











Regional Challenges for Electronic Health Implementation

Introduction to RACSEL Technical Recommendations

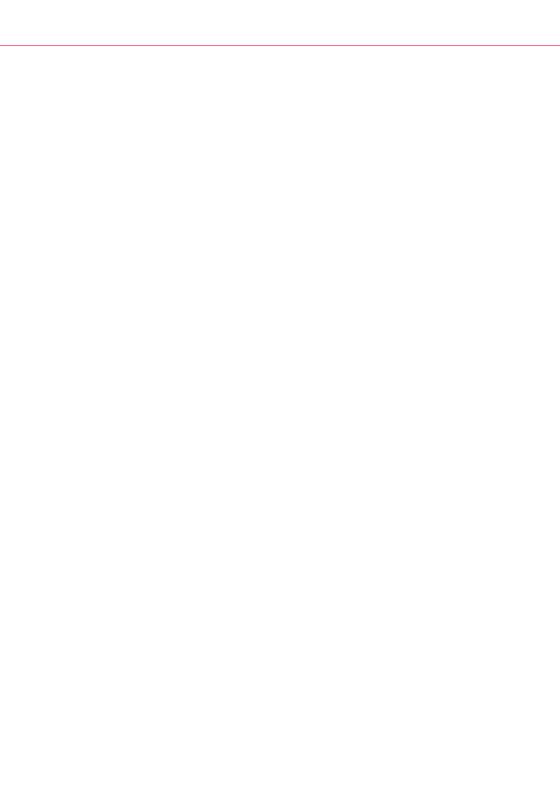
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NETWORK FOR THE DEVELOPMENT OF THE DIGITAL HEALTH IN LATIN AMERICA AND THE CARIBBEAN









AUTHORITIES

COLOMBIA

Ministry of Information and Communications Technologies:

Dr. David Luna Sánchez, Minister of Information Technology and Telecommunication

Dra. Juanita Rodríguez Kattah, Vice Minister of Digital Economy

Dra. Martha Liliana Amaya Parra, Director of Digital Transformation

Dra. Elizabeth Blandón Bermúdez, Digital Government Director

Ing. Iván Darío Castaño Pérez, Deputy Director of Sector Digitization

Ing. Rafael Londoño Carantón, Deputy Director of IT Standards and Architecture

Ministry of Health and Social Protection:

Dr. Alejandro Gaviria Uribe, Minister of Health and Social Protection

Ing. Dolly Esperanza Ovalle Carranza. Chief Information and Communication Technology Office -TIC [AP1]

COSTA RICA

Dra. Karen Mayorga Quirós, Minister of Health

Dr. Fernando Llorca Castro, Executive President of the Costa Rican Social Security Fund

CHILE

Dr. Emilio Santelices Cuevas, Minister of Health Marco Antonio Navarrete Mehech, ICT Division Chief

PERU

Dr. Abel Salinas Rivas. Minister of Health

Karim Jacqueline Pardo Ruiz, General Director of the General Office of Technologies of the Information - Ministry of Health

Pedro Julio Best Bandenay, Executive Director of the Office of Innovation and Development Technological - Ministry of Health

URUGUAY

Dr. Jorge Basso, Minister of Public Health

Ing. José Clastornik, Executive Director of Agesic

Ing. Pablo José Orefice, Program Director Salud.uy

REGIONAL TECHNICAL COMMITTEE

Alejandra Lozano Schälchli, Ministry of Health, Chile Mario Ruiz Cubillo, Caja Costarricense de Seguro Social Juan José Castillo, Ministry of Health, Peru Martha Cajaleón Alcántara, Ministry of Health, Peru Carlos Mauricio Parra Trillos, ICT Ministry of Colombia Pablo Orefice, AGESIC Salud.uy Uruguay Fernando Portilla, AGESIC Salud.uy Uruguay María Alejandra Piermarini, Racsel Regional Technical Committee Coordinator Marcelo Morante, Julio Ricaldoni Fundation

TECHNICAL WORK TEAMS

COLOMBIA

José Ricardo Aponte, Ministry of Information Technology Telecommunications
Carlos Mauricio Parra Trillos, Ministry of Information Technology Telecommunications
Esteban Armando Gaviria, Ministry of Information Technology Telecommunications
Alexander Alfonso Pérez, Ministry of Information Technology Telecommunications
Jennifer Andrée Uribe Montoya, Ministry of Information Technology Telecommunications
Jorge Iván Rodríguez Rojas, Sector Studies Advisor, Ministry of Information Technology
Telecommunications

COSTA RICA

Ana Lorena Solís, Caja Costarricense de Seguro Social
Anton Zamora Ilarionov, Ministry of Health
Eduardo Rodriguez, Caja Costarricense de Seguro Social
Jeffry Elizondo Saldaña - Caja Costarricense de Seguro Social
José Manuel Zamora Moreira, Caja Costarricense de Seguro Social
José Willy Cortés Carrera, Caja Costarricense de Seguro Social
Manuel Oporto Mejía, Caja Costarricense de Seguro Social
Manuel Rodriguez Arce, EDUS Executing Unit Director, Caja Costarricense de Seguro
Social

María del Rocío Saenz, Caja Costarricense de Seguro Social Mario Ruiz Cubillo, Caja Costarricense de Seguro Social Priscila Balmaceda Chaves, Caja Costarricense de Seguro Social Roger Lopez, Caja Costarricense de Seguro Social Susana Lopez Delgado, Caja Costarricense de Salud Xinia Cordero Sobalbarro, Caja Costarricense de Seguro Social

CHILE

Msc. Lorena Donoso Abarca, Ministry of Health, Chile Ing. Jorge Herrera Reyes, Ministry of Health, Chile Periodista Gonzalo León Erices, Ministry of Health, Chile Msc. Alejandra Lozano Schälchli Ministry of Health, Chile Sra. Hsiao - lan Lung Hsie, Ministry of Health, Chile Dr. Alejandro Mauro Lalanne, Clínica Alemana Santiago Ing. Nabelka Muñoz, Ministry of Health, Chile Msc. Dr. Juan José Ortega Callejas, Ministry of Health, Chile Ing. José Villa Catalán, Ministry of Health, Chile Msc. Gabriela Villavicencio Cárdenas, Ministry of Health, Chile Dr. Soledad Zapata Villaseñor, Ministry of Health, Chile

PERU

Juan José Castillo Cueva, Ministry of Health Claudia Córdova Yamauchi, Ministry of Health Alicia Cedamanos Medina, Ministry of Health Martha Cajaleón Alcántara, Ministry of Health José Luis Huamán Villar, Ministry of Health Isabel Falla Zevallos, Ministry of Health Rocío Huamán Ramos, Ministry of Health Boris Fazio Luna, Ministry of Health Karol Bulnes García, Ministry of Health Roxana Hilachoque Chumbe, Ministry of Health

URUGUAY

Cecilia Muxi, Institutional articulation - AGESIC
Juan Bertón, Digital Agenda Monitoring Coordinator - AGESIC
Maria Jimena Hernández, Lgeal Group - AGESIC
Betania Arispe, National Resource Center - AGESIC
Walter Callero, Doctor Salud.uy - AGESIC
Paulo Sande, National Electronic Health Record Coordinator - AGESIC
Mauricio Bouza, National Electronic Health Record Architect - AGESIC
Ignacio Friedman, Interoperability Platform Architect - AGESIC
Fernando Portilla, Interoperability Standards Specialist - AGESIC

CONSULTING TEAM

IN2 - TIC SALUT

Architecture

Bernat López

Regional challenges for electronic health implementation

Felix Vilar

Standards

David Rodríguez Cocinero Eli Marín

Normative

Vanesa Alarcón

Terminology

Ariadna Rius

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INTRODUCTIONS

IN2 INTRODUCTION. Challenges for the system's sustainability.

Challenge 1: Population aging.

Nearly 30% of the population of many regions of the world has at least one chronic condition. This group accounts for close to 80% of expenditure on health care, a figure that all studies predict will continue to rise.

Challenge 2: Social equality

When populations are geographically dispersed, it is often difficult to achieve specialization in health care processes. Bringing processes to where patients live is one of the many challenges of achieving this equality and efficiency.

Challenge 3: Mobility

People increasingly cross international borders to pursue their life goals. Movements for job opportunities or simply for tourism are another reality that health systems have to deal with.

In this study, we have set out to describe how information systems can help us build a sustainable and equitable system, focusing on four core aspects:

- Order for management and learning.
- A common language for sharing knowledge.
- Legal and regulatory challenges.
- Architectures for technology and interoperability.

It has been a true pleasure and privilege to work with the excellent professionals from the different countries in the RACSEL network, as well as with the Julio Ricaldoni Foundation team in charge of coordinating the project. We know from experience that coordinating this kind of project is not easy. As the four volumes that have been published attest, the team very successfully met the considerable challenge of bringing together different countries with distinct realities.

IN2 has been working in the healthcare sector for almost 25 years. As its technology has changed, we too have evolved, but with a clear vision that the focus of our contribution is care and efficiency.

We hope that our support, leadership, and coordination, which is sponsored by the IDB, has contributed to building a present and future framework that will support more sustainable and equitable healthcare systems throughout the region.

Rafael Paulet President of IN2 http://www.in2.es/



CHILE

An opportunity to transform the health system

In recent years, Chile has made significant strides in incorporating information and communication technologies (ICTs) into the public health sector. This progress has been possible largely due to the State's modernization agenda, as well as the eHealth Plan promoted by our Ministry. One of the objectives of this plan is the digital transformation of our healthcare network.

This process has unfolded alongside two changes in the world of health. The first is the transformation in the population's epidemiological and demographic profile, as well as people's new behaviors and demands when it comes to health care. The second is the implementation of new health care models and processes, together with the management and implementation challenges of the Integrated Health Service Delivery Networks (IHSDN) model advanced by the Pan American Health Organization (PAHO).

We are convinced that information and communications technology is essential and very relevant to improving health, since it can be used to manage standardized information quickly, efficiently, and reliably, which is the basis for decision-making.

But adding technology for technology's sake is not the best course of action. Rather, this addition should serve the sector's strategic objectives, and, ultimately, its health goals.

This forces us to take a different approach to the digital transformation of health care. First, we have to constantly evaluate technological tools to make sure they indeed do help improve health outcomes by bettering care processes, continuity of care, and public policy. We also need to start measuring how the use of technology affects our patients' access to care, as well as its timeliness and quality.

Chile's current technological governance model should continue to be strengthened, as recommended by the OECD, to ensure that public institutions use ICT in a coordinated and consistent manner in order to efficiently meet people's needs. We have thus created a Sector-Specific ICT Committee, a formal body that is meant to develop and coordinate the national technological strategy for the health sector and carry out sector-specific initiatives in this area in a coordinated manner, with focus on their impact on people.

There is no question that today's technologies represent and major opportunity to accelerate substantial changes within the health systems. We are therefore committed to taking coordinated action to advance this technology throughout Chile in order to achieve better and more equitable health for all.

Dr. Emilio Santelices Minister of Health

COLOMBIA

Improve health quality and access through digitization

In the health sector, service providers have to exchange large volumes of information so professionals at all stages of the continuum of care can make the best decisions. But this information is currently fragmented and scattered across numerous databases of different hospital information system providers, which makes it difficult for people to quickly access their complete medical records.

This fragmentation is confirmed by the results of the Institutional and Regulatory Framework, Standards, Architecture and Terminology report. This document was prepared with support from the technical groups of the member countries of the Regional Public Good (RPG) initiative, as well as the Network for the development of Electronic Health Records in Latin America and the Caribbean, and financed by the Inter-American Development Bank (IDB). It found that our countries use a wide variety of medical information systems and have made scant progress towards creating standards for their unification.

In this document, international organizations stress the importance of working to make hospital information systems interoperable, of adopting standards that help optimize the use of resources, and of coordinating policies, plans, projects, initiatives and/or strategies that will use information and communications technology (ICT) to improve access to and the quality of health care.

It is thus necessary to move towards making the health sector interoperable, which means service providers must modernize their information systems. To avoid data silos and/or isolated digital environments that make information hard to access, Colombia's Ministry of Information Technology and Communications (MinTIC) is launching the ICT and Health Care initiative, spearheaded by its the Sector-Specific Digitization office in conjunction with the IT Standards and Architecture Office of the Directorate of Digital Governance. The aim of the initiative is to design, adopt, and promote policies and plans to increase and simplify people's access to ICT and channel efforts to digitize the health sector. It seeks to bring order to these digitization efforts and ensure the application of standards and interoperability criteria that make it easier to securely and efficiently exchange people's information.

This interoperability is developed using Colombia's IT Architecture, which is based on the Enterprise Architecture Reference Framework and has an Interoperability Framework, which defines the conditions and standards for exchanging information to apply precise criteria to processes and data, thus making health services easier to use and more appropriate.

Interoperability, at all of its levels, will ensure that information is correctly secured, exchanged, interpreted, and used by the health sector's wide variety of providers and hospi-

tal information system technologies. The aim is that this information can be quickly and securely consulted by health care professionals, as well as citizens through the Citizens Folder (in the case of Colombia).

Countries will prepare to exchange health information so these interactions can be efficient and high-quality. The results shown by the Network show much progress in this regard and contain a set of recommendations and best practices for moving towards the digitization of health care.

David Luna Sanchez Ministry of Information Technologies and Communications

COSTA RICA

Disruptive technologies and eHealth

Health systems are in need of a new disruptive transformation that achieves a different balance between the system's inputs and the tangible results for users. This challenge is compounded by the obsolescence of traditional administration models, the outdatedness of highly complex and interdependent process, and the limited resources available for meeting the needs of a constantly evolving epidemiological profile.

The convergence of technology and medical sciences is revolutionizing the health care industry and how health care is managed. Today someone with a smart phone could do an electrocardiogram in a distant corner of Lima, email a copy of it to a cardiologist in Montevideo, who could then make a diagnosis and set up a video conference to consult a specialist in San Jose about a treatment, which could be delivered efficiently and accurately by a drone. This scenario would cost significantly less than transferring the patient or flying in the cardiologist, and would avoid the possible complications of addressing the issue more slowly.

Electronic Health Records are already crucial to upholding the right to health information. They are a tool for organizational transformation that can bring down health care costs and drive more democratic and universal access to healthcare services, saving millions of lives.

They enable care that is centered on the patient, based on their medical history, pathologies, and even risk factors, which results in more effective and efficient diagnoses and treatments. In some cases, assisted intelligence is even used to help make clinical decisions.

Using the information compiled in electronic health records, we can predict how demographic and epidemiological profiles will behave. This allows us to take proactive measures to protect the population's health, as well as monitor that health in real time.

Now is the time to form inter-sectoral and multidisciplinary clusters in order to move into this new era with production chains that add value to the process and final product. Governments, organized civil society, professional associations, universities, and private enterprises, working as a team, should guide the technological change on aspects ranging from policy to redesigning and continuously improving processes. The ultimate aim of this joint and cooperative effort is for the region's healthcare systems to not only thrive, but also improve, as is the case in any disruptive process.

^{1.} In Costa Rica, for example, the information from 100% of primary healthcare services nationwide is included in an Electronic Health Record system, as part of the Unified Digital Health Record [EDUS] project. More recently, the country is undertaking an ambitious program to automate hospitals so patients' medical information can be viewed from anywhere within the healthcare network of the Costa Rican Social Security System (the sole provider of public health services in Costa Rica), and users can access this information from mobile phones.

This series of documents prepared as part of RACSEL is rooted in that same spirit of creating synergies and managing innovation. We invite you to be part of the transformation and spread it within your immediate sphere of action.

Written by:

Dr. Mario Ruiz Cubillo

Ms. Ana Lorena Solis Guevara

Dr. Priscila Balmaceda Chavez

Mr. Manuel Rodrigez Arce

Members of the EDUS-ARCA Steering Committee

Costa Rican Social Security System

PERU

International collaboration: key to implementing a national and regional electronic health records system

As it approaches its 200th anniversary in 2021, Peru envisions itself as a more modern, competitive, and democratic country, with high human development, supported by a diversified production structure.² By 2021, comprehensive health care will be universal for both individuals and groups, regardless of their socioeconomic status or geographical location, and this care will respect gender equity, human rights, and cross-cultural considerations. Public health care will also be comprehensive, charitable, equitable, fast, free at the point of delivery, high-quality, easy to access, and adapted to the characteristics of the population's lifecycle.³

Peru has made significant strides in eHealth in recent years.⁴ To summarize the progress it has made on health records, in 2006 it updated the formats and minimum requirements for the information a health record should contain, as well as the general guidelines for computerizing them.⁵ In 2011, Peru established six specifications for standardizing entries in electronic health records,⁶ and it adopted the XML, HL7 and DICOM standards for exchanging medical information.

An especially important milestone was the passage on May 22, 2013 of the congressional bill creating the National Registry of Electronic Health Records (RENHICE). In 2016, a decree-law defined the RENHICE as the specialized technological health infrastructure that keeps a backup of the information in electronic health records and gives patients, or their legal representatives, and the healthcare professionals they authorize, access to the medical information contained in the electronic health records, as well as the basic medical information and summarized medical information they contain, as strictly necessary to ensure the quality of care at health facilities and in public, private or public-private medical services, under Law 26842, the General Health Act.

- 2. Updated Strategic National Development Plan: "Peru En Route to 2021."
- 3. 2016-2021 Sector-Specific Multi-Year Strategic Plan for the Health Industry, approved by Ministerial Resolution No. 367-2016/MINSA
- 4. Curioso WH. La Telesalud y las nuevas fronteras de la informática biomédica en el Perú [editorial] [Telemedicine and the New Frontiers of Biomedical Information Technology in Peru [op-ed]]. La Revista Peruana de Medicina Experimental y Salud Pública. 2015; Volume 32 [2]: 217-220.
- 5. Technical Health Standard (NTS) No. 022-MINSA/DGSP-V.02 for the Management of Health Records, approved by Ministerial Resolution No. 597-2006/MINSA.
- 6. Administrative Directive No. 183-MINSA/OGEI-V.01. This directive lays out the specifications for standardizing Electronic Health Record entries. Approved by Ministerial Resolution No. 576-2011/MINSA.
- 7. Law No. 30024, Law that creates the National Registry of Electronic Health Records.
- 8. Legislative Decree No. 1306. Legislative Decree that optimizes processes associated with the National Registry of Electronic Health Records.
- 9. Article 2, paragraph 2.1 of Law No. 30024, which creates the National Registry of Electronic Health Records; paragraph modified by Article 2 of Decree Law No. 1306.

In 2016, the definition of the Electronic Health Records Information System (SIHCE) was also updated to the set of human, organizational, regulatory, and information and communication technology elements that interact to process electronic health records at a health facility, a supporting medical service, or a combination of the two. ¹⁰ Additionally, the country approved the use of the National Electronic Identification Document (DNIe) to digitally sign documents generated by medical and healthcare acts. ¹¹ In 2017, it passed the provisions for applying and correctly enforcing Law No. 30024 ¹² and began the process of updating the industry-wide Technical Health Standard for Managing Health Records. The standard will soon be adopted via a Ministerial Resolution.

Finally, in recent years Peru's Ministry of Health has been progressively implementing an electronic health records system in public health establishments nationwide as one of the systems within the RENHICE.

Motives

The process of developing and implementing electronic health records in Peru comes with many challenges, so it is strategic to look to the experiences, lessons learned, and recommendations that have created knowledge and models for planning, implementing, and advancing projects with a regional, national, and international scope, with international health information technology standards.

For this reason, the Ministry of Health, as Peru's National Health Authority, joined the Network for the Development of Electronic Health Records in Latin America and the Caribbean in November of 2014 through its General Information Technology Office. This initiative is part of the Regional Public Good project funded by the Inter-American Development Bank. Peru also began to fully participate as a member of the Digital Health Cooperation Network of the Americas (RACSEL).

Benefits

Being part of RACSEL has given us a clearer idea of strategic actions and specific technical definitions related to institutions, regulations, standards, terminology, architectures, and security and interoperability that we should include in the implementation plan, in the specific directives, and as part of the work to design, validate, and launch the RENHICE as a platform for integrating and sharing electronic health records.

The institutions, people, and achievements of the Salud.UY program and the National Electronic Health Records (HCEN) system in Uruguay; of the Healthcare Network Information Systems (SIDRA) strategy and the Pharmaceutical Terminology Services with SNOMED in

^{10.} Article 3(r) of Law No. 30024, which creates the National Registry of Electronic Health Records; modified by Article 2 of Decree Law No. 1306.

^{11.} Administrative Directive No. 221-MINSA/2016/0GTI "Administrative Directive authorizing the use of digital signatures for medical and healthcare acts," approved by Ministerial Resolution No. 978-2016-MINSA.

^{12.} Implementing Regulations of Law No. 30024, approved via Supreme Decree No. 009-2019-SA.

Chile; of the ICT Reference Framework and the sector- and territory-specific architectures approach in Colombia; and the Unified Digital Health Record (EDUS) in Costa Rica, among many other experiences, inspire and challenge us to step up our efforts to continue writing the history of the digitization of the health sector for the benefit of the people.

Next steps

RACSEL lays a Latin America-wide foundation for international collaboration at the country/region/global level. This foundation was built by sharing the challenges States face as they strive to ensure the highest possible quality, efficiency, and transparency in health care.

Not only does international collaboration allow different parties to exchange best practices for eHealth, it also provides opportunities to work together on new projects and to enhance how eHealth knowledge is managed.

During this next stage, the strategic priorities will be to share products and create new opportunities for exchanges within and beyond the region so countries can evaluate and adjust their initiatives, as well as add to the knowledge that has already been shared and work together towards the ultimate goal of constant, increasing, and equitable improvements to healthcare services and people's health.

ABEL HERNÁN JORGE SALINAS RIVAS Minister of Health Republic of Peru

URUGUAY

We need to consider how to capitalize on this effort and continue collaborating in the future

Historically, Uruguay has sought to engage collaboratively with the countries in the region and is convinced that joint initiatives generate value and knowledge and allow countries to address and work to solve common needs that arise.

We have thus supported and led processes to develop collaboration networks between different countries. A clear example is the Gealc Network, formed 15 years ago. This network brings together 30 countries in the region and was established to promote horizontal cooperation, support for citizen-centered eGovernment policy initiatives, training for public officials, knowledge of key aspects of building a national electronic governance strategy, and exchanges of solutions and experts between the countries in the region.

Uruguay has playing a leading role within the RACSEL network and has been highly involved in the development of a Regional Public Good (RPG) to implement electronic health records in Latin America and the Caribbean. In this regard, the contributions and experiences generated by Uruguay's Digital Agenda were key. This document sets developing eHealth as one of the government's strategic objectives, one that is being achieved through the initiatives of the Salud.uy program.

We know that the field of digital health is broad and complex, and thus requires specialized knowledge. We are also aware of the challenges that arise when digital health is applied to the population. For those reasons, we believe the progress we have made in different areas (standards, terminology, architecture, and regulations) can be of use to other initiatives in the region. But we also recognize the need to look to the practices and experience of neighboring countries to help us address our local concerns.

By doing so, we have found countries in other regions that generate knowledge about interoperability for electronic health records and form collaborative networks, which allow them to strengthen their local initiatives and exchange experiences between working groups. This helps them solve similar sets of problems or create international proposals for interoperability in the area of health.

The products and work that RACSEL has delivered so far are a solid and concrete first step that lays the groundwork for aligning the national initiatives of Latin American and Caribbean countries. In the medium and long term, as the region's digital health dynamics mature, we will need to continue deepening these collaborative processes as we face new challenges and consider new scenarios for interoperability in the field of health. Examples of this collaborative work include tackling the specifics of exchanging medical data between countries and constantly sharing progress and lessons learned to move forward on this issue as a region.

New challenges push us to continue to strengthen the network and create new tools and instruments that contribute to governments' policies on Electronic Health Records. We have taken an important first step towards achieving the transformations that currently need to take place, but there is a long road ahead of us. If we have a strong network, we will be better equipped to overcome future challenges.

José Clastornik

Executive Director AGESIC

CHAPTER 1

DEMAND-SIDE CHALLENGES

Health systems the world over face major challenges. In recent years, the economic crisis has led to harsh budget cuts in all areas of government activity, and health has unquestionably been one of the hardest hit. Health systems inherently consume large quantities of public resources, so they are at the center of the controversy when governments are forced to adopt restrictive economic policies. But since health care carries such great social and personal weight, economic restrictions on health care have a profound impact on society.

The great contradiction, however, is that even as its sustainability is called into question, healthcare spending continues to climb. Experience shows that health costs go up as countries develop and concern themselves with raising their citizens' quality of life. In many countries, increases in healthcare spending have significantly outstripped economic growth.¹³

Beyond development factors, the sustainability of healthcare systems is also beset by a combination of major demographic, social, cultural, and technological challenges, and the economic viability of the systems is constantly called into question.

- **Demographic shifts.** Longer life expectancies, population aging, and the rising incidence of chronic conditions are major challenges for health systems.
- **New expectations.** The health profile of systems' users is changing drastically, and these users continually demand and expect more in terms of health care.
- **Innovation costs.** Innovations for new treatments and diagnostic methods tend to drive up costs and threaten to push healthcare spending even higher.
- Increased use of health systems. Risk factors like obesity, physical inactivity, and
 tobacco use mean people require healthcare services more frequently. Together
 with high blood pressure and high cholesterol, these factors explain an epidemic
 of premature cardiovascular mortality that increasingly jeopardizes the viability
 of health systems.
- Lack of integration between levels of care. Factors within the system itself, like
 low integration between its levels of care, lead to ballooning administration and
 coordination costs. The most visible examples of these factors are repeated medical appointments and diagnostic tests.

^{13.} Nuevo contexto y viejos retos en el sistema sanitario [New Context and Old Challenges in the Health System]. ESADE Business School.-Peiró, Manel, Joan Barrubés: Nuevo contexto y viejos retos en el sistema sanitario [New Context and Old Challenges in the Health System]. Revista Española de Cardiología, vol. 65, No. 7, July 2012, pp. 651-655. DOI: 10.1016/j.recesp.2012.02.019

Different parameters

Current health care models are unsustainable because they were designed based on parameters that have shifted significantly in recent decades. One of the most significant changes is life expectancy, which is rising worldwide. According to the World Health Organization (WHO), people's life expectancy increased by a full five years between 2000 and 2015. This is the largest gain since the 1960s.

In Latin America, the average for this quality-of-life indicator is approaching that of more developed countries. According to the WHO, the region's average life expectancy in 2015 was 75 years, a figure set to reach 78 by 2030.¹⁴

Longer life expectancy goes hand in hand with the progressive aging of the population, which is equally relevant to the future of health systems. The WHO states¹⁵ that people over age 60 are the world's fasted growing demographic segment. In 2050, one in every five people will be part of this group, and by the end of this decade, there will be around 1 billion people over age 60.

The aging trend is also intensified by the drop in fertility rates triggered by greater awareness of family planning, more prevalent contraceptive methods, and health gains in general

Falling birthrates and population aging are often thought of as essentially a problem of developed countries, but in reality this demographic transition is especially acute in developing countries. In either case, more and more older people depend on a resource that is proportionally ever scarcer: the population of young people.

As the population is aging, older people's quality of life and health is also improving markedly. But no matter how healthy and active people over 60 are, at some point they begin to weaken and become less independent. The fact is that the number of patients with cognitive impairment and dementia will go up as the population ages. A larger and larger segment of the population will have health costs that are 4 to 12 times higher than the rest. Healthcare systems will thus have to be prepared to respond to this need.

Chronic conditions are another major challenge that health systems face. The medical advances and increased well-being of recent decades have gradually caused societies to age, with the consequent rise in conditions associated with old age. However, it should be clarified that not all chronic conditions are exclusively tied to aging. They are also associated with unhealthy life habits, such as tobacco use, physical inactivity, unhealthy diets, or excessive alcohol consumption. Most medical appointments are for patients with chronic conditions, a trend that will continue to rise sharply.

^{14.} World Health Organization: *Proyecciones de la mortalidad y las causas de la muerte* [Projections of mortality and causes of death], 2015 and 2030.

^{15.} Boletín de la Organización Mundial de la Salud [Bulletin of the World Health Organization], vol. 90, no. 2, February 2012.

According to a report by The Boston Consulting Group, ¹⁶ cardiovascular diseases, cancer, respiratory illnesses, and diabetes are responsible for 60% of deaths worldwide. At a global level, 36 million people die each year from chronic conditions. Of these, more than 70% are over age 60.

The new composition of the demand

The composition of the demand for health services demand has changed dramatically in recent years, which has also played a significant role in driving up expenditure on health. People have less tolerance for diseases and increasingly insist on better and safer health-care services: they are unwilling to have their quality of life be affected. In addition to demanding fewer medical errors and increased capabilities to detect and prevent disease outbreaks, patients have become activists and call for broader medical coverage that reduces social disparities.

Additionally, new treatments and technologies (advances in molecular genetics, less invasive surgeries, personalized medicine, etc.) fuel greater demand by making new procedures and treatments possible. Treatment costs will skyrocket in upcoming years to levels much higher than today's. For example, annual per-patient costs for cancer treatments are expected to rise sharply.

These increasingly exacting expectations for health care will be compounded by longer life expectancies, a trend inversely proportional to the availability of resources. The lack of resources for health care seems to be a constant. It is a great paradox: more developed health systems and increasingly sophisticated treatments and diagnoses have led to longer life expectancies and more healthy people, and this very circumstance has created a problem for the systems' sustainability.

Change of course

How can we tackle the colossal challenges the health systems are facing? There seems to be a strong global consensus among experts that the current model for health systems is not sustainable for any length of time. A profound transformation has to take place for them to be viable. Their structure needs to be overhauled entirely to ensure both their sustainability and universal access to their services.

Public health systems have not traditionally been quick to introduce reforms and adopt new approaches. One reason is that to do so they have to navigate many bureaucratic processes. But beyond this obvious hurdle, it is quite difficult to address current challenges using the old strategies and health management models that continue to exist today.

There needs to be a change of course that ensures that older people continue to contribute

^{16.} Informe Cronos: hacia el cambio de paradigma en la atención a los enfermos crónicos [Chronos Report: Towards a paradigm shift in care for people with chronic conditions]. The Boston Consulting Group. April 2014. Available at: <enfermeriacomunitaria.org/web/attachments/article/1075/INFORME%20CRONOS.pdf>.

to society as part of what is termed "active aging," which is a key to remaining in good health after age 60. Cultivating healthy life habits at all ages is extremely important and can guarantee the continued participation of this age group in social, economic, cultural, and civic spheres.

Another major challenge for the system is building a model that centers on caring for patients with chronic conditions and different diseases. Today's healthcare model revolves around providing care for acute medical conditions, but actual healthcare needs clearly call for system that is also designed to provide care for chronic conditions. In order to care for patients with chronic conditions, it is crucial to design a more integrated and coordinated system with a shared strategy for caring for patients. Health care models for this type of patient require patients themselves to be more responsible and capable of making decisions about how to handle their conditions.

To be successful, initiatives thus have to be based on prevention, the integration and coordination of all elements of healthcare delivery, continuity of care, and informed patients who are committed to managing their condition. The general public also needs to be made aware of the health system's limited capacity and how to use resources responsibly.

Using resources more efficiently and improving effectiveness is essential to health systems' ongoing sustainability. In this context, patient-centered care and expanding the use of new technologies are two factors that can set health systems up to successfully overcome the significant challenges that lie ahead.

One of the most promising experiences in this vein is the implementation of electronic health record (EHR) systems. In Canada, for example, more than twice as many primary care physicians used EHR in 2012 than in 2006, rising from 23% to 56%. Over these six years, the Canadian public health system reaped benefits worth around C\$1.3 billion, as calculated in an independent study commissioned by Canada Health Infoway, an organization associated with the government that supports ICT projects in the Canadian healthcare industry. The report identifies solid reasons to continue developing EHR systems and working to expand their use to the entire country. In addition to savings for the health system, the study identified other existing and emerging benefits of implementing EHR, like more efficient workflows in health care, better health outcomes, increased patient safety, and improved interactions and communication. The study identified of the care increased patient safety, and improved interactions and communication.

Another recent success story is the implementation of electronic prescriptions in Spain. This innovation is well established and covers more than 80% of all prescriptions.²⁰ It

^{17.} Boletín de la Organización Mundial de la Salud [Bulletin of the World Health Organization], vol. 90, no. 2, op. cit.

^{18.} The emerging benefits of electronic medical record use in community-based care. A study commissioned by Canada Health Infoway. PwC, 2013. Available at: <infoway-inforoute.ca/component/edocman/resources/reports/benefits-evaluation/1225-the-emerging-benefits-of-electronic-medical-record-use-in-community-based-care-executive-summary?lang=en&Itemid=188>.

¹⁹ Ihidem

^{20.} Estudio de interoperabilidad en el sector sanitario: el paciente como actor principal [Study on Interoperability in the Health Sector: The patient as the primary actor]. Instituto para el Desarrollo e Integración de la Sanidad (IDIS), 2015. Available at: <fundacionidis.com/wp-content/informes/informe_interoperabilidad_idis_web.pdf>.

allows greater control over drug spending and increases patient safety. After successfully implementing the system in most autonomous communities, Spain's goal is to make the electronic prescriptions interoperable between different regions to accommodate citizens' movements throughout the country.

CHAPTER 2

PATIENT-CENTERED CARE

The role of patients in health systems has changed radically in recent years. Patients are better informed and much more involved in processes related to their wellbeing. They are more educated, have much higher standards, and are more proactive about their own care. They also have more sources of information and resources and more freedom to choose between professionals. No longer passive recipients of medical care, they rather demand service that meets the same standards for quality and satisfaction they seek in other spheres.

Health system users are becoming consumers who play an increasingly active part in making decisions about their health. This new position gives patients more autonomy in managing their treatment process (medications, diets, scheduling appointments, etc.), and it grants them more ownership of their own health. This boosts their quality of life and directly contributes to optimizing the health system.

Furthermore, people are increasingly aware of their right to control, access, and use their medical information whenever, wherever, and however they choose.

Patient empowerment—or people taking an active role in managing their own health—is radically changing healthcare models. It has been proven that a patient's level of involvement is usually a decisive factor in treatment. And this involvement unquestionably helps lighten the system's load and make it more sustainable.

Users, by taking an active role in decision-making and caring for their own health, become key partners in reducing the costs of current healthcare models. The evidence for this is even more certain in the case of chronic conditions. These conditions inherently consume the most resources, but the exact amount largely depends on how well people with these conditions look after their own health. Thus, patients' decisions about life habits, exercise, diet, or taking medications correctly can have a direct impact on the course of the disease and its treatment, and can, for example, reduce the number of medical procedures and tests or the need to constantly monitor a patient.

When patients engage, their treatments can be personalized, adapted to their specific life circumstances, and made safer.

Patients are more empowered largely because they have more knowledge and more access to sources of information. The spread of information and communication technologies (ICT) has contributed decisively to the rise of this new model that put patients at the center of the system. Advances in the reliability and precision of medical devices, together with the boom of monitoring technology, result in more personalized care, better self-management, and more empowered patients. Meanwhile, eHealth (electronic health) has

the potential to bring health benefits to broader swaths of the population in a context of severe budget constraints.

Over the last 10 years, an increasing number of countries have gradually incorporated new clinical applications, telemedicine solutions, or computerized healthcare management systems into their health systems. Home medical care, digital management of radiological imaging, and electronic prescriptions are now a reality in many regions. Significant efforts have also been made to computerize health centers.

On one hand, the internet and social media give patients more choices for where to go for information on their conditions and allow them to compare impressions and experiences with other people in the same medical situation. This information is available independent of time and place through different channels, sources, and networks.

On the other hand, the technology for devices that track people's health habits and remotely monitor their general health continues to advance. Devices provide new and more accurate options for monitoring the behavior of certain health parameters like weight, blood pressure, or physical activity, or for correctly tracking medication. There are also mobile apps that can help patients with chronic conditions like diabetes have more control over their disease by entering different parameters to measure glucose levels or insulin injected. They can use the same app to track the food they eat throughout the day, get advice about doing exercise, or find more varied meal options. All of this technology encourages healthy lifestyles and facilitates health campaigns.

Telemedicine, in turn, can be used to remotely monitor patients, overcome geographic barriers, and make travel unnecessary. Internet and mobile devices make it easier for patients to manage their health care and simplify bureaucratic processes. Patients can schedule appointments or examinations without having to physically go to the health center, and they can conveniently make any necessary changes or adjustments. They also have easier access to the medical professional or health center that best aligns with their needs, inclinations, and preferences.

All of these changes lead to increasingly more personalized medical care. Patient-centered care is now recognized as the starting point for improving healthcare outcomes and quality and cutting down on the amount of resources used.

Health services that incorporate technology are more flexible, integrated, and continuous. They allow patients to share their medical records with any professional, which facilitates their care regardless of time and place and helps drive a shift in healthcare models towards a system characterized by continuity of care and coordination between levels of care.

Everyone in the health sector benefits from embedding technology in health care, but the patient benefits most of all. Technology makes disease prevention and healthcare mana-

gement more personalized and efficient. These benefits²¹ take the form of more accessible medical information and greater co-responsibility from users. They make it easier for patients to move within the health system, improve safety, and potentially lead to better health outcomes.

When health professionals have access to extensive and more accurate information, they can make quicker, evidence-based diagnoses. Digitizing processes can also cut down on unnecessary diagnostic tests, which could entail health risks, in addition to being a hassle for patients. Eliminating tests can also bring down costs, prevent delays in decision-making due to lack of information, and reduce the number of healthcare procedures performed.

Likewise, having access to documentation that is better structured thanks to new technology will give healthcare professionals more time to help patients instead of doing administrative work. In short, if clinical and therapeutic coordination were substantially improved and simplified, professionals could focus more on diagnoses and provide exhaustive follow-up for patients.

Equally as important is how new health technology can influence prevention and patient quality of life. Electronic health records (EHR) allow professionals to prevent and even predict the progression of patients' health and of certain medical conditions. Professionals have more, more accurate and reliable, information. EHRs also make it easier to coordinate care for a patient who switches health professionals: the new professional can access medical information on the care already provided to the patient.

In sum, properly combining patients' new role and the advantages of new technology can help strengthen health care systems in today's complex socioeconomic context.

^{21.} Estudio de interoperabilidad en el sector sanitario: el paciente como actor principal [Study on Interoperability in the Health Sector: The patient as the primary actor]. Informe IDIS [IDIS Report]. October 2015 Available at: <fundacionidis.com/es/informes/interoperabilidad-en-sector-sanitario-paciente-como-actor-principal>.

CHAPTER 3

INFORMATION AND COMMUNICATION TECHNOLOGY AND HEALTH SYSTEMS

As described above, today's health systems face major challenges. Their sustainability is under pressure as societies increasingly demand higher quality and economic resources become scarcer. Information and communication technology (ICT) can help solve this complex conundrum. The ICT revolution is improving all areas of people's wellbeing and quality of life. It is radically changing the relationship between the general populace, governments, and companies. Information societies have achieved location-independent access to information, increased efficiency, and more streamlined processes, and these gains will only become more pronounced in the future. ICT goes beyond the classic conception associated chiefly with hardware or telecommunications. In the field of health, ICT is a combination of software and hardware systems, services, management actions, and expert knowledge that makes projects with high added value possible.

Technology helps health and healthcare systems manage and use resources optimally and offer better services and care to users. The advantages of these benefits are undeniable, given the substantial service and sustainability challenges that public health systems face.

In the field of health, technological progress has initially materialized as major transformations in techniques for research and for diagnosing and treating patients. And ICT is already helping the system function better by making healthcare processes and the work of healthcare professionals easier. Its implementation simplifies many internal bureaucratic and organizational processes and provides patients with more specific, clear, and timely information. In short, it allows health centers to be more efficient.

But applying ICT to health does not necessarily mean creating a new healthcare model. It rather offers a more efficient and effective way to provide services, which ultimately results in more equitable health care. This new reality means improved accessibility, faster care, shorter wait times, or more effective diagnoses and treatments.

Harnessing technology for health

Electronic health records (EHR), telemedicine, interoperability, or mobile devices are a few of the new technological tools²² that medical science and public health can draw on to help improve the quality of and access to health care and make it more economical.

An EHR is a digital record of all clinical and healthcare activities performed on a patient. These records make it easier for health care professionals to make decisions and provide treatment.

^{22.} World Health Organization (WHO). Perfiles de países de Atlas eHealth: basados en los hallazgos de la segunda encuesta global sobre eHealth [Atlas of eHealth country profiles: Based on the findings of the second global survey on eHealth]. (Observatorio Global para la Serie eHealth [Global Observatory for eHealth], 1). Geneva: World Health Organization; 2010.

- Telemedicine is the interaction between health centers and users via telecommunications. It can be used to provide remote diagnoses and treatments, and it keeps patients or professionals from having to travel.
- Interoperability is the communication between different technologies and software applications for an effective, accurate, and sound exchange and use of data between the different levels of the healthcare network.
- mHealth is the term for practicing medicine and implementing public health measures with the support of mobile devices—like cell phones—, patient monitoring devices, and other wireless technologies.

Other technological gains include the use of electronic prescription systems to improve prescription and pharmaceutical dispensation processes, remote management of users' appointments with healthcare professionals, and the availability of remote diagnosis and treatment devices.

Health systems can leverage new technologies to make their medical care processes more efficient: better coverage, more interaction between patients and physicians, shorter wait lists, or more accurate diagnoses. Technology enables more personalized, integrated, and continuous services

Numerous experiences show that introducing ICT has improved access to health services and has facilitated fast and secure exchanges of administrative and clinical information between different levels of health care. This has resulted in higher-quality and more efficient healthcare systems, with the ensuing societal benefits.

From an economic point of view, ICT leads to more efficient use of time and resources, simplifies complex decisions, and, in particular, allows systems to set priorities.

ICT's potential to streamline processes, improve service quality, and meet society's needs is thus obvious. But much of this potential has yet to be realized. Though some countries have been working for years to implement eHealth, with positive results, there is still much work to be done.

Barriers to introducing technology

Incorporating ICT into health systems has its difficulties. Obstacles include: 23, 24

Citizens, patients, and healthcare professionals who are unaware of or lack confidence in the application of these new health technologies.

^{23.} European Commission. Plan de acción sobre la salud electrónica 2012-2020: atención sanitaria innovadora para el siglo xxi[eHealth Action Plan 2012-2020: Innovative healthcare for the 21st century].

^{24.} La eSalud en la Región de las Américas: derribando las barreras a la implementación [eHealth in the Region of the Americas: breaking down the barriers to implementation]. Resultados de la Tercera Encuesta Global de eSalud de la Organización Mundial de la Salud [Results of the World Health Organization's Third Global Survey on eHealth] 2016

- Difficulty adopting set standards that foster interoperability —or the exchange of data between different technological platforms and different levels of care—due to cultural, organizational, security, or economic factors.
- The return on investments in eHealth tools and services needs to be confirmed, though this is not a simple process. This return may be measured in economic terms (cost goes down as efficiency goes up), but also in purely qualitative aspects that are equally as important, like better quality and care for users.
- High initial implementation costs, despite savings in some areas and generally low replication costs.
- Regional differences in access to technology and limited access in less privileged areas
- Rigid organizational structures.
- A lack of proper legal frameworks for supporting and governing the use of health technology.
- Resistance to change due to refusal to "be controlled." In some cases, professionals do not want medical records to be audited. This social factor has often led to the demise of projects; it is a real obstacle that the highest authorities should address.
- Lack of readily available proof and evidence of the effectiveness of EHR and telehealth programs.
- Low trust among patients and health professionals because of insufficient guarantees that the data collected by online health systems and applications will be processed securely and privately.

There are also several circumstances specific to Latin America that shape the debate on digitizing health. Despite substantial efforts and reforms in recent years, as well as the economic, social, and human progress that has been made, social inequalities based on uneven wealth distribution continue to be a reality. For health care, they mean unequal access to services. The shortage of suitable human resources, infrastructure, and equipment, as well as the physical distance separating certain segments of the population from public services results in to limited access, or no access at all, for large groups. There is also a more basic problem for eHealth: ICT is not universally available, and in some regions people's access to it is very inconsistent.

Lastly, when introducing these new technologies, is important to not lose sight of Latin America's unique health situation. The economic and social progress of recent decades has led to a significant drop in mortality in general, while life expectancy in the region is starting to approach that of more developed countries. But in Latin America, conditions

typical of developing countries exist side-by-side with others that are characteristic of advanced societies (cardiovascular diseases, degenerative diseases, or cancer).

These factors raise the question of whether to first address these unresolved issues or to rather take decisive action to make ICT part of the solution to these deficiencies.

The fact is that various health care initiatives based on new technologies are already up and running in Latin America and are yielding very good results, as we can see for example in Chile, Colombia, Costa Rica, Peru, and Uruguay, countries that have taken the lead in implementing EHR. It seems clear that technological development provides an opportunity to overcome the inequalities and challenges of different health contexts.

For example, telehealth or mobile devices can be used to provide services to remote populations and marginalized communities. And EHRs markedly improve patient diagnoses and treatments because they more quickly furnish professionals with much more accurate information. This benefits patients with chronic conditions and also allows professionals to foresee potential negative side effects of prescribing a drug. Technology also enables better management of crises and pandemics, and provides immediate access to specialists. ICT can also play a pivotal role in training: e-learning can improve the education of health personnel.

In essence, applying ICT to health enhances the relationships between all parties involved in the system: the general populace, patients, managers, officials, and providers. Properly implementing new technologies can contribute to answer to the challenges of Latin American health systems. Here are a few examples of their impact on the field of health:²⁵

- They bring health services to areas that are remote or isolated, with few resources, or with low population densities. This leads to more equitable and universal healthcare.
- Lower medical treatment costs: they help shorten hospital stays by reducing the number of medical procedures and checks.
- They move certain decisions to lower levels of the health system. In other words, they help shift some activities from hospitals to health centers or even into homes, resulting in lower costs and fewer transfers.
- They support professionals' activities, whether care provision, support, or training.
- Better management, storage, processing, and transportation of information (safeguarding its completeness, confidentiality, and availability).
- Less likelihood of errors in activities like writing prescriptions.

The health sector by nature tends to consume and ever increasing amount of resources.

25. Las tic y el sector salud en Latinoamérica [ICT and the Latin American Health Sector]. Fundación Telefónica.

But the economic reality demands sustainability without lessening the quality of service, even as users are constantly requiring more and better care. The only way to ensure this sustainability is to equip the system with any and all technological tools that could help optimize processes and increase efficiency.

To achieve these benefits, Latin America has to overcome a few challenges. A study conducted by the WHO, ²⁶ with the support of the Pan American Health Organization (PAHO) and the International Telecommunication Union (ITU), found that one of the chief difficulties is improving the organizational and technological infrastructure. This lack of basic infrastructure is critical in projects involving mass data collection and electronic prescriptions, for example. Another important challenge already mentioned above is interoperability, or the need for greater integration between existing national and regional health information systems. Additionally, many health care institutions would struggle to manage large volumes of digital information, and the millions of handwritten medical records at many of these facilities further complicates matters. And from an operational standpoint, keeping information secure and the possibility of being exposed to the mass cyber-attacks that have occurred recently is equally as daunting.

It is thus necessary to change systems' governance models and give ICT experts and new technologies a strategic role within their structure. In initial strategy evaluation, decision makers should add specific applications of health information technology, even if the current operating schemes remain in place.

New technologies' contribution to healthcare goes beyond improving technological equipment and networks and equipping health care centers and professionals with them. It also includes models and tools that use IT to enhance health, guarantee continuity of care, and improve the quality of information.

But none of these technological challenges can be met without the necessary support from the political arena and society. Countries with concrete experiences implementing ICT for health care have already achieved improvements and increased efficiency in terms of productivity, service quality, time, and expenditure. These gains should be presented in easily measurable terms that can be clearly communicated to the general public.

This will increase institutional support in the form of national policies or strategies and, more importantly, eliminate the disparities between procedures for implementing new health technologies that currently exist in Latin America.

The use of ICT in public health should be seen as a chance to make national health care systems more efficient. Strategically speaking, countries should apply this efficiency-based approach in each division of the health care system to improve its governance. This includes the areas in charge of services and funding; epidemiological surveillance; supervision, oversight, and monitoring; and logistics, planning, and budgeting.

^{26.} World Health Organization (WHO). eHealth and innovation in women's and children's health.

The goal of all of these actions is to improve overall health, ensure continuity of care, and enhance the quality of information. In essence, the aim is to improve people's quality of life and, ultimately, unite society and ensure its economic sustainability.

CHAPTER 4

THE RACSEL PROJECT EHR in Latin America and the Caribbean

The social and economic progress made in recent decades in Latin America and the Caribbean has also impacted the region's health systems. Countries have launched various reforms to improve the quality of services and make access more equal than it traditionally has been in the region. Today, equitable and universal access to quality health care is among the rights that members of any society demand, and this demand is reinforced by citizens' increased participation in, and higher standards for, health care. The challenges of these higher expectations have to be met while simultaneously reining in the rise in healthcare spending.²⁷

Incorporating information and communication technology is key to managing systems more effectively and improving the quality of health services. In recent years, several Latin American countries have been implementing different ICT- and health-related actions and initiatives at a national level.²⁸ But despite their significant progress, major obstacles still stand in the way of truly tapping into the potential advantages of introducing ICT into health systems.

One barrier to effectively applying ICT is the unavailability of comprehensive health information that is accessible to patients. This is a gap that could be filled by creating an EHR system, or in other words, by digitizing patient medical records that traditionally were, and in many cases still are, kept in handwritten documents. In an increasingly globalized world, information should be available anytime and anywhere. Using paper documents to manage clinical information is no longer an option. The volume of data has increased significantly, and information has become more complex to categorize and interpret, so IT systems are needed to record, store, and re-collect medical data.

A complex implementation

In recent decades, EHR systems have been successfully introduced in many countries, although essentially through local or regional projects. Most of these projects cover one health center or one network of health centers with different levels of care under the umbrella of a single public or private organization. An electronic health record is a complete record of all relevant information on a person's health over the course of their life. It allows everyone involved in health care—physicians, specialists, health professionals, laboratories, etc.—to share and exchange information whenever and wherever. An EHR contains all of a patient's health reports and diagnoses, as well as all tests, analyses, and studies done on him or her.

^{27.} Consejo Directivo 66.a Sesión del Comité Regional de la Organización Mundial de Salud para las Américas [53rd Directing Council 66th Session of the Regional Committee of the World Health Organization for the Americas]. 9/29/2014.

^{28.} Las tic y el sector salud en Latinoamérica [ICT and the Latin American Health Sector]. Fundación Telefónica. 2008.

Setting up an EHR system benefits everyone involved in the healthcare process in multiple ways. Health professionals have more information when caring for patients and can thus tangibly improve the care, prevention, and treatment they provide. This electronic record is very useful not only for improving immediate care, but also for providing long-term treatments

Additionally, having access to documentation on the procedures used to address different medical conditions provides an opportunity to improve care for new patients. In other words, exchanging experiences enhances professionals' expertise and helps improve treatments.

An EHR system, when successful, is highly beneficial, but it is extremely complex to implement. The inevitable budget constraints are compounded by the projects' long timelines, which makes it harder to secure political commitment. Their length also obviously makes projects more prone to changes or interruptions as the political agenda shifts in response to important and unforeseen events in the country, or simply due to administration changes. Also, regional entities with broad authority over health care services often launch well-intentioned initiatives based on their own needs and agendas. This approach is not necessarily wrong, as the initiatives reflect a reality and socio-political structure with a certain level of decentralization that is very common in many countries, but they do make launching a nationwide EHR system a highly complex challenge.

A high level of political commitment is even more necessary in Latin America and the Caribbean, where EHR is being introduced at varying speeds and with no systematic mechanism that allows countries to share experiences and solutions and reap the benefits of doing so.

Though implementing nationwide EHR systems is a formidable challenge, some developed countries have managed to do so on a broad scale. In Australia, New Zealand, the United Kingdom, and the Netherlands, most family physicians now use EHR as part of their work routine.²⁹

The international vision of the Digital Health Cooperation Network of the Americas

The Digital Health Cooperation Network of the Americas (RACSEL) was formed in October 2014. Its overarching objective is to help countries establish a permanent way of exchanging knowledge and experiences so they can establish shared standards for eventually creating a regional electronic health records system. The project is part of the Regional Public Goods initiative of the Inter-American Development Bank and is coordinated by the Fundación Julio Ricaldoni based in Uruguay. This institution was chosen as the Project Executing Agency and tasked with coordinating and carrying out all activities needed to achieve the expected objectives and results. Five countries are currently part of RACSEL: Colombia, Chile, Costa Rica, Peru and Uruguay.

29. Flash TicSalut. 06/06/2013. http://www.ticsalut.cat/flashticsalut/html/es/articulos/doc36499.html

RACSEL's mission is to develop a collaboration network to coordinate and exchange knowledge and experiences related to EHR so that best practices, lessons learned, and results achieved can transcend national borders to improve efficiency and effectiveness in other countries. As part of this work, the network also carried out a large-scale consulting project covering four aspects of EHR: Institutional and Regulatory Framework, Medical Terminology, Technical Standards, and Information Systems Architecture.

RACSEL also aspires to be a top digital health cooperation network and a leader in creating standards based on dialogue, coordination, and exchanges of knowledge and experience. The network is thus very open to including new countries whose experiences and knowledge might further enrich exchanges and prepare the ground for future projects.

There are wide disparities in the development of eHealth in Latin America. But if areas with more knowledge and experience share generously with less developed regions, much quicker progress will be possible. This is one of RACSEL's biggest goals: fostering an environment of exchanges and cooperative learning that benefits all parties and breaks down the operational and logistical barriers to introducing ICT into Latin America's health systems

RACSEL's objectives are part of a global trend towards the interoperability in digital health systems and towards recognizing how important standardized, accurate, and timely information is for improving the performance of health systems and services. RACSEL ultimately seeks to help achieve better health outcomes by promoting a more efficient use of health-related information, services, and resources, and by leveraging ICT to both manage and provide health care services.

Interoperability ensures that data is exchanged consistently, without losing its meaning, between departments, organizations, levels of care, or regions such as countries or continents. It also allows access to that information regardless of where it was entered and contributes to more continuous and efficient care. Additionally, it gives professionals an effective tool for making efficient and safe decisions.

The collaboration network has become well established since its formation, and it has held various workshops and technical exchanges to share knowledge and experience related to EHR. RACSEL's Technical Committee has acted as the coordinating body, creating a clear and systematic mechanism for collaborative work so that countries can capitalize on the best practices and results achieved by their peers.

There is another reason why these types of projects are important. This type of initiative is often led by the United States or European Union, which have extensive experience and a broad portfolio of projects. Organizations involved in creating and sharing health IT standards then build on this leadership. Despite the obvious benefits that spill over from the global dissemination of that experience and knowledge, Latin America needs to find its own voice in these forums through the active participation of governments and entities from all levels that, like RACSEL, are involved in launching EHR so that more and better

progress can be made. In Latin America, organizations like the Pan-American Health Organization (PAHO), together with the World Health Organization (WHO) and also the Economic Commission for Latin America and the Caribbean (ECLAC), have made notable efforts in this regard.

There is a strong consensus that the emergence of new technologies and trends is paramount. An example is the rise of mobile devices; its impact on health and care provision models is increasingly evident. These new trends are mirrored by the initiatives led by governments and entities around the world. This is a pivotal moment to seek to participate in these forums so that the health and ICT initiatives and concerns common to all of Latin America can be heard.

Transferring knowledge

These points are key to coordinating a system that can be efficient over the long term. Interoperable systems will allow access from different countries by coordinating the different technologies they use. In this vein, RACSEL is working to improve technical and semantic standards. The legal framework of each country involved is another crucial factor, because the ability to launch the system and share sensitive data, like patient information, will depend on it.

The joint work of the region's health agendas on EHR services and standardized, interoperable terminology will strengthen current initiatives and create a baseline so that the countries starting the process can adopt best practices that have been validated in the region.

In essence, a forum like RACSEL that brings together the experiences and best practices of those already making inroads into eHealth will be a very valuable resource for both countries that have already made progress on the issue and those just starting out.

One of RACSEL's main aims is to ensure its long-term sustainability and becoming one of the main digital health cooperation networks. This network is intended to give Latin America its own voice in the international organizations involved in developing EHR systems, a voice arising from exchanging models and collaboration.

As it coalesces, RACSEL aims to involve and broaden the base of participating Latin American countries to strengthen its structure and make the exchanges of knowledge and experience even more valuable, resulting in much more efficient and patient-centered health care systems

CHAPTER 5

CHANGE PROCESSES Remember the micro level

The underlying aim of this book is to cast a vision for implementing national-level EHR systems. This essentially macro approach could neglect certain factors that, though micro, warrant discussion. To be specific, it is important to address how health organizations manage change processes when implementing EHR projects. Since the models for provider networks are more or less the same as those used to implement a national-level EHR system, this point is very important.

Managing change

When implementing an EHR system, it is important to pay attention to two closely linked facts. The first is that digitizing means doing things differently, and the second is that digitization always involves change management. It is neither possible nor conceivable to replicate manual processes using digital technology. So there has to be change, which is always met with at least some degree of resistance from health professionals. Therefore, the design of all projects must necessarily take both of these facts into account in order to be successful.

The main steps for managing EHR implementation projects at a health center are:

- **1.** Form a multidisciplinary implementation team.
- 2. Design an internal communications plan.
- **3.** Configure/customize the software
- 4. Identify auxiliary hardware and software needs
- **5.** Migrate data (from other systems)
- 6. Optimize processes
- 7. Decide how to launch the system: big bang vs. phased
- 8. Create a transition plan (in the phased scenario)
- 9. Make contingency plans in case the EHR system crashes
- 10. Launch a user training plan.

These phases are very recognizable and may even seem obvious, but when this type of implementing process fails, it is almost invariably because one or more of these points was poorly executed.

1. Form a multidisciplinary implementation team

The first step is to set up a team of people—from different disciplines and with specific roles—in charge of correctly managing the change during the project's different phases. Team members should have the leadership and communication skills needed to implement a complex system. They should also have a wide range of skills and knowledge. A change manager should be designated to oversee the project. This leader should be well-trained, comfortable with digital transformation, and committed to seeing the change through. The technical team will be made up of the person in charge of implementing the system and the professional responsible for installing the software and hardware. On the healthcare side, there should be a medical director and different nursing professionals and technicians. The latter two roles are included in order to identify specific needs and opportunities. The team should also include an expert user who is tasked with learning to use the system. He or she will then recruit other users to speed up tech support and quickly fix problems after implementation.

Depending on the situation, one person may perform several of these roles, or, conversely, one role may be covered by a team of multiple people due to time constraints.

2. Design an internal communications plan

Without a good communication strategy, the change will likely never be implemented at all or only be partially or unsatisfactorily implemented. Communicating the reasons for a change works on two levels to break down resistance from internal and external users. First, it counters the effects of misinformation and bad communication. Second, communication helps "sell" the need for the change by presenting it properly. To motivate people to change, those affected by the change need to be proactively informed or trained. During the implementation process, maintain constant, clear, transparent, and timely communication with the different groups within the organization, and create an environment that precludes rumors and uncertainty. Openly communicating the vision for the change, the new ways of working, and the new skills needed is key to successfully transitioning to the new technology. This plan will give employees access to a leader or other person working on the change in order to address any uncertainties and questions they might have about the challenges, implications, benefits, and consequences of the change.

3. Configure/customize the software

The software configuration process depends on whether the solution was developed beforehand or was partially or fully purchased. The decision whether to buy or develop an EHR system is highly complex and involves many different factors related to function, warranties, technology, economic considerations, and others. For a national-level project, a team

of different professionals representing all affected parties should reach a consensus on this matter. Each option has its pros and cons, and they are not necessarily mutually exclusive, since EHR involves many medical processes that can be covered partly by modular systems that in turn may be developed or purchased.

But whether the application is purchased or developed, it is important to decide on the level of customization, consider the needs of users, and even involve them in the design and implementation process. For this reason, the software should be simple, use effective and consistent language, and present information effectively. It should make the job easier for health care professionals and improve the quality of care.

4. Identify auxiliary hardware and software needs

To implement an EHR system, a health center needs to buy infrastructure, which must be planned, financed, installed, and launched for the relevant tests. Managing infrastructure effectively is important because it saves money and prevents technological incidents that even the best leadership or most cooperative stakeholders would not be able to resolve. Most systems require ordinary infrastructure components, like servers, computers, and peripheral systems (for example for displays). But technical support is also required for each of the communication channels created. Network capacity has to be solid and stable enough to allow for new volumes of information, and hard drives need to have enough space available to store this data. There needs to be a local network of computers connected to central servers. Each office, hospital admission area, treatment room, and workstation should be equipped with a computer. The system should be scaled to allow all professionals in a normal care provision scenario to work simultaneously.

One key decision will be whether to centralize all resources or manage this infrastructure in a decentralized way. Decision-makers need to consider the security risks of a centralized system, since any incident could expose all of the system's records if they are stored centrally. If the information is decentralized, risks are lower but more variable, since the level of security will depend on the privacy and security measures in place for each independent data source.

5. Migrate data (from other systems)

Migrating to an application is a complex process that should keep all features that endusers need intact and be as non-intrusive as possible for them. Planning is the most important step in a data migration process. At this stage, implementers need to decide which method to use for the migration. The data migration plan should cover preparation of the data and systems prior to the migration. Next is an analytical phase, which examines variables like the completeness, accuracy, or consistency of the data to be migrated and assesses the characteristics of the source and target databases. The next step is to select the application: it can be developed internally or purchased after assessing the different alternatives. Then the applications that will use the database undergo testing cycles. After the tests, the migration itself is performed by extracting, transforming, and loading data.

The last step is evaluation, where the team measures and analyzes the results to see if any adjustments are needed.

6. Optimize processes

Implementing an EHR system requires a good strategy for optimizing operational processes. With proper support, leaders of health sector organizations can review existing processes and design a plan for improving them. This will allow them to more effectively integrate existing IT systems and significantly cut down on time-consuming administrative processes. With this new approach and the time it saves, health professionals will be able to focus their efforts on providing quality services to patients.

7. Decide how to launch the system: big bang vs. phased

Does it make more sense to implement major changes just once (known as "big bang" adoption) or in phases? Proponents of the "big bang" approach argue that its implementation time is shorter, which also reduces training time. Of course, this solution requires exhaustive advance planning. But it also has its downsides. Users have less time to get used to the new system, and some details may be overlooked in the push to switch to the new system all at once. It also may be difficult to test out the entire system before implementing it, and an error in any given part can affect all the other parts.

If the system is launched in phases, the project can be divided into multiple distinct and easily verifiable steps. This approach allows time for training, and users have longer to adjust to the changes. The main problem is how fast technology evolves. If a plan based on today's technical environment establishes a set of incremental changes in the application over the next five years, it is possible, and even probable, that the environment will become obsolete before the process is finished. Decision-makers should thus consider these factors and evaluate the best option for launching a new system.

8. Create a transition plan (in the phased scenario)

In a phased implementation, technical problems are addressed in an orderly fashion rather than all at once. As the system's complexity increases, so does the organization's maturity in dealing with that complexity.

Under this scenario, the organizational culture changes over time, making it simpler and more feasible to establish a new model. A change of this magnitude always has hassles and problems, so a progressive approach gives users a better chance to get used to the new way of working.

9. Make contingency plans in case the EHR system crashes

Since health information is so important and has to be available immediately in certain cases, systems need to be especially robust. An error could bring a large number of ac-

tivities to a halt, with the consequent social and financial impact. In addition to ensuring the strength of the most critical systems, there also need to be backup centers that can be used if these critical systems crash. A team of technical personnel and medical professionals should be assembled create a clear contingency plan for emergencies that ensures continuous and quality care, as well as patient safely. The contingency plan should cover all possible scenarios, be planned in advance, be updated regularly, and be shared with users.

10. Launch a training plan.

Training is the key driver of any organizational change and is especially important for the process of digitizing health and implementing EHR. People will need specific training to learn the new knowledge and skills required for some activities. The team should analyze the skills needed to execute the change strategy and build training for those skills into the transition process. It should identify professional roles and evaluate their level of ICT expertise to determine training needs and create the different training plans. Training can be given either in person —by teams with operational and technical expertise —or remotely using digital technology.

The system's usability needs to be measured beforehand by running tests before creating a training plan or rushing into demonstrations. Poor use of the system during the first few days could have consequences down the road.

Measure the impact

The expected results and impacts are another important aspect of the process of implementing an EHR system and are essential to ensuring its continuity. One possible source of resistance to change, especially in management spheres, is the difficulty of measuring the return on investment of digitizing health care processes. Implementing a digital health system is usually costly and will impact different care providers, patients, and other stakeholders. The people who set policies need clear proof of its costs and benefits. If the large-scale implementation of an EHR system justifies government investment, the government too will require demonstrable benefits for patients, providers, and society in general. The economic benefits of implementing ICT are often only seen many years after the investment was made or when systems are functional enough to truly meet medical care needs.

Implementing EHR has high initial and maintenance costs, which are a significant obstacle to their adoption. The benefits of using technology, like fewer hospitalizations or more efficient use of resources, are felt by government agencies or insurance companies, for example, before health professionals.

A cost-benefit analysis is only one part of a comprehensive analysis of the effects of implementing an EHR system. Certain benefits cannot be measured in financial terms, and EHR should be considered a component of an organization's strategic plan. Costs and benefits should be analyzed within the context of the entire process. It is thus important to factor in

patient or user satisfaction when measuring the usefulness (demand for) the new system. In fact, the value of an eHealth practice can only be determined with complete certainty by taking this contribution into account.

CHAPTER 6

NECESSARY POLICY, LEGAL, AND INSTITUTIONAL INITIATIVES

To establish an electronic health records (EHR) system, countries need to develop a national approach based on integrated strategic actions that foster collaboration between the fields of health care and information technology. This approach should be based on the specific eHealth situation of each specific country and its available and potential resources.

The adoption of national EHR systems for health care institutions should be aligned with a strategic plan for the health sector that pursues equitable, high-quality care and that meets the country's public health objectives. If the adoption of EHR is not guided by these aims, the solutions created might not align properly with the plan's objectives, making it difficult to correctly implement the system.

To achieve these objectives, each State needs to thoroughly assess its ability to adopt EHR systems. This assessment³⁰ should cover infrastructure and resources required, standards and regulations, training, human resource capacity, and user openness, in line with the contents of this publication. Each country should adapt this assessment process to its specific needs.

The classic dilemma of whether to develop or purchase the information systems that support EHR should be briefly addressed. There are no set formulas for this decision, and each country should follow its own criteria and advocate for its own course of action, whether developing or purchasing or a mix of both. This decision merits careful consideration and a close examination of all present and future factors that could influence this and future decisions, without losing sight of each country's specific constraints.

Digital health dimensions

A digital health strategy should take two dimensions into account: first, the country's digital environment in terms of the true penetration of information and communication technology (ICT) into infrastructures and networks; and second, the environment in terms of governance, policies, regulatory aspects, as well as human resources needed to support the implementation and maintenance of an EHR system.

The next step is to design a multidisciplinary team as part of the leadership structure. Countries should assemble one or more teams responsible for monitoring the project's process and forming possible working groups within those teams. This team can be set up various ways according to each country's unique context, but its structure and organization should remain stable over time. It should also have sufficient authority, funds, and human resources.

^{30.} There are some existing examples of this type of assessment initiative, like the one conducted by CETIC.br

Funding and results

Funding merits separate treatment. No countrywide EHR initiative, however modest, could be carried out without proper funding. Here too leadership and political involvement are essential. An EHR implementation projects like any other information system project, involves software, services, hardware/networks, and maintenance. However, there can be hidden costs—for example, providing substitutes for professionals while they are being trained on the new system. All of these costs, including hidden ones, should be carefully considered and included in the budget.

Additionally, information system implementation projects should be understood as initiatives that provide a return on investment. There are studies that demonstrate cost savings. But it can be difficult to obtain data to back up the projections, even if they are based on these potential efficiency gains. But even when no cost-saving efficiency improvements materialize, objective indicators of the increased quality of health care can be logged to support the project's viability.

Legal framework

National laws and their implementing regulations or decrees, as well as the aspects that determine the transition towards electronic health records, should be subjected to review and analysis, since they will invariably become elements that regulate, and also facilitate, all national EHR initiatives. The shift to EHR requires profound changes to and revisions of countries' laws, and it affects many spheres, like security, patient identification, informed consent.

From a regulatory standpoint, the following key aspects should be analyzed:

- patients' right to information and the duty to provide it to them;
- patient consent;
- the minimum data set or essential information that EHR should contain:
- measures to safeguard and keep EHR secure, and
- user identification and authentication processes.

Given the new way health information is processed using advanced technology, the challenge lies in how to protect patients' right to information, as well as how obtain their consent to provide a healthcare service or perform a procedure involving a risk (informed consent) and to process their data (personal information).

Countries need protocols that ensure that the patient has been informed and that take into account that the data will be processed electronically. They should also have clear and va-

lid mechanisms for informing patients and obtaining their consent, and also for clarifying whether they consent to this medical information being confidential and to determine the situations in which it should not be in order to ensure the continuity of care.

There should be effective tools that automatically include consent as part of the process and that ensure that the signature indeed belongs to the owner of the data or the person receiving the health care.

Minimum data set

A minimum data set has very valuable information that gives a snapshot of a population's health. In addition to the usual demographic data (age, sex, place of residence), it contains the diagnosis that led to admission (principal diagnosis), risk factors, the patient's comorbidities and complications upon admission (secondary diagnosis), relevant diagnostic techniques, and the medical actions, especially surgical ones, taken to treat the patient (the procedures).

The legally defined minimum data set is in turn the basis of the patient summary report, the key clinical document that gives health professionals the essential information on a patient.

Security and custody

The custody and security of digitally stored medical information are two of the most important aspects when introducing EHR. In all countries, health-related data is considered highly confidential, and data security is one of the biggest challenges associated with implementing an eHealth model. For this reason, countries should put in place all legal and ethical frameworks needed in order to assure patients that their data is well protected and will not be misused. Laws should therefore focus on matters like the privacy, confidentiality, ownership, quality, and completeness of data, as well as access to it and its shared use. Essentially, an EHR system's objective in terms of security is to store all comprehensive information needed to provide health care to patients, provide easy access to that information, and guarantee that it is stored securely and cannot be altered.

The models adopted will need to preserve and keep information secure and inspire maximum confidence in the digital information that is administrated or provided. This means putting proper technical security measures in place for EHR, as well as designing complementary protocols to ensure that information is also always secure when being processed.

Identification and authentication

Another key aspect that it is important for governments to address is how to unambiguously identify people. This is often the weak spot of information systems based on new technologies. It is not possible to develop patient-centered health systems, like those pursued by implementing digital health and EHR, without protocols for correctly identifying and authenticating users. Governments thus need to establish security measures for authorizing access to data using identification and authentication procedures that ensure that personal data is processed securely. Uniform criteria for authenticating and identifying users when they access systems and programs should be established. Systems should have a unique patient identification code that is authenticated by the different service providers and that meets the necessary security and authenticity conditions so that health professionals can confirm users' existence or authenticity. One possible technique for implementing this unique user identification nationwide and in a centralized manner is using an authentication server that identifies users and then authenticates them in all other computers that the user may connect to.

Institutional framework: bodies and groups involved

This framework encompasses all existing organizations or interest groups that develop or manage the resources, application, and implementation of EHR, or that may directly or indirectly receive certain benefits from EHR and thus might take an active role in terms of providing pertinent feedback or requests.

These organizations may include service providers, regulatory and implementing bodies, local authorities, the private sector, civil society organizations, as well as relevant patient groups and community organizations, and any other entity that has a hand in operating EHR systems.

1. Government, ministries, and social security institutions

Although the specifics of which institutions are most important in terms of health care may vary from country to country, the Ministry of Health is generally the highest authority. This agency is in charge of managing all aspects of health and carrying out any legislative initiatives that are needed for the matters under its authority. The ministry that oversees new technologies will obviously also play a key role in implementing eHealth. Its basic function will be to define and develop the guidelines for the country's IT architecture reference framework to allow interoperability to be developed.

As stated earlier, cooperation with social security institutions and any other bodies with a key role in EHR projects will also be necessary.

2. Regional and municipal governments

Each country's political structure grants a certain amount of authority to its departments, provinces, or other administrative divisions. As part of this authority, these divisions may be responsible for providing health care. It is therefore especially important to involve these entities with visions, plans, and budgets that are strictly tied to a specific geographical area. It is thus crucial to orchestrate collaboration between national and regional levels in order to implement EHR, and this collaboration should be managed in a way appropriate to its importance.

3. Users

Many of today's health policies now place citizens at the center of the model. There has been a paradigm shift from a model focused on providing healthcare services to one focused on patients, or in other words, from treating health conditions to caring for people's health and ensuring disease prevention and public health. This change underscores the need to involve people in developing EHR at the following stages:

- before developing each country's objective for implementing EHR or to determine their improvements, through questionnaires, holding debates, etc., and
- during implementation, so they can give their feedback on its functionality and it can be used to make improvements.

There should be clear mechanisms and specific channels allowing users to participate in the development, implementation, and successful operation of an EHR system. If EHR is viewed as a system used strictly by health professionals, this involvement is perhaps irrelevant. But when it is understood as the foundation of all initiatives aiming to empower users with digital information on their health, information that ultimately they own, their involvement is pertinent. The system should thus use formats that make medical information as easy for users to understand and manage as possible.

4. Professionals

Health professionals are an integral component of EHR projects, so it is important to emphasize a few specific considerations regarding this group beyond those covered in Chapter 5. Achieving sufficient engagement from them is paramount. EHR is often associated with oversight tools that cause extra work, which inevitably leads professionals to resist adopting the systems, which can seriously hinder their progress. Health professionals may therefore fail to notice or undervalue some or all of the advantages of adopting an EHR system—like better clinical decision-making, not repeating diagnostic tests, or improving the continuity of care—to the detriment of the quality of their work and the general improvement of the healthcare systems. It is therefore crucial that health professionals be part of the working groups that oversee the project, as mentioned earlier, but the involvement of the group as a whole demands broader consideration. Project leaders should create ambitious, nationwide strategies to communicate and share about the project that address health professionals' misguided conceptions or expectations and bring them on board in order to successfully implement the system.

5. Private healthcare providers

The structure of healthcare networks, in terms of their funding, insurance, and service models, varies widely from country to country. Since many countries have a substantial structure of private providers, all legal and institutional initiatives should provide for their involvement. Failure to do so could limit the success of national EHR projects. Countries thus need

to create cooperation strategies, establish incentives for the participation of these providers, and involve them in the projects from the outset. Also worth addressing are the regulatory aspects that could pose a major technical and organizational obstacle to the shared management of data between these private providers and other healthcare providers.

It is not a matter of merely forcing compliance, if it were even possible to do so. The basis of a win-win strategy is rather to highlight economic and service quality incentives and stress how detrimental it would be for these providers to be left out of these projects, which clearly represent a major step forward for healthcare systems nationwide.

6. Other entities and institutions involved

In addition to the entities and groups described above that should play a prominent role in developing an EHR system, others may have a secondary but still important role. Their participation, whether in an advisory capacity or just as recipients of information, should also be coordinated by ministry of Health leadership³¹ and by the entity specifically in charge of implementing the EHR system in the country.

7. Data protection authority

There are different bodies in charge of carrying out specific initiatives within each ministry's programs. One such body is the data protection authority. The healthcare sector must ensure the confidentiality and privacy of the data contained in EHR, so there needs to be an authority that oversees company and institutional compliance.

This authority can also be in charge of setting guidelines for security in healthcare.

Each country's government should take steps to reinforce the relationship between this type of authority and the institutions that provide healthcare services. Here are several recommendations for achieving this:

- create codes of best practices for the healthcare sector that are validated by the authorities. They can be prepared at the initiative of healthcare provider associations or groups and validated by the authorities;
- establish recommendations related to security measures, data custody, and identifying and authenticating users that are technically and legally validated, in terms of how well they protect users, for example, by the authorities themselves.

8. Universities and continuing education

These organizations should play key role in preparing and training different professionals to provide health services, both before they begin practicing and afterward through

^{31.} Other ministries can be in charge of this inter-ministerial leadership and coordination, as is the case with Colombia's MinTic, which has broad responsibility over the use of ICT standards in the country.

continuing education. This training should cover how to process information securely and confidentially when using new technologies.

All degrees related to health care could potentially include coursework on, for example, data protection aspects. This content should be integrated into the curriculum for nursing, technical degrees, all specializations in medicine, and it could also be made a part of the education of laboratory technicians, researchers, home care coordinators or workers, dietitians, and any other professionals whose jobs might involve processing sensitive information using new technologies.

Professionals can also be trained on using new technology and other matters relevant to health care, like IT engineering, where they learn about the impact of processing data using new technology.

9. Healthcare providers and insurance companies

The insurers and providers of many of the patients' health benefits should participate in the creation of EHR systems. Though perhaps they would not be part of the work groups, they should be involved at some stage of development or planning process.

10. Professional organizations and associations

These groups defend the interests of their members; they should be consulted as part of the process of developing an EHR system.

11. User groups

Since these groups defend patients' interests, they should also potentially be given an advisory role in developing an EHR system. For EHR initiatives that focus on a specific disease, like oncological EHR, this role could be more active.

12. Special groups

Sometimes special groups of government workers receive healthcare through a separate system from the rest of the population. All EHR initiatives for those groups could be under the control of entities other than the Ministry of Health. Thus, they are normally independent projects and their scope is limited to those groups. However, it is worth considering whether there should be a system for tying these initiatives in to others for the purpose of drawing conclusions and sharing experiences, models, and even investments from which all projects can mutually benefit.

13. Information system technology providers

It is important to properly coordinate the participation of health information system technology providers in EHR projects. They may be involved to varying degrees in multiple areas, like process consulting or consulting on software development strategy, services, or cloud storage. Project leaders should determine the value and scope of this participation, and it should always follow a specific plan so that it fits in properly with the project's overarching direction. Market research initiatives could be an option worth considering. Their structure would depend to some degree on each country's rules on collecting initial proposals for how to approach projects that would provide options for future actions.

In short, the participation of ICT providers is necessary and valuable, but it should be adapted to the vision of the project leaders and other inherent constraints of the country's healthcare systems.

CHAPTER 7

INTEROPERABILITY

To provide continuity of care for patients and meet their growing need to access health information regardless of time and place, there has to be a constant flow of information between the different parties involved and between the different health centers and levels of care. This exchange of information also has to take place with personal identification systems, with platforms for managing health information for public policies, with the entities that fund health care, and with entities that provide services in a public key infrastructure (PKI), like digital certificates, timestamps, etc.

Information and communication technologies (ICT) can ensure the effective flow and exchange of this information. But the reality is that fragmentation is the norm for many health systems today: most health centers are not interconnected.

In many countries, both developed and developing, health systems are still organized around different levels of medical centers, ranging from hospitals to health centers closer to the population. Each of these establishments normally manages its own information, which cannot be accessed externally. They operate as sealed compartments, and information exchanges are ineffective or nonexistent. From a medical standpoint, this disjointedness leads to several problems, like duplicated information, having to repeat tests, losing information, or data processing errors.

People's new habits need to be factored in; they are now much more mobile (due to migration, for example). There needs to be a solution that covers patients' entire care process, regardless of their location, and ensures the continuity of their care. This continuity requires coordination between the different levels of care while diagnosing and treating patients, wherever and whenever the care is delivered.

Truly achieving continuity of care between members of a healthcare team and between different levels of care requires a constant flow of information.

Interoperability in the healthcare sector

This fluid exchange of information cannot be accomplished without applying standards to ensure the interoperability of the systems that support the healthcare process.

Despite its countless advantages, interoperability has not gained ground in the healthcare sector the same way it has in other sectors like banking or telecommunications. Regulatory, cultural, and organizational obstacles continue to stand in the way.

The World Health Organization (WHO) defines interoperability as the capacity of different health information systems (hospital systems, departmental systems, electronic health

record systems, etc.) to exchange data and use the information that was exchanged within and beyond the organization in order to enhance the health care provided to individuals and communities. 32

Interoperability guarantees access to information regardless of where it was entered, in addition to facilitating its reuse and ensuring the continuity of care.

Levels of interoperability

The five levels of interoperability are:33

- **Organizational.** First there has to be a need to exchange information. Then interoperability implementers need to define what information is going to be exchanged, as well as when and with whom, and make sure this interoperability is possible from an organizational standpoint. This process requires cooperation between the different entities that want to exchange information, with each retaining its own management models and business processes. To achieve this cooperation, there has to be a shared context that includes both procedures and workflows.
- **Legal.** Within the organizational level, there needs to be a legal framework for this exchange of information that ensures that each party involved in the exchange follows the laws in force. This aspect is particularly important in cross-border projects where countries with different legal frameworks are exchanging information.
- **Technical.** For two systems to communicate with each other, they have to be connected and have networks, open interfaces, data formats, and communication protocols that ensure interoperability.
- **Syntactical.** The information has to be structured in such a way that systems can process it consistently and traceably. This makes it possible to exchange documents with the certainty that the files are transferred in the correct format, without having to evaluate them.
- **Semantic.** To be exchanged, information also has to have the correct semantic framework so the recipient of the information can process it, interpret it, and incorporate it into their systems. In other words, it is necessary to ensure the exact significance of the content and data to make it comprehensible. This ultimately allows the data that was exchanged to be interpreted correctly and used by external applications. With a good semantic design, parties can process and use the information better and draw on it for decision-making, research, epidemiology, or statistics.

^{32.} Revisión de estándares de interoperabilidad para la eSalud en Latinoamérica y el Caribe [eHealth in Latin America and the Caribbean: interoperability standards review]. Pan American Health Organization (PAHO). World Health Organization (WHO). 2016

^{33.} Un camino hacia la interoperabilidad [A Path to Interoperability]. Carlos Gallego. Cátedra Sanitas

Use of standards

Interoperability can only be attained by using standards. Standardization is the process of making and applying rules for an orderly approach to a specific activity for the beneficiary and with the cooperation of everyone involved. Its objectives are simplification, unification, and specification.

Standards have to be implemented in order to optimize eHealth resources: it is not possible to achieve the projected benefits of implementing new technologies without standardizing most aspects related to health information.

These standards define how to integrate the information. They should be mature, international standards that are upheld by practical experience, that are followed by a critical mass of both users and members of the software industry, and that continue to be developed to adapt them to new healthcare and technological realities.

The best-known international health standards for exchanging medical information provide a common reference framework for interactions and coordinating patient care. The standards homogenize the terms for the components of the health system, such as diagnoses, procedures, people, and interventions, as well as how they are transmitted, which enables interoperability between the different parties that are interacting. They also ensure that the data is available and meaningful in a variety of clinical and public health situations and on an administrative level.

One of the best known standards in the field of health is HL7 (Health Level Seven). The organization that created it focuses on developing specific standards for interoperability in the field of health. It established the health sector's most widely used international messaging standard for digitally exchanging clinical, care-related, economic, and logistical data. It covers information on admissions, discharges, or transfers; lab test orders; imaging studies; etc. HL7 is compatible with most of the common interfaces used in the healthcare industry.

One of the standards developed by HL7 is Clinical Document Architecture (CDA), which specifies the structure and semantics of clinical documents—discharge summaries, admission notes, pathology reports. With CDA, professionals can read these documents and computers can process them. In the context of the rise of web standards, mobile health, and EHR, one of HL7's most recent standards is the Fast Healthcare Interoperability Resources (FHIR).

One of the most widely used standards is DICOM (Digital Imaging and Communications in Medicine) developed by NEMA (the association of electrical equipment and medical imaging manufacturers). It is the internationally recognized standard for managing, storing, coding, printing, and transmitting medical images. The standard is a response to the need for a format capable of including all information (text and images) in a single file and for sending this information using a shared communication protocol for the different teams in a diagnostic imaging network.

For maximum effectiveness, the use of these standards has to be coordinated. The standards are extensive and designed to generically address all possible scenarios, so they need to be contextualized and adapted to specific contexts like radiology, laboratories, anatomic pathology, shared health records, etc. The IHE (Integrating the Healthcare Enterprise) was formed to accomplish this goal. This initiative, started by healthcare professionals and service provider companies, aims to improve communication between the information systems used for patient care. IHE defines certain standards-based integration profiles that provide effective interoperability and an efficient workflow. IHE does not create standards, but rather promotes coordinated use of existing ones, provides instructions on how to use them, and offers tools to support compliance with them.

This list of standards is not exhaustive, and it does not aim to chart a course for countries undertaking EHR digitization initiatives by recommending any specific standard. What truly matters is that decision-makers back the adoption and use of recognized standards, whichever they may be, and that the standards align well with the country's strategy for the eHealth projects. This step can decide the success or failure of these projects.

In the same vein, part of RACSEL's work has been to foster an exchange regarding the use of standards between countries. This knowledge transfer should continue or be expanded, if possible, because it gives countries useful criteria for making their own decisions in the future.

Benefits

As explained above, the use of well-known and verified standards favors interoperability in health systems, which results in better care for patients, safer treatments, and a more effective and efficient system. The specific benefits can be seen at different levels:³⁴

- Individual level. When correct and complete data is available, those participating in the healthcare process receive full and accurate information, and medical information system users can make diagnosis and treatment decisions based on comprehensive and up-to-date information about the patient, which improves healthcare and provides a chance to find errors.
- Health organization level. When consistent, standards-based interoperability protocols are used, systems can be adapted using one or a few standardized interfaces, which have a lower cost of design, implementation, testing, and maintenance.
- **Government level.** With interoperability based on mutually agreed-upon standards, manual data entry and incomplete and error-ridden reports can be replaced with much more accurate automated reports. This gives government agencies and healthcare providers more access to disaggregated data. This data can then potentially be used for disease statistics, population-based pathology records, public health research, and improved disaster response.

^{34.} Revisión de estándares de interoperabilidad para la eSalud en Latinoamérica y el Caribe [eHealth in Latin America and the Caribbean: interoperability standards review]. Pan American Health Organization (PAHO). World Health Organization (WHO). 2016

• **Economic level.** Standards-based interoperability improves the management of health services and lowers costs. By making previous results available, it prevents repeated studies and eliminates the need to give patients paper results. The same benefits apply to drug requests, imaging studies and surgical indications, as well as unplanned emergency room visits.

Barriers to interoperability

Despite interoperability's potential benefits for the quality of medical care, achieving it is no simple task. The barriers fall into different categories:³⁵

- **Use of inappropriate standards.** One of the problems lies in selecting, obtaining, and using standards. Decision-makers often select inappropriate standards or develop new systems that are incomplete and costly because they lack of knowledge of or access to internationally accepted standards.
- **Costs.** Successfully implementing standards may have a high initial cost, with a return on investment that is unclear at first.
- **Cultural barriers.** Interoperability is characterized by the transparency of the information that is shared. This may cause some actors within the system to feel they have lost autonomy and are more vulnerable and exposed to criticism. These concerns can be significant cultural obstacles to the adoption of standards.
- Security. Concerns about the security and privacy of data are another problem.
 Patients and other people may be worried that their personal data will be unprotected, and medical teams could be concerned about being exposed to lawsuits or potential modifications to medical records that could lead to misinterpretation or other errors
- **Training.** Adopting standards and achieving interoperability requires properly trained professionals who can take on the challenge of making the necessary changes. It will be necessary to train IT specialists on this matter, as well as health professionals who do not have proper IT training.
- **Commitment.** Lastly, it is important to take into account the great variability of IT systems and organizational cultures. Profound changes will be needed to standardize them, and health leaders will have to be clearly committed to seeing the process through.

^{35.} Revisión de estándares de interoperabilidad para la eSalud en Latinoamérica y el Caribe [eHealth in Latin America and the Caribbean: interoperability standards review]. Pan American Health Organization (PAHO). World Health Organization (WHO). 2016

Regional interoperability commission

Another relevant recommendation is to have countries that wish to participate create a regional and joint body. This commission would take the lead on all initiatives to create a regional EHR system. It would therefore be multidisciplinary, addressing legal, terminological, standards-related, and architectural issues.

This commission could bring together the members of the interoperability office (or supervising entity) of each country in the network. The commission should serve as a space to pool services for developing, supporting, sharing, and providing training on standards for interoperability to implement health ICT in their respective RACSEL network countries.

The interoperability commission is envisioned as a space to share decisions that affect the exchange of information between countries. Local aspects would be left to the respective national entities. The main goal is for everyone to benefit by tapping into other countries' experience, knowledge, lessons learned, and solutions.

The commission's roles could include:

- further aligning the interoperability aspects of public policies in the region by making policy recommendations;
- promoting joint standardization initiatives for medical vocabulary, terminology, and coding;
- devising cooperation strategies for patient identification;
- planning new joint activities and coordinating and consolidating existing ones.
 These activities include providing terminological services, defining strategies for implementing a regional patient summary format, or developing models for implementing electronic prescriptions, among other possible initiatives;
- reinforcing and supporting the implementation and use of reference models for implementing eHealth and, especially, EHR in the different countries, and
- representing the region and strengthening its presence within international bodies and forums linked to health ICT and even promoting joint negotiation strategies on issues where countries can combine forces.

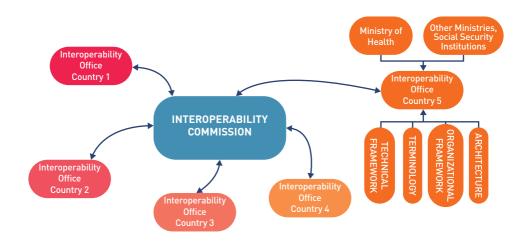


Figure 1. Example Diagram of the RACSEL Interoperability Commission

The commission could give rise to future, more ambitious initiatives—like pilot projects for exchanging medical documents such as patient summaries—in a context where people are increasingly migrating between countries and where users expect the technological innovation to be applied to improve health services, regardless of where they are. If different countries' EHR systems could create, share, and interpret this fundamental medical document, this would be a milestone for the development of ICT for health in Latin America.

Though there is clearly a long road ahead, many countries are making extraordinary strides that should allow the first pilot projects to be launched in the near future. Vision, determination, and commitment from governments are key to successfully implementing any future plan.

CHAPTER 8 TRANSFORMING HEALTHCARE MODELS IN LATIN AMERICA

The preceding chapters cover how implementing EHR creates numerous opportunities to improve people's quality of life and health.

But though EHR is a necessary condition for achieving this improvement in people's quality of life and health, it alone is not enough. Technology and the digitization of medical records give us extraordinary opportunities to improve decision-making at all levels, from nurses providing palliative care to heads of internal medicine departments to directors of tertiary hospitals or ministry officials who make decisions about where to build a new health center. All of this requires change and transformation. In other words, replicating old models and processes using new ICT systems can distort these systems and could even cause projects to fail. The implementation of EHR systems should thus be a driver of transformation and change.

Such enormously important opportunities and challenges always come with risks. Political decisions always have a complicated relationship with risk, so as mentioned previously, political leadership has to be solid and sustained, even despite turnover in legislatures.

The principle of future innovations

Though important, EHR is just one component of future innovations in the health sector. Another is telemedicine, which is increasingly widespread. This technology makes it easier to evaluate, diagnose, treat, and follow up with patients, all remotely. The use of mobile devices in health and in clinical practice is also helping change the way medical care is delivered and understood, both for healthcare professionals who can access information on their patients at any time and place, and for patients, who take a more active role in caring for their health.

Projects harnessing big data, which will allow a greater volume of knowledge and information to be generated and shared, or those related to electronic prescriptions are already a reality in some countries and are making health systems much more efficient. In other countries, they continue to pose a major challenge.

Digitizing health empowers users, improves their health and quality of life, and allows them to play an active role in achieving a healthier lifestyle or properly managing their medical condition.

Closing social gaps

As explained previously, by digitizing health Latin American countries can help close some of the healthcare gaps that still persist in the region as a result of enduring social inequalities. And this digitization can play an especially key role in achieving universal healthcare coverage, one of the region's major unresolved issues.

New technologies can be used to provide services to remote populations and marginalized communities using telemedicine, or health benefits can be provided via mobile devices. They can also play a crucial part in extending healthcare coverage to remote areas, where mobile technology has been essential for responding to the health needs of rural populations, in emergencies, and in disaster situations.³⁶

Digital health also facilitate better training for health professionals through e-learning, and it makes education more accessible, especially for more isolated groups.

In recent years, eHealth has developed very rapidly and is changing the face of health care. As the use of new information and communication technology grows in the region, initiatives in this field are being launched in various Latin American and Caribbean countries. These initiatives without question help improve access to, and the quality of, health care.

As ICT spreads, it brings the possibility of creating equal conditions, since it breaks down certain barriers and allows an exchange of information that will help narrow social gaps. Many ICT systems and devices that were originally costly and rare are now attainable and used at many levels of society.³⁷

Digitization and health

There is still much to be done. Despite evidence of digital health's positive impact on medical practice, health management, or patients' medical conditions, as well as indications of the resources it can save, not enough progress has been made to implement it.

The many technological, functional, legal, cultural, and economic barriers that continue to stand in the way include:³⁸

- the need for clinical evidence and evidence on its socioeconomic impact;
- interoperability and standards for digital solutions to improve rule-based exchanges of health information and data between systems;
- security in transferring information;
- secure personal access to health information;
- the fast pace of technological change, and
- the business model.

^{36. 53}rd Directing Council 66th Session of the Regional Committee of the World Health Organization for the Americas. 9/29/2014

^{37.} Rev Panam Salud Publica 35 "eSalud en las Américas" [eHealth in the Americas]. 2014

^{38.} Asociación Salud Digital (http://salud-digital.es)

As described in Chapter 6, in the face of such an enormous transformation, it is also necessary to correctly manage the organizational change and the changes to professional roles brought about by implementing ICT in medical practice.

Political commitment

It is important to remember the barriers to and difficulties of implementing eHealth because they can lead to a lack of political commitment, which is one of the main factors that hinder its implementation.³⁹ There has to be a firm and sustained political commitment to infrastructure, specific devices, and applications for particular diseases or conditions; to regulating the exchange of data within and between systems; and to encouraging a wider exchange of information and practices to promote health.

The implications of tackling an EHR project cannot be divorced from the socioeconomic reality of many countries in the region. The shortage of human and financial resources is a formidable obstacle that should not be underestimated. Therefore, vision and leadership capacity should be coupled with shrewd management ability, pragmatism, perseverance, and political intelligence.

Governments need to intensify their initiatives to raise awareness about current and planned ICT and eHealth policies. The goal of these initiatives should be to facilitate their use and communicate with direct stakeholders, as well as promote international collaboration initiatives. A better understanding of the economic effect of mass ICT implementation as part of health reform initiatives will help establish clearer prospects for what is possible to achieve.

The slowness to take action and the lack of political commitment in the area of eHealth can also be explained by the absence of solid and comparable data on the costs and benefits of implementing eHealth. As some reports indicate,⁴¹ there is still a lack of consistent proof that introducing eHealth services substantially lowers health costs. This situation makes it difficult for governments to make clear decisions on this issue. Verifiable arguments about costs and benefits are needed, not just for public and government authorities, but also so that users, providers, and society in general can contribute to effectively implementing eHealth. And this objective is not easy to achieve: when implementing a digital health system, any savings can end up being erased by the high initial costs of buying and running new IT systems. Various studies suggest that the financial benefits of implementing ICT are often only seen many years after making the investment or when the systems are functional enough to truly meet professionals' needs as they provide care.

^{39.} Rev Panam Salud Publica 35 "eSalud en las Américas" [eHealth in the Americas]. 2014

^{40.} Rev Panam Salud Publica 35 "eSalud en las Américas" [eHealth in the Americas]. 2014

^{41. &}quot;Transforming eHealth into a political and economic advantage". Polytika Insight Research. Dec-2016 Feb-2017

Economic projections

Nevertheless, some current projections do paint a positive medium-term picture and predict that implementing eHealth will bring significant savings that offset the expenditure. A study on the European Union found that these solutions could reduce healthcare spending in the region by an average of 0.31% of GDP.⁴² Underlying this gain is the increased efficiency and lower impact of chronic conditions on the healthcare system that the solutions would cause, thus outweighing the cost of implementing an ICT-based health system.

RAND Corporation in the United States developed projections as a modeling exercise prepared for the U.S. Congress and based on a broad review of the literature containing evidence of ICT's effects on health. These projections estimate potential ICT-related efficiency gains for outpatient and inpatient care worth more than 77 billion dollars per year (around 3% of the country's total spending on healthcare).⁴³

These savings would be achieved through a substantial drop in hospital admissions and by a reduction in the time healthcare professionals spent on administrative tasks during patient care, as well as through more efficient prescription methods. However, countries should take a prudent economic approach to the possible economic benefits of implementing her, one that acknowledges the specific factors intrinsic to the health sector.

First, the potential savings cited above are considerably lower than the savings from productivity gains seen when ICT is adopted in other sectors.⁴⁴

Second, for this kind of implementation to yield economic benefits in a sector as complex as health care, major changes must be made to the health system—especially its processes—and resources have to be cut in some cases. To reiterate, potential savings will not materialize immediately. First, ICT has to be widely adopted by service providers, changes have to be made to the processes listed above, and resources have to be used more efficiently. Given the social nature of the sector, it is a distinct possibility that in some cases these efficiency gains will be used to improve the quality of health care instead of reducing costs.

Since both the changes and possible benefits need time in order to become established, net savings may be low at first, although they may then grow considerably. In the US, it is estimated that over the course of 15 years, the potential cumulative net savings in terms of efficiency and security in hospital systems could reach almost \$371 billion, while the potential cumulative savings for medical practice through the use of EHR systems would reach \$142 billion. This potential net benefit could as much as double if gains occur in the area of preventing and treating chronic conditions.⁴⁵

- 42. "Transforming eHealth into a political and economic advantage". Polytika Insight Research. Dec-2016 Feb-2017
- 43. "Transforming eHealth into a political and economic advantage". Polytika Insight Research. Dec-2016 Feb-2017
- 44. "Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, And Costs." http://content.healthaffairs.org/
- 45. "Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, And Costs."

In conclusion, better care for patients; new, patient-centered ways of organizing health services; and new approaches to funding the sector can result in potential long-term savings.







