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Interoperability in healthcare: the state of affairs in Latin America

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Introduction

Interoperability in healthcare: why it matters

Recent crises experienced in the health sector worldwide have made evident the weaknesses of public and private healthcare systems. In order to change this situation and improve healthcare overall, it is crucial to address the need for investment in technologies which enable precise and complete data consistency, as well as a broad knowledge of the health sector's real needs. This would allow for improved strategies for continuity of care, better population health management, operational efficiency and evidence-based practices. Interoperability is a possible answer to all these issues.

According to the World Health Organization (WHO), the use of health technologies is fundamental to achieving universal healthcare coverage. For the WHO's Director-General Tedros Adhanom Ghebreyesus, digital technologies are vital tools for promoting good health.[1] For this reason, the WHO has been adopting strategies for the development of digital health around the world since 2005.[2]

Despite the rapid advancement of technology and the digitalisation of health data, patients surprisingly do not own their health information. Instead, it is held by various entities, such as providers, payers, healthcare professionals and hospitals. Health data has become digitalised within distinct clusters, both private and public. This has led to the significant challenge of achieving health data interoperability among these diverse players. Overcoming this challenge is crucial in achieving improved health management for several reasons outlined below.

Data consistency

The adoption of interoperability standards is critical for the consistent representation of data and information in health. This consistency allows for various digital health solutions to communicate seamlessly and exchange information.[3]

Continuity of care

Data-driven care is the safest and most efficient way forward. Integrated access to health data enables and supports continuity of care in a coordinated fashion at all levels of the health system, regardless of the software used. It helps clinicians deliver safe, effective patient-centred care.[4]

1 RETS, 'WHO releases first guideline on digital health interventions', 26 July 2019 www.rets.epsjv.fiocruz.br/noticias/oms-divulga-primeira-diretriz-sobre-intervencoes-de-saude-digital accessed 31 May 2024.

2 WHO, 'WHO launches new global digital health initiative supported by G20 Presidency', 19 August 2023 www.who.int/es/news/item/19-08-2023-who-launches-a-new-global-initiative-on-digital-health-at-the-g20-summit-in-india accessed 31 May 2024.

3 WHO, 'WHO and HL7 collaborate to support adoption of open interoperability standards', 3 July 2023 See www.who.int/news/item/03-07-2023-who-and-hl7-collaborate-to-support-adoption-of-open-interoperability-standards accessed 31 May 2024.

4 *Ibid.*

Population health management

Applications that capture, manage or analyse population health information are likely to require interoperability as they leverage data and information from a wide array of systems used in clinical environments, as well as those in governmental and non-governmental public health organisations.[5] Full access to health information allows strategic decisions to be made based on an accurate understanding of the needs of the population and the inefficiencies of the health system.

Operational efficiency

Interoperability can improve service provision and patient care, while improving operational efficiencies and reducing overall costs, enabling sustainable and resilient health systems. Sustainability can only be achieved if the leaders of the entity have a data-driven orientated view of the process of implementing interoperability in healthcare. Data lakes in health institutions can and should be used to refine and structure patient data. This will allow for a number of developments, including the generation of analysis and insights into how such patients are being treated, their medical appointments, which medical specialties are most sought after.[6]

Evidence-based practices

The analysis of large data sets is a useful method to identify trends in areas that support treatment. Practitioners can use this data to define and implement evidence-based practices for the broader healthcare field.[7]

Health information democratisation

Health data interoperability not only facilitates the exchange of information among healthcare professionals and providers, it also empowers individuals with deeper insights into their own health information. This, in turn, enables them to take proactive measures for their health management.

Report coverage and methodology

This Report is structured in the format of questions and answers and covers the current state of affairs on the subject in the following nine Latin American countries: Argentina, Bolivia, Brazil, Chile, Colombia, Mexico, Paraguay, Peru and Uruguay.

The questions posed to the contributing firms and authors aim to understand:

1. *Regulations on interoperability* – regulations related to health data, particularly those governing interoperability, which includes assessing how different countries handle health data exchange within legal frameworks.

5 Brian E Dixon, 'Public Health: Interoperability Applications to Support Population Health' in Ursula H Hübner, Gabriela Mustata Wilson, Toria Shaw Morawski, Marion J Ball (eds), *Nursing Informatics* (Springer 2022) https://doi.org/10.1007/978-3-030-91237-6_23 accessed 31 May 2024.

6 Portal Hospitals Brazil, 'Data Lake is already a possible reality in healthcare in Brazil', 5 April 2023 https://portalhospitaisbrasil.com.br/artigo-data-lake-ja-e-uma-realidade-possivel-em-saude-no-brasil accessed 31 May 2024.

7 Joy Doll, Julie Malloy and Jaime Bland, 'The Promise of Interoperability' (July/August 2021) 75(4) *Am J Occup Ther* 7504090010 https://doi.org/10.5014/ajot.2021.049002 accessed 31 May 2024.

2. *Health data identification systems* – whether countries have a single health data identification system or rely on decentralised approaches; a centralised system streamlines data management and exchange.
3. *Incentives for data exchange* – incentives for health data exchange among stakeholders for improved healthcare outcomes.
4. *Data protection laws* – how data protection laws and privacy regulations deal with health data interoperability.
5. *Challenges for implementation* – technical interoperability, security, data quality and governance pose challenges. Proprietary formats hinder data exchange, whereas open standards promote interoperability.
6. *Data compilation* – how relevant data on digital health implementation and expenditure can be found through national health agencies, research institutions and reports.

The Report coordinator

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Questions and answers

Argentina

Ana Andrés *Beccar Varela, Argentina*

1. What regulations govern the interoperability of health data in your country? If there are none, please inform us of any bills on the subject and how the issue of 'digital health' is being addressed in the country.

In 2018, through Resolution 189/2018, the Secretary of Health of the Nation in Argentina approved the National Digital Health Strategy 2018–2024 (the 'Strategy'), initiating a regulatory path in Argentina for the interoperability of health data.

The Strategy established specific goals for the adoption and improvement of digital health systems and was divided into specific phases until 2024.

A year later, Resolution 115/2019 of the Ministry of Health, issued under the Strategy, established the National Health Interoperability Network, a central platform to unify and standardise health information throughout Argentina. Additionally, it created a Registry of Interoperability Domains to identify and ensure compliance with standards by network participants.

Finally, on 28 February 2023, Law 27,706 was approved, creating the Unique Federal Programme for Computerisation and Digitalisation of Medical Records (the 'Programme'). The purpose of this Programme is to establish a Single System for the Registration of Electronic Medical Records (the 'System').

The System aims to guarantee patients and healthcare professionals access to a unique database containing and recording clinical data of the patient and every medical/sanitary intervention, from birth to death, relevant to the individual's healthcare, from any location in the national territory, whether attended to by public or private health system establishments.

In July 2023, Decree 393/2023 was published, regulating Law 27,206, providing further clarity on some concepts outlined in that law and establishing certain possibilities for the System. Its objective is to enable access to information contained in electronic medical records stored in each electronic medical record system, starting from the System.

2. Is there a single health data identification system in your country?

There is currently no single system for health data identification in Argentina. However, as mentioned, Law 27,706, recently enacted, creates the Programme aimed at establishing this System, respecting patient rights and data protection laws.

Decree 393/2023 states that the System is a network operated by the Ministry of Health, interconnecting and interoperating different electronic medical record systems according to the technical requirements stipulated by the Ministry of Health in the 'National Health Interoperability Network' (Resolution 115/19). The System includes clinical patient data from birth to death, allowing healthcare professionals to access a database with important clinical information for each patient.

It has been established that the System must have the following characteristics:

- its clinical information must be confidential;
- its clinical information, its capture, update or modification, and consultation are carried out under strict conditions of security, integrity, authenticity, reliability, accuracy, intelligibility, conservation, availability, access and traceability;
- computer mechanisms for authenticating individuals participating in the System will be guaranteed;
- free access and monitoring by the patient will be ensured;
- it will contemplate file recovery and information durability;
- it will be auditable and subject to inspection by the relevant authorities; and
- its information will constitute authentic documentation and, as such, be valid and admissible as probative evidence and fully faithful for all purposes, provided it is authenticated.

Among the points that the regulatory authority must regulate are: (1) determining the technical and operational characteristics of the computerisation and digitisation of medical records; (2) designing and implementing electronic medical record software, as well as preparing protocol for loading them; (3) coordinating the operation of the system to be created with the functioning systems of the public, private and social security sectors; (4) installing software in all hospitals and health centres nationwide; and (5) providing technical training for healthcare personnel and financial support to different provinces.

It is important to note that the regulation clarifies that the Programme must communicate and coordinate with the competent authorities the necessary mechanisms for the authentication of individuals, agents, professionals and health assistants participating in the electronic medical record systems. The Ministry of Health, as the enforcement authority, must establish the standards which define access profiles for the electronic medical record systems.

3. Is there any kind of incentive (public or private) for the exchange of health data among stakeholders, particularly by the Ministry of Health or the corresponding agency in the country?

No, there are currently no incentives in Argentina for the exchange of health data.

4. Is health data interoperability covered by a data protection law in your country?

Health data is considered sensitive data under Law 25,326 (Personal Data Protection Law). According to this law, any data referring to an individual's health is classified as 'sensitive data' and is therefore subject to this legislation.

Additionally, Law No 27,706 on electronic health records (EHRs), consistent with the Patient Rights Law, Law 26,529, establishes that the patient is the owner of their EHR data and has the consistent right to know the information the record contains. Healthcare establishments and professionals are responsible for its custody, assuming the role of custodians and implementing the necessary means and resources to prevent unauthorised access to the information.

The protection and custody of clinical data must be carried out in accordance with the provisions of the Personal Data Protection Law 25,326 and Patient Rights Law 26,529.

5. What are the main challenges for the implementation of health data interoperability in your country?

One of the main challenges in implementing health data interoperability is how the healthcare system is divided up. Currently, multiple independent healthcare systems operate in Argentina, including the public sector, social security health insurers and the private sector. Each of these systems may have its own set of rules, processes and technologies for managing health data. Interoperability requires these systems to communicate and share information efficiently and securely. This can be challenging due to differences in the number of patients treated, the time professionals can dedicate to implementing these systems, available resources, technological platforms, privacy policies and data standards. These factors can hinder the creation of an integrated and efficient healthcare system, affecting the quality and continuity of patient care.

6. Is there any compilation of relevant data on the topic? For example, public or private expenditure on implementing digital health and data sharing using technology.

No, there is currently no publicly available information that provides relevant data on the topic.

Specific questions for Argentina

A. According to the Ministry of Health of Argentina, the implementation of the digital health network would be carried out in stages, with interoperability being part of the first stage. Has this stage been achieved? What stage has the process reached?

The Ministry of Health has established the implementation of the digital health network in two stages. The country is currently at stage two.

The first stage involved the implementation of the Digital Health Network, which included:

- awareness about digital health was raised through the training of specialised human resources in health information systems;
- standards for terminology, communication, minimum basic data sets etc were defined and documented;
- a central infrastructure for health data interoperability was implemented, facilitating communication between jurisdictions and health subsystems; and
- the National Connectivity Plan was implemented – as part of the plan, a connectivity diagnosis was carried out in all public healthcare centres across the country, and connectivity activities were planned; and
- the National Telehealth Plan was implemented – the plan works on regulatory, economic, health and technical aspects of telehealth.

The second stage, which is currently in progress, focuses on extending coverage of the network and its tools. The goal is to improve the tools used and ensure that the systems also reach health insurers and private healthcare systems nationwide.

B. Is there any data collection on the results obtained so far?

There is no public information available on the results.

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Bolivia

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1. What regulations govern the interoperability of health data in your country? If there are none, please inform us of any bills on the subject and how the issue of 'digital health' is being addressed in the country.

The Council for Information and Communication Technologies (CTIC) was established in 2017 to oversee health data interoperability. Comprising representatives from all public agencies, the CTIC, through collaborative efforts and discussions within the Interoperability Group, produced the 'Guidelines for the Implementation of Interoperability Services for Public Sector Entities of Bolivia'. This document, published on 19 March 2019, serves as a basis for standardising the implementation of interoperability services.

The Guidelines specifically designate the health sector as a pivotal mechanism for developing an early warning system, establishing foundations for health resource management, and creating platforms for seamless access to information and sector-specific queries. This strategic approach ensures that health information systems transcend organisational boundaries, fostering effective healthcare services by providing accurate information to address the health issues of individuals and populations. Electronic health records (EHRs) play a vital role in facilitating the comprehensive and secure collection of interactions between individuals and the healthcare system.

Bolivia's regulatory framework, as outlined by the CTIC guidelines, emphasises the crucial role of interoperability in the health sector, promoting effective healthcare services and enabling comprehensive information exchange.

2. Is there a single health data identification system in your country?

The enactment of Law 1152, 'Towards a Unified Health System' on 20 February 2019, marked a significant step towards ensuring free healthcare in Bolivia. The subsequent implementation of the Unified Health System (Sistema Único de Salud or SUS) in March of that year was a pivotal move in realising the overarching goal of establishing a comprehensive unified health system.

Bolivia's health system operates across three key sectors: the public sector, social security sector and private sector. Each sector functions independently, equipped with distinct resources, finances, and management and care models. Each sector has developed internal and external protection mechanisms, adding complexity to integration efforts into SUS.

The envisaged transition towards SUS is anticipated to create a harmonised and integrated approach across these sectors. However, currently, this transition is only partially realised, exclusively encompassing the public sector and individuals without access to social security or private medical care. The phased implementation indicates a gradual evolution towards a unified health data identification system, aligning with the broader objectives of legislation and the ongoing transformation of Bolivia's healthcare landscape.

3. Is there any kind of incentive (public or private) for the exchange of health data among stakeholders, particularly by the Ministry of Health or the corresponding agency in the country?

There is currently no evidence of specific incentives designed to facilitate efficient data exchange among different sectors.

At present, there is no information suggesting plans to introduce incentives, whether public or private, to stimulate the exchange of health data among various stakeholders, including the Ministry of Health and other pertinent agencies. Despite the enactment of Law 1,152, 'Towards a Unified Health System', and the establishment of SUS in 2019, integrating health data across the public, social security and private sectors remains a considerable challenge. It is anticipated that, with the ongoing implementation of SUS, there will be increased strides towards integration.

However, to date, this integration has primarily been confined to the public sector.

4. Is health data interoperability covered by a data protection law in your country?

Bolivia does not currently have a data protection law enacted. Discussion about a data protection law began in 2018. Since then, there have been at least four draft bills, the latest publicly of which was presented in early April 2023 by the Agency for Electronic Government and Information and Communication Technologies (Agencia de Gobierno Electrónico y Tecnologías de Información y Comunicación or AGETIC) during sessions in the Plurinational Legislative Assembly. To date, it is still under discussion.

5. What are the main challenges for the implementation of health data interoperability in your country?

The implementation of health data interoperability faces several challenges. The diversity of health sectors, the lack of standardised technological infrastructure, the absence of common standards and protocols, and concerns about security and privacy are key obstacles. Additionally, the need for adequate training, sufficient financial resources, coordination among health entities, a specific legal framework and the committed participation of all stakeholders are highlighted. These challenges underline the complexity and importance of addressing various aspects to achieve successful health data interoperability in Bolivia.

6. Is there any compilation of relevant data on the topic? For example, public or private expenditure on implementing digital health and data sharing using technology.

In response to the need for clear guidelines, the Information and Communication Technologies Council (*Consejo para las Tecnologías de Información y Comunicación* or CTIC) developed the document titled 'Guidelines for the Implementation of Interoperability Services for Public Sector Entities', which was published on 19 March 2019. The guidelines aim to standardise the implementation of interoperability services, assigning the health sector a central role. The significance of the guidelines lies in their role in developing the early warning system, efficient management of health resources and the implementation of platforms for accessing sector-specific information and queries. The existence of these guidelines reflects Bolivia's efforts to promote interoperability in the healthcare sector, thereby improving the comprehensive and secure collection of healthcare-related data. While efforts are being made to implement them to the extent possible within the health sectors, it is still an ongoing process and not yet fully tangible.

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1. What regulations govern the interoperability of health data in your country? If there are none, please inform us of any bills on the subject and how the issue of 'digital health' is being addressed in the country.

In Brazil, the main regulations that govern the issue are as follows:

Ministry of Health Consolidation Ordinance 1/2017

This Ordinance consolidates the rules on the rights and duties of healthcare users, and the organisation and functioning of the Public National Unified Health System (Sistema Único de Saúde or SUS).8 It defines information standards, terminology, premises and technical specifications for health, as well as data interoperability between SUS and healthcare systems, private healthcare and supplementary healthcare. This Consolidation Ordinance incorporates Ordinance No 2,073 from 31 August 2011, which had been the main precursor of interoperability efforts in healthcare in Brazil, applicable to both public and private entities, over the years. This background highlights the steady pace at which public policies have been fostering initiatives to improve the healthcare data infrastructure in Brazil.

Title VII of the Ministry of Health Consolidation Ordinance 1/2017 states that interoperability standards shall be established with the purpose of enabling information sharing between establishments involved in SUS via standardised concepts and models of information representation, in order to make access to relevant and reliable user information more agile.

Furthermore, in Chapter I-A of Title VII, the Consolidation Ordinance specifically addresses the implementation of the Digital Health Strategy in SUS as follows:

- Digital Health Strategy – The Ordinance aims to establish guidelines for the implementation of the Digital Health Strategy within SUS to promote the use of information and communication technologies to enhance the quality and efficiency of health services.
- Interoperability and information exchange – The Ordinance emphasises the importance of interoperability among health information systems. It advocates for the adoption of standards and protocols that facilitate the secure and efficient exchange of information among various system stakeholders, including healthcare units, laboratories, healthcare professionals and managers.
- Citizen's Electronic Health Record (EHR) – The Ordinance addresses the creation of the Citizen's EHR, which aims to consolidate the health information of each individual in an electronic system accessible to authorised professionals.

8 See https://bvsms.saude.gov.br/bvs/saudelegis/gm/2017/prc0001_03_10_2017_comp.html accessed 31 May 2024.

- Innovation and Emerging Technologies – The strategy also recognises the importance of innovation and monitoring emerging technologies, such as artificial intelligence (AI) and telemedicine, to enhance health services.
- Technical Standards and Governance – The Ordinance establishes the need to define and adopt interoperability technical standards, as well as to implement effective governance for digital health in SUS.

Furthermore, in Chapter II-A of Title VII, the Consolidation Ordinance sets out the National Healthcare Data Network (Rede Nacional de Dados em Saúde or RNDS) in compliance with the General Data Protection Law (Law No 13,709/2018 – *Lei Geral de Proteção de Dados Pessoais* or LGPD).

Ministry of Health Consolidation Ordinance 2/2017

This Ordinance consolidates the norms on the national healthcare policies of SUS.9 Annex XLII provides for the National Health Information and IT Policy, with the objective of guiding the public and private sectors regarding guiding principles for the integration of health information systems.

Ministry of Health Consolidation Ordinance 5/2017

This Ordinance unifies the standards for healthcare actions and services within SUS,10 including the standards for the Digital SUS Program,11 and provides for the steps towards a digital transformation across the entire healthcare sector, including the interoperability of healthcare data.

Law No 14,129/2021

This law sets out principles, standards and tools for digital government plan, including conditions for interoperability that the public administration must adhere to in its services and activities. Despite the broad scope of the law, the aforementioned Consolidation Ordinances specifically enhance it with regard to healthcare matters.

Decree 10,046/2019

This decree institutes governance for data sharing across the federal public administration and sets up the Citizen's Basic Registry along with the Central Data Governance Committee. These entities are tasked with ensuring interoperability conditions to enhance data governance processes and standards within the activities of the direct public administration.

National Congress Bill of Law No 2,224/202112

Finally, it is worth noting that the National Congress is currently deliberating on Draft Bill No 2,224/2021. This proposed legislation aims to regulate the promotion of real-time data interoperability services. Importantly, the draft bill includes provisions for the reimbursement of costs or expenses associated with

9 See https://bvsms.saude.gov.br/bvs/saudelegis/gm/2017/prc0002_03_10_2017_comp.html accessed 31 May 2024.

10 See https://bvsms.saude.gov.br/bvs/saudelegis/gm/2017/prc0005_03_10_2017_comp.html accessed 31 May 2024.

11 See www.in.gov.br/web/dou/-/portaria-gm/ms-n-3.232-de-1-de-marco-de-2024-546278935 accessed 31 May 2024.

12 Bill No 2224/2021 www.congressonacional.leg.br/materias/materias-bicamerais/-/ver/pl-2224-2021 accessed 31 May 2024.

providing these interoperability services. This is intended to facilitate investment by the relevant body or entity to ensure the viability of data.

2. Is there a single health data identification system in your country?

No. The main system used for health data is the SUS Outpatient Information System (Sistema de Informações Ambulatoriais do SUS or SIA/SUS), which contains over seven billion records. However, there are at least ten other systems used throughout Brazil, such as:

- SISPRENATAL (Monitoring System for Pregnant Women, Postpartum Women and Newborns) – This system aims to monitor the evolution of pregnancy, childbirth and the postpartum period, ensuring a detailed record of information related to maternal and newborn health.
- SINASC (Live Birth Information System) – SINASC is responsible for collecting, processing and disseminating information on live births in Brazil, providing essential data for the planning and evaluation of maternal and child health policies.
- SISREG (National Regulation System) – This system is used to manage and regulate outpatient and hospital procedures, facilitating patients' access to different health services.
- SIA/SUS – This system collects data on outpatient procedures carried out within the scope of SUS, providing information for planning and managing resources in the outpatient area.
- SIH/SUS (SUS Hospital Information System) – SIH/SUS is responsible for collecting data on hospital procedures carried out in the SUS, helping to evaluate and regulate hospital services.
- CIH (National Health Card) – The National Health Card is a document that contains a unique identification number for each citizen. It is used to record and control health actions and services, connecting different citizen health information into an integrated system.
- CNES (National Registry of Health Establishments) – CNES is a registration system that contains information about health establishments in Brazil. It includes data on hospitals, clinics and laboratories, among others. The CNES is essential for the planning, regulation and evaluation of health services.
- PNI (National Immunisation Programme) – The PNI is responsible for coordinating vaccination actions across Brazil. It aims to control, eliminate and eradicate vaccine-preventable diseases, ensuring the distribution and application of vaccines in accordance with Ministry of Health guidelines.

3. Is there any kind of incentive (public or private) for the exchange of health data among stakeholders, particularly by the Ministry of Health or the corresponding agency in the country?

There are no incentives in the form of direct monetary transfer of values by the public administration towards the private sector. The public administration does feature a financial incentive to foster the adoption of digital and interoperable initiatives by states and cities, as defined by Ministry of Health Ordinance 3,233/2024.13 This Ordinance aims to develop the Digital SUS Programme, intended to classify the levels of maturity of miscellaneous systems, software and hardware, taking into account many

13 See www.in.gov.br/en/web/dou/-/portaria-gm/ms-n-3.233-de-1-de-marco-de-2024-546282453 accessed 31 May 2024.

related definitions and activities connected to healthcare. Interoperability is featured as a key criterion for such a classification.

The incentives towards the private sector are in the form of public policies to foster the technological infrastructure upgrades, as set by the Consolidation Ordinances. For example, the RNDS establishes that the adoption of interoperability standards in healthcare is applicable to both the public and private sectors, according to Article 254-A,14 and provides resources regarding syntactic interoperability standards, information models, governance, management and policies, as set out in Article 233.15

Therefore, the clear incentive for the exchange of data by healthcare stakeholders is the regulatory requirement by the Ministry of Health Consolidation Ordinance 1/2017, in which healthcare infrastructure, including the necessary interoperability, is described as an element that must be observed by both the public and private sectors, as provided for in Article 232, sole paragraph.

4. Is health data interoperability covered by a data protection law in your country?

Yes. LGPD establishes guidelines for the processing of personal data, including health data, aiming to ensure the privacy and protection of the holders of this information. The processing of healthcare data that is identified or identifiable, by both the private sector and public administration, is governed by the general rules and principles set out in LGPD.

5. What are the main challenges for the implementation of health data interoperability in your country?

With a land area of over 8.51 million square kilometres16 (approx. 3.29 million square miles) and a population of over 220 million,17 Brazil's interoperability efforts need to overcome geographical and economic challenges in order to be implemented into the national public SUS, on which a significant majority of citizens rely.

On this basis, there have been recent government initiatives to bolster and foster interoperability in public healthcare, such as the creation of the Digital Health and Information Office (SEIDIGI),18 within the Ministry of Health. The SEIDIGI is responsible for assisting the various Ministry of Health offices in the planning and adoption of policies, information technology products and services, software development, interoperability and data integration, and protection.

Another challenge for the implementation of health data interoperability relates to the willingness of data sharing by the different players. There are financial and cultural challenges to be overcome.

In our opinion, there are the key factors to consider when implementing health data interoperability. These are:

- Fragmentation of the healthcare system – Brazil has a fragmented healthcare system with multiple stakeholders, including SUS, the private sector and health insurance plans. Consequently, the system

14 See https://bvsms.saude.gov.br/bvs/saudelegis/gm/2017/prc0001_03_10_2017_comp.html accessed 31 May 2024.

15 See https://bvsms.saude.gov.br/bvs/saudelegis/gm/2017/prc0001_03_10_2017_comp.html accessed 31 May 2024.

16 See www.ibge.gov.br/geociencias/organisacao-do-territorio/estrutura-territorial/15761-areas-dos-municipios.html?t=acesso-ao-produto&c=1 accessed 31 May 2024.

17 Brazil population projection https://cidades.ibge.gov.br/brasil/pesquisa/53/49645 accessed 31 May 2024.

18 See www.planalto.gov.br/ccivil_03/_ato2023-2026/2023/decreto/D11358.htm accessed 31 May 2024.

continues to produce a significant volume of non-integrated data. In other words, a serious effort needs to be made towards the integration of available health data. In addition, data is not even integrated within the same information system.

- Divergent standards – The existence of different standards and technologies used by various healthcare systems can complicate the creation of an interoperable framework. Standardisation is crucial in ensuring efficient communication between systems.
- Technology investment – The implementation of interoperable systems often requires significant investment in infrastructure and technology. The lack of financial resources can be a barrier to updating and integration of existing systems.
- Professional training – The need for trained healthcare professionals and technicians to handle interoperable systems is crucial. Proper training is essential in ensuring the efficient and secure use of interoperability technologies.
- Security and privacy – Interoperability of health data involves the exchange of sensitive information. Ensuring the security and privacy of this data is a constant challenge, requiring rigorous protection measures against cyber threats and compliance with data protection laws. In Brazil, although there is substantial investment in technology in the health sector, there is still strong resistance to investing in certain technologies, especially those related to LGPD standards, that is, cloud data storage.

6. Is there any compilation of relevant data on the topic? For example, public or private expenditure on implementing digital health and data sharing using technology.

In Brazil, there is still no official compilation of health data – public or private. However, several initiatives are underway, both by the legislative power and federal government, both aimed at making the flow of information more efficient to support decisions in the healthcare sector and expanding access to healthcare. This includes the implementation of mechanisms which enable the sharing and integration of health data.

During a public hearing promoted by the House of Representatives to discuss the reality of health data interoperability in Brazil, representatives of the National Council of Health Secretaries showed that there is still a massive collection of health data in a fragmented manner in healthcare entities. Studies have revealed that both the public and private sectors are at the early stages of digitising health data. Based on available information, it is fair to say that, regardless of the region, type of facility and whether the healthcare entity is public or private, currently, most of these establishments do not have interoperable electronic systems and maintain electronic health records (EHRs) which are both digitised and in physical files. A minority still maintains EHRs exclusively in physical files. On this basis, it was suggested that a possible path to integrate public and private data would be to establish the National Health Data Network (Rede Nacional de Dados em Saúde or RNDS) as the sole route for the repository of health data which is deemed essential.19

Ministry of Health Ordinance No 1,434/2020, which created the RNDS, establishes interoperability standards in health for both public and private healthcare services. The RNDS was scheduled to start

19 See www2.camara.leg.br/atividade-legislativa/comissoes/comissoes-permanentes/cssf/arquivos/24.10.2023-%20AP%20Subtele%20interoperabilidade%20em%20saude%20-%20Felipe%20Ferre.pdf accessed 31 May 2024.

a pilot phase in March 2020. However, the project was reorganised to receive and share information to support healthcare professionals in combating Covid-19. The Ministry of Health, with the support of public and private laboratories, supported the acceptance and sharing of Covid-19-related tests through the RNDS. Since then, the RNDS has been expanded to include new products and services within the Ministry of Health's Digital Health Strategy. These include the integration of other types of healthcare facilities (eg, specialised clinics and diagnostic imaging services); interoperability with supplementary healthcare; standardisation of clinical terminology; integration of new information services using (eg, artificial intelligence, analytics, big data and the internet of things); and other emerging technologies for health data retrieval. However, the RNDS is still underutilised because its database does not cover all relevant information for public health, nor does it include health data generated by private and supplementary healthcare systems.

Furthermore, since the beginning of 2023, the Secretariat of Information and Digital Health has been established in Brazil, implementing various initiatives aimed at expanding access to healthcare through the use of health information technologies. A recent example is the publication of Ministry of Health Ordinance No 3,233/2024, which will allocate approximately BRL 232m to federative entities that join the SUS Digital Project. The Project first aims to map the digital development level of public entities involved in providing healthcare services. This project is viewed with optimism because it seeks to nationalise digital health initiatives, which includes the integration and protection of health data collected in all spheres of public healthcare services. However, the project is still in its initial phase and is focussing on the activities of the public sector.

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Chile

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Jorge Tisné *Bolfill Mir Abogados, Chile*
Anamaría Verdugo *Bolfill Mir Abogados, Chile*

1. What regulations govern the interoperability of health data in your country? If there are none, please inform us of any bills on the subject and how the issue of 'digital health' is being addressed in the country.

Health data interoperability has recently been regulated under Law No 20,584, which regulates the rights and duties of patients. However, its regulation is not exhaustive and depends on regulations which should be issued by the Health Ministry.

Its implementation is a national challenge, which is why the principle of interoperability has begun to be anticipated in recent health regulations, but without greater practical significance so far.

On this basis, Decree No 6 of 2022 of the Ministry of Health, which will probably be updated considering the new regulation, contains the regulation on actions related to remote healthcare. It requires that providers that implement remote care must guarantee 'technological neutrality, in the sense that it is designed and implemented to interoperate from a semantic and syntactic point of view, at the level of data, systems, and communication networks'.

Similarly, recent Law No 21,451 of 2023 modified Law No 20,584. It regulates the rights and duties of patients to authorise health providers to provide care through telemedicine. It establishes as an obligation that 'the electronic medical record and the systems that support it must be designed to interoperate with other systems necessary for the granting of health actions and benefits. A regulation of the Ministry of Health, signed by the Ministry of Finance, will establish the technical and administrative standards that must be met for its certification.'

It should be noted that the regulation that must determine the necessary standards to guarantee the integration and integrity of data, interoperability, availability, authenticity and confidentiality of information has not yet been issued by the Ministry of Health.

Chile has committed to implementing and developing a national policy related to digital health. During 2018, a Digital Health Department was created under the Subsecretariat of Health Networks under the Ministry of Health. Its objective is to provide support to all health services in the implementation and development of digital strategies for the healthcare of the population.

The Digital Health Department has stated that one of its challenges is the interoperability and integration of systems, which will improve system usability, avoid double digitisation by users and help reduce possible digitisation errors, improving data recording.

Within this framework, the Digital Health Department has begun testing an interoperability system based on the international standard HL7® FHIR®©, (Fast Healthcare Interoperability Resource) through a SMILE server. Alongside this, a data standardisation process has begun to facilitate the exchange and availability of clinical information.

2. Is there a single health data identification system in your country?

No.

3. Is there any kind of incentive (public or private) for the exchange of health data among stakeholders, particularly by the Ministry of Health or the corresponding agency in the country?

No.

4. Is health data interoperability covered by a data protection law in your country?

Health data is defined as sensitive data and is regulated by Law No 19,628 on the Protection of Private Life, which regulates personal data.

5. What are the main challenges for the implementation of health data interoperability in your country?

The main challenges for the implementation of health data interoperability are:

- There is low digitisation of public health services in Chile.
- There is a lack of clear guidelines to implement a general interoperability system that allows the sharing of health data. On this regard, there is no governance on the matter which allows for the setting unique standards in the technical aspects of data communication between systems, data format, interpretation of exchanged data (language use) and organisational-level guidelines.
- The regulation which recognises interoperability is very recent and lacks practical application.
- The Ministry of Health has not issued the regulation of Law No 21,451 of 2023.
- Health regulations impose the obligation to retain information for providers, so they are reluctant to share patient information.
- Currently, Law No 19,628 on the Protection of Private Life classifies health data as sensitive data. Therefore, in the absence of an adequate interoperability regulation, the exchange of information between public and private health systems could affect the informational self-determination of patients.
- Public and private systems currently do not share data, which makes it difficult to implement a cross-cutting interoperability policy in Chile's health system. Patient clinical information is disaggregated in different health providers' systems, in formats which are unsearchable online or reusable.

6. Is there any compilation of relevant data on the topic? For example, public or private spending on implementing digital health and data sharing through technology.

Although important efficiencies have been postulated regarding public health spending, with attention paid to the correct implementation of interoperability, there is no official public data on this point.

Specific questions for Chile

A. Is interoperability already a reality in the health model adopted in Chile? What are its main applications?

Interoperability is not yet a reality, although as previously explained, its implementation is a challenge that Chile has recognised and is working on, mindful of the obvious benefits it brings to the population and the state.

B. At what stage is the implementation of interoperability in Chile's health system?

It is in an exploratory phase, through the Digital Health Department. Similarly, there is a lack of legal regulations to allow its implementation. This should be under analysis and elaboration by the involved ministries.

C. Is there any data collection on the results obtained so far?

There is no information available regarding the interoperability of the system.

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Colombia

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María Alejandra de Los Rios *Lloreda Camacho & Co, Colombia*

1. What regulations govern the interoperability of health data in your country? If there are none, please inform us of any bills on the subject and how the issue of 'digital health' is being addressed in the country.

Health data interoperability in Colombia focuses on the patient's medical history. The first precedent can be found in Law 1,955 of 2019, which, in Article 246, states:

> 'The Ministry of Health and Social Protection will adopt an electronic mechanism that develops the interoperability of the medical history. This mechanism must ensure that all public and private health service providers, as well as other individuals or legal entities related to health care, share the vital data defined by the national government to continue health care, which must comply with the standards established for this purpose.'

While Law 1,955 of 2019 was the first approach in the country regarding health data interoperability, specifically for medical history, it was Law 2,015 of 2020 that established the main legal framework for the creation and regulation of electronic medical history interoperability in Colombia. It determined that its implementation should be progressive, indicating a five-year timeframe for compliance with the standard from its entry into force, that is, from 31 January 2020 to 31 January 2025. Implementation will be a coordinated effort between the Ministry of Health and Social Protection and the Ministry of Information and Communications Technologies for the technological development of the platform.

In conjunction with this law, the Ministry of Health and Social Protection issued Resolution 866 of 2021, which regulates the set of relevant clinical data elements for medical history interoperability.

The Ministry of Information and Communications Technologies (MinTIC), in fulfilment of its technological development function, created the Guide to Guidelines for Digital Citizen Services – Annex 1 in May 2020. This Guide establishes the necessary conditions for the implementation of an interoperability platform in Colombia, which will involve the implementation of the interoperability health sector roadmap proposed by the Ministry of Health and Social Protection.

Regarding digital health, note that, in Colombia, some health services can be provided through telemedicine. Consequently, Resolution 2,654 of 2019 from the Ministry of Health and Social Protection sets out the requirements to be considered for the provision of health services in these modalities, and Resolution 3,100 of 2019 specifies in which cases the provision of health services under the telemedicine modality will be allowed.

2. Is there a single health data identification system in your country?

In Colombia, there is the Comprehensive Social Protection Information System – SISPRO – which encompasses four major components: health, pensions, occupational risks and social promotion. Currently, the Ministry of Health and Social Protection is responsible for: its administration; obtaining, processing and consolidating the information necessary for decision-making that supports policy

development; regulatory monitoring; and service management at each level and in the essential processes of the sector – assurance, financing, supply, demand and service use.20

Regarding the interoperability of electronic medical history, Resolution 866 of 2021 states that the administration of the set of relevant clinical data will be carried out through the SISPRO platform. Therefore, it is expected that procedures enabling this integration will be established.

3. Is there any kind of incentive (public or private) for the exchange of health data among stakeholders, particularly by the Ministry of Health or the corresponding agency in the country?

Currently, there are no incentives; however, a set of obligations is expected to apply once the mechanisms of interoperability are established by the Ministries of Health and Social Protection and Information and Communications Technologies. In this sense, Resolution 866 of 2021 will require health service providers, both public and private, as well as any individual or legal entity related to medical care, to use the relevant clinical data format from the technical annex of the resolution to facilitate information exchange among different actors in the country's health system. This obligation will extend to requests or exchanges of information made by the Ministry of Health and Social Protection with any system participant.

4. Is health data interoperability covered by a data protection law in your country?

The regulation governing the protection of personal data in Colombia is Law 1,581 of 2012. In general terms, this law establishes a regime for the protection of personal data without specifically referring to the principle of interoperability. Health data interoperability in Colombia has typically been associated with open information available to citizens and managed by the national government or various public entities. Consequently, there is currently no specific regulation regarding the interoperability of personal data.

However, it is important to highlight the following:

- The regulation of personal data protection specifically addresses and regulates the use of sensitive personal data. Health information associated with or that can be associated with an individual, especially information contained in medical records, is considered sensitive personal data subject to the data processing conditions established in Law 1,581 of 2012. In general terms, the processing of this type of data requires more specific authorisation from the data subject, and under the necessity principle, it has a stricter application, requiring the adequate demonstration and justification of the need to process sensitive personal data.
- Resolution 866 of 2021 issued by the Ministry of Health and Social Protection, referring to medical history interoperability, emphasises that the treatment of such information must follow the principles of Law 1,581 of 2012 and its regulatory decrees. The resolution aims for the adoption of appropriate measures to demonstrate compliance with personal data regulations and the adoption of criteria for demonstrated responsibility when processing relevant clinical data incorporated into medical records.

Additionally, the resolution mentions that privacy by design and by default in the treatment of relevant clinical data for medical history will be indispensable in the project and software development through which interoperability is implemented. This ensures the privacy of personal information managed in such systems. In this regard, the norm clearly establishes the obligation to appoint a privacy officer (in line with

20 Ministry of Health and Social Protection of Colombia, SISPRO Comprehensive Information System. Sourced from 'SISPRO Comprehensive Information System' minsalud.gov.co accessed 31 May 2024.

personal data regulations) who will be in charge of processing requests from data subjects. While this is a general privacy obligation, the resolution emphasises that, for this type of information, it will be essential to have appointed someone responsible for these procedures and to manage them properly within the framework of data exchange in the interoperability platform.

In line with the need to implement the demonstrated responsibility principle when processing medical history data as part of that interoperability system, the resolution requires the implementation of a robust information security and digital security system. Finally, it refers to the implementation of privacy impact assessments, which must be conducted when evaluating the impact that processing relevant data for medical history interoperability may have. This should allow the proper identification of general risks, risks related to information security, among others, and ways to mitigate these risks, as well as the actions that will be taken in case they occur.

5. What are the main challenges for the implementation of health data interoperability in your country?

Apart from individual advancements by some entities, national-level interoperability in health faces the challenge of overcoming fragmentation, and lack of communication among institutions and healthcare organisations. The first significant challenge is establishing connection and communication among all healthcare operators in Colombia, which amount to more than 10,000 institutions, including nearly 1,000 public hospitals.[21]

In addition to the above, the Ministry of Health and Social Protection has identified challenges for the implementation of digital health. Such challenges include: regulatory development that aligns with both innovations and the national reality; generating digital competencies in healthcare teams and users; digital security and protection of personal data; public-private and intersectoral coordination (information technology sector/health sector); connectivity for healthcare service providers in remote areas; and secondary use of data for exchange with other stakeholders.[22]

The Presidential Agency of International Cooperation has emphasised the need for public and private efforts to create an enabling environment for digital health. The Agency advocates for a significant investment of economic resources, especially from territorial actors, such as health secretariats and the public hospital network. This is due to the lack of development and management capacity at these levels, hindering the implementation of digital transformation.[23]

6. Is there any compilation of relevant data on the topic? For example, public or private spending on implementing digital health and data sharing through technology.

A significant budget has been allocated Within the Ministry of Health and Social Protection's Digital Transformation Plan (PDT) 2020–2022, for interoperability implementation. Initiatives relating to digital transformation that were allocated resources include:

- Information technology (IT) architecture for designing the technical support system;

21 Ministry of Health and Social Protection of Colombia, 'Colombia is a pioneer in digital transformation of the health sector', 2022 minsalud.gov.co accessed 31 May 2024.

22 *Ibid.*

23 Presidential Agency for International Cooperation, 'Digital Health', 2022 apccolombia.gov.co accessed 31 May 2024.

- implementation of fields for electronic billing in the healthcare sector;
- IT architecture for the interoperability of the healthcare and social protection sector;
- implementation of the sanitation and fiscal monitoring system – final point agreement;
- IT architecture for designing the horizon scanning information system;
- implementation of medical history interoperability;
- strengthening the transactional affiliation system (sistema de afiliación transaccional or SAT); and
- IT architecture for designing the document management system of the healthcare sector.

These initiatives had an approximate investment of: COP2 5.8bn (approximately US$6.26m) in 2019, COP27.33bn (approximately US$6.63m) in 2020, COP 31.02bn (approximately US$7.5m) in 2021, and COP 34.03bn (approximately US$8.25m) in 2022.

Specific questions for Colombia

A. Is interoperability already a reality in the adopted healthcare model in Colombia? What are its main applications?

While there has been significant progress with the creation of the regulatory framework for the application of interoperability in the digital medical history, interoperability is not yet a reality in Colombia's healthcare model.

Notwithstanding the above, during the Covid-19 pandemic, as part of the Digital Health Project, the implementation of an application designed to provide citizens nationwide with access to information on free health services was carried out. It also offered resources for monitoring their wellbeing. In 2022, the Ministry indicated that this application would enable health tracking and control, access to electronic certificates, submission of PQRS or other procedures. Another feature included is 'Mi Ruta de Salud', which outlines examinations and the health status of individuals, including data from preventive medicine follow-ups.24 According to data from the Ministry of Health and Social Protection, this application had over 11 million users. While MinSalud Digital no longer exists, a new application is being developed by the National Digital Agency. Additionally, various mobile applications and online platforms currently allow users to access their medical records, schedule appointments with healthcare professionals and receive medication reminders provided by institutions with these information systems.

Another aspect highlighted by the Ministry of Health and Social Protection is the results in telehealth, which is part of the Digital Health Project. Before the pandemic, one million consultations were conducted per month and, currently, around ten million are conducted monthly.

B. What stage is the implementation of interoperability in Colombia's healthcare system?

Colombia has experienced notable advances in the field of digital health, especially during and after the pandemic, recognising the importance of digitally transforming the healthcare system. The country has

24 Ministry of Health and Social Protection of Colombia, 'The Digital Health agenda to generate interoperability', 2021 minsalud.gov.co accessed 31 May 2024.

demonstrated significant progress in digital areas, such as telemedicine, systems integration, data analysis and strengthening digital applications.

However, in terms of interoperability, the development has been fragmented. Several entities, both private and public, have made significant strides and become leaders in this field. However, other entities have faced challenges in their implementation.

Based on data from the Ministry of Health and Social Protection, there is a Digital Health Roadmap for 2022–2031,25 consisting of a series of plans, actions and policies promoting various aspects of digital transformation in health. These include:

- Adoption Plan for Electronic Medical Record Interoperability;
- Health Data Analytics Unit;
- strengthening MinSalud Digital and RIAS;
- online certificates (Covid-19 and tests);
- Health Contracts Portal;
- integration of social security information systems;
- integrated financial information subsystem; and
- Digital Health Policy through the Digital Health Roadmap 2021–2031, Public Health 2022–2031 and Digital Health in Health Security 2022–2026.

As part of the adoption plan, the government is in the testing phase of interoperability between regions and the implementation of the Colombian private cloud HCE, a technological platform. There is also the preparation for a group of health service providers (instituciones prestadoras de servicios de salud or IPS) to interoperate. At the end of 2022, the first Interoperability Connectathon IHC Colombia was held, validating guides and components of the Exchange Model and the National Interoperability Adoption Strategy HCE.

Lastly, it is important to note that, since the beginning of 2023, the current national government has been working on a healthcare system reform project currently in the approval process in the Congress of the Republic. This project proposes the implementation of a Unified and Interoperable Public Health Information System. Healthcare system stakeholders are eagerly awaiting the impact this bill will have on the Colombian healthcare system, affecting both digital health and interoperability, and influencing the roadmap set by the previous government and progress made until the end of 2022.

C. Is there any data collection on the results obtained so far?

As previously pointed out, in Colombia, currently progress on interoperability has been fragmented. Without prejudice to the above, different private and public entities, to a greater or lesser extent, have managed to integrate the interoperability of the information they manage into their health systems, managing to optimise and improve their processes.

25 Launch of the 2022 Digital Transformation and Interoperability Agenda for the Health Sector (2022), YouTube.

One of the most advanced projects at the regional level is that of the capital Bogotá. Since 2016, the district launched a health interoperability project for the implementation of the Unified Electronic Health Record (Historia Clínica Electrónica Unificada en Cundinamarca or HCEU). Currently, the Health Secretariat of the Mayor's Office of Bogotá indicates that it manages the provision and care of health services in a network made up of 22 hospitals and 142 medical care centres, the management and administration of more than 80 million medical records, the management and processing of more than 7.5 million medical appointments per year, the issuance of more than 2.6 million medical formulas and more than 100,000 daily clinical events[26] through the integration of a single database where it has all the information about patients' health that has been previously registered in the systems of the different hospital centres. This is made available to medical professionals immediately and permanently under a HCEU model. According to data from the Bogotá Ministry of Health, as of March 2023, Bogotá had achieved an 89 per cent reciprocal exchange of information, with a goal of 95 per cent by the end of 2023. This translates into greater efficiency and effectiveness for citizens, promoting the use of technology in medical care and moving towards a preventive model.[27]

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26 Indra Company (2021), Colombia White Paper Health Interoperability 210121_np_colombia_libro_blanco_interoperaibilidad_salud.pdf indracompany.com accessed 31 May 2024.

27 Inter-American Development Bank. (2023). Implementation process of the unified electronic medical record (HCEU) in Bogotá, consulted from https://publications.iadb.org/publications/spanish/viewer/Proceso-de-implementacion-de-la-historia-clinica-electronica-unificación-HCEU-en-Bogota.pdf accessed 31 May 2024.

Mexico

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1. **What regulations govern the interoperability of health data in your country? If there are none, please inform us of any bills on the subject and how the issue of 'digital health' is being addressed in the country.**

An important precedent in digital health in Mexico was the constitutional reform on telecoms published on 11 June 2013. This reform incorporated specific provisions for the federal government to assume responsibility for universal digital inclusion policy, including objectives and goals relating to infrastructure, accessibility, connectivity, information and communication technologies and digital skills, as well as government digital programmes, open government, promotion of public and private investment in telehealth, telemedicine, electronic health records and development of digital applications, systems and content, among other aspects.

As a result of this reform, the National Digital Strategy (NDS) was formulated, with its Objective 4, 'Universal and Effective Health', establishing the integral digital health policy to leverage information and communication technology (ICT), which had two priorities: increasing coverage, effective access and quality of health services; and using existing infrastructure and resources for health more efficiently.

The NDS promoted five secondary objectives: (1) the use of ICT in promoting inter-institutional convergence; (2) the establishment of a unique health identity (unique records of service users and healthcare professionals) through a general health registry; (3) electronic health record registration systems; (4) electronic birth and vaccination records; and (5) telehealth/telemedicine systems.

However, the regulation of digital health in Mexico is still in the process of consolidating a legal framework that provides certainty to all stakeholders involved, therefore requiring an appropriate framework to establish conditions for access and development of digital health.

Nevertheless, limited progress in General Health Law and some sporadic aspects in secondary regulation, such as the Mexican Official Standard NOM-024-SSA3-2012, leave the sector without adequate regulation. The search for the regulation of digital health has gained momentum since 2015. In that year, an attempt was made to publish an Official Mexican Standard (Norma Oficial Mexicana or NOM), albeit with a very limited focus, to regulate the sector, but this project was cancelled in 2018 and has yet to be revived. The consequence of this legal gap is that there is no clear and comprehensive regulation for the provision of healthcare services through technological means.

Finally, the Official Mexican Standard NOM-024-SSA3-2012 is the regulation governing the interoperability of health data in Mexico. This standard sets out guidelines for information exchange in the health sector, promoting the adoption of electronic information systems, and the use of interoperability standards and protocols.

General definitions

There is no single definition in Mexican law for interoperability. The Institute of Electrical and Electronics Engineers defines it as 'the ability or capacity of two or more systems to exchange information and utilise the exchanged information'.

In healthcare, interoperability is more specifically defined as 'the ability of different health information systems (hospital systems, departmental systems, electronic health records, etc) to exchange data and use the exchanged information within and across organisational boundaries, to improve the effective provision of healthcare to individuals and communities'.

The European Telecommunication Standards Institute establishes four levels of interoperability: technical, syntactic, semantic and organisational.

Various barriers to achieving interoperability include the selection, acquisition and use of standards; the use of diverse brands and generations of information technology (IT) systems and programming languages in the public and private healthcare sectors; costs associated with standard implementation; and the absence of regulatory frameworks for personal data protection.

However, the benefits of implementing interoperability in the National Health System are greater and more plausible than not implementing interoperability. Such benefits include healthcare quality, organisational efficiency, government effectiveness and economic outcomes.

2. Is there a single health data identification system in your country?

In Mexico, NOM-024-SSA3-2012 establishes the need to use unique identifiers for patients in health information systems. However, no single system has been implemented nationwide, although efforts have been made towards creating unique identifiers, such as the Unique Population Registry Code (Clave Única de Registro de Población or CURP), which is used in some state health systems.

In this regard, we found that the Integral Information System from the Health Ministry (or SIS)[28,29] integrates information from various areas of the Ministry of Health at the national level, including epidemiological data, health statistics, administrative information and human resource data. The implementation of SIS aims to streamline data management and improve decision-making processes within the Ministry of Health.

3. Is there any kind of incentive (public or private) for the exchange of health data among stakeholders, particularly by the Ministry of Health or the corresponding agency in the country?

Regarding incentives for the exchange of health data, there are no specific provisions in the standard. However, compliance with NOM-024-SSA3-2012 may be considered a requirement to access certain government financing or support programmes in the health sector. Additionally, there are both public and private initiatives aimed at fostering collaboration and information exchange among different sector actors.

28 See www.dgis.salud.gob.mx/contenidos/sinais/subsistema1.html accessed 31 May 2024.

29 See http://sinaiscap.salud.gob.mx:8080/DGIS/ accessed 31 May 2024.

4. Is health data interoperability covered by a data protection law in your country?

The interoperability of health data is not specifically covered by a data protection law in Mexico. Although there are general provisions on personal data protection that could apply, there is no specific legislation which comprehensively addresses this issue.

In addition to the provisions of the Federal Law for the Protection of Personal Data Held by Private Parties, it is also relevant to consider the provisions of the General Law for the Protection of Personal Data Held by Obligated Subjects, which regulates the handling of personal data by federal and local authorities in Mexico.

Some important provisions of this law are relevant to the interoperability of sensitive data or clinical data. These include:

1. *Consent principle* – Similar to the law applicable to individuals, the General Law establishes that the handling of personal data by authorities requires the consent of the individual, unless there is a legal exception.
2. *Purpose principle* – Authorities must collect personal data for specific, explicit and legitimate purposes, and may not use the information for other purposes without the consent of the individual, except in cases provided for by law.
3. *Data security* – Authorities are required to implement appropriate security measures to protect the personal data they handle, including sensitive data, such as clinical data. This includes technical, administrative and physical measures to prevent unauthorised access, loss or misuse of information.
4. *Rights of individuals* – Individuals have rights recognised by the General Law, including the right of access, rectification, cancellation and objection (ARCO). This means that patients have the right to access their clinical data, request corrections, cancel consent for data processing and object to processing under certain circumstances.

It is important to consider these provisions of the General Law for the Protection of Personal Data Held by Obligated Subjects along with the provisions of the Federal Law for the Protection of Personal Data Held by Private Parties to ensure the proper treatment and protection of sensitive data or clinical data in the context of interoperability of information systems in the healthcare sector.

5. What are the main challenges for the implementation of health data interoperability in your country?

Some of the main challenges facing the implementation of health data interoperability in Mexico include: the lack of standardisation of health information systems; the diversity of actors in the sector; the lack of adequate technological infrastructure; and the need to address concerns about the privacy and security of data.

As for the collection of relevant data, the government and various institutions often conduct studies and gather information on public and private spending on digital health and the implementation of technologies for data exchange. However, the availability and accuracy of this data may vary.

Based on the above and recognising the urgency of regulating digital health services, it is considered that regulatory projects must comply with and at least consider the following:

- clear quality standards for providers of these services;
- a regulatory regime that aligns with the nature of the technological tools used by companies; and,
- necessary flexibility reflected in the conditions for applying the rules.

The National Centre for Technological Excellence in Health (Centro Nacional de Excelencia Tecnológica en Salud or CENETEC)[30] operates as a decentralised administrative entity under the Ministry of Health, focusing on digital health initiatives. Its responsibilities include the systematic and unbiased dissemination of health technology; the development and dissemination of national guidelines for technological infrastructure, and policies to foster the growth of telemedicine services; and the creation of clinical practice guidelines to aid healthcare providers and users in decision-making processes. Furthermore, CENETEC is tasked with establishing mechanisms to integrate technical information and standards for the exchange of data between biomedical technology and telehealth applications, promoting the adoption and use of telehealth services within the National Health System, and facilitating the integration of telematics technologies related to healthcare services. CENETEC has published the Specific Action Programme 2013–2018, aiming to advance policies and tools for the implementation and assessment of telehealth initiatives in Mexico. However, while the institution has issued criteria, recommendations, guidelines and best practices, these are not obligatory for the health system, underlining the necessity for a regulatory framework to provide clear guidelines for digital health.

Therefore, strengthening CENETEC has been suggested by giving it the capacity to: (1) establish requirements and authorise individuals or legal entities to operate as digital health service providers; (2) develop, issue and disseminate technical guidelines, policies and regulations in general to ensure quality in telemedicine and teleconsultation services; (3) supervise compliance with the Digital Health Law; (4) impose administrative sanctions; (5) promote the adoption of digital health technologies and the continuous training of health professionals and/or digital health service providers; (6) oversee the implementation of public policies on digital health within the public sector; and (7) supervise, promote and implement the interoperability of health information systems in coordination and collaboration with authorities, administrative bodies, digital health service providers and civil associations.

6. Is there any compilation of relevant data on the topic? For example, public or private expenditure on implementing digital health[31] and data sharing using technology.

In addition to NOM-024-SSA3-2012, the Federal Law for the Protection of Personal Data Held by Private Parties is another relevant legal framework in Mexico. This law regulates the processing of personal data by private entities and establishes principles and obligations regarding the collection, use and safeguarding of personal information. Some of its provisions include obtaining consent for data processing, informing individuals about the purpose of data collection, ensuring data accuracy and implementing security measures to protect personal data from unauthorised access, use or disclosure.

30 Centro Nacional de Excelencia Tecnológica en Salud www.gob.mx/salud/cenetec accessed 31 May 2024.

31 Digital Health emerges through the development of the Salud.uy programme which was initiated in 2012. The Digital Health Programme can be viewed at www.gub.uy/agencia-gobierno-electronico-sociedad-informacion-conocimiento/politicas-y-gestion/programas/es-saluduy accessed 31 May 2024.

Below are the names of the most recent information systems used in the healthcare sector in Mexico which have been developed or promoted by the federal government to improve interoperability:

1. Plataforma Nacional de Información en Salud (PNIS).[32] This platform aims to centralise and standardise health information, allowing for its exchange among different institutions and levels of care. It facilitates the management of clinical, epidemiological and administrative information nationwide. The PNIS initiative was launched as part of efforts to enhance data interoperability and strengthen health information systems across Mexico.

2. Expediente Clínico Electrónico Único (e-CU).[33] e-CU is an electronic medical record system designed to manage patients' clinical information electronically. It has been implemented in various health institutions nationwide to improve continuity of care and the quality of medical services. The rollout of the e-CU initiative has begun to modernise healthcare delivery and enhance patient outcomes through digital health records.

3. SIS. See the response to Question 2.

Moreover, specific issues to be considered in the Mexican case include: the absence of a specific regulation for the provision of online health services; issuance of electronic prescriptions – General Health Law (Art 64) versus Health Inputs Regulation (Art 29); electronic signature – lack of clarity in existing regulations regarding the validity of the signature; electronic health records – lack of clarity in the regulation of electronic health records; digital service providers – lack of a regulatory framework that regulates individuals or legal entities providing services related to digital health. In other words, it is important to have a starting point for the regulation of health services provided digitally. Therefore, it is recommended that authorities should be knowledgeable about the characteristics of each service and start by regulating elements that have been identified as cross-cutting by various members of the digital health sector, such as: (1) quality standards for video consultation services and digital health services in general; (2) electronic medical records; (3) remote issuance of medical prescriptions; and (4) providers of digital health services.

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32 Plataforma Nacional de Información en Salud www.gob.mx/salud/acciones-y-programas/direccion-general-de-informacion-en-salud-dgis accessed 31 May 2024.

33 Expediente Clínico Electrónico Único https://dof.gob.mx/nota_detalle.php?codigo=5280847&fecha=30/11/2012#gsc.tab=0 accessed 31 May 2024.

Paraguay

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1. What regulations govern the interoperability of health data in your country? If there are none, please inform us of any bills on the subject and how the issue of 'digital health' is being addressed in the country.

Although there is no specific regulation exclusively dedicated to governing data interoperability within Paraguay's healthcare system, several existing regulations serve this purpose. These are:

- Resolution No 527/2010 issued by the Ministry of Public Health and Social Welfare introduces the creation of a clinical record designed for the effective management of health service provision. It mandates the compulsory implementation of this clinical record across all health facilities, encompassing both public and private entities throughout the country.
- Resolution No 853/2015, also from the Ministry of Public Health and Social Welfare, stipulates the mandatory use of computer tools integrated into the National Health Information System (SINAIS). It is specifically designed for recording data obtained from the forms of the Health Information System (Sistema Integral de Información de la Secretaría de Salud or SIS). Its primary objective is to generate reliable, timely and accurate indicators, thereby facilitating a robust decision-making process within public, private and combined healthcare establishments.
- Resolution No 544/2018 signifies the approval of a phased implementation plan for the Health Information System (HIS) across all establishments falling under the jurisdiction of Public Health and Social Welfare.
- Organisation Manual for Health Services (RIISS) – As outlined in Resolution 423/2019 of the Ministry of Public Health and Social Welfare, this manual within the framework of the Integrated and Comprehensive Health Service Networks (RIISS), is a key methodology for governing interoperability. It serves as a comprehensive management tool, offering guidelines to facilitate the seamless implementation and monitoring of essential processes. Its overarching goals include driving progress towards achieving universal health coverage.
- Resolution No 622/2020, approved by the Ministry of Public Health and Social Welfare, validates the adoption of a new Daily Consultation Record form. This form is scheduled for implementation across all health establishments, contributing to the ongoing efforts for enhanced data interoperability.

2. Is there a single health data identification system in your country?

There is currently no unified system for health data identification at a national level in Paraguay. However, efforts are being made to make progress in this direction.

Both the creation of the clinical record for use in managing health service provision, as a mandatory implementation format in all health establishments, and the compulsory use of SINAIS computer tools could be considered steps towards establishing a unified system for health data identification.

3. Is there any kind of incentive (public or private) for the exchange of health data among stakeholders, particularly by the Ministry of Health or the corresponding agency in the country?

In Paraguay, efforts are being made to promote the exchange of health data among various stakeholders in both the public and private sectors. The Ministry of Public Health and Social Welfare is developing policies and programmes aimed at promoting interoperability and the exchange of health information between institutions and medical service providers.

In the public sector, a project is being implemented to establish a unified system of identification and registration of health data nationwide. This initiative aims to facilitate the secure and confidential exchange of clinical information among the different stakeholders in the health system. Its goal is to establish a single system for the identification and registration of health data, such as the National Digital Health System (SINASAD), enabling access to patients' clinical information by different healthcare system stakeholders, thereby improving coordination and the quality of healthcare. Furthermore, the Digital Disability Certificate (Certificado de Condición de Discapacidad or CUD) aims to implement a digital system for issuing and managing the Unique Disability Certificate. The aim is to streamline the process of obtaining and renewing the certificate, as well as to facilitate its use and validity across various public and private institutions in Paraguay.

Finally, in the private sector, we could mention the proposal for the 'SIECS' project (Health Information System) from the United States Agency for International Development (USAID) and Center for Information and Resources for Development (CIRD). The aim of this project is to develop a strategic element to drive true healthcare reform and it is committed to conceptualisation within a relevant and cutting-edge framework.

4. Is health data interoperability covered by a data protection law in your country?

It should be noted that there are other regulations, apart from those mentioned, such as the protection of the publication of information or data considered 'open data', which are not specifically for health, but apply in general terms. Open data refers to government data intended to be used, reused and freely redistributed by any citizen.

To promote transparency in Paraguayan state institutions, there are specific regulations for the protection of this data, and access to public information considered of a constitutional nature. In this regard, the relevant laws to ensure the effectiveness of this constitutional right include Law 5,189/14, 'Which establishes the obligation to provide information on the use of public resources concerning salaries and other remunerations assigned to public servants of the Republic of Paraguay'.

Law 5,282/14 on 'Free Citizen Access to Public Information and Government Transparency' establishes the minimum requirements for the disclosure of public information and citizen access to it. This law includes health data and, therefore, applies to the interoperability of health data.

Furthermore, Paraguay has ratified the Universal Declaration of Human Rights of 1948, which guarantees the right to privacy and protection against arbitrary interference in private life. This provision is also reflected in Article 17 of the International Covenant on Civil and Political Rights of 1966, ratified in Paraguay by Law No 5/1992.

As noted above, Paraguay does not have a comprehensive data protection law, but Law No 1,682/01 regulates private information. However, it was amended after a short time by Law 1,969/02.

In addition, the National Secretariat of Information and Communication Technologies (SENATICs) is the entity in charge of ensuring the protection of personal data and promoting the appropriate use of information and communication technology (ICT) in Paraguay.

5. What are the main challenges for the implementation of health data interoperability in your country?

The implementation of health data interoperability in Paraguay encounters several significant challenges. These include:

- *ICT* – The availability of advanced and suitable technology, such as computers, reliable communication networks and software, is crucial for seamless health information sharing across diverse medical services.
- *Regulatory framework* – Establishing comprehensive regulations for the exchange of health information among medical systems is imperative. Common rules ensure secure and effective information sharing. Overlapping regulations could pose obstacles, affecting the successful execution of both short- and long-term projects due to potential contradictions.
- *Data privacy* – Safeguarding patient information is paramount in upholding privacy. Robust measures must be in place, respecting constitutional and regulatory rights to prevent data leakage or inappropriate use with malicious intent.
- *Technology training* – Adequate training for healthcare personnel and those handling information is essential in comprehending the intricacies of health data exchange.
- *Cooperation across civil society sectors* – Collaboration is key among various stakeholders, including physicians, health authorities, technology companies and the private sector. Smooth health information exchange relies on collective efforts, allowing diverse perspectives to be shared and fostering collaborative initiatives based on scientific knowledge.
- *Overcoming challenges* – To address these challenges effectively, a holistic approach involving all relevant stakeholders is imperative. Such an approach should encompass strategic investment in technology, the establishment and adherence to standards and regulations, robust data protection measures, comprehensive staff training and collaborative efforts among the diverse actors within the healthcare system. This concerted strategy will be instrumental in achieving a seamless and secure exchange of health information in Paraguay.

6. Is there any compilation of relevant data on the topic? For example, public or private expenditure on implementing digital health and data sharing using technology.

There is no direct compilation of relevant data for interoperability by the Ministry of Public Health and Social Welfare, but there is some data on digital health spending and the implementation of technology for sharing data in the health sector.

For example, the health ecosystem Boldo is an innovative and revolutionary tool driven and developed by the ITAIPU Technological Park – Paraguay (PTI-PY). The system emerged to facilitate citizens' healthcare

through telemedicine and its use was widespread during the Covid-19 pandemic in response to quarantine measures.

Similarly, the health regulatory body in Paraguay has invested in digital health initiatives, such as the implementation of electronic health records and systems for the exchange of medical information. However, there is no comprehensive compilation of specific expenses made in these areas, nor in the Integrated Health Information System (SIIS), which aims to integrate and share clinical data from different healthcare institutions.

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Peru

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1. What regulations govern the interoperability of health data in your country? If there are none, please inform us of any bills on the subject and how the issue of 'digital health' is being addressed in the country.

The regulation addressing the interoperability of health data is detailed in Chapter V of the Regulation of Law No 30,024, which establishes the creation of the National Registry of Electronic Medical Records. This regulation was approved by Supreme Decree No 009-2017-SA.

To ensure the interoperability of health information systems in Peru, the Ministry of Health is expected to promulgate an additional regulation which specifies the requirements information systems must meet to ensure interoperability. This additional regulation is known as the Administrative Directive which regulates Interoperability in Healthcare Information Systems. It was approved by Ministerial Resolution No 464-2019/MINSA.

It is important to emphasise that the implementation of health data interoperability is in its initial phase in Peru.[34] Although the legal framework and guidelines for interoperability have been established, the necessary infrastructure for full implementation has not yet been completed. The Ministry of Health, through a Working Group,[35] is dedicating efforts to create a standardised clinical terminology platform and implement interoperability between public health establishments.[36]

It is essential to understand that, although the regulations exist, the process of implementing health data interoperability can be a complicated, time-consuming challenge. However, these initiatives are crucial to improving the quality of healthcare and health data management, which will benefit patients and healthcare professionals in future.

2. Is there a single health data identification system in your country?

There is currently no unique health data identification system in Peru. However, the creation of the National Repository of Standard Health Data Identifications (Repositorio Nacional de Identificaciones Estándar de Datos en Salud or RNIEDS) has been established, which aims to be the single point for the storage and management of catalogues of Standard Health Data Identifications. This will facilitate the interoperability of health information systems.

34 See the Implementation Plan of the Digital Agenda of the Health Sector – Foundational Phase 2022, approved by Ministerial Resolution No 758-2022/MINSA www.gob.pe/institucion/minsa/informes-publicaciones/3730893-plan-de-implementacion-de-la-agenda-digital-del-sector-salud-fase-fundacional-2022 accessed 31 May 2024; the Implementation Plan of the National Registry of Electronic Medical Records – RENHICE, approved by Ministerial Resolution No 618-2019/MINSA https://cdn.www.gob.pe/uploads/document/file/3690893/Documento%20T%C3%A9cnico.pdf?v=1664209158 accessed 31 May 2024.

35 Temporary nature working group responsible for supporting the implementation of the Digital Health Sector Agenda 2020-2025 (approved by Ministerial Resolution No 816-2020/MINSA), created by Ministerial Resolution No 781-2021/MINSA.

36 Implementation Plan of the Digital Agenda of the Health Sector – Foundational Phase 2022, approved by Ministerial Resolution No 758-2022/MINSA, p26.

Under this initiative, Supreme Decree No 024-2005-SA has been approved, which establishes Standard Health Data Identifications. Subsequently, these identifications were complemented and standardised through Ministerial Resolution No 902-2017-MINSA, which focuses on the identification of medical and health procedures. These health data identification standards are currently in effect.

Although a unique health data identification system has not yet been implemented, the creation of RNIEDS and the standardisation of identifications are important steps towards interoperability and the effective exchange of health data in the Peruvian healthcare system. These measures are essential in ensuring the consistency and quality of health information, which in turn will contribute to better healthcare and the more efficient management of health information.

3. Is there any kind of incentive (public or private) for the exchange of health data among stakeholders, particularly by the Ministry of Health or the corresponding agency in the country?

Regarding incentives for health data exchange among sector actors, it is important to note that, in Peru, there is a legal framework that establishes the obligation to accredit electronic information systems in health establishments. This obligation is derived from Articles 13 and 26 of Regulation No 30,024.[37] One of the essential requirements for the accreditation is that these systems comply with interoperability requirements, as established in Article 22(d).

Nevertheless, because the implementation of health data interoperability has not yet been completed by the Ministry of Health, specific details on the accreditation procedure have yet to be established. In other words, this obligation is not yet fully in force due to the continuing phase of interoperability implementation.

In this context, it is expected that once the foundational phase of the Implementation Plan of the National Electronic Medical Records Registry (Registro Nacional de Historias Clínicas Electrónicas or RENHICE) has been completed, procedures and requirements for accrediting electronic information systems in health establishments will be established. These interoperability requirements will serve as an incentive for healthcare sector actors to comply with regulations and participate in health data exchange, therefore promoting improvements in healthcare quality and health information management.

4. Is health data interoperability covered by a data protection law in your country?

Yes, health data interoperability is supported by data protection legislation in Peru. According to Regulation No 30,024, electronic information systems must be accredited by all health establishments (Article 13). To obtain this accreditation, a fundamental requirement is that the information system was previously authorised by the National Authority for Personal Data Protection and complies with the data protection requirements established in Law No 29,733 (Article 22(d) of Regulation No 30,024).

37 Art 13: 'Every public, private or mixed health establishment that has an electronic medical record information system must accredit it, on a mandatory basis, before the Ministry of Health or the Regional Health Authority, in accordance with the provisions of the Law, this Regulation and other complementary regulations'.
Art 26: 'All health establishments and public, private or mixed medical support services that have electronic or computerized medical records are required to be part of RENHICE'.

This legal approach ensures that health information is handled with due respect for patient data privacy and security. Data protection requirements are essential in protecting the confidentiality and integrity of health information, ensuring that it is not misused or accessed without authorisation.

However, it is important to note that this data protection does not limit the use of anonymised data for public policy and scientific research purposes. According to numeral 6 of Article 14 of Law No 29,733,[38] the use of anonymised data is allowed without requiring the owner's consent. This is crucial in promoting the realisation of health data-based research and public policies while protecting individuals' privacy.

5. What are the main challenges for the implementation of health data interoperability in your country?

There are essentially two main challenges. The first is that the shortage of healthcare facilities equipped with electronic information systems poses a significant problem. Currently, only a small number of medical centres have managed to implement electronic information systems.

The second is that implementation of health data interoperability is a critical step in modernising and improving a country's healthcare system. In this context, the Ministry of Health faces an important challenge as it has not yet created the necessary digital infrastructure or completed the regulatory framework to achieve health data interoperability. Health data interoperability refers to the ability of different healthcare information systems to exchange and use of data efficiently and effectively.

This is essential in ensuring that healthcare professionals have access to relevant medical information about patients, regardless of where that information was generated. This is also fundamental to improving healthcare coordination, clinical decision-making and overall healthcare system efficiency. One of the main barriers to achieving health data interoperability is the semantic standardisation of information. This involves standardising the way medical data is recorded and presented so that it can be understood and used in a digital context. This is crucial for avoiding misunderstandings and ensuring that data is used consistently throughout the healthcare system.

To address this challenge, the Ministry of Health has designed RENHICE, which establishes the steps and deadlines to achieve health data interoperability. This plan, approved by Ministerial Resolution No 618-2019-MINSA, sets a clear path towards the implementation of standardised and shareable electronic medical record systems.

The 'foundational phase' of the plan is estimated to last for three years, starting in September 2022 from the publication of the Digital Health Sector Agenda – Foundational Phase 2022, approved by Ministerial Resolution No 758-2022/MINSA. During this phase, significant progress is expected in digital infrastructure and health data standardisation, laying the groundwork for interoperability in the healthcare system.

The implementation of health data interoperability in Peru is a process of vital importance. As the Ministry of Health advances in the execution of its plan, the healthcare system will be better equipped to address future challenges effectively and offer higher quality and coordinated healthcare. This will result in more

38 See the Administrative Directive, which establishes the processing of personal data related to health or personal health data, approved by Ministerial Resolution No 688-2020/MINSA.

effective patient care, more efficient management of medical cases and better-informed clinical decision-making.

6. Is there any compilation of relevant data on the topic? For example, public or private expenditure on implementing digital health and data sharing using technology.

Information on the planned public budget is available in RENHICE and was approved through Ministerial Resolution No 618-2019-MINSA, as well as in the Implementation Plan of the Digital Health Sector Agenda – Foundational Phase 2022, approved through Ministerial Resolution No 758-2022/MINSA.

General data related to this topic is collected and stored in the National Health Information Repository.

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Uruguay

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1. What regulations govern the interoperability of health data in your country? If there are none, please inform us of any bills on the subject and how the issue of 'digital health' is being addressed in the country.

Decree No 607/2011 incorporated health as a priority in the 'Uruguay Digital Agenda 2011-2015' in order to promote improvements in the quality of health services and support technological advancements. This measure, endorsed by the Presidency of the Republic, was initiated by the Agency for Electronic Government and the Information and Knowledge Society (Agencia de Gobierno Electrónico y Sociedad de la Información y del Conocimiento or AGESIC).

There was a notable emphasis on developing information and communication technology (ICT) in health within the Uruguay Digital Agenda 2011–2015. The Agenda proposed the implementation of 'advanced health networks and electronic health records (I) integrated at the national level' to monitor the health status of the population and evaluate service conditions provided by healthcare providers. The Salud.uy project was approved in 2012 to implement this strategy, involving the Ministry of Economy, Ministry of Public Health (Ministerio de Salud Publica or MSP) and AGESIC in its governance mechanism.

In 2017, Decree 242/017 and its Ordinance 1085 established progressively obligatory phases for healthcare institutions within the National Integrated Health System (Sistema Nacional de Información en Salud or SNIS). The following year, healthcare providers collaborated with the programme to develop the implementation plan for the National Electronic Health Record (Historia Clínica Electrónica Nacional or HCEN), following regulations and using a tool for monitoring progress.

2. Is there a single health data identification system in your country?

To strengthen IT in the healthcare sector, the Salud.uy programme emerged through an agreement between the Presidency of the Republic, Agency for Electronic Government, AGESIC, MSP and Ministry of Economy and Finance (Ministerio de Economía y Finanzas or MEF).

The governance of the Salud.uy programme was established by Decree 184/015 and embodied in an Advisory Council on Digital Health Policies, comprised of representatives from the MSP, MEF, Public Policy Monitoring and Evaluation Agency, AGESIC and Health Technology Assessment Agency.

The main purpose outlined in the guidelines to support and strengthen health policies was the creation of a HCEN. This interoperability platform had two differentiated goals. In stage one, the aim was to promote continuity of care, improve record quality and enhance service complementarity among providers. In the current, second stage, the aim is to advance data analytics to support decision-making in defining public health policies, managing healthcare service providers and evaluating the quality of services provided to healthcare system users.

Uruguay's healthcare system comprises comprehensive healthcare providers, both public and private, as well as partial providers. Members of the Uruguayan population choose one of these providers to receive

healthcare, as mandated by law. Each healthcare service provider has management systems and electronic health records to administer and record the provision of services to users.

When the government decided to include healthcare in Uruguay's digital strategy, most providers had already implemented their electronic health record systems or were in the process of doing so. To recognise the work which had already been carried out and the investment made, it was established that each provider advanced health networks and electronic health records, therefore avoiding the need for a standardised nationwide installation.

In 2017, Decree 242/017 was enacted, which addresses the 'mechanisms for the exchange of clinical information for healthcare purposes through the HCEN system'.[39] Its Article 3 makes it mandatory for both public and private providers to keep electronic medical records, granting the MSP the power to define the conditions and deadlines for its implementation.

This decree also required all healthcare providers to use the National Electronic Health Record platform. In October 2017, Ministerial Ordinance No 1085/017 was approved, which supports the adoption plan of the National Electronic Health Record by all healthcare providers nationwide.

3. Is there any kind of incentive (public or private) for the exchange of health data among stakeholders, particularly by the Ministry of Health or the corresponding agency in the country?

There are currently no incentives. However, to foster compatibility through the exchange and use of clinical data managed by various IT systems, Salud.uy conceived and implemented a strategic plan known as the HCEN Adoption Plan (Plan de Adopción or PDA). Through its implementation, Uruguay's network of health service providers has achieved essential technical, syntactic and semantic interoperability, therefore establishing a fundamental component in ensuring continuity in medical care.

Within the PDA framework, deadlines and goals were established to be met by collective stakeholders in the public and private health sectors, categorised according to institutional types. This was undertaken to progress through the four stages outlined in the regulations, following the technical guidelines developed by the Salud.uy programme.

Progress continues with the implementation of the HCEN, providing support to healthcare institutions and collaborating in determining implementation priorities, as well as products related to the HCEN. These efforts are carried out by supporting each situation with its respective institutional strategic plan.

Currently, 95 per cent of the Uruguayan population has some clinical record in the HCEN. The platform has surpassed the milestone of 65 million clinical documents filed, with over 17 million event consultations conducted on the platform and an effective exchange of more than 600,000 documents.[40]

4. Is health data interoperability covered by a data protection law in your country?

The integration of Health into Uruguay's Digital Agenda, along with all the progress made possible by it, became a reality thanks to the enactment of the Personal Data Protection Law in 2008: Law No 18,331.

39 Salud Digital Uruguay, *Accesibilidad e interoperabilidad*, MSP 2023.

40 *Ibid.*

While the protection of personal data was already considered in the Constitution of the Republic, specifically in Article 72, this law establishes that such protection should extend to 'personal data recorded in any means that allows them to be processed, and to any form of subsequent use of such data by the public or private sectors'.

5. What are the main challenges for the implementation of health data interoperability in your country?

Among the fundamental challenges that Salud.uy faces for its evolution are the analytical phases aimed at decision-making, the creation of intelligent health maps and the clinical monitoring of population groups appropriate to public health. It is crucial to emphasise the importance of data quality in these contexts.

6. Is there any compilation of relevant data on the topic? For example, public or private expenditure on implementing digital health[41] and data sharing using technology.

In the 2025 Digital Agenda 2025, the main defined line of action focuses on promoting the adoption and continuous development of a technological integration platform in the health sector, both public and private. The goal is to obtain relevant data for decision-making on public policy issues. There are two notable cases of interoperability in Uruguay: the CoronavirusUy App and medical certifications.

CoronavirusUy App

The national digital strategy adopted to address the Covid-19 pandemic consisted of the gradual incorporation of various components and tools, adapting to the evolving epidemiological situation in Uruguay. These elements were developed and implemented within tight timelines thanks to close collaboration between the public and private sectors, reflecting a collective effort to respond effectively to the health crisis.

In the initial phase, to reach a larger number of people, avoid unnecessary in-person visits, relieve phone line congestion and keep the population informed, different information channels on Covid-19 were set up. Multiple digital communication channels were implemented between the population, the national health authority and health institutions.

In March 2020, a virtual assistant was launched as a chatbot to provide detailed information about the disease, preventive measures and an epidemiological questionnaire. This resource was available on state and healthcare service provider websites. Subsequently, the same virtual assistant was adapted to work on messaging platforms such as WhatsApp and Facebook Messenger, thereby expanding its reach to the entire population.

By September 2021, a total of 5.2 million transactions had been recorded through these digital channels. The most frequently used function related to the vaccination schedule, and even when the purpose was to obtain general information, there were between 2,500 and 10,000 queries generated per month. This significant use reflects the effectiveness and acceptance of these digital tools in managing pandemic-related information.

41 Digital Health emerges as the advancement of the Salud.uy programme which was initiated in 2012. The Digital Health Programme can be viewed at www.gub.uy/agencia-gobierno-electronico-sociedad-informacion-conocimiento/politicas-y-gestion/programas/es-saluduy accessed 31 May 2024.

A single form was also implemented to gather epidemiological information, which was fed with data from healthcare in both the public and private sectors. Providers utilised the platform developed from digital health records as a foundation for achieving interoperability. To ensure a continuous flow of information with laboratories, the use of virtual private networks (VPNs) was chosen. In this process, the 43 comprehensive health providers and six laboratories shared data on number of swabs and positive results.

The Ministry of Public Health processed this data and sent it to the National Emergency System (Sistema Nacional de Emergencias or SINAE), which presented a daily report to the population. Approximately one week after the first cases of Covid-19 in Uruguay, the government, with the honorary participation of the private sector, launched the CoronavirusUy App. Its main goal was to reduce waiting times and medical consultation delays, guarantee data privacy and prevent overcrowding of emergency services. In addition to providing information and facilitating the epidemiological questionnaire for the population, the App guided users in their interaction with healthcare services.

Through the CoronavirusUy App, users had the opportunity to report their travel history to countries considered at risk, the presence of symptoms and/or contact with positive cases. This data was directly routed to the respective healthcare provider, which then contacted the user and conducted a follow-up on the case, avoiding the need for the citizen to initiate communication.

This digital strategy made it possible to group the information in a single database, which facilitated the effective care of clinically suspicious cases. Moreover, it allowed the organisation of service demand according to health criteria, therefore optimising the provision of services to the population.

Medical certifications

In the final months of 2022, Uruguay introduced an innovative system for occupational medical certifications. One of its key features is that the health professional in charge of issuing the certification must enter the patient's medical information in the HCEN. In other words, the clinical act performed by the physician must be recorded.

Under this law, the Social Security Bank (Banco de Previsión Social or BPS) established the National System of Medical Certifications. This new system is currently being implemented in all public and private healthcare providers in the country.

This innovative system facilitates the coding of medical certification diagnoses. If the certification is recorded in the HCEN, a conversion process to the International Classification of Diseases, 10th edition (ICD-10), which is the coding used by the BPS, is followed. This unified approach aims to improve efficiency and consistency in the management of medical certifications, providing greater clarity and accuracy in the documentation of occupational health.

The process by which the healthcare provider uploads the patient's clinical information to be certified in the HCEN, followed by its analysis by the BPS, constitutes an extremely valuable tool in the decision-making process. In addition to enabling the conduct of statistical analyses on approved certifications, this mechanism facilitates system auditing and contributes to achieving an efficient allocation of available resources. Overall, this practice has proved key to the optimisation of management and enhancement in the quality of medical care.

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Conclusion

The examination of interoperability implementation within the healthcare sector across Latin America reveals a striking similarity in the adopted systems and structural models. The challenges encountered are also alike, including regulatory deficiencies and a plethora of non-interoperable systems.

Considering this situation, it is reasonable to anticipate both triumphs and setbacks in the quest to make interoperability in healthcare a reality. Success, however, hinges on the collaborative efforts of all stakeholders involved in its implementation. The establishment and reliance on comprehensive data lakes and data repositories, which are vital for enhancing healthcare delivery for individuals and communities, can only be achieved through standardised system communication. Without this, the healthcare sector will persist in its struggle to improve healthcare outcomes. This is due to the lack of a seamless flow of patient data between various health systems and providers, which is essential for informed decision-making and the enhancement of patient care.

The outlook for possible game changers

Technological breakthroughs

A groundbreaking technology that is often expected to revolutionise the future is blockchain. One perspective is that when applied to healthcare, it could be a key tool for achieving interoperable systems in either the public or private sector, by lowering the necessary adoption costs and streamlining technological standards.

In such a scenario, blockchain is referred to as a 'centralised platform that decentralises health data (medical records), increasing security of sensitive information [...]. This model lifts the costly burden of maintaining a patient's medical histories away from the hospitals: eventually, cost savings will make it full cycle back to the patient receiving care.'[42]

Financial incentives

Private sector interest in investing time and resources into interoperable solutions can only occur provided the costs associated with it do not hinder the return on the investments made, otherwise companies would not benefit from adhering to interoperable standards.

'Interoperability is a monumental challenge which is rarely discussed nationally and needs to be confronted before costs are driven down to open access and allow providers to explore models for improved quality of patient care'.[43]

Comprehensive public policies

As is the case with many social and economic issues, strategic government intervention can be the turning point for the future of interoperability in healthcare. As public health is often a national topic, political

42 Peter B Nichol, *The Power of Blockchain for Healthcare: How Blockchain Will Ignite The Future of Healthcare* (Peter B Nichol, 2017).

43 *Ibid.*

effort to support and invest in healthcare could be a factor to accelerate the development and adoption of interoperable standards across the system, in both public and private sectors.

In such a scenario, governments also stand to benefit from the enhanced infrastructure of data management that would help to improve public policies and resource allocation.

The future trajectory of interoperability therefore hinges on the proactive engagement of both public and private entities. While its implementation aligns with the global trend of technological progression, it requires active encouragement and acceleration from both sectors. This is particularly important as data-driven treatment and care have emerged as the basis of efficient and sustainable healthcare systems.

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