



Comisión
Nacional de
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**Disruptive Technologies:
Regulation of Digital Platforms**

**Chapter 5
Telemedicine**

Abstract

This chapter deals with telemedicine and characterizes the traditional health and medical provisions' sector. Telemedicine is presented as a contribution to the shortage problem of both doctors and specialists in remote zones or areas of difficult access. The effects it could have on patients and the healthcare community are analyzed, as well as the main challenges in its implementation. Based on international regulatory experience, recommendations for Chile are delivered.

6.1 Introduction

Modernity has led to demographic and epidemiological phenomena that pose new and demanding challenges for health systems. At the global level, the rapid aging of the population, the emergence of new diseases, the higher frequency of some old ones and increased pressure over health systems require solutions that will not only aid the population but also cover the rising costs.

Chile is familiar with these global trends and additionally, faces challenges due to the country's geographical characteristics. Part of the population has traditionally been isolated due to their location (especially in rural areas and extreme regions¹) from medical provisions related to complex diseases. Waiting lists for health professionals in the different Chilean regions are a case in point.² The country has successfully implemented preventive health programs including community education, information delivery, vaccination campaigns, etc., however; these efforts are not enough and require complementary actions.

The technological advances in information systems, data processing and communication appear as an opportunity to face this scenario, making Digital Health a promising alternative. In the health sector, it will be possible to increase the efficiency of clinical processes concerning prevention, diagnosis, treatment and follow-up; while administratively improve access.

Technological advances have revolutionized the healthcare sector with tools and services to support clinical processes. These include Health Information Systems (electronic medical records), mobile monitoring and assistance devices (monitors integrated into clothing or accessories), data processing (image based diagnosis), health video games (with remote nano devices), genomics (gene mapping and modification), robotics (robotic surgeries, robotic assistance and intelligent prosthetics), artificial intelligence (data processing) amongst many others. The combination of these tools, that allow remote medical attention in several specialties and with different degrees of complexity, is generically known as telemedicine. In simple, the technology frees from distance

¹ Chile is administratively divided in 15 Regions, from north to south.

² According to of the Ministry of Health, the regions of Los Ríos, Biobío, la Araucanía and Magallanes have 12.5%, 12.4%, 12% and 11.1% of their population on waiting lists for non-GES specialties (either for surgical interventions or consultations for a new specialty). These are the regions with the highest waiting lists. The Metropolitan region has 8.5%.

restrictions, reducing the need to match the patient and the doctor in time and space. Some of the digital health initiatives implemented in Chile are: 1) the Ministry of Health's e-Health Plan and its Healthcare Network Information System (SIDRA) project;³ 2) the Government's 2020 Digital Agenda, which includes telemedicine in nephrology and stroke; 3) CORFO's Health+Development⁴ strategy and its Interoperable Medical Account project,⁵ and telemedicine programs such as those developed by Hospital de la Higuera, among others. The idea of telemedicine has been present in the digital agendas of governments since the late 1990s.

This chapter focuses on the application of telemedicine as ICT to transfer medical information for diagnostic, therapeutic or educational purposes. Telemedicine seeks to connect doctors (mainly specialists) and patients through audiovisual devices, and thus forego physical presence, allowing patients and professionals to avoid traveling and makes better use of doctors' time, manage waiting lists and reduce costs. From a welfare standpoint, this would reduce waiting times for specialty care, highly improving patients' quality of life.

Telemedicine expansion in Chile faces several challenges that can limit its successful implementation, including legal, cultural, technological, political, and economic aspects. Its development depends on administrative aspects, the improvement of infrastructure and enabling legal provisions; but its success will depend on the incentives and safeguards that will steer both professionals and patients to accept the non-contact modality.

6.2 The Health System in Chile

6.2.1 General characteristics

The health system includes the public sector (which covers 75.2% percent of the population), the private sector (18.5% percent) and armed forces sub-system (6.5% percent). Financing corresponds to a 7% minimum compulsory contribution (excepting for indigents), which is allocated to either public insurance (FONASA) or private providers (ISAPRES). The armed forces subsystem is paid for by the State. The Ministry of Health (MINSAL) is the governing and regulatory body that formulates and executes health policies and carries out its functions through FONASA, the Under-Secretariat of Healthcare Networks, the Under-Secretariat of Public Health, the Regional Ministerial Secretariats, and other organizations.

³ Clinical and administrative information platform available for the public health network at all levels.

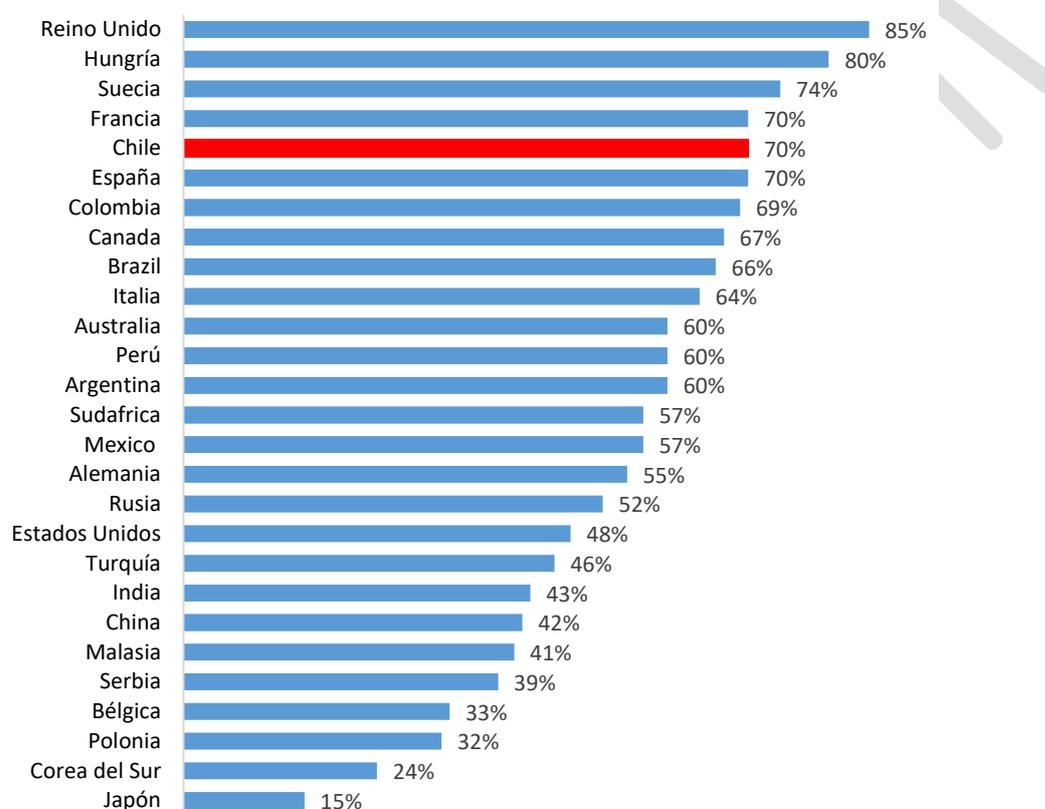
⁴ It seeks to accelerate ICT absorption in the health sector, reduce information asymmetries between suppliers and consumers and promote the development of key technologies and services to meet the sector's real, immediate and long-term needs.

⁵ It seeks to reduce procedures and improve care by providing a digital clinical record of each Fonasa patient. Thus, the public insurance will have access to precise information regarding where, with which doctors, in what provisions, and at what costs their patients were attended. Hopefully, this will also reduce risks of misdiagnosis and treatment, since the clinical history will be online, accessible to professionals.

The Chilean health system faces significant challenges in guaranteeing timely and quality care to the population. The average number of hospital beds in Chile is 2.2 per thousand inhabitants, while the OECD average is 4.8. The average of doctors is 1.9 per thousand inhabitants, while the OECD average is 3.4. These constraints, along with the challenges of resources and geography, suggest considering telemedicine as a contribution.

General perception abides this. According to the study "Global Views on Healthcare 2018" conducted by Ipsos Global Advisor, 70% of residents in Chile believe that the health system is burdened. From the group of countries surveyed, Chile appears in the fifth place worldwide, and first in Latin America.

Figure 6.1. Opinion on whether the health system is overloaded.



Source: Ipsos Global Advisor (2018)

Demographic change and new diseases

Lower conception rates⁶ and higher life expectancy⁷ have led to a sharp demographic shift, which has resulted in an aging population. Chile's age structure is increasingly

⁶ According to the study carried out by the World Bank in 2015, the fertility rate of Chilean women is 1.75, below that of most Latin American countries.

⁷ According to the World Bank study conducted in 2015, life expectancy is almost 82 years (versus 76 years in 2000).

similar to that of developed countries (Table 6.1), and as of 2050, a fourth of the Chilean population will be over 65 years old which implies upward pressure on health costs and significant challenges in caring for elderly patients, with chronic diseases, limited mobility, and high life expectancy.

Table 6.1. Population Percentage over 65 years old (2016)

País	2015	2030	2050
Argentina	11%	13%	18%
Australia	15%	19%	22%
Brasil	8%	14%	23%
Chile	10%	17%	24%
China	10%	17%	26%
United States	15%	20%	22%
Japan	26%	30%	36%
Latin America and Caribbean	8%	12%	19%
European Union	19%	25%	30%

Source; National Productivity Commission based on World Population Prospects 2017 data.

On the other hand, current detrimental physical and psychosocial conditions, such as stress and poor eating habits, have caused the emergence of chronic (e.g., cardiovascular, diabetes and obesity) or degenerative (e.g., cancer and tumors) diseases. According to WHO, in 2014 hypertension (one of the leading causes of cardiovascular disease in adults) prevalence was 27% in Chile (22% worldwide, and diabetes doubled in 25 years, Chile being the country with the highest rates in South America: 9.5% (8.5% worldwide).

Equity

Our public health system mainly attends lower-income patients, who also have a higher prevalence of disease, chronic conditions, and disabilities at an early age. Unlike the private health service, the public sector generally has lower standards of care, with long waiting lists where two million Chileans wait 13 months on average for specialty care, and 14 months for elective surgeries.

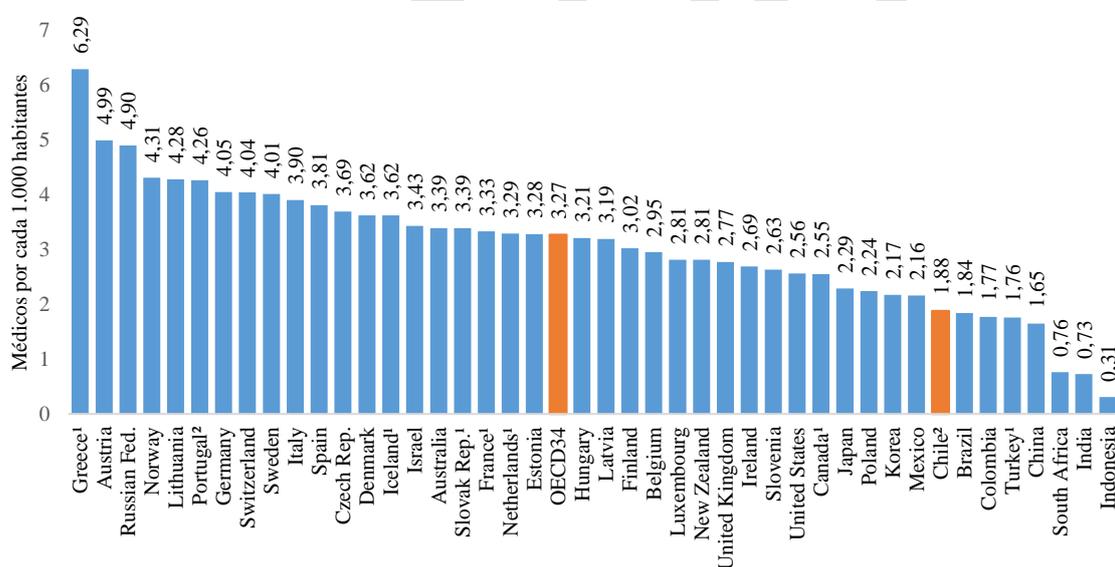
Those who live in extreme areas or far from major urban centers are deprived of specialists and isolated from services that are more complex. They are therefore forced to travel to major cities whenever they require special medical attention. This is partly due to a marked territorial inequality, for medical personnel is concentrated in large cities and private sector providers (67% of physicians). The Metropolitan, Valparaíso, and Biobío regions concentrate 77% of medical professionals for 63% of Chile's population. This means that only 23% of the remaining professionals are available for the other 13 regions, and must attend 37% of the population.

Training of professionals

67% of medical doctors work exclusively with private healthcare providers. According to OECD and WHO statistics, Chile has a rate of 19 doctors per 10,000 inhabitants, well below the level of developed countries, but relatively similar to other countries with comparable per capita income (Figure 6.2). According to the Disability and Survivorship Insurance National Register (DSI), towards the end of 2015, 54% of doctors had a medical specialty, lower than the 62% OECD average.^{8 9}

The shortage of specialists and their concentration in large cities have led to an increase in waiting lists, becoming a public health problem, especially for the most vulnerable population, who also suffer a higher prevalence of chronic diseases, and have reduced possibilities to face a negative impact at the household level.

Figure 6.2. Doctors for every 1,000 inhabitants 2013 (or closest year).



Source: OECD Health statistics (2015). Notes: 1.- It includes not only doctors providing direct care, but also those who work in the health sector as administrators, educators, researchers, etc., which could lead to an overestimation of medical personnel. 2.- The information is for all those doctors licensed to practice, which could generate an overestimation of available medical personnel.

The lack of specialists poses challenges both in the long and short term. In the long term, a more significant number of specialists is required. In the short term, the better use of

⁸ Although this average hides a significant heterogeneity, for example, the figure is 88% for the United States, 65% for Mexico, and values similar to Chile in Canada or France.

⁹ The discussion regarding the distribution between specialists and general practitioners has given rise to an interesting debate in the international community. While more specialists can address more complex health problems, this also results in increased care costs that may be undesirable. Faced with this situation, countries such as Canada and France have implemented policies to maintain a proportion of general practitioners in the health system of around 45% and 50%. At the same time, the systems that have managed to contain their costs make greater use of general practitioners and are more selective in the referral to specialists.

scarce resources (which in this case are the specialists) is desirable, which implies not only having new hospitals but also being able to examine more patients, considering that these variables are not necessarily correlated.

System costs and drug expenses

Rising health costs are a major concern worldwide, where health spending is growing faster than the economy (especially in the OECD). This trend will continue as the population ages and the prevalence of chronic diseases increases. In 2014, total health expenditure represented 7.8% of Chilean GDP (against 12.3% in the OECD and 7.2% in ALAC¹⁰). About 50% of this expenditure was financed through public resources (against 62% in OECD and 51% in ALAC), while 31% was directly funded by households (against 13.6% in OECD and 31% in ALAC).

Finding 6.1: The availability of physicians in Chile is limited, and they should be able to address risk factors associated with population aging and the prevalence of chronic diseases, which will mean an increase in health spending.

6.3 Telemedicine

6.3.1 General Characteristics

According to WHO, telemedicine is: *"the delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interest of advancing the health of individuals and their communities"*.

Indeed, telemedicine refers to the provision of health services using information and communication technologies, whereby the traditional medical services are delivered in another mode and are preceded with the prefix "tele" (e.g., teleconsultation and telecardiology). Telemedical services can be synchronous (live), whereby the signal is transmitted in real time and instantly displayed or processed; or asynchronous (delayed), where the data is obtained, stored and transmitted for later evaluation, at any time or place the physician has. The functions are broad and include telediagnosis, teleconsultation, telemonitoring, tele-assistance, and telesurgery, and a "tele-etcetera", which evolves along with the technology. Additionally, telemedicine is also useful in the training of health professionals, research, and as a means of informing the public of health campaigns.

Telemedicine affects the entire health sector. It offers enormous advantages to patients, including the following: (1) more equal and rapid access, (2) avoids traveling, (3) minimizes consultation procedures and requirements, (4) allows care continuity and

¹⁰ For further details and a good synthesis of initiatives to date, see the report "National Telehealth Program".

makes it easier to ask for second opinions. On the other hand, regarding health professionals and facilities, telemedicine facilitates (1) patient care from remote or inaccessible geographical areas; (2) increasing the professionals' care capacity (3) circumventing travels; (4) the establishment new models of doctor-patient and doctor-doctor relations, improving effectiveness; (5) allowing faster and cheaper access to information; (vi) creating new training and employment opportunities; (vii) providing quicker and more timely diagnosis and treatment by increasing the productivity of health resources. It is also a governmental ally, with the potential to improve services, effectiveness and efficiency.

Finding 6.2: Telemedicine offers an opportunity to use technology in the diagnosis and treatment of disease. As such, it is potentially a care tool and an alternative to make health resources management more efficient, especially in isolated areas, and for patients on waiting lists.

6.3.2 Some experiences in Chile

Although there are experiences at the national level rather than a public policy aimed at making the most of telemedicine's potential, the first positive experiences in the country arose from the endeavors of individuals, groups and institutions. These local experiences are highly valuable, firstly, because of the direct impact on patients, but also as a demonstration. Recently, national-scale programs that rely on technology have become popular.

VIII Region of Bío Bío

A pioneer in Chile, the Las Higueras Hospital of Talcahuano has an active telemedicine program since 2008. The hospitals and Family Health Centers (CESFAM) of the Talcahuano Health Network installed telemedicine units for real-time health care through video, and nurses were trained to perform tests previously performed exclusively by specialists. Between 2012 and 2016, more than 76 thousand health tele-transactions have been carried out at the Hospital las Higueras, and currently, around 65 establishments can access their specialists virtually. Thanks to the program, by 2015, the waiting lists' index had decreased by 20 percent in neurology, (from 3,085 in March to 2,475 in December).

Between 2014 and 2015, 1,033 patients were diagnosed with diabetic retinopathy thanks to a telemedicine program promoted by the Ministry of Health and the University of Concepción (UdeC) that examined 7,382 people with diabetes. The program allowed the CESFAM diabetic patients of the Concepción communes to see an ophthalmologist. The University of Concepción's Telemedicine Unit, in partnership with the Primary Ophthalmic Care Unit, implemented an initiative that included training, retinal cameras (for eye photographs), a web platform for transmission, storage and visualization of eye fundus, and each user's relevant medical information. The ocular pressure measurement was also included, and each patient's visual capacity was measured. With this information, the specialist was able to assess the patient's condition asynchronously and remotely, diagnose the severity and recommend actions.

In the same region, the Arauco Health Service evaluated over 1,200 patients through tele-dermatology, reported more than 11,000 radiology exams through tele-radiology, and implemented a tele-gastroenterology program.

IV Region of Coquimbo

A comprehensive teleconsultation project was carried out in the Coquimbo Region to provide ophthalmic care for the fundus. Implemented by the Municipal Health Department of Salamanca and the Coquimbo Health Service, they brought together all the low complexity hospitals and health centers in the Choapa Province. Through this project, 1,300 fundus and 600 tele-ophthalmic care services were provided by two specialists located in Santiago and one in London (England), solving pathologies such as diabetic retinopathy, cataracts, glaucoma, refractive error, and pterygium.

Likewise, there have been other initiatives that can be grouped into Tele reports; and Telemedicine in High Complexity Network and Ges Networks.

Tele reports

As for Tele-reports, the Tele-ECG, Tele-Radiology, and Tele-Ophthalmology implemented in 2005, 2012 and 2013 respectively stand out. All three strategies have produced over 1.9 million reports to date.

Tele ECG is a strategy that allows patients who consult an Emergency Primary Care Service (SAPU in Spanish) for chest pain to access an ECG and its particular report through a central reporting system. In this way, an acute myocardial infarction is either confirmed or ruled out within 20 minutes. SAPUs implemented it throughout the country and is currently operating in 452 establishments. Since its application until the end of 2017, approximately over 847,000 reports have been made.

Tele Radiology is a strategy that arises from the need to fill gaps between the radiologist appointments available and the demands for radiological reports, providing coverage during non-institutional hours (after 14 or 16 hours depending on the facility) on working days and 24 hours on weekends and public holidays. Under this strategy, radiological reporting, interoperability, and image transmission services are purchased through open tender. Since its implementation at the end of 2017, more than 730,000 reports have been made in 34 establishments.

Tele-Ophthalmology is a strategy implemented in ophthalmic primary care units. It consists of performing a detailed examination to detect diabetic retinopathy through an analysis of the fundus, whereby an ophthalmologist delivers a report through a platform. By 2017, it had produced more than 300,000 reports.

High Complexity Network Telemedicine and Ges Networks

In the area of High Complexity Network Telemedicine and Ges Networks, the following complex networks stand out: Child Neuropsychiatry, Cancer, Adult Extracorporeal Oxygenation Therapy, Brain-vascular infarction, HIV Network, Network of Operable Congenital Heart Diseases, Neuro-Surgical Network, and Burn Network. The strategy of

Child Neuropsychiatry is in operation since 2014 and consists of a mobile video conference evaluation to children and adolescents with neuro-psychiatry care requirements.

The San Borja Arriarán hospital has specialists and sub-specialists, who perform case evaluations of 11 hospitals throughout the country. By the end of 2017, 58 medical attentions had been performed. Cancer telemedicine is in operation in 2016, with the aim of favoring timely access to oncological care in four main lines: (a) patient multispecialty evaluation by an oncology committee for the definition of treatment therapy; (b) early detection of oral cancer; (c) palliative care and pain relief; (d) diagnostic confirmation and follow-up. During 2017, the oncology committee carried out 2,427 evaluations, 285 evaluations were carried out in oral pathology and 44 in palliative care, totaling more than 2,750 telemedicine sessions.

Adult extracorporeal oxygenation therapy has been in operation since 2016 and aims at evaluating patients in the critical patient unit in need of such treatment. Evaluations are made by using video conference equipment that enables monitoring the patient's clinical parameters. Stroke telemedicine has been in operation since 2016 and consists of having a team of neurologists supporting doctors from emergency units in other establishments (who do not have emergency neurologists) in the acute phase diagnosis and thrombolysis procedures. Between January and December 2017, 293 teleconsultations and 14 tele-thrombolysis were carried out. Telemedicine in the HIV network seeks to optimize the management of HIV positive patients with clinical complications and / or difficulties with a therapeutic scheme of the Specialty Care Centers of the country. The professionals receive advice from a team of experts from Lucio Cordova Hospital, through videoconferences, which allows them to communicate via videoconferences. Only clinical meetings have been carried out, no individual evaluations yet.

Telemedicine in the operable congenital heart diseases network is in operation since 2017 and consists of conducting committees on operable congenital heart diseases through video conferencing technologies, whereby professionals from a referral hospital evaluate their patient together with specialists from the reference hospital. During 2017, 17 committee evaluations were carried out. Neurosurgical network telemedicine is based on the resolution of complex pathologies between a minor establishment and one of greater complexity. Physicians evaluate clinical backgrounds and radiological images and define a treatment plan that may include patient transfer or management in the hospital of origin. As of 2017, there had been no services provided. Telemedicine in the Burn network is based on enhancing and strengthening the GES Burn patient improving the relevance of the referral and optimize the patient's management before their transfer. During 2017, the reference relevance for 113 patients was evaluated.

At the beginning of 2018, the National Telehealth Program was launched as part of the integrated Health Services networks, which seeks to develop a consolidated system bringing together the different initiatives under a common conceptual and operational framework. The definitions and guidelines for all Telehealth initiatives implemented in healthcare networks are presented.

The private sector has also developed telemedicine initiatives. Some telemedicine platforms include diabetic retinopathy detection services in digital images (DART), teleconsultations and tele-examinations platform (TOTH), tele-electro cardiology and tele-imaging (ITMS), in-home detection of pathologies in patients with chronic or recently operated diseases (ACCUEHEALTH), time management for health specialists (SALUD INNOVA), tele-dermatology (TELEDERMA) and tele-consultation (MEDICLIC), among others.

Finding 6.3: There are successful experiences in the application of information technologies in telemedicine settings in the country. Most of them respond to local initiatives, either at the level of health establishments or health services.

6.4 International Regulation Experiences

The World Medical Association at its 51st General Assembly proposes the following rules regarding telemedicine:

- The treating practitioner who asks for another colleague's opinion is responsible for the treatment and other decisions, as well as recommendations delivered to the patient. However, the tele-expert is accountable for the quality of the judgment delivered and must specify the conditions under which the opinion is valid, being obliged to abstain from participating if they lack the knowledge, competence or sufficient information of the patient.
- The professional who uses telemedicine is responsible for the quality of care received by the patient and should not opt for the telemedicine consultation unless he considers it the best available option. The physician must take into account the quality, access, and cost.¹¹

Specific regulations have already been developed for telemedicine in several countries. Others extend consumer protection and the right to data ownership to the general standards of electronic commerce and services provided through ICT to the health sector.

Colombia

Colombia defines telemedicine as: *"the provision of remote health services in promotion, prevention, diagnosis, treatment and rehabilitation, by health professionals who use information and communication technologies, allowing them to share data with the purpose of facilitating access and opportunity in the provision of services to the population that has supply and / or access to services limitations, in their geographical area."*

Colombia drafted a specific regulation on "telehealth" that, among other things (i) creates a governing entity that oversees its correct implementation; (ii) defines authorized

¹¹ <https://www.wma.net/policies-post/wma-statement-on-accountability-responsibilities-and-ethical-guidelines-in-the-practice-of-telemedicine/>

telemedicine services providers and specifies an authorization process; (iii) promotes the inclusion of telehealth knowledge in related university courses; (iv) grants specific financing for communications infrastructure investment; (v) includes telemedicine service provision in the Compulsory Health Plan.

The Ministry of Health and Social Protection advisory body in this issue is an Advisory Committee composed of the Ministries of Health and Social Protection, Communications, National Education, Finance and Public Credit, Housing, Territorial Development, and Environment, and permanent guests, representatives of scientific associations, universities, and research centers. Among several functions, it is responsible for "promoting education in the use of Information Technology and Communications applied to health," and has the power to include them in the curricular grid of health sector careers, and others. It also established by law the development of a connectivity map, to be implemented by the Ministry of Communications, which should meet the requirements set for the implementation and development of telehealth. To this end, it granted a specific financing item of up to 5% of the Investment Funds in Communications Funds.

The compulsory health plan covers telemedicine, and by resolution, it is not considered a service but rather a provision modality. Among other things, it regulates who may provide and contract services under the telemedicine modality (with established standards), including referral providers and reference centers. Both are deemed health care providers and must, therefore, comply with the established requirements and procedures that apply to healthcare facilities. Regional health entities are responsible for promoting and supporting the provision of services under the telemedicine modality, with the aim of improving the opportunity and access to health services, regardless of their geographical location.

The standard allows all existing health specialties to be enabled and performed under the telemedicine modality. However, it specifies when they should be synchronous or asynchronous, depending on the complexity and risks posed to the patient. Furthermore, telemedicine health services provided by a foreign institution is authorized, but only if it is headquartered in the national territory or has an agreement or contract with a Colombian health-care institution. In any case, the local institution must be registered as such. If there are language differences between the reference center and the referring provider, it is essential to be familiar with the language of the reference venue including specialized vocabulary and language modalities. The provider who offers telemedicine services shall be responsible for compliance with all standards applicable to the service it registers, and its legal representative shall be responsible for compliance with all enabling conditions.

Colombian norms also define concepts such as data message,¹² digital signature,¹³ and informed consent. For care via telemedicine, the patient will be informed of the service, including its risks and benefits, and the patient's medical record must state that he or she understood the information and expressly agreed to be treated under this modality.

United States

The United States does not have specific federal regulations on digital health, only at a State level. The standards are robust concerning access, mobility, and availability of health data by citizens, and forces providers to comply with functional and technological requirements to ensure this. The patient owns his or her data, and has various consultation, download, and use mechanisms, in pursuit of better care and mobility within the system.

In 2010, the *Blue Button* was launched: a blue button image on the e-client portals that allows downloading a person's medical history formatted in such a way they may be uploaded on other platforms. Personal data portability grants patients' enormous freedom.

Medicaid authorizes states to decide how to structure and administer their telemedicine policy. The Medicare program covers telemedicine only in areas where there is a shortage of physicians (rural areas) and requires synchronous delivery (live video). Asynchronous storage and transfer services are forbidden. Medicare does not reimburse for remote patient monitoring services.

European Union

Europe's Digital Agenda, promoted by the European Union, seeks to disseminate the use of telemedicine, although the Member States are responsible for its organization, management, and financing. Directive 2011/24/EU defines patients' rights to receive cross-border healthcare, including telemedicine. These involve receiving treatment in another Member State, being reimbursed under certain conditions and having access to a copy of the medical record both in writing or by electronic means. It is assumed that telemedicine service providers comply with the professional practice requirements of the Member State where they are established.

Spain

Spain is one of the pioneering countries in the implementation of technological solutions such as electronic prescriptions and digital medical records. A report by the Information Society in Spain (Fundación Telefónica) highlights that the digital health services usage rate is among the highest in Europe. However, it does not have specific regulations on digital health, although it does have broad rules on electronic commerce and information exchange that sets responsibilities and obligations applicable to the provision of services,

¹² It is information generated, sent, received, stored or communicated by electronic, optical or similar means, such as, among others, Electronic Data Interchange (EDI), Internet, electronic mail, telegram, telex or fax.

¹³ A numerical value that adheres to a data message and that linked to the initiator key and the text of the message, allows determining that the message has not been modified.

including telemedicine. In particular, there are rules on personal data protection, regarding service quality, right to information, consent, etc., which cover data relating to health.

In addition, European rules on electronic commerce in the Union's internal market also apply to telemedicine.¹⁴ It covers information society and electronic commerce services.¹⁵ The norm covers the procurement of goods and services by electronic means, the provision of information and the transmission of data, services or applications provided by others. It also covers any service delivered at the request of users, as long as it represents an economic activity for the provider.

Concerning data treatment, the data owner's rights and the obligations of those who generate, store or transfer data are set out in the Personal Data Protection Act.¹⁶ It creates the Data Protection Agency, as a public law entity, with legal personality, and is independent, in the exercise of its functions, of public administrations. It also protects personal data, and in particular "personal and familial honor and privacy," and applies to data recorded on physical media which may be processed, and to any subsequent use of such data by the public and private sectors. The norm distinguishes between the data controller (whoever decides on the purpose, content, and use) and the data processor (whoever processes the data), determines the principles associated with the right to information, consent, protection of specially protected data, and those relating to health, among others. It expressly specifies that no permission is required when data transfer takes place between public administrations and is intended for further processing for historical, statistical or scientific purposes.

6.5 Recommendations

Extending telemedicine services requires a joint effort in the technological, educational, economic, regulatory, and evaluation fields. It is necessary for patients and health personnel at all levels to trust and encourage the use of these services, which involves education and training. Likewise, public and private service providers must generate enough safeguards to extend the privileges and resources of patients and professionals from face-to-face to the virtual world. Financial and administrative mechanisms should be created for public network providers to increase telemedicine use, primarily to reduce waiting lists of specialists and care for residents in areas far from the health infrastructure.

¹⁴ Directive No. 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on legal aspects of information society services, in particular electronic commerce, in the Internal Market.

¹⁵ Law 34/2002, of 11 July, on information society services and electronic commerce (LSSI). "BOE" no. 166, 12/07/2002. Access on 17/06/16]. Available at: <https://www.boe.es/buscar/act.php?id=BOE-A-2002-13758> 37 Article 8.1, b) of LSSI.

¹⁶ Organic Law 15/1999, of 13 December 1999

6.5.1 General

In Chile, telemedicine is considered a provision of service and not as a (service) modality, and this is an error. This regulatory constraint reduces the economic motivation in the use of telemedicine, because when considered a provision of services, it does not distinguish according to the corresponding medical specialty and prevents differentiating prices according to the service or specialty provided through telemedicine. That is, it would not be possible to differentiate a tele-ophthalmology from a tele-dermatology in cost, for all tele-consultations are considered equal.

The difference between an ophthalmological consultation and an ophthalmological tele-consultation in the Chilean legal and regulatory framework is that they are considered two different provision of services and not different modalities (face to face versus virtual) for the same benefit (consultation with an ophthalmology professional). In this way, tele-ophthalmology, along with other tele medical services such as tele-neurology, tele-dermatology, are considered equal benefits and not different modalities of the treating physicians' provision of services. This is because, in FONASA, telemedicine care is grouped into a single code, which implies the financing of the benefits or copayment does not consider the specialty of the provision that is delivered by medical tele-modality. The Isapres financing model is similar, the benefits are identified with a specific tariff and the co-payment will depend on that tariff and the affiliate's plan. In this way, the time allocated by the professionals to each benefit (which is the specialty), and the respective reimbursements that should be associated with the corresponding specialty is not valued or adequately incentivized.

Finding 6.4: The tariff system considers telemedicine as a provision and not as a mode of provision. This makes paying *professionals difficult and discourages its intensive use.*

Exempt Decree No. 530 of the Ministry of Health (2015) is the first regulation that explicitly incorporates telemedicine, reinforcing its definition as a modality in healthcare provision. Meanwhile, Law No. 20,724 (2014) amending the Health Code regarding regulation of pharmacies and medicines included the possibility that the medical prescription be issued electronically -which is a relevant enabling factor for telemedicine. In the absence of a complete and specific regulatory framework for telemedicine services, there is a tendency to apply the rules of pre-existing laws to the virtual world. Some of the most important are the Health Code (1968), DFL No. 1 of the Ministry of Health (2006), and Law No. 19,628 on the Protection of Private Life (1999), which regulate various areas associated with medical services, the treatment of health data, aspects related to the rights and duties of patients, the liability of professionals for malpractice, and health services' organization, among others.

Finding 6.5: There is no specific regulatory framework for telemedicine, making its scalability difficult.

Finding 6.6: Physicians may issue prescriptions electronically and without meeting physically with the patient. Pharmacies must regard either handwritten or electronically signed prescriptions equally.

Concerning medical liability, there are many legal regimes that protect the patient. There is 'culpable negligence' with criminal sanction, 'civil liability' seeking financial redress from the doctor or the private health center, and the administrative liability of the Health Service for "lack of service" of a public hospital. These rules do not necessarily have to be interpreted any differently according to the manner in which the health care is provided, so their extension to remotely offered services should keep the same level of consumer protection.

Finding 6.7: The general and special legal system governing medical liability is sufficiently flexible and adaptable to telemedicine consultations.

Recommendation 6.1: Develop a national telemedicine strategy for public health.

Recommendation 6.2: Acknowledge telemedicine as a mode of general care and not as a health service provision. Allow it to be financed by both the public and private sectors.

6.5.2 Technology and Infrastructure

Chile is a good candidate for the widespread use of telemedicine, for it is the Latin American country with the highest connectivity. It also has an enabling infrastructure capable of transferring complex information at high speed. Since 2015, the 4G mobile connection increased from 3% to 27% and is expected to reach 60% of the country's mobile connections (15 million) by 2020. This broadband deployment is very relevant, especially concerning telemedicine expansion in rural areas. As for the fixed connection, the fiber optic network of the National University Network (REUNA) and the Southern Optical Fiber Project (PFOA) -under deployment- are of high importance.

However, the country's long and narrow geography makes it difficult to build a stable data network and equipment capable of connecting the country's remote areas. At present, it is not clear how much is lacking regarding physical and/or digital infrastructure to achieve an operational system in most of the country's localities. A national diagnosis of capacities and needs in the different health centers and localities is required. In this regard, what the National Telehealth Plan define and the efforts for a greater systematization in this area are highly valued, although the National Productivity Commission considers that there is an important space for improvement, given the experiences observed throughout the country (see Chapter 1, Infrastructure section).

Finding 6.8: Despite advances in data transmission potential, which include fixed and mobile networks, the country needs to increase coverage and anticipate the necessary

investments to cover the increase in capacity. It is also *essential to improve the digital infrastructure of health services at different levels of care.*

An Electronic Patient Medical Record would enable the use of telemedicine by storing each user's information and making it accessible to the entire system. A starting point would be the digitalization of medical processes. While there have been particular efforts to digitize, these are not yet widespread, and most of the medical attention is backed up in paper. In the absence of diagnoses, examinations, and details of the services in their digital version, it is impossible to have an Electronic Patient Clinical Record.

Recommendation 6.3: To move forward in the process of digitalization of medical information related to diagnoses, examinations, and medical attention until 100% of the patient's clinical history is digitized.

The electronic record allows for continuity of care¹⁷ and patient mobility between healthcare providers. The country has made progress in this area through the Healthcare Network Information System (SIDRA), which allows patients to maintain updated information, share it among professionals (with the patient's authorization), and allow the latter to access it through their Personal Health Folder. For the electronic file of each user be shared between the different health facilities (public or private), it is necessary to, in addition to the data protection safeguards already existing in the physical world and easily standardized to the virtual environment, define minimum standards in the clinical history. SIDRA seeks to make these standards enforceable and thus create a platform that promotes comprehensive digital services. Additionally, the Interoperable Medical Bill seeks to converge toward international standards.

Finding 6.9: Chile has installed capacity for the elaboration of a Clinical Electronic Record, which builds on experiences such as SIDRA. Moving forward at the national public and private levels requires the definition of different standards as to medical information presentation.

Recommendation 6.4: Create a single electronic record containing the patient's medical history. The file must follow a protocol that facilitates its exchange between providers.

6.5.3 Education

The training curricula in medical schools, nursing schools, medical technicians, etc. needs to be updated and incorporate digital education, for all health personnel should be able to interact through information technology. The curricula for undergraduate students entering the healthcare sector (Medicine, Nursing, Dentistry and Medical Technology) in 2018 were reviewed at thirteen universities, including the most reputable in the country,

¹⁷ The ability of the health services to offer a common healthcare objective, without causing problems that may harm the patient, regardless of where and when he/she is attended.

and no specific courses were identified in this area. Additionally, it will also be necessary to train already active professionals.

Patients also require digital training and education. Although the patient may be assisted by a health professional in the use of technology to carry out the telemedicine consultation for some medical provisions, other services require basic knowledge in computer use. Chile exhibits low digital literacy achievement, which may be a significant constraint on implementation. Therefore, patients that are to be treated through telemedicine will require functional education programs.

Finding 6.10: Medical professionals, patients, and other users require training in the field of telemedicine.

Recommendation 6.5: To train health professionals in the use of telemedicine, from the undergraduate level onwards. This may be through specific courses or by the transversal inclusion of problem solving in technological environments in the different courses. It also requires training patients and other users to acquire the minimum competencies for the use of telemedicine.

Another critical challenge has to do with society's cultural predisposition to remote care, especially among the elderly. Patients must rely on the attention of a doctor who is not physically by their side (and perhaps not at the same time either) According to the CNP survey, professionals are also reluctant to change their routines due to the use of unfamiliar new technologies.

Recommendation 6.6: Develop a dissemination plan on telemedicine benefits to educate the public and service providers.

6.5.4 Evaluation

Although there have been exciting telemedicine experiences in the country, these initiatives have not yet been evaluated from a cost/benefit perspective. It is vital to determine how much can waiting lists be reduced, how far can care attention perception change, how much can the costs be reduced, among other possible effects, if these initiatives are to be scaled up to the national level. The evaluation will be crucial in adapting patients and health professionals to a widespread use of technology for remote consultations and other interventions.

Finding 6.11: Implementation and experimentation in telemedicine require evaluation protocols to determine its effects and results more accurately. This requires, as a minimum, systematizing the data of the treatments carried out.

6.6 Conclusions

The Chilean health system faces significant challenges in ensuring timely and quality care. Socio-cultural and economic transformations have forced the health sector to update its priorities, and the organization and processes of service delivery. In particular, age

structure and the causes of morbidity and mortality have made it necessary to reformulate health strategies.

Chile has an inefficient and socially segmented health system that reproduces the inequitable development that characterizes the country, both through socio-economic groups and regions. This concentration and the shortage of specialists at certain levels of care enhance the enormous challenge of reducing waiting lists, which mainly affect low-income people (and high-risk) and rural residents. In all these challenges, telemedicine emerges as a significant tool.

However, the widespread adoption of technological elements that allow the provision of medical services at a distance has significant difficulties. There is a need for strong political will on the part of health policy and strategy makers to incorporate ICTs into health care and for real progress in technological, educational, economic, regulatory, and evaluation areas.

An important step would be to define "digital health" concepts and telemedicine, and all regulations associated with these activities, as well as a governing body. From international experiences, it is conceivable that: in the absence of specific telemedicine regulations, enabling standards of protection and guarantees are required for services provided through ICT, including a robust and guaranteed data protection law; data exchange protocols (for an electronic health record), etc. Finally, data infrastructure, bandwidth, connectivity, cloud computing, and mobile devices are the elements that provide the right context to expand telemedicine not only as to the different medical provisions but also geographically.

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