



# Governance for Digital Health

The art of health systems  
transformation.



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# Contents

<b>Overview</b>	<b>5</b>
<b>Introduction</b>	<b>8</b>
<b>Context: the challenges health systems face</b>	<b>10</b>
<b>The contribution of ICT: digital health</b>	<b>12</b>
<b>Preconditions</b>	<b>15</b>
<b>National governments and governance for digital health</b>	<b>18</b>
The government's role in governance for digital health	18
Government actions	19
<b>General management of the health system and governance for digital health</b>	<b>22</b>
The role of the health system's general management in governance for digital health	22
Actions by senior officials or general management of the health system	25
<b>Hospitals, primary care centers, and other health service providers and governance for digital health</b>	<b>28</b>
The role of hospitals and primary care centers in governance for digital health	29
Actions by hospitals and primary care centers	30
<b>Health system professionals and governance for digital health</b>	<b>32</b>
The role of health professionals in governance for digital health	33
Actions by health professionals	33
<b>Citizens and patients and governance for digital health</b>	<b>35</b>
The role of citizens and patients in governance for digital health	36
Actions by citizens and patients	36
<b>Ethical requirements and legislation on digital health</b>	<b>37</b>
Ethical requirements and digital health	38
Legislation on digital health	39
<b>Data protection and information security</b>	<b>43</b>
<b>Legal provisions on health information</b>	<b>46</b>
<b>Intellectual property rights</b>	<b>48</b>
<b>Conclusion</b>	<b>49</b>
<b>Appendix: Governance for digital health during health emergencies</b>	<b>51</b>
<b>Acknowledgments</b>	<b>54</b>
<b>References</b>	<b>55</b>

# Overview

**The digital transformation of the health system is achieved by incorporating information and communication technologies into its value chain.** This transformation requires governance that addresses rights, regulations, responsibilities, and risks in areas such as internet and health; using health data; and information systems. The aim of digital health governance is to improve the quality, efficiency, and effectiveness of the health system. The triple Burden of Disease (non-communicable diseases, infectious diseases, and external factors); fiscal and financial sustainability; and the need to improve the effectiveness and quality of medical care necessitate profound changes in the health system and make it critical to bring about its digital transformation.

**Governance for digital health requires strategy, funding, guarantees of the rights of all involved, and connectivity.** The leadership and commitment of the authorities and of health system directors form part of this strategy. Digital health is related to strategic government and health system decisions, health expenditure, health professionals, patients, and human rights, and it also requires specific laws.

The government's role is to explicitly back digital transformation, ensure consistency and synergies between different policies, provide funding and infrastructure, and pass or promote the necessary laws. **To make the digital transformation of the health system possible, governments must take the following steps, among others:**

1. Declare digital health a national priority.
2. Provide precise, clear, and public support for the digital health strategy.
3. Give digital health multi-year funding.
4. Make sure the digital health and digital agenda strategies are consistent with each other.
5. Promote training for IT engineers.
6. Promote training on digital health for IT engineers and health personnel.

7. Ensure connectivity for hospitals and other health centers and services, and equip them with the necessary infrastructure.
8. Promote and pass laws needed to grant legal certainty to all stakeholders.

The health system's senior officials, its general management, are responsible for designing and implementing the digital health strategy. The strategy's general objectives should center on improving the quality, efficiency, and effectiveness of the health system. Senior officials should ensure that information systems, and later digital health, form part of the health strategy. The implementation of that strategy also needs to be planned and monitored, evaluating the criteria for success, which measure the extent to which digital transformation improves the health system.

Hospitals and health centers must ensure that digital transformation adds value for patients and professionals. They also need to implement health information systems and promote responsible use of information. To achieve this, they need to take part in decision-making, as well as encourage and facilitate the participation of health professionals.

Professionals should continually seek the innovation that makes digital transformation possible, define their health information needs, support the implementation of electronic health records, participate in pilot programs, and evaluate new functionalities. Citizens and patients should defend their rights, confirm that digital transformation adds value, and advocate for necessary legislative changes.

Digital transformation should be based on the requirements of professional ethics, since that transformation directly relates to people's fundamental rights, such as the rights to privacy, bodily integrity, health, liberty, a private life, and confidentiality. Laws are needed to turn ethical principles into human rights.

#### **Digital health laws must cover at least the following aspects:**

1. The legal validity of electronic records of health information and documents, of electronic prescriptions, and of telehealth.
2. The obligation to record, safeguard, and guarantee the security of information resulting from health care. Information security includes all aspects related to data protection.
3. The content of health records, specifying the medical documents, their structure, and the minimum information they should contain.
4. The protocols and standards to be used to ensure interoperability and the governance procedures for that interoperability.
5. Patients' specific rights in relation to their data.
6. The uses of health records, which can be care-related, legal, and for generating knowledge.

**Digital transformation aims to improve the health system, which means bettering the health of individuals and the population.**

The criteria used to measure the impact of digital transformation should take the perspective of the patient and the population into account. Digital transformation should never lose sight of people's rights, in accordance with ethical requirements and the law.

# Introduction

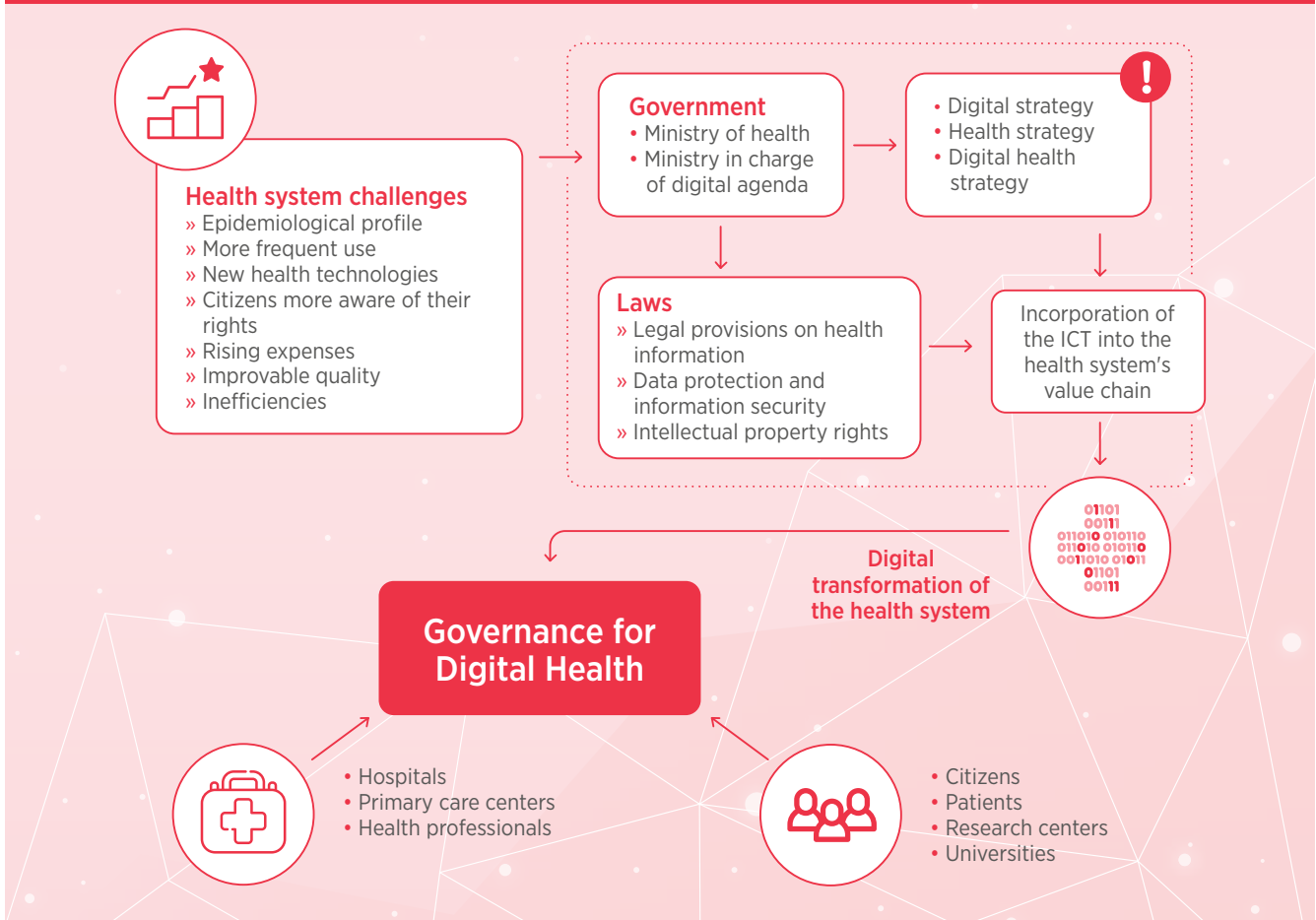
**Governance is defined as the art or method of governing that pursues lasting economic, social, and institutional development, fostering a healthy balance between the state, civil society, and the market.** Kauffman specifies that “governance is the traditions and institutions that determine how authority is exercised in a particular country. This includes (1) the process by which governments are selected, monitored, and replaced, and held accountable to the general public; (2) the capacity of governments to manage resources efficiently and formulate, implement, and enforce sound policies and regulations for the development of the country and the good of all; and (3) the respect of citizens and the state for the institutions that govern economic and social interactions among them.” Essentially, governance requires prioritizing the general good in a context of rule of law. Applying this concept to digital health, governance includes aspects related to rights, regulations, responsibilities, and risks in areas such as internet and health; use of health data; and information systems. Sound digital health governance involves participation, transparency, accountability to society, fairness, and effectiveness, all in a context of rule of law (Kauffman 2000, WHO).

Governance for digital health can be defined as the exercise of political, administrative, and technical authority to manage everything associated with the health information system, in all areas of a national health system. The structure of this governance consists of the mechanisms, processes, and institutions through which all stakeholders articulate their interests, exercise their rights, meet their obligations, resolve their differences, and oversee the operation of the health information system (Smith 2013).

Digital health is the result of incorporating information and communication technologies (ICT) into health systems and services—an opportunity for transformation that requires a new form of governance. Digital health governance should take into account the health system’s challenges and strategies, its leadership, the interests and rights of all stakeholders, the laws needed, and the difficulties of implementing ICT in the health system, among many other aspects (Figure 1)



Figure 1: Elements that shape governance for digital health



ICT help transform the health system when incorporated into its value chain. They become an essential tool for planning, managing, and evaluating healthcare, and most of all for providing the care itself. This is achieved when incorporating ICT into the value chain makes them a clinical tool in their own right. This transformation of the health system requires a new form of governance: governance for digital health.

The purpose of this publication is to describe the main characteristics of digital health governance in order to analyze the role that should be played by the main stakeholders, such as the national government, health authorities, professionals, and citizens and patients. It also describes the main aspects that laws should address.

# Context: the challenges health systems face

**The Americas region has a triple burden of disease: chronic or non-communicable diseases, infectious or communicable diseases, and injuries or morbidity caused by external agents<sup>1</sup>.** Most public health systems face various challenges, including population aging, which raises the incidence and prevalence of chronic diseases, and more frequent use of healthcare services. Another major challenge for health systems is the constant incorporation of new health technologies resulting from research and development, whether pharmaceuticals or instruments and techniques for diagnosis and treatment. Additionally, there is greater civic awareness of people's rights, which translates to stronger demands for quality in health services. All of this drives up health expenditure, putting significant strain on budgets that is further exacerbated by economic crises. **Figure 1.**

In addition to these factors that lead to increased health spending, Western health systems have five shortcomings that cannot be resolved by scientific progress: failure to prevent preventable diseases, low patient safety levels, undesired variations in quality, inefficient use of resources, and inequality, both in access to the system and in terms of outcomes (Muir Gray 2011). These shortcomings are partly responsible for rising health expenditure and take a heavy toll on society (Carnicero 2016).

In short, the triple burden of disease; fiscal and financial sustainability; and the need to improve the effectiveness and quality of medical care require intensive data processing to obtain exhaustive and high-quality information to be used to take the steps needed to improve the health system's quality, effectiveness, and sustainability. This push to generate knowledge is unthinkable without incorporating ICT into the health system's value chain. Incorporating ICT into the health system improves its efficacy, but when they are part of the value chain, they also help improve its quality, efficiency, and effectiveness, and drive the digital transformation of the health system (Rojas 2015).

A demographic transition is underway in the Americas, which is experiencing population aging. In 2019, the profile of all sub-regions showed a growing proportion of older people. That same year, people over age 65 in the Americas numbered 116 million, or 12% of the region's total population. Excess weight and

<sup>1</sup> Causes due to external agents: mortality due to accidents and violence, including self-inflicted injuries.

obesity are the main risk factors associated with cardiovascular diseases, diabetes, and some types of cancer. The prevalence of excess weight and obesity has risen sharply over the last 20 years (PAHO 2019).

**Progressive population aging, along with the increased prevalence of risk factors, has resulted in a higher incidence of non-communicable chronic diseases (NCD) such as cardiovascular diseases, which are the leading cause of death, followed by cancer.** Although cancer's mortality rate has declined, it is estimated that more than half of all cancer deaths could be prevented using existing treatments. When mortality is broken down into broad categories, NCDs predominate: in 2000, they accounted for 77% of all deaths, a figure which rose to 81% in 2016. Meanwhile, deaths due to infectious and neonatal diseases have fallen, as has maternal and nutrition-related mortality. It can be concluded that the region continues to experience a demographic and epidemiological transition (PAHO 2019).

The pharmaceutical industry generates high expectations but also causes major headaches for health systems. Some new medications are highly beneficial to patients, like new treatments for cancer or acquired immunodeficiency syndrome that have made these diseases chronic instead of terminal, or the new treatment for hepatitis C, which is indisputably effective but also cost-prohibitive for some health systems. However, the added value of new medications does not always justify their high price tag. (OECD 2017).

**All of this context indicates that health systems should go beyond just evaluating activity and cost, as they traditionally do, and also pursue results that bring value to both patients and society. They should therefore make sense for both, no matter how intangible or difficult to evaluate these results may be.** To guarantee the system's sustainability, there has to be a move away from the concepts of efficacy and cost and towards quality, efficiency, and effectiveness. Effectiveness and efficiency form part of quality. To measure quality, the assessment of patients and citizens of the services they received should also be taken into account. In addition to addressing general satisfaction, these assessments should also contain indicators that evaluate specific aspects of the process used to provide them care. This scheme proposes a patient-centered way of organizing health care that focuses on achieving outcomes defined previously in general objectives, is lean, clearly defines roles and responsibilities, and cuts costs wherever it is possible and reasonable to do so (Porter 2013).

**The triple burden of disease, fiscal and financial sustainability, and the need to improve the effectiveness and quality of medical care all necessitate a digital transformation of the health system. This transformation requires a new form of governance: governance for digital health.**

# The Contribution of ICT: Digital Health

There is widespread agreement about the benefits of incorporating ICT into the health system. These benefits are: (González Bernaldo de Quirós 2012, OECD 2010).

- **Improved quality and efficiency**
- **Lower operating costs for medical services**
- **Lower administrative costs**
- **The possibility of new forms of care**
- **Greater effectiveness**

In short, ICT help improve the health system's quality, efficiency, and effectiveness because health care and public health systems operate based on intensive data processing and the generation of new information, and ICT facilitate or enable that processing. In addition to processing data and producing information, the health system has always been an important generator of knowledge. The challenges described in the previous section make it imperative that this knowledge be applied to the health system as soon as possible to improve the three attributes mentioned above: quality, efficiency, and effectiveness.

ICT help improve efficiency, because data, when recorded electronically, can be shared with anyone providing care to the patient, regardless of time or location, and even concurrently. Sharing information and making it easier to access whenever needed improves the continuity of care, which in itself is a measure of quality, and also helps prevent repeated examinations and make care more effective, because it constantly adds the new knowledge being generated and allows treatments to be tailored to the patient's specific characteristics. Among other benefits that contribute to efficiency and quality, ICT also make it possible to implement clinical decision support systems. All of these benefits reduce administrative costs and the cost of care for patients. (Carnicero 2002, Carnicero 2012, Carnicero 2005-2006).

**ICT improve quality and patient safety.** To use ICT in health systems, unique identification systems must be in place to prevent serious errors. Electronic records allow confirmation that the treatments supplied or given match prescriptions; warn of possible drug interactions; and prevent examinations, medications

and other treatments that could be counter-indicated from being prescribed. ICT also make it possible to electronically record the pre-surgery checklist immediately prior to surgery and generally help health professionals make the best clinical decisions in each situation. Additionally, ICT allow each doctor, clinical service, hospital, or health center to evaluate their objectives and shortcomings, and verify their contribution to the health system's value chain and their addition to improving the population's health. (Ay Ayaad 2019, Robinson 2018, Tanoubi 2017, Campanella 2016, Carnicero 2005- 2006, Carnicero 2016)

**ICT enable personalized and precise medicine, which means better quality and effectiveness.** Diagnostic imaging is an example that can already be used, because diagnostic support systems, especially for breast diseases, were introduced years ago. Diagnostic imaging has been enhanced by the inclusion of radiomics, which is the process of converting medical images into objective and quantifiable data to detect patterns that provide information on a specific patient's disease. This tool is already being used to screen medical images as a diagnostic support, and some claim it will revolutionize the medical specialties of diagnostic imaging. Since radiomics uses big data, it eliminates—or at least reduces—subjectivity and variations between professionals. This technology allows professionals to more quickly narrow in on an approach to diagnosing and treating each patient. This improves the accuracy of diagnoses, and therefore quality and effectiveness as well (Lambin 2017, Rizzo 2018).

**Similar strides have been made in the different but closely related discipline of radiogenomics.** This computational discipline matches the data taken from medical images of a tissue or tumor with its genetic information (gene expression patterns, genetic mutations). Radiomics and radiogenomics signify a shift in biomedical imaging from a descriptive, essentially qualitative role to a predictive, more quantitative one. The potential of both disciplines lies not only in identifying pathological processes, but also in discovering the underlying pathophysiological mechanisms using only the medical image. When used together, the two disciplines hold great potential for personalized cancer treatment (Saini 2019).

**ICT also help improve effectiveness because they make it possible to quickly apply new knowledge to improve care and to continue to generate further new knowledge.** Applying new knowledge in a clinical setting helps tailor care to each patient's specific needs and makes it easier to achieve the expected outcomes for society as a whole and for each patient. Furthermore, ICT make it possible to analyze health data, which in turn facilitates self-assessment by professionals, planning, evaluation, and administration of the health system. All this allows the decisions made in each area to be based on information generated by the health system itself, instead of on theoretical information or

information with little scientific basis. Given these properties, ITC are an invaluable tool for achieving a health system based on providing value to patients and citizens.

In addition to the advantages already described above, ICT enable the processing and analysis of large data streams that exist precisely because these technologies were incorporated into the health system. This data processing and knowledge generation that contributes to efficiency and effectiveness should be framed as a direct step toward achieving the health system's general objectives (Carnicero 2019, Rojas 2018, Carnicero 2018, Martin-Sanchez 2014, Martin-Sanchez 2017).

Digital health also allows patients to securely access their medical information and also to enter their own health information in their electronic health record, thus furthering self-care, which is key to controlling NCD. For example patients themselves can enter key information such as weight in patients with heart failure, blood pressure, blood glucose levels, or heart rate, making this data available to their healthcare team. Additionally, ICT make telehealth possible. This solution is very important for areas that are remote, have a highly dispersed population, or have trouble hiring professionals.

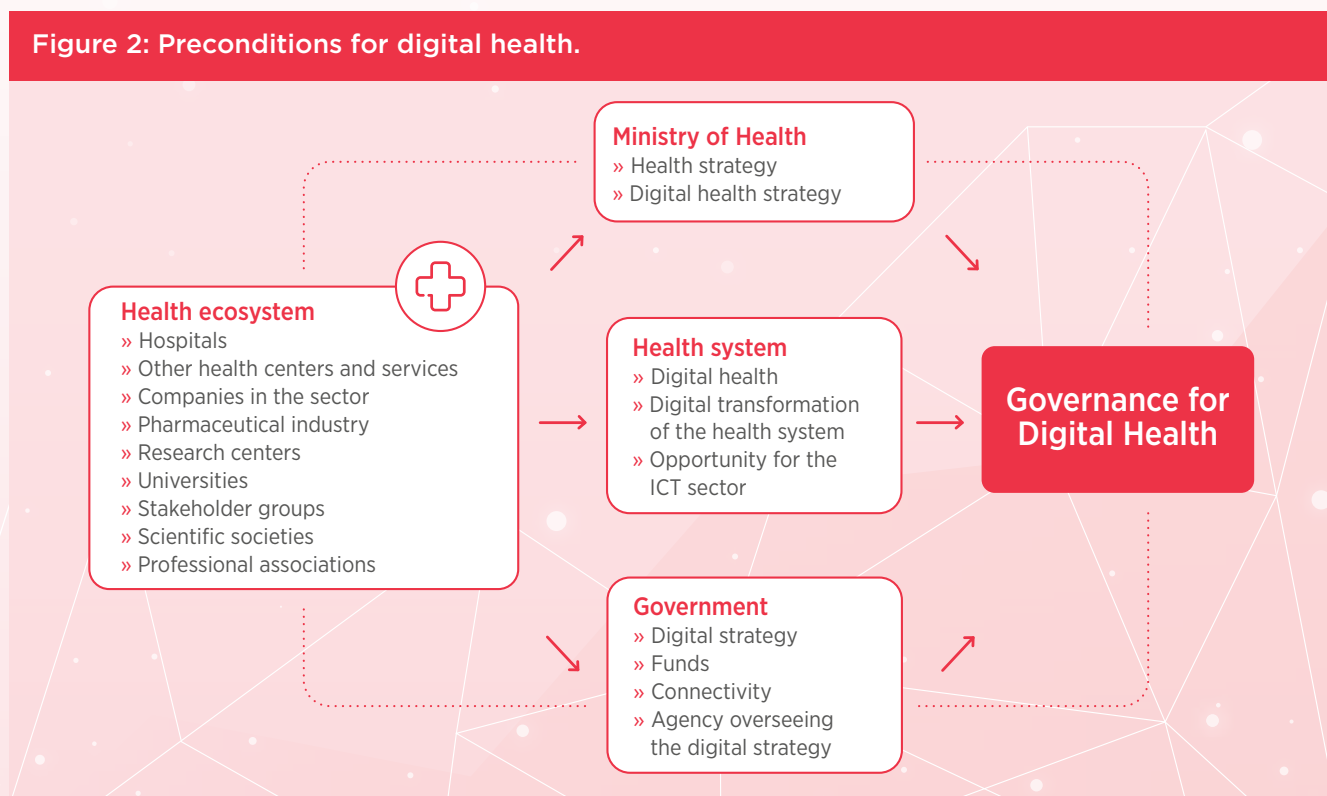
The contribution of ICT enables the transformation of the health system. This transformation relies so heavily on digital health that it becomes strategic. Digital transformation affects people's rights, strategic health system decisions, health expenditure, clinical professionals, and patients, and it also requires specific laws. The strategic contribution of ICT to the digital transformation of the health system, its repercussions for people's rights, and the need for specific laws make it crucial to have a system for digital health governance.

# Preconditions

**Digital health governance requires strategy, funding, guarantees of the rights of all involved, and connectivity.** The leadership and commitment of the authorities and of health system directors form part of this strategy. Transforming the system by incorporating digital health is a complex, costly, and lengthy task in which the interests of all parties need to be reconciled.

This requires government planning to set broad objectives and guarantee the coherence of its actions. This planning materializes in the digital and health strategies, of which the digital health strategy forms part. The ultimate aim is to transform the health system, which is also a major opportunity for the ICT sector.

Figure 2 sums up the preconditions for digital health.



**The national government should have a funded digital strategy to bring all citizens and businesses into the digital age and equip the country with communication infrastructure.** This strategy should also set goals for implementing e-government, and it should make well qualified professionals available to companies and government agencies to make all of these projects possible. This strategy is generally called the digital agenda. However, the digital agenda tackle the digitalization, much less the digital transformation, of the health system; this is the responsibility of the health system authorities.

It is important to avoid confusing the digitalization of the government administration with the digitalization and digital transformation of the health system. The digital health strategy must form part of and be integrated into the health system strategy. Health authorities should have primary responsibility for administrating it, with the collaboration of those in charge of the digital agenda. One possibility to consider is creating an agency that oversees the digital agenda. Among other responsibilities, it would be tasked with working with the health system to achieve digitalization. This would create joint management with the health system that would leverage the synergies created between the digital agenda and the digital transformation of the health system<sup>2</sup>.

The Ministry of Health should devise a health strategy with objectives set based on the population's health and that relies on information technologies and systems to achieve those objectives. The digital health strategy is an essential tool for transforming the health system. It is not an end in itself, but is rather part of the health strategy because it aims to improve the quality, efficiency, and effectiveness of the system. The health strategy and the digital health strategy share the same objectives. The digital strategy for the health system should be designed by those in charge of the health system according to each country's organizational structure and approved by the Ministry of Health. The strategy should also have multi-year funding and health and IT professionals who specialize in health information technologies and systems.

Government and health authorities must ensure the consistency of their strategies to leverage the synergies that might arise between them. For example, digital health requires communication infrastructure and qualified professionals, aspects which the government should include in its digital strategy. Additionally, digitalizing health is an opportunity for countries' businesses to develop technologically, which is one of the objectives of the digital agenda. All this requires strong leadership that champions digitalization, sets priorities that reconcile objectives and interests, and ensures the necessary long-term vision.

The health system is part of a health ecosystem, a concept broader than the health system itself. This ecosystem is a set of

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<sup>2</sup> AGESIC and Salud.uy in Uruguay are examples of this type of agency.  
<https://www.gub.uy/agencia-gobierno-electronico-sociedad-informacion-conocimiento/>  
<https://www.gub.uy/agencia-gobierno-electronico-sociedad-informacion-conocimiento/saluduy>



patient-centered entities that can become a cluster or business hub that taps into its synergies. The ecosystem includes hospitals and other health centers and services, businesses in the medical industry, research centers, universities, stakeholder groups, and professional associations, among others. Both the health system and all of these organizations can and should cooperate on service delivery, professional training plans, innovation, and research, which are shared objectives of the health system and digital agenda. Additionally, these organizations generate, share, and process health information, and they should be included in the process of digitalizing health (**Table 1**).

All of this leads to the conclusion that the following actors are relevant to governance for digital health.

1. National government, ministries of health and of the digital agenda.
2. General management of the health system, including its system and IT managers.
3. Hospitals, primary care centers, and other health services.
4. Health system professionals.
5. Citizens and patients.

All of these parties have an important role to play and are responsible for the actions needed to ensure the transformation of the health system and contribute to digital health governance. The other entities in the health ecosystem have a smaller role in digital health governance, even though they use the system and generate health information.

# National governments and governance for digital health

The Ministry of Health should take the lead on digital health governance, but as explained above, the ministry responsible for the digital agenda also plays a very important part. Table 1 gives an overview of the government's role in digital health governance.

Table 1: National governments and governance for digital health

ROLE	ACTIONS
Explicit support for the project	Define digital health as a country-wide or national project.
Funding	Approve a digital health strategy as part of the health strategy and fund it.
Guaranteeing consistency and synergies between different policies	Establish priorities and fund them.
Infrastructure and connectivity Interoperability and standards	Equip the country with the necessary communication infrastructure and define the interoperability framework.
Legal certainty	Pass laws on data protection, patient rights, the validity of electronic records, and other matters.
Propose laws needed for digital health governance to the legislature Pass regulations that allow laws on digital health to be enforced	Draft the bills needed for digital health governance Draft the regulations and technical notes needed in order to enforce laws.

## >> The government's role in governance for digital health

The digital transformation of the health system requires a multi-year plan. This plan must have the express and explicit **support of the government**. This backing must be precise, clear, and public: precise because it lays out the plan's objectives and resources in a specific way; clear because in addition to being publicized, it removes obstacles to implementing this plan; and public, because the plan is shared with the population.

The government should establish the core focuses of the digital agenda and health strategy. The different ministerial departments are responsible for fleshing out the strategies, funding them, and

setting them as a priority in their yearly and multi-year plans. These steps will make all directors and professionals, and even citizens, aware of the government's objectives, of the priority given to digitalization objectives, and of the explicit support in the form of funding for this priority. Additionally, it is the government's job to ensure **consistency** between the digital agenda and the digital health strategy in order to leverage their **synergies** and keep them from conflicting with each other.

The health planning objectives should also be precise, clear, and explicit. The best way to make these objectives precise and explicit is to use them as criteria for assessing the performance of directors and professionals. The digital health strategy, as mentioned before, needs to be linked to the health strategy, form part of it, be **funded**, meaning it has been allocated the necessary budget. Since the duration of the plan is measured in years, the budget plan should span several years. It is essential that funding covers **infrastructure, connectivity**, info-structure (**interoperability, standards**), change management, and training for digital health professionals, among other aspects.

Incorporating ICT into the health system means shifting to a new way of managing data, information, and the system itself. It changes how information is processed, as well as how care is provided and how hospitals and primary care centers are managed. It also changes patient relations and patients' role in their own care. Given all of these shifts, the legal framework has to be updated to ensure **legislation** that protects the rights of all stakeholders. This legal overhaul must be done systematically and establish the rules that will govern digital health. Such a reform will give all stakeholders the **legal certainty** required for the digital transformation of the health system.

## >> **Government actions**

As asserted above, the government must expressly and explicitly support the digitalization of the health system. This support should manifest itself in specific actions, some of which have high symbolic value, such as declaring digital health a **national or countrywide project**. The value of this type of declaration more than just symbolic for three reasons. First, because everyone will be aware of the importance the authorities place on digital health. There is no better motivation for senior officials and government workers than the importance the authorities place on a specific project. Second, because following that declaration, the project is more likely to be well-funded when competing with other government programs or projects. Third, the declaration becomes a tool for bridging the digital divide since citizens become aware of the priority the government is giving to digital health. But fourth, and most of all, because it means the government makes a commitment to citizens, who in turn can demand results, whether directly

or through their representatives. However, it should be emphasized that making digital health a hallmark of an administration or of a certain political group is not a good practice. As explained previously, it is a nationwide state project that transcends specific administrations and outlasts the typical political cycles in the executive branch. On the other hand, it is a good practice for the current administration and the opposition to agree to approach the health system and digital health as state policies designed to improve the population's health.

Again, it is imperative that the **digital health strategy be linked to the health strategy**. This connection is much more involved than just tacking a digital health plan onto the planning for the health system. Rather, it means ensuring that the health objectives and digital health objectives are one in the same; that digital health planning and objectives materialize in a way that meets the health plan's objectives; and that from the outset the digital strategy is considered a tool for improving the quality, efficiency, and effectiveness of the health system. For example, if one of the health system's priorities is to improve care for patients with non-communicable diseases and the evaluation criterion is the ratio of hospital admissions or emergency room visits to the number of patients covered by the plan, the information system should take this into account and help managers monitor this metric. A plan for caring for these patients requires being able to identify them. It also requires that the whole healthcare team be able to access and record each patient's health information in their file, and that hospital records keep track of readmissions of these patients and the emergency care they are provided, among other functions needed to successfully implement the plan. In short, the health system's priorities are the priorities of its information system.

On the other hand, the digital health strategy should also set its own **priorities**, taking into account the basic tools and features needed for the information system to work properly. This strategy should establish the patient identification system; the architecture of the information system; the information security and patient safety policies; and the teams in charge of analyzing, developing, implementing, maintaining, and upgrading the information system, among many other tasks. But the strategy should never lose sight of the health system's objectives. All this should materialize in short-term and long-term plans. One of the short-term plans should be for preparing and approving the **interoperability framework**.

Once the objectives have been set, resources need to be allocated to the plan. These resources can be professionals: ICT engineers, medical professionals, health system administrators, and digital health administrators. Material resources are needed as well: **communications infrastructures**, equipment, and basic software. It is important not to overlook the costs of developing, maintaining and upgrading the system. All this should be reflected

in the **budget**. It is important for the digital health strategy to have measurement criteria and standards that allow managers to monitor it and evaluate the plan. Publishing the results of this type of plan is not a widespread practice, but it is important to do so at least every two years to keep citizens informed and maintain a certain level of pressure that drives its success.

Governments must undertake another task that falls within their responsibility: promoting the **laws** needed for digital health, as well as preparing and approving the **regulations and technical notes** needed in order to enforce the laws. Although the necessary legislation is described in more detail in Section 9, the basic laws needed to ensure legal certainty for all should address:

- The **validity of electronic records** containing health information, like electronic health records, electronic prescriptions, electronic medical documents, as well as the validity of mobile health, telehealth, and the use of remote patient monitoring devices. A key aspect of these regulations is the patient identification procedure (unique identifier)<sup>3</sup>.
- **Data protection** and the security of health information. These regulations should also cover the use of digital certificates and electronic signatures.
- **Patient rights** in relation to health information.
- The rights and obligations of health professionals, organizations, and health establishments with regards to health information.

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<sup>3</sup> The term for health records varies from country to country; medical file, medical records or other expressions are used.

# General management of the health system and governance for digital health

Health systems usually have a specific general director's office, general management, or department with a similar name that answers to the Ministry of Health. The director or general manager represents the health system, has final authority over it, sets specific objectives, allocates resources, and evaluates results. These duties also apply to digital health. **Table 2** provides an overview of the role of the health system's general management in digital health governance.

There are four reasons why it is essential for digital health to be administered and governed by the health system. First, digital health is the health system's main tool for achieving its objectives. Second, as was already mentioned, the digital health strategy is part of the health system. Third, the health system is not public administration, but is rather a public service, which is very different. Lastly, the complex implementation of digital health requires deep knowledge of the health system and of the needs of its professionals, patients, and citizens. Digital health should be consistent with the digital agenda and leverage synergies between them, but this does not mean that another government department should be in charge of digital health. This would be the opposite of what is most advisable, as explained previously.

## >> The role of the health system's general management in governance for digital health

The top leadership of the health system should include digital health as one of its core strategies supporting its objectives, and as the essential tool for improving the system. Usually one of the health system's management bodies is in charge of directly overseeing digital health. The strategy must ensure that information systems, and later on digital health, form part of the health strategy.

It is the responsibility of the health system's leadership to **create the digital health strategy** and **put it into practice**. The strategy involves planning, and therefore also evaluating, the implementation of electronic health records, which are the backbone of the health information system.

**Table 2: General management of the health system and governance for digital health**

ROLE	ACTIONS
<b>Creating the digital health strategy</b>	Create the digital health strategy with the objectives of improving the quality, efficiency, and effectiveness of the health system. Ensure that information systems, and later on digital health, form part of the health strategy.
<b>Practical implementation of the health and digital health strategies</b>	The short- and medium-term plan should set the objectives, goals, and budget for a period of about 6 to 8 years. It should establish milestones and targets every two years to evaluate outcomes and progressively introduce new functionalities.
<b>Operational planning and management oversight</b>	Develop the two- and four-year work plan with intermediate goals. The plan should have a budget and specific funding for centers where pilot projects take place and for the most advanced centers.
<b>Defining the criteria for success</b>	Specify the scope, timeframe, and cost of each milestone. It is crucial to link these criteria and standards to health system improvements.
<b>Defining the model for information systems and electronic health records</b>	Develop and follow the policies and procedures for information security and patient safety from the outset. Define the model for electronic health records, their information architecture, and a framework for interoperability with standards to be used by all health organizations and establishments, among other important matters.
<b>Guaranteeing the participation of all stakeholders</b>	Create task forces to establish the model for information systems and electronic health records. These support teams should have the resources they need to do their job. One or more task force should participate in the process of developing, implementing, maintaining, evaluating, and upgrading the system.
<b>Leadership and plan facilitator</b>	Senior officials should lead the digital transformation of the health system. The facilitator role consists of giving the plan the resources it needs beyond just funds; for example, ensuring the availability of experts and explicitly supporting task forces. Promote the creation or strengthening of programs for degrees in IT engineering and other technical fields. Ensure initial training for both ICT and health professionals on digital health, health information, and medical documentation.

One of the tasks of the health system's senior officials is to define the **criteria for success** for digital health. It is important to define these criteria and implement them to avoid having a system that meets all the requirements set in the operational and strategic planning, but is not useful.

In other words, the criteria for success should reflect operational and efficacy factors, but they should also center on effectiveness and be guided by the question of what digital health contributes to improving the health system and to its digital transformation. Therefore, **these criteria should be linked to improving the health system**. This forces digital health planning to adopt the objectives of the health system itself to keep digital health from becoming an end in itself.

The aspects that the **model for information systems and health records** should define include:

- **Information security policies and procedures.**
- **Health records model.** This task is crucial for medical and nursing professionals.
- The **information architecture**, which is closely tied to the previous point, in order to organize the information and make it easier to use.
- The **interoperability frameworks, standards**, report templates and structures, and models for other essential medical documents.

An important way to eliminate organizational obstacles is to ensure **the participation of all digital health stakeholders**. In addition to eliminating obstacles, this participation is one way to ensure the efficacy and effectiveness of digital health, as well as to ensure that its objectives are consistent with those of the health system and that the organization's operational needs will be taken into account.

Senior officials have other key roles, such as **leadership** and **facilitation**. The role of facilitator involves more than allocating funds and declaring digital health a priority objective. It should also **guarantee participation** in order to engage health system professionals with digital health projects, for example, by establishing that the time those professionals spend on these tasks will be counted as part of their activity. The facilitator must also be attentive so that the inevitable obstacles to implementing the information systems, which are generally organizational, can be quickly removed. Senior officials should facilitate and also **lead** the plan. The two roles are intertwined because the leadership role, which is essential for the plan, is strengthened by the role of facilitator.



## >> **Actions by the senior officials or general management of the health system**

The health system's management is responsible for designing the digital health strategy, which should have the general objectives of **improving the quality, efficiency, and effectiveness of the health system**. It must be ensured that **information systems, and later on digital health, form part of the health strategy**. To achieve this close connection, it is necessary to define the information system and technology needs for each health system objective. This binds the objectives of the health system and the digital health objectives to each other, ensuring that health system directors will be motivated to develop digital health.

The digital strategy has to have a specific **short- and medium-term plan**. This plan should set the **objectives, goals, and budget** for a period of about 6 to 8 years. The plan should also include a long-term vision to guarantee the coherence of all actions, but it is important for it to have intermediate goals. A short term plan (for example, two years) that establishes these intermediate **goals** and how they are to be evaluated is important to avoid the discouragement that arises in all projects when results are slow to materialize despite having worked intensely and enthusiastically during the first stages of analysis. Launching **new information system functionalities** in a short timeframe, for example, every 6 to 12 months, also helps start the cycle of improving systems, as everyone learns about ICT's potential for their activity and the analysis and development of subsequent stages is also enriched. To execute this strategy, the achievements of each stage should be tested out in pilot centers, which should have resources (**budget**), leadership, and support from senior officials. After evaluating the results of experiences at pilot centers, the necessary management oversight will be applied to correct shortcomings, adjust time frames and objectives, and set new goals where necessary. This results evaluation should verify whether the criteria for success have been met and whether the results are **linked to improving the health system**. In other words, the evaluation covers **scope, timeframe, and cost**, as well as the effectiveness of new digital health functionalities.

It is important to follow **patient safety and information security policies and procedures** at all times when analyzing, developing, implementing, maintaining, and upgrading the information system. It is also crucial to exercise **leadership**, always on the basis of technical studies, to define the proper architecture, identifying and listing the different functional blocks to meet all requirements for the information system. This work should also encompass information to be shared between different centers and services; the rules for accessing, recording and analyzing data and information; and interoperability. All of these tasks require expert professionals in the areas of ICT, medicine, and health service administration, and even legal advisors. It is the health system's

responsibility to make these resources available to the project and, if necessary, apply to the relevant authorities for training for professionals who specialize in these disciplines.

The task of establishing the **model for information and electronic health record systems** includes the following aspects, in addition to those already mentioned:

- **Defining the model for both electronic and traditional health records.** This task can be difficult because there will be staunch proponents of problem-based or episode-based health records; of one single record for primary and hospital care; or of separate primary and hospital care records. This controversy is unnecessary, since the records contain the same information, just in different formats.
- Establishing the **information architecture**, which is closely tied to the previous point, to organize the information and make it easier to use.
- Determining the **interoperability frameworks, standards**, report templates and structures, and models for other essential medical documents. It is very important for the interoperability framework to be established at the outset, because not all organizations and establishments will be using the same systems and applications. Thus everyone is obligated to use an interoperability framework that ensures patients will always have their medical information when needed for their care, regardless of when and where that care is provided. This also helps integrate the health information system with public health and epidemiological surveillance systems, as well as with health system administration systems, like those for logistics and human resource management, among others.

It is important that **all stakeholders participate** in designing the digital health strategy. This ensures that information systems will be valuable for everyone and also makes it possible to predict future resistance to change. **Task forces** are created to achieve this. Of especial importance is health professionals' participation in analyzing and designing the technical requirements, but so is the participation of patients, researchers, and epidemiologists, for similar reasons. Reconciling everyone's interests can be a complex job requiring extensive knowledge and strong **leadership**. And one of the jobs of the health system's management is to identify possible leaders and support their work, so they can later also lead upgrades and improvements to the information system. Another important task for senior officials is to **provide these task forces with the support and resources they need**. These task forces actively collaborate to **develop, implement, maintain, and upgrade the system**.

The health system's management should exercise **leadership** that directs digital health actions, promotes their development, and ensures that they are linked to the health system's objectives. This leadership is also important at each level of the health system, both for digital health and in the general management of primary care centers and hospitals. This leadership is successful when: senior officials actively engage with the task of defining the strategic objectives and criteria for success, with the participation of key people; the link between the objectives of the health system and those of digital health is made explicit; the creation of task forces is facilitated and these groups are given resources and report back on their activity; differences are resolved and the necessary decisions are made; and, lastly, the plan's results are evaluated. In short, leadership is achieved by setting objectives, allocating resources, defining criteria, making decisions, and evaluating the plan's implementation. Management oversight and evaluation should lead to, among other things, improvements to management and modifications to objectives and goals to make them more in line with reality. Good leadership also means that task forces are aware that oversight is paired with the actions needed to achieve the plan.

The health system cannot be digitalized and transformed without the necessary knowledge. The process requires expert professionals in both health and technical fields. To have these professionals, it is crucial **to promote the creation or strengthening of undergraduate or graduate degrees in information and communications technology** engineering, and specializations in digital health. Also needed are professionals who specialize **in digital health, health information, and medical documents.**

# Hospitals, primary care centers, and other health service providers and governance for digital health

Broadly speaking, the purposes of a health system are to improve the health of each of its patients and of the population. The resources needed to achieve these objectives are essentially professionals, centers where health care is provided, and public health services. Most activity occurs in hospitals and other health-care centers, so it is critical that they have an information system that provides optimal conditions for their work. **Table 3** gives an overview of the role of healthcare centers in digital health governance.

Digital health is a major opportunity for disease prevention and health promotion programs implemented at the primary care level. A good information system allows the population to be segmented by needs. Examples of these needs include health education programs, immunizations, or breast or colon cancer screenings. With this type of system, these activities can also be recorded and entered in the electronic health record system. Digital health also allows integration between the public health and healthcare information systems, giving public health professionals constant access to the relevant medical information. Again, it is important to link the digital health and health strategies.

**Table 3: Hospitals, primary care centers, and other health service providers and digital health governance**

ROLE	ACTIONS
Participating in decision-making	Create and support task forces and committees
Guaranteeing that digital health provides value for patients and professionals	Professional should support, supervise, and evaluate the implementation. The quest for innovation should be constant
Implementing electronic health records	Evaluate each project goal. Propose improvements
Promoting responsible use of information and of the improvements brought by digital health	Promote clinical activity self-assessment systems and clinical decision support systems. Use health information as the principal tool for the establishment's planning, management oversight, and evaluation

### >> The role of hospitals and primary care centers in governance for digital health

The implementation of ICT is particularly important at primary care centers and hospitals because they are the core of the health system's activities. To incorporate ICT into their value chain, it is crucial to ensure the technology is useful to health professionals, especially doctors and nurses. Therefore, the first objectives is that the information system **be valuable to medical professionals**, because if the information system does not facilitate and improve their work, it will not be possible to achieve the objectives of digital health or of the health system. Therefore, health professionals and health center administrators need to **be involved in making decisions** in the following areas:

- The analysis and development process, as this is the best way to ensure the efficacy and good human factors design of the information system, which are both essential to its success.
- **Implementing** information systems, which is always a difficult task and requires constant support for the primary users.
- This support should take the form of training, guidance during the first steps, swift correction of errors or incidents, and availability.
- **Supervision and evaluation**, because these professionals should be the ones commenting on how useful the system is in their work and proposing improvements. Proposed improvements should be implemented quickly to avoid discouragement. These suggestions are crucial and should be given on a reoccurring basis because for information systems, anything that does not improve matters inevitably makes them worse.

Health establishments should promote **responsible use of information** and the improvements brought by digital health. As stated before, digital health is not an end in itself, but is rather a means to improving the health system.

To achieve this improvement, the information generated as a result of digitalization must be used responsibly to help accomplish the health system's objectives.

Therefore, the role of hospitals and health centers is to first facilitate the participation of their professionals. Second, they should foster the incorporation of ICT into healthcare, and third, they need to provide the necessary conditions for pilot tests. The aim of all of these steps is to collect the information needed to help the health system meet its objectives.

## >> **Actions by hospitals and primary care centers**

As explained previously, ensuring the participation of professionals at all stages of creating a health information system is key. This participation can be guaranteed by providing the necessary resources and arrangements for them to be part of **task forces and committees**. These arrangements include, for example, counting time spent on this participation as time worked, or considering participation on these task forces as a plus in performance evaluations. Directors of centers and services should encourage professionals to review how they organize patient care, seeking ways to improve processes and freeing physicians from having to do tasks that bring little value and that can be done by people whose professional profile is more appropriate for these jobs. As already explained, electronically recording health information is a major opportunity to improve its quality. Hospitals and health centers should **constantly strive for innovation** to keep health information in electronic format from becoming a copy of paper versions and to take full advantage of the benefits offered by information technologies and systems. Without this innovation, the health system can be made more efficacious, at best, but it will not be possible to achieve its digitalization, much less digital transformation.

Involving medical professionals, who are usually the ones entering and analyzing health information, is critical for ensuring that the system **provides value to patients and professionals**. Identifying key people and having them participate in designing how data is entered, in modeling information, and in the overall design of the system greatly increases the chances of successfully implementing that system. Their perspective is also indispensable to achieving an information system that increases the efficiency and utility, and therefore value, of electronic health records. This will allow professionals to record and analyze information at the time of providing care, evaluate the healthcare process, evaluate their own performance based on the health information recorded, and also use that information for research projects.

It is also important for physicians and other professionals involved in digital health to have the resources they need for this task, particularly time, assistance from IT engineers, knowledge of the digital health strategy, and recognition of their work. Also, those involved in these projects should get to propose the centers and services where trial runs and pilot projects will be carried out. This is a way of rewarding their efforts and also of ensuring that the first trials of the system will be spearheaded by people deeply engaged with digital health. However, if the professionals' proposals, initiatives, and assessments are not heeded, all of these efforts will be pointless and participation will inevitably drop off.

On the other hand, it is critical for the center's objectives to be aligned with the strategies for the health system and digital health. To guarantee that consistency, the digital health project must be part of the center's management plan, meaning its objectives are too. Its outcomes are assessed under the same plan, and successes are rewarded in accordance with it.

Management teams at hospitals and primary care centers should identify the professionals who can act as leaders for digital health and who will play a key role in analyzing, implementing, evaluating, and proposing improvements. This leadership is especially necessary during the stage of **supervising and evaluating implementation** and proposing improvements. Lack of professional leadership virtually guarantees failure. That is why it is so important for management teams to support especially engaged professionals in all aspects. For example, in their interactions with information technology services, they should support their suggestions and criteria and provide them with resources, as mentioned previously.

The management of health establishments should promote **clinical activity self-assessment systems and clinical decision support systems**, as well as other functionalities offered by digital health. There is no improvement without evaluations, and this evaluation chiefly concerns physicians themselves, who should know the quality and cost of their activity. Information systems should have an easy-to-use functionality that allows physicians to conduct this self-assessment. Senior managers should have access to a similar assessment feature.

Hospitals should use health information as the fundamental tool for the establishment's **planning, management oversight, and evaluation. To go beyond merely** evaluating activity and cost to also pursue results that provide value to patients and society, health information must be used in management teams' main tasks. The way to evaluate quality and effectiveness is to analyze health information. This analysis must be rounded out by the patient's point of view.

# Health system professionals and governance for digital health

The health system is characterized by medical professionals who provide care directly to people, make independent decisions that affect their patients' health, and are the system's main expense. Therefore, health information systems, like electronic health records and information systems for clinical analysis, diagnostic imaging, and pharmaceuticals, among others, should help care be delivered with the highest possible quality and efficiency. One of the main attributes of quality is patient safety, which is closely linked to information systems (Carnicero 2016).

**Table 4: Health system professionals and governance for digital health**

ROLE	ACTIONS
Innovation	Propose changes within the organization (innovation)
Establishing requirements	Participate in establishing requirements and semantic definitions
Supporting implementation	Use electronic health records and other health information systems, participate in pilot projects and in the implementation phase
Participating in pilot projects	Evaluate results (how much value is provided) Propose improvements

The digital health governance needs of the health system's professionals have to do with the legal validity of health records, including medical prescriptions or other medical orders, as well as the confidentiality of health information and information security aspects such as the availability, completeness, and non-repudiation of information. Other frequent concerns of this group include the legal requirements for analyzing health data for assessments, quality improvement, innovation, and research, as well as who owns the intellectual property rights to research that uses health data.



## >> The role of health professionals in governance for digital health

Health professionals, especially doctors and nurses, are digital health's main users. They listen to and examine patients, record the resulting information, analyze it, and make decisions based on that analysis, on their knowledge, and on clinical decision support tools when available. All of this goes into electronic health records, which is the backbone of the health information system.

Therefore, as described previously, they play a key role in analyzing, implementing, using, assessing, and upgrading the information system. If the information system is valuable to their daily work, they will not only accept it, but also champion it and take advantage of all of its possibilities. For this to happen, professionals need to engage and share their perspectives and needs. They also need to reflect on how health care is **organized** to seek **innovation**, define their requirements, help implement new versions, and participate in **pilot projects**. Finally, they have to **use** these new versions in their daily activity, **assess the value they provide**, and **propose improvements**. They have to accept that digital health goes beyond mimicking paper processes and rather analyze these processes to innovate in search of excellence, tapping into the new possibilities of digital health.

## >> Actions by health professionals

Health professionals should actively participate in all digital health projects. They play an essential role in the analysis phase, during which they share how they are organized, their information recording and analysis needs, the connections to other sources of information, and the medical documents they use, among other key information. This means that they need to be involved in task forces and committees. Their work should generate the **proposed changes** within the organization that drive the innovation needed for digital transformation, and the proposals for the necessary **requirements**. Health professionals plan an important role in the **semantic** definitions that will be used in the governance of the health ecosystem.

It is important to do trials or pilot projects before implementation to evaluate whether systems meet the established requirements, are useful, and are feasible to implement. Professionals, both those already involved and others who have not participated in the project, should evaluate these tests and propose improvements prior to final **implementation**, for which their participation is necessary.

**Evaluation** is always a thankless task that requires time and patience, but the axiom that there is no improvement without evaluation applies here, as does the principle that whatever does not improve tends to get worse. That is why it is so important for health professionals to evaluate information systems, their human factors design, and the value they provide, as well as to suggest improvements. It is important for these proposals to be taken into account and rapidly incorporated into new versions to avoid discouragement, which inevitably leads to difficulties.

Of equal importance to all of these actions is reflecting on healthcare processes and how they can be improved through digitalization. Out-of-date processes that are digitalized are still out-of-date processes, only now they are much more expensive, a situation that should be avoided at all costs. This innovation is only possible when health professionals engage and exercise leadership.

# Citizens and patients and governance for digital health

The point of public health systems and healthcare systems is to improve the health of the population and of each patient. This patient-centered focus should materialize as respect for their rights and as participation by patients in decisions that concern them. People’s relationship to the health system has gradually shifted over the last several decades. The classic, paternalistic model where patients passively accepted their physician’s decisions about their health, with limited information that at best was shared with a family member or close friend, no longer exists. In the 21st century, patients demand information on their health and the opportunity to participate in decisions that concern them. Patients now know and demand their rights. **Table 5** provides an overview of the role of citizens and patients in governance for digital health.

**Table 5: Citizens and patients and governance for digital health**

ROLE	ACTIONS
Defending their rights	Forming associations as a channel for participation
Promoting improvements	Participating in task forces
Pushing for necessary legislative changes	Making proposals Evaluating results (the value they provide)

Among other rights, patients have a right to health care that meets the quality standards needed for them to regain their health, to make decisions about the health care they receive, to have their information available when needed, and to access health information. Citizens have a right to have conditions needed to maintain and improve their health be guaranteed.

## >> **The role of citizens and patients in governance for digital health**

Individuals' main role in digital health is **defending their rights**. Patients should request and even require or demand access to their health information, and demand medical documentation that reflects their health status, is available when needed, meets pre-established quality standards, and is kept secure. They also have a right to authorize the diagnostic procedures and treatments recommended to them.

Digital health can entail certain changes in how citizens and patients interact with the health system. In theory, the aim of these changes is to improve the quality of service. Although people may be somewhat resistant in some cases, the hope is that patients will support the improvements they suggest, evaluate them, accept them, and recommend ways to perfect them.

Digitalization usually brings with it a need for new laws, because incorporating ICT into the health system means transforming that system. For example, one useful feature of digital health is patients' ability to directly and remotely access their health information. Laws are needed to govern what can be accessed and the security conditions for that access. Citizens and patients play the role of **promoting** and influencing the **development of laws** on all matters related to digital health.

## >> **Actions by citizens and patients**

For citizens and patients to take the measures needed for exercising their rights, their best course of action is to form **associations** that **channel their participation** and interaction with the system and healthcare providers. Through these organizations, they should participate in **task forces** and advisory bodies to weigh in on decisions that affect them.

That participation should not become merely a means for demanding improvements. It is also a channel for making well-founded **proposals** to government and health system authorities and directors. In matters that directly affect them, both patients and the general populace should be familiar with and analyze the evaluations of digital health. It is crucial to ascertain whether the progress made in digital health actually **provides value** to those it concerns most directly, whether it makes their life better or easier, and whether they can better control their diseases. All of these actions require people who are engaged and generous enough to give their time and effort for the benefit of all.

# Ethical requirements and legislation on digital health

As explained previously, digital health makes intensive processing of data and information inherent to the health system more efficacious. Additionally, it provides ease of access; the ability to share, reproduce, and send information and use it simultaneously; and the ability to analyze large quantities of data. This last characteristic is very valuable for research and for health system planning and management.

Since health information is a private matter, respecting confidentiality is mandatory for everyone. This is a common point of concern for patients and citizens in general, professionals, and health system directors. There is a widely recognized tension between availability, which makes it easier to use and record health information when needed, and mechanisms for controlling access to information, which sacrifice availability for the sake of confidentiality (MacDonald 2001). This tension between access to information and confidentiality also extends to ease of analysis of information and respect for patient rights, because respecting confidentiality makes it more difficult to analyze data. These and other conflicts should be resolved through ethical requirements and laws<sup>4</sup>.

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<sup>4</sup> Here is my dilemma. I want my notes to be strictly confidential but readily accessible to those who need them (Rhona MacDonald 2001).

## >> Ethical requirements and digital health

The aim of professional ethics is to inspire health professionals' conduct and hold them to high standards for the quality of the care they provide to patients. Professional ethics promotes trust-based relationships with patients, where both parties acknowledge and respect each other based on each other's dignity. Professional-patient, professional-professional, or professional-third-party relationships are aspects that cannot be governed just by laws. For ethical rules and recommendations to be valid, they do not need legal approval. Their validity is not something added or imposed by an external authority; rather, it is something that society demands and requires of professionals (León-Sanz 2008).

As stated in the Declaration “*Ética de la historia*” [*Ethics of Health Records*]: “*The goods and values related to health records are especially important, as they are directly related to people’s fundamental rights, such as the rights to a private life, bodily integrity, health, liberty, confidentiality, and privacy*” (Yuguero del Moral 2004).

The availability of technology that can analyze big data related to people’s health brings new concerns that are not limited to confidentiality. As summarized by Pilar León (Leon-Sanz, P. 2019), the six key areas of the bioethical debate on analyzing big data in healthcare are:

- 1. *The quality, accuracy, adequacy, and validity of the data and algorithms, questions related to transparency and confidence in the use of the data;***
- 2. *The need for adequate information for professionals, researchers, citizens, and policy makers to understand the implications of big data;***
- 3. *The requirement to respect the privacy of individuals and of groups of people with similar profiles, because the possibility of discrimination derived from the information obtained through big data should be avoided;***
- 4. *The consent of the persons to the cession of data and to the flow of the information, as well as good practices regarding the ways to obtain them;***
- 5. *The responsibility of health professionals in general, of researchers, of the managers, and computer specialists in their professional performance has been emphasized;***

**6. That Institutions and Public Administrations have to support the development of big data, taking into account equity and solidarity to avoid inequalities or discrimination, especially of vulnerable persons or groups.**

Analysis of large databases is a complex social practice, where ethical tensions and possible conflicts of interest exist. Spaces for ethical reflection should be built to account for their use, to resolve possible contradictions, and promote procedures based on the search for good—not merely acceptable—solutions. Ultimately, good uses and good practices will be a function of the improvements that the analysis of large masses of data can introduce to the care of the individual patient and the health of society in general.

Professor Pilar León also clearly summarized the relationship between ethics and legislation: *“Ideally, professional ethics and laws should be one and the same. Indeed, the regulations on the security of medical information show that it is possible for the spheres of professional ethics and law to coincide, as most of the laws in force were already stated in codes of conduct and ethical recommendations for health professions. In recent years, certain ethical duties have transformed into legal ones: society can now require that responsibility. Specific legal regulations on health information and documentation is a recent development; normally these matters were addressed in the professional ethics aspect of health professions.”* (León-Sanz 2008).

**>> Legislation on digital health**

The incorporation of information and communication technologies systems into health systems always leads to debates about information security (especially confidentiality), the validity of electronic records, and intellectual property rights. Essentially, the concerns triggered by digital health center on legal certainty for everyone directly involved in the health system: citizens and patients; the professionals who provide care and those who analyze health information; and health systems, health centers, hospitals, and public health services. All of these concerns highlight the need for laws that reconcile everyone’s rights, and, therefore, their obligations and responsibilities as well. **Table 6** lists the concerns of different digital health stakeholders and the legal provisions that should govern those matters.

**Table 6: Concerns and laws about digital health**

Stakeholders	Main concerns	Laws
<b>Citizens and patients</b>	Access to their health information Health information kept in a safe and readily available way	Access to their health information Data protection and information security
<b>Health professionals</b>	Validity of electronic records and medical orders Validity of telehealth Validity of electronic prescriptions Confidentiality Access to medical information for improving quality and research Interoperability	Content and validity of electronic health records, telehealth, and electronic prescriptions Data protection Secondary uses of health information Use of dictionaries for terminology (CIE 10; SNOMED)
<b>Health centers and hospitals</b>	Secure storage of health information for a set period of time Access to health information for assessment, management oversight, inspection, and quality improvement purposes Interoperability	Purposes of health records and their safekeeping Data protection Secondary uses of health information Use of standards (HL7) for exchanging and storing information (governance for interoperability) Responsibility of the health establishment for its information system, for correctly integrating it, and for communication standards and protocols (like FHIR)
<b>Public health systems</b>	Access to and processing of medical data for public health	Legal requirements for sending data between different centers and services within the health system Secondary uses of health information Data protection Responsibility of public health for its information system, for correctly integrating it, and for communication standards and protocols (like FHIR)
<b>Research centers</b>	Access to health information Intellectual property rights	Secondary uses of health information Data protection Intellectual property laws



Anyone who works with health information processes data that others have recorded and generates new data that becomes information. All stakeholders—patients, healthcare professionals, hospitals or other health centers, the health system, and research centers—hold rights to health information. For that reason, **attempting to determine who owns the health information is not advisable. It is more appropriate to determine who holds what rights. Essentially, legal provisions should establish who has a right to do what with the health information, under what conditions, and what their obligations are** (Andérez 2003). This criterion is the most logical and the one best aligned with the fundamentals of health information. Patients have a right to access their information and obtain a copy of their records. Physicians and other health professionals are required to record the information and create the health record using the information the patient gives them, the information they provide and record, and their analysis of that information. Hospitals and other health establishments contribute the infrastructure and information systems and have the duty of safeguarding health records. Medical research and its findings are of public interest, so they need to be taken into account. Additionally, a person's medical file or health record is considered a legal document, and this status has ramifications for all the parties mentioned.

In Spain, which follows the criterion outlined above regarding who holds rights to the health information, there has been minimal litigation on the issue. The Supreme Court has issued no decisions on the matter, and the judgments that have been issued uphold this criterion. For instance, Judgment 36/2019 from January 21, 2019, issued by the Provincial Court of Málaga (Appeal 1092/2017) explicitly states:

*“The Court essentially agrees with the above considerations and does not accept the criterion put forth by the appellant that gives the patient absolute and exclusive power to decide what is done with the health record created by the defendant physician in order to carry out the process of providing care to Ms. Delfina. Rather, it supports the inclusive or eclectic theory—of the theories that have been articulated in the sphere of scientific literature—which holds that a **health record belongs to the doctor, the patient, and the institution**. It belongs to the physician in that he or she created it, the patient in that the file contains records of the entire process of his or her care, and the health institution as the entity in charge of its safekeeping.”*

Judgment 529/2010 from July 23, 2010, issued by the Provincial Court of Pontevedra (Appeal 3016/2008), reaches a similar conclusion:

“The Court holds that **the ‘ownership’ of health records can only be spoken of in a figurative or incorrect sense**. When speaking of the ownership of medical files, we are ultimately attempting

to decide and determine who is supposed to possess and keep them, which is essentially what is at issue in this proceeding, which is to say, whether Dr. Donato could on his own decide to take with him the records of the offices of the plaintiffs as if they were his and his alone, to deliver them to and keep them at another center, or whether to the contrary he was required to respect the right and duty of safekeeping primarily and legally granted to COG Pintado and CM Pintado. An author once wrote that **none of these three parties is the absolute owner of the record; there is a convergence of rights and duties.** Of course, physicians that practice medicine with the full autonomy of a private practice do “own” health records, and are therefore responsible for their safekeeping. In the case of practitioners who provide services as employees, for example at a center or institution, the health record belongs to the center where the professional provides his or her services. In these cases it must be understood that preparing the health record is among the duties inherent to the employment relationship between the physician and the center. This holds true for the statutory relationship between physicians and Social Security, for example. In both cases, this is without prejudice to the moral right the professional may hold, for example, in relation to defending his or her authorship or the right to be cited or recognized as author in situations where the file is legitimately divulged, or, lastly, respect for the completeness of its contents.”

The main legal concepts related to digital health are data protection, validity, uses and content of health records, and the laws on intellectual property. The general aspects that should be taken into account when drafting these laws are outlined below.

# Data protection and information security

<sup>5</sup> For example:

- Statutory law 1581 of 2012 of the Republic of Colombia. Available at: <http://www.suin-juriscol.gov.co/view-Document.asp?ruta=Leyes/1684507>
- Law 18331 of Uruguay on personal data protection. Available at: <https://www.impo.com.uy/bases/leyes/18331-2008/29>
- The Chilean personal data protection law. Available at: <https://www.levchile.cl/Navegar?idNorma=141599>

<sup>6</sup> For example:

- Law 18335 on the rights and obligations of patients and users of Uruguay's health services. Available at: <https://www.impo.com.uy/bases/leyes/18335-2008>
- Law 26529 of Argentina on Patient Rights in their Relationship with Health Professionals and Institutions. Available at: <http://servicios.infoleg.gob.ar/infolegInternet/anexos/160000-164999/160432/norma.htm>
- Lei nº 13.787 de 27 de dezembro de 2018 Dispõe sobre a digitalização e a utilização de sistemas informatizados para a guarda, o armazenamento e o manuseio de prontuário de paciente. Available at: [https://legislacao.presidencia.gov.br/ficha/?legisla/legislacao.nsf/View\\_Identificacao/lei%2013.787-2018&OpenDocument](https://legislacao.presidencia.gov.br/ficha/?legisla/legislacao.nsf/View_Identificacao/lei%2013.787-2018&OpenDocument)
- El Salvador. Resolution No. 941.- Technical Regulations for Compiling, Safeguarding, and Consulting Medical Records. Available at: <http://asp.salud.gob.sv/regulacion/pdf/norma/normatecnicaconformacioncustodiacion-sultaexpedienteclinico.pdf>
- Basic Law 41/2002 of November 14 governing patient autonomy and rights and obligations for health information and documentation in Spain. Available at: <https://www.boe.es/buscar/act.php?id=BOE-A-2002-22188>

The concept of information security is broader than just data protection. It concerns the policies, organization, and mechanisms needed to ensure that security. Protecting health data has always been a right and an obligation. Long before digital health was developed and ICT were available, hospitals and other healthcare centers were already required to store their patients' medical information, make it available when necessary, and maintain confidentiality. These obligations were explicitly stated in a specific law or implied in regulations on healthcare.

However, the development of ICT brought with it a greater awareness of all aspects related to data protection and information security, which resulted in, among other things, a new generation of data protection laws and, in the health industry, laws on electronic health records. In the health sector, patients and professionals expressed concern about confidentiality and secondary uses of data. Hospitals and other centers articulated unease about the security measures they were required to implement, about safeguarding information, about their responsibilities with regards to information security, and about the arrangements needed to ensure medical information remains secure. Health systems and services showed interest in using data for evaluations, planning, management oversight, quality improvement, innovation, and research. In addition to all this, patients requested access to the data, and even the ability to modify or erase it. All of these developments made it necessary to update regulations on data protection and make them explicit. **The laws passed in different countries cover the following aspects:**

- Data protection and information security<sup>5</sup>.
- Validity of and requirements for health information in digital format<sup>6</sup>.
- Validity of electronic prescriptions<sup>7</sup>.

**7** For example:

- Chile. Decree amending Decree No. 466 of 1984 of the Ministry of Health, which approves the regulations for pharmacies, drugstores, pharmaceutical warehouses, medical supplies units, and authorized storage areas with regards to pharmaceutical e-commerce. Available at: <https://www.diariooficial.interior.gob.cl/publicaciones/2020/05/07/42649/01/1759228.pdf>
- Royal Decree 1718/2010 of Spain, from December 17, on medical prescriptions and dispensation orders. Available at: <https://www.boe.es/buscar/pdf/2011/BOE-A-2011-1013-consolidado.pdf>
- Provisions in Brazil in response to the coronavirus pandemic. Available at: [http://www.sbis.org.br/images/Nota\\_de\\_Posicionamento\\_Receita\\_Digital.pdf](http://www.sbis.org.br/images/Nota_de_Posicionamento_Receita_Digital.pdf)

**8** Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data defines the rights of access, rectification, erasure, and objection as follows:

1. Right of access: the right to obtain from the controller confirmation as to whether or not personal data concerning him or her are being processed, and, where that is the case, access to the personal data and information on the purposes of the processing of that data, its safeguarding, and others.
2. Right to rectification: the data subject shall have the right to obtain from the controller without undue delay the rectification of inaccurate personal data concerning him or her.
3. Right to erasure: the data subject shall have the right to obtain from the controller the erasure of personal data concerning him or her without undue delay.
4. Right to object: the data subject shall have the right to object, on grounds relating to his or her particular situation, at any time to processing of personal data concerning him or her when necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller or when processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child, unless the controller demonstrates compelling legitimate grounds for the processing which override the interests, rights and freedoms of the data subject or for the establishment, exercise or defense of legal claims.

Regulation (EU) 2016/679 on data protection Available at:

- <https://www.boe.es/buscar/doc.php?id=DOUE-L-2016-80807>

Information security requires guaranteeing the following aspects of health information: (Garbayo 2002)

1. That it be available. This means it can be accessed and used when needed. Service-level agreements are established for this purpose.
2. That only authorized parties have access to and the ability to use the information. This requires identifying those authorized parties, who are granted permission for specific tasks. These are the processes of identification, authorization, and assigning profiles and roles. Digital certificates are the best identification mechanism.
3. That information remain complete, meaning it is not modified while stored or transported. This is the quality of completeness. The most appropriate mechanism is the electronic signature.
4. That whoever participates in a transaction cannot then deny it. This is the quality of non-repudiation. The best mechanisms are digital certificates and electronic signatures.
5. That the organization be able to verify who accessed the information and what transactions they participated in. This is the audit process.

The safekeeping of the health information also needs to be ensured. As mentioned previously, this is the responsibility of establishments, hospitals, primary care centers, and other places where care is provided.

The legal provisions on information security and data protection should recognize that health information is a private matter and should therefore have the highest level of legal protection. More specifically, laws on data protection are expected to address people's rights in relation to their personal data: access, rectification, erasure, and objection, as established, for example, in the European Union's General Data Protection Regulation (GDPR)<sup>8</sup>. However, when dealing with health information, certain qualifications apply to the right of erasure. Hospitals and healthcare centers have the obligation to safeguard the health information of their patients, and that health information is a legal document as well. Additionally, as already explained, various parties have rights and obligations with regards to health information.

Therefore, health information cannot be erased based on the patient's sole decision, unless the erasure is to correct an error in

that information<sup>9</sup>. Furthermore, it is important to avoid the inconsistencies between general data protection provisions and regulations on health information that have arisen on some occasions. For example, in some cases periods for safeguarding and storing health information that are different from those established in general data protection regulations have been set.

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<sup>9</sup> Article 18 of Argentina's Law 26.529 on Patient Rights in their Relationship with Health Professionals and Institutions, which establishes the obligation of health establishments to keep data for 10 years, reads as follows: "The obligation to safeguard data does not allow it to be erased: Inviolability. Depositaries. Health records are inviolable. Public or private health establishments and health professionals, when operating private practices, are in charge of safeguarding health records, and are considered their depositaries, and they are required to arrange the measures and resources keep unauthorized people from accessing the information contained in them. The provisions on contracts set forth in Book II, Section III, of Title XV of the Civil Code "on depositing" and related rules extend to and apply to depositaries.

The obligations stated in the preceding paragraph should remain in effect for at least TEN (10) years before they are released from contractual liability. This term is calculated from the last action recorded in the health records. Once the term has ended, the depositary will dispose of the records as established by in the regulations." Article 8 of El Salvador's Technical Regulations for Compiling, Safeguarding, and Consulting Medical Records limits the right to erasure as follows:

"In exercising the right to erasure, all data that is unsuitable or beyond what is needed for healthcare may be erased. In the erasure request, the user must specify the data in question, providing supporting documents, except when these documents are specialized medical tests that must be performed by the entities bound by the Public Information Access Law, through the Public Information Access Unit for the establishment or institution, which will bring it to the attention of the establishment's senior management in order to carry out the request. The senior management of the establishment, along with the health professionals who entered the data in question in the medical record, will decide whether to erase the data as requested, provided the data is not needed for the patient's medical care."

# Legal provisions on health information

When health information is recorded and kept on paper, its validity is not questioned. However, when it is recorded electronically, professionals and healthcare centers become uncertain of its legal validity. Healthcare professionals constantly aim to ensure the confidentiality and legal validity of electronic records to avoid potential liability. Later, when they experience the first service level incidents in relation to electronic health records, their concern shifts to availability. In other words, their focus is on being able to access the health information they need to provide care to their patients. Just as paper health records used to get lost on occasion, incidents (service outages) that block access to the health information can occur when the information is in electronic format. Losing paper information and not having health information available when needed are both serious security incidents that should be addressed in the relevant prevention and contingency plans.

**Laws that address all of these concerns should cover at least the following aspects of health information:**

- 1.** The legal validity of electronic records of health information and documents, as well as the legal validity of electronic prescriptions, mobile health, and telehealth.
- 2.** The procedure for identifying (common identifier) and also authenticating patients for accessing their health information.
- 3.** The obligation to record health information, keep it safe, and guarantee its security. The use of the digital certificates and electronic signatures.
- 4.** The content of health records, specifying the medical documents, their structure, and the minimum information they should contain.
- 5.** The protocols and standards to be used to ensure interoperability and the governance procedures for that interoperability.
- 6.** Patients' specific rights in relation to their data.
- 7.** The uses of health records, which can be care-related, educational, legal, and for knowledge generation.

Knowledge generation from analyzing health information has been revolutionized by the availability of technologies that can rapidly process and make use of big data. This analysis of big health data has led to another source of concern for society, and

especially researchers, regarding laws that allow them to analyze health data. This analysis requires good data and algorithms: simply analyzing millions of data points does not provide a better picture of reality unless the right algorithms are used. The following ethical requirements should be met (Leon-Sanz 2019).

- Data analysis needs to be technically correct, accurate, and have good statistical performance.
- The study's objectives should be defined to show whether the potential benefits justify the use of the data.
- The algorithm that best fits the objectives of the analysis to be performed should be used. Different types of algorithms involve different ethical challenges.
- Results should not be extrapolated beyond the scope of the study, and the inevitable limitations arising from uncertainty about the accuracy of the data and the statistical power of the analysis should be taken into account.
- It is essential to avoid bias in the data analysis expert who designs a given algorithm, or who attempts to adjust the performance of each algorithm to the dataset or to the objectives of the research.

The general regulations on data protection and people's rights are applicable to analysis of big data. According to the GDPR and other data protection laws,<sup>10</sup> the basic legal grounds for processing personal data in projects using big data are:

- Consent. Consent must be freely given, explicit, and able to be withdrawn (Article 7 GDPR).
- Processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract.
- Processing is necessary for compliance with a legal obligation to which the controller is subject.
- Processing is necessary in order to protect the vital interests of the data subject or of another natural person. This principle should be construed in the strict sense, because the vital interest should be linked to a serious and direct risk, not a potential and future one.
- Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller. This will be the most useful tool in research projects involving big data.
- Satisfying legitimate interests pursued by the controller, provided the fundamental rights and freedoms of the data subject are not violated. To apply this principle, it will be necessary to analyze the balance between legitimate interest and rights and freedoms.

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<sup>10</sup> Por ejemplo:

- Uruguay's personal data protection law
- Statutory law 1581 of 2012 of the Republic of Colombia

# Intellectual property rights

Intellectual property rights to health information are a frequent concern. Physicians often argue that they hold the intellectual property rights to health records. However, as explained previously, the discussion should not center on who owns the health information, but rather on who holds what rights. Some laws on health records, for example, grant patients access to their health information, but also give physicians the right to exclude from that access the subjective notes that physicians enter in those records. This access restriction does not cover everything physicians enter in the records, but rather specifically and solely the *subjective* notes physicians want to record in the file to remind them of certain circumstances that can help them care for their patients, for example, references to family or domestic matters that a physician suspects could be related to the process affecting that specific patient, or similar situations<sup>11</sup>.

Health information is a very valuable source for generating knowledge. The information's richness and the effort that goes into recording and analyzing it inevitably give rise to difficulties in determining the intellectual property rights to the medical data. One debate, for example, is whether the health professional who record the information used in research projects have a right that should be reflected in that information's use and, where relevant, its publication. The same concern can arise for directors of healthcare centers, because these centers supply the resources for providing care and keeping record of it. Private entities, like those involved with pharmaceuticals or other technologies, also form part of this group of parties with a stake in the medical information.

The purpose of laws is to facilitate relationships and coexistence by establishing the rules that everyone should follow in their interactions with others. That is why it is important for legal provisions, whether related to health information or other rules, to clearly establish everyone's rights and obligations in relation to analyzing and processing health data for innovation, research, and even commercial purposes. These legal provisions are more necessary now than ever because technology enables the analysis of big data from different sources and with constantly growing research potential.

<sup>11</sup> Spain. Article 18 of Basic Law 41/2002 of November 14 governing patient autonomy and rights and obligations for health information and documentation.



# Conclusion

Digital health is an opportunity to transform the health system that requires a new form of governance. Governance for digital health should address the challenges and strategies of the health system, its leadership, the interests and rights of all stakeholders, the ethics of the health care and research, and the laws needed, among many other aspects.

**For successful digital transformation, it is crucial for the national government to take the following actions:**

- 1.** Declare digital health a national priority.
- 2.** Provide precise, clear, and public support for the digital health strategy.
- 3.** Give digital health multi-year funding.
- 4.** Make sure the digital health and digital agenda strategies are consistent with each other.
- 5.** Promote training for IT engineers.
- 6.** Promote training in digital health for IT engineers and health personnel.
- 7.** Ensure connectivity for hospitals and other health centers and services, and equip them with the necessary infrastructure.
- 8.** Promote and pass the legislation needed to grant legal certainty to all stakeholders.

The strategies for digital agenda, health, and digital health should be aligned with each other to leverage synergies. The digital health strategy is part of the health strategy and shares its objectives, and it is the main tool for achieving the health system's objectives. This is the primary reason why it is best for health system administrators to be in charge of digital health.

The general management of the health system should design the digital health strategy and submit it to the health authorities for approval. It is also responsible for implementing it as part of its management plan. The health strategy's objectives should also be precise, clear, and public.

The health system's general management should define the criteria and standards that determine the success and effectiveness of digital health. These criteria and standards should measure the quality, efficiency, and effectiveness of the health system.

Citizens, patients, healthcare professionals, and the health system are also responsible for the actions needed to ensure the transformation of the health system and contribute to governance for digital health.

It is crucial to engage medical professionals and ensure their participation in the strategy, take their suggestions into consideration, facilitate that participation, support them at the implementation stage, and rapidly incorporate the improvements they suggest upon assessing the information system's functionalities.

Governance for digital health requires observing the ethical requirements, as well as passing and enforcing laws on data protection and information security, and laws related to the validity of and requirements for health information in digital format. The following laws are needed to give legal certainty to all stakeholders:

1. Validity of electronic records with health information, like electronic health records, electronic prescriptions, and electronic medical documents, as well as of mobile health, telehealth, and the use of remote patient monitoring devices. A key aspect of these regulations is the patient identification procedure (unique identifier).
2. Data protection and the security of health information. These regulations should also cover the use of digital certificates and electronic signatures.
3. Patient rights with regards to health information.
4. The rights and obligations of health professionals, organizations, and health establishments with regards to health information.

As a general conclusion, governance requires prioritizing the common good in a context of rule of law. In digital health, the common good means transforming the health system to improve its quality, efficiency, and effectiveness so it can meet the challenges it faces. For digital transformation to be successful, the interests of all stakeholders must be reconciled so that this digital transformation becomes their shared objective. **Digital transformation requires legislative changes that guarantee legal certainty for all and respect for everyone's rights.**

# APPENDIX: Governance for digital health during health emergencies

**Health emergencies can be classified as internal or external.** A classic example of an internal emergency is a fire in a hospital that requires it to be evacuated. The most common example of an external emergency is an accident or attack that results in multiple seriously wounded people. Another example of an external emergency is an epidemic or mass poisoning, like the one that occurred in Spain in the early 1980s when multiple victims consumed adulterated cooking oil. Many survivors ended up with serious sequelae. A more recent example is the COVID-19 pandemic.

**Informational needs are not always the same.** For example, in the case of an internal emergency, the main concern will be identifying and locating evacuated patients and having their medical information available. In an external emergency where a large number of victims are brought to an emergency department at the same time, the priority will be to identify and triage them and record their medical information in electronic health records. In the event of an epidemic or mass poisoning, an epidemiological survey will also need to be conducted, in addition to the steps listed above, in order to locate the source and contacts and prevent contagion or new poisonings.

In any of these cases, informational needs in health emergencies are always added to the normal ones for healthcare because, in addition to requiring intensive use of the health information system's normal resources, the public health services need to analyze data very quickly. If the health information system has been developed according to the criteria laid out in this publication, public health services will have the data they need to manage the crisis.

Specifically, as explained previously, if a health information system has been developed with an interoperability framework and international standards have been used for information exchanges, public health services will immediately have the healthcare information they need. This information includes, for example, the date and time at which patients checked into primary care centers or hospitals, whether or not they need to be hospitalized, their diagnosis, the date and time of hospitalization and of transfers to intensive care units, discharges and reasons for discharge (death,

recovery, transfer to another center), and discharge diagnoses. For infectious diseases with a vaccine, electronic health records should contain the necessary information about whether each patient has been immunized, when, and the vaccine identification data. Including this information allows professionals to calculate incidence and prevalence, critical information during an epidemic, or to ascertain the seriousness of the accident or other external causes of an emergency, in addition to vaccination coverage levels, where relevant.

In the event of an epidemic, the information obtained from the epidemiological survey is added as well. The aim of this information is to pinpoint contacts and the source of infection (or poisoning). Public health services should have an information system that, in addition to health information, includes environmental health and food safety information, among other sources. Health data and information from epidemiological surveys, as well as data on environmental health and food safety, constitute the essential sets of information needed to rigorously combat an epidemic. Of course, the information supplied by researchers is also important, but how this information is handled is beyond the scope of this publication.

Other healthcare procedures are also used during an epidemic, for example, telecare or telehealth. If these procedures are commonplace or there are regulations for using them, it can be assumed that it was considered a healthcare activity that should form part of each patient's health record. If this is not the case and improvised systems are being used, the procedures and mechanisms needed to record this health information in the electronic health record must be established without delay. As long as this is not possible, priority should be given to making the data health services need available to them. It is also important to remember that this information should meet the normal security requirements for health information.

To trace contacts during epidemics, the use of geographic information from mobile phone technology has been proposed. This information could come from three sources: telecommunication companies, contact tracing apps, and large companies like Google or Apple. From a practical point of view, all of these sources have advantages and drawbacks. However the information that can be obtained from these contact tracing tools, from public health information systems and health records, or from research are all subject to the legal and ethical principles that apply to digital health. A health emergency does not justify eliminating people's rights, although certain rights can be limited if permitted by law, provided it is for the benefit the community. For example, there is a common obligation to hospitalize an infectious patient to prevent the risk of spreading the disease. Self-discharge is not allowed in this case. During the COVID-19 crisis, governments have often been forced to restrict people's freedom of movement

in order to control the pandemic. Restricting fundamental rights for public health reasons merits an in-depth ethical and legal analysis that is beyond the scope of this publication.

During any kind of health emergency, the services that manage digital health must be made available to the authorities so they can provide the tools needed to swiftly handle the epidemic with the best information possible. Here the principle that the objectives of the health system and digital health are one and the same should be followed to an extreme.

**In summary, governance for digital health in the event of emergencies should respect people's rights and be designed so that authorities have enough information to make the necessary decisions for the good of patients and of the general public.** If the health information system has been developed using an interoperability framework that allows different sources of information to be integrated, a large portion of this information will already be available to public health services, or it will be less difficult to add. New information from recently launched tools should be subject to the same security requirements as all other health information, and it should be incorporated into the health information system as quickly as possible.













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