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Governança Global para Saúde Digital no Brasil: Uma aplicação de Análise de Risco

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Glossary

ABIMED: Associação Brasileira da Indústria de Tecnologia para Saúde (Brazilian Association of the Health Technology Industry)

ACF: Advocacy Coalition Framework

AGHU: Aplicativo de Gestão para Hospitais Universitários (Management Application for University Hospitals)

ANATEL: Agência Nacional de Telecomunicações (National Telecommunications Agency)

ANVISA: Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency)

ANS: Agência Nacional de Saúde Suplementar (National Supplementary Health Agency)

API: Application Programming Interface

BPMN: Business Process Model and Notation

CAPES: Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (Coordination for the Improvement of Higher Education Personnel)

CIT: Comissão Intergestores Tripartite (Tripartite Intermanagerial Commission)

CNS: Conselho Nacional de Saúde (National Health Council)

CONASS: Conselho Nacional dos Secretários de Saúde (National Council of Health Secretaries)

CONASEMS: Conselho Nacional de Secretarias Municipais de Saúde (National Council of Municipal Health Secretariats)

CSDP: Common Security and Defence Policy (EU)

DATASUS: Departamento de Informática do Sistema Único de Saúde (Department of Informatics of the Unified Health System)

DEMAS: Departamento de Monitoramento, Avaliação e Disseminação de Informações Estratégicas em Saúde (Department of Monitoring, Evaluation and Dissemination of Strategic Health Information of the Brazilian Ministry of Health)

EBSERH: Empresa Brasileira de Serviços Hospitalares (Brazilian Company of Hospital Services)

EGSD: Estratégia Global de Saúde Digital (Global Strategy on Digital Health)

EMR: Electronic Medical Record

EHR: Electronic Health Record

ESD28: Estratégia de Saúde Digital para o Brasil 2020-2028 (Digital Health Strategy for Brazil 2020-2028)

FHIR: Fast Healthcare Interoperability Resources

Fiocruz: Fundação Oswaldo Cruz (Oswaldo Cruz Foundation)

GDPR: General Data Protection Regulation (EU)

GIZ: Deutsche Gesellschaft für Internationale Zusammenarbeit (German Agency for International Cooperation)

HIE: Health Information Exchange

HL7: Health Level Seven International

ICT: Information and Communication Technology

IR: International Relations

ISO: International Organization for Standardization

LGPD: Lei Geral de Proteção de Dados (General Data Protection Law, Brazil)

LMICs: Low- and Middle-Income Countries

MOH/MS: Ministério da Saúde, the Brazilian Ministry of Health

NGO: Non-Governmental Organization

OAuth: Open Authorization

OpenHIE: Open Health Information Exchange

PAHO: Pan American Health Organization

PPPs: Public-Private Partnerships

RASs: Redes de Atenção à Saúde (Health Care Networks)

RNDS: Rede Nacional de Dados em Saúde (National Health Data Network)

RNP: Rede Nacional de Ensino e Pesquisa (National Education and Research Network)

SaMD: Software as a Medical Device

SBIS: Sociedade Brasileira de Informática em Saúde (Brazilian Society for Health Informatics)

SEIDIGI: Secretaria de Informação e Saúde Digital (Secretariat of Information and Digital Health)

SIPOC: Suppliers, Inputs, Processes, Outputs, Customers

SNOMED CT: Systematized Nomenclature of Medicine – Clinical Terms

SUS: Sistema Único de Saúde (Unified Health System, Brazil)

TLS: Transport Layer Security

UnB: Universidade de Brasília (University of Brasília)

WHO: World Health Organization

Overview

This study is structured in ten chapters, which are, as follows:

1. Introduction

Objective:

This chapter sets the stage for the research by presenting the central problem, defining key terms, and laying out the study's research questions and hypotheses.

- Establishes the need for risk analysis in international relations and governance.
- Justifies the choice of digital health as an **instrumental case study**.
- Frames **governance and risk** as interdependent concepts in global governance studies.
- Introduces **Brazil's digital health strategy** as a crucial empirical field for exploring risk governance.

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2. A Risk-Centred Approach to Global Governance

Objective:

To present the theoretical framework guiding the study, particularly focusing on **constructivism**, **stakeholder theory**, and in global governance.

- Defines **risk as a socially constructed concept** in international relations.
- Connects risk perception to governance structures and political decision-making.
- Introduces the **theoretical justifications for using risk analysis in global governance**.
- Sets up the foundation for later methodological discussions by framing risk **not just as an object of study, but as a tool for governance analysis**.

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3. Interoperability, Security, Infrastructure, Data, and International Cooperation on Digital Health

Objective:

To provide an in-depth examination of key governance challenges in digital health, specifically focusing on interoperability, security, infrastructure, data governance, and international cooperation.

- Outlines **the key governance challenges** that must be addressed by risk analysis.
- Introduces the **multi-level structure of governance** in digital health (international, national, and local actors).
- Provides a **framework for understanding the governance gaps** that will later be analyzed through risk assessment methodologies.
- Connects digital health governance to **international cooperation**, emphasizing how interoperability failures, cybersecurity risks, and legal fragmentation create vulnerabilities.
- Lays the groundwork for **why Brazil is a crucial case study** in digital health governance.

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4. The Brazilian System of Digital Health

Objective:

To **map the Brazilian digital health system**, identify key stakeholders, and establish a baseline understanding of governance structures, legal frameworks, and operational challenges.

Role in the Research Design:

This is one of the most **methodologically complex** chapters, as it serves as a **foundational mapping exercise** for the rest of the study. The findings in this chapter **directly inform** the Delphi consultation, cross-impact analysis, and risk evaluation in later chapters.

Key Methodologies Used in Chapter 4:

1. **Stakeholder Mapping:**

    - Identifies **which actors participate in digital health governance** in Brazil, through the Advocacy Coalition Framework method.
    - Differentiates between **public actors** (Ministry of Health, regulatory agencies), **private actors** (tech companies, hospitals), and **international organizations** (WHO, PAHO) and their roles within the coalitions.
2. **Governance Analysis and Initial consultation:**

    - Consult how stakeholders perceive the presented governance frameworks.
    - Construct a value-chain and analyse it based on stakeholder input.
    - Construct the **suppliers, inputs, process, outputs and customers** matrix.
3. **Process Modelling & Institutional Analysis:**

    - Maps **how health data flows through different governance structures**.
    - Examines **institutional coordination mechanisms** between national and international regulatory bodies.
    - Uses **process-tracing methodology** to **understand decision-making pathways** in health governance.

Implications for the Rest of the Study:

- **Informs the Delphi questionnaire design** (Chapters 7-8), as the stakeholder mapping helps define **which experts to consult**.
- **Identifies priority risks** that will later be analyzed through cross-impact analysis (Chapter 8).
- **Maps out governance failures and institutional bottlenecks** that contribute to risk proliferation.
- **Serves as a baseline for evaluating risk mitigation strategies**, which are discussed in the final chapters.

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5. Risk Analysis and Its Importance to International Relations

Objective:

To establish the methodological foundation for risk analysis in governance and international relations.

- Explains **why risk is a relevant analytical tool** for governance studies.
- Introduces key **risk methodologies**.
- Defines the **analytical categories for risk evaluation** (probability, impact, interdependencies).
- Justifies the selection of **an instrumental case study** for global risk analysis.

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6. Risks in Digital Health

Objective:

To showcase the research design behind the following risk methods applications, narrating in greater detail how the processes were made to arrive to the conclusions.

- Uses data from **Chapter 4** (Brazilian digital health system) to **categorize key risks**.
- Introduces **risk typologies**, including:
    - **Cybersecurity risks** (data breaches, ransomware attacks).
    - **Interoperability risks** (fragmented IT infrastructure).
    - **Regulatory risks** (conflicting international and national regulations).
    - **Governance risks** (institutional misalignment, lack of coordination).
- Establishes the **initial hypothesis on risk perceptions**, which is later tested in the Delphi consultations.

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7. Risk Analysis: The Delphi Technique

Objective:

To apply the Delphi technique to assess expert perceptions of digital health risks.

Role in the Research Design:

- Defines the **expert consultation process**, building on **stakeholder mapping (Chapter 4)**.
- Describes how the **Delphi method was conducted**, including:
    - Selection of experts.
    - Development of the questionnaire.
    - Iterative rounds of feedback.
- Analyzes **expert consensus on risk priorities**.

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8. Risk Analysis: Cross-Impact Analysis

Objective:

To analyze the interdependencies between different risks using cross-impact analysis.

Role in the Research Design:

- Addresses **a key limitation of the Delphi method** (i.e., it does not capture risk interdependencies).
- Uses cross-impact matrices to **evaluate how risks influence each other**.
- Generates **policy recommendations** based on risk interactions.
- Integrate the findings from the consultations to the field research.

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9. Risk Contributions to Governance

Objective:

To synthesize findings from previous chapters and discuss how risk analysis contributes to governance.

- Integrates results from the Delphi technique and cross-impact analysis with the field research.
- Discusses **how risk analysis can be institutionalized** in digital health governance.
- Provides **strategic recommendations** for policymakers.

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10. Final Considerations on Risk in Digital Health

Objective:

To conclude the study by summarizing key findings, contributions, and future research directions.

- Reflects on the **effectiveness of risk analysis as a governance tool**.
- Evaluates **whether the initial research hypothesis was confirmed or refuted**.
- Discusses final findings of the study.
- Suggests **future applications of risk analysis** in global governance studies.

Summary of the Research:

1. **Theoretical Foundations** → Chapters **2 & 5**
2. **Conceptual & Empirical Background** → Chapters **3 & 4**
3. **Risk Identification & Categorization** → Chapters **6 & 7**
4. **Analytical Methods & Application** → Chapters **8 & 9**
5. **Conclusion & Future Research** → Chapter **10**

Abstract

This study explores the application of risk analysis in global governance, using digital health in Brazil as an instrumental case study. By integrating risk as both an analytical and methodological tool, the research aims to expand its role beyond decision-making, positioning it as a central construct in global governance studies. The research question investigates the main risks associated with implementing global governance in Brazil's digital health landscape and how effective governance strategies can mitigate these risks while ensuring privacy, security, interoperability, and equitable access to healthcare services.

To address this, the study employs a multi-methodological approach, combining the Delphi Method, Cross-Impact Analysis, and field research, structured within a constructivist framework using the Advocacy Coalition Framework (ACF) and Stakeholder Theory. Chapter 4 serves as a pivotal mapping chapter, identifying key actors, institutional dynamics, and risk areas that structure the entire research design.

The results challenge the initial hypothesis that risks would differ significantly among the public, private, and user perspectives. Instead, interoperability emerged as the central concern shared by all stakeholders, indicating a common risk framework that transcends sectoral divisions. Contrary to expectations, financial concerns were not prioritized, highlighting a governance gap rather than a purely economic challenge.

By demonstrating how risk analysis can be effectively applied to governance, this research contributes to both International Relations in general, and, more specifically, to Global Governance studies, providing a replicable model for integrating risk into policy planning and decision-making. The findings suggest that shared risk perceptions can foster more cooperative governance structures, reinforcing the importance of multi-stakeholder engagement in digital health and beyond.

Keywords: Global Governance, Digital Health, Risk Analysis, Interoperability, Delphi Method.

Resumo

Este estudo investiga a aplicação da análise de risco na governança global, utilizando a saúde digital no Brasil como estudo de caso instrumental. Ao integrar o risco como ferramenta analítica e metodológica, a pesquisa busca expandir seu papel além do processo decisório, posicionando-o como um elemento central nos estudos de governança global. A pergunta de pesquisa investiga quais são os principais riscos associados à implementação da governança global na saúde digital do Brasil e como estratégias eficazes de governança podem mitigar esses riscos, garantindo privacidade, segurança, interoperabilidade e acesso equitativo aos serviços de saúde.

Para responder a essa questão, a pesquisa adota uma abordagem multi-metodológica, combinando o Método Delphi, a Análise de Impacto Cruzado e pesquisa de campo, estruturada dentro de um referencial construtivista, utilizando Intergovernamentalismo, o Advocacy Coalition Framework (ACF) e a Teoria dos Stakeholders. O Capítulo 4 se destaca como um capítulo de mapeamento, identificando os principais atores, dinâmicas institucionais e áreas de risco que estruturam todo o desenho da pesquisa.

Os resultados desafiam a hipótese inicial, que previa diferenças significativas na percepção de risco entre os setores público, privado e usuários. Em vez disso, a interoperabilidade emergiu como a principal preocupação comum a todos os stakeholders, indicando um arcabouço de risco compartilhado que transcende divisões setoriais. Além disso, contrariamente às expectativas, questões financeiras não foram priorizadas, revelando que os desafios de governança são mais estruturais do que econômicos.

Ao demonstrar como a análise de risco pode ser aplicada efetivamente à governança, esta pesquisa contribui para os estudos de Relações Internacionais, de forma mais ampla, e Governança Global, de forma mais específica, oferecendo um modelo replicável para integrar o risco ao planejamento e à tomada de decisão em políticas públicas. Os achados sugerem que percepções de risco compartilhadas podem fomentar estruturas de governança mais cooperativas, reforçando a importância da participação multissetorial na saúde digital e em outros domínios da governança global.

Palavras-chave: Governança Global, Saúde Digital, Análise de Risco, Interoperabilidade, Método Delphi.

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1. Introduction

In an increasingly uncertain world, risk is not merely a variable to be managed but a structuring element of decision-making across all levels of governance. From economic planning to security strategies and public health policies, risk informs institutional actions and strategic choices (Molak, 1997, p. 15). Yet, in the realm of international relations, risk remains an underutilized concept, often sidelined as a reactive measure rather than a methodological framework for shaping governance itself (Clapton, 2011). This study challenges that perception, proposing risk analysis as a foundational element in global governance—one that not only anticipates uncertainty but also constructs the very conditions for cooperation.

This approach draws from constructivism, which asserts that international structures are shaped by the beliefs and interactions of actors. However, constructivism has long been critiqued for its lack of deep methodological grounding, particularly in operationalizing the ways in which institutions form, sustain, and transform governance norms (Weber, 2001). To address this gap, this study integrates risk analysis as a constructivist tool—one that does not merely quantify threats but maps how shared risk perceptions influence institutional alignments and decision-making. This framing shifts risk from a passive constraint to an active force in structuring international governance, particularly in digital health.

By adopting Delphi and Cross-Impact Analysis, this study operationalizes risk as a socially constructed and negotiated process—not merely a probability assessment but a dynamic framework shaping institutional behaviors. In doing so, it redefines risk as an instrument of governance, embedding it at the core of decision-making processes rather than treating it as an external force to be mitigated. This approach not only advances the field of digital health governance but also expands the methodological toolkit of international relations, demonstrating how risk analysis can serve as a mechanism for institutional coherence in an era of complex global challenges.

1.1. Research Design and Objectives

This study adopts an instrumental case study design, wherein the Brazilian context and digital health governance are not explored as ends in themselves, but rather as means to a broader methodological objective: to test and refine the application of risk analysis as a tool for global

governance research. The theoretical framework, empirical findings, and case study were selected and structured not to exhaustively explain the Brazilian digital health landscape, but to function as vehicles for the development and validation of risk analysis methodologies in international relations.

Because of this instrumental nature, the depth of theoretical exploration, case detailing, and normative extrapolation is intentionally limited. The central aim is methodological: to demonstrate how structured risk analysis tools—such as the Delphi Technique and Cross-Impact Analysis—can be operationalized in global governance research. As such, much of the study's structure and emphasis rests on designing, executing, and interpreting these methods, rather than fully unpacking all theoretical implications or the complete complexity of Brazil's healthcare governance.

In line with this, the scope of the study was shaped by stakeholder consultations, not merely to gather opinions but also to define the focus and object of analysis. Through iterative dialogues with key actors in the digital health ecosystem, the study allowed stakeholders themselves to help determine the contours of the research. This participatory approach meant that the research question, specific objectives, and focus areas emerged gradually, informed by institutional perspectives and risk perceptions revealed during the field research.

As a result, the object of analysis—digital health governance risks in Brazil—only becomes clearly delineated in the final stages of the study. This is not a methodological flaw, but rather an intentional design feature that reflects the constructivist assumption that problems are co-constructed by the actors involved. The key findings, particularly in Chapter 4, highlight how risk analysis methodologies unveil stakeholder dynamics, inter-institutional connections, and governance process modeling—all of which underscore the study's primary contribution: the demonstration of risk analysis as a viable and necessary methodological tool for international governance research.

Research Theme

This study examines the application of risk analysis as a methodological tool in governance, using digital health as an instrumental case study for global governance. Digital health presents governance challenges that are structurally different from those in other policy

domains—it depends on global interoperability to function, requiring a level of coordination that transcends national sovereignty and traditional regulatory frameworks. In this sense, risk analysis becomes essential not only to identify vulnerabilities but also to map the institutional conditions that shape governance decisions. Unlike in finance or security, where risk is often mitigated through national regulatory control, digital health requires shared risk frameworks, as cooperation is not optional but a prerequisite for its very existence.

As global governance mechanisms face systemic failures (Ikenberry, 2010), it is imperative to explore new methodological approaches to bridge the gap between governance theory and practical policymaking. Risk analysis offers a functional lens to assess governance breakdowns, identify key actors, and propose institutional frameworks that enhance decision-making coherence at international, national, and local levels. This study aims to redefine risk from a reactive concept to an active governance tool, positioning it as a structural force shaping digital health policy formation, stakeholder alignment, and institutional resilience.

Case Selection: Brazil as a Governance Model

Brazil was chosen as the primary case study for two key reasons:

First, Institutional and Geopolitical Relevance

Brazil's Unified Health System (SUS) is the largest public healthcare system in the world (Castro, 2019), making it an ideal testing ground for governance models at scale.

The Digital Health Strategy for Brazil (2020-2028) is directly tied to global governance frameworks, such as the WHO's Global Strategy on Digital Health, offering a structured case of policy implementation within an evolving global governance landscape.

As a Global South actor, Brazil presents a contrasting perspective to dominant governance models in North America and Europe, highlighting asymmetries in regulatory alignment, interoperability, and data governance.

Second, access and Field Research Feasibility

As a Brazilian researcher based in the capital, proximity to key institutions such as SEDIGI (Secretaria de Saúde Digital), DATASUS, and regulatory agencies facilitated direct

engagement with policymakers, health professionals, and data governance experts (Riese, 2018).

Field research included participation in governance committees, expert consultations, and structured Delphi methodology rounds, ensuring a deeper and more comprehensive risk assessment.

By examining Brazil's experience, this study moves beyond national applications to generate global insights on risk governance, interoperability frameworks, and institutional adaptation. The findings contribute to an emerging body of research on how governance structures can be designed to promote cooperation, mitigate systemic risks, and strengthen digital health ecosystems at scale.

1.2. Bridging Risk Analysis and Global Governance

By applying risk analysis to digital health governance, this study explores how risks and uncertainties are identified, negotiated, and institutionalized at multiple governance levels—from international policy frameworks to national strategies and local implementation. This approach moves risk analysis beyond its conventional role as an external constraint, positioning it as a central methodological tool for international relations and governance studies.

In doing so, this research challenges traditional risk assessments, such as those seen in global reports (World Economic Forum, 2023), which often treat risk as an isolated variable, or an object lacking clear methodological approaches, rather than an evolving governance process. By embedding risk analysis within governance structures, this study advances a new paradigm for digital health governance, offering both theoretical contributions to global governance scholarship and practical frameworks for policymakers navigating digital transformation in health systems worldwide.

1.3. Key Conceptual Definitions

To ensure conceptual clarity, the study operates with the following definitions:

- **Health**: A state of **physical, mental, and social well-being**, beyond merely the absence of disease .

- **Digital Health**: The use of **digital technologies to improve physical, mental, and social well-being**, including telemedicine, electronic health records, artificial intelligence, and interoperability systems (World Health Organization, 2022).
- **Governance**: The **application of joint action mechanisms** in a given topic, ensuring coordination between multiple stakeholders and decision-making processes (Ostrom, 2005).
- **Global Governance**: The use of **extraterritorial mechanisms** for government, decision-making, and enforcement in a specific domain, extending beyond national jurisdictions (Keohane, 2011).
- **Risk**: The events or processes that may cause harm, disruptions, or obstacles in the implementation of a given plan.
- **Risk Analysis**: The assessment of the likelihood and impact of these risks, along with the development of mitigation strategies (Bernstein, 1996).

Bridging Risk Analysis and Global Governance in Digital Health

Based on these definitions, the research establishes a direct connection between risk analysis and global governance in digital health. The study conceptualizes **risk analysis as a methodological tool for governance, rather than just an object of study**. The application of risk analysis in **global digital health governance** thus entails:

- Identifying potential risks and challenges in the implementation of international health governance strategies.
- Analyzing the interaction between global, national, and local governance structures in managing these risks.
- Developing effective governance mechanisms that mitigate identified risks and promote collaboration across multiple stakeholders.

By integrating risk analysis into governance frameworks, this study demonstrates how risk management can serve as a foundation for global cooperation, institutional coordination, and policy development in digital health.

Research Problem

Despite the increasing importance of digital health in global governance, few studies systematically apply risk analysis as a methodological tool in international relations and

governance studies. Risk is often treated as **an external challenge to be managed post-factum**, rather than as an **intrinsic component of governance structures themselves**.

Thus, this research is guided by the following core research question:

How can risk analysis contribute to the international dimension of governance research?

This question addresses a fundamental gap in international relations, seeking to establish risk analysis as a central methodological tool for understanding governance mechanisms in digital health and beyond.

General Objectives

The study aims to achieve the following overarching objectives:

1. Establish risk as an analytical and methodological tool in global governance research.
2. Expand the application of risk analysis beyond individual decision-making processes, positioning it within international governance frameworks.
3. Use digital health as an instrumental case study to demonstrate how risk analysis can be integrated into global governance structures and international relations.

Through this approach, the study contributes to broadening the methodological scope of international relations and governance studies, integrating risk analysis as a fundamental aspect of global governance design.

Research Question

To operationalize the broader research problem, the study formulates a specific research question that directly guides the investigation:

- **What are the main risks associated with implementing global governance in Brazil's digital health sector, and how can effective governance strategies be developed to mitigate these risks while ensuring privacy, security, interoperability, and equitable access to healthcare services?**

This question serves as the instrumental research question, allowing for an empirical investigation that provides insights into how risk analysis can enhance governance mechanisms.

Hypothesis

The study begins with the following instrumental hypothesis:

- **The primary risks associated with digital health governance in Brazil will likely differ across public, private, and societal levels, especially because of the differences of resources and financial constraints between those sectors. Understanding and addressing these risks through risk analysis will lead to the development of effective governance strategies that enhance data privacy, security, interoperability, and equitable access to healthcare services.**

This hypothesis assumes that risk perceptions and governance priorities differ across stakeholders, and that a structured risk analysis framework will allow for the development of more effective, inclusive, and responsive governance models.

By testing this hypothesis, the study aims to provide practical recommendations for improving global digital health governance, while also demonstrating how risk analysis can serve as a fundamental methodological approach in international relations and governance studies.

To explore this question, the research employs an instrumental case study approach, using Brazil's digital health governance framework as a testing ground for applying risk analysis in an international governance context. Brazil presents a unique case: its Unified Health System (SUS) is the largest public healthcare system in the world, making it a valuable model for studying the complexities of implementing global health governance strategies at a national level. Additionally, digital health, as a field inherently dependent on cooperation, interoperability, and data governance, provides an ideal setting for assessing how risk analysis can be used to identify, evaluate, and mitigate governance challenges.

Governance is inherently about managing complexity, aligning stakeholders, and ensuring coordinated action across different sectors and levels of decision-making. In global health governance, these challenges are exacerbated by the need for cross-border cooperation,

regulatory harmonization, and technological integration. This is particularly evident in digital health, where issues of data interoperability, cybersecurity, privacy, and regulatory alignment present significant risks to successful policy implementation.

While governance studies traditionally emphasize institutional design and legal frameworks, this research proposes that risk analysis can provide a more dynamic approach to governance, one that identifies vulnerabilities in governance structures before they lead to failures. By integrating risk analysis methodologies—**the Delphi Technique and Cross-Impact Analysis**—the study moves beyond theoretical discussions to offer **practical tools for assessing and improving governance mechanisms**.

This study combines qualitative research methods with structured risk analysis, applying two key methodologies:

1. **Delphi Technique** (Yoe, 2019, p. 294): A structured expert consultation method that gathers insights from key stakeholders across public and private sectors, as well as regulatory and civil society actors. The Delphi method was used to **identify and rank governance risks** in digital health, allowing for iterative consensus-building among experts.

2. **Cross-Impact Analysis** (Gordon, 1994): A method used to examine **interdependencies between different governance risks**. While the Delphi Technique identifies risks, Cross-Impact Analysis explores how these risks interact, helping policymakers prioritize interventions and design more resilient governance structures.

Within this study, two key governance mechanisms were analyzed: the ***Estratégia de Saúde Digital para o Brasil 2020-2028*** **(Digital Health Strategy for Brazil 2020-2028 - ESD28)** and the World Health Organization's **Global Strategy on Digital Health 2020-2025 (EGSD)**. The ESD28 serves as the national framework guiding Brazil's digital health policies, aligning with broader international standards while addressing the country's unique healthcare challenges. The WHO Global Strategy, in turn, provides an overarching global governance structure, establishing principles for digital health interoperability, security, and equitable access across nations. These strategies were central to the Delphi Method

application, as they structured the questionnaire design and guided expert discussions on the risks of translating global governance principles into national policies. By integrating these frameworks into the risk analysis process, the study evaluated how governance mechanisms function in practice, identifying gaps, challenges, and areas requiring further stakeholder engagement to ensure effective policy implementation in Brazil.

Additionally, **field research** (Louis, Maertens and Saiget, 2018), including technical visits to the Ministry of Health and the Secretariat for Digital Health (SEIDIGI), played a crucial role in validating findings. Field research in international relations remains underutilized, yet it provides essential empirical insights into how policies are formulated, debated, and implemented. By observing institutional processes firsthand, this study was able to **map governance networks, institutional interactions, and policy bottlenecks**.

The study's findings challenge some of the initial assumptions regarding digital health governance risks. Contrary to expectations, financial constraints were not perceived as a primary governance risk. Instead, **interoperability** emerged as the most critical governance challenge, recognized as a shared concern across public and private sectors. This finding is significant, as it indicates that governance failures in digital health are not primarily financial but structural, requiring regulatory and institutional alignment rather than mere resource allocation.

The results also underscore the importance of **stakeholder engagement** in shaping risk perceptions. Governance risks are not objective realities but are constructed through the interactions and priorities of institutional actors. By employing a **constructivist lens** (Onuf, 2012), the study highlights how governance structures evolve through negotiated processes rather than through top-down policy imposition.

This study contributes to the field of global governance by demonstrating how risk analysis can serve as a methodological bridge between governance theory and practical policy implementation. By treating risk as a governance tool rather than merely a constraint, the study proposes a new approach to decision-making in international relations—one that is adaptive, evidence-based, and participatory.

By focusing on digital health, the research illustrates how risk analysis can be operationalized in a governance context where cooperation is not just beneficial but essential. The findings

suggest that future governance models should integrate structured risk assessment methodologies to enhance institutional responsiveness and stakeholder coordination.

Ultimately, this study is not just about digital health—it is about redefining how risk is understood and applied in international relations and global governance. By embedding risk analysis within governance frameworks, this research paves the way for more resilient, adaptive, and cooperative governance systems, capable of addressing the complex challenges of an interconnected world.

This Chapter:

1. Introduces the research problem: the underutilization of risk analysis in global governance, particularly in digital health.
2. Positions Brazil's Unified Health System (SUS) as a case study due to its scale, complexity, and relevance to global governance challenges.
3. Outlines the research objectives: integrating risk analysis into governance frameworks and addressing interoperability, security, and equity in digital health.

   Building on this foundation, Chapter 2 establishes the theoretical framework guiding the study, focusing on constructivism, institutionalism, and stakeholder theory.

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2. A Risk-centred approach to Global Governance

The study of global governance requires an integrated theoretical approach that accommodates both the dynamic interactions of social actors and the structural constraints imposed by institutions. This study is grounded in **constructivism**, which postulates that international actors, including states, are shaped by ideas, identities, and norms that, in turn, influence the international system in a continuous cycle of mutual constitution (Wendt, 1999; Ruggie, 1998). Constructivism challenges rationalist approaches by asserting that political outcomes are not merely the result of material forces but are deeply embedded in historical and discursive processes.

At the same time, the research also draws on **institutionalism**, particularly historical institutionalism and constructivist institutionalism, to understand how institutions mediate governance outcomes. Institutions, understood as enduring rules and norms, shape behavior by structuring incentives and cognitive frameworks through which actors interpret and respond to political challenges (Mahoney & Thelen, 2010; Schmidt, 2020). This institutional approach complements constructivist theory by emphasizing that governance structures are both shaped by and shape actor preferences, reinforcing patterns of authority and cooperation in international settings.

By integrating these two perspectives, this study examines the **evolution of global governance in digital health**, using Brazil as an instrumental case study to demonstrate how risk analysis can be systematically applied within stakeholder driven governance structures. **Risk analysis**, within this framework, is not an objective assessment of material threats but a socially constructed process influenced by power relations, institutional constraints, and stakeholder perceptions (Bernstein, 2012). The conceptualization of risk is informed by discursive institutionalism (Schmidt, 2007), which asserts that meaning-making processes shape governance responses and institutional adaptations.

2.1. Constructivism and Global Governance

Constructivism, as developed by Wendt (1995, 1999) and Ruggie (1998), posits that international politics is shaped by social structures rather than simply by material power distributions. The theory argues that state behavior and global governance mechanisms

emerge from historically constructed identities, shared beliefs, and social interactions rather than pre-existing rational choices. This approach is particularly useful in understanding governance in digital health, where evolving technological norms and collective perceptions of risk play a crucial role in shaping international cooperation.

One of the key implications of constructivism for this study is the recognition that **risk in global governance is not merely an empirical phenomenon but a negotiated reality**. For example, the perception of cybersecurity threats in digital health is framed by dominant narratives about data sovereignty, privacy, and technological dependency, influencing regulatory responses at both national and international levels (Keohane and Nye, 2012). The adoption of digital health governance frameworks in Brazil reflects a broader constructivist process in which policy choices are informed by the interplay of domestic institutional actors, international organizations, and transnational technology firms.

Additionally, constructivism provides insights into the **role of norms and identities in shaping governance structures**. The institutionalization of digital health policies in Brazil has been shaped by discourses on health equity, technological modernization, and global cooperation. These normative structures create pressures for the state to adopt specific policy frameworks that align with international expectations, illustrating how governance models emerge as a product of discursive struggles.

Constructivism, as a theoretical lens, emphasizes that knowledge, perceptions, and risks are socially constructed through interactions, discourses, and shared understandings among individuals and institutions. In the context of the Delphi method, this means that stakeholder perceptions of risks in digital health governance are not objective or static but are shaped by their social, institutional, and cultural contexts. For example, the dominance of certain risks, explored later in this study, across public, private, and user perspectives reflects a socially constructed consensus or discensus. Stakeholders collectively prioritize the risks they perceive, because it aligns with their shared experiences of fragmented systems and inefficiencies in Brazil's healthcare system, highlighting how risks are co-constructed through collective negotiation rather than being inherent or universal.

2.2. Institutionalism and the Role of Governance Structures

Institutionalism provides a framework to understand how rules, norms, and practices shape governance structures. This study draws on **historical institutionalism**, which emphasizes that institutional development is path-dependent and influenced by previous governance decisions (Mahoney & Thelen, 2010). The historical evolution of Brazil's Unified Health System (SUS), for example, has significantly influenced the implementation of digital health policies, reflecting a long-standing institutional commitment to universal health access.

Moreover, **constructivist institutionalism**, as proposed by Schmidt (2008) and Hay (2006), is particularly relevant for understanding **policy innovation in digital health governance**. This perspective highlights that institutions are not static entities but are continuously reshaped by ideational shifts and discursive interactions among stakeholders. In the case of Brazil, the digital transformation of healthcare governance has been facilitated by institutional reforms that integrate emerging technologies while accommodating existing bureaucratic and legal structures.

The institutionalist perspective also explains the **role of stakeholder coordination** in digital health governance. The decentralized nature of Brazil's federal system poses challenges for policy harmonization across municipal, state, and federal levels, necessitating a **multi-level governance approach**.

2.3. Stakeholder Theory and Participatory Governance

Stakeholder theory is instrumental in analyzing the governance of digital health because it provides a framework for understanding how different actors—governments, private sector firms, civil society organizations, and international bodies—interact within governance structures (Freeman, 1984; Rowley, 1997). Governance is not solely the domain of states but rather the outcome of negotiations between diverse stakeholders with competing interests.

Brazil's digital health governance illustrates how stakeholder engagement influences policy outcomes. The increasing role of tech companies and international donors in shaping Brazil's digital health policies demonstrates that governance is no longer monopolized by public institutions. However, power asymmetries in stakeholder participation raise concerns about representation and accountability, as certain actors—such as marginalized communities—may lack sufficient influence in policy negotiations.

The multi-stakeholder governance model observed in Brazil's digital health strategy is emblematic of hybrid governance arrangements, where public-private partnerships (PPPs) play a crucial role in policy implementation. While PPPs enable resource mobilization and innovation, they also pose challenges in terms of regulatory oversight and equitable access to healthcare technologies.

2.4. Risk Analysis as a Tool for Governance

The final component of this study's theoretical framework is **risk analysis**, which serves as an operational tool for global governance. Constructivist institutionalism posits that risk is **socially constructed** rather than objectively determined. **Risk perception is shaped by institutional narratives, regulatory frameworks, and stakeholder interests**. As such, risk analysis provides an essential lens to evaluate how governance mechanisms manage uncertainties related to digital health, including **data privacy, cybersecurity, and interoperability** (Nye and Donahue, 2000).

The Brazilian case exemplifies the **interplay between risk assessment and policy formulation**. For instance, the national strategy for digital health incorporates cybersecurity risk assessments that align with global regulatory trends while balancing domestic priorities. This reflects a broader trend in global governance, where risk frameworks influence **the design of institutional responses** to technological disruptions.

Furthermore, risk analysis also plays a **critical role in crisis response**, as observed during the **COVID-19 pandemic**, where **digital health governance became central to managing public health risks** (Alaszewski, 2021). The pandemic accelerated the adoption of telemedicine and electronic health records, highlighting the need for adaptive governance structures capable of integrating real-time risk assessments into decision-making processes.

Finally, constructivism highlights the importance of adaptive, participatory governance strategies that account for the socially constructed nature of risks. The Delphi technique, one of the main tools used to develop this study, suggests that addressing interoperability requires fostering multi-stakeholder collaboration to align divergent perspectives and institutional priorities. This approach aligns with constructivism's emphasis on negotiated solutions and shared understandings, rather than rigid, top-down policies. By integrating constructivism into the interpretation of Delphi results, the study will provide a deeper understanding of how

stakeholder perceptions are shaped by social, institutional, and normative factors, offering a robust foundation for developing adaptive governance frameworks in digital health.

2.5. Bibliometric Review

The bibliometric review presented in this study is necessary to establish the current state of academic discourse in the fields of global governance, digital health, health governance, and interoperability while identifying existing gaps and potential areas for integration. Given the theoretical framework that underpins this research—combining constructivism, institutionalism, stakeholder theory and risk analysis—this review serves several key purposes, such as Identifying Fragmentation in the Literature, Addressing the Gap Between Global Governance and Digital Health, Establishing the Lack of a Theoretical and Empirical Framework for Risk Analysis in Digital Health, Reinforcing the Need for a Stakeholder-Oriented Approach and Confirming the Absence of Research on International Relations in Health.

So, the chosen keyword are: Digital Health; Health Governance; Interoperability; Global Governance; International Relations in Health; DataSUS

2.5.1. Bibliometric Research Methodology

The research was conducted in the Web of Science database, using the keywords above, and selecting the 200 most cited articles in each area, using the Publish or Perish software. These selected articles identified the most influential and relevant publications.

International Relations in Health: A search did not find relevant results, highlighting a gap in studies that address the intersection between health and international relations.

Out of the 800 most cited articles, the 500 most cited ones were selected for the bibliometric review, due to the restrictions imposed by the database.

2.5.2. Bradford's Law: Reviews analyzed:

1. Science
2. IEEE Communications Magazine
3. Proceedings - International Conference on Open Data and Big Data
4. Public Health BMC
5. Journal of Business Ethics

6. New England Journal of Medicine

7. Society and Natural Resources

8. Information, Communication and Society

9. International Migration Review

10. Global environmental change

11. Health Matters

12. Proceedings of the National Academy of Sciences of the United States of America

13. Stroke

14. World Neurosurgery

15. Brazilian Journal of Psychiatry

16. Clinical Microbiology Reviews

17. Review of International Political Economy

18. Mycoses

19. Circulation

20. Health Technology Assessment

21. International Journal of Medical Informatics

22. Nature

23. Regional Studies

24. Brazilian Journal of Psychiatry

25. International Journal of Infectious Diseases

26. International Journal of Mental Health Systems

27. Brazilian Journal of Epidemiology

28. Future Generation Computer Systems

29. npj Digital Medicine

30. Ecology and Society

31. SN Computer Science

32. Journal of Management Studies

33. Public Health Notebooks

34. IEEE Transactions on Industrial Informatics

35. Human Reproduction

36. The Lance

Journals were classified into Bradford zones, identifying core journals in each area.

Zone 1:

New England Journal of Medicine

The Lancet

Science

	Public Health BMC Health Matters Journal of Management Studies	listed, each with one or a few articles.
Zone 2: Proceedings of the National Academy of Sciences	IEEE Communications Journal Journal of Business Ethics	
	Zone 3: All other journals	

The analysis indicated that there is no overlap of core journals between the themes of global governance and health governance, indicating a fragmentation between these fields, with studies being published in different journals and without communication between the areas

2.5.3. Lotka's Law:

The productivity of authors in each area was verified, according to Lotka's Law, to verify whether there were relevant authors in both areas. The analysis showed that the most productive authors are dedicated to a specific field, with rare cases of publications integrating the themes of global governance and digital health.

The only point of connection identified were studies on the Anthropocene, which address global governance and its impacts on health and the environment, and Global Value Chains, namely the ones from Gereffi Gardy, from 1994, 1999 and 2001, which address global production and capitalism. But none of the points of connection directly address healthcare or digital health, health digitalization or international health.

Although studies on the Anthropocene present significant internal communication, they mainly communicate with each other, without integrating other areas, such as digital health or health interoperability. Thus, despite providing relevant insights for global governance and environmental and health impacts, these studies do not foster a direct connection with the themes of health governance or interoperability.

2.5.4. Results of the Systematic Review and Gaps Identified:

This analysis revealed that despite separate scientific output on global governance and digital health, there is little integration between the two fields. The themes of interoperability and governance in digital health remain disconnected.

No co-citation was identified between the most cited articles in global governance and governance for health, indicating a lack of dialogue between the fields.

Although there are studies that connect global governance, health and the environment based on the concept of the Anthropocene, these works do not integrate other areas such as digital health or the Brazilian health system (SUS), remaining restricted to a dialogue between them.

The lack of any relevant articles published using the terms international relations and health indicates an even more glaring gap in this area of research. And in the same areas that should have joint publications, such as digital health and health governance, no concrete relevant references were considered.

2.5.5. Conclusion of the bibliometric review:

The survey highlights a fragmentation in the literature on global governance and digital health, without substantial integration between these themes.

Studies on the Anthropocene emerge as the unique link between global governance, health and the environment; however, they do not extend this integration to include digital health or interoperability.

The absence of studies on "international relations in health" and the fragmentation in co-citation confirm that there is a need for integrative studies that connect global governance, health and international relations, with a focus on the interoperability of the SUS in the global scenario.

Table 2.1.: Summary table with the most relevant articles

Title	**Author**	**Year of publication**	**Review**	**Citations**
Trajectories of	Steffen, W.,	2018	Proceedings of	1829

the Earth System in the Anthropocene	Rockström, J., Richardson, K., (...), Winkelmann, R., Schellnhuber, H.J.		the National Academy of Sciences of the United States of America 115(33), pp. 8252-8259	
The governance of global value chains	Gereffi, G., Humphrey, J., Sturgeon, T.	2005	Review of International Political Economy	3649
Community Resilience: Towards an Integrated Approach	Berkes, F. , Ross, H.	2013	Society and Natural Resources 26(1), pp. 5-20	1104
A diagnostic approach to go beyond panaceas	Ostrom, E.	2007	Proceedings of the National Academy of Sciences of the United States of America 104(39), pp. 15181-15187	1957

Source: Self-elaboration.

The articles from Rockström et al (2018), Berkes and Ross (2013), and Ostrom (2007), listed in the summary table are highly cited and address fundamental themes related to the Anthropocene, community resilience and environmental governance, offering a solid theoretical basis for discussion on sustainability and environmental adaptation, while the one

from Gereffi, Humphrey and Sturgeon (2005), addresses political changes and stakeholder collaboration on governance.

These three articles make fundamental contributions to contemporary discussions on environmental governance, resilience and the human role in global transformations. Each of them addresses different and complementary aspects:

Steffen et al. (2018) brings a global perspective on the risks of the Anthropocene and the need for new planetary governance.

Gereffi, Humphrey and Sturgeon (2005) contribute to a perspective on global value chains integration with new governance procedures, in a complex network that can be modelled using different classifications.

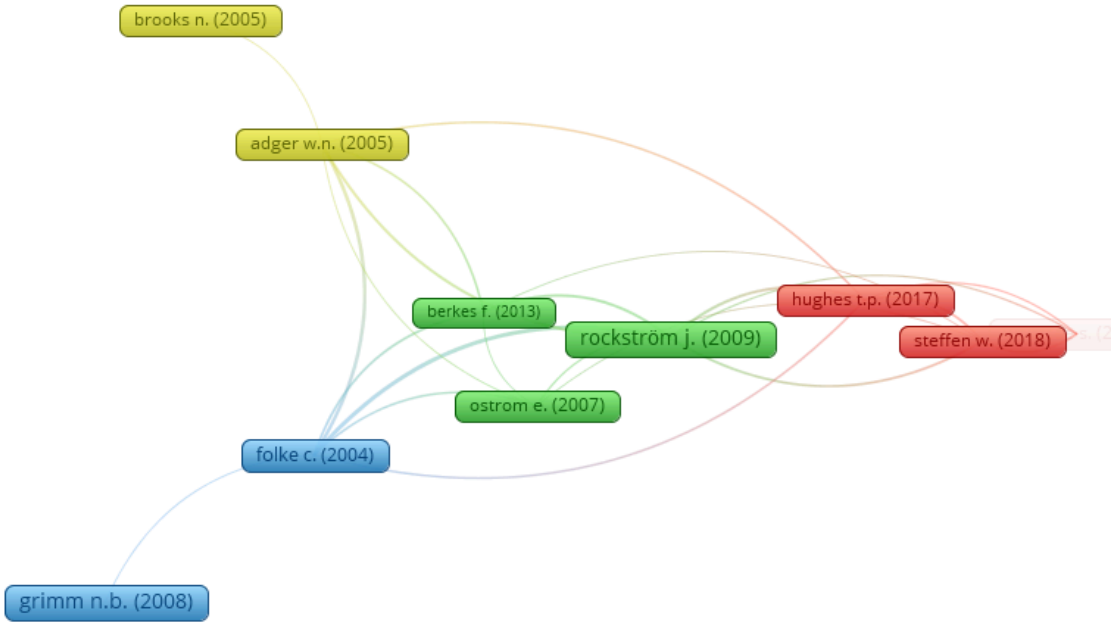
Berkes and Ross (2013) propose an integrated approach to resilience, relevant to communities facing environmental and social impacts.

Ostrom (2007) challenges the idea of universal solutions, advocating adaptive and contextual approaches to resource governance.

Despite their significant contributions, the three articles lack an explicit connection to the health field, especially on topics such as digital health, interoperability, and global health governance. These gaps suggest research opportunities to explore how concepts of resilience and environmental governance can be applied to the health sector, especially in a global and digital context. Moreover, none of those articles directly address risk analysis or propose a methodological integration of risk within their studies, suggesting, just as expected, that while risk is an object that is studied in IR, it is not methodologically analysed.

2.5.6. Coupling analysis

Image 2.1.: Coupling Analysis.



Source: Self-elaboration, made with VOS viewer software.

A coupling analysis (bibliographic coupling) reveals three main areas of research that are organized around themes of environmental governance, ecological resilience and the impacts of human activities on the ecosystem. These groups, or clusters, are highlighted in the presented network and groupings of authors who analyze similar references indicate close thematic relationships.

2.5.6.1 Green Cluster (Rockström articles and connections with environmental governance)

Main Authors: Rockström (2009), Ostrom (2007), Berkes (2013)

Central Theme: These articles discuss concepts of planetary boundaries and environmental governance with an emphasis on resilience and ecosystem management.

2.5.6.2. Yellow Cluster (Adger and Brooks - Vulnerability and Adaptability)

Main Authors: Adger (2005), Brooks (2005)

Central Theme: This group focuses on vulnerability and adaptability to environmental disasters and socio-ecological response capacities.

2.5.6.3. Red Cluster (Articles on the Anthropocene and Biodiversity)

Lead Authors: Hughes (2017), Steffen (2018)

Central Theme: This group explores the concept of the Anthropocene and the impacts of human activities on biodiversity and ecosystem health.

2.5.6.4. Blue Cluster (Resilience and Urban Change)

Main Authors: Folke (2004), Grimm (2008)

Central Theme: Discussion about resilience in urban environments and how cities respond to environmental pressures and changes.

2.5.6.5. Analysis

The first cluster, represented in green, includes works such as those by Rockström (2009), Ostrom (2007) and Berkes (2013), which discuss concepts of planetary boundaries and environmental governance with an emphasis on resilience and ecosystem management. Rockström (2009) appears as a central reference that connects most of the studies in this group, presenting a common approach in controlled governance strategies to face the impacts of global environmental change.

The second cluster, in yellow, groups together the works of Adger (2005) and Brooks (2005), which focus on vulnerability and socio-ecological adaptive capacity in the face of environmental disasters. These articles explore how communities and natural systems respond to adverse changes, with a specific focus on vulnerability and adaptability, connecting to the green cluster through the issue of resilience, but with an approach more focused on the social response to environmental challenges.

The third cluster, in red, includes authors such as Hughes (2017) and Steffen (2018), who investigate the concept of the Anthropocene and the impacts of human activities on biodiversity and ecosystem health. These works discuss how anthropogenic activities affect the environment and the need for mitigation strategies. The strong connection with the study by Rockström (2009) highlights a common interest in human-driven global changes and strategies to mitigate these effects.

Finally, the blue cluster, which includes authors such as Folke (2004) and Grimm (2008), addresses resilience in urban environments and the responses of cities to environmental

pressures. This group connects with the green cluster, indicating a common interest in resilience applied at different scales, both in natural ecosystems and in urban environments.

However, a closer look at these clusters reveals some significant gaps. First, the relationship between these themes and the health field is very weak. Although climate change and environmental manipulation have indirect implications for public health, there is no explicit link to health policies or practices in the articles analyzed. Second, there is no connection to digital health or health interoperability issues. None of the articles discussed address how environmental governance or ecological resilience could be connected to digital health systems, which highlights an important gap in the dialogue between these themes and technological innovations applied to health.

Furthermore, the articles analyzed do not refer to the context of international relations. When discussing our clusters focused on environmental governance and resilience, they do not explore how these issues interconnect with global health governance or health policies at the international level.

Finally, the method of risk analysis isn't explored whatsoever on those governance studies, suggesting that the method is largely unexplored, since the most cited and impactful articles of the area don't utilize it.

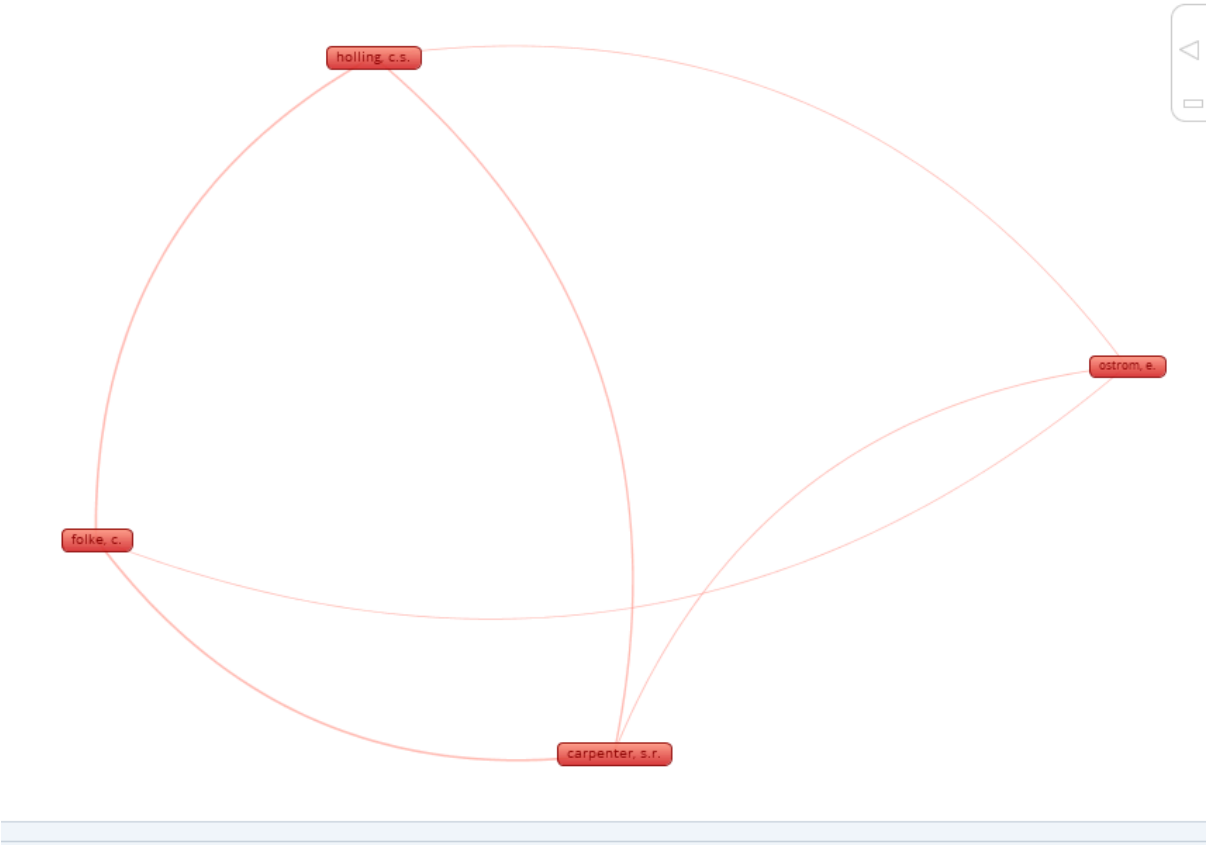
These gaps demonstrate that, despite the relevance of environmental issues and the Anthropocene concept for global governance, there is still little integration with the health sector, especially with regard to digital health and data interoperability. The lack of an interdisciplinary dialogue that connects environmental governance, public health, digital health and international relations indicates an opportunity for future research that addresses these intersections in a more integrated way, promoting a more comprehensive vision of global governance and sustainability.

2.5.7. Co-citation

Image 2.2.: Co-citation by references.

Source: Made with VOSviewer software.

Image 2.3.: Co-citation by authors



Source: Self-elaboration, made with VOS viewer software.

The analysis of co-citation by authors was discarded due to its low relevance and relationship. In co-citation by references, two clusters are established:

2.5.7.1 Red Cluster

The red cluster contains authors such as Crutzen (known for popularizing the term "Anthropocene"), Polasky and Carpenter, who discuss topics related to the impact of human

activities on the environment and the idea of a new geological era dominated by human actions. This group mainly explores the concept of the Anthropocene and the social norms associated with human behavior in relation to the environment. Works such as Nyborg's on social norms and Waters on the Anthropocene reinforce this emphasis on human effects on ecosystems and the recognition of human responsibility in the transformation of the planet.

2.5.7.2. Green Cluster

The green cluster includes authors such as Bellwood, Hughes, and Foley, whose work also addresses environmental issues, but with a more specific focus on biodiversity and ecological resilience. Hughes and Bellwood, for example, explore ecosystem conservation, with a particular focus on environments such as coral reefs and their vulnerabilities. This cluster appears to be more focused on the preservation of specific ecosystems and on analyzing the resilience of these ecosystems in the face of environmental pressures.

2.5.7.3. Analysis

While there is a connection between the two clusters, it is relatively limited and suggests that while the two groups share a common interest in environmental issues, they approach these issues in distinct ways. The red cluster focuses more broadly on human influence and social norms that are important for the Anthropocene, while the green cluster focuses on issues of ecological resilience and the response of specific ecosystems to change.

2.5.8. Additional Observations

Both clusters are predominantly focused on environmental and biodiversity issues, with little or no connection to the health sector.

There are no discussions on digital health, interoperability, risk or integration of health systems, highlighting a significant gap between these topics and environmental governance.

Furthermore, there are no references that address the context of international relations, indicating that the main focus remains on ecological and environmental aspects without integration with global governance policies in health.

2.5.9. Conclusion: Integrating Theoretical Frameworks and Bridging Research Gaps in Global Digital Health Governance

By integrating constructivism, institutionalism, stakeholder theory, and risk analysis, this study provides a multi-theoretical approach to analyzing global governance in digital health. The Brazilian case study illustrates how historical institutional developments, normative structures, and stakeholder dynamics shape governance frameworks, reinforcing the need for adaptive and participatory models that balance state authority with multi-stakeholder engagement.

The bibliometric review confirms the fragmentation in the academic discourse on global governance and digital health. The lack of overlap between core journals and the absence of co-citation links highlight a structural disconnect that limits interdisciplinary integration. Additionally, Lotka's Law analysis indicates that most scholars specialize in either global governance or digital health, but not both, reinforcing disciplinary silos that prevent holistic approaches to governance challenges.

Moreover, the absence of theoretical and empirical frameworks linking risk analysis to digital health governance underscores the necessity of a risk-centered governance approach. While global governance studies address risk from an institutional perspective, and digital health studies focus on technological and regulatory risks, the integration of these perspectives remains absent. This study seeks to fill this gap by positioning risk as a socially constructed governance challenge, influenced by institutional arrangements, stakeholder interactions, and regulatory constraints.

Furthermore, the disconnect between stakeholder theory and global governance reveals a lack of studies on how multi-actor coordination operates in digital health governance. While stakeholder theory highlights collaboration, and global governance focuses on state-driven governance, these two approaches have yet to be systematically combined in the context of digital health interoperability and global cooperation. This study builds on Schmidt's constructivist institutionalism (2008) to propose a governance model that aligns multi-stakeholder engagement with institutional structures.

Finally, the complete absence of studies on “international relations in health” represents a critical gap, confirming that health governance remains largely excluded from global governance debates. Given the growing role of international institutions, cross-border data sharing, and digital health frameworks, this study advocates for the integration of international relations perspectives into digital health governance.

By validating these research gaps through bibliometric analysis and theoretically bridging these fragmented domains, this study establishes a new research agenda that integrates:

Global governance frameworks (stakeholder theory, institutionalism);
Risk analysis as a governance tool;
Stakeholder theory to enhance multi-actor governance;
Constructivist institutionalism to explain governance evolution in digital health.

Ultimately, this study contributes to the broader discourse on global governance by demonstrating how risk-centered approaches can enhance institutional responsiveness and stakeholder coordination in complex policy environments. By addressing the interdisciplinary divide between global governance and digital health, it proposes a conceptual and empirical contribution that redefines how digital health is governed in a globalized world.

This chapter:

1. Presents the theoretical framework, combining constructivism, institutionalism, and stakeholder theory to analyze digital health governance.
2. Highlights how risk is socially constructed and shaped by institutional norms, power dynamics, and stakeholder interactions.
3. Introduces risk analysis as a methodological tool for governance, emphasizing its role in identifying and mitigating systemic vulnerabilities.

   With this theoretical foundation, Chapter 3 examines the key governance challenges in digital health, including interoperability, security, and international cooperation.

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3. Interoperability, Security, Infrastructure, Data and International Cooperation on digital health

Digital health represents a transformative frontier in contemporary health systems, integrating information and communication technologies with medical practices to improve patient outcomes, streamline workflows, and enable personalized healthcare experiences. As the global shift toward digitization continues to gain momentum, ensuring that disparate health information systems can communicate effectively and share data becomes increasingly essential. Interoperability thus emerges as a fundamental pillar of digital health, enabling the seamless exchange of health information across various platforms and organizations—critical for coordinated patient care and informed clinical decision-making.

Alongside interoperability, security is a crucial concern in digital health initiatives. The vast amounts of sensitive health data being transmitted and stored require robust security measures to prevent breaches and unauthorized access. This is particularly important for preserving patient confidentiality and maintaining trust in digital health systems. Additionally, an effective infrastructure is essential to support the reliable exchange of health information. Infrastructure encompasses both technological frameworks, including software and hardware components, as well as the underlying policies and governance that dictate how data can be shared, accessed, and utilized. Without a strong infrastructure, the full potential of digital health cannot be realized.

Data management also plays a critical role in the digital health ecosystem. Effective data management practices ensure that health data is not only collected and stored securely but is also available in a meaningful format that enhances healthcare interventions. The reliability, accuracy, and accessibility of health data are vital for improving patient outcomes, highlighting the importance of robust data governance and management strategies.

The Fast Healthcare Interoperability Resources (FHIR) standard, developed by HL7, is a pivotal protocol for addressing challenges related to interoperability, security, and digital

health data management. FHIR promotes the use of web standards for healthcare information exchange, facilitating the integration of various health information systems. Its structure allows the modular implementation of resources, making it adaptable to diverse healthcare environments. The significance of FHIR is particularly evident in its adoption by Brazil's Unified Health System (SUS) and the World Health Organization (WHO), both of which aim to enhance public health infrastructure and global health data exchange.

As part of the Unified Health System (SUS), FHIR can potentially streamline access to health information, enhance the coordination of interinstitutional care, and support real-time data exchange between primary care, specialized care, and emergency services. In the context of the World Health Organization (WHO), FHIR plays a crucial role in promoting international cooperation in health data interoperability, enabling nations to respond swiftly and effectively to public health emergencies—such as pandemics—by facilitating the sharing of critical health information.

Additionally, the roles of various stakeholders—ranging from government organizations and healthcare providers to technology developers and patients—are essential in the successful implementation of interoperability standards like FHIR. Each stakeholder contributes to the digital health landscape, working toward the common goal of improving health outcomes through optimized data sharing and usage. Analyzing these concepts through FHIR's objectives, alongside the collaborative efforts within SUS and WHO, highlights the multifaceted nature of digital health and underscores the critical interdependencies between interoperability, security, infrastructure, and data management. The integration of these elements establishes a solid foundation for advancing digital health initiatives that prioritize patient care and public health imperatives.

3.1. Interoperability in Digital Health

Interoperability in digital health refers to the ability of different health information systems, devices, and applications to communicate effectively, enabling seamless data exchange and utilization across various platforms (Bhartiya & Mehrotra, 2014). This concept extends beyond the technical aspects of data sharing to include semantic interoperability, which

ensures that the meaning of exchanged data is preserved and correctly interpreted across different systems. As digital health continues to evolve, interoperability has emerged as a fundamental prerequisite for a cohesive healthcare ecosystem, allowing healthcare professionals to enhance patient care, streamline operations, and reduce costs through improved collaboration and data sharing.

The critical role of interoperability lies in its ability to integrate disparate health information systems, facilitating seamless data flow that ultimately improves clinical decision-making and patient outcomes. In this context, the adoption of Health Information Exchange (HIE) networks and standards is essential. However, achieving interoperability remains a complex challenge, as it requires overcoming differences in data formats, variations in data standards, and the existence of data silos within healthcare organizations that hinder smooth information exchange.

One significant challenge is the proliferation of proprietary systems that limit data accessibility and interoperability. Many healthcare organizations utilize electronic medical records (EMRs) that were not designed to communicate with one another, creating fragmentation in patient care. This fragmentation leads to inefficiencies in healthcare delivery, complicates care coordination, and prevents the development of comprehensive patient health profiles. The situation is further exacerbated by privacy and data security concerns, which create reluctance among stakeholders to share sensitive health information.

To address these challenges, the FHIR (Fast Healthcare Interoperability Resources) standard, developed by Health Level 7 (HL7), has emerged as a key framework for achieving interoperability in digital health. FHIR provides a modern architecture for health data exchange, utilizing web-based technologies and standardized data formats that facilitate the implementation of APIs (Application Programming Interfaces). This approach enables the seamless integration of diverse health information systems, allowing for real-time data sharing between electronic health records (EHRs), clinical applications, and external data sources.

FHIR’s design is inherently favorable to interoperability, as its resources represent common clinical and administrative data elements. For example, FHIR standards promote uniformity in coding systems such as SNOMED CT and LOINC, ensuring that exchanged health data

maintains semantic consistency across systems. This alignment significantly reduces the complexities often associated with data normalization and interpretation between various entities.

Additionally, FHIR places a strong emphasis on patient security and consent, addressing critical concerns about data sharing in the healthcare sector. By integrating security protocols such as OAuth 2.0 and OpenID Connect, FHIR standardizes mechanisms for protecting sensitive health information, which is essential for fostering trust among stakeholders involved in health data exchange.

In the broader context of Brazil's Unified Health System (SUS) and World Health Organization (WHO) frameworks, FHIR-facilitated interoperability is crucial for enhancing public health initiatives, optimizing resource allocation, and improving the quality of care provided to populations. Stakeholders—including healthcare professionals, policymakers, and technology developers—are increasingly recognizing the importance of interoperability initiatives that comply with global standards established by organizations such as WHO. By promoting a culture of collaboration and information sharing, FHIR contributes to an environment where health data can drive healthcare innovations, ultimately benefiting patients on a global scale.

3.2. The Role of Security in Digital Health

Security in digital health environments is fundamental, particularly given the sensitive nature of patient information and the associated ethical and legal imperatives. As digital technologies become more integrated into healthcare, systems handling personal health data must prioritize robust security measures and standards to mitigate the risk of data breaches

FHIR plays a critical role in not only enhancing interoperability across different healthcare systems, as previously mentioned, but also by embedding security protocols to protect sensitive patient data. FHIR's architecture incorporates secure access mechanisms, including OAuth 2.0 for authentication, ensuring that only authorized personnel can access specific health information. This emphasis on secure access is vital for building trust between patients and healthcare professionals, thereby enabling better data sharing and collaboration within the healthcare ecosystem (OSMOM et al., 2022).

The adoption of security measures such as encryption is equally crucial for protecting digital health data. Encryption transforms data into an unreadable format without a decryption key, safeguarding confidential information from unauthorized access during storage and transmission. In the context of FHIR, secure data exchange is facilitated by the use of Transport Layer Security (TLS), which prevents interception and tampering by malicious actors. Ensuring end-to-end encryption plays a significant role in preserving patient privacy and complying with regulatory requirements, such as the General Data Protection Regulation (GDPR) in Europe and the Health Insurance Portability and Accountability Act (HIPAA) in the United States.

Additionally, the implementation of comprehensive access control policies is essential in digital health environments. Role-Based Access Control (RBAC), for instance, defines the level of access healthcare professionals have to patient information based on their role within the organization. By implementing these measures, healthcare organizations can ensure that confidential data is not indiscriminately accessible, thereby limiting exposure to potential breaches. FHIR's ability to integrate these access control features aligns with broader health information system security objectives, making it a critical tool for protecting patient data.

The application of these security measures within organizations such as Brazil's Unified Health System (SUS) and the World Health Organization (WHO) is essential. Both entities emphasize the need to protect health information to promote universal health coverage and facilitate international health reporting. Within these frameworks, stakeholders must collaborate to establish common security standards, ensuring that interoperability does not compromise patient data security across borders. By doing so, nations can create a secure and reliable digital health ecosystem that promotes international cooperation and supports the global health agenda.

In summary, the protection of sensitive patient information in digital health environments can be strengthened through the implementation of standards and protocols such as FHIR, which incorporates security features at its core. As digital health continues to evolve, so too must security measures that safeguard these systems, underscoring the need for continuous collaboration among stakeholders within national and international health frameworks. Such efforts are critical to ensuring that the promise of digital health is realized without compromising patient privacy or data integrity.

3.3. Technological and Organizational Infrastructure in Digital Health

The successful development and implementation of digital health solutions require a thorough understanding of technological and organizational infrastructure considerations. Infrastructure in digital health encompasses a wide spectrum, including physical components (such as hardware and networking capabilities) as well as frameworks, organizational policies, and human resources that facilitate the effective use of digital health systems. Various country-specific case studies illustrate how robust infrastructure plays a critical role in the successful integration of digital health solutions, particularly in Brazil.

In Brazil, Oliveira et al. (2023) highlight how the deployment of a digital health solution leveraging Fast Healthcare Interoperability Resources (FHIR) was instrumental in enhancing the efficiency of Brazil's Unified Health System (SUS). Their study underscores the importance of both interoperability and security mechanisms in IT infrastructure to ensure the effective exchange of data between disparate healthcare entities while maintaining patient confidentiality. The FHIR standard, developed by HL7, supports this effort by offering standardized APIs that enable seamless data sharing across diverse information systems. This is particularly crucial in a heterogeneous healthcare system such as SUS, which includes both public and private healthcare facilities that often operate on different technological platforms.

In addition, organizational leaders must align with technological advancements to facilitate the full integration of digital health. Effective governance models that define the roles of stakeholders—including government agencies, healthcare providers, and patients—are essential in navigating the complexities of digital health systems. In Brazil, the Ministry of Health has launched policies that promote collaborative governance structures, ensuring that digital health initiatives are not only technologically sound but also socially inclusive and responsive to community needs.

International cooperation also plays a crucial role in improving infrastructure, as demonstrated by the operational paradigms established by the World Health Organization (WHO). The WHO's Digital Health Strategy highlights the importance of global

collaboration in accelerating the adoption of digital health solutions. Successful case studies in Kenya and India illustrate how public-private partnerships have facilitated the development of digital health infrastructures, enhancing access to healthcare services.

3.4. Equitable access: Why Brazil's healthcare system matters

While digital health is often discussed in terms of technological infrastructure and regulatory challenges, its societal impact remains at the core of governance concerns. The effectiveness of digital health systems is not simply a matter of efficiency, but of equitable access, particularly for marginalized populations, including rural communities, indigenous groups, quilombolas, and urban peripheries. Without a structured governance model that prioritizes inclusion, digital health risks deepening existing inequalities rather than mitigating them.

Health information systems, such as those overseen by DEMAS (General Coordination of Monitoring and Evaluation in Health - Coordenação Geral de Monitoramento e Avaliação em Saúde), play a crucial role in ensuring that decision-making in public health is evidence-based and inclusive. DEMAS integrates monitoring, evaluation, and strategic information management, creating a governance framework that connects national policy decisions with regional and municipal realities. By systematically collecting and analyzing data on health services and patient demographics, DEMAS enables policymakers to assess disparities in healthcare access and design interventions that address systemic inequalities.

Moreover, international frameworks, such as SAGE (Strategic Advisory Group of Experts on Immunization), demonstrate how data-driven governance can support public health equity. SAGE provides global guidance on immunization policies, leveraging risk analysis and data-driven recommendations to ensure that vaccine distribution prioritizes vulnerable populations. Applying a similar approach to digital health governance could facilitate more inclusive policy design, ensuring that digital health technologies reach populations who need them most.

Health Governance as a Cross-Sectoral Challenge

Digital health does not exist in isolation—it is transversal, intersecting with sectors such as education, infrastructure, social assistance, and human rights. For example, access to reliable internet is essential for telemedicine and electronic health records, yet digital infrastructure remains unevenly distributed across Brazil, disproportionately affecting low-income

communities. The digital divide in healthcare is therefore not just a technological issue, but a fundamental governance challenge that requires cross-sectoral collaboration.

The failure to integrate risk assessment into digital health governance can exacerbate these disparities. Without robust risk frameworks, digital health strategies may unintentionally reinforce exclusion, favoring regions with existing infrastructure and administrative capacity while leaving others behind. Governance models must move beyond a technocratic approach, embedding social equity as a core principle of digital health policy.

Embedding Risk Analysis in Equity-Oriented Digital Health Governance

To bridge this gap, this study argues that risk analysis must be integrated into governance as a structuring element—not just as a tool for identifying vulnerabilities, but as a means to proactively shape policies that ensure digital health access is equitable and sustainable. This requires:

- Interoperability beyond technology – ensuring cross-platform data sharing does not exclude underfunded health centers.
- Risk-sensitive funding allocation – prioritizing investment in regions where data gaps and digital exclusion are most severe.
- Governance accountability mechanisms – linking international digital health strategies to municipal-level implementation to track whether global health policies translate into tangible improvements in underserved communities.

By integrating DEMAS' governance framework and SAGE's international policy models, this study demonstrates how risk analysis can be leveraged as a governance tool for equity. Without such mechanisms, digital health governance risks becoming an enabler of existing inequalities, rather than a catalyst for inclusion and public health equity.

3.5. The Role of Stakeholders in Digital Health Governance

Stakeholders play a crucial role in the digital health ecosystem, including government agencies, healthcare providers, technology developers, and patients. In Brazil's Unified Health System (SUS), these actors collectively contribute to the implementation of interoperable digital health solutions.

- Government agencies, such as the Ministry of Health, formulate policies and standards that enable interoperability and ensure compliance with FHIR mandates.
- Healthcare providers, including doctors and nurses, are responsible for adopting and utilizing compliant technologies, thereby facilitating seamless patient data exchange.
- Patients, as central beneficiaries of digital health, must develop digital literacy to engage with interoperable health systems, ensuring the accuracy and integrity of their health records.

The interaction between these stakeholders forms a collaborative ecosystem where individual roles align toward a shared goal: enhancing healthcare outcomes through interoperable digital health solutions. Aligning their efforts around the FHIR framework fosters a unified health information infrastructure, ensuring that digital health adoption remains both effective and inclusive.

3.6. Conclusion and Next Steps

In conclusion, a comprehensive approach to digital health infrastructure—incorporating interoperability, security, data governance, and international cooperation—is essential to advancing healthcare systems globally. The integration of international standards, coupled with international collaboration and robust cybersecurity measures, forms the foundation for an effective digital health framework.

However, to fully understand and optimize this system, it is crucial to map and analyze stakeholders involved in digital health governance, infrastructure, and data security/interoperability. A systematic consultation of stakeholders can provide insights into governance challenges, policy constraints, and technical barriers that shape digital health ecosystems.

This chapter:

1. Identifies interoperability as the central governance challenge, with semantic, syntactic, and organizational dimensions.
2. Discusses the critical role of cybersecurity and data governance in ensuring trust and compliance with global standards like FHIR.
3. Highlights the importance of international cooperation and multi-stakeholder collaboration in addressing these challenges.

The next chapter will focus on stakeholder dynamics, using a constructivist lens to explore how stakeholders influence digital health governance through stakeholder theory. By analyzing stakeholder interactions, power structures, and institutional frameworks, this study will shed light on how governance models evolve and how collaborative efforts can drive sustainable improvements in digital health systems.

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4. The Brazilian system of digital health

To test this study's hypothesis, we need first to address who are the actors involved and the system that they act upon. To do so, I will model part of this system and categorize its actors.

4.1. Introduction to the digital health system in Brazil

Global governance, particularly in the context of health, is increasingly seen not just as a matter of control or power but as a platform for legitimacy and collective action across various governance levels, from local to global (Barnett and Sikkink, 2008). This shift is crucial in the realm of health because public health challenges often transcend national boundaries, necessitating a coherent strategy that integrates efforts from local to international levels (Nilson, 2021).

In addressing global health challenges, modern global governance frameworks have evolved to include a wider array of actors, including states, international organisations, the private sector, and non-governmental organisations. This inclusivity is essential, as it recognizes that tackling global health issues requires diverse contributions and harmonized actions across different sectors and authority levels (Bexell and Mörth, 2010).

A key aspect of such governance in the digital health sphere is interoperability among health information systems. This concept is central to enhancing health service delivery through efficient exchanges of health information across various administrative and geographical boundaries. The push for digital health records interoperability across Brazil's Unified Health System (SUS) exemplifies this need, aiming to ensure seamless health service continuity through an integrated, nationwide system (DATASUS, 2020). Studying healthcare governance in Brazil is particularly useful, because of the country's massive healthcare system, which is the largest universal healthcare in the world, making any governance application, from international organizations down to the public policy aspects of it, a finding that could prove to be a lesson for other governance models in International Relations (IR).

In this field of IR, the urgent need for more refined and clearly defined governance models is evident. While the concept of global governance provides a theoretical framework for such integration, its practical application often lacks real-world effectiveness, due to the more broad stem of those theoretical approaches that, while good for a conceptual creation, are not often used on specific applications on public policies. This study is an exercise on addressing this issue, by focusing on the healthcare governance in Brazil, and the implications it has for the international, national and local levels. Our focus here is to create a concrete mapping and application of stakeholder theories to analysis and possible creation of public policies.

This research, on its methodology, introduces a process modelling approach to address this issue, beginning with extensive mapping of stakeholders, through the Advocacy Coalition Framework method (ACF), and proceeding to consultations to identify and address processes that may compromise governance efficiency, using a survey method (Check, 2012), finally, a use case is selected by using this survey as a way to address which processes, in healthcare governance of Digital Health in Brazil, are more urgent as defined by stakeholders from the is. These discussions help shape practical public policy frameworks that span from the global level down to national and local contexts, using a stakeholder perspective.

Specifically, this research applies to the digital health strategy outlined by DATASUS in Brazil, emphasizing the critical role of interoperability within digital healthcare systems as identified by stakeholders, through the conducted survey. It examines the effects of adopting international interoperability standards within EBSERH's AGHU system, employing both AS-IS and TO-BE modelling to evaluate current implementations and propose future enhancements (Standards Development Organization, 2014). This project aims to showcase how digital patient records can transform primary, secondary, and tertiary healthcare in Brazil's Unified Health System (SUS), aligning it with global governance standards for more integrated and effective healthcare delivery.

4.2. Theoretical Framework and Literature Review for stakeholder analysis

To advance this research as previously proposed, a few key elements need to be addressed first, and they are some of the basic presuppositions that come from the theoretical framework used here:

1. Shared Common Values: Global governance theory posits that for governments to cooperate effectively on any given topic, there must be a foundation of shared values among them. This principle is fundamental as it dictates that cooperative actions are based on mutual interests and goals which are understood and valued across different governmental boundaries (Keohane and Nye, 1977).
2. Stakeholder Inclusion: The concept extends beyond state actors to include non-state actors. This broadens the scope of who is involved in the cooperative processes, acknowledging the significant roles played by NGOs, private sectors, and civil society. These groups often bring unique perspectives and resources to the table, enhancing the comprehensiveness and effectiveness of multi-level initiatives (Betsill and Bulkeley, 2004).
3. Institutional Focus: According to Garrett and Tsebelis (1996), stakeholder research primarily focuses on institutions as they are the entities through which cooperation and policy implementation are facilitated. Institutions serve as mechanisms for stability and continuity, ensuring that shared values are upheld and operationalized within governance structures.
4. Coalition Building: The shared values and institutional engagements naturally lead to the formation of coalitions. These coalitions work towards common interests, pooling resources, and aligning strategies to address complex issues more effectively. The dynamics within these coalitions can significantly influence the policy outcomes and the scope of impact of stakeholder agreements (Axelrod and Keohane, 1985).

In Brazil, DATASUS exemplifies the integration of digital health within the national healthcare framework, demonstrating the effectiveness of managing data and utilizing digital technologies to streamline healthcare processes. This integration enhances patient care and system efficiency by facilitating the flow of health information across different governmental levels, thus enabling better resource allocation and informed policy-making (Ministry of Health, Brazil, 2021).

Adopting a constructivist institutionalism perspective, this initiative highlights the importance of cross-layer cooperation and data integration to effectively tackle global health challenges. The implementation of a digital patient record system serves as a critical use case for examining complex governance systems, revealing how various governance levels and stakeholders impact health service delivery. This analysis underscores the necessity for rigorous process mapping as advocated by the Project Management Institute, ensuring strategic planning and execution to enhance transparency and accountability in health governance (Project Management Institute, 2002).

The study employs Porter's value chain analysis to dissect healthcare delivery, identifying areas where digital solutions can add significant value (Porter, 1985). Moreover, Davenport and Short's framework emphasizes the need for reengineering healthcare processes to integrate digital systems effectively, crucial for improving service delivery across healthcare settings (Davenport and Short, 1990).

This methodology, grounded in constructivist institutionalism, provides vital insights into the governance of digital health initiatives, illustrating how theoretical governance models are applied to address real-world healthcare challenges. This approach significantly improves healthcare outcomes and enhances the resilience and responsiveness of health systems by identifying critical points where policy interventions are necessary to strengthen governance mechanisms (Soucat and Kickbusch, 2020). This strategic approach ensures that digital health initiatives are not only technically feasible but also align with broader health policies and stakeholder interests, fostering a collaborative environment conducive to sustainable healthcare improvements.

4.3. Methodological framework

The methodology selected for this study was specifically designed to concretize the theoretical models of global governance and apply them to a practical setting within Brazil's healthcare system. A key component of this approach involved engaging with the relevant stakeholders identified from DATASUS's governance strategy. This engagement was critical

to ensure that the study's objectives aligned with the needs and expectations of those directly involved in or impacted by the healthcare system.

To thoroughly understand the system and its current capabilities, a value chain analysis (Porter, 1985) and a SIPOC (Supplier, Input, Process, Output, Customer) diagram were developed. These tools were instrumental in mapping out the healthcare system's processes from start to finish, identifying key activities, and understanding the flow of information and materials through the system (Davenport and Short, 1990). They provided a structured way to look at the service creation and delivery processes, which are crucial for identifying areas of improvement in the system.

Following the initial analysis, a comprehensive survey was conducted among the stakeholders to gather their insights and priorities. The feedback collected from this anonymous survey was pivotal in selecting the specific use case for the study. The survey results highlighted particular areas of concern and interest among the stakeholders, guiding the focus of the process modelling and subsequent interventions.

The Advocacy Coalition Framework (ACF) is employed in the study to analyze the complex dynamics and policy changes within digital health governance. ACF is particularly useful for examining how different coalitions of stakeholders, including policymakers, healthcare providers, and technology experts, influence policy processes over time (Oliveira and Sanches Filho, 2022). ACF application here is through the following phases:

1. **Coalition Formation**: ACF posits that actors within a policy subsystem, who share beliefs and values, tend to cluster into advocacy coalitions. In the study, this is observed as different groups (e.g., health professionals, IT experts, government officials) form coalitions around common goals such as enhancing the interoperability of digital health systems.
2. **Belief Systems**: ACF emphasizes the role of deep core, policy core, and secondary beliefs in shaping coalition behavior. The study examines these belief systems to understand how they guide coalition actions and strategies in promoting or resisting digital health initiatives.
3. **Policy Learning**: ACF suggests that policy change occurs through learning across coalitions, facilitated by the analysis of new evidence or the reevaluation of existing

strategies. The study investigates how information from digital health implementations and international best practices leads to learning and policy adaptation within and between coalitions, especially by mapping which process is more impactful for the current Digital Health Strategies.

4. **External Events**: According to ACF, external events can significantly impact policy subsystems and the balance of power within them. The study assesses how global health crises or technological advancements act as external shocks that drive coalitions to modify their strategies or form new alliances.

So, we arrive at the basic theoretical framework used here:

Table 4.1.: Theoretical and methodological Framework.

Framework	Description
Process Modeling	Used to map and analyze the current and desired future states of health system processes, emphasizing the flow and integration of information
Advocacy Coalition Framework (ACF)	Analyzes how coalitions of stakeholders with shared beliefs influence policy changes within a particular domain, such as digital health.
Constructivist Institutionalism	Emphasizes the role of institutions in shaping social and economic behaviors and outcomes, particularly how they adapt and evolve in response to societal needs.
Global Governance	Examines the management of global issues through international cooperation and the role of various governmental and non-governmental organizations.

Source: Self-elaboration.

This methodological framework, combining theoretical analysis with practical stakeholder engagement and feedback-driven process selection, ensures that the study not only addresses

the theoretical aspects of global governance but also delivers practical solutions tailored to the specific needs and challenges identified by those within the system. This approach enhances the relevance and applicability of the research findings, aiming to contribute effectively to the improvement of digital health governance in Brazil.

4.4. Methodology

4.4.1. Stakeholder Mapping

The initial step involves identifying most of the key stakeholders relevant to the digital health ecosystem within Brazil. This includes healthcare providers, government regulators, technology developers, patient advocacy groups, and funding bodies. The purpose of stakeholder mapping is to ensure that all perspectives are considered in the study and that subsequent actions address the needs and concerns of these varied groups. The mapping process involved gathering data from existing government and international organization governance plans, and feedback from various events and policy consultations from the Brazilian Chamber of Deputies, especially the ones concerning the voting sessions and discussions regarding Law Proposal 1998/2020, in 2021, which was the Proposal that was made into the Digital Health Law, N° 14.510/2022.

The stakeholder mapping process in this study was enhanced by applying the Advocacy Coalition Framework (ACF), as previously defined on the theoretical framework, to better understand the alignment and dynamics among various stakeholders within the digital health ecosystem in Brazil, and to help identify and categorise the many stakeholders involved in this process. ACF was integrated into the stakeholder mapping process via the following steps:

- Identification of Coalitions: Using ACF, stakeholders were grouped based on their shared beliefs and policy goals related to digital health. This approach helped to identify distinct coalitions within the digital health sector, such as coalitions of healthcare providers, technology developers, patient advocacy groups, and policy-makers.

- Belief Systems Analysis: ACF emphasizes the importance of understanding the deep core, policy core, and secondary beliefs of stakeholders. In this context, the mapping process involved analyzing stakeholders' beliefs about digital health technologies, governance, and their expected outcomes. This analysis was crucial in understanding the motivations and expectations of different groups, facilitating more targeted and effective engagement strategies.

- Policy Consultations and Feedback: After mapping, the stakeholders' inputs were gathered through a survey. ACF guided these consultations by focusing on eliciting stakeholders' perspectives on policy issues and identifying points of consensus and conflict among different coalitions.

- Data Collection from Governance Plans: Information was also sourced from existing government and international organization governance plans, namely the Global Digital Health Strategy (2020-2025) (EGSD, in Portuguese) and the Brazilian Digital Health Strategy (2020-2028) (ESD28). ACF was used to analyze these documents not just for content but also to understand the policy narratives and frameworks supported by different stakeholder coalitions within these plans.

After this process, the mapping generated was as follows:

Table 4.2.: Overview of identified coalitions through ACF methodology.

Coalition	Actors Involved	Role of Actor	Coalition Alignments to Beliefs and Values
Governmental Oversight and Regulation	Federal Government (*Governo Federal*)	As the primary executive authority, it oversees the entire health system structure and integration of digital health.	Strong regulatory oversight, protection of public interest, ensuring compliance with health and safety standards.

	Ministry of Health, Business Areas (*Ministério da Saúde, áreas de negócios*)	Focuses on the implementation and oversight of health policies, including digital health.	
	National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária - Anvisa*)	Regulates health standards and ensures compliance within digital health implementations.	
	National Supplementary Health Agency (*Agência Nacional de Saúde Suplementar - ANS*)	Oversees private health insurance sectors, ensuring they align with national digital health strategies.	
Strategic Health Policy Development	Pan American Health Organization (PAHO)	Regional office for the Americas of the World Health Organization, focusing on improving health and living standards. OPAS would play a key role in integrating international health standards and practices into	Development and implementation of comprehensive health policies, fostering collaboration across different levels of government. Alignment with international health standards, cooperation with global health entities

		Brazil's digital health strategies.	to improve domestic health policies.
	World Health Organization (WHO)	Directs and coordinates international health within the United Nations' system. WHO provides guidelines, standards, and expertise to improve health systems globally.	
	National Health Council (*Conselho Nacional de Saúde - CNS*)	Deliberates on national health policies and ensures that digital health strategies meet public health needs.	
	Tripartite Intermanagerial Commission (*Comissão Intergestores Tripartite - CIT*)	A key player in negotiating and implementing health policies across different government levels.	
	National Council of Health Secretaries (*Conselho Nacional dos Secretários de Saúde - CONASS*)	Both entities help formulate and advocate for policies that integrate digital systems into state	

	and National Council of Municipal Health Departments (*Conselho Nacional de Secretarias Municipais de Saúde - CONASEMS*)	and municipal health services.	
Technological Implementation and Support	Department of Informatics of the Unified Health System (*Departamento de Informática do Sistema Único de Saúde - DATASUS*), from the Ministry of Health	Central to the deployment and maintenance of digital health records systems across public health facilities.	Advancement of healthcare through technology, support for innovation in health IT systems.
	Health Industry and Technological sector	Provides the necessary technology and innovation to support digital health infrastructures.	
	Brazilian Association of Technical Standards (*Associação Brasileira de Normas Técnicas - ABNT*), Committee	Develops and implements technical standards in Brazil. In the context of digital health, ABNT would be crucial for	

	of Health Informatics	standardizing processes, data formats, and interoperability standards.	
	HL7 International and HL7 Brasil	It is a non-profit association that publishes the FHIR protocol (Fast Healthcare Interoperability Resources), which is an open source standard that enables the exchange of healthcare information between systems and organizations.	
Advocacy and Public Engagement	Patient Associations (Such as the: Children's Cancer Assistance Group - GACC, *Nossa Casa* Association supporting people with cancer, Brazilian Interdisciplinary AIDS Association, among others)	Represents the interests of patients in policy discussions, ensuring that digital health systems address patient needs effectively.	Patient-centric care, transparency in healthcare, consumer protection, equitable access to health services, focuses on changing policies and sharing their opinions with the public sector, to modify its behavior.

	Consumer protection agencies	Protects consumer rights within the health sector, including rights related to digital health data and privacy.	
	Associations of Health Industry Products	These associations represent companies that manufacture and supply medical devices, pharmaceuticals, and other health-related products. Their role in the coalition would be to advocate for regulations and policies that support innovation while ensuring product efficacy.	
	Private Healthcare Providers, Health Plans and Insurance Associations	This group includes private hospitals, clinics, and individual healthcare practitioners. They are crucial in advocating for policies that affect the operational	

		aspects of healthcare delivery, such as reimbursement policies, digital health technology adoption, and regulatory compliance.	
Research and Academic Insight	National Education and Research Network (*Rede Nacional de Ensino e Pesquisa - RNP*)	Manages internet infrastructure and promotes technological innovation and research in Brazil. In digital health, RNP provides the necessary network infrastructure to support the connectivity requirements of digital health platforms in various programs it develops.	Evidence-based policy making, the importance of research and data in shaping health policies. Focuses on innovation and integration beyond governmental bodies.
	Universities and training centers	Engage in research that informs digital health policy and practice.	
	Technical-scientific societies	Contribute scientific knowledge and	

		expertise to the development of digital health policies and practices.	

Source: Self-elaboration.

The table below synthesizes the various beliefs and values extracted from discussions and debates on digital health policies in Brazil. These beliefs and values are categorized to clarify how they influence the formation of coalitions within the digital health sector and their impact on policy-making. Understanding these dynamics is crucial for navigating the legislative and regulatory landscape and to better map the stakeholders and their roles on aiming to influence or implement digital health strategies.

Table 4.3.: Coalition Dynamics and Policy Implications.

Category	Belief/Value Description	Coalition Dynamics
Deep Core Beliefs	Public Health as a Priority: There's a strong emphasis on enhancing public health infrastructure through digital means. This belief likely unifies various coalitions, driving consensus on the necessity of digital health initiatives. Privacy and Security: Concerns about data privacy and security are prevalent, highlighting a foundational belief in the sanctity of personal health information.	Drives consensus across coalitions, the deep core beliefs shared among the coalitions is focused on technological advancements and broader access to healthcare.
Policy Core Beliefs	Access to Healthcare:	Forms the basis of policy

	Stakeholders express a core policy belief in increasing access to healthcare services through digital platforms. This includes expanding remote healthcare services to underserved populations. Integration of Healthcare Services: There is a shared belief in the need for better integration of healthcare services across different levels of government and private sectors using digital tools.	initiatives, emphasizing cautious, regulated growth of digital health to protect patient data and ensure equity. This point is divided between amplifying access but guaranteeing security of data and integrating the public health initiatives with international and national standards for interoperability.
Secondary Aspects	Implementation Strategies: Differing opinions emerged on the best strategies to implement digital health frameworks, reflecting secondary beliefs about resource allocation, technological choices, and partnership models with private entities, as well as inequality on digitalisation strategies. Regulatory Frameworks: Variations in how strict or lenient the regulatory	Source of contention within and between coalitions, where the balance between innovation and regulation is debated. Those secondary aspects are the main critique of the coalitions defending patients and local initiatives, which say that technology has an uneven base in the country, and instead of granting access, digital health could make the healthcare services more precarious.

	frameworks should be, depending on the perceived trade-offs between innovation and control.	

Source: Self-elaboration.

This table breaks down the primary and secondary beliefs influencing the governance of digital health in Brazil, mapping them against the types of coalition dynamics they foster. Core beliefs unify stakeholders around common goals, policy core beliefs guide specific policy frameworks, and secondary aspects often lead to debates and negotiations reflecting differing stakeholder priorities. This categorization aids in identifying potential areas of agreement and conflict, which are instrumental in shaping effective digital health policies and practices. Understanding these relationships helps stakeholders anticipate challenges and align their strategies more effectively within the broader policy environment.

4.4.1.1. Policy learning

Based on the table, a subsequent analysis of the Advocacy Coalition Framework (ACF) in the context of the recent legislative changes from telemedicine to a broader digital health scope reveals significant insights for policy learning, particularly as it relates to the adoption and implementation of the law. From the table and the analysis of the processes viewed during the research, especially the voting and debate regarding Law Proposal 1998/2020, here are some insights on how policy learning was undergone by the coalitions in consonance with the belief systems:

- Expansion of the Law's Scope

The transition in legislative focus from telemedicine to encompass digital health more broadly indicates a strategic alignment with the deep core beliefs of various coalitions. This broader scope ensures that the law addresses more comprehensive aspects of healthcare delivery, which are crucial for modernizing Brazil's health system. By guaranteeing what the coalitions wanted at a fundamental level, the law fosters broader buy-in and support, facilitating smoother implementation.

- Policy Core Beliefs and Implementation Challenges

Despite the alignment with deep core beliefs, challenges persist in the realm of policy core beliefs, particularly around the implementation of governance plans and the establishment of technical standards by regulatory agencies. These challenges stem from the complexities of translating broad legislative goals into specific, actionable governance strategies and technical protocols.

- Implications for Policy Learning:

The ongoing nature of implementing governance plans suggests a need for continuous learning and adaptation within the policy environment. Stakeholders must remain flexible and responsive to emerging challenges and technological advancements. This is highlighted on ESD 2020-2028 on what is named “Collaboration spaces”.

For those collaboration spaces to be effective, implementation requires sustained engagement with all relevant stakeholders, including government agencies, private sector players, and civil society. This engagement helps to ensure that governance plans are inclusive and that technical standards are practical and reflective of the needs of all users. Besides the governmental bodies that already foster this dialogue, such as the CIT, there are also some private bodies, such as the associations, that also partake in this, especially regarding self-imposed standards, as the ones from ISO, which are translated to Brazil by ABNT.

For those spaces to be functional, however, the establishment of robust feedback mechanisms is crucial for monitoring the effectiveness of implemented policies and for identifying areas where adjustments may be necessary. As ACF literature says, conflicts and collaborations will inevitably arise as stakeholders interpret and react to policy changes, influencing the pace and direction of policy learning.

So, there is still a wide landscape for improvement in this aspect, since most of the important discussions, either national or international, all focus on changing governmental policies, and, although there are coalitions from the private bodies, they all still focus on influencing public policy decision making.

4.4.1.2 External events

The significant need for capacity building across all levels of the healthcare system to manage new technologies and governance frameworks reflects broader systemic challenges

heightened by external events. Here's how these external pressures have accelerated the need for more robust digital health policies, as per the ACF made:

- Public Demonstrations and Strikes

The demand for better compensation for healthcare professionals, influenced by public demonstrations and strikes, dominated the discourse of the healthcare professionals, associations and their representatives during the policymaking consultations. In the ACF framework, those public demonstrations and strikes represent external shocks that can lead to significant changes within a policy subsystem. These events force a reassessment of existing policies and can accelerate the shift towards more sustainable compensation models for healthcare professionals. This aligns with the ACF's focus on the dynamics of policy-oriented learning where new strategies are developed in response to changing external conditions.

- COVID-19 Pandemic

The pandemic acted as a significant catalyst for the adoption and legalization of digital health practices, such as telemedicine. With the temporary lifting of bans on telemedicine, there was a nationwide push to adopt digital health solutions to maintain healthcare delivery during lockdowns. This period also saw the accelerated adoption of other digital practices, like electronic document signing and recognition of software as medical devices.

As a critical external event, the COVID-19 pandemic dramatically impacted the policy landscape, consistent with ACF’s emphasis on external events as catalysts for policy change. The temporary legalization of telemedicine and the rapid adoption of digital health technologies were responses to the immediate needs imposed by the pandemic. This period of crisis facilitated rapid policy-oriented learning across healthcare coalitions, leading to the swift implementation of practices that were previously stalled.

- Integration of National and International Policies

The pandemic underscored the importance of integrating national health policies with international standards. This was crucial not only for adopting global best practices but also for ensuring that local health data could contribute to global health monitoring. Information sharing during the pandemic was essential for managing public health responses and facilitated by bilateral agreements that also influenced vaccine distribution strategies.

According to ACF, the alignment of local policies with international standards often follows significant external pressures that highlight deficiencies in local systems. The pandemic emphasized the necessity for interoperable health data systems that can operate across borders, leading to enhanced cooperation and shared strategies between nations. This reflects ACF's notion that coalitions may adapt their beliefs and strategies in response to the successes and failures of other systems observed during crises.

- Data Sharing and International Collaboration

The pandemic underscored the importance of effective data sharing mechanisms, which ACF would categorize as a response to external stimuli necessitating cross-coalition collaboration. The sharing of health data internationally not only facilitated public health responses but also aligned with broader global digital health strategies, promoting a more integrated approach to health governance.

The need for real-time data sharing became evident as the pandemic required countries to share health data to monitor and control the spread of the virus effectively. This push for international collaboration and data integration highlighted the need for digital health policies that support data interoperability across borders.

4.4.1.3 Conclusions

The Table 4.3. developed in the analysis serves as a foundational tool for understanding the complex interplay of beliefs and values that influence the structuring of digital health policies in Brazil. This understanding is crucial for the subsequent mapping of processes and structuring of the survey used in the study, using the Digital Health Strategy of Brazil as a basis of consultation.

4.5. Stakeholder Consultation

The table and analysis previously outlined serve as a crucial foundation for the comprehensive mapping of digital health processes in Brazil. Based on this mapping, an anonymous survey was conducted via email to delve deeper into the stakeholder beliefs and values identified. The survey was distributed to all elected stakeholders, including those from the public sector and representatives from the private sector such as companies in the health

industry, private hospitals, and various associations representing patients, health professionals, and the healthcare industry.

From the 157 emails sent, the study garnered 22 responses over the course of 8 months. This was an effort to capture a diverse array of perspectives and insights, which are essential for understanding the key components of stakeholder networks, institutions and their beliefs in shaping policies, which were used to map out the processes that were most critical for them.

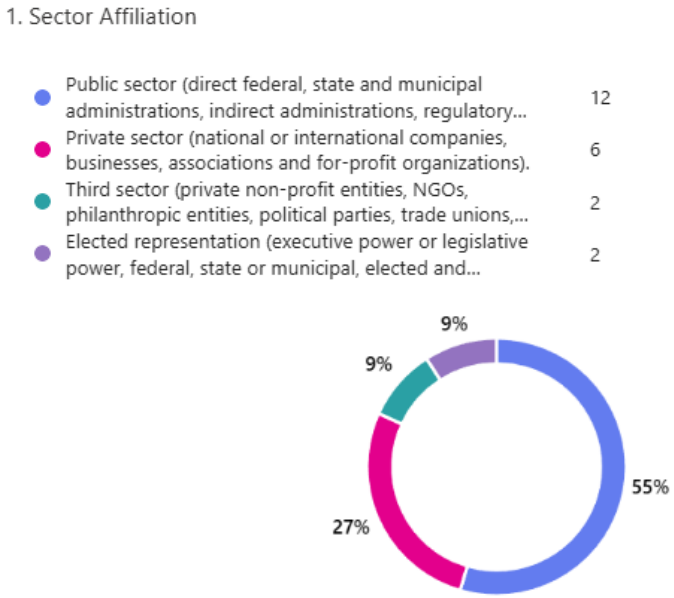
The survey consisting of 14 questions was strategically designed to gauge the respondents' familiarity and engagement with two significant digital health strategies: the Digital Health Strategy of Brazil (ESD 2020-2028) and the Global Strategy on Digital Health 2020-2025 by the World Health Organization (WHO). The purpose of the survey was not only to ascertain the level of knowledge among stakeholders regarding these frameworks but also to understand their priorities within the context of digital health governance.

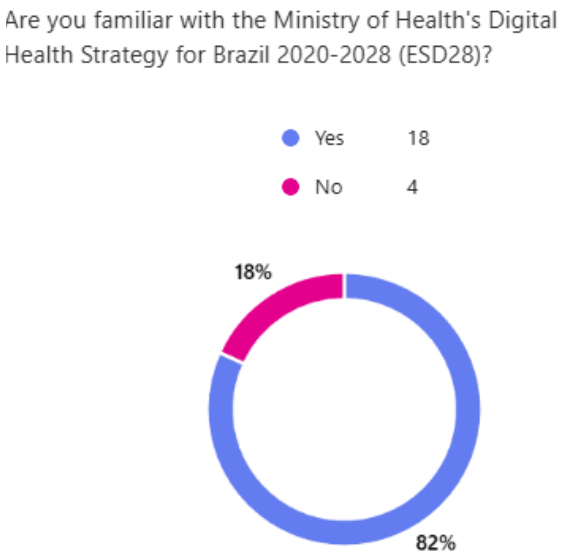
This dual focus on both national and global strategies allowed the survey to capture a comprehensive view of how stakeholders align their local practices with international standards. The questions were structured to elicit detailed insights into the challenges and priorities perceived by the participants, thereby enabling a more nuanced understanding of the governance aspects within the realm of digital health. This approach ensures that the survey findings could directly inform the ongoing development and refinement of digital health policies and practices, bridging gaps between current capabilities and desired outcomes in health governance.

All of the questions were made and answered in portuguese and hereby translated. The questions were divided in blocks, as follows:

Sector Affiliation (Question 1); Familiarity with Brazil's Digital Health Strategy 2020-2028 (ESD28) (Question 2) and Ranking ESD28's Action Plan Priorities, Ranking from most challenging to most manageable, based on personal experience and opinion (Question 3). Afterwards, they were asked which was the main implementation challenges for the Top Priority elected by them (Question 4);

Images 4.1. and 4.2.: Sector Affiliation and familiarity with ESD28.

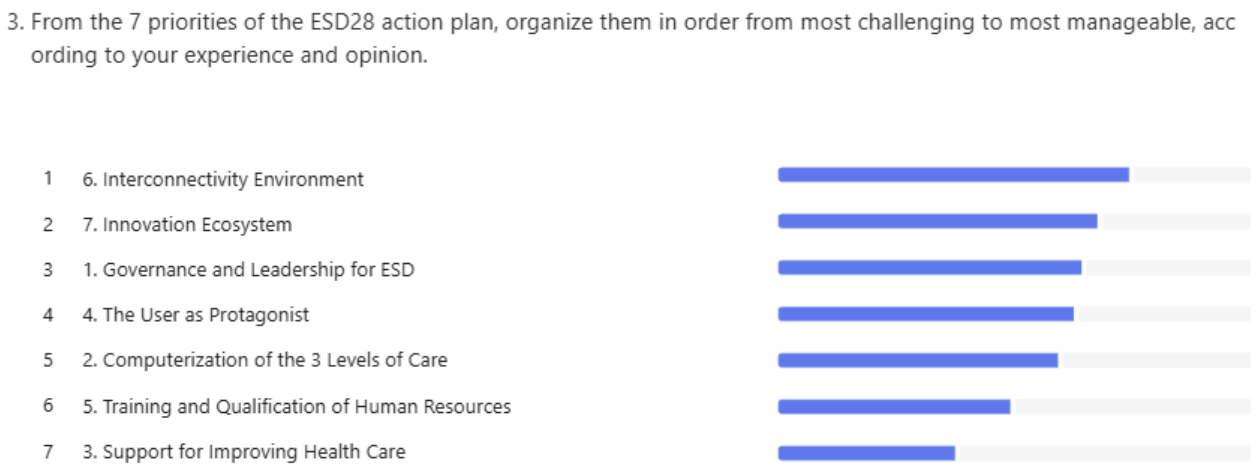




Source: Extracted from Microsoft Forms.

Participants who said they were familiar with the ESD28 governance model were asked the subsequent questions, from questions 3 to 6, while participants who said were unfamiliar with the strategy were skipped to question 7.

Image 4.3.: Implementation challenges of the 7 priorities of ESD28.



Source: Extracted from Microsoft Forms.

The question asked participants to rank the most challenging to least challenging priority. The most challenging by each participant was given a rank of 7, while the least was given a rank of 1. It is clear to see that out of the seven priorities, priority number 6, Interconnectivity Environment, was the most challenging by a wide margin, with 33% of participants electing it as their top most challenging priority, and another 33% elected it as their second-most challenging.

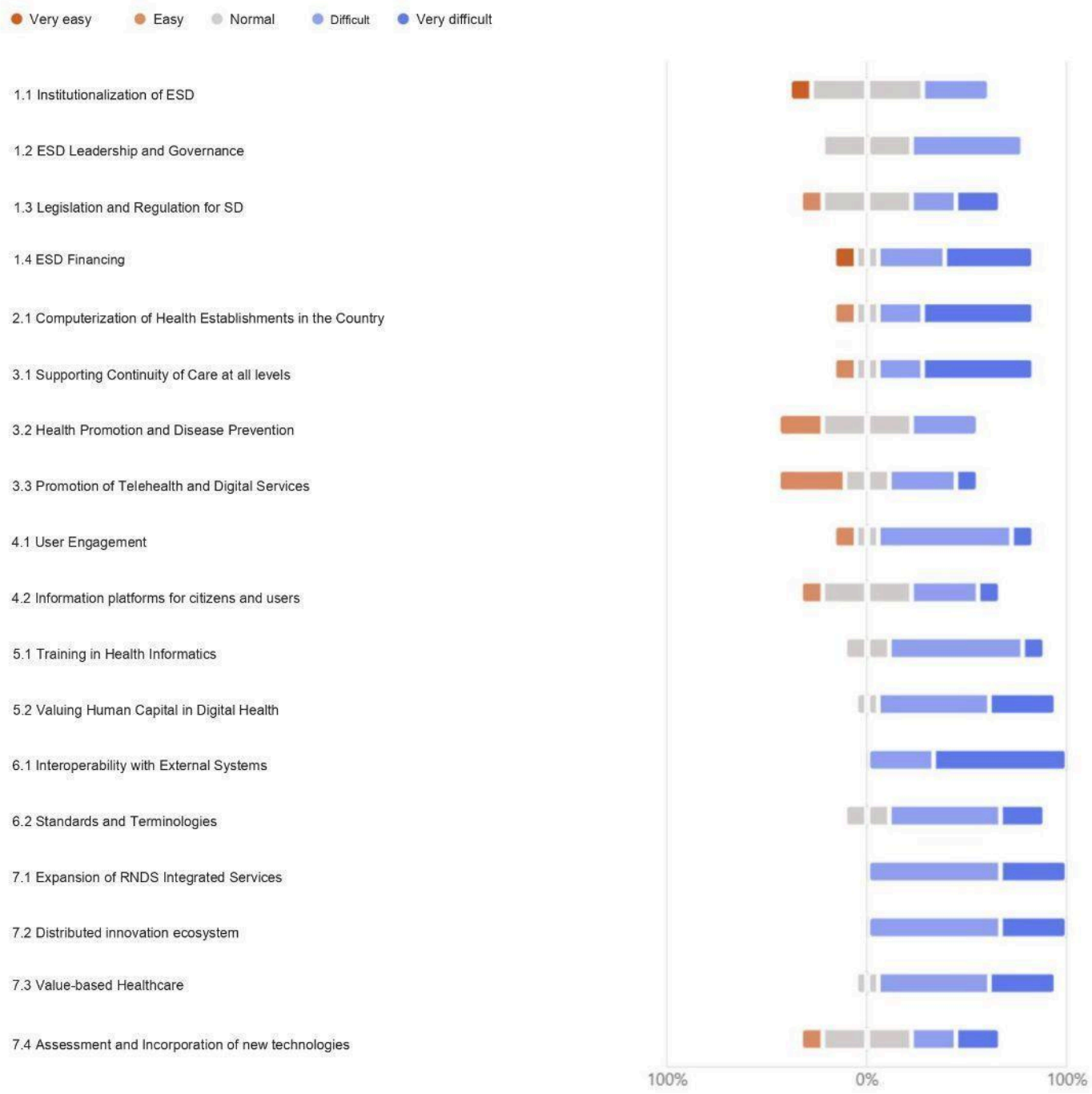
Image 4.4.: Word cloud of main implementation challenges.

Source: Extracted from Microsoft Forms.

This question was in a written format, and it was optional, but out of the 18 participants who said they were familiar with ESD28, all of them decided to answer. From the word cloud, and based on an analysis of the answers, it is clear that most of the participants worry about digital ecosystems and infrastructure, especially considering the challenges it poses for the

Brazilian Unified Healthcare System (SUS). The system not only is massive but also has to be present in very different regions of the country that have widely different technological infrastructure challenges. Another issue pointed out by participants was the security of health data, which is considered the most sensitive of all personal data by Brazilian authorities and the current legislation.

Image 4.5.: Ranking of sub-priorities of ESD.



Source: Extracted from Microsoft Forms.

Afterwards, participants rated ESD28's Sub-Priorities (Question 5), and Risks Associated with the most Difficult Sub-Priorities elected by them (Question 6); out of the 18 answers, sub-priority 6.1, Interoperability with External system was also by a wide margin elected as the most difficult, with 66,7% of participants saying it is “very difficult” to implement, while 33,3% elected it as “difficult”. Tied in second place, sub-priorities 7.1, Expansion of RNDS

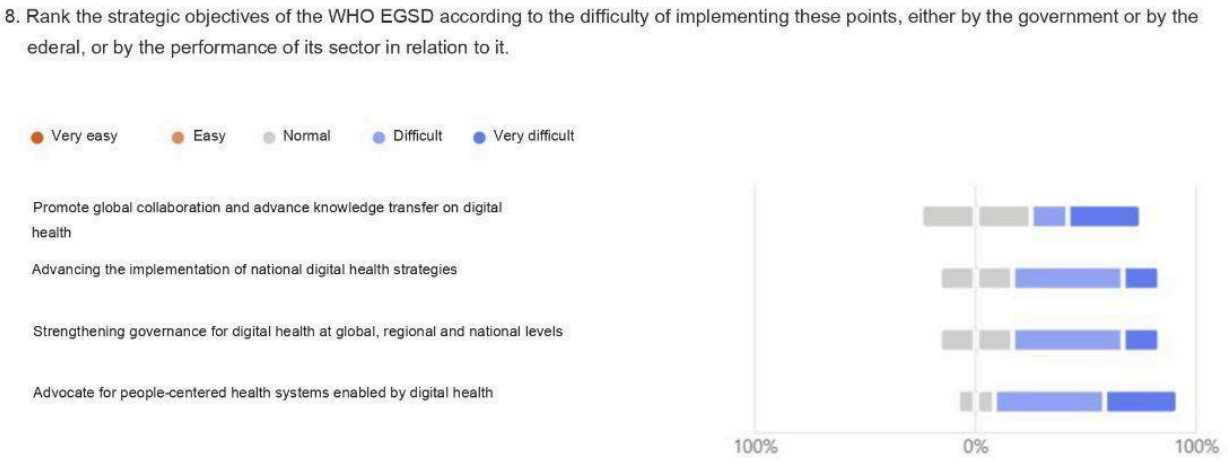
Integrated Services, and 7.2, Distributed innovation ecosystem, had 33,3% of participants saying they were “very difficult” to implement, while 66,7% said they were “difficult”.

This was also reflected in the answer to question 6, as participants highlighted the need for integration of different systems, both public and private healthcare providers, hospitals and human capacitation would pose challenges for Digital Health implementation, according to them. And all of those issues would be aggravated by the lack of interoperable systems.

Next, to address the WHO's Global Digital Health Strategy 2020-2025 (EGSD), participants were asked if they were familiar with it (Question 7), and Difficulty Rating of WHO Strategic Objectives (Question 8), Challenges in Implementing WHO's Objectives in Brazil (Question 9), Alignment of WHO's Global Strategy with Brazilian Realities and Local Strategies (Question 10);

Only 12, or 55% of participants said they were familiar with WHO’s governance strategy, and answered questions 8 to 10, while the others were skipped to question 11.

Image 4.6.: Ranking of WHO's Global Digital Health Strategy strategic objectives.



Source: Extracted from Microsoft Forms.

Contrary to ESD28, no strategic objective of EGSD was elected as “very easy” or “easy”, but participants agreed that “Advocate for people-centred health systems enabled by digital health” is the most challenging objective, with 88.3% saying that it is either “very difficult” or “difficult” to implement it.

For question 10, answers varied more than the one for ESD28, with participants citing the uneven international playing field as a challenge, and, again cited the inequality in

infrastructure in Brazil as a potential barrier. The country's laws and barriers for knowledge transfer were also showcased in answers.

Next, four written questions, all optional, were presented. Only question 13 had 16 answers, while questions 11, 12 and 14 were answered by all participants. They were: main Challenges in Implementing Global Digital Health Governance in Brazil (Question 11) and Most Important Global Challenge to Adapt to Brazilian Reality (Question 12), Challenges That Should Be Primarily Resolved at an International Level (Question 13), Comparison of Local vs. International Challenges Faced by Brazil (Question 14).

Image 4.7.: Question 11 word cloud of answers.

Source: Extracted from Microsoft Forms.

Image 4.8.: Question 12 word cloud of answers.

Source: Extracted from Microsoft Forms.

Image 4.9.: Question 13 word cloud of answers.

Source: Extracted from Microsoft Forms.

As it is present on the word clouds, interoperability was the main challenge elected in almost all the answers, being cited 22 different times by respondents in the 3 questions. Interoperability is seen as the root cause of the problems faced by both governance strategies, and also that Brazil should adequate its infrastructure and public software to international interoperability standards.

This opinion was also shared on question 14, in which, although most participants said that the challenges Brazil face are unique to the country, that interoperability should be an agenda of cooperation, to better the infrastructure of Digital Health in the country.

After this consultation, for me it was clear that interoperability should be, from now on, the focus of this study, especially aligned with Interoperability to External Systems, as participants pointed out that not only it is the most dire of the problems faced by Digital Health strategies, but also because it is the one to integrate international, national and local level policies. This is consonant with what was interpreted from the ACF analysis.

4.6. Value Chain Analysis

Value chain analysis is a strategic tool that breaks down the key activities within an organization or a sector to identify areas where value can be added. In the context of healthcare, this analysis provides a structured way to examine how each component—from patient intake and data entry to diagnosis and treatment—contributes to the overall effectiveness and efficiency of the service delivery. It helps pinpoint where inefficiencies or bottlenecks exist and identifies opportunities for improving service delivery and patient outcomes.

In this study, I elected to use a value chain analysis because of the insights from the Advocacy Coalition Framework (ACF), which highlights the importance of understanding the roles and interactions of various stakeholders within a policy subsystem. The ACF analysis revealed that different stakeholder coalitions have varying priorities and beliefs about digital health, which can influence policy outcomes. By employing a value chain analysis, the study can map these stakeholder interactions in the context of digital health processes, particularly in how data and services flow across the system. This mapping is crucial for identifying misalignments and opportunities for enhancing interoperability.

Interoperability in digital health, particularly regarding patient records, serves as a practical use case to apply the value chain analysis. Patient records are central to healthcare delivery, involving multiple stakeholders (e.g., healthcare providers, insurance companies, regulatory bodies) and processes (e.g., data collection, storage, access, and sharing). So, as the objective here is to concretize governance actions, a process mapping would be useful to take interoperability, as posed by stakeholders on the survey, from a theoretical concept to a concrete, policy-oriented one.

Since interoperability refers to the ability of different IT systems and software applications to communicate, exchange data, and use the information that has been exchanged effectively, a process mapping to understand activities that need interoperable communication standards. In the realm of healthcare, interoperability is vital for ensuring that patient records are accessible and usable across different care settings, which enhances care coordination and improves health outcomes. This is necessary not only in the internal healthcare system, but, as pointed out in the external factors of ACF, interoperable systems in the international level are also necessary for health monitoring between countries and International Organizations, and, as such, interoperability communication standards should be an international standard.

4.6.1 Definition of scope

Based on the strategic focus of the ESD (Estratégia de Saúde Digital) for Brazil and the activities outlined in Priority 6.1, action 6.1.3 was identified as a key area of focus due to its emphasis on promoting interoperability between different levels of care. The decision to prioritize this specific action arises from the survey findings, which highlighted interoperability as a major challenge and a critical need within the Brazilian health system.

Why Focus on Interoperability (Action 6.1.3)?

- **Multi-sectoral Coordination**: Action 6.1.3 aims to enhance syntactic, semantic, operational, and organizational interoperability across levels of healthcare. This is crucial for achieving seamless communication and data exchange between various health providers and systems, facilitating better continuity and coordination of care.
- **Survey Insights**: Responses from the survey underscored interoperability as a substantial hurdle, with many stakeholders pointing out the difficulties in achieving effective communication between different healthcare information systems. This aligns with the broader goals of RNDS to establish a comprehensive online health services platform.
- **Integrated Healthcare Management**: Efficient interoperability supports the management and monitoring of healthcare services, improving the efficiency, effectiveness, and efficacy of healthcare delivery across all levels.

This approach not only aids in understanding the operational challenges but also provides empirical data that can inform policy decisions, ensuring that digital health initiatives are practical, meet the stakeholders' needs, and are aligned with international best practices in healthcare interoperability, by targeting a concrete action inside the governance plan.

To better understand how interoperable levels of care work, we need to take a step back and understand the current model of the Unified Healthcare System in Brazil.

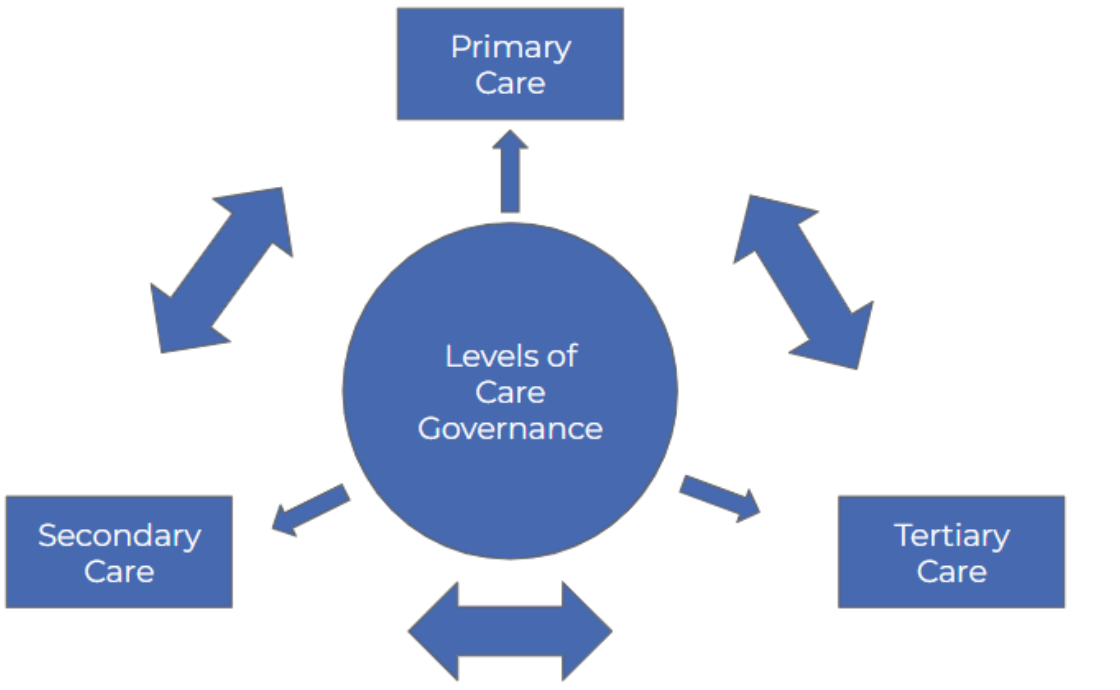
Healthcare in Brazil operates under a system known as the Unified Health System (Sistema Único de Saúde, SUS), which provides universal healthcare to all residents. The system is funded by federal, state, and municipal government revenues. Healthcare services in Brazil are managed at three levels:

- **Primary Care** (Atenção Primária): This is the first level of contact for individuals with the health system, providing a broad range of services including preventive care, treatment of common diseases and injuries, maternal and child healthcare, vaccinations, and health education. Primary care is typically delivered through family health programs and community health centers.
- **Secondary Care** (Atenção Secundária): This level of care involves specialized services provided by hospitals or specialist clinics for patients referred from the primary level. It includes more complex diagnostic services, specialized medical consultations, and surgeries.

- **Tertiary Care** (Atenção Terciária): The most specialized level of care, offering advanced medical investigation and treatment, such as complex surgeries and treatments for severe diseases. Tertiary care is provided by specialized hospitals and centres equipped with high-tech facilities and equipment.

The Brazilian healthcare system has historically been conceptualized as a pyramid, with primary care at the base, secondary care in the middle, and tertiary care at the apex. This model suggested a hierarchical flow where patients would start at the primary level and be referred upwards as needed for more specialized care. However, this perspective has evolved towards a more network-oriented approach, emphasizing the importance of communication and seamless interaction across all levels of care, from which governance is the main connection that is intertwined among all subsystems.

Image 4.10.: The governance of the levels of care in SUS.

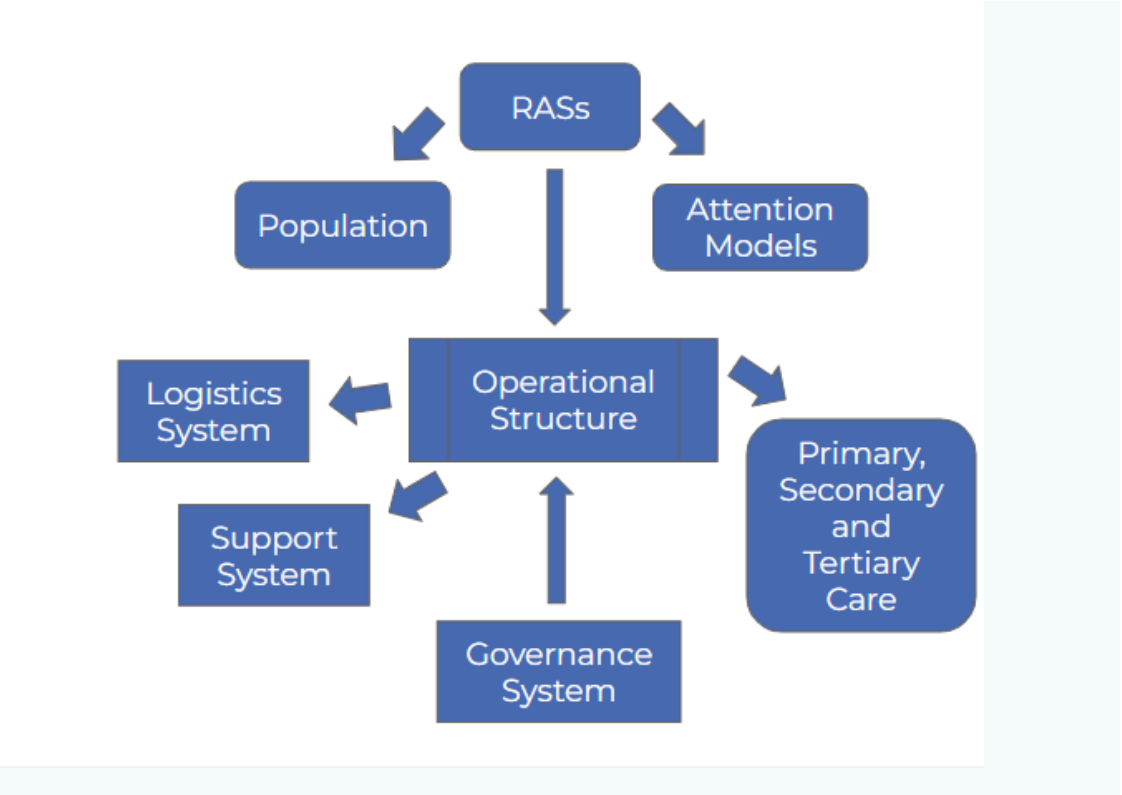


Source: Self-elaboration based on Ministério da Saúde, 2022.

The operational system of Brazil's Unified Health System (SUS) can be depicted through the diagram which organizes the system into several interconnected components that ensure its functionality across all levels of healthcare:

1. **RASs (Redes de Atenção à Saúde - Health Care Networks)**: These networks are a crucial component of the SUS, designed to integrate health services across different levels to ensure continuity of care. They connect various health facilities and services to coordinate patient care seamlessly from primary to tertiary levels.
2. **Population**: The system is centred around the population it serves, aiming to provide accessible, high-quality healthcare to all Brazilian citizens.
3. **Attention Models**: These refer to the healthcare models or approaches adopted within the system to address different health needs. These models guide how services are delivered at various levels (primary, secondary, and tertiary care) and ensure that care is provided efficiently and effectively according to the health demands of the population.
4. **Operational Structure**: This is the core of the system where the actual delivery of healthcare services takes place. It includes the facilities, healthcare professionals, and the processes they follow to provide care. This structure is supported by logistical and governance systems to enhance its efficiency.
5. **Primary, Secondary, and Tertiary Care**: These are the levels of care provided within SUS, each serving a specific function in healthcare delivery. Primary care acts as the first point of contact for individuals entering the health system, secondary care provides specialized services referred from the primary level, and tertiary care offers advanced medical treatment for complex health conditions.
6. **Governance System**: This includes the policies, regulations, and management practices that govern the operation of SUS. It ensures that the health system is compliant with national and international health policies and standards, and is responsive to the needs of the population.
7. **Support System**: This system provides the necessary support functions like HR, finance, and technology services which are essential for the smooth functioning of healthcare services.
8. **Logistics System**: Manages the supply chain and ensures that healthcare providers have the necessary medical supplies and equipment to deliver services effectively.

Image 4.11.: Operational structure of SUS, based on the Governance Model of levels of care.



Source: Self-elaboration, based on Ministério da Saúde, 2022.

Interoperability's Role: Interoperability is crucial in this networked model. It ensures that patient information flows smoothly and securely from one level to another, supporting effective and efficient treatment and care management. Interoperability enables:

- **Data Sharing**: Health information systems that can communicate across primary, secondary, and tertiary levels ensure that a patient's health records are accessible wherever care is provided. This avoids repetition of tests and delays in treatment.
- **Continuity of Care**: Seamless data exchange supports continuity of care, ensuring that the treatment plan is followed and adjusted as needed without any information loss.
- **Decision Support**: Integrated systems provide healthcare professionals with comprehensive data to make informed decisions. This includes everything from previous doctor visits and medication history to diagnostic tests and specialist inputs across all care levels.

By ensuring that health systems at all levels can effectively communicate and exchange information, interoperability plays a critical role in enhancing the quality of care, improving patient outcomes, and optimizing resource use across Brazil's health network.

4.6.2 Definition of activities

A **support activity** is a function or operation that, while not directly involved in the creation or delivery of a product or service, plays a crucial role in enhancing the efficiency and effectiveness of the primary activities. Support activities provide the necessary infrastructure, skills, and inputs that enable primary activities to occur efficiently and effectively. Inside the Action 6.1.3 plan, the support activities elected, based on ESD28 were:

Multisectoral and Global Coordination and Governance: To align national standards with international ones, ensuring that the Brazilian health system is compatible with global health information systems.

Regulation, Monitoring, and Guarantee of Data Privacy and Anonymity: Vital for maintaining the integrity and confidentiality of health data.

R&D for Continuous Adaptation of Local Needs to Emerging Technologies and Global Standards: This involves ongoing research and development to keep up with technological advancements and global health data standards.

Training and Qualification of Managers and Health Professionals: Essential for ensuring that healthcare providers are well-equipped to utilize advanced health information systems effectively.

In a value chain analysis, primary activities are the direct actions taken by an organization that add value to its products or services and are essential to its business operations. These activities are integral to producing and delivering the product or service to the market and directly influence customer satisfaction. As we adapt this view to the healthcare sector, the customer becomes the patient, and the business operation is, in fact, the delivery of Universal Healthcare. For this to be achieved, based on the discourse of healthcare professionals, the survey and the governance plan, we arrive at the following primary activities for action 6.1.3:

Collection and Standardization of Health Data: This foundational activity involves the systematic collection and standardization of health data across various healthcare platforms to ensure consistency and reliability in data handling and usage.

Integration of Municipal, State, and Federal Systems with RNDS: This activity focuses on integrating health information systems across municipal, state, and federal levels into the National Digital Health Network (RNDS), enhancing the coherence and connectivity of health data across the nation.

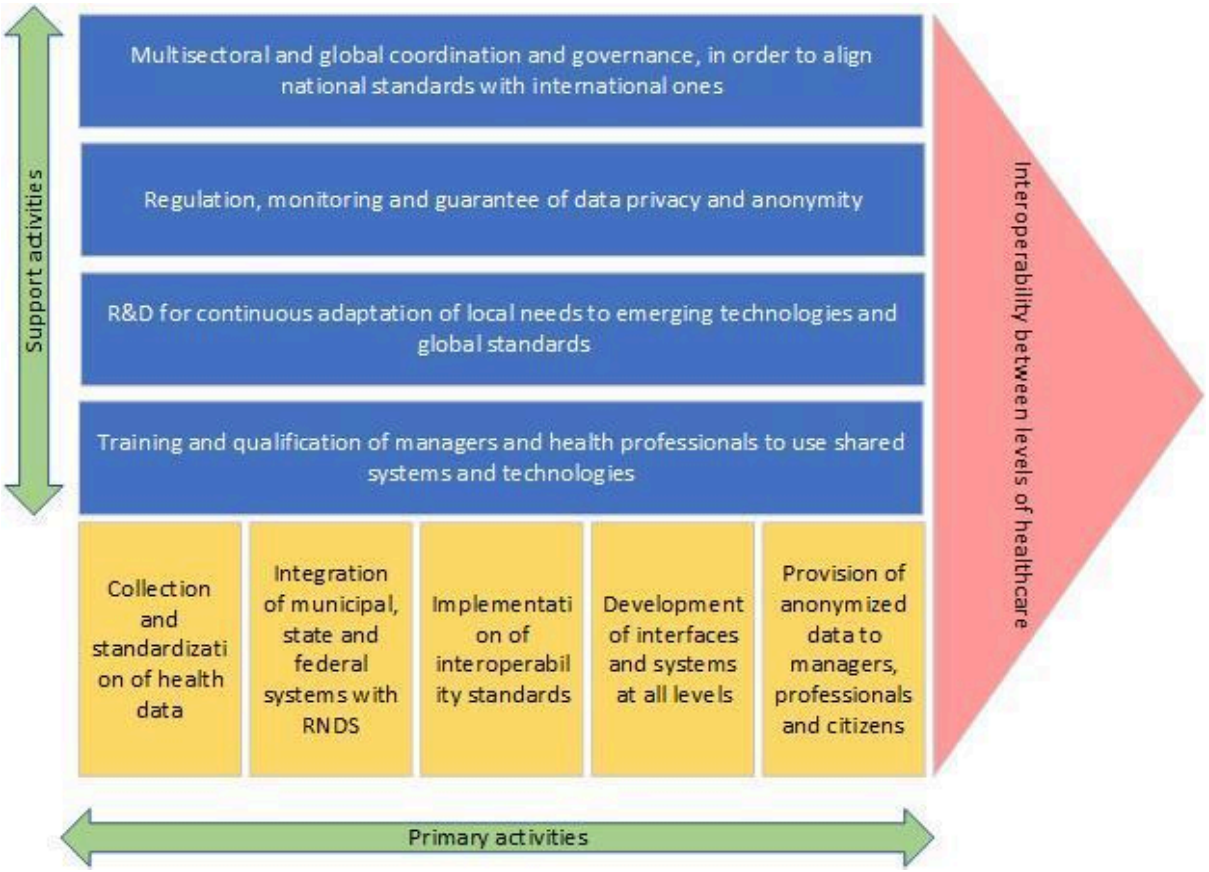
Implementation of Interoperability Standards: It involves setting and implementing interoperability standards to ensure that different health information systems can communicate and exchange data seamlessly.

Development of Interfaces and Systems at All Levels: This refers to the creation and refinement of user interfaces and backend systems that support the smooth operation and accessibility of health information systems at all levels of healthcare.

Provision of Anonymized Data to Managers, Professionals, and Citizens: Ensuring that anonymized health data is accessible to healthcare managers, professionals, and the general public, supporting informed decision-making and public health monitoring.

Uniting those aspects, we arrive at the value chain:

Image 4.12.: Value chain analysis.



Source: Self-elaboration.

Incorporating a value chain perspective allows policymakers to see not just the direct impacts of these activities but also how they interlink to create a holistic improvement in healthcare services. This analysis is especially pertinent in a system like SUS, where the integration of various health levels and the standardization of data are critical for efficient operation. The focus on interoperability, identified as a critical area through both stakeholder surveys and ACF analysis, underlines its pivotal role in connecting these activities cohesively within the healthcare network.

4.7. SIPOC Diagram Development

SIPOC, which stands for Suppliers, Inputs, Processes, Outputs, and Customers, is a tool used to visually document a process from beginning to end.

The SIPOC diagram is an invaluable tool for detailing the complex processes involved in healthcare interoperability, particularly within the scope of digital health initiatives. It clarifies the entire flow from start to finish, emphasizing interactions among various components of the health system. This tool is particularly useful for visualizing the sequence and dependencies of processes involved in the implementation and management of digital health records, ensuring clarity in understanding roles, inputs, outputs, and final recipients of these processes.

4.7.1 SIPOC Diagram Development

1. Suppliers: Who provides the information or services needed for the process?

   These are the entities that provide essential inputs for the interoperability process. In the context of Brazilian healthcare, this includes bodies like the Ministry of Health, international organizations like PAHO/WHO, and private sector entities providing standards like HL7.

2. Inputs: What information, materials, and other resources are required?

   Critical inputs necessary for successful interoperability include international standards like HL7 FHIR, health data from various levels of care, technological infrastructure (including local health systems and RNDS), and the educational tools required for training healthcare professionals in these systems.

3. Processes: What actions are taken with the inputs to provide the outputs?

   This encompasses all actions taken to transform inputs into valuable outputs. Processes include the collection and standardization of health data, integration with RNDS, implementation of interoperability tools and protocols, training for stakeholders, and ongoing monitoring and evaluation to ensure continual improvement.

4. Outputs: What are the end results of the process?

   The results of the processes which are directly utilized by the end users. Outputs include standardized and integrated clinical data that improves continuity of care,

supports public policy decisions through detailed reports, and increases the accessibility of digital health tools for both citizens and health professionals.

5. Customers: Who receives or benefits from these outputs?

   The direct beneficiaries of the interoperable digital health system outputs. These include Brazilian citizens who use the health system, healthcare professionals, health managers, and international partners such as WHO and PAHO.

The SIPOC (Suppliers, Inputs, Processes, Outputs, Customers) framework plays a crucial role in making global governance more concrete by systematically visualizing how processes interlink and influence various levels of implementation, from local to global. This tool is particularly effective in the context of digital health interoperability across different levels of healthcare management.

Table 4.4.: SIPOC diagramm.

PROCESS NAME: **Promoting Interoperability between Levels of Health Care**		
LAWS, RULES, REGULATIONS	PURPOSE OF THE PROCESS	INDICATORS
Global Digital Health Strategy (2020-2025) Digital Health Strategy (2020-2028) ISO 23903:2021 Health informatics — Interoperability and integration reference architecture — Model and framework Law 14.510/2022	To generate data interoperability between different levels of healthcare, from primary care to monitoring.	Increase flux of DATASUS users, through the “My Digital SUS” app. Increase in the percentage of Hospitals, software and other medical devices using FHIR protocol in the country. Increase in the percentage of healthcare unities participants of RNDS.

		Increase in electronic medical records compared to physical ones.

SUPPLIERS	INPUTS	PROCESS	OUTPUTS	CUSTOMERS
Ministry of Health (Brazil) PAHO/WHO HL7 (private sector)	International standards and norms, such as HL7 FHIR and OpenHIE. Health data collected at all levels of care (primary, secondary and tertiary). Technological infrastructure (local health systems and the National Health Data Network - RNDS). Training and education of professionals to operate and maintain interoperable systems. Financial and regulatory resources to support implementation.	Collection and Standardisation of Health Data Integration with RNDS Implementation of Tools and Protocols Training of Teams and Stakeholders Continuous Monitoring and Evaluation	Standardised and integrated clinical data available to managers, professionals and citizens. Improved continuity of care between levels of care (primary, secondary and tertiary). Detailed reports to support decision-making and monitoring of public policies. Digital health tools accessible to citizens and health professionals. Reduction of redundancies and errors in the management of clinical information.	Brazilian Citizens (patients and users of the health system) Health Professionals Health Managers WHO and PAHO Private Sectors

ACTORS INVOLVED	SYSTEMS USED
DataSUS and RNDS Health Councils (CONASS and CONASEMS) Private sector (companies that supply medical devices, health system suppliers, health	FHIR HL7 National Health Data Network (RNDS) “My Digital SUS” app

associations) Regulatory agencies (ANVISA and ANS) Technological research and development centers (Universities and private entities)	

Source: Self-elaboration.

By deploying a SIPOC diagram in this context, we systematically connect the dots between every element of the healthcare interoperability initiative. This comprehensive overview aids in identifying potential inefficiencies and areas for policy intervention, making it an essential tool for the strategic planning and execution of digital health policies aimed at enhancing the Brazilian Unified Health System (SUS). It ensures that every stakeholder understands how their contributions and interactions impact the broader goal of improving healthcare delivery through enhanced digital capabilities.

4.8. Process Modeling (AS-IS and TO-BE)

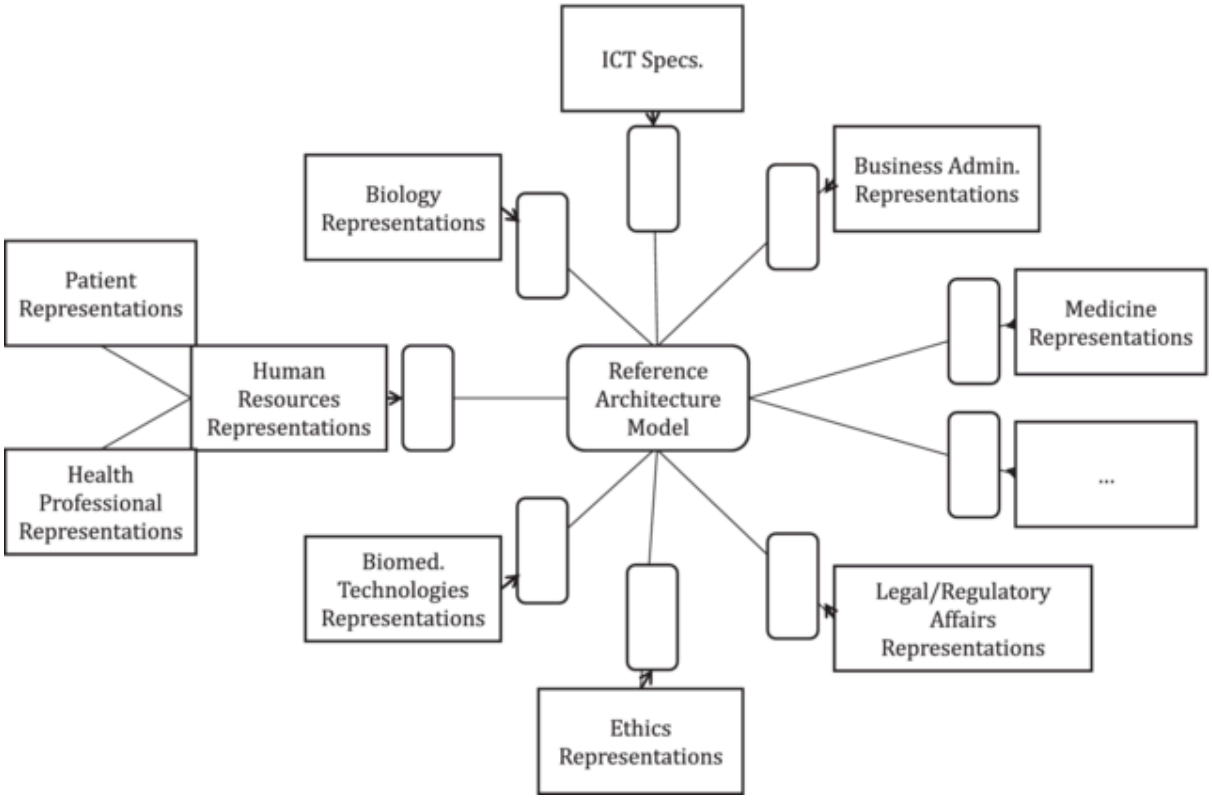
In this study, we're synthesizing several analytical approaches—SIPOC, value chain analysis, stakeholder surveys, and the Advocacy Coalition Framework—to develop a comprehensive understanding of digital health interoperability within Brazil's healthcare system. This multi-faceted approach culminates in the modeling of key processes, focusing first on a broad analysis of how interoperability standards are enacted within the context of global health governance.

This study’s approach incorporates a stakeholder perspective, recognizing that health governance involves multiple levels of government—from federal to state to municipal—each playing a role in healthcare delivery. The use of international interoperability standards within Brazil’s federative structure highlights the need for coordinated policies and practices that can operate across diverse administrative and geographical boundaries.

Modeling the Global Standards in Interoperability: Initially, we map the current application of global interoperability standards, exploring how these international norms and practices are integrated into national systems. This broader view helps to identify gaps,

inconsistencies, and opportunities for enhancement in how Brazil aligns with global health data standards.

Image 4.13.: International standards for Interoperability framework.



Source: Extracted from ISO 23903:2021.

In the reference architecture model depicted, the critical role of both public and private sectors in shaping global health informatics standards reflects a complex interplay of local and international influences, fitting within a broader framework of global governance and stakeholder cooperation. This model underscores the importance of various representations such as ICT specifications, business administration, medicine, legal/regulatory affairs, and ethics, all converging through a reference architecture that facilitates interoperability.

Private sector entities, often key drivers in the development of biomed technologies and ICT specifications, collaborate closely with public sector agencies to align technological advances with regulatory standards and healthcare needs. This cooperation is crucial for the development of frameworks like Health Level 7 (HL7) and the International Organization for Standardization (ISO) standards, which require both innovative technological input from the private sector and regulatory oversight and implementation by public institutions.

At the local level, healthcare providers incorporate these standards into their operational practices, directly impacting patient care by improving data fluidity across systems. Internationally, these standards allow for a unified approach to health data management, enabling global health monitoring and response strategies that are critical in managing public health emergencies.

From the perspective of the Advocacy Coalition Framework (ACF), interactions within the digital health governance are brought to standardisation practices, reflecting the dynamics of the stakeholders each playing specialized roles on their own level. The Technological Implementation and Support Coalition, notably active in championing standardization, advocates for greater system integration and innovation. In contrast, the Governmental Oversight and Regulation Coalition emphasizes the need for stringent data security and ethical considerations in handling health data. These contrasting priorities underscore the ongoing dialogue between pushing technological boundaries and ensuring robust privacy protections.

This governance model is designed not only to enhance operational efficiencies across international health systems but also to address critical issues such as data sovereignty and the balance between innovation and regulation. The challenge lies in crafting a governance framework that both facilitates global technological integration and respects the diverse needs of international healthcare environments.

This dynamic encapsulation of global governance in health informatics exemplifies the necessity for stakeholder collaboration. It highlights the importance of adaptive standardization bodies that reconcile local implementation complexities with the overarching goal of international cooperation, ensuring that policies remain relevant and responsive to both global imperatives and local realities.

Specific Use Case: EBSERH and AGHU System: The specific use case selected for deeper analysis involves the Empresa Brasileira de Serviços Hospitalares (EBSERH), or the Brazilian Company of Hospital Services. EBSERH is a government-owned corporation under the Ministry of Education that manages university hospitals across Brazil. The AGHU (Aplicativo de Gestão para Hospitais Universitários), or Management Application for University Hospitals, is a software system developed by EBSERH to streamline operations and enhance record-keeping across these institutions. This use case was selected based on

stakeholder input from the discourses during the sessions of voting for Law Proposal 1998/2020, as previously mentioned, but also because of its relevance in other means, such as for stakeholder participation for global governance and the coalitions studied.

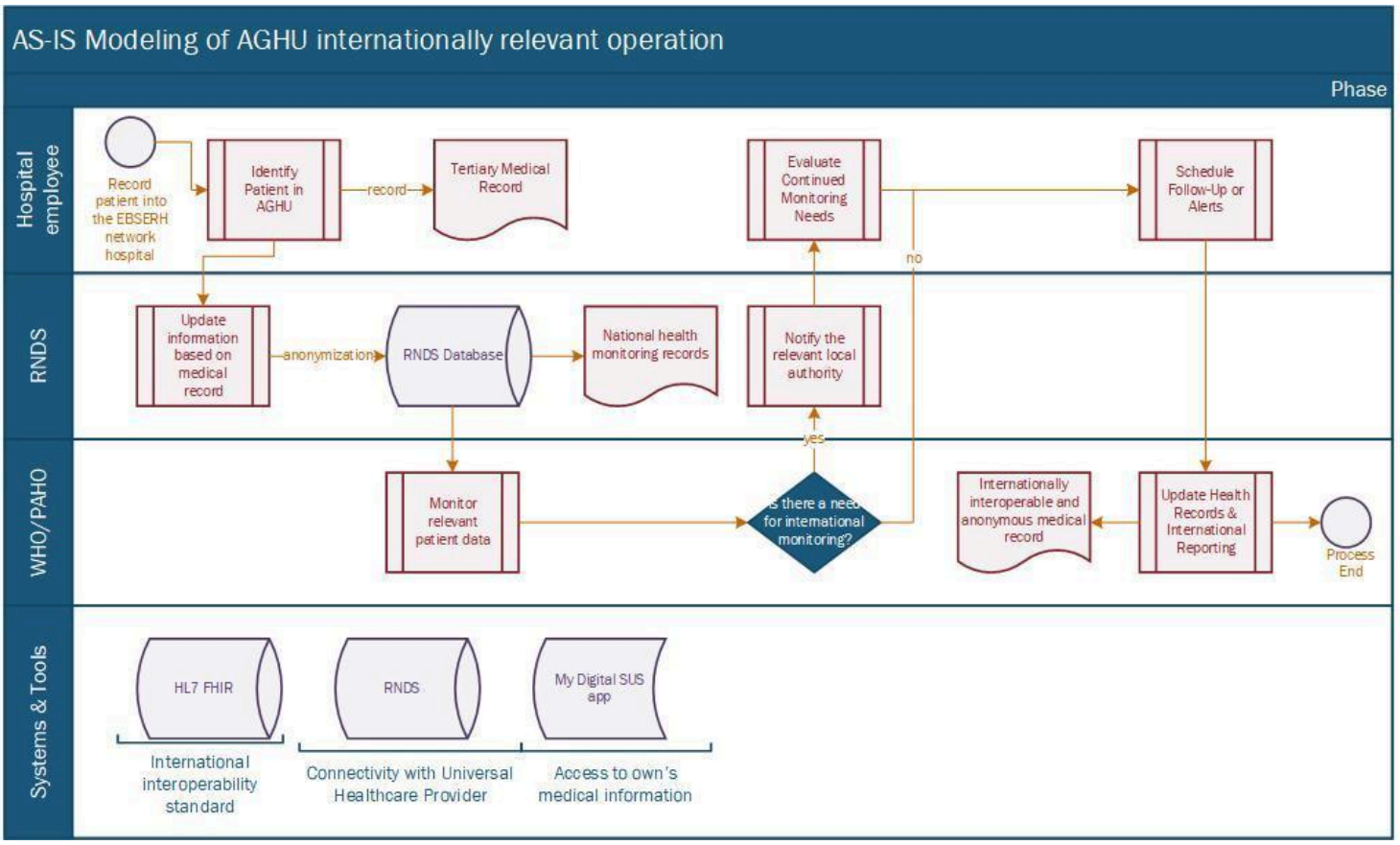
This scenario serves as a practical illustration of how digital health tools like AGHU are pivotal in modernizing healthcare infrastructure to meet global health information standards, reflecting broader themes of global governance and stakeholder cooperation. By aligning local healthcare operations with international best practices, systems such as AGHU facilitate seamless interaction and improve responsiveness to both national and international health challenges, emphasizing the importance of interoperability in global health systems, when there is the need for monitoring patient records.

Moreover, the integration of AGHU within EBSERH-managed hospitals aligns with the Advocacy Coalition Framework (ACF), offering a lens to understand coalition dynamics among government bodies, healthcare providers, and academic institutions. Since EBSERH is a stakeholder that is part of all three of those categories, it means that it is a swing stakeholder that varies its position between different coalitions. This makes the use case even more relevant to the study, as the institution itself needs to take a position that already benefits and shares multiple policy core beliefs.

AS-IS Modeling of AGHU: This involves documenting the current state of the selected processes using detailed process maps. It helps to visualize how digital health records are currently managed and identifies bottlenecks or inefficiencies. The current state of the AGHU system demonstrates a practical instance of interoperability, necessitating the adoption of international standards within a national framework that includes university hospitals.

This system's integration showcases both the challenges and the potentials in expanding interoperable solutions across the healthcare spectrum, especially because these interoperable standards are only present on tertiary care, necessitating an expansion to fully encompass what is proposed on activity 6.1.3 of the ESD28 governance plan.

Image 4.14.: AS-IS modelling of internationally relevant operation of patient records in AGHU.

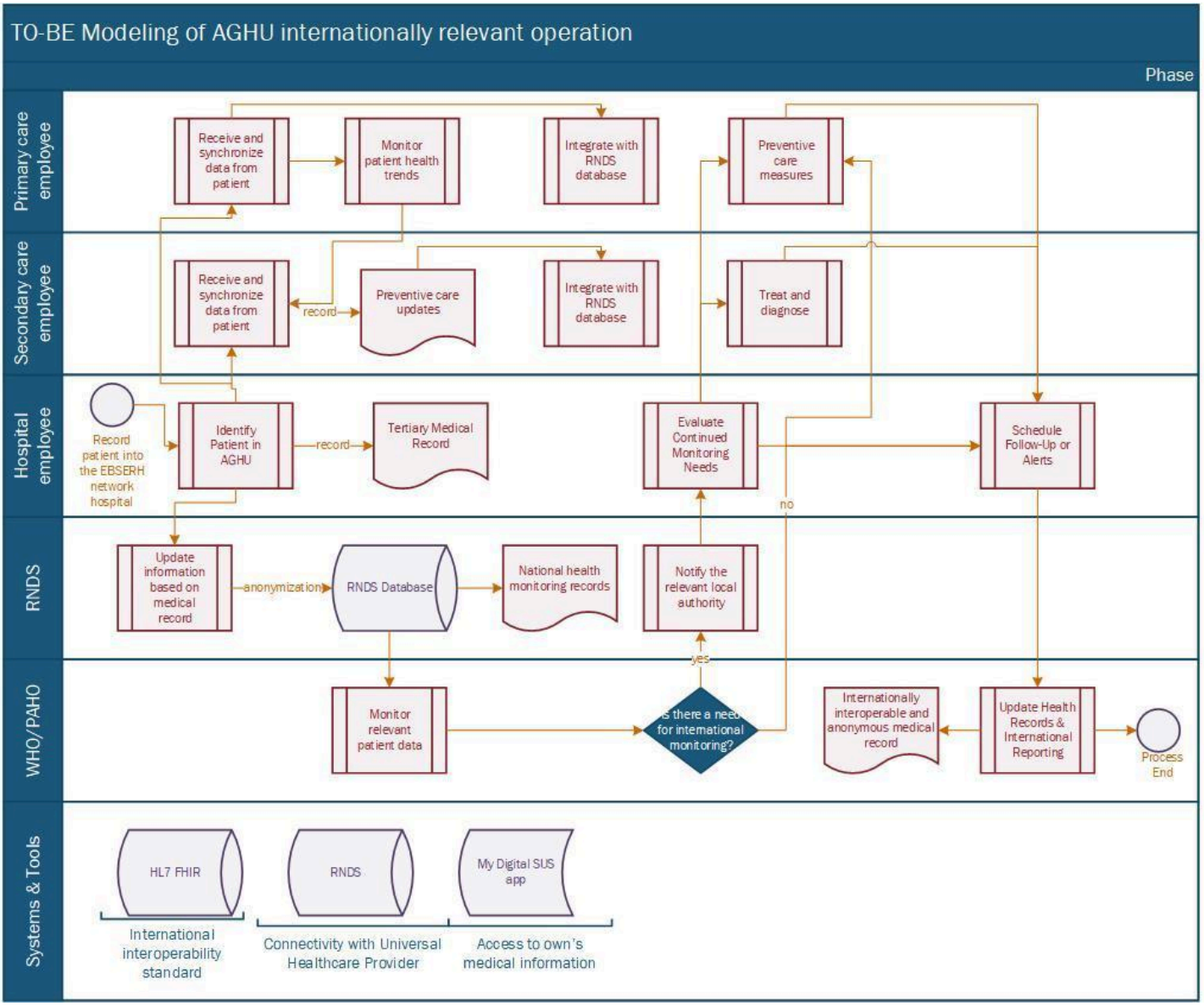


Source: Self-elaboration.

TO-BE Modeling Process: Based on the issues identified in the AS-IS model and the stakeholder feedback, the TO-BE model proposes an optimized future state. This model incorporates best practices, technological advancements, and stakeholder input to design a more efficient and effective process.

From the tertiary care provided in hospitals down to secondary and primary care, the proposed TO-BE model envisions a fully integrated process that not only links various levels of care within the SUS (Unified Health System) but also across the broader national healthcare network. The goal is to create a scalable and interoperable framework that encompasses the entire Brazilian healthcare system, enhancing data flow and improving patient care outcomes.

Image 4.15.: TO-BE modelling of internationally relevant operation of patient records in AGHU.



Source: Self-elaboration.

Subprocesses

Patient Data Entry at Tertiary Level: When a patient is admitted to a tertiary care hospital, their initial medical data, diagnosis, and treatment plans are entered into the system.

Data Synchronization with Secondary Care: Patient data from tertiary hospitals is automatically updated to secondary care facilities like specialist clinics. This ensures that all subsequent care stages have real-time access to the patient's latest health records.

Feedback Loop to Primary Care: Information from both tertiary and secondary care interventions is sent back to the primary care providers to update ongoing care plans and preventive measures.

Continuous Health Monitoring: Utilize data analytics to monitor patient health trends across all care levels, facilitating proactive healthcare interventions.

Cross-Sector Data Integration: Integrate data from other health-related sectors such as pharmacy, dental, and alternative medicine to provide a holistic view of patient health.

Public Health Reporting: Automated reports generated from patient data across all care levels to aid public health officials in disease surveillance and health policy adjustments.

Data Entries

- **Preventive Care Updates:** Updates on preventive care measures applied at the primary care level based on insights gained from secondary and tertiary interventions.

Goals of the TO-BE Model

Enhanced Interoperability: Implementing advanced IT solutions like HL7 FHIR standards across all levels to ensure seamless data flow and interoperability.

Improved Patient Outcomes: Leveraging integrated data to enhance diagnostic accuracy, treatment efficacy, and patient satisfaction.

Optimized Resource Utilization: Using data-driven insights to allocate healthcare resources more efficiently and reduce unnecessary procedures.

4.9. Policy implications

The policy implications of this study are extensive and multifaceted, given its focus on enhancing the interoperability of digital health systems within Brazil's Unified Health System (SUS). Some examples of policies derived from this TO-BE model are:

Enhanced Policy Frameworks for Digital Health: The study underscores the need for robust digital health policies that support seamless interoperability and data sharing across all levels of healthcare. It advocates for the development of standardized procedures and regulations that can accommodate new technological advancements while ensuring the security and privacy of patient data. This includes adopting and implementing international standards such as HL7 FHIR to facilitate better data integration and system communication.

Strengthened Multisectoral Collaboration: The research highlights the importance of collaborative efforts between government entities, private sector players, and international organizations. Policies should encourage partnerships that leverage the strengths of each sector to foster innovation and improve system efficiency. The findings suggest that a collaborative governance model can better address the complexities of health informatics, thereby enhancing the overall healthcare delivery system.

Public and Private Sector Roles: Clear delineation of roles within digital health initiatives is critical. The study illustrates how both sectors must work together, with the public sector providing regulatory oversight and the private sector driving technological innovation. Policies must facilitate this synergy, offering frameworks that allow for agile responses to technological advancements while ensuring compliance with regulatory standards.

Global and Local Integration: This research promotes the integration of local health data standards with global health information practices to enhance the global governance of health informatics. This approach not only improves local healthcare outcomes but also contributes to global health security by enabling better monitoring and response to health crises. Policy implications here involve Brazil's active participation in international health informatics forums to both contribute to and learn from global best practices.

Continuous Education and Training: The findings stress the importance of continuous professional development in health informatics for healthcare providers at all levels. Policies should support ongoing education and training programs to ensure that health professionals are well-equipped to handle new technologies and systems. This will facilitate smoother transitions as digital health systems evolve and expand.

Data Sovereignty and Ethics: As digital health systems become more integrated globally, issues of data sovereignty and ethical considerations in data handling become paramount. The study suggests that policies should not only enforce stringent data protection measures but also ensure that these measures do not impede the effective use of digital health technologies in clinical practice.

Responsive and Adaptive Policy Making: Given the rapid pace of technological change, the study advocates for a dynamic policy-making process that can quickly adapt to new developments and challenges in health informatics. This includes creating provisions for regular review and revision of digital health policies to accommodate emerging technologies and changing healthcare needs.

In summary, the policy implications are what the policy core beliefs of stakeholders has been given before, but in a more concrete manner, as taken from the conclusions of this modelling. The objective here was to create a roadmap for enhancing digital health governance in Brazil, emphasizing the need for comprehensive, integrated, and adaptive policies that support the sustainable development of the nation’s digital health infrastructure, with institutions on the focus.

4.10. Conclusions

The study undertaken here significantly contributes to understanding the complex interplay of global governance, stakeholder cooperation, and the practical implications of digital health initiatives within Brazil's healthcare system. By applying a methodological framework that integrates the Advocacy Coalition Framework (ACF), SIPOC diagrams, and process modeling, this research has pinpointed critical areas where policy adjustments and enhanced interoperability standards can substantially improve healthcare delivery across different levels of care.

Key findings highlight the necessity of robust policies that facilitate seamless data sharing and integration across primary, secondary, and tertiary healthcare services. The research supports the theoretical assertions of stakeholder theory, showing that shared governance structures capable of supporting widespread digital health applications can enhance service delivery and patient outcomes while ensuring data security and system integrity.

Future studies should focus on exploring how these frameworks can be adapted and applied in other national contexts with similar challenges and complexities. Researchers should particularly examine the dynamic interaction between local implementation strategies and international health standards to devise more effective governance models. This could involve a deeper dive into how differing regional infrastructures impact the adoption of global health information standards, potentially influencing the design of more adaptable and resilient health information systems.

By building on the foundational work this study provides, subsequent research can expand on the nuances of policy learning and adaptation within the sphere of global health governance, contributing to a more thorough understanding and implementation of digital health solutions worldwide.

This chapter:

1. Maps the Brazilian digital health system, identifying four key coalitions: governmental oversight, strategic policy development, technological implementation, and advocacy.
2. Uses SIPOC diagrams and value chain analysis to highlight gaps in data flow between primary, secondary, and tertiary care.
3. Emphasizes the need for interoperability standards and multi-level governance to address systemic inefficiencies.

   With this systemic understanding, Chapter 5 establishes the methodological foundation for risk analysis in international relations.

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5. Risk analysis and its importance to International Relations: understanding the study's methodology

The previous chapter provided an in-depth examination of interoperability as a key component of global governance in digital health, particularly within Brazil's Unified Health System (SUS). By applying methodologies such as the Advocacy Coalition Framework (ACF), SIPOC diagrams, and process modeling, the study highlighted the critical role of cooperation in ensuring the seamless exchange of health data. These findings reinforced the importance of structured governance and international standardization to enhance digital health systems and improve healthcare outcomes.

Building upon these insights, this chapter introduces risk analysis as a crucial methodological approach in international relations. Given the complexity and interdependence of global governance structures, risk analysis provides a systematic framework to assess vulnerabilities, uncertainties, and potential disruptions that may impact policy implementation. This approach is particularly relevant in digital health governance, where security, data integrity, and interoperability present significant challenges.

The chapter first justifies the selection of an instrumental case study methodology, explaining why risk analysis is essential in international relations. It then elaborates on the rationale behind choosing digital health governance as the focal case, considering its implications for future studies on global health governance, cybersecurity, and policy coordination. Finally, the chapter outlines the specific risk analysis methods employed, demonstrating how they integrate into the case study and how they will be applied in subsequent sections. By doing so, this chapter provides a structured foundation for understanding how risk assessment enhances the resilience and adaptability of international governance frameworks, ultimately shaping more effective policy responses in global health and beyond.

5.1. Methodological Considerations: An Instrumental Case Study Approach

This study employs an instrumental case study methodology (Baxter and Jack, 2008), using digital health governance as a means to develop a comprehensive risk analysis framework within the field of International Relations, particularly in the context of global governance. While digital health serves as the primary context of analysis, the central objective is to advance risk assessment methodologies applicable to broader governance issues, illustrating how risk is constructed, perceived, and managed at various levels of international cooperation. By focusing on digital health governance, this study provides a concrete foundation for refining risk analysis tools that can be adapted to other global governance challenges.

Some of the following parts of the study, especially the methodological explanation, **may be overly analytical and descriptive**. I apologise in advance for this, but this is why I stress on how it is an instrumental case study that aims to fully develop and explain the methods employed. This is precisely to show, with the highest amount of detail as possible, how everything was developed, in case future researchers and policy-makers need to use any risk analysis methodologies on the context of Global Governance.

Risk analysis in international relations is not merely a technical or predictive exercise; rather, it is deeply embedded in social, political, and institutional processes. Understanding risk requires an examination of the actors involved, their interests, and the narratives they construct about uncertainty, security, and governance (Beck, 1992). Thus, a critical question guides this study: **Who defines risk in international digital health governance, and how do these definitions shape global decision-making processes in this sector?**

This inquiry highlights that risk is not an objective reality waiting to be measured—it is a social construct shaped by political discourse, institutional frameworks, and stakeholder interactions.

To explore this dynamic, this chapter critically examines the theoretical underpinnings of risk assessment through a constructivist lens. Constructivism, as previously established in the theoretical framework, provides a crucial perspective by emphasizing how risk is framed,

interpreted, and institutionalized within international governance structures (Neuman, 1995; Adler, 1997). By applying this approach to digital health governance, the study reveals how perceptions of risk influence policymaking, regulatory frameworks, and global cooperation. Risk is not simply an event to be anticipated, but a concept negotiated among actors within the global digital health ecosystem, reflecting shared norms, power structures, and institutional priorities (Luhmann, 2017).

In the following sections, this chapter further elaborates on the methodological application of risk analysis within the study's framework. It presents the key concepts of risk perception, stakeholder mapping, and governance mechanisms, demonstrating how these elements interact within the case of digital health governance. This discussion aims to contribute not only to a deeper understanding of risk in international relations but also to the broader evolution of risk analysis methodologies in global governance, ensuring they are responsive to the complexities of contemporary global challenges.

5.2. Defining Risk: Theoretical Framework

The integration of risk analysis into the study of International Relations (IR) remains an underexplored field, as highlighted in the bibliometric review (Section 1). While risk has been studied in specific domains such as security studies (Aradau; Van Munster, 2007) and financial markets (Hafner-Burton; Kahler; Montgomery, 2009), broader applications to global governance structures and political decision-making remain limited. This study proposes that risk analysis methodologies, commonly applied in technical fields, could also serve as a valuable tool for international governance, fostering cooperation among actors and improving decision-making.

The **concepts of risk analysis, risk management, and risk intelligence**, while well-established in different academic disciplines, have not been systematically integrated into IR. **Risk analysis** refers to the identification, evaluation, and assessment of potential risks that states and international organizations face in an increasingly complex geopolitical landscape. Renn (2017) emphasizes that recognizing and understanding uncertainty is critical to formulating effective responses to multifaceted threats—suggesting that risk analysis may be a fundamental but **underutilized** tool in international political decision-making.

Some studies, such as those by Aradau and Van Munster (2007), illustrate how risk-based approaches have shaped counterterrorism policies, leading to frameworks that emphasize preemptive action. While their analysis highlights the role of risk perception in shaping political responses, it does not explicitly conceptualize risk as a governance mechanism applicable to **broader areas of international relations**. Similarly, Biermann et al. (2009) discuss the fragmentation of global governance but do not directly apply risk analysis to understand how actors manage governance gaps. However, their findings suggest that risk-based frameworks could enhance coordination between international institutions, offering a potential avenue for risk analysis within global governance.

Thus, while **risk management**—the implementation of strategies to mitigate identified risks—has been explored in the context of national security and economic stability (Fridman, 2020), its application to governance remains largely theoretical. The concept of **risk intelligence**, which extends beyond traditional risk management by incorporating **real-time data analytics and predictive modeling**, has also been proposed in business and security contexts (Birnbaum, 2021), but remains absent from mainstream IR discussions. By integrating risk intelligence into **international governance**, this study suggests that states and non-state actors could develop **proactive, rather than reactive**, approaches to complex global challenges such as pandemics, environmental crises, and economic shocks.

Despite the clear distinctions among risk analysis, risk management, and risk intelligence, their interplay remains largely unexplored in IR. The works of Pahl-Wostl (2009) and Boin et al. (2017) discuss institutional responses to crises but do not explicitly frame these responses within a risk analysis methodology. If integrated properly, risk-based approaches could enhance institutional practices, improve strategic decision-making, and provide a unified theoretical framework for governance under uncertainty.

Risk management in international relations could evolve significantly, adapting to an increasingly interconnected world. Historically, it has been state-centric, primarily focusing on military and economic risks, and very rarely was it used academically. However, contemporary challenges—from climate change to cybersecurity threats—transcend national borders and require **collaborative, multi-stakeholder responses** (Duffield, 2014). If risk analysis methodologies were systematically integrated into global governance, they could serve as a structured approach to managing these complex interdependencies.

Biermann et al. (2009) highlight how fragmented governance structures hinder the efficient management of shared risks, yet their work does not propose a structured risk-based approach to address these inefficiencies. A risk analysis framework—if applied to global governance—could fill these gaps, **offering decision-makers a way to anticipate, prioritize, and mitigate risks systematically**. This aligns with Hafner-Burton, Kahler, and Montgomery (2009), who suggest that governance actors are increasingly dependent on network-based collaboration. If risk-based methodologies were integrated into these networks, states and organizations could move beyond traditional hierarchical governance models toward more adaptive and cooperative structures.

Furthermore, Duffield (2014) argues that governance strategies should merge development and security considerations for resilience. However, his work **does not explicitly frame this within a risk intelligence paradigm**. If risk intelligence were incorporated into decision-making at the international level, it could bridge the gap between security concerns and long-term development strategies, making governance mechanisms more adaptive and responsive to emerging threats.

Table 5.1.: Integrating Risk Analysis into International Relations and Global Governance.

Concept	**Definition**	**Existing Applications**	**Relevance to International Relations (IR)**	**Gap in Literature & This Study's Contribution**
Risk Analysis	Identification, assessment, and evaluation of uncertainties affecting decision-making (Renn, 2017).	Applied in **security** (Aradau; Van Munster, 2007) and **finance** (Hafner-Burton; Kahler;	Could provide a **structured method** to anticipate and address **global governance risks**.	**Not widely applied** to IR governance structures; this study proposes its use for **political decision-making**

		Montgomery, 2009).		**and cooperation**.
Risk Management	Strategies to mitigate identified risks through avoidance, reduction, transfer, or acceptance (Fridman, 2020).	Used in **national security, economic stability, and crisis response** (Duffield, 2014).	Could improve **policy coordination, crisis response, and multilateral risk-sharing**.	Literature lacks a **systematic integration of risk management** into **governance frameworks and political institutions**.
Risk Intelligence	Advanced use of **real-time data, predictive analytics, and monitoring** to improve decision-making (Birnbaum, 2021).	Found in **business intelligence, cybersecurity, and military strategy**.	If applied to IR, could **transform governance from reactive to proactive**, improving **global stability and cooperation**.	Current governance models remain **static and bureaucratic**—this study suggests using risk intelligence to create **adaptive governance mechanisms**.

Governance Fragmentation & Risk	Disjointed structures and lack of coordination in global governance hinder effective risk management (Biermann et al., 2009).	Seen in **environmental governance, health governance, and trade policies**.	Risk analysis could **help integrate** actors across different governance layers, reducing inefficiencies.	No formal application of **risk-based integration frameworks** in global governance models—this study fills this gap.
Network-Based Risk Governance	Recognition that **state and non-state actors** form complex networks to share resources and mitigate risks (Hafner-Burton; Kahler; Montgomery, 2009).	Applied in **supply chain risk management, cybersecurity, and financial regulation**.	Could **enhance cooperation** between international organizations, governments, and the private sector.	Literature lacks **models that operationalize network-based risk governance** in IR—this study proposes risk analysis as a structuring tool.
Adaptive Risk Governance	Governance approach that adjusts to emerging risks through **learning,**	Used in **disaster management, public health crises (e.g.,**	Would improve **resilience in global governance**, ensuring that institutions	Existing studies focus on **reactive** responses—this study promotes **proactive** governance

	flexibility, and stakeholder collaboration (Folke et al., 2005).	**COVID-19 response)**.	adapt **before** crises escalate.	through risk intelligence.

Source: Self-elaboration.

5.3. Conceptual Framework: Approaching Risk Assessment in International Relations

Risk analysis tools are traditionally designed for specific objects of study, leading to a wide variety of methodologies that differ depending on the field of application. In International Relations (IR), risk is often examined as an object of analysis, focusing on the consequences of uncertainty and threats within global governance. However, the adaptation of risk as a methodology—as opposed to merely an analytical object—remains largely underexplored in the literature, as per observed by the bibliometric review.

To effectively integrate risk methodologies into IR and global governance, it is crucial to align the selected method with both the theoretical framework and the specific object of study. Risk manuals have a wide variety of methods that can be best suited for each object and theoretical lenses on which the work is done (See, for example: Roeser, 2012; Yoe, 2019; Molak, 1997). This study employs a constructivist lens within Advocacy Coalition Framework (ACF) and Stakeholder Theory, as previously established. Given these foundations, a risk methodology that accounts for stakeholder interactions, power dynamics, and policy influence is necessary—particularly in the context of digital health governance.

Considering the interplay between stakeholders, governance structures, and policy formulation, the study employs two complementary risk analysis methodologies:

Delphi Method – Chosen for its ability to structure expert opinions and facilitate stakeholder-driven forecasting within governance models.

Cross-Impact Analysis – Selected to address the interdependencies between risks and governance factors, closing the gaps left by the Delphi approach.

Why these methods?

Table 5.2.: Method Justification.

Risk Method	Purpose	Relevance to IR & Governance	Adaptation for Digital Health
Delphi Method	Uses iterative rounds of expert consultation to refine consensus-based risk assessment.	Well-suited for stakeholder-driven governance under stakeholder theory, especially in policy design.	Applied to digital health governance to identify policy risks, regulatory uncertainties, and interoperability challenges via direct input from interested parties.
Cross-Impact Analysis	Evaluates how different risks influence each other, identifying cascading effects in complex systems.	Aligns with ACF & Stakeholder Theory by examining interdependencies between actors, institutions, and risks.	Applied to map risk interactions between different governance levels (local, national, and international) in health data governance, thus understanding different coalitions roles and preoccupations

Source: Self-elaboration.

5.4. Overall Methodology Integration

While the **Delphi Method** provides **stakeholder-driven foresight**, it does not account for **the interdependencies between risks, policies, and governance structures**. The **Cross-Impact Method** compensates for this limitation by analyzing **how different risks interact and influence one another**, making it a more comprehensive tool for global governance analysis.

However, both methods rely on **expert knowledge and structured stakeholder engagement**, which, while insightful, may not fully capture the institutional, operational, and political realities of governance implementation. To address this gap, field research was integrated into the methodology, allowing for direct observation, validation of findings, and enhanced contextual understanding.

The inclusion of **technical visits to the Ministry of Health and SEDIGI** ensured that governance structures, decision-making processes, and institutional frameworks were examined beyond theoretical models. By engaging directly with policymakers, regulatory

bodies, and institutional representatives, the field research component bridged the gap between structured risk methodologies and real-world governance constraints.

The following chapter will thoroughly explain how these methods—Delphi, Cross-Impact Analysis, and Field Research—were applied within the risk analysis framework of digital health governance. This integrated approach ensures that risk is not only analyzed as an object but also employed as a methodological tool to enhance decision-making, international cooperation, and institutional capacity-building in governance structures.

5.5. Challenges, Advantages, and Expected Results of the Methodology Application

The application of Delphi and Cross-Impact Analysis in the study of risk and international relations within digital health governance presents both challenges and advantages. This Table 3 outlines potential obstacles, strategies for mitigation, and the expected outcomes of implementing these methodologies.

Table 5.3.: Challenges and mitigations.

Challenge	Expert Panel Diversity	Anonymity and Bias	Cross-impact Matrix Complexity	Resource Intensiveness
Challenges	Ensuring a diverse and representative expert panel may be challenging due to varied schedules and commitments.	Maintaining anonymity in the Delphi Technique may be difficult, potentially leading to biased responses.	Constructing a comprehensive cross-impact matrix might be complex due to the multitude of factors involved.	The methodology involves resource-intensive processes such as expert engagement, multiple rounds, and event participation.
Mitigation	Implement a flexible	Emphasize the importance of	Thoroughly identify and	Plan resources effectively,

	approach, considering asking the questions during events, providing online participation, and providing multiple rounds for participation.	unbiased responses, assure participants of confidentiality, and employ techniques to minimize bias. Integrate anonymization techniques.	prioritize key factors, engage experts for input, and iteratively refine the matrix.	leverage technology for virtual engagement, and maintain flexibility in the research timeline, using most of the available time to participate, engage and support the stakeholder network built previously.

Source: Based on MOLAK, Vlasta. Fundamentals of risk analysis and risk management. Self elaboration.

Delphi Technique iterations are expected to yield a consensus on key dimensions, challenges, and opportunities in digital health governance, although the different stakeholder coalitions may have different expectations. Cross-impact Analysis is anticipated to identify critical factors influencing the governance of digital health in alignment with global strategies.

The methodology aims to provide practical recommendations for policymakers, stakeholders, and institutions involved in digital health governance. The study is expected to contribute a robust framework for future research on risk analysis within international relations, specifically in the dynamic landscape of digital health governance.

The insights gained from the methodology application will inform decision-making processes, contributing to effective governance strategies in digital health at both national and global levels. By acknowledging and navigating these challenges while capitalizing on the advantages, the study anticipates generating valuable and applicable results that contribute to the evolving field of digital health governance within the international context.

This chapter:

1. Introduces risk analysis as a methodological tool for governance, emphasizing its relevance to international relations and digital health.
2. Explains the selection of the Delphi Method and Cross-Impact Analysis to assess stakeholder perceptions and risk interdependencies.
3. Highlights the integration of field research to validate findings and bridge the gap between theory and practice.

   Building on this methodological framework, Chapter 6 details the design and implementation of the Delphi technique and Cross-Impact Analysis.

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6. Risks in digital health: Designing the study methodology

In response to the previously identified challenges—ensuring anonymity, fostering expert panel diversity, and securing expert engagement—the research design incorporates a strategic approach to expert participation. Given the specificity of global governance in digital health, stakeholder involvement was prioritized to reflect the multiplicity of actors shaping policy. A key strategy was leveraging structured events to facilitate expert consultation, ensuring meaningful engagement within institutional frameworks.

6.1. The First Intersectoral Forum on Digital Health

The First Intersectoral Forum on Digital Health, held from September 20 to 24, 2021, served as a cornerstone for this approach. Organized by the Brazilian Ministries of Economy, Health, and Science, Technology, and Innovation, the event provided a structured space for discussions among key actors shaping digital health governance. The forum was structured into thematic sessions, each engaging relevant stakeholders and addressing fundamental dimensions of digital health governance.

Day 1 – Introduction and Opening Discussions

The event commenced with an overview of digital health governance, featuring presentations from government agencies and representatives of interministerial cooperation. This opening session framed the discussions by emphasizing the role of interoperability, risk governance, and stakeholder cooperation in the national digital health strategy. It set the stage for addressing digital health challenges within the broader framework of global governance and international cooperation.

Day 2 – Products, People, and Processes

The second day focused on the technological and human aspects of digital health, gathering key private sector actors, health professionals, and regulatory bodies to discuss the interaction

between healthcare technologies and professional practices. The following key themes were addressed:

1. Medical Devices and Digital Health Technologies: The expansion of digital health solutions, including software as a medical device (SaMD), wearable health trackers, AI-driven diagnostics, and telemedicine platforms, was debated. The regulatory challenges for approving and standardizing these innovations were central concerns .

2. Workforce and Professional Training: The integration of digital health into clinical practice requires significant investment in capacity-building for healthcare professionals. The lack of digital literacy among professionals and disparities in technological adoption across different regions of Brazil were highlighted.

3. Processes and Standardization: Efficient digital health systems depend on standardized workflows, protocols, and documentation procedures. Participants discussed the need to align national processes with international standards (e.g., HL7 FHIR, ISO 23903) to ensure cross-border interoperability (Belli and Foditsch, 2015).

By bringing together industry leaders, medical associations, and policymakers, this session underscored the critical role of private-public partnerships in scaling digital health solutions while ensuring that professionals receive adequate training and support.

Day 3 – Infrastructure, Security, and Network Interoperability

The third day addressed the technological backbone of digital health, focusing on infrastructure requirements, data security, and system interoperability. Representatives from government innovation departments, regulatory agencies, and private technology providers contributed to discussions on:

1. Network Infrastructure and Connectivity Gaps: Brazil’s diverse geographic and socio-economic landscape creates digital divides that must be addressed to ensure equitable access to digital health services. The role of 5G networks, fiber optics expansion, and telehealth infrastructure was analyzed in the context of expanding healthcare access.

2. Cybersecurity in Digital Health: Health data is among the most sensitive categories of personal information, making digital health systems prime targets for cyber threats. The discussion focused on data encryption, multi-factor authentication, and resilience against cyberattacks, particularly in the context of LGPD (Lei Geral de Proteção de Dados) compliance (Brasil, 2018).

3. Interoperability Challenges and Solutions: Digital health governance is only effective if systems can communicate across different healthcare levels and institutions. Participants explored technical and policy solutions for interoperability, such as API-based integrations, cloud-based health records, and international data-sharing frameworks.

This session emphasized the necessity of strengthening Brazil's digital infrastructure while ensuring that security and interoperability frameworks align with international governance standards.

Day 4 – Privacy and Security of Health Data

The fourth day delved into the legal and ethical dimensions of health data privacy, featuring contributions from the Ministry of Justice, regulatory bodies, research institutions, and private sector initiatives. The key topics included:

1. Health Data as a Critical Asset: The increasing reliance on digital health systems has elevated health data to the status of a national security concern. Experts discussed how global regulations such as GDPR (General Data Protection Regulation) and Brazil's LGPD are shaping the governance of patient data.

2. Ethical Considerations in Digital Health: Issues of patient consent, anonymization, and secondary use of health data for research were widely debated. Ensuring informed patient consent while promoting data-sharing mechanisms for scientific advancements was a central concern (Aicardi et al., 2016).

3. Role of the Private Sector in Data Protection: While tech companies play a major role in digital health innovation, there are growing concerns regarding data monetization,

algorithmic biases, and the risk of surveillance capitalism. Policymakers debated whether stricter regulatory oversight is needed to curb commercial exploitation of health data.

By highlighting the intersection of privacy rights, regulatory compliance, and ethical considerations, this session contributed to shaping policies that balance innovation with patient protection.

Day 5 – Regulatory Challenges and Governance

The final day brought together representatives from all aligned ministries, as well as regulatory agencies (ANVISA, ANS, and ANATEL), to debate the regulatory landscape for digital health governance. Discussions focused on:

1. Regulatory Harmonization Across Agencies: Digital health governance falls under the jurisdiction of multiple entities. Experts discussed ways to harmonize regulations across health, telecommunications, and data protection agencies to reduce bureaucratic inefficiencies.

2. Public-Private Sector Regulatory Compliance: Private companies operating in the healthcare space must navigate complex compliance requirements. There was a focus on creating flexible yet robust regulations that allow innovation while ensuring patient safety and public trust.

3. Alignment with International Governance Standards: As digital health becomes increasingly globalized, Brazilian regulations must align with international frameworks to enable cross-border data exchange, research collaborations, and medical technology approvals.

This session reinforced the need for integrated governance mechanisms that foster regulatory coherence, support innovation, and protect patient rights.

The First Intersectoral Forum on Digital Health played a pivotal role in shaping discussions surrounding Law Proposal 1998/2020, which ultimately led to Brazil's Digital Health Law

(Law No. 14.510/2022). The forum served as an early-stage policy deliberation mechanism, bringing together key stakeholders in a governance setting.

From a methodological perspective, this event provided invaluable expert insights that aligned with the Delphi Method and Cross-Impact Analysis used in this study. The structured, multi-day discussions enabled:

- Broad stakeholder engagement: The forum's virtual format facilitated participation from diverse actors across different sectors.

- Iterative expert input: The recorded sessions allowed for multiple rounds of expert analysis, aligning with the Delphi Method's iterative approach.

- Contextualizing governance challenges: By identifying cross-sector dependencies, the forum informed the construction of the Cross-Impact Matrix.

At the time of assisting in organizing the event, I was working for the German Cooperation Agency (GIZ), and had not yet conducted the Advocacy Coalition Framework (ACF) analysis, Value-Chain Analysis, Process Modeling, or Stakeholder Mapping. In fact, the First Intersectoral Forum on Digital Health played a pivotal role in shaping these steps of the research. The structured discussions and expert insights gained throughout the event provided a foundational understanding of the actors, challenges, and governance structures involved in digital health policy in Brazil.

The identification of the expert panel was conducted through two complementary approaches:

1. Legislative Session Analysis: Prior to the event, we reviewed multiple law proposal discussion sessions related to Law Proposal 1998/2020, mapping the stakeholders who actively participated in these debates (Câmara dos Deputados, 2021). This allowed us to identify key actors already engaged in shaping digital health policies. Once these stakeholders were identified, we formally invited them to participate in the expert panel.

2. Stakeholder Referral Mechanism: After inviting the initially identified stakeholders, we leveraged their networks to expand participation, requesting recommendations for additional experts who could contribute valuable perspectives to the discussions (Biernacki and Waldorf, 1981). This ensured a diverse and representative expert panel, covering multiple sectors and perspectives.

The four thematic areas of the forum—Products, People, and Processes; Infrastructure, Security, and Interoperability; Privacy and Data Protection; and Regulatory Challenges—were not pre-determined but emerged organically from the key issues debated in the legislative discussions on Law Proposal 1998/2020. After identifying the major themes discussed by legislators and stakeholders, these topics were suggested to the ministries involved in the event's organization. The ministries agreed with the proposed structure, recognizing the alignment of these themes with the ongoing regulatory discussions in digital health governance.

This process not only strengthened the methodological approach of the research but also provided critical empirical data for subsequent stages, such as the Stakeholder Mapping, ACF analysis, and Process Modeling. By integrating insights from legislative debates and expert discussions, the research was able to construct a comprehensive and multi-layered perspective on digital health governance, directly informed by the actors shaping policy at different governance levels.

6.2. Implementing the Delphi Technique: The Hybrid Event and Real-Time Data Collection

Building on the methodological framework established in previous stages, the Delphi technique was refined and prepared for its first implementation through an interactive, hybrid event format. The choice of a Real-Time Delphi approach , conducted through the Mentimeter software (Moorhouse and Kohnke, 2020), was strategically designed to address several challenges previously identified:

Stakeholder engagement barriers were mitigated by hosting the Delphi process within a broader public event, rather than in a formalized, institutional setting that might discourage participation (Stoecker, 2020).

Bias in public collaboration was minimized by incorporating both in-person and online participation, ensuring that multiple perspectives were captured from different sectors, including governmental agencies, private sector representatives, and civil society actors.

Anonymity concerns (Saunders, Kitzinger and Kitzinger, 2015) —critical for ensuring unbiased expert input—were resolved through Mentimeter's anonymous submission format, allowing participants to respond freely without concerns of political or institutional repercussions.

Inclusivity and accessibility were enhanced by allowing simultaneous in-person and online participation, ensuring that stakeholders from diverse geographic and institutional backgrounds could contribute.

6.2.1. Leveraging the University of Brasília's 24th Universitary Week

To facilitate broader participation and interdisciplinary engagement, the Delphi process was incorporated into the University of Brasília's 24th Universitary Week, held from November 4 to 10, 2024 (Nery, 2024). The event, titled "The World Within Us: Building a Sustainable Present" (O Mundo Em Nós: Construindo Um Presente Sustentável), provided an ideal platform due to its alignment with the research themes and its thematic axis III: Health, Sport, and Well-being in the Community (Universidade de Brasília, 2024).

By integrating the research within a university-led initiative, the study also reinforced the principles of UnB's Research and Extension model, ensuring that academic inquiry was directly connected to societal needs and public engagement (Nóbrega et al., 2021; Brasil, 1996). This multistakeholder integration—which included policy actors, community members, and experts—not only enriched the quality of responses but also expanded the scope of discussion to include citizen perspectives, making it a more inclusive governance debate.

The event was formally submitted and approved as a joint collaboration between the Institute of International Relations and the Law Faculty of UnB.

The Delphi process was structured across two days (November 6 and 7, 2024), each focusing on distinct but interconnected themes:

Table 6.1.: Event proposal as it was accepted by the University of Brasília.

Schedule	General Objectives	Expected Results
Day 1: 06/11/2024 14:00 - 14:30: Opening and Welcome 14:30 - 15:00: Inaugural Lecture: "Governance in Digital Health: Challenges and Opportunities" 15:00 - 16:30: Round Table: "Regulation and Digital Health: The Role of Regulatory Agencies" 16:30 - 17:00: Coffee break Day 2: 07/11/2024 14:00 - 14:30: Panel: "The Impact of Digital Health Policies on Innovation and Competitiveness"	Analyze and identify the main risks associated with the implementation of digital health governance projects in Brazil and internationally. Promote intersectoral dialogue between different actors involved in digital health, seeking consensus on best governance practices. Encourage innovation and the development of technological solutions that integrate health and society, with a focus on quality of life and human rights.	Identification of critical risks and opportunities for digital health governance in Brazil and in international contexts. Production of strategic recommendations for the development and implementation of effective public policies in digital health. Strengthening the collaboration network between stakeholders from different sectors, promoting innovation and integration of digital health practices. Establishment of a joint action plan for the continuous improvement of digital health governance practices, based on the

14:30 - 15:15: Workshop: "Risk Analysis Tools and Methodologies in Digital Health" 15:15 - 15:30: Coffee break 15:30 - 17:00: Interactive Panel: "Real-Time Delphi Analysis: Risk Identification and Mitigation" 17:00 - 17:15: Questions and Answers Session: "Paths for Implementing Efficient Digital Health Governance" 17:15 - 17:30: Closing, presentation of results and Final Considerations		results of the Delphi methodology.

Source: Self-elaboration.

By embedding the Delphi study within an established, multi-sectoral public event, this approach bridged the gap between academia, governance, and public participation. The hybrid model allowed for a broad, interdisciplinary conversation on digital health risks and governance while ensuring rigorous methodological control through real-time anonymous data collection.

The findings from this Delphi round were used to further refine the cross-impact analysis, validate initial ACF mappings, and enhance process modelling accuracy. This iterative approach ensured that the research remained responsive to evolving governance dynamics, strengthening its practical implications for policy recommendations and international cooperation strategies in digital health.

6.3. Expert Panel Identification and Delphi Questionnaire Design

Expert Panel Identification

The selection of **experts** for the **Delphi process** was directly informed by the **Advocacy Coalition Framework (ACF) mapping** conducted earlier in the research. This ensured that the panel was composed of **key stakeholders actively engaged in digital health governance**, including:

- **International Organizations:** Representatives from the **World Health Organization (WHO)** and the **Pan-American Health Organization (PAHO)**, ensuring alignment with global governance structures.
- **Government Entities:** Officials from Brazil's **Ministry of Health**, particularly from **DATASUS**, the department responsible for digital health initiatives, and representatives from **regulatory agencies (ANVISA, ANS, ANATEL)**.
- **Private Sector Representatives:** Industry professionals from **health technology companies, interoperability standardization bodies (HL7 Brasil, ABNT), and cybersecurity firms**.
- **Academia and Research Institutions: Professors, researchers, and experts in digital health, governance, and international relations**, bringing theoretical and policy-oriented insights.
- **Healthcare Professionals and Civil Society: Doctors, nurses, and representatives from patient advocacy organizations**, ensuring the inclusion of on-the-ground healthcare perspectives and concerns from the general community.

Panel Structure and Participation Format

The **Delphi process** was integrated into a **two-day hybrid event**:

1. **Day 1: Thematic Discussions & Expert Insights**
    - Each **expert provided a brief speech** within their area of expertise.
    - These discussions provided **key insights into digital health governance challenges**, forming the basis for refining the questionnaire.
    - Observations from these discussions helped identify **gaps in stakeholder perspectives**, leading to **adaptations in the questionnaire for Day 2**.

2. **Day 2: Interactive Delphi Panel & Consensus Building**

    - Experts participated in an **interactive panel discussion using the Real-Time Delphi approach** via **Mentimeter software**.
    - The methodology allowed for **real-time anonymous input**, reducing potential biases.
    - Participants engaged in **iterative rounds** of feedback, refining their responses based on previous submissions.

Questionnaire Design for the Delphi Technique

The questionnaire was developed to **capture key dimensions of digital health governance** based on:

- The governance models of WHO (EGSD) and the Brazilian Ministry of Health (ESD28).
- Risk analysis frameworks and insights from ACF and stakeholder theory.
- Stakeholder concerns expressed in previous policy debates and the First Intersectoral Forum on Digital Health.

The **Delphi questionnaire** followed a **three-part structure**, **progressing from general to specific** themes to ensure a comprehensive analysis:

Block 1: Risks in the Implementation of Global and Brazilian Digital Health Strategies

Objective: Identify and prioritize governance risks affecting digital health implementation.

Questions:

- About healthcare professionals and new technologies: Selecting statements through the software.
- Which factors related to limited and uneven infrastructure are most critical for the implementation of digital health strategies in Brazil?

- What short-term solutions can be implemented to mitigate the lack of training for professionals in digital health?
- How do you see the relationship between data security and the need for robust investment? Do you believe there is a sufficient balance?
- Indicate which of these problems generate the greatest difficulty in creating a digital health network in Brazil, ranking them from most to least impactful.
- Interactive question regarding cyber attacks.

Block 2: Risks in Translating the Global Strategy into Local Health Policies

Objective: Assess challenges in adapting international governance frameworks (EGSD) to the Brazilian health system.

Questions:

- What aspects of global governance should be prioritized to ensure effective implementation in Brazil?
- Regarding Brazil's current digital health governance, what are the main challenges in adapting the Global Digital Health Strategy (EGSD) to the national context?
- What types of local policies can strengthen data security and privacy in digital health?
- To what extent does inequality in technological infrastructure affect the implementation of the global strategy in Brazil?

Block 3: Intersectoral Implementation of Health Strategies

Objective: Analyze multi-stakeholder collaboration challenges and identify risk interactions.

Questions:

- **Rank the following events in terms of their likelihood of occurrence and the potential impact they would have on digital health in Brazil.**
- **What would be the most effective mechanisms to ensure that all sectors collaborate efficiently?**

- **Consider which events have the greatest potential to influence each other, creating a domino effect.**

Multi-Level Participant Engagement

To ensure **diverse perspectives**, the Delphi panel included **participants from multiple sectors**:

- **Public sector:** Ministry of Health, regulatory agencies, public hospitals.
- **Private sector:** HealthTech companies, software providers, cybersecurity experts.
- **General population:** Representatives from civil society and patient associations.
- **Political actors:** Representatives from legislative bodies involved in digital health policymaking.
- **Academia & research institutions:** Scholars specializing in digital health governance.

Some direct examples of representatives included: Researchers on digital health from the University of Brasília and Fiocruz, employees from WHO, PAHO, Anvisa, ANS, and the Brazilian Ministry of Health, representatives from hospitals and tech companies, as well as from third sector parties and associations, such as SBIS and ABIMED.

Participation Results:

- The **Delphi process engaged between 9 to 13 participants per question round**.
- This ensured **adequate representation across sectors**, despite variations in availability.

Key Insights and Adjustments from the Delphi Process

- **Day 1 discussions provided valuable context**, leading to **refinements in questionnaire design**.
- **Participants dynamically influenced the questionnaire structure**, reinforcing **adaptive methodology principles**.

- **A multi-sectoral lens was successfully applied**, integrating **stakeholder-specific risks** into governance assessments.

By applying the **Real-Time Delphi Technique**, the research effectively **captured diverse governance perspectives**, ensuring that **risk assessment and policy recommendations were rooted in empirical stakeholder input**.

In the **next chapter**, the findings from this **Delphi round are analyzed**, integrating them into the **broader risk analysis framework** and **governance recommendations**.

6.4. Data Collection and Analysis Strategy

6.4.1. Data Collection Process

The data collection process for the **Delphi method**, **Cross-Impact Matrix analysis**, and **field research** was structured to ensure a **robust and comprehensive evaluation of digital health governance risks**. The methodology relied on **both qualitative and quantitative data sources**, integrating:

1. **Real-Time Delphi Questionnaire Responses:**
    - The **Mentimeter software** was used for **live data collection and analysis**, providing real-time aggregation of participant responses.
    - This tool allowed for **anonymous contributions**, reducing potential biases and encouraging more open and diverse input from stakeholders.
2. **Expert Presentations and Stakeholder Insights:**
    - Each **stakeholder representative's presentation** was **documented and analyzed**, serving as a secondary data source.
    - The presentations **complemented survey responses**, offering **in-depth qualitative perspectives** on governance and risk concerns.
3. **Cross-Impact Matrix Construction:**
    - The last question of the **Delphi questionnaire directly consulted experts** on their opinions regarding **real-world risk impacts** and their **interactions**.

- These responses were used to **construct a Cross-Impact Matrix**, mapping out **how different risks influence each other** and their **potential cascading effects** in Brazil's digital health governance framework.

4. **Field Research: Technical Visits to the Ministry of Health and SEDIGI**

   - In addition to the structured Delphi process, a **technical visit** was conducted to **the Brazilian Ministry of Health and SEDIGI (Secretaria de Informação e Saúde Digital – Secretariat for Information and Digital Health)**.
   - These visits allowed for **direct observation of governance structures, discussions with policymakers, and firsthand insights into operational challenges**.
   - The findings from these visits were **instrumental in contextualizing Delphi results**, providing a **real-world verification** of governance barriers, institutional alignments, and stakeholder engagement.

6.4.2. The Field Research

Methodology and Research Process

The field research for this study was conducted in February 5th, 2025, focusing on direct engagement with key stakeholders involved in digital health governance in Brazil. The objective was to validate theoretical findings, assess institutional risk perception, and examine the practical challenges in implementing digital health policies at different levels of governance. The study combined semi-structured interviews with policymakers, regulatory officials, and digital health experts, along with participant and non-participant observation in institutional meetings, technical working groups, and governance forums. Additionally, document analysis was conducted on government reports, strategic plans, and policy guidelines.

The technical visit was led by Professor Diego Mota Vieira, within the discipline of State, Government and Public Policy of the University of Brasília, from. The visit was scheduled with representatives from **SEDIGI (Secretaria de Saúde Digital), DATASUS, and DEMAS.** These institutions play a central role in shaping Brazil's digital health strategy, coordinating data management, and implementing interoperability policies. However, despite

efforts to integrate health systems, the findings reveal persistent governance bottlenecks that hinder effective risk management.

Key Findings and Governance Challenges

One of the most critical issues identified was the **fragmented nature of digital health governance**. While SEDIGI is responsible for formulating national digital health strategies, its effective implementation depends on coordination with state and municipal governments, which often operate under different priorities and technical capacities. DATASUS, tasked with managing Brazil's digital health infrastructure, oversees more than 400 platforms, yet many remain **incompatible with each other**, resulting in data silos that hinder patient record integration and public health monitoring. DEMAS, in turn, plays a crucial role in evaluating digital health initiatives but struggles with **data inconsistencies and a lack of standardized reporting mechanisms** across different levels of governance.

A recurring theme in interviews was the **lack of interoperability between health data systems**, a structural issue that reflects not only technical shortcomings but also deeper governance misalignments. Municipal health agencies often rely on **legacy software that is incompatible with national databases**, creating barriers to efficient data exchange. The **RNDS (Rede Nacional de Dados em Saúde)**, intended to address these challenges, faces slow adoption due to institutional resistance and competing regulatory frameworks. Consequently, the absence of a cohesive interoperability strategy limits Brazil's ability to coordinate healthcare data across jurisdictions, affecting both patient care and national public health responses.

Cybersecurity also emerged as a major risk, with numerous public health institutions lacking dedicated cybersecurity teams and operating under **minimal data protection protocols**. Compliance with Brazil's **LGPD** remains inconsistent, particularly at the municipal level, where financial and human resource constraints prevent the implementation of robust data governance practices. Several respondents expressed concerns about the rising threat of **ransomware attacks targeting health institutions**, yet there is no standardized national response framework to address such incidents. Without a more comprehensive cybersecurity governance model, the increasing reliance on digital health systems exposes Brazil to **significant risks related to data breaches, privacy violations, and systemic failures**.

Beyond technical challenges, the research highlighted **the digital divide as a core governance issue**, disproportionately affecting rural, indigenous, and economically disadvantaged communities. Limited access to digital infrastructure, particularly in remote areas, prevents the effective adoption of **telemedicine and electronic health records**, exacerbating health inequalities. Initiatives such as **GT da Terra and GT da Maré**, which focus on providing digital health solutions for indigenous populations and urban peripheries, were identified as promising models for bridging this divide. However, without broader investment in digital literacy and infrastructure expansion, these efforts remain **localized rather than systemic solutions**.

Another crucial finding was the **disconnection between international governance frameworks and local implementation strategies**. Brazil's digital health policies frequently reference **global strategies such as the WHO's Global Strategy on Digital Health**, yet these frameworks often fail to translate into effective municipal policies. While national-level decision-makers prioritize alignment with global governance mechanisms, municipal health secretariats struggle with **immediate operational concerns**, including budget constraints, workforce training, and infrastructure development. Decision-making remains **highly centralized**, limiting the ability of local governments to tailor digital health initiatives to their specific needs. SEDIGI has attempted to bridge this gap through **regional action plans**, but implementation remains uneven due to **political misalignment and inconsistent resource allocation**.

Implications for Risk Analysis in Digital Health Governance

The field research confirms that **risk in digital health governance is not merely a technical issue but a deeply institutional and political challenge**. Different governance levels prioritize risks in conflicting ways: national agencies emphasize **cybersecurity and interoperability**, whereas local health authorities focus on **funding shortages, staff training, and digital accessibility**. This divergence in risk perception contributes to **policy misalignment and inefficient digital health implementation**.

Governance risks in digital health require **multi-level coordination** to ensure that international digital health standards are adaptable to municipal realities. The research also highlights the necessity of **strengthening public-private collaboration**, as many digital health innovations stem from the private sector, yet regulatory structures remain slow to

accommodate these advancements. The absence of coordinated governance mechanisms results in **fragmented digital health adoption and inefficient risk management strategies**.

Rather than being treated as an **externalized technical challenge**, risk analysis should be embedded into governance structures from the outset, shaping **policy planning and decision-making** rather than simply reacting to crises. This study proposes a governance model that categorizes risks into **structural risks** (institutional misalignment and governance fragmentation), **operational risks** (data security failures, interoperability gaps), and **equity risks** (digital divide, exclusion of vulnerable populations). By integrating risk analysis within digital health governance frameworks, policymakers can **anticipate systemic vulnerabilities rather than merely addressing their consequences**.

Bridging Research and Policy: Risk Analysis as a Governance Tool

The findings emphasize that risk analysis must be reconceptualized from a crisis management tool to a governance structuring mechanism. Embedding risk assessment into decision-making processes would allow policymakers to proactively address vulnerabilities rather than reacting to failures. Institutional coordination must be reinforced to ensure that international digital health strategies align with municipal implementation capacities and that governance mechanisms incorporate a cross-sectoral, equity-driven approach. Without a structured risk governance model, digital health policies risk deepening existing inequalities and reinforcing systemic inefficiencies rather than enabling inclusive and effective healthcare delivery.

Analysis and Feedback Process

To ensure validity and transparency, the data was iteratively analyzed and refined, following these steps:

1. **First-Round Delphi Analysis:**
    - Responses were compiled and summarized using Mentimeter's built-in analytical tools.
    - Key trends, agreements, and divergences were identified for each question.
2. **Expert Feedback Reports:**

- Participants received feedback reports outlining areas of strong consensus and points of divergence.
- These reports allowed experts to review collective responses and refine their answers in subsequent rounds.

3. **Iterative Delphi Rounds:**

   - The process was repeated until a sufficient level of consensus was reached on critical governance risks.
   - Conflicting responses were further analyzed to identify root causes of disagreement.

4. **Integration with Cross-Impact Matrix:**

   - The final responses were synthesized into the Cross-Impact Matrix, mapping how each identified risk influences or is influenced by others.
   - This provided a structured, systemic view of risk interdependencies in digital health governance.

5. **Field Research Integration:**

   - Findings from the technical visits to the Ministry of Health and SEDIGI were incorporated to complement Delphi and Cross-Impact results.
   - Direct observations were cross-referenced with stakeholder feedback, ensuring policy recommendations were both theoretically sound and practically viable, which also happened during the technical visit, after the Delphi rounds.
   - Providing the analysed results to the experts and policymakers, to make sure that the observed events were indeed what their own experience would expect.

Expected Results and Next Steps

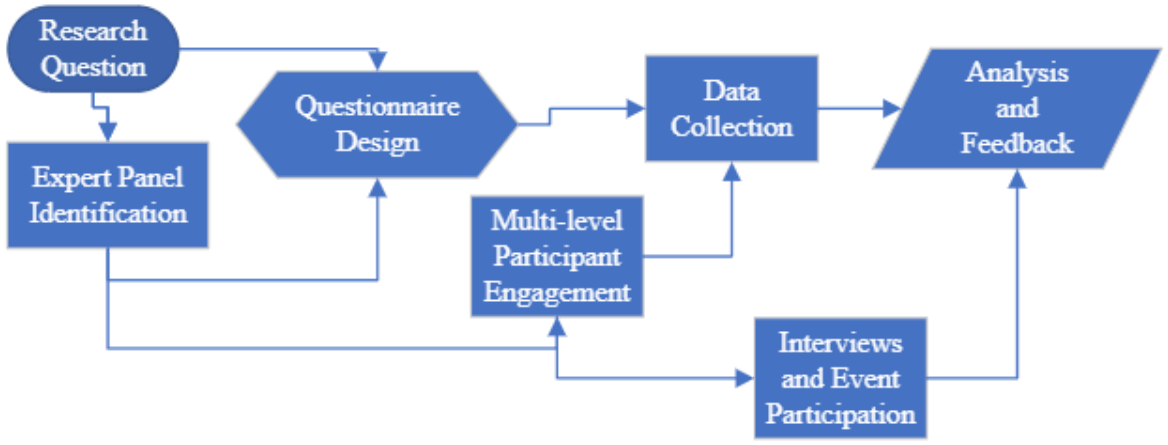
The results obtained from these methodologies are presented in the following chapters, where:

- Delphi findings are analysed in depth, highlighting major governance risks, stakeholder priorities, and potential intervention strategies.

- The Cross-Impact Matrix results are detailed, demonstrating risk interactions and their implications for decision-making in digital health governance.
- Technical visit insights are incorporated, bridging the gap between institutional theory and real-world governance challenges.

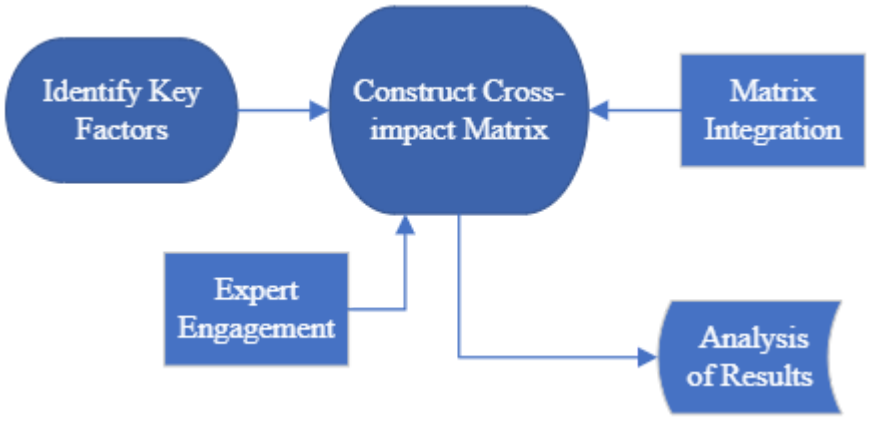
By integrating Delphi insights, cross-impact analysis, and field research, the study offers a structured approach to understanding and mitigating risks, ensuring that policy recommendations are aligned with stakeholder perspectives and governance needs.

Image 6.1.: Delphi method analysis.



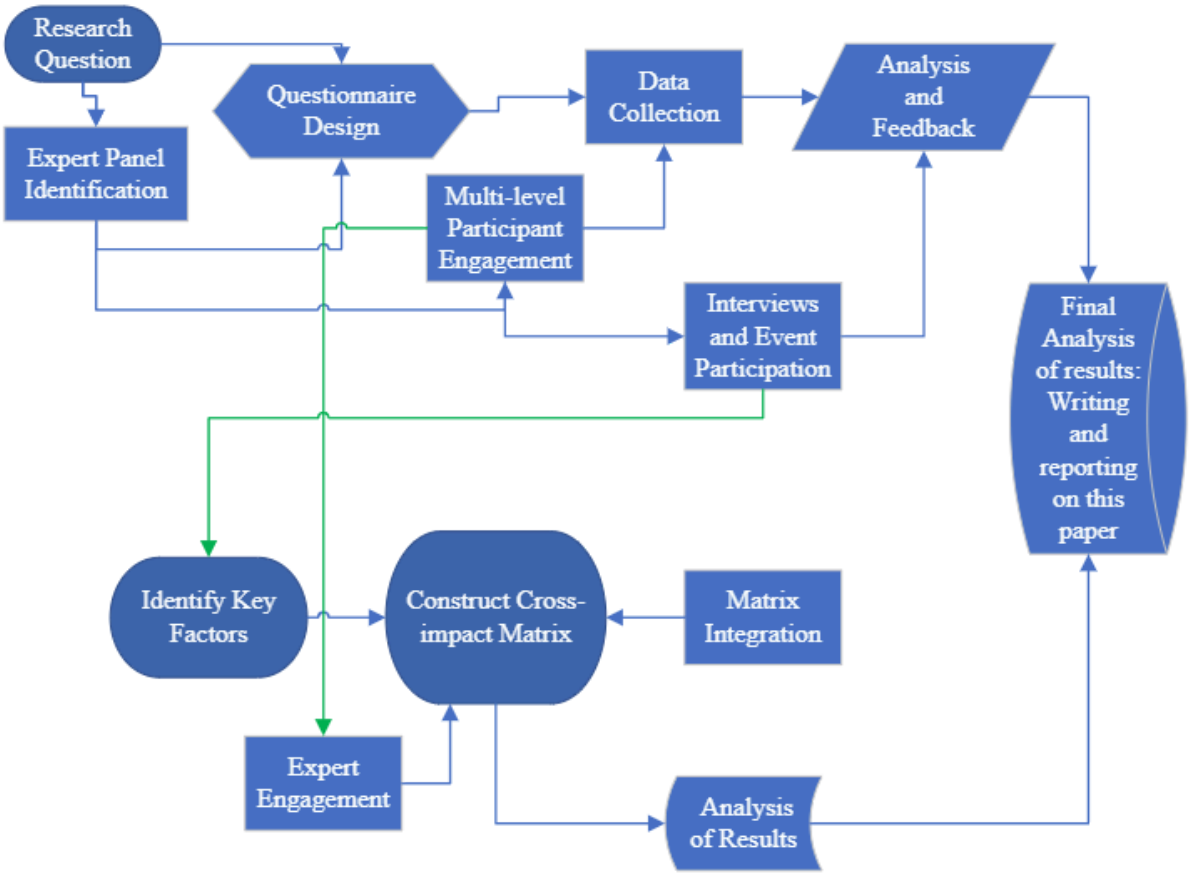
Source: Based on MOLAK, Vlasta. Fundamentals of risk analysis and risk management. Self elaboration.

Image 6.2.: Applying Cross-impact Analysis.



Source: Based on MOLAK, Vlasta. Fundamentals of risk analysis and risk management. Self elaboration.

Image 6.3.: Overall Methodology Integration.



Green arrows represent integration between the different methods. Source: Based on MOLAK, Vlasta. Fundamentals of risk analysis and risk management. Self elaboration.

With the methodology in place, Chapter 7 presents the Delphi results, focusing on stakeholder perceptions of risks in digital health governance.

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7. Risk Analysis: The Delphi Technique

The Delphi consultation provided structured input from diverse stakeholders, including government agencies, regulatory bodies, private sector representatives, researchers, and healthcare professionals. The responses offer a comprehensive view of digital health governance challenges in Brazil, particularly regarding **risk perception, governance strategies, interoperability, and infrastructure limitations**.

The iterative nature of the Delphi method aligns with constructivism's emphasis on knowledge as a dynamic, negotiated process. Through multiple rounds of feedback, stakeholders refine their perceptions of risks based on interactions with others, leading to a consensus that reflects their collective understanding. For instance, initial disagreements about the priority of data security versus interoperability were resolved through discussions that highlighted their interdependence. This iterative process underscores the constructivist view that consensus is not a fixed outcome but emerges through dialogue and shared experiences, shaped by the institutional roles and power dynamics of the participants.

The consultation was structured around three main blocks:

1. **Risks in the Implementation of Global and Brazilian Digital Health Strategies**
2. **Challenges in Translating Global Strategies into Local Policies**
3. **Intersectoral Implementation of Health Strategies and Risk Interdependencies**

These blocks guided the analysis of key risks, stakeholder expectations, and potential solutions.

7.1. Key Findings by Thematic Blocks

7.1.1 Risks in the Implementation of Digital Health Strategies

Key Issues Identified:

- **Interoperability as the Most Critical Risk:** Similar to the previous survey, interoperability risks were the most cited concern among stakeholders. However, the Delphi consultation provided more depth into which aspects of interoperability posed

the greatest risks:

  - **Semantic Interoperability:** The inability to standardize medical terminologies and data formats across different healthcare systems.
  - **Syntactic Interoperability:** The lack of uniform technical protocols and APIs that allow systems to communicate effectively.
  - **Organizational Interoperability:** Governance fragmentation and misalignment between national and international health policies, leading to inconsistencies in implementation.
  - **Operational Interoperability:** The difficulty of ensuring real-time data exchange across different levels of care (primary, secondary, tertiary).
- **Cybersecurity Risks:** Concerns over cyberattacks were a recurring theme, with participants emphasizing that Brazil's digital health system is highly vulnerable to hacking, data breaches, and unauthorized access. This was also seen as a risk to interoperability, since insecure data-sharing environments could lead to reduced trust and reluctance to integrate systems.

- **Lack of Professional Training:** There is a skill gap among healthcare professionals in adopting and effectively using digital tools, further complicating interoperability.

- **Data Security and Investment:** Many respondents felt that financial investments in digital health security were insufficient, particularly when compared to the increasing risks of digitalization. However, financial investment was not considered a core issue overall—an unexpected result that contrasts with prior hypotheses.

Consensus and Divergences:

- **High Agreement:** Infrastructure, interoperability, and cybersecurity risks were identified as the most urgent priorities.
- **Disagreement:** Some stakeholders believed that data security concerns were exaggerated, while others emphasized that without strict cybersecurity measures, digital health adoption could fail due to patient distrust.

7.1.2 Challenges in Translating Global Strategy into Local Policies

Key Issues Identified:

- **Governance Gaps:** There is a mismatch between global health strategies (e.g., WHO's EGSD) and national implementation realities.
- **Regulatory Uncertainty:** Stakeholders expressed concern over fragmented regulatory frameworks, making compliance complex for both public and private actors.
- **Integration with Local Policies:** National health policies do not fully align with international digital health frameworks, leading to inefficiencies in governance and interoperability challenges.

Consensus and Divergences:

- **High Agreement:** Regulatory inconsistencies hinder digital health policy execution.
- **Disagreement:** Almost all participants argued for a **more centralized approach** in regulating digital health, but the role of the Ministry of Health on this was put in different ways: Some argued that it should operationalize all parts of the centralization of networks, especially with RNDS, while others wanted it to be more of a general application of governance practices, that should be locally implemented.

7.1.3 Intersectoral Implementation and Risk Interdependencies

Key Issues Identified:

- **Stakeholder Collaboration: Public-private cooperation is essential**, but trust issues between sectors remain a challenge.
- **Cross-Sectoral Influence: Digital health risks are interconnected**—cybersecurity vulnerabilities, regulatory gaps, and poor infrastructure mutually reinforce each other.
- **Regulatory Bottlenecks:** The **lack of standardization across different health IT systems** limits interoperability.

A Notable and Unexpected Finding:

- **Financial resources were not perceived as a major barrier.** Contrary to prior expectations, neither public nor private sector actors identified financial constraints as a significant risk. Instead, both groups overwhelmingly agreed that interoperability was the core risk affecting digital health implementation.
- **Unlike the initial hypothesis, public and private sector stakeholders did not see different risks but rather identified interoperability as a shared concern.** This suggests that both groups recognize that fragmented digital health systems and governance misalignment are the primary obstacles, rather than funding limitations.

Consensus and Divergences:

- **High Agreement:** The biggest systemic risk is **interoperability failure**, preventing data flow between different healthcare systems.
- **Disagreement:** Some stakeholders believed **private investment should lead digital health transformation**, while others saw **public institutions as the primary driver**.

7.2. Insights for Risk Management and Policy Recommendations

From these findings, **risk interdependencies** are evident, and the Delphi consultation has confirmed several critical insights:

1. **Interoperability is the Core Issue:** The inability to integrate health systems across sectors and regions is a **major governance failure**.
2. **Cybersecurity Threats Must be Prioritized:** Stakeholders agree that **without robust security measures, trust in digital health systems will erode**.
3. **Infrastructure Investment is Urgent: Public and private investments are needed to bridge the technological gap** between different regions of Brazil.
4. **Regulatory Harmonization is Essential:** Aligning **WHO's EGSD and Brazil's ESD28** requires **better coordination across ministries, regulatory bodies, and private stakeholders**.
5. **Stakeholder Cooperation is Key: Strengthening partnerships between the government, private sector, and healthcare professionals** will help overcome policy fragmentation.

Conclusion

The Delphi consultation has revealed a **high level of agreement** on key digital health risks, particularly regarding **interoperability, cybersecurity, and governance**. Interestingly, **financial constraints were not perceived as a major obstacle**, contradicting prior assumptions. Instead, **interoperability risks were universally recognized by both public and private sector stakeholders**, demonstrating a rare alignment of priorities.

These findings provide a **solid foundation for the Cross-Impact Analysis**, ensuring that risk management strategies align with both global governance models and local realities.

Institutional and normative influences further shape how risks are perceived and prioritized in the Delphi results. Stakeholders' perceptions are influenced by global norms, such as the WHO's Global Strategy on Digital Health and the adoption of FHIR standards, which frame interoperability and data security as critical governance challenges. These norms are internalized by stakeholders, reinforcing their prioritization in the Delphi process. At the same time, power asymmetries among stakeholders influence how risks are framed. For example, private sector actors emphasize innovation and market opportunities, while public sector actors focus on equity and regulatory compliance. These divergent framings reflect the constructivist insight that risk perceptions are shaped by the institutional positions and interests of stakeholders. To mitigate this, the anonymity of the Delphi method was crucial.

8. Risk Analysis: Cross-impact analysis

Below is a concise cross‑impact analysis of the five hypothetical events identified in Brazil's digital health context, from stakeholder inputs during their speeches on the event. Participants were asked to determine their likelihood and impact, and, based on this, their relationship was drawn. This matrix looks beyond isolated probabilities and impacts, asking instead: **How might the occurrence of one event exacerbate or lessen the likelihood or severity of another?** The horizontal axis lists possible "trigger" events, and the vertical axis lists "affected" events. Each cell briefly explains the nature (and direction) of the influence.

Table 8.1.: Cross‑Impact Matrix of likelihood and severity.

Affected Event	**(1) Cyberattack**	**(2) Connectivity Failure**	**(3) Doctor Untrained**	**(4) Pharmacy Refusal**	**(5) Patient Death**
(1) Cyberattack leaks exam data Sensitive patient information is compromised.	— (self)	**Moderate:** Disconnected regions can't patch or monitor systems promptly, raising vulnerability.	**Low:** An untrained doctor is not a direct vector for cyberattacks, though if systems go unused or unpatched, it can weaken security posture.	**Low:** Pharmacy refusals won't directly lead to more or fewer attacks, though lack of e-prescription usage might keep some data offline.	**High:** A widely publicized death can prompt closer scrutiny, diverting resources from cybersecurity improvements or fueling distrust, ironically making systems more prone to breaches.

(2) Connectivity failure Thousands lose access to digital health tools.	**Moderate:** A large leak erodes trust, spurring stricter policies. If not well-implemented, new rules could make connectivity more fragile.	— (self)	**Moderate:** If doctors cannot rely on stable connectivity, they may revert to paper, eroding momentum for digital adoption.	**Low:** A pharmacy refusing electronic prescriptions is mostly a local policy/administrative barrier, though repeated refusals can further fragment the digital network.	**High:** If a bed-allocation or triage system is offline, emergency care is delayed. This heightens risk of fatal outcomes and can intensify calls for redundant connectivity.
(3) Doctor can't fill out the digital chart Poor user training.	**Low:** Cyberattacks don't directly cause skill gaps, but major breaches could trigger new software rollouts, leaving staff untrained.	**Moderate:** Ongoing connectivity lapses hamper training and real-time support, thus reinforcing the doctor's inability to use the system.	— (self)	**Low:** Pharmacy practices are independent of a single doctor's proficiency, but widespread confusion about e-prescriptions can deepen system distrust.	**Moderate:** A doctor failing to record data properly can disrupt patient flow or hamper urgent referrals, potentially raising mortality risks in critical cases.

(4) Pharmacy refuses medication because the prescription is electronic	**Low:** A data leak doesn't strongly affect pharmacies' willingness to accept e-prescriptions, although public fear of digital systems might embolden refusals.	**Low:** Connectivity failures do not directly cause these refusals—but repeated outages could foster more skepticism about digital reliability.	**Moderate:** If many doctors remain untrained or revert to paper scripts, pharmacies see fewer e-prescriptions overall, reinforcing a negative cycle.	— (self)	**Low to Moderate:** A patient's care could worsen if timely medications are refused, but lethal outcomes typically require multiple failures, including broader system breakdowns.
(5) A patient goes to fatal outcome Bed-distribution data never reached the ER	**High:** A major cyberattack that shuts down or corrupts hospital networks can easily delay bed assignments or triage data, elevating mortality risk.	**High:** If the system is offline or unreachable, critical data about beds and real-time triage cannot flow, leading to errors in urgent care.	**Moderate:** A doctor's inability to input timely patient data is a key breakdown; though by itself it's not always fatal, it heightens systemic risk.	**Low to Moderate:** Isolated prescription refusals rarely escalate to fatalities. However, if lack of e-scripts is widespread, it can undermine overall trust in digital processes.	— (self)

Source: Self-elaboration based on stakeholder input.

Observations and Key Interdependencies

1. **Cybersecurity Intertwined with Connectivity**

    - If connectivity is unstable, systems cannot receive security patches consistently, thus **raising the probability of successful cyberattacks** (Event 1). Simultaneously, a publicized death (Event 5) or major scandal can divert attention and budget away from structural cybersecurity reforms, aggravating the longer‑term breach risk.

2. **Connectivity Failures Amplify Nearly Every Other Risk**

    - Without reliable networks, **doctors rely on manual records** (Event 3), further eroding digital health adoption. Vital data (bed availability, triage status, etc.) does not flow to the ER (Event 5), increasing serious patient harms.
    - **Interoperability**, cited repeatedly in your Delphi discussions, underpins almost all of these events: if the system cannot sync or share data, the entire chain of care frays.

3. **Human Factors and Training**

    - While overshadowed in immediate severity by catastrophic events (cyberattacks, system failures), **human training** deficits can **multiply** the impact of technology problems. A workforce that cannot navigate new or emergency workflows aggravates otherwise contained disruptions.

4. **Pharmacy Refusals—Primarily a Local Governance and Adoption Barrier**

    - This refusal problem (Event 4) exerts only mild to moderate cross‑impacts on others, but it does reflect broader resistance to digital prescriptions. Over time, repeated local refusals could slow overall digital acceptance, leaving the system more vulnerable to cracks in trust that hamper investment or policy backing.

5. **Fatalities from Systemic Breakdown**

    - Deaths tied to digital system errors (Event 5) highlight the ultimate “tipping point” scenario, where **trust in digital health** collapses if these tragedies are

attributed to technology. Such events drastically increase political pressure for radical reforms, new regulations, or abrupt rollbacks of digital solutions—potentially leading to even more fragmented systems.

Policy and Governance Takeaways

1. **Double Down on Interoperability and Cybersecurity**
    - These two domains dominate both first-order (direct) and second-order (cascading) risks. Rapid, secure data exchange must be a strategic pillar—coupled with robust cybersecurity to keep that exchange from eroding public trust.
2. **Strengthen Capacity Building for Health Professionals**
    - Untrained medical staff (Event 3) might sound less dramatic than a data breach, but it **exacerbates** every other hazard by creating operational fragility. Broad digital literacy campaigns—and ongoing re-training after system upgrades—should be a core policy.
3. **Connectivity as a Fundamental Public Good**
    - The wide-ranging influence of connectivity failures underscores the need for better telecommunications infrastructure (including rural and underserved areas) and redundancy. Policymakers should treat network reliability as crucial to patient safety.
4. **Harmonize the Regulatory Environment**
    - Pharmacy refusals (Event 4) and inconsistent compliance at different healthcare levels reflect **weak or fragmented oversight**. Clear guidelines, e-prescription mandates, and consistent enforcement across states and municipalities would help standardize digital acceptance.
5. **Cascading Failures**

- The final column (Event 5) shows how one small glitch or delay in data—be it from a breach, a connectivity gap, or staff confusion—can become deadly. Multilayered risk strategies (like local offline backups, contingency protocols) should be integrated into national digital health guidelines to prevent single points of failure.

Taken together, these cross‑impacts suggest that **no single "fix"** will resolve Brazil's digital health vulnerabilities; each risk bleeds into the next. Strengthening interoperability—while boosting digital literacy, ensuring network reliability, and embedding cybersecurity—must happen in tandem. And although some events are more dramatic than others, it is often the **compounding interplay** of smaller, "everyday" failures (training gaps, minor outages, local policy friction) that sets the stage for larger crises.

Cross-impact of general governance risks

Below is a **Cross‑Impact Matrix** showing how the five key risks in Brazilian digital health—**(1) Cybersecurity, (2) Interoperability, (3) Lack of Professional Training, (4) Data Security & Investment**, and **(5) Infrastructure Disparity**—can influence and exacerbate one another. Those are the underlying themes of the previous matrix. Following the matrix, we will find an explanation that draws on (i) stakeholder presentations and speeches, as well as the Delphi Technique, (ii) observations from the First Intersectoral Forum on Digital Health, and (iii) technical visits to SEDIGI. These data sources consistently indicate that **"Infrastructure Disparity"** is a root cause for many governance issues, from uneven connectivity to weak interoperability and inefficient regulation.

Table 8.2.: Cross‑Impact Matrix of general governance risks

Affected Risk	**(1) Cybersecurity**	**(2) Interoperability**	**(3) Lack of Professional Training**	**(4) Data Security & Investment**	**(5) Infrastructure Disparity**

(1) Cybersecurity Threats to system integrity, data breaches, etc.	— (self)	**High:** Gaps in interoperability often mean unpatched, non-standard systems prone to exploits.	**Moderate:** If staff is undertrained, they may inadvertently bypass security protocols or fail to report vulnerabilities.	**High:** Under-financed or poorly managed cybersecurity leads to outdated infrastructure, weaker cryptography, and fewer resources for security upgrades.	**High:** Poor infrastructure—especially in remote or underfunded areas—means fewer network safeguards, minimal IT oversight, and greater exposure to cyber risks. Governance shortfalls amplify these issues.
(2) Interoperability The ability of systems to "talk" seamlessly	**Moderate:** A major cyber incident can force systems offline, discourage data exchange, or spur abrupt regulatory overhauls that hamper standards.	— (self)	**High:** Staff who can't properly use e-systems hamper the entire data flow, reinforcing fragmentation in health records and interfaces.	**Moderate:** If data protection is weak or not well-funded, organizations become wary of sharing data across platforms, eroding true interoperability.	**High:** Regional disparities—lack of broadband, patchy networks—directly undermine the consistent connectivity needed to exchange health data. Inefficient governance often overlooks these gaps.

(3) Lack of Professional Training Workforce not fluent in digital	**Moderate:** Even strong security frameworks fail if staff ignore best practices (password hygiene, phishing alerts, etc.).	**High:** Undertrained personnel cannot implement or adhere to interoperability standards, causing inconsistent data entry and system usage.	— (self)	**Moderate:** Staff who do not grasp data-handling policies and tools raise the likelihood of data leaks or misconfigurations, deterring future investment.	**Moderate:** Training programs often fail in remote or underserved regions lacking stable networks; the more pronounced the infrastructure gap, the harder it is to upskill staff.
(4) Data Security & Investment Funding and governance of data protection	**High:** Insufficient budget or poor governance for cybersecurity leaves systems patchy, inviting breaches and data thefts.	**Moderate:** Limited investment in secure, interoperable solutions leads to "islands" of digital services, fueling fragmentation.	**Moderate:** If employees don't fully understand or value data protection, resources get misallocated, and or lose political momentum.	— (self)	**High:** Infrastructure gaps force triage in resource allocation—basic connectivity overshadowing specialized security investments—undermining data protection in the hardest-hit areas.

(5) Infrastructure Disparity Uneven connectivity & technology across Brazil	**High:** Sparse or outdated infrastructure makes maintaining robust firewalls, intrusion detection, and patch cycles difficult, thereby raising risk.	**High:** With severe connectivity gaps and legacy systems, it becomes nearly impossible to achieve uniform data standards or real-time info exchange.	**Moderate:** Underserved areas lacking reliable broadband hamper e-learning and skill-building, perpetuating the training gap.	**High:** If core infrastructure is missing, the first priority becomes basic connectivity, pushing data protection budgets and advanced cybersecurity to the back burner.	— (self)

Source: Self-elaboration.

Observations and Underlying Themes

1. **Infrastructure Disparity as a Root Cause**

    - Stakeholders (in both forum discussions and SEDIGI visits) repeatedly mentioned how **uneven connectivity**, outdated hardware, and spotty networks across Brazil **undercut nearly all digital health goals**.
    - Where local infrastructure is poor, hospitals cannot patch or update software properly (higher cybersecurity risk), cannot exchange data reliably (undermining interoperability), cannot deliver consistent training (weakening workforce capacities), and tend to forgo advanced data protection since basic connectivity becomes the urgent priority.

2. **Inefficient Regulation and Governance Shortfalls**

- Poor infrastructure is made worse by **fragmented regulations and inefficient governance**. Different states, municipalities, and private actors often use incompatible systems and data formats. This fragmentation fosters "islands" of partial adoption, further complicating national interoperability.
- A lack of coherent funding strategies can also perpetuate poor data security practices. If agencies do not coordinate, budgets for cybersecurity or staff training remain minimal or scattered.

3. **Interoperability & Cybersecurity Form a Critical Feedback Loop**

    - If systems cannot talk to each other, they often resort to ad‑hoc solutions (i.e., physical transfers of patient data or insecure "patchwork" networks). That inevitably opens security holes (weak encryption, reliance on email attachments, etc.).
    - Conversely, serious cybersecurity incidents can lead organizations to shut down or isolate systems, which sabotages real‑time data sharing and trust in digital governance.

4. **Human Factors: Training as a Cross‑Cutting Issue**

    - **Undertrained staff** worsens nearly every other risk. For example, an overburdened nurse might store passwords improperly, or a rural clinic might not know how to sync patient records if the local network is patchy. Participants at the Forum expressed strong consensus that capacity‑building must be a **continual** process, not a one‑time rollout.

5. **Underinvestment in Data Protection**

    - Some organizations only invest in data security after a breach or in reaction to new rules, rather than proactively. Combined with limited infrastructure, data‑privacy concerns often take a back seat to simpler connectivity goals.
    - Civil society groups worry that when data protection is sidelined, patient trust declines, fueling reluctance to adopt digital health services.

Main Takeaways

- **Infrastructure Disparity** underpins numerous problems. Its **cascading effects** appear in every other risk cell: poor physical connectivity, limited broadband, and inadequate hardware hamper large‑scale interoperability, degrade cybersecurity readiness, and complicate staff training.
- **Inefficient regulations**—itself symptomatic of larger governance lapses—compound these issues by failing to enforce uniform standards and by not aligning budgets to real needs in the most underserved regions.
- **Interoperability** emerges again as a **linchpin risk**: it both depends on stable networks (infrastructure) and is undermined by limited staff expertise and patchy regulations.
- **Cybersecurity** should not be seen merely as a technical add‑on. If underfunded, each system tries to "protect itself" in isolation, reinforcing fragmentation and exposing the entire network.
- **Lack of Professional Training** is both a cause and a consequence of poor digital adoption. Staff in underconnected areas struggle the most—and yet these regions typically have the greatest resource gaps.

By integrating these insights—especially the realization that **infrastructure disparity** stands at the core—Brazilian digital health policies can prioritize more equitable development of connectivity, streamlined governance, and capacity‑building. In turn, such foundational improvements make the other pillars (security, interoperability, data stewardship) far more attainable at scale.

9. Risk contributions to governance

This chapter synthesizes how core risks—interoperability gaps, cybersecurity threats, infrastructure disparities, regulatory fragmentation, and insufficient cooperation—shape Brazil's digital health governance. Rather than treating risk as an external obstacle, we explore how it compels institutions to adapt, innovate, or, in some cases, stall. Each vulnerability simultaneously exposes governance shortcomings and pushes for more coherent frameworks: interoperability failures spur unified standards; cybersecurity breaches prompt robust cross‑agency coordination; infrastructure gaps reveal the need for multi‑level investment.

By examining these pressures, we see that risk can be a catalyst for reform if recognized and managed holistically. The chapter closes by situating these findings within global governance and international relations, illustrating how similar tensions—between rapid digital expansion, uneven resources, and stakeholder misalignment—resonate across borders.

9.1. Risk analysis in Digital Health Governance

Below is a concise analysis of how the five main digital health risks—**(1) Interoperability Gaps**, **(2) Cybersecurity Threats**, **(3) Infrastructure Disparities**, **(4) Regulatory Gaps**, e **(5) Insufficient Stakeholder Cooperation**—contribute to or undermine governance in the Brazilian digital health context.

1. Interoperability Gaps

- **Impact on Governance:**
    - Fragmented data flows impede coordinated decision‑making at different levels (federal, state, municipal).
    - Public and private actors may adopt competing standards and protocols, weakening centralized oversight.

    - Overlaps in software and data silos hamper transparency, making it hard for governing bodies to track real‑time health information.
- **Governance Contribution (if well‑addressed):**

    - Encourages the creation of unified technical and policy frameworks, such as national standards for patient data exchange.
    - Drives collaborative platforms across ministries and agencies, improving accountability and strategic resource allocation.

2. Cybersecurity Threats

- **Impact on Governance:**

    - Frequent cyber incidents erode public trust in digital health solutions, pressuring officials to respond through reactive or fragmented measures.
    - Vulnerable systems create complex liability questions among government bodies, private vendors, and healthcare institutions.
- **Governance Contribution (if well‑addressed):**

    - Spurs more rigorous, **security‑by‑design** approaches in regulatory frameworks.
    - Encourages interagency coordination (health, justice, technology) and fosters cross‑border cybersecurity collaboration, aligning with global governance standards.

3. Infrastructure Disparities

- **Impact on Governance:**

    - Regions with poor connectivity remain out of step with national digital health agendas, widening inequalities.
    - Policy directives from the federal level can’t be uniformly enforced or monitored where infrastructure is lacking.
- **Governance Contribution (if well‑addressed):**

- Makes a strong case for integrated, multi‑level governance: bridging local needs with national resources.
- Strengthens the argument for “digital health as a public good,” prompting investments that unify all regions under equitable service delivery.

4. Regulatory Gaps

- **Impact on Governance:**
  - Conflicting or outdated regulations produce a patchwork of standards, slowing health system modernization.
  - Weak oversight fosters misalignment: local entities might over‑ or under‑regulate, creating legal uncertainty for private providers.
- **Governance Contribution (if well‑addressed):**
  - Incentivizes more coherent, centralized policy‑making, balancing autonomy at subnational levels with consistent national norms.
  - Can catalyze the development of multi‑sector councils or task forces that harmonize regulations and encourage widespread compliance.

5. Insufficient Stakeholder Cooperation

- **Impact on Governance:**
  - Lack of collaboration undermines integrated health data systems, fueling duplication of efforts and wasted resources.
  - Inter‑ministerial disputes and mistrust between public/private actors may paralyze policy execution.
- **Governance Contribution (if well‑addressed):**
  - Encourages the rise of multi‑stakeholder governance forums, bridging the gap between sectoral interests.
  - Reinforces transparent decision‑making processes and fosters sustained dialogue for consensus on regulatory and technical frameworks.

Putting It All Together: Governance as a Systemic Response

When these five risks are addressed in tandem, **digital health governance** transforms from a reactive, siloed process into a **cohesive, forward‑looking system** that:

1. **Promotes Equity:** Ensuring consistent infrastructure development and standards helps reduce healthcare disparities.
2. **Builds Trust:** Robust security and interoperability frameworks strengthen public confidence in e‑health solutions.
3. **Enhances Accountability:** Clear and harmonized regulations allow government bodies to track compliance, outcomes, and resource use effectively.
4. **Encourages Innovation:** Stable governance structures enable the private sector to invest more confidently in new digital tools and services.

Ultimately, **effective risk management** in these domains boosts the legitimacy and effectiveness of digital health governance—enabling Brazilian institutions to respond nimbly to public health needs, scale innovations responsibly, and cooperate more seamlessly with international partners.

Below is an overview of how this study's findings and methodologies extend beyond the specific case of digital health in Brazil, offering **broader contributions** to the fields of governance, global governance, and International Relations (IR).

9.2. Contributions to Governance Theory and Practice

1. **Multi‑Level and Multi‑Actor Integration**

    - By demonstrating how interoperability, cybersecurity, and infrastructure shortfalls cut across multiple layers (federal, state, municipal) and involve various sectors (public, private, civil society), the study provides a **model of "networked governance."** This approach breaks from hierarchical or single‑agency solutions, illustrating how modern governance challenges demand **multi‑actor coordination** and iterative policy design.
2. **Risk‑Centered Policy Framework**

- Employing Delphi consultations, cross‑impact analysis, and field research reveals a **systemic** method of mapping and prioritizing risks within governance structures.
- This risk‑centered framework can be adapted for broader policy domains—such as environmental regulation, financial governance, and public security—showcasing how risk analysis helps pinpoint "linchpin" issues (e.g., interoperability for digital health) that disrupt entire governance systems.

3. **Adaptive and Learning‑Oriented Governance**

   - The study underscores the role of stakeholder feedback loops and iterative data collection (e.g., Delphi rounds) in **adaptive governance**. Through continuous stakeholder engagement and real‑time expert input, policies can be reconfigured to address emerging challenges, bridging the gap between top‑down directives and frontline realities.

9.2.1. Contributions to Global Governance

1. **Bridging Local Implementations with Global Standards**

   - By aligning WHO's Global Digital Health Strategy (EGSD) with Brazil's national health policy (ESD28), the study showcases **how local realities intersect with universal frameworks**. This offers a case study on how "global norms" can become more than aspirational guidelines—when carefully translated and adapted into local governance systems.

2. **Demonstrating the Criticality of Transnational Interoperability**

   - Digital health inherently crosses borders—particularly when disease surveillance, telemedicine, or data sharing are international in scope. Highlighting the **interoperability risk** thus underscores a universal challenge for global governance: **without robust data exchange, coordinated responses to transboundary problems (e.g., pandemics) falter.**
   - This insight extends beyond healthcare, speaking to any domain (climate, trade, migration) that relies on multi‑country data harmonization and resource sharing.

3. **Reinforcing the Role of "Experimentalist Governance"**

    - The study's recommendation that health governance bodies remain flexible, incorporate stakeholder‑led risk assessments, and build pilot programs (for training, cybersecurity, or infrastructure) exemplifies **experimentalist governance**: an evolving cycle of planning, testing, feedback, and recalibration. This framework can help global institutions (e.g., WHO) to coordinate more effectively with local actors, forging pragmatic solutions that can then be "scaled up" internationally.

9.2.2. Contributions to International Relations (IR)

1. **Elevating Risk Analysis as a Tool in IR**

    - By **applying risk methodologies** (Delphi, cross‑impact analysis) within an IR context, the study demonstrates how structured risk frameworks can enhance traditional IR approaches (e.g., institutionalism, constructivism). This deepens the discipline's capacity to handle complex, cross‑border challenges, rather than focusing solely on security or power dynamics.
2. **Illustrating the Hybrid Nature of Contemporary Issues**

    - Digital health governance merges **technical** concerns (data protocols, cybersecurity) with **political** concerns (regulatory autonomy, institutional legitimacy). This underscores how modern IR issues require **multi‑disciplinary lenses**—linking sociotechnical analysis with state and non‑state actor behavior—broadening IR's scope beyond military or trade concerns alone.
3. **Emphasizing Constructivist Insights into Global Cooperation**

    - The study's findings highlight how **risk perceptions, stakeholder narratives, and institutional beliefs** shape policy outcomes as much as tangible resources do. In line with constructivist IR theory, it demonstrates that **shared norms, identities, and discourses** (in this case, about data interoperability or digital privacy) can drive multilateral coordination or stall it.

- This reveals how **ideas** and **perceptions** of risk—such as fear of cyberattacks—can significantly alter international cooperation patterns, affecting treaties, frameworks, or knowledge exchange among states.

9.3. Summary of Broader Implications

- **Governance**: Encourages a shift from siloed, top‑down policymaking toward flexible, risk‑informed governance arrangements that integrate a wide circle of stakeholders.
- **Global Governance**: Shows that aligning local implementation with international norms benefits from iterative, experimental approaches that respect on‑the‑ground realities—a replicable template for broader global challenges (climate action, health crises, digital transformation).
- **International Relations**: Advances the utility of systematic risk analysis and stakeholder engagement in IR theory and practice, demonstrating that issues of cooperation, regulation, and institutional design in the digital era often hinge on intangible factors like trust, norms, and shared risk perceptions.

By weaving these insights together, the study ultimately **enriches** the academic and policy debates on governance—locally and globally—and indicates how international relations can better incorporate **risk analysis** as a core methodology for addressing the increasingly interconnected challenges of our time.

10. Final considerations on risk in digital health

This study aimed to bridge the gap between global governance and digital health, using Brazil as an instrumental case study to develop a risk-based approach to governance. By integrating theoretical frameworks such as constructivism, stakeholder theory, and risk analysis, it proposed a novel methodological framework for analysing digital health governance.

The research was structured around the hypothesis that risk assessment methods, particularly the Delphi and Cross-Impact Methods, could enhance decision-making in governance structures by incorporating stakeholder perceptions and interdependencies between different governance risks.

To answer this, and test this hypothesis, the study employed a methodological combination, applying stakeholder mapping, process modelling, expert consultations, to finally arrive at a structured risk analysis technique. Through this approach, the study identified key risks and governance gaps in digital health policy and proposed a structured methodology to integrate risk assessment into governance decision-making.

Key Findings

While methodologically grounded in structured tools such as the Delphi Technique and Cross-Impact Analysis, this study deliberately moves away from positivist traditions. Rather than simply measuring outcomes or prescribing linear policy interventions, it focuses on digital health as a public policy domain shaped by global governance principles, but enacted through interactions, identities, and belief systems. Governance, in this framing, is not a top-down mandate nor a purely bottom-up movement, but a relational space—a negotiated field where shared values, institutional cultures, and stakeholder dynamics converge. These shared values, once identified, can operate as navigational instruments—a roadmap to guide implementation and strengthen the communicative interface between national systems and international frameworks.

The Delphi results revealed a striking consensus: interoperability is the most critical and persistent risk in Brazil's digital health governance. This risk, paradoxically, is precisely where global governance mechanisms could—and should—intervene more decisively.

Despite critiques that the WHO's governance strategy has had limited impact on national policymaking, interoperability remains a field inherently dependent on global alignment. The absence of concrete, enforceable international standards leaves national stakeholders to improvise, generating fragmented systems and deepening regional disparities. In this sense, the lack of global interoperability frameworks is not just a governance failure—it is a governance risk in itself.

Though the WHO does address standards in its partnerships with Brazil, as evidenced in the fieldwork, these efforts lack systemic integration into national practice. Stakeholders indicated that in the absence of consistent international benchmarks, local agencies tend to build isolated solutions, exacerbating the problem of digital health fragmentation. The TO-BE model developed in Chapter 4 highlights how such gaps could be bridged through proactive global engagement. International organizations, by providing unified digital health standards, could enable alignment and reduce the institutional entropy currently burdening national systems.

However, the responsibility for effective governance does not lie solely at the global level. The cross-impact analysis revealed how infrastructure disparities within Brazil function as systemic multipliers of risk. Interoperability is not merely a technical challenge—it is undermined by regional inequalities in digital infrastructure, workforce capacity, and public investment. These internal asymmetries form a cascading architecture of governance breakdowns. Yet, this does not imply that global governance is irrelevant or should be abandoned. On the contrary, the study finds that paradiplomatic interactions—between subnational governments and international institutions—offer promising pathways for fostering resilience where national alignment falters. This is especially evident in the stakeholder mapping, which uncovers networks of municipal and state actors leveraging international cooperation to advance digital health goals.

The findings thus underscore a broader methodological argument: governance must be treated as a dynamic process shaped by risk, belief systems, and the spatial distribution of institutional capacity. Risk is not merely a measurement of vulnerability; it is a driver of political negotiation and institutional learning. The study suggests that many stakeholders—despite not employing formal risk analysis tools—already use risk heuristically to navigate uncertainty, coordinate with partners, and formulate implementation

strategies. The structured methods deployed here only make those informal processes more visible, actionable, and scalable.

This research does not pretend to exhaust the analytical potential of these methods, nor does it aim to fully resolve the complex risks facing digital health governance. Rather, it offers a conceptual and methodological roadmap—an invitation for future studies to explore more specific facets of this terrain. Whether in public policymaking or private-sector strategy, the Delphi and Cross-Impact results demonstrate that different actors within the system share common challenges, and that these can be collectively addressed when revealed through structured risk analysis.

In short, governance by risk—when understood as a method of institutional mapping, belief negotiation, and systemic modeling—offers a powerful contribution to the field of global governance. It creates space for coordination without coercion, allowing diverse actors to identify shared concerns and act on them collectively. It is this potential for alignment, even amidst institutional fragmentation, that this study highlights as its core contribution.

1. **Fragmentation Between Global Governance and Digital Health Studies:**
   The bibliometric review confirmed a lack of dialogue between the fields of digital health and global governance. Few studies integrate risk analysis as a methodological tool in international relations, reinforcing the need for interdisciplinary research.

2. **Interoperability as the Central Governance Risk:**
   Stakeholders across the public and private sectors consistently identified interoperability as the most pressing risk in digital health governance. This was an unexpected finding, as initial hypotheses suggested that private and public actors would have divergent risk perceptions. Instead, both groups viewed interoperability failures as the greatest barrier to digital health implementation.

3. **Absence of Financial Concerns as a Major Governance Issue:**
   Contrary to initial expectations, financial constraints were not highlighted as a primary governance risk. This challenges the common assumption that resource allocation is the dominant barrier in digital health governance. Instead, structural issues related to interoperability, regulatory alignment, and data security were seen as

more critical.

4. **Stakeholder-Driven Governance and Risk Perception:**
   The application of the Delphi method demonstrated that governance risks are socially constructed and shaped by the interactions between institutions and stakeholders. This aligns with constructivist institutionalism, which posits that governance structures evolve through negotiated processes rather than being predetermined by material constraints.

5. **Advantages of Field Research in International Relations:**
   Field research, including expert consultations, technical visits to the Ministry of Health SEIDIGI, and stakeholder mapping, provided crucial insights into the institutional structures and governance dynamics of digital health in Brazil. This demonstrated the importance of empirical data in international relations research, which is often overly theoretical.

Impact of the Instrumental Case Study

By focusing on Brazil's digital health governance framework, the study provided a concrete application of risk analysis in governance. Brazil's Unified Health System (SUS) served as a valuable case due to its scale and complexity, making it an ideal testing ground for applying global governance frameworks.

This case study illustrated that governance models need to incorporate:

- **Stakeholder networks** to foster cooperation,
- **Risk assessment methodologies** to guide policy decisions,
- **Adaptive governance mechanisms** to accommodate emerging risks such as cybersecurity threats and regulatory fragmentation.

Methodological Contributions

The study successfully applied and integrated multiple methodologies:

1. **Bibliometric Review:** Identified gaps in the literature and confirmed the need for interdisciplinary integration.
2. **Stakeholder Mapping (ACF):** Provided a structured approach to identifying relevant actors in digital health governance.
3. **Delphi Technique:** Enabled structured, iterative consultation with experts, ensuring a stakeholder-driven assessment of risks.
4. **Cross-Impact Analysis:** Complemented the Delphi method by examining the interdependencies between governance risks.
5. **Field Research and Institutional Visits:** Provided empirical validation of theoretical frameworks, reinforcing the importance of fieldwork in international governance research.

Final Considerations

This study contributes to the discourse on global governance by demonstrating how risk-centred approaches can enhance institutional responsiveness and stakeholder coordination in complex policy environments. By addressing the interdisciplinary divide between global governance and digital health, it proposes a conceptual and empirical framework that redefines how digital health is governed in an increasingly interconnected world.

The results suggest that future governance models should:

- Incorporate **structured risk assessment** methodologies to enhance decision-making.
- Strengthen **interoperability frameworks** to mitigate governance risks.
- Prioritize **stakeholder engagement** to ensure participatory governance.

By integrating risk analysis into governance frameworks, this study provides a foundation for future research in international relations, global health governance, and digital transformation policies. The methodologies developed here can be adapted to other areas of global governance, making this study a stepping stone for broader applications in policy analysis and governance innovation.

Annexes

Videos

All relevant mentioned videos, including raw data, are available on YouTube:

Voting Sessions of PL 1998/2020:

CÂMARA DOS DEPUTADOS. *Seguridade Social e Família - Integração de dados na Saúde - 07/07/2022*. Disponível em: <https://www.youtube.com/watch?v=3w4FnpBZH-0>. Acesso em: 5 fev 2025.

CÂMARA DOS DEPUTADOS. *Seguridade Social e Família - PL 1998/20 - Telemedicina após a Pandemia da Covid-19 - 08/07/2021*. Disponível em: <https://www.youtube.com/watch?v=8oW6eRvpml4>. Acesso em: 5 fev 2025.

CÂMARA DOS DEPUTADOS. *Seguridade Social e Família - Prontuário eletrônico e a transformação digital na saúde - 13/12/22*. Disponível em: <https://www.youtube.com/watch?v=CzPOZoNZL70>. Acesso em: 5 fev 2025.

CÂMARA DOS DEPUTADOS. *Seguridade Social e Família - Prontuário Eletrônico Único e o PL 3.814/2020 – 25/10/2021*. Disponível em: <https://www.youtube.com/watch?v=mTkDk1hK__g>. Acesso em: 5 fev 2025.

1st Intersectorial Forum on Digital Health:

MINISTÉRIO DO PLANEJAMENTO E ORÇAMENTO. *1º Fórum Intersetorial de Saúde Digital - Parte 1*. Disponível em: <https://www.youtube.com/watch?v=i-oT_fz_gxw>. Acesso em: 5 fev 2025.

MINISTÉRIO DO PLANEJAMENTO E ORÇAMENTO. *1º Fórum Intersetorial de Saúde Digital - Parte 2*. Disponível em: <https://www.youtube.com/watch?v=QcGccF45l3U>. Acesso em: 5 fev 2025.

MINISTÉRIO DO PLANEJAMENTO E ORÇAMENTO. *1º Fórum Intersetorial de Saúde Digital - Parte 3*. Disponível em: <https://www.youtube.com/watch?v=dRu2srDaYhQ>. Acesso em: 5 fev 2025.

MINISTÉRIO DO PLANEJAMENTO E ORÇAMENTO. *1o Fórum Intersetorial de Saúde Digital - Parte 4*. Disponível em: <https://www.youtube.com/watch?v=_u7XpGKenTk>. Acesso em: 5 fev 2025.

MINISTÉRIO DO PLANEJAMENTO E ORÇAMENTO. *1o Fórum Intersetorial de Saúde Digital - Parte 5*. Disponível em: <https://www.youtube.com/watch?v=pb9AFrp8gJs>. Acesso em: 5 fev 2025.

2nd Intersectorial Forum on Digital Health:
INEZ LOPES. *2o Fórum Intersetorial Em Saúde Digital - Semana Universitária UnB 2024 (6/11)*. Disponível em: <https://www.youtube.com/watch?v=c3NRNliN7TM>. Acesso em: 5 fev 2025.

INEZ LOPES. *2o Fórum Intersetorial Em Saúde Digital - Semana Universitária UnB 2024 (07/11)*. Disponível em: <https://www.youtube.com/watch?v=ElGMKjbwwus>. Acesso em: 5 fev 2025.