

Telemedicine in Italy: an overview of laws and guidelines

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Abstract

Although telemedicine has been known since 1970, in Italy it has never been considered a priority in the healthcare system until the SARS-CoV-2 pandemic.

In a couple of years, from 2020 to 2022, we assisted to a dramatic increase in the interest for telemedicine at all institutional levels and to a tremendous amount of guidelines and national laws that tried to set a precise framework for the correct implementation of this remote healthcare assistance.

In this article, we reported the most important laws and guidelines for telemedicine in Italy.

Introduction

In Italy, telemedicine has been known since the 1970s, but we had to wait until 2014 to have the first legal framework that disci-

plines more concisely this type of remote health assistance. From 2014 to 2020, telemedicine was sparsely used and not considered a priority in the healthcare system.

Due to the Covid-19 pandemic, the use of telemedicine applications and the making of telemedicine laws and guidelines increased. In this article, we reported the most important laws and guidelines for telemedicine in Italy.

Telemedicine: definition

The term “telemedicine” was coined in the 1970s in the United States to identify computer and telecommunication technologies, through which diagnostic services and medical care can be provided to patients located far from hospitals or clinics. The word “telemedicine” was introduced by Thomas Bird to refer to “the practice of medicine without the usual physical confrontation between physician and patient, using an interactive multimedia communication system”.¹

The term “telemedicine” is a neologism that comes from two words: telematics and medicine.²

In 1983, Conrath argued how telemedicine was “the use of telecommunications technology to improve care services in health care”.³ Forty years later, this statement makes even more sense, especially considering the current healthcare emergency.

The definition of telemedicine, however, has never been definitive and has evolved over the decades.⁴

In 1990, the European Union defined it as the “Integration, monitoring and management of patients, as well as education of patients and staff, using systems that provide ready access to expert advice and patient information, regardless of where the patient or information resides”.⁵

A few years later, in 1997, the World Health Organization (WHO) defined telemedicine as “the delivery of health care services when distance is a critical factor, whereby it is necessary for practitioners to use information and telecommunications technologies in order to exchange information useful for the diagnosis, treatment and prevention of disease”.⁴

Telemedicine is not an alternative way to cure, but an innovative tool to ensure care at any time and any distance. Covid-19 has accelerated the use and implementation of these systems: prior to the arrival of SARS-CoV-2, they were not as widespread as they are today.⁶

The many definitions highlight that this is an open and evolving discipline as it incorporates new technological advances and adapts according to changing healthcare needs and social contexts.

Some authors distinguish “telemedicine” from “telehealth”, the former being limited to the provision of services by physicians, the latter being a more general concept and covering the services of all health professionals, including nurses, pharmacists, and others.⁴

According to WHO, there are four elements that distinguish telemedicine:

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Key words: Telemedicine, connected care, home care, healthcare, telemedicine laws, telemedicine in Italy.

Funding: None.

Conflict of interest: The author declares no potential conflict of interest.

Availability of data and materials: All data generated or analyzed during this study are included in this published article.

Received: 24 October 2022.
Accepted: 22 November 2022.

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Licensee PAGEPress, Italy
Telemedicine International 2023; 1:242
doi:10.4081/tmi.2023.242

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- i) providing clinical care
- ii) overcoming geographical barriers by connecting users who are not in the same place
- iii) use various types of Information and Communications Technology (ICT)
- iv) having health improvement as the ultimate goal.⁴

Telemedicine services, according to Italian regulations, can be classified into the following categories:

- televisit
- teleconsultation
- telecooperation
- telemonitoring
- teleassistance (by other healthcare operators)
- telereferral⁷

The purpose of “telemonitoring” is to keep patients controlled, constantly, through devices that send data almost continuously to a telemedicine operations center. This center decides what healthcare services to deliver according to the information received and takes responsibility for it.

“Telecontrol” is still medical monitoring of the patient, but that is done periodically, not continuously, and does not necessarily involve sending data to an operations center. It can also be done very easily and inexpensively by several healthcare providers, again with medical coordination.

“Teleassistance” (TeleHealth) is the remote delivery of nursing and care services, it can be done by all healthcare providers, but is not a medical act. It provides a telemedicine center to support the activities that will increasingly be delivered in the patient’s home.

“Televisit” and “teleconsultation”, on the other hand, are both medical acts and can only be done by physicians. Teleconsultation is basically a consultation between physicians to agree on how to treat the patient, and the patient may not even be present at the consultation. There is also “telecooperation”, which is an exchange of ideas and information between different kinds of health professionals to better collaborate (for example to assist a patient).

It should be clarified that triage or telephone counseling, are not considered telemedicine services.

In addition, the use of Information and Communications Technology (ICT) tools for the online processing or sharing of data and/or health information, such as health information portals, social networks, forums, newsgroups, e-mail, or others, do not constitute telemedicine services *per se*.⁶

The areas in which telemedicine is applied are diverse and, depending on the field, take on different names such as, but not limited to:

- teleradiology
- telecardiology
- telepathology
- teledermatology
- clinical teleneurophysiology
- telerehabilitation
- etc.

Telemedicine services can be divided into four types:

- i) visits assimilated to any traditional diagnostic and/or therapeutic health act
- ii) acts that support the traditional visit, making it more accessible and/or increasing its efficiency and distributional equity
- iii) supplements to the in-person visit, more capable of adapting to changes in patients’ needs
- iv) visits that completely replace traditional visits, representing new diagnostic and/or therapeutic methods and/or techniques and implementing new care practices useful to patients.⁶

In some ways, these are new performance modalities that

introduce major changes in organizational processes. Therefore, to use new technologies in clinical care settings, one must have as a reference the existing scientific evidence on their effectiveness and appropriateness for their intended use. One cannot use tools for which effectiveness is not proven.

Brief history of telemedicine

Telemedicine, in its modern form, began in the 1960s-1970s, largely because of technological activities in the military and space fields.⁴

Before then, however, there were attempts to communicate and transmit medical information and referrals remotely. In the book “History of telemedicine” by Rashid L. Bashshur and Gary W. Shannon, it is reported that the first physician in Europe to use something like modern telemedicine was the Dutch cardiologist Willem Einthoven, who managed to transfer some electrocardiograms remotely back in 1905.⁸

Later, there were other attempts at remote communication to provide healthcare, such as many radio consultations from medical centers in Norway, Italy, and France in the 1920s, 1930s and 1940s to assist patients aboard ships and on remote islands.

Transmission of X-ray images began in the early 1950s in the United States, followed by similar experiments in Canada.⁹

Early examples of telemedicine involved the use of televisions to facilitate consultations, for example between specialists in psychiatric institutions and general practitioners and between a university hospital and an airport medical center.¹⁰

Telemedicine in general has proved revolutionary for the entire field of digital imaging, beginning with teleradiology through which physicians can examine images anywhere in the world and make diagnoses more quickly than at the time when examinations were seen only on film. Teleradiology was indeed one of the very first applications of telemedicine worldwide.⁴

Since the 2000s, with the advances in information technology, the advent of the internet, and the use of digital applications by the public, the use of telemedicine has increased. Since that time, remote care has held great potential to reduce variability in diagnosis and to improve clinical management and delivery of health care services worldwide, improving access, quality, efficiency, and affordability of care.⁹ Telemedicine has taken on a supportive role for the most disadvantaged or geographically isolated communities.

In recent years, several studies have shown how remote care can improve coordination, integration and continuity of care between the hospital and the local area, providing more opportunities for remote digital data sharing, communication and consultation, and also reducing the cost of healthcare utilization.

In addition, patients can overcome barriers to accessing healthcare services and benefit from improved monitoring and continuity of care, better management of their health, and independent living at home (especially for the elderly).¹¹

Telemedicine should go a step further and be deployed in emergencies where seconds matter and cardiac arrest is definitely the absolute emergency.¹²

Despite its great potential, telemedicine, at least until the arrival of Covid-19, had spread somewhat patchily around the world, with some countries ahead of others.

Although available for many years, these tools have in fact struggled to gain a foothold in the medical profession, among patients and health managers. The reasons, historically, are many, and include overly strict regulation for their use, reimbursement policies that are not always clear, limited evidence on their reliability, validity, and cost-effectiveness, privacy problems with data collected from patients, and interoperability problems between

regions and hospitals. These limits are worsened by the absence of an adequate technological framework, difficulties in incorporating these tools into daily clinical practice, and a general digital literacy gap on the part of health professionals and patients.

Telemedicine in Italy

Italy has a long tradition of telemedicine dating back to the early 1970s: during that period, the hospital of the Catholic University of Rome set up a teleconsulting service for poisoning. It was initially run on the telephone network and in local areas and then became a nationwide system.

In 1976, the University of Bologna introduced a prototype system for the acquisition and transmission

of Electrocardiograms (ECGs) via the telephone network. In the same year, CSELT (the Research Center of the Public Telecommunications Company) set up a teleconsulting service between the San Giovanni Hospital in Turin and the hospital at Susa (50 km away). In 1982 the Ministry of Research admitted the potential of telemedicine for improving the quality of healthcare and reducing its costs. For this reason, in the late 1980s, the Ministry conceived a national plan for research and training in telemedicine.¹³

In the official documents, telemedicine is defined as “a particular mode of healthcare assistance which allows diagnostic services and medical assistance to be provided in an integrated way, by overcoming the limits related to the geographical distribution of expertise and the distance between physician and patient”.

The national plan aimed to facilitate the transfer of telematic technologies to healthcare and to help biomedical companies to devise innovative solutions.¹¹

For years, the Italian army has supported the development of telemedicine for military operations and humanitarian missions, also as a tool for peacekeeping action.

Even the Italian Civil Defense (Protezione Civile), as part of its activities in emergencies and disaster response, has developed remote assistance models.

Finally, the International Radio Medical Center (CIRM), founded in 1935, fulfills the role of Italy's national Telemedicine Assistance Service (TMAS) as part of Search and Rescue (SAR) systems both at sea and for air navigation.¹⁴

But aside from this use in military and maritime settings, telemedicine to treat patients has never been widely and systematically used, at least until the outbreak of the Covid-19 pandemic.

As a matter of fact, until 2020 the only reference legislation for telemedicine in Italy was the “National Telemedicine Guidelines” approved in 2014.⁶ With the arrival of Covid-19, remote care accelerated, proving to be essential to manage patients at home who were unable to go to the hospital because they were in isolation or because hospitals were not accessible: within 14 weeks of the start of the pandemic, alongside the dematerialization of prescriptions for drugs by family physicians,¹⁵ more than 180 solutions for the remote treatment of Covid-19 and non-Covid-19 patients were introduced, adopting simple (e.g., telephone) or more elaborate technological solutions (new web platforms or chatbots).¹⁶

In 2020 and 2021 regulatory output to regulate remote patient care increased dramatically: new national indications and guidelines were approved (on top of the ones of 2014), telemedicine solutions were implemented in many regions, local health authorities and hospitals, and general practitioners and paediatricians organized themselves to assist patients remotely using dedicated software. In many cases, efforts have been made to use existing systems, as recommended by the “Telemedicine Now”

(Telemedicina Subito) program promoted by the ALTEMS laboratory of the Catholic University of Rome¹⁷ precisely to help health-care facilities implement telemedicine as quickly as possible. From the very first weeks, the Italian National Institute of Health (Istituto Superiore di Sanità) has been working to provide temporary guides on how to apply telemedicine in emergencies.¹⁸

Once the most critical phase of the pandemic had passed, the importance of telemedicine did not wane, however, but a national coordination was needed to implement it, coordinating the various regions, both from an application and interoperability point of view. With the PNRR approved in 2021, telemedicine became an essential pillar of health care with a dedicated fund of 1 billion euros. Regulatory production continued, regarding, on the one hand, the establishment of a national platform for telemedicine to whom regions must comply and, on the other hand, indications on the digital home care model.

The evolution of legislation in Italy on telemedicine

Since 2008, the European Commission has given special importance to telemedicine.

In fact, with the European Communication (COM-2008-689) “Telemedicine for the benefit of patients, health systems and society” of November 4, 2008, a series of actions were identified involving all levels of government, both in the community and in the individual member states, to encourage greater integration of telemedicine services in clinical practice, removing the main barriers that could hinder its full and effective implementation.¹⁹

Key recommendations included:

- building confidence in telemedicine services
- fostering its acceptance
- bringing legal clarity
- solving technical problems
- facilitating market development

With this Communication, the European Commission asked member states to clarify what obstacles needed to be overcome to implement telemedicine services. It then asked them to address issues such as accreditation, healthcare liability, reimbursement, privacy, and data protection. This European legislation paved the way for subsequent Italian legislative initiatives on telemedicine.

In fact, to arrive at the 2014 national guidelines we have already mentioned, there was a preparatory work of experience, documents, and research. Among the most important normative references of that period we have Decree No.179 of October 18, 2012²⁰ by which the Electronic Health Record, (Fascicolo Sanitario Elettronico, FSE), is established. Regarding the feasibility of health services in telemedicine, with the Law n.189 of 2012, containing “Urgent provisions to promote the development of the country through a higher level of health protection” it was indicated that the Complex Primary Care Units “operate in coordination and telematics connection with hospitals”. Therefore, already in 2012, the Law established that the telematics connection between UCCP (Complex Primary Care Units) and hospital structures “is used, and consequently also designed, as an ordinary working tool and does not provide for further authorization and accreditation procedures for it due to the telematics nature of the connection”.²¹

Other important documents are:

- the Pact for Health for the years 2014 to 2016²²
- the Pact for Digital Health²³
- the National Chronicity Plan (NCP)²⁴

The “Pact for health for the years 2014 to 2016” stated that Functional Territorial Aggregations (AFT) and Complex Primary Care Units (UCCP) must constitute the only forms of aggregation of primary care. These units were set up mainly for logistical-orga-

nizational reasons to cope with ongoing assistance. In the future, the function of the AFT will also be to share care paths, guidelines, auditing, and professional tools by integrating these networks both in the territory and in the hospital “through an adequate telematics network”. Furthermore, explicit reference is made to the “new information and telephone technologies”, especially the urgent emergency functions carried out by the operational centers in managing medical assistance requests. These technologies make it possible to optimize interventions and the management of high volumes of activities, to reduce the number of call reception centres, and to activate integrated and interacting operational functions at the regional level. This document provides a series of priorities, which must be implemented and subsequently monitored.²⁵

The purpose of the NCP is to activate all the necessary and useful initiatives to promote the dissemination of ICT tools and technologies to support chronicity, enhance the ability to access resources and promote innovation in the organization and management of health services. Referring to the specific use of telemedicine services in favor of chronically ill patients, the document indicates the health purposes to be achieved.

The Pact for Digital Health approved in the State-Regions and Autonomous Provinces Conference on June 26, 2016, stated that in reorganizing the National Health System (NHS) care network in all regions, digital innovation is an enabling and determining factor for the implementation of new care and organizational models. It referred to telehealth, teleconsultation, telereferral, tediagnosis, telemedicine and integration with the Electronic Health Record (EHR), one of the issues still under discussion today because, without this integration with EHR, there is no telemedicine.

The national guidelines on telemedicine (2014)

In 2012, to systematically employ telemedicine within the National Health Service and to implement the 2008 European Communication, a technical group on telemedicine was established at the National Health Council (Consiglio Superiore di Sanità) to:

- i) set the priority areas of application of telemedicine
- ii) analyze models, processes, and ways of integrating telemedicine services into clinical practice
- iii) define common taxonomies and classifications,
- iv) define aspects concerning legal and regulatory profiles and economic sustainability of telemedicine services.

The first national guidelines on telemedicine were approved by the general assembly of the National Health Council on July 10, 2012.

On February 20, 2014, an agreement was signed between the government, the regions and the autonomous provinces of Trento and Bolzano to approve the final draft of the national guidelines.⁶ The agreement represents a particularly relevant result considering the need to rethink the organizational and structural model of the National Health Service in our country, with respect to which the territorial spread of telemedicine services can be an important enabling factor.

One year later, in 2015, the Ministerial Decree n.70 was approved²⁶ (currently under review): it introduced the “regulation on quality, technological, structural and quantitative standards for hospital care” It’s about the process of structural reorganization and qualification of the hospital care network. In all this, the hospital integrates its function with other territorial services through the adoption of guidelines for the integrated management of Therapeutic and Diagnostic Programs (PDT) for complex and long-term diseases and “safe discharge” protocols for patients requiring continuity of care in the post-acute phase. To do all this,

the text says, regions will initiate telemedicine programs for the integrated management between hospital and territory, for specific clinical conditions where appropriate, including heart failure, chronic broncho pneumopathies, and diabetes.

In 2017, Telemedicine became part of the essential levels of care (Livelli Essenziali di Assistenza, LEA), as indicated in the last law of 2017 that updated them.²⁷ Paragraph 4 of Article 21 states, “In the context of territorial district care, interventions that favor the permanence of assisted persons in their own homes are privileged, through the activation of available formal and informal resources”.

As of 2018, all regions have implemented the 2014 guidelines with their own resolutions.

In 2019, the Ministry of Health introduced a working group on telemedicine, which included representatives from the regions of Lombardy, Veneto, Emilia Romagna, Piedmont and Tuscany, as well as the National Centre for Telemedicine and New Care Technologies of the National Institute of Health (Istituto Superiore di Sanità), which mapped regional experiences nationwide.

From guidelines to interim indications from the National Institute of Health

As anticipated in the preceding paragraphs, in 2020, with the outbreak of the Sars-Cov-2 pandemic and the lockdown that forced all people who did not require hospitalization for Covid-19 to stay at home, telemedicine suddenly became critical. But aside from the 2014 guidelines, there were no other references to help activating telemedicine immediately, with clear operational guidance. For this reason, the National Centre for Telemedicine and New Care Technologies of the National Institute of Health has produced important documents: report No. 12/2020 “Interim indications for telemedicine care services during the Covid-19 health emergency” dated April 13, 2020, and report No. 60/2020 “Interim directions for telemedicine care services in pediatrics during and beyond the COVID-19 pandemic” dated October 10, 2020.¹⁶ These reports emphasize that it must be the physician who identifies the diagnostic, therapeutic, and care activities that can be carried out remotely, with the technologies available and truly usable by the patient.

The guiding principles that physicians should therefore dwell on are:

- i) assessing the preconditions for enabling the service: checking connectivity at home and at the health care provider’s location, the accessibility of the service by the patient, data security, the possibility of providing prescriptions only in electronic format, the possible option of home delivery of medications
- ii) knowing how to choose, as physician, the operational solutions that offer the best guarantees of proportionality, appropriateness, effectiveness, and safety and in respect of the rights of the person
- iii) using appropriate interfaces for managing visit objectives, threshold values of certain parameters, and corresponding alarms
- iv) having different systems available to communicate with the patient (SMS, email with encrypted texts, video communication)
- v) realizing video calling quickly and easily, using web-based systems that do not require specific programs and with the support of medical devices that help detect key parameters (thermometer, scale, pulse oximeter, sphygmomanometer).

The 2020 and 2021 national directions

Following up all these *ad interim* indications, and all the autonomous initiatives that regions, hospitals and local health institutions did to provide remote health assistance, the Ministry of

Health, the regions and provinces of Trento and Bolzano shared the need to provide uniform indications throughout the country for the provision of telemedicine.

The working group on telemedicine, also integrated by experts and representatives of the national federations of health professions (FNOMCeO and FNOPI), therefore prepared the “National indications for the provision of telemedicine services”, which was adopted by agreement in the State-Regions Conference on December 17, 2020.²⁸

This document aims to provide guidelines to be adopted at the national level for the provision of certain telemedicine services such as televisit, teleconsultation, teleassistance and telereferral, so that the possibility of using telemedicine services finally represents a concrete element of organizational innovation in the care process. A year later, the document “Indications for the provision of telerehabilitation services by the health professions” was adopted with an agreement in the State-Regions Conference.²⁹

This document is intended to provide uniform indications for the entire Italian health system regarding telerehabilitation services by health professions, as well as the services that may result from the combination of these services with each other and with other health services.

Like rehabilitation, telerehabilitation finds application in all age groups, from the developmental age to the elderly, in different areas, including cognitive motor telerehabilitation, neuropsychological, occupational, communication, swallowing, behavioral, cardiological and pulmonary telerehabilitation. Due to their specificity aspects, these indications do not cover the areas of cardiologic and pulmonary telerehabilitation: the Italian Institute of Health is working on producing these specific documents.

The National Recovery and Resilience Plan (2021)

Two-thousand and twenty-one is the year of the National Recovery and Resilience Plan (NRRP), which allocates one of its missions, the sixth, to health, with a funding of 15.63 billion euros.³⁰ A large part of these investments is earmarked for the modernization of hospitals, the creation of community hospitals and the realization of the concept of home as a place of care, effectively marking a turning point in our country's healthcare, which in many cases has always been hospital-centric. Component 1 of Mission 6 of the NRRP has among its investments the one related to “Home as the first place of care and telemedicine”. Within this investment of 4 billion, one billion is dedicated to “Telemedicine in the care of patients with chronic conditions”. To achieve this goal, a working group on telemedicine was established at the Italian National Agency for Regional Healthcare Services (AGENAS), to define the “guidelines of digital model for the implementation of home care”.³¹

AGENAS, which in the meantime has also become the National Agency for Digital Health (Asd), published the notice for the National Telemedicine Platform (NTP) in March 2022 to collect expressions of interest for the submission of Public Private Partnership (PPP) proposals.³¹ The main objective of the NTP is to create a fundamental level of interoperability that ensures common standards for telemedicine services developed by the regions, enhancing what is already available in the landscape of local contexts, complementing or completing the portfolio of services.

Finally, it should be remembered that in 2021 the EU Regulation 2017/745 came into force: many apps and software programs will be equated with medical devices; therefore, some software used for telemedicine will require special validation and certification, which also considers the security of the data management and the risk for the patient.³²

Organizational guidelines (2022)

In April 2022, the “Organizational guidelines on the digital model for the implementation of home care” were approved: they define the model for implementing telemedicine services, and are part of the interventions aimed at strengthening territorial care.³³ In particular, the implementation of the various telemedicine services at the patient's home is envisaged, through the rationalization of the intake processes and the definition of related operational aspects.

The key structures and professional figures in the reorganization of territorial care, with an impact on the organization of home care, are mainly: the Community House (CoC), the General Practitioner/Paediatrician (GP/PLS), the Territorial Operations Centre (COT), the Family or Community Nurse (IFoC), the Continuity of Care Unit (UCA), and the palliative care network.

The main components of the home care organizational model, referred to in these guidelines, are:

- i) the home care service, which ensures continuity of care as specified by current national and regional regulations
- ii) the planning of home access by health professionals, developed over the entire week, according to the legislation, taking into account the clinical and care complexity of patients
- iii) the home care service integrated with remote telemedicine services.

The standards of territorial care Ministerial Decree n. 77)

In May 2022, “The regulation of models and standards for the development of territorial care in the National Health Service” was approved: home care is being redesigned, and includes telemedicine.³⁴ The chapter regulating remote care partly echoes what the organizational guidelines state, especially for telemedicine. The regulation elaborates on the contours of physician liability, Information Technology (IT) and security requirements, the importance of gathering informed consent from the patient, and ensuring that the patient (or caregiver) can use the tools for telemedicine. The decree introduces the concept of population stratification according to health needs (from level I, to the most complex, level VI) but does not specify for which levels telemedicine is deliverable. Potentially, for everyone.

The guidelines for the implementation of the Electronic Health Record

Also in May, ten years after EHR was first established, the guidelines for the implementation of the EHR were adopted: they provide, at the national level, a single strategic direction for initiatives to evolve the EHR and the systems integrated with it: by 2025, 85% of primary care physicians will have to feed the EHR, and all regions and autonomous provinces will have to adopt and use it by 2026.³⁵

The guidelines for telemedicine services

In November 2022 the guidelines for telemedicine services have become law.³⁶ They establish the technical requirements essential to ensure national homogeneity and efficiency in implementing telemedicine services.

The law specifies who are the recipients of telemedicine services, and this is the most important part of the entire law: to be eligible for telemedicine services, a patient must be eligible from a clinical, technological, cultural and autonomy point of view, or must have the availability of a caregiver, if necessary, in the use of telemedicine.

Since telemedicine is a remote service, certain technological capabilities, and endowments, as well as compatible clinical conditions for the service, are required. So, it is necessary to assess whether the patient is “enrollable” for this type of service.

The minimum services that the regional telemedicine infrastructure must deliver are:

- vi) televisit
- vii) teleconsultation
- viii) telemonitoring
- ix) telehealth/teleassistance.

For each regional telemedicine infrastructure, there should be one or more service centers, with technical tasks, and one or more provider centers, with healthcare tasks. The two entities, depending on the different territorial contexts, may also coexist in a single organization.

Another interesting aspect is the reference to basic and advanced telemonitoring intended for high-complexity patients.

For the first time, telemedicine guidelines are defined by national law. A step that will impress a dramatic acceleration in the use and implementation of this technology in Italy.

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