



REGULATORY FRAMEWORK FOR TELEMEDICINE

Current status and next steps

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Introduction

We are living in an era in which digital technologies are transforming the healthcare sector. Blurring the lines between the physical, digital, and biological spheres, technology is fusing these dimensions in ways that pose truly disruptive changes.¹

Digitalization is proceeding apace in the sector, fueled by surging volumes of data, computer processing power, and internet access, and digital health is one of the outcomes of this global phenomenon.

According to the World Health Organization's "Global Strategy on Digital Health 2020-2025,"² digital health should be an integral part of states' health priorities and should follow the principles of transparency, accessibility, scalability, replicability, interoperability, privacy, security and confidentiality. This vision is consistent with the guidelines of the United Nations' Sustainable Development Goals, which include making high-quality health and wellness services accessible to all people around the world.³

At the regional level, countries in the Americas have been urged to adopt the "Eight Guiding Principles for Digital Transformation of the Health Sector," a Pan American Health Organization (PAHO) initiative that calls on countries to coordinate strategies and design plans for digital health transformation processes, with "no one left behind."⁴ Digital health's potential to create smart, comprehensive, high-quality, and patient-centered health systems⁵ is one of its most promising facets.

In this context, digital health presents an opportunity to plan, manage, and evaluate health care better, with widespread agreement that it makes health systems more efficient, effective, sustainable, and of higher quality.

The integration of innovative digital technologies—such as the Internet of things, advanced computing, data science, blockchain,⁶ artificial intelligence, and robotics—in health care brings both incredible potential for transformation and enormous challenges for the sector, giving rise to a need for strategies to guide these complex processes.

¹ Basco, A.I. et al., (2018). *Industria 4.0: fabricando el futuro*. IDB. <https://publications.iadb.org/publications/spanish/document/Industria-40-Fabricando-el-Futuro.pdf>

² World Health Organization. (2021). *Global Strategy on Digital Health 2020-2025*. <https://apps.who.int/iris/bitstream/handle/10665/344249/9789240020924-eng.pdf>

³ Fatehi, F., Samadbeik, M., & Kazemi, A. *What Is Digital Health? Review of Definitions*. *Stud. Health Technol. Inform.* 2020 Nov 23; 275:67-71. doi: 10.3233/SHTI200696. PMID: 33227742

⁴ PAHO. (2021). *Eight Guiding Principles for Digital Transformation of the Health Sector*. <https://iris.paho.org/handle/10665.2/54256>

⁵ IDB. (2020). *Regulatory Frameworks for Digital Health in Latin America. Electronic Health Records: Progresses and Next Steps*. <https://publications.iadb.org/publications/english/document/Regulatory-Frameworks-for-Digital-Health-in-Latin-American-and-the-Caribbean-Electronic-Health-Records-Progresses-and-Next-Steps.pdf>

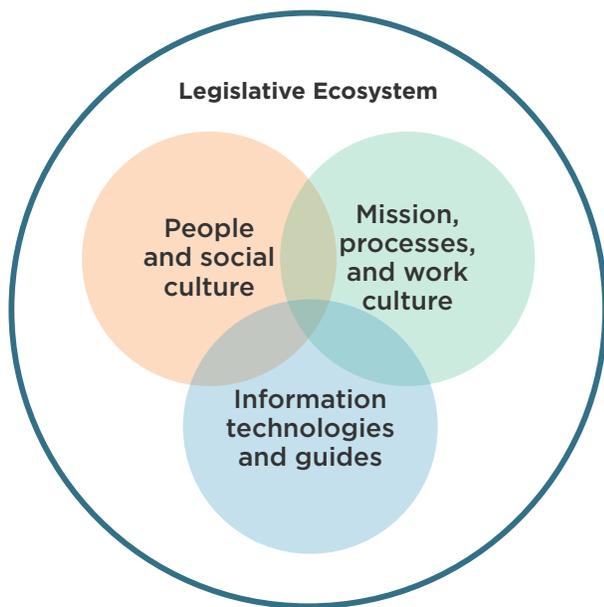
⁶ Blockchain is defined here as the technology used to record, verify, and guarantee the integrity and availability of an asset. It is typically used to record transactions and track assets in a network without the need for intermediaries, but its applications are wide-ranging.

To be successful, digital transformation strategies must ensure that various components are aligned: the mission and organizational processes (including the work culture), the people in charge of implementing the strategy, and the tools and/or technologies used (hardware and software).⁷ These components exist on top of a legislative ecosystem.

In the health sector, the aim of digital transformation is to improve a health system and individual and population health outcomes.

Telemedicine answers this call and thus emerges as a key tool from a health, technological, cultural, and social standpoint, promoting healthcare access and increasing both care quality and organizational efficiency.⁸ Telemedicine is a subset of telehealth that concerns the delivery of remote health services for

FIGURE 1 • Digital transformation components in the legislative ecosystem



promotion, prevention, diagnosis, treatment, and rehabilitation by health professionals using information and communication technologies (ICT) that allow them to exchange data with the purpose of improving access and timeliness in service delivery.⁹

Telemedicine was initially conceived and developed as a way to bring health services to populations living in remote locations with limited access to health resources, which is why early definitions considered distance a critical factor.¹⁰ However, the COVID-19 pandemic¹¹ catalyzed telemedicine, boosting its use, importance, and usefulness as a strategy for providing care without the risk of contagion. Telemedicine also made it possible to ensure continuity of care, evaluate patients suspected to have COVID-19, and notify and monitor close contacts.¹²

According to survey data from the American Telemedicine Association, in April 2020 nearly all primary care physicians (97%) reported using telemedicine to see patients. 83% of patients said they were likely to continue using telemedicine after the pandemic; and over three-quarters of physicians surveyed said telemedicine helped them provide better patient care.¹³

In Latin America and the Caribbean (LAC), telemedicine is seen as an opportunity to make health care more efficient and ensure both equity and quality. Without appropriate regulations, however, telemedicine could end up widening and further entrenching the very gaps it is intended to close.

Many countries in the region provide a snapshot of the rise of telemedicine. In Colombia, there were more than 9 million telemedicine appointments in 2020 following the start of the pandemic, a 7,000% increase in virtual appointments

⁷ Nelson, J., Tejerina, L., Cafagna, G., & Ulrich, A. (2019). *Social Protection and Health Division's Approach to Digital Transformation: Guidelines and Recommendations*. IDB. https://publications.iadb.org/publications/english/document/Approach_to_Digital_Transformation_Guidelines_and_Recommendations.pdf

⁸ PAHO. (2016). *Marco de Implementación de un Servicio de Telemedicina*. <https://iris.paho.org/handle/10665.2/28413>

⁹ PAHO. *Conversaciones sobre eSalud*. <https://iris.paho.org/handle/10665.2/28391>

¹⁰ PAHO. *Marco de implementación...*, op. cit. <https://iris.paho.org/handle/10665.2/28413>

¹¹ On March 11, 2020, the World Health Organization declared the SARS-CoV-2 outbreak a pandemic. <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>

¹² Aizenberg M. (2020). *Ante la pandemia, el valor de la telemedicina y la necesidad de su regulación*, Thomson Reuters, La Ley Online. Quote: TR LALEY AR/DOC/1033/2020

¹³ American Telemedicine Association. (2020). *The Adoption of Telehealth*. <https://www.americantelemed.org/wp-content/uploads/2021/05/Adoption-of-Telehealth.pdf>

compared to 2019.¹⁴ Chile's experience has also reflected this trend, with 198,854 telemedicine consultations between March and October 2020. The pandemic's disruptions forced many countries to adapt their health systems' strategies.¹⁵ Argentina, for example, doubled the number of public health centers with telemedicine services, and its Ministry of Health supplied provinces with necessary technical equipment (computers, TVs, cameras, and video conferencing services).¹⁶

In sum, **the telemedicine healthcare modality is growing exponentially and has the potential to transform the access of millions of people to healthcare services for the better, including people living in remote areas, homebound patients dependent on caregivers (including those receiving home care),** and those for whom transportation can be difficult (patients with disabilities, patients deprived of their liberty, etc.), among other groups.¹⁷

However, **to implement telemedicine services effectively,¹⁸ various regulatory issues must first be addressed. This is necessary because, while technology promises to make health care more equal and democratic in the face of inequalities and barriers to access in LAC,** *"The lack of specific legislation on telemedicine discourages its use. In some cases, laws do exist, but legal disparities between countries make it hard to reach agreements. To promote the use of telemedicine in general and international telemedicine in particular, it is important to remedy the lack of legal clarity when there is no legislation on a specific issue, and, ideally, to have regulations that are compatible between countries."*¹⁹

Few studies have examined the current state of LAC countries' regulatory frameworks and the key elements of their implementation from a human rights perspective, **so this analysis is important given that:**

- LAC countries are currently undertaking digital transformation processes, with a view to providing health services with greater equity, efficiency, and quality.
- The digital transformation agenda extends to the health sector, and telemedicine holds enormous transformative potential to achieve and manage patient-centered health systems.²⁰
- Digital transformation demands that countries strengthen their institutional capacities, which can be challenging.

The ultimate goal of this publication is to analyze the current state of regulatory frameworks for telemedicine in LAC countries and share best practices and lessons learned in the region in order to identify opportunities for regulatory improvements. To this end, this publication maps out the existing regulations in 26 LAC countries,²¹ presents a conceptual framework and methodology for analyzing their level of maturity, shares the results of applying the assessment tool, identify strengths and weaknesses, and, finally, makes recommendations regarding both challenges and aspects that should be modified or included.

¹⁴ See Latin American Federation of the Pharmaceutical Industry, 2020. *Recorrido por la telemedicina en América Latina*. <https://fifarma.org/es/recorrido-por-la-telemedicina-en-america-latina/>

¹⁵ See Superintendence of Health, Government of Chile, 2020. <https://www.supersalud.gob.cl/prensa/672/w3-article-19740.html>

¹⁶ See Ministry of Health, Government of Argentina, 2020. <https://www.argentina.gob.ar/noticias/durante-la-pandemia-se-duplico-la-cantidad-de-centros-publicos-con-servicio-de-telesalud>

¹⁷ For more information on the benefits of telemedicine, see García Meza, G.I. (2017). *Beneficios de la telemedicina para facilitar el acceso de las personas de áreas remotas rurales y urbano marginales a servicios de salud especializados*, 2017. <http://repositorio.uwiener.edu.pe/handle/123456789/1121>

¹⁸ PAHO. (2016). *Marco de implementación de un servicio de telemedicina*. Pg. 12. <https://iris.paho.org/handle/10665.2/28413>

¹⁹ Saigi-Rubió, F. et al. (2021). *Estudio sobre telemedicina internacional en América Latina: motivaciones, usos, resultados, estrategias y políticas*. IDB. <http://dx.doi.org/10.18235/0003438>

²⁰ CAF, Op. Cit. Pg. 179.

²¹ This study analyzes the regulations of the following countries: Argentina, Bahamas, Barbados, Belize, Bolivia, Brazil, Chile, Colombia, Costa Rica, Ecuador, El Salvador, Guatemala, Guyana, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, Dominican Republic, Suriname, Trinidad and Tobago, Uruguay, and Venezuela. The database of regulations used in this study is current as of November 2021. The unit of analysis is the national level; subnational regulations are excluded from this version. <https://socialdigital.iadb.org/en/sph/dashboard>

Section I: Conceptual reference framework and methodology

>> a) Conceptual framework. Taxonomy for telehealth and telemedicine

Both regionally and globally, various terms related to telemedicine regulations are used in similar ways, despite referring to different underlying concepts. In order to establish a common vocabulary for the regulatory frameworks, this study uses a taxonomy that reflects a certain degree of consensus in the specialized literature and that fully takes into account the region's socioeconomic and cultural characteristics.

Telehealth is all health-related activities, services, and methods undertaken remotely using ICT. Guided by a human rights-based approach, telehealth integrates interdisciplinary knowledge and tools from the fields of medicine and technology in order to exchange healthcare information, whether for care, education, research, or management purposes; reduce barriers and increase access to health services; and optimize individual and public health outcomes.

Telemedicine is a subset of telehealth that concerns the delivery of remote health services for promotion, prevention, diagnosis, treatment, and rehabilitation by health professionals using ICT,²² allowing them to exchange data with the

purpose of improving access and timeliness in the service delivery.²³ Currently, the LAC region needs a conceptual reference framework with the criteria for identifying the main legal and strategic considerations that should be taken into account in the short, medium, and long term when integrating regulatory ecosystems in telemedicine.

In response to this need, this conceptual framework for telemedicine regulations aims to be easy to implement and use in a safe and ethical manner and applies a human rights-based approach. It also aims to be readily adaptable to national legal systems, taking into account the unique characteristics of countries' health systems and local conditions.

A review of existing conceptual frameworks, as well as regulations in LAC and other regions, reveals a general consensus in the literature about fundamental dimensions to be included in regulations to facilitate and encourage the use and implementation of telemedicine.

This publication identifies seven key categories to address in telemedicine regulations (see **Figure 2**). The first is designated the “core” category, and it is complemented by six other categories.

²² PAHO. *Conversaciones sobre eSalud*. <https://iris.paho.org/handle/10665.2/28391>

²³ PAHO. *Conversaciones sobre eSalud*. <https://iris.paho.org/handle/10665.2/28391>

The categories are divided into 23 dimensions that provide greater detail on the specific components of each category. Taken together, these

dimensions represent the key elements of a regulatory framework for telemedicine.

FIGURE 2 • Categories to be addressed in telemedicine regulations



Source: Own work.
Conceptual reference framework: 7 categories and 23 dimensions.

These categories and their respective dimensions capture the diversity and complexity of the topics that telemedicine regulations must address:

- 1. Regulatory aspects of telemedicine:** This core category covers issues related to the use of telemedicine as a healthcare tool. It includes, at minimum, a legal framework that expressly enables the practice of telemedicine and addresses its nature as a complementary or substitute service for in-person consultation; secure data transmission methods during teleconsultations; different modalities (synchronous and asynchronous); a special liability regime for health professionals practicing telemedicine; and bodies for the certification, licensing, and accreditation of professionals, institutions, and information technology (IT) developers, among other issues.
- 2. Telemedicine governance:** It is essential to have solid and sustainable public policies for telemedicine grounded in a national health strategy that defines a regulatory framework.²⁴ This category thus includes the existence of national regulatory frameworks and their alignment with a national health strategy or government digital agenda; quality standards for telemedicine; professional training requirements; and the availability of telemedicine as a healthcare tool at all levels of care (from the most basic to the most complex).
- 3. Personal data protection in telemedicine:** This category includes regulations covering the privacy and confidentiality of patients' health information, as well as the international transfer of personal data for teleconsultations involving more than one country. It also includes consent for health data processing, disclosure, and/or transfer; security guarantees, secondary uses, etc. These regulations may be broader in scope than just the area of health or telemedicine.
- 4. Technological aspects of telemedicine:** This category deals with regulations concerning actions for promoting infrastructure and connectivity to facilitate telemedicine, as well as the technological requirements that must be met for successful and secure implementation (including the ability to correctly identify health professionals and patients, the use of approved medical devices, and certified platforms for providing telemedicine services). Also falling under this category are regulations for the digital services related to telemedicine, such as systems interoperability, electronic health records, electronic prescriptions, and digital signatures. As in the previous category, the regulatory frameworks may not have been specifically intended for telemedicine but are still analogically applicable.
- 5. Actions of health teams:** This category covers regulatory frameworks that govern professional practice, such as enabling standards for telemedicine, specific registries for health teams providing telemedicine services, rules of conduct for professional practice, provisions on professional fees, insurance for telemedicine practitioners, health team rights and obligations, interjurisdictional telemedicine services, and actions to humanize telemedicine services.
- 6. Role of patients in telemedicine:** This category includes regulations that comprehensively address the rights and obligations of telemedicine patients regarding: access to consultation, personal data and records, specific consent for the use of their voice and image, conditions for entering and participating in virtual consultations, and patients' obligations regarding the health team and their use of digital health services.
- 7. Cross-cutting legal aspects of telemedicine:** This category encompasses measures aimed at ensuring optimal implementation of telemedicine programs, guided by the PAHO

²⁴ Saigi-Rubió, F. et al, op. cit. <http://dx.doi.org/10.18235/0003438>

slogan of “no one left behind” and a human rights perspective. It includes regulations for bridging existing access gaps and digital divides; special legislation or reasonable adjustments for vulnerable groups; actions to prevent discriminatory practices; the application of a gender perspective; and respect for the rights and guarantees of children and adolescents, older people, and people with disabilities in telemedicine services.

>> **b) Telemedicine regulatory framework maturity model. Methodology and interpretation of data**

Based on the conceptual reference framework for telemedicine regulations, an **assessment tool** structured around a series of statements arranged in the same order as the 23 dimensions of the conceptual framework was developed. Each statement is scored on a five-point scale representing the regulatory framework’s maturity level (1 to 5) for each dimension and category (see **Figure 2**). The higher the score, the more mature the regulatory framework is in that dimension.

Each successive level represents one more step towards a strong and consolidated regulatory framework, recognizing from the outset that the LAC region has, for a variety of complex reasons, generally not yet been able to engage in the necessary in-depth discussions on many of the issues directly and indirectly affecting telemedicine.

Level 1 (basic) indicates regulatory gaps or a complete lack of regulatory frameworks. In other words, the country does not have any telemedicine regulations for the dimension in question.

Level 2 (development phase) recognizes existing regulations that broadly refer to telemedicine in isolated instances but do not provide an overarching framework or effective enforcement mechanisms. The following are included in this category: ordinances or ministerial resolutions that do not have the formal status of law, recommendations, protocols, and best practice guides.

Level 3 (advanced) refers to states and countries with regulatory frameworks largely consisting of formal laws, but whose regulatory aspects are insufficient and/or not specific to telemedicine.

Level 4 (optimal) indicates states and countries with regulatory frameworks based on formal laws that have implementing regulations and/or a greater degree of progress in their content, even if they are not yet self-contained.

Level 5 (well-established) groups states and countries with regulatory frameworks consisting of formal laws that have implementing regulations, are self-contained, and are supported by monitoring, assessment, and continuous improvement processes that make them fully operational.

Since some dimensions have a greater impact than others on the development of regulatory frameworks for telemedicine, each statement was assigned a level of importance: low, medium, or high. This classification is based on strategic aspects for implementing and developing regulatory frameworks for telemedicine in the region taken from: a) specialized and non-specialized literature on telemedicine, b) existing regulatory models for telemedicine, and c) the opinions of expert consultants following an initial validation of the conceptual reference framework.

As shown in Figure 4 and in the example in Table 1, the dimensions considered most important (in the example, “Telemedicine regulations exist”) have a maximum score of 60 points. Dimensions with a medium level of importance (“The regulatory framework defines common terms used in telemedicine”) have a maximum

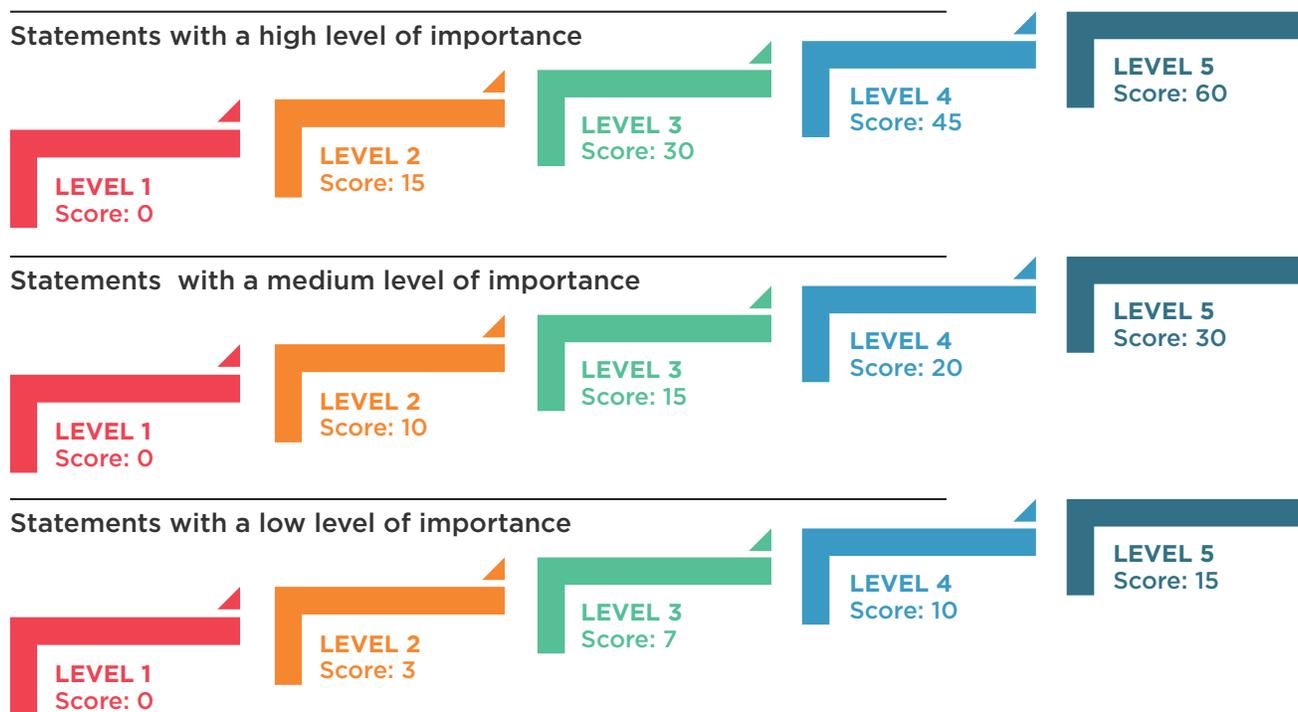
score of 30 points, and dimensions with a low level of importance (“The regulatory framework requires the telemedicine tool to establish secure communication channels”) have a maximum score of 15 points. Appendix 1 contains the exact calculation details for each country.

FIGURE 3 • Statement levels



Source: Own work.

FIGURE 4 • Levels of importance of the statements



Source: Own work.

TABLE 1 • Rubric for scoring statements, by level

CATEGORY No. 1: REGULATORY ASPECTS OF TELEMEDICINE							
Dimension	Statement	Level of importance	Score Level 1	Score Level 2	Score Level 3	Score Level 4	Score Level 5
General regulatory issues in telemedicine	Telemedicine regulations exist	High	0	15	30	45	60
	The regulatory framework defines common terms used in telemedicine	Medium	0	10	15	20	30
	The regulatory framework requires the telemedicine tool to establish secure communication channels	Low	0	3	5	7	15

Source: Own work.

In the global health crisis triggered by the COVID-19 pandemic, telemedicine emerged as a valuable strategy for overcoming disruptions to the healthcare triad of patients, health teams, and supportive care environments caused by social distancing measures and protections necessary to stem the spread of the virus. Consequently, countries fast-tracked regulations to enable the provision of virtual services, which served to ensure a certain level of safety.

In addition to analyzing regulatory frameworks, this study looked at the impact of the COVID-19 pandemic on countries' telemedicine regulations, **assigning one of three possible statuses to each country:**

Status 1: The health emergency caused by the pandemic did not lead to the passage of temporary regulatory frameworks enabling telemedicine services, nor was there previous legislation on this topic.

Status 2: The health emergency caused by the pandemic led to the development of regulatory frameworks for telemedicine, with time limits linked to the duration of the pandemic.

Status 3: The health emergency caused by the pandemic led to the development of long-term regulatory frameworks.

These results are presented in Section IV.

Section II: A snapshot of regulatory progress in the region

The regional analysis shows uneven progress on telemedicine regulations. Of the 26 countries included in the study, only two scored²⁵ in the upper half of the range of points for overall regulatory maturity.²⁶ The study found 34.61% of the countries to be at Level 1, 46.15% at Level 2, and 19.23% at Level 3. No country's total score put them at Level 4 or 5. According to the results, most LAC countries are within a range of 300-700 points.

First, only 13 countries (50% of the 26 countries in the study) were found to have regulations in force that, to a greater or lesser extent, enable telemedicine services. One such regulation is **Uruguay's** Law No. 19.869, which establishes general guidelines for implementing and developing telemedicine as a form of providing health services, in order to improve the efficiency and quality of those services and increase their coverage by using ICT. Article 3 of this regulation lays out the applicable principles that support telemedicine. For its part, **Panama** passed Law No. 203 to regulate the development and implementation of telehealth, with the purpose of "helping reduce congestion in hospitals, performing faster preventive and/or initial diagnoses, and monitoring patients remotely, while adhering to the principles of efficiency, universality,

solidarity, comprehensiveness, unity, and quality, among others."

Peru has also made progress in this area, and its Telehealth Law No. 30.421 (with implementing regulations in Supreme Decree No. 005-2021-SA) establishes guidelines for implementing and developing telehealth as a nationwide service delivery strategy. The law also establishes the specific obligations and responsibilities of health personnel and determines the principles that should govern telehealth services: a) universality, b) equity, c) efficiency, d) service quality, e) decentralization, and f) social development.

Other countries such as **Brazil**²⁷ and Chile have regulations issued during the COVID-19 pandemic that will cease to apply once the health emergency is over. **Argentina** is an outlier in this respect, passing Law No. 27.553 to regulate electronic or digital prescriptions and adding a subsection to the bill during parliamentary debate that enabled the use of telecare platforms. However, the implementing regulations for that provision have yet to be issued as of the completion of this publication. The country's Ministry of Health also issued lower-level regulations before the pandemic with recommendations for the use of telemedicine services.

²⁵ The total score is calculated by adding all the points from each of the seven categories.

²⁶ Colombia and Peru obtained scores of 55.63% and 56.66%, respectively.

²⁷ Brazil's Law No. 13.989 regulates the practice of telemedicine for the duration of the health emergency, and Article 1 of Resolution No. 1643/2002, issued by the Federal Council of Medicine (Portuguese acronym: CFM), defines telemedicine as "the practice of medicine through the use of interactive communication methodologies and audiovisual data, for the purpose of health care, education, and research." Article 2 of the same regulation states that services provided via telemedicine must have the appropriate and necessary technological infrastructure and comply with the CFM technical regulations regarding data's custody, handling, transmission, confidentiality, and privacy, as well as the guarantee of professional secrecy.

Second, and despite the outsized role of governance in digital health,²⁸ the regional overview reveals that 13 of the 26 countries do not have regulatory frameworks that expressly support digital transformation processes, ensure coherence and synergies between different sectors and telemedicine policies, provide sustainable financing and infrastructure, and/or pass or enact the legislation needed to successfully implement the services.

Among the countries that have made the most progress on telemedicine governance is **Peru**. Its Ministerial Resolution No. 1010-2020-MINSA approved its “National Telehealth Plan,” which includes guidelines, strategic actions, and technical assistance to implement and develop telehealth, primarily in rural areas and areas with limited response capacity. **Panama’s** “Digital Agenda 2021” explicitly names the health sector as a priority area that should be included in the processes of digital government transformation and digital technologies implementation, while **Colombia** has made telemedicine part of its national health strategy.

Third, and as mentioned in the previous publication in this series,²⁹ personal data protection is the category with the highest number of laws, decrees, and regulations in the countries covered in the study. More specifically, this category includes laws on *habeas data*³⁰ that cover both

institutions in the public and private sector and individuals. Only **Haiti** and **Suriname** (representing 8% of the countries in the study) have no regulatory framework to protect personal data or regulations on access to public information that address this topic. To clarify, some countries, like **Honduras** and **Guatemala**, do not have personal data protection regulations per se, but do have regulations on access to public information that establish some rights for data subjects (including health data), although to a lesser extent.³¹ For example, Article 9 of Guatemala’s Decree No. 57-2008, which regulates access to public information, defines personal data (“data related to any information concerning identified or identifiable individuals”) and sensitive personal data (“personal data referring to the physical or moral characteristics of persons or to facts or circumstances of their private life or activity, such as personal habits, racial origin, ethnic origin, political ideologies and opinions, religious beliefs or convictions, physical or psychological health, sexual preference or activity, moral status, family situation, and other private matters of a similar nature”).

Finally, only 19% of the countries in the study have made progress on cross-cutting principles and human rights in telemedicine (Category 7): **Uruguay, Peru, Panama, Paraguay, and Colombia**.

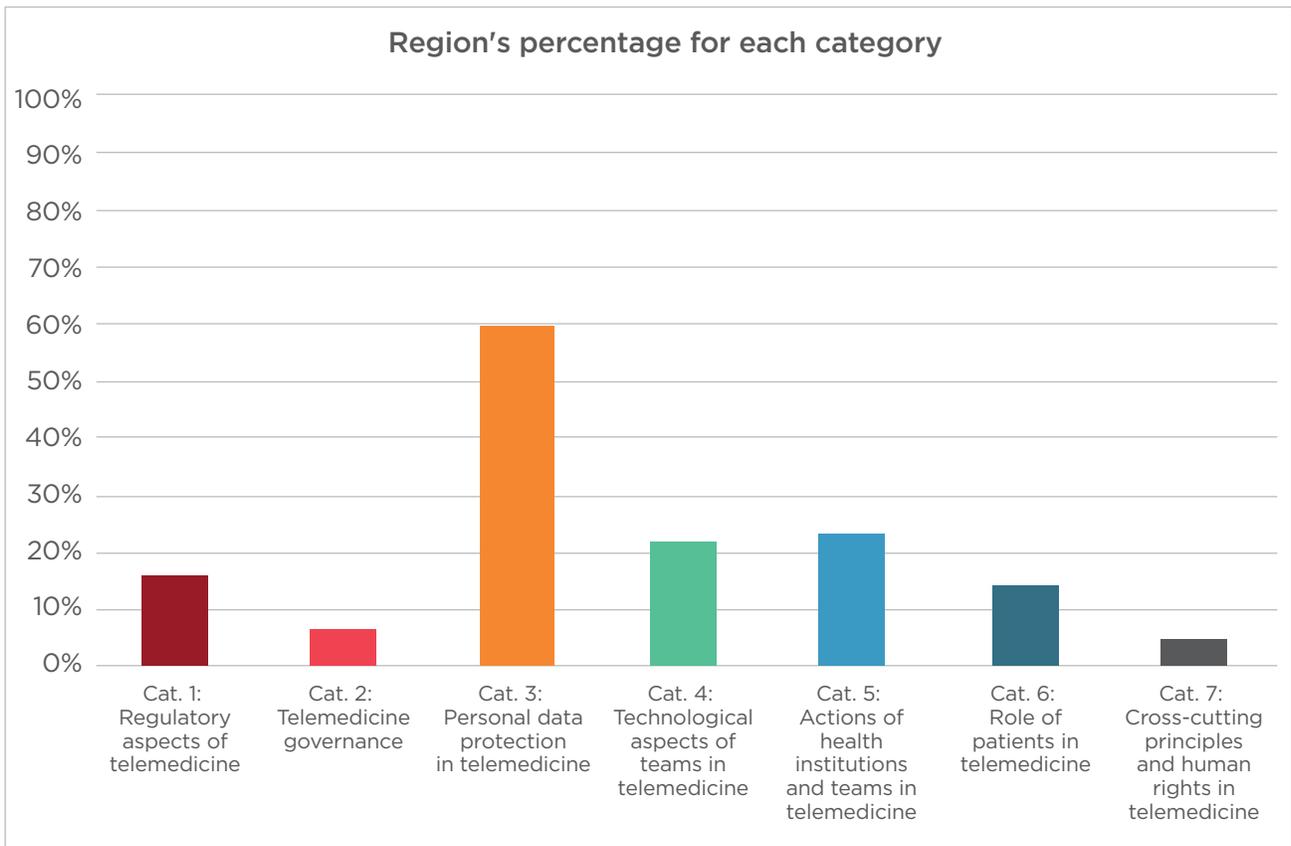
²⁸ “The digital transformation of the health system requires governance that addresses rights, regulations, responsibilities, and risks in areas such as the internet and health, the use of health data, and information systems. Digital health governance aims to improve the quality, efficiency, and effectiveness of the health system.” Carnicero, J., op. cit.

²⁹ Bagolle, A., Park, M., & Marti, M. (2020). *Regulatory Frameworks for Digital Health in Latin America and the Caribbean*. IDB. <http://dx.doi.org/10.18235/0003073>

³⁰ *Habeas data* is a legal remedy that enables individuals to exercise their right of access to public or private records or databases containing their personal information in order to review or update their contents.

³¹ This is because laws on access to public information regulate the information and data held by public agencies, which are under the authority of states.

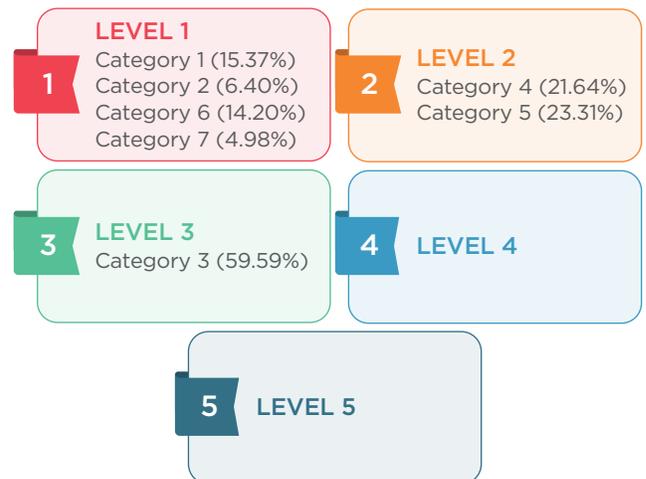
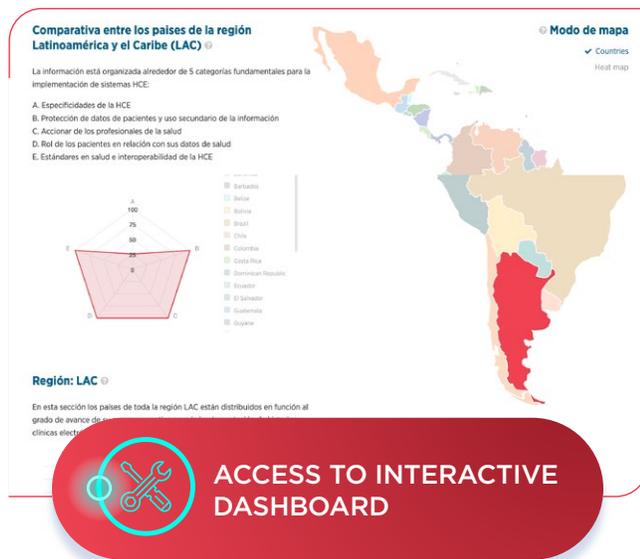
FIGURE 5 • Regional progress in the conceptual reference framework categories based on percentage of points obtained



Source: Own work.

The regulations of each country analyzed in this document as well as tools for their analysis can be found in the Telemedicine Regulatory Map.

FIGURE 6 • Regional progress in the conceptual reference framework categories based on average number of points obtained, by level



Source: Own work.

Figure 7 provides an overview of the regulatory frameworks in the 26 LAC countries included in the study. The shades of blue shown below

represent the level achieved by each regulatory framework in the various dimensions:



FIGURE 7 • Overview of the regulatory frameworks of the 26 LAC countries

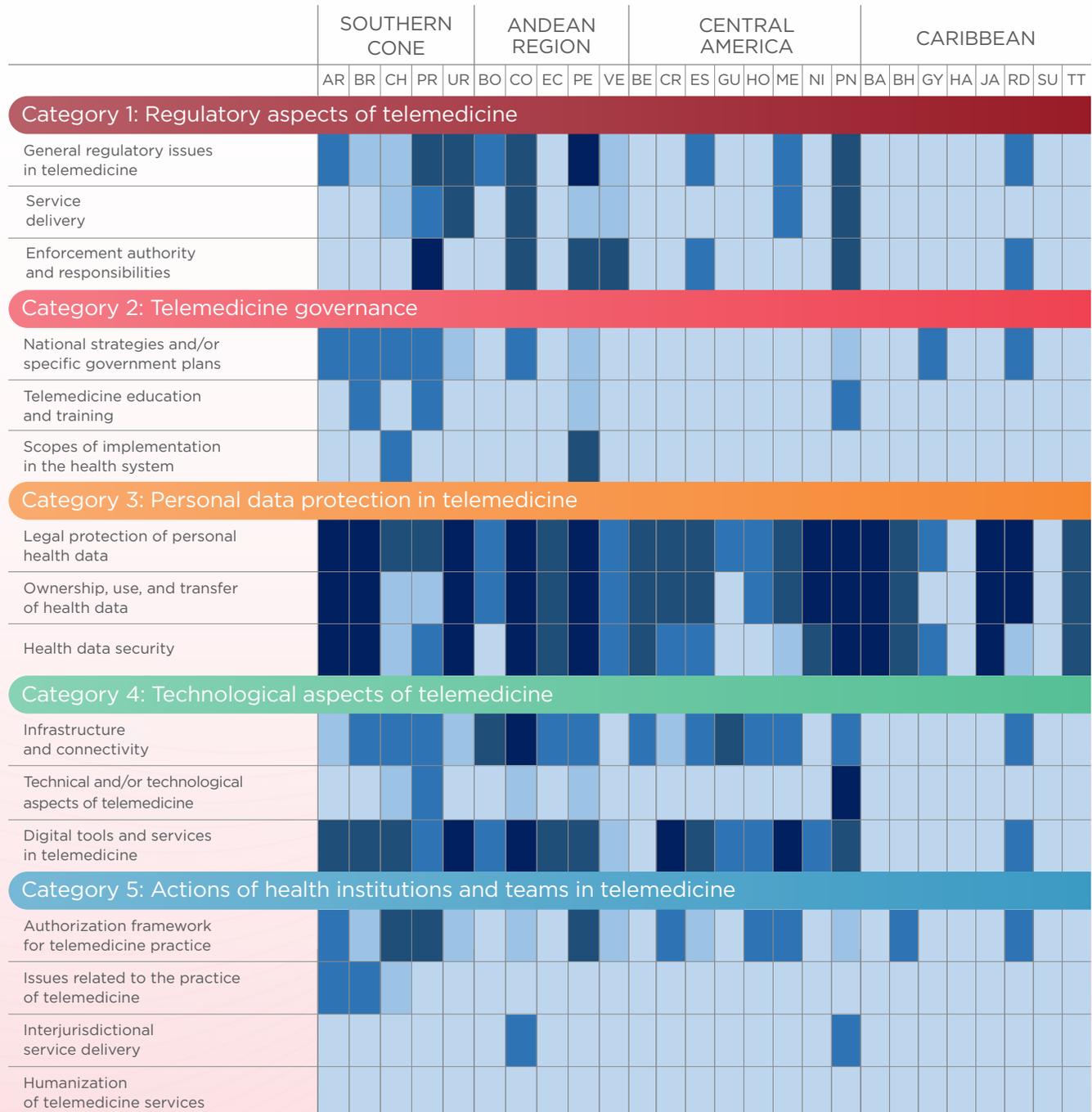
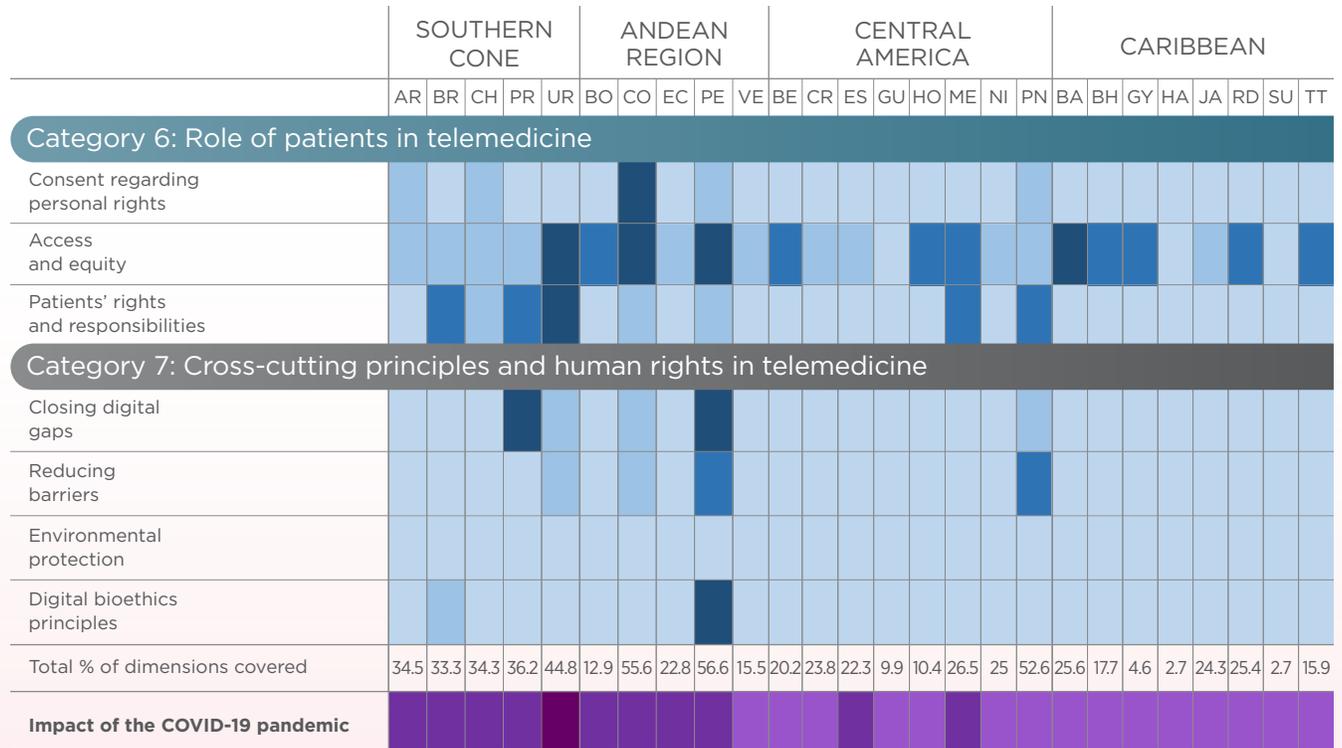


FIGURE 7 • Overview of the regulatory frameworks of the 26 LAC countries (Cont.)



Source: Own work.

These levels are calculated based on the average score for all statements for each dimension. The table also shows the impact the COVID-19

pandemic had on each country's regulatory framework, based on the methodology explained in [Section I](#).



Section III: Approaches to the regulatory framework dimensions

This section shares the main progress LAC countries have made in each of the conceptual reference framework categories.

>> a) Category 1: Regulatory aspects of telemedicine

This study found an overall lack of legislation on telemedicine in most Latin American and Caribbean countries. Despite this situation, several countries address telemedicine through other government documents, such as best practice guidelines and recommendations. While these documents do not have the status of law, they nonetheless provide guidance on how telemedicine services should be provided.

The countries with laws on regulatory aspects of telemedicine include **Uruguay** (Law No. 19.869), **Colombia** (Law No. 1.419), **Peru** (Law No. 30.421), **Paraguay** (Law No. 5482/2015), and **Panama** (Law No. 203).

In **Brazil**, Law No. 13.989 authorizes the use of telemedicine for the duration of the COVID-19 pandemic, while CFM Resolution No. 1643/2002 defines telemedicine as the practice of medicine using interactive communication methodologies and audiovisual data for the purpose of health care, education, and research. **Venezuela's** Telehealth Law, published in Official Gazette No. 6.207, devotes a large part of its text to listing the public authorities in charge of supervising telemedicine services. In the case of **Chile**, Resolution No. 204/2020 was issued to enable telemedicine in the context of the pandemic, with a duration that is contingent on the length of the health emergency. **Argentina** enabled the use of telemedicine services through Law No.

27.553, but the regulations for its implementation have not been issued as of the completion of this report.

>> b) Category 2: Telemedicine governance

Governance is defined as the art or manner of governing so as to achieve lasting economic, social, and institutional development, and it is key to establishing national telemedicine strategies. Evaluating this category involved reviewing all regulatory frameworks that have incorporated telemedicine into their healthcare strategies through laws and/or lower-ranking documents (technical guides, strategies, and/or plans). The analysis showed that 13 of the 26 countries do not have any guidelines related to telemedicine governance.

Panama is among the countries that have made the most overall progress on this aspect. Section 3.5.1. of the country's "Digital Agenda 2021," focused on the health sector, discusses the impacts of the pandemic. More specifically, it mentions the need to improve health systems and infrastructure and to implement new services like telemedicine, in order to take the burden off health centers and thus mitigate the negative effects of the health emergency. In addition, Panamanian Law No. 203/2021 on telehealth establishes the requirement for healthcare teams to receive continuous education and training in digital skills needed for telemedicine services (Article 18).

Another country that has made great strides on telemedicine governance is **Peru**. Its Ministerial Resolution No. 1010-2020-MINSA approved its

“National Telehealth Plan,” which regulates guidelines, strategic actions, and technical assistance to implement and develop telehealth at the national level, primarily in rural areas and areas with limited response capacity.

The other countries that have shown some progress in this category are the **Dominican Republic, Paraguay, Brazil, Argentina, Chile, Colombia, Mexico, Uruguay, Guatemala**, and **Guyana**, most of which treat telemedicine as a strategic objective in their digital government agendas.

>> c) Category 3: Personal data protection in telemedicine

It is clear that the implementation and use of telemedicine programs must be accompanied by regulations guaranteeing the integrity and protection of personal data.³² Such regulations must also incorporate technical mechanisms and standards to ensure smooth, reliable, and secure handling of information. As stated in the overview, only two of the 26 countries in the study have no regulations to protect personal data. Some other countries lack regulations to protect this specific type of data, but do have laws or other types of provisions governing access to public information and/or *habeas data* actions that are partially applicable to this field. However, the unique nature of health in general and telemedicine in particular calls for specific legal responses to these issues.

This need for special protection of the security and confidentiality of health data often comes up against the need to facilitate the use of such data to improve individual and population health outcomes, posing a challenge to efforts to safeguard citizens’ rights.

Because telemedicine services collect, store, and process health data, they require robust regulations that clearly define the legal protection status and ownership of such data, the bodies responsible for ensuring legal guarantees, levels of access to the information, rules for the disclosure and/or international transfer³³ of the data, how the data is stored, and the applicable jurisdiction and principles.

One finding from the analysis is that most of the countries with regulations on personal data protection do not provide for questions of subject-matter jurisdiction. As a result, their regulatory frameworks do not specify which court or forum would have authority to hear a claim for a rights violation that falls under that framework.³⁴ Meanwhile, **Brazil** boasts some of the region’s most advanced data protection regulations, passing its General Data Protection Law No. 13.709, which is modelled after the European Union’s General Data Protection Regulation. This law considers data protection to be a human right and does not restrict its application to specific areas, requiring that data be protected in all areas of life. The law impacts almost all areas of business and administration, including the handling of health data.

Other countries with advanced regulations on personal data are **Argentina** (Law No. 25.326), **Nicaragua** (Law No. 787 and its regulations), **Panama** (Law No. 81), **Peru** (Supreme Decree No. 003-2013-JUS), **Chile** (Law No. 19.628), **Colombia** (Statutory Law No. 1.581), **Jamaica** (Data Protection Act of 2007), and **Barbados** (Data Protection Bill of 2019).

³² The countries without regulations governing the use and processing of personal data are Haiti and Suriname.

³³ The international transfer of personal data and a framework for its protection are essential to enable and strengthen the delivery of telemedicine services by medical/healthcare entities in foreign countries. Such frameworks determine which countries ensure an adequate level of protection for personal data, and non-national providers are unable to offer their services when no such framework is in place. For more information on the subject, see: Saigi-Rubió, F. et al. (2021). *Estudio sobre telemedicina internacional en América Latina: motivaciones, usos, resultados, estrategias y políticas*. <http://dx.doi.org/10.18235/O003438>

³⁴ Argentina, for example, is one of the countries with regulations (in its case, Article 44) that specify the scope of application, stating that: “(...) The federal court system shall hear all cases involving records, files, databases, or data banks interconnected in networks of interjurisdictional, national, or international scope.” <http://servicios.infoleg.gob.ar/infolegInternet/anexos/60000-64999/64790/norma.htm>

>> d) Category 4: Technological aspects of telemedicine

Analysis of the various technologies used in telemedicine found mixed results regionally. 42.30% of the countries are considered to be at Level 1, another 46.15% are currently at Level 2, and 11.53% have reached Level 3, the highest level found in the study. On average, the region obtained 21.64% of the points possible in this category. Most of the points countries earned are connected to regulations on other digital health tools that are related to telemedicine, such as electronic medical records, electronic prescriptions, and interoperability standards, responsible for many of the points that were obtained. The vast majority of these regulations are not aligned with countries' legal frameworks for telemedicine and coexist in an uncoordinated, piecemeal fashion.

One technological gap in particular stands out in the region, which is regulations to develop infrastructure and connectivity in order to make it easier to practice telemedicine.

However, significant progress has been made by countries such as **Argentina, Chile, Colombia, El Salvador, Guatemala, Mexico, Panama, Paraguay, Peru, Uruguay, and Venezuela**. In general, a review of documents like national strategies, recommendations, and best practice manuals for these countries shows infrastructure and connectivity to be key aspects of their telemedicine service implementation plan.

>> e) Category 5: Actions of health institutions and teams in telemedicine

The first conclusion to emerge from the regional analysis is that many aspects related to health institutions and teams have yet to be defined

for telemedicine service implementation. On average, LAC countries obtained 23.31% of the possible points in this category. The top-scoring countries (11.53% of the total) reached Level 3. The overwhelming majority, however, only reached Level 1 (53.84%) or Level 2 (34.61%).

Among the countries with a higher maturity level was **Paraguay**. Its Law No. 5482 and implementing regulations establish the requirement to document telemedicine services and the obligations of health professionals (Article 10 of the implementing regulations).³⁵ However, Paraguay's legislation was found to lack details about the regulation of fees, interjurisdictional services, and consensus on professional rules of conduct during teleconsultations. **Chile** addresses some regulatory aspects of the actions of health teams, requiring, for example: a registry for telemedicine service providers; the identification of the rules of etiquette at the beginning of such services; a statement on the rights and obligations of professionals; and guidelines for determining fees in a manner equivalent to traditional consultations.

The vast majority of LAC countries must work to regulate issues related to actions to humanize telemedicine services, especially interjurisdictional service delivery, the regulation and payment of professional fees, insurance contracts for telemedicine practitioners, rules of etiquette, the involvement of scientific societies to define scopes of practice by specialty, and others. Some countries, like Haiti, Suriname, and the Dominican Republic, among others, only scored points in this category because they have no regulations prohibiting the practice of telemedicine, although they have not passed any legislation or technical guidelines to guide the actions of health personnel.

³⁵ Article 10 of the implementing regulations states: "OBLIGATIONS AND RESPONSIBILITIES. 1) EPSS that include telehealth services in their service portfolio must ensure their sustainability. 2) EPSS shall be responsible for updating the telehealth services in their service portfolio. 3) Health personnel involved in providing telehealth services shall bear the liability arising from failure to fulfill their obligations related to ensuring the confidentiality of patient information and protecting the personal data and sensitive data of users and patients, as well as keeping the necessary professional secrecy, as established in the current legal framework."

>> f) Category 6: Role of patients in telemedicine

This category includes legal regulations that address the role of patients in telemedicine services. Virtually all LAC countries allow patients to access their health data, and this permission can be applied by analogy to telemedicine as well. In contrast, relatively few LAC countries guarantee their citizens access to telemedicine regardless of their coverage and/or health insurance, establish specific rights and obligations in relation to telemedicine care, or define the information that should be provided to patients about eligibility conditions and how virtual consultations are carried out.

Many of the laws in the region governing patients' rights were written without any mention of virtual settings, so most LAC countries share the need to build regulatory frameworks that take into account this new reality.

>> g) Category 7: Cross-cutting principles and human rights in telemedicine

This category is undoubtedly one of the least addressed by the current regulatory frameworks. Discrimination is typically addressed through general regulations meant to prevent and punish such acts in any sphere of life, and these principles are rarely considered in the context of implementing telemedicine services as a strategic tool in healthcare policies for citizens.

Telemedicine-specific regulations on this topic should be firmly grounded in a human rights perspective that treats telemedicine as a real and viable opportunity to facilitate access to health services. At the same time, there must be a recognition that telemedicine programs should be run in a way that respects cultural diversity and personal beliefs and values, taking into account the varying needs of people with disabilities, children, adolescents, older people, migrants, and other populations. Among LAC countries, **Colombia, Panama, Paraguay, Peru, and Uruguay** stand out for their progress in this area. The telemedicine provisions of all of these countries included the principle of universality, ways to adapt telemedicine services to adequately integrate vulnerable groups, and information on the usefulness of telemedicine in bridging geographic gaps, among other details.

Telemedicine holds the potential to achieve both equity and quality in health care, with the caveat that unregulated telemedicine may end up worsening and reinforcing gaps instead of reducing them.

Section IV: Impact of the COVID-19 pandemic on telemedicine regulatory frameworks

Applying the methodology described in Section I, this publication categorizes LAC countries as described in this section based on the impact of the COVID-19 pandemic on their regulatory frameworks:

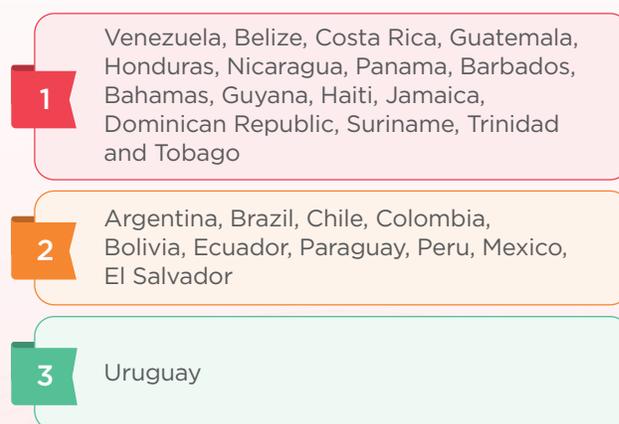
Interested in learning how countries have used telemedicine? Check out these IDB/PAHO webinars

- COVID-19 and Telemedicine: Ready, Set, Click! - May 2020: <https://socialdigital.iadb.org/en/sph/resources/events/7070>
- Telemedicine During the COVID-19 Pandemic— Lessons Learned One Year Later - May 2021: <https://socialdigital.iadb.org/en/sph/resources/events/15214>

In **Chile**, the main regulation on telemedicine (Resolution No. 204/2020) is of an emergency nature, meaning it is tied to the duration of the COVID-19 pandemic. Once the emergency measures are lifted, telemedicine in Chile will revert in regulatory terms to the status it held prior to the pandemic, and throwing aspects of the services currently being provided into legal uncertainty. In addition to this resolution, Chile has published various documents on providing telemedicine services. One such guide was

“Telemedicine During the COVID-19 Epidemic in Chile,”³⁶ published in April 2020. It compiles best practices and recommendations for professionals on how to carry out virtual consultations.

FIGURE 8 • Countries grouped based on the impact COVID-19 had on their telemedicine regulations³⁷



Source: Own work.

Uruguay opted to use a bill sent to Parliament to pass a law without a time limit determined by the length of the health emergency. Despite a number of health bills proposed in recent years, the COVID-19 pandemic gave telemedicine the push it needed to finally be signed into law.

³⁶ CENS. (2020). *Guía de buenas prácticas y recomendaciones en Telemedicina durante la epidemia de COVID-19 en Chile*. <https://cens.cl/wp-content/uploads/2020/04/cens-gua-teleconsulta-en-tiempos-de-pandemia.pdf>.

³⁷ This division was made to organize the information and does not represent a value judgment of any kind. A country in Status 1 does not necessarily have a poorer regulatory framework than a country in Status 3—it may have already had extensive telemedicine regulations in place and thus had no sudden need to create regulations of this kind when the pandemic broke out.

As mentioned in the previous section, **Argentina** passed a telemedicine law with no time limits, although it does not yet have implementing regulations. However, other actions with a duration tied to the health crisis were implemented as well. One example is the TELE-COVID-19 program, designed to detect suspected and confirmed cases of COVID-19 and identify people in risk groups (people over age 60, people with chronic diseases, people with disabilities, pregnant women, postpartum women, newborns, and children under one year of age). By offering an alternative to in-person consultations, the program sought to reduce the burden on the health system. Argentina's "Guide for Health Teams"³⁸ was also published to explain how to document and follow up on remote consultation cases and obtain patients' informed consent when using telehealth and virtual communication platforms, among other technical issues. In parallel, a basic guide was prepared to walk patients through how to access the virtual tool and the recommended precautions to follow during use.

In **Peru**, Law No. 30.421 provides a framework for telehealth. In 2020, Supreme Decree No. 013-2020-SA put the Ministry of Health in charge of establishing the procedures to "provide telemedicine services with special emphasis on remote medical teleguidance, telemonitoring, and mental health during the health emergency, determining the types of care records and the considerations of the corresponding health activity or medical activity."

The situation is similar in **Colombia**, which also has telemedicine-specific regulations. The document "Telehealth and Telemedicine for the Provision of Health Services During the COVID-19 Pandemic," prepared by the country's Ministry of Health, highlights the advantages of this care modality, including reducing cross infection, shortening wait times, promoting equity and access, and ensuring a rapid response to citizens' immediate needs, among other benefits. The document guides providers interested in offering telemedicine services through the administrative process to obtain a temporary

authorization and gives a step-by-step description of how to use technological means to provide care.

The **Bolivian** government's "COVID-19 Management Guide" recommends telehealth options, including phone calls, as a replacement for routine checkups and visits to assess symptoms and health complications.

In **Ecuador**, the Ministry of Health advocates "ensuring continuity of care for patients with palliative needs, through coordinated referrals to a primary palliative care team or establishing follow-up through telemedicine when possible" in the document "Consensus Recommendations on Palliative Care During the SARS-CoV-2/ COVID-19 Pandemic." When specifying what channels it considers appropriate for these purposes, the document lists "a phone call, a video-based telemedicine platform, or a commercial video chat platform," insisting that patients' privacy must be respected no matter which channel is used.

Brazil passed Law No. 13.989, which authorized the use of telemedicine for the duration of the public health crisis caused by the COVID-19 pandemic. Article 5 of the law establishes that "telemedicine services shall adhere to the same regulatory and ethical standards as in-person care, including regarding financial compensation for services provided, and that the authorities are not responsible for funding or paying for such activities when they are not an exclusive service of the Universal Health System." The law also states that physicians must inform patients of telemedicine's inherent limitations, given the impossibility of performing a physical examination during remote consultations.

In the absence of regulatory framework enabling telemedicine, in June 2020 **Mexico** prepared a document titled "Remote Consultation Contact Unit (UCID) Mexico: Care for Chronic Diseases." It aims to propose services, logistics, and criteria for implementing this care modality for patients with chronic diseases (diabetes, hypertension, overweight, and obesity). The document begins

³⁸ <https://bancos.salud.gob.ar/sites/default/files/2020-07/guia-para-equipos-de-salud-programa-telecovid19.pdf>.

with an overview of telehealth and telemedicine experiences both in Mexico and internationally. It then covers the technical details (human resources, infrastructure, etc.) of the guidelines that should be followed when creating remote units for professionals to consult colleagues located in different regions.

During the COVID-19 pandemic, **El Salvador** prepared a technical document with various recommendations. The objective of this document was to “establish technical regulations for implementing telehealth remotely (telecare) in its modalities of teletriage, telemonitoring, teleguidance, and telecounseling by means of calls or video calls, in order to ensure continuity of care to the prioritized population of women of childbearing age, pregnant or postpartum women, children under 10 years of age, adolescents, older people, and people with chronic noncommunicable diseases and mental health disorders during the COVID-19 pandemic.” It also included the requirement to document all telemedicine activities. Accordingly, all calls must be recorded for the amount of time established in the institutional

care regulations, and users must be notified of this by the physician and other call handlers. These recordings may also be used as legal evidence if needed. All care forms used to provide the telemedicine service will have the call's recording code on them, and the recordings will be posted on a website and safeguarded by the Ministry of Health in a centralized manner. The document also enables the Integrated Patient Care System for keeping records of information. All of these provisions are only for the duration of the COVID-19 pandemic, meaning that telemedicine will likely lose its legal status in the country once the health emergency has passed. Finally, **Paraguay's** Ministry of Health issued Resolutions Nos. 139/2020 and 367/2020, authorizing, in view of the health emergency (declared via Decree No. 3456/2020), healthcare entities and medical professionals to use ICT to provide remote health services for promotion, prevention, diagnosis, treatment, and rehabilitation, with the purpose of facilitating access and timeliness in the provision of services to the population, without detriment to those who require personalized care.

Section V: Conclusions and next steps

Telemedicine, as a modality of health care, holds tremendous potential to transform the delivery and management of health systems.

Situations such as patient referrals and communication between health professionals at different levels of care (primary and specialized care, primary care and community pharmacies, etc.), long waiting lists for in-person consultations, and unnecessarily repetitive administrative tasks all stand to be improved by the implementation of telemedicine programs.³⁹

Countries in the LAC region must design and implement roadmaps to construct the legislative ecosystems needed to facilitate advances in telemedicine as a strategy for delivering health services to citizens and ensuring sound governance mechanisms. The exact details of this legislation will depend on each country's specific context and needs.

While it is possible to apply laws by analogy (for example, enforcing regulations establishing patients' rights, even when they do not address virtual environments), the unique nature of this care modality calls for clear and specific regulatory guidelines.

The region has seen legislative progress on the most basic aspects of telemedicine services, but regulatory vacuums (the absence of regulations) still abound, creating ambiguity for practitioners and hindering the design, implementation, and adoption of new telemedicine programs in

the region. This lack of clarity has raised doubts about matters such as the scope of use of telemedicine tools, professional responsibilities, financial compensation for services, and the determination of liability in the event of damages. Health institutions, professionals, and other telemedicine service providers (such as IT developers and operators, internet service providers, and platform companies and designers) also find themselves in limbo when planning telemedicine activities without clear rules to establish their respective responsibilities.

Other **gray areas** currently under debate include licensing for practitioners, determination of which court system has jurisdiction to hear cases when practitioners and patients are located in different countries, and the protection or cross-border transfer of data. Given this context, regulations are viewed as a decisive factor in either speeding up or delaying the effective implementation of digital tools in health care.

According to the regional analysis, the countries with specific regulations on telemedicine implementation have included provisions on the definition of different services, guiding principles, information security, and the complementary nature of telemedicine and in-person care, among other aspects.

In sum, regulatory frameworks have proven to be essential springboards for launching telemedicine and digital transformation processes.

³⁹ Mahtani Chugani, V., Martín Fernández, R.L., Soto Pedre, E., Yanes López, V., Serrano Aguilar, P. *Implantación de programas de telemedicina en la sanidad pública de España: experiencia desde la perspectiva de clínicos y decisores*, Gaceta Sanitaria, Volume 23, Issue 3, 2009. <https://www.sciencedirect.com/science/article/pii/S0213911108000137>.

Meanwhile, telemedicine technologies raise ethical questions about, for example, data privacy and the use of images, which are sometimes accessed and stored with insufficient security measures.

To avoid these pitfalls, telemedicine programs and the privacy policies for the personal data exchanged in them must be designed according to ethical and legal criteria.

While the analysis found higher levels of maturity in the area of **personal data protection**, the speed of technological advances means that the existing regulatory frameworks will need continual updates. Genomic and biometric data, for example, poses new legal and legislative challenges regarding its use, processing, storage, disclosure, transfer, and secondary uses, as well as data security issues. The analysis also identified regulatory gaps for certain technological aspects, especially those related to digital health technologies used in telemedicine, like electronic health records, electronic prescriptions, and digital signatures. Regulations in these areas require updates given how fast digital transformation is changing the health field.

Two other key areas that should be considered in greater depth are **governance** and **cross-cutting principles and human rights in telemedicine**. No strategy for implementing telemedicine programs can succeed in isolation. These programs have to be the product of coordinated and interconnected actions based on solid governance,⁴⁰ with public policies that pool the efforts of all stakeholders. Digital transformation presents states with an opportunity to strengthen and improve their governance capacity.

The region still has much work to do to include in its regulations principles linked to the category of **human rights** in digital health in general and telemedicine in particular. This study found a significant lack of public policies and regulatory instruments that enable accessible and

inclusive telemedicine,⁴¹ which should include a focus on the most vulnerable populations and be guided by ethical standards.⁴²

To view the status of EHR regulations, visit:

- Document: <https://publications.iadb.org/es/marco-normativo-para-la-salud-digital-en-america-latina-y-el-caribe-el-caso-de-las-historias>
- Dashboard: <https://socialdigital.iadb.org/en/sph/dashboard>

Countries need specific regulations to promote the implementation of telemedicine at the national level. These regulations should ideally include and address: a) a proper legal framework that expressly enables the practice of telemedicine; b) telemedicine's status as a service that complements or replaces in-person consultation; c) secure data transmission methods during teleconsultations; d) different modalities (synchronous and asynchronous); e) the professional responsibilities of telemedicine practitioners; f) bodies for the certification, licensing, and accreditation of practitioners, institutions, and IT developers; g) the modalities for obtaining informed consent in digital environments; h) terms and conditions of use of platforms and applications; i) rules and authorities governing the cross-border service delivery; j) principles governing telemedicine; k) fees and insurance; l) the rights and obligations of patients; m) the documentation of telemedicine activities and the interoperability of those records with electronic/digital health records, electronic prescriptions, etc.; and n) the creation of an enforcement authority and its financing.

⁴⁰ For more information on the subject, see the IDB's *Governance for Digital Health: The Art of Health Systems Transformation*, <https://socialdigital.iadb.org/en/sph/resources/research-publications/6825>.

⁴¹ Inclusive digital health is the third principle of the PAHO's *Eight Guiding Principles for Digital Transformation of the Health Sector*. <https://iris.paho.org/handle/10665.2/53730>.

⁴² For more information on ethical standards, see fAIR LAC. <https://fairlac.iadb.org/en>.

Interested in learning more about how telehealth can provide access to health services in remote areas? Watch:

- Interview with Rafael Figueroa
<https://socialdigital.iadb.org/en/sph/resources/interviews/801>

The development of such regulations represents a practical step towards **supporting digital transformation processes**, with other important steps including **mapping out existing regulations to identify regulatory vacuums and creating integrated, organic, and systematized digital legislative ecosystems for telemedicine**. All three of these steps hinge on strategies that treat these regulations as a key to accelerating development and guaranteeing fundamental rights.

It is also recommended that countries:

- Design **roadmaps** with achievable milestones (with the support of academia and all stakeholders) in telehealth and telemedicine development strategies.
- To drive the adoption of telemedicine as a healthcare tool in LAC countries, **develop regulatory frameworks, programs, plans, guides, manuals, guidelines, and best practices in telemedicine**, aligned with the short-, medium-, and long-term objectives outlined in the roadmap and inspired by the principles identified in each dimension.
- Implement **training actions** and work to increase **citizens' digital health literacy**, making them aware of their rights and obligations according to the regulations in force in their country.
- **Develop regional regulatory models** to establish general guidelines based on the reference framework from this document for use by LAC countries, recognizing that each model will need to be adapted to local circumstances. Also, states' regulatory frameworks

should address how to handle cross-border telemedicine issues.

- **Strengthening telemedicine requires a combination of healthcare, technological, and legislative approaches**. Having human resources trained in the health field and access to the necessary technological infrastructure are key components of the process, but it is just as essential to have regulatory frameworks to support telemedicine's implementation.

Countries must make it a priority to build solid, intelligent, and comprehensive legislative and regulatory foundations for mainstreaming human rights in telemedicine and all areas of digital health. To this end, this report aims to provide a further step towards achieving a health system with greater equity and respect for patients' rights.

The pandemic has created opportunities for regulatory innovation, in the form of both legislation and ministerial regulations. Policymakers should consider leveraging these developments and making the improvements to the regulatory environment for telemedicine permanent.

Where to start? This analysis allows us to map out all the elements needed to create a regulatory ecosystem for telemedicine. **However, there are seven crucial elements that must be taken into account when developing a national enabling legislative framework for telemedicine:**

1. Recognize the decisive role of regulations as either a barrier or facilitator for implementing telemedicine services.
2. Map out national and regional regulations based on the dimensions identified in this document.
3. Build the necessary consensus to develop a roadmap to a comprehensive regulatory ecosystem for telemedicine, within the framework of a digital health plan, if such plan exists, taking into account the context and conditions of the local health system.

4. Collaborate with universities and scientific organizations to implement continuous training plans and professional guidelines for healthcare teams.
5. Undertake community-based digital literacy actions, with a focus on increasing access to telemedicine services for the most vulnerable sectors and building public confidence in the use of digital health tools.
6. Promote regulatory frameworks for telemedicine from a human rights perspective, with considerations for respect for individuals' fundamental rights.
7. Establish bodies for the accreditation and certification of telemedicine institutions, products, services, and practitioners.

Interested in learning more about cross-border telemedicine? Check out this IDB study on the topic.

- Study on international telemedicine in Latin America, September 2021:
<https://socialdigital.iadb.org/en/sph/resources/research-publications/18979>

Acknowledgments

The author would like to thank Myrna Marti, Giselle Ricur, Daniel Luna, Marcelo Carrascal, Alexandre Bagolle, Marcelo Lamy, Angélica Baptista Silva, Juan Alberto Lecaros, Felipe Mejía Medina, Alejandro Marín Mora, Adrián Pacheco López, Javier Carnicero, Irene Melamed, Mihwa Park, and Luis Morales for their valuable comments, suggestions, and contributions to the validation of the methodology used and its results.

The author is also grateful for the assistance of the following institutions, which were contacted during the preparation of this document to validate its methods and results: the Central American Health Informatics Network (RECAINSA), the Civil Association of Telemedicine of the Argentine Republic (ACTRA), the Ibero-American Association of Telehealth and Telemedicine (AITT), the American Telemedicine Association (ATA), the Venezuelan Association of Telehealth and Telemedicine (AVTT), and the Telemedicine University Network (RUTE).

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Appendix I: Assessment Tool Applied to Each Country

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