CHALMERS
UNIVERSITY OF TECHNOLOGY

Anticipating Adoption: Developing a National Digital Health Registry in a Centralized Healthcare System

Design, Adoption, and Governance in the Early-Phase Development of a National Cleft Lip and Palate Registry in Rwanda

Master thesis in Technology Management and Economics

VIKTORIA ANDERSSON

ELVIRA MOBERG

DEPARTMENT OF TECHNOLOGY MANAGEMENT AND ECONOMICS
DIVISION OF ENTREPRENEURSHIP AND STRATEGY

CHALMERS UNIVERSITY OF TECHNOLOGY
Gothenburg, Sweden 2026
www.chalmers.se

Anticipating Adoption: Developing a National Digital Health Registry in a Centralized Healthcare System

Design, Adoption, and Governance in the Early-Phase Development of a National Cleft Lip and Palate Registry in Rwanda

VIKTORIA ANDERSSON
ELVIRA MOBERG

Department of Technology Management and Economics
Division of Entrepreneurship and Strategy
CHALMERS UNIVERSITY OF TECHNOLOGY
Gothenburg, Sweden 2026

Anticipating Adoption: Developing a National Digital Health Registry in a Centralized Healthcare System
Design, Adoption, and Governance in the Early-Phase Development of a National Cleft Lip and Palate Registry in Rwanda
VIKTORIA ANDERSSON
ELVIRA MOBERG

Department of Technology Management and Economics
Chalmers University of Technology
SE-412 96 Gothenburg
Sweden
Telephone +46 31 772 1000

Gothenburg, Sweden 2026

Anticipating Adoption: Developing a National Digital Health Registry in a Centralized Healthcare System
Design, Adoption, and Governance in the Early-Phase Development of a National Cleft Lip and Palate Registry in Rwanda

VIKTORIA ANDERSSON
ELVIRA MOBERG

Department of Technology Management and Economics
Chalmers University of Technology

Abstract

Across low- and middle-income countries, digital health registries are increasingly introduced to strengthen health information systems and support coordinated care, yet their early-phase development remains understudied, particularly in centralized healthcare contexts. This study examines how a national digital health registry is developed and established during its early phase, using the design and prototyping of a cleft lip and palate registry in Rwanda as an empirical case. Data was collected through a qualitative single case study combining semi-structured and exploratory interviews with iterative prototype feedback sessions involving clinicians, registry developers, NGO actors, and policymakers. The findings show that some adoption barriers, including documentation workload and infrastructure constraints, can be identified and addressed through design choices before deployment, a process the study describes through the concept of anticipatory adoption, while others, such as double entry, can be anticipated during this phase but not resolved through design alone. The design process also revealed trade-offs between dataset scope and data quality, standardization and local fit, and top-down implementation versus bottom-up clinical involvement. For long-term sustainability, early institutional anchoring within national structures is identified as essential, as formal recognition at the national level shifts registry use from voluntary to required. Sustained use however depends on continuous engagement through training, feedback and incentives, and explicit planning for long-term ownership must be addressed during development rather than treated as a post-project concern. Together, the findings suggest that the early-phase development of sustainable digital health registries in centralized contexts requires three complementary conditions: bottom-up clinical involvement in design, top-down institutional anchoring in implementation, and continuous engagement work at all levels.

Keywords: Digital health registry, cleft lip and palate, Rwanda, centralized governance, low-resource settings, health information systems, participatory design, technology adoption, institutional anchoring, anticipatory adoption

Acknowledgements

We would like to thank our supervisor Rabih Darwish at Chalmers University of Technology for his support, encouragement, and thoughtful engagement with our work. His questions and reflections pushed us to deepen our thinking and helped shape the thesis into what it became. We would also like to thank our examiner, Susanne Ollila, for reviewing and supporting our thesis work throughout the semester.

We would also like to extend our sincere gratitude to Patrik Boivie, Robert Åberg, and Faustin Ntirenganya for initiating this project and for their dedication to improve cleft care in Rwanda. Their drive and commitment throughout the project, both in Sweden and in Rwanda, meant a lot to us. Patrik's surgical expertise through his work with Operation Smile and his willingness to share his knowledge and clinical experience proved invaluable to the work, while Robert's vision and broader industry perspective through Sigma Technology Insight helped ground the project in a wider context. Dr. Faustin's local knowledge and presence in Rwanda gave us the practical conditions we needed to carry out the fieldwork, which was highly appreciated.

Furthermore, we are grateful to all respondents who generously gave their time and shared their insights and experiences with us. Their openness and willingness to engage made this project possible and genuinely rewarding.

We also thank Maria Saline at Chalmers University of Technology, whose facilitation of contacts in Rwanda through the collaboration between Chalmers and the University of Rwanda was essential to this research. Jean Pierre Nganabashaka and the local research group at University of Rwanda deserve recognition as well for their support in navigating local processes, which made the fieldwork possible in practice.

Finally, this project was made possible through financial support from Sida via the Minor Field Studies scholarship and from the Stena Foundation, for which we are truly grateful.

Viktoria Andersson, Gothenburg, June 2026
Elvira Moberg, Gothenburg, June 2026

List of Acronyms

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

AI	Artificial Intelligence
CLP	Cleft Lip and Palate
DHIS2	District Health Information Software 2
EHR	Electronic Health Record
HMIS	Health Management Information System
MoH	Ministry of Health
NGO	Non-Governmental Organization
NIN	National Identification Number
NPT	Normalization Process Theory
RBC	Rwanda Biomedical Centre
UTAUT	Unified Theory of Acceptance and Use of Technology

Contents

1
Introduction

Digital health systems are increasingly being introduced in low- and middle-income countries as part of broader efforts to strengthen healthcare systems. They are often described as technical solutions that are designed to improve health information management and support service delivery through efficiency, data quality and coordination. However, their introduction into healthcare practice is rarely straightforward. Existing routines, organizational arrangements, and broader institutional conditions shape how such systems are adopted and sustained over time (Marwaha et al., 2022). In many settings, healthcare systems are also characterized by fragmented data structures and parallel information systems, which further complicates integration and use (Chaulagai et al., 2005). Empirical studies show that health workers often continue to rely on parallel paper-based systems when digital ones are introduced, which creates additional workload and affects the adoption of the digital information system (Uwera et al., 2024). Understanding how digital health systems are introduced and sustained therefore requires attention to the organizational and institutional conditions in which they operate, not only to the information systems themselves.

The following terms are used throughout this thesis. Digital health system is used as an overarching term for digital technology within healthcare settings. Health information system is narrower and refers to a system for collecting, storing and reporting health data. A digital health registry is one type of health information system, and therefore also a digital health system. Healthcare system refers to how healthcare is organized and governed at the national level.

Existing studies examine the implementation of digital health systems in low- and middle-income countries from several perspectives. Prior research has shown that introducing digital health systems in public healthcare reshapes work routines, coordination patterns, support structures, and organizational responsibilities over time (Aanestad et al., 2014). Further, studies of disease-specific registries, a type of digital health system designed to collect structured, longitudinal patient-level data for a particular condition, describe processes of data compilation and challenges related to maintaining follow-up across institutions (Ntaganda et al., 2020; Uwera et al., 2024).

In parallel, many articles discuss how digital health systems are governed, often contrasting centralized and decentralized models and their implications for coordination, efficiency, and service delivery (Bustamante, 2010; Dwicaksono & Fox, 2018). These studies highlight trade-offs between national standardization and lo-

cal flexibility and primarily focus on national level outcomes.

However, prior research provides limited insight into how a digital health registry is designed and established in its early stages within a centrally governed healthcare system. In particular, there is limited understanding of how early design choices are shaped to support user adoption and continued use, how registry development is coordinated across clinical, technical and governmental actors, and how digital registries are institutionally anchored for long-term sustainability. While existing studies address either governance structures or information system implementation, few studies examine how these dimensions are brought together in practice during the early phases of developing a digital health registry.

This master's thesis therefore focuses on the early phases of developing and establishing a digital health registry in a healthcare context characterized by centralized governance. Using the development and prototyping of a CLP registry in Rwanda as an empirical case, the study examines how a digital health system is shaped in practice during its initial design and establishment. It specifically investigates how technical design choices, clinical workflows and information needs, and institutional conditions are addressed and aligned early in the process for the registry to become usable in practice and sustainable over time. In this way, the study brings together perspectives on design, user adoption, and governance, which are often treated separately in prior research. It thereby contributes empirical insight into how the conditions for adoption and long-term sustainability are actively shaped during the early phases of digital health system development within a centrally governed healthcare system.

1.1 Background

This section provides background on the context in which the registry is being developed. It covers Rwanda's development trajectory, the structure of its healthcare system, existing digital health initiatives, and the current state of cleft care and follow-up.

1.1.1 Rwanda's post-genocide reconstruction

The 1994 genocide against the Tutsi had devastating consequences for Rwanda resulting in deaths of more than a million people and a collapse of social and institutional structures (United Nations, n.d.). Rwanda faced widespread poverty and severely weakened state capacity. In 1994, Rwanda's annual GDP growth fell to around -50 percent, reflecting the immediate economic disruption caused by the genocide (World Bank, 2025b). The rebuilding of state capacity in the aftermath of the genocide laid the foundation for a highly centralized governance structure that continues to shape the country today (Bertelsmann Stiftung, 2024).

Since the early 2000s, Rwanda has experienced sustained economic growth and steady development progress, with clear improvements in poverty reduction and in key social indicators, particularly in health and education (World Bank, n.d.). Access to basic services has improved substantially, including increased electricity coverage and expanded internet access (World Bank, 2025a, 2026). This development has been coordinated through strong executive control and coherent policy implementation across sectors (Bertelsmann Stiftung, 2024). Further, Rwanda is increasingly described as a country with strong development momentum and high implementation capacity, a trajectory reflected in long-term national strategies such as Vision 2050, which outline ambitions to reach middle-income status by 2035 and high-income status by 2050, with a focus on technology and human capital development (Government Offices of Sweden, 2020; World Bank, n.d.). International attention has been further strengthened by Rwanda's early adoption of technical solutions within public services. An example in the healthcare sector is the national deployment of drones for transporting blood, introduced earlier than in many higher-income countries (World Health Organization, 2019).

1.1.2 Structure of the Rwandan healthcare system

Rwanda's centralized governance structure extends directly into how the healthcare system is organized and managed. Health policy, priorities, and information systems are all coordinated at national level, which shapes how care is delivered and documented across facilities. The levels of public care in Rwanda are structured as a pyramid, with community health workers as a base, serving smaller treatments to remote and rural populations and promoting health. Often, they are the patients' first point of contact in the healthcare system. Organized above the community health workers are health posts, where patients turn to for primary care such as checkups, screenings, and appointments with midwives. From here, patients are referred to health centers and district hospitals, where the referred cases are treated. At the top level are referral hospitals, where cases from district hospitals are referred for specialized or emergency care. (Ministry of Health Rwanda, 2017) This structure indicates that a single patient's care often spans multiple facilities and levels of care over several years.

The healthcare system in Rwanda is centrally governed by the Ministry of Health (MoH), which sets national policy, standards, and priorities (Ministry of Health Rwanda, 2024b). Health information systems are also centrally coordinated, while data collection takes place across decentralized levels of care. Under the MoH, the Rwanda Biomedical Centre (RBC) is responsible for implementing public health programs and managing disease-specific monitoring and data systems. Several programs, including HIV, malaria, and non-communicable diseases, operate with dedicated follow-up structures (Rwanda Biomedical Centre, 2024).

1.1.3 Digital health systems in Rwanda

Rwanda's national strategies emphasize digitalization and data-driven healthcare development. This also includes ongoing work to strengthen digital identification through the National Identification Agency (NIDA), with the aim of providing a unique digital identity, and enabling more secure data sharing across public services (National Identification Agency, 2026). The national digital ID rollout was launched in 2025 and nationwide enrollment is expected to be completed by 2026, which may also support more reliable patient identification across health information systems (Parliament of Rwanda, 2026). Several digital health systems are already in place, including electronic health records (EHR) and national health information systems that support data aggregation and reporting across facilities (Bananeza, 2025). These systems enable coordination and longitudinal documentation of patient data across levels of care, which shows an institutional emphasis on patient-level data over time.

Rwanda has also established disease-specific digital registries for certain conditions. Examples include the electronic immunization registry, e-Tracker, which operates on the District Health Information Software 2 (DHIS2), Rwanda's national Health Management Information System (HMIS) platform, to track individual vaccination status over time (Uwera et al., 2024). Another example is the national Rheumatic Heart Disease registry, established in 2017 to centralize postoperative patient data and support long-term follow-up (Ntaganda et al., 2020). In addition, telemedicine and mobile health solutions are used to improve access in remote areas, and more recent initiatives include the integration of artificial intelligence for health data analysis (Bananeza, 2025). However, despite these developments, challenges remain related to digital infrastructure, information system integration, and long-term sustainability (Bananeza, 2025).

1.1.4 Specialist capacity building in plastic surgery

Rwanda has also invested in developing healthcare capacity through long-term specialist training. In 2019 the country had only two trained plastic surgeons, serving a population of approximately 13 million, and relied heavily on international surgical missions. Since then, a structured specialist training program in plastic and reconstructive surgery has been established in collaboration with international partners and integrated into Rwanda's national medical education program. The number of plastic surgeons has now increased to five, with an additional 14 surgeons currently in specialist training. Rwandan plastic surgeons are trained to manage a wide range of conditions, including burns, cancer-related tumors, traumatic injuries, hand surgery, and CLP. As surgical capacity increases, ensuring systematic long-term follow-up becomes challenging without national patient registries (Operation Smile Sverige, 2023).

1.1.5 Cleft care and longitudinal coordination

CLP is a condition where continued follow-up and tracking of patients is particularly important and requires coordination across multiple levels of care over several years (Operation Smile Sverige, 2023). Despite Rwanda's expansion of specialist surgical training and digital health governance, no national registry currently exists for long-term follow-up of patients with CLP, according to findings from exploratory background interviews with cleft personnel. This includes surgical follow-up as well as multidisciplinary care, for instance speech therapy, dental and orthodontic follow-up.

Exploratory interviews with Rwandan cleft care stakeholders during early phases of this study also indicated a perceived need for more systematic follow-up. A plastic surgeon described follow-up as difficult to maintain over time, as patients may return after surgery but are seen by different clinicians. The interviews also pointed to the lack of a system for identifying and re-contacting patients over time, and clinicians described patient data as fragmented and difficult to access across facilities. This makes it difficult to locate patients at scale and, in a context where care is delivered across geographically scattered sites and specialist capacity remains limited, increases the risk that patients are lost between levels of care (Klintö et al., 2020). This limits national oversight, structured follow-up, and long-term planning.

These challenges point to the need for a national CLP registry to enable systematic tracking of patients and coordinated follow-up across facilities and levels of care. A national registry could support the gradual development of more comprehensive cleft care by making long-term patient needs more visible over time. One such registry is the Swedish national cleft lip and palate (CLP) registry (see Appendix A), which collects standardized patient-level data across the country and enables evaluation of surgical, orthodontic and speech outcomes over time (Klintö et al., 2020). The absence of a comparable national structure in Rwanda creates a gap between increasing surgical capacity and the ability to ensure sustained and coordinated follow-up.

1.2 Aim

Despite existing research on digital health system establishment and its implications, limited research has addressed how digital health systems are shaped during their early stages of development and establishment in fragmented healthcare systems under centralized governance. The purpose of this report is therefore to examine this process through the case of developing and prototyping a digital patient registry for cleft lip and palate in Rwanda, as this serves as an empirical case of how a digital health system is designed and established within such a context. The prototype is built by the authors of this report and the project is carried out in collaboration with clinicians involved in cleft care, including plastic surgeons working in the field, as well as technical partners, using the Swedish CLP registry as an important point of reference. The Swedish registry has been developed and refined over several decades and provides an example of how longitudinal, patient-level data can be systemati-

cally collected and used to support monitoring, follow-up, and coordination of care over time.

The motivation for the thesis originates from challenges experienced by clinicians and organizations involved in cleft care in Rwanda. Currently, there is no national registry for the long-term monitoring and follow-up of patients, leading to fragmented and incomplete data that complicates planning. By focusing on the early-stage design and prototyping of a digital patient registry, the thesis aims to improve monitoring, patient tracking, follow-up, and planning across the cleft care trajectory. As the intended result of our prototype is a modular and extensible foundation, additional data can be incorporated in the future. In the long term, the registry is further intended to provide a data foundation for clinical research, national statistics and planning, and AI-based applications, such as tools to support speech assessment and post-operative speech training.

1.3 Limitations

This master thesis focuses on the early-stage development and establishment of a digital patient registry. It does not involve the implementation of a full-scale national registry, but instead explores how such a registry could be designed and established in practice in early-stage.

The thesis does not evaluate long term clinical outcomes or patient health effects resulting from using the registry. Furthermore, the thesis does not describe or assess the collection, quality and completeness of already existing patient data. Instead, it focuses on the design of a registry structure for future full-scale data collection.

Patients were not included as interview participants, since the thesis focuses on the early-stage development and establishment of a registry intended primarily for healthcare professionals and decision-makers, rather than for direct patient use. The focus was therefore placed on stakeholders involved in registry design, clinical documentation, implementation, and governance. If the registry is further developed to include more direct patient involvement, patient perspectives would become important to include in future research.

1.4 Specification of the Issue being Investigated

Based on the aim of the study, this thesis is guided by the following research question:

RQ: How is a national digital health registry developed and established during its early phase under centralized governance?

To further specify the issue in relation to the purpose of the thesis, the following sub-questions are addressed:

SRQ1: How can the registry be designed to fit clinical workflows, data needs, and local constraints?

SRQ2: What factors influence the adoption and sustained use of the registry among healthcare workers?

SRQ3: How can the registry be governed to ensure long-term sustainability and support future development?

2
Theory

This chapter presents the theoretical framework used in this study. It starts by examining how digital health systems are shaped by their organizational and institutional contexts, and how design decisions influence conditions for adoption. Then it addresses how digital health systems are adopted in practice, with particular focus on low-resource settings and the role of the pre-deployment phase. Finally, it examines how governance structures at national level shape implementation and long-term sustainability. Together, these perspectives form the analytical framework used to examine the development and establishment of a national digital patient registry in a centralized context.

2.1 Context-Sensitive Design of Digital Health Systems

Digital health systems, including registries, are described as technical solutions that are designed to enhance efficiency, data quality and coordination in healthcare systems. However, research on information systems has for many years emphasized that technology should not be understood as a tool operating without regard to its organizational context. Orlikowski (1992) argues that technology is both shaped by human actions and at the same time shapes organizational practice, since it both enables and constrains those practices. Given this, digital health systems are better understood as socio-technical systems that are embedded in institutional structures and work routines (Orlikowski, 1992). How they function and their effects therefore do not only depend on technical features, since it emerges from interactions between the technical system and social contexts. Consequently, when digital health systems are introduced, they interact with existing structures rather than operating in isolation (Orlikowski, 1992).

Monteiro and Hanseth (1996) further discuss how information infrastructures are socially shaped through ongoing negotiations around standards and technical specifications. They argue that standards are created through complex processes where different stakeholders try to make their interests into technical solutions, which then shape how the information system is used. These "technical" details, such as a field in a form, therefore lead to specific ways of working and relationships between organizations. As a result, the design of standards does not only reflect existing organizational structures but also shape them. When more organizations start to adapt these standards, they influence how responsibilities are divided and how ac-

tors interact. This means that design decisions, even minor ones such as which fields to include in a form, carry organizational and institutional consequences that go beyond the information system itself (Monteiro & Hanseth, 1996).

2.1.1 Participatory and interactive design for integration

Traditional information system design methods are often based on the idea that user requirements are defined in advance and translated into technical solutions. However, these approaches have received criticism for not capturing the complexity and context of the real-world situation (Cherry & Macredie, 1999).

In response to these traditional methods, participatory design has emerged as an alternative approach that places users at the center of the design process. Instead of viewing information system design as only a technical task, participatory design treats it as a social and collaborative process, where users actively contribute based on their knowledge and everyday work. This perspective emphasizes that information system requirements cannot be fully specified beforehand, but are instead developed through engagement with users in their work context. By involving them directly in the design process, participatory design aims to create information systems that are better aligned with actual practices and organizational settings (Cherry & Macredie, 1999). Boland (1978) further highlights that information system design is a process where both designers and users contribute to shaping the understanding of the problem and possible solutions. Instead of only collecting requirements, the process involves ongoing dialogue and learning, where different perspectives are discussed and refined over time.

This is particularly important within healthcare settings, where information systems must be aligned with user needs, and also with existing workflows, resource constraints, and institutional structures. For example, Chaulagai et al. (2005) show in their study of a national health management information system in Malawi that successful information system design required simplifying data collection processes, integrating previously fragmented data and adapting the information system to the actual routines of healthcare workers. The study highlights that digital health systems designed without considering these contextual factors risk not being used or adding extra workload to already overworked staff. This means that designing digital health systems is a matter of involving users, and also of embedding the digital health system within the broader healthcare context (Chaulagai et al., 2005).

Another empirical example is presented by Aanestad et al. (2014), who study the development and scaling of a hospital information system in India. In this case, information system design and implementation involved continuous interaction between multiple actors across organizational levels, including healthcare workers, technical developers, and institutional stakeholders. Information system requirements emerged through ongoing adjustments to local work practices, which showed that achieving integration in such settings also requires coordination between different actors at different levels. This highlights that participatory and interactive design

can be extended to also include a wider network of stakeholders (Aanestad et al., 2014).

2.1.2 Prototyping healthcare systems

Prototyping is also emphasized as a central part of the design process in healthcare contexts. Chamorro-Koc (2024) highlights that low-fidelity prototypes are important for exploring ideas, testing assumptions, and supporting continuous learning throughout the development process. Developing a complete and final solution from the start is difficult, if not impossible. Chamorro-Koc (2024) therefore argues that prototyping is a more suitable approach, since it enables an iterative process where both designers and users can be involved and help refine the final solution. This is mentioned as particularly valuable in complex healthcare environments, where requirements are uncertain and can evolve over time.

Hevner et al. (2004) also states that prototyping can be considered a central component of design science research overall, since this is a type of research in which artifacts are used as an important means of learning. He means that design is inherently iterative, since it involves several cycles of building and evaluating artifacts in order to refine both the problem itself and the solution. In this sense, prototypes serve as exploratory tools at the same time as preliminary versions of a final product.

2.1.3 Designing for national adoption

Many design decisions early in the development of a new information system affect the conditions for adoption and the possibilities for scaling the information system to a broader context later on. Pacifico Silva et al. (2018) argue that how well an information system scales is to a large extent determined already in the design phase. They further argue that innovations need to be designed with consideration for the broader health system in which they will operate, rather than being optimized only for local pilot settings. It is important that new innovations align with existing organizational structures and institutional priorities, because if the health system requires additional resources or introduces parallel workflows, it risks adding to the burden of health workers and remaining a pilot. This becomes important when designing the health system, since it needs to be designed for the available workforce, infrastructure, and financing (Pacifico Silva et al., 2018).

Pacifico Silva et al. (2018) further mention that designing for scale means designing something that is adaptable over time. The design should not be treated as a one-time activity; instead, it should allow for iterative refinements and learning. World Health Organization (2026b) similarly emphasize that evidence generation should be built into the design from the beginning, to allow the information system to demonstrate its own relevance and impact early. By generating evidence and getting a proof of concept early on, the innovation will be better positioned to gain support from key stakeholders and decision-makers, which is also a condition for sustained use. An information system that is not adopted cannot scale, and these

design principles are therefore as much about creating conditions for adoption as they are about enabling future expansion.

2.1.4 Local adaptation

When digital health systems are introduced into new settings, some degree of adaptation is often necessary to create a fit between the digital health system and the context in which it is introduced. Sahay et al. (2013) show that expansion sometimes requires the design to be based on a standardized platform while making local adaptations in response to national and organizational conditions, suggesting that local adaptation is a central part of how digital health systems are designed for new contexts.

A related but distinct argument is made by Kumar et al. (2018) in the context of India's national digital health infrastructure development. They argue that health information systems designed primarily for the needs of policymakers and program managers may fail to support the information needs of healthcare providers. As a response, they propose a federated health information architecture that balances the autonomy of local health information systems with the requirements of a centralized monitoring agency. This is relevant for local adaptation because it shows that national health information systems need to support central coordination while still allowing sufficient flexibility for local use (Kumar et al., 2018).

This tension between standardization and flexibility is further discussed by Hanseth et al. (1996). They argue that standardization is necessary to support coordination, comparability and future scaling, while local adjustment is often required for the information system to fit the institutional and infrastructural conditions of the setting. Local adaptation can therefore be understood as both necessary and constrained. It is necessary because information systems rarely function across contexts without modification. It is constrained because too much variation may weaken coordination across settings and make broader scale-up more difficult. (Ansari et al., 2010; Sahay et al., 2013).

Together, the perspectives discussed throughout chapter 2.1 show that design decisions shape more than the technical information system itself. Choices about standards, flexibility, who is involved, and how the digital health system relates to the broader healthcare system all have consequences that extend into how the digital health system will function in practice. When such decisions are made without sufficient consideration of organizational context or local infrastructure, a gap between the information system and the reality it enters may already be embedded before deployment begins. Adoption is therefore shaped earlier in the process than is often assumed.

2.2 Adoption of Digital Health Systems

Technology adoption is commonly understood as users' acceptance, intention to use and actual use of a new technology. In the Unified Theory of Acceptance and Use of Technology (UTAUT), adoption is explained through four main perspectives. These are performance expectancy, effort expectancy, social influence, and facilitating conditions. In other words, adoption depends on whether users believe that the technology will improve their work, whether it is perceived as easy to use, whether others encourage its use, and whether sufficient technical and organizational support exists (Venkatesh et al., 2003).

A UTAUT-based study of DHIS2 in Kenya shows how these dimensions play out in practice in a low-resource setting. Social influence was the strongest predictor of intention to use the digital health system, while for actual use, facilitating conditions mattered most, which included whether staff had access to computers and internet. These findings suggest that adoption was shaped both by users' perceptions of the digital health system and by the practical conditions surrounding its use (Karuri et al., 2017).

While UTAUT captures individual perceptions of a technology, it does not account for the collective and organizational work that is required to embed a new practice into work routines. Normalization Process Theory (NPT) addresses this gap by focusing on how new practices are adopted into everyday work through collective effort over time (Murray et al., 2010). NPT includes four mechanisms through which this can be done. The first one, coherence, refers to the sense-making work of understanding what a new practice is and why it matters. Furthermore, cognitive participation is the engagement and commitment that is needed for the practice to be sustained. Collective action refers to the practical work of carrying it out in daily routines, and lastly, reflexive monitoring is the ongoing evaluation of how it is working in practice. Together, these mechanisms describe whether and why an information system becomes accepted as a natural part of working routines (Murray et al., 2010).

2.2.1 Adoption in low-resource clinical settings

Within digital health, this concerns the acceptance and use of digital health technology by health workers (Wang et al., 2025). Adoption therefore also needs to be understood in relation to everyday clinical practice. In health-care settings, adoption is closely linked to how a digital health system fits into routine work. Research on health information technology and EHRs has emphasized that successful implementation and meaningful use depend on the integration of digital tools into clinical workflow. Adoption in clinical settings can therefore also be understood in relation to whether a digital health system can be incorporated into daily routines and work processes (Bowens et al., 2010).

In low-resource settings, this issue may be particularly important. Adoption depends on whether information systems can be used within existing organizational routines (McCool et al., 2020). The lack of facilitating conditions has been identified as the most frequently reported barrier in such settings. Adoption therefore depends both on how useful the technology is perceived to be, and whether the practical conditions for using it are in place. Supportive infrastructure, tailored training programs and incentive policies have been identified as important conditions for enabling adoption in practice (Wang et al., 2025). Studies on digital health sustainability in low-resource settings have likewise emphasized the importance of embedding interventions in local health systems, practices, and capacities (McCool et al., 2020).

The consequences of poor workflow integration become particularly apparent when digital health systems fail at a larger scale. A recent example is Babyl, Rwanda's largest telemedicine platform, which reached 450 of 510 primary health facilities and enrolled 2 million patients before it was suspended in September 2023. The reason was information system redesign (Musange Furere et al., 2026). A qualitative study of the platform found that clinicians and officers working at physical health centers could not access Babyl consultation records, which disrupted clinical workflows when patients arrived at the facilities. The platform operated alongside existing health services rather than being integrated into them, which made it difficult for the care providers to engage with the platform and contributed to its closure (Musange Furere et al., 2026). This case suggests that in low-resource settings, where resources are limited and information systems are difficult to redesign after deployment, adoption conditions may need to be addressed earlier in the development process.

2.2.2 Adoption as a design-phase concern

Most research on digital health adoption focuses on what happens after a digital health system has been deployed. Yang et al. (2015) show that the phase before the adoption decision has received little attention, despite being important for outcomes. They argue that poor management of this phase can lead to poor decisions, such as adopting an information system that does not fit organizational needs. Their framework covers stages like awareness, requirement gathering, and trialing, all of which take place before deployment.

A related perspective is provided by Heeks (2002), who argues that information systems in developing countries fail at high rates, and that a key explanation lies in the gap between information system design and organizational reality. Heeks (2002) refers to this as the design-actuality gap, and describes it as a mismatch between what an information system is designed to work with and what the organization actually looks like in terms of processes, practices, and conditions. The larger that this gap is, the higher is the risk of failure. Most importantly, he means that this gap is determined before an information system is deployed. It is embedded in the design through assumptions that designers made about users, workflows, infrastructure, and organizational structures. Heeks (2002) argues that in developing country

contexts, these gaps have shown to be particularly large, partly because information systems often are designed in contexts that are very different from the context where it will be used. This means that many failures result not from poor implementation or user resistance, but from design choices that were made before the information system was introduced (Heeks, 2002).

Together, the perspectives brought up in 2.2 show that adoption is more than a question of whether users accept a new technology. It also depends on whether digital health systems fit into existing workflows and whether the practical conditions for use are in place. In low-resource settings, these conditions are often fragile, and poor workflow integration can contribute to failure even at scale. The phase before deployment also matters. When design assumptions do not match organizational reality, adoption is at risk before the information system has even been introduced. Whether adoption succeeds therefore cannot be understood at the facility level alone. It is also shaped by how information systems are governed, financed, and coordinated at national level, which is what the following section examines.

2.3 Information System Implementation and Governance

The implementation of digital health systems at national level involves organizing governance structures, responsibilities and coordination across different levels of the healthcare system. Research shows that introducing such systems requires alignment between national strategies, local practices and institutional arrangements (Aanestad et al., 2014). It is also important that the system addresses clearly defined problems within the institution. If it does not respond to urgent needs, it risks not gaining the legitimacy and support needed for adoption and scaling. Information systems that show clear value for decision-makers are more likely to be adopted and expanded (Pacifico Silva et al., 2018). Finally, long-term sustainability also depends on how ownership, resources, and capacity are established and maintained over time (Moucheraud et al., 2017; Watson-Grant et al., 2017).

2.3.1 Centralized governance and health system performance

In many countries, healthcare governance has shifted between decentralization and centralization over time, which shows that priorities have been changing around efficiency, ownership and coordination. Centralization in this context refers to the transfer of decision-making authority, resources, and administrative control upward to national or central government levels (Shishkin et al., 2025). During the 1980s and 1990s, decentralization was widely promoted by international development agencies as a way to improve responsiveness and local ownership. However, several countries have since then recentralized again to respond to fragmentation, inequality, and coordination failures (Dwicaksono & Fox, 2018).

Research on how governance structure affects health system performance shows mixed results. A systematic review of studies in low- and middle-income countries found that decentralization had some positive effects on health outcomes, but that the results differed depending on the context and what was measured (Dwicaksono & Fox, 2018). This means that there is no simple answer to whether centralized or decentralized governance leads to better health systems, since local factors such as capacity, funding, and existing conditions all influence the outcome.

Centralized governance can work well when health services are relatively standardized and need to reach a large population. A study from rural Mexico found that clinics run by the federal government performed better than clinics run by state governments in terms of how much patients had to pay for healthcare out of their own pocket and how often they used preventive health services (Bustamante, 2010). This was partly explained by better coordination and economies of scale.

Further, centralized governance can also enable standardization, coordinated planning, and uniform implementation of national programs more broadly. In a study about Russia, centralization had several benefits related to service delivery, such as the creation of new types of medical organizations and the development of multilevel care systems (Shishkin et al., 2025). However, standardized solutions that were applied across different regions did not always take local needs and conditions into account, which in some cases limited accessibility and reduced the effectiveness of the reforms. This means that while centralization can provide strong coordination, it may constrain the flexibility that is needed to respond to local variation.

2.3.2 National-level implementation

This tension between centralization and local flexibility is particularly evident in the implementation of large-scale digital health systems. Klecun et al. (2025) analyze large-scale EHR initiatives in England and show that too much centralization can create inflexibility and resistance, while too much local autonomy may lead to fragmentation. Scaling successfully therefore depends on maintaining a balance between central coordination and local steering (Klecun et al., 2025).

In the India case, the national roll-out of the digital health system involved coordination between state authorities, hospitals, and external partners, which highlights that governance involves multiple actors (Aanestad et al., 2014). To support implementation at national level, dedicated IT units were established at different administrative levels to act as a link between technical development and local use. These units played an important role in supporting adoption, resolving issues, and adapting the system to local conditions. The case therefore shows that national-level implementation requires governance structures that provide coordination and support at different levels of the healthcare system.

2.3.3 Sustainability and ownership

The long-term sustainability of a health information system is closely linked to how responsibility, resources, and arrangements for continuation are organized over time. In a qualitative study of electronic health information systems in Malawi, Zambia, and Zimbabwe, Moucheraud et al. (2017) identify several factors related to sustainability, including financial resources, human resources, operating capacity, and integration with existing information systems and processes. They also show that sustainability may be uncertain when information systems are established through external funding and continuation after the original support period is unclear (Moucheraud et al., 2017). Watson-Grant et al. (2017) likewise argue that ownership contributes to the long-term sustainability of health information systems, and that systems developed primarily through external support, without sufficient involvement of the recipient country, risk losing sustainability once that support ends (Watson-Grant et al., 2017). Ilesanmi and Afolabi (2022) similarly conclude, in a systematic review of health-related programs in Africa, that sustainability should be considered during program planning and that facilitators and barriers within the local context influence whether programs continue over time.

The consequences of failing to achieve this are illustrated by Babyl, the previously mentioned telemedicine platform in Rwanda (Musange Furere et al., 2026). The study found that the platform relied on donor-dependent financing, and lacked the governance alignment that comparable platforms in India and Kenya had achieved through government-led integration from the start. The case shows that in the context of Rwanda, information systems that are not embedded in national health infrastructure and financing structures from the start may be difficult to sustain regardless of their technical reach. Aanestad et al. (2014) also conclude that over time, responsibility for information system maintenance needs to be transferred to local actors and supported by internal capacity (Aanestad et al., 2014).

The studies in 2.3 together emphasize that digital health systems require alignment between national strategies, local practices as well as institutional arrangements. Centralized governance can support coordination and standardization, but may reduce flexibility and local responsiveness. National-level implementation involves multiple actors across administrative levels, and dedicated support structures are needed to bridge technical development and local use. Long-term sustainability depends on how ownership, capacity, and resources are organized, and information systems that rely on external support without being embedded in national infrastructure risk failing over time.

Taken together, the literature reviewed in 2.1–2.3 shows that digital health systems are shaped by technical, organizational, and governance factors. Standards and infrastructure influence how the systems can be used, and design assumptions that do not match organizational reality increase the risk of failure before deployment. Adoption depends on user acceptance, workflow fit, and practical conditions for use. Implementation and sustainability at scale further depend on how governance, ownership, and coordination are organized across levels. The analytical framework

in the following section is based on these insights through three dimensions: technical design, adoption, and governance involvement.

2.4 Analytical Framework: Technical Design, Adoption and Governance

Drawing on socio-technical and digital health research, this thesis uses technical design, adoption, and governance involvement as analytical dimensions to guide the analysis of the empirical material. These dimensions structure the analysis of how the proposed registry is shaped, what may influence whether healthcare workers accept and sustain its use, and how institutional involvement influences its establishment over time. Together, they provide a basis for examining how a national digital health registry is developed and established in practice.

2.4.1 Technical design

The technical dimension focuses on how digital health systems are designed through standards, data structures and architectural choices. Research emphasizes that technical design is not neutral, as standards and data definitions involve assumptions on how work should be organized and coordinated (Monteiro & Hanseth, 1996).

The choice of which digital platform to use is shaped by the existing information ecosystem and institutional arrangements. Platforms are often chosen based on how well they can integrate with national platforms, support interoperability, and align with governance structures (Sahay et al., 2013). Instead of being selected solely based on technical functionality, platforms must fit within ongoing infrastructuring processes, where technical solutions evolve through negotiation between stakeholders and adaptation to local conditions (Aanestad et al., 2014).

Small design decisions such as which variables are included in a core dataset influence how information is interpreted and acted upon across organizations. A standardized core is necessary to enable interoperability, however too much of it may limit future development (Hanseth et al., 1996). Therefore, the technical dimension involves both standardization and adaptation elements. A standard that is too rigid risks not being used in practice, while too much flexibility undermines coordination across facilities. In national digital health initiatives, finding this balance is therefore both a technical and organizational decision.

2.4.2 Adoption

The adoption dimension addresses what influences whether healthcare workers accept and sustain the use of a digital health system in practice. Adoption depends on whether users perceive the system as useful and easy to use, whether others encourage its use, and whether the practical conditions for using it are in place (Venkatesh et al., 2003). In low-resource settings, the absence of facilitating conditions such as

infrastructure, training, and organizational support has been identified as a particularly significant barrier (Wang et al., 2025).

Adoption is also shaped by how well an information system fits into existing work routines and whether it adds to or replaces existing documentation obligations (Bowens et al., 2010). When digital information systems are introduced alongside paper-based systems rather than replacing them, parallel entry creates additional workload that can erode motivation over time (Uwera et al., 2024). Whether an information system becomes a natural part of everyday practice further depends on whether users understand its purpose and value, and whether that understanding is actively maintained through feedback and continued engagement (Murray et al., 2010).

2.4.3 Governance involvement

The governance dimension concerns how digital health systems are coordinated, managed and owned at institutional and national levels. This includes governance structures, decision-making processes and how responsibilities are distributed between different actors. Governance is important for aligning technical information systems with organizational and national priorities (Sahay et al., 2013). Digital health systems often involve multiple actors, such as ministries, hospitals and external partners, which creates challenges in coordinating efforts and aligning technical solutions with institutional arrangements and available resources (Aanestad et al., 2014).

At the same time, governance involves a balance between central coordination and local flexibility. Central governance can support standardization and national alignment, while local adaptation is needed to ensure that information systems work in practice (Sahay et al., 2013). Governance therefore plays a key role in enabling integration and long-term sustainability, including how ownership is organized and transferred over time to ensure that information systems remain embedded in national structures beyond the initial implementation phase (Moucheraud et al., 2017; Watson-Grant et al., 2017).

3
Methodology

This chapter describes how the study was conducted. It covers the research design, how data was collected and from whom, how the material was analyzed, and the ethical considerations that guided the research process.

3.1 Research Design and Approach

This study is designed as a qualitative single case study. Case study research focuses on an in-depth analysis of a bounded system or situation, where the goal is to understand complexity, context, and processes rather than to achieve statistical generalization (Bell et al., 2022). This design is suitable for the study at hand as it examines the early-stage development and establishment of a national digital patient registry under centralized governance. Case study research is further often consistent with qualitative methods such as unstructured interviews and informal conversations, which are used in this study (Bell et al., 2022). The study prioritizes depth over breadth and focuses on understanding the case in detail, making a qualitative approach appropriate. Additionally, the study aims to understand processes, stakeholder perspectives, and contextual dynamics rather than to measure variables or test predefined hypotheses (Bell et al., 2022). The case is intrinsically interesting as it addresses a concrete and context-bound healthcare challenge. It can also be seen as revelatory, as limited research has examined how national patient registries are developed and established in the early-phase in centralized healthcare systems (Bell et al., 2022).

Moreover, the study follows an abductive approach to research. This means that theory and empirical observations inform each other iteratively, moving back and forth between data and theoretical concepts (Bell et al., 2022). This approach is appropriate because the early phase development and establishment of a national CLP registry in Rwanda is an understudied and context-specific phenomenon. The study therefore has an exploratory focus, where insights emerge from interviews, conversations, and design activities, while existing theoretical frameworks are used to interpret and refine those insights. This means that the study is not limited by prior theoretical assumptions (Bell et al., 2022).

A design-oriented approach is simultaneously adopted, where prototyping is used to explore and address a concrete problem context. Following design science principles,

the prototype is treated as an exploratory artifact and not a finalized information system. It is used to iteratively learn and reflect on early-stage design decisions (Hevner et al., 2004). A prototype helps make design assumptions explicit and works as a support in the dialogues with stakeholders regarding data structures, workflows, and governance. Our prototype was designed with the existing Swedish CLP registry as a reference. It has guided the scope and follow-up logic of the prototype and also allowed it to be adapted to the Rwandan context.

3.2 Data Collection

The data collection process for this project has primarily been through qualitative interviews and prototype feedback.

Qualitative interviews were used since the main importance of the interviews is the interviewee's perspective, which often require flexibility in questionnaires. It also allows the interviewer to adapt the questions and ask follow-up questions, allowing interviews to go more into depth (Bell et al., 2022). The interviews were divided into two phases: the first phase consisting of unstructured exploratory interviews, and the second consisting of semi-structured interviews. Unstructured interviews are similar to a conversation and might include only a few open-ended questions (Bell et al., 2022). This was carried out early in the data collection process, to obtain background information about the context, actors, and environment. The second phase, consisting of semi-structured interviews, was conducted when the context had been clearly mapped out and more specific topics were to be investigated more into depth. Semi-structured interviews are advantageous when the researcher does not necessarily know exactly everything that needs to be asked and learned, since theories and concepts can emerge from the interviewee's responses. For this, different interview guides were used for the different participants groups (see Appendix B). The questions in the interview guide were formulated based on the insights gained from the unstructured interviews from the first phase and were divided into categories corresponding to the research questions. Much emphasis was put on the interviewees point of view, as the interviewee's work settings and work processes are of great importance for this project.

Furthermore, prototype-based feedback sessions were used as a data collection approach to capture clinicians' perspectives on the design and usability of the registry. These sessions were conducted to ensure that the development of the registry prototype was informed by the local context and the needs of the people who will use the registry in practice. During these sessions, participants were introduced to the prototype and its structure, variables, design, and follow-up logic were shown and demonstrated. Participants were asked to reflect on the relevance, clarity, and feasibility of the proposed data points, as well as the overall structure and usability of the registry. Feedback was collected through open discussions where participants could suggest modifications, such as variables to include or remove, and highlight potential challenges on integration of the registry into their daily work. These sessions were conducted to support iterative refinement of the registry design and logic. Rather

than collecting all feedback before making revisions, each session built directly on changes from the previous one, allowing us to develop the prototype continuously throughout the data collection process. This was consistent with principles of participatory design and iterative prototyping (Chamorro-Koc, 2024; Cherry & Macredie, 1999), and was made necessary primarily by the time constraints of this project, but also by limited access to respondents and geographical distances.

Table 3.1 provides an overview of the respondents included in the study.

Respondent	**Role / Background**	**Interview**	**Feedback**
Registry developers			
R1	Digital birth registry pilot	✓	
R2	Birth defect registry pilot	✓	
R3	Swedish CLP registry	✓	
R4	Trauma registry	✓	
Plastic surgeons			
S1	Plastic surgeon	✓	✓
S2	Plastic surgeon	✓	✓
S3	Resident plastic surgeon	✓	✓
NGOs			
N1	Operation Smile, surgeon	✓	✓
N2	Smile Train, surgeon	✓	✓
N3	Operation Smile, anesthetist		✓
N4	Operation Smile, speech therapist		✓
Policymakers			
P1	Data Scientist, RBC	✓	

Table 3.1: List of respondents by group and their participation in interviews and prototype feedback sessions

Purposive sampling was used in this thesis project, meaning that participants were selected based on their relevance to the research questions rather than through random or convenience-based procedures (Bell et al., 2022). For this single case study, participants are individuals with direct knowledge of or involvement in cleft care, digital health governance, or registry development in Rwanda. An advantage of purposive sampling is that it allows the researcher to select participants who have direct experience of the topic being studied (Bell et al., 2022). Snowball sampling was used as a complementary approach, where initial participants were asked to suggest additional interviewees who may be relevant to the study (Bell et al., 2022).

Participants were selected to represent the key stakeholder groups whose perspectives are directly relevant to the early-stage development and establishment of the registry. Registry developers were included to provide empirically grounded insight into success factors and barriers from actual registry implementations in Rwanda, drawing on direct experience from comparable pilot projects. Plastic surgeons were

included as primary intended users of the registry, and NGO clinicians were included both as clinical users and because the organizations they represent already have cleft-specific registries in Rwanda. Their inclusion made it possible to understand how existing registries for CLP patient documentation are structured, and to ensure that the new registry could be designed to work in continuity with these currently used registries. Policymakers were included to capture the governance and institutional perspective relevant to national anchoring and long-term sustainability. Although only one participant has a formal policymaking role, governance-related perspectives were further reflected through other participants with direct experience in health information systems and collaboration with government actors. For the remaining interview groups, sample size was determined iteratively and considered sufficient for the exploratory purpose of the thesis. According to Bell et al. (2022), data collection can end once theoretical saturation is reached, meaning that no new themes or insights emerge from additional interviews. The interviews were complemented by the feedback sessions, which provided further input on practical design needs, usability, and implementation considerations, increasing the thematic saturation.

Interviews and prototype feedback sessions were conducted both remotely and on site, depending on the location and availability of the participants. Remote interviews were carried out using online communication tools, while on-site interviews were conducted in person when possible. The interviews were audio-recorded with the participants' consent, to ensure that the documentation of responses was accurate. Recorded interviews were transcribed afterwards for analysis. The duration of the interviews varied depending on the interview format and role of the participant, but most interviews lasted between 45 and 75 minutes, which is common for qualitative interviews (Bell et al., 2022).

Another source of complementary data used was documents and secondary sources. These were used to inform the registry development process and to contextualize the role of a national CLP registry within the Rwandan healthcare system. These sources included the Rwanda Ministry of Health's *Health Sector Strategic Plan V* (Ministry of Health Rwanda, 2024a), WHO's malnutrition definitions (World Health Organization, 2026a) and the Swedish CLP registry forms (see Appendix A).

3.3 Data Analysis

The data analysis was based on qualitative methods, as the empirical material consists primarily of interview transcripts and notes from the feedback sessions (Bell et al., 2022). Since qualitative data derived from interviews and feedback sessions contains a large amount of unstructured textual material, it is complex to analyze. There is no single prescribed procedure for qualitative data analysis, but two widely used strategies are thematic analysis and grounded theory (Bell et al., 2022). Thematic analysis was used in this study as it enables the identification of recurring patterns, similarities and variations across the material.

The thematic analysis followed an iterative process. First, interview transcripts and notes from prototype feedback sessions were read thoroughly to become familiar with the material. Second, relevant segments of text were assigned initial codes. These codes summarized issues, concerns, or ideas related to the research questions, including registry design, adoption conditions and governance. Third, codes that addressed similar issues were compared and grouped into broader themes. The themes were then refined by revisiting the empirical material and assessing whether they captured meaningful patterns across interviews, feedback sessions, and stakeholder groups. The final themes are presented in the results section.

The data analysis was conducted in parallel with data collection. Initial interviews and feedback notes were analyzed as they were collected, rather than only after all data had been gathered. Insights from early coding and preliminary themes were used to refine the interview guide and clarify which issues required further exploration in later interviews and feedback sessions. This enabled a more focused analysis throughout the project (Bell et al., 2022).

3.4 Ethical Considerations

Ethical considerations are central to qualitative research, particularly when interviews involve identifiable individuals. All interviewees were provided with participant information and a consent form, which they were required to review and accept before the interview took place. This procedure follows established research ethics guidelines (Bell et al., 2022). It also aligns with national requirements for research involving human participants in Rwanda, where ethical approval and informed consent are required by the Rwanda National Ethics Committee (RNEC) (Rwanda National Ethics Committee, n.d.). The participant information and consent form included details about the purpose of the study, what participation involved, potential risks and how data was handled and used, to ensure informed consent and transparency (Bell et al., 2022). It also clearly stated that participation is voluntary, that participants may withdraw at any time without consequences, and that confidentiality will be ensured through secure data storage and anonymization of personal information, which also reflects existing methodology research (Bell et al., 2022).

Ethical approval for the study was obtained from the Rwanda National Ethics Committee, which reviews research involving human participants in Rwanda. This approval was necessary in order to conduct interviews in Rwanda, and ethical requirements are particularly strict within the healthcare sector (Rwanda National Ethics Committee, n.d.). The application to the national ethics committee included the research protocol, interview materials, and the participant information and consent form. Because the study involved health related institutional actors, special care was taken to protect confidentiality.

Participants were asked for permission to audio-record the interview to ensure accurate documentation (Bell et al., 2022). They were informed about how recordings

and transcripts were handled and stored, and participants were given the opportunity to review their interview transcripts if requested. They could correct statements, clarify meanings, or remove information, which allowed participants to validate their contributions. It also strengthened the reliability of the findings and ensured that their perspectives were represented accurately. All data was stored securely and only accessible to the research team and until the end of the research period. As the study involved transferring data outside of Rwanda, it should be noted that the data collected consisted of anonymized interview transcripts capturing respondents' professional roles and perspectives, rather than identifiable personal data. As such, the data falls outside the scope of Law n°058/2021 relating to the protection of personal data and privacy, and no additional authorization for cross-border transfer was required (Republic of Rwanda, 2021). Anonymity and confidentiality was addressed throughout the research process (Bell et al., 2022).

Given the cross-cultural context of the study, particular attention was paid to conducting interviews in a respectful and context-sensitive manner. This included adapting communication to the local setting and being aware of differences in language, institutional practices, and cultural norms.

4

Results and Analysis

This chapter presents the findings from interviews and prototype feedback sessions conducted throughout the study. The analysis identified eight themes, which have been grouped according to the three research sub-questions. Figure 4.1 provides an overview of the themes and their relation to each sub-question. The first two themes address how the registry was designed to fit clinical workflows, data needs, and local constraints. Themes three and four concern the factors that influence adoption and sustained use among healthcare workers, and the remaining four themes address governance and long-term sustainability.

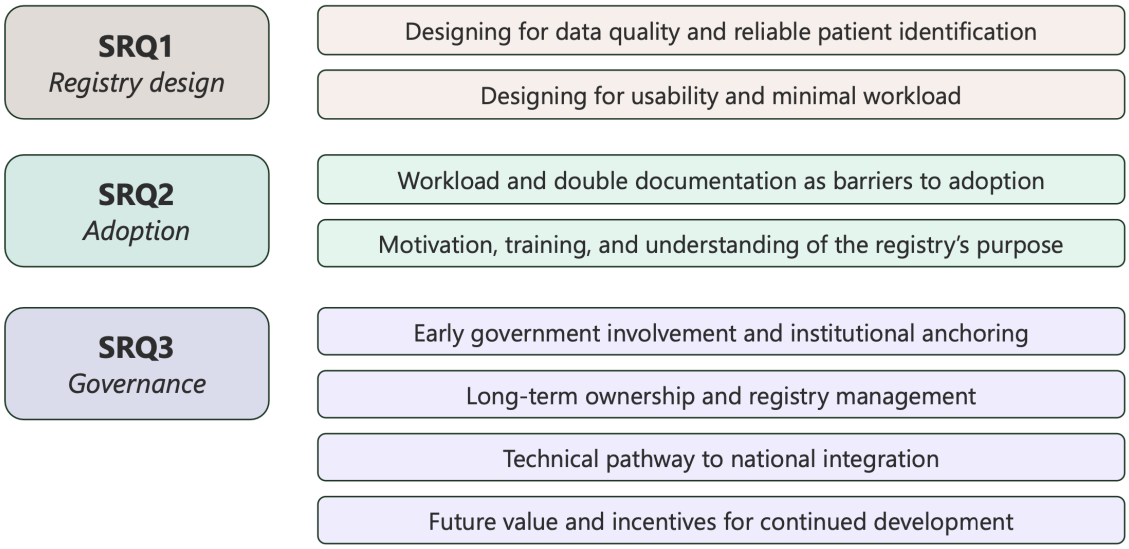

Figure 4.1: Overview of identified themes grouped by research sub-question.

4.1 Registry Design in Relation to Clinical Workflows, Data Needs, and Local Constraints

The registry prototype was developed using the Swedish CLP registry as a starting point. During prototype feedback sessions conducted with clinicians and NGO representatives, the prototype was reviewed and revised iteratively. Each respondent reviewed the prototype forms and provided specific comments on variables, structure, and usability. Appendix C summarizes the variable and feature adaptations

that were made to the Swedish CLP registry during prototype development.

Two recurring concerns shaped the adaptation of the Swedish CLP registry throughout the feedback sessions and interviews: the need to ensure reliable and consistent data quality, and the importance of keeping the registry realistic and usable for everyday clinical use. These concerns influenced decisions about variables, form structure, and platform choice.

4.1.1 Registry structure and forms

The Swedish registry was adapted and structured into two main forms: a baseline form for initial patient registration and a surgical form for documenting completed surgeries. The baseline form captures key patient information and initial clinical characteristics, while the surgical form allows repeated entries for each intervention.

Two additional forms were also developed, a follow-up form for longitudinal tracking over time, and a speech assessment form. The follow-up form allows several entries and is designed to support ongoing documentation of patient outcomes, including non-surgical visits. In the Swedish registry, there is no separate follow-up form, however, R3 reviewed the prototype and raised the need for a short follow-up form for visits that do not involve surgery, as this should still be documented. S1 also mentioned this and emphasized the importance of being able to update the registry over time across multiple types of visits. The speech assessment form was added as a first step towards documenting speech outcomes, since speech follow-up is currently limited in Rwanda. Although the Swedish registry includes a speech form, a simpler version was developed for the prototype based on initial feedback from N4, a speech therapist. This reflects the current stage of speech care in Rwanda while still allowing speech outcomes to be documented over time. Figure 4.2 illustrates an overview of the registry structure with all forms including their corresponding events and key contents.

Recurring discussions across all sessions related to where photos, videos, and audio recordings should be placed. An initial design included a separate media form, however, S2 suggested removing this and instead embedding media upload directly into each form (baseline, surgical, and follow-up) so that images are linked to the specific clinical event they document. S3 agreed regarding this and emphasized that access to photos is critical during follow-up, to be able to track the outcome over time. R3 mentioned the importance of recording the date and patient age when each photo or video is uploaded, either through an automatic timestamp or a manually entered field, so that media can be interpreted correctly.

4.1.1.1 Baseline form

Most variables in the Swedish registry were kept in the Rwandan prototype, while several others were flagged as not applicable in the Rwandan context. N1 noted that the transferred field does not apply in Rwanda in the same way as in Sweden.

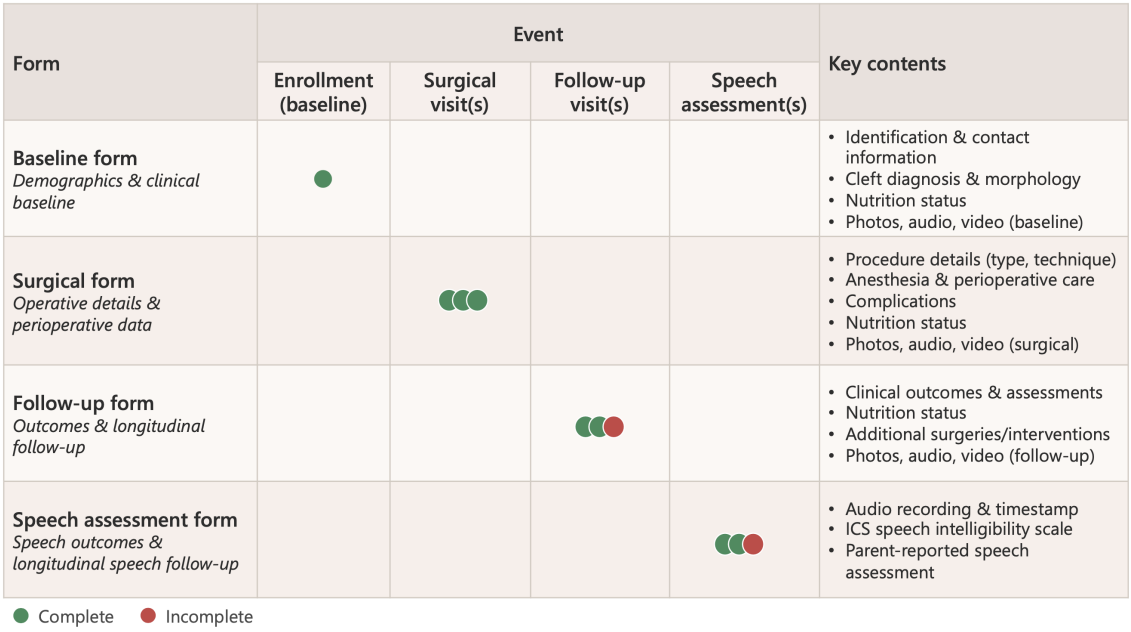

Figure 4.2: Overview of the registry structure. Multiple circles indicate forms that can be completed repeatedly for the same patient.

Several variables were kept but modified, either because of differences in the Rwandan context, or as general improvements for interpretation. One such modification is related to the variable for secondary diagnoses. In the Swedish registry, this variable focuses primarily on Pierre Robin sequence. However, according to S2, this condition is less common in Rwanda. Instead, S2 recommended first distinguishing whether the cleft is syndromic or not, followed by the inclusion of a broader set of relevant syndromes when applicable. This change was intended to make the registry more flexible across different contexts, rather than being tailored to a specific country.

In addition to the variables that were kept from the Swedish registry, some new ones were added after gaining input from local stakeholders. First, additional patient identification and contact information was added, including the mother's name, phone number, physical address, and closest health center, as suggested by S1 and S2. These additions were considered important for improving patient traceability and follow-up, since the formal national identification system is not yet consistently applied. The national identification number (NIN) field was nonetheless retained in the prototype to align with how patient identification is expected to be handled in the future. Nutritional status was also included as a new variable. This was initially proposed by N1 and supported by S1, with S2 then further elaborating on how it may be extended. Based on the input from S2, the final prototype design included fields for height and weight, along with automatically calculated nutritional indicators such as z-scores. This was considered particularly relevant for surgical decision-making and to monitor patients' health over time.

4.1.1.2 Surgical form

No variables from the Swedish registry were removed in the surgical form of the Rwandan prototype. However, several changes were made to adapt the form to the Rwandan context and improve usability. More detailed questions about surgical technique and method were added to the prototype, as suggested by S2 and S3. For instance, when cleft repair is specified as lip repair, additional fields appear regarding which technique was used. S3 also suggested using conditional fields, so that these questions are only displayed when relevant. This made the form more specific to local surgical practice while reducing irrelevant information and making data entry easier.

A variable concerning antibiotics was kept but made more detailed in the Rwandan prototype. While the Swedish form only records whether antibiotics were given, N1 suggested adding more specific fields on why antibiotics were given, what type was used, and the amount administered. This makes it possible to distinguish between prophylactic antibiotic use and antibiotics given in response to a confirmed infection. The adaptation was considered relevant in the Rwandan context, since tracking antibiotic use was described as important by N1, particularly in relation to antibiotic resistance.

Nutritional status was also added to the surgical form as a Rwanda-specific variable. This was suggested by S1, who emphasized that nutritional status is important to document in relation to surgical readiness and outcomes. S2 and S3 also indicated that nutrition is clinically relevant in the Rwandan context. Including this variable therefore made the form better adapted to local patient needs and conditions.

4.1.1.3 Follow-up form

The follow-up form includes a subjective assessment of the outcome and follow-up situation. More specifically, it includes an overall satisfaction rating on a scale from 1 to 10, as suggested by S3. It also includes predefined options for whether the outcome is considered good, what recommendations are given, and whether the patient needs another follow-up visit or another surgery. These additions were suggested by S1, who also raised the importance of defining what should count as a good outcome.

It also includes media uploads for photos, videos and audio recordings. This was added after several respondents highlighted the importance of being able to access media during follow-up. S3 specifically highlighted that before-and-after pictures are important for assessing outcomes over time.

Further, it includes nutritional status and whether the patient attends school. School attendance was suggested by S1 as an important variable as it indicates how the patient is doing beyond the clinical outcome.

4.1.1.4 Speech assessment form

The speech assessment form includes audio upload with the date of recording, to make it possible to follow speech development over time. Based on feedback from the speech therapist, N4, the form also includes a simple parent-reported assessment inspired by the *Intelligibility in Context Scale*, where speech is rated according to how well the child is understood by different listeners. N4 noted that this type of scale is used internationally and in the Swedish registry, which made it relevant as a starting point for the prototype.

4.1.2 Data quality and reliable patient identification

Designing for data quality and reliable patient identification emerged as a central theme. Several respondents highlight the importance of ensuring good data quality in the registry. They explain that if the quality of the data is poor, the registry is unlikely to be used in practice, and the data will have limited value. Poor data quality is described in different ways, but inconsistency is one of the most common concerns. Different respondents point to different ways in which registry design could help improve data quality. These include using mandatory fields, providing clear descriptions, relying on predefined response options, and introducing validation rules and different access levels.

R1 refers to mandatory fields and validation rules as ways to improve consistency and completeness in the data. S2 and S3 both mention the importance of predefined response options, both to improve consistency and to make the registry easier to use. S3 also points to the value of explanatory text or field descriptions, which could help users understand what should be entered and thereby improve both data quality and ease of use. S1 and S3 further discuss different access levels for different user groups as another way to support more reliable data entry.

The feedback sessions also reinforce these findings. Several comments focus on the need for clearer field descriptions, stronger validations, and more precise structure in the forms. For instance, feedback from many respondents point to the importance of making classifications easier to understand, clarifying what should be entered in each field, and reducing the risk of incorrect or inconsistent entries. At the same time, some feedback suggests that not all fields should necessarily be mandatory, since requiring completion may lead users to enter incorrect information simply to move forward. Ensuring data quality therefore requires structure and validation, and also careful judgment about where strictness helps and where it risks creating new sources of error.

Respondents also link data quality to reliable patient identification. This is seen as an important challenge by most interviewees, since duplicate records and inconsistent identifiers across facilities would make the registry less reliable over time. Several respondents describe current registry identification practices as problematic for a future national registry. N2 explains that hospital IDs are not useful as unique identifiers for a national registry, since a patient may receive a different hospital

number at each facility they visit. R4 similarly describes this from the trauma registry:

> *The big challenge we still have is that someone can come from one hospital and be recorded there, and when they come to another hospital they start as a new patient. Even though the IDs are different, it is actually the same person recorded in two different hospitals.* (R4)

S2 also points to current practical challenges, explaining that newborns are initially recorded under their mother's name, which can make identification and deduplication more difficult.

When discussing how this problem should be addressed, several respondents suggest the national identification number as the most appropriate long-term solution. R4, who works with developing the trauma registry, recommends using the national ID:

> *Use the national ID as patient identifier from the start. This is the single most important structural decision. It enables cross-facility follow-up and prevents the duplicate patient problem the trauma registry still struggles with.* (R4)

R1 explains that children born recently are assigned a personal number at birth, and P1 confirms that this system is already in place through the national civil registration system. However, several respondents note that implementation of the identification system is not yet fully consistent in practice. Feedback sessions reinforced this, with participants suggesting that reliable identification should still rely on multiple fields, such as parents' names, phone number, and physical address, to reduce the risk of duplicates. Taken together, the responses suggest that the registry should be designed to support NIN as the long-term identifier, while also allowing for other identification solutions while NIN is not yet consistently available.

Taken together, these findings suggest that data quality depends on careful registry design, including validation rules, field descriptions, and predefined response options. At the same time, judgment is required about where strict requirements help and where they risk introducing new sources of error. Reliable patient identification emerges as a closely related challenge, pointing to the need for a registry that supports NIN as the long-term identifier while allowing for additional identification fields until national identification can be applied consistently.

4.1.3 Usability and minimal workload

Another recurring theme in the interviews is the importance of designing the registry so that it will be easy to use in everyday clinical practice. Several respondents highlight that the registry should not become an additional burden for healthcare workers, especially in settings where time, staff, and technical resources are already limited. Ease of use is therefore described as an important condition for future

adoption and consistent data entry. Usability is also connected to whether the registry would feel realistic and manageable in the local clinical setting. The registry should fit existing workflows and not require more time or effort than staff could reasonably be expected to give. R3 particularly highlights the importance of keeping the number of variables low in order to reduce workload and make it easier to achieve complete and reliable data entry:

> *Fewer variables with high completeness and accuracy is better than many variables with poor data quality. The Swedish registry has improved significantly by removing variables over time and focusing on what really matters.* (R3)

This draws on R3's experience with the Swedish CLP registry that has been developed over a long period of time with continuous efforts to remove unnecessary variables. Similar views are also reflected by R4 and R1, who both describe the importance of reducing the registry to variables that are relevant in the local context.

At the same time, the interviews also reveal a different view on how comprehensive the dataset should be. While several respondents argue for a focused and practical dataset with few variables, P1 highlights the value of collecting broader data in order to identify patterns that may not yet be visible. This suggests a tension between minimizing workload and designing the registry in a way that may support future research and long-term learning.

Another decision that improves usability is the choice of digital platform. Several respondents identify offline functionality and mobile access as key technical requirements, so that data can be captured without internet connectivity and entered directly with the patient rather than in a desktop system. S1 also highlights the importance of being able to update records after the initial consultation, both to complement incomplete entries and to update information that may have changed over time, such as contact details or physical address. Two platforms were considered: Kobo Toolbox, which was used in a prior birth defect registry pilot and described as easy to use for nurses and midwives, and REDCap, which is already available at RBC and widely used in clinical research. Ultimately, REDCap was selected as the prototype platform since it supports offline data entry, mobile access, and longitudinal follow-up structures. These are features that Kobo Toolbox does not fully support.

These findings suggest that usability depends on keeping the dataset limited, supporting repeated use across multiple visits, and ensuring that the registry functions reliably under varying infrastructure conditions. These requirements directly shaped both the variable selection and the choice of platform.

4.2 Barriers and Enablers of Registry Adoption and Sustained Use

Across all interview groups, two recurrent concerns regarding adoption emerged: the risk that the registry adds to an already heavy documentation burden, and the challenge of maintaining staff motivation and understanding of purpose over time.

4.2.1 Workload and double documentation

One of the most consistent findings across all interview groups, and the first theme concerning registry adoption, is the concern about double-entry burden. Respondents from all groups identify parallel documentation systems and double documentation as a potential threat to long-term adoption, as it may erode staff motivation over time.

R1 and R2, both of whom have been involved in registry pilot projects in Rwanda, experienced this issue first-hand. In both pilots, the digital registry never fully replaced the paper-based registry, meaning staff had to enter the same information twice. This is described as a key driver of disengagement among facility personnel. R2 argues that this issue must be resolved before any registry can be nationalized:

> *During the pilot, staff were filling in both the existing national paper registry and the new Kobo tool - parallel reporting. This needs to be resolved if the registry is to be sustainable at scale.* (R2)

R3, who is well familiar with the Swedish CLP registry, notes that reducing parallel entry is critical to long-term sustainability. This concern is reinforced by several surgeons who emphasize that data entry will be perceived as an additional task, potentially leading clinicians to rush entries or skip fields under time pressure. N2, a plastic surgeon who works with the NGO Smile Train, notes during a prototype feedback session that the structure of the CLP registry prototype closely mirrors how he already works in the Smile Train portal, and that this alignment with existing workflows reduces the perceived duplication.

This finding emerges across all interview groups and almost all individual respondents, making double documentation one of the most important adoption barriers identified in the study. Designing the registry to replace rather than add to existing documentation systems is therefore essential, as is ensuring alignment with current clinical workflows.

4.2.2 Motivation, training, and understanding of purpose

The other clear finding regarding registry adoption concerns staff motivation, training, and the importance of clinicians understanding the purpose and value of the registry. This theme was most strongly emphasized by registry developers, but was also highlighted by respondents at both facility and national levels.

Across all registry projects discussed, respondents describe a decline in motivation over time. R1, who was involved in a digital birth registry pilot in Rwanda, explains how motivation declined:

> *After approximately one year, engagement dropped significantly - staff missed large numbers of entries, used workload as an excuse, and showed signs of fatigue.* (R1)

Similarly, S2 identifies "registry fatigue" as the main long-term risk, particularly when clinicians do not see the value of their efforts. This pattern is not unique to a single group of people, but emerges across all interview groups, which suggests that initial enthusiasm alone is not enough for a sustainable registry use over time.

To mitigate this decline, multiple respondents suggest similar methods concerning feedback and incentives. Several interviewees emphasize the importance of showing data back to the clinicians that uses the registry. R4 describes how presenting hospitals with concrete gaps in their own data proved more motivating than training alone. Similarly, R3 highlights the role of annual reports displaying completeness, as it creates a form of social accountability where no hospital or clinic wants to perform the worst. R1 further explains that comparing HMIS data with registry entries and introducing per-case financial incentives helped restore engagement:

> *The team began comparing HMIS-reported case numbers against actual registry entries at the end of each month and showing staff the gap. This prompted some improvement, from approximately 20 percent to 60 percent completion rates. Ultimately, a financial incentive per entered case was introduced from the study budget, which proved effective.* (R1)

Beyond motivation, multiple respondents consistently emphasize that understanding the purpose of the registry is a requirement for sustained use. P1 also emphasizes this:

> *If anyone doesn't understand the need for follow-up for these people, it will not be in their priorities. It can challenge the implementation and success.* (P1)

Furthermore, R2 points out that structured engagement, such as monthly online teaching sessions, can also work as a motivational mechanism. Similarly, S3 highlights the importance of training and how it should be structured around understanding of the registry:

> *Training should start with why the registry matters. Staff are more likely to engage when they understand the broader purpose and benefit.* (S3)

Training is therefore described as more than a technical introduction to the registry, since it is also a process of building understanding. This includes both hands-on sessions on how to use the registry and supporting materials such as written guides.

In addition, several respondents stress the importance of ensuring that facility leadership, such as nurse team leaders and hospital administrators, are engaged and supportive of the initiative.

Altogether, the findings indicate that sustained registry use depends on a combination of aligned incentives and a shared understanding of the registry's purpose. Motivation must be actively maintained through continuous training and feedback loops, visible outputs, and in some cases, financial incentives.

4.3 Registry Governance and Future Development for Long-Term Sustainability

The findings on registry governance suggest that the long-term sustainability of the registry depends on how it is institutionally positioned, who owns it after the research phase ends, what technical pathway leads from prototype to national information system, and what kind of value the registry will bring that will support continued investment over time.

4.3.1 Early government involvement and institutional anchoring

A central finding across interviews is the importance of early government involvement and anchoring to ensure long-term sustainability of the registry. This theme is most strongly emphasized by respondents at the national level and registry developers, but is also supported by some clinicians and NGO actors.

Several respondents argue that anchoring the registry within existing governmental structures is critical for enabling nationalization in the future. P1 mentions that the project must align with the current *Health Sector Strategic Plan*, since RBC allocates resources according to national priorities defined in that plan. Without this alignment, there is no institutional basis for investing in the registry. P1 also mentions that a formal collaboration agreement between RBC and the project team is required for practical aspects of the collaboration, such as being recognized as an institutional initiative, and using RBC's REDCap instance. Further, R2 emphasizes the importance of including representatives from the RBC already at the investigator level, as a strategic approach to coalition-building. This early involvement is described as creating a legitimate pathway for scaling the registry beyond the research phase.

Apart from ensuring formal alignment with national institutions, respondents also highlight the importance of engaging the actors within these institutions early in the process. R1 describes that this is an efficient way of adding pressure when facilities fall behind. N1 strengthens this perspective and says:

> *If it is established at the Ministry of Health level from the start, it is not voluntary work but a national requirement. Rwanda's hierarchical structure is an advantage here: if something is mandated at a high level, it will be followed through.* (N1)

Altogether, these findings suggest that early institutional anchoring and involvement of actors with formal authority is critical to position the CLP registry within the national health information system landscape. Establishing these collaborations early simplifies the opportunity for future scaling and integration, and it reduces the risk of the registry remaining a separate system or temporary initiative.

4.3.2 Long-term ownership and registry management

A related but distinct theme concerns the question of long-term ownership and registry management beyond the research project. R4 identifies this as one of the primary reasons why the Rwanda MoH and RBC sometimes hesitate to formally approve information system projects at their research phase:

> *The main reason MoH or RBC hesitates to approve research-phase systems is the question of who manages the system after the research ends. The project needs to demonstrate a credible answer to this before formal institutional approval will be granted.* (R4)

Long-term ownership is therefore not only a post-project concern, but a prerequisite for getting the project approved in the first place. S2 notes that a registry does not run itself, it requires either a committed volunteer or a dedicated paid role for coordination, administration and maintenance of data quality over time. This need for ongoing management is also reflected in R3's experience with the Swedish CLP registry, which transitioned from volunteer maintenance to having a full-time employed coordinator. P1 similarly describes the research team's role as producing an assessment and recommendation, after which RBC and MoH are expected to take over, and notes that funding is a critical enabler for this transition if the registry has been developed outside of RBC's own infrastructure. Without funding, even a well-founded recommendation may not be prioritized.

R4 further suggests that an NGO for cleft care could serve as a host or manager for the registry, given their institutional presence in Rwanda. This would provide the continuity of ownership that RBC requires before committing to formally support the project. S3 agrees on having cleft care clinicians control the registry, but disagrees about tying it to an NGO:

> *For a sustainable long-term registry, the ideal is a dedicated cleft-specific software platform, controlled by cleft care personnel, not regulated by the hospital. Something analogous to what the NGOs have, but national in scope and not tied to a specific NGO.* (S3)

S3 explains that this is to ensure that control remains with the clinical community that it serves instead of having a registry dependent on a particular organization's continued presence and priorities.

Together, these findings suggest that long-term ownership should be addressed explicitly early in the project, and not suspended until the research phase has ended. A clear answer to who manages the registry after the project ends is, according to many respondents, a condition for institutional approval rather than a small detail.

4.3.3 Technical pathway to national integration

The question of long-term ownership is closely tied to the technical pathway the registry will follow. Which platform is ultimately used depends in large part on who owns and manages the registry after the research phase ends. This connection between ownership and technical choice emerged as a recurring theme across the governance findings.

A suggestion that R4 and P1 make is that DHIS2 could be an appropriate long-term platform for a nationally owned registry, as it aligns with Rwanda's existing health information infrastructure and is already used for other disease registries in the country, including trauma, cancer, and diabetes. P1 clarifies that the project's role is to deliver a recommendation and demonstrate a working prototype, after which RBC or MoH would determine the final information system format and be responsible for its development. R2 further confirms that if the registry is eventually owned by RBC, those decisions will be made by them.

A different perspective is raised by S2 and S3, who suggest that the registry could alternatively be developed as a standalone, customized information system independent of any specific hospital. As presented in the citation above, S3 further argues that the standalone solution should be similar to current NGO patient registries but national in scope.

This means that no single technical pathway is determined at this stage. DHIS2 emerges as the natural platform if the registry transitions to RBC ownership, while a dedicated standalone information system is seen as an alternative if the clinical community or an NGO manages it. The choice of platform is therefore as much a governance decision as a technical one.

4.3.4 Future value and incentives for continued development

Future value and incentives for continued development emerged as a final governance theme. Respondents describe several forms of future value that could support continuous investments in the registry over time. One recurring idea is that the registry can create a basis for research and reporting. Both R3 and S3 describes

this as a possible incentive for continued use of the registry. If the data can be used by clinicians, students, and researchers for reports, thesis work, and publications, the registry may become more valuable over time. R3, for instance, suggests that resident doctors can use registry data in research projects, which will give them a direct interest in data quality. The respondent also suggests that the registry must be seen as belonging to the local users and institutions rather than as an external project. In this way, future academic and clinical use of the data may strengthen both motivation and data quality.

R3 further explains that the Swedish registry has developed a funding model around registry-based output. At first, clinics paid to participate in the registry, but over time funding came to depend more on quality standards and publications based on registry data. This creates a cycle where the registry produces data, the data can be used for reports and research, and those outputs can support further funding and development. R3 suggests that a similar model can also be useful in Rwanda as a way to support long-term sustainability. In that way, the registry can support clinical work, generate research, and help create financial sustainability over time.

Respondents describe a broader long-term value of the registry in relation to multidisciplinary care. Several interviewees describe that cleft care in Rwanda is still largely limited to surgery and nutrition support, while speech therapy and orthodontics remain very limited. The registry is described as a way to support longer-term follow-up and make it possible to track outcomes beyond surgery alone:

> *A national registry would help by making the scale of unmet need visible, which could attract interest and funding to build capacity in the missing specialties.* (S1)

> *There is already a will here in Rwanda to follow up patients on speech and dental outcomes – not just operate and move on. A registry would make that possible. It would fundamentally change the quality of care.* (N1)

S2 also describes multidisciplinary team development as something still in progress, and R2 suggests that national registries can provide a basis for more detailed follow-up as capacity is growing. N1 also elaborates on the potential of the follow-up form and suggests that it could support remote follow-up over time, by allowing parents or caregivers to answer selected questions online without having to attend the hospital in person. This would reduce the clinical workload while still enabling continuous tracking of patient outcomes.

S2 also describes a broader future value of the registry:

> *There is currently no single open-source CLP registry in the world which is flexible enough to be deployed in multiple settings. If we create a registry, everyone can download it from the web and use it.* (S2)

He suggests that Rwanda potentially can develop an open-source CLP registry that may be useful in other countries and settings, not only nationally, meaning that Rwanda can become a pioneer in this area.

Research output, registry-based funding models, and multidisciplinary care development are identified as key sources of future value. Making unmet needs visible is seen as a means of attracting investment and building capacity over time, and developing an open-source registry model would extend its value beyond Rwanda's borders.

5
Discussion

This chapter discusses the findings in relation to the theoretical framework. Three interconnected themes are addressed, where the first concerns how adoption barriers can be identified and addressed before a system is deployed. The second examines the design trade-offs that arise when developing a registry within a centralized, low-resource context. The third addresses how a centralized governance structure shapes the conditions for adoption and long-term sustainability.

5.1 Anticipating Adoption Through Design

The findings from this case study show something that is largely absent from existing adoption research: that barriers to adoption can be identified and addressed before a system is deployed. This stands in contrast to how adoption is normally studied. In the UTAUT framework, adoption is explained through performance expectancy, effort expectancy, social influence, and facilitating conditions, all measured through users' perceptions after they have encountered the technology (Venkatesh et al., 2003). Studies in low- and middle-income country settings similarly gather evidence after implementation (Karuri et al., 2017; Wang et al., 2025). Across this literature, there is a shared assumption that adoption is something to be measured and addressed once a system has already been deployed.

In the development of the CLP registry, barriers that are usually discovered after deployment were instead identified during interviews and feedback sessions and translated into design decisions during prototyping. We propose the concept of *anticipatory adoption* to describe this approach: a design process where known or predictable adoption barriers are identified prior to deployment and translated into concrete design choices, with an explicit aim of reducing the risk of adoption failure before the system is introduced. That these barriers were identified and addressed before deployment is significant. Yang et al. (2015) identify this pre-adoption phase as systematically underexamined, noting that neglect of it frequently results in poor fit between system and organizational context. The approach taken in this study addresses precisely that phase.

5.1.1 Early identification of adoption barriers

The identification of some barriers was made possible by how the design process itself was structured with iterative feedback sessions. Through this process, many adoption barriers became visible during the design phase. Concerns regarding workload, infrastructure constraints and the registry's purpose all emerged while the system was still being shaped. This reflects the principles of participatory design, where system requirements emerge through engagement with users rather than being specified in advance (Boland, 1978; Cherry & Macredie, 1999). It is also consistent with Aanestad et al. (2014)'s finding that integration in complex health settings depends on continuous interaction across organizational levels.

It is important, however, to distinguish between anticipatory adoption and the already existing concept of participatory design. The participatory design literature primarily concerns how users are involved in the design process, it does not map known adoption barriers onto design decisions. Participatory design is oriented toward co-creation and democratic involvement in shaping a system, but user involvement does not automatically surface adoption barriers unless those barriers are actively sought. A design session might not necessarily reveal that parallel paper systems create double documentation burdens, or that staff motivation declines when purpose is not understood. Anticipatory adoption therefore adds a layer where it treats user engagement as an opportunity to identify predictable barriers before deployment. In this sense, participatory design provides the method, while anticipatory adoption provides the purpose of that engagement.

Other barriers were instead identified during early interviews, such as double documentation. Across all interview groups, parallel entry into both the registry and existing paper-based systems was identified as the main reason for disengagement and a threat to long-term sustainability. This threat is not a perception that users form after using the system. Findings of this study point to evidence from prior registry pilots, where parallel entry emerged because the digital tool was introduced alongside an existing paper registry rather than replacing it. Early interviews also identified unreliable internet connectivity and the absence of consistent desktop access across clinical settings as predictable infrastructure constraints that would affect routine use.

5.1.2 Translating barriers into design decisions

A recurring concern among clinicians was that the registry would add to an already demanding workload without making individual tasks easier. In response, the number of variables was kept to a minimum, conditional fields were introduced so that more specific questions only appear when relevant, and media uploads were embedded within each clinical form to align data entry with the natural flow of clinical events. A feature for automatically calculated z-scores was also included, to minimize manual work and make the registry immediately useful at the point of data entry. These design decisions can be seen as a way of anticipating effort expectancy, which is one of the dimensions in the UTAUT framework. However, in this case,

the decisions were made during the design phase, and not in response to complaints after deployment.

A related but structurally distinct barrier concerns double documentation. Where workload from variable quantity can be addressed through form design, the burden of parallel entry into both the registry and existing paper-based or NGO systems cannot be solved by a feature decision. This connects to the theoretical argument made by Orlikowski (1992) and Monteiro and Hanseth (1996), who argue that design decisions shape how work is organized in practice. In this context, their argument would suggest that adoption failures caused by parallel entry are not accidental but the result of specific design choices about whether a system replaces or adds to existing documentation. In the case of this registry, the concrete design response was to align the prototype structure with registries already in use by NGO actors. Beyond that, however, the findings are limited in relation to design-related solution to double documentation. Although it was identified as a critical barrier by respondents across all groups, it was difficult to identify further design decisions that could structurally prevent it. Whether the registry replaces or adds to existing systems therefore also depends on implementation decisions and institutional coordination that lie outside the design itself.

Infrastructure presented another important barrier. It was clear from early interviews that reliable internet connectivity could not be guaranteed across clinical settings in Rwanda. Instead of selecting a platform and adapting later, a platform with mobile access and offline functionality was chosen from the start. This is what UTAUT describes as facilitating conditions, which in the literature was identified as the most frequently reported barrier to adoption in low- and middle-income settings (Wang et al., 2025). In the CLP registry prototype, it was addressed prospectively through a platform decision rather than later through technical support after rollout.

A more complex finding concerned how clinicians understood the purpose of the registry. Several respondents noted that if the staff does not understand why follow-up matters for this group of patients, the registry will not be prioritized. Unlike effort expectancy or infrastructure, this barrier could not be addressed through a single design feature. It required making the registry's value visible before use begins, through training designed around purpose. This connects to NPT's concept of coherence: the collective sense-making work that must happen before a new practice can become routine (Murray et al., 2010). In NPT, coherence typically develops after a system is introduced. What this case suggests is that coherence work can be initiated through design choices made before deployment, by building purpose visibly into the system itself. Taken together, the UTAUT dimensions and NPT's concept of coherence were in this case applied during the design phase itself instead of after, which suggests that the design phase can be understood as an adoption activity.

Anticipatory adoption does not replace post-implementation strategies. Training,

feedback loops, financial incentives, and institutional anchoring remain necessary for sustained use. Rather, it represents a prior layer of adoption work that reduces the burden on those later interventions by removing predictable barriers before they arise. This matters particularly in low-resource settings like Rwanda, where the capacity to course-correct after deployment is limited and the costs of adoption failure are correspondingly higher.

5.2 Design Trade-Offs in a Centralized, Low-Resource Context

The design of the registry involved several trade-offs due to context-specific conditions in Rwanda. Tensions appear between dataset scope and data quality, standardization and local fit and between top-down implementation and a need for bottom-up clinical input in the design process.

5.2.1 Dataset scope and data quality

A central tension in the registry design process concerned how many variables to include and what level of detail to capture. This was identified through anticipatory adoption as described in 5.1. The results from the interviews and feedback sessions show a clear difference between national-level and clinical perspectives. From a governance perspective, broader data collection was seen as valuable for future research, planning and national oversight. Clinicians, however, consistently argued for a smaller and more focused dataset as a condition for reliable and sustained data entry. As a registry developer noted, drawing on experience from the Swedish registry, fewer variables with high completeness are preferable to a broader dataset with poor data quality.

This tension reflects what Hanseth et al. (1996) describe as a core challenge in information infrastructure design: every variable added to a registry becomes part of a shared standard that clinicians across sites are expected to follow, and a standard that is too demanding risks not being followed consistently. From this perspective, a broader dataset does not automatically create more value. If it becomes too demanding to complete reliably, the attempt to capture more information could paradoxically weaken the quality of the data produced. The value of a standard therefore depends on whether it can be sustained in everyday clinical work. In Rwanda, where clinicians already face constraints in time, staffing, and documentation workload, this makes the scope of the dataset a critical design decision.

This same logic extends to how the registry could support AI-based tools over time. One example that was mentioned was AI-based speech training built using speech recordings which would support the expansion of speech therapy in Rwanda. However, these possibilities depend on data that is complete, consistent and clinically meaningful. More data is therefore not automatically better preparation for AI either. A smaller set of well-documented speech, media and follow-up variables may

provide a stronger future foundation than a broader dataset with missing or unreliable entries.

A related tension emerged at the level of individual field design. Mandatory fields and validation rules were identified as important mechanisms for ensuring completeness and consistency. However, feedback from the prototype sessions suggested that making too many fields mandatory risks producing a different kind of data quality problem: users may enter incorrect information simply to progress through the form. A mandatory field that cannot always be completed accurately may therefore introduce errors rather than prevent them, which also points to a limit of standardization as a quality mechanism.

Taken together, these findings suggest that the registry should be built around a limited core of essential variables: those needed to identify patients, follow them over time, and coordinate care across facilities. The tension between governance needs and clinical workload may not fully resolve over time, suggesting that decisions about dataset scope will need to be revisited continuously as the registry develops. As Hanseth et al. (1996) argue, a standard that cannot be sustained in practice loses its coordinating value, and in Rwanda's context, keeping the dataset realistic is therefore a prerequisite for the standard to function at all.

5.2.2 Standardization versus local fit

A central trade-off in the registry design concerned how much to standardize across contexts and how much to adapt to local conditions. One of the surgeons observed that there is currently no open-source CLP registry flexible enough to be deployed across different settings, and suggested that Rwanda has the potential to develop one. This ambition requires a sufficiently general standard where context-specific elements can be flexibly modified. However, the process of adapting the Swedish registry to Rwanda revealed how much needed to change. Variables that were meaningful in the Swedish context were not always relevant or feasible in Rwanda, and new variables specific to the Rwandan clinical and institutional context had to be added. This suggests that developing a registry general enough to be directly transferable to other countries would be a significant challenge.

This experience is consistent with the idea of "same, same but different" presented by Sahay et al. (2013), where systems transferred across contexts retain a shared structure while being adapted to local conditions. It also reflects the tension that Hanseth et al. (1996) describe between standardization and flexibility: standards enable coordination and comparability, but if they do not fit local conditions they risk not being used consistently. This adaptation process therefore points to a broader challenge: developing a registry general enough to function across different settings, while still being specific enough to be used reliably in each one. A registry designed to function across multiple settings would need a sufficiently general core, standardized cleft classifications, outcome measures, and follow-up logic meaningful beyond one country, while allowing context-specific variables to be added or mod-

ified locally. The experience from adapting the Swedish registry suggests that this balance is difficult to achieve, as the line between what is generalizable and what is context-specific is not always clear in advance.

Pacifico Silva et al. (2018) argue that health innovations need to be designed for the workforce, infrastructure and financing of the setting where they will operate. This suggests that the open-source ambition is better understood as a longer-term possibility than a first-version design goal. The registry first needs to work in Rwanda before it can travel elsewhere.

5.2.3 Top-down implementation, bottom-up design

A central finding across the results is that Rwanda's centralized governance creates a clear tension in registry development. It may support implementation but creates risks in the design phase. More specifically, the findings suggest that centralized governance can strengthen the authority and coordination needed for national implementation, while simultaneously increasing the risk when early design decisions are made without sufficient clinical input. These two dimensions sometimes pull in different directions, and how that tension is managed has direct implications for whether a registry becomes both adoptable and useful in practice.

One of the NGO respondents illustrated the advantage of centralized implementation most directly: if system implementation is mandated at ministry level in Rwanda's hierarchical structure, it will be followed through. This aligns with what Bustamante (2010) identifies as a core strength of centralized governance: the capacity to drive coordinated adoption across facilities. However, Dwicaksono and Fox (2018) caution that governance structure alone does not determine outcomes. What matters is how the balance between central control and local input is managed in practice.

The design risk of centralized governance became visible mainly through the policymakers' perspective. Their preference for broader data collection reflects a governance logic focused on what the registry should produce at national scale rather than what clinicians could realistically document in daily practice. Kumar et al. (2018) describe a structurally similar pattern in India, where health information systems designed primarily around policymaker needs failed to support healthcare providers in their work. This does not mean that national planning needs are unimportant. Rather, it shows that a registry designed mainly from a reporting perspective risks becoming disconnected from the clinical work through which the data is actually produced.

The most concrete and practically relevant design improvements in this study came from the surgeons in their prototype feedback sessions, rather than from governance actors. They contributed suggestions related to conditional fields, embedded media, nutritional status variables and workflow-aligned form structures. These suggestions reflected that decentralized design can offer knowledge of everyday clinical work that

was not visible from a national governance perspective. These are not minor details. As Monteiro and Hanseth (1996) argue, small design decisions have implications beyond the technical system itself. In a centralized context, those decisions risk being made too far from clinical practice. In Rwanda, where resources are limited and staff already face parallel documentation systems, this risk is particularly consequential.

This points to a broader pattern in how governance structure shapes the pace and quality of different phases of system development. Aanestad et al. (2014) describe in the Indian case how a centralized governance structure slowed the design process considerably: even minor adjustments required coordination across institutional levels. Yet once political support was established from above, implementation accelerated. This illustrates a trade-off relevant also to Rwanda's case: centralized governance may constrain the design phase by limiting whose knowledge shapes the system, but it can accelerate implementation when institutional alignment is in place. Although Rwanda is not yet in the implementation phase, similar challenges are likely to emerge. It can therefore be argued that a decentralized design logic could help mitigate this tension. By incorporating clinical input early, data quality may be preserved and the registry can remain aligned with everyday work practices even within a centralized implementation structure.

The core argument from the findings is therefore that centralized implementation requires a decentralized design process to work well in practice. In a strongly centralized system like Rwanda's, that connection does not emerge automatically, it has to be built into the development process. Building in a participatory, bottom-up design is therefore a necessary condition for the registry to be both adoptable and useful.

5.3 Governance, Institutional Anchoring, and Long-Term Sustainability

Rwanda's centralized governance structure has direct implications for how the registry is adopted and sustained over time. Centralization provides institutional authority that can drive adoption in ways that decentralized systems cannot, but this authority only leads to adoption if the registry is genuinely anchored within national structures and not only approved by them. Beyond initial anchoring, long-term sustainability further depends on whether institutional actors understand the registry's value and see reason to maintain and develop it over time, considerations that must be addressed already during the early development phase. The findings therefore address three related challenges: how institutional anchoring shapes initial compliance, why compliance does not guarantee sustained use, and what conditions support long-term ownership and continued investment.

5.3.1 Institutional anchoring as an adoption mechanism

A central finding across the interviews is that formal recognition at MoH or RBC level changes how adoption works in a way that has no direct equivalence in decentralized settings. When the registry is institutionally anchored, clinicians are no longer in a position to decide whether to engage with it. Instead, engagement becomes an organizational requirement. Several respondents explicitly described this and stated that a mandate issued at the ministry level in Rwanda's hierarchical structure will be followed.

This dynamic has implications for how social influence, one of the mechanisms in the UTAUT framework, works in Rwanda's context. Venkatesh et al. (2003) describe social influence as peer norms and recommendations from colleagues. However, in Rwanda's centralized context, this influence could be argued to work vertically through the institutional hierarchy. A ministry-level mandate does not encourage clinicians to use the registry, but it requires clinicians to justify why they do not use the registry.

The findings also show how coherence, as described in NPT, develops around a new practice. Murray et al. (2010) describe coherence as something built gradually through experience, once participants start to understand what a practice is and why it matters. Institutional anchoring can be seen as a pre-establishment of this, before the registry starts to be used. It signals that the registry has legitimacy, and reduces the sense-making work that otherwise would be need to be built up through use. Further, cognitive participation, meaning the sustained commitment required for a practice to become routine, is easier to sustain when institutional actors are visibly committed to the initiative.

The consequences of not establishing institutional anchoring are visible in the case of Babyl, Rwanda's telemedicine platform, which achieved a wide reach before being suspended. Despite its initial scale, the platform operated as a parallel system with limited integration into Rwanda's national health infrastructure and relied on donor-dependent financing, unlike a comparable system in India, which was integrated within the national digital health strategy through government leadership from the start and achieved sustained scale as a result (Musange Furere et al., 2026). This pattern is consistent with what registry developers in this study described from prior pilot projects in Rwanda, where the absence of formal institutional coalitions contributed to declining engagement and, in some cases, systems that never moved beyond the pilot phase. Together, these cases suggest that in Rwanda's context, institutional anchoring is a highly important support for adoption.

5.3.2 The gap between compliance and sustained use

Although institutional anchoring is a condition for adoption, the findings show that it does not determine what happens after the initial engagement. A consistent pattern from the interviews and experiences with prior registry projects in Rwanda was that early motivation is often high, but it declines over time.

A factor contributing to this pattern was that when clinicians did not understand the purpose of the registry, it was not prioritized in daily work regardless of formal requirements. In the context of this study, purpose understanding and incentives are closely linked: feedback mechanisms that make registry data and completeness visible to those entering it were identified in the interviews as a means of reinforcing why the registry matters, not only as a motivational tool. When this is absent, registry use risks being reduced to a formal requirement. This pattern is consistent with what Wang et al. (2025) discuss regarding adoption challenges in low-resource settings. They identified the absence of facilitating conditions, including training, feedback mechanisms, incentive structures and supporting infrastructure, as the most frequently reported barrier to sustained use.

A structural response to the need of supporting infrastructure is described by Aanestad et al. (2014) in the Indian case. Dedicated IT units were established at different administrative levels to maintain the connection between central governance and local use. These units resolved practical problems and ensured that the system remained usable in everyday clinical work over time. A comparable function may be needed in Rwanda once the research phase ends. Several respondents identified the need for dedicated operational capacity beyond the project period, and support structured at different levels of the health system is one way of meeting that need.

This connects to the argument made in section 5.1, and a conclusion can be drawn that neither anticipatory adoption nor institutional anchoring alone is sufficient for sustained registry use. Anticipatory adoption reduces predictable barriers before deployment, and institutional anchoring establishes the authority that makes engagement an organizational requirement. Both are preconditions, not guarantees. Achieving sustained use over time requires continuous work with staff motivation and ensuring that operational support is in place after the research phase ends.

5.3.3 Long-term registry ownership and management

A recurring finding across the interviews is that a plan for long-term ownership is required for institutional approval, and must be resolved during the development phase rather than after it ends. Respondents with experience from other registry projects in Rwanda describe how MoH and RBC may hesitate to formally support research-phase systems if no plan for post-project management exists.

The findings reveal different perspectives on how the registry should be managed and its ownership. One approach is government ownership, where the registry is managed by RBC, which would determine how the system is integrated into national health infrastructure, with DHIS2 integration as one possible solution. This is most consistent with how national registries in Rwanda are normally organized in the long term. Another suggestion from the findings is NGO-anchored ownership, where an organization with an established presence in Rwanda serves as an intermediate owner, to give RBC assurance of continuity before the registry is formally

transitioned to government ownership. Another suggestion was to have the registry as a standalone system managed by the clinical cleft community, independent of any single organization. Which alternative for ownership and management is most appropriate depends partly on how well the registry aligns with RBC's own priorities. This is a condition that reflects a broader pattern identified by Pacifico Silva et al. (2018), who argue that innovations must align with institutional priorities to gain legitimacy. However, if there is insufficient alignment with national priorities, NGO-anchored ownership may serve as an intermediate arrangement while the conditions for full nationalization are established. In Rwanda's centralized context, the long-term endpoint is RBC ownership, where the system is embedded within the national health infrastructure, regardless of whether the system is built in DHIS2 or in a standalone system.

What these approaches have in common is that ownership in all cases remains with actors who are institutionally rooted in Rwanda's health system, despite the registry building on the Swedish registry and the prototype having been developed externally. This reflects a consistent view among respondents that local institutional ownership and management is a prerequisite for long-term sustainability. Moucheraud et al. (2017) and Watson-Grant et al. (2017) both identify insufficient local ownership as a sustainability risk, particularly when systems have been built and maintained externally. The findings from this study reinforce that argument: regardless of which approach is pursued, the transition to local ownership must be planned explicitly and early.

5.3.4 Future value as an incentive for adoption

For the registry to achieve long-term sustainability, it is not sufficient that clinical users adopt it. The institutions responsible for maintaining and financing it must also come to understand its value and see reason to invest in its continued development. This can be understood as a form of adoption at the institutional level, where government actors and national bodies must be convinced that the registry is worth owning over time.

Several sources of future value identified in the findings may support this. As discussed in relation to design trade-offs, the registry could over time serve as a foundation for AI-based tools and potentially as an open-source model that can be deployed in other low-resource settings, which would extend its value beyond Rwanda. Beyond these possibilities, the findings point to two additional sources of future value that are likely to be developed earlier.

The first concerns remote follow-up. One NGO respondent suggested that the follow-up form could over time allow parents or caregivers to answer selected questions online without attending the hospital in person. In a setting where geographic distance and limited resources make repeated hospital visits difficult, this could reduce the burden on clinical staff while still enabling continuous tracking of patient outcomes.

This possibility, like AI-based tools, depends on the core registry first being reliable and consistently used.

The second concerns research and funding cycles. The Swedish registry demonstrates how this kind of future value can develop over time: registry data has contributed to publications and reports, which in turn has strengthened the registry's legitimacy and supported continued funding. This reflects what Moucheraud et al. (2017) identify as a key condition for sustainability: that systems demonstrate ongoing value to the institutions and actors responsible for maintaining them. A similar logic could apply in Rwanda, where data on follow-up, speech outcomes or multidisciplinary care gaps could become a basis for local research and help create a justification for continued investment that does not depend only on external funding.

6
Conclusion

The purpose of this study was to examine how a national digital health registry is developed and established during its early phase in a centralized context, through the case of a CLP registry in Rwanda. The study found that development and establishment are closely intertwined processes, and that technical design, adoption, and governance cannot be considered in isolation. The central argument is that these processes need to be managed through two complementary logics: design requires bottom-up clinical involvement, while implementation benefits from top-down institutional authority. In a centralized healthcare system, national authority can provide the legitimacy, ownership, and coordination needed to establish a registry, but it does not ensure that the registry works in clinical practice. Bottom-up clinical involvement must therefore be built into the development process, so that centralized institutional anchoring is combined with a design that fits everyday clinical practice.

The design phase is where adoption conditions are most actively shaped. Adoption barriers were in this case identified before deployment and translated into concrete design decisions. The approach is referred to as anticipatory adoption. This means that instead of addressing barriers after a digital health system has been introduced, predictable barriers are anticipated during the design phase and addressed through specific design choices. Ease of use is one of the clearest examples: clinician concerns about increased workload were addressed through design before the registry was deployed, through decisions such as keeping the number of variables to a minimum and introducing conditional fields so that more specific questions only appear when relevant.

Through the approach of anticipatory adoption, several design trade-offs were identified and considered when deciding on specific registry features and variables. The most significant concerned the balance between collecting sufficient data for governance purposes and keeping the registry realistic enough for clinical use. The most important design decisions emerged from clinicians during prototype feedback sessions, which reinforces the importance of involving them directly in the design process.

At the same time, the study found that involving government actors early is critical for the registry to be formally recognized and eventually nationally owned. In centralized context, institutional anchoring changes how adoption works: a ministry-level mandate makes registry use required instead of voluntary. For this reason, a top-down implementation strategy is proposed alongside the bottom-up design

approach, with governmental ownership as the preferred long-term endpoint. In Rwanda, ownership may initially be anchored at RBC or through an NGO before transitioning toward full government ownership, and planning this transition explicitly is a governance requirement that must be addressed during the development phase.

Institutional anchoring establishes the conditions for adoption but does not guarantee sustained use. Evidence from prior registry projects in Rwanda shows that motivation declines over time even when formal requirements are in place. Continuous engagement work with training, feedback, motivation, and incentives is therefore needed alongside institutional mandates to avoid registry fatigue and maintain sustained use.

Together, anticipatory adoption in the design phase with bottom-up clinical involvement, top-down institutional anchoring, and continuous engagement work at all levels are the conditions that need to be addressed during the early-phase development of a sustainable national digital health registry in a centralized context, as illustrated in Figure 6.1.

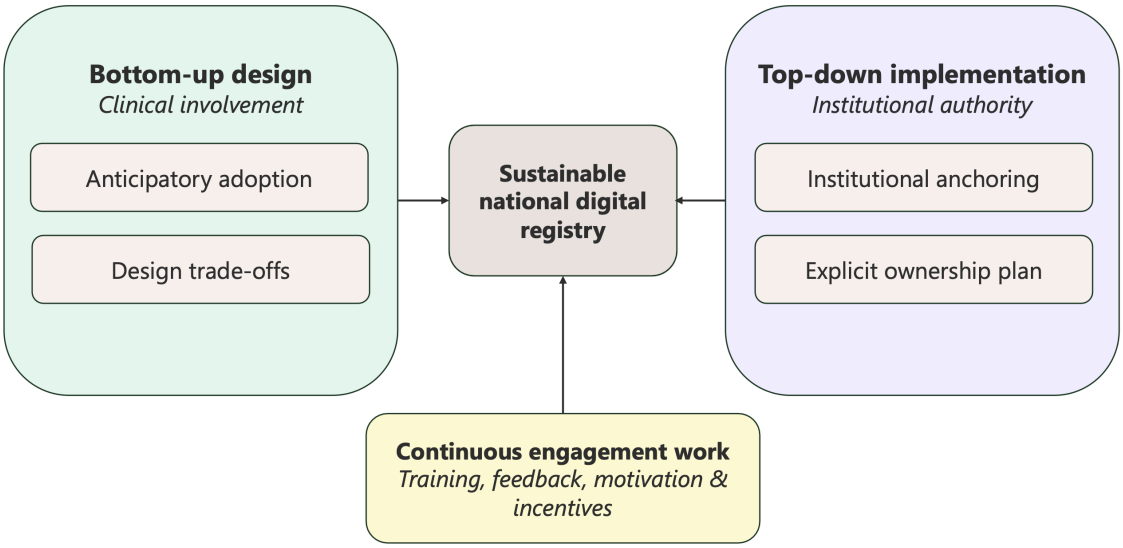

Figure 6.1: Conditions for early phase development and establishment of a sustainable national digital health registry in a centralized context.

6.1 Directions for Future Research

Future research could include a broader group of policymakers and institutional actors. This would strengthen understanding of ownership, funding, and national integration. If the registry develops toward remote follow-up or caregiver-reported data, patient and caregiver perspectives should also be included.

A central finding was the importance of avoiding double documentation as a barrier to adoption, yet the study did not produce sufficiently clear answers regarding how this can be addressed during the early development phase. Future research could therefore examine whether double documentation is preventable through concrete design decisions, or whether it is primarily a question of implementation strategy and how facilities coordinate the replacement of existing documentation systems.

Finally, comparative studies on disease specific registries could examine whether the combination of top-down implementation with bottom-up design and its associated concepts are relevant beyond this case. The registry may also create potential for future research on multidisciplinary cleft care in low-resource countries and connected AI-based tools.

Bibliography

Aanestad, M., Jolliffe, B., Mukherjee, A., & Sahay, S. (2014). Infrastructuring work: Building a state-wide hospital information infrastructure in india. *Information Systems Research*, *25*(4), 834–845. https://doi.org/10.1287/isre.2014.0557

Ansari, S., Fiss, P. C., & Zajac, E. J. (2010). Made to fit: How practices vary as they diffuse. *Academy of Management Review*, *35*(1), 67–92. https://doi.org/10.5465/amr.35.1.zok67

Bananeza, R. M. (2025). Revolutionizing digital health in rwanda: Progress toward universal health coverage. *Journal of Indian Physician Associates*, *1*(1), Article 4. https://digitalshowcase.lynchburg.edu/jipa/vol1/iss1/4/

Bell, E., Bryman, A., & Harley, B. (2022). *Business research methods* (6th ed.). Oxford University Press.

Bertelsmann Stiftung. (2024). *Rwanda country report 2024*. Bertelsmann Stiftung. https://bti-project.org/en/reports/country-report/RWA

Boland, R. J. (1978). The process and product of system design. *Management Science*, *24*(9), 887–898. http://www.jstor.org/stable/2630626

Bowens, F. M., Frye, P. A., & Jones, W. A. (2010). Health information technology: Integration of clinical workflow into meaningful use of electronic health records. *Perspectives in Health Information Management*, *7*, 1d.

Bustamante, A. V. (2010). The tradeoff between centralized and decentralized health services: Evidence from rural areas in mexico. *Social Science & Medicine*, *71*(5), 925–934. https://doi.org/10.1016/j.socscimed.2010.05.022

Chamorro-Koc, M. (2024). Prototyping for healthcare innovation. In E. Miller, A. Winter, & S. Chari (Eds.), *How designers are transforming healthcare*. Springer. https://doi.org/10.1007/978-981-99-6811-4_6

Chaulagai, C. N., Moyo, C. M., Koot, J., Moyo, H. B. M., Sambakunsi, T. C., Khunga, F. M., & Naphini, P. D. (2005). Design and implementation of a health management information system in malawi: Issues, innovations and results. *Health Policy and Planning*, *20*(6), 375–384. https://doi.org/10.1093/heapol/czi044

Cherry, C., & Macredie, R. D. (1999). The importance of context in information system design: An assessment of participatory design. *Requirements Engineering*, *4*(2), 103–114. https://doi.org/10.1007/s007660050017

Dwicaksono, A., & Fox, A. M. (2018). Does decentralization improve health system performance and outcomes in low- and middle-income countries? a systematic review of evidence from quantitative studies. *The Milbank Quarterly*, *96*(2), 323–368. https://doi.org/10.1111/1468-0009.12327

Government Offices of Sweden. (2020). *Swedish development cooperation with rwanda.* https://www.swedenabroad.se/sv/utlandsmyndigheter/rwanda-kigali/development-cooperation/swedish-development-cooperation-with-rwanda/

Hanseth, O., Monteiro, E., & Hatling, M. (1996). Developing information infrastructure: The tension between standardization and flexibility. *Science, Technology, & Human Values*, *21*(4), 407–426.

Heeks, R. (2002). Information systems and developing countries: Failure, success, and local improvisations. *The Information Society*, *18*(2), 101–112. https://doi.org/10.1080/01972240290075039

Hevner, A. R., March, S. T., Park, J., & Ram, S. (2004). Design science in information systems research. *MIS Quarterly*, *28*(1), 75–105.

Ilesanmi, O. S., & Afolabi, A. A. (2022). Sustainability of donor-funded health-related programs beyond the funding lifecycle in africa: A systematic review. *Cureus*, *14*(5), e24643. https://doi.org/10.7759/cureus.24643

Karuri, J., Waiganjo, P., & Orwa, D. (2017). Determinants of acceptance and use of dhis2 in kenya: Utaut-based model. *Journal of Health Informatics in Developing Countries*, *11*(2). https://www.jhidc.org/index.php/jhidc/article/view/167

Klecun, E., Kankanhalli, A., & Zhou, Y. (2025). Advancing understanding of scaling health information infrastructures: Learning from ehr initiatives in england. *MIS Quarterly*, *49*(2), 759–776. https://doi.org/10.25300/MISQ/2024/17307

Klintö, K., Karsten, A., Marcusson, A., Paganini, A., Rizell, S., Cajander, J., Brunnegård, K., Hakelius, M., Okhiria, Å., Peterson, P., Abdiu, A., Havstam, C., Mark, H., Hagberg, E., Björnström, L., Wiedel, A.-P., & Becker, M. (2020). Coverage, reporting degree and design of the swedish quality registry for patients born with cleft lip and/or palate. *BMC Health Services Research*, *20*, 528. https://doi.org/10.1186/s12913-020-05389-x

Kumar, M., Mostafa, J., & Ramaswamy, R. (2018). Federated health information architecture: Enabling healthcare providers and policymakers to use data for decision-making. *Health Information Management Journal*, *47*(2), 90–101. https://doi.org/10.1177/1833358317709704

Marwaha, J. S., Landman, A. B., Brat, G. A., Dunn, T., & Gordon, W. J. (2022). Deploying digital health tools within large, complex health systems: Key considerations for adoption and implementation. *npj Digital Medicine*, *5*(1), 13. https://doi.org/10.1038/s41746-022-00557-1

McCool, J., Dobson, R., Muinga, N., Paton, C., Pagliari, C., Agawal, S., Labrique, A., Tanielu, H., & Whittaker, R. (2020). Factors influencing the sustainability of digital health interventions in low-resource settings: Lessons from five countries. *Journal of Global Health*, *10*(2), 020396. https://doi.org/10.7189/jogh.10.020396

Ministry of Health Rwanda. (2017). *Health service packages for public health facilities.* Ministry of Health Rwanda. Retrieved February 12, 2026, from https://www.moh.gov.rw/fileadmin/user_upload/Moh/Publications/Legal_Framework/Public_health_Facilities_service_packages_in_Rwanda-1.pdf

Ministry of Health Rwanda. (2024a). *Health sector strategic plan V: July 2024–june 2029* (tech. rep.). Ministry of Health, Republic of Rwanda. Retrieved May

27, 2026, from https://www.moh.gov.rw/fileadmin/user_upload/Moh/Publications/Reports/new_annual_Report/HSSP_V_signed.pdf

Ministry of Health Rwanda. (2024b). *Mission*. Retrieved February 12, 2026, from https://www.moh.gov.rw/about/overview

Monteiro, E., & Hanseth, O. (1996). Social shaping of information infrastructure: On being specific about the technology. In W. J. Orlikowski, G. Walsham, M. R. Jones, & J. I. DeGross (Eds.), *Information technology and changes in organizational work*. Chapman; Hall. https://doi.org/10.1007/978-0-387-34872-8_20

Moucheraud, C., Schwitters, A., Boudreaux, C., Giles, D., Kilmarx, P. H., Ntolo, N., Bangani, Z., St. Louis, M. E., & Bossert, T. J. (2017). Sustainability of health information systems: A three-country qualitative study in southern africa. *BMC Health Services Research*, *17*(1), 23. https://doi.org/10.1186/s12913-016-1971-8

Murray, E., Treweek, S., Pope, C., MacFarlane, A., Ballini, L., Dowrick, C., Finch, T., Kennedy, A., Mair, F., O'Donnell, C., Ong, B. N., Rapley, T., Rogers, A., & May, C. (2010). Normalisation process theory: A framework for developing, evaluating and implementing complex interventions. *BMC Medicine*, *8*, 63. https://doi.org/10.1186/1741-7015-8-63

Musange Furere, S., Absolomon, G., Umutoni, N., Matutina Umuhoza, S., K Rubuga, F., Nsaba-Uwera, Y., Singa Muhoza, P., Hitimana, R., Condo, J., & Humuza, J. (2026). Digital primary health in rwanda: Qualitative study of user experiences and implementation lessons from babyl's telemedicine platform. *Journal of Medical Internet Research*, *28*, e84832. https://doi.org/10.2196/84832

National Identification Agency. (2026). *About nida*. Retrieved May 4, 2026, from https://www.nida.gov.rw/about-nida

Ntaganda, E., Rusingiza, E., Rukundo, G., Ng'ang'a, L., Hedt-Gauthier, B., El-Khatib, Z., Kwan, G. F., Gapira, G., Worral, N. K., Swain, J., Kagame, A., Mutumbira, C., Ruhamya, N., Bolman, C., Sewase, J., Ndayisiba, G., Bolman, R. M., Goldberg, H., & Mucumbitsi, J. (2020). Postoperative rheumatic heart disease follow-up: Creating a national registry and first results from rwanda. *Annals of Global Health*, *86*(1), 115. https://doi.org/10.5334/aogh.2719

Operation Smile Sverige. (2023). *Nu är vi redo att ta nästa steg i rwanda*. Retrieved February 12, 2026, from https://operationsmile.se/berattelse/nu-ar-vi-redo-att-ta-nasta-steg-i-rwanda/

Orlikowski, W. J. (1992). The duality of technology: Rethinking the concept of technology in organizations. *Organization Science*, *3*(3), 398–427. https://www.jstor.org/stable/2635280

Pacifico Silva, H., Lehoux, P., Miller, F. A., & Denis, J.-L. (2018). Introducing responsible innovation in health: A policy-oriented framework. *Health Research Policy and Systems*, *16*(1), 90. https://doi.org/10.1186/s12961-018-0362-5

Parliament of Rwanda. (2026, February). *Senators commend progress on rwanda's digital id rollout*. Retrieved May 4, 2026, from https://www.parliament.gov.rw/news-detail?cHash=349550b59d9f16c1cdbfe62d270d5c3c&tx_news_

pi1%5Baction%5D=detail&tx_news_pi1%5Bcontroller%5D=News&tx_news_pi1%5Bnews%5D=58639

Republic of Rwanda. (2021). Law n°058/2021 of 13/10/2021 relating to the protection of personal data and privacy. https://rwandalii.org/akn/rw/act/law/2021/58/eng@2021-10-15

Rwanda Biomedical Centre. (2024). What we do. Retrieved February 12, 2026, from https://rbc.gov.rw/what-we-do

Rwanda National Ethics Committee. (n.d.). About rwanda national ethics committee [Accessed: 2026-03-22]. https://www.rnec.rw/About-RNEC/

Sahay, S., Sæbø, J., & Braa, J. (2013). Same, same, but different: Exploring the adoption of public health information systems in india. *Information and Organization*, *23*(3), 123–142. https://doi.org/10.1016/j.infoandorg.2013.07.001

Shishkin, S., Sheiman, I., Potapchik, E., Vlassov, V., & Sazhina, S. (2025). The impact of centralization on structural changes in healthcare: When it works. *Frontiers in Health Services*, *5*, 1484225. https://doi.org/10.3389/frhs.2025.1484225

United Nations. (n.d.). *Rwanda: Historical background*. Retrieved February 12, 2026, from https://www.un.org/en/preventgenocide/rwanda/historical-background.shtml

Uwera, T., Venkateswaran, M., Bhutada, K., Papadopoulou, E., Rukundo, E., Tumusiime, D. K., & Frøen, J. F. (2024). Electronic immunization registry in rwanda: Qualitative study of health worker experiences. *JMIR Human Factors*, *11*, e53071. https://doi.org/10.2196/53071

Venkatesh, V., Morris, M. G., Davis, G. B., & Davis, F. D. (2003). User acceptance of information technology: Toward a unified view. *MIS Quarterly*, *27*(3), 425–478. https://doi.org/10.2307/30036540

Wang, M., Huang, K., Li, X., Zhao, X., Downey, L., Hassounah, S., Liu, X., Jin, Y., & Ren, M. (2025). Health workers' adoption of digital health technology in low- and middle-income countries: A systematic review and meta-analysis. *Bulletin of the World Health Organization*, *103*(2), 126–135F. https://doi.org/10.2471/BLT.24.292157

Watson-Grant, S., Xiong, K., & Thomas, J. C. (2017). Achieving sustainability in health information systems: A field tested measure of country ownership. *International Journal for Equity in Health*, *16*(1), 81. https://doi.org/10.1186/s12992-017-0258-0

World Bank. (2025a). *Access to electricity (% of population)*. Retrieved February 12, 2026, from https://data360.worldbank.org/en/indicator/WB_SE4ALL_EG_ACS_ELEC?country=RWA&view=map

World Bank. (2025b). *Gdp growth (annual %)*. Retrieved February 12, 2026, from http://data360.worldbank.org/en/indicator/WB_WDI_NY_GDP_MKTP_KD_ZG?country=RWA&view=trend

World Bank. (2026). Individuals using the internet (% of population) – Rwanda. Retrieved February 12, 2026, from https://data.worldbank.org/indicator/IT.NET.USER.ZS?locations=RW

World Bank. (n.d.). *Rwanda: Overview*. Retrieved February 12, 2026, from https://www.worldbank.org/ext/en/country/rwanda#tab-development

World Health Organization. (2019). *Drones take rwanda's national blood service to new heights*. Retrieved February 12, 2026, from https://www.who.int/news-room/feature-stories/detail/drones-take-rwandas-national-blood-service-to-new-heights

World Health Organization. (2026a). Malnutrition in children: Stunting, wasting, overweight and underweight. Retrieved May 27, 2026, from https://www.who.int/data/nutrition/nlis/info/malnutrition-in-children

World Health Organization. (2026b). *Scaling innovations in public health systems: Guidance and toolkit* [Licence: CC BY-NC-SA 3.0 IGO]. https://www.who.int/publications/i/item/9789240120761

Yang, Z., Kankanhalli, A., Ng, B.-Y., & Lim, J. T. Y. (2015). Examining the pre-adoption stages of healthcare IT: A case study of vital signs monitoring systems. *Information & Management*, *52*(4), 454–467. https://doi.org/10.1016/j.im.2015.01.007

A

Swedish CLP Registry

Report to CLP Registry **Baseline Form**

Treatment centre: .....

Civic registration number ⌊_⌊_⌊_⌊_⌊_⌊_⌊_⌊_⌊–⌊_⌊_⌊_⌊_⌋ (yyyymmdd-nnnn)

Date of birth, same as above ☐ Yes

***Last name*:** ..... (Please, use block letters) ***First name*:** ..... (Please, use block letters)

Sex ☐ Male ☐ Female

Date of first patient contact ⌊_⌊_⌊_⌊_⌋–⌊_⌊_⌋–⌊_⌊_⌋ (yyyy-mm-dd)

Prenatal detection of cleft ☐ Yes ☐ No ☐ Unknown

Born in Sweden ☐ Yes
☐ No, date of arrival in Sweden ⌊_⌊_⌊_⌊_⌋–⌊_⌊_⌋–⌊_⌊_⌋ (yyyy-mm-dd)

Primary surgery abroad ☐ Yes ☐ No ☐ Unknown

Adopted ☐ Yes ☐ No

Weight at birth ⌊_⌊_⌊_⌊_⌋ (grams) ☐ Unknown

Pre-operative treatment

Pre-operative treatment (such as tape, plate etc.)

☐ Yes ☐ No ☐ Unknown

Cleft

Untreated at assessment ☐ Yes ☐ No

Cleft morphology

	Right		*Left*	
Nasal floor	☐ No	☐ Yes	☐ No	☐ Yes
Lip	☐ No	☐ Yes	☐ No	☐ Yes
Alveolus	☐ No	☐ Yes	☐ No	☐ Yes
Primary palate	☐ No	☐ Yes	☐ No	☐ Yes
Hard palate	☐ No	☐ Yes		
Soft palate	☐ No	☐ Yes		

Heredity (includes all known relatives)

Family history of clefts ☐ No ☐ Yes ☐ Unknown

Civic registration number ⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋–⌊_⌋⌊_⌋⌊_⌋⌊_⌋ (yyyymmdd-nnnn)

Diagnosis (which the patient's care plan follows)

ICD10 code

Q35.3 (Cleft soft palate)	☐
Q35.5 (Cleft hard palate with cleft soft palate)	☐
Q36.0 (Cleft lip, bilateral)	☐
Q36.9 (Cleft lip, unilateral)	☐
Q37.4 (Cleft hard and soft palate with bilateral cleft lip)	☐
Q37.5 (Cleft hard and soft palate with unilateral cleft lip)	☐
Secondary cleft diagnosis exists, see morphology	☐ Yes

Other diagnoses

Updates due to identified conditions can be performed at any time in the web-application form.

Pierre Robin Sequence

☐ No ☐ Unknown

☐ Yes*)

*) **Yes** must only be ticked if all the three conditions Glossoptosis, Micrognathi and Cleft palate are present and in case the child is in need of more interventions than positional advice, such as ng-tube or breathing help

Syndrome

☐ No ☐ Unknown

☐ Yes

Other deformity

☐ No ☐ Yes .....

Specify (Please, use block letters)

Updates regarding death and transfer information can be performed at any time in the web-application

Deceased

☐ Yes, give date ⌊_⌋⌊_⌋⌊_⌋⌊_⌋–⌊_⌋⌊_⌋–⌊_⌋⌊_⌋ (yyyymmdd)

Transfer information is to be registerered by the recipient center

Transferred from ..... ***Transferred to*** .....

Transfer date ⌊_⌋⌊_⌋⌊_⌋⌊_⌋–⌊_⌋⌊_⌋–⌊_⌋⌊_⌋ (yyyymmdd)

Moved abroad ☐ Yes ***Date*** ⌊_⌋⌊_⌋⌊_⌋⌊_⌋–⌊_⌋⌊_⌋–⌊_⌋⌊_⌋ (yyyy-mm-dd)

Report to CLP Registry

Surgical Form

Treatment center: .....

Civic registration number ⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋–⌊_⌋⌊_⌋⌊_⌋⌊_⌋ (yyyymmdd-nnnn)

***Last name*:** ..... (Please, use block letters) ***First name*:** ..... (Please, use block letters)

Date of operation ⌊_⌋⌊_⌋⌊_⌋⌊_⌋–⌊_⌋⌊_⌋–⌊_⌋⌊_⌋ (yyyy-mm-dd)

Lip operation ☐ Not performed ☐ Primary surgery ☐ Secondary surgery

Operation code

EAB00	Lipadhesion	☐
EAB30	Lipplasty	☐
EAW99	Other procedures	☐

Cleft soft and hard palate operation

☐ Not performed ☐ Primary surgery ☐ Secondary surgery

Operation code

EHC10	Repair of fistula	☐
EHC30	Hard and soft palate closure	☐
EHC31	Hard palate closure	☐
EHC32	Soft palate closure	☐
EHC45	Re-repair of palate	☐
EHC50	Pharyngeal flap	☐
ENC30	Plastic operation of pharynx	☐
EHC99+ZZR45	Buccal flap	☐

Nose operation ☐ Not performed ☐ Primary surgery ☐ Secondary surgery

Operation code

DJD20	Plastic repair of septum	☐
DLD00	Reconstruction of cartilage of nose	☐
DLD10	Reconstruction of bone of nose	☐
DLD20	Rhinoplasty, bone and cartilage	☐
DLW99	V to Y plasty	☐

Jaw operation ☐ Not performed ☐ Primary surgery ☐ Secondary surgery

Operation code

EBA10	Tooth extraction	☐
ECB05	Mucogingival repair	☐
ECB15	Oronasal fistula repair	☐
EEC05	Lefort I osteotomi	☐
EEC40	Distraction of maxilla	☐
ECB50	Bone transplant to alveolar ridge	☐
EEW99	Vomer osteotomi	☐

Operation

Operation time (from cutting to end of suturing)

Start time ☐☐:☐☐ (hh:mm) ***End time*** ☐☐:☐☐ (hh:mm)

Surgeons comment

☐ No ☐ Yes: .....
Specification (Please, use block letters)

Hospital Stay

Sign in date ☐☐☐☐-☐☐-☐☐ (yyyy-mm-dd)

Discharge date ☐☐☐☐-☐☐-☐☐ (yyyy-mm-dd)

Complications (within first two days)

☐ No ☐ Yes, Specify below

Bleeding ☐ No ☐ Yes

Infection ☐ No ☐ Yes

Rupture ☐ No ☐ Yes

Antibiotics

☐ No ☐ Yes

Report to CLP Registry

Record Speech Evaluation

Treatment centre: _____

Civic registration number ⌊_⌊_⌊_⌊_⌊_⌊_⌊_⌊_⌋–⌊_⌊_⌊_⌊_⌋ (yyyymmdd-nnnn)

***Last name*:** _____ ***First name*:** _____
(Please, use block letters) (Please, use block letters)

Date of registration ⌊_⌊_⌊_⌊_⌋–⌊_⌊_⌋–⌊_⌊_⌋ (yyyy-mm-dd)

No show ☐ Yes

No further follow ups ☐ Yes

Age of registration ☐ 5 years ☐ 10 years ☐ 16 years ☐ 19 years

Residual cleft alveolus ☐ No ☐ Unoperated

Fistula ☐ No ☐ Yes ☐ Unknown

Other problems

Diagnosed language and/or motor speech disorder ☐ No ☐ Yes ☐ Unknown

Diagnosed intellectual disability ☐ No ☐ Yes ☐ Unknown

Diagnosed neuropsychiatric disorder ☐ No ☐ Yes ☐ Unknown

Diagnosed hearing impairment ☐ No ☐ Yes ☐ Unknown

SLP services

Routines and reviews ☐ No ☐ Yes

Treatment ☐ No ☐ Yes

Number of visits ⌊_⌊_⌋ Max number 99
(since last registration in RSE form)

Recording

Audio ☐ No ☐ Yes

Video ☐ No ☐ Yes

Instrumental evaluation (since last registration)

Videoradiography

☐ Not evaluated
☐ Not judgeable
☐ Evaluated, give number (1-10) ☐☐

Nasoendoscopy

☐ Not evaluated
☐ Not judgeable
☐ Evaluated, give number (1-10) ☐☐

Evaluation data

Velopharyngeal competence (choose one alternative)

☐ Not evaluated ☐ Not judgeable
☐ Competent/sufficient ☐ Marginally incompetent/insufficient
☐ Incompetent/insufficient

Perceptual evaluation of consonants (choose one alternative)

☐ Not evaluated ☐ Not judgeable
☐ Evaluated, please continue:

PCC

Number completed ☐☐ **Number correct** ☐☐

Speech errors behind velopharynx

Number completed ☐☐ **Number of errors** ☐☐

Parent-reported intelligibility

☐ Not evaluated ☐ Not judgeable
☐ Evaluated, give value (between 1 and 5 with one decimal) ☐☐

Examiner SLP

***Last name*:** _____ ***First name*:** _____
(Please, use block letters) (Please, use block letters)

B

Interview Guides

Policymakers

Background and role

- Could you describe your role within the Rwandan health system?
- To what extent are you involved in national health data systems and/or registries?

Governance and coordination

- Which institutions or departments are responsible for health registries?
  - Under what department or program could a CLP registry fit?
- How is registry data governed, who owns it, and who has access to it?

Current health data systems

- What national health registries currently exist in Rwanda, and are they usually integrated into larger health management information systems?
- What national digital health platforms are currently used to collect and manage health data?
- Are there ongoing efforts to expand or improve digital health infrastructure?
- Does RBC run or manage pilot projects for data collection?
  - What platform is used?
  - What does the process of scaling the project to national level look like?
- How are external pilot registry projects usually transferred to RBC? (platform, data, etc)
  - What are common challenges?

Data needs for decision-making

- What types of health data are most important for policymakers?
- From your perspective, what role could a CLP registry play in strengthening healthcare systems in Rwanda?
- Have you previously worked with collecting data in retrospective?
  - What are the most common challenges?

Experiences with new systems

- Has a health system from outside of Rwanda been deployed within the RBC?
  - What local adaptations were needed?

Challenges and opportunities

- What would be important factors for successfully implementing a national CLP registry?

Registry Developers

Background and role

- Could you describe your role and how you are involved in health registries?
- What type of registry do you work with?

Technical infrastructure

- What technical platform or system is used for the registry?
  - How is data stored?
- Is the registry integrated with other health information systems?

Data collection and design

- What types of personal data are typically collected in the registry?
- How is person identification handled?
- How is data entered into the registry over time?
  - Who enters the data?
  - Once or multiple entries?
  - How is this handled technically?
- How do you decide which variables should be included in the registry?
- Is the registry based on an already existing registry, or is there another background for it?
- Has retrospective data collection been part of building the registry?
  - If yes, could you describe how that process worked in practice?

Governance

- Who is responsible for managing and governing the registry?
- How is access to registry data controlled?

Challenges, success factors and opportunities

- What are the main challenges in establishing and maintaining a health registry?
- Based on your experience, what are the most important factors for successfully implementing a health registry?
- How do you see the role of digital health registries evolving in the future?

Plastic Surgeons

Background and role

- Could you briefly describe your role and your involvement in cleft care?
- How long have you been working with cleft patients?

Current clinical practice and decision making

- How are patients with cleft lip and palate currently registered when they first arrive at the hospital?
- What does the typical care pathway look like for a cleft patient (from diagnosis to surgery and follow-up)?
- How are follow-up visits typically organized?
- What works well with how patient data is stored today?

Data and documentation

- What types of clinical data are currently recorded for cleft patients?
- How is patient information recorded today?
- How easy is it to retrieve historical data about patients?

Registry design and considerations

- If a national cleft registry existed, what information would be most useful for you as a clinician?
- What features would make a registry practical and easy to use in daily work?
- What barriers might exist when implementing a digital registry in hospitals?
- What kind of training or support would clinicians need?
- Have you experienced a deployment of a new health system?
  - What worked well and what challenges appeared?
- What would you suggest to be included in a speech assessment form?

Challenges and future perspective

- What challenges do you face when documenting and following up with cleft patients?
- How do you think better data could improve cleft care in Rwanda? In what way?
- If you imagine an ideal system for collecting data about cleft patients in Rwanda, what would it look like?

NGOs

Background and role

- Could you describe your organization's role in cleft care in Rwanda?
- What types of activities do you currently conduct (e.g., surgeries, patient identification, follow-up, training)?

Patient identification and care pathway

- How are patients with cleft lip and palate typically identified and referred to treatment?
- What does the typical patient pathway look like from identification to surgery and follow-up?
- How do you currently track patients after surgery?
- What challenges exist in maintaining long-term follow-up with patients?

Data collection and management

- What types of patient data are currently collected during screening, treatment, and follow-up?
- How is this data currently recorded and stored?

Collaboration with the health system

- How does your organization collaborate with hospitals or national health authorities regarding patient data?
- Are there systems in place for sharing data with the national health system?

Challenges and opportunities

- What are the main challenges your organization faces in collecting and managing cleft patient data?
- How could a national cleft registry support the work of organizations like yours?
- What types of data would be most important to include in such a registry?
- Have you worked with or introduced new systems over time? (Rwanda or elsewhere)
  - What challenges did you face when using or adapting to them?

Implementation considerations

- How could NGOs collaborate with hospitals and national institutions in maintaining such a registry?

C

Summary of variable adaptations

Variable / Feature	Form	Change	Source
Adopted	B	Removed	N1
Height, weight and z-score	B, Su, F	Added	N1, S1, S2
Cleft morphology sequence	B	Adapted	S2
ICD-11 codes	B	Updated	S2
Syndromic diagnosis field	B	Adapted	S2
Parent names, phone, address	B	Added	S1, S2
Transferred	B	Removed	N1
Moved abroad	B	Removed	N1
Deceased field placement	B	Moved	N1
Surgical technique	Su	Added	S2, S3
Soft/hard palate separation	Su	Adapted	S3
"Other" operation type	Su	Added	S3
Antibiotic prophylaxis	Su	Added	N1
Discharge date placement	Su	Moved	S1, S2
School attendance	F	Added	S1
Patient satisfaction rating	F	Added	S3
Outcome and recommendation	F	Added	S1
ICS speech intelligibility scale	Sp	Added	N4
Sound recording upload	Sp	Added	N4
Timestamp on recording	Sp	Added	R3
Patient age at recording	Sp	Added	N1, N4
Yes/no gates before free-text	B, Su, F	Added	N3
Field descriptions	B, Su, F, Sp	Added	N3, R1, S3
Validations	B, Su, F, Sp	Added	N3
Media upload (embedded per form)	B, Su, F	Restructured	S2, S3

Table C.1: Adaptations made to the Swedish CLP registry during prototype development. B = Baseline, Su = Surgical, F = Follow-up, Sp = Speech assessment.

DEPARTMENT OF TECHNOLOGY MANAGEMENT AND ECONOMICS
DIVISION OF ENTREPRENEURSHIP AND STRATEGY
CHALMERS UNIVERSITY OF TECHNOLOGY
Gothenburg, Sweden 2026
www.chalmers.se

CHALMERS
UNIVERSITY OF TECHNOLOGY