

## Navigating governance challenges in a decentralised healthcare ecosystem

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### Abstract

*Polycentric governance has often been theorized as a desirable model for digital ecosystems due to its potential to spur innovation and enhance adaptability. However, in decentralised healthcare systems like Sweden's, low innovation rates and interoperability issues persist. This paper examines Sweden's efforts to achieve national digital health goals within its decentralised health model. Analysing qualitative data from interviews and archival documents, we utilised the COOF framework (Context, Operations, Outcomes, Feedbacks) to assess the outcomes of the ecosystem's operational arrangements and its feedback pathways. We identified governance outcomes such as vendor lock-ins and inadequate digital adaptation structures. Furthermore, the presence of suboptimal feedback pathways and adjustment mechanisms explain the persistent governance challenges, which we refer to as governance opacity and over-reliance on regulation. By exploring the implications of polycentric governance, this study provides recommendations for enhancing collective action and enabling successful digital transformation in decentralised healthcare ecosystems.*

**Keywords:** Digital health transformation, digital health ecosystems, polycentric governance, decentralised health systems.

### 1 Introduction

In response to the increasing healthcare challenges across the globe, digitalisation is emerging as a potential solution to address the institutional challenges faced by national health systems (Constantinides, 2023; World Health Organization, 2021). Beyond simply addressing the growing demand for healthcare, digitalisation offers the promise of improving healthcare efficiency, enhancing patient access and engagement, and potentially transforming how healthcare is delivered (Hermes et al., 2020; Pietronudo et al., 2022).

However, realising the full potential of digital transformation in healthcare requires more than technological advancements. Both practitioners and researchers have emphasized the critical role of fostering collaboration among multiple stakeholders through the creation of digital health ecosystems to effectively harness digital technologies to address these healthcare challenges (Constantinides, 2023; McKinsey, 2020; Reidy et al., 2023; World Health Organization, 2021). An ecosystem approach is essential as no individual stakeholder possesses the resources, expertise, nor influence to address these complex healthcare challenges in isolation (Constantinides, 2023).

However, the involvement of multiple stakeholders introduces the potential for collective action problems which arise when the realization of a common goal depends on the actions of various individuals or organizations whose interests and incentives may not always align (Holahan & Lubell, 2022; Ostrom, 2010). These misaligned interests can hinder an ecosystem's ability to achieve its full potential. While research suggests that governance mechanisms can be employed to address such collective action problems (Constantinides & Barrett, 2015; Holahan & Lubell, 2022; Ostrom, 2010), the unique structure of some healthcare systems presents additional challenges in effectively governing them. This paper aims at investigating such challenges by focusing on digital transformation efforts in Swedish healthcare system which is decentralised (Socialstyrelsen, 2024). Decentralised systems are characterised by polycentric governance (PG) in which power and decision-making responsibilities are distributed from central authorities to regional and local governments (Carlisle & Gruby, 2019; Ciani et al., 2012; Ostrom, 2010). Such systems present a particularly complex governance challenge in achieving collective goals. For instance, national digital health strategies, might be interpreted and implemented differently across regions due to varying local needs and priorities (Reidy et al., 2023). This multiplicity of autonomous regional stakeholders, therefore, complicates the effective governance of

digital health ecosystems. The challenge lies not only in coordinating diverse perspectives and priorities but also in creating digital adaptation frameworks that are responsive to the emerging and evolving technological advancements within the ecosystem.

Previous studies have indicated that decentralised ecosystems may promote local innovation through increased collaboration and diverse perspectives (Damanpour & Aravind, 2012; Sørensen, 2012), however, simply having multiple actors does not guarantee a functional ecosystem. As Reidy et al. (2023) aptly put it, "*the plural of silo is not ecosystem.*" Furthermore, research has highlighted instances where decentralised institutions were forced to recentralize due to concerns about fragmentation hindering innovation (Scarffe et al., 2022). We use the 'ecosystem' term to describe the interconnected network of stakeholders in the healthcare sector. This includes healthcare providers, technology providers, policymakers, research institutions and even patients who work together towards improving access to good quality healthcare.

While the broader challenges of governing digital health ecosystems are understood, the discourse on healthcare decentralisation has often been politically driven (Fredriksson & Winblad, 2008), with proponents highlighting its theoretical benefits (Scarffe et al., 2022). However, there is limited empirical evidence and analysis regarding how decentralised or polycentric systems effectively achieve national goals in the digital transformation of healthcare.

This paper addresses this gap by focusing on the Swedish digital health ecosystem, in a decentralised healthcare system grappling with low interoperability and low innovation rates compared to other sectors (e-halsa2025, 2020). Utilising the "*Context – Operations – Outcomes – Feedbacks*" (COOF) by Baldwin et al. (2023), we delineate the unique characteristics of this ecosystem, describe its operational arrangements and analyse the impact of their outcomes on the subsequent governance policies. By doing so, we seek to answer the following research question:

*Why do problems persist in achieving digital health goals in decentralised healthcare systems?*

This analysis aims to shed light on the practical effects of polycentric governance on national digital health transformation efforts and suggest ways to enhance governing collective action of digital health in decentralised healthcare systems. Here, we define digital health goals as the desired outcomes that can be achieved through the effective implementation of digital health technologies. In the Swedish context, these goals have been set by both national and local entities (as explained in section (3.1).

## 2 Theoretical context: Governing digital health ecosystems

Previous research suggests that a "triple-helix model" ecosystem, involving government, academia, and industry, drives successful digital health transformations (Iyawa et al., 2016; Oksanen & Hautamäki, 2014). This model leverages the diverse capabilities of these stakeholders to foster collaboration and implement innovative solutions effectively. Innovation companies and researchers often curate the ecosystem's development, while governments shape it through funding, regulations, and policymaking (Oksanen & Hautamäki, 2014). Depending on the scope and intended outcomes, the stakeholder composition may even extend beyond national borders, incorporating international health institutions (Iyawa et al., 2016).

Existing literature has identified two primary governing approaches for digital ecosystems: hierarchical and non-hierarchical. Hierarchical governance, also known as top-down governance, relies on a centralised authority to make decisions and enforce rules (Jacobides et al., 2024). This approach tends to concentrate power in a dominant actor in the ecosystem (Hein et al., 2020). In contrast, non-hierarchical governance, sometimes referred to as bottom-up or polycentric governance (Constantinides & Barrett, 2015) emphasizes collaboration and distributed decision-making among diverse stakeholders.

In Polycentric governance (PG) multiple independent decision-making centres operate at various levels, from local to national (Baldwin et al., 2023). Given the decentralised nature of the healthcare system, the Swedish digital health ecosystem inherently operates under a polycentric governance model. This model is often favoured in complex systems due to its potential to balance localized control with central coordination. It achieves this balance through overlapping responsibilities, which serve to check power imbalances and tensions between actors (Carlisle & Gruby, 2019). Some scholars have even considered it to be the very essence of ecosystem emergence, promoting adaptability and innovation (Adner, 2017; Jacobides et al., 2024).

Despite the attractiveness it presents, polycentric governance is not without its challenges. While it empowers local communities and fosters innovation, it often leads to loosely organized structures, hindering effective decision-making and potentially resulting in bureaucratic structures that compromise an ecosystem's adaptiveness (Burns & Welker, 2023; Jacobides et al., 2024). Moreover, the lack of decision-making simplicity can create

difficulties in coordinating activities, resolving conflicts, and managing competition among different stakeholders (Carlisle & Gruby, 2019). Furthermore, digital technologies with their layered modular architecture (Yoo et al., 2010) present new capabilities for data sharing and accessibility. While this is assumed to lower coordination costs, it also calls for deliberate coordination efforts towards creating interoperability within ecosystems.

Therefore, there is need to examine the specific conditions under which this model thrives in practice. While some studies assume that a polycentric governance model automatically guarantees positive outcomes (Baldwin et al., 2023), others, like Constantinides and Barrett (2015) have identified specific conditions for its effectiveness. They advocated for a bottom-up approach where local groups maintain complete autonomy until their actions create "spillover effects", necessitating intervention from higher-level entities to establish collective rules.

Existing research on collective digital health goals in polycentric models, such as the work of (Bygstad et al., 2023; Ciani et al., 2012; Vassilakopoulou et al., 2017) has explored diverse approaches to addressing governance challenges. However, these studies do not fully explain why achieving collective goals remains challenging. Moreover, while national authorities may have a unified vision for achieving digital health goals, the actual implementation often varies by region. Ciani et al. (2012) found that when regional governments have more control, they develop their own digital health programmes, leading to varied approach and results, which affect equal access to healthcare technologies and resources across a country.

Understanding the nuances of this model is, therefore, crucial for addressing our research question regarding why problems persist in achieving collective digital health goals within decentralised healthcare systems. To this end, we employ the context-operations-outcomes-feedback (COOF) framework proposed by Baldwin et al. (2023) to analyse the Swedish context. This framework enables a more in-depth exploration of the complexities of polycentric governance, analysing the interplay of contextual factors, decision-making processes, outcomes, and feedback mechanisms that influence its effectiveness.

## 2.1 Context –Operations – Outcomes - Feedbacks (COOF) framework.

To address the need for a deeper understanding of the conditions under which polycentric governance (PG) thrives, Baldwin et al. (2023) introduced a framework that examines the complex interplay of

contextual factors, decision-making processes, outcomes, and feedback mechanisms. The context-operations-outcomes-feedback (COOF) framework, as shown in figure 1 below, aims to shed light on why PG succeeds in certain situations while failing in others, moving beyond simply identifying its positive and negative aspects. By analysing the interactions between these key elements, we can gain valuable insights into the contextual factors and operational dynamics that contribute to the effectiveness of PG in various settings.

Drawing upon the Institutional Analysis and Development (IAD) framework by Ostrom (2009), the COOF framework is designed to analyse collective action situations involving organizations. This is a departure from the IAD framework, which primarily focused on individual actors. COOF emphasizes the importance of “contextual characteristics”, “operational arrangements”, “outcomes” and “feedback pathways and adjustment mechanisms”. Contextual characteristics include the environment and conditions in which governance operates, like laws, culture, and the political set up. They highlighted three different type of contextual factors; the nature of the collective action problem, the people and communities involved and the formal or informal rules that set the stage on how governance works on daily basis.

Operational arrangements on the other hand involve the mutual adjustments and interactions between decision-making centres, influenced by the contextual characteristics. These arrangements centre on both the structure (the manner in which these collectives are structured and their authorities) and the processes (the ways in which they engage, such as through collaboration or competition).

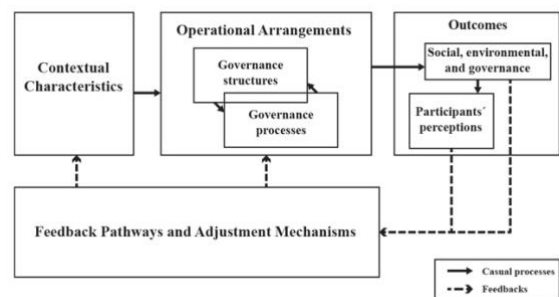


Figure 1. COOF Framework (Baldwin et al., 2023).

Outcomes are the results produced by the interactions of multiple decision-making centres over time, which can vary widely depending on the context. They are usually observed as patterns emerging from these collective actions rather than being directed by a

single centre. The authors also draw a distinction between outcomes and outcomes as perceived by stakeholders as its people’s perceptions that influence any future changes to a system.

Lastly, the framework points to feedback pathways and adjustment mechanisms, which are ways that outcomes can influence changes in the governance system over time, allowing it to evolve and adapt to new challenges. Feedback pathways are the ways outcomes of policies affect future policies while adjustment mechanisms are how people react to these outcomes.

We utilize this framework to analyse the digital health landscape in Sweden in order to not only identify the challenges faced by stakeholders but also to understand the underlying reasons behind these challenges.

### 3 Methods

#### 3.1 Research setting: Swedish digital health ecosystem

Swedish healthcare is organized in and delivered by the 21 regions and 290 municipalities. This means that a lot of digitalisation efforts and development of health information systems are carried out within regional and municipal boundaries leading to silos of information.

The Swedish digital health ecosystem and its actors are presented in Figure 2 as a triple-helix representation. On the national level, the government decides on legislation, financial budget, and targeted state subsidies. The government has the overriding responsibility for the political direction of health and social care (SALAR, 2023). Another actor on the state level is the Swedish eHealth Agency, whose assignment is to digitalise and improve the sharing of information between patients, the healthcare system, and pharmacies in Sweden (The Swedish eHealth Agency, 2023).

The Swedish Association of Local Authorities and Regions (SALAR) is an organisation that represents and advocates local government in Sweden. All of Sweden’s municipalities and regions are members of SALAR (SALAR, 2023).

The national government together with the Association of Local Authorities and Regions (SALAR) jointly created a vision to make Sweden “the best in the world at using the possibilities of digitalisation and e-health in order to make it easier for people to achieve good and equal health and welfare” by 2025 (eHälsa2025, 2016). Hence, their collective goal is to utilise digital tools in enhancing equitable access to good quality healthcare.

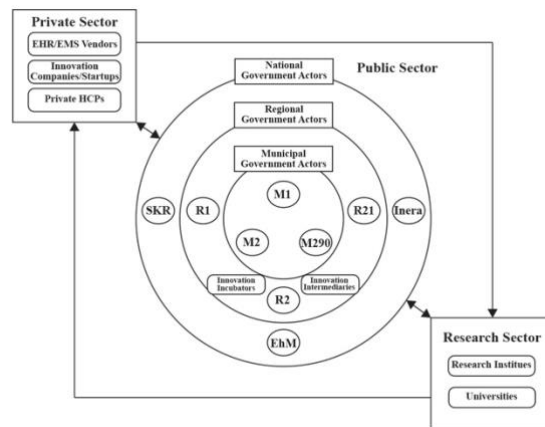


Figure 2. A triple helix representation of the digital health ecosystem actors in Sweden.

The vision is supported by two overriding goals; timely access to the right information and knowledge and, the development of conditions for digitalisation in collaboration with multiple stakeholders in the healthcare ecosystem (eHälsa2025, 2020). One way to achieve this is through the provision of common national digital infrastructure by Inera, a company jointly owned by the members of SALAR (Inera\_AB, 2020). This common infrastructure facilitates interoperability within the ecosystem.

While the national bodies influence the overarching framework and objectives, the Swedish regions and municipalities possess significant autonomy in healthcare governance. Moreover, they retain the decision-making authority at the operational level despite state funding.

Other actors in the private sector are equally important in the ecosystem, with EHR vendors playing a major role in the regions while innovation companies provide some of the much-needed digital solutions to the ecosystem. Research institutions and universities on the other hand, work closely with all stakeholders to create new knowledge

#### 3.2 Data collection

The study draws upon primary data sources, including interviews with stakeholders in the digital health ecosystem and on secondary data, that include online excerpts of public interviews and discussions held by key figures in the Swedish digital health ecosystem, and a selection of documents that include policy documents, strategic frameworks, annual reports, and evaluation reports carried out by various governmental agencies.

Interview respondents were purposefully selected to capture a diverse representation of viewpoints

across the digital health ecosystem in Sweden. They included representatives from the national ehealth and digital infrastructure agencies, regional governments, innovation hubs and enterprises, as well as consultants in digital health. Table 1 provides a summary of the interview data sources. The consultants have all worked with different digital health projects in Sweden. R9 has also been the digitalisation manager in one of Sweden's largest region, R10 has worked with various regional projects, including the recently completed AI Sweden initiative, focusing on healthcare. On the other hand, R11 has mainly worked as a consultant with the national digital infrastructure provider.

12 semi-structured interviews were conducted over a period of six months, from March 2023 to October 2023. They included two group interviews and 10 individual interviews lasting between 45-80 minutes. All interviews were conducted through online video conferencing, except for the interview with R4 and R5 which was conducted face to face. The interviews used open-ended questions to explore stakeholder's experiences, perceptions and challenges regarding coordinating and implementing digital health transformation initiatives in Sweden.

Interviewees discussed their involvement in digital health initiatives, providing detailed accounts of processes, strategies, and obstacles encountered within the ecosystem. By triangulating these insights with other data sources, we were able to corroborate and enrich our understanding of their experiences.

### 3.3 Data Analysis

Data collection and analysis proceeded concurrently, allowing preliminary interviews to inform subsequent data gathering. Interviews were transcribed using OpenAI's Whisper Large language model. Each transcript was then reviewed carefully, referencing the audio recordings, to ensure accuracy and proper formatting. Our analysis involved several iterative stages. Initially, we mapped the Swedish digital health ecosystem using the first 4 interviews in conjunction with archival documents.

Next, author one inductively coded the interviews, cross-referencing them with online excerpts from public interviews and relevant documents for consistency. This highlighted governance challenges as a recurring theme. Concurrently, we immersed ourselves in existing research on digital transformation and ecosystems in healthcare, with a particular focus on decentralised governance models. This iterative process led us to reflect on the literature and recognize that the COOF (Context-Operations-Outcomes-Feedback) framework could

provide valuable insights into explaining the "why" behind the identified governance challenges.

**Table 1. Summary of interviews.**

| Organization                           | Position                             | Respondent code | Interview mins |
|--|--------------------------------------|-----------------|----------------|
| National digital health infrastructure | Project Manager and Medical Editor   | R1 and R2       | 80             |
| Regional Innovation intermediary       | Digital health innovation Manager    | R3              | 75             |
| Digital health Innovation company      | Project Manager and Customer Manager | R4 and R5       | 70             |
| Digital health Innovation company      | CEO                                  | R6              | 45             |
| National digital health infrastructure | Information architect                | R7              | 60             |
| National digital health infrastructure | Solutions architect                  | R8              | 75             |
|  | Digital health consultant            | R9              | 60             |
|  | Digital health consultant            | R10             | 60             |
|  | Consultant, Solutions architect      | R11             | 50             |
| Regional                               | ehealth Strategist                   | R12             | 55             |
| Ehealth Agency                         | Senior advisor and Coordinator       | R13             | 65             |
| Innovation Incubator                   | Programme Manager                    | R14             | 50             |

Consequently, we proceeded to use the directed content analysis (Hsieh & Shannon, 2005) where pre-defined categories can be applied to develop a theory further or to reveal the relationships between its constituent elements. Here, the preliminary codes identified earlier were then organised under the COOF framework while at the same time dropping those that could not be explained by the framework. The codes were further refined. For example, "equitable access to healthcare" emerged as a core need for collective action in digital health transformation as follows:

*"We are making this platform, so the patient gets to the right healthcare professional at the right time."* (R12) was initially coded as "timely access to the right healthcare"

*"In rich regions like Stockholm or Skåne, we have great access to our own medical records and other*

digital services. But if you live in a smaller region, which does not have the same taxation basis, they will never be able to provide the same kinds of digital services. The actual healthcare is not too different between regions, but the add-ons, the extras, really vary.” (R13) was initially coded as “equal access to healthcare.”

Additionally, the eHälsa2025 (2016) document, which aims to “use the opportunities offered by digitalisation and eHealth to make it easier for people to achieve good and equal health and welfare,” was coded under “equal healthcare.”

These three codes were then grouped under “equitable access to healthcare”, identified as a core need for collective action in digital health transformation.

Similarly, operational arrangements identified in the data were inductively coded to different arrangements within the ecosystem, as presented in Table 3. To answer our research question, we then focused our analysis on the resulting outcomes (section 4.3) and their subsequent feedback and pathways adjustment mechanisms (section 4.4), prompting a deeper reflection of this missing link in the discussion section.

## 4 Findings

### 4.1 Contextual characteristics

Using the COOF framework, we mapped the ecosystem’s contextual characteristics and operational arrangements (see Tables 3 and 2). Core needs for collective digital transformation initiatives were identified as the need for equitable access to healthcare which aligns with the government’s eHealth vision. Through digital transformation initiatives, they also aim to increase the efficiency of healthcare delivery while moving towards a patient- centric care system.

On the other hand, the ecosystem is characterised by resource inequities across different regions resulting in unequal healthcare access. It is dominated by the public sector and major electronic health record (EHR) providers as an outcome of governance arrangements. Additionally, data regulation regimes define the boundaries for data sharing within the ecosystem, and procurement regulations dictate how public agencies can interact with private actors.

### 4.2 Operational arrangements

Implementing new digital solutions at a national level requires collaboration to ensure alignment with local needs and financial sustainability. Inera

evaluates proposed solutions in consultation with representatives from regions and municipalities. The development phase begins only after 60% of the population (regions) have shown interest and committed to financing. At local level, digital transformation is carried out through internal initiatives, innovation intermediaries, incubator programs and through the normal market dynamic as shown in Table 2.

**Table 2. Operational arrangements of the Swedish digital health ecosystem.**

| Level                                     | Process                           | Description   |
|---|-----------------------------------|---|
| Digital transformation at national        | Bottom-up approach                | Need identification, evaluation, and proposal by national developer                                     |
| Local (peripheral Digital transformation) | Local (Internal) initiatives      | Needs are identified and initiated locally within organisations/regions                                 |
|   | Through innovation intermediaries | Regions create intermediaries to facilitate collaboration between public and private sector innovators. |
|   | Incubator Programs                | Regional programs foster collaboration between startups and the public sector.                          |
| Local (peripheral Digital transformation) | Market Dynamics                   | Startups directly enter the market, competing for adoption by local procurement departments.            |

### 4.3 Outcomes

#### 4.3.1 Lack of interoperability

The very autonomy that allows diverse approaches within Sweden's digital health ecosystem has led to varied, incompatible systems through independent regional procurement, creating data silos and hindering information exchange. Furthermore, municipalities within the regions often procure diverse systems, exacerbating this fragmentation. These issues have raised concerns regarding access to patient’s health records, limiting their ability to seek care across regions. Interviewees noted challenges related to system compatibility, proprietary interests, regional disparities, and information sharing among healthcare organisations.

“I mean like we are facing the reality that the municipalities have data for its people who live there, the citizens, they belong to the municipalities right? But when they get sick they go to the hospital, which is the region's department. To get the data to go through easily, they have two different systems that don't talk the same language. And this is a huge problem”. (R3)

**Table 3. Contextual characteristics of the Swedish digital health ecosystem**

| Contextual characteristics | Core needs for collective action in digital health transformation | Attributes of Actors and Communities     | Overarching Institutions                    |
|----------------------------|---|--|---|
| Attributes                 | Equitable access to healthcare                                    | Resource Inequities in different regions | GDPR Regulation & Patient Data Law          |
|                            | Patient-Centric Care & Engagement                                 | Public Sector & EHR Vendor dominance     | EU Medical device Regulation (MDR)          |
|                            | Efficiency and resource optimization                              | Misaligned Incentives                    | Procurement Regulation                      |
|                            | Data Interoperability and management                              | Embedded local practices                 | Nationwide entities like SKR, EHM and Inera |

There is also a struggle to keep up with advancements in interoperability standards, as it is costly to implement changes to the existing national interoperability platform. Adopting new standards can take a minimum of five years due to the challenges of coordinating across 21 regions and numerous system vendors.

*“If we are to use FHIR, we can only do it when our customers or owners are ready to do so,... we cannot apply on a full-scale level until our customers and their healthcare systems are ready.” (R2)*

Addressing interoperability as a collective action, through Inera, the efforts revolve around creating common infrastructure for sharing patient data efficiently and securely across regions and organizations. However, Inera has limited authority to enforce the use of its interoperability services on a national scale. Despite their technical expertise, their recommendations lack legal backing, making it difficult for them to ensure widespread adoption of their services

*“..unfortunately, they can't force their owners to actually use the services they produce. Which is sad because they are good services. If everybody used Inera's services, there would not be need for the government to step in and say, we really need to solve this because this is not working anymore.” (R13)*

#### **4.3.2 Tendency to create Vendor-lock ins and Gatekeepers**

For small players in the ecosystem, such as startups, entry into the market is challenging due to the dominance of larger Electronic Health Record (EHR) companies. These companies often act as gatekeepers, causing some regions to become overly reliant on them. While partnering with established vendors whose systems are proven may seem prudent, it creates a 'lock-in' effect, creating high barriers of entry for emerging innovators

Furthermore, regions often lack a mandate to actively support smaller players, further limiting their market access. This dependence on established EHR

providers impacts the national interoperability platform, as regions inadvertently become mini gatekeepers to broader system integration. Healthcare professionals frequently express a desire for integration with innovative solutions, but EHR owners are often reluctant to accommodate these changes as expressed by R13.

*“ it's so frustrating, where you have to rely on the region that already has a system, a main system. And if your aim is to connect to that system and if that system is not interested, it's that project, they can say.” (R13)*

#### **4.3.3 Insufficient frameworks for digital adaptation**

While bottom-up initiatives and regional autonomies spur local innovation, scaling these successes faces challenges. For promising innovations, navigating the initial hurdles is just the first step. Many successful proof-of-concepts struggle to scale beyond a small user base, languishing in what one interviewee termed as the "Proof of concept (POC) Graveyard." They face significant hurdles in fostering and scaling healthcare innovations not only due to regulatory challenges but also as a result, of limited financial support and lack of proper organisational structures that support emerging businesses models.

*“When you have created a prototype that is very, very useful... but they don't have funding or competencies to build a company. So, it stays in the proof-of-concept stage... a very tragic but very common end of many good ideas.” (R10).*

Institutions operate under varying legal frameworks. For instance, hospitals adhere to strict patient privacy laws and regulations, posing challenges for startups seeking access to necessary patient data for testing purposes. However, there are no established structural frameworks defining how such collaborations should occur, leaving them in a Catch-22 situation

*“There's a science incubator, there is also university hospital. ...., and you think they're just*

*across the road, right? I mean this road is the hardest road to cross, you know, it's almost like this, desert where people die on the way, desert of death” (R14)*

Furthermore, current frameworks struggle to support cross-regional data sharing, causing financial and legal uncertainties. Interviewee R10 highlighted concerns about cost and revenue sharing in inter-region data exchanges.

*“It's a key obstacle.... the business model, how can you finance, the exchange of the data, who should pay for what...regions are normally not permitted more or less to sell services to other regions.” (R10).*

#### **4.4 Feedback pathways and adjustment mechanisms**

Despite the successful bottom-up approach in localized contexts, it has marginalized some actors, especially smaller actors and limited the potential for transformative change at the national level. Some stakeholders, who felt excluded from the ecosystem expressed frustration with the lack of defined structures to provide feedback and address challenges, reinforcing the status quo. They further pointed out the need for overarching governance as the current set up lacked clear directions.

*“There is no national entity that can help or enable something to be spread nationally both practically and also economically, or a business model that supports it.” (R10)*

Another significant challenge we found was what we term as an “opaque hand” to refer to unclear and non-transparent influences with the ecosystem that might hinder the effective decision-making and coordination across the different entities.

*“There's a lack of shared goals for all of this work. There are many initiatives but it's hard to say, it's hard for the regions and municipalities to take the next step because they don't know where... What should be provided by the government and what should be done in the regions or municipalities? If the government is giving signals that they want to do more, then everyone stops making investments regionally because they want to see where this is going.” (R11)*

They also pointed out opacity in accountability and ownership within the ecosystem. Fragmentation has led to a proliferation of government representatives with overlapping or ambiguous roles, hindering clear responsibility and fostering an environment resistant to adapting to rapid technological advancements and evolving patient needs. During a public forum, a panellist, who likened digital transformation to the most significant societal transformation since industrialisation, succinctly captured this concern:

*“As splintered as it has been, .... you cannot behave in such a way that you have that no one responsible for the implementation.....we have had a parade of people who have represented different parts of the state. In the end, you get so confused that you don't know who does what”.*

Finally, they raised concerns that the ecosystem overly relies on regulations without enough emphasis on creating adaptive structures for digital transformation. This reliance on regulations alone may hinder the agility needed to effectively evolve and innovate within the digital landscape.

*“Some players sit up from regulation authorities like EMA and others, ..... they only see problems... And if we only see problems in new technology and how that is being implemented and used, then there's no change to be done”*

## **5 Discussion**

This study investigated the underlying reasons behind persistent challenges in achieving national digital transformation goals within a decentralised healthcare system, despite the expected benefits of such governance arrangements like increased innovation rates and adaptability to ecosystems changes (Carlisle & Gruby, 2019).

The COOF framework assumes that formal or informal feedback mechanisms are triggered as a response to the outcomes of governance actions, enabling adaptation and improvement over time. However, our findings indicate that this assumption does not always hold true, particularly in cases where feedback mechanisms are suboptimal or ineffective. These weak feedback loops tend to reinforce the status quo rather than driving necessary adjustments or improvements. We describe these ineffective mechanisms in terms of an overreliance on regulation and the concept of an “opaque hand.”

### **5.1 Governance opacity**

Many stakeholders expressed their frustration with non-existent or lack of clear feedback pathways in the ecosystems. This aligns with studies on polycentric governance systems, which show that the complexity of having many decision-makers with overlapping responsibilities can obscure accountability, leading to a non-adaptive ecosystem (Baldwin et al., 2023; Lieberman, 2011). Research on ecosystem governance in the public sector further argues that despite the desired autonomy for participating stakeholders, there is a need for overarching governance that provides both vision and directionality. Sørensen and Torfing (2017) advocate for metagovernance as a strategy that

public authorities can use to influence processes and outcomes in polycentric systems without relying on traditional command-and-control approaches. Both public and private actors can assume the role of meta-governors, but public actors often possess the necessary resources within the political and administrative system to take charge (Sørensen, 2012). However, they also point out that successful metagovernance requires access to centrality, authority whether formal or informal, funding to facilitate collective action and the organisational capacity to support the activities.

On the other hand, Altman et al. (2022) discuss the necessity of a "translucent hand" in ecosystems to steer activities outside an organization's boundaries. The lack of defined feedback pathways and adjustment mechanisms in the Swedish ecosystem points to the existence of an opaque hand that is unable to offer direction to the ecosystem.

## 5.2 Overreliance on regulations

In the absence of digital adaptation structures, stakeholders tended to rely on regulations whenever new developments required input outside the norm, which is expected as a result of digital transformation and innovation. This over-reliance on regulatory compliance, which often lags behind technological advancements, creates compliance hurdles that hinder the implementation of new technologies and processes necessary for digital transformation (Könnölä et al., 2021). Instead, transformative ecosystem governance advocates for policies that create structural frameworks, allowing stakeholders to quickly adapt to emerging needs and models without being hindered by rigid rules.

To reduce over-reliance on regulations, ecosystems should deliberately create structures where actors can easily share data and collaborate without excluding potential collaborators based on regulatory constraints (Könnölä et al., 2021).

By explaining the underlying reasons for the persistent challenges against achieving national digital health goals, our findings underscore the need for a metagoverning digital transformation in healthcare. Furthermore, by shifting the focus from analysing organisational contexts to a broader national context and its singularities, we contribute to the literature on polycentric governance of ecosystems by investigating its implications in digital health ecosystems.

## 6 Contribution and future research

By applying the COOF framework, our study highlights the critical role of feedback mechanisms in

in polycentric governance. When these mechanisms fail, they can reinforce the status quo rather than driving the necessary changes. Our findings extend the theoretical discussion on governance models by showing how PG systems can inadvertently create opacity in governance and foster an overreliance on regulation as the primary feedback mechanism, which may hinder effective decision-making and adaptation. It further provides actionable insights to policymakers by emphasising the need for a "translucent" hand in decentralised systems.

However, our study did not focus on patients, physicians, or research institutions as ecosystem participants, leaving their experiences unexamined. Future work could address how these stakeholders interact within the ecosystem and contribute to digital transformation efforts.

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