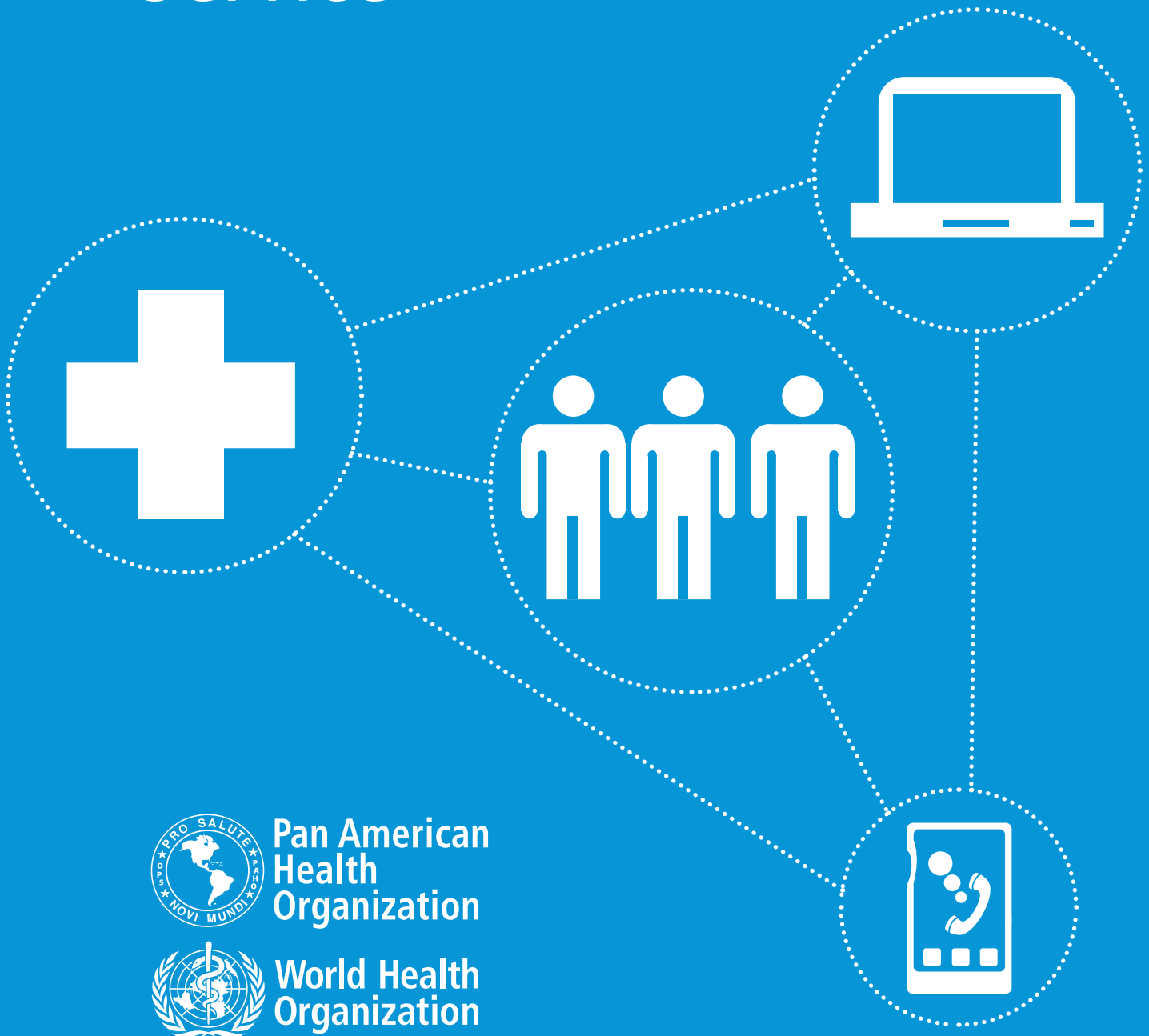
Framework for the Implementation of a Telemedicine Service



Pan American Health Organization
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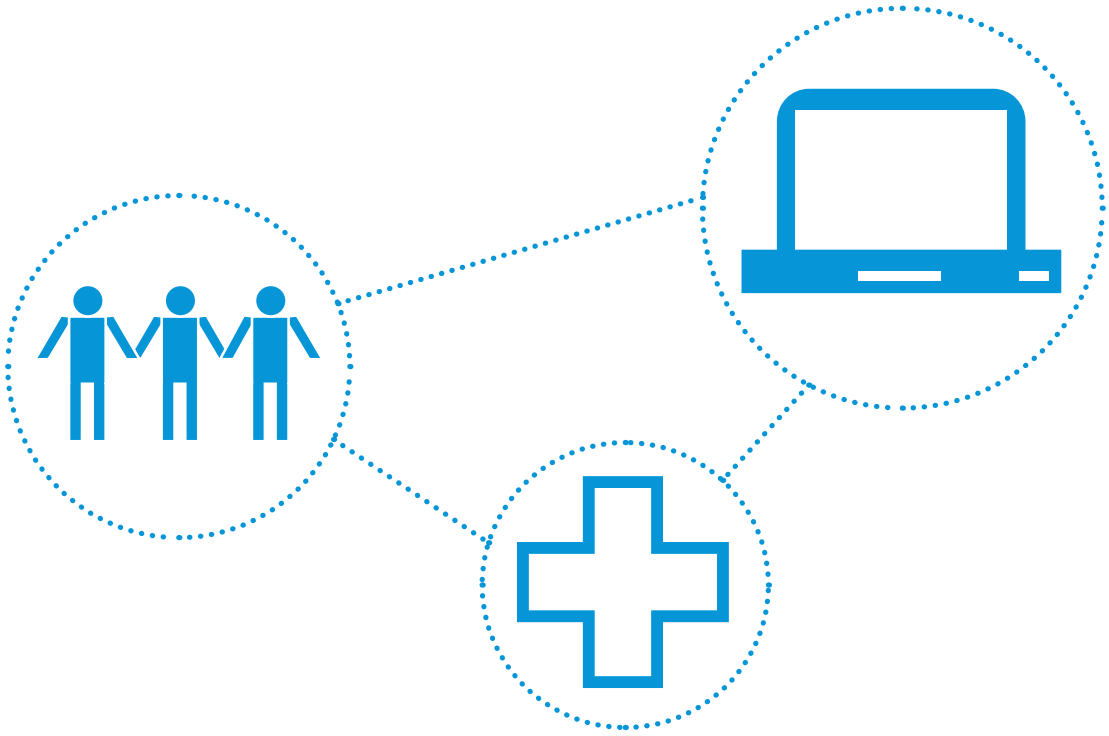

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1 Introduction

Telemedicine is regarded as one of the major innovations in health services, not only from the technological but also from the cultural and social perspectives since it benefits accessibility to health care services and improves the quality of medical care and organizational efficiency. Telemedicine has a role in providing solutions to the challenges posed by socioeconomic changes in health care systems in the 21st century (greater demands on health care, aging populations, increased mobility of citizens, the need to manage large amounts of information, global competitiveness, and improved health care provision), all in an environment of limited budgets and restrictions on spending. Nevertheless, there are significant barriers to standardizing telemedicine and for its full consolidation and expansion. In spite of the strong political will to incorporate Information and Communication Technologies (ICTs) into health care and increased activity in relation to telemedicine, in it continues to have little more than a token presence in clinical and health care settings.. Additionally, although an increasing number of pilot projects and viability studies are being carried out, only a few telemedicine applications have been established in clinical practice and incorporated into medical processes, and even these have often been abandoned once the initial stage was over (1)(2).

This document aims to provide solutions for the successful implementation of telemedicine services (and eHealth, in general) in the health care setting. Following a literature review that identifies key theories, models, and frameworks used in the science of implementation, we introduce a theoretical framework that addresses the obstacles to incorporating and standardizing the use of telemedicine in health care institutions. This narrative review gathers qualitative information from different sources on a particular topic, and summarizes and synthesizes the literature in order to determine "what is known" about a topic (3).

This theoretical framework is based on understanding the context within its broader structure, together with existing challenges and opportunities. The document introduces the reader to the reality of implementing telemedicine services in actual health care settings; analyzes interactions that occur during the process of ICT implementation and changes that occur in organizations, management models, culture, and medical care services; and, finally, reflects on key aspects related to prioritization, design, deployment, integration, and assessment. Analysis of this theoretical framework should allow for the creation of a research program that focuses on major aspects in the successful development of telemedicine, and generate proposed actions to overcome difficulties.

Bearing in mind its cross-cutting nature, this report is aimed at the community of professionals (in its broadest sense) willing to work in any field related to the advancement of the health care sector, both in health and social settings, with the implementation and intensive use of ICTs.

This publication consists of eight chapters. Chapter 2 provides a context for information presented later in the report, with a special emphasis on terminology and key concepts and their relationship with the subject under study. With that aim, it provides a brief summary of "state of the art" scientific publications on telemedicine and introduces the main obstacles and facilitators that should be kept in mind during implementation.

Chapter 3 introduces the implementation model of a telemedicine service and presents a holistic perspective of the process. This model can be optimized throughout the entire process of collecting and structuring information. Chapters 4, 5, and 6 describe the strategic, organizational, and public policy levels of the planning model. Chapter 7 discusses the development stage of the telemedicine service,

focusing on key dimensions such as legal and regulatory, technology and infrastructure, human resources, and service funding issues.

The final chapter deals with service follow-up and monitoring for later optimization, and it addresses major issues such as the monitoring of the telemedicine service operation and of the assessment models useful for the implementation and management of information for service optimization. With that purpose, an overall perspective is provided on the evaluation of ICT projects in the health sector as a way to produce thorough and objective information for the decision-making process based on the best available evidence.

Conceptual Framework

In May 2005, Health Ministers of the 192 Member Countries of the World Health Organization (WHO) met in Geneva for the 58th WHO Assembly and approved the eHealth Resolution (4). Member Countries thereby recognized the contribution of incorporating ICTs in health and health system management, considering it a unique opportunity for the development of public health. The WHO report defines eHealth as the "cost-effective and secure use of Information and Communication Technologies in support of health and health-related fields, including health care services, health surveillance, health literature, and health education, knowledge and research," and it states that eHealth "reinforces fundamental human rights by improving equity, solidarity, quality of life, and quality of care" (5). This document provides WHO a global strategy in the eHealth field and urges Member States to establish long-term strategic plans for the development and implementation of eHealth services.

The interest in fostering and promoting the incorporation of ICTs in the health field is shared by other supranational, national, and regional organizations. In fact, as early as April 2004, the European Union established a Plan of Action (EU eHealth Action Plan 2004–2010) for the creation of what was called the "European eHealth Area." The EU Action Plan states that eHealth ". . . can improve access and boost the quality and effectiveness of the services offered." It continues: "When combined with organisational changes and the development of new skills, e-Health can help to deliver better care for less money within citizen-centred health delivery systems. It thus responds to the major challenges that the health sector is currently facing" (6). In 2011, the Pan American Health Organization (PAHO) reinforced this interest by developing the *Strategy and Plan of Action on eHealth (2012–2017)* for Latin American and Caribbean countries (7).

In summary, eHealth can be understood as the application of the Internet and other related technologies in the health sector for improving access, efficiency, efficacy, and quality of clinical and corporate processes used by health organizations, physicians, patients, and consumers in an effort to improve the health status of patients.

Components

The field of application of ICTs is ever changing due to continuous technological advances and the socioeconomic context. For that reason, the different concepts used may become confusing and, in many cases, no complete and precise definitions are available. According to R.E. Scott (8), the four primary eHealth components are as follows:

1. **Health informatics:** the integration of health information networks and distributed systems of electronic medical histories and records and associated services for gathering, analyzing, and distributing health-related information. For example, in the case of electronic health records, they can occasionally be managed and shared by the patient. In this case, they are known as "personal health folders" or electronic patient records.
2. **Telehealth and telemedicine:** direct or indirect interaction with other health care providers (for a second or expert opinion), ill patients, or citizens. An example would be teleconsultation and social media. Whereas the term telemedicine is restricted to direct health care, telehealth has a broader definition (9).

3. **E-learning:** the use of ICTs to offer learning and education opportunities to health providers and citizens.
4. **Electronic commerce** (associated with business aspects of health care, for instance, electronic reimbursement). For example, hospital information systems allow the control of services delivered to patients and their associated costs, as well as other administrative information.

Telemedicine

Among the different elements that make up the mosaic known as eHealth, telemedicine, defined as the use of ICTs for the transmission of medical information with diagnostic, therapeutic, and learning purposes (10) has, undoubtedly, captured the greatest interest over time. WHO adopted the following definition for telemedicine: "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 interests of advancing the health of individuals and their communities" (2)(7)(11). As early as 2007, Sood *et al.* reviewed a total of 104 different definitions for telemedicine (12).

Although it is difficult to define a particular moment for the "genesis" of any innovation, telemedicine beginnings can be traced back to the 1960s, when the National Aeronautics and Space Administration of the United States (NASA) started monitoring the vital signs of astronauts during space missions. Other pioneering experiences not associated with NASA include the use of a closed-circuit TV link to conduct group sessions between the Nebraska Psychiatric Institute in Omaha and the Norfolk State Hospital, 112 miles away, in 1959; and the establishment, in 1967, of the first prototype of an interactive telemedicine service linking a medical station at Boston airport and the Massachusetts General Hospital (13). However, this form of health service delivery developed slowly and sporadically until the 1990s, when stunning advancements in microelectronics, informatics, and telecommunications led to the ICT revolution, which, in turn, triggered a renewed interest in telemedicine (14).

Thus, telemedicine has been divided in three historical periods (13). The "telecommunications era", in the 1970s, was characterized by dependence on radio and television as information broadcasting media, the lack of integration of audiovisual data with any other type of clinical data, and difficult storage and access. In the "digital era", which spanned the 1980s and early 1990s, information was digitalized and telecommunication networks and computers were integrated through protocols that supported simultaneous and high-speed integrated transmission of sound, image, and data. The current "Internet era", is the consequence of increased integration between telecommunication networks and computers through standardized and open access protocols that allow broader and more rapid accessibility with less expensive technology.

According to an International Telecommunication Union (ITU) report (15), during the 1960–2000 period, the "traditional cycle of telemedicine projects" was disappointing, and thousands of pilot tests were carried out but only a few of the initiatives survived beyond the end of the initial funding period. The report concluded that, during the 20th century, fewer than 10% of the projects carried out in developing countries were successful, 45% were faltering after one year, and the remaining 45% were failing after three years. Regarding the initiatives implemented in the 21st century, there is little evidence to show that this panorama has changed. Ekeland et al. (16) observed that current evidence on the value of telemedicine varies from "promising but incomplete" to "limited and inconsistent", and that the economic analysis of telemedicine is a particularly troublesome area. Likewise, van Eland-de Kok *et al.* (17) identified only small and moderate positive effects of eHealth on primary outcomes of chronically ill patients and noted that due to the limited number of studies and methodological limitations, evidence was not fully convincing.

The interest and expectations regarding telemedicine as one of the key elements to overcome the challenges we are facing seem entirely justified. Proof of this is the number of projects implemented and the increase in scientific and research activity generated. The United States Telemedicine Research Center survey in 2003 (18) identified a total of 145 active telemedicine programs in the United States, while there were only 10 in the previous decade. The activity tended to focus on specific specialties (mental health, cardiology, pediatrics, dermatology, neurology, orthopedics, radiology, and home care). The mean number of teleconsultations (other than x-ray transmission) had gone from 682 in 2000 to 1,806 in 2003, that is, a 60% increase. In spite of this, five states did not have electronic health networks available yet. The *Centro de Telessaúde* in Minas Gerais, Brazil (RTMG), which reaches 480 municipalities, has already performed more than two million electrocardiograms (19).

With regard to scientific activity, the assessment made by Moser et al. (20) highlighted the substantial rise in the number of telemedicine publications in international literature: from a few in 1990, to about 100 in 1994, and over 800 in 1998, a number that remained almost constant during the last few years. A total of 5,911 publications were issued during the period studied. The highest number of publications was found in North America (United States and Canada), with 54% of the total, while 35% came from European countries, and 5% from Australia and New Zealand. Analysis of the number of publications per million population revealed that, the most active countries were Norway, Finland, Australia, United Kingdom, and Greece, all of them ahead of the United States.

Telemedicine services

Telemedicine was initially developed to bring health services closer to populations living in remote places with limited health resources, thus improving accessibility. Later, it became a means to improve the quality of medical care by facilitating training and decision making of health care professionals in remote areas. More recently, it has been proposed as a tool to improve the efficiency of health services since it allows sharing and coordinating resources that are geographically remote or redesigning health services to optimize resources. Telemedicine services are currently available for most specialties.

According to the classification proposed by Hersh et al. in 2006 (21), telemedicine services or programs are grouped into services based on stored images (store and forward) such as teleradiology, telehistopathology, teledermatology, etc.; home monitoring programs and systems (home-based services) and real-time specialized care (hospital-based services)* However, other authors consider other categories, such as the type of service delivered, teleconsultation, telemonitoring, and teleradiology, for different specialties.

The principal telemedicine services are:

Remote assistance: They may refer both to **teleconsultations** for remote **follow-up, diagnosis,** or **treatment** of patients, and to **telemonitoring** services for--usually chronic--patients, and often include recording of biological parameters. These services also include electronic communication between professionals to facilitate coordinated actions.

Remote assistance services usually differentiate **telecare** from **telemonitoring.** Telemonitoring services offer more options to patients and allow continued care at home. They are driven by health professionals and empower citizens and patients to play an active role in the management of their disease. In addition, hospital stays for patients are reduced, physicians are assigned a new role as second line support in certain multidisciplinary professional service settings (generally coordinated by nursing professionals), and patients may take responsibility for and control of their disease.

* - Synchronous telemedicine is the transmission of signals as they are obtained and is intended for immediate viewing or processing. By contrast, in asynchronous telemedicine, patient data are obtained, stored, and transmitted for further review by health professionals.

- **Administrative management of patients:** This service includes both laboratory test requirements and issues related to billing for service delivery.
- **Distance learning for professionals:** Provides health guidelines and evidence to facilitate continuing education of health professionals.
- **Evaluation and collaborative research networks:** The use of ICTs to share and disseminate best practices and to build knowledge through the actions and reactions of its participants.

Telemedicine application areas

The key areas for telemedicine application are home-based patient health care, emergency services, or information services. **Teleconsultations** refer to the use of telemedicine resources to get a second opinion from a health care professional through the exchange of clinical information.

Telemedicine applications are used in almost all medical specialties, but the most common services include the use of telemedicine resources for: transmitting or exchanging diagnostic x-ray or other images (teleradiology); clinical laboratory and the management of records and electronic clinical history (telepathology); dermatology assisted by videoconference or image transmission (teledermatology); to help psychiatric patients by means of videoconferences and chats (telepsychiatry); the treatment of cardiovascular disorders (telecardiology). In addition, telemedicine resources are used together with resources derived from virtual reality, robotics, and artificial intelligence to support and monitor surgical procedures or even to perform remote surgery (telesurgery).

Telemedicine benefits

The socioeconomic changes of recent decades are increasingly affecting the age structure of modern societies. The improvement in the quality of life, which materializes in better food and hygiene conditions along with improved efficiency of health policies and health systems, leads to a demographic transition characterized by an increasing number of adults and a decreasing proportion of younger population. This situation poses new challenges because of the higher prevalence of chronic diseases, which, in turn, entail high health care costs that are actually growing in most countries. The economic sustainability of health systems, especially in countries with health care systems mainly supported by public funds, is certainly one of the most critical challenges. Even though the influence of lower death rates and longer life expectancy on health costs is still under study, available evidence seems to indicate that the current model of intensive use of health care resources during the last stage of life is shifting to increased expenditure in prevention and treatment of chronic diseases (22). ICT implementation at the level of social assistance now provides the possibility of improving comprehensive support and follow-up of both chronic patients and low-prevalence diseases while facilitating education in preventive medicine and public health.

However, not only economic issues are challenging. Inequalities in the access to health resources are evident even among citizens of the same country and health care system. In the United States, 1999 data showed that the distribution of primary care physicians and specialists varied significantly between the northern and southern areas of the country (23): from 39 to 113 and from 12 to 69 per 100,000 population, respectively. In India, 89% of patients in rural areas have to travel an average of 8 km to access basic medical care, while the remaining 11% have to travel even longer distances (24). Consequently, most of the money intended for health care is spent in travel and accommodation expenses in the cities with health care facilities available. In Spain, while people living in Barcelona can be seen for a stroke in a tertiary care facility and have access to a neurologist in a relatively short period of time, people living in other areas may need to travel more than 70 km to get to the referral

hospital (25). The management of the stroke patient depends on a precise diagnosis by a physician with expertise in stroke, the therapeutic window for rTPA treatment is within three hours from the onset of symptoms, and the drug should be administered only in hospitals with qualified personnel and the necessary equipment (26). It follows that inequalities in access to emergency care specialists and, therefore, to an accurate diagnosis and the initiation of adequate treatment may clearly affect the health of the patient. The incorporation of telemedicine into clinical practice creates great expectations as a means of cost containment and improved care quality since it facilitates the access to and the availability of medical services in rural areas that are otherwise difficult to obtain (27).

Thus, telemedicine facilitates equitable access to medical care services regardless of the geographical location; reduces waiting times (both for diagnosis and treatment), preventing more serious complications; enables remote consultation from primary care to the referral hospital, thus reducing the number of referrals; and it influences education and competence both at primary health care and hospital levels.

Finally, telemedicine facilitates the viability of organizational models such as continuity of care and patient-centered health care, applying the concepts of comprehensiveness and interoperability in health care organizations (11), leading to new organizational and networking settings.

Barriers to telemedicine implementation

Evidence published in international literature on the difficulties of introducing technologies such as telemedicine (and eHealth in general) in health care organizations (28)(29) points to internal resistance to changes in work processes and organizational transformations (30)(32). International literature has also described economic factors as a barrier, and studies in the United States (33)(34) point to the lack of reimbursement models for telemedicine as a key factor. Barriers to implementation are summarized in Table 1.

Table 1: Barriers to the implementation of telemedicine.
Adapted from the qualitative study on telemedicine incorporation into health care organizations (35)

Technological environment	• Lack of technological infrastructure and skills; • Poor coverage in certain areas of the territory; • Diverse information systems available, with a large number of internal, tailor-made applications not providing for the possibility of interconnection; • Complex use of implemented solutions; • Data security, confidentiality, and protection.
Organizational environment	• The (re)design of the medical care model and the consequent need for learning about the new health care model; • Lack of strategic alignment between different participants of telemedicine projects; • The (re)definition of some existing roles and the emergence of new professional profiles which, together with the redistribution of responsibilities, give rise to conflicts about professional recognition and insecurity when taking over tasks at the highly hierarchical level typical of health care organizations; • The permanent change in which projects are forced to advance as the result of the speed of technological changes and the ever-improving health care environment.

Human environment	• he human factor, generically defined as "resistant to change"; • The lack of emotional bond and sense of belonging to the project; • The level of individual competence in the information field and/or the necessary skills to perform confidently; • Existing opinions about telemedicine; • Skepticism toward certain types of "pilot" tests, considered almost unnecessary due to the very nature of the technology to be tested; • The workload required to implement this type of program in the existing setting; • Resistance to changing routines from one in which professionals feel safe and comfortable for a new and unfamiliar one, which entails a certain level of initial uncertainty; • Different interests, concerns, and priorities of professionals who have to implement telemedicine compared to those promoting the implementation.
Economic environment	• Implementation costs; • Initial funding and project sustainability. The fact that telemedicine is not included in the portfolio of administration services, and therefore lacks a well-defined and explicit economic framework to which all organizations can adhere, is widely considered the most important barrier for standardization. This barrier is associated with the lack of scientific evidence regarding clinical and economic benefits.

Factors facilitating telemedicine development

In the process of implementation and standardization a telemedicine service, a set of factors are identified which favor a faster and simpler incorporation of the project into routine clinical practice. These are summarized in Table 2:

Table 2: Factors facilitating telemedicine development.

The development of telemedicine should respond to a clearly perceived need by medical professionals of the organization.
The environment. When initiatives that have been successful in other organizations are transferred, it is necessary to take into account the reality and the needs of the specific environment of implementation.
Guarantee leadership. Having clear, identifiable, and proactive leadership that is capable of energizing and managing correctly all the parties, and is flexible enough to adapt to emerging situations, is a key factor in facilitating any telemedicine project.
Involve health professionals who will later use the new service in telemedicine projects as partners.
Establish collaboration with other organizations participating directly or indirectly in the project (health care, technological and service companies, administration) beyond the customer-provider relationship.
Together with the aforesaid, involve scientific institutions.
Implement public policies and strategies for telemedicine.
Verify the cultural predisposition toward telemedicine as a routine element of clinical practice; also determine previous experience of professionals in working with existing care models that incorporate technology.
Ensure that the technology to be implemented is functional and user-friendly.
Prepare the necessary resources for implementation and sustainability. The strategy should consider the changes implied by incorporating telemedicine and what changes will be necessary to introduce it, including necessary human and technological resources, dissemination of the new service, as well as required funding and time.
Resources and visibility. The initiative should be part of international projects, collaborating with organizations from other countries. It should generate its own resources and improve the visibility of participants in their own setting as well as internationally.
Establish meticulous evaluation mechanisms.
Establish efficient governance mechanisms.
Elaborate and implement a business plan.

Put the patient at the center of the service.
Ask for expert advice regarding legal, ethical, privacy, and security issues. Establish the necessary legal mechanisms. Apply the relevant security guidelines (for specific countries and for specific groups of health professionals, e.g., physicians) that encode legal and security measures and ethical and political considerations. Ensure privacy awareness of authors and telemedicine users (having adequate knowledge of conduct relating to privacy and security, based on current ethical and legal principles).
Control service operation to ensure the service is working smoothly, observing users' needs.
Ensure that technology has the potential to be amplified (*Think Big*).

WHO and PAHO telemedicine initiatives

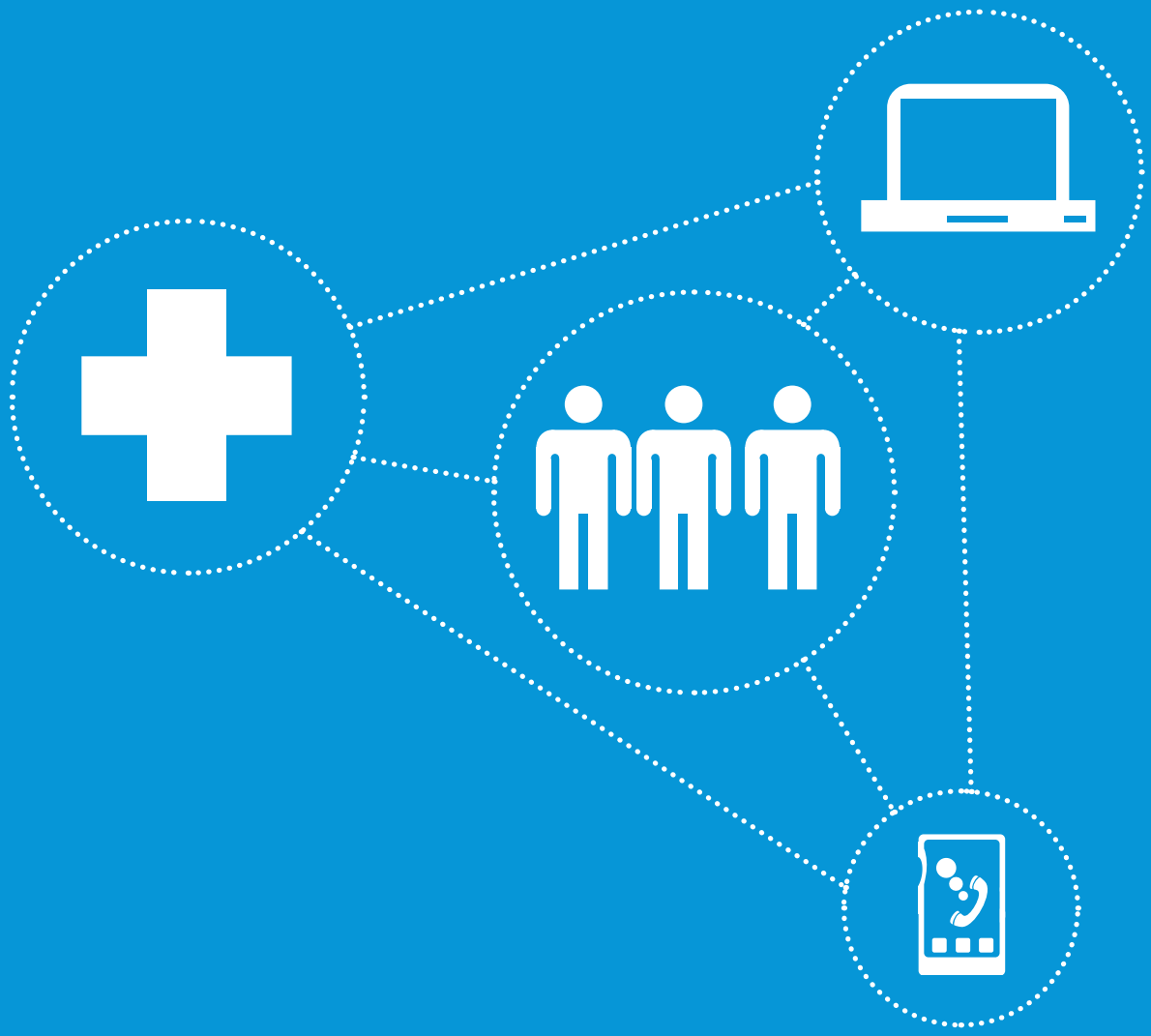
The role of WHO in telemedicine-related issues fits into its global eHealth strategy. Table 3 provides a brief summary of the main actions taken by WHO regarding telemedicine.

Table 3. Main WHO actions related to telemedicine

Action	Milestone	Detail
58th Assembly of the World Health Organization (WHO) (2005)	"*eHealth Resolution*"	WHO acknowledges, for the first time, the contribution of incorporating ICTs into health care and the management of health systems. Through the "eHealth Resolution" (4), WHO adopted a global strategy in the eHealth sector, urging Member States to establish long-term strategic plans for the development and implementation of eHealth services. Specifically, the following objectives were established: • strengthening health care systems in countries through the use of eHealth; • creating public-private partnerships for ICT development and deployment for health; • supporting capacity building for the application of eHealth in Member States; and • development and adoption of eHealth standards.
Expert Group Meeting with the aim of supporting national plans for eHealth development (2005)	Global eHealth survey	This survey was intended to: determine the development and deployment status of eHealth; to support its expansion at the national, regional, and global level: to furnish governments with data that could be used as a reference for further development: and to provide a way to assess progress in comparison with other Member States.
(Action derived from the previous one)	Global Observatory for eHealth (GOe) 2005	This initiative was devoted to study and analyze the situation of eHealth considering its role in the health care services delivered by health systems worldwide. In the second volume of the Global Observatory for eHealth series, the report "Telemedicine: Opportunities and Developments in Member States" was published. It examined telemedicine trends, with special emphasis on strategic needs of developing countries and the actions taken to support and reinforce telemedicine. This publication targeted telemedicine health professionals or those interested in adopting these services as well as public health policymakers and ICTs.
Joint action with the International Telecommunication Union (ITU) (2012)	*National eHealth Strategy Toolkit*	Development of a toolkit for national eHealth strategy. Using this document and together with representatives of relevant ministries of Member States, online training and workshops on health and ICT issues are being developed to support the development of eHealth national strategies.

Action	Milestone	Detail
(Action derived from the previous one)	*Issues related to promoting telemedicine access and interoperability*	WHO plays a key role in addressing the need to create telemedicine standards in terms of system infrastructure and security, patient data, diagnostic imaging and medical research, as well as the wide range of devices, software systems or database management systems and process management. The adoption of telemedicine standards is essential for the implementation of information systems allowing for the effective, coherent, and precise exchange of data. It is worth mentioning the document on a strategy for universal access to health and universal coverage elaborated within the framework of the 53rd Directing Council, 66th Session of PAHO Regional Committee.
eHealth at PAHO	eHealth Strategy and Plan of Action (2012–2017)	This Strategy and Plan of Action was developed to contribute to the sustainable development of health systems of Member States. Its adoption seeks to improve access and quality of health services; training in digital literacy and ICTs; access to scientific, evidence-based information and continuing education; and implementation of different adoption methods.
(Action derived from the previous one)	PAHO eHealth Portal	The eHealth Portal has disseminated telemedicine experiences as well as knowledge building and management, and the development of Practice Communities on specific telemedicine topics including development of related webinars.
52nd Directing Council, 65th Session of the Regional Committee of WHO for the Americas (2014)	PAHO Strategic Plan (2014–2019): "Championing health: Sustainable development and equity".	The Plan sets out the strategic orientation of the Organization based on collective priorities of Member States and country focus, and establishes the results to be achieved during the period 2014–2019. Health information is considered a basic right of people. Therefore, the Organization supports the development and use of ICTs, the broadening of digital literacy, and increased access to scientific knowledge and training. Special reference is made to the development and use of mobile devices (mHealth) and applications as an option to change the way health services are delivered.

Implementation Model of a Telemedicine Service



This chapter introduces the implementation model of a telemedicine service, showing the process from a holistic perspective.

Introduction

As pointed out in current literature, the implementation of technology--telemedicine in this case--to solve health problems should be addressed from a perspective that encompasses a large set of interactions (36).

Since the 1990s, social research on technological innovation has corroborated that the interpretation of innovation processes should be addressed from a holistic perspective, considering interactions among all of its dimensions. In fact, technology adoption models (Technology Acceptance Model, TAM) have indicated that technological innovation is much more than a linear and scheduled process. Technological innovation is a complex system that responds to trial and error processes and works in a disruptive way, not usually following ordered time sequences.

We understand technological innovation as a learning process based on the productive application of knowledge, fueled by both tacit and observable knowledge, and affected by a variety of internal organizational factors and other environmental factors. It is the product of both highly formalized systems and other basically informal systems; it benefits from competition and cooperation between organizations and/or institutions, and leads both to radical technological changes and small, incremental developments that improve the performance of existing technologies (37).

Due to the organizational reality of many health institutions that have a very heterogeneous structure of activity and poorly formalized innovation areas, technological innovation is usually the result of alignment in two areas:

1. The assimilation of new knowledge and technology from the outside; and
2. The product of internal processes in the organization, which are generally poorly formalized but which produce incremental and continued improvements rather than radical changes in the management of scientific and technical knowledge.

Therefore, for the development of telemedicine-related innovations, the cumulative specific and observable knowledge is probably as important as that of tacit knowledge provided by people in their jobs. Consequently, due to the nature of the organizational fabric, technological innovation in the health care field is highly dependent on both the characteristics of an environment and the peculiarities of internal innovation processes of organizations.

This fact has direct consequences on the potential to produce innovations endogenously and on the capacity to assimilate new external technology and knowledge. In summary, a wide range of dimensions should be considered (holistic model), going beyond the time-sequenced dimensions, in order to analyze the impact of telemedicine on the process of generating value in health care institutions.

The first element to emphasize is that the use of telemedicine, as a means of innovation, favors networking of health care organizations (38). This is basically due to three reasons:

- First, because the use of telemedicine promotes innovative dynamism by partially reducing

its obstacles and improving the efficiency of interactions between the agents involved in the innovation process (both internal and external to the organization).

- Second, because it modifies the nature of innovations and allows more sophisticated and interdependent processes to be developed.
- Finally, because of the complexity of processes related to telemedicine, its use should be considered a sustainable competitive advantage only if this technology is used together with the resources and capacities available in the organization.

Thus, the material and immaterial knowledge and resources available, the way they are structured and managed, and the quality of the environment in which every health organization operates, determine the outcome of the innovation process. Hence, it is necessary to observe telemedicine innovation activities of health care organizations from the perspective of their internal and external determinants as well as the consequences for the organizations.

It is useful to analyze whether innovative dynamism is associated with the level of sophistication of telemedicine used inside the organization.* The use of telemedicine by health care organizations can streamline the organization's management, operations, or human resource practices, improve outcomes, and, particularly, efficiency level (39)(41). Furthermore, telemedicine would favor a cultural change within the organization and foster more innovative behavior.

Likewise, it can be expected that telemedicine use associated with the Internet will also encourage innovation in health care organizations, since innovation depends on knowledge building and is positively influenced by access to information and the network effects of increased interaction with the environment (42). The close relationship between innovation and Internet use has been confirmed, and health care organizations with higher levels of equipment and Internet use are the most innovative (43) (45). This effect is probably the result not only of the innovation implied in introducing the Internet to the organization, but also because it encourages the health care facility to participate for the first time or to improve the efficiency of its integration into networks that cooperate in developing innovations. This would be the case in the paradigm of smaller health care organizations, or those having connectivity issues, where participation in cooperating networks would compensate for insufficient economic resources and the lack of a specific research, development, and innovation (R&D&I) department.

Together with the consolidation of the knowledge economy (46), it can be expected that innovative dynamism will be linked to organizational change and new practices of human resource management in health care organizations. Organizing by processes or projects, building flexible work teams that can adapt to the different lines of activities in the organization, and basing task coordination and monitoring on objectives and results rather than on organizational hierarchy will have a favorable influence on technological innovations associated with telemedicine (47, 48).

Other internal factors also condition the success of the technological innovation process. One of the major factors is the existence of an R&D&I department.** It is to be expected that having these departments will result in the explanation of the innovation process in health care organizations. The economies of scale typical of these departments, with significant fixed costs and medium-term returns, largely explain the differences between organizational segments. These economic factors would therefore point to the existence of a certain threshold of size necessary to create a R&D&I department. While research output could be more significant and allow the development of more sustainable competitive

* - The results obtained for the business sector confirm the existence of a close relationship between intensive use of information and communication technologies (ICTs) and the development of innovations supported by these technologies. For more information refer to: Vilaseca, J., Torrent, J., Jiménez, A.I. (2007), "ICT use in marketing as a innovation success factor. Enhancing cooperation in new product development processes", *European Journal of Innovation Management*, 10(2): 268-288.

** - Evidence from the commercial sector confirms that formalization of R&D&I structures inside businesses is a powerful stimulus for undertaking innovation in a continuous and interactive process, especially when developing more complex innovations. See Jiménez, A.I., Torrent, J., Martínez, M.P. (2012). "Proactive orientation effects on product innovation activities. Empirical evidence", Innovation: Management, Policy & Practice, 14(1): 90–106.

advantage over time, initial investment cost, the tendency to seek returns in the short term, plus daily pressures, reduce the formalization and adoption of research and innovation in small and medium-size health care organizations. Therefore, larger organizations tend to generate new knowledge endogenously, while the technological innovation process of smaller organizations that are remote from scientific and innovation networks are reliant on the support of their immediate environment and on their capacity to benefit from the network effect through cooperation.

It can also be expected that if the key factors of the knowledge economy are creativity and the development of talent in people to implement innovation processes, the work should be increasingly self-driven, enabling staff to continuously reprogram themselves in the new skills and requirements of their positions. Thus, constant learning by health professionals, especially through continuing and personalized education within health care organizations, becomes a critical element for the improvement of the stock of technical and scientific knowledge that favors the development of technological innovations associated with telemedicine (49). At the same time, the role of distance learning for health professionals as a tool to continually reprocess information and learn throughout their professional lives becomes evident (50).

This set of internal determinants explains that the use of telemedicine has a positive effect on the behavior of innovation processes in health care organizations. Nevertheless, as stated earlier, an innovation system relies not only on organizational activities directed toward the development of new products, services, or processes, but innovation capacity is also influenced by the provider-customer chain and the quality of interactions of the organization with its immediate environment, especially the health care professional/patient relationship. Indeed, the network effects associated with the use of telemedicine in the technological innovation process seem to be important mainly at the time of developing more complex innovations. It can therefore be stated that the way that the relationship between health care facilities and their providers and customers is organized has a direct influence on their innovation capacity and, accordingly, on the outcomes of their activity (51).

Telemedicine has significantly advanced interactions throughout the value chain, favoring a style of work that tends toward innovation and ongoing improvement. Therefore, among the different factors that lead to the success of technological innovation we should include the value chain and customer-oriented innovations. For that reason, telemedicine enables the development of an organization as part of a network, not only internally, but also as regards its interaction with providers and collaborating institutions. In this way, cooperation throughout the provider-customer chain with the aim of developing innovation endeavors to attain the following: more efficient production, improved products or services, complementary technology, improved productive flexibility, more information regarding customers' needs, and the development of product differentiation strategies based on a quicker response to changes in health service demands. All strategies are critical for competitiveness in the knowledge economy, but success requires that there be shared objectives and very close contact between all participants in the chain. Specifically, the use of telemedicine demands that interactions between health professionals and agents outside of the health care organization be more frequent, rapid, and efficient.

Technological innovation based on the use of telemedicine allows the development of complex competitive factors with the potential for increased differentiation from the competition. It follows that the most innovative health care organizations should be expected to develop sophisticated competitive strategies that differ from the traditional models based on cost of service, and which provide higher levels of efficiency and efficacy. New competitiveness models of health care organizations are more aligned with value generation strategies in the knowledge economy. In fact, telemedicine makes the innovation process more dynamic, but also more interactive and interdependent. Hence, continued innovation is a critical strategy for the most competitive health care organizations, facilitating advanced technological features and sustained improvement in the quality of services offered to the market. Therefore, the continued development of technological innovation reinforces the market position of health care organizations in relation to the competition, and allows greater efficiency and efficacy of service delivery (52).

Implementation model of a telemedicine service

In the context of the effect of telemedicine on the process of innovation and generation of results in health care organizations, we will introduce the model that addresses the implementation of a telemedicine service. Our starting point will be the multidimensional and complex concept of competitiveness, a suitable approach to the design and measurement of the effects of technological implementation on organizations, economy and the whole society.

Multidimensional concept

According to social research, a model on technological innovation should be addressed from a holistic perspective; that is, it should consider a range of dimensions beyond technology (personal, educational, economic, organizational, social, cultural, and institutional) which do not follow a homogeneous or sequential path. That is, they are complex, latent, and interact with one another. The fact is that telemedicine is implemented in a complex, interrelated environment with different interactions in their explanatory dimensions. That is why the multidimensional concept is included in the model.

Why competitiveness?

Undoubtedly, competitiveness is the new notion of the model. Competitiveness is the set of factors, institutions, and policies that explain productivity, the capacity to improve levels of income and wellbeing of people within a society. (53). In terms of sectors of economic activity, including health services, competitiveness is the capacity of institutions and organizations of the sector to maintain sustainable growth in the long term and develop an intensive model of growth. Because of its multidimensional nature, competitiveness is an indicator of results accrued from adopting technology and raises questions such as: What are the effects of telemedicine adoption on personal, organizational, economic, and social outcomes of the adopting institution?

National setting

It is evident that investment and ICT use, jointly with knowledge flows, are major factors in explaining economic growth and productivity in an increasing number of countries in the world (54)(55)(56).

Regional setting

At the regional level, competitive advantage is also determined by economic conditions of the region, although, unlike national scale, external territorial factors and the spatial dimension of the activity should be kept in mind in the explanation of regional productivity.

Regional and urban economics has developed two major concepts for the analysis of regional competitiveness: the industrial district and the activity cluster. The cluster, understood as a grouping of sectors with competitive advantage linked by vertical (buyer/seller) and horizontal (shared customers or technologies) relationships, also explains many aspects of the competitive advantage of territories. Geographic concentration of rival institutions in specialized sectors, as well as of customers and providers, contributes not only to greater efficiency of institutions, but also encourages innovation. Competitive importance of the cluster derives from the fact that, although cost reduction in transportation and globalization of the economy have a negative influence on agglomeration in the region, localization of economic activities is still highly significant for competitiveness among institutions.

In this sense, regional or local clusters build on dynamic agglomeration economies. Taking into consideration that the concentration of knowledge, inputs, and highly specialized institutions, the benefits of high local competitiveness, and the existence of sophisticated local demand for some goods

and services only emerge in certain regional or local sectors of economic activity. In summary, clusters affect the competitive capacity of a region in three different ways:

1. First, by increasing the productivity of institutions located in the area;
2. Second, by directing the pace and direction of innovation processes;
3. Third, by encouraging the emergence of new institutions that would find a favorable environment in the cluster, thereby strengthening it.

Based on the idea of the geographic concentration of rival institutions in specialized sectors, and a high level of interaction between the local production system and the social capital around it, regional and urban economics describe the fundamentals of regional competitiveness.

The transition to the knowledge economy, a new, long-term economic cycle based on the critical importance of ICTs and flows of knowledge, has also changed dramatically the sources of production and competitive advantage. At the regional level, the advent of the knowledge economy has changed the concept of space, the basic element of dynamic agglomeration economies. We have moved from a heterogeneous physical space to a cognitive space in which externalities and increasing returns from regional competitive advantage are attained by the capacity of economic agents to share flows of technology, knowledge, and innovation. Economic literature has developed new models and metrics to measure competitiveness, and the "competitiveness hat" stands out. It has been used for European regions to establish three types of competitive advantage:

1. The regions as production sites,
2. The regions as increasing sources of return, and
3. The regions as knowledge centers.

Institutional setting

Finally, in the institutional setting, new sources of competitive advantage are associated with the construction of a new strategic and organizational practice of production and work: the **network organization**. Network organization is the new way of structuring and coordinating economic activity based on functional autonomy, organizational decentralization, and network interconnection between internal and external economic agents in a company by intensive use of ICTs. In this context, international empirical evidence has shown that new processes of value generation and new sources of corporate competitive advantage are consolidated in the network institution. Specifically, the establishment of complementary relationships and co-innovation processes, the use of ICTs, organizational change, and staff training explain the levels of improvement in corporate productivity around the world.

Interpreting competitiveness in the global knowledge economy

Responding to the new ways and models of interpreting competitiveness in the global knowledge economy, where innovation is the most appropriate competitive strategy, economic and social research has developed the *"competitiveness hat"* model (57). The graphic depiction of the model forms a hat with overlapping layers, showing the multiple influences determining the competitive advantage of a region. The top three layers form the cylinder of the hat, and the bottom layer is composed of several concentric circles, which are the actual determinants of competitiveness (Figure 1).

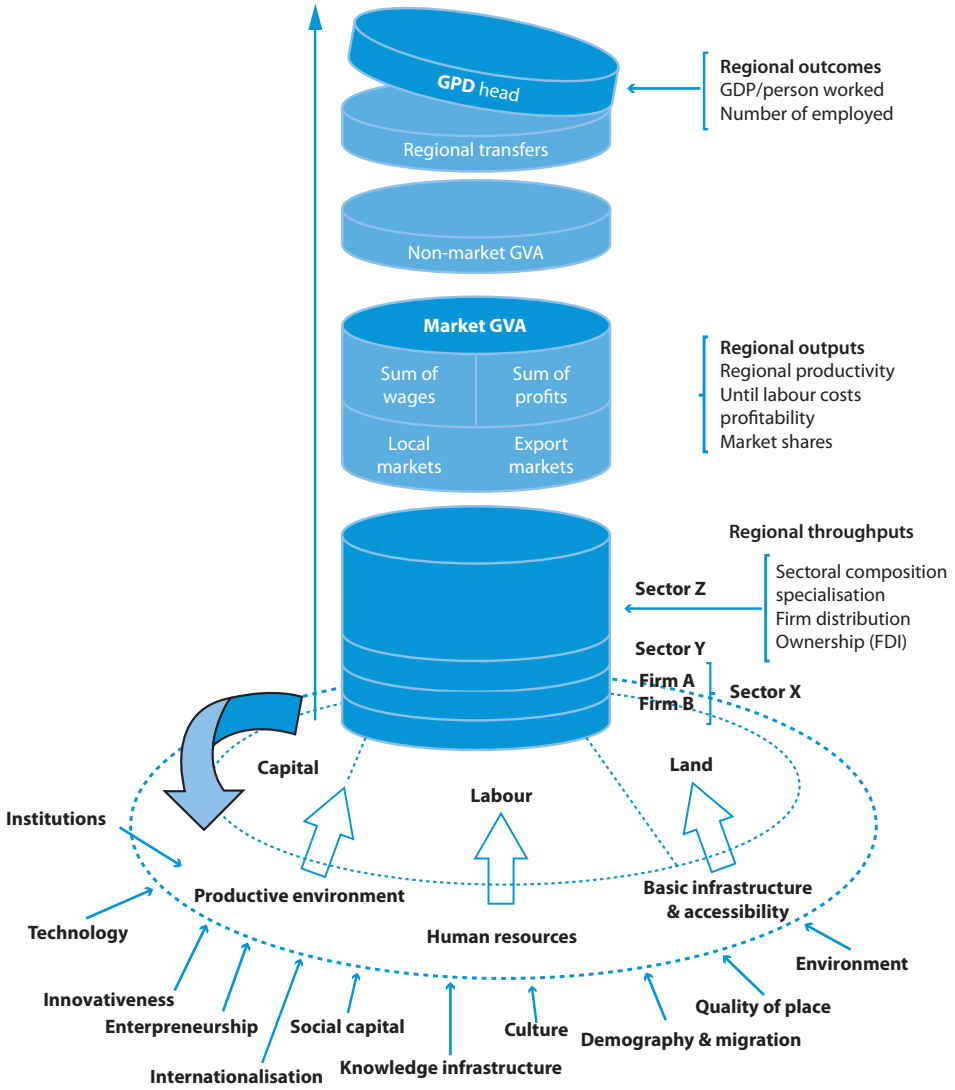
In the "competitiveness hat" model **economic outputs** are presented first, including a basic indicator of economic activity: income or well-being. The indicator for income per inhabitant, by region, displays not only market productivity activities but also public and private transfers to the population, and non-market activities of public administration. In general, this top layer is expressed by a decomposition of GDP per capita.

Second, the model considers the **productivity of the region or sector analyzed**. This category includes all those indicators relating to the outcomes of economic activity, such as gross value added (GVA), labor costs, profits by unit of product, and participation of the region or sector of activity in local and export markets (market share).

Third, the model shows **intermediate products**. This layer comprises management and innovation capacities of the region or sector. At more aggregated levels, this includes elements of specialization and business structure, such as sectoral structure of production, specialization, and product differentiation; dimension and value generation of institutions; as well as the presence of foreign direct investment.

Below the cylinder of the hat, the model has concentric rings at the base which constitute the **determinants of regional competitiveness**. The first ring includes basic production factors: land, capital, and labor. The second ring is made up of elements directly related to productive factors such as investment climate, infrastructure and accessibility, human resources, and the productive environment. Finally, the third and outside ring incorporates elements behind regional or sectoral competitiveness, such as institutions, demography, appeal of the region or sector, level of internationalization, entrepreneurship and innovation, economic environment, social capital, and technological and knowledge capacity.

Figure 1. The "competitiveness hat" model



Source: Adapted from: European Commission (2003), *A study on the factors on regional competitiveness*, Brussels: European Commission

Introducing the telemedicine "hat" model

Consistent with the competitiveness model, we introduce the model proposed for the implementation of a telemedicine service: the "telemedicine hat" (see Figure 2). Like the general model, telemedicine is implemented based on complex, interrelated, and varying interactions in its explanatory dimensions.

The top layer of the "telemedicine hat" has a f**ollow-up, evaluation, and optimization phase** where the results of implementation are presented. The incorporation of ICTs into the health care sector should occur after a specific need is identified and different aspects of the value of the technology are verified (effectiveness, safety, cost-effectiveness, and any organizational, ethical, or social impacts), taking into account the social and political characteristics of the place where telemedicine activity is intended to be implemented. When the process of introducing telemedicine in the health care sector is poorly planned, designed, and managed, the results may differ from those initially sought. For that reason, as documented in a number of telemedicine projects, a development more focused on technology (telemedicine as the end in itself) than on its role as a "means" to meet a specific need of the population or health care system is one of the major causes of failure. This layer would thus include measurement indicators (follow-up, evaluation, and optimization) of the practice performed. This would include the metrics of clinical, economic, and social results and all sub-indicators associated by arithmetical decomposition (for instance, the number of consultations, referrals or patients seen, user satisfaction, or the results of the cost-effectiveness analysis of the practice). In order to analyze these aspects, we should measure: ICT response capacity compared to the usual medical care alternative (i.e., ICT advantages and disadvantages in responding to the problems posed) and security-related aspects such as detrimental effects resulting from its use (e.g., wrong diagnosis) or related to privacy and confidentiality of data; etc.

Second, in the **development phase of the telemedicine service** the "telemedicine hat" considers internal explanatory factors of health care organizations that clarify the use of telemedicine. Telemedicine is a complex technology proposed as an alternative to current health care service delivery. It may affect all stages of health care and modify the role of professionals and how they interact with each other and with patients. Likewise, it has ethical and legal implications (professional accountability for decisions, privacy of data, information security, informed consent, among others). In particular, this layer would include financial, human resource, organizational, technological, and infrastructure factors, as well as those legal and institutional aspects defining the implementation of telemedicine within the organization. Some of these factors include the financial costs of instituting the practice; people and equipment employed; technological elements and limitations, especially usability and security; and the legal and institutional drivers and barriers to implementing telemedicine, such as medical and clinical effectiveness. In order to carry out this analysis we should identify various measures, such as ethical and legal aspects. These two factors are important because of the principles they represent and because they are different in each country.

Below the cylinder of the telemedicine "hat" are concentric rings at the base, which are the real determinants of the competitiveness of telemedicine. The first ring includes the **basic factors associated with public policy**: planning, management, and communication within health care public systems. This includes the potential advantages and disadvantages of telemedicine in responding to health needs and the analysis of needs, resources, and organizational models (i.e., characteristics of health care supply and demand for different health needs of a specific population or of the health care organization in specific locations).

The second ring includes the **elements of telemedicine as they relate directly to the organization**, that is, work teams, training, organizational structure, remuneration and incentives, and relationship with immediate external agents, among others. This analysis would need information on certain measures such as the availability of human resources. This would include selection and training of professionals to manage the new telemedicine service, and the participation of professionals from the initial stages of design and evaluation, etc.

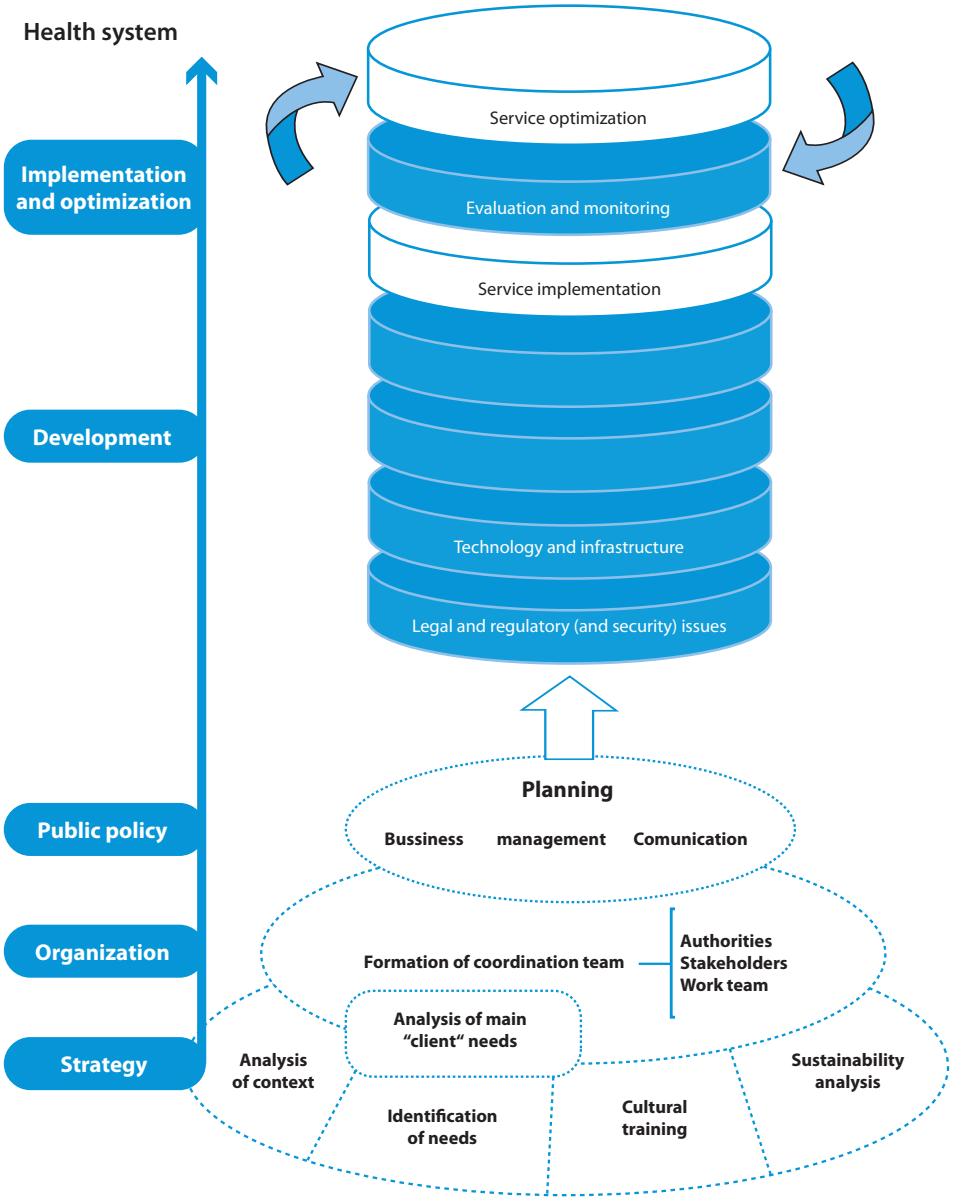
Finally, the third, and outermost, ring incorporates other **elements behind telemedicine competitiveness, especially those associated with the strategy of implementing the technological tool**. This includes analysis of the socio-economic context, user needs, cultural aspects, and sustainability of the technology and innovation linked to telemedicine in a specific area of the health care system. Selection, prioritization, and design of telemedicine activities, and determining which activities will add the most value, require a thorough analysis of the context in which the technology will be deployed. This analysis relies on the assessment of health needs and characteristics of conventional services used to respond to these needs and familiarity with a variety of issues that address the magnitude of health problems and needs. This requires a description of geographic, social, epidemiological, and demographic characteristics of the context; assessment of the need and opportunity for the development of new health services; and questions related to reorganization or complementation using telemedicine. The inventory of resources in the area should include the type and number of resources available to respond to the problem under study. An examination should be made of the evolution of the medical care activity as it relates to the services or specialty to be delivered through telemedicine (number of consultations, number of admissions, number of transfers to public and private referral hospitals). Included in the analysis would be a description of processes and conventional medical care flows, such as the existing organizational model of service delivery, health and non-health resources employed, accessibility, user satisfaction, and health outcomes. Availability of infrastructure (equipment, communications, spaces) and sustainability of the technology (capacity to go beyond the pilot phase) would be assessed. This analysis provides information for decision makers regarding prioritization and selection of the telemedicine program, application, or service.

Scientific literature offers evidence on the value of particular telemedicine services based on studies carried out in different locations. Even when scientific evidence seems to be robust,, prior to deployment the characteristics of a local health care system in a different context, both from the socio-cultural and the ethical and legal perspectives, should be assessed. When evaluating telemedicine implementation based on available scientific evidence, two different issues should be considered

- The results of complex health care interventions, such as telemedicine, involving both devices and professionals, cannot be directly applied to other contexts in which different equipment, systems, and professionals try to reproduce the intervention.
- In most cases, published scientific studies on telemedicine still have rather poor designs with poor bias control, have small sample size, use non-relevant outcome measures, employ non-validated measurement tools, and have short-term follow-up.

In this regard, it is necessary to make advances in research on the effects of introducing telemedicine in health care organizations, specifically identifying the changes resulting from interactions between the organization and the technology introduced. Empirical evidence obtained by studying and analyzing these transformations, rather than the a priori design of formal implementation models, will allow a definition of success factors in telemedicine dissemination as well as addressing with certainty the challenges it implies for any health care system.

Figure 2. Telemedicine implementation model ("telemedicine hat")



Strategic Level

The elements behind telemedicine competitiveness, especially those linked to the strategy of introducing the tool, include analysis of the socio-economic context, users' needs, cultural aspects, and sustainability of the technological and innovation system associated with telemedicine in a specific area of the health care system.

Context analysis

For the successful implementation of a telemedicine program, it is critical to determine its **priorities and needs** within the **context** of social/cultural, social/health, and resource realities. Carrying out a **holistic analysis** is essential for a better understanding of the most relevant **needs**, **conditions**, and **resources** for the process of incorporating the telemedicine service into the relevant scenario (considering issues of infrastructure, funding, human and organizational resources, standards, legality, ethics, and information privacy).

Identifying needs

The evaluation of needs to be met is performed by a systematic process addressing the differences between current and intended results. This analysis will optimize resources and increase possibilities of success, avoiding the natural tendency to implement the first plausible solution (which usually leads to negative results).

This analysis assesses aspects of health needs and the characteristics of conventional services responding to those needs. This evaluation may be scaled up or down to fit projects of any size, timeframe, and/or budget. As a general rule, to determine the size and scope of the needs assessment it is necessary to clearly determine what type of information to collect for the use of decision-makers, as well as to establish the strategy for its collection.

Once it is clear what information is needed and how to structure it, the data collection process starts, which consists of three basic stages.

1. First, identify the necessary information as well as the sources and how to access them.
2. Second, analyze the information to determine if it meets expectations.
3. Finally, decide whether such information should be included or not in the analysis of needs.

These stages do not necessarily follow a chronological order, but they are required to ensure the final needs analysis has the correct information. Clearly, any information-based decision-making should include this logical process.

Identifying the necessary information

The first step for the identification of needs is to determine the required data. The range of clinical situations is too broad to think of only one or a few relevant questions. In spite of this large variability, it is possible to identify three groups of questions to ask at this stage of implementation

Questions regarding final users

Among the necessary questions are those about patients as users of the programs. This would include asking what specific health problems the telemedicine program could address, as well as what is the prevalence of this health problem and/or the geographic area of action. What are the patients' health needs? What health issues that cause the most frequent visits to a hospital? Which of these needs could a telemedicine service satisfy? What are the most frequent diagnoses? Is it possible to make these diagnoses remotely (by using ICTs)? Is it possible to treat these diseases remotely (ICTs)? Are patients ready and willing to be treated using a telemedicine service? Is there a real need for a telemedicine service? Is there a real demand for a telemedicine service?

Questions regarding service delivery

An adequate evaluation of needs should also consider issues about service delivery. If they are not considered from the very beginning, the workflow could be negatively altered or anxiety could arise in teams responsible for implementation. What diagnoses require more time and/or experience for effective treatment? What additional services do other health providers close to your service offer? Is your health facility ready and willing to provide telemedicine services? What are the needs or opportunities that could be resolved by the telemedicine service (for example, training opportunities, network collaboration with specialized providers, e.g., Communities of Practice)? What level of training could the health facility provide?

Questions regarding organizational issues

Once again, we stress the importance of determining priorities and needs of the telemedicine program within the context of social/health, social/cultural, and resource realities. Does the organization allocate resources to perform an evaluation of needs? What are the most appropriate specialty services for the telemedicine service? What technologies are available to provide the telemedicine service? What legal and reimbursement standards are available at local and regional levels to implement a telemedicine service? Is the initiative to adopt telemedicine aligned with the mission or strategic plan of the organization? Does the tertiary health facility linked with the telemedicine service have the capacity to treat those diagnoses effectively? What telemedicine services would be more suitable for the services already offered? Are there organizational and/or technological barriers?

Sources of information

The second step for identifying needs is to determine the availability or viability of sources for data collection. This, in turn, may limit the types of questions. These data may come from two types of sources: (secondary) data collected by others and (primary) data that are possible to collect informally. Advantages and disadvantages of each are clear: while secondary data are simpler, more rapid, and less expensive to obtain, they might have been collected for a different purpose and, therefore, they would not satisfy exactly the information needed. Instead, exactly the opposite occurs with primary data. Therefore, determining the optimal mix of sources of information will depend on each specific case, bearing in mind the limitations of the context in which the telemedicine service will be implemented.

Analyzing the information to determine whether it meets expectations

Once the information regarding needs for the telemedicine program has been collected, it is necessary to perform a thorough analysis. The analysis of data in the context of the evaluation of needs goes beyond presenting reports with a list of partial results. It must establish a solid reference base for decision-makers and offer a preliminary list of areas in which the application of telemedicine may offer a solution. Information should be arranged so that an organization can respond to key questions. The process may also reveal information gaps that require attention

Information to include in the analysis of needs

It is necessary to analyze many factors other than health to guide decisions toward a particular direction and to identify possible barriers to some presumed solutions (this holistic approach has been used in other contexts) (58). The goal is to examine a broad socio-economic, political, and environmental context in relation to its impact on health needs, and to identify available assets, strengths, and capacities that could be exercised on the identified topics.

Most telemedicine programs are implemented because of a clear need not covered by the available delivery of health services. Reasons usually vary and, in general, they are related to: patients (for example, to provide access for certain rural communities to specialty clinical services) (59); geography (to remove or mitigate time and space barriers imposed by physical geography) (60); service (to enlarge the field of application of a service that is either already available or under development); or to reduce pressure in hospitals (for example, by remote monitoring of chronic patients). Although these are just a few examples, the information regarding each would have an impact on the decisions about a telemedicine program.

Both individually and collectively, these factors influence the type of telemedicine solution that would be most suitable and sustainable for any health need and population identified. Software like "Mind Mapping," which diagrams relationships between concepts, ideas, or other pieces of information, is a valuable tool to help in this process.

Analysis of beliefs, perceptions, and attitudes about telemedicine

Telemedicine solutions identified for application should be technologically appropriate and culturally sensitive (61)(62). Appropriate technology can be defined as the most benign technological solution that achieves the desired purpose in the confines of current social, cultural, economic, and environmental conditions of the setting where it is to be applied and that promotes self-sufficiency for those using it (63). Described in this fashion, an appropriate technology would typically be simple to adopt and require fewer resources to operate and maintain, making it more likely to be sustainable (64).

Knowledge about cultural limitations should guide the design and the implementation of suggested telemedicine solutions (8). Cultural sensitivity requires solutions that respect local traditions, expectations for the health care system, beliefs about health and disease, and the patterns of usage of available health services. Ignoring local health culture may undermine telemedicine initiatives (64).

Ensuring sustainability of the telemedicine service

It is reasonable to think that, due to limited resources, not all options are possible. At this point of the process, needs have been identified and there is an understanding of the extent to which the current and future setting can tolerate internal and external influences. Bearing these conditions in mind, it is possible to think of a variety of solutions to address the health problems detected; these may or may not work at one or more levels of practice or process, and they may or may not respond to more than one need. But not all solutions can be optimal for specific settings, culturally sensitive, and economically viable. The analysis should be done based on potential costs and percentage of population affected, complexity of implementation, available and necessary infrastructure, funding, human and organizational resources, the capacity of professionals to implement it, legal aspects, standards, and ethical and information privacy issues. These features can be used to organize available options. When there are not enough data to establish objective priorities, a more subjective approach should be used. At this point, each potential solution can be classified considering "what would be good to have versus what might be nice to have" (64). These innovative solutions do not necessarily imply sophisticated technological solutions, just a new way to operate.

Undoubtedly, this is a critical stage in developing the strategy for telemedicine service implementation, since it sets the direction for allocation of resources and seeks political will to develop ICT infrastructure. This is the stage where a wide number of local stakeholders (at the institution, regional, and country levels) including governments, agents of the public and private sectors, and scientific experts (who may later become part of the local work group), should form the **advisory team** of the telemedicine project. The team should be informed about all the material gathered and analyzed in the previous steps. Its principal task is to evaluate identified and prioritized needs, bearing in mind the context and the development of innovative solutions. The secondary purpose of this team is to develop the capacity to address the cultural change implied by implementation.

The results of the analysis of detected needs and selected solutions should be summarized in a strategy report for the implementation of the telemedicine program. This strategy document should inform about the new measures to be taken, the design and the guidelines for creating the new program, the necessary ICT infrastructure, the implementation plan, the management plan for change, the evaluation study, and the sustainability program for selected telemedicine applications.

Organizational Level

The elements of telemedicine that are directly linked to different features of an organization should be understood when assessing implementation. These include an organization's work teams, training, organizational structure, remuneration and incentives, relationship with immediate external agents, among others.

The organization during transformations

An organization, defined as a consciously coordinated social unit, assigns, performs, and coordinates specific tasks. The elements that constitute the organization are defined in different ways and with different approaches: based on physical structure, social relationships, technology, and the culture of the organization. Hence, an organization's structure determines task assignment, information systems, and interaction and coordination mechanisms. Other elements related to the social and cultural context may also influence the organization and its function.

There are different types of organizations: profit-centered organization, matrix organizations, and network organizations. The complexity of health care systems and, in particular, their processes complicate aspects concerning the organization. An organization's objectives are usually commitments developed over time, and different objectives may coexist.

In the health setting, organizational issues include different levels:

1. Intra-organizational (i.e., the patient is provided with information on a new technology);
2. Inter-organizational (i.e., cooperation and coordination between facilities through a network); and in the
3. Health system setting (i.e., health plans).

These levels include other players besides staff and patients, such as funders, providers, suppliers, etc., that may have different objectives and expectations regarding health technologies.

Therefore, the organization refers to process, structure, management, and cultural aspects of different players who interact both between the services of an organization and between organizations. Likewise, it includes those aspects that may reveal essential problems such as barriers to the implementation of health technologies. Finally, information about organizational aspects may overlap with economic or social dimensions.

Organizational aspects in telemedicine services

Table 4 lists aspects of an organization's process, structure, financing, management, and culture that should be considered in the development of a telemedicine service.

Table 4. Organizational aspects related to the development of a telemedicine service

Organizational Aspectss
1) Process • Ensure clear, identifiable, and proactive leadership; • Establish effective communication mechanisms; • Establish all the requirements and specifications from the very beginning; • Establish clear objectives, defining functions and responsibilities; • Establish realistic expectations and avoid underestimating the complexity of the project; • Establish realistic time limits and credibility in the program; • Define how the telemedicine program affects the health care model; • Analyze internal and external factors that affect the organization; • Bear in mind all the issues related to technology, ensuring that the technology to be used is functional and user-friendly; • Establish health policy objectives including security, ethical and legal requirements, as well as data protection; • Ensure that authors and users of telemedicine applications are aware of privacy issues (knowledge about appropriate practices regarding privacy and security behavior based on current ethical and legal principles); • Ensure that technology has expansion potential (*Think Big*).
2) Structure • Involve health professionals who will later use the new telemedicine service; • Align telemedicine projects strategically between different participants; • Define which roles will be affected, redistribution of responsibilities, and new professional profiles; • Improve the level of individual competence in computing environments and/or required skills to develop the program safely; • Establish incentives to overcome fear and resistance; • Establish training options for the new health care model; • Determine the workload implied by implementing this type of program in the current setting.
3) Budget • PPrepare and implement a business plan that includes implementation costs (initial funding and sustainability of the project); • Establish collaboration with other organizations participating directly or indirectly in the project (health care, companies in the technological and service sectors, administration) beyond the customer-provider relationship. • Organize the necessary resources for implementation and sustainability. The strategy should consider: the transformation that incorporating telemedicine implies, necessary changes, requirements for human and technological resources, dissemination of the new service, as well as necessary funding and time.
4) Management and control • Establish effective governance mechanisms; • Establish strict mechanisms for ongoing evaluation; • Control operation of the service to ensure it is working smoothly, observing user needs.
5) Organizational culture • Remain cognizant of the human factor, generically defined as "resistant to change"; • Bear in mind existing opinions about telemedicine: determine the cultural disposition toward telemedicine as a routine element of clinical practice, and ascertain previous experiences with health care models designed to incorporate technology; • Establish an emotional bond and a sense of belonging to the project; • Strategically align all the participants; • Work on the resistance to change: a certain level of initial uncertainty occurs when professionals must change routines with which they feel comfortable for new and unfamiliar ones; • Consider the different interests, concerns, and priorities of health professionals who have to implement telemedicine compared to those who are promoting the technology.

Change management

Change management is the process designed to address the human factor, generically defined as "resistance to change" that intervenes in the project (65). Change is the process of switching from an "old" to a "new" situation, where the individuals involved are aware of the reasons why they are leaving the current situation and going to the future one, what changes are necessary, what the new technologies are and how to implement them, and what new skills are necessary.

According to Campbell (66), this process requires the following three measures:

1. Create a climate for change;
2. Allow the participation of the organization;
3. Maintain the changes implemented.

Creating a climate for change

Project leaders should create a favorable climate for change. With that purpose, they should confirm the need for change within the context of the service, translate current needs into a project plan, communicate project priorities and implementation objectives, create a **guiding team** capable of driving the transformation, identify possible **leaders**, and select the support staff that can drive the transformation and move forward (67). During this stage, it is essential to clearly establish expectations and a realistic timeline.

Participation of the organization

Leaders and persons involved should be committed to allowing **stakeholders** and different levels of the organization to take an active part in the design of the implementation strategy. They should ensure that all the staff involved has ownership in the process, thus engaging the organization in every aspect of the process, including usability assessment, system selection, and implementation process. The dialogue with stakeholders is essential: their perceptions, behaviors, troubles, expectations, and needs should be defined, understood, and considered. During this phase, the guiding team will lead the transformation by creating a domino effect, encouraging others to move forward. A critical action at this stage is to maintain a channel for the systematic exchange of information with stakeholders. In this way, the value of the changes is highlighted and, in turn, it becomes a means of training and education. Therefore, as changes are made to the processes, good communication management will allow for rapid action. It will also facilitate planning for and creating short-term successes and empowering more people.

Supporting the implementation of changes

Finally, the **guiding team** should support the implemented changes, promote implemented solutions, and help to change individual behaviors to attain the organization goals. Analysis of workflow and integration will allow an understanding of current processes and new opportunities for successfully introducing different technological solutions. If the way that people work and manage the enterprise is unknown, it is not possible to introduce a new tool or health practice and results in wasted resources and a slowdown in progress. It is essential that people understand the value of technology and can adapt to it simply and comfortably. For that reason, it is important to implement short-term rewards and celebrate achievements as often as possible. Training, education, professional retraining, and continual technical support on updates are essential at this stage to maintain efficient workflow. It is also vital to resolve problems by implementing a system of updates that are based on feedback. Ongoing monitoring of the system makes it possible to detect risks, identify inconsistencies, and recognize successes. The best proposals should be integrated in real time to avoid failed attempts.

Establishing a coordination team

Any implementation process implies working with a wide range of stakeholders. It is important to clearly identify who should be part of the group of stakeholders and develop a strategy on how to act toward them, define the reasons for their participation, and determine how best to get them involved (68). The aim is to establish a network among the parties who are interested in the development through the vision of the process and the creation of the guiding team.

The guiding team plays a pivotal role between project leaders and other stakeholders. This team should develop a stakeholder consultation plan and describe how they will participate, considering the impact of future circumstances.

Stakeholders include individuals or a group of individuals with an interest or concern in the application of the telemedicine program. They would include both health and non-health parties who play an important role in the development and the implementation of the vision. They can be classified into larger groups, such as the general public, decision-makers responsible for the vision and the strategic direction, and key, influential persons who can provide advice to decision-makers according to their role in the development. Thus, government committees would be part of the group of decision-makers. Academics and senior health care, funding, and investment executives would be part of the influential group.

Finally, there are stakeholders who will be directly affected by the application under analysis (health care professionals, managers and administrators, patient associations, etc.) and stakeholders in the broadest sense (individuals, caretakers, families, and community groups) who will be interested in the potential impact on them.

Public Policy Level

The telemedicine implementation model, factors linked to public policy include planning, management, and communication of the tool within the public health system. It is at this level that we conduct the analysis of potential advantages and disadvantages of telemedicine for health needs, the analysis of needs and resources, and organizational models (typical of supply and demand of health care services for different health needs of the population or health care organization in specific places) (69)(70).

Analysis of potential ICT advantages and disadvantages for health needs

he political will to introduce and expand the use of ICTs in the health sector is not solely the consequence of a modernizing impulse: it derives from the needs the health systems are obliged to address. The final document of the European Union's 2006 eHealth Conference, held in Malaga, entitled "eHealth and health policies: synergies for better health in a Europe of regions" (71), emphasized many of the main concerns of introducing eHealth. They include the demand for health care, aging populations, increased mobility of citizens, the need to manage large amounts of information, global competitiveness, and the provision of better health care delivery, all in a setting of budgetary limitations and expenditure restraint.

Hillestad *et al.* (72) estimated the possibilities of improved efficacy and cost savings resulting from the extensive implementation of ICTs in health care settings. In the United States, the large-scale adoption of an interoperable form of electronic health records (EHR) could translate into average savings of US$ 77 billion per year, mainly through a reduction in hospital stays, a decline in the time spent by professionals on administrative work, and a reduction in the use of drugs and diagnostic tests. Their research indicated that the use of electronic prescriptions could avoid about 2 million adverse reactions, corresponding to approximately two thirds of preventable events (almost one half of all the events occurring each year), mostly caused by medication misuse; this, in turn, would save US$ 3.5 billion annually. Finally, based on available scientific evidence, they state that the integration of EHR could improve preventive actions that, with a low direct increase in spending, would imply high benefits in the medium- and long-term. According to the authors, 13,000 life years would be gained by increasing cervical cancer screening at an added cost as low as US$ 0.1–0.4 million.

Analyzing needs, resources, and organizational models

Economic sustainability of health systems, especially in countries with health care systems mainly supported by public funds, is a critical challenge. Since the health care sector takes up a significant part of the budget in any country, ICT introduction in this sector is a major public policy issue. Technologies have determined not only the funding of national health systems, being the primary cause of increasing costs (73)(74), but they have also influenced the unstoppable and poorly evaluated offer of services. New treatments associated with the emergence of new technologies have an impact on the organization of health service delivery itself.

If we classify technologies according to their proximity to professionals and their immediate

application for patients, at one extreme we would place all those technologies used directly by health professionals and whose results are applied immediately to diagnosis or treatment. This type of technology ranges from simple radiology to MRI, and a variety of devices that have determined the organization of health institutions. If we observe hospital changes over the last 40 years, we see that they have gone from an internal medicine service to a sequence of services: cardiology, nephrology, pulmonology, etc.; the origin of these services has been primarily associated with the emergence of a specific technology tailored for each of them. Many of these services have been fragmented into increasingly specialized areas. Thus, the cardiology service has been subdivided into hemodynamics, cardiac ultrasound, arrhythmology, etc. While these technologies contribute to improving the quality and efficiency of these specialties, it occurs at the expense of an integral understanding of patients and their conditions, and adds considerably to the increased cost of health care. In general, this type of technology has been very well received by professionals because they can immediately corroborate results. However, many have been introduced without proper evaluation and due to commercial influences and self-interest of professionals themselves.

At the other extreme would be information and communication technology systems, ICTs, which try to efficiently collect, store, analyze, and share all the information generated in health care processes, and to evolve from data to information and ultimately to knowledge. These information systems have been slowly and ineffectively incorporated into health care organizations. Because of the variability of the first operating systems and languages, health professionals did not embrace the development of information systems in the same way as occurred in other sectors such as industry or banking. Professionals viewed information systems (probably correctly) as tools that controlled their activities without the kind of feedback that would influence their daily work or research or teaching capacity. Only during the last few years have we seen the deployment of reasonably integrated information systems, such as electronic prescriptions, hospital intranet, or the shared electronic health record. However, these systems are still far from providing the required and desirable interoperability that has been available in other sectors of the information society for several years.

The planning and evaluation of any technology we want to introduce in a health care system should be aligned with public policies due to its impact on health care quality and cost. With the introduction of mobile devices (mHealth), telemedicine and home care services allow the disengagement of patient care from time and space in diverse circumstances, a process that would be impossible without the introduction of technology. If technology is a public asset, it should be promoted as a primary value of public service.

Although the previous chapters discuss options for the efficient implementation of a telemedicine application together with the need for repeated evaluation, we should not forget what Eisenberg (75) describes in his 10 lessons for technology assessment: "Technology is much more than devices." The effectiveness and efficiency of technology is conditioned by organizational or model changes. The fact is that eHealth evolution depends not only on technological development but also on the organizational changes that are necessary for its efficient use (76). The application of telemedicine could change not only the organization of health care but, as a consequence, also redefine organizational planning and improve funding. Planning would focus on integration of technology and reduce the costs for adjustment of health care support systems. At the same time, professionals could focus on the functions they should really perform in the current information society. People are the main asset but also account for most of the cost, as usually occurs in a service enterprise. These changes, which should occur with the proper ICT introduction and generalization, should take place at macro level (State government), mezzo level (affecting health care structures such as hospitals and health care centers), and micro level (with specific applications in clinical and social care units).

How would extensive and efficient implementation of telemedicine affect the design of our hospitals? And the roles of our physicians and nurses? Would any of the current medical specialties make sense? Could social and health coordination become a reality?

The main difficulty for widespread implementation of telemedicine does not lie in technological development, which will clearly need evaluation as new technologies are incorporated into health care. Rather, it is the need for an organization which can adequately support the properly planned and assessed changes required by the introduction of the telemedicine service.

As regards telemedicine deployment in a more clinical setting, efficiency depends on the quantity and quality of professionals delivering health care as well as on the infrastructures that support such activity, which must adapt to the new health care model. New health care structures will certainly be different and will probably require less concentration and broader distribution of the spaces devoted to the health care of citizens.

While the deployment of information systems in European acute care hospitals has increased during the last few years, the exchange of information between hospitals and their communities has not evolved in the same way; this is true both for community health professionals outside of the hospitals and citizens. While 65% of European hospitals have implemented the electronic medical record, only 11% have implemented electronic appointments, and 8% can provide telemonitoring of outpatients (76).

Public policy considerations

Some considerations regarding public policies should be taken into account:

- According to the literature, the process of incorporating any telemedicine service as a routine tool of work faces a wide array of challenges and demands considerable time. It is possible to reduce impact by establishing a deployment strategy based on evidence. But the process is even more effective when it is carried out by a local team that is the best acquainted with the characteristics of the environment and more committed to the project.
- Possible approaches and solutions should align with the specific needs of the health system and culture of the country, should be technologically appropriate for the social, cultural, environmental, and economic conditions of the setting where they will be applied, should promote self-sufficiency, and have medium-term goals (77)(78). In order to achieve this complex goal, it is essential to develop an environment-focused strategy providing an evidence-based guide, and describing needs. Monitoring and evaluation are essential to measure efficacy, utility, and level of acceptance, and account for any expenses.
- Costs should be extended to other sectors. It is highly advisable to create discussion spaces to identify stakeholders. Appropriate networking should provide the opportunity to extend the cost of infrastructure to other sectors, both public and private.
- Experts on the subject should be involved in innovation projects along with professionals who will use and disseminate the technologies. While the project should be considered in terms of solving the problems that triggered its execution, there is the opportunity to consider further possibilities afforded by the new technology. This can occur through the integrated participation of its developers, within a framework of objective assessment of results and sustainability.
- Communication and dissemination of the strategy is required to reach the target audience and promote its adoption.
- Training plans suited to innovations should be created since the roles of professionals will be inevitably different. Training will be needed on topics that are not yet included in the curricula of colleges of health sciences (79).
- The organization of processes should be changed to fit innovations as well as the patient care agenda, assigning more time to distance consultations.

- Professionals should be ensured that the information they receive is reliable, since they will be not be near the primary data source, and that data are protected.
- Improvements in efficiency, quality, and cost reductions should be reflected in the remuneration of professionals who can add value to patients' health care.

Citizens actively participate in their health care, and telemedicine changes this into a more virtual process. This change can only take place if information and training are provided so that individuals can incorporate the technology into their routine health care. Training will be easier in the future as digital natives become the main patients in our health system (80).

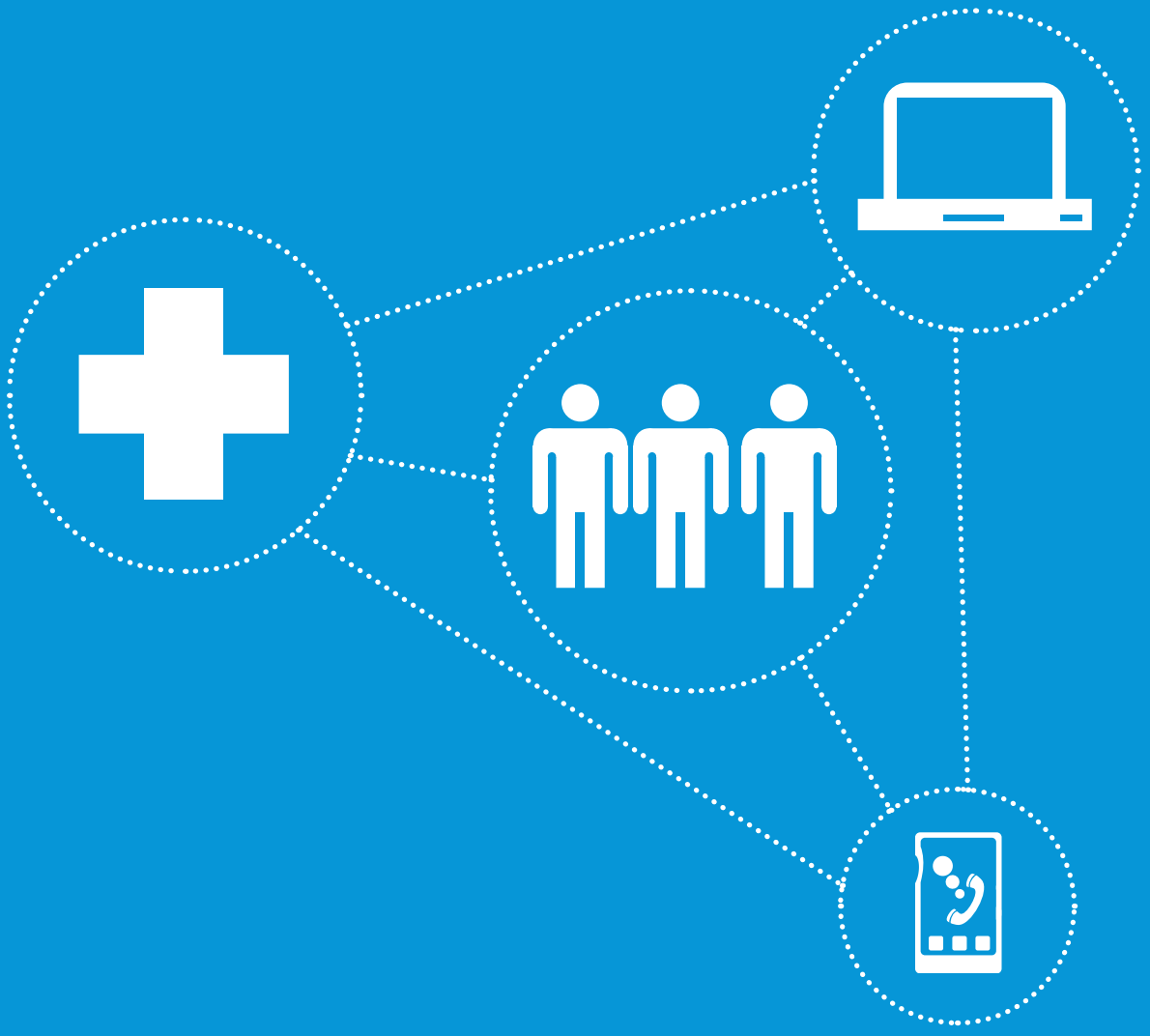
With the support of integrated public policies, telemedicine should transform not only the organization of health care, as already mentioned, but also influence the improvement of planning and funding through these radical changes.

The current state of telemedicine development demands a governance structure that can ensure effective and sustainable evolution for efficient implementation and future growth. This is the only way to guarantee the benefits telemedicine will bring to funding, planning, and delivery of health services.

Public policy has given priority to the promotion of certain clusters. The theory of competition underlines the importance of influencing the way of doing business rather than on prioritizing certain business models. All clusters can be competitive but market forces determine the results. In this context, the public policy of competition should focus on providing macroeconomic stability and microeconomic efficiency, particularly policies providing high quality inputs, so that all clusters can evolve favorably within the dynamics of the market.

Public authorities should facilitate all those actions that help break the barriers to deployment, as well as the actions to make it possible. In this way, while the strategy portrayed in the implementation framework defines what actions should be taken and where, policies should describe how to take those actions.

Development of the Telemedicine Service



Once the three basic layers of the process of implementing a telemedicine service have been addressed (i.e., strategic, organizational, and public policy), we approach the stage of service development, which involves internal explanatory factors of health care organizations describing the use of telemedicine. This chapter offers a guide on telemedicine development focusing on four key dimensions, namely:

1. Legal, regulatory, and security issues;
2. Technological and infrastructure issues;
3. Human resource issues; and
4. Financial issues.

Legal, regulatory, and security issues

Regulatory issues are critical in telemedicine. It is essential to analyze the status of regulations at the time of implementing and developing the telemedicine service. In general, these regulatory aspects are:

1. Protection of data;
2. Privacy and confidentiality of data; and
3. Issues related to responsibility for data.

Comprehensive regulatory frameworks are rarely available, and they are usually based on pre-existing laws about protection of data.

All countries regard health-related and derived data highly confidential and data security is one of the major challenges to be addressed by the implementation of a telemedicine service. For instance, unauthorized dissemination of a particular clinical condition may have very negative effects in the life of affected individuals. Therefore, to ensure the rights and responsibilities of patients, the telemedicine service implementation strategy needs to establish what the protection measures are, and strictly define appropriate compliance for confidential medical protection (81), for example:

1. Clearly establish the criteria for responsible storage of data and different electronic records in a decentralized way, both for clinical or medical documents of a specific health event and for the medical record containing the complete clinical evolution of the patient.
2. Clearly identify which of the users who are linked to the telemedicine service are authorized to have access to the information.
3. If appropriate for the telemedicine service implemented, establish different information levels of access for professionals related to that service.
4. Establish a training program to ensure that professionals involved are familiar with clinical standards related to this topic.
5. Define a data security plan for storing, transferring, and processing this sensitive information. It should be remembered that these matters become increasingly sensitive as systems are more and more interconnected.

6. Ensure that all patients are aware of their rights and responsibilities. In an environment where citizens are increasingly aware of security, privacy, and reliability of data, this issue may become an important barrier for telemedicine service users.
7. The data security and protection plan should clearly establish the responsibility of all involved actors.
8. Clearly determine the ownership of clinical records derived from the telemedicine service implementation.
9. Establish a procedure for patients' informed consent whereby they authorize the use of clinical data derived from using the telemedicine service.

We should point out that obstacles to the development of a telemedicine service, such as legal clarity and the specific fragmentation of a particular legal context, can only be addressed through coordination among the array of organizations that manage health resources.

Technological and infrastructure issues

Telemedicine is one of the most complicated settings as regards implementation, partly because the health industry has many legacy systems based on proprietary technology with a large amount of information stored. Interoperability and technological infrastructure issues, among others, must be considered when implementing a telemedicine service:

Interoperability issues

Any data derived from the health care process, from patients, from medical knowledge, and from clinical medical experience must be understandable for computers, so they can interact with each other and with health professionals (82). It is therefore necessary to build a comprehensive and completely interoperable "infostructure"*.

Interoperability is the capacity for two or more applications and the procedures they support to share data, and to enable the exchange of information and knowledge between applications. It also allows for the provision of service to all those involved in delivering the intended telemedicine service. From this perspective, it is possible to establish different types of interoperability;

- **Organizational interoperability:** this refers to defining business goals and processes and the collaboration of different organizations, their structures, and internal processes involved in the delivery of the telemedicine service. Thus, organizational interoperability aims to make services accessible, easily identifiable, and oriented toward users' needs.
- **Syntactic and semantic interoperability:** syntactic interoperability refers to data formats, while semantic interoperability ensures the exact meaning of information so that it can be understood by any application, whether or not originally developed for a specific purpose. Semantic interoperability allows the systems to combine the information received with other sources of information, and process them so they can be easily interpreted.
- **Technical interoperability:** this refers to technical aspects involved in linking different IT equipment such as: open interfaces, data interconnection services, data integration, data presentation and exchange, and accessibility and security services.

Telemedicine service must observe regulations and strategic plans on interoperability both for

* - Unlike "physical components", infostructure may be described as human resources, organizational and administrative structures, policies, regulations, and incentives that facilitate a totally integrated and sustainable use of ICTs and innovative services. The objective is to improve health care in a response that is organized according to health needs and medical care problems and challenges (on-line health care).

adequate service delivery and cost reduction, and in order to drive the development of the market. This is especially significant in the health market, which is fragmented, has many incompatible applications, and lacks terminological standardization.

Technological infrastructure issues

When addressing issues related to technological infrastructure for the implementation of the intended telemedicine service, four major issues should be considered: (1) ICT infrastructures; (2) eHealth infrastructures; (3) the support of the National Research and Education Networks (NREN); and (4) ensuring the technological usability and scalability of the service:

- **ICT Infrastructures:** the maturity level of the technology needed for the implementation of the telemedicine service should be taken into account. If a technology is needed that is at initial stages of development or insufficiently tested, this should be considered a serious risk for service implementation. Numerous problems may arise for first-time users, or, in any case, they should be fully aware of risks if they decide to implement the service. Usually, a sufficiently extended and tested technology is a guarantee of adequate development. On the other hand, development should consider all core components and the architecture of information systems necessary for implementing and developing the service, from software to hardware, as well as the required networks and communications.
- **eHealth Infrastructures:** along with general ICT issues, specific eHealth infrastructures necessary for the development of the telemedicine service should be determined and ensured. It is important to bear in mind that the service will incorporate some kind of health information system that is linked to others for the exchange of health information at different levels, both with providers and patients.
- **National Research and Education Networks (NRENs):** the NREN is a specialized provider of high-speed Internet services that supports, with the assistance of the relevant infrastructure for the exchange of data, interconnection requirements of research and education communities within a country, and with research networks all over the world. Some examples of this support are the *Rede Universitária de Telemedicina in Brazil*, the National Medical College Network in India, the Asian eHealth Information Network in Asia, the Asia Pacific Advanced Network (APAN), and the Latin American Cooperation of Advanced Networks (RedCLARA).
- **Usability and scalability of the service:** finally, it is necessary to ensure technological usability and scalability for proper implementation and development of the telemedicine service. The technological infrastructure should be user-friendly for health professionals and patients; it should be comfortable to use, easy to learn and manage, and simple to maintain. On the other hand, it should be kept in mind that while information is increasingly being recorded in electronic storage systems, the lack of protocols necessary to standardize and regulate data definitions in telemedicine limit the effective use of these technologies and restrict benefits by limiting scalability. Rapid changes in technology and its high level of obsolescence also should be kept in mind. Therefore, at the time of implementing the telemedicine service, it is necessary to develop systems that can be upgraded as cost-effectively as possible.

Human resources issues

With the advent of eHealth, relationships between health professionals and users of health services are changing substantially. Patients are more reluctant to give up control of their health to the "expert," nor do they accept uncritically the information and intervention provided.

Within this context, health professionals should adapt to these changes and develop new communication strategies with patients, providing information and guidance about the information resources that patients can access, bearing in mind psychosocial factors that influence health promotion and disease prevention.

Beyond this general change in the attitude of health professionals, it is important to consider three key issues related to human resources when implementing a telemedicine service:

- First, it is essential to clearly define the tasks of the health professionals involved in the intended telemedicine service and requirements for performing these tasks. A chart showing skills of the professionals responsible for performing such tasks should be created, and possible gaps between the skills of the team and the tasks to be developed should be evaluated in order to establish a strategy to bridge them.
- Second, while certain tasks may be taken on by the professional team responsible for developing the telemedicine service, it is essential to establish a complete training plan including all the skills and knowledge the work team needs to perform their jobs. This includes training for all communication, ethical, technical, and health care issues, as well as a strategy for continued improvement in this regard. This training plan should include the necessary professional education as well as certifications required for the development and delivery of the telemedicine service.
- Finally, considering that the intended telemedicine service will most probably require multidisciplinary work, and different agents will be involved in health care, it is critical to use complete, systematic, and standardized information and communication services so that shared interventions will be possible.

Financial issues

In general, the implementation of telemedicine services implies high initial costs both for the technology and the necessary training for its optimal use. This should be taken into account in the initial development stages of the intended telemedicine service. Thus, to benefit from cost reduction while improving health care quality, it is necessary to determine actual evidence for the efficiency of the telemedicine service to help public administrators make informed decisions regarding resource use and allocation.

In order to ensure the proper development of the telemedicine service, it is crucial to carry out a complete assessment of costs and prepare a budget to guarantee viability and continuity of the project. To that end, it is important to perform an economic evaluation using the quantitative technique that evaluates public funding programs.

The main purpose of an economic evaluation is to promote the efficient use of resources (83). The health system is regarded as a series of processes where inputs (hospitals, health professionals, etc.) are transformed into health products (health programs, quality of life, etc.) that are finally consumed by patients. In this context, the economic evaluation of health care interventions compares the relationship between their costs and their outcomes.

At present, the most common way of carrying out any economic evaluation is the cost-effectiveness analysis (CEA) (84). A CEA determines the relationship between the costs and outcomes of an intervention measured in the same units used in regular clinical practice. This relative value of the intervention is usually expressed as the quotient obtained by dividing net cost of an intervention by its effectiveness, known as the average cost-effectiveness ratio (ACER). The incremental cost-effectiveness ratio (ICER) applies when comparing the cost of a different clinical intervention. In general, interventions with low ACER are cost-effective (efficient), since they have lower costs per unit of effectiveness.

Once the telemedicine service is fully implemented, and the funding mechanisms are transparent and guaranteed, it is necessary to carry out the same rigorous cost analysis and budgetary control that is used in the organization for clinical practice.

Finally, it is very important to take into account the reimbursement mechanisms and incentives for clinical practice entailed in the implementation of telemedicine service. It is worth noting that the issue of reimbursement for health professionals, for instance, in distance monitoring of patients, is usually not adequately addressed with current regulatory frameworks. Katz and Moyer (85) warn that the problems caused by payment for distance services and the lack of structured incentive programs for health professionals to see patients using telemedicine tools are significant obstacles to its adequate development. The solution to this problem is not simple and it depends mostly on the regulatory setting in which the telemedicine service will be developed. Nevertheless, decision makers and promoters of the intended telemedicine service must be aware of the importance of this issue and give it thorough consideration in financing the project. It is even more important in view of the increasing demands placed on health professionals in terms of the time and effort they must devote to the use of these systems in the health care of patients.

Both clinical solutions and those derived from implementing a telemedicine service aim to reduce hospitalizations. Many of the incentive schedules for health care professionals are currently linked to the number of patients seen, so it is easy to see how new incentive schedules should be provided for the adequate development of a telemedicine project.

Follow-up, evaluation and optimization Level

The follow-up, evaluation, and optimization stage presents the results of telemedicine implementation. This stage considers indicators that measure performance of the implementation process.

Supervising the operation of a telemedicine service

When considering the implementation of a telemedicine service to fulfill a particular health care need, research should be carried out as part of evaluating the project. This evaluation should occur in parallel with the implementation of telemedicine application; that is, it should be integrated into its comprehensive design, development, and implementation. The evaluation should be designed from the very beginning of the project to avoid possible errors or loss of information as a result of poor calculations. It should be approached as part of ongoing reevaluation so that the results of the preliminary evaluation provide the information necessary to assess and adjust performance and further evaluation of services.

An article by Ekeland and others (16) on systematic reviews of methodologies for evaluating telemedicine corroborates the shortage of quality scientific evidence on clinical effectiveness, impact on patient management, organization, and costs. The authors highlight the need to:

- Develop studies with larger samples than current studies and with rigorous methodology based on controlled designs to evaluate the impact of telemedicine;
- Standardize populations and/or interventions and outcome measures to reduce heterogeneity between studies, and facilitate the possibility of performing meta-analysis;
- Combine quantitative and qualitative research methods.

It is necessary for new telemedicine projects to improve their design and execution quality in order to provide valid scientific evidence for existing information gaps. Responses to questions such as the following would contribute to this process: Is the telemedicine service clinically effective and safe compared to the existing alternatives? Does it fulfill its purpose? What is its cost-effectiveness? Is it accepted by patients and health care professionals? What is the impact of its introduction and dissemination on regular clinical practice?

As in any research project, in order to answer these questions it is advisable to take the following steps (86):

1. Formulate the research questions;
2. Conduct a critical review of scientific literature;
3. Design a research protocol to answer the research questions.

The research question

The first step is to clearly define what we want to know. With that purpose, the research question needs to be developed. This question consists of four elements, and is referred to as the PICO question:

P: Patients/health or health service problem

I: Intervention to be evaluated (telemedicine service)

C: Control or intervention to be compared (routine care)

O: Outcomes or results to be evaluated

A good research question should meet certain conditions in order to be:

- **Feasible.** There are an adequate number of individuals, satisfactory technical experience, reasonable time and budget requirements, and it has a manageable scope.
- **Relevant.** It provides new results or confirms, rebuts, or expands on previous findings.
- **Ethical and timely.** It contributes to scientific knowledge, to making decisions on health policies, or for future lines of investigation.

Critical review of scientific literature

The research protocol should include a critical review of the studies which have tried to answer the research question, including problems and limitations.

Designing a research protocol to answer research questions

It is advisable to establish, before start up, a research protocol including the stages outlined by Hulley and Cummings (87) and presented in Table 5.

Table 5: Stages in designing a research protocol (87).

Stages in design of a research protocol
1) Presentation of the research problem • Brief summary of intended goal: significance, relevance, objectives, and design • Description of the questions to be answered by the research • Critical review of the studies that have tried to answer the research question, including problems and limitations • Relevance of the study: justify the need of the project • Objectives
2) Study design • Specify the type of design chosen • Define study duration • Select the population • Define the reference population for which the study intends to extrapolate its findings • Define eligible population: a population that meets the study selection criteria • Develop a sampling plan to recruit the study population (participants) • Estimate sample size • Gather information • Describe data (what data will be obtained); include operative and detailed definitions of variables • Information gathering from sources. Specify how information will be extracted from the sources; provide sample questionnaires and coding schemes • Quality of data (what measurement quality is expected) • Quality control during information collection • Data analysis • Organization of data for storing and analysis; data cleaning techniques • Statistical analysis procedures to be used • Interpretation of results • Assessment of possible bias interference and study limitations • Generalizability of results • Elaboration of conclusions

Stages in design of a research protocol
3) Human and material resources • Number of researchers and assignment of tasks • Required material • Schedule of activities • Detailed budget • Assessment of logistical problems during execution
4) Ethical and legal considerations

When a protocol is developed, the selection of the variables to be included in the study (also called outcome measures) is one of the most important steps since that will determine the study outcome and its impact. The starting point in identifying the variables is the research question.

In order to identify the outcome measures in the evaluation of telemedicine services, a review of scientific literature on telemedicine projects similar to the one being evaluated may be very useful. This review will provide information on possible outcome measures to be used, as well as potential problems in the selection of certain measures, and in the execution of the activity. Likewise, it will help identify the methodology to ensure appropriate data collection and analysis. Each type of telemedicine service will also require the selection of the outcome measures best suited to its objectives (88). The most relevant outcome measures are summarized in Table 6.

Table 6: Variables or outcome measures to be included in a research study.

Outcome measures

1) Technology-related
• System accuracy. Adequacy of technical characteristics to facilitate quality performance
• Reliability or reproducibility. Degree to which the system gives the same results when it is used repeatedly in the same situation
• System dependability. The probability that the system is working properly. Attributes related to dependability are:
  • System robustness: the ratio of failures per time unit is low
  • System security: this refers to complications, adverse, or harmful effects associated with telemedicine use
  • Interoperability: telemedicine system under evaluation should comply with medical data collection, forwarding, processing, and visualization standards.
• Ease of use (usability). Refers to the simplicity of handling and the extent to which it can be easily adapted to the logical behavior of users
• According to the type of telemedicine service (e.g., teleradiology), the following should be considered:
  • Diagnostic accuracy. Sensitivity, specificity, and calculation of positive and negative predictive values
  • Reliability or diagnostic agreement

2) Related to patient-centered efficacy and effectiveness • Intermediate clinical outcomes: physical signs or symptoms, morbidity rates, health-related behaviors, etc. • Final clinical outcomes: physical, mental, or social function; survival rate, mortality rate, important complications rate, and years of life gained • Outcome measures reported by patients: health-related quality of life (HRQoL), satisfaction with telemedicine services

Patient-centered efficacy and effectiveness

Evaluation of effectiveness requires a comparison of the outcome measures between the new telemedicine service and the conventional service; that is, a comparison against the usual care accepted by both the professional and scientific communities and by society. Thus, every evaluation of effectiveness should be preceded by an evaluation of technology-related characteristics. We should check that the system works, that it is accepted and therefore used by professionals and patients, and that its effectiveness can be measured.

Effectiveness should be measured in the short and long terms. If immediate or intermediate outcome measures are chosen because there is not enough time to provide long-term information, an association should be established between the short- and medium-term measures and the final health improvement outcome, or the measures used should prove to add value themselves. The potential success of a telemedicine program will be closely linked to the results obtained on the most important issues regarding health or health resources management.

As in any other field of health services research, it is advisable to combine objective clinical measures with health measures perceived by patients in order to obtain a broader and more consistent assessment of the results of new telemedicine services. Self-perceived health status measures such as health-related quality of life (HRQoL) of patients are increasingly important as estimators of the overall outcome of programs and interventions in the health field. Their use, together with other subjective measures, such as satisfaction, is part of patient-centered health measures (89). When these outcome measures are included in the study protocol, validated instruments adapted to the language and culture of the country where the study is being carried out should be used. Likewise, the method for data collection should be specified (interviewer- or self-managed questionnaires), as well as the questionnaire transmission medium or channel (mail or telephone).

Patient satisfaction

The assessment of a population's acceptance of telemedicine by using satisfaction questionnaires is one of the most widely evaluated aspects in the field of telemedicine (90)(91). Information on the satisfaction of patients and professionals with the different components of a telemedicine program, when appropriately performed, allows continual improvement in the design, choice, or replacement of equipment, and program organization and management. Nevertheless, despite its frequent use and the importance of evaluating this outcome measure, some limitations exist that reduce its validity and, consequently, its usefulness (92). The most important limitation is that questionnaires used are usually not validated and are developed informally. Besides, they are frequently applied by the health staff involved in telehealth care, which may introduce significant bias (93). For that reason, it is important to use validated instruments and to use application strategies to reduce the degree of bias and improve the legitimacy of this information, e.g., by engaging interviewers not involved in the health care process.

Special features to consider when designing studies to evaluate telemedicine services

The evaluation of a complex health care intervention such as telemedicine presents distinctive features that should be taken into account (94). First, the evaluation of the intervention will only rarely focus on a single effect. Second, the intrinsic features of telemedicine in providing a service with an impact on the organization require that the evaluation take place under real conditions. The measurement of different components and dimensions, and the interaction between players makes this evaluation more complex than the evaluation of other health technologies such as medications. Telemedicine is a complex technology that affects different players and levels, requires specific equipment and telecommunications for its execution, and calls for new organizational modalities for its development. All these factors may act independently or interdependently. For these reasons, it is important to identify key elements so that the intervention remains effective when it is transferred to contexts other than that used for the initial evaluation (95).

When a telemedicine application is designed and evaluated, it is possible to obtain information on effectiveness, security, and cost-effectiveness of the new intervention, along with information on the social context (96). For that reason, the telemedicine study design should have a multidisciplinary

perspective, combining the use of quantitative and qualitative methodologies. The timeframe should be long enough to verify that results remain stable over time and are not driven by enthusiasm. In order to obtain quantifiable information on effectiveness, security, and cost-effectiveness, experimental or observational designs and/or mathematical-statistical techniques, such as modeling, may be used. The following three issues should be considered when choosing the method or design:

- The research question;
- The characteristics of each design in terms of scientific validity; and
- The availability of time and/or resources to obtain the information (feasibility) needed to answer the research question (95).

Qualitative research methods are the most appropriate for the social context. This aspect of research is often overlooked, but provides valuable information for the successful implementation of this type of service.

It is important to emphasize that the research question should determine the selection of the research method and design, and not the other way around.

In order to evaluate a telemedicine service, it is advisable to carry out a comparative analysis to check results of the new technology against the conventional health care service. The most commonly used study designs are outlined below.

Experimental studies

Randomized clinical trial (RCT)

The aim of this type of study is to evaluate the efficacy of preventive, curative, or restorative interventions. This design provides the best quality evidence on the causal relationship between an intervention and the observed effect (97). It attempts to show that the intervention applied (drug, surgery, etc.) is the only cause of the potential differences observed between each group's results. In the RCT, the investigator manipulates one or more study factors (what treatment and protocol and length of time the patients in each group will receive treatment) for the subsequent assessment of the effects produced (response, outcome) based on a previously established plan. A blinded evaluation of outcomes is performed using masking techniques which attempt to prevent expectations of the patient, physician/investigator, or reviewer from influencing the observed outcome. Masking techniques may be single blind (the patient is unaware of the assigned group), double blind (the patient and the physician are unaware of the group), and triple blind (all are unaware of the group). Notwithstanding, if they are carried out in highly selected samples, or interventions are too rigid, the generation of results becomes difficult. Usually, only the relationship between an intervention and its effect is addressed. The limitations described, very common in available telemedicine evaluation studies, have required a search for different designs for evaluation of these applications within a more realistic and feasible framework.

Quasi-experimental study

These studies are also known as nonrandomized evaluation or intervention studies (87), in which there is an intervention, and an answer and a hypothesis to test, but individuals are not randomly assigned to treatment and control groups, or there is not a control group as such. This type of research shares most of the characteristics of an experiment but comparisons of individual responses are performed between nonequivalent groups, that is, groups that may differ in many aspects besides exposure (98). If there is no control group, it will not be possible to ensure that the changes observed are due to the intervention itself, or to other uncontrolled interventions or factors that may influence the results.

The most common design in this type of research is the pre-post test using a single group or a nonequivalent control group. This type of design relies on measurement and comparison of the response variable before and after an individual undergoes the experimental intervention. Pre-post designs with a single group do not include a comparison group and each individual acts as its own control. An improvement on this design is the incorporation of a (nonrandomized) nonequivalent control group. These designs include two (pre-post) measures in two samples and one intervention.

Observational studies

In these studies, the investigator is limited to observing the effects of an intervention or study factor and is not involved in its manipulation. The aim of this type of study is to assess the effect of exposure on the response of individuals. The characteristic of the non-experimental research is that the investigator observes a natural exposure and does not manipulate the intervention or study factor. In non-experimental designs, individuals are selected for the study based on certain characteristics and there is no random assignment to comparison groups. The results of observational studies are more generalizable than for experimental studies, but it is more difficult to draw causal conclusions. These designs can have a prospective (cohort studies) or retrospective (case-control studies) structure (98).

Cohort studies (or follow-up studies)

Cohort studies are also referred to as follow-up, prospective, or incidence studies. Individuals are identified based on the presence or absence of exposure to a particular factor.

The structure of cohort studies is similar to that of randomized clinical trials, with two important differences: individuals are not randomly assigned to study groups, and study factors are not controlled by investigators.

Cross sectional study

In cross-sectional studies, the investigator makes observations at a specific time and obtains data relative to exposure and effect concurrently. They are mainly used to generate hypotheses and inform resource planning by providing data on the frequency of certain characteristics of patients or professionals exposed to these new technologies. They are not expensive and, although not generally used to suggest causal relationships, they are very useful in evaluating telemedicine applications for diagnostic purposes.

Telemedicine research can also benefit from carrying out **mathematical-statistical modeling studies**. They make it possible to perform theoretical simulations of what the introduction of the new technology would represent for traditional health care before implementing the necessary organizational changes.

Qualitative studies

Qualitative methods are oriented particularly toward researching what people do, think, and know, and when applying them to the health care setting, they seek to answeri the "what," "how," and "why" about health care services (99). The main contributions of qualitative research are: study of the context, the possibility of including the "voice" of the actors involved in the problem under study, research is performed in the real world, generation of theories, and detection of phenomena. It is possible to find in the literature different ways to classify qualitative studies according to the methodology used, data collection techniques, or analysis methods. The common link for qualitative methodologies is the inductive approach of studies. Table 7 shows the most commonly used techniques for data collection in the health care field (100).

Table 7. Relationship between qualitative research studies and techniques applied

Techniques	Types of studies
Observational techniques	Ethnography, participant observation, non-participant observation
Individual techniques	Interviews
Group techniques	Focal groups, consensus panels, natural groups, community interviews
Document analysis	Based on publications, the media, photographs, reports, newspapers, etc.

Cost analysis and economic evaluation in telemedicine

Decision making in the health sector should be based on the identification of a need and the assessment of both effects and costs of the different alternatives that are available to address the need. However, the incorporation of the evaluation of effects (efficacy, effectiveness, and safety) into the economic evaluation in planning health care services occurs rarely. This may result from the limited number of economic studies to inform decision making or the lack of clarity of these reports, or from decision makers who do not incorporate these results into decisions. The shortage of economic evaluations is especially surprising in telemedicine literature; therefore, it is necessary to incorporate economic evaluation as an essential outcome measure for the design, execution, evaluation, and deployment of telemedicine programs (101).

Economic evaluation is defined as the "comparative analysis of alternative courses of action based on the joint consideration of costs and consequences" (101).

How to design an economic evaluation in telemedicine

For the correct design of any economic evaluation, we should follow a series of steps and provide answers to questions that will indicate the type of design we should use to respond, in a more effective way, to the established objectives.

This activity usually should be performed in parallel with the evaluation of the effectiveness of the program or intervention. The stages of an economic evaluation are briefly described below (102):

1. **Define the question or problem to be answered:** this will determine the object of analysis and guide the search for information to report the needs of the study audience, defined as the beneficiaries of results: patients, health professionals, planners, etc.
2. **Define the perspective of the analysis:** this will guide the economic evaluation, which will vary according to the analysis perspective adopted.
    a. **Financing perspective:** a hospital or health service that considers whether to include a new technology in its portfolio of services. The evaluation is aimed at management and the only requirement for the decision is the analysis of costs and results the organization will incur (staff, equipment, etc.), whereas (direct or indirect) costs assumed by patients or society are beyond the scope of the study.
    b. **Social perspective:** all costs and results incurred by all actors involved in the health care process are considered, including those affecting providers (hospital or health service), patients, and the society. In general, the economic analysis is considered from the social perspective since it is the most comprehensive.
3. **Select and describe health care alternatives to be compared:** any new telemedicine-based program should be compared with conventional (face-to-face) care.
4. **Define the chosen timeframe:** period of time during which costs and effects of the inter-

ventions being compared are measured. This choice should consider that costs and effects do not always appear simultaneously or with the same progression. Likewise, it may occur that the benefits of the intervention emerge immediately or are delayed. Therefore, to avoid favoring any alternative with our analysis, we should establish an adequate timeframe to allow the most complete identification of all relevant costs and effects to report the decision.

5. **Define costs to be estimated:** the value, expressed in monetary terms, of a series of resources and efforts combined to obtain a product or service.

The classifications of costs of a product or service are outlined in Table 8.

Table 8. Costs related to the application of a service or product

Costs	Service or product
Direct costs	Incurred during health care delivery. These costs are identifiable and can be unequivocally attributed to a particular product or activity. Direct costs can be divided into: • Health costs: remuneration of health staff (formal care), drugs, instruments, diagnostic tests, consultations, equipment, hospitalizations, etc. • Non-health costs: transport of patients to the hospital, home care by non-health professionals (informal care), among others.
Indirect costs	Social costs deriving from reduced productive capacity of an individual as a consequence of a disease or treatment (lost or reduced work productivity).
Intangible costs	They cannot be quantified in monetary terms. They refer, for instance, to pain or suffering. They are usually not taken into account in cost quantification or economic evaluation because they are difficult to measure.
Fixed costs	They do not vary based on the quantity of the goods or services produced. In telemedicine, fixed costs are usually the most significant, especially at the beginning of the activity (equipment, software, building or repairing consulting rooms, maintenance service, etc.).
Variable costs	Expenses incurred when using the system and that depend on the degree of usage (travel expenses, communication costs, duration of consultations, electricity, etc.).

Cost estimation of programs or interventions analyzed and compared in any economic evaluation includes the following three stages:

- **Identification.** To quantify costs, we should identify and include in the study protocol the information to establish the resources consumed in the different stages of the health care programs being evaluated (who, how, where, with what, and when).
- **Measurement or calculation.** We will determine the number of resources used in each stage.
- **Assessment.** This consists in attributing a unit cost to the resources used.

6. **Define the key health care results:** defining the most relevant effects or consequences of the telemedicine service in order to measure the effectiveness of the alternatives compared. The following may be used:

- **Final results:** straightforward evaluation of the effect of the intervention on the population's health, for instance, number of deaths prevented, years of life gained, etc.
- **Intermediate results:** i.e., reduced waiting times, reduced hospital admissions, improved monitoring of biochemical parameters, etc.

- **Results expressed in monetary units**
- **Results using constructs** which combine quantity and quality of life, such as quality adjusted life years (QALY).

The way of measuring and assessing, the results of the alternatives under analysis will determine the analytical technique to be used.

7. **Types of economic evaluation.** The main economic analysis techniques are:
   - **Cost minimization.** In cases in which the alternatives being compared offer the same result or effect, the evaluation activity will be limited to a detailed estimation and comparison of costs (from the predetermined perspective), to opt for the less expensive alternative. Equal results of the alternatives compared should be clearly justified for the obtained results to be valid. However, when evaluating the introduction of a new medical care program using telemedicine compared to conventional programs, it would be rare to see equal effects.
   - **Cost-effectiveness analysis (CEA).** It compares the costs of the interventions under study with health gains assessed in physical or natural units. It may rely on intermediate measures (for instance, blood pressure reduction) or final outcomes (for instance, mortality or years of life gained). The CEA is the most commonly used technique and it requires that the outcome measure be selected early on, since the analysis should capture the main effect of the intervention under study.
   - **Cost-utility analysis (CUA).** It compares the cost of the interventions under study with their outcomes by combining survival improvement and quality of life gains (quality adjusted life years or QALY). It is especially useful when quality of life is an important result of the intervention under study, when the intervention affects both mortality and morbidity in a patient, or when there are multiple types of results or benefits expected and a single outcome measure combining all the effects is required.
   - **Cost-benefit analysis (CBA).** It compares the costs of the interventions under study with their outcomes assessed in monetary units. Direct comparison of costs and outcomes in the same units allows calculation of the net value of an intervention (difference between both magnitudes) and, if positive (benefits outweigh costs), the adoption of the new intervention would be economically justified. One of the advantages of this technique is its solid theoretical basis as well as the feasibility of comparing very different programs by working with the same outcome units (monetary). However, this technique is rarely used due to the difficult and controversial conversion of health benefits into monetary terms.
8. **Presentation of aggregated cost and outcome measures:** this calculation aims to determine how much more should be paid for each additional outcome unit. In other words, it analyzes additional costs imposed by a telemedicine service over face-to-face health care against the additional effects or benefits it provides.
9. **Performing a sensitivity analysis:** it consists in modifying (reducing or increasing) the values of costs and outcomes where uncertainty exists about their real value in order to consider other scenarios and provide greater certainty to the decision. Sensitivity analyses are essential to determining the result of the evaluation and they can be deterministic (assigning a range of values to one or more variables while the others remain fixed) or probabilistic (through the Monte Carlo simulation technique).
10. **Mathematical modeling to implement the economic evaluation:** the most commonly used mathematical modeling tools are decision trees and Markov models. Selecting one technique or the other will depend on the disease under study and the characteristics of the health technology being evaluated.

Evaluating the impact of telemedicine on the organization

Telemedicine improves organizational efficiency of health services, but uncertainty about its impact on the organization has hindered its use. Various studies have been carried out on issues concerning the changes implied by ICT incorporation and use in health care organizations (103–107).

The selection of areas to be evaluated should be guided by the information requirements of the end users (information needs are different for decision makers of regional services and of hospitals). The complex nature of the health system and of its processes complicates issues concerning the evaluation. Within an organization, objectives are frequently commitments developed over time, and different objectives may coexist. Due to the multiplicity of objectives, the evaluation of the organization in terms of health care technologies is more complicated than the cost-effectiveness analysis or efficacy evaluation of a health technology. On the other hand, the results obtained from this evaluation are closely related to the context and not easy to transfer.

Organizational issues are evaluated at different levels: intra-organizational, inter-organizational, and at the level of the health system. At these levels, in addition to staff and patients, other players are involved such as funders, providers, suppliers, etc., who may have different objectives and expectations regarding health technologies. Thus, information on organizational issues may overlap with others, such as economic or social dimensions. It is not surprising that some systematic reviews on the social and economic impact of telemedicine also provide information about changes in the use of certain services that can be attributed to telemedicine implementation.

Measures to evaluate the organization

Different telemedicine evaluation frameworks agree on the outcome measures to be evaluated such as quality of care, acceptability, accessibility, and costs. However, they do not clearly identify measures relative to the organization. An attempt to arrange these measures was carried out by Serrano and Yanes in 2008 (102) and the European Union's project which produced the HTA core model handbook (108). There, aspects of the organization include process, structure, management, and culture among the different players that interact both between services within an organization and between organizations. Likewise, it tries to identify aspects of the organization that may pose problems or barriers to the implementation of health technologies.

Table 9 summarizes evaluation measures for different aspects of an organization. These questions serve as a guide and their inclusion in a research project will depend on the type of technology under evaluation.

Table 9. Measures for organization-related issues of telemedicine, based on Serrano and Yanes (102).

Measures to evaluate organization-related issues of telemedicine services
1) Process
• How does the organization accept telemedicine?
• What type of technical problems might arise with the use of telemedicine?
• What type of changes in the organization of work does telemedicine implementation require?
• What type of changes are required regarding patient care?
• What type of changes might result for quality of care with telemedicine implementation?
• What type of changes does the work process require after telemedicine is implemented?
• Where will telemedicine be deployed (primary care or tertiary care facilities)?
• Has accessibility been considered?
• What are the economies of scale?

Measures to evaluate organization-related issues of telemedicine services
2) Structure • What type of experts are involved in telemedicine? What type of education do they need? • What type of incentives will experts receive when they use telemedicine? • What type of impact will telemedicine have on work satisfaction? • How will knowledge be shared among experts? • What type of coordination and communication activities does telemedicine require? • What type of information will be given to patients regarding telemedicine?
3) Budget • What type of investment is required? • How does the cost of the new technology influence on investment decisions? • What organizations share the funding? • What is the potential impact on the funders' (e.g., government) budget? • What organizations participate in modalities of payment (investment and operating expenses)?
4) Management and control • Who controls the fulfillment of general objectives at national, regional, and organizational levels? Who establishes the goals? Who is responsible for the follow-up and fulfillment of goals? Who makes decisions about telemedicine investment? • Who decides that telemedicine will be used for certain patients and according to what protocol? • Who will be responsible for management, accountability, and evaluation of information? • What management skills are required at all levels? • Who has approval authority, at all levels?
5) Organizational culture • How will other stakeholders be incorporated into telemedicine planning? • To what degree is telemedicine accepted?

The research question is the starting point for evaluating aspects relative to the organization. We should ask: What type of study design provides the most reliable answer to that question? Both quantitative and qualitative studies and their synthesis are important for this type of evaluation. However, observational quantitative studies and qualitative studies, in particular, are the most appropriate designs to answer most research questions in this context. On the other hand, it is always important to verify the existence of controlled or quasi-experimental studies. National and international reports, statistics, registries, and handbooks may also provide relevant information regarding organizational issues.

Documentary sources

It is advisable to search for information from a wide range of sources when evaluating an organization, including gray literature, magazines, databases, contacts with experts, etc. Some of the most important available databases on organizational studies are:

- Medical databases: Medline (U.S. National Library of Medicine); Cochrane Library's Health Technology Assessment Database (HTA) and Database of Abstracts of Reviews of Effects (DARE); National Health Service (U.K.) Economic Evaluation Database (NHS EED); Cumulative Index to Nursing and Allied Health Literature (Cinahl)
- Social sciences databases: Sociological Abstracts, Caredata and SocINDEX, PsycInfo, Applied Social Sciences Index and Abstracts (ASSIA)
- Administrative studies: scientific publisher databases such as the Biblioteca Esmeralda, ScienceDirect, Ebsco Academic Search Elite, Pub Med Central, and Bio-Med Central, ProQuest, Health Service Technology, Administration and Research (HealthSTAR)
- Gray literature: Dissertational Abstracts, Scirus (Abstracts of hospital studies and doctoral thesis), OAIster
- National and international statistics; mortality, hospital Diagnosis Related Groups (DRG), etc.
- Expert opinions

- Reports from organizations (NHS Technology Adoption Centre)
- SciELO (Scientific Electronic Library Online)
- LILACS (Literatura Latinoamericana y del Caribe en Ciencias de la Salud)
- Regional Repository La Referencia
- Virtual Health Library

Useful evaluation models for implementation

Although evaluation models may be considered a category per se (104), other frameworks such as the normalization process theory have been widely used as evaluation frameworks since they state what concepts and constructs, which can be operational and measurable, should be considered for development and implementation (109)(110).

Several evaluation frameworks of telemedicine-based health care services have been developed, such as those proposed by Bashshur, or elaborated by the U.S. Institute of Medicine (IOM). The evaluation framework of the "*Guía de diseño, evaluación e implantación de servicios de salud basados en telemedicina*" (GDEISST) authored by Serrano and Yanes (102) is suggested as a reference, which, in turn, is based on the proposal elaborated by the IOM (111). It presents a comprehensive approach to telemedicine evaluation from the social perspective.

Another evaluation framework is that being used in the European "Renewing Health" project, whose objective is to evaluate telemedicine services for the home care of chronic patients. This framework includes the evaluation of seven dimensions or domains of telemedicine services: technical and safety issues, clinical efficacy, the perspective of the patient, economical aspects, issues regarding the organization, and sociocultural, ethical, and legal issues.

The main dimensions of the GDEISST conceptual framework are summarized below.

Evaluation of quality of telemedicine services

To measure the quality of services, the main focus is on measuring telemedicine effects on immediate, intermediate, and long-term health results—compared to other alternatives—and on the medical care process.

Evaluation of access to telemedicine services

Accessibility, as a multidimensional concept, refers both to the level of difficulty to obtain health services (geographic, economic, architectural, cultural, and social barriers) as well as to the time needed to access them. From the social perspective, telemedicine should reduce the need to travel and improve the satisfaction level of communities in remote areas with poor health services. Moreover, telemedicine could lessen not only distance barriers but also those related to quality and time

Evaluation of acceptability of telemedicine services

Within the context of new telemedicine-based health services, acceptability is referred to as the capability of both health care staff and patients to work with ICTs in a "friendly" way.

This is one of the most frequently evaluated aspects in telemedicine experiences and it generally produces high levels of satisfaction. The main tools used to evaluate acceptability of patients and professionals are questionnaires. Although questionnaires are an appropriate tool, it is important to ensure that their validity and reliability have been previously determined, as well as to avoid some

common difficulties of the methodology such as low response rate and bias toward a positive answer.

- **Evaluation of the impact of telemedicine costs**

  For this element, refer to section "Cost analysis and economic evaluation in telemedicine".

- **Evaluation in the health care organization**

  For this element, refer to section "Evaluating the impact of telemedicine on the organization".

The GDEISST evaluation framework also incorporates a series of contextual considerations that should be kept in mind in the initial stages of a telemedicine service deployment.

Comprehensive framework for telemedicine evaluation: the MAST model

MAST is the abbreviation for "model for assessment of telemedicine applications". This is an evaluation model developed in 2009–2010 for a project funded by the European Commission (Metho Telemed Project, SMART 2008/0064) with a special focus on telemedicine.

At that time, a literature review on the efficacy of telemedicine services showed that evaluation studies were not of high quality, used questionable methodologies and techniques, or had a limited scope regarding major results.

Based on a series of similar data, the European Commission identified the need to promote telemedicine evaluation, since the lack of high quality studies is considered an obstacle for wider deployment of different telemedicine applications available in the health care systems of Member States (Commission Communication, 2008).

The MAST model uses the conceptual framework proposed by the EUnetHTA—*HTA core model for interventions*—as the starting point and adapts it to the evaluation of telemedicine-based health services. This adaptation and its later development were based on the results of two interactive workshops with key players of the European health system (professionals, managers, decision-makers, and users) and on the results of a systematic literature review on the topic (16). This combination of qualitative (focal groups in workshops) and quantitative methods allowed for complementarity between available scientific evidence and the opinions and needs of potential users.

Objective of the MAST-based evaluation

If the objective of evaluating a telemedicine-based service is to describe its efficacy and contribution to the quality of care, as well as laying the foundations for decision-making, then the appropriate evaluation framework is a multidisciplinary process. This process would summarize and evaluate the information about clinical, social, economic, and ethical issues related to telemedicine use in a systematic, objective, and robust way.

The key terms in this description are "multidisciplinary, systematic, objective, and robust". The first means that evaluations should include all the results relevant for patients, professionals, health care institutions, and the society as a whole. The other concepts suggest that evaluations should be based on data from scientific studies, using scientific criteria and methods for the quality of evidence. This declaration of principles is based on the definition of HTA in the EUnetHTA project.

Therefore, the objective of the MAST model is to provide a structure for the process of evaluating efficacy and the contribution of telemedicine applications to the quality of care so that its conclusions can serve as the basis for decision-making. In this context, the term "evaluation model" is regarded as a structure for the features or results of telemedicine applications which should be included,

following a particular order, in the evaluation of telemedicine-based services.

EThe MAST model can be used in the following three ways:

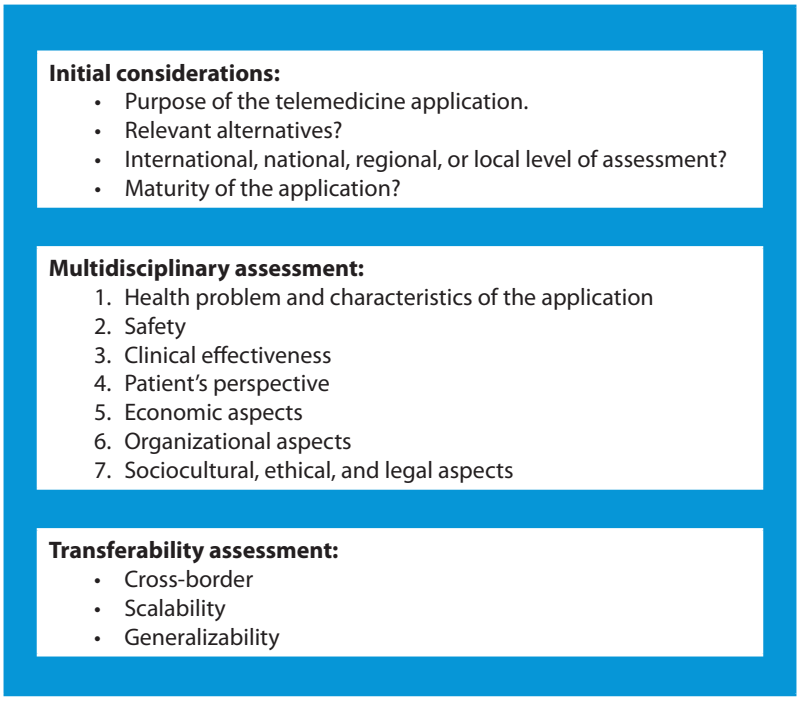
- As the model for the design of new telemedicine studies;
- As a checklist for the relevant domains and outcome measures in the description of telemedicine studies;
- As a model for the development of an evaluation based on the review of scientific literature or on information available about the effects of a specific telemedicine application.

Model structure and evaluation domains

he structure of the model defines a pre-evaluation stage in which a series of initial considerations should be taken into account that are complementary to the evaluation itself. The evaluation is organized into seven different domains that define its multidisciplinary nature. And finally, a major element is the need to assess the degree of transferability of results to other contexts.

The MAST model and the elements of its structure are presented in Figure 3.

Figure 3: Structure of the MAST model.



Source: K. Kidholm *et al.* (2012). A model for assessment of telemedicine applications: MAST. International Journal of Technology Assessment in Health Care (vol. 28, Nº. 1, p. 44–51).

Initial considerations

In this first stage, the description of the objectives of the telemedicine application should include the definition of patients (potential users), their health problem, and the purposes for using the technology under these conditions. A description should be given of potential improvements the telemedicine service evaluation can provide compared with other relevant technologies used for the same health problem. The objectives of the telemedicine service will determine the main results that should be considered in the evaluation.

Additionally, the following questions should be answered:

- ¿How does this telemedicine-based service fit in current legislation?
- Are there reimbursement conditions for this telemedicine service?
- What is the level of technological maturity of the telemedicine application?
- How many patients are expected to use the application?

Consideration of the MAST model and the answers to the previous questions will help to detect potential barriers for future implementation of telemedicine services. It follows that these issues should be addressed before developing a complete analysis of the advantages of introducing a new telemedicine-based service.

Actual evaluation and outcome measures

A multidisciplinary evaluation is carried out to describe and evaluate the different results of the telemedicine application. As shown in Figure 3, "Structure of the MAST model", this process implies evaluating the effects of the telemedicine application compared to one or more alternatives (usually, with conventional health care received by potential users), where the evaluation of impact is divided into seven domains. Table 10 introduces these different evaluation domains, including their definition and content.

Table 10. Domains of the MAST model

Domain	Definition	Content
1) Health problem and characteristics of the application	Description of the health problem of patients, potential users of the telemedicine application, and description of the application under evaluation, including current use (if applicable).	• Health problem • Description of application • Technical characteristics • Current use of application
2) Safety	Identification and evaluation of adverse effects.	• Clinical safety (patients and staff) • Technical security (technical reliability)
3) Clinical effectiveness	Effects on patients' health.	• Effects on mortality • Effects on morbidity • Effects on health-related quality of life (HRQoL) • Effects on habits and behavior. • Use of health care service
4) Patients' perspective	Issues related to the perception of patients, their families, and/or caretakers, regarding the telemedicine application.	• Satisfaction and acceptance • Understanding of information • Trust • Capacity to use the application • Access and accessibility • Empowerment and self efficacy
5) Economic aspects	Economic evaluation from the social perspective, comparing the telemedicine application with relevant alternatives in terms of costs and implications, and business case describing the economic impact for health care facilities.	Economic evaluation: • Number of resources used for the application and for comparators • Price of each resource • Changes related to the use of health services • Clinical effectiveness Business case: • Annual expenses • Annual income
6) Organizational aspects	Evaluation of the types of resources that should be mobilized and organized for the application of a new technology and potential changes for the health organization as a result of its use.	• Process • Structure • Culture

Domain	Definition	Content
7) ASociocultural, ethical, and legal aspects	Sociocultural aspects include the context where the patient lives and acts while using the telemedicine application. The ethical analysis assesses ethical aspects presented by the technological application itself, and by the consequences of using or not using it. Legal aspects focus on legal obligations that should be fulfilled and specific legal barriers that may exist for a widespread application deployment.	• Ethical aspects • Legal aspects • Social aspects

Source: K. Kidholm *et al.* (2012). A model for assessment of telemedicine applications: MAST. International Journal of Technology Assessment in Health Care (vol. 28, Nº. 1, p. 44–51).

When choosing among different study designs and methods for gathering data within each domain, the general principle is that research designs and methods should produce valid and reliable estimations of the impact of the telemedicine application. The selection of outcome measures should be based on careful consideration of the objectives of the specific application, the group of patients, and the context of the organization in which it is used.

Evaluation of transferability of results

The transferability of the results obtained from health technology assessment studies from one context to another is a general problem and should be given special attention in the evaluation of telemedicine applications.

One of the reasons for this difficulty is that the application of telemedicine in health systems is generally a process that affects the organization. In order to achieve telemedicine's full potential, adjustments sometimes must be made in the distribution of tasks between health professionals as well as in communication methods between professionals. Likewise, interoperability and the level of integration with other clinical or administrative systems are crucial if patients and health facilities are to benefit from the use of a new telemedicine service. Another problem is that technical infrastructures usually vary between countries, and this may bring about substantial differences in costs per patient and in the possibility of introducing the same telemedicine service in different countries.

Therefore, according to the MAST model, a comprehensive evaluation of the impact of the telemedicine service should provide relevant information to draw conclusions regarding transferability of results in other contexts, thus facilitating the decision-making process

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