



## REVIEW

# Reflections on Healthcare Document Management in the Age of 4.0 Technologies

## Reflexiones en Torno a la Gestión Documental Sanitaria en la Era de las Tecnologías 4.0

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### ABSTRACT

The purpose of this study is to examine certain aspects associated with the 4.0 Revolution in the field of health data, with particular emphasis on decision-making and organizational models implemented in the information systems of the health sector. This analysis is conducted in the context following the implementation of the Federal Unified Program for the Computerization of the Digital Medical Record, which establishes a unified registry of patient data. The practices and tools used in document management of health data, biometric and genetic data are identified and examined, which, due to their sensitive nature, require rigorous protection. Various aspects related to the responsible provision of health services are discussed. For efficient and effective management of health systems, both public and private, the implications of using technologies in health from the perspective of safety and privacy are considered.

**Keywords:** Revolution 4.0; Health; Security and Privacy; Organizational Strategies; Health System.

### RESUMEN

El propósito de este estudio es examinar ciertos aspectos asociados a la Revolución 4.0 en el ámbito de los datos de salud, con especial énfasis en la toma de decisiones y los modelos organizativos implementados en los sistemas de información del sector sanitario. Este análisis se realiza en el contexto posterior a la implementación del Programa Federal Único de Informatización de la Historia Clínica Digital, el cual establece un registro unificado de los datos del paciente. Se identifican y examinan las prácticas y herramientas utilizadas en la gestión documental de los datos de salud, datos biométricos y genéticos, los cuales, por su naturaleza sensible, requieren una protección rigurosa. Se discuten diversos aspectos relacionados con la prestación responsable de los servicios de salud. Para una gestión eficiente y efectiva de los sistemas sanitarios, tanto públicos como privados, se consideran las implicancias del uso de tecnologías en la salud desde la perspectiva de la seguridad y la privacidad.

**Palabras clave:** Revolución 4.0; Salud; Seguridad y Privacidad; Estrategias Organizacionales; Sistema de Salud.

### INTRODUCTION

The demands of users in the face of scientific and technological advancements, coupled with recent legislative reforms, are leading executives of organizations across all sectors to take on new challenges in strategic decision-making.

These challenges arise from a complex and changing environment, with the aim of strengthening the right

to health as a fundamental human right. Regulatory norms in our country had already recognized a complex of rights, such as the patient's right to good quality medical care, to consultation and to a second opinion, ensuring their dignified and respectful treatment, to privacy, confidentiality, and protection of their sensitive health data and to the protection of their informational self-determination. With the recent sanction of Law 27.706 (BO 16/03/23), the Federal Program for the computerization and digitization of the Electronic Clinical History is created, and an issue arises that must be addressed both by law and by computer science, requiring strategic planning to ensure respect for the dignity of the general population.

The challenges currently facing health systems necessitate a transformation of the healthcare sector to correct abusive practices. Within this purpose, the improvement of health outcomes is a key aspect that requires a change in strategic orientation and advances in its implementation and evaluation. From this new approach, the need for changes at a strategic, tactical, and operational level emerges.

Organizations must adapt to changes in the environment and to do this, they must promote their own actions that allow them to innovate internally and externally, taking into account controllable and uncontrollable factors. Leadership must be able to discern both resistance and agents of change, emphasizing the latter, so that the process can be carried out, controlling the innovation value chain and selecting those R&D projects aligned with the company's strategy.<sup>(1)</sup>

While the law determines the technical and operational characteristics of the computerization and digitization of Clinical Histories of the Health system of the Argentine Republic. It plans to develop a loading protocol and the design and implementation of a Clinical History software coordinating its interjurisdictional implementation. Article 7 establishes a glossary where the involved terms are listed. Article 8 establishes that the patient owns the H.C.D.

The holder of the information, regardless of the medium, is the patient's property. Article 12 creates an interdisciplinary commission of experts guaranteeing joint work between public and private organizations, and the training that will be required. It is established that the patient is the holder of the right to access this document and has at all times the right to know the information of the ECH which is the compulsory legal and digital document with a timestamp, individualized and complete, in which all health assistance actions performed by professionals and health auxiliaries for each patient are endorsed by the digital signature of the responsible party. The system ensures that its consultation and access can only be available only to those who are authorized to do so.

Finally, in Article 15 in accordance with the Patient Protection Law, a list of requirements is included. It also creates a framework of interoperability between the systems that are functioning and those to be created, both in the public and private sectors and in the field of social security. While the law has not yet been regulated, there are numerous risks regarding privacy and data security, since health systems have been attacked and are increasingly subject to vulnerabilities and threats. The challenges that exist in the matter of Clinical History are enormous, which can make the situation critical.

As we have affirmed,<sup>(2)</sup> it is necessary to advance in technical-judicial frameworks that facilitate the incorporation of technologies and interoperability in the management of the ECH and that in turn ensure compliance with technical standards that improve accessibility and proper handling of sensitive data in accordance with current regulations.

#### **The 4.0 Revolution in the Health Area**

In 2011, the term "industry 4.0" was coined at the Hannover Fair in Germany. It described how global value chains were going to be revolutionized. "Industry 4.0", also called "intelligent industry", is considered the "fourth industrial revolution" (revolution 4.0) and contributes to innovation, establishing guidelines to achieve competitive organizations. Within any innovative process, expected objectives are not achieved if the changes do not generate value, thereby making it a critical factor in planning. The most relevant short-term changes in health involve the personalization of patient-centered medicine, with custom treatments and the possibility of telematic assistance from home.<sup>(3)</sup>

In the health sector, the application of technologies can be observed in the participating sectors of organizations, including healthcare providers. These are organizations involved in the prevention, treatment, and health therapies at both the public and private levels. Among them, the pharmaceutical industry can be cited.

The incorporation of "4.0 technologies" has allowed them to make great strides towards precision health and the development of personalized medications. It coincides with another change in the chemical industry, which is the growth and diffusion of biotechnology-based products and processes, with directed manipulation of the genome of organisms. The development of biotechnology applied to the pharmaceutical industry has seen rapid progress in the last four decades.

Technology enables remote monitoring and connectivity between devices that provide real-time information, with an immediate response in the event of possible unforeseen circumstances or changes resulting from

uncertain scenarios, as can be seen in our country. It is estimated that this monitoring can be done from mobile devices that make queries (<https://www.researchgate.net/publication>).

The use of technological advances in telemedicine can be mentioned, as it provides the opportunity to use cloud-generated information by work teams in the diagnosis and treatment of diseases. Especially in isolated areas and for patients on waiting lists. In Argentina, telemedicine is not associated with a corresponding medical specialty but is a service in itself.

### **Innovation and Quality in Health Companies**

Since the beginning of the 21st century, different management approaches have been planned, among which concepts of quality have been implemented to varying degrees in health sector organizations. Currently, the aim is to design a different strategy for healthcare services, emphasizing the patient as a participant in the process, as a partner, with the so-called Value-Based Healthcare (VBHC). This implies using the value delivered to the patient as the main indicator, measured as a complete process, evaluating the result and its costs, and making it understandable to the patient.

Healthcare value is co-produced between the patient and the different agents needed to create it, under the guidance and supervision of an advisory team. The creation of these cooperative relationships (partnerships) among all the agents, along with the deployment of information systems that revolve around the interests of final value for each individual, will lay the foundations for future healthcare.<sup>(4)</sup>

An alignment of the concepts described in this approach with models such as Total Quality Management can be observed; also with Social Responsibility and its standards, in particular, those related to general concepts of responsible conduct and principles, emphasizing the role of participating sectors. Value-based medicine allows for projecting a revolutionary change in the use and connection of healthcare resources.

Care is an act of interaction that requires scientific technological knowledge and knowledge of the cultural context where the subjects of care live, work, recreate, and become ill. The use of Information and Communication Technologies optimizes these processes.<sup>(5)</sup> Likewise, the patient will be connected and will have real-time measurement of biological parameters and self-managed clinical history, becoming the center of the process, and for this reason, the right to health incorporates co-responsibility.<sup>(6)</sup>

From a systems perspective, cultural, personal, and organizational variables directly or indirectly related to innovation management in an organization come together. It is necessary to identify facilitating elements to maintain and enhance them, as well as those elements that imply resistance to innovation, to minimize or eliminate them. Among the former are participatory style, managers motivated by change, and decision-making oriented towards a certain level of risk.

On the other hand, there are social factors that discourage innovation, such as a lack of participation, even reaching cases of management styles and organizational culture that do not allow creativity in the workplace. Furthermore, a lack of tolerance for failure or policies that allow the generation and analysis of ideas will be elements that hinder innovative behaviors that currently motivate the analysis of the 4.0 revolution to improve customer service.

On the other hand, it is necessary not to overvalue the external acquisition of knowledge and to consider designing policies focused on strengthening the internal capabilities of organizations. From this perspective, the existence of real organizational flexibility that adapts to environmental changes, the design of an organization based on teams with the potential to respond to changes, the creation of routines and procedures, an organizational and technological structure compatible with innovation are necessary elements to be able to speak of innovative organizations. The management of people and technology must be linked in the innovative process to, in this way, have certain guarantees of success.<sup>(7)</sup>

The interoperability of a health information system is almost a fundamental element of any system and becomes increasingly critical when optimizing administrative processes, caring for a patient, making clinical decisions, supporting professionals in making clinical decisions, and managing a health organization. The objective was to achieve quick access to patient health information, distribute it through multiple health providers, standardize the way of representing medical terms, reduce errors, avoid double loading and paper records.

What was known as the "interoperability bus" is now framed in what is now called the "Health Information Cloud", securely connecting different information systems and digitally integrating public and private health providers to organize the system in a network, allowing the interaction of health information between hospitals and health centers. The National Directorate of Health System Governance and Integration continues to push the provinces in the development of information exchange, in the creation of tools to facilitate its adoption, and in the training of human capital. Such was the state of affairs in 2021, with ongoing projects and much ground to cover, but with a hopeful future.

An important and aware community continues to be generated, conscious of the need to interoperate.

### Organizational Strategies for the Health System

The force of technological change from the 4.0 revolution is transforming Operations Management, modifying processes in all activities where the decision to incorporate technology of this nature is adopted to improve outcomes. Notably, in the health sector, it contributes to making better decisions, reducing costs, optimizing resources, and curing diseases.

Organizations can implement various combinations of strategies according to anticipated resistance, the position of agents, available information and energy within the organization to adapt and, finally, the risks involved in this.<sup>(8)</sup>

Value chain management is the development of a series of functional level strategies that support the business's strategy to gain and support competitive advantages. It can be affirmed that the value chain applies to all sectors, including health, and is the coordinated sequence of activities that allow professional skills and knowledge to be transformed into products, whether goods or services that customers/users value and wish to obtain. Strategies are put into practice in all phases, from ideas, innovations, product design and development, marketing, to outcomes (goods and/or services) and after-sales service.

It is possible to create or discover unknown needs and design strategies to improve the customer/user experience, seeking new ways to continually improve within the framework of organizational quality. One of these is customer relationship management, a technique that leverages Information Technology to establish a continuous relationship with customers, thus maximizing the value that an organization can provide to them over time.<sup>(9)</sup>

Management models that have a systems perspective, such as Total Quality Management and Innovation, are means for performance with social responsibility and allow evaluating connections that individuals cannot resolve when a holistic vision and thinking about more general objectives is required. Also, from a diagnostic point of view, it allows analyzing where the imbalances are in the set.<sup>(10)</sup> The systemic approach indicates that innovations are carried out through a network of agents, which are related to each other by an institutional framework.

The patent system is fundamental, allowing the commercial exploitation of inventions and their legal protection, as well as the possibility of technology licensing and the creation of new high-knowledge-value companies.<sup>(3)</sup>

The fourth industrial revolution is distinguished from the previous three by the exponential speed of its growth and adoption, by the breadth, continuously updating and making necessary and sustainable the effort of technologies that intersect, and by the profound system-level change, from factories to industries, from companies to countries, and society in general.<sup>(11)</sup>

The governance of organizations facing change processes is related to the emergence or aggravation of crisis situations, in which governance refers to 1) the ability to make decisions in response to events that are challenges and require a rapid and appropriate response, 2) the effectiveness and efficiency of actions adopted on the basis of rapid pre-diagnoses, 3) the ability to structure a strategic alliance that provides the appropriate support, 4) the formulation of a policy, programs, and projects that minimize damage, find emerging opportunities from the crisis and safeguard the identity of the organizations.<sup>(10)</sup>

A shift in innovation related to Industry 4.0 has been observed. From a focus on hardware and Information and Communication Technologies (ICT), there has been a shift to a focus on software and, more precisely, Computer-Related Inventions (CRI). This has allowed conventional objects to adapt to smart objects.

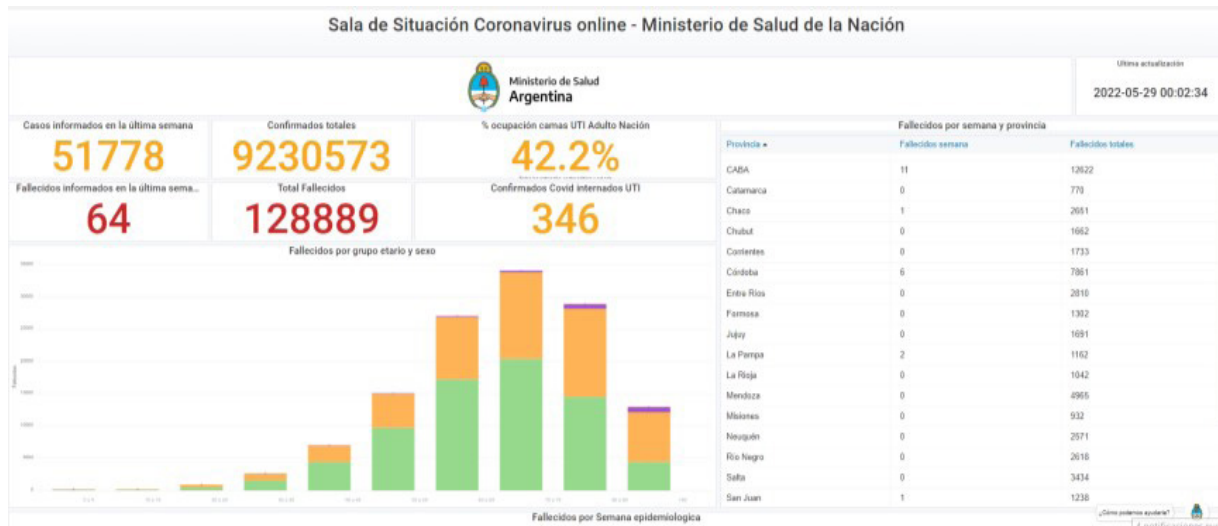
This change has posed a significant challenge to patent offices globally.

Efficient service provision in the health field is possible with a gradual digitalization and automation of processes; adaptation takes predefined times that must be poured into programs. Executed plans allow us to envision the erasure of the boundaries between physical objects, turning them into a complex and integral system of interrelated elements.

In the field of health, the need to dynamically handle large volumes of information, and perhaps in different formats, makes care centers, in general, have to prioritize the implementation of information systems. Thus, these entities are being assisted by Decision Support Systems (DSS), incorporating Business Intelligence (BI) techniques and tools.

The emergence of these DSS brought about a revolution in decision-making processes. The evolution of these systems has allowed having DSS that can be applied not only in different domains of knowledge, but also enabled their functional diversity.<sup>(12)</sup> A specific case can be observed in Figure 1, as through a dashboard, the Ministry of Health of Argentina visualizes, in real time, the epidemiological situation in Argentina.





**Figure 1.** Epidemiological information for Argentina as of 29-05-22

Source: Ministry of Health, 2021.

In the field of healthcare, globally, work is being done, and advances have been made in interoperability protocols between different health information systems. Argentina is considered one of the most advanced countries in Latin America in health interoperability, presenting successful strategies regarding interoperability in projects such as the National Health Network.<sup>(13)</sup> Specifically, the province of San Juan signed a collaboration agreement between the Ministry of Public Health and its counterpart in the province of Neuquén for the implementation of the public system, ANDES.<sup>(14)</sup>

This system is a digital platform aimed at patients and health team members. Its main objective is to digitally organize patient health data, ensuring its quick and secure accessibility; interrelating the agents involved in the health care process (Andes, n.d). Furthermore, this system works with an ontology called SNOMED CT (Systematized Nomenclature of Medicine - Clinical Terms), a standard of clinical terminology that the Ministry of Health of the Nation recommends including in health applications to structure, register, analyze and share health information. The terminology is maintained and updated by SNOMED International, an organization composed of more than 40 member countries, of which Argentina has been a part since January 2018.<sup>(15)</sup>

The global objectives of incorporating the 4.0 revolution into health organizations must integrate with the behavior of exogenous variables in the design of short, medium, and long-term plans to improve organizational performance. It is necessary to define the scope and limitations of projects and evaluate the level of achievement, based on the mission and defined values, so that, in the face of mutual influence with the environment, services are provided with quality and social responsibility.<sup>(16)</sup>

### Issues with the digitization of health data

In the health sector, to meet the challenges in providing efficient services, progress has been made towards a convergent system with the advent of the fourth industrial revolution (4.0) and biotechnological development. Emerging technologies not only serve to develop new drugs, but they also open the possibility of a new form of therapies, based on software solutions that can treat and support a specific disorder or disease. Digital health has a growing impact on the provision of care and provides the opportunity to address the next frontier in health care, shifting the current focus from treatment to prevention.<sup>(3)</sup>

In these new scenarios, EHRs must meet the requirements, change controls, rewriting and security requirements must be established to ensure integrity. Functional transparency should also be contemplated. When we talk about EHR sensitivity from the technicians, if we do not have a robust system, knowledge and management could result in damage, the threats and vulnerabilities are enormous.

### CONCLUSIONS

Innovation will be fundamental to maintain the health system, an open and convergent model, in which collaboration and the diffusion of inter and transdisciplinary ideas among specialized teams and human resources, among companies and industries, and finally among governments<sup>(11)</sup> are allowed. But we still do not have a robust healthcare system, this will result in a disaster if we continue to load a system with data from the entire population, it is very risky. A profound transformation is necessary that benefits both users and medical service providers and allows for cost reduction.

The directors of health institutions must have an adequate organizational capacity that allows them to carry

out these services and allows the system to maintain and grow in an uncertain and changing environment.

The planned shift towards digitization requires coordinated efforts from all participants, from government entities to users, for the design and development of new procedures that facilitate the implementation of this change, combined with learning, essential for the improvement of processes and results. The resources that science and technology make available to those responsible require commitment and specialized management. The implementation of strategies and policies that incorporate the new, must lead each boss or manager to reorganize the areas and people and start monitoring the implementation, with necessary control and adjustments.

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## CONFLICT OF INTEREST

None exist.

**AUTHORSHIP CONTRIBUTION**

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