Secure, Interoperable Patient Portals with Quality Data

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Secure, Interoperable Patient Portals with Quality Data

Technical guidelines for developing secure, reliable, technically interoperable patient portals with quality data
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Executive Summary

The main objective of the Information Systems for Health (IS4H) initiative is to introduce a renewed vision to help countries define strategies, policies, standards for interoperable and interconnected systems, and best practices in health data management to improve decision-making and the well-being of their populations. The Pan American Health Organization (PAHO) is fully committed to working with all its member countries on IS4H initiatives (1) at the regional and national levels.

This document is aimed at decision-makers to help them understand the importance, and guide them in the implementation, of patient portals (PP) as part of their national digital agendas. It takes into account the eight guiding principles for the digital transformation of the health sector (2) promoted by PAHO, which in turn are based on the principles established by the United Nations in its roadmap for digital cooperation in the age of digital interdependence (3).

A patient portal (PP) is a type of personal health record (PHR) in the form of an electronic application which individuals can use to enter, manage, and share their health information with others, in a private, secure, and confidential environment. Noteworthy elements of the great potential of PP are the accuracy and availability of the health information they provide, such as the results of studies and diagnoses; rapid communication with health professionals; accessibility to health knowledge bases; medication management and access to medical information through a single interface; and maintaining data security, reliability, and quality.

PPs are key tools to empower people by giving them the opportunity to actively participate in their health care. For this tool to be adopted, its use must be promoted, encouraging the public's knowledge of the benefits that this system brings, considering age ranges, degrees of digital literacy, educational levels, health knowledge, self-sufficiency, and confidence in the use of technology. Moreover, health professionals and patients must build new levels of trust: patients must be encouraged to enter data, while trusting that this information is being uploaded for their benefit.

Interoperability is a crucial component in the design of secure, interoperable patient portals. Interoperability is the ability to exchange electronic health information using two or more systems, and for that information to be accessible by the target users of health care data. This is achieved through standards, which must be applied according to the type of portal being implemented. The types of portals that we can encounter are the view type (focused on the health care provider); freestanding portals (data stored on a physical device or in the cloud); tethered portals (allowing access to certain information from an electronic medical record); and interoperable portals (using standards enabling them to integrate with other systems).

The implementation of interoperable PPs has gained significant attention from governments and policymakers. In this guide, we will examine the interoperability, legal, and infrastructure aspects within the framework of digital agendas, as well as project management, implementation, and monitoring to apply this type of technology to transform and improve health care quality, accessibility, and delivery at the national level.
Introduction

The implementation strategy of the patient portal (PP) component must be fully aligned with the national digital agenda, both at the general government level and at the health care system level in particular. This falls within the scope of the Plan of Action for Strengthening Information Systems for Health proposed by the Pan American Health Organization (PAHO) and approved by all the countries of the Region of the Americas in 2019 at the PAHO Executive Committee (4).

The countries of the Region are making major strides towards the digital transformation of their governments (e-government or digital government). The digitalization of government bureaucracy, properly understood, generates tangible benefits for the citizenry, such as eliminating unnecessary procedures, providing greater accessibility to services and public information, reducing response times to meet needs, and optimizing spending (5). Furthermore, it guides and facilitates the digital development of every sector of the national economy. Digital agendas are the roadmaps marking the path chosen by each country to advance in this digital transformation, with a clear vision, priorities, and targets to be met by certain deadlines.

One aspect of government health agendas is related to what is usually called a digital health strategy. This strategy should support national health policies, such as universal health coverage. In 2012, the International Telecommunication Union (ITU), together with the World Health Organization (WHO), published a recommendation for the creation of such strategies at the national level. The document describes the components to consider: leadership and governance; strategies and investments; services and applications; standards and interoperability; legislation, policy and compliance; infrastructure; and workforce capacity building (6). It also proposes three stages for implementation: establishing a national digital health vision for the country; developing the strategy itself; and monitoring and evaluating its progress.

PAHO is promoting the Information Systems for Health (IS4H) initiative to help countries define strategies, policies, standards for interoperable and interconnected systems, and best practices in health data management to improve decision-making and the well-being of their populations. How does this relate to the idea of eight principles for the digital transformation of public health? In mid-2020, the United Nations presented eight areas of collaboration based on recommendations from a high-level task force on technical cooperation in the age of digital interdependence. PAHO has adopted and adapted these areas into eight guiding principles to reflect the imperatives of the digital transformation of the health sector: 1) universal connectivity; 2) digital public goods; 3) inclusive digital health; 4) interoperability; 5) human rights; 6) artificial intelligence; 7) information security, and 8) public health architecture. Both frames of reference must be taken into account for the effective implementation of patient portals (PPs) in the context of a digital agenda in health.

The traditional health care model focuses on the provider, giving the professional a position of decision-making authority, as the source of all information. Care is provided exclusively in clinics and hospitals and is essentially oriented towards diagnostics and therapeutics. This structure is very hierarchical, with
physicians occupying the place of power; this same viewpoint is then transferred to information and communications technology (ICT) projects, where systems are developed that consider health professionals as the only end users (7).

The primary health care (PHC) strategy proposed in Alma-Ata in 1978 puts the patient at the center, creating enabling environments for health promotion, disease prevention, timely care, and rehabilitation. This paradigm shift requires professionals to establish a partnership or agreement with their patients, including them in shared decision-making and taking into account the preferences, needs, and values of patients and their environments (8). The focus is on patients, considering them as unique, empowered individuals capable of making informed decisions. Integrated progressive care networks are required to provide solutions to patients' health needs according to the level of complexity required (9). This is why health institutions are needed that respect the patient-centered model with a focus on interdisciplinary treatment, personalized care, and the coordination of levels of care both intramurally and in the integration of extramural services. It is also of the utmost importance to apply the principles of preventive medicine, primary care, and health education. The latter is achieved thanks to the patients having greater access to information and to communication about their current state of health and the care they should have. As highlighted in the PAHO position paper “Renewing Primary Health Care in the Americas”, the integration of different levels of care requires good information systems that enable adequate planning, monitoring, and performance evaluation; appropriate financing mechanisms that eliminate perverse incentives and assure continuity of care; and evidence-based approaches to diagnosis, treatment, and rehabilitation (10). Finally, 40 years after the Declaration of Alma-Ata, the 2018 Declaration of Astana sought to empower patients and communities by promoting the use of such technological interventions as digital health (11).

The concept of patient-centered health refers to individuals’ participation in their own health care, with the aim of empowering them to participate jointly in making well-informed decisions about their health and medical care (12). It can also be referred to as the set of behaviors that patients, family members, and health professionals have that encourage the inclusion of patients and family members as active members of the health care team (13). In this new paradigm, decision-making is collaborative, between the physician and the patient, and both are involved in seeking and analyzing information. The care provided is home- or community-centered, and more disease prevention-oriented (14).

Community-oriented informatics or patient-oriented informatics are ideas that refer to the concept of consumer health informatics, a sub-network of health informatics that seeks to bring health resources closer to the community (mainly to patients). Considering this concept of patient-centered health, patient-oriented informatics are increasingly being used to involve patients in shared decision-making, personal control, and disease prevention, which facilitates access to health information, provides social and clinical support, and also encourages electronic communication between professionals and patients (15–17).

To achieve a continuum of care, it is necessary to provide a continuum of information. Because, as we know, health information systems are a reflection of the health system, it is very common to find that in countries with fragmented health systems, this information is also fragmented into different information silos. To ensure that information systems are able to address all these requirements, it will be necessary to effectively exchange information between individuals, providers, and organizations. Interoperability
between different information technologies is therefore crucial (18). The most empowered patients are often those dealing with a chronic illness; indeed, they are the ones driving the need for interoperability because they need to have all their information in one place.

New technologies are bridging the distances between patients and health professionals, particularly in global emergencies such as the COVID-19 pandemic (19). The general population's widespread and increasing use of mobile phones and the Internet provides new forms of communication between patients and physicians. Social networks, patient forums, the thousands of answers about health issues available on the Internet, are just a few examples of how patients are using health information technologies to interact with their doctors or other health professionals (20). Through these technologies, patients are constantly generating data. The data displayed on a PP could be generated by different devices and sensors (also known as wearables); the challenge is for this data to have high quality and be available to health professionals.

This document aims to support PAHO member states in implementing secure, reliable PPs with quality and technologically interoperable data, as well as to describe what PPs are, and the different types that exist and can be used; what is their function; and the services and information that are obtained from them. It also details the steps for their implementation and integration with national digital health agendas.
Patient portals

What are patient portals?

A PP is a people-centered health information system enabling individuals to manage and share their health information in a secure and confidential manner (21). These platforms empower individuals by making them the protagonists and owners of their health information, enabling, among other things, communication with health personnel according to their needs and generating spaces for health promotion and disease prevention. Being people-centered, one of the fundamental characteristics of PPs is that they are for life; that is, they accompany individuals over the course of their lifetimes, and throughout the health system (22–25).

What kinds of patient portals are there?

According to the degree of control that the person has and the interoperability of the system where the PP is developed, four types of personal health record (PHR) can be defined. Here, we are defining degree of control as an individual’s ability to choose to whom to give specific information, and interoperability as the ability to exchange standardized information with other information systems that patients trust (26, 27).

● **View PHR.** This is a PP centered on the health care provider, which only allows patients to view certain information contained in the care center’s electronic medical records. This type of PP is offered to health professionals, hospitals, or health systems, giving patients access to part of their medical records. It offers the possibility to upload information, in general, through structured templates, but with little coding and, therefore, little control.

● **Freestanding PHR.** A portal where data is stored in the cloud or on a physical device, such as a pendrive. The patient has some control over the information uploaded, and there is no interoperability or connection with the records of health care providers. Its updating depends purely and exclusively on the patient.

● **Tethered PHR.** Provides patients with access to certain information from the electronic clinical records of a medical plan or health system. Modifications in the PP are reflected in clinical histories, which are accessible for health professionals. Patients have little control over access to information and permissions, but it is interoperable with their health coverage or health insurance. This type of PP is the most used, disseminated, and published, and provides functionalities such as making appointments (agenda), renewing prescriptions, and offering a secure communication channel with health professionals.

● **Consumer-controlled or interoperable PHR.** This type of PP enables patients to have access to their own medical records and to those of the people who authorize them to do so. It manages
health information and enables part of the information to be accessible to those who need it, providing integration with other clinical records systems through the use of standards and also complete control of patient access permits.

The different types of portals encourage patients to play a more active role in their health care, so that they have healthier lifestyles and better control over chronic illnesses. Moreover, from the viewpoint of health policies and management, these portals are allies for prevention in health, cutting costs, and improving quality of life (28).

What can patient portals do?

The concept of people-centered health refers to individuals’ participation in managing their own health, with the aim of empowering them to participate jointly in informed decision-making and medical care (12). Empowering patients means putting them in charge of their information, giving them tools with which they can decide how their data is used, respecting their rights and desires, and keeping that information safe and secure. This paradigm has been strengthened by technological advances; the preponderance of the principles of person-centered care and the possibility of unprecedented access to information have enabled a new age, characterized by the constant, progressive transformation of the role and opportunities of individuals regarding their health in at least five domains (29)(30):

- **Decision-making.** Shared and collaborative between the professional, the patient, and their environment, taking into account their needs, preferences, and values.

- **Sources and use of health information.** Information comes from different sources and is generated by patients as well as by health professionals and institutions. All are involved in seeking and analyzing information.

- **Organization of care systems.** This model requires integrated service networks that provide interdisciplinary, longitudinal care, bringing patients closer to their homes and the community and moving away from episodic hospital care.

- **Levels of care.** Emphasizes primary care, and health promotion and disease prevention strategies.

- **Role of the community.** Requires a holistic view of the individual as part of a community, considering every dimension of health, including social well-being.

Ideally, the PP should include as much objective data about individuals’ lives as possible, from multiple sources: medical history, information entered by the patients themselves, external sources (laboratory studies, pharmacies, diagnostic centers), and even mobile devices and sensors.

What information/services should a patient portal contain?

Despite the absence of a consensus on what kind of information a PP should contain and what the sources of that data should be, the American Medical Informatics Association and the American College of Medical
Informatics suggest the following (21):

- Information generated by the patient
- Clinical history
- Transactional and administrative information
- Some automatic interfaces that measure parameters such as blood pressure or blood glucose
- Immunization registries
- Reports from diagnostic and therapeutic studies
- Curated, reliable information on health issues

A PP places the individual at the center of care, considering these domains and providing different services that allow the patient to have a more active role in their health care, as depicted in figure 1.

![Figure 1. Services that can be provided by a patient portal](image)

Patient portals should also offer the following benefits for patients and the health system:

- Timesaving for health personnel
- Enabling health team members to focus on those patients who most need face-to-face appointments
- Reducing phone calls
- Reducing processes that require the use of paper
• Automating the management of appointments and reminders
• Improving safety by providing patients with a record of clinical instructions
• Providing 24/7 access for patients, without extending hours of care
• Reducing absenteeism by enabling patients to schedule appointments at the time that suits them best

For more information on the functionalities that a patient portal should contain, see Annex 1, which describes the functional model of the HL7 organization’s PHRs.

What are the barriers and facilitators to their adoption?

However, as is the case with Electronic Health Records (EHR), barriers to their adoption of patient portals are not only technical; organizational and behavioral changes influence the implementation of a PP, along with the individual barriers of professionals as well as of patients. Facilitators include the many functions of a PP described above, which encourage patients to use this type of system, as long as there is an incentive from health professionals to do so, and to trust the information provided.

Among the first challenges to consider are those related to patients’ communication preferences; that is, the value of in-person or telephone contacts between patients and professionals. Regarding security and confidentiality, patients may be afraid to enter data if they are unsure about its protection; however, aggressive protection can lead to low system utilization and little utility (31).

Moreover, health professionals and patients must build new levels of trust: patients must be encouraged to enter data, while trusting that this information is being uploaded for their benefit (31).

The main barriers are:

- **Interoperability.** In the case of PPs that do not interoperate with a clinical registry, they may require more time and work on the part of health professionals, who must take on a double load of data.
- **Accuracy of information.** Professionals may question the accuracy of the data uploaded by patients; questions may also arise about whether the information entered should be used to make medical decisions (32).
- **Age range.** The literature associates people under 18 years of age with a greater propensity to use PPs. Those over the age of 65, on the other hand, are much less likely to use them (31).
- **Availability of health education resources.** The existence of resources such as MedlinePlus, among others, drives people’s use of the Internet. Chronic patients or relatives of a sick person are more receptive to information; they can see this need satisfied by PPs, since they are able to obtain reliable information about medication and ailments and have a channel of communication with the health professionals in charge of their care.
- **Degree of digital literacy.** Many studies have associated the educational level achieved, health knowledge, self-sufficiency, and confidence in the use of technology with greater adoption and use of PPs. Having a paid job, high income, residence in a neighborhood with high socioeconomic
status, and health insurance were also associated with higher PP use (31).

- **Usability.** The extent to which end users achieve the desired results in an effective, efficient, and satisfactory manner within a specific context of use. This concept, also called user-centered design, quantifies how useful, usable, and satisfactory a system is for users by performing certain task sequences to meet objectives (33). To maximize the benefits of PPs and increase their use, they must be easily accessible, intuitive, and easy to use. This reduces future efforts to train end users in the use of the tool.
Steps for incorporating a patient portal into the digital agenda

The implementation of a PP component must be framed within a digital health strategy, and fully aligned with the country's digital agenda.

Recommendations for incorporating a PP into the digital agenda are provided below. It is important for this type of project and technological initiative to be aligned with the country’s digital transformation project, and also to have the necessary governance for implementation. Moreover, it is extremely important to consider infrastructure (hardware, software, and connectivity) and interoperability aspects in order for the PP to be accessible to the population, safe, complete, and of high quality. The necessary regulatory framework must also be considered, including the protection of sensitive data and the patients’ rights. Just like any other project it must be managed properly, analyzing its viability and sustainability, with detailed planning for its implementation, monitoring, and control. In line with other authors and international experiences, it is known that up to 80% of the success of digital transformation projects depends on the human factor. Here, change management is a crucial aspect for successful implementation. The trust and support that a PP project receives from managers and health professionals, and especially from the general population, is the key to its effective adoption. Preparing a communication and support plan is essential to encourage and incentivize its use, to publicize the benefits of using a PP, not only for the patients, but also for health professionals. Once a PP is implemented, the evaluation and monitoring stage enables us not only to measure the impact and benefits it brings, but also to quickly recognize mistakes and lessons learned from each step in its development, implementation, and adoption, establishing improvement feedback loops.

The following aspects should be considered:

- Having a digital agenda
- Considering interoperability issues
- Considering legal aspects and the regulatory framework
- Securing infrastructure
- Services and applications
- Governance and change management
- Generating a communication, training, and support plan
- Evaluation and monitoring

Having a digital agenda

It is well known that many countries have fragile systems for collecting, managing, analyzing, and using individual and population health information, which are usually paper-based. Furthermore, the
foundations for a good health information system still present major challenges in most countries of the Region, regardless of their socioeconomic status (34). In 2016, PAHO, in collaboration with its member countries, and supported by international experts, established the new IS4H conceptual model and framework for action, creating a renewed vision through an active process of technical cooperation across the continent. The IS4H initiative seeks to provide a frame of reference for Member States, understanding that the current context created by the information society and the data revolution makes it possible to develop public policies and decision-making based on the best available evidence (35).

A key aspect is to bring all the actors involved to the table when designing a vision of digital health for the short, medium and long term. Only in this way can agreements be reached that provide the project with sustainable governance over time.

From an operational point of view, the IS4H initiative proposes a series of steps, understanding that the reality of each country is different, and that the allocation of priorities will vary depending on local factors which may be national or subnational. At first, it proposes linking health information systems and national health strategies. Then, each country, in collaboration with PAHO and its network of experts, must measure the level of maturity of its information systems, considering the central pillars on which the proposal is based: data management and information technologies, management and governance, knowledge management and exchange, and innovation. For this point, IS4H has a tool to evaluate the maturity model of each country (IS4H-MM) at five levels. An organization could present different maturity levels in each strategic area. The analysis of the five progressive levels of the IS4H-MM provides the necessary knowledge to plan the way forward, with plans and roadmaps for information systems, including exercises for prioritization and funds allocation. Once the level of maturity has been measured, the country team, in collaboration with PAHO and other partners, defines the human, financial, and infrastructure resources that are necessary to move forward, identifying gaps, challenges, and growth opportunities. Progress can be made towards creating a tactical and operational roadmap, which will make it possible to establish the necessary policies, design a digital health strategy, create an appropriate digital literacy program, determine a change management strategy, and define the necessary indicators to evaluate (35).

“8 Guiding Principles for Digital Transformation of the Health Sector”, published by PAHO in 2021, aims to provide orientation for countries of the Region of the Americas in their digital health transformation processes. Its purpose is to support them in making informed decisions, formulating short- and long-term goals, and developing sound and sustainable public policies, leaving no one behind.

This step relates to the principle of public health architecture in the age of digital interdependence. It must be situated within the government’s digital agenda and take a cross-cutting approach to weave together different aspects of governance and optimize strategic planning and resource management. Moreover, it must leverage rules and procedures to advance multiple areas, not only within the field of health; this is the case of connectivity and bandwidth, which not only have an influence on health, but on education and all other sectors.
The PP should be a window through which each individual can view and manage their own health information and that of third parties for whom they are responsible (e.g., children and dependent older adults). Likewise, it must enable communication with health professionals and provide access to other health-related procedures and services.

PP-enabled information exchange allows for the retrieval and collection of clinical documents and abstracts, minimal data sets, and other records. To interconnect the PP with different systems that provide such data (e.g., electronic medical records, laboratory or images systems, or appointment managers), it is crucial to consider interoperability. Interoperability is the ability of different systems to communicate with one another; to exchange data accurately, effectively, and consistently; and to use that information (36).

An interoperability framework contains the set of policies, guidelines, standards, rules, and recommendations formulated by a network of actors with a view to achieving the highest possible level of effective exchange of information. From this, data can be accessed, exchanged, integrated, and used cooperatively in a coordinated manner, within and across organizational, regional, and national boundaries, to provide timely and smooth information portability and optimize the health of individuals and populations globally (37).

The use of common standards is important, not only for interoperability but also for scalability. Within an ICT framework, common uses of standards include the definition of data exchange formats, communication protocols, programming languages, and hardware technologies. It is important to note that sharing health data in a system that does not use such standards increases the risk of harming the patient; for example, due to potential ambiguity or inaccuracy in the information exchanged. For this reason, it is essential to select and apply the appropriate standards (38).

While there is a wide range of organizations and authorities responsible for developing and overseeing standards, each of them defining and validating various standards, explicit national and international policies are needed that require the use of standards when creating digital health tools.

The implementation of interoperable PPs has attracted significant attention from governments and policymakers, because applying health technologies in this way has the potential to improve and transform the quality, accessibility, and delivery of health care (39).

Transformative capabilities of interoperable PPs:

- **Accuracy, depth, and availability of health information.** This enables the aggregation of data from different health systems, as citizens receive health services or use home monitoring systems. For example, wearable sensor systems could be used to constantly upload real-time health data to a database integrated into real-time PPs (40).
- **Rapid communication.** Interoperable PPs enable both synchronous and asynchronous interaction between patients and their families and health professionals, providing a mechanism for shared decision-making. (39)

- **Accessibility to health knowledge.** Internet-based PPs can facilitate access to health knowledge, thereby improving people's awareness and well-being by providing access to validated sources of information (41).

- **Portability.** People’s ability to access their information through a single interface, regardless of location and time, represents the real value of any portable medical records system (42). Such a system enables people to access their PP at any time and place, as long as they have an Internet connection and a browser. This eliminates the need to download and install software; moreover, it is easy to integrate with mobile communication devices, enabling access to health portals, not only through a computer, but also through other devices (e.g., smartphone, tablet).

- **Workload.** The automatic collection and insertion of health information from various systems is a crucial element. Integration between different clinical record systems operating according to national interoperability standards is the only way to facilitate the exchange of health information (43).

When it is necessary to address an interoperability requirement, there are contexts that need to be considered to determine whether the conditions exist to do so. Here are some objectives and keywords to be considered in advance (44):

- **Strategic alignment.** If the organization does not want to share the information it generates, it will be difficult to initiate a process of adopting interoperability. This requires reviewing the organization’s mission, vision, and objectives; considering the needs of patients, health providers, and other users of the system; and studying the potential solutions available, both public and private. Local and national laws and regulations must also be evaluated to prepare the organization.

- **Resource allocation.** This can include infrastructure, human resources, payment of licenses, and dedicating time to key areas of the institution (e.g., pharmacy, systems, administration, physicians); as part of this, the risks and impact involved for the organization must also be evaluated.

- **Information sharing.** Communicating the importance of the information that is shared—and understanding how and for what the data is used—makes it possible to unite the interests of patients and health providers, among others, in the business plan.

- **Benefits of the project.** Since the costs associated with implementation are often borne by suppliers, it should be emphasized that some of these benefits are not economic, but result in an improvement in the quality of care and patient safety.

- **Adoption of standards.** It is important to emphasize the need to adopt standards at all levels (local, regional, national), to avoid breaking the chain. Otherwise, an integrated health information system will never be achieved (45). Depending on the level, the information to be exchanged will have to be modified. For example, locally, we expect to have patient outcomes at
the observation level; regionally, at the protocol or complete study level; and at the national level, certain specific findings. However, the strategy should be the same.

Figure 2 shows an example of a PP structure in which blocks of data are replicated to different nodes in the network.

Figure 2. Example of the structure of a personal health record where datablocks are replicated to different nodes of the network. Source: adapted from Roehrs, da Costa and da Rosa Righi, 2017 (46). PHR: personal health record

Considering legal aspects and the regulatory framework

When planning a health informatics project, many legal and/or regulatory aspects must be considered, because a modern regulatory framework is generally lacking. In reality, the problem lies in the lack of comprehensive legislation on health information—not only on health information, but involving all the applications, systems, and devices that have access to it, to manage it or perform any type of action related to people's health. It is crucial to define the rules for how the applications that will manage health information should be developed. It is essential to establish minimum levels of interoperability able to guarantee that, regardless of the application, the information can be accessed ubiquitously at some point, so that the entire health system has the same information.

This lack of regulation is mainly due to the fact that most health institutions (especially public ones) do
not have electronic records. In many cases, they still use paper, and there are usually multiple records with fractional information (each center maintains its own medical histories, and sometimes more than one system can coexist, even in the same center). When filing these records, in some cases the information is integrated and stored for 10 years (which requires an immense amount of physical space).

Although it has been shown that the use of PPs is associated with better clinical outcomes (47), their adoption has been relatively slow. One of the reasons cited for this has been patients’ concerns regarding the privacy and security of their medical information (48). The flow of information presents multiple points of vulnerability, potentially compromising the privacy of information and the security of those to whom it belongs. One starting point is mobile devices, which can collect health information but have also been shown to be susceptible to interception and manipulation. Moreover, there is the electronic transmission of data, through the Internet and wireless connections, and finally the storage and retrieval of information (49).

Privacy and information security are on many countries’ legislative agendas. Legal regulations can take such forms as laws, acts, and constitutional articles, imposing responsibilities on the institutions that store personal information and granting rights to individuals. In some countries there are specific regulations for health information; other countries have general regulations that include health issues. Data on the health of individuals is considered sensitive or of greater impact if their privacy is violated.

In the Region of Latin America, data protection mechanisms are inspired by European legislation, including Directive 95/46/EC, known as the EU Data Protection Directive. A common concept in almost all countries in this area is that regulations are based on *habeas data*: This is the principle by which every individual has the right to know what personal data is being stored by third parties and to update, modify, or even delete it. The realization of this right implies the need to register the databases containing personal data and to designate those responsible for each one. The following table shows how this issue is treated in countries of the Region; in some, it is enshrined in constitutional law, and in others it is covered by specific laws (50).

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<tr>
<td>Paraguay</td>
<td>National Constitution (art. 135)</td>
</tr>
<tr>
<td></td>
<td>Law No. 1682</td>
</tr>
<tr>
<td>Venezuela</td>
<td>Plans for inclusion in the next amendment of the National Constitution</td>
</tr>
<tr>
<td>Uruguay</td>
<td>Law No. 17,838</td>
</tr>
<tr>
<td></td>
<td>Law No. 18,331</td>
</tr>
</tbody>
</table>
Some of the most significant challenges facing health information systems are related to ensuring access to information and protecting privacy and confidentiality. Since these two concepts are closely related to security, it is essential to define them, because in this scenario they have very specific meanings:

- **Privacy.** The right to keep information to oneself.
- **Confidentiality.** The right for information communicated to someone (in confidence) not to be transmitted to third parties.
- **Security.** Comprises the means used to guarantee confidentiality and prevent the violation of privacy and loss of information.

In other words, information security encompasses processes and controls designed to protect information from unauthorized disclosure, transfer, modification, or destruction, in order to ensure continuity, minimize potential damage, and maximize opportunities (51).

Privacy and confidentiality of information are the rights of individuals, and it is not necessary to give a reason for sensitive information to be considered protected data. According to a 2005 survey conducted in the United States, less than 60% of the general public believed that the federal and state health privacy protection laws provided a reasonable level of privacy protection for their health information (52). Therefore, it is possible to say that guaranteeing privacy and confidentiality also benefits the health system.

It is still difficult to define what level of security is needed for health information. Highly secure sites implement a large number of measures, including access controls; prohibition of the use of portable devices, controlled by security cameras; and mandatory periodic password changes. The challenge is to find the ideal balance between the costs and benefits of electronic information security control measures in the field of health.

There are other prominent components regarding the security and privacy of health data (53):

- **Certification.** Service responsible for ensuring that health portal providers have adequate privacy and security measures in place to protect beneficiaries’ data.
- **Authentication.** Service responsible for verifying that the users are who they say they are, based on a set of identification criteria.
- **Authorization.** Service responsible for verifying that an authenticated user asking to perform an action actually has the right of access to perform that action. This is related to role-based access; i.e., roles that a user can perform (for example, to view, add, edit, or delete information).
- **Auditing.** Service responsible for recording/capturing all activities involving a member’s access to the system.
- **Delegation.** Service that provides users with the possibility of delegating access rights (reading, writing) in part of their health portal to other individuals involved in their care.
- **Data security.** Service responsible for encrypting the data transmitted and stored.

In any case, notwithstanding the possibility of people accessing their complete medical records as a legal
right, there are very few implemented medical records systems in the world that allow this. This is because legislation does not specify the modality of such access; moreover, certain deadlines must be met, access is not in real time, and, to a large extent, it depends on the policies of each health system or health organization. In most cases, a request form must be filled out, and then the data is received on a variable medium (paper or electronic) as a legible and printable copy of the medical record (for example, a set of PDF files sent by email). This reflects the persistence of the traditionally paternalistic model of health professionals (54–56).

Data reliability depends on the nature of the information, and the individual’s health and educational level. For example, people provide reliable information about certain data, such as symptoms or some easy-to-remember parameters (e.g., height, weight, and temperature), but most do not reliably report more complex data (e.g., specific laboratory results) (57). Therefore, it is essential to specify the source of each piece of information, so that the professional can have a critical viewpoint when making decisions.

Infrastructure

In terms of the strategy for its implementation, the development of specific infrastructure at the national level to improve the safety, quality, and delivery of health care has been a primary objective for many countries. This infrastructure is essential to facilitate and support secure access to health-related information from various electronic medical records systems in different regions of a country.

The national implementation of interoperable PPs can be addressed through different approaches:

- **Top-down approach.** Implementation is directed by a centralized management; i.e., the idea is to implement an interoperable, shared, and centralized PP system. This approach involves the essential step of replacing existing local clinical records systems that do not meet the appropriate requirements with alternative software, to achieve a nationwide interoperable system.

- **Bottom-up approach.** Here, local health professionals are responsible for ensuring that their clinical records system meets interoperability standards. In this model, there are several clinical record systems running locally, with the goal of sharing data through integration over time (58).

- **Middle-out approach.** Uses elements of both the top-down and bottom-up approaches. In this approach, the government focuses on nationally accepted interoperability standards, with targets to be implemented by local health agencies (59). Therefore, the focus is on standards development, rather than government-led implementation. Moreover, the government encourages local health care providers to ensure that their local software meets national interoperability standards by offering incentives and support.

The existing variety of platforms and data types has led to the generation of different storage formats. This is because data are not only limited to text formatting or numbers in structured tables; there are also, for example, electronic messages comprising text and metadata that describe the time at which the message was sent and the identity of the communicating parties. There are also documents and forms with templates, which are used for standard reports, such as legal documents. Images or graphs are used
to measure such individual health trends as growth, mood changes, blood sugar levels, or variations in laboratory results. Audio and video can be used to capture the content of phone calls. The latest data formats, generated by patient tools and mobile apps, include the use of Google Maps for location information (hospitals, health centers, clinics, and services) and Google calendar events that are associated with scheduling medical appointments and outpatient services (57, 60).

Integration between different medical records systems is a key element for implementing PPs (61).

### Services and applications

When deciding which functionalities a PP will have, it is important to know in detail what considerations must be considered when incorporating different services, such as making appointments, prescriptions management, and rules regarding communication with professionals.

Table 2 shows some key decisions that must be made to develop the different functionalities of a PP.

<table>
<thead>
<tr>
<th>Service</th>
<th>Decision</th>
</tr>
</thead>
</table>
| Making an appointment | How many appointments will be available for online booking, and at what times?  
Will there be an approval process, or will appointments be fully automated?  
Will all physicians make some appointments available online?  
Will patients be able to book an appointment to see a nurse?  
What will be the terms and conditions for making an appointment? |
| Prescriptions      | Who will receive prescription requests?  
How quickly will requests be responded to? |
| Messaging          | Who will receive the messages?  
Will patients be allowed to choose who receives their messages?  
When will a message become an online query?  
How quickly will requests be responded to? |
| Health summary     | What optional health information will be made available to patients, and from what date? |
| Results of studies | Who will publish the results of supplementary tests?  
Will the results be reviewed prior to publication?  
Is there a need to standardize the comments on lab results, or to provide the patient with an interpretation of the comments/abbreviations? |
Are there any laboratory results, such as HIV testing, that will not be published? How quickly will lab results be available online?

| Reminders and calls | What activities can involve calling patients? What will be the criteria for calling patients? |

Table 2. Key decisions for developing the different functionalities of a patient portal

Governance and change management

Centers that have PPs available should further investigate their uses, frequency of employment, and impact on individual health and workflow. More research is also needed on mental models of awareness in individual health care. In addition, more technological and economic research into standards and vocabularies is needed.

We should also note that it is necessary to create a simple and usable registration process; to decide what information is displayed and who has access to the information; and to adjust the system, so that it does not interrupt the care processes or disturb the health team in its daily practice in the different areas of care (31, 62).

Furthermore, it is imperative for change management be a significant component of any attempt to lead a team. The relationship we have with change will condition our beliefs, actions, and subsequent outcomes. Transformation is therefore a fundamental and irreversible change. The essence of the transformation of any organization is the result of the change management process. To achieve a transformational change, by definition, you must change the culture of an organization—that is, its belief system and behavior. There is no easy way to change organizational culture, especially if it is deeply rooted. It requires creating a transdisciplinary work team able to carry out the design, implementation, and adoption of the project.

Consensus, teamwork, and clear direction are essential to co-create technically robust digital products within the planned times.

Generating a communication, training, and support plan

Training all the users of a health system is an essential part of communicating the validity of the new scheme, with its challenges, changes, etc. This involves everyone: professionals, patients, and administrative staff. The goal is to lower barriers and allay fears, facilitating its adoption and providing implementers with the means to lead the change appropriately, and trained technical support staff.
It is important to understand that before a portal can serve as a tool for people to participate more in their own care, they must first adopt the tool. To promote people’s adoption of a tool, it is essential to foster public awareness of the benefits that these systems bring.

The mechanisms proposed to encourage the use of PPs are as follows:

- Promote health education for individuals as early as possible.
- Raise awareness of the need to keep each individual’s PP up to date.
- Update the curriculum of medical and health education centers (undergraduate and graduate).
- Incorporate the study of electronic medical records and PPs into the curricula of schools of medicine and of nursing, residencies, and doctorates, among other programs.
- Teach health professionals about educating their patients on the correct use of PPs.
- Promote research on PPs, as people’s needs in this regard are not yet well known.

It is also important to consider the following points to facilitate and encourage the correct use of a PP:

- Inform patients about PPs
- Provide patients with complete information about how to use the portal, including data security, risks, and benefits.
- Provide the most important information during the registration process (such as not sharing your password, and with whom you may share your information), with more details available elsewhere (for example, a website/brochure).
- Inform users of the process to follow if they have security concerns about their records (e.g., if someone has their password).
- Inform patients that the portals are voluntary, and that they may choose whether to participate, or to opt out of participating at any time. Keep a record of having provided this information to patients. Also record any consents patients have given you.
- Clearly indicate to patients that portals should not be used in an emergency. Patients who plan to use the portal to track their health must be informed of what actions to take if their values exceed certain parameters; for example, if they have an excessively high blood pressure reading.

Patients can access a portal from different devices (such as smartphones, laptops, tablets, or personal computers) with an email address and Internet access, from anywhere and at any time. Ways to promote portals include:

- Sending letters to patients
- Providing flyers in the waiting room
- Displaying posters in waiting rooms and offices
- Showing videos on television screens in health center waiting rooms
- Recording an audio message to be played on the phone’s standby function when handling phone appointments
- Publishing an update on the website
Evaluation and monitoring

The development and implementation of a PP is a complex, multi-level process that requires a holistic assessment approach, taking into account the relationship between the fidelity of the intervention (the degree to which an intervention was implemented as intended) and its results (the extent to which the intervention has achieved its objectives).

Five elements must be measured to better understand this relationship, namely:

- **Compliance** (the intervention was used as intended)
- **Exposure** (the amount of intervention received by users)
- **Quality of delivery** (the way a caregiver provides care/response)
- **Responsiveness of participants** (the extent to which users engage with the technology)
- **Differentiation of programs** (identification of the essential elements needed to achieve the expected effects)

The evaluation of these elements requires input from the perspectives of different stakeholders in different contexts, meaning that the incorporation of PPs into routine care cannot be assessed by focusing on a single level (e.g., the viewpoint of care providers) or outcome (e.g., increased blood glucose control) (63).
The patient as data generator

In this paradigm of people-centered care, it is the individuals themselves who, through health technology applications, constantly generate data. The data generated by these devices, ranging from daily physical activity to vital signs, are usually not integrated into their clinical records and probably do not reach the professionals who treat them.

The data displayed on a PP are generated by different devices and uploaded by different actors (the health team, patients, family members) through different platforms. For example, some data related to consultations, such as general patient information (self-monitoring), diagnoses, psychosocial status, treatments, and outcomes, are usually extracted from medical records. Other elements, such as educational resources, come directly from the portal or are transmitted by sensors and tracking devices (e.g., number of kilometers walked, or heart rate).

The technologies available for people to manage their health information can be divided into four groups, as shown in table 3.

<table>
<thead>
<tr>
<th>Mobile health (mHealth)</th>
<th>Mobile health is an emerging concept that refers to the combined use of medical informatics, mobile devices, communication technologies, and medical sensors for health care (64).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensors and wearable devices</td>
<td>Electronic devices that are attached as an accessory to a part of the human body and continuously interact with the user and with other devices to perform a specific function. There is a constant interaction between the device and the user, which allows it to be incorporated as an extension of the body and accompany it everywhere; this feature enables multitasking, so that users do not have to interrupt their everyday activities. The most important category of wearables is smartwatches, followed by activity bracelets. The prices of these devices are becoming increasingly accessible, enabling constant developments in health care delivery, mainly in the monitoring of an individual’s physiological processes (65).</td>
</tr>
<tr>
<td>Smart wearable systems</td>
<td>Smart wearable systems are mainly used in health care and monitoring. These systems provide support for certain groups, such as the elderly, especially those living alone; people who, after surgery, need to control their recovery process; or for the study of an individual’s sports activities (66). These systems also include implanted devices, such as sensors, smart fabrics, electrical equipment, wireless communication networks, processing units, multimedia devices, user interfaces, and software algorithms to support decision-making. These systems have a wide range of applications, including measuring body temperature, heart</td>
</tr>
</tbody>
</table>
rate, blood pressure, and respiratory rate, and conducting electrocardiograms (67, 68).

<table>
<thead>
<tr>
<th>Assisted living</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICT is being used to improve the quality of life of older people, enabling their autonomy and preventing the institutionalization of the elderly by keeping them in their homes safely and independently, thus ensuring the sustainability of health and social services (69). This includes integrating the Internet of Things (IoT), mobile health, sensors and wearables, artificial intelligence tools, and robotic assistants (70)(71).</td>
</tr>
</tbody>
</table>

**Table 3. Technologies available for people to manage their health information**

The increasing use of mobile phones and data services has made them an indispensable part of our daily lives. The development and use of health-related applications is growing rapidly, but the current level of functionality is limited; they are primarily being used to promote disease prevention and general well-being (72).

Mobile applications and cloud communication infrastructures will continue to steadily penetrate health services, to the point of becoming an essential component of everyday routines. New smart algorithms will make it possible to deal with an enormous amount of data and information, to be deployed in a timely and individualized manner to the patient; these are the new challenges that must be addressed. Moreover, policies are needed to regulate these advances, to ensure that they are truly beneficial to public health.

Regarding sensors or wearable devices, in the field of health they can be viewed from two perspectives. The first is that devices or medical equipment with specific indications are evolving towards portability, as part of their natural technological development. Technology in health and performance are now moving towards miniaturized sensors, integrated computing, and artificial intelligence. Thus, technology is becoming smarter and more personalized, offering the possibility of providing real-time feedback to users (73). Also, thanks to standard wireless communication protocols, today many wearable sensors and devices can connect with any mobile phone and integrate with its native health applications, or with other commercial ones. Once the information is integrated into a single device, it can be shared with medical applications, such as a PP or electronic medical record.

For wearables to be successful, patient empowerment is vitally important. We must bear in mind that this concept involves giving people an active role in managing their own health. In the coming years, these devices will empower patients by making them responsible for their personal care. Furthermore, remote monitoring will help older people to take better care of their health at home, in a more independent way, offering them better quality of life, with lower care costs for their families and for the State (74).

Another major concept is that of assisted living, resulting from the integration of the IoT, mobile health, and sensors and wearables. Assisted living here refers to a European initiative, a program called Ambient Assisted Living, which was later renamed Active and Assisted Living (AAL). AAL, then, refers to using ICT to improve older peoples’ quality of life. It is based on a program that seeks to strengthen autonomy and
ensure the sustainability of health and social services (69). It is a means of prolonging the time people can live in their preferred environment (usually their homes), avoiding social isolation by providing them with adequate support (75).

Ageing populations will put pressure on social and medical care systems, leading to a lower availability of health professionals in the affected areas. To address these challenges, ICT and assistive technologies will play an important role in helping people to stay healthy and live independently at home longer (76).

This situation of increased longevity is the result of the considerable improvement in health care and quality of life in Europe, and the steady drop in the birth rate, due to difficulties in finding a job, the scarcity and price of housing, work and family life, lifestyle choices, and a higher average age at the birth of the first child. In Europe, life expectancy is rising, from about 76 years for men and 81 for women to a projected 79 and 85 years, respectively, in 2050.

If these trends continue and the policies of AAL programs are properly implemented, older people in the future will be more active and in better health; therefore, they will demand more and better services. In line with demographic and social developments, a significant increase in people living alone is expected, with varying degrees of dependence and different needs that will also vary over time, according to different deterioration models.

In the future, the older population will be more active and in better health; they will probably also have more savings than their ancestors and their descendants. These people will also consume more and better products and services, and engage in very active social participation.
Annex 1. HL7 functional model

The patient portal (PP) systems implemented so far range from webpages, where patients enter data about their health, to systems directly connected to an electronic medical record, making it possible to see information uploaded by the physicians responsible for the patient’s health. The Health Level Seven (HL7) Personal Health Record Work Group (PHR-WG) on Patient Portals defined a functional model of options for PPs approved by the American National Standards Institute (ANSI) in 2014 (46.78), based on the functional model of electronic medical records approved by ANSI in 2008. In general terms, the PP functionalities included are reduced to the following (50):

<table>
<thead>
<tr>
<th>Category and features</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Use of account holder information</td>
<td></td>
</tr>
<tr>
<td>Demographic information</td>
<td>Gender, type and number of document, birthdate, first name, surname.</td>
</tr>
<tr>
<td>Preferences of the holder and their family members</td>
<td>Preferences about blood transfusions or certain clinical practices.</td>
</tr>
<tr>
<td>Authorizations and consents</td>
<td>Authorizations or consents signed by the patient.</td>
</tr>
<tr>
<td>Connecting and uploading clinical information</td>
<td>Connection to electronic medical records, laboratories or imaging centers, and pharmacies, among others.</td>
</tr>
<tr>
<td>Clinical information entered by the patient</td>
<td>In structured or narrative form.</td>
</tr>
<tr>
<td>2. Medical history and current health situation</td>
<td></td>
</tr>
<tr>
<td>List of problems/diagnoses</td>
<td>Problem list management: uploaded problems/diagnoses can be added, deleted, or modified.</td>
</tr>
<tr>
<td>List of medications</td>
<td>Medication management: add/drop/modify.</td>
</tr>
<tr>
<td>List of allergies</td>
<td>Allergies management: add/drop/modify.</td>
</tr>
<tr>
<td>List of vaccines</td>
<td>Vaccines/immunizations management.</td>
</tr>
<tr>
<td>Results of studies</td>
<td>Data visualization</td>
</tr>
<tr>
<td>List of procedures/surgeries</td>
<td>Visualization of procedures/surgeries.</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td>Family and genetic background</td>
<td>Visualization and entry of family or genetic history.</td>
</tr>
<tr>
<td>Use of social data</td>
<td>Social habits and risk factors.</td>
</tr>
<tr>
<td>Use of information and incorporation into research studies</td>
<td>Visualization of potential studies for the patient, admission to them.</td>
</tr>
<tr>
<td>Use of organ donation information</td>
<td>Management of the donor’s status and modalities.</td>
</tr>
</tbody>
</table>

3. Preventive actions and personal care

<table>
<thead>
<tr>
<th>Entry of specific data</th>
<th>Vital signs, laboratory results or monitoring (e.g., blood glucose, blood pressure).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entering information from devices</td>
<td>Monitoring blood glucose, blood pressure, coagulation status, among others.</td>
</tr>
<tr>
<td>Management of special care plans</td>
<td>Visualization and entry into special care plans (e.g., treatment of chronic diseases, healthy habits).</td>
</tr>
<tr>
<td>Use of self-care tools</td>
<td>Calculators, graphics, alerts.</td>
</tr>
<tr>
<td>Use of educational information</td>
<td>Access to biomedical sources of information (e.g., medication, diagnostic studies, treatments, clinical conditions)</td>
</tr>
</tbody>
</table>

4. Support systems

<table>
<thead>
<tr>
<th>Clinical practice guidelines and protocols</th>
<th>Visualization of appropriate guidelines for the patient.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug interactions</td>
<td>Visualization of alerts or possible interactions according to the list of medications.</td>
</tr>
<tr>
<td>User-configured alerts</td>
<td>Presentation of configurable alerts based on the guidelines. Possibility of managing specific alerts.</td>
</tr>
</tbody>
</table>
5. Electronic communication and appointment schedule

| Communication with administrative services | Possibility of making administrative inquiries about information visible in the personal medical record. |
| Communication with treating professionals | Channels of communication with treating professionals. Possibility of completing online forms to be integrated into the clinical registry. |
| Request for specialist referral | Referral request for a specialist consultation. |

6. Safety and security

| Authentication, authorization, and access control | Computer security protocols for registration, entry, and authorization. |
| Privacy and confidentiality management | Protection mechanisms for sensitive data. |
| Secure messaging | Encryption of messages between patients and professionals. |

7. Interoperability and standards

| Use of interoperability standards | Communication standards and information integration. |

8. Administrative management

| Information about health coverage, providers, and professionals | Access to information about health coverage, benefits, and professionals |
| Information about care locations | Information about medical centers, hospitals, and other care locations. |
Annex 2. Acknowledgements

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