisive factor in an already constrained system.

Due to existing budget constraints, resistance often arises when academics introduce unfunded projects into the public sector. When hospitals apply for funding for the coming year, they are required to provide clear justification for the resources they request. In recent years, the National Treasury has reduced funding across government departments, including the health sector, which has further complicated the process of securing financial support for new initiatives. Each year, funding requests amount to roughly four times more than the resources available, creating significant challenges for hospitals in obtaining the funding they need. One respondent noted that "The bottom line is that each hospital is fighting to get as much equipment as it can from that budget, from that pot".

There appear to be some contradictions in perceptions of what is required to secure funding for hospitals from the provincial department. One perspective suggests that as long as the perceived value is clearly articulated in the business case, and the justification is strong, obtaining approval for funding should not be a major challenge, respondents explained that "If you have a strong case, there is budget

allocated to that kind of initiative". What is required is to demonstrate that the intervention will provide substantial benefit for patients, and that the perceived cost represents a worthwhile investment. Ultimately, the decision is based on which intervention is expected to deliver the greatest return on investment in terms of health outcomes. It is stated that "If the perceived benefit or the perceived value extraction is so much higher, that will convince them".

On the other hand, there are also examples where a strong case is not enough if the cost is too high. Even when there are good reasons for why an innovation is needed, the reality is that the available budget is limited. In addition, there may be many proposals that are well justified. As a result, even when the reasons are clear and the need is real, funding may still be denied due to high demand and limited financial resources. Ultimately, it comes down to a trade-off between the applications that are submitted, as not all requests can be approved. One respondent had an example where "they presented a very convincing case. The problem was that the amount that would be required almost consumed the whole budget. There would be a whole lot of other equipment that would not be able to be procured. So essentially, it's that trade off".

Given the challenges associated with securing funding from the provincial department, alternative options for financing implementation have been described. There are cases, although not very common, where non-governmental organisations (NGOs) can provide financial support. If an NGO can be identified that has an interest in the specific purpose of the implementation, it may be possible to present the value of the intervention to them in order to seek funding. It is also possible to approach multiple NGOs that can share the costs of the implementation.

4.2.3 Regulatory and market access requirements

As described in Section 4.1.1.2, SAHPRA oversees both product registration and establishment licensing for medical devices in SA. Interviews confirmed that both are required for commercialising medical devices in the Western Cape.

Regarding product registration, respondents noted that the existing CE marking is a significant advantage, since SAHPRA's reliance-based pathway allows prior approvals from recognised jurisdictions to simplify the process. As one respondent put it, "with imports, it's easier because they come with CE marking or FDA approval. And that is recognized by SAHPRA, which makes the process much, much easier." There is also a broader perception that European and American products carry an implied quality assurance, "Products produced in Europe and in the US, I think still do have the perceived higher quality elements to it".

For establishment licensing, respondents indicated that ISO 13485 certification is effectively required, even if not always explicitly stated, "ISO 13485 is also required. It's not always stated, but in practice, it is necessary". This suggests that having a certified quality management system should be treated as a practical prerequisite.

SAHPRA covers most of the regulatory aspects required to sell and distribute a medical device, but beyond that, the BBBEE certificate, short for Broad-Based Black Economic Empowerment, has emerged as an important component. As one respondent stated, “If you don’t have a BBBEE certificate, you’re not going to take off.”. Respondents explained that it is a governmental framework in SA aimed at reducing economic inequalities from the apartheid era by increasing the participation of Black South Africans in the economy. The framework includes a scorecard system, where companies are evaluated based on factors such as equitable ownership, management and board representation, as well as contributions to socio-economic development. In interviews, it is described in a way that suggests that without a reasonable score on the scorecard, a distributor will not be considered. This makes it effectively a requirement for succeeding in the commercialization of the product. A higher score also translates into greater competitiveness.

4.2.4 Local representation

A recurring theme across interviews was that a local representative in SA is essential for managing contact, sales, and after-sales support. Respondents generally agreed that having someone nearby who represents both the product and the company increases trust and reliability. There are differing opinions on who should take on this role. One option is for the manufacturer to move production to SA and personally represent the product, something that is preferred by some: "We get lots of distributors coming and approaching us. If I see a distributor, I don’t engage with them. More often, they are salespeople. We would really be keen to speak with technically oriented manufacturing teams".

However, more respondents favoured working through a local distributor. Distributors bring established networks, customer relationships, and implementation experience: "A distributor would be better because then they’ve got the history, they’ve got the reputation, they’ve got the infrastructure in place, they’ll already know people". This is described as the most common route through which hospitals are approached regarding new products, and it is further recommended that whoever was involved in the preceding clinical trial continues in that role throughout the implementation process.

From a company perspective, direct customer contact offers full control over communication and relationship management, as one respondent emphasized: "The closer you are to the customer as a principal, the better you do, always". At the same time, relying on a distributor carries the risk that "they may down-prioritize your product over something that’s maybe more valuable to them". From a cost perspective, however, managing all activities independently is often not feasible, making collaboration with a distributor the more practical choice. Once responsibility for customer contact has been determined, respondents agree that hospitals constitute the primary potential customers and should therefore be approached. This is where the process of identifying a champion begins, which is presented in Section 4.2.5.

4.2.5 Identify a champion

Something that has been strongly emphasized as directly decisive for successful implementation is the need to have a champion. It is described as not only beneficial, but as absolutely necessary in order to have any realistic chance of implementing the innovation. There is no formal process in which the product is introduced through government channels, and there is usually no direct line of contact between researchers and policy makers in this regard. Instead, the intermediary is always a medical practitioner. It is the medical practitioner who develops an interest in the innovation and who will apply for funding in order to procure the device. Therefore, without a champion, there is effectively no pathway to actual implementation. This importance was repeatedly highlighted in the interviews, where one respondent noted that "you need champions who can actually advocate for your technology". Similarly, another respondent emphasized that "it's very important to have someone like a champion. I keep on emphasizing it because it's something that is overlooked".

It is clear that it is not recommended for the champion to be someone other than a medical practitioner. For example, if a policymaker were to take on the role of champion, resistance is likely to arise, as there may be limited trust in their understanding of the practical value of the innovation. The role of champion is expected to be taken on by those who will actually use the innovation, as this is more likely to create support among other stakeholders. Many respondents describe that the Head of Department is often best suited to act as champion, and that this is commonly how the process unfolds in practice. It is also recommended that the individual who served as Principal Investigator (PI) during the previous clinical trial continues in the role of champion, as they have strong insight into the project and its evidence base. Another perspective is that nurses can be particularly effective champions, as they are the ones who will drive the change forward in daily practice and work directly with the innovation in a hands-on manner.

A major challenge related to champions is the difficulty in identifying the right person. There is no established process for how to do this; instead, it is often described as happening through networking and word of mouth. It is important to find someone who is passionate about the clinical area in which the implementation is planned. The individual needs to feel personally engaged in the topic and willing to take ownership of the innovation. The role requires significant effort to communicate and promote the innovation to both policymakers and medical practitioner colleagues. Another challenge is that the champion role represents additional work on top of their normal responsibilities. This can lead to a lack of sustained engagement over time, or difficulties in balancing the champion role with their daily tasks, a challenge that needs to be acknowledged and addressed.

4.2.6 System-wide alignment

Planning is required regarding how the change will be implemented in practice. The importance of recognizing that change does not occur within a single unit or with a single individual is emphasized; rather, it represents a broader system-level change

that must take place, requiring careful preparation in advance. When a change is introduced early in a process flow, it will have consequences later in the process, and it is therefore necessary to develop an understanding of what those consequences will be. Processes may need to be adjusted, and such adjustments require formal approval. In order to act differently based on the results of a new medical device, a decision must first be made that it is acceptable to change established practices. Consequently, new processes need to be defined and approved before the actual implementation can take place. This need for formal decisions prior to implementation was highlighted in the interviews, where one respondent explained that "a key step before you train and implement is... there needs to be a decision in place that allows staff to act on the result. Otherwise it's just going to frustrate everybody, right?".

Furthermore, even when a formal decision has been made that it is acceptable to act differently, this does not necessarily mean that staff will actually change their behaviour. Effective communication of the change is required to ensure that all relevant stakeholders are informed, not only in the areas where the actual change takes place, but also among those who will be affected by it. Otherwise, the intended benefits of the change may not be fully realized. It is therefore necessary to build understanding and acceptance of the change throughout the entire system. Challenges related to trust and communication across different levels of care were described in the interviews, where one respondent pointed out that "often staff at higher level hospitals don't believe anything that happens in primary care. They just want to repeat it all again".

It is described that it is not uncommon for changes to be implemented incorrectly, with new initiatives introduced and carried out without prior communication about the purpose of the change. As one respondent described, "many times, change has occurred in our systems because someone said so, with no further explanation.". It is also emphasized that it is not sustainable to begin training staff on how to use a new medical device before an understanding has been established regarding the value it is intended to provide. Without a clear understanding of the purpose and benefits of the intervention, staff may lack motivation to engage with the training and integrate the device into routine practice. Furthermore, it is noted that communication and engagement efforts often focus on senior leadership, while frontline staff, the individuals responsible for carrying out the change in practice, may be overlooked.

4.2.7 Training and support

To ensure successful implementation of a new medical device, staff training is required for those who will be using it. Both theoretical training is needed to build an understanding of the technology, and hands-on training is necessary to develop practical skills in operating the device. The objective is for staff to understand the value of using the device and to feel comfortable applying it in a real-world context. It should be expected that training will take place over multiple sessions in order to

reach all users and to allow sufficient time for full confidence in using the device to develop.

A major challenge when it comes to training on a device is the high level of staff turnover that exists in public health care. As one respondent described, “They leave every two years or so. So, that means that when you are implementing it, every couple of years, it’s a brand new person coming in that you have to train.”. This creates a continuous need for training and makes it difficult to maintain competence over time. Once the initial training has been completed, a key priority is to continue with ongoing training. Otherwise, the device may be implemented initially but will struggle to remain sustained over time. The goal is to avoid a situation where one trained individual leaves and, over time, no one else knows how to use the device.

Another challenge related to training is that it requires both time and financial resources, and it is important to ensure that training does not consume more resources than planned. In the current context, resources are limited, and there is little room for activities to take longer than expected. As one respondent emphasized, “If it’s creating more work it will be a problem. It is supposed to make things go faster, not slower”.

There also needs to be clear routines in place for what happens if the device breaks down. Staff need to know what actions to take and how to manage that situation. It emerged from the interviews that hospitals have technical engineering departments responsible for maintaining hospital equipment. If these departments are expected to perform maintenance on a new medical device, they will also require training on how to carry out that work. This therefore represents an additional aspect to consider in training: beyond doctors and nurses, maintenance personnel also need to receive appropriate training. If it is determined that maintenance cannot be performed internally and instead requires support from the local representative, established routines are necessary so that staff know who to contact to carry out maintenance. In addition, the local representative must be available to handle such requests.

The responsibility for delivering the training most commonly lies with the local representative who has been involved in earlier stages of the implementation. In cases where a local distributor is involved, it is not unusual for the distributor and the manufacturer to agree that a representative from the manufacturer will conduct the training, as this is often where the highest level of technical expertise resides. Regardless of the arrangement, the responsibility for providing training typically rests with the distributor or manufacturer rather than with the hospital itself.

4.2.8 Feasibility

For a technology to be successfully integrated and used in real-world settings, attention must be paid to its usability. The medical device needs to be easy to use, which includes not being large or cumbersome. It should be straightforward to retrieve

and operate, without generating errors. It should also be easy to clean. Furthermore, during patient encounters, the device should not require excessive time to use. The context is described as being characterized by limited resources and time constraints, and a device that consumes unnecessary time is unlikely to be adopted or used sustainably in the long term. As one respondent noted, "Anything that adds time to that consultation is going to be resisted because, you know, we all just want to get through this thing and finish". In addition to time efficiency, usability is also influenced by how easily the technology can be integrated into existing routines. As another respondent expressed, "If there's an easier way, water will find its path to get to where it needs to go". This suggests that staff will naturally adopt solutions that are simpler and more practical to use in daily work.

A functioning infrastructure is another factor that is often not sufficiently considered in the specific context. The infrastructure in the region is described as inconsistent, with electricity not always reliably available. The medical device must be able to communicate with already existing systems that are established within the setting. If it requires electricity or an internet connection, these are also elements that must be ensured at the intended location of the device, which is not always a given. Equipment may be needed to connect the device or to read and interpret the results, and this must also be taken into account. This type of robustness needs to be considered, where the technology should be able to function under varying conditions and be as independent of external resources as possible.

When the device is needed, it is also important that it is ready for use. It needs to be located in the right place, it needs to be charged, and staff need to know where it is. It may be physically present but still unusable due to other practical factors, and this is something that should be avoided.

4.2.9 Perceived impact on workload and workflow

The working climate for hospital staff is frequently described as extremely burdensome. It is highly resource-constrained, with a substantial inflow of patients. This is particularly evident in the Emergency Department, where all patients arrive for an initial assessment, creating a significant workload for staff. A high level of burnout is also commonly reported, especially among younger staff. This represents a major driver of resistance to change among staff. Given the already heavy workload, new initiatives are often perceived by doctors and nurses as additional tasks to be added to their already long list of responsibilities. As one respondent stated, "If it makes my life harder in terms of getting through the workload, getting stuff done, it's not gonna work". A similar sentiment was expressed by another respondent, who noted, "You want me to do this, but I'm already doing these 10 million things, now you want me to do something additional". These perspectives reflect the limited capacity for additional tasks in an already strained working environment.

The picture is similar from both leaders and staff themselves; the issue is not that people dislike change or innovation. The main problem is simply that there is no

time. Anything that adds time and work is not of interest, because those margins do not exist. When staff are just trying to get through the day, as someone described it, "operating in survival mode", new innovations are not particularly appealing. At the same time, there is significant potential in this context. As one respondent explained, "I think if you can show me how it will improve either the workflow or reduce the amount of work that we have to do, then it might get buy-ins". If a change instead makes the work easier, there is a strong openness to change. If it is possible to clearly communicate how the change will lead to more efficient processes and reduced workload, it will likely be welcomed by those working in the setting. A similar perspective was expressed by another respondent, who stated, "You show me how this is going to make my life more efficient and take away some of those things". The value needs to be made visible.

However, the experience is that this type of communication is often lacking during change initiatives. Typically, the value of the change is not made visible to staff, which is one of the reasons why changes are not sustained over time. Another form of resistance may arise when changes affect the workflow, how things are usually done. If a change alters practices that staff feel they have already learned and mastered, a certain level of skepticism can emerge.

4.2.10 Perceived value and evidence

In addition to the perceived impact on workload and workflow, perceived value and evidence also have a strong influence on people's openness to change. It is often described that staff in public healthcare are driven by strong human values, they want to help. Therefore, if a change clearly benefits the patient, there is generally a willingness to adopt it. As one respondent noted, "If it's a technology where they see the benefits to the patients, I think they'd be very open". Once again, people need to see the value of the change.

The value also needs to be communicated in the right way for people to recognize that it exists. Even if a change has real value, it will not achieve perceived value if that value is not clearly communicated. This risk was reflected in the interviews, where one respondent explained that "if something is forced on them and they do not see the need or the benefit, then there might be resistance". The challenge lies in making the information visible and demonstrating the value in practice.

One concrete way to demonstrate value is by providing evidence that the new medical device delivers real benefit. It is often described that staff want to understand measures such as sensitivity, specificity, and other data that show how the device will improve outcomes for patients. They need to be able to trust the results, and that trust is built on clear evidence.

4.2.11 Organizational culture

Despite demonstrated value in the innovation and clearly communicated benefits, other factors may still cause resistance to remain. Organizational culture is something that needs to be understood, and it has been described as resistant to some extent. From interviews, it emerged that an internal survey had been conducted within the metro in the Western Cape healthcare system regarding organizational culture. The results indicated that innovation was perceived as having little or no value among respondents. This suggested that the organization was not viewed as experimental or innovative, but rather as hierarchical, with a strong emphasis on following rules. This provides an indication of how the culture around innovation is perceived, and that openness to change is not the primary narrative within the organization, which may help explain the presence of resistance.

Furthermore, it has emerged that different roles may show resistance for different reasons. Older staff are often mentioned as a group that may be more likely to express resistance. Regardless of role, however, there appears to be a relatively shared perception that when something has been done in the same way for a long time and is experienced as working well, there is little perceived reason to change. As one respondent described, "I think the principal main challenge is stasis. Because we're currently doing things this way, that is the way it's always been done, that is the way they should be in the future." A similar sentiment was reflected in another interview, where a respondent noted, "We have a line that's most common in this hospital. It's 'things have been running like this for 20 years, I've been here for 20 years, why must we do this?'". These perspectives highlight the strong influence of established routines on attitudes toward change.

On the other hand, another perspective is that older staff may have more routine and experience, and are therefore less stressed and less affected by the high workload, which could indicate a greater openness to change. Differences in these perceptions may suggest that individual differences also play a role in openness to change, even among people with similar experience and roles. Beyond the amount of experience, the general perception is that nurses often show resistance due to the high workload, while doctors more commonly express resistance related to patient safety. There is a reluctance to make changes for the sake of change alone, and this scepticism toward new innovations is also described as something positive, as it reflects a commitment to keeping the patient as the primary focus. Regarding paramedics, it is described that there is not a single standardized pathway into the profession, and that their backgrounds and training can vary considerably. The level of education is perceived to influence the degree of openness to change.

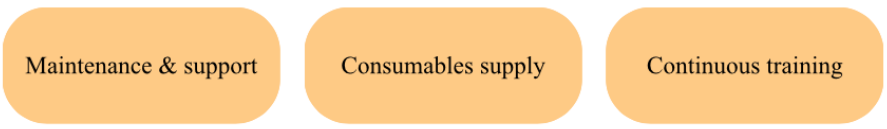
It is believed that much of the resistance that arises is due to a lack of engagement, communication, and ownership. It is not surprising that resistance occurs when the experience is that people are being told to do things without understanding the reason behind it. Some level of resistance may remain, but if the value of the change is clearly demonstrated, it is believed that the culture can gradually shift.

At the same time as resistance is described as present, there is also a more positive picture of openness. Due to the significant challenges faced in the system, primarily related to limited resources, there is a strong willingness to change things toward more functional and effective ways of working. As one respondent expressed, "It's got unique challenges but in that lies an opportunity if you can bring something that is valuable that can make a real difference, you actually have a real shot because people want it to make it work".

4.2.12 Sustainability

It has emerged that the main difficulty with implementation in the current context is not necessarily achieving initial implementation, but ensuring that the innovation can be sustained over time. As one respondent noted, "The sustainability is often a much bigger concern in terms of implementation of new technologies than the technology itself". One respondent described the facility as a graveyard of good ideas that were never sustained, which was seen as a waste of resources and effort. In many cases, there is no clear plan for how innovations and new initiatives should be maintained once they have been introduced, and as a result, they gradually disappear. It was also described that there may be a greater risk in introducing innovations that are not sustained than in not introducing them at all. When a system begins to rely on a new way of working, it becomes problematic if that change suddenly disappears due to difficulties in sustaining it, which makes it even more important to ensure that the innovation can be sustained over time. As one respondent explained, "there are so many examples of technology dumping across the continent of well-meaning people who think that this is going to solve the problem, but actually it just makes matters worse when it's not sustained". The core components ensuring sustainability are illustrated in Figure 11.

Figure 11
Core components required to sustain implementation.



Note. Own illustration based on empirical data.

During the implementation phase of an innovation, it is important to have a clear plan for how after-sales services will be managed. This includes a long-term perspective. In many cases, there is a short-term plan in place, but when the initial contract expires a few months later, there may no longer be funding available to renew it, and the innovation is gradually discontinued. A central aspect of sustainability is maintenance, what happens when something breaks. Maintenance is described as having two main challenges: the availability of knowledge and technical expertise to repair the innovation, and access to spare parts. In many cases, neither the necessary expertise nor the spare parts are available within the country. As one

respondent described, “many times they have to send the stuff to Germany or China or somewhere to have it fixed”. As a result, someone may need to be flown in to carry out maintenance, or the innovation must be shipped elsewhere for repair. In practice, this often leads to delays, or the device remains unrepaired and becomes non-functional. In some situations, the cost of maintenance is simply too high, which can also result in the innovation being left unused. Maintenance therefore needs to be both accessible and affordable in order to support long-term sustainability.

A second central aspect of sustainability is the supply of consumables. It is described that companies selling medical devices often rely on associated consumables as a way to generate additional revenue. In the current context, however, it is preferable for the device not to require consumables, due to the limited budget available. Similar to maintenance, there needs to be a long-term plan from the outset for how consumables will be supplied, both in terms of availability and cost, in order to ensure continued use over time. One recommendation from a respondent is to work together with end users to develop a forecast of consumable needs, in order to better understand how procurement should be organised, as well as the expected quantities and frequency of supply. Having this initial plan in place could create better conditions for sustaining the innovation in the long term. Despite having a forecast, there may still be situations where faster delivery is required. As one respondent described, “we bought something and then the consumables needed to come from Japan, and then it took six weeks, it was just a mess”, highlighting how delays in supply can disrupt the use of the device in practice. In such cases, it is advantageous if consumables are available locally or nearby.

In addition, ongoing training and support were described as essential factors for the long-term sustainability of the innovation. Respondents highlighted that sustainability depends not only on the device itself remaining functional, but also on maintaining competence among staff over time. In contexts characterised by high staff turnover, continuous training and support were therefore described as essential for ensuring sustained use of the device in practice. The need for ongoing training was discussed further in Section 4.2.7.

4.2.13 Overview of enabling and hampering conditions

To synthesize the empirical findings presented above, Table 5 provides an overview of the twelve identified conditions influencing implementation of the intervention. The table illustrates how each condition can function both as an enabling and a hampering factor, depending on how it is addressed and enacted in practice. Rather than being fixed determinants, these conditions are context-dependent and may shift in effect across different implementation stages and settings. The table provides a condensed overview of how each condition is reflected in the empirical material, illustrated through interview quotations showing enabling and hampering dynamics in practice.

Table 5
Illustrative quotations of identified enabling and hampering conditions for implementation

Condition [interview]	**Example quotes from interviews**	
	Enabling conditions	**Hampering conditions**
Contextual fit [2], [3], [6], [7], [8], [9], [10],[12], [13], [14], [15], [16], [17]	"So the demand is the key, you need to figure out whether the technology can actually solve this problem" (8) "I think the first thing would be making sure that the solution is actually fit for purpose, we need to solve the right problem" (14)	"Technology push will not be accepted" (8) "So a lot of ideas and implementations fail because of poor analysis of the context" (15)
Cost and funding [1], [2], [3], [5], [6], [7], [8], [10], [11], [12], [14], [17]	"If you have a strong case, there is budget allocated to that kind of initiative" (2) "If the perceived benefit or the perceived value extraction is so much higher, that will convince them" (12)	"It could be a very good motivation, but we need to say no, because it would consume a significant component of the budget and then all the other needs that were pressing would not be met" (5) "There's always budget constraints in the public sector because it's very much underfunded, under-resourced. So there's always that issue" (14)

Condition [interview]	**Example quotes from interviews**	
	Enabling conditions	**Hampering conditions**
Regulatory and market access requirements [2], [4], [5], [8], [11], [12]	"So with imports, it's easier because they come with CE marking or FDA approval. And that is recognized by SAHPRA, which makes the process much, much easier" (2) "I think if the device has got a CE mark, I think it's a fairly straightforward process. There wouldn't be any, there wouldn't be any issues from the regulatory side if it does have a CE mark" (5) "It's actually pretty straightforward" (12)	"It's just that when it comes to implementing, there's a lot of regulations, that's the harder part" (3) "If you don't have a BBBEE certificate, you're not going to take off" (8) "The risk for, and just to be clear, if you don't have a license and you try to import the product, they could be stopped at the border" (12)
Local representation [4], [5], [6], [8], [12], [17]	"So you being overseas, the smart move you do is you have a distributor here in South Africa" (4) "A distributor would be better because then they've got the history, they've got the reputation, they've got the infrastructure in place, they'll already know people." (5) "The closer you are to the customer as a principal, the better you do, always" (12)	"We get lots of distributors coming and approaching us. If I see a distributor, I don't engage with them" (8) "And with a distributor they may down-prioritize your product over something that's maybe more valuable to them" (12)

Condition [interview]	**Example quotes from interviews**	
	Enabling conditions	**Hampering conditions**
Identify a champion [2], [4], [5], [6], [7], [8], [9], [14]	"It's a person that understands the need and can see the potential of this technology in the environment" (5) "So you would find someone that's passionate about something, and they would then take on that role of championing this intervention" (14)	"Because if you take someone like a policymaker and they are advocating for your device, they might face resistance because the doctors are the ones who are going to be using that device" (2) "The issue, however, is oftentimes the champion is doing the championing over and above their actual main role. So they don't necessarily get protected time or additional time" (14)
System-wide alignment [14], [7], [4], [10], [17]	"There needs to be a decision in place that allows staff to act on the result" (7) "It's a lot of people that you need to sort of engage with as stakeholders" (10)	"Because even if ambulance staff say yes to the change, it's not gonna do any difference if they are the only one approving" (4) "Because often staff at higher level hospitals don't believe anything that happens in primary care. They just want to repeat it all again" (10) "Many times, change has occurred in our systems because someone said so, with no further explanation" (14)
Training and support [2], [3], [4], [5], [6], [10], [12], [14]	"When implementing a new thing, you have to make people comfortable with it" (3) "The engineering department needs to be trained on the equipment because those are the first guys to tell you if something is faulty" (5)	"If it's creating more work it will be a problem" (2) "Every couple of years, it's a brand new person coming in that you have to train" (12)

Condition [interview]	**Example quotes from interviews**	
	Enabling conditions	**Hampering conditions**
Feasibility [3], [4], [10], [12], [14]	"Minor practical changes that make a task quicker or easier to perform can ultimately determine whether a device becomes part of routine practice" (12)	"Anything that adds time to that consultation is going to be resisted because, you know, we all just want to get through this thing and finish" (10) "If the device is clunky, like big, heavy, difficult to use, it gives lots of errors, those kinds of things that I would bother" (14)
Perceived impact on workload and workflow [2], [5], [6], [7], [9], [10], [14], [15], [16]	"People are open to new innovation. Majority are, especially in resource-constrained environments. As long as it makes their job easier, they are" (2) "You show me how this is going to make my life more efficient and take away some of those things" (15) "I think if you can show me how it will improve either the workflow or reduce the amount of work that we have to do, then it might get buy-ins" (16)	"Your ability to innovate and adapt and consider anything new other than survival is not high" (10) "Oftentimes, nursing staff are very resistant to change, very resistant to change. And I think a lot of it has to do with the fact that there's quite a high cognitive burden on people in an emergency department" (14) "If it makes my life harder in terms of getting through the workload, getting stuff done, it's not gonna work" (15) "You want me to do this, but I'm already doing these 10 million things, now you want me to do something additional" (16)

Condition [interview]	**Example quotes from interviews**	
	Enabling conditions	**Hampering conditions**
Perceived value and evidence [5], [6], [7], [12], [15]	"If it's a technology where they see the benefits to the patients, I think they'd be very open" (5) "I think they definitely are open to change. I think as long as they understand the product and the purpose of the product and the intention behind it" (6)	"If something is forced on them and they do not see the need or the benefit, then there might be resistance" (5)
Organizational culture [2], [3], [4], [7], [8], [9], [10],[12], [14], [15]	"It's got unique challenges but in that lies an opportunity if you can bring something that is valuable that can make a real difference you actually have a real shot because people want it to make it work" (12)	"I think the principal main challenge is stasis. Because we're currently doing things this way, that is the way it's always been done, that is the way they should be in the future" (7) "People are not seeing the organization as being a, you know, one that innovates and experiments" (10) "We have a line that's most common in this hospital. It´s 'things have been running like this for 20 years, I've been here for 20 years, why must we do this?" (15) "And often, especially with our nurses, that have been here for 20 years -25 years, just trying to get one small thing done, there's a lot of resistance, just a lot of resistance. Whether there's benefit or not, that's not the point, but just habit, habit and culture" (16)

Condition [interview]	**Example quotes from interviews**	
	Enabling conditions	**Hampering conditions**
Sustainability [4], [6], [7], [8], [9], [10],[11], [12], [14], [15], [17]	"The support functions need to be in place to ensure it will be sustained" (9) "Making sure that those people are trained in how to do this, making sure that the technologies and the components that go into the device is not so niche that it's only available in a particular place" (14)	"Let's say after service plan is over and then they cannot renew because it's too expensive. So what do they do? They leave it die. Just let it die" (4) "Lack of sustainability is one of the main reasons why these things don't have a big uptake" (8) "You've got all this wonderful equipment, but after six months it's broken and nobody can get it repaired, and there's no spare parts or there's no system for that" (10)

5

Analysis

This chapter presents the analysis of the empirical data in relation to the theoretical framework. The chapter begins by mapping the identified enabling and hampering conditions onto the CFIR domains, followed by an examination of the conditions structured according to their directional relationship to the implementation process. The conditions are divided into static conditions, covering intervention characteristics and the outer setting, and dynamic conditions, covering the inner setting, characteristics of individuals, and the process. Unlike static conditions, dynamic conditions are not only influential but also subject to change throughout the implementation process, and are therefore conceptualized as antecedents to change readiness. These dynamic conditions are further dividied into two categories: pre-change antecedents and change antecedents. The chapter concludes by addressing sustainability as an additional construct identified in the empirical material that is not fully captured within the existing CFIR framework.

5.1 Enabling and hampering conditions

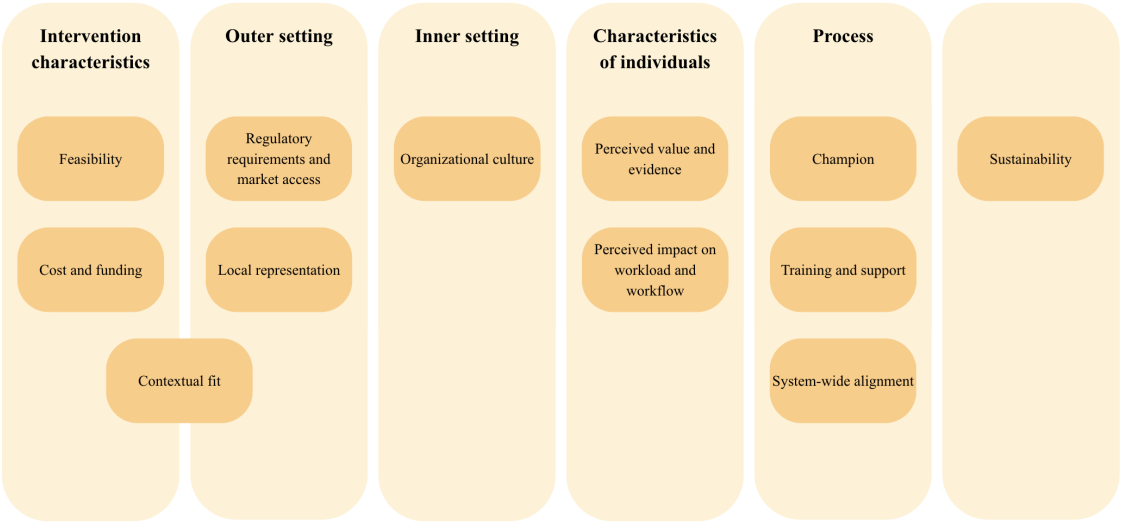
The identified enabling and hampering conditions from the empirical material have been categorized under their respective CFIR domains (Damschroder et al., 2009), as illustrated in Figure 12. Rather than clustering within one or two domains, these conditions are distributed across intervention characteristics, outer setting, inner setting, characteristics of individuals, and process in relatively equal measure. This suggests that successful implementation in LMIC contexts is not dependent on any single domain; instead, all identified conditions are relevant and need to be considered in combination.

This finding both aligns with and extends existing literature. Prior research has shown that the domains of intervention characteristics and outer setting tend to present the greatest barriers in LMIC contexts (Means et al., 2020). The most commonly reported challenges in these settings are linked to structural and contextual factors, including limited political support and policy constraints. The present analysis confirms the importance of intervention- and outer setting conditions, while also demonstrating that individual-, and process-level factors are equally represented in the data. The inner setting is presented as having fewer conditions than the other

domains; however, this does not imply that it is less important. Rather, the number of identified conditions within each domain should not be interpreted as an indicator of their relative importance. Based on the empirical material, there is no clear evidence that any single domain is more important than the others; rather, all domains appear to play a significant role in the success of implementation, which contrasts with previous theory (Means et al., 2020). Additionally, sustainability has been identified as an important construct that is not encompassed within any of the existing CFIR domains.

Figure 12

Enabling and hampering conditions across CFIR domains.



Note. Own illustration inspired by Damschroder et al. (2009).

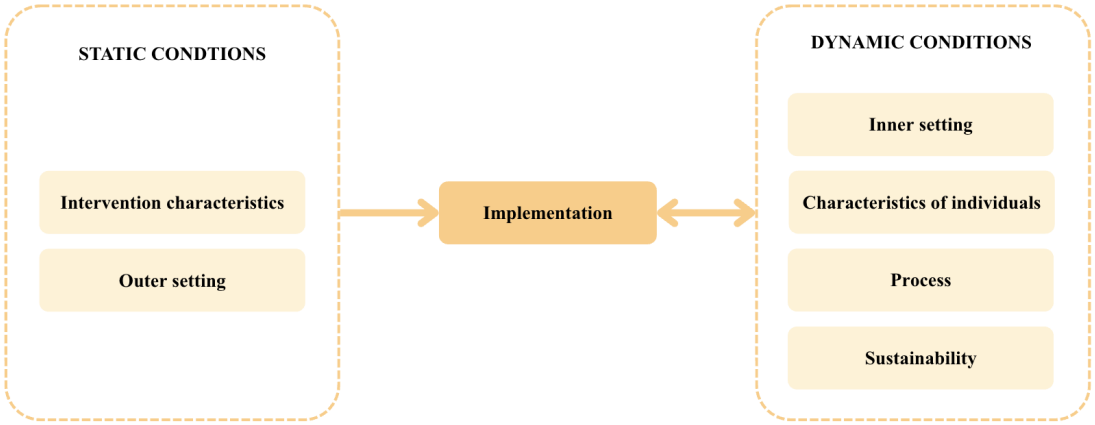
Beyond their distribution across the CFIR domains, the identified conditions were further analysed in relation to how they interact with the implementation process over time. CFIR distinguishes between factors that are non-modifiable and those that can be modified during implementation (Damschroder et al., 2009). Building on this distinction, this study introduces an additional analytical layer by differentiating conditions according to whether they remain relatively stable throughout the implementation process or whether they are subject to change as implementation unfolds.

This results in a distinction between static and dynamic conditions. Static conditions are characterized by their stability during implementation and their limited responsiveness to implementation processes. Dynamic conditions, in contrast, are conditions that both influence implementation and are themselves influenced by how implementation is carried out over time, thereby exhibiting a bidirectional relationship with the implementation process. As presented in Section 2.2, the dynamic conditions are subject to change and will therefore be analysed through a change management perspective.

In this analysis, intervention characteristics and the outer setting are primarily con-

ceptualised as static conditions, whereas the inner setting, characteristics of individuals, and the implementation process itself are conceptualised as dynamic conditions. This distinction is illustrated in Figure 13 .

Figure 13
Static and dynamic conditions in relation to the implementation.



Note. Own illustration.

5.1.1 Static conditions

Building on this distinction, the following section focuses on static conditions, conditions that influence implementation outcomes but remain largely unchanged by the implementation process itself. These conditions primarily shape the context in which implementation occurs rather than being shaped by it.

5.1.1.1 Intervention characteristics

The characteristics that define an intervention have a direct impact on implementation outcomes (Damschroder et al., 2009). Within the scope of this study, three factors emerge as particularly central: feasibility, contextual fit, and cost and funding.

Due to a lack of resources in LMICs, both human and material, challenges may arise in ensuring that an intervention can function effectively in practice within the local context (Leonard et al., 2020). This is also reflected in the empirical data of this study, which indicate that, particularly due to time and resource constraints, a new intervention cannot be cumbersome to use or require unnecessary time. It is therefore important that a new medical device is easy to use and demonstrates high feasibility. Furthermore, it was noted that existing infrastructure, such as electricity supply and system support, is not consistent across the context. As a result, a new medical device that is dependent on such infrastructure is less likely to be successfully implemented. This observation is consistent with previous research on implementation challenges in LMIC contexts (Leonard et al., 2020).

A common mistake in the implementation of new medical devices is failing to design for dissemination (Last et al., 2018), meaning that the context is not sufficiently taken into account during the design phase. The empirical material in this study also emphasizes the importance of understanding the problem prior to implementation, highlighting the need for alignment between the intervention and the context. Achieving such alignment becomes more difficult when the design process takes place before the problem and local needs have been properly identified. In the case examined in this study, design for dissemination was not applied. Instead, the medical device was developed primarily for HIC settings, which reflects what previous research suggests often occurs in practice (Last et al., 2018).

The most common reason for implementation failure is challenges related to the local context (Adlung et al., 2025). This is also reflected in the empirical material of this study, where concerns were not primarily directed at the intervention itself, but rather at how it is expected to adapt to and function within the local context. When a technology has been approved and used in a HIC, there is generally a high level of trust that the technology itself works. However, there is considerable skepticism regarding whether it will function equally well in a different context. Previous theory suggests that the intervention and the context interact dynamically, where implementation success depends both on the flexibility of the context and on how adaptable the intervention is (May et al., 2016). In contrast, the empirical results in this study indicate that the context is not perceived as adaptable. Instead, the context is viewed as relatively static, meaning that the intervention must fully match the existing conditions. The dynamic interaction between intervention and context highlighted in theory is therefore not evident in this case, where greater emphasis is placed on ensuring that the intervention fits the context from the outset.

The cost of an intervention is a critical factor in implementation, particularly in LMICs, where financing new initiatives is often challenging (Damschroder et al., 2009; Malkin, 2007). Similarly, the results of this study indicate that financial resources are limited and that the cost of the intervention must be adapted to the local context. Previous research suggests that the initial purchase price is not necessarily the primary financial barrier; rather, the main challenge lies in securing sustainable long-term funding (Malkin, 2007). The empirical material in this study partly aligns with this perspective, as emphasis is placed on the strength of the perceived need. When the need is considered sufficiently high, funding for the initial purchase can often be secured. However, the data also indicate that there is a limit to what can be financed, and that the purchase price itself can still constitute a barrier. There appears to be a threshold beyond which the costs are perceived as unreasonable, even when the intervention is considered valuable, and seeking external funders, such as NGOs, is indicated as necessary in order to cover excessive costs.

Beyond the purchase price, resources more broadly constitute a critical factor within the internal context, encompassing not only financial constraints but also limitations in human resources, maintenance capacity, staff expenses, and time. This reflects

previous research emphasizing that healthcare change initiatives must account for practical and resource-related constraints in order to be sustainable over time (Harrison et al., 2021). The empirical findings of this study reinforce this, illustrating how resource limitations influence implementation in multiple, compounding ways. Without adequate consideration of these constraints, there is a risk that implementation cannot be practically carried out, regardless of the perceived value of the intervention.

5.1.1.2 Outer setting

The outer setting refers to the external factors that influence implementation, including patients, external actors, and regulations (Damschroder et al., 2009). The empirical results of this study have identified three key aspects within this domain: contextual fit, regulatory requirements and market access, and local representation.

As previously established, the context and its unique characteristics are of critical importance for implementation, a point supported by both theory and the empirical results of this study (Adlung et al., 2025). The setting in which the intervention is intended to operate will inevitably influence implementation outcomes. One key insight emerging from the empirical material is the importance of understanding the problem before introducing a solution. The case examined in this research demonstrates that the medical device is likely to address some of the challenges present in the investigated healthcare processes, but not all of them. Geographic distances, shortages of staff and equipment, and gaps in knowledge represent barriers that cannot be resolved solely through the introduction of a new medical device. These practical constraints have previously been identified as common challenges to implementation in LMICs (Leonard et al., 2020). Without a sufficient understanding of the context, there is a risk of assuming that the problem has been fully addressed when, in reality, significant operational barriers remain due to the absence of these essential practical conditions.

Patients are a key component of the outer setting, and their needs should be prioritized (Damschroder et al., 2009). The empirical results indicate a substantial need for improvements in the investigated care pathway, where patients currently do not receive well-functioning care. As a result, there has been a positive attitude and openness toward change, given the evident shortcomings and opportunities for improvement. It is clear that there is little value in attempting to solve a problem that does not exist, particularly in an already resource-constrained context. However, when a clear need is present within the setting, the likelihood of successful implementation increases (Damschroder et al., 2009).

Government regulations are also encompassed within the outer setting and are highly context-specific (Damschroder et al., 2009). Political support and policies have been described as major barriers to implementation, where active commitment from government authorities is considered essential for successful implementation (Leonard et al., 2020; Nnaji et al., 2021). The empirical material in this study presents a partly

similar picture. Regulatory requirements are, in line with theory, described as essential for moving forward with implementation. However, in the context examined in this study, these requirements do not typically function as barriers. Instead, they are described as relatively straightforward and uncomplicated to meet. While they must be in place, they are rarely perceived as obstacles. Where previous research characterizes government regulations as one of the most significant constraining factors in LMIC settings (Means et al., 2020), the empirical material in this case does not reflect the same pattern. Rather, regulatory requirements are perceived as enabling conditions for implementation.

Furthermore, the empirical material indicates broad agreement that a local representation is essential for establishing credibility and reliability in the market, which concerns the degree to which an organization is networked with and connected to external actors (Damschroder et al., 2009). In the studied case, the absence of such a network would constitute a significant barrier to implementation, whereas its presence functions as an enabling condition.

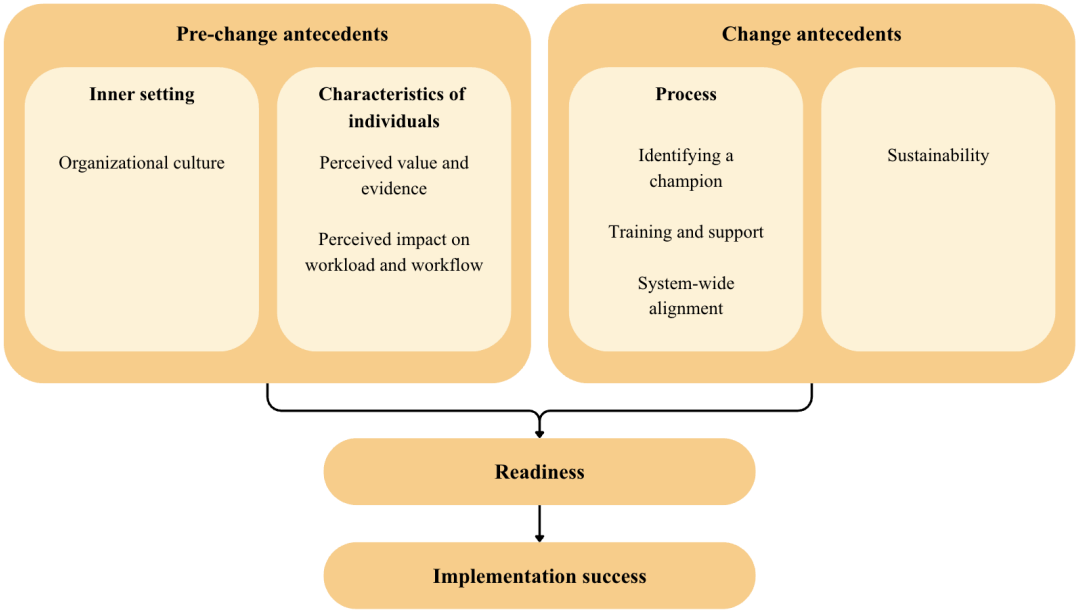
Collaboration with an established local distributor provides existing networks, market knowledge, and credibility that a new market entrant would otherwise lack. This is particularly relevant given that poor coordination among actors within the health system has been identified as a common barrier to implementation in LMICs (Leonard et al., 2020). A well-connected local partner can therefore serve not only a commercial function but also a bridging role between the implementing organization and the healthcare system. Strong relationships between stakeholders have similarly been described as essential for successful implementation, where shared goals and trust reduce the risk of conflict and resistance (Nnaji et al., 2021).

5.1.2 Dynamic conditions

Having outlined the static conditions that shape the implementation context, the focus now shifts to conditions that are not only influential but also subject to change throughout the implementation process. Because of their bidirectionality, they are likely to be influenced by the implementation and will thus need to undergo change. Therefore, these conditions are conceptualized as antecedents to change readiness, which in turn is understood as a key determinant of implementation success. Readiness can be understood through two broad categories of antecedents: pre-change antecedents and change antecedents (Oreg et al., 2011). Pre-change antecedents concern factors that exist prior to and independently of the change itself, yet shape how individuals and organizations respond to it. In the present analysis, two CFIR domains are positioned within this category: the inner setting and characteristics of individuals. Change antecedents, in contrast, concern factors directly tied to the change process itself. Here, the CFIR process domain captures how the implementation is carried out. Alongside this, sustainability has been identified as an emerging construct within this category, reflecting the importance of maintaining and embedding the change into organizational routines over time.

Higher readiness across these dimensions is associated with greater effort, persistence, and collaboration during implementation, thereby contributing to implementation success (Weiner, 2009). This structure is reflected in Figure 14, which organizes the identified conditions accordingly.

Figure 14
Dynamic conditions as antecedents to change readiness.



Note. Own illustration inspired by Oreg et al. (2011).

5.1.2.1 Inner setting

The first central component within pre-change antecedents is the internal setting (Oreg et al., 2011). The inner setting refers to the structural, cultural, and organizational characteristics of the implementing organization that influence how an implementation effort unfolds (Damschroder et al., 2009). The empirical results of this study have identified one condition within this domain: organizational culture. Even when all tangible aspects of an implementation are taken into account, there remain less visible but influential factors embedded within the organizational culture (Damschroder et al., 2009). Organizational culture exists within the internal context of the organization, shaping how individuals interpret, respond to, and engage with implementation efforts.

The empirical findings indicate that the organization is characterized by a hierarchical structure where rules are followed and there is limited emphasis on innovation and new thinking. There is a strong sense of cultural stasis, where practices have been carried out in the same way for a long time and there is little perceived need for change. Such a culture can act as a pre-change antecedent that constrains the readiness for change (Oreg et al., 2011). In contrast, a strong teamwork culture can increase readiness for change (Armenakis et al., 1993), which is not reflected in this

study. Previous implementation research in LMICs similarly shows high levels of hierarchical structures (Means et al., 2020), which negatively influence readiness for change (Armenakis et al., 1993; Oreg et al., 2011).

Change in such top-down cultures can be understood as planned change, where change is carried out in a structured and sequential manner, and is viewed as a series of steps that need to be followed (Todnem By, 2005). This approach has been criticized for insufficiently considering organizational culture, as it often assumes stable conditions, whereas in reality deeply rooted routines may hinder change from taking hold. Hidden factors within the organizational culture are not taken into account, which means that a central part of the pre-change antecedents is overlooked despite its significant influence on the change process (Oreg et al., 2011). It has also been observed that a bottom-up approach in healthcare increases the likelihood of successful change, as more individuals feel involved and gain a better understanding of the change (Hastings, 2025). In this context, addressing a hierarchical culture characterized by embedded stasis becomes a key challenge.

During implementation, it is not uncommon for organizational culture to act as a barrier due to lack of community acceptance (Leonard et al., 2020). The empirical findings similarly indicate concerns that new medical devices may struggle to gain acceptance among healthcare staff. This can largely be explained by the fact that previous training and professional socialization have been based on established routines and existing technologies. When new practices conflict with what has already been learned, this can be understood through the cognitive dimension of reactions to change, where individuals evaluate the change based on their existing knowledge and beliefs (Oreg, 2006; Piderit, 2000). As a result, the change may be perceived as inappropriate or incorrect. In this way, achieving community acceptance becomes challenging, as the change is not perceived as compatible with existing knowledge and established practices.

5.1.2.2 Characteristics of individuals

The second component within the pre-change antecedents, which refers to factors present prior to the change, concerns individuals (Oreg et al., 2011). The empirical material shows that attitudes toward change vary between individuals. For example, one perspective suggests that older individuals may be more open to change due to having more routine and time to engage with it, while another argues that older individuals may be less open because they have performed tasks in the same way for a long time and therefore do not see the purpose of change. There is thus no clear pattern regarding openness to change based on role or experience. This can be explained by the fact that individuals respond to change across cognitive, emotional, and intentional dimensions, making it difficult to generalize groups as either open or resistant to change (Oreg, 2006; Piderit, 2000). As a result, responses to change may differ even among individuals working in the same setting, which adds complexity to implementation. However, despite this variation between individuals, two conditions, related to the characteristics of individuals, have been identified as

central to attitudes toward change: perceived value and evidence, and perceived workload and workflow.

Clear patient benefit emerges in the empirical material as a decisive factor for individuals' openness and readiness for change. It is described that individuals working in the context have a strong commitment to ensuring the best possible care for patients, and that any change positively affecting patient outcomes is generally welcomed. Readiness for change can be described in terms of change commitment and appropriateness, which refer to whether the change is perceived as necessary (Armenakis et al., 1993). If patient benefits are clearly demonstrated, the change is more likely to be perceived as necessary, thereby increasing readiness for change. Expected outcomes are also highlighted as important, as they influence both the cognitive and emotional dimensions of reactions to change, meaning that when staff perceive clear benefits for patients, their reactions tend to become more positive (Oreg, 2006). In healthcare settings, a clear focus on patient benefit has also been shown to positively influence change initiatives (Harrison et al., 2021). Thus, both empirical findings and theory support that perceived patient impact plays a major role in individuals' attitudes toward change and, consequently, in the success of implementation.

The perceived impact on workload and workflow plays an equally significant role in individuals' attitudes toward change. The empirical material indicates that, due to already high workloads, additional tasks are not considered feasible, and if implementation is perceived as increasing workload, resistance is likely to arise. This resistance can be understood as justified given the current level of strain, as there is insufficient capacity to accommodate additional tasks (Weiner, 2009). In an already pressured situation, change may also contribute to uncertainty, and it is not uncommon for change initiatives to increase stress and the risk of burnout (Cheraghi et al., 2023; Ellis et al., 2023). Importantly, however, the empirical findings also reveal a strong willingness to change when it is perceived as leading to a reduction in workload. Resistance should therefore not only be interpreted as an obstacle, but as a signal of what is actually valued within the organization, a meaningful form of feedback that highlights where the pressures lie and what must be addressed for change to be sustainable (Ford & Ford, 2010). Implementation is often perceived as an additional task rather than an integrated part of daily work, which, in the context of limited resources, is not seen as feasible. As a result, change initiatives risk being perceived as an added burden, reducing employees' willingness and ability to engage, and thereby lowering overall readiness for change (Weiner, 2009).

Taken together, these two conditions, perceived patient benefit and perceived workload impact, point to a central challenge in implementation regarding the perceived value of the change. Although the change may objectively generate value for patients and potentially improve workload in practice, this has limited impact if individuals perceived value does not align with the intended benefits. The main challenge therefore lies in communicating and engaging staff in a way that ensures the perceived value corresponds with the intended vision of the change.

Previous research has shown that frontline staff are often not sufficiently involved in implementation processes, despite their significant influence on outcomes (Breimaier et al., 2015). Similarly, fostering motivation and understanding of the change is frequently overlooked (Harrison et al., 2022), which is also reflected in the empirical findings, where frontline staff often report limited involvement and insufficient information regarding changes occurring in their work environment. To create a shared perception of value, communication of the change must effectively reach staff, thereby increasing readiness for change (Ellis et al., 2023). Through staff involvement and engagement, individuals are more likely to perceive the change as necessary and to develop a personal understanding of the problem, rather than only being informed about it (Armenakis et al., 1993; Silvola et al., 2024). This process is closely related to the creation of a sense of urgency, where individuals come to recognize the importance and necessity of change as a result of both communication and their own work-related experiences (Kotter, 1995).

5.1.2.3 Process

The success of a change is not determined solely by factors present before the change occurs, but also by how the change is implemented, which relates to change antecedents (Oreg et al., 2011). It has even been suggested that how a change is implemented may be more important than the content of the change itself. Three conditions, representing key aspects of the implementation process, have been identified: identifying a champion, training and support, and system-wide alignment.

The presence of a champion is regarded as a key facilitator in implementation processes (Leonard et al., 2020). The empirical findings further suggest that a champion is not only an enabler but a decisive factor for success; without a champion, implementation may not occur at all. Consequently, identifying this individual becomes of critical importance. The empirical material also highlights the importance of the champion being a medical practitioner in order to establish trust among those involved. Similarly, authentic leadership has been emphasized as important for inspiring others and building trust (Kosiol et al., 2024). This also aligns with a more bottom-up approach, where individuals working closest to the innovation in practice drive the change forward in a way that enhances acceptance among staff (Cheraghi et al., 2023; Silvola et al., 2024).

The findings also indicate that training and support will be of great importance in the implementation of a new medical device. Staff need to feel confident in using the device and trust their own ability, referred to as change efficacy (Weiner, 2009). Without sufficient change efficacy, readiness for change is likely to decrease. The empirical findings highlight the need for both theoretical and practical training, as both components are necessary to achieve sufficient efficacy (Weiner, 2009). In this context, the importance of training becomes even more pronounced in settings characterized by high staff turnover, which is common in LMICs (Malkin, 2007). Frequent staff changes risk undermining accumulated competence, making continuous training essential to sustain knowledge over time. This need for ongoing

training is also reflected in the empirical material, suggesting that competence must be renewed at a pace that exceeds its loss. This aligns with the final stage of the eight-step model for transforming organizations, which emphasizes institutionalizing new practices (Kotter, 1995).

Training constitutes part of the task demands, defined as the activities required to carry out the change (Weiner, 2009). While training and support are essential, the empirical material shows significant resource constraints. Training and use of the medical device cannot be too time-consuming, as time is limited and staff are already managing high workloads. This creates a tension between the need for comprehensive training to build change efficacy and the practical realities of clinical environments. This reflects previous research emphasizing that healthcare change initiatives must consider practical limitations to be sustainable over time (Harrison et al., 2021). If training is perceived as too demanding or disruptive, there is a risk that it will not be prioritized, ultimately undermining both adoption and long-term use of the medical device.

Finally, understanding the inner setting requires considering the entire system. The empirical findings highlight the need for system-wide alignment in implementation. Even if a change has theoretical value, it will not be effective unless it is implemented in a way that works across the entire system. In systems where multiple units are interdependent, all parts must be aligned for the change to function in practice. Similarly, theory emphasizes the importance of communication (Ellis et al., 2023; Kotter, 1995). Effective and continuous communication therefore becomes a critical mechanism for ensuring coordination, shared understanding, and sustained alignment across all parts of the system.

5.1.2.4 Additional construct - Sustainability

A prominent theme emerging from the empirical material is sustainability, the capacity to maintain an innovation in active use over time. This theme represents a critical but underrepresented dimension within CFIR. While the framework touches on related aspects implicitly, for instance, resources under readiness for implementation and costs under intervention characteristics, sustainability as a coherent analytical concept lacks a dedicated construct or domain. The empirical material suggest that this constitutes a significant gap when CFIR is applied in LMIC contexts. Sustainability should furthermore be recognised as a critical antecedent to change processes.

Consistent with previous research (Leonard et al., 2020; Malkin, 2007), the empirical material suggests that the initial purchase price is rarely the primary barrier to sustained implementation. Rather, long-term operational demands, such as maintenance, spare parts, and consumables, appear to be more decisive in determining whether an innovation remains functional over time. Structural conditions characteristic of LMIC settings, including limited local technical capacity and constrained supply chains, further complicate these challenges. Such conditions are not sys-

tematically captured within CFIR, which has largely been developed and validated in HIC contexts, and may therefore be insufficiently adapted to the system-level realities of LMICs (Damschroder et al., 2022).

Characteristics of systems has been proposed as an additional domain when applying CFIR in LMIC contexts, emphasizing the importance of understanding long-term resource availability, funding mechanisms, and how innovations align with existing system structures (Means et al., 2020). The present result provides empirical grounding for this proposal and offer a more specific account of what such a domain would need to encompass: local capacity for maintenance and technical support, reliable access to consumables and spare parts, and structures for continuous training in contexts characterized by high staff turnover. Together, these three dimensions constitute the core of the sustainability concept that emerges from the results.

Beyond what existing theory anticipates, the results point to staff turnover as a particularly consequential LMIC-specific factor for sustainability. High turnover means that training cannot be treated as a one-time activity during the implementation phase, but must be embedded as a recurring component of ongoing operations. This insight is not explicitly accommodated within CFIR's process domain, which focuses on engagement and execution during the implementation period but does not extend to the continuous knowledge maintenance required thereafter. Furthermore, as noted both in the empirical data and in the literature, there is a greater risk in introducing innovations that are not sustained than in not introducing them at all, when a system begins to rely on a new way of working, its sudden discontinuation creates disruption (Nnaji et al., 2021). This reinforces the argument that sustainability should not be treated as an afterthought or subsumed under existing constructs, but recognized as an additional domain within CFIR when applied in LMIC contexts, with its own determinants and implications for practice.

6

Discussion

This chapter discusses the findings of the study in relation to both the specific case and the broader theoretical framework. The chapter begins by examining the practical implications of the identified conditions as they manifest in the context of Strokefinder MD100 in the Western Cape, distinguishing between conditions that are likely to enable and those likely to hamper implementation. The chapter subsequently presents the theoretical implications of the study, including a contribution to implementation theory through a framework for differentiating types of implementation implications, and a contribution to CFIR through the identification of sustainability as an additional construct of particular relevance in LMIC contexts.

6.1 Practical implications

The conditions identified in previous sections can, depending on context and circumstance, function as either enabling or hampering factors for implementation. The same condition may facilitate implementation in one setting while constituting a barrier in another. Building on the preceding analysis, this section applies those conditions to the specific case of Strokefinder MD100 in the Western Cape. Rather than treating them as neutral or context-independent, the aim is to examine how each condition currently manifests in this particular context, that is, whether it is likely to support or impede implementation in practice. Both policymakers and healthcare managers need to account for these enabling and hampering conditions when planning and implementing the use of Strokefinder MD100 in the Western Cape.

6.1.1 Enabling implications

Several conditions in the current context are likely to support the implementation of Strokefinder MD100. Together, they suggest that a foundation for successful implementation exists, provided that the hampering conditions discussed below are actively managed. Figure 15 summarizes the enabling conditions for the implementation of Strokefinder in the Western Cape.

Figure 15
Enabling implications.

Note. Own illustration.

A particularly strong enabling factor is the clear contextual need for change. Stroke care in the Western Cape is currently not functioning optimally, with few patients receiving treatment within the recommended time window. This creates a meaningful opening for an intervention that can improve triage and shorten referral pathways. When a genuine problem exists and is widely recognized, the case for change becomes considerably easier to make, both to decision-makers and to frontline staff.

Closely connected to this is the strong commitment to improving patient outcomes that characterizes those working in the context. Staff are motivated by patient benefit, and when a change is perceived as genuinely improving care, it is more likely to be welcomed. This commitment is also influenced by the perceived need for change, as the high workload experienced by healthcare staff creates pressure to improve current practices. When staff experience firsthand the inefficiencies of the current stroke pathway, there is a pre-existing receptiveness to solutions that could reduce that burden. This is described as a form of organizational readiness, when people recognize the discrepancy between current and desired states, commitment to change is more readily mobilized (Armenakis et al., 1993). The challenge, as discussed below, lies in ensuring that Strokefinder MD100 is perceived as reducing rather than adding to that burden.

On the intervention side, the fact that Strokefinder MD100 operates as a standalone system via a tablet-based interface independent of existing digital infrastructure is a meaningful advantage in a context where power supply and connectivity are inconsistent. The device's demonstrated ease of use, short measurement time, and manageable training requirements further support feasibility. Previous feasibility studies indicate that the device can be operated with approximately 12 hours of training, produces results in approximately 45 seconds, and has not been shown to negatively affect time to treatment (Tsiftsis et al., 2024). These characteristics align well with the practical realities of a resource-constrained environment.

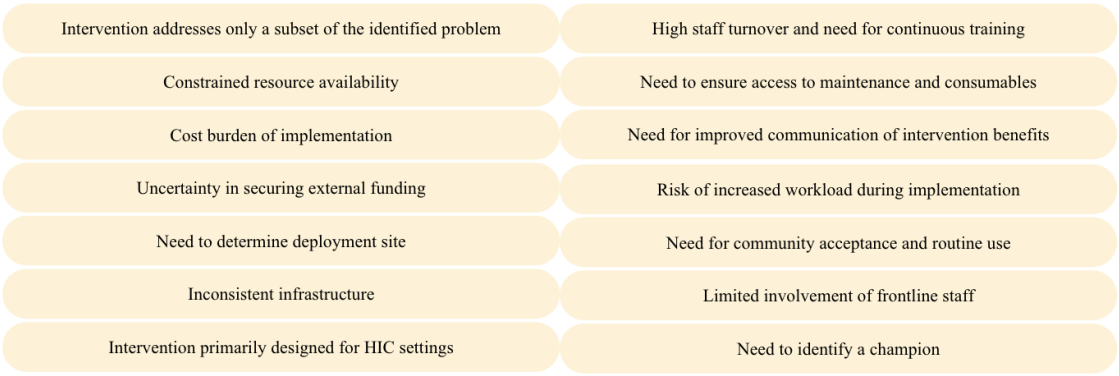
Regulatory requirements are also likely to function as an enabling rather than ham-

pering condition. Given that Strokefinder MD100 already holds CE approval, SAHPRA registration is expected to be relatively straightforward. While manufacturing and distribution requirements, including ISO 13485 certification and BBBEE compliance, will need to be addressed, these are manageable conditions rather than fundamental barriers, provided they are approached proactively. Finally, the opportunity to establish local representation through an experienced distributor represents a further enabling factor. A well-connected local partner brings existing networks, market knowledge, and regulatory familiarity that would otherwise take considerable time and investment to develop independently, and that can meaningfully reduce the risk of the coordination failures that commonly hamper implementation in LMIC health systems (Leonard et al., 2020).

6.1.2 Hampering implications

Against these enabling factors, a number of conditions are likely to complicate implementation and will require focused attention. Figure 16 summarizes the hampering conditions for the implementation of Strokefinder in the Western Cape.

Figure 16
Hampering implications.



Note. Own illustration.

A fundamental starting point is that Strokefinder MD100 addresses only part of the problem in the studied stroke pathway. The delays currently present in stroke pathways have multiple causes, and the device is likely to positively influence some but not all of them, as outlined in Section 4.1.2.4. Earlier and more reliable identification of stroke can potentially shorten or reduce delays as it may enable faster prioritization and avoiding unnecessary transport steps. However, a substantial set of challenges will remain unaffected. Limited public awareness of stroke symptoms, ambulance shortages and geographical distances between facilities are some of the reasons that many of the presented delays in the stroke pathway will remain. At the tertiary level, resource constraints and competing priorities among seriously ill patients will persist, making it hard to prioritize patients. It is therefore important that Strokefinder MD100 is framed and understood as one component within a broader set of interventions, rather than as a comprehensive solution. Overstating

the device's capabilities may create misaligned expectations that ultimately weaken the case for implementation when those expectations are not met.

The most overarching hampering condition is limited resources, which manifests across multiple dimensions simultaneously. Financial constraints limit what can be procured and sustained; human resource shortages mean that staff are already operating near capacity; and time constraints reduce the space available for training, adaptation, and engagement with new practices. The cost of Strokefinder MD100 has been perceived as high for the current context, and while cost-effectiveness evidence exists, this alone is unlikely to be sufficient to secure funding. Seeking support from external partners such as NGOs with a specific interest in stroke care will likely be necessary, and building a compelling case around demonstrated clinical need and system-level value will be central to that process. The placement decision of Strokefinder MD100 is important not only for maximizing overall clinical benefit, but also for its cost implications. Deployment in ambulances and lower-level facilities is likely to yield the greatest clinical benefit but requires a larger number of devices, resulting in higher overall costs. In contrast, placement at higher-level facilities would require fewer devices, but the potential clinical benefit is more limited. This reflects a clear trade-off between maximizing clinical benefit and minimizing costs.

Related to resource constraints is the challenge of infrastructure and contextual factors. Although the device itself is infrastructure-independent in terms of digital connectivity, it requires reliable access to electricity for battery charging. In settings where power supply is inconsistent, this must be addressed through established routines rather than assumed. More broadly, the fact that the device was originally designed for HIC settings means that contextual alignment cannot be taken for granted. Failing to design for dissemination, that is, developing an intervention without sufficient consideration of the context in which it will be used, is a common reason why innovations developed in high-income settings fail to transfer successfully to LMIC contexts (Last et al., 2018). This places a greater burden on the implementation process itself to ensure that the device is introduced in a way that reflects local realities.

High staff turnover represents a further structural challenge with direct implications for sustainability. Training cannot be treated as a one-time activity; it must be embedded as a recurring component of ongoing operations so that competence is renewed at a pace that keeps up with staff changes. This is particularly consequential in settings where stroke cases may not occur daily, raising legitimate concerns about whether staff will retain sufficient familiarity with the device to use it reliably when needed.

In relation to sustainability, ensuring access to maintenance and consumables must be planned for explicitly rather than left as a logistical afterthought in this context. Service agreements need a local base, with someone within the country able to carry out repairs and access spare parts. The protective bags used with each patient represent a recurring consumable cost that requires a stable and reliable procurement

system. It is in these operational dimensions, not in the initial implementation, that innovations most often fail to be sustained over time in LMIC contexts (Malkin, 2007). There is a greater risk in introducing an innovation that is not sustained than in not introducing it at all, when a system restructures itself around a new way of working, discontinuation creates disruption that is difficult to reverse (Nnaji et al., 2021).

A cluster of interrelated hampering conditions concerns the social and organizational dimensions of implementation. Communicating the perceived benefits of implementation effectively and system-wide will be essential but is not straightforward. The value of the device must be understood not only in clinical terms but also in relation to workload. If staff perceive implementation as an additional burden rather than a relief, resistance is likely to follow. This concern is amplified by the low specificity of the current CE-marked version. While some staff view false positives as an acceptable trade-off given the priority of identifying all potential stroke patients, others anticipate an unmanageable increase in referrals to already strained tertiary facilities. Without transparent communication about how the device fits into the pathway and what its limitations are, this latter form of skepticism is likely to persist.

Organizational culture adds a further layer of complexity, in hierarchical settings where practices have been stable over time, there is a strong sense of cultural stasis that can act as a pre-change antecedent constraining readiness for change (Oreg et al., 2011). The device must be clearly positioned as a prescreening and triage tool, not as a replacement for neuroimaging, since any perception that it threatens established clinical practice is likely to generate significant resistance. Achieving community acceptance and system-wide alignment therefore requires not only communication but genuine involvement of frontline staff throughout the implementation process, which is often not the case in practice. Even where acceptance is achieved, translating that acceptance into consistent routine use represents a separate challenge. New practical routines must be established and maintained; charging batteries, replacing protective bags, and ensuring that the device is reliably used when a relevant patient presents. Without these routines becoming an integrated part of daily work, there is a risk that the device is available in principle but not used consistently in practice.

Identifying a champion is a critical process-level condition. The empirical material suggests that without a champion, implementation may not advance at all. The individual must be a medical practitioner with credibility among peers, an understanding of the clinical context, and a recognition of the need for change. Some awareness of Strokefinder MD100 already exists in relevant professional networks, which provides a starting point. The forward-looking challenge is sustaining that relationship over time, given that the champion role adds responsibility on top of existing clinical duties. Identifying this individual and retaining them over time emerges as a central challenge.

6.2 Theoretical implications

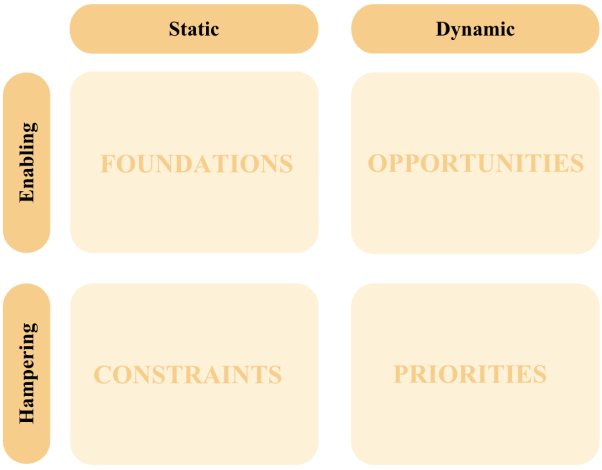
This section discusses the theoretical implications of the study and is structured in two parts. First, it elaborates on the contribution to implementation theory by refining how implementation conditions can be understood and categorized along the dimensions of enabling and hampering, as well as static and dynamic characteristics. Second, it outlines the study's contribution to CFIR, with particular attention to the emergence of sustainability as a cross-cutting construct not fully captured within the existing framework.

6.2.1 Contribution to implementation theory: differentiating types of implications

Having identified which factors function as enabling or hampering in the present case, the discussion can be extended by drawing on Damschroder et al. (2009) distinction between modifiable and non-modifiable factors. Building on this, the present study distinguishes between two dimensions of implementation implications: whether they are enabling or hampering, and whether they are static or dynamic in nature. Static factors remain relatively stable throughout the implementation process, whereas dynamic factors are subject to change as implementation unfolds. The dynamic factors identified in this study were previously shown in the analysis to be responsive to implementation processes and therefore require active management to support optimal implementation readiness.

Taken together, these two dimensions are used to distinguish between four types of implementation implications: foundations, opportunities, constraints, and priorities, as illustrated in Figure 17.

Figure 17
Differentiating types of implications.



Note. Own illustration.

Conditions that function as enabling factors are categorized as either foundations or opportunities, depending on whether they are static or dynamic in nature. Conditions that function as hampering factors are, in turn, categorized as either constraints or priorities, following the same distinction. The sections below present each category.

6.2.1.1 Foundations

Foundations represent static conditions that are already in place and that provide a favorable basis for implementation. Although they cannot be altered, they constitute important assets that the implementation can rely upon and build from. Figure 18 summarizes the implications categorized as foundations.

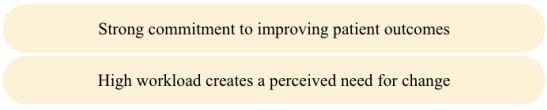
Figure 18
Foundations.

Note. Own illustration.

6.2.1.2 Opportunities

Opportunities represent dynamic factors that function as enabling conditions and are subject to change. Unlike foundations, they can be actively reinforced and further developed throughout the implementation process. They therefore represent areas where targeted efforts can strengthen implementation and enhance readiness. Figure 19 summarizes the implications categorized as opportunities.

Figure 19
Opportunities.



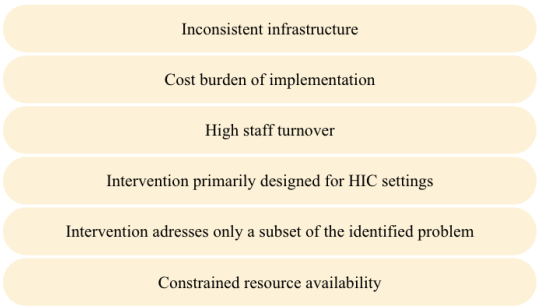
Note. Own illustration.

6.2.1.3 Constraints

Constraints are static conditions that limit the implementation and cannot be directly altered. It encompasses conditions that represent structural risks inherent to the implementation context. These are factors that are neither favorable for implementation nor possible to eliminate. Rather than attempting to remove them,

implementation efforts must be designed around them. Certain contextual conditions fall outside the sphere of influence and must therefore be acknowledged and accounted for rather than resolved (Damschroder et al., 2009). Awareness of their presence is in itself a critical first step, as it allows to proactively design strategies that mitigate their impact. Figure 20 summarizes the implications categorized as constraints.

Figure 20
Constraints.

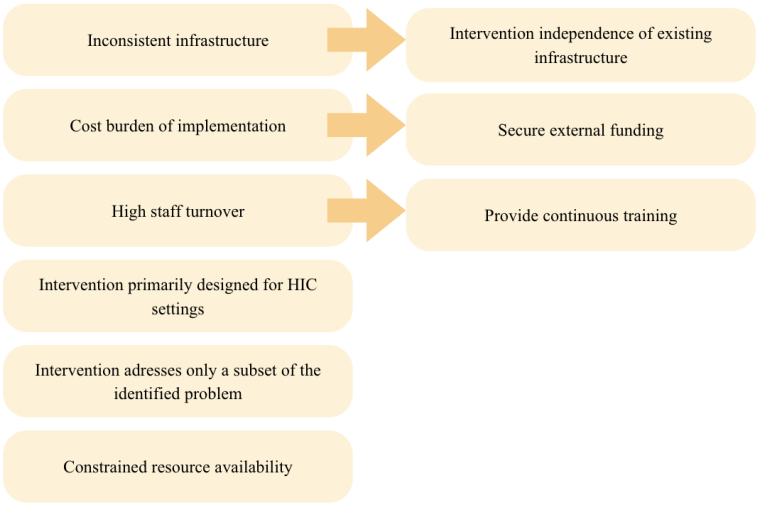


Note. Own illustration.

Several of the identified constraints can be addressed through directed actions and established foundations. Inconsistent infrastructure is partly offset by the intervention's limited dependence on external systems, allowing it to function adequately even under variable conditions. The cost of the intervention has been identified as a significant barrier in this resource-constrained context. To address this, it is recommended that external funding sources, such as NGOs or research funding bodies, are explored in order to cover implementation costs. High staff turnover represents a persistent structural challenge that, while impossible to eliminate, can be partially mitigated through ongoing training that ensures competence is maintained despite staff changes.

However, three constraints remain that cannot be resolved through additional measures. The intervention is fundamentally designed for a HIC context and has therefore not been developed from the outset to address the specific problem and conditions present in this setting. This may also help explain the second remaining issue, namely that the intervention does not fully resolve the identified problem. In addition, limited resources constitute an underlying structural constraint that further affects the scope and feasibility of the intervention. The constraints, with and without mitigation measures, are illustrated in Figure 21.

Figure 21
Constraints, with and without mitigation measures.



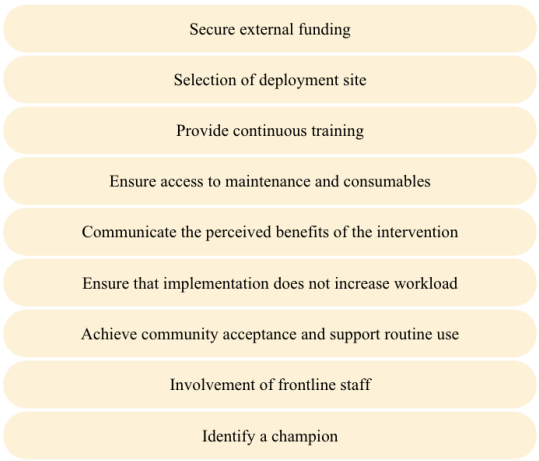
Note. Own illustration.

The contextual fit is therefore not complete, and these three aspects represent central considerations, as they constitute both hampering and static factors that cannot be addressed. The implementation will thus proceed with these constraints in place, raising the question of whether it is justified to continue despite these constraints.

6.2.1.4 Priorities

Priorities represent conditions that currently generate low readiness for change but that, unlike constraints, have the capacity to shift. These are factors that have not yet been addressed but that carry significant potential to shift from hampering to enabling through targeted action. Collectively, they represent the most critical action areas for the implementation, as progress within these areas is likely to have the greatest impact on overall readiness and implementation success. While each of these conditions has been analyzed in detail in the foregoing sections, they are summarized in Figure 22 as concrete recommendations to guide the continued direction of the implementation.

Figure 22
Priorities.

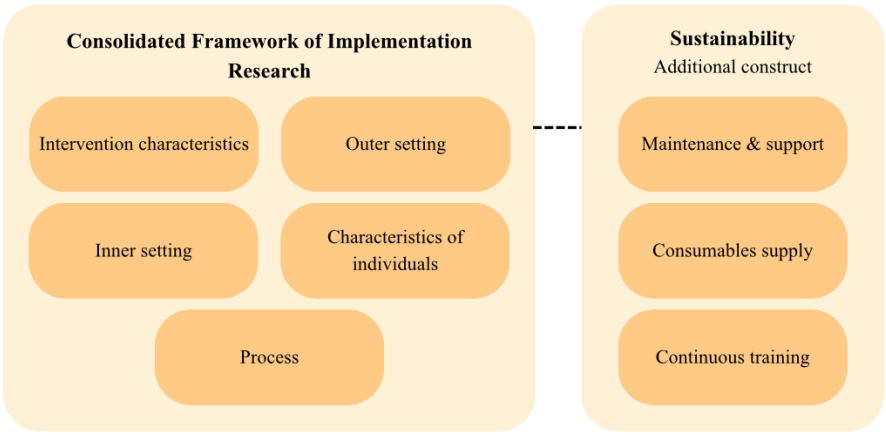


Note. Own illustration.

6.2.2 Contribution to Consolidated Framework for Implementation Research

This study applied the CFIR as its primary analytical lens for identifying enabling and hampering conditions for the implementation of medical devices in stroke diagnostic processes in LMICs. While CFIR proved valuable in structuring the analysis across its five established domains, intervention characteristics, outer setting, inner setting, characteristics of individuals, and process, the empirical findings of this study reveal a critical condition that cannot be adequately accommodated within any of these existing domains (Damschroder et al., 2009). Specifically, sustainability emerged as a distinct and cross-cutting construct that operates beyond the scope of what CFIR currently captures, thereby constituting a theoretical extension to the framework, as illustrated in Figure 23.

Figure 23
Sustainability as an additional construct to the Consolidated Framework for Implementation Research.



Note. Own illustration based on Damschroder et al. (2009).

Within CFIR, the concept of sustainability is not explicitly represented as a construct. Aspects related to long-term viability of an implementation are touched upon indirectly across some domains, for instance, long-term cost and resource considerations appear under intervention characteristics (Damschroder et al., 2009). Yet none of the domains addresses sustainability as a coherent and standalone condition for implementation success. This study argues that this represents a conceptual gap, particularly consequential in resource-constrained settings where the sustainability of an innovation may be an even greater determinant of real-world value than initial implementation itself.

The empirical evidence gathered in the Western Cape context demonstrates that sustainability constitutes a qualitatively different concern from the conditions captured within CFIR's existing domains. Respondents consistently identified sustainability not as a downstream concern but as a prerequisite that must be planned for from the outset of implementation. Three dimensions of sustainability were found to be particularly critical: maintenance capacity, including the availability of local technical expertise and spare parts, the supply of consumables, in terms of both affordability and accessibility, and the continuity of training and support structures over time.

The implementation gap, the persistent delay or failure of evidence-based innovations to reach routine clinical use, is well documented in the implementation science literature (Balas & Boren, 2000; Brailsford, 2023; Morris et al., 2011). This study's findings suggest that sustainability constitutes an underexplored dimension of this gap: innovations may be successfully adopted initially, yet still fail to produce lasting value if conditions for their continued use are not secured. This dynamic is particularly acute in LMIC contexts, where structural resource constraints mean that discontinuation risk is not an exception but a systemic feature of the implementation environment.

The contribution of this study to CFIR is therefore that sustainability should be incorporated as an explicit additional construct in future applications of the framework, particularly in LMICs and other resource-constrained settings, to ensure that implementation analyses capture not only the conditions for initial adoption but also those required for continued use over time.

7

Conclusion

This conclusion first addresses the research questions guiding the study. It then presents the key conclusions drawn from the analysis, highlighting the main insights on implementation in relation to both the empirical case and the broader theoretical framework. Finally, it outlines the study's limitations and future research directions, highlighting areas that require further investigation.

7.1 Current implementation context for stroke diagnostic processes in the Western Cape, South Africa

The Western Cape healthcare system operates under substantial structural strain, shaped by a deeply unequal dual-sector structure in which approximately 80% of the population depends on an underfunded public system. Stroke care within this system is neither linear nor uniform. Patients enter the pathway through multiple routes, via EMS or private transport, and move sequentially through a referral hierarchy of clinics, district hospitals, regional and tertiary hospitals. At each transition, delays accumulate. These include delayed symptom recognition, ambulance shortages, limited CT imaging availability at lower-level facilities, long waiting times for inter-facility transfers, and competition for diagnostic resources at tertiary level. The cumulative effect is that most patients fall outside the treatment window before diagnosis is completed, meaning that only a small proportion ultimately receives timely treatment.

Within this context, Strokefinder MD100 is most applicable in the early stages of the pathway, in ambulances and at lower-level facilities such as clinics and district hospitals, where it could function as a triage and pre-screening tool. By enabling earlier identification of suspected stroke, the device could support faster prioritization and more targeted referral decisions. However, its impact is inherently limited: delays rooted in public awareness, ambulance capacity, geographical distances, and resource constraints at tertiary level would remain unaffected. Strokefinder MD100 should therefore be understood as a partial intervention capable of improving specific segments of the pathway, not as a comprehensive solution to stroke care in the

Western Cape.

7.2 Enabling and hampering conditions for an implementation of medical devices in stroke diagnostic processes in LMICs

Twelve conditions were identified as influencing implementation, each capable of functioning as either enabling or hampering depending on how it is managed in practice, see Table 4. These conditions span five domains drawn from CFIR: intervention characteristics, outer setting, inner setting, characteristics of individuals, and process. In addition, sustainability emerged as a cross-cutting condition not adequately captured within any of the existing CFIR domains, and is therefore proposed as an additional construct of particular relevance in LMIC contexts. Rather than being fixed determinants, these conditions are context-dependent and can shift in how they matter across different stages of implementation and settings. When they are addressed and managed early, they are more likely to support implementation. When they are overlooked or poorly managed, the same conditions can instead become barriers to adoption and sustained use.

Furthermore, the identified conditions were found to function as either static or dynamic. Static conditions remain stable throughout the implementation process and are not significantly altered by it, whereas dynamic conditions are subject to change as implementation unfolds. This distinction is practically important: static conditions must be acknowledged and accommodated, while dynamic conditions can be actively managed during the implementation process.

7.3 Implications for achieving a successful implementation of medical devices in stroke diagnostic processes in LMICs

Building on the identified conditions, the study contributes a framework for differentiating types of implementation implications along two dimensions: enabling versus hampering, and static versus dynamic. This yields four categories, foundations, opportunities, constraints, and priorities, each carrying different implications for action, see Figure 17. Static enabling conditions, referred to as foundations, represent assets that cannot be altered but that the implementation can rely upon. Dynamic enabling conditions, opportunities, can be actively strengthened through targeted action. Static hampering conditions, constraints, must be designed around rather than resolved. Dynamic hampering conditions, priorities, represent the most actionable areas for intervention, as they carry the greatest potential to shift from hampering to enabling through deliberate effort. Taken together, the implications suggest that successful implementation requires not only that enabling conditions are reinforced, but that the process is explicitly designed to address priorities, while

acknowledging the constraints that will persist. Practical implications of each category, as applied to the case of Strokefinder MD100 in the Western Cape, are explained in Section 6.2.1.

A central implication of this study is that sustainability must be treated as a prerequisite from the outset of implementation, not as an afterthought. The empirical material consistently showed that the principal challenge in LMIC contexts is not achieving initial adoption but ensuring that an innovation remains in use over time. Introducing an innovation that is subsequently not sustained carries greater risk than not introducing it at all, since systems that restructure around a new practice are severely disrupted when it disappears. These findings provide empirical grounding for sustainability to be incorporated as an explicit additional construct within CFIR when applied in resource-constrained settings, extending the framework's applicability beyond its original high-income context.

7.4 Key conclusions

Key conclusions from this thesis are presented below, structured as the main insights.

- Context is fundamental to implementation
- In LMICs, sustainability is the central challenge
- Distinguishing static and dynamic conditions matters

Implementation cannot be assumed to transfer directly between settings. Contextual factors; structural, organizational, cultural and resource related, significantly shape how implementation unfolds. Understanding the local context is therefore a prerequisite, not an afterthought, particularly when comparing LMICs and HICs where differences are substantial. Importantly, context should be seen as largely fixed in the short term, meaning that technology must be adapted to fit the setting rather than assumed to transform it. For this reason, it is essential to first understand the problem and local conditions, rather than relying on a technology-push approach.

In LMICs, sustainability is often undermined by structural constraints such as limited financial resources, weak infrastructure, and a lack of established routines and support systems, making innovations more vulnerable to discontinuation than in HICs. The primary barrier is therefore not implementation itself, but sustaining it over time. Long-term success depends on continuous access to maintenance and consumables, as well as ongoing staff training, all supported by adequate funding. Without these, even well-executed implementations are at risk of collapse. This makes sustainability a structural constraint that must be planned for from the outset, rather than something considered only once the intervention is in place.

Some conditions are static and must be worked around, while others are dynamic and can be influenced by the implementation process. Recognizing this distinction

matters because it directly determines how to act in practice. It shapes what can realistically be changed, what must be adapted to, and where effort should be focused. Effective change management is therefore key for dynamic conditions, while static constraints define the boundaries within which implementation must operate.

7.5 Limitations and future research

This study is subject to several limitations that should be acknowledged. First, the study is designed as a single in-depth case study focusing exclusively on the Strokefinder MD100 in one specific LMIC context, the Western Cape, SA. While a case study approach enables rich contextual understanding, it inherently limits the generalisability of the findings. Although SA shares many characteristics with other LMICs, such as high stroke burden, resource constraints, and infrastructure challenges, caution should be exercised when applying these findings to other settings, as contextual conditions vary considerably across LMICs.

These limitations point to several directions for future research. Future studies should examine the implementation of medical devices for stroke diagnostics across a broader range of LMIC contexts, to assess whether the conditions and implications identified here hold across different healthcare systems and cultural settings. Similarly, investigating the implementation of other medical devices beyond Strokefinder MD100 would help determine the extent to which the findings and proposed framework are generalisable. Furthermore, as this study was conducted prior to implementation, future research could follow the process during and after implementation to examine how enabling and hampering conditions evolve over time, and whether sustainability is achieved in practice. Such longitudinal studies would be particularly valuable given that sustainability was identified as a central challenge in this study.

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