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Barriers and Facilitators of Implementing Point-of-Care Diagnostics in Resource-Constrained Healthcare Systems:

The case of Strokefinder MD100 in Rwanda

Master's thesis in Management and Economics of Innovation

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Cover: The Medfield Diagnostics Strokefinder MD100 which is a portable, microwave-based diagnostic helmet designed to detect strokes.

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Abstract

Stroke represents a growing health burden in low- and middle-income countries (LMICs), where limited diagnostic capacity and delayed care result in high rates of preventable mortality and disability. In Rwanda, access to imaging technology is restricted to higher-level facilities, and time-sensitive treatments such as thrombolysis depend on rapid and accurate diagnosis that lower levels of care cannot currently provide. A critical gap therefore exists between clinical need and available diagnostic infrastructure.

This thesis examines how organizational, institutional, and system-level factors influence the market entry and implementation of point-of-care diagnostic technologies in resource-constrained healthcare systems, using the Strokefinder MD100 in Rwanda as a case. The study combines market entry theory with implementation science, to follow the technology from entry into the market through to its integration into clinical practice. It uses a qualitative case study design, drawing on semi-structured interviews with clinicians, hospital staff, system-level actors, and startup representatives conducted during field work in Rwanda in from February to end of April 2026. Thematic analysis identified key themes, which were mapped onto the Consolidated Framework for Implementation Research (CFIR) and interpreted alongside market entry theory to identify factors relevant across both stages.

The findings reveal six facilitating themes and seven barriers spanning the regulatory, organisational, financial, and contextual conditions that shape whether the technology reaches the market and becomes part of routine practice. The study also sets out practical considerations for firms entering the Rwandan market.

Keywords: Stroke, point-of-care diagnostics, implementation, market entry, Rwanda, CFIR, LMIC, barriers, facilitators, healthcare innovation, qualitative.

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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
CHUK	Centre Hospitalier Universitaire de Kigali
CHW	Community Healthcare Worker
CT	Computed Tomography
EMS	Emergency Medical Service
FDA	Food and Drug Authority
HTA	Health Technology Assessment
LMIC	Low- and Middle-Income Country
MOH	Ministry of Health
MOU	Memorandum of Understanding
MRI	Magnetic Resonance Imaging
NCD	Non-Communicable Disease
NGO	Non-Governmental Organisation
NHIC	National Health Intelligence Center
RDB	Rwanda Development Board
RSSB	Rwanda Social Security Board
USAID	United States Agency for International Development

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1

Introduction

This chapter sets out the context of the study, beginning with the background to stroke care and diagnostic capacity in resource-constrained healthcare systems and the gap that motivates the research. The aim of the study is then stated, followed by the research questions, and the chapter closes by defining the scope and limitations of the work.

1.1 Background

Stroke is the second leading cause of mortality worldwide, accounting for approximately 11.6% of all deaths (Feigin et al., 2021). While the risk of dying from stroke has declined globally when adjusted for age, the overall burden continues to increase, particularly in LMICs, where 86% of stroke-related deaths occur (Feigin et al., 2021). Key factors underlying this imbalance is increased exposure to risk factors, limited access to timely diagnosis and acute care. In many LMIC settings delays in recognizing and diagnosing stroke significantly reduce the effectiveness of available treatments. This makes minimization of delays one of the most important levers for reducing preventable mortality and long-term disability (Urimubenshi & Laude, 2019).

Sub-Saharan Africa carries a large part of this burden where stroke occurs two to three times more often compared to Europe and the US, and a larger share of cases happens earlier in life (Akinyemi et al., 2021). This is linked to changing lifestyles and rising risk factors such as hypertension, less physical activity, processed diets, and urbanization, which expose younger people to cardiovascular disease sooner (Akinyemi et al., 2021; Owolabi et al., 2015). Earlier onset means longer disability, lost work capacity, and greater need for rehabilitation which implies higher long-term costs and a heavier burden on households (ICRC et al., 2021; Urimubenshi & Laude, 2019). Rehabilitation capacity in many LMICs is already limited, which makes fast and accurate diagnosis especially important. Effective acute care is one of the few ways to reduce lasting disability and reduce the need for post-acute services (ICRC et al., 2021).

Stroke treatment is highly time-sensitive and depends on rapid diagnosis and correct classification of stroke type. Early assessment together with brain imaging is necessary to determine whether the stroke is caused by a blocked artery (ischemic) or bleeding in the brain (hemorrhagic), as the treatments differ significantly (Greenberg

et al., 2022; Powers et al., 2019). The urgency is often described by the concept "time is brain", and Saver (2006) estimates that millions of neurons may be lost each minute during an untreated stroke. Accurate and timely diagnosis depends on access to appropriate imaging methods that can distinguish between different types of stroke. Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) form the foundation of stroke diagnosis in high-income settings, access to such technologies is often limited or centralized in LMIC healthcare systems (Akinyemi et al., 2021; Owolabi et al., 2015). This creates a structural delay between symptom onset, diagnosis, and treatment, particularly in pre-hospital settings and lower-level facilities, and a significant gap emerges between clinical need and available diagnostic capacity (Urimubenshi & Laude, 2019).

These constraints are reinforced by broader characteristics of LMIC healthcare systems, which operate under conditions that limit both service delivery and the integration of new technologies (Belardi et al., 2023). Resource limitations restrict service capacity, out-of-pocket payments still represent a large share of total health expenditure, and high mortality from treatable conditions reflects weaknesses in timely diagnosis and adherence to clinical guidelines (Kruk et al., 2018; Peabody et al., 2006; WHO, 2023b). LMICs are also experiencing an epidemiological transition, facing a double burden of communicable diseases and increasing rates of non-communicable diseases such as stroke and diabetes (WHO, 2023b). This increase requires coordinated and long-term models of care that many systems were not originally designed to deliver (Kruk et al., 2018).

Given these structural problems, point-of-care diagnostics have emerged as a potential approach to bridge the gap between clinical need and diagnostic capacity (WHO, 2018). Point-of-care diagnostics refer to medical tests performed close to the patient rather than in centralized hospitals or advanced imaging facilities with the purpose to provide rapid results and support immediate clinical decision making (Kaplan et al., 2013). However, the successful introduction of new medical technologies does not depend solely on their technical performance, but also on how they are integrated into existing healthcare systems (Nilsen, 2015). The introduction of such a medical innovation therefore cannot be understood only as a clinical problem, but also as a market entry and implementation problem. Medical technology in LMICs has to be brought into a new institutional and organizational context shaped by economic, infrastructural and regulatory conditions that differ from those in which it was originally developed.

Market entry theory explains how firms extend their activities into new markets, including the analytical, managerial and relational dimensions of entry (Johanson & Vahlne, 2009; Root, 1994). Implementation science has been developed to study how research findings and medical innovations are brought into routine practice, providing structured frameworks for analysing the factors that influence implementation (Nilsen, 2015). Both perspectives have limitations when applied to medical technologies in LMIC healthcare systems. Many dominant implementation frameworks have been developed and tested in high-income settings and are largely grounded in relatively stable and well-resourced institutional environments (Damschroder et al., 2009). Traditional market entry theory has similarly been developed in the context

of mature, well-functioning markets. The focus of earlier market entry research has been on the factors leading up to the entry decision itself, while the implementation that follows remains comparatively under-researched (Canabal & White, 2008; Schellenberg et al., 2017). The two perspectives therefore leave complementary gaps: implementation research describes integration into organizational processes but largely assumes the technology is already present in the market. Market entry research on the other hand describes the conditions for bringing a technology into a new context but pays less attention to how it is subsequently embedded in routine practice. Combining the two perspectives makes it possible to follow the technology from entry into a new market through to its integration into clinical practice, which neither covers on its own.

This combined view becomes relevant in resource-constrained healthcare systems with limited diagnostic capacity, where the conditions shaping both market entry and implementation differ substantially from the high-income and mature-market settings in which the two literatures were developed. How medical devices are introduced into such systems and subsequently integrated into existing healthcare processes therefore remains an open question.

1.2 Purpose

The purpose of this thesis is to examine how organizational, institutional, and system-level factors influence the market entry and implementation of point-of-care diagnostic technologies within a resource-constrained healthcare system, using the Rwandan healthcare system as a case. This leads to the formulation of the following research questions.

- *RQ1: What barriers and facilitators influence the market entry and implementation of new point-of-care diagnostic technologies within the Rwandan healthcare system?*
- *RQ2: What should be considered before implementing point-of-care diagnostic technologies within the Rwandan healthcare system?*

1.3 Scope & Limitations

This thesis examines how organizational, institutional, and system-level factors influence the market entry and implementation of point-of-care diagnostic technologies in resource-constrained healthcare systems. The scope is therefore limited to the market entry and implementation processes, and does not address the clinical, technical, or medical dimensions of point-of-care technology. Questions related to clinical effectiveness, technical performance, patient outcomes, and treatment time therefore fall outside the scope of this study, and the analysis is based on the assumption that the device functions correctly from a clinical perspective.

The study is further restricted to a single national context, using Rwanda as the empirical case, and is thereby limited in generalizability across East African or

other LMIC settings. Rwanda was assigned as the study is conducted within an ongoing research collaboration between the Department of Electrical Engineering at Chalmers University of Technology and the University of Rwanda, which provides help in understanding the local environment and ease access to relevant stakeholders.

The study is limited to analyse the Strokefinder MD100 as it is a part of the ongoing research collaboration and assigned by the project owner. Previous work within the research collaboration has applied a Health Technology Assessment framework to evaluate the suitability of the MD100, but did not address how the technology may be brought into and embedded within the healthcare system. This study builds on this foundation by examining how contextual conditions shape the market entry and implementation of the technology in practice.

As the empirical material is based on qualitative interviews with a limited number of stakeholders, it is not possible to capture all perspectives within the Rwandan healthcare system. The sampling strategy aims to include key actors at different levels of the system, but certain viewpoints may remain under-represented, particularly those of frontline staff at lower-level facilities and end-users such as patients. While the results may offer insights relevant to similar resource-constrained healthcare settings, the findings have limited external validity and are not directly generalizable to other contexts, as the factors influencing market entry and implementation vary across healthcare systems.

Finally, the study is conducted within the time and resource constraints of a master's thesis. Access to participants, scheduling, and institutional conditions can influence the breadth and depth of data collection, and the analysis reflects the perspectives captured within this scope rather than an exhaustive account of the Rwandan healthcare system.

2

Theory

This chapter establishes the theoretical foundations of the study, drawing on market entry theory and implementation science and combining them into the analytical framework that guides the analysis.

2.1 Market entry

Market entry has been described in several ways across the international business literature. One approach is seeing market entry as a dynamic process and internationalisation as gradual acquisition of knowledge about foreign markets and the incremental commitment of resources to those markets (Johanson & Vahlne, 1977). In this view, lack of market knowledge is the main obstacle to entry and the necessary knowledge is acquired through operations in the market itself. This leads firms to begin with low commitment activities and then gradually move toward higher-commitment operation (Johanson & Vahlne, 1977). Another approach is analysis that helps firms narrow down potential foreign markets through a series of evaluation steps, leaving the entry process itself outside the scope of his analysis (Cavusgil, 1985).

Market entry can also be described as the comprehensive strategic decisions through which a firm extends its business activities into a foreign target market, including choices related to product, target segment, entry mode and marketing plan (Root, 1994). Entry is therefore treated as a structured managerial process where multiple decisions need to be aligned for a firm to operate in a new market. Market entry is divided into three stages: a pre-entry stage focused on market analysis, an entry stage focused on the choice of mode and strategy, and a post-entry stage focused on operations and growth in the new market (Root, 1994). This may however vary for smaller firms that internationalise in less foreseeable ways and will not always follow these sequential stages (Bruneel & De Cock, 2016).

Successful market entry depends on preparatory work in the form of market analysis. Lack of market knowledge is a main obstacle to international operations. A distinction can be made between objective knowledge, which can be obtained through formal research, and experiential knowledge, which can only be acquired through actual operations in the market (Johanson & Vahlne, 1977). A more normative position is describing market analysis as a structured assessment of market and sales potential before resources are committed. This makes systematic analysis a

way to reduce uncertainty in the early stages of entry (Cavusgil, 1985; Root, 1994). The purpose of such analysis is to evaluate the external and internal factors that may influence a firm's ability to enter and compete within a market (Khanna et al., 2010). Typical factors for analysis include organisational, political, economic, social, technological, legal and environmental factors (Cavusgil, 1985; Root, 1994). These factors are described more in depth in the Section 2.1.1.

These factors cover the variables frequently examined in market entry research, although their importance varies depending on the country, region or industry in question (Canabal & White, 2008). The focus of earlier research has been on the stages leading up to the entry decision itself, while the implementation that follows remains less researched (Canabal & White, 2008; Schellenberg et al., 2017).

Market entry can viewed as the gradual movement from outsidership to insidership in the relevant business network. A central part of this movement is knowledge and commitment but recent work has recognized a shift in what causes uncertainty during entry from psychic which is the cultural distance between countries to a firm's lack of position within the network of relationships in the new market (Johanson & Vahlne, 2009; Johanson & Vahlne, 1977). Market entry analysis should therefore not only be viewed as process of building knowledge, but also a process of building trust and relational ties with local actors (Johanson & Vahlne, 2009). Formal market analysis can provide useful information, but cannot substitute for the experiential learning and network position that determine whether a firm is able to operate effectively in the new market (Johanson & Vahlne, 2009).

2.1.1 Market entry barriers and facilitators

Within the factors of market analysis, previous research has identified specific conditions that act as either barriers or facilitators for entry into new markets. These conditions apply to entry in general, but often take on different forms or are joined by additional ones in emerging markets and LMIC contexts. In these markets structural and institutional gaps shape entry in ways that are hard to analyse.

Political factors cover government stability, regulations and the bargaining dynamics that shape the rules of the market (Meyer & Peng, 2016). These conditions shape entry through the predictability of the regulatory environment and through the relationships firms are able to build with public actors. Instability in regulatory institutions, triggered by events such as government transitions or shifts in policy direction, creates uncertainty around long-term investments and increases the perceived risk of entering a market (Meyer & Peng, 2016). Political risk can therefore be seen as a factor that consistently raises the cost of entry into countries with unstable institutions (Zhang et al., 2023). The same political environment can also work in the opposite direction . Government accelerators where direct or indirect state support through financial incentives, diplomatic backing or strategic priorities can lower the perceived risk of entering challenging countries (Gammeltoft & Cuervo-Cazurra, 2021). In emerging markets where there is a absence of strong formal rules, personal ties between managers and government officials become an important mechanism for navigating business to government bargaining. These in-

formal mechanisms often operate as a substitute for formal institutional safeguards (Meyer & Peng, 2016).

Economic factors can be market size, purchasing power and the institutional voids in capital markets which also make up entry barriers (Khanna et al., 2010). On the barrier side of economic factors, and a internalisation perspective market imperfections raise the cost of doing business unless firms have ownership advantages strong enough to compensate (Dunning, 1980). In emerging markets and LMIC contexts, this friction is amplified by the existence of institutional voids in capital markets and intermediary services, which force firms to either build internal substitutes or accept higher operating costs (Khanna et al., 2010). Such voids can increase transaction costs because firms cannot rely on the market to match buyers and sellers efficiently, meaning that firms in these contexts often have to take on functions that would otherwise be handled by external intermediaries (Meyer & Peng, 2016).

Facilitators on the economic side could be alternative financing mechanisms that bridge the gap created by underdeveloped capital markets. In an LMIC context, donor funding and grants from international organisations provide capital that local financial systems cannot supply. Another alternative is public–private partnerships that combine public and private resources into co-financed arrangements that allow firms to enter markets that would not be commercially viable under their own funding alone (Hushie, 2016).

Social and cultural factors are the cultural differences and variations in consumer behaviour. Johanson and Vahlne (1977) describe this as psychic distance and Zhang et al. (2023) describe it as informal institutional distance. Social and cultural conditions influence entry through both information gaps and network position. Psychic distance is the sum of factors such as language, culture, education and business practices that prevent the flow of information between markets and that make it harder for firms to interpret local behaviour (Johanson & Vahlne, 1977). The more critical social barrier is outsidership, where the firm is unable to access opportunities, partners and information that are only visible to those within local networks (Johanson & Vahlne, 2009). In an LMIC context this could be casued by domestic psychic distance between higher-income and lower-income segments within the same country, where firms that already operate in the high-income segment may still find that their existing knowledge has limited value when entering the low-income segment of the same market (Schuster & Holtbrügge, 2012). On the facilitator side social networks are important for smaller firms, since it can be a substitute for internal resources and allow the firm to learn about the new markets conditions through trusted contacts (Laufs, 2015). Another central mechanism is trust-building which gradually reduce uncertainty and allow firms to deepen their position in the market over time (Johanson & Vahlne, 2009). In LMIC contexts, a embedded subsidiary model where firms move beyond local manufacturing and become embedded insiders by investing in non-market partners such as NGOs, local authorities and community groups can sthrenghten their position (Schuster & Holtbrügge, 2012). Partnerships between governments and NGOs in LMIC health systems generate added value both from an economical perspective and through community legitimacy and implementation capacity in geographical areas that the public sector can not reach alone (Hushie,

2016).

Technological factors include both infrastructure and digital capacity, since weak transportation and communication systems can limit how a firm operates in practice (Meyer & Peng, 2016). Technological conditions affect both the feasibility of operations and the ability of the host market to absorb new innovations. Deficiencies in physical infrastructure, such as transportation and communication systems can be direct operational barriers for technologies that depend on logistics, electricity or connectivity (Meyer & Peng, 2016). Limited absorptive capacity in the host market and local actors that lack the technical knowledge or training needed to use new technologies effectively will also become a barrier (Meyer & Peng, 2016).

The lack of established technological infrastructure can sometimes work in the firm's favour. Technological leapfrogging, where countries skip earlier stages of technology adoption and move directly to newer solutions because they are not locked into existing legacy systems is an example of this (Steinmueller, 2001) .

Environmental factors include sustainability expectations and climate-related risks that can affect both reputation and operations (Gammeltoft & Cuervo-Cazurra, 2021; Meyer & Peng, 2016). Environmental conditions are driven mainly through legitimacy and stakeholder expectations. Pressures to act in environmentally and socially responsible ways have grown globally, but what counts as legitimate practice varies across societies (Meyer & Peng, 2016). Firms entering emerging markets often need to manage conflicting reasoning regarding sustainability, and tensions arise when a firm's environmental strategy is perceived as out of step with local values (Kostova & Hult, 2016). The challenge of building social legitimacy grows with the institutional distance between home market and the new market (Zhang et al., 2023). The same conditions can also act as facilitators. Environmental issues increasingly shape strategic choices in foreign markets, meaning that proactive alignment with local expectations can support the firm's standing and reduce friction with regulators and communities (Gammeltoft & Cuervo-Cazurra, 2021). Environmental factors therefore operate as facilitators when they are integrated into the firm's strategy and as barriers when they are treated as an afterthought (Meyer & Peng, 2016).

Legal factors cover the laws and regulations firms must follow. This can be both the formal institutional distance or weak property rights enforcement which is more common in emerging markets (Meyer & Peng, 2016; Zhang et al., 2023). Legal conditions affect entry through both the content of laws and the consistency with which they are enforced. Weak or inconsistently enforced property rights can be a legal barrier in emerging markets, since they make it difficult for firms to protect intellectual property, brands or contractual agreements (Meyer & Peng, 2016). Furthermore does the formal institutional distance which is the difference in laws and regulations between home and host country have a stronger effect on entry decisions compared to cultural differences (Zhang et al., 2023). Another barrier in the LMIC legal environment is the unreliability of secondary data. Managers face information overload but struggle to find data that is relevant, useful, timely and consistent (Cavusgil, 1985). However, if the new market contain credible legal safeguards and predictable legal protection the perceived risk of committing resources to the market is lowered (Zhang et al., 2023).

Organisational factors concern the internal resources and capabilities of the firm rather than the external market. They influence whether the firm is able to act on the opportunities and constraints described in the earlier factors (Dunning, 1980; Laufs, 2015). Resource scarcity, particularly in financial and personnel terms, is a central barrier for SMEs and limits the scope of activities they can pursue abroad (Laufs, 2015). Liability of newness is another barrier, where younger firms lack the routines and accumulated experience needed to navigate foreign environments (Johanson & Vahlne, 2009). This is important as prior multinational experience is one of the most substantial factors associated with successful entry, since it equips firms with the know-how to manage distance and uncertainty (Canabal & White, 2008). Another driver for entry is strategic intent, where a clear ambition to upgrade and compete internationally can drive firms into markets that would otherwise be rejected on purely commercial grounds (Gammeltoft & Cuervo-Cazurra, 2021).

2.1.2 Market entry in Emerging markets and LMICs

The perspectives described in traditional market entry theory are largely developed in the context of mature, well-functioning markets. Entry into emerging markets and LMICs on the other hand requires a more nuanced point of view since the economic, institutional and infrastructural environment in these contexts differs in ways that change the entry process in fundamental ways (Kostova & Hult, 2016; Prahalad & Hart, 2008).

Emerging economies can be defined as LMICs with growth potential that makes them attractive for international business (Meyer & Peng, 2016). Within this category, LMICs typically face additional structural challenges. Entering such markets requires firms to rethink their strategy and implementation process, since technologies developed for higher-income markets often fail to address the resource-constrained realities of LMICs (Prahalad & Hart, 2008). Institutional voids and underdeveloped distribution infrastructure mean that firms cannot rely on home market experiences alone, instead there is a need to generate the specific local capabilities required to operate within unfamiliar the new market and networks (Schuster & Holtbrügge, 2012).

Institutional voids associated with LMIC markets are the absence of specialised intermediaries, regulatory systems and contract enforcement mechanisms that firms in mature markets take for granted (Khanna et al., 2010). Institutional voids undermine the effectiveness of market coordination, since firms cannot rely on stable rules of the game to govern their interactions with partners, customers and authorities (Meyer & Peng, 2016). The gap between Western theoretical assumptions and LMIC realities is significant, since most mainstream management theories were developed in environments where clearly defined rules exist. The absence of such rules in LMICs challenges the underlying assumptions of these theories (Kostova & Hult, 2016).

The motives for entering these markets have evolved alongside the recognition of these challenges. Emerging markets accounted for approximately half of the world's purchasing power parity GDP in 2021, which makes them economically significant

despite the frictions associated with entry (Gammeltoft & Cuervo-Cazurra, 2021). A motive for firms to enter foreign markets is specifically to upgrade capabilities, acquire technology or develop knowledge they lack at home. This turn the entry into a learning mechanism rather than only a market seeking activity. Entry can be motivated by global concerns such as climate change, sustainability and rapid technological change, which are framed as challenges that shape the strategic choices firms make when committing to foreign markets (Gammeltoft & Cuervo-Cazurra, 2021).

The gap between developed and emerging market environments has direct consequences for how entry unfolds. Institutional distance is the firm's familiarity with the new markets environment and gives rise to the liability of foreignness when this distance is large (Zhang et al., 2023). The costs of doing business abroad rise with this distance since firms lack the institutional knowledge and relational embeddedness needed to operate effectively (Meyer & Peng, 2016; Zhang et al., 2023). Gaps in managerial knowledge and norms can also hamper firms from responding effectively when formal institutions in an unfamiliar LMIC change (Meyer & Peng, 2016). For firms entering LMIC markets, to succeed they have to radically rethink price–performance relationships and design solutions specifically for local conditions, rather than transferring products developed for high income markets without modification (Prahalad & Hart, 2008). One way to achieve this modification is through the consideration of frugal innovation, where firms adapt products to be affordable for low income segments and use this affordability as a competitive advantage in markets where high income pricing models would not work (Gammeltoft & Cuervo-Cazurra, 2021).

These conditions of affect smaller firms in particular. Limited financial and personnel resources restrict the range of activities SMEs can pursue in foreign markets, which is especially relevant in LMIC healthcare contexts where entrants are often SMEs, research spin-offs or non-governmental actors rather than large companies (Laufs, 2015).

Even where market entry theory looks at adapting a product to local conditions, it does so from the firms side and still says little about the people meant to use the product once it arrives. Market entry theory treats reaching the market as the end point and stops where the question of use begins. To understand how a product moves from entering the market to actually being used, implementation science offers a perspective that continues where market entry theory stops.

2.2 Implementation Science

Implementation science is the study of how to promote and bring research findings and innovations within the healthcare sector into routine practice (Bauer et al., 2015; Eccles & Mittman, 2006). In healthcare, innovations are typically evaluated through their efficacy under optimal conditions and the effectiveness they show in reality (Bauer et al., 2015). However, these two conditions do not guarantee that the innovation will be taken up and used in practice (Bauer et al., 2015). The

actual benefit of an innovation depends on whether it reaches the practitioners and patients it is designed for, and an innovation that cannot achieve effective implementation carries little real-world value (Peters et al., 2014). Implementation science addresses this by providing a structured lens of analysis for how to shift the focus from innovation performance to integration (Peters et al., 2014).

The need for implementation science is based on the gap that arises between research and practice, and bridging this gap is neither automatic nor spontaneous but requires structured efforts (Bauer et al., 2015). Without a deliberate strategy for bringing innovations into use, the uptake may be uneven, which will result in inappropriate care across settings (Eccles & Mittman, 2006). Empirical observations have shown that the average time for innovations to reach routine clinical practice can be up to 17 years, and even then only about half achieve widespread usage (Bauer et al., 2015). By minimizing the gap between what is known and how it is practised, it is possible to accelerate how innovations are used and thereby minimize disparities in healthcare and improve both quality and access to care (Bauer et al., 2015; Brown et al., 2021).

To achieve improved quality of care and address the consequences that the implementation gap poses, evidence-based practices have to be effectively managed and easily accessible. Without these structures, resources are committed in the hope that innovations will work out, while known best practices remain partially or never implemented (Brown et al., 2021; Peters et al., 2014). This is a problem that creates greater consequences in resource-constrained settings such as LMICs, where it is estimated that 70% of medical equipment transferred from high-income settings fails due to the implementation context being ignored (Malkin, 2007). Implementation science should therefore be seen as an essential part of converting innovations into effective improvements in care (Bauer et al., 2015).

2.2.1 Frameworks for Implementation

To translate implementation science into actual practice, there are several theoretical approaches that structure how implementation is studied and guided (Nilsen, 2015). The field has, however, produced such a large number of these approaches that selecting and applying the most suitable one has become a challenge in itself, which risks limiting both the comparability and the development of implementation research (Nilsen, 2015). To address this, Nilsen (2015) proposes a classification that organises theoretical approaches according to three overarching aims: describing or guiding the process of translating research into practice, understanding or explaining what influences implementation outcomes, and evaluating implementation efforts.

Within this classification, five categories are distinguished. Process models describe the steps involved in moving research findings into practice and provide a structured guide for action. Determinant frameworks specify the types of factors, such as barriers and enablers, that influence implementation outcomes. Classic theories are borrowed from disciplines such as psychology, sociology, and organisational theory, and are used to explain aspects of implementation through established mechanisms. Implementation theories are developed specifically within the field to explain par-

ticular aspects of implementation. Evaluation frameworks, finally, provide structure for assessing the success of an implementation effort (Nilsen, 2015).

Among the determinant frameworks, the Consolidated Framework for Implementation Research (CFIR) has emerged as one of the most widely applied (Nilsen, 2015). Several frameworks exist, but vary in scope. Some focus mainly on organizational aspects like leadership and resources, while others emphasize individual-level factors such as attitudes and knowledge, meaning individual frameworks may capture only parts of the process (Nilsen, 2015). CFIR consolidates these determinants across multiple levels, making it well suited for examining a complex LMIC healthcare context.

2.2.2 Consolidated Framework for Implementation Research

The Consolidated Framework for Implementation Research (CFIR) enables a structured analysis of how factors interact across levels, making it suitable for studying implementation in complex healthcare systems. CFIR was developed as a synthesis of constructs from multiple implementation theories, integrating determinants related to the innovation, external environment, organizational conditions, individuals, and implementation process. It is organized into five domains: innovation, outer setting, inner setting, individuals, and implementation process, which are presented in the following sections (Damschroder et al., 2009, 2022).

2.2.2.1 Domains

Innovation Domain

Within the framework, the innovation refers to what is being implemented, for example a new treatment method or a medical service. The focus of this domain is therefore on the characteristics of the innovation itself, rather than how it is introduced into practice. This makes it distinct from the implementation process domain, which instead deals with how implementation is carried out (Damschroder et al., 2022)

The domain includes several determinants that shape how the innovation is perceived and evaluated. These cover aspects such as where the innovation originates from, the strength of the evidence supporting it, and whether it is seen as better than current alternatives. Other important factors include how adaptable the innovation is to different contexts, whether it can be tested on a smaller scale, and how complex it is to use. Design and cost are also included, as they influence both usability and feasibility in practice. (Damschroder et al., 2009, 2022)

Innovation domain	
Construct	**Definition** *To which level:*

Innovation Source	The group that developed and/or visibly sponsored use of the innovation is reputable, credible, and/or trustable
Innovation Evidence Base	The innovation has robust evidence supporting its effectiveness
Innovation Relative Advantage	The innovation is better than other available innovations or current practice
Innovation Adaptability	The innovation can be modified, tailored, or refined to fit local context or needs
Innovation Trialability	The innovation can be tested or piloted on a small scale and undone
Innovation Complexity	The innovation is complicated, which may be reflected by its scope and/or the nature and number of connections and steps
Innovation Design	The innovation is well designed and packaged, including how it is assembled, bundled, and presented
Innovation Cost	The innovation purchase and operating costs are affordable.

Table 2.1: Key factors influencing innovation implementation reproduced from Damschroder et al. (2022)

Outer Setting

The outer setting refers to the broader environment surrounding the organization, meaning the context in which the inner setting exists. It includes external conditions that influence implementation but are not directly controlled by the organization itself, such as policies, regulations, and overall system conditions. The domain consists of several constructs, including policies and laws, financing structures, and external pressures that may affect implementation. It also covers local conditions and attitudes, reflecting the economic, social, and cultural environment, as well as partnerships and connections with other organizations. Critical incidents, such as unexpected events or disruptions, are included as factors that can influence how implementation develops.(Damschroder et al., 2009, 2022)

Outer setting domain	
Construct	**Definition** *To which level:*
Critical Incidents	Large-scale and/or unanticipated events disrupt

Local Attitudes	Sociocultural values and beliefs encourage the Outer Setting to support implementation and/or delivery of the innovation
Local Conditions	Economic, environmental, political, and/or technological conditions enable the Outer Setting to support implementation and/or delivery of the innovation
Partnerships & Connections	The Inner Setting is networked with external entities, including referral networks, academic affiliations, and professional organization networks
Policies & Laws	Legislation, regulations, professional group guidelines and recommendations, or accreditation standards support implementation and/or delivery of the innovation
Financing	Funding from external entities (e.g., grants, reimbursement) is available to implement and/or deliver the innovation
External Pressure	External pressures drive implementation and/or delivery of the innovation

Table 2.2: Key factors influencing the external environment of implementation reproduced from Damschroder et al. (2022)

Inner Setting

The inner setting domain refers to the organizational context where the implementation takes place. An implementation can involve multiple inner settings, and each of these may include several levels within the organization. The domain focuses on internal conditions that influence how an innovation fits into existing work and how it is managed in practice. It includes a set of constructs that describe both general organizational characteristics and factors more directly related to implementation. Some constructs represent more stable features of the organization, such as structural characteristics, relational connections, communication, and culture, which exist regardless of whether an innovation is being implemented. In addition, there are constructs that are more specific to the implementation itself, including tension for change, compatibility, relative priority, incentive systems, mission alignment, and available resources.(Damschroder et al., 2009, 2022)

Inner setting domain	
Construct	**Definition** *To which level:*

Structural Characteristics	Infrastructure components support functional performance of the inner setting
Relational Connections	High quality formal and informal relationships, networks, and teamwork within the inner setting
Communications	High quality information sharing practices within and across the inner setting
Culture	Shared values, beliefs, and norms across the inner setting
Tension for Change	The current situation is perceived as needing change
Compatibility	The innovation fits with existing workflows, systems, and processes
Relative Priority	Implementation is important compared to other initiatives
Incentive Systems	Incentives and/or disincentives support implementation
Mission Alignment	Implementation aligns with the organisation's goals and mission
Available Resources	Resources (e.g., funding, space, materials) are available
Access to Knowledge & Information	Training, guidance, and knowledge are accessible for implementation

Table 2.3: Determinants of the internal implementation environment reproduced from Damschroder et al. (2022)

Individuals

The individuals domain focuses on the people involved in the implementation and is divided into two subdomains: roles and characteristics. It includes different types of actors depending on the context, such as high-level leaders, mid-level leaders, opinion leaders, implementation facilitators, implementation leads, team members, other support roles, as well as those delivering or receiving the innovation. In addition to these roles, the domain also considers individual characteristics through four constructs: need, capability, opportunity, and motivation. These reflect whether individuals perceive a need for the innovation, have the necessary knowledge and skills, are given the opportunity to use it in practice, and are motivated to engage with it. (Damschroder et al., 2009, 2022)

Individuals subdomain: Roles	
Construct	**Definition** *To which level:*

High-level Leaders	Individuals with a high level of authority, including key decision-makers, executive leaders, or directors
Mid-level Leaders	Individuals with a moderate level of authority who supervise others
Opinion Leaders	Individuals with informal influence on the attitudes and behaviors of others
Implementation Facilitators	Individuals with subject matter expertise who assist, coach, or support implementation
Implementation Leads	Individuals who lead efforts to implement the innovation
Implementation Team Members	Individuals who collaborate with and support implementation leads
Other Implementation Support	Individuals who support implementation leads and implementation team members
Innovation Deliverers	Individuals who are directly or indirectly delivering the innovation
Innovation Recipients	Individuals who are directly or indirectly receiving the innovation

Table 2.4: Determinants related to individuals involved in implementation reproduced from Damschroder et al. (2022)

Individuals subdomain: Characteristics	
Subconstruct	**Definition** *To which level:*
Need	The individual has deficits related to survival, well-being, or personal fulfillment, which will be addressed by implementation and/or delivery of the innovation.
Capability	Individuals have the knowledge, skills, and competence to fulfil their role
Opportunity	Individuals have the availability, scope, and power to fulfil their role
Motivation	Individuals are committed to fulfilling their role

Table 2.5: Characteristics of individuals influencing implementation reproduced from Damschroder et al. (2022)

Implementation Process

The implementation process domain focuses on how an innovation is introduced and put into practice, rather than what is being implemented. It captures the different strategies and activities used throughout the implementation, including forming teams, assessing needs and context, planning, adapting strategies, engaging relevant actors, carrying out the implementation, and continuously reflecting, evaluating, and making adjustments. The domain therefore highlights implementation as an ongoing and structured process that develops through different activities and adjustments, and it focuses on how the innovation is introduced and used in practice, including how it is planned, carried out, and adapted to fit the context, rather than on the characteristics of the innovation itself. (Damschroder et al., 2009, 2022)

Implementation process domain	
Construct	**Definition** *To which level:*
Teaming	Individuals coordinate and collaborate on interdependent tasks to implement the innovation
Assessing Needs	Information is collected about needs, priorities, and preferences of stakeholders
Assessing Context	Information is collected to identify barriers and facilitators to implementation
Planning	Roles, responsibilities, steps, and goals for implementation are defined in advance
Tailoring Strategies	Implementation strategies are selected and adapted to fit the context
Engaging	Individuals are attracted and encouraged to participate in implementation
Doing	The innovation is implemented through iterative steps or cycles of change
Reflecting & Evaluating	Data and feedback are collected and used to assess implementation success
Adapting	The innovation and/or context is modified to improve fit and integration

Table 2.6: Determinants of the implementation process reproduced from Damschroder et al. (2022)

2.3 Tentative Analytical Framework

Market entry research focuses on the period before and during entry, and gives less attention to what happens once the firm is operating in the market. Johanson and Vahlne (2009) make this point directly, describing the firm's work in a foreign market as an ongoing process of building trust and moving from outsidership to

insidership, rather than something that ends at entry. Canabal and White (2008) and Brouthers and Hennart (2007) reach a similar conclusion from a different angle, noting that empirical entry mode research has largely stopped at the entry decision and calling for more attention to what happens afterwards including how entry conditions translate into operational outcomes. Barriers and facilitators identified in the market entry stage may therefore stay relevant even after entry and carried into the implementation phase, but that the literature offers limited tools for analysing this transition.

The implementation stage that market entry theory does not develop in depth is the focus of implementation science (Bauer et al., 2015; Nilsen, 2015). Several CFIR domains cover the same conditions market entry theory identifies as barriers and facilitators of entry, but follow them into the implementation stage (Damschroder et al., 2009, 2022). Where market entry theory points to a political environment, CFIR shows the policies, partnerships and critical incidents through which it acts during implementation. Where market entry theory points to a network position, CFIR shows the partnerships and engagement work through which Johanson and Vahlne (2009) insidership is built on. The two areas of research therefore describe a single trajectory: market entry theory identifies the conditions that shape whether a technology reaches the market, and CFIR shows how the same conditions shape whether it becomes part of practice once it has.

The market entry factors described in Section 2.1.1 identify the conditions that act as barriers and facilitators at the point of entry. The aim of the mapping is to show which determinants influence both market entry and implementation. The CFIR domains do not replace the market entry factors, but instead they describe how the market entry factors operate once the firm is no longer trying to enter the market but is operating within it.

This mapping is treated as a tentative analytical framework rather than a settled model. It states the expected links between market entry factors and CFIR constructs, which Chapter 5 then tests against the Rwandan case. Each factor is examined for where the expected carry-over from entry into implementation holds, where it needs refinement, and where the case shows mechanisms the framework does not capture.

2.3.1 Mapping Market Entry Factors through CFIR

Political factors are seen mainly as entry conditions in the market entry literature, where instability raises perceived risk and stable government relationships lower it (Gammeltoft & Cuervo-Cazurra, 2021; Zhang et al., 2023). CFIR treats the same conditions as ongoing influences on implementation rather than as a one-off entry hurdle and places it in the *Outer Setting*. *Policies and Laws* construct covers legislation, regulations and accreditation standards. *Partnerships and Connections* construct covers the relational ties through which informal political access is built and kept. A third construct, *Critical Incidents* captures disruptive events such as government transitions or policy reversals, which Meyer and Peng (2016) describe as the main source of political risk within market entry theory. Market entry theory

asks whether the firm can navigate the political environment well enough to enter, while CFIR asks whether the same environment keeps supporting implementation once the firm is inside the system.

Economic factors are seen in the market entry literature as large-scale conditions such as market size, purchasing power, gaps in capital markets and the cost of doing business (Khanna et al., 2010; Meyer & Peng, 2016). CFIR treats these same conditions as the context in which implementation takes place, and splits them across two domains. The *Outer Setting* captures the system-level environment through *Local Conditions* and *Financing*, where *Financing* cover aspects such as donor funding, grants and public–private collaborations that often substitute for underdeveloped capital markets (Damschroder et al., 2022; Hushie, 2016). The *Inner Setting* captures what these conditions demand of the firm, where missing intermediaries push firms to handle functions internally that would normally be outsourced (Khanna et al., 2010). *Available Resources* covers whether the firm has the financial structure, staff and materials to take on these added functions, and *Compatibility* construct covers whether its existing routines fit a context where it has to run these functions itself. Market entry theory asks whether the economic environment is viable to enter, while CFIR asks whether the firm has the internal resources to keep operating within it.

Social and cultural factors are from a market entry perspective seen as the cultural distance, network position and trust dynamics that shape access to a foreign market (Johanson & Vahlne, 2009; Schuster & Holtbrügge, 2012). CFIR treats the same conditions as ongoing influences on implementation and spreads them across several domains. The network dimension relates to the *Partnerships and Connections* construct in the *Outer Setting* and onto *Engaging* construct in the *Implementation Process*, which describes the work of identifying, attracting and securing the actors needed for implementation to succeed. The cultural dimension, including the liability of foreignness described by Johanson and Vahlne (2009) and the domestic psychic distance of Schuster and Holtbrügge (2012), maps onto the *Outer Setting* construct *Local Attitudes*. At the individual level, social conditions show up through *Motivation* and *Need*, whether local actors see a reason to engage with the innovation depends partly on how it fits with local norms. Market entry theory asks whether the firm can build the relational and cultural position needed to enter, while CFIR asks whether the same factors will keep supporting implementation once the firm is operating.

Technological factors are seen in the market entry literature along three dimensions: the infrastructure available in the host market, the ability of local actors to take up new technologies, and the adaptability of the technology itself to local conditions (Gammeltoft & Cuervo-Cazurra, 2021; Meyer & Peng, 2016; Prahalad & Hart, 2008). CFIR treats both dimensions as ongoing conditions of implementation and splits each by level. Technological infrastructure maps onto *Local Conditions* in the *Outer Setting* for system wide infrastructure and onto *Structural Characteristics* in the *Inner Setting* for infrastructure inside the implementing organisation, such as facilities and equipment. Absorptive capacity maps onto *Capability* in the *Individuals* domain for the technical skill of the people who use the technology, and

onto *Access to Knowledge and Information* in the *Inner Setting* for the availability of training, documentation and expertise. The *Innovation* domain becomes relevant here as well through *Innovation Adaptability*, *Innovation Complexity* and *Innovation Design*, which describe whether the technology itself can be adapted to local conditions, relating to the frugal innovation logic of Gammeltoft and Cuervo-Cazurra (2021) and the price–performance argument of Prahalad and Hart (2008). Market entry theory asks whether the host market can support the technology, while CFIR asks how the technology continues to operate within it.

Environmental factors are seen in the market entry literature as the new markets environmental and sustainability expectations and the pressure on firms to act in ways that local stakeholders consider legitimate (Gammeltoft & Cuervo-Cazurra, 2021; Meyer & Peng, 2016). CFIR treats the same conditions as continuing influences on implementation and places them mainly in the *Outer Setting*. *Local Attitudes* covers the sociocultural values that determine what counts as legitimate practice, and *External Pressure* covers the demands placed on firms to align with sustainability expectations. When environmental considerations are integrated into the firm's own strategy, they also show up in the *Inner Setting* through *Mission Alignment*, which links the firm's stated purpose to the implementation effort (Gammeltoft & Cuervo-Cazurra, 2021). Market entry theory asks whether the firm can establish legitimacy at the point of entry, while CFIR asks whether the same legitimacy holds across the duration of the implementation.

Legal factors are seen in market entry as the content of formal rules and the consistency with which they are enforced (Meyer & Peng, 2016; Zhang et al., 2023). CFIR treats these conditions as continuing context for implementation and places them in the *Outer Setting*. *Policies and Laws* captures the formal regulatory layer regardless of whether it acts as protection or as friction. *External Pressure* captures the formal requirements that firms adhere to through channels such as licensing and clinical guidelines, which reflect the credibility of the institutions enforcing the rules. The unreliability of legal information in emerging markets noted by Cavusgil (1985), where rules are often inconsistent and hard to verify, also shows up in the *Implementation Process* domain through *Assessing Context*, since the work of identifying what shapes implementation depends on what information is actually available. Market entry theory asks whether the legal environment supports entry, while CFIR asks how legal information is processed and how rules act during the work of implementation.

Organisational factors are seen in the market entry literature as the resources, capabilities and structural features the entering firm brings into the new market (Dunning, 1980; Laufs, 2015). CFIR treats these conditions as features of the implementing organisation and picks them up primarily in the *Inner Setting*, where *Structural Characteristics*, *Available Resources*, *Access to Knowledge and Information* and *Relational Connections* describe whether the organisation has the infrastructure, funding, expertise and internal ties needed to put the innovation into routine use. *Access to Knowledge and Information* also picks up the prior multinational experience that Canabal and White (2008) identify as a consistent driver of successful entry. The same firm-level factors also shape the *Individuals* domain through *Capability* and

Opportunity, where *Capability* describes whether the people who use or deliver the innovation have the ability to do so, and *Opportunity* describes whether they have the authority and practical conditions to do it, both of which depend on the resources and structures the firm provides. Liability of newness, described by Johanson and Vahlne (2009) as the disadvantage younger firms face from not having built up routines and experience, maps onto *Teaming* in the *Implementation Process*, since *Teaming* relates to the coordinated routines that newer firms have not yet developed. While strategic intent explains why a firm enters a market (Gammeltoft & Cuervo-Cazurra, 2021), *Mission Alignment* captures how a specific implementation effort is evaluated once the firm is pursuing it. The two therefore overlap only when the firm's original reason for entering remains its reason for committing resources to implementation. Market entry theory asks what the entering firm brings into the market, while CFIR asks how the same conditions act inside the organisation that implements.

Market entry factor	**CFIR domain**	**CFIR constructs**
Political	Outer Setting	Policies & Laws, Partnerships & Connections, Critical Incidents
Economic	Outer Setting, Inner Setting	Local Conditions, Financing, Available Resources, Compatibility
Social & Cultural	Outer Setting, Individuals, Implementation Process	Partnerships & Connections, Local Attitudes, Motivation, Need, Engaging
Technological	Innovation, Outer Setting, Inner Setting, Individuals	Innovation Adaptability, Innovation Complexity, Innovation Design, Local Conditions, Structural Characteristics, Access to Knowledge & Information, Capability
Environmental	Outer Setting, Inner Setting	Local Attitudes, External Pressure, Mission Alignment
Legal	Outer Setting, Implementation Process	Policies & Laws, External Pressure, Assessing Context
Organisational	Inner Setting, Individuals, Implementation Process	Structural Characteristics, Available Resources, Access to Knowledge & Information, Relational Connections, Mission Alignment, Capability, Opportunity, Teaming

Table 2.7: Mapping Market Entry factors to CFIR domains and constructs

2.3.2 Implications for the Empirical Analysis

A direct consequence of the mapping is that the same empirical finding can be coded against both a market entry factor and one or more CFIR constructs. This is what allows the study to identify determinants that act at both entry and implementation, rather than confining each finding to one stage. The mapping is also uneven, since the market entry factors do not distribute evenly across the CFIR domains. The *Outer Setting* and *Inner Setting* absorb most of the market entry factors, while the *Innovation*, *Individuals* and *Implementation Process* domains pick up dimensions that market entry theory acknowledges but does not develop in depth.

These overlaps mean that several determinants in this study do not fit cleanly into either market entry or implementation alone. A determinant can both block or facilitate entry and shape the implementation that follows. A determinant can also both build a firm's position in the market and support the work of putting the technology into use. The empirical analysis in Chapter 5 uses this framework to read each theme from the field study as a determinant that operates across both stages, rather than as a barrier or facilitator tied to either market entry or implementation alone.

3

Methods

This chapter presents the research design, research context, the data collection, and the thematic analysis used in the study, followed by a discussion of the methodological choices.

3.1 Research design

The choice of research strategy is important to ensure alignment between the research aim, theoretical framework, and methods. In research on healthcare and innovation, a distinction is often made between quantitative and qualitative approaches (Bell et al., 2022). Quantitative studies typically focus on testing hypotheses using measurable data, while qualitative studies aim to understand experiences, perceptions, and context-dependent processes (B. Merriam, 2015). This distinction is not specific to healthcare or innovation research, but applies broadly across the social sciences. However, in studies focusing on complex and context-dependent processes such as healthcare implementation, qualitative approaches are often more suitable as they enable a deeper understanding of perceptions, experiences, and system dynamics (B. Merriam, 2015; Bell et al., 2022).

Since this study focus on how new innovations may be implemented in a specific healthcare context, a qualitative approach is considered appropriate. The aim is to understand implementation dynamics of new diagnostic innovations within the Rwandan healthcare system, rather than measuring outcomes. The study follows a case study design, which is suitable when investigating a phenomenon within a real-life context, especially when context plays an important role (Bell et al., 2022). This research design is considered appropriate as it allows for an in-depth understanding of context-dependent processes, which would be difficult to capture through quantitative methods. It is also feasible within the time frame of the study and suitable for exploring perceptions and system-level dynamics rather than measuring outcomes (Bell et al., 2022).

3.2 Frame of reference

A literature review is used to support the research design and provide theoretical background and research context for the study. Given the scope of the thesis, a narrative literature review is applied (Bell et al., 2022), allowing insights from dif-

ferent research areas to be combined. The review shape both the development of the interview guide and the analytical approach by identifying relevant factors related to market entry and implementation.

The literature review was conducted iteratively throughout the project rather than as a single up-front activity, allowing the frame of reference to evolve in parallel with the empirical work. Initial searches focused on stroke epidemiology, point-of-care diagnostics, and healthcare systems in LMICs in order to establish the problem context. As the study progressed, the search was expanded toward implementation science and determinant frameworks, where CFIR was identified as a suitable analytical lens. Searches were carried out through academic databases and library platforms such as Scopus, PubMed, Web of Science, and the Chalmers Library, using combinations of relevant keywords. Sources were screened based on relevance to the research questions and peer-review status Information produced outside of traditional commercial or academic publishing channels, such as reports from the WHO, the World Bank, and the Rwandan Ministry of Health, was also included to capture system-level context that is not always reflected in academic sources.

3.3 Data collection

The study is based on qualitative data collection, primarily through semi-structured interviews. This method allows the researcher to follow predefined topics while giving participants the possibility to describe their experiences in their own words (McIntosh & Morse, 2015). An interview guide is developed based on the research questions and literature review, with selected constructs used as starting points to structure the interviews and ensure coverage of relevant aspects related to implementation. The interview guide was also updated during the study as new insights came up in earlier interviews, allowing the questions to be refined over time. It was partly based on Damschroder et al. (2022) CFIR framework, which helped structure the interviews to cover different aspects of market entry and implementation, while still allowing participants to speak freely about their experiences. The interviews were conducted in person, with the exception of one that was conducted online, and lasted approximately 30–60 minutes. All interviews were audio recorded with verbal consent and transcribed shortly after being conducted to enable a detailed review of the material.

The development of the interview guide was guided by the CFIR framework. Rather than applying all five CFIR domains and their full set of constructs, a selection was made based on relevance to the research questions and on the scope of prior work conducted within the same research project. Specifically, constructs that had already been addressed through the Health Technology Assessment carried out by Alshaqouq (2025) concerning the technical performance, safety, and clinical suitability of the Strokefinder MD100 were given less attention in order to avoid duplication. Instead the guide concentrated on constructs related to the outer setting, inner setting, individuals, and implementation process. The innovation domain was addressed primarily in relation to perceived relative advantage, adaptability, and cost rather than evidence base, which had been examined previously.

Participants were selected with support from local supervisors and their professional networks, as well as through contacts from a previous master's thesis by Alshaqouq (2025), which facilitated access to relevant stakeholders within the healthcare system. Local supervisors supported the recruitment process by identifying relevant stakeholders and therby facilitating initial contact and in some cases introducing the researchers directly to participants. The sample included stakeholders involved in stroke care and healthcare decision-making, such as clinicians, hospital staff, and system-level actors but also some with general knowledge about the local business landscape. Snowball sampling was used to identify additional participants, meaning that initial respondents suggested other relevant individuals to include in the study. This approach is commonly used in qualitative research when the population is difficult to access or not clearly defined.(Bell et al., 2022). A further set of participants was recruited through the two industry conferences attended during fieldwork, described later in this section.

The interview guide was structured into thematic blocks corresponding to these constructs and contained a broad pool of questions from which a set was selected for each interview depending on the role and expertise of the participant. As the interviews were semi-structured, not all questions were asked in every interview. For example, questions concerning clinical workflows were prioritized in interviews with clinicians, whereas questions concerning regulation, financing, and partnerships were emphasized in interviews with system-level actors and representatives from startup environments. The guide was also revised iteratively as new themes emerged from earlier interviews, allowing the questions to be sharpened and adapted as the empirical understanding developed.

Both researchers were present at all interviews and divided responsibilities between them. One researcher led the questioning and managed the audio recording, while the other took notes throughout and occasionally posed follow-up questions when relevant. The lead interviewer also took brief notes during the conversation, primarily as reminders to revisit specific points later in the interview. This division of roles allowed for a more focused conversation while still ensuring that both researchers remained actively engaged.

The majority of the interviews were conducted in English, with two conducted in Swedish where this was the participant's preferred language. As English was a second language for most respondents, occasional communication barriers arose. In such cases, follow-up and clarification questions were used to confirm the intended meaning of responses and reduce the risk of misinterpretation.

To ensure a shared understanding of the technology under discussion, a short introductory video of approximately one minute was prepared in advance, illustrating how the Strokefinder MD100 is used in practice and explaining the underlying microwave-based technology. The video was shown to participants who were not already familiar with the device, which was the case in approximately 60% of the interviews. Showing the video provided a common reference point and helped participants reflect more concretely on how the technology might or might not fit within their part of the healthcare system.

In total 35 individuals were contacted in order to secure the 15 interviews included in the study. The remaining contacts either did not respond, declined participation, or were unable to schedule a meeting within the time frame of the field study. The full list of participants, including their roles and the dates of their interviews, is presented in Table 3.1.

The selection aims to include perspectives from different parts of the healthcare system in order to capture variation in experiences and responsibilities. In addition to healthcare professionals and system-level actors, representatives from startup and innovation environments were included when relevant, as they provide insights into how new healthcare technologies are developed and introduced into the system.

Ethical considerations were addressed throughout the data collection process. Participation was voluntary and all participants were informed of the purpose of the study before consenting to take part. Anonymity was maintained by ensuring that no individual participants are identifiable in the reported findings. Given the hierarchical structures observed within the healthcare system, care was taken to ensure that participation did not place individuals in a vulnerable position relative to their supervisors or organizations.

All data collection was conducted in Rwanda from February until end of April 2026. In addition to the 15 interviews, two industry conferences and one site visit were included as complementary data sources. The first conference was the Nordic-Baltic Business Forum, a three-day conference organized in collaboration between the Rwandan government and the Nordic and Baltic embassies, with participation from companies, universities and investors from these regions. At this event, the researchers participated actively, presenting the Strokefinder MD100 at a booth and engaging in conversations both with attendees who approached the booth and with stakeholders the researchers approached themselves. Some of these conversations identified actors who were later approached for interviews. The second event was hosted by an entrepreneurship hub serving as a meeting point for startups, investors, and policymakers within the East African and Rwandan innovation ecosystem. At this conference, the researchers participated more passively, primarily attending sessions and observing discussions, while still having the opportunity to engage in informal conversations with other attendees. This event served a similar recruitment function for actors in the startup and investment ecosystem. Recruitment through both settings is a form of opportunistic sampling that ran alongside the supervisor-led and snowball approaches. These conferences provided complementary insights into how the device was perceived by stakeholders from the broader regional ecosystem. Both conferences acted as points of primary data collection through attending seminars and discussion groups hosted by local and international industry professionals who shared insights in the general and healthcare specific business environment of Rwanda. References to these events in the empirical findings appear as C1 (Nordic-Baltic Business forum) and C2 (Entrepreneurship Hub Conference).

The site visit was conducted at King Faisal Hospital, the largest and most technologically advanced hospital in Kigali. The visit consisted of an interview with a clinician at the EMS unit of the hospital. The purpose of the visit was to develop

an understanding of the highest level of medical technology available within the Rwandan healthcare system, providing a reference point to complement the literature. Due to limited time on site the visit did not yield any substantial insights, and it was therefore treated as contextual background rather than as a primary data source.

Respondent	Organisation	Position	Date	Duration	Location
R1	Healthcare Data Analytics	Office Manager & People Strategy	3/3-26	32 min	Kigali, Rwanda
R2	Medtech Company	CEO/Founder	13/3-26	48 min	Kigali, Rwanda
R3	Ministry of Health	Prehospital & EMS Specialist, Coordinator of EMS	17/3-26	31 min	Kigali, Rwanda
R4	Medtech Company	Founder/CEO	17/3-26	42 min	Kigali, Rwanda
R5	Tech Company	Co-Founder & CIO	18/3-26	38 min	Kigali, Rwanda
R6	Private Clinic / NCD Network	Chairman, Joint Founder, Ex President	18/3-26	53 min	Kigali, Rwanda
R7	Embassy	Medicine/Vaccine Expert	19/3-26	35 min	Kigali, Rwanda
R8	King Faisal Hospital	Head of Department	21/3-26	37 min	Kigali, Rwanda
R9	NGO	Health Manager	23/3-26	35 min	Kigali, Rwanda
R10	NGO	Health Advisor	23/3-26	35 min	Kigali, Rwanda
R11	Venture Capital Hub	Ecosystem & Marketing Director	24/3-26	49 min	Kigali, Rwanda
R12	Ministry of Health	Maternal, Child & Adolescent Health Quality Specialist	24/3-26	35 min	Kigali, Rwanda
R13	RSSB	Head of Benefits Package	24/3-26	35 min	Kigali, Rwanda
R14	Medtech Company	CMO/Founder	25/3-26	45 min	Teams (Online)
R15	Private Hospital	Chief Medical Officer & Deputy CEO	26/3-26	65 min	Kigali, Rwanda

Table 3.1: List of interview respondents

3.4 Data analysis

The data analysis was conducted in several stages, beginning with the transcription of the interview recordings. Transcription was carried out using the AI-based transcription service provided by Chalmers University of Technology. The automatically generated transcripts were subsequently reviewed and corrected manually against the original audio recordings to ensure accuracy, particularly for technical terminology and passages where pronunciation or audio quality affected the automatic output. Brief notes taken during the interviews were used as a complementary reference during this verification step.

The collected data were analysed using thematic analysis, which provides a flexible yet structured approach to identifying and structuring recurring patterns in qualitative data. It was chosen as it is well suited for exploring complex and context-dependent implementation processes (Bell et al., 2022).

The analysis followed a multi-step and iterative process, where data collection and analysis were carried out in parallel, allowing insights from earlier interviews to inform later ones. The different steps of the analytic process has been highlighted in Table 3.2.

The analysis began with open coding, where relevant segments of the data were identified and labelled without predefined categories. These initial codes were then compared and grouped into broader categories, which were further developed into themes representing barriers and facilitators to implementation. The themes were generated inductively from the data rather than being predefined, allowing patterns to emerge based on participants' experiences (Bell et al., 2022).

The coding was performed in Microsoft Excel, which provided a structured but flexible environment for organizing extractions, codes, and emerging themes side by side. Both researchers coded the transcripts together rather than independently, discussing the interpretation of each segment as it was identified. This collaborative approach was chosen to enable continuous calibration of interpretations and reduce the risk that individual perspectives would shape the coding in inconsistent ways. After the initial coding was completed, the codes were reviewed to identify overlaps and to merge codes that captured similar content. Codes were also refined to ensure that each was sufficiently distinct from the others while remaining specific enough to retain interpretive value. From this process, a total of 52 unique codes were generated, comprising 25 codes relating to facilitators and 27 codes relating to barriers, derived from 136 data extractions across the interview material. The codes were then grouped into broader categories, which were further developed into 13 themes, including 6 facilitator themes and 7 barrier themes.

In order to provide a more structured interpretation, the identified themes were subsequently mapped onto CFIR domains and constructs(Damschroder et al., 2009,

Steps	Step-by-step description
1. Familiarization with data	Interviews were transcribed and read multiple times to gain an overall understanding of the material and to note initial impressions.
2. Generating initial codes	Relevant segments of the data were identified and labeled through an open coding approach without predefined categories.
3. Searching for themes	Codes were compared and grouped into broader categories, which were then developed into preliminary themes representing recurring patterns.
4. Reviewing themes	The themes were refined and reviewed in relation to the coded data and the full dataset to ensure consistency and relevance.
5. Defining and naming themes	The themes were clearly defined and specified as barriers and facilitators to implementation across different levels.
6. Mapping to CFIR	The identified themes were mapped onto CFIR domains and constructs to enable a structured and theory-informed interpretation of the findings.
7. Producing the analysis	The final step involved interpreting the themes and presenting the results in relation to the research questions and theoretical framework.

Table 3.2: Phases of thematic analysis in this study based on Bell et al. (2022)

2022). The updated 2022 version of CFIR was used, which retains the original five-domain structure of innovation, outer setting, inner setting, individuals, and implementation process, while incorporating refined and expanded constructs based on user feedback from prior applications of the framework. All five domains were used in the mapping, as the empirical themes spanned innovation characteristics, system-level conditions, organizational factors, individual perspectives, and process-related considerations. This introduced a deductive element to the analysis, as the inductively generated themes were interpreted in relation to an established theoretical framework and across different levels, including individual, organizational, and external factors. The combined inductive-deductive approach allowed the analysis to remain grounded in the participants own descriptions while enabling a structured comparison with established implementation science constructs.

3.5 Method discussion

During the course of the study, a few methodological challenges were identified. One of the main challenges concerned the selection of participants. The study aimed to include a range of stakeholders with different roles within the healthcare system

in order to capture multiple perspectives on implementation. However, access to participants was partly dependent on local contacts, which influenced who could be included, meaning that some relevant perspectives may not have been represented. Some attempts to reach certain stakeholders were unsuccessful, which further limited the inclusion of specific perspectives. For instance, one authority partly responsible for clinical trials redirected the request upward due to a perceived conflict of interest, as participation required clearance from senior leadership. This reflects broader patterns of cultural and organizational hierarchies, where individuals at lower organizational levels appeared hesitant to participate without formal approval from supervisors. Time constraints limited the number of interviews that could be conducted, which may have affected both the depth and variation of the data. Unforeseen challenges, such as difficulties in scheduling interviews and navigating organizational structures, further influenced the data collection process and limited the ability to reach certain stakeholders.

Another challenge relates to the use of semi-structured interviews. While this approach made it possible to capture detailed and context-specific insights, it also meant that responses varied in depth and clarity. In some cases, participants focused on aspects outside the main scope, which required follow-up questions and interpretation during the analysis. This is a common trade-off in qualitative research, where flexibility comes at the cost of consistency (Bell et al., 2022).

Given the hierarchical and cultural context in which the interviews were conducted, there is a risk that some participants provided desirable answers or withheld information rather than speaking freely as they perhaps perceived certain questions as sensitive. Individuals in lower organizational positions may have been reluctant to express critical views about their organizations or supervisors, which could have influenced the depth and honesty of certain responses. While follow-up questions were used to probe further where relevant, this limitation cannot be fully eliminated in a qualitative study of this nature. In hindsight, relying primarily on interviews as the main empirical data source therefore represents a methodological limitation. Although the study drew on document and literature analysis in developing its theoretical framework, more systematic document analysis of implementation-specific material or more extensive observations could have provided a more comprehensive and deeper understanding of the implementation process, allowing for a comparison between what participants described and what could be observed in practice. However, regulatory and implementation processes are lengthy, making systematic observation difficult within the time frame of the field study.

The researchers active participation at the Nordic-Baltic Business Forum, where they presented the Strokefinder MD100 at a booth, may also have shaped the conversations conducted in that setting. While this dual role provided valuable opportunities to engage directly with stakeholders from the regional ecosystem, it also meant that the researchers were not neutral observers in those interactions. Insights gathered in this context were therefore treated as complementary to, rather than equivalent in standing to the formal interview data.

Credibility concerns the extent to which the findings are believable and accurately represent the participants views and the studied reality (Bell et al., 2022). In this

study credibility was addressed through several practical measures. The interviews were recorded and transcribed, making it possible to revisit the material and check interpretations. During the interviews, follow-up questions were used to clarify responses and reduce misunderstandings. Including participants from different parts of the healthcare system also contributed to a broader and more nuanced understanding of the topic.

As the study focuses on a specific healthcare context, the findings are not intended to be directly transferable to other settings. However, by describing the research context, data collection, and analysis process, the study allows for analytical transferability to similar contexts where comparable conditions exist. Transferability concerns the extent to which the findings can be applied to other contexts or settings beyond the one studied (Bell et al., 2022).

A further limitation is technological bias. The study is built around one device, and respondents were introduced to the Strokefinder MD100 before discussing market entry and implementation. Framing the conversation around one technology may have led participants to assess the problem through the lens of that solution rather than questioning whether a technological response was the right one. Several respondents were from startup and innovation environments, who may hold a more favourable view of new technology than the wider healthcare workforce. To mitigate this, interview questions were kept open and covered system-level conditions rather than the device alone, and the sample included ministry officials, NGO staff, and insurance actors whose perspective is not tied to any single technology. The findings describe the conditions under which one technological device could enter and be implemented in the Rwandan healthcare system. They do not address whether a technological response is the right one in the first place.

Dependability refers to whether the research process is consistent and could be repeated, with the findings remaining stable over time (Bell et al., 2022). The dependability of the study is supported by documenting the research process, including how data was collected and analysed. Interview recordings, transcriptions, and coding provide a form of audit trail, making it possible to follow how conclusions were reached. Supervision during the study was limited, which placed greater responsibility on the researchers to maintain consistency throughout the process.

Confirmability is the degree to which the findings are shaped by the data rather than the researcher's own assumptions (Bell et al., 2022). While complete objectivity is not possible, efforts were made to remain close to the empirical material and avoid over-interpretation. This was done by consistently comparing interpretations with the original transcripts to ensure that conclusions were grounded in the data and not on personal beliefs or values from the researchers.

The methodological choices represent a balance between feasibility and depth. While limitations exist, the approach is considered appropriate for exploring implementation in a complex and context-dependent healthcare setting, where understanding perceptions, interactions, and system-level conditions is central to the research aim and feasible within the time-frame of the project.

3.6 Research context

The section below presents the context that the study is investigated within by describing stroke, elaborate on the technical specification of the Strokefinder MD100 and the Rwandan healthcare system.

3.6.1 Stroke

Stroke is defined as a sudden disturbance in brain function caused by a problem in the blood supply to the brain. Stroke is characterized by rapidly developing signs of focal or global neurological impairment of vascular origin (Hatano, 1976). These disturbances commonly lead to symptoms such as weakness, speech difficulties, vision problems, or loss of coordination. If reduced blood flow or bleeding continues, brain cells are damaged and can die. Current clinical guidelines distinguish between two main types of stroke: ischemic stroke and hemorrhagic stroke (Feigin et al., 2021; Powers et al., 2019).

Stroke is considered a medical emergency, and early assessment together with brain imaging is necessary to determine whether the stroke is caused by a blocked artery (ischemic) or bleeding in the brain (hemorrhagic) (Greenberg et al., 2022; Powers et al., 2019). This distinction is important because the treatments differ significantly. In ischemic stroke, the goal is to restore blood flow, often through medicinal thrombolytic treatment or in some cases mechanical thrombectomy (Campbell & Khatri, 2020; Powers et al., 2019). In hemorrhagic stroke, treatment instead focuses on limiting further bleeding, controlling blood pressure, and reducing additional damage to the brain (Greenberg et al., 2022; Van Gijn et al., 2007).

The urgency of early diagnosis is often described by the concept “time is brain”, which highlights how delays in treatment lead to worse outcomes. Saver (2006) estimates that millions of neurons may be lost each minute during an untreated stroke. This makes it important to minimize delays throughout the care process, from symptom recognition to diagnosis and treatment. However, accurate and timely diagnosis depends on access to appropriate diagnostic tools, especially imaging methods that can distinguish between different types of stroke (Greenberg et al., 2022; Powers et al., 2019).

3.6.1.1 Stroke in the LMIC Context

Sub-Saharan Africa carries much of the global stroke burden. Stroke rate relative to population size is 2-3 times more higher than in Europe and the US, and a larger share of cases happens earlier in life (Akinyemi et al., 2021). This is linked to changing lifestyles and rising risk factors such as hypertension, less physical activity, processed diets, and urbanization, which expose younger people to cardiovascular disease earlier (Akinyemi et al., 2021; Owolabi et al., 2015).

The higher proportion of stroke among the younger population has effects on both patients and the health system. Earlier onset means longer disability, more lost work capacity, and greater need for rehabilitation, leading to higher long-term costs and

a heavier burden on households (ICRC et al., 2021; Urimubenshi & Laude, 2019). Rehabilitation capacity in many LMICs is already limited which makes fast and accurate diagnosis especially important as good acute care is one of the few ways to reduce lasting disability and ease pressure on post-acute services (ICRC et al., 2021).

A key factor underlying the imbalance in stroke burden between high-income countries and LMICs is not only increased exposure to risk factors, but also limited access to timely diagnosis and acute care. In many LMIC settings, delays in recognizing and diagnosing stroke significantly reduce the effectiveness of available treatments. This make minimization of delays one of the most important levers for reducing preventable mortality and long-term disability (Urimubenshi & Laude, 2019).

3.6.1.2 Diagnosis and Treatment

Brain imaging is a key part of stroke diagnosis and treatment. In the acute phase, imaging is needed to confirm the diagnosis and determine whether the stroke is caused by a blocked artery or bleeding in the brain. Imaging also helps identify the location and extent of brain injury (Greenberg et al., 2022; Powers et al., 2019).

Computed tomography, CT, is the most widely used imaging method in emergency stroke care because it can be performed quickly and reliably to detect bleeding within the brain (Greenberg et al., 2022). It is often the first test performed when a stroke is suspected. In ischemic stroke, early CT findings may be limited, but CT is still required to rule out bleeding before clot dissolving treatment is given (Powers et al., 2019). However, access to CT scanners is not the same across healthcare systems. In many settings outside of larger metropolitan hospitals, CT may be limited or unavailable due to infrastructure and cost (Akinyemi et al., 2021; Owolabi et al., 2015).

Magnetic resonance imaging, MRI, provides more detailed images of brain tissue and is better at detecting early changes caused by reduced blood flow (Campbell & Khatri, 2020). MRI requires more advanced equipment and trained staff and is less accessible in many resource constrained environments (Akinyemi et al., 2021; Owolabi et al., 2015).

While CT and MRI imaging is the foundation of stroke diagnosis in high-income settings, access to such technologies is often limited or centralized in LMIC healthcare systems. This contributes to delay between the first appearance of symptoms, diagnosis, and treatment, in pre-hospital settings and lower-level facilities. As a result, a gap emerges between clinical need and available diagnostic capacity (Urimubenshi & Laude, 2019). Point-of-care diagnostics have emerged as a approach to bridge this gap, by enabling tests to be performed close to the patient and providing rapid results that support immediate clinical decision making (Kaplan et al., 2013; WHO, 2018). By reducing delays between tests and treatment, point-of-care technologies can improve efficiency in acute care settings and the diagnostic capacity where more advanced infrastructure is limited (Kaplan et al., 2013).

3.6.2 The Strokefinder MD100

This thesis is conducted as a case study with a focus on a specific point-of-care device, the Strokefinder MD100 a portable diagnostic device developed to support early triage of patients with suspected stroke. The device uses non-ionizing microwave technology combined with artificial intelligence to detect differences in the electrical properties of brain tissue, enabling differentiation between stroke and no-stroke conditions. It is intended to assist pre-hospital and early in-hospital decision making by providing rapid diagnostic support and facilitating faster access to appropriate imaging and treatment, rather than replacing CT imaging.

The device itself is designed as a headrest equipped with adjustable microwave antennas and is operated through a tablet without requiring internet access. Measurements can typically be obtained within minutes, and feasibility studies in emergency department settings have shown that usable results were achieved in most patients and that the device was considered easy to use without interfering with ongoing care. Reported performance indicates high sensitivity for distinguishing stroke from non-stroke, while specificity is more moderate. See Appendix A for an in depth product description.

Earlier studies have been conducted to assess the technology through the standardized European Network for Health Technology Assessment (EUnetHTA) to evaluate clinical performance, safety, ethical considerations, and organizational fit within the healthcare system. The assessments have primarily focused on determining whether the device is suitable for use in these contexts, identifying potential benefits, risks, and system-level requirements, including future sites for implementation.

This thesis is a continuation of the ongoing project, building on prior HTA work that has established an initial understanding of the technology's relevance, potential use cases, and system requirements. These assessments provide a foundation for considering the device within the healthcare system but do not fully address how implementation may unfold in practice. The focus of this thesis is therefore to deepen this understanding by examining the conditions surrounding implementation.

3.6.3 LMIC Healthcare Systems

Healthcare systems in LMICs operate under conditions that limit both service delivery and the integration of new technologies (Belardi et al., 2023). Although these systems pursue the same core goals as high-income systems such as improving access, quality, and fair distribution of healthcare services, resource limitations restrict this capacity (The World Bank, 2026; WHO, 2023b). Out-of-pocket payments still represent a large share of total health expenditure in many LMICs which contribute to financial hardship and limiting effective access to care (Kruk et al., 2018; WHO, 2023b). In recent years, the focus has shifted from expanding access to improving quality. Evidence shows that poor quality of care now contributes more to excess mortality than lack of access alone (Kruk et al., 2018). High mortality from treatable conditions, including cardiovascular diseases such as stroke, birth-related complications, and tuberculosis, reflects weaknesses in timely diagnosis, appropri-

ate treatment, and adherence to clinical guidelines (Kruk et al., 2018; Peabody et al., 2006). Gaps between what providers know and what they actually do in practice limit improvements in health outcomes (Kruk et al., 2018). LMICs are also experiencing an epidemiological transition, meaning they face a double burden of both communicable diseases and increasing rates of non-communicable diseases (NCDs) such as stroke and diabetes (WHO, 2023b). While infectious diseases remain important, the growing occurrence of chronic conditions requires coordinated and long-term models of care that many systems were not originally designed to deliver (Kruk et al., 2018).

3.6.3.1 Structure of the Rwandan Healthcare System

Rwanda's healthcare system is organized in a decentralized, tiered structure consisting of community health workers, health posts, health centers, district hospitals, provincial hospitals, and national referral hospitals (WHO Africa, 2018). Community health workers serve as the first point of contact at village level and play an important role in preventive services, health promotion, and referral to formal facilities. Health centers provide consultations and basic stabilization, while district hospitals offer long term care and general surgery.

Public healthcare constitutes the primary mode of of care and is organized through community health workers to national referral hospitals. The system is largely financed through a public health insurance scheme (Mutuelle de santé) and it covers the majority of the population and enables access to basic healthcare services (Binagwaho et al., 2014; WHO Africa, 2018). Despite this broad coverage, resource and workforce constraints remain at lower levels of care.

Private healthcare providers operate mainly in urban areas and complement the public system by offering specialized services at higher cost. While some private hospitals have access to CT imaging, many still lack access to MRI, meaning that diagnostic availability is limited (Urimubenshi & Laude, 2019).

Emergency care is coordinated through the Rwanda National Emergency Medical Service (EMS), which manages ambulances and transfers between hospitals (WHO Africa, 2018). District hospitals provide general emergency services, but specialist care is limited at this level. Triage in Rwandan emergency care rely on adapted Emergency Triage Assessment and Treatment protocols and the Glasgow Coma Scale. These are designed for general emergency assessment rather than stroke specific evaluation (Urimubenshi & Laude, 2019). As a result, standardized pathways for rapid identification and management of stroke are limited (WHO Africa, 2018).

Workforce shortages is a structural challenge. Rwanda has approximately 1-2 physicians per 10,000 population, compared to more than 30 per 10,000 in many high income countries (The World Bank, 2026; WHO, 2023b). Specialist physicians are few and concentrated in urban areas. National training programs have expanded in recent years to strengthen domestic workforce education but specialistsa are still limited (HDI, 2023).

Rehabilitation services are also constrained. Limited infrastructure, shortages of as-

sistive technologies and fewer than one rehabilitation professional per 10,000 population creates limitations together with services concentrated in higher-level facilities. As non-communicable diseases such as stroke increase, demand for both acute and post acute services is expected to rise (Humanity & Inclusion, 2021; WHO, 2023a).

While higher level facilities provide advanced diagnostic capabilities, early diagnosis is constrained at lower levels of care. This creates a critical gap in the patient pathway, where timely identification and triage of stroke is limited by both infrastructure and systems. Such conditions make Rwanda a relevant case for studying the implementation of point-of-care diagnostic technologies.

4

Empirical Findings

This section presents the empirical findings from the qualitative interviews. The results are structured around barriers and facilitators related to the market entry and implementation of new technologies within the Rwandan healthcare system. The findings are organized by first presenting facilitators, followed by barriers, comprising six and seven themes respectively.

4.1 Facilitators

A total of 72 extractions were made from the transcribed interview data that address facilitators in the Rwandan healthcare system. The extractions were analysed and coded, which resulted in the identification of 25 unique codes of facilitators. Further categorization of the identified facilitators generated the following six themes: governmental participation; problem solution fit; partnership networks; trust and legitimacy; supportive digital infrastructure; and shifting disease burden creating structural pull. The data extractions, in combination with the facilitators and resulting themes are presented in the following sections.

4.1.1 Governmental participation

Rwanda's government emerged as a central actor in shaping the conditions for innovation adoption across the healthcare system. Several respondents described the Ministry of Health as operating both as a top-down distributor of innovations and as a bottom-up facilitator of health facility readiness. One respondent reflected about an iterative governance approach that continuously adapts to the environment creating responsive governance rather than rigid long range planning (R7). A key feature of this role as described by R9 and R10 is the government's ability to prevent duplication of efforts by directing innovators toward genuine gaps in the healthcare system, ensuring that new technologies address unmet needs rather than overlapping with existing solutions.

Central procurement approval was identified as a particularly powerful mechanism, as a single decision at the ministry level can translate into simultaneous national deployment across facilities (R1). This policy-to-practice alignment was reinforced by the government's track record, where prior government contracts were described as building cumulative credibility for companies operating in the market. A respondent from the Ministry of Health was noted their efforts in actively channeling funding

and partnerships toward youth-led health technology startups, complemented by competition-based startup selection as an alternative funding mechanism (R3).

Several formal market entry mechanisms were highlighted as enabling structured and transparent pathways for foreign companies, including MOU submission and MOH feasibility analysis. Combined with short company registration times and tax incentives for new medtech companies, these mechanisms were seen as lowering the barrier for entry. Respondents R4 and R5 also pointed to a culture of openness and active co-development, describing it as genuine rather than rhetorical, supported by health sector policy stability and cumulative policy development over time.

At the regulatory level, Rwanda was described by respondent R5 as engaging in regulatory leapfrogging by drawing inspiration from more mature systems, while maintaining the highest rule of law ranking in Africa. The government's use of sandbox proof-of-concept environments as a formal promotion strategy was highlighted as a distinctive feature during a conference (C1), enabling companies to test innovations within a structured and government-sanctioned framework before broader rollout. This perception was however challenged by respondent R5 who thought high tax barriers led to fewer companies being able to test their early stage ideas.

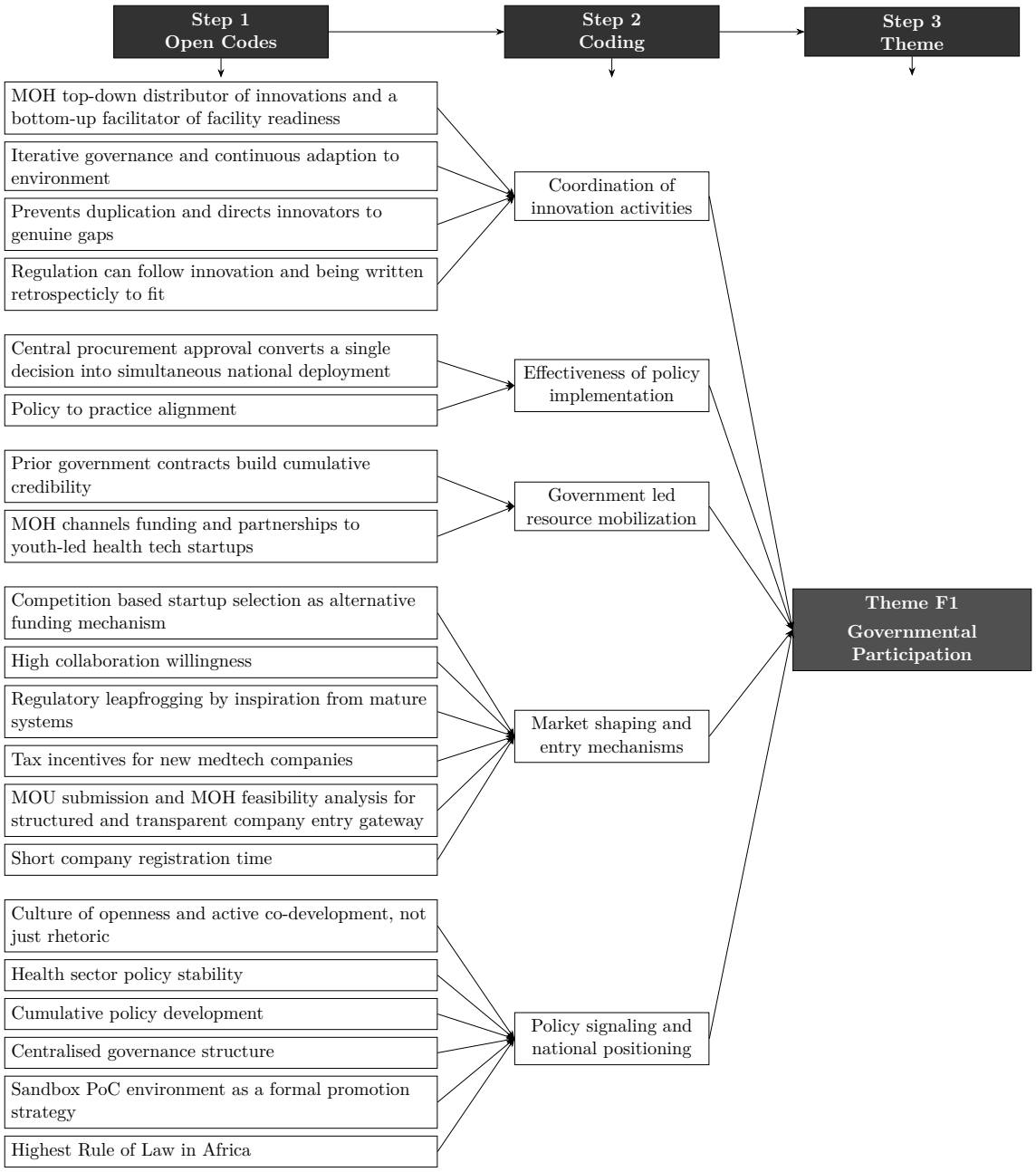

Figure 4.1: Thematic analysis – Theme F1: Governmental Participation

4.1.2 Problem Solution Fit

A recurring theme across interviews was the extent to which the Strokefinder MD100 addresses a pre-existing and clearly identified pain point within the healthcare system. One respondent described how the government had already recognized the diagnostic gap at district and lower-level hospitals as a priority challenge, with an ongoing procurement process underway to equip some of these facilities with improved diagnostic tools (R8). This active alignment between the technology's function and a government-identified need was seen as a significant facilitator, as it positions the device as a response to a known gap rather than an externally im-

posed solution and was described by one respondent as their main way of entry to the Rwandan MedTech market (R2).

Clinical urgency further reinforced this fit. Respondent R8 emphasized the importance of shortening the time to diagnosis in order to enable treatment through thrombolysis, underlining how the time-sensitive nature of stroke care creates a structural demand for rapid point-of-care diagnostic support. The scarcity of existing diagnostic alternatives at lower levels of care was also highlighted by respondent R3, who saw the absence of viable substitutes strengthening the perceived relevance of the technology within the current system.

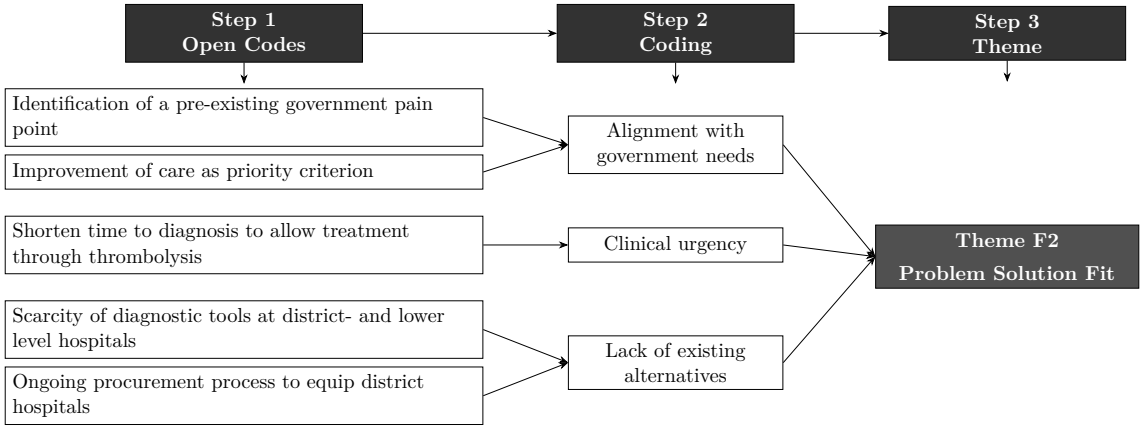

Figure 4.2: Thematic analysis – Theme F2: Problem Solution Fit

4.1.3 Partnership Networks

Respondents identified a range of formal and informal network relationships as significant accelerators for innovation adoption. Established advocacy groups with strong knowledge and influence were described as high-leverage partners, particularly professional clinical associations whose credibility within the system enables them to shape both clinical practice and institutional decision-making. Similarly, NGOs with established credibility were seen by respondent R9 and R10 as capable of opening doors to government planning processes that would otherwise be difficult to access directly.

Embassy and ambassador networks were identified as operating across both formal and informal channels, providing efficient pathways to senior decision-makers. Informal embassy events in particular were highlighted as low-barrier settings for making connections that would otherwise require extensive formal engagement (R7). Local entrepreneurship hubs were also described by respondent R11 as serving a bridging function, being able to link companies to officials and decision-makers faster, while providing affiliation that enhances perceived legitimacy.

Access to trusted intermediaries emerged as a particularly valuable facilitator. Respondent R1 noted the existence of organizations with a near zero rejection rate from MOH for proposals on new technology submitted through them, as well as local champions capable of navigating cultural dynamics that external actors might

otherwise struggle to understand (R5). Respondent R14 had further seen great value in validation from independent local research organizations was also cited as a means of building credibility without relying solely on international evidence.

The interconnection of information systems and patient records was noted by R1 as an enabling structural feature. Prior implementation of similar technologies in comparable African contexts was highlighted by R2 as reducing uncertainty, providing reference points that strengthen confidence among decision-makers, while also helping to identify existing healthcare gaps and clarify what constitutes critical needs within the system. R15 identified private NCD screening clinics with established infrastructure as potential complementary partners, offering existing networks and operational capacity that could support broader piloting, and later, rollout.

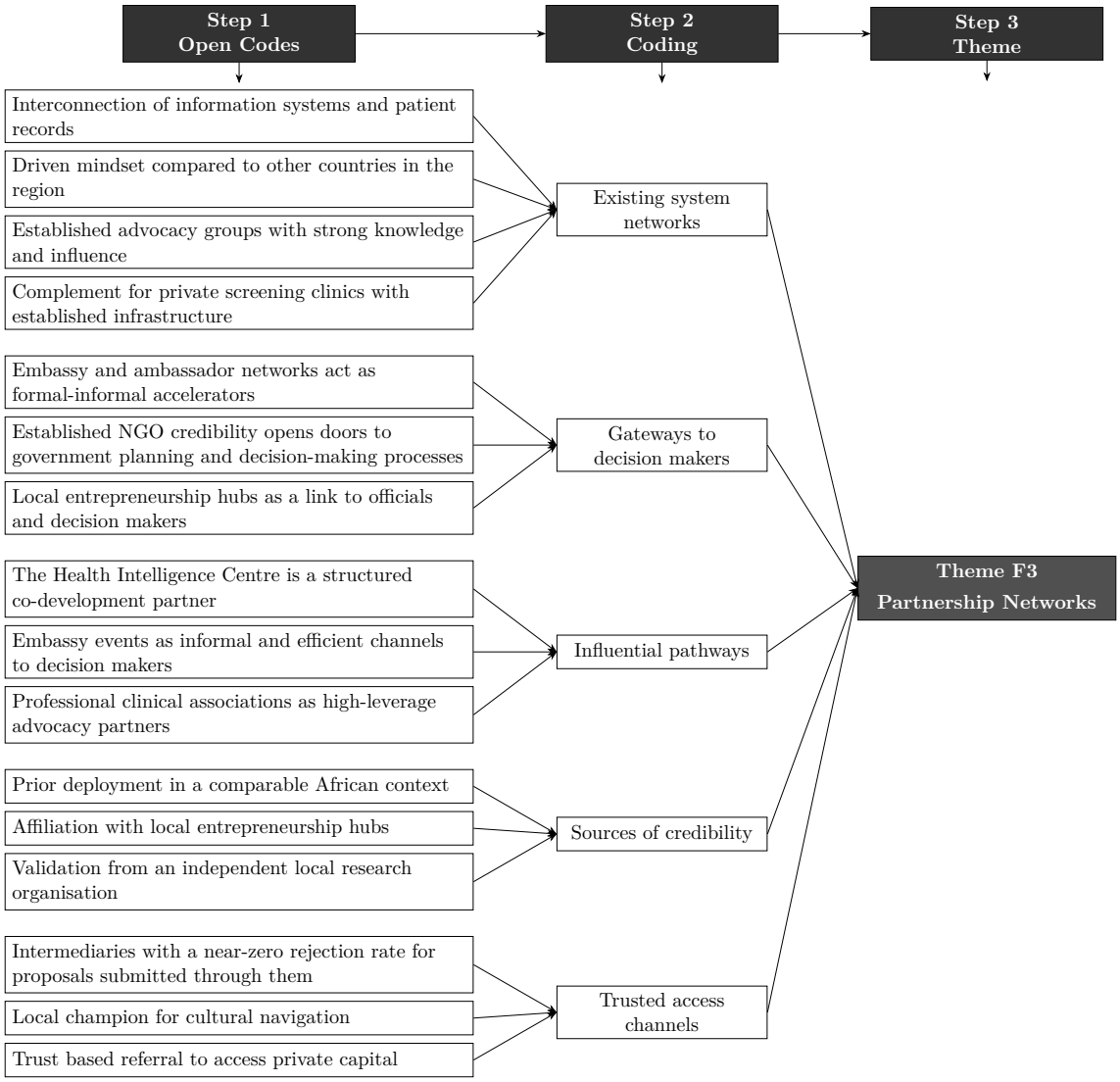

Figure 4.3: Thematic analysis – Theme F3: Partnership Networks

4.1.4 Trust and Legitimacy

Piloting was consistently described as a key mechanism for building the trust and institutional ownership necessary for broader adoption. Respondent R3 emphasized that early co-ownership through piloting improves receptiveness among healthcare staff and decision-makers, as involvement in the process fosters a sense of stake in the outcome. This was seen as distinct from simply presenting evidence, as active participation in a pilot was described as generating a qualitatively different level of institutional commitment.

University collaboration was highlighted by R12 as a pathway to fast-tracking national ethics clearance, reducing one of the procedural barriers to initiating a proof-of-concept study. Integration into existing system infrastructure during the piloting phase was identified by R4 as important for demonstrating compatibility and reducing the perceived disruption of adoption. Respondent R8 also noted that international evidence from prior studies reduces the local validation burden, meaning that a local pilot does not need to replicate all previous work but can instead focus on demonstrating contextual fit and value.

Insurance-related considerations were raised by R13 as part of the piloting strategy. Securing an insurance tariff and ensuring coverage by the Mutuelle de Santé were described as steps that de-risk capital investment and make adoption financially viable within the existing reimbursement framework. Finally, successful local proof-of-concept was described by R11 as creating spillover benefits, with a strong local pilot seen as capable of opening doors to neighboring markets and strengthening the overall case for regional expansion.

Healthcare staff receptiveness to new technologies was identified as a facilitating factor, though the conditions under which it emerges were seen as specific. Respondent R3 and R8 described the ability to see a direct improvement in workflows as the primary trigger for adoption among frontline staff. Comparative demonstration, where staff could observe the technology in use alongside existing methods, was highlighted as an effective approach for translating initial curiosity into active interest and acceptance.

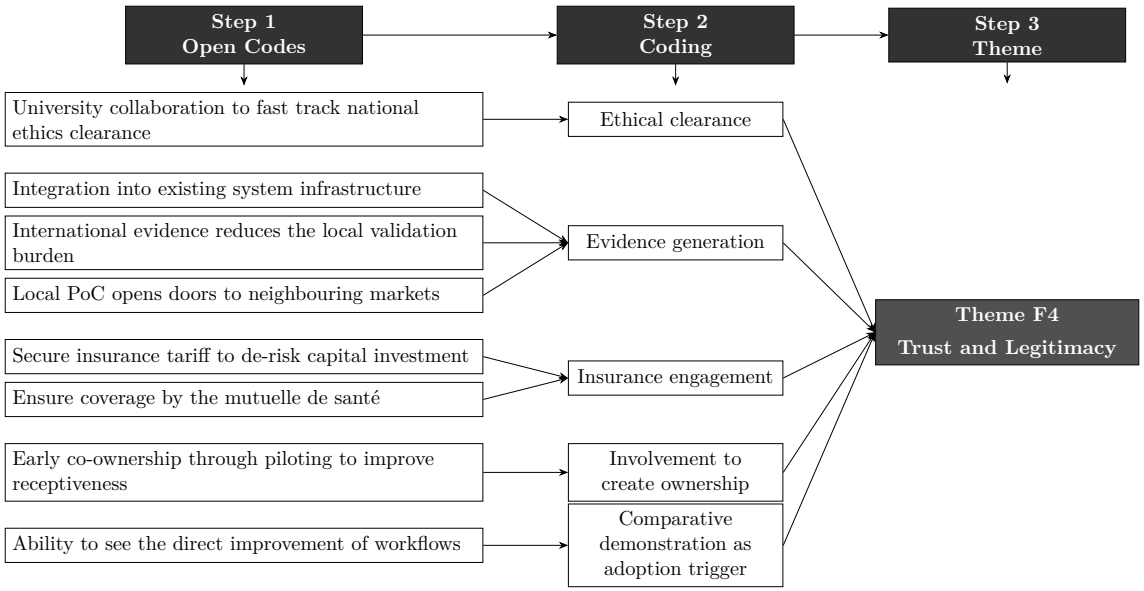

Figure 4.4: Thematic analysis – Theme F4: Trust and Legitimacy

4.1.5 Supportive Digital Infrastructure

Rwanda's digital infrastructure was identified as a facilitating condition for the adoption of health technologies. Respondent R4 highlighted the country's data-driven approach to national priority setting, describing how mandatory data reporting generates a large evidence base that informs decision-making at the system level. This infrastructure was seen as creating favorable conditions for technologies that produce data and integrate with existing reporting systems.

Interoperability between systems were also noted by R4 as practical enablers, with existing alternative satellite-based infrastructure available to fill connectivity gaps in settings where standard connectivity may be limited. Backup power solutions were also described as important, allowing operations to continue during outages. This resilience in the digital environment was described as reducing one of the common barriers associated with deploying technology-dependent health tools in resource-constrained settings.

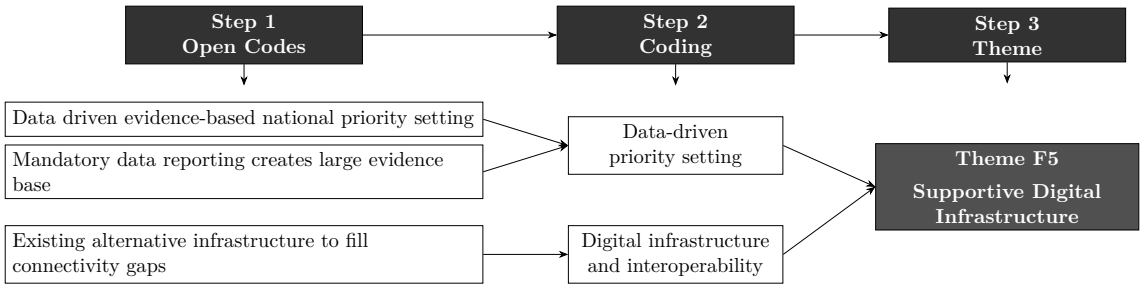

Figure 4.5: Thematic analysis – Theme F5: Supportive Digital Infrastructure

4.1.6 Shifting Disease Burden Creating Structural Pull

The epidemiological transition towards higher rate of NCD cases was identified as generating a structural pull toward investment in new diagnostic and emergency care technologies. Respondent R3 and R8 described a growing governmental awareness of the changing NCD burden, with active system-level investment already underway, including the procurement of CT scanners at district level and the supply of thrombolysis treatment. This signals that the healthcare system is moving toward building the capacity needed for stroke care, even in lower level settings, creating an environment where point-of-care diagnostic tools can fit into an expanding care pathway rather than requiring the construction of entirely new infrastructure which was brought up during conference C1.

Reforms in emergency medical services education were highlighted by R3 as a concurrent development, with new training programs for EMS personnel underway and proposals to include digital training in ongoing education reforms. These changes were seen as reducing the workforce capacity gap over time and increasing the system's readiness to adopt and use new diagnostic tools.

At the community level, increased stroke awareness driven by civil society advocacy efforts and high community demand for NCD screening were described as generating visible unmet patient need. This demand-side pressure was identified as reinforcing the case for investment, as the gap between patient need and available services becomes increasingly apparent to both clinicians and decision-makers (R6, R15).

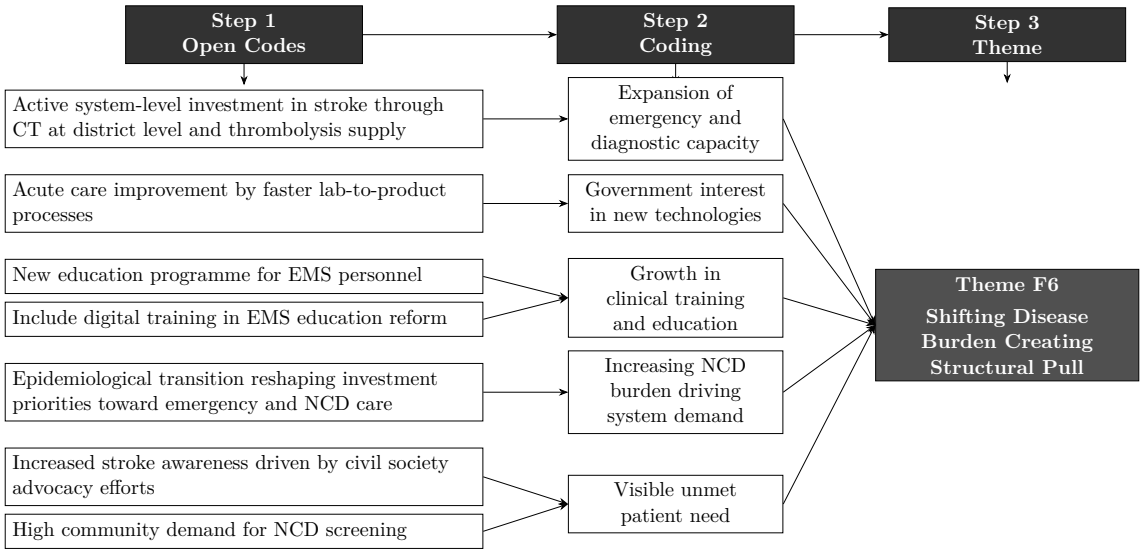

Figure 4.6: Thematic analysis – Theme F6: Shifting Disease Burden Creating Structural Pull

4.2 Barriers

A total of 64 extractions were made from the transcribed interview data that addressed barriers in the Rwandan healthcare system. The extractions were analysed

and coded, which resulted in the identification of 27 unique codes of barriers. Further categorization of the identified barriers generated the following seven themes: regulatory complexity; organizational culture; health workforce capacity; financial constraints; commercial landscape; health literacy and awareness; contextual mismatch. The data extractions, in combination with the facilitators and resulting themes are presented in the following sections.

4.2.1 Regulatory complexity

Rwanda's regulatory environment presented a multi-layered and often sequential set of approval requirements that collectively could create significant delays and uncertainty for foreign companies seeking to introduce new health technologies. Respondents described a system were international regulatory approval, such as CE marking or FDA clearance, was treated as a necessary but insufficient prerequisite, with local processes always additionally required regardless of prior validation elsewhere (R12, R13). Rwanda's sense of national distinctiveness was highlighted by R14 as a contributing factor, with cross-country African evidence carrying limited transfer value in the local context, meaning that evidence from comparable settings such as Malawi was not considered adequate for local approval purposes.

The Rwanda FDA operates on a first-in-first-out queue system, and respondent R14 described certification timelines sometimes extending to two years due to both queue position and iterative documentation revision cycles. For devices incorporating an AI component, a compounded regulatory burden emerged from the requirement for dual-track licensing, covering both the physical device and the AI layer separately (R3). Clinical trials introduced a further layer of complexity, as first-in-Rwanda trials were treated with particular sensitivity, requiring international safety data before any local patient contact and mandating that a Rwandan national serve as the primary co-investigator, obliging foreign companies to formally partner with a local researcher before trials could proceed (R12).

Sequential approvals added further unpredictability, with respondent R2 describing being redirected between institutions such as the MOH and SFH, each requiring its own separate agreement, creating compounding delays rather than a unified approval pathway. Data localization rules further extended the compliance burden, requiring Rwanda-based servers and ICT Ministry approval as a parallel obligation that could be overlooked by incoming companies which were described by R5. At the administrative level, translation errors in company registration documents caused unexpected delays for R2, and the absence of an SME sandbox environment combined with regulatory instability was described by R5 as preventing companies from scaling beyond a small size. Bureaucratic friction, further described by R5 as a functional substitute for corruption, emerged as a persistent feature of administrative processes. Unlike corruption, this friction was not attributed to bad intent but rather to procedural complexity and the absence of streamlined pathways for foreign companies. Respondents noted that this type of friction could not be resolved remotely, as compounding delays accumulated when companies attempted to manage processes from abroad.

The absence of a Good Samaritan law in Rwanda was identified by R2 as a direct structural barrier to task-shifting at community and lower facility levels. Community health workers and nurses operating outside their formally defined scope faced personal legal liability in the event of adverse outcomes, creating a strong disincentive to perform functions beyond their official mandate even when practically capable of doing so. This legal gap was particularly consequential for point-of-care diagnostic technologies that depend on task-shifting to lower-level workers for the devices deployment plan to be realised.

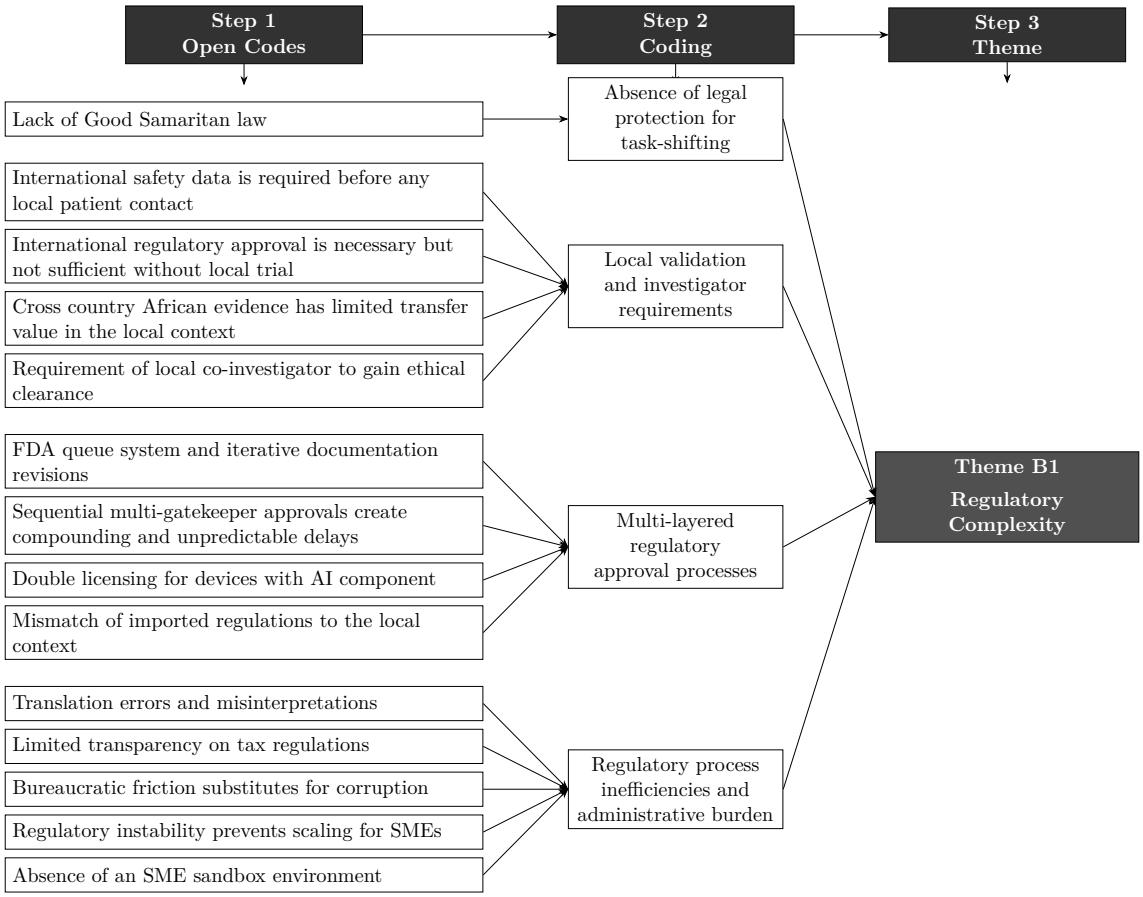

Figure 4.7: Thematic analysis – Theme B1: Regulatory Complexity

4.2.2 Organizational culture

The legal barriers was further reinforced by the hierarchical top-down decision-making culture. The culture was identified as a barrier operating across multiple levels of the healthcare system. Respondents R5 and R7 described a context in which mid-level agreement carried no practical weight without senior sign-off, and where formal legal mandates at lower levels were routinely overridden by informal cultural deference upward. Health post workers were described by R2 as requiring informal supervisor permission to participate even in research activities, despite existing MOH-level frameworks formally authorizing such participation. This dynamic extended beyond research access to shape all operational decisions, with frontline

actors effectively unable to exercise formally granted rights without explicit approval from their immediate superiors.

Decentralization efforts were acknowledged by R5 as underway, but it was also noted that structural reform and cultural change were not progressing at the same pace, with hierarchical practices persisting in everyday operations long after formal frameworks had changed. A related pattern was the systematic detachment of Kigali-based decision-makers from rural realities, creating a disconnect between centrally produced policies and the actual conditions and needs experienced at lower levels of care (R2).

The dual nature of the hierarchy was also highlighted by R7. Without the right signal from above, nothing moves, creating absolute bottlenecks at every stage of implementation. However, respondents noted that when senior-level activation did occur, execution could proceed extremely rapidly. This dynamic makes the hierarchy both the primary obstacle and the primary accelerator depending on whether top-level engagement has been secured. Limited transparency in decision-making processes compounded this challenge further, with decisions frequently delivered as ultimatums and rationale shared only retrospectively, leaving implementing partners with little opportunity for collaborative planning or adaptation.

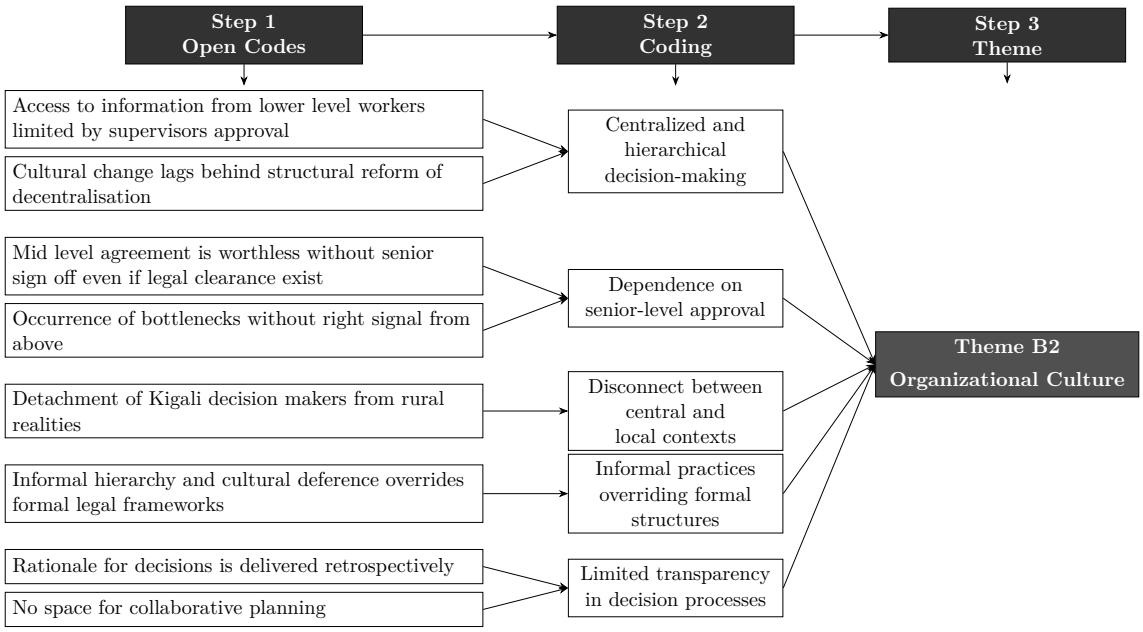

Figure 4.8: Thematic analysis – Theme B2: Organizational Culture

4.2.3 Health workforce capacity

Workforce-related barriers operated across multiple levels and actor groups, forming a persistent and interconnected set of challenges for implementation. At the frontline level, health post nurses were describedby R1 and R13 as having limited technical training, with devices needing to be extremely simple to use in order to be viable at this level of care. Language presented an additional barrier, as training

community health workers required a bilingual train-the-trainer approach given that many CHWs operate in Kinyarwanda rather than English or French (R2, R4).

The responsibility for staff training was identified by R4 as falling entirely on companies in practice, with government pledges of support rarely translated into action. Respondent R3 noted that without contextually appropriate training, staff reverted to old ways of operation when encountering problems, meaning that deployment without adequate preparation risked complete adoption failure. Clinician comprehension of workflow benefits was described as a prerequisite for adoption rather than a post-implementation outcome, requiring that staff understand specifically how the device improves their daily practice before sustained use could be expected.

At the specialist level, a distinct form of resistance emerged. Specialist physicians were described by R6 and R15 as occasionally actively opposing devices perceived to threaten their clinical exclusivity, with resistance strongest among the most specialized professionals. This was not framed as a general skepticism toward technology but as a specific fear of role displacement, persisting even among close professional peers of innovators.

At the community level, structural limitations constrained the role that community health workers could play. CHWs were described as capable of identifying and referring patients but unable to confirm diagnostic findings due to a structural equipment gap rather than a knowledge deficit. NCD-related outreach at community level was also identified as chronically deprioritised relative to maternal health, leaving CHW knowledge of stroke and NCDs underdeveloped. Workforce instability further compounded these challenges, with nurses trained in specialized NCD skills receiving no formal pay recognition for their additional competencies and consequently leaving for the private sector (R6).

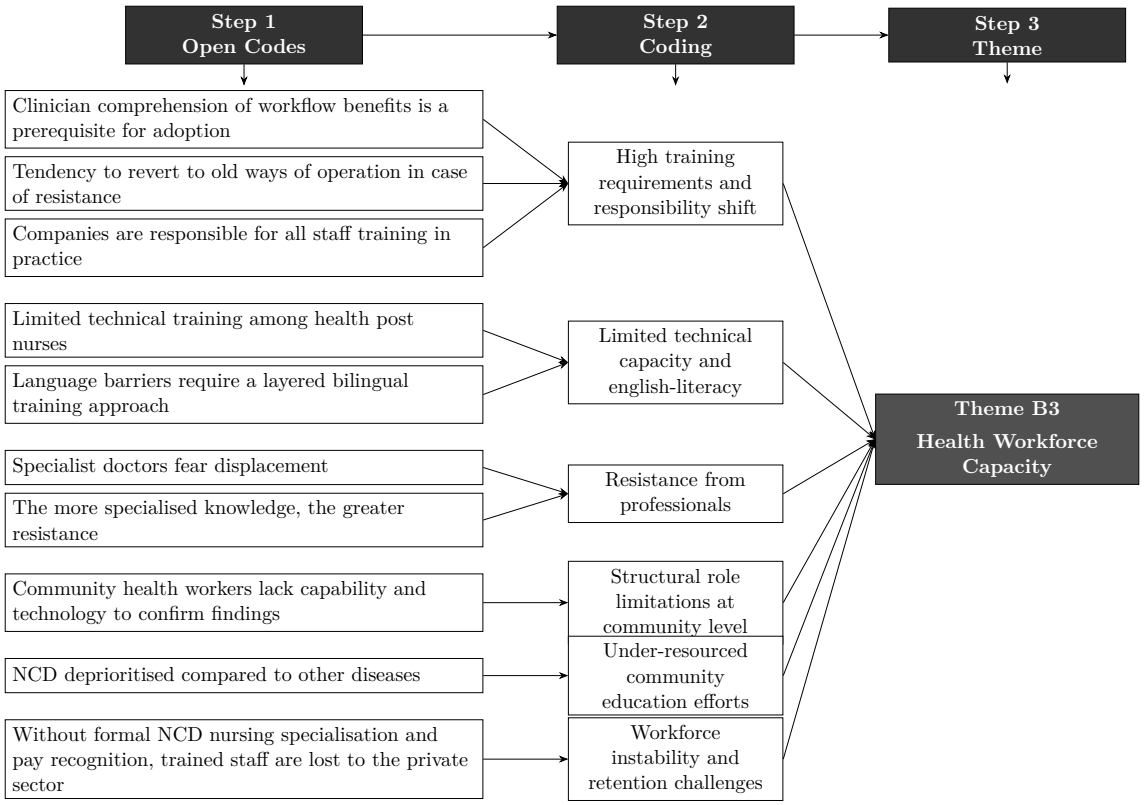

Figure 4.9: Thematic analysis – Theme B3: Health Workforce Capacity

4.2.4 Financial constraints

Financial barriers operated at multiple levels simultaneously, creating structural constraints that limited both initial adoption and long-term sustainability. At the system level, a substantial funding gap was identified between the estimated cost of implementing the national NCD strategic plan, and the government's actual financial commitment. Respondent R6 described funding rather than political will as the binding constraint, noting that the policy ambition existed but was not matched by the resources needed to realize it.

Dependence on donor and grant funding was highlighted during conference C1 and C2 as well as by R5 as a systemic fragility, with recent cuts to USAID and Swedish development aid cited by R11 as evidence of the structural vulnerability of grant-dependent operating models. The phenomenon of grantrepreneurship, where organizations survive on philanthropic grants without developing organic revenue, was identified as a widespread and unsustainable pattern. Organizations operating in this way were described as lacking a viable path to self-sufficiency, with ongoing grant dependency observed even after several years of operation.

Procurement and payment model misalignment created a further set of tensions. Government procurement preferences favored upfront purchase, which conflicted with subscription-based models that respondent R14 described as economically superior for both parties given the budget constraints involved. The absence of a sizeable middle class was identified by R6 and during conference C1 as a structural

market limitation, making domestic scale structurally impossible and positioning Rwanda as a pilot country rather than a home market for health technology companies.

At the patient level, even the relatively small co-payment required under the Mutuelle de Santé insurance scheme was described as deterring the most economically vulnerable patients. Patients without any insurance coverage faced full out-of-pocket costs, effectively collapsing the addressable patient base for any new diagnostic service (R12, R13).

High tax rates, described as comparable to Swedish levels but lacking transparency, added a further layer of financial friction according to R5, particularly for smaller companies navigating the transition from informal to formal sector operation.

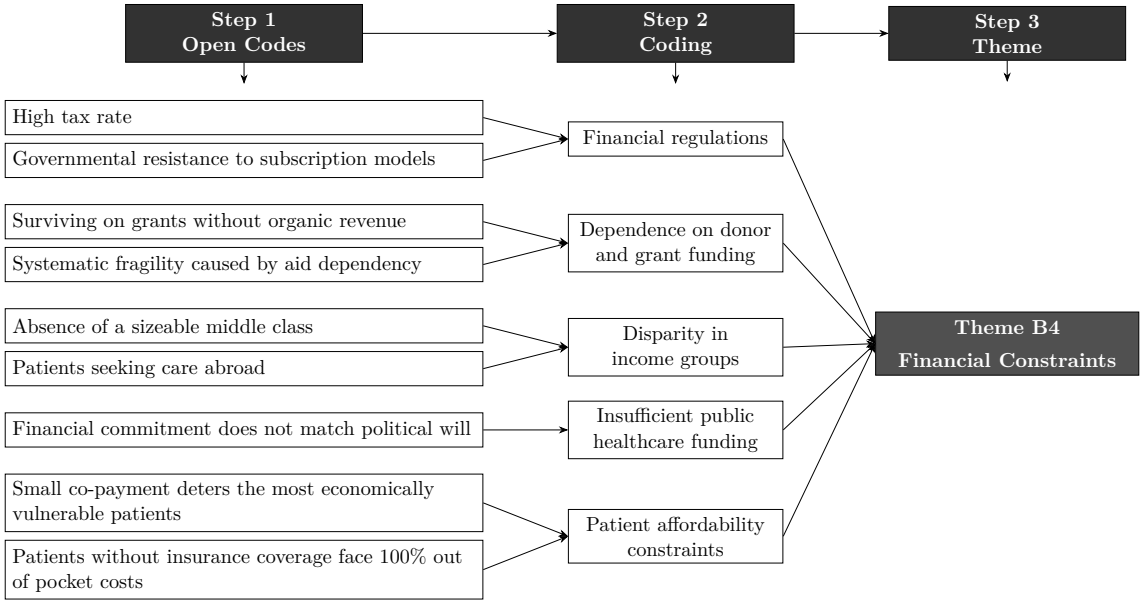

Figure 4.10: Thematic analysis – Theme B4: Financial Constraints

4.2.5 Commercial landscape

While Rwanda's policy environment was consistently described as open and pro-innovation, respondents identified a significant gap between policy intent and real commercial infrastructure. Weak payment systems and underdeveloped funding mechanisms for health technology were highlighted by R2 as practical obstacles that slowed scaling even when regulatory and policy conditions were favourable. The immaturity of the commercial ecosystem meant that companies could enter the market relatively easily but encountered persistent friction when attempting to operate, formalise, and grow beyond an initial pilot scale (R11).

Rwanda's small domestic market was identified by R14 as a structural limitation, making regional expansion a necessity rather than an ambition for companies seeking financial viability. The absence of local medtech service infrastructure meant that foreign companies bore full responsibility for maintenance and supply chain management, adding operational costs and complexity that further constrained sus-

tainability. Funding systems remained underdeveloped, creating uncertainty around revenue pathways that limited the attractiveness of the market for companies evaluating commercial feasibility (R2).

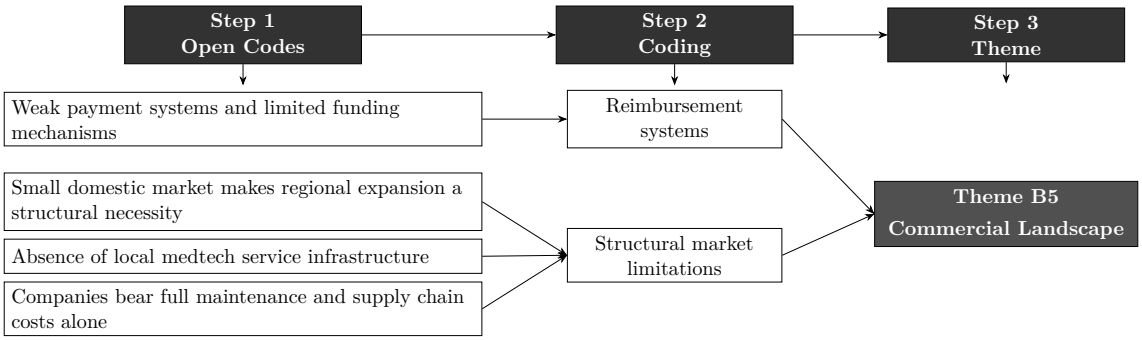

Figure 4.11: Thematic analysis – Theme B5: Commercial Landscape

4.2.6 Health literacy and awareness

Low health literacy and limited public awareness of stroke and non-communicable diseases emerged as a barrier operating across community, clinical, and system levels. At the community level, the screening-to-care gap was described as an education and awareness problem rather than a only financial one. Respondent R6 noted that individuals identified as abnormal through NCD screening frequently did not follow through to health centers, despite the community health insurance co-payment being negligible at approximately 200 Rwandan francs (O,12 euro). This pattern pointed to low health literacy as the primary driver of care-seeking behaviour rather than cost.

The average delay from stroke onset to hospital care was described by R6 and R8 as approximately four days, driven by a combination of factors. Low awareness of stroke symptoms meant that patients and families did not recognise the emergency and delayed seeking care. Detours via traditional healers were common, reflecting cultural health beliefs that competed with formal healthcare pathways. Referral chain length added further systemic delay, with patients passing through multiple care levels before reaching a facility capable of stroke diagnosis and treatment. The result was that a majority of stroke patients arriving at emergency departments did so outside the four-hour thrombolysis treatment window, with onset-to-arrival times typically ranging between three hours up to several days (if they seek care at all) (R6, R8, R15).

At the clinical level, a distinct awareness gap was identified around the value of preventive care. Respondent R15 described clinicians as not naturally grasping the return-on-investment logic of prevention, contrasting this with business professionals who were said to understand preventive value more intuitively. Community education efforts on NCDs were described by R9 and R10 as chronically underfunded, with outreach activities concentrated on maternal health and CHW knowledge of stroke and NCDs remaining low as a result.

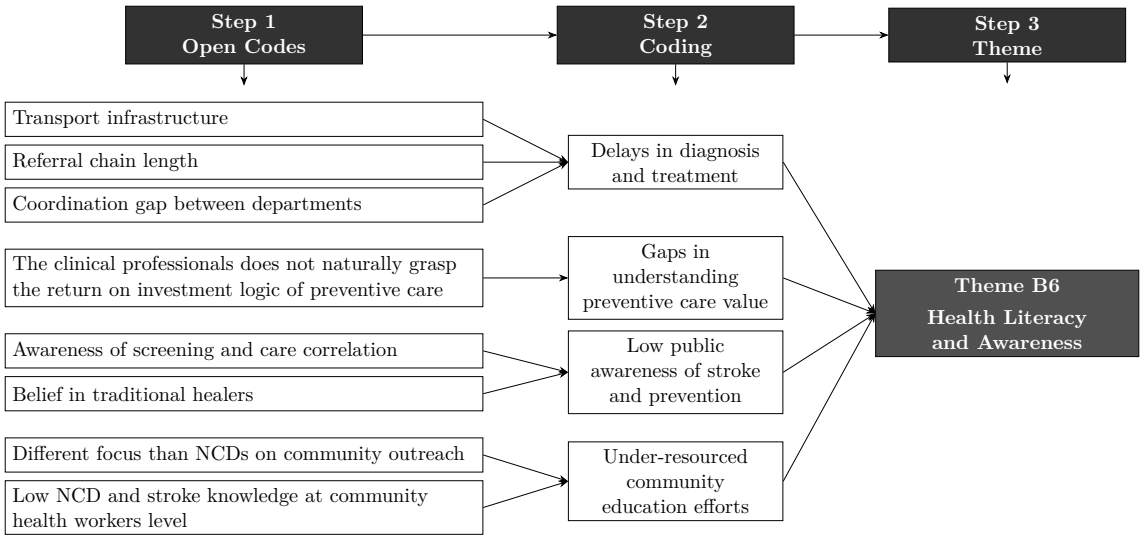

Figure 4.12: Thematic analysis – Theme B6: Health Literacy and Awareness

4.2.7 Contextual mismatch

The mismatch between the design and operational requirements of imported medical technologies and the realities of LMIC deployment contexts was identified as a fundamental and largely avoidable barrier. Respondent R14 cited evidence that a large share of medical devices deployed in rural LMIC settings fail, with the primary causes consistently traced to context-blind design rather than clinical ineffectiveness. Devices were described as failing because they were not designed for the local operational environment or were priced for high-income markets and therefore too expensive for available budgets. They could also lack local language manuals limiting correct use among frontline staff, as well as being unsupported by local service and maintenance infrastructure meaning that breakdowns led to abandonment rather than repair. Further on, some technologies were not built to withstand the harsh physical conditions of rural deployment including heat, humidity, dust, and power instability.

Logistics and supply chain infrastructure was identified by R14 as an underdeveloped aspect, creating structural distribution barriers for any business model dependent on physical product delivery at scale. The absence of permanent and stable infrastructure in rural settings led to hardware reliability risks, particularly for devices requiring consistent electricity supply (R9, R10). These contextual factors pointed to a broader pattern in which technologies designed and validated in high-income settings were introduced into environments for which they were not intended, with predictable consequences for adoption and sustained use. Lastly, transport infrastructure was highlighted during C1 as a structural limitation, particularly in rural areas where physical access to facilities could be constrained.

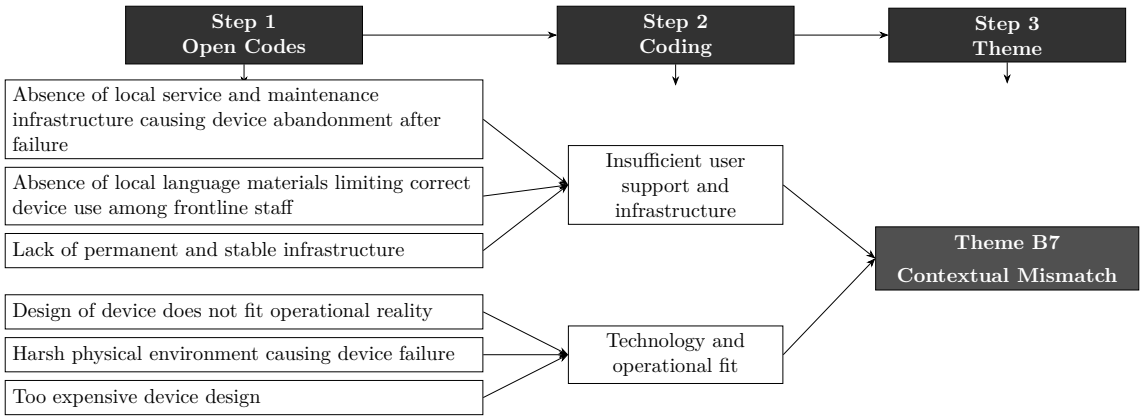

Figure 4.13: Thematic analysis – Theme B7: Contextual Mismatch

5

Analysis

This chapter interprets the empirical findings through the theoretical framework, examining how each theme operates across both the entry and implementation stages.

5.1 Analytical approach

The analysis has two purposes. First, it maps the empirical themes onto the market-entry factor and CFIR constructs it corresponds to, in order to identify determinants that operate across both the entry and implementation stages. Second, it evaluates the analytical framework itself by examining where the mapped relationships hold and where the Rwandan case reveals mechanisms the framework does not fully capture. The seven-factor structure is therefore used as an organising lens rather than as a fixed template. Where a theme maps onto more than one factor, it is discussed under the factor it speaks to most directly and cross-referenced elsewhere. The factor sections address RQ1 analytically and the considerations they raise (RQ2) are drawn together in the Discussion.

5.2 Political

The analytical framework establishes that political conditions act on both entry and implementation. Market entry theory treats these conditions through two mechanisms. First, governments as accelerators: state intervention through funding, incentives and strategic prioritisation lowers entry costs (Gammeltoft & Cuervo-Cazurra, 2021). Second, perceived risk: political conditions raise or lower the cost of committing resources (Zhang et al., 2023). The mapping of market entry and CFIR places both in the Outer Setting through Policies & Laws, Partnerships & Connections, and Critical Incidents. The expectation is that the same conditions that shape entry continue to shape implementation through these constructs.

The facilitator theme Governmental Participation supports the accelerator mechanism, and what respondents said about Rwanda fits this expectation. Central procurement through MOH can turn a single approval into nationwide deployment and thereby reduce the search and contracting cost. Public funding is, for example, allocated to youth-led startups through competition-based selection, and Rwanda actively strives to position itself as a regional sandbox for East African expansion. These match the state interventions in market entry theory, as they show the ex-

istence of government-led mechanisms that lower the entry cost (Gammeltoft & Cuervo-Cazurra, 2021). They also continue into later implementation, as procurement systems remain the route through which deployment scales, and ministerial relationships remain the channel through which approvals are sustained. This is consistent with the framework's claim that Policies & Laws and Partnerships & Connections carry across both stages, as the political decisions and incentives that ease market entry continue to affect implementation. It indicates that political factors weigh heavily during the market entry stage, where they actively ease and lower the cost of entry, while the implementation stage centres on sustaining the political approvals and conditions already granted.

There are, however, two tensions that the analytical framework does not handle. First, the sandbox mechanism varies between firm sizes. Government respondents describe a functioning sandbox environment, while local entrepreneurs report that no functioning SME sandbox exists and that high taxation prevents smaller firms from scaling. Zhang et al. (2023) treat the perceived-risk mechanism as independent of firm size, where institutional safeguards lower risk for entrants uniformly. The Rwandan case shows that the same mechanism lowers perceived risk for larger external entrants while raising it for smaller domestic firms. The accelerator mechanism remains valid, but the effect is uneven across firm size. Where the framework assumes that institutional safeguards lower risk equally for all entrants, the Rwandan case shows that the same safeguards lower risk for one type of firm while raising it for another, which the framework does not account for.

Second, iterative policy changes under the theme Governmental Participation act as a facilitator at entry but can be mapped onto Critical Incidents, a CFIR construct described by Damschroder et al. (2022) as an unanticipated or large event that may disrupt implementation. For an entering firm, iterative policy can signal responsive governance and lower the perceived risk. For the same firm during implementation, frequent changes require continuous reassessment of routines, training and compliance. Neither market entry theory nor implementation science captures this on its own, since each treats policy change as belonging to a single stage. Mapping the same theme onto both constructs shows that one iterative policy can facilitate entry and disrupt implementation, depending on which stage the firm is in which neither theory captures alone.

5.3 Economic

As established in the analytical framework, market entry theory treats economic conditions as large-scale features of the new market such as market size, purchasing power, gaps in capital markets and the cost of doing business that shape whether entry is viable (Khanna et al., 2010; Meyer & Peng, 2016). The analytical mapping splits these conditions across two CFIR domains. The Outer Setting captures the system-level environment through Local Conditions and Financing. Financing covers donor funding, grants and public–private arrangements that substitute for weak capital markets (Damschroder et al., 2022). The Inner Setting captures what these conditions mean for the firm through Available Resources. Missing intermediaries

can push firms to handle functions they would normally outsource (Khanna et al., 2010).

The theme Trust and Legitimacy contains an economic facilitator that relates to the alternative financing mechanism. The case of an investor first securing the MOH tariff and an RSSB commitment letter guaranteeing coverage under the local insurance scheme, and only then committing capital. Public reimbursement guarantees in this case perform the function that commercial financing instruments and private insurance would perform in a more developed market. This fits the institutional-substitute logic in the market entry stage but carries most weight in the following implementation stage, as it provides a structured approach to ensuring revenue once the device is implemented.

In the analytical framework it is transferred to the implementation stage through the construct Financing in the Outer Setting, as the reimbursement guarantee is a feature of the system environment. It can also be related to the Inner Setting, as securing the tariff commitment before implementation can be seen as a firm-level action, which places it in the Inner Setting of the company. In market entry theory the importance of institutional voids is firm-relative (Khanna et al., 2010). In CFIR it can instead be separated across the Outer and Inner Setting, depending on whether the focus is the system-level feature or the firm's internal action

On the barrier side, the themes Financial Constraints and Commercial Landscape show the further examples of institutional voids. Donor dependence and the term Grantrepreneurship describe firms surviving on grants without organic revenue, and recent aid cuts expose how fragile these models can be. A reduction in financial support can affect the ease of implementation and relates to the CFIR Outer Setting and Financing construct, as it contains the funding from external entities. In market entry theory, donor funding is treated as a facilitator, and the existence of grants and public–private arrangements works as a substitute for weak capital markets that would otherwise make market entry unviable (Khanna et al., 2010). On the implementation side, on the other hand, the same condition can be seen as a barrier, as the focus shifts from a single-stage entry decision to maintaining a sustainable revenue model, which becomes harder to uphold on grants alone. The analytical framework thereby shows how the implication of a condition may change from entry to implementation.

The lack of a substantial middle class and low patient affordability for private healthcare further limit the market potential. The redesign requirement for market entry in LMIC contexts becomes central, as the product otherwise becomes non-viable (Prahalad & Hart, 2008). During implementation this becomes relevant through Local Conditions in the Outer Setting, as it contains the structure of the market and customer affordability, which affect the redesign requirements pre-entry. Another market entry condition that has to be considered is the absence of local medtech service infrastructure, which forces foreign firms to handle maintenance and supply chain functions internally. This condition is carried over to implementation and to Available Resources in the Inner Setting, as the firm has to allocate internal funding, staff and materials to meet these demands.

5.4 Social and Cultural

Social and cultural conditions act across both the market entry and implementation stages. Market entry theory treats these conditions as cultural distance, network position and trust, which affect access to a foreign market. Psychic distance prevents the flow of information between markets (Johanson & Vahlne, 1977). Liability of outsidership blocks firms from opportunities visible only to those within local networks (Johanson & Vahlne, 2009). Networks may also act as a substitute for internal resources, especially for smaller firms (Laufs, 2015). Furthermore, trust building gradually reduces uncertainty and lets firms deepen engagement in the market over time (Johanson & Vahlne, 2009). These market entry conditions carry over to implementation through the CFIR constructs Partnerships & Connections in the Outer Setting and Available Resources in the Inner Setting.

The theme Partnership Networks supports the assumption that networks can act as a substitute mechanism for missing resources. Through collaboration with intermediaries that have established connections to the MOH, the use of local champions for cultural navigation, and the use of embassy networks and entrepreneurship hubs as access channels, these connections can be carried over from the market entry stage to implementation through Partnerships & Connections in the Outer Setting. There is, however, a difference in the function of the network between the entry and implementation stage. In the market entry stage the network focuses on the firm's position relative to the market, in the form of outsidership, psychic distance and the gradual movement from outsider to insider (Johanson & Vahlne, 2009; Johanson & Vahlne, 1977). In CFIR, on the other hand, and the construct Partnerships & Connections, the focus is on the connections from the Inner Setting (the firm) towards the Outer Setting in the form of external entities (Damschroder et al., 2022). Relating the two to each other is relevant, as actors may persist across both stages but the theoretical objective changes from overcoming outsidership to upholding connections.

Further on, seeing networks as a substitute for internal resources and capabilities creates a connection to the implementation construct Available Resources in the Inner Setting of the organisation, as it concerns the firm's internal resources for implementation (Damschroder et al., 2022). Relating this to the earlier discussion of the function of the network between the market entry and implementation stage, a variation in the role of different actors can be seen. In the market entry stage, with a focus on moving from outsider to insider, governmental connections, embassy connections and entrepreneurship hubs can be of higher importance, as they allow the firm to establish an understanding of the industry. In the implementation stage, local champions and ties to clinical associations and other clinical referrals become more important for operational purposes.

By making the distinction between the Outer and Inner Setting relationship of the network and partnerships, a more nuanced view can be captured compared to using market entry theory alone, where the network is otherwise treated as one single mechanism but describes both the function of external access to actors and the substitution of internal resources.

5.5 Technological

The analytical framework describes technological conditions through three market entry mechanisms: infrastructure available in the new market, absorptive capacity of local actors, and adaptability of the technology itself (Gammeltoft & Cuervo-Cazurra, 2021; Meyer & Peng, 2016; Prahalad & Hart, 2008). These market entry conditions can be carried over to implementation through four CFIR dimensions. Infrastructure splits between Local Conditions in the Outer Setting and Structural Characteristics in the Inner Setting. Adaptability relates to Innovation Adaptability and Innovation Design in the Innovation domain.

The theme Supportive Digital Infrastructure from the empirical findings supports the infrastructure entry mechanism. Mandatory data reporting, system interoperability and backup infrastructure such as generators and satellite internet lower the infrastructural threshold for a foreign firm entering the market. Seeing this through market entry theory alone poses infrastructure as a threshold, and once it is cleared, entry becomes viable. Complementing it with the implementation perspective shows that this is not sufficient, as the same conditions continue to affect implementation and do not end at entry. The construct Local Conditions is therefore a relevant link from market entry onto CFIR and shows how infrastructure continues as an operational condition.

On the barrier side, the theme Contextual Mismatch shows that imported devices fail in rural LMIC settings because they are priced for high-income markets, lack local-language manuals or cannot withstand local physical conditions. This corresponds to the need for adaptability and to the frugal-innovation logic of considering the need for redesign pre-entry to fit resource-constrained settings (Gammeltoft & Cuervo-Cazurra, 2021). This logic continue during implementation through the constructs Innovation Design and Innovation Adaptability, as the design choices that fit the device to lower levels of care at entry remain the conditions under which it can be operated (Damschroder et al., 2022). In market entry theory, frugal innovation treats redesign as a pre-entry decision that then becomes fixed to the market (Gammeltoft & Cuervo-Cazurra, 2021). This is most similar to the CFIR construct Innovation Design, and is complemented by Innovation Adaptability, which concerns the ongoing modification of the innovation in use (Damschroder et al., 2022).

By combining the market entry and implementation perspectives, it is shown that factors that would at entry be treated only as a one-off condition should instead be seen as a continuous consideration across both stages.

5.6 Environmental

Environmental factors in the market entry sense such as sustainability expectations, climate risks and stakeholder pressure for environmentally responsible practice (Gammeltoft & Cuervo-Cazurra, 2021; Meyer & Peng, 2016) were not included in the data collection of this study. The analytical framework maps Environmental factors in the market entry sense onto Local Conditions, Local Attitudes and Exter-

nal Pressure in the Outer Setting and Mission Alignment in the Inner Setting, but no empirical material was collected to confirm these connections. Environmental factors are therefore not analysed further in this chapter.

5.7 Legal

The analytical framework treats legal conditions as formal rules and the consistency with which they are enforced. Weak or inconsistent rules raise the cost of doing business, and predictable legal protection lowers perceived risk (Meyer & Peng, 2016; Zhang et al., 2023). The analytical mapping to CFIR places this condition in the Outer Setting construct Policies & Laws, which captures the formal regulatory layer regardless of whether it acts as protection or as friction.

The theme Regulatory Complexity relates to the formal-rule mechanism as a barrier. Empirical examples of these mechanisms are that international approvals such as CE marking are treated as necessary but not sufficient to enter the Rwandan market; that a first-in-first-out approach in administration for ministry approval can extend certification timelines; that devices incorporating AI components require double licensing covering both hardware and AI separately; and that clinical trials require international safety data and a Rwandan co-investigator before any local patient contact. These conditions relate primarily to the formal institutional distance and to how the predictability of the legal environment affects the risk of doing business (Zhang et al., 2023).

The majority of these empirical findings are more important in the market entry stage, as they pose barriers that have to be cleared before entry is possible examples being the CE marking requirement, the dual AI license and the clinical co-investigator. Compliance with these entry requirements is, however, still important in the implementation phase, and can then be related to the construct Policies & Laws, since certification, licensing and ethics clearance are not just a first entry hurdle but conditions that shape the whole implementation phase, as the construct includes legislation, regulations and guidelines as well as accreditation standards (Damschroder et al., 2022). One example with greater weight in implementation is the absence of a Good Samaritan law. Without such protection, medical personnel remain personally liable for acting outside their area of responsibility, which constrains the task shifting that implementation requires as it requires a broader area of responsibility for lower-level medical personnel.

What differentiates market entry theory from CFIR in this case is that market entry theory sees the legal dimension as directional, able to change from barrier to facilitator. A predictable legal environment will lower the perceived risk and act as a facilitator, while a weak and inconsistent legal environment will become a barrier to entry (Zhang et al., 2023). This nuance is not captured in CFIR and the construct Policies & Laws, which is neutral in this aspect and only captures the existence of rules, not how the effect may change. This observation is similar to the one made regarding policy in the political factor, but changes perspective from the policy intent of policymakers to the laws and changes as actually realised.

5.8 Organisational

In the analytical framework, organisational conditions are the resources and capabilities the entering firm needs to operate in the new market (Laufs, 2015). Resource scarcity is a central barrier, and liability of outsidership adds a further disadvantage for firms without network position. These conditions can be related to implementation through the Inner Setting constructs Available Resources and Access to Knowledge and Information.

The empirical findings identify two sets of resources and capabilities that firms need to hold in the Rwandan context. The first is the ability to develop functions that would be available externally in mature markets. The empirical findings show a need to internalise device management and repair due to a lack of service infrastructure as well as supply of spare parts. The second is knowledge and information that firms must hold or acquire. Bilingual user training, access to local research practice and expertise, as well as regulatory knowledge, may be needed to succeed in implementation.

The examples above show resources and capabilities that the entering firm has to develop on its own, and which act as a barrier to entry. The analytical framework is misaligned on this point, as the market entry perspective and the implementation perspective do not refer to the same unit of analysis in this case. Market entry theory treats the resources and capabilities as properties of the internal firm (Laufs, 2015). Available Resources and Access to Knowledge and Information in CFIR, on the other hand, refer to the resources and available knowledge in the implementation setting, which may not always be the entering firm itself but another implementation setting the the focal firm (Damschroder et al., 2022). The approaches are therefore not equivalent but remain relevant, as the firm's internal resources and capabilities may act as substitutes for what the implementation setting lacks.

The empirical findings also vary in importance between stages, where some play a more crucial role for entry while others are more central during implementation. The need for regulatory knowledge and the initial decision on company structuring to internalise functions are important in the entry stage, as they are needed to establish the operations. In the implementation stage, more weight is put on service infrastructure, spare part supply and bilingual training, since these recur throughout the operation period. They are, however, still intertwined, as the decision is taken at entry but continues throughout implementation.

6

Discussion

This chapter answers the second research questions and discusses the practical implications of the findings.

6.1 Practical implications

Each recommendation below comes from a theme in Chapter 4. The link back to it is given briefly so the reasoning can be followed, and the recommendations lean towards the factors that stay active across both entry and implementation, since those are the easiest to mishandle by treating an entry task as finished once the device is on the market.

The first thing a firm should clarify for themselves is the purpose of entering the Rwandan market. The data shows that Rwanda is more suited to be a pilot country than a long-term home market, since the middle class is small, meaning the domestic market cannot sustain commercial scale, and wealthier patients tend to seek care abroad. Government contracts can generate meaningful revenue once secured, but the small market caps domestic revenue at a level that funds operation rather than scale. Entry should therefore be justified by seeking to obtain regional credibility and capability building rather than by domestic revenue, and success criteria for the first two to three years should be defined in terms of regulatory milestones and successful pilots rather than sales figures. This framing carries into implementation. Once the device is in use, the same logic decides whether early results count as success, since a firm judging itself on domestic sales would read a working pilot with limited revenue as a failure, while a firm judging itself on credibility and capability would read it as the intended outcome. It also sets when to push for regional expansion, since the signal to scale comes from a proven pilot and a government reference rather than from domestic demand the market cannot supply.

Since domestic revenue alone is unlikely to support commercial scale in Rwanda, firms may initially rely on external funding sources during the entry phase. Donor and grant funding can bridge entry but cannot sustain operation alone, as recent aid cuts and the local pattern of "grantrepreneurship" demonstrate. Firms should identify a domestic revenue channel before entry, such as government procurement or insurance reimbursement, while planning regional expansion as the path to commercial scale. Grant and donor money usually runs on a fixed term, so the domestic revenue channel has to be working before it ends, not merely identified. During op-

eration the risk shifts from securing funding to keeping it flowing, since procurement budgets and reimbursement payments can be delayed and donor support can be cut mid-project, as the recent aid reductions showed. A firm that treats the revenue channel as a box ticked at entry rather than a relationship it manages during use can find its cash flow exposed at the point where it has committed the most.

The regulatory environment is transparent in form but layered in practice, with parallel processes for international approval, Rwanda FDA certification, AI-specific licensing, ICT Ministry approval for data localisation, and ethics clearance with a Rwandan co-investigator. Each is a separate process with its own timeline, and the Rwanda FDA approval queue alone can take up a long time. For European medtech firms specifically, Rwanda may require less regulatory translation than would typically be expected in LMIC entry contexts, since parts of the regulatory architecture take inspiration from internationally recognised systems. Firms should therefore focus less on redesigning regulatory strategy and more on managing the additional local processes layered onto it. The formal pathway is fast in theory but rarely functions without a relationship behind it, so the first six months in Rwanda should be spent building these positions rather than pushing applications forward. Once the device is deployed the company should be prepared for potential sudden changes, with certifications that have to be renewed, documentation that has to be revised or other new requirements within the regulatory environment. The firm is better treating compliance as an ongoing job with its own with dedicated time and staff, not a one-time box you tick before launch.

The iterative governance described by many respondents may function as flexibility for firms with network access while creating unpredictability for firms without it. The firm must assume that policy changes may arrive unexpectedly and that even though the processes may be transparent, they may still involve significant delays and administrative burden, and should therefore build buffer time into each regulatory milestone. It is therefore useful to establish contact with senior stakeholders in ministries early in the process to gain help and insight in regulatory requirements and approvals. During implementation those changes land on the things a firm relies on day to day, such as procurement plans, reimbursement tariffs and the rules on who may operate the device, and a shift in any of these can force a firm to revise training, budgets or deployment routines at short notice. This is similar to the point made regarding the regulatory environment where it should be seen as something ongoing and iterative. The ministry contact is therefore worth holding past entry as that person can mention potential changes early, making it possible to adjust before a change takes effect while those without it learn only once it has been put in place.

The empirical findings pointed on some specific connections and potential partners that can be helpful in implementing a new product on the Rwandan market. Examples of this can be NGO partnerships to open government planning processes, a professional clinical association tie for access to clinicians, a local co-founder for cultural navigation, and an independent local research organisation for third-party validation. And during the implementation process the clinical association keeps the firm in touch with the clinicians who actually use the device and the local co-founder keeps handling the cultural and admin side, both of which doesn't stop once you're

in.

Tax rates are comparable to Swedish levels and not always transparent in public sources. A local accountant should be engaged early. This becomes relevant for implementation as the Rwandan government offers tax exemptions during the first years of operation. These exemptions are not publicly documented, and each firm has to investigate the available options with relevant authorities. A firm that treats tax as an entry calculation can be caught out when an exemption ends and the cost base rises during first years of operation.

The MOU (Memorandum of Understanding) and feasibility-analysis route should be used as the default entry gateway. The first concrete step on entry should be drafting a clear MOU proposal identifying the partner ministry, the scope of collaboration, and the deliverables on each side. The scope and deliverables written into it also govern what each side is responsible for once the device is in use, so a vague MOU agreed quickly to clear entry can leave these unsettled at the point they start to matter.

Stakeholders may also appear positive and supportive while nothing is actually progressing, which makes it difficult to know when an approval is real. This dynamic was described in the data as a "culture of four yeses", where a verbal yes, an email yes, or a calendar invitation on its own are not sufficient. Real agreement requires confirmation across all four channels: verbal, email, calendar invite, and a written message such as WhatsApp or SMS. In practice, this means following up a verbal commitment with a written commitment. This implication is mostly suited towards implementation but is relevant when a firm is trying to establish themselves as well, especially since this cultural dynamic may be unknown for the firm.

At the point of entry, it could be useful to secure reimbursement before putting money in. One respondent described how investors first agree on an MOH tariff and get an RSSB letter confirming Mutuelle de Santé coverage, and only to then invest. It could be useful to hold off on buying equipment or signing supplier contracts until a relationship is established and the four-yeses logic above is met. The agreed tariff and the Mutuelle de Santé coverage are also what turn each use of the device into revenue, so they decide whether deployment is financially sustainable and not only whether entry is affordable. A tariff set too low, or coverage that is later narrowed, undermines the operation even after a successful entry, which is why the terms are worth confirming in writing before committing and worth watching as they can change during use.

Clinical trials new to Rwanda require international safety data and a Rwandan primary co-investigator. A partnership with the University of Rwanda fast-tracks ethics clearance and provides the co-investigator naturally, and should be formalised through a written research agreement before the ethics application is submitted. Partnerships can supply the co-investigator and the local evidence that later studies need, whether for scaling to new facilities, supporting reimbursement decisions, or meeting new evidence requirements that arise during use. Keeping the research agreement throughout therefore gives the firm a route to generate local validation throughout deployment rather than only at the point of the first approval.

Translation errors in registration documents where seen causing unexpected delays in past cases. Documents should be reviewed by a Kinyarwanda-English speaker with sector context, typically a local co-founder or administrative hire, rather than outsourced.

Implementation depends not only on the technical performance of the device itself, but also on how well it fits local working conditions. Attention should be given to local-language training and documentation, since frontline workers such as community health workers primarily operate in Kinyarwanda. Device design should also account for practical conditions such as local infrastructure, maintenance capacity, and the availability of after sales support that does not rely on returning equipment abroad.

Device implementation may also fail if pilots do not involve clinicians and facilities in the design process. Participation in the process builds stronger commitment than pilots that only demonstrate performance. Rather than presenting a finished protocol, the firm should invite clinicians to co-design, as early involvement can strengthen trust and commitment. This is important in the Rwandan healthcare system where relationships and network positions influenced implementation processes. Each new facility the device reaches brings its own workflow and staff, so the involvement that built commitment in the first pilot has to be repeated rather than assumed as the rollout widens. Continuing to invite clinicians to shape how the device fits their work, and feeding their input back into refinements, sustains the adoption a single early pilot cannot secure on its own.

Mid-level agreement is worth little without senior sign-off, and frontline staff often require informal supervisor permission even where formal frameworks already authorise their participation. Something to keep in mind is that no facility-level deployment activity should begin until written senior sign-off is in hand. Even when agreements are secured centrally in Kigali, firms should still check that the proposed implementation model is feasible at rural facilities before scaling, since resource conditions, workflows, and staff capacity may differ from the assumptions made during central planning.

Frontline staff are more likely to adopt the device when they see it improve their daily practice, not when they see strong clinical performance figures. The most effective approach is comparative demonstration, where staff use the device in parallel with the existing workflow on real patients and evaluate where it saves time or improves care. Another approach to facilitate adoption is recruiting personnel from the existing public health structures, since their existing relationships accelerate implementation network effects. Trusted instructors who use and showcase the device can make more clinicians willing to use the device.

Firms should be prepared to develop functions that external markets would normally supply. Training, maintenance, supply chain, and after-sales service fall on the firm in practice. A firm that budgets for these only as an entry hurdle will find them recurring as operating costs it has not staffed for, so they should be planned and funded from the entry decision and kept resourced for the life of the operation.

6.1.1 For the Strokefinder MD100 project

Five findings translate directly into recommendations for the ongoing project. The device addresses a pre-existing gap at district and lower-level facilities. The MD100 should be positioned in dialogue with the Ministry of Health as a response to a known priority, not as an externally proposed solution. This positioning is likely to encourage senior decision makers to support and accelerate the processes.

Ongoing CT scanner procurement at district level narrows the window in which the device's leapfrogging potential applies. The relevant deployment targets are settings that CT will not realistically reach. These areas are communities, ambulances, and health posts and health centres at the lower levels of the referral system.

A further consideration is the AI component the device incorporates, which under Rwandan regulation need dual licensing covering both the hardware and the AI layer separately.

Data generated by the device should be accessible to the Rwandan government so that it can be integrated into the National Health Intelligence Center for analysis and contribute to the country's broader health monitoring system. This data integration should be planned for from the start of the regulatory and deployment process.

The existing research collaboration between Chalmers and the University of Rwanda lays the ground for university partnership identified as an efficient route to ethics clearance and approval for the first trial of its kind in Rwanda. This relationship should be used as a channel for clinical validation.

6.2 Theoretical Implications

Market entry research treats its factors as conditions for getting in, and implementation research treats a separate set of domains as conditions for routine use, with little crossing between the two (Canabal & White, 2008; Damschroder et al., 2022). Mapping the entry factors onto CFIR constructs let one finding be read at both stages at once, and the analysis in Chapter 5 used this to test the framework factor by factor. What that testing returned, and what neither framework returns alone, is that some determinants do not persist unchanged across the stages but switch the role they play, behaving as a facilitator at one stage and a source of disruption at the other. A single-construct treatment such as CFIR's Critical Incidents, or a single-stage treatment such as regulatory risk in entry theory, cannot always register that switch in a local context. Reading the two literatures together is what makes it visible, and naming this stage-dependent behaviour is what the combination of the two theories adds.

As for the broader literature, the case gives two ideas to test, not firm conclusions. The first is the "government accelerator" from Gammeltoft and Cuervo-Cazurra (2021), who describe home governments helping their own firms expand abroad. Here it shows up on the host side instead, and it smooths entry for foreign firms who want to invest or expand into Rwanda. The second is the "institutional void" idea from Khanna et al. (2010). Their argument is that emerging markets often

lack the institutions firms normally rely on, and that firms have to close these gaps themselves by building private substitutes. Part of what creates the void in the first place is a state that cannot or will not provide these market-supporting institutions, so the firm is left to work around it. This case shows a state whom which took an active role in closing the institutional gaps and effectively want help firms enter. The point is not that the institutional voids do not exist in Rwanda, but that the actor the theory treats as part of the problem is also a part of the solution. This is unusual, since an actively supportive state is not the norm in these markets, which is an interesting point that doesn't line up with other emerging markets.

7

Conclusion

This thesis examined how organizational, institutional, and system-level factors influence the market entry and implementation of point-of-care diagnostic technologies in resource-constrained healthcare systems. Rwanda was used as the case, with the Strokefinder MD100 as the empirical example. The study was guided by two research questions, addressing facilitators, barriers, and considerations for implementing point-of-care diagnostic technologies within the Rwandan healthcare system.

It has been concluded that the Rwandan context offers several conditions that facilitate market entry and implementation, with government engagement standing out as a strong driver. Government actors enable innovation through policy, directing innovators toward gaps and converting central procurement decisions into nationwide deployment. This active role is reinforced by a problem-solution fit, partnership networks linking firms to decision-makers, trust built through early piloting and reimbursement coverage, a supportive digital infrastructure, and a shifting disease burden that creates structural demand for new diagnostic capacity.

Alongside these enablers, several barriers continue to hamper market entry and implementation. Regulatory processes are layered and time-consuming, reinforced by a hierarchical organizational culture in which senior sign-off determines whether things move forward. Workforce capacity is limited at both frontline and specialist levels, and financial constraints arise from donor dependency, a small middle class, and patient affordability limits. The commercial infrastructure for medtech remains underdeveloped, the populations knowledge regarding stroke is low, and imported technologies often do not fit the realities of local deployment.

Several considerations follow from these findings for firms preparing to enter the Rwandan medtech market. Rwanda works better as a pilot country and starting point for regional expansion than as a long-term home market, which means entry should be justified by regional credibility and capability-building rather than by domestic revenue alone. Financial viability should be addressed early, with reimbursement pathways and political backing in place before capital is committed, since the active role of the government shapes both funding access and approval timelines. Local partnerships are decisive for navigating regulatory and cultural processes in Rwanda, since trusted intermediaries provide access, legitimacy, and the ability to interpret signals that outside actors cannot read on their own. Connected to this, the weight of senior level decision makers mean that the right relationships often determine whether processes move forward or not. Functions that a mature mar-

ket normally supplies externally must also be handled internally by the entering firm, including aspects of training, maintenance, and operational support. Technology design and deployment should be adapted to local conditions rather than transferred unchanged from high-income settings. For the Strokefinder MD100, important things to plan for include the regulatory requirements that follow from its AI component, ensuring compatibility with national health information systems, and building on the existing research collaboration as a foundation for clinical validation and local engagement.

7.1 Future Research

Future research could build on this study by following the actual implementation of the Strokefinder MD100 or a comparable point-of-care diagnostic technology in Rwanda over time, in order to test whether the identified facilitators and barriers play out as expected in practice. Applying the same combined framework to other LMIC settings would also help clarify which factors remain important across different LMICs and which are specific to Rwanda.

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Appendix

A

MD100 Description

The following (five) pages present the manufacturers technical description of the Strokefinder MD100, the point-of-care diagnostic device used as the case in this thesis. The document is included for reference and explains what the device is used for, how it works, and its main technical details.

Product Description

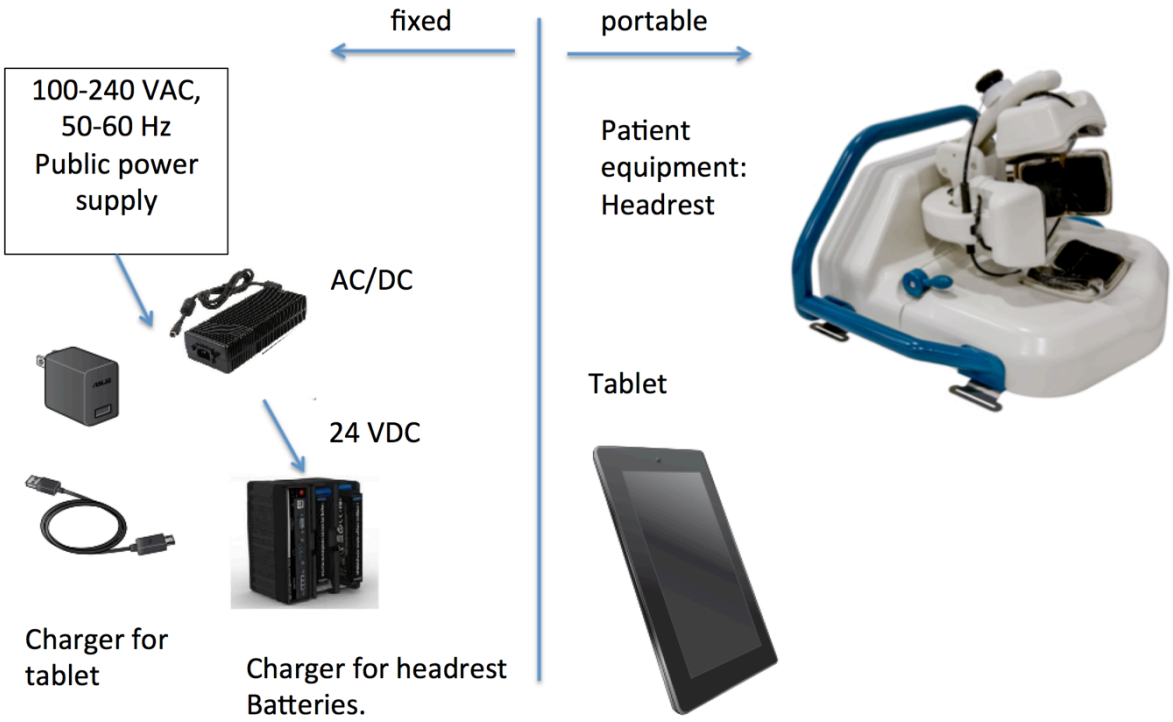
Strokefinder MD100

Product Overview

Strokefinder MD100 is aimed for diagnostic detection of intracranial hemorrhaging in individuals with clinical symptoms of stroke.

The measurement uses microwaves, which are transmitted through the patient's head, and recorded,. During a measurement, one applicator acts as a transmitter whereas all other applicators act as receivers. In a complete measurement, all combinations of transmitter and receivers are cycled through.

Strokefinder MD100 medical instrument system consists of a of portable headrest, which is powered by a rechargeable battery and communicates wirelessly with a touch screen tablet. See illustration below.



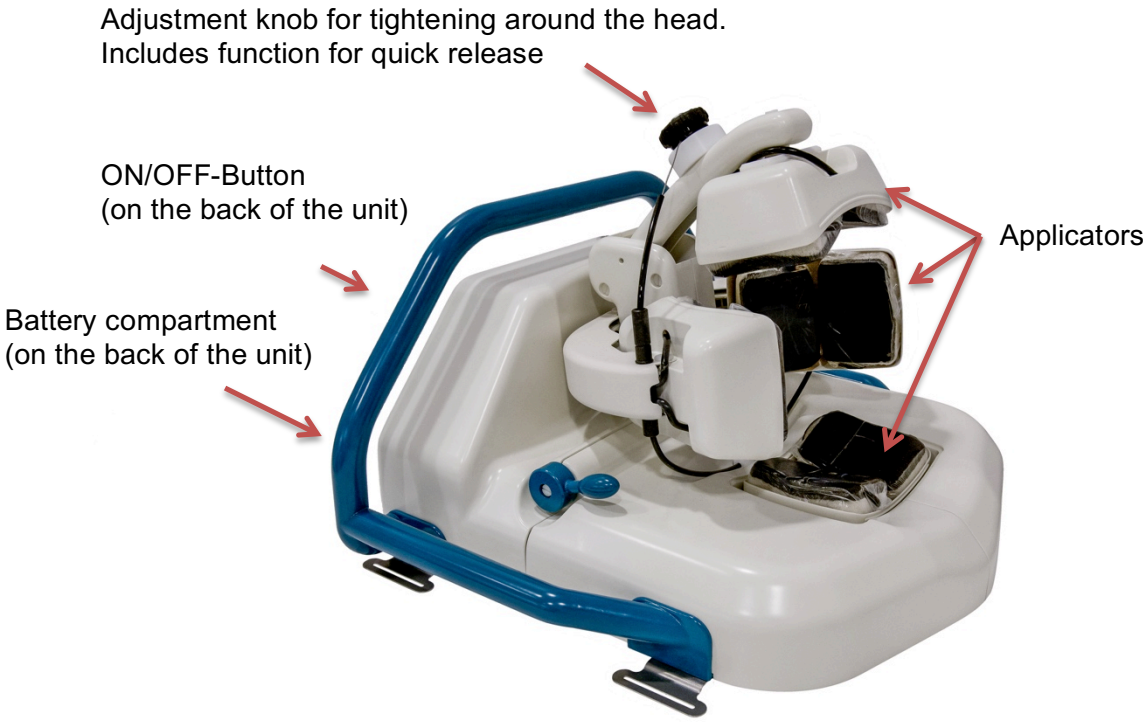
The stationary part of the system consists of a battery charger with two slots to charge the battery for the headrest. It is powered by a AC/DC supply (100-240 VAC to 24 VDC, IEC 60601 certified)

The tablet is charged using a USB charger.

A reference object is available as a headrest accessory. It may be used for functional tests and reference measurements before patient measurement.

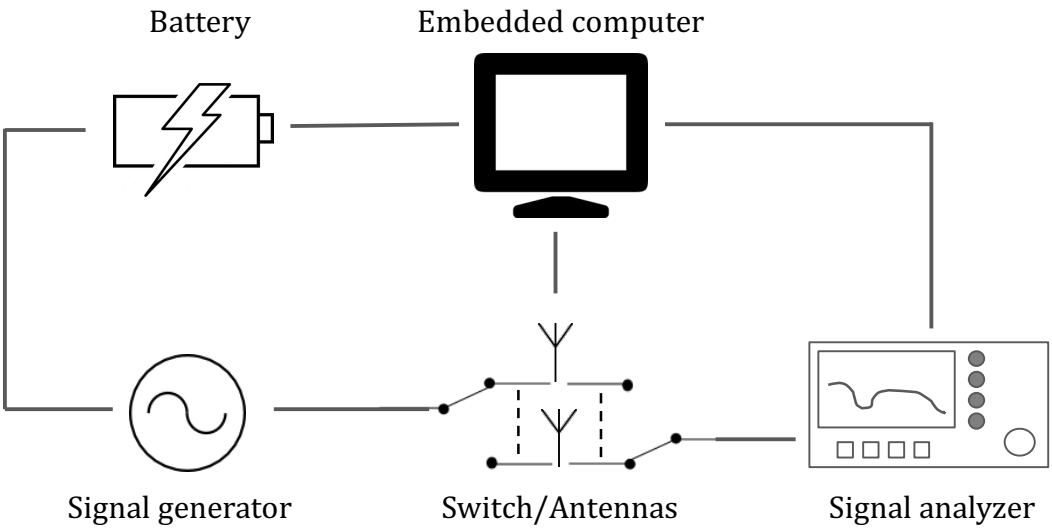
Headrest

The headrest is the key part of the system and contains all of the functionality required for a complete measurement. It has 8 applicators: two on the neck, two on the forehead and two on either side of the head just above the ears. The applicators are adjusted with the help of an adjustment knob and a handle so that they are correctly positioned on the head.



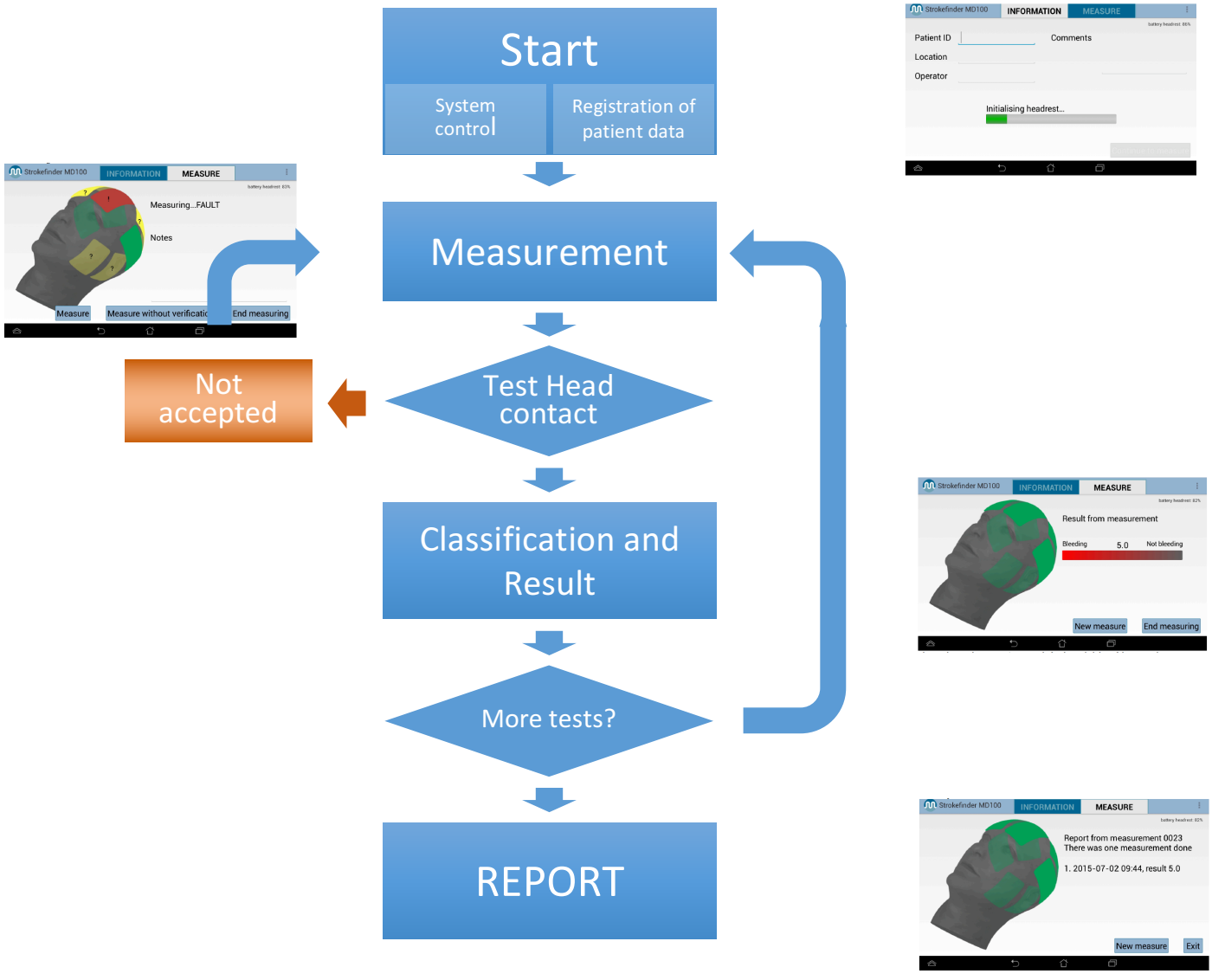
The head rest contains all necessary components and includes:

- Microwave signal generator and analyzer
- Computer that controls the measurement, analyzes the measurements and reports the result via Bluetooth communication to a tablet.
- Rechargeable battery



1 Software

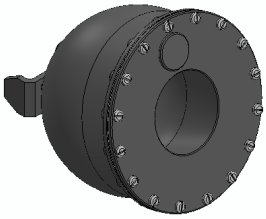
The measurement process is described in the figure below.



Accessories

The system has the following accessories: Two batteries, battery charger, tablet charger, reference object for system test, and a transportation and storage bag.

Battery for the headrest



Reference object for system test

Bag

2 Environmental Specifications

Category	Specification
Operating temperature	0°C to 40°C
Storage temperature	-20°C to 70°C
Relative humidity	5% to 95%, non-condensing
Maximum height above sea level	2 000 meters above see level
Maximum tilt angle	30°
Open space around heat sink	5 cm
IP classification (IEC 60529) headrest	IP 2X, shall only be unpacked at sheltered locations

Electromagnetic environment declaration

Guidance and manufacturer's declaration - electromagnetic emissions	
Emission test	Compliance
RF emissions CISPR 11	Group 2
RF emissions CISPR 11	Class A

Guidance and manufacturer's declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air
Radiated RF IEC 61000-4-3	3 V/m 80 MHz - 2,5 GHz	3 V/m

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