Telemedicine: Impact and Perspectives in Healthcare Delivery and Organization of the Italian National Health Service

European Review of Digital Administration & Law - Erdal
2023, Volume 4, Issue 1, pp. 153-167
ISSN 2724-5969 – ISBN 979-12-218-1128-5 – DOI 10.53136/9791221811285 11

*Telemedicine: Impact and Perspectives in Healthcare Delivery and Organization of the Italian National Health Service**

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ABSTRACT The paper discusses the development of telemedicine, the original core and pillar of digital health, in Italy. After having preliminarily framed the topic, also tracing its evolution at European and Italian levels, the analysis devotes ample space to the provisions of the National Recovery and Resilience Plan, for which e-Health and, in particular, telemedicine, represents one of the most important factors for the strengthening of the healthcare system. The reflections are twofold: the effects of remote care on the physician-patient relationship and the impact on service delivery and healthcare organization.

1. *Preliminary considerations*

Scientific-technological innovation affects almost every sphere of contemporary societies, touching also particularly sensitive aspects of our existence such as health.

E-Health is the new frontier both of medicine and healthcare services.[1] This paper will try to offer some insights into telemedicine,[2] one of its most significant forms.

As has been observed by scholars, telemedicine has "relocated" healthcare delivery to a virtual world[3] or, in any case, to a world whose physical location ceases to be relevant in whole or in part. The therapeutic relationship and the treatment, in fact, are characterized by telematic sharing of medical data and remote clinical interventions.

As a consequence of the Covid-19 pandemic, telemedicine has received an extraordinary boost. Hospitals and healthcare facilities were themselves places at risk of contagion, especially for frail individuals (and their families), but also for healthcare personnel: digital healthcare made it possible to provide care while respecting social distancing, thereby containing the spread of the virus.

In addition, coping with the pandemic took a lot of human, instrumental, and organizational resources away from "ordinary" healthcare, resulting in the reduction and suspension of many services. Telemedicine ensured alternative forms of service delivery, albeit with not a few critical issues.

This new way of "practicing medicine" has impacted both the doctor-patient relationship and the delivery and organization of health services, which are now trying to consolidate and systematize the innovations that have had an exceptional impetus in the emergency phase of the pandemic.

This institutional and technical evolutionary effort is also due to the fact that telemedicine is seen as one of the possible responses to the problems that the Italian National Health Service (NHS) has long suffered from, and that Covid-19 has laid bare and exacerbated: the scarcity of economic resources, which had been reduced over the years before the pandemic; the inequalities between the country's various regional healthcare services; criticalities in the healthcare delivery system, such as weakness

* Article submitted to double-blind peer review.

[1] In this regard see A. den Exter, *Editorial: EHealth Law: The Final Frontier?*, in *European Journal of Health Law*, 23, 2016, 227.

[2] Among the earliest scholars of telemedicine, with a specific attention to the public-law perspective, A.L. Tarasco, *La telemedicina per lo sviluppo della sanità del Mezzogiorno: una introduzione giuridica*, in *Rivista giuridica del Mezzogiorno*, 2010, 4, 1387. For an overview of the challenges, problems and opportunities related to this field see, recently, A. Mazza Laboccetta, *Telemedicina: sfide, problemi, opportunità*, in *federalismi.it*, 22, 2023, 135. On telemedicine as a new (and problematic) frontier of the right to health see L. Ferraro, *La telemedicina quale nuova (e problematica) frontiera del diritto alla salute*, in *Il diritto dell'informazione e dell'informatica*, 2022, 837.

[3] On this kind of "relocation" of healthcare services see A. Mazza Laboccetta, *Telemedicina: sfide, problemi, opportunità*, 137.

of the territorial services, which burdened hospitals with pressure that proved unbearable during the health emergency. As to the latter, the Covid emergency has highlighted the harmful consequences of some regions' decisions to reduce the network of home services, in connection with the downsizing of territorial ones, including those provided by general practitioners. This is one of the reasons behind the heavy impact of the pandemic on the hospital system, which risked collapse.[4]

Starting with framing the relevant context - what telemedicine is, what evolution it has had at the European and national level - the article will discuss in particular the reforms and interventions provided by the National Recovery and Resilience Plan (NRRP) of 2021 and its subsequent implementation.

Concluding remarks will address, firstly, some issues relating to how the development of telemedicine affects the physician-patient relationship and the role of the patient with respect to his or her own health.

Excluded from the discussion are profiles such as data protection[5] and the liability regime,[6] which are also part of the complex and articulated law, in the making, for telemedicine.[7]

The paper, moreover, will investigate the effects of telemedicine on healthcare supply and on the guarantees of care provided by the healthcare system, while also offering remarks on some issues relating to healthcare organization.

2. *Telemedicine: development and definitions*

By digital health (e-Health) is meant the use of information-and-communication-technologies (ICTs) tools and services in healthcare in order to support and improve prevention, diagnosis and treatment of diseases, monitoring and management of health as well as the lifestyles affecting it.[8]

It is therefore a heterogeneous set of instruments, partly because of the fluidity and pervasiveness of the technologies that make its "substrate". Indeed, scholars have pointed out that "giving an unambiguous definition of digital health constitutes a balancing act between oversimplification and incompleteness".[9]

Political-administrative processes that relate to e-Health should also be included in the definition.[10]

Telemedicine, which is, in a nutshell, remote diagnosis, treatment and monitoring of patients, is the first antecedent and original core of e-Health. In fact, its origins go back in time.[11]

Among the most cited examples is that of electrocardiographic consultations that the inventor of electrocardiography, physiologist Willem Einthoven, carried out over the telephone around 1906. Despite the conspicuous limitations of the technologies of the time, the idea of telemedicine was already conceived.

The first remote transmission of radiological images happened for the first time in 1950, in Pennsylvania. In 1959, the Nebraska Psychiatric Institute and Norfolk State Hospital developed the first interactive teleconsultation service. Finally, in the late 1960s, Boston International Airport and

[4] On these issues, one may refer to V. Molaschi, *Integrazione socio-sanitaria e COVID-19: alcuni spunti di riflessione*, in *Il Piemonte delle Autonomie*, 2020, 2.

[5] On the protection of privacy in the field of telemedicine see, *ex multis*, F.G. Cuttaia, *Lo sviluppo della telemedicina e i profili di tutela della privacy ad essa connessi*, in *Studi parlamentari e di politica costituzionale*, 2018, 201-202, 27. With special reference to data protection in healthcare data bases see M. Campagna, *Il regolamento europeo 679/2016 e l'utilizzo delle banche dati in sanità*, in A. Monica and G. Balduzzi (eds.), *Governare il cambiamento istituzionale e organizzativo nelle amministrazioni europee*, Pavia, Pavia University Press, 2019, 59 *et seq*. More in general, on data protection in the new world of artificial intelligence see F. Pizzetti, *Intelligenza artificiale, protezione dei dati personali e regolazione*, Turin, Giappichelli, 2018.

[6] For some issues of professional liability arising from the provision of services remotely see F. Aperio Bella, *The Role of Law in Preventing "Remote" Defensive Medicine: Challenges and Perspectives in the Use of Telemedicine*, in *federalismi.it*, 1, 2023, 305.

[7] In this regard see C. Botrugno, *Un diritto per la telemedicina: analisi di un complesso normativo in formazione*, in *Politica del diritto*, 2014, 639.

[8] For this definition see N. Matteucci and N. Marcatili, *E-health ed evoluzione dei sistemi sanitari. Un'analisi empirica sull'Europa*, in G. Vicarelli and M. Bronzini (eds.), *Sanità digitale. Riflessioni teoriche ed esperienze applicative*, Bologna, il Mulino, 2019, 51.

[9] In these terms see M. Campagna, *Linee guida per la Telemedicina: considerazioni alla luce dell'emergenza Covid-19*, in *Corti supreme e salute*, 2020, 601.

[10] See again N. Matteucci and N. Marcatili, *E-health ed evoluzione dei sistemi sanitari. Un'analisi empirica sull'Europa*, cit., 51.

[11] For a brief history of telemedicine, with a description of the first experiments and experiences, see C. Botrugno, *Telemedicina e trasformazione dei sistemi sanitari. Un'indagine di bioetica*, Roma, Aracne, 2018, 15.

Massachusetts General Hospital pioneered a teledermatology project involving the transmission of gray-scale images.

Last but not least, one must not forget the experiments that the National Aeronautics and Space Administration (N.A.S.A.) carried out, at the turn of the 1960s, to provide medical care to personnel on orbital missions and to monitor the physical condition of astronauts away from Earth.

The introduction of telemedicine went through ups and downs, including moments of failure. This first season of experimentation continued until the late 1980s, but did not yield the desired results due to the poor quality of the audio and video systems and the elementary operation of the transmission devices. For these reasons, as well as for issues of cost-effectiveness, telemedicine remained relegated to extraordinary interventions and failed to make its way into ordinary medical practice.

Telemedicine has developed mainly since the 1990s, thanks to the improvement of audio-video transmission instruments and the decreasing cost of ICTs.

At this time, particularly in the United States and Canada, there was a change in perspective. Medical trials in the field acknowledged the idea that telemedicine was no longer merely an extraordinary measure, but also a tool for addressing structural deficiencies in health services in specific territories, such as rural areas.

In the 1990s, remote medical intervention underwent conceptualization, and various notions of telemedicine were elaborated, including the WHO's definition of telemedicine (1997). According to it, telemedicine is "the delivery of healthcare services, where distance is a critical factor, by all healthcare professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interest of advancing the health of individuals and their communities".[12]

In Italy, the "National Guidelines" ("Telemedicina – Linee di indirizzo nazionali"), adopted through an Agreement stipulated in the State-Regions Permanent Conference on February 20, 2014, provided one of the first -and still- relevant definition of telemedicine: telemedicine is "a mode of delivery of healthcare services, through the use of innovative technologies, in particular Information and Communication Technologies (ICT), in situations where the health professional and the patient (or two professionals) are not in the same location". It implies "the secure transmission of medical information and data in the form of text, sound, images, or other forms necessary for the prevention, diagnosis, treatment, and subsequent follow-up of patients". The document also clarifies that telemedicine "does not represent a separate medical specialty": telemedicine services "should be equated with any diagnostic/therapeutic health service".

The 2014 Guidelines set the course for subsequent definitions.

According to the "National Directions for the Delivery of Telemedicine Services" ("Indicazioni nazionali per l'erogazione di prestazioni in telemedicina") of 2020, telemedicine "represents an innovative approach to healthcare practice by enabling the delivery of services at a distance through the use of digital devices, software, and telecommunication networks". Thanks to it, "it is possible to ensure the use of health services without the patient or caregiver having to travel to healthcare facilities".

The National Directions bear a classification of telemedicine services on the basis of their appropriateness, which outlines an interesting articulation of their relationship with traditional services. Four types of services are provided: services that can be assimilated to any traditional diagnostic and/or therapeutic healthcare service, representing an alternative delivery; services that cannot replace the traditional healthcare services but rather support them by making them more accessible and/or increasing their efficiency and distributive equity; services that supplement the traditional ones in varying proportions by making them more effective and more capable of adapting dynamically to changes in patients' care needs; services that are capable of completely replacing the traditional healthcare services, representing new diagnostic and/or therapeutic methods and/or techniques and implementing new care

[12] WHO, *A health telematics policy in support of WHO's Health-For-All strategy for global health development. Report of the WHO group consultation on health telematics*, 11-16 December 1997, Geneva, Switzerland.

practices useful to patients.

A more recent definition can be found in Ministerial decree 77 of 23 May 2022, "Regulation defining standard models for the development of territorial care of the National Health Service" ("Regolamento recante la definizione di modelli standard per lo sviluppo dell'assistenza territoriale del Servizio Sanitario nazionale"), according to which telemedicine is "a mode of delivery of sociomedical health-care services and services having health relevance at a distance, enabled by information and communication technologies, and used by a health professional to provide healthcare services to the patients (telemedicine health professional - patient) or consulting with and support services to other health professionals (telemedicine health professional - health professional)". Interestingly, according to this definition, telemedicine encompasses not only healthcare, but also integrated healthcare and social services.

3. *Brief references to the role played by the European Union in the development of telemedicine*

The European Union has played a significant role in the digitization of health services and, specifically, in the development of telemedicine. However, since this paper is focused on its evolution at the national level, suffice it to recall just a few key moments of the European push in this direction.

As scholars have duly noted, the European Union's attention to telemedicine traces back to three reasons of interest that have shaped its development:[13] reducing the economic burden of public healthcare, due primarily to chronic-degenerative diseases, which become more and more common with ever-lengthening life expectancy; fostering EU health mobility and allowing EU citizens to access healthcare services in any Member State; promoting technological innovation in e-Health to foster capital and economic growth. In this framework, the Covid-19 pandemic occurred and gave strong impulse to e-Health, including remote care, in the healthcare systems of Member Countries.

Given the States' competences on health,[14] the EU intervention has mainly consisted of *soft law*. The Union and, specifically, the Commission works on coordinating and integrating services, with the aim of creating an efficient European health governance[15] able to address health emergencies.

These efforts urge States in the direction of greater legal clarity to give institutions, practitioners, and patients confidence in the digital health system; encourage good practices and promote their spreading. Crucial in this framework is achieving interoperability across different health systems.

In a Communication of 2004,[16] the European Commission identified e-Health as an important tool for improving the full range of functions of the health sector: prevention, diagnosis, treatment, health surveillance, and lifestyle management. The EU has envisioned a European e-Health space and defined actions to be taken for its realization. And telemedicine was also part of this framework.

The European Commission specifically tackled the issue in 2008, with a Communication, which (already in the title: "telemedicine for the benefit of patients, healthcare systems and society") revealed high expectations.[17] The Union aimed at supporting and encouraging Member States by identifying and helping to overcome the main barriers to the wider use of telemedicine and by providing elements to build trust and foster

[13] For this analysis see A. Mazza Laboccetta, *Telemedicina: sfide, problemi, opportunità*, 143. On the European policies on e-Health see E. di Carpegna Brivio, *e-Health as a multilevel public policy*, in *European Review of Digital Administration & Law*, vol. 4, issue 1, 2023, 7.

[14] EU and Member States competences on health are established by art. 168(7) of the Treaty on the Functioning of the European Union. On the dynamic relationship between the European and the national competences see M. Guy, *Towards a European Health Union: What Role for Member States*, in *European Journal of Risk Regulation*, 4, 2020, 757 et seq.

[15] The topic of digital healthcare governance has recently been tackled, including with insights on its multilevel articulation, by F. Cimbali, *La governance della sanità digitale*, Padova, Wolters Kluwer/Cedam, 2023. More in general, see E. Mossialos, G. Permanand, R. Baeten and T. Hervey (eds.), *Health Systems Governance in Europe. The Role of European Union Law and Policy*, European Observatory on Heath Systems and Policies, Cambridge, Cambridge University Press, 2010.

[16] COM (2004) 356 final, Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions: e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area.

[17] COM (2008) 689 final, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society.

its acceptance.

Also significant was the Digital European Agenda of 2010,[18] in particular Key Action 13, which underlined the need for useful pilot actions to provide European citizens with secure access to their personal-health data and to widely deploy, as far as relevant here, telemedicine services, a goal to be achieved, according to this document, by 2020.

Telemedicine facilitates cross-border healthcare: from this point of view, the evolution of the issue has been marked by the EU's Cross-Border Healthcare Directive, passed in 2011,[19] aimed at ensuring that patients would be able to access safe and high-quality healthcare services (including telemedicine services) across the EU. The Directive, transposed into Italian law with Legislative Decree n. 38 of March 2014, gives EU citizens right to receive healthcare services in Member States other than their own, and to obtain reimbursement for the costs incurred.

In 2012, the Commission outlined the eHealth Action Plan 2012-2020,[20] which shows great awareness of the market potential of e-Health, including telemedicine, in particular as a tool for managing chronic diseases. Among others, it sets the goals to enhance interoperability of e-Health systems across Member States and improve exchange of patient information.

Institutions and health professionals' need for shared guidance led to the 2013 Telehealth Service Code of Practice for Europe, focused on collecting and systematizing best practices related to the use of telemedicine services, and on guaranteeing quality standards for the beneficiaries.

Also worth mentioning is the 2018 Communication on the Digital Transformation of Health,[21] dealing with the need to provide reforms and innovative solutions to the health sector, in order to achieve more resilient, accessible, and effective welfare systems, able to provide quality care to European citizens. The Commission sees digital health and care solutions as means to enhance the well-being of millions of citizens. In fact, according to the Communication, such tools bring numerous benefits: supporting continuity of care across borders; promoting health and preventing disease, including in the workplace; supporting the reform of health systems and their transition to new care models, centred on people's necessities; enabling a shift from hospital-centred systems to more community-based and integrated care structures. The latter is one of the main reasons for Italy's expansion of telemedicine.

As anticipated, the pandemic has brought health to the center of European policies, despite the noticeable (and unchanged) limits of the Union's competence in the field. In the words of Ursula von der Leyen, President of the European Commission, speaking at the World Health Summit (25 October 2020), "We cannot wait for the end of the pandemic to repair and prepare for the future. We will build the foundations of a stronger European Health Union in which 27 Countries work together to detect, prepare and respond collectively".

In order to face the Covid-19 health crisis, the Union adopted the EU4Health programme (2021-2027), established by EU regulation 2021(522).[22] The programme, supported by an unprecedented financial effort in the health sector,[23] has four general objectives (art. 3), which can be summarized as follows: improving and fostering health in the Union; protecting people from serious cross-border threats to health; improving the availability, accessibility and affordability of medical products, medical devices and crisis-relevant products in the Union; strengthening health systems by improving their resilience and

[18] COM(2010)245 final, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A Digital Agenda for Europe.

[19] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare.

[20] COM(2012) 736 final, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century.

[21] COM(2018) 233 final, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society.

[22] Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014.

[23] The investment is € 5.3 billion budget during the 2021-27 period.

resource efficiency.

General objectives are articulated into specific ones, which also devote attention to e-Health and to the digital transformation of healthcare systems, especially as far as the creation of a European health-data space is concerned (art. 4, point f). The "possible eligible actions" referred to e-Health are: "Supporting the optimal use of telemedicine and telehealth, including through satellite communication for remote areas, fostering digitally-driven organisational innovation in healthcare facilities and promoting digital tools to support citizen empowerment and patient-centred care" (Annex I, point 6, lett. d); "Actions to support e-Health, such as the transition to telemedicine and at-home administration of medication" (Annex I, point 6, lett. i).

With Next Generation EU and, in particular, through the Recovery and Resilience Facility (RRF),[24] the EU is pursuing two fundamental goals: mitigating the social and economic impact of the pandemic; building a greener and more digital Europe.[25] Thanks to this instrument, EU Countries receive financing on the basis of their national recovery and resilience plans,[26] which outline the reforms and investments they will implement by the end of 2026.[27]

The RRP and the follow-up measures take into account the implementation of the European Pillar of Social Rights.[28] "Health, and economic, social and institutional resilience, with the aim of, *inter alia*, increasing crisis preparedness and crisis response capacity" is also one of its columns.

The goal of modernizing and strengthening healthcare services is a priority for the Italian NRRP. As will be illustrated in this paper, in Italy e-Health and, in particular, telemedicine are an essential tool for the transformation of the NHS.

4. *Evolution of telemedicine in the Italian NHS: a general overview*

In order to both better frame the meaning of telemedicine in the Italian NHS, and to provide some concluding remarks it is important to recall some of the stages that have marked the "evolution" of telemedicine in the Country.

First of all, the aforementioned National Guidelines of 2014 gave an initial definition. The purpose of the Guidelines was to provide, after a season of multiple experimental initiatives in the territory, "the unified national reference for the implementation of telemedicine services", with a view to move from an experimental to a structured logic. The document thus aimed to provide a shared governance model for the various actions, and to harmonize guidelines and application models to the benefit of services' interoperability.

The Guidelines provided a classification of telemedicine services,[29] later taken on, specified and supplemented by the subsequent National Directions for the Delivery of Telemedicine Services of 2020 (Indicazioni nazionali per l'erogazione di prestazioni in telemedicina),[30] whose contents will be explained shortly.

The Guidelines of 2014 gave important guidance on the organization of telemedicine services, information and training, integration of telemedicine into the NHS, and so on.

Another important step toward the

[24] Regulation (EU) 2021/241 of the European Parliament and of the Council of 12 February 2021 establishing the Recovery and Resilience Facility.

[25] The amount of resources put in place to boost growth, investment and reforms amounts to 750 billion euros, of which more than half, 390 billion, are grants.

[26] For an overview of the various Member States' recovery and resilience plans see the reports published on the *Italian Labour Law e-Journal*, 1s/2022.

[27] The plans had to allocate at least 37% of their budget to green measures and 20% to digital ones.

[28] See the European Parliament Resolution of 19 January 2017 on a European Pillar of Social Rights (2016/2095(INI)), and COM(2021) 102 final, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: The European Pillar of Social Rights Action Plan.

[29] According to the Guidelines of 2014, the main branches of telemedicine are:
i) Specialist telemedicine, which is divided into:
- Televisit: health act in which the physician interacts remotely with the patient (perhaps with the support of a care-giver),
- Teleconsultation: remote consulting activity between physicians, without the physical presence of the patient, about diagnosis, choice of appropriate treatment,
- Telecooperation health care: an act consisting of assistance provided by one physician or other health care provider to another physician or health care provider (the term is also used for counseling provided to emergency responders);
(ii) Telehealth: a telemedicine activity carried out at the primary care level. Among the activities carried out under telehealth is telemonitoring.
(iii) Telehealth: a social welfare system for taking care of the elderly or frail person at home.

[30] For example, according to the Directions of 2020, telemedicine also includes telereferral and telephone triage.

development of telemedicine in Italy was taken with the 2016 "National Plan for Chronic Care" ("Piano nazionale delle cronicità"), the outcome of an Agreement sanctioned in the State-Regions Conference on September 15, 2016, in which telemedicine, together with teleassistance, were seen as instruments to facilitate management of patients' homecare, including chronic ones.

However, the European Commission's "Report State of Health in the EU - Italy. Health Profile of 2019"[31] revealed that the digitization of the NHS had advanced at different pace across Italian regions and that since the approval of the 2014 Guidelines "little" had been done to implement the various opportunities.

The insufficient progress of digital health and, specifically, telemedicine was made manifest during the Covid-19 pandemic, which called attention to the need for adequate territorial healthcare and a strong hospital-territory relationship, and highlighted the importance of remote-care models (and of their uniformity). During the health emergency, the NHS was called upon to provide services to an unprecedented number of persons obliged to go into quarantine or "trust" isolation. It was necessary to counter the spread of Covid-19 and to ensure, as far as possible, the continuity of care and assistance to which people are entitled. Moreover, people who were isolated in their own homes as a result of necessary social-distancing regulations could also need care and assistance.

Very significant in the evolution of telemedicine are the 2020 Reports of the Istituto Superiore di Sanità (ISS), that is the main center for research, control and technical-scientific advice on public health in Italy, which provided *interim* directions for telemedicine healthcare services to both adult patients and pediatric patients in their early childhood and developmental age.[32] These documents supported the implementation of remote services during the Covid-19 emergency, offering guidance, identifying operational issues and proposing solutions that were evidence-based and, at the same time, also easily employable in practice.

2020 is also the year of the National Directions for the Delivery of Telemedicine Services (Indicazioni nazionali per l'erogazione di prestazioni in telemedicina), adopted by a State-Regions Conference Agreement on December 17, 2020, which marked the "full-fledged" entry of telemedicine into the NHS,[33] setting rules for the provision of remote healthcare services as to payment, prescriptions, bookings, reporting.

Concerning payments, the Agreement has established that the national/regional regulatory framework on access to the various essential levels of care granted by the NHS, together with the remuneration/tariff system in force for their supply, including the rules for any cost-sharing, also applies to all health services provided remotely.

On November 18, 2021 an Agreement in the State-Regions Conference adopted the "Directions for the provision of telerehabilitation services by the health professions" ("Indicazioni nazionali per l'erogazione di prestazioni e servizi di teleriabilitazione da parte delle professioni sanitarie"). This document has provided uniform directions for the entire Italian healthcare system and especially in the matters of telerehabilitation services by health professions, physicians and psychologists (collectively referred to as "health professionals"), alone or in combination with one another and with other health services.

As already said, the pandemic has marked an acceleration in the evolution of telemedicine, whose development has been boosted by the National Recovery and Resilience Plan (NRRP) of 2021.[34] The Plan defines goals, reforms and investments that Italy intends to carry out through Next

[31] See the OECD/European Observatory on Health Systems and Policies, *Italy: Country Health Profile 2019*, State of Health in the EU, OECD Publishing, Paris/European Observatory on Health Systems and Policies, Brussels, 2019.

[32] See the ISS Covid 19 Report n. 12/2020 of April 13, 2020, "*Interim* provisions for telemedicine healthcare services during the Covid-19 health emergency", and the ISS Covid-19 Report n. 60/2020 of October 10, 2020, "*Interim* provisions for telemedicine healthcare services in pediatrics during and beyond the Covid-19 pandemic".

[33] For this observation see L. Fassari, *La telemedicina entra a pieno titolo nel Ssn. Ecco le linee guida del Ministero con le regole per visite, consulti, referti e teleassistenza* (15 December 2020), in *quotidianosanità.it*.

[34] For an analysis of the NRRP provisions on telemedicine see N. Posteraro, *La telemedicina*, in V. Bontempi (ed.), *Lo Stato digitale nel Piano Nazionale di Ripresa e Resilienza*, Roma, Roma TrE-Press, 2022, 201.

Generation EU funds to mitigate the Covid-19 socio-economic impact and to make Italy a greener, more digitalized and more inclusive Country, with a dynamic and stronger economy. It also aims at enhancing the national health welfare through policies of reform and massive economic contribution after years of defunding.[35] The Plan, in fact, has a specific Mission, N. 6, devoted to "Health".[36]

As the NRRP itself points out, the pandemic has highlighted that health is an area that requires "significant digital upgrading".[37] Digital health is a "cross-cutting" area of action that characterizes both of the components of Mission 6 of the Plan, entitled "Health",[38] which are 1) "Proximity networks, facilities and telemedicine for territorial care" (M6C1) and 2) "Innovation, research and digitalization of the National Health Service" (M6C2).

The first component aims at strengthening healthcare services provided in the territory through the enhancement and creation of territorial facilities and units (such as the Community Homes and Community Hospitals), the reinforcement of home care and more effective integration with all social and health services. It also deals, as the title suggests, with telemedicine, whose implementation is essential for the realization of the other NHS priorities.

The goals of the measures under the second component are the renovation and modernization of existing technological and digital facilities; the completion and dissemination of the electronic health record; the improvement of the capacity for the delivery and monitoring of the essential levels of healthcare (the so called, in Italian, "Lea sanitari"[39]) through more effective information systems. As to the latter, the NRRP action is aimed at enhancing the Nuovo Sistema Informativo Sanitario (NSIS), a new health information system consisting of a technological infrastructure managed by the Ministry of Health, which is also conceived as a support for the policy and planning functions relating to health services.

Significant resources are also allocated by the Plan to scientific research and to foster technology transfer, as well as to strengthen the skills and human capital of the NHS, including training of health staff.

The second component of the NRRP also returns to deal with telemedicine through the funding of the National Platform of Telemedicine.

The next paragraph is devoted to analyzing in detail the provisions regarding telemedicine. Before explaining them, it must be remembered that, for "Health", as for the other Missions of the Plan, the components of the State action bear both funding aimed at specific interventions and reforms that are needed for the progress of the Country.

4.1. *In particular: reforms and interventions on telemedicine provided by the National Recovery and Resilience Plan and by subsequent regulations*

The general goals listed in Mission 6 on "Health" by the NRRP with respect to telemedicine are: a) developing telemedicine and overcoming the fragmentation and lack of homogeneity of health services offered in the territory; b) developing advanced telemedicine solutions to support home care.

As seen, telemedicine is addressed in both of the components of the Mission under analysis.

The first one, "Proximity networks, facilities and telemedicine for territorial healthcare" (M6C1), makes evident from its very title that telemedicine is the "backbone of strengthening territorial healthcare":[40] telemedicine, in fact, shifts the center of gravity of healthcare intervention from the hospital to patients' homes.[41]

[35] On the Plan's push in the direction of revitalizing national health welfare see L. Chieffi, *Una nuova stagione per I diritti sociali? La spinta offerta dal* Recovery Fund *per il rilancio dei welfare sanitari*, in *BioLaw Journal – Rivista di BioDiritto*, 2021, 4, 3. More specifically, on the reforms and interventions of the Plan in the healthcare field see A. Pioggia, *La sanità nel Piano Nazionale di Ripresa e Resilienza,* in *Giornale di diritto amministrativo*, 2022, 2, 165.

[36] The Plan is articulated into six Missions: Digitization, Innovation, Competitiveness, Culture and Tourism; Green Revolution and Ecological Transition; Infrastructure for Sustainable Mobility; Education and Research; Inclusion and Cohesion; and Health. Every Mission is made up of various components.

[37] See page 18 of the NRRP.

[38] For the provisions on "Health" see pages 225 et seq. of the NRRP.

[39] On the meaning of the "Lea sanitari" within the Italian NHS see section 5.2.

[40] See page 18 of the NRRP.

[41] For this comment see C. Botrugno, *La diffusione dei modelli di cura a distanza: verso un "diritto alla telesalute"?,* in *BioLaw Journal – Rivista di BioDiritto*, 2014, 1, 164.

In this context Reform 1, entitled "Proximity networks, facilities and telemedicine for territorial healthcare, and national health, environment and climate network",[42] has provided for the "definition of homogeneous structural, organizational and technological standards for territorial healthcare and the identification of the facilities deputed to it", a provision that has been implemented by the aforementioned Ministerial decree No. 77 of May 23, 2022. In this decree, telemedicine is integrated into the new design of the territorial healthcare system.

Another important regulation in which telemedicine fits into the context of the interventions envisaged in the NRRP for the reform of territorial care is the Ministerial decree of April 29, 2022 ("Approvazione delle linee guida organizzative contenenti il 'Modello digitale per l'attuazione dell'assistenza domiciliare'"), that approves the organizational guidelines containing the "Digital model for the implementation of home care". The guidelines define a reference model for the realization and development of the various telemedicine services in the home setting, through the identification of innovative processes for taking care of the patient at home and the definition of the related operational aspects and the enhancement of multiprofessional and multidisciplinary collaboration between different professionals.

Finally, with the decree of September 21, 2022 ("Approvazione delle linee guida per i servizi di telemedicina - Requisiti funzionali e livelli di servizio"), the Ministry of Health has approved guidelines for the functional requirements and service levels of telemedicine. The guidelines lay down technical and service standards for telemedicine healthcare delivery to be widespread and homogeneous across the territory.

As to interventions, the NRRP considers home care and telemedicine in the same investment line (Investment 1.2: "Home as the first place of care and telemedicine"). This makes it again clear that the Plan focuses on telemedicine as a tool for enhancing home care. The use of telemedicine enables continuity of care and is functional to supporting patients with chronic diseases.[43]

Telemedicine is conceived as a means that can, firstly, contribute to the reduction of geographic and territorial gaps through the harmonization of standards of care provided by technology; secondly, ensure a better "care experience" for the assisted; thirdly, improve the efficiency levels of regional health systems through the promotion of home care and remote monitoring protocols.

The NRRP intervention takes the form of funding for telemedicine projects proposed by regions. There are no limits as to what clinical areas can be covered. A wide range of functionalities along the entire pathway of prevention and care can be promoted: tele-care, tele-consultation, tele-monitoring and tele-referral.[44]

Among the conditions set for funding regional projects is their integration with the electronic health record: this provision builds a "bridge" between telemedicine and the other pillar of digital health in the NRRP.[45]

In addition, projects have to achieve quantitative performance targets related to the main goals of telemedicine and the National Health System, as well as to ensure that their development results in the effective harmonization of health services. Moreover, the NRRP clarifies that projects that insist on multiple regions, leverage existing successful experiences, and seek to build true telemedicine platforms that are easily "scalable" will be privileged.

Telemedicine is also addressed in the second component of the NRRP Mission on

[42] According to Reform 1, the NRRP also aims to implement a new institutional arrangement for health, environmental and climate prevention, in line with the "One-Health" approach. The "One-Health" philosophy is a healthcare model, based on the recognition that human health, animal health and ecosystem health are inextricably connected.

[43] The Decree of the Ministry of Economy and Finance of August 6, 2021 has provided within this investment a specific sub-investment 1.2.3, "Telemedicine for better support of chronic patients". It consists of one billion euro.

[44] For the definition of these sub-categories within telemedicine services see the Ministry of Health's 2014 Guidelines and the subsequent 2020 National Directions.

[45] For a comprehensive analysis of the development of the electronic health record in Italy see N. Posteraro and S. Corso, *The Italian Electronic Health Record*, published in this issue of *Erdal*; Id., *Il fascicolo sanitario elettronico*, in V. Bontempi (ed.), *Lo Stato digitale nel Piano Nazionale di Ripresa e Resilienza*, 187; Id., *La digitalizzazione della sanità in Italia: uno sguardo al Fascicolo Sanitario Elettronico (anche alla luce del Piano Nazionale di Ripresa e Resilienza)*, in *federalismi.it*, 2021, 26,189.

"Health", regarding "Innovation, research and digitalization of the National Health Service" (M6C2), which provides for the creation of a National Telemedicine Platform where demand and supply of telemedicine services provided by accredited entities can meet.[46] The purpose of the Platform is to promote common standards for telemedicine services developed by the regions in order to allow their interoperability and to improve their quality. The initiative aims at facing the challenge of overcoming inequalities in the provision of services and care among different territorial areas.

The entity responsible for the design, implementation and management of the enabling services of the National Telemedicine Platform has been identified as the Agenzia nazionale per i servizi sanitari regionali (Agenas), that is the National Agency for Regional Health Services. According to the Report on the status of implementation of the National Recovery and Resilience Plan of May 31, 2023, the procedure carried out by Agenas for selecting proposals for Public Private Partnership was concluded and a contract was signed.[47]

5. *Concluding remarks: some considerations on the impact of telemedicine on the doctor-patient relationship*

Digital healthcare affects the doctor-patient relationship in many ways.[48] The ambivalence that characterizes all technological progress[49] also arises with respect to this issue.

Telemedicine offers the possibility of treatment from afar, without being present, which allows for patient care anytime and in any place, but sacrifices the value and meaning of the in-person interaction, itself having therapeutic relevance.[50]

As early as 2006, the National Bioethics Committee expressed concern about the "loss of full communication" between the physician and the patient and, in particular, the "loss of that group of objective signs (general look of the patient, posture, deambulation, objective examination by inspection, palpitation, auscultation, percussion, etc.) which, together with elements of emotive perception, guide the diagnostic process in the context of the correct medical semeiotic on the physicality of the person".[51]

The National Guidelines of 2014 have clarified that telemedicine does not replace traditional healthcare in the personal doctor-patient relation, but rather complements it to potentially improve effectiveness, efficiency and appropriateness. However, the risks of "dehumanization" has been nevertheless stressed by several authors. Scholars have highlighted a potential contradiction between the trend toward a more humane, "dialogic" medicine, which is embodied, for instance, in the legislation on informed consent,[52] and the "robot-doctor".[53]

Generally, when speaking about privacy, one thinks of issues concerning data protection. In the field of telemedicine, management of health data, which is necessary to make healthcare delivery itself possible, is particularly complex because of the large amount of data transmitted (through texts, images, audio, video, and so on) and the variety of subjects that can potentially access them.

[46] The above-mentioned sub-investment 1.2.3, "Telemedicine for better support of chronic patients", consisting of 1 billion euro, has been allocated by the decree of the Ministry of health of April 1, 2022, in two lines: 250 million for the implementation of the National Telemedicine Platform and 750 million for regional services.

[47] On February 15, 2023, a contract was signed between AGENAS and the Temporary Business Grouping (RTI) Engineering Ingegneria Informatica S.p.A. and Almaviva S.p.A. for the concession awarding of the "Design, Implementation and Management of the Enabling Services of the PNRR National Telemedicine Platform".

[48] On the metamorphosis of the doctor-patient relationship resulting from the use of telemedicine see C. Casonato, *Telemedicina. Vantaggi e rischi della telemedicina assistita da intelligenza artificiale*, in E. Rigo (a cura di), *Per una ragione artificiale. In dialogo con Lorenzo d'Avack su Costituzione, ordine giuridico e biodiritto*, Roma, Roma TrE-Press, 2023, 219, and C. Botrugno, *Telemedicina e trasformazione dei sistemi sanitari. Un'indagine di bioetica*, 133.

[49] On such ambivalence see A. Simoncini, *Sovranità e potere nell'era digitale*, in T.E. Frosini, O. Pollicino, E. Apa and M. Bassini (eds.), *Diritti e libertà in Internet*, Milan, Mondadori education, 2017, 26.

[50] See F.E. Brozzetti, G.M. Cannella and A. Randazzo, *Telemedicina, teleassistenza e intelligenza artificiale in un sistema socio-sanitario di prossimità: nuovi paradigmi etico-giuridici*, in *Rapporto DIPAB 2022*, *L'integrazione socio-sanitaria e il diritto delle regioni*, Turin, Giappichelli, 2022, 277.

[51] See the document of the National Bioethics Committee, *Ethics, health and new information technologies*, 21 April 2006, 49-50.

[52] In Italy, the matter is governed by Law 217 of 22 December 2019, on informed consent and advance treatment directives.

[53] See R. Balduzzi, *Cinque cose da fare (e da non fare) in sanità nella (lunga e faticosa) transizione verso il post-pandemia*, in *Corti supreme e salute*, 2020, 353.

However, such issues are not discussed in these concluding remarks, and the impact of technologies on privacy is considered from another perspective: the risk of affecting the specific confidentiality and intimacy of the doctor-patient relationship that allow the individual, in a situation of vulnerability due to illness, to open up in person, which is very important both from a therapeutic and a human point of view.

Both the National Directions of 2020 and the Ministerial Decree on telemedicine requirements of September 2022 devote more attention to these aspects: for instance, it is provided that the televisit can never be the sole means for conducting the doctor-patient relationship, nor can it automatically be considered a substitute for the first in-person medical examination.

However, these provisions do not seem able to dispel all doubts. Is it possible to recreate the "safe place" of the physician-patient relationship in the virtual world, in the "non-place" of telemedicine,[54] in that "distance" that nevertheless remains in spite of (or because of) the use of technologies?

Another issue deals with the trend toward combining digital tools for telemedicine and artificial intelligence techniques.

Telemedicine and artificial intelligence represent a combination that has great potential for transforming treatment pathways and the organization of health services.[55] The use of algorithms to support medical decisions can certainly enable the identification of highly effective disease-management strategies and therapies and equips the physician with an uncommon predictive ability.

Nevertheless, the processing of algorithms, especially the more advanced ones, is not always intelligible and there can be grey areas in the operation: this is the issue of the so called "black box".[56] That is, there are cases in which programmers themselves are unable to understand the steps taken by the algorithm nor its future developments, a problem that concerns physicians all the more, as they are certainly not computer technicians. It was therefore pointed out that difficulties in understanding the reasons and processes of certain algorithms can undermine confidence in such tools even in those who interpret them, i.e. the physician, who is required to give complete information to patients, as well as in patients themselves, thus ultimately undermining the legitimacy of clinical decisions.[57]

5.1. *New and old inequalities generated or exacerbated by digital health. Further insights into the physician-patient relationship*

Telemedicine can certainly be said to be a tool of equality in that it can bring care and treatment to those who would otherwise be deprived of them due to the lack or scarcity of healthcare personnel or nearby facilities. Think of the case of those who live in remote locations or otherwise without health services.

However, the use of increasingly advanced technologies also brings problems from the point of view of accessibility to them. That is, at an individual level, the critical issue of the exclusion of those who do not have access to, or are unable to consciously use the technologies on which digital services depend. This is the so-called digital divide, which may be caused by multiple factors − geographical, economic, gender, cultural, religious, language and generational − often mutually influencing each other.

It can be observed that there is a tragic "circularity": the existence of disadvantaged situations underlies the digital divide, which in turn worsens existing inequalities.[58] Think of the elderly and the poor (often, moreover, the two situations coincide) or of young people living in disadvantaged contexts: age, frailty, lack of resources might make it impossible or difficult to access online

[54] "How to recreate in the non-place mediated by technological tools, however clever, that safe space necessary for a vulnerable subject to expose himself to medical evaluation?": this is the question posed by F.E. Brozzetti, G.M. Cannella and A. Randazzo, *Telemedicina, teleassistenza e intelligenza artificiale in un sistema socio-sanitario di prossimità: nuovi paradigmi etico-giuridici,* cit., 278.

[55] For an analysis of such potentials see A.E. Tozzi, *Il connubio tra telemedicina e intelligenza artificiale per un salto di qualità nelle cure*, in *Monitor*, 2021, 46, 39 *et seq*.

[56] The reference is to the book by F. Pasquale, *The Black Box Society*, Cambridge, MA, Harvard University Press, 2016.

[57] In this regard see M. Fasan*, La tecnologia ci salverà? Intelligenza artificiale, salute individuale e salute collettiva ai tempi del Coronavirus*, in *BioLaw Journal – Rivista di BioDiritto*, 2020, 1, 682-683.

[58] Hints on this aspect can be read in E.Mª Menéndez Sebastián and Javier Ballina Díaz, *Digital Citizenship: Fighting the Digital Divide*, in *Erdal*, 2/2021, Issue 1, 155.

services, which reverberates negatively on the condition of the person, aggravating his or her difficulties.

The NRRP has funding lines aimed at overcoming the digital divide,[59] but one cannot help but wonder whether this is enough to address the complexities that arise from accessing and using digital health.

The guidelines of the Ministerial decree of September 2022 show a more mature awareness of these issues than in the past and take into more consideration the "eligibility"/"enrollment" of the patient "from the clinical, technological, cultural point of view and autonomy or availability of a caregiver, if necessary, in the use of telemedicine services" and the "digital literacy of the patient and/or caregiver".

Clinical eligibility is at the sole discretion of the physician. Regarding the other profiles, there are quite a few uncertainties about the parameters for evaluating such conditions and situations and the subjects in charge of this assessment.

Finally, one should not overlook the case of those who do not adhere to the prevailing digital society model of information, which in its totalizing dimension affects everyone's freedom. Here, too, there are consequences in terms of exclusion and discrimination.[60]

As to this aspect, the doctor-patient relationship, within which one can assess who is suitable for telemedicine services and who is not, comes again into consideration. Cultural eligibility does not only mean the ability to know how to use certain ICT tools; the concept can also encompass cultural attitudes toward them.

Based on the above considerations, the silence in the September 2022 Decree on the patient's informed consent for activation of telemedicine services, which was instead provided for in both the 2014 and 2020 Guidelines and Directions,[61] is incomprehensible.[62]

5.2. *Telemedicine and the essential levels of care (the so called "Lea sanitari")*

Digital health also deeply affects the supply of healthcare services, as shown by the depicted evolution of telemedicine. In assessing its impact on the latter a first issue concerns its relationship with the "essential levels of care", in Italian the so-called "Lea sanitari", which are the services and benefits that the National Health Service is required to provide to all citizens, free of charge or upon payment of a participation fee (ticket).[63]

The "Lea sanitari" or, simply, "Lea" are the concretization in healthcare of the Constitutional provision relating to the "determination of the essential levels of services and benefits concerning civil and social rights that must be guaranteed throughout the national territory". By virtue of this competence, provided by second paragraph, letter m), of article 117 of the new Title V of the Italian Constitution, the State legislature has a fundamental tool to ensure throughout the Country an adequate uniformity of treatment in terms of the rights of all subjects, including the right to health.[64]

[59] See investment 1.7, also with reference to the population groups most exposed to this issue.

[60] The issue has been studied, for example, with reference to those who do not adhere to the technological model that underlies the smart-cities phenomenon: see F. Fracchia and P. Pantalone, *Smart City: condividere per innovare (e con il rischio di escludere?)* (25 novembre 2015), in *Federalismi.it*, 22, 2015, in partic. 23 *et seq*. More generally, on the discriminations that originate in contemporary algorithmic societies may we refer to V. Molaschi, *Algoritmi e discriminazione*, in M. Andreis, G. Crepaldi, S. Foà, R. Morzenti Pellegrini and M. Ricciardo Calderaro (eds.), *Studi in onore di C.E. Gallo*, Turin, 2023, vol. I, 355, and in *Fundamental rights*, https://fundamentalrights.it, 2022, 2, 19.

[61] On this point the 2020 National Directions stipulate that, in order to access the telemedicine healthcare service, the patient must give express informed consent to telemedicine healthcare treatment after being made aware by the physician about the following: the precise manner in which the service is to be performed, the objective of the service, the typical benefits and risks of providing telemedicine services, as well as how his or her personal data are managed, how to contact the data controller or processor, and what his or her rights are as a data subject.

[62] See C. Anderlini, *Approvate le linee guida per i servizi di telemedicina, il decreto del ministero della salute* (November 24, 2022), in studiolegalestefanelli.it/approfondimenti/linee-guida-telemedicina, who considers this lack of provision a "major absence", which, in any case, does not rule out the possibility that this tool could still be implemented by regions and autonomous provinces.

[63] The literature on the essential levels of care is very extensive: for a general overview see C. Tubertini, *Pubblica amministrazione e garanzia dei livelli essenziali delle prestazioni. Il caso della tutela della salute*, Bologna, Bononia University Press, 2008. Moreover, may we refer to V. Molaschi, *I rapporti di prestazione nei servizi sociali. Livelli essenziali delle prestazioni e situazioni giuridiche soggettive*, Turin, Giappichelli, 2008.

[64] On the guarantee of the right to health in Italy see, *ex multis*, R. Balduzzi and D. Servetti, *La garanzia costituzionale del diritto alla salute e la sua attuazione*

Indeed, scholars have referred to the essential levels as "the new name for equality".[65]

Are telemedicine services part of the "Lea"? Do they belong to this crucial pillar of the health offer of the Italian NHS?

Answering this question is not easy and requires going back over some of the stages of the gradual introduction of telemedicine in the healthcare system.

In this regard, it should be recalled that article 3 of the State-Regions Agreement establishing the Guidelines on telemedicine of 2014 provided that the regions' transposition of the Guidelines would be assessed during the annual verification of regional health performance by the Permanent Committee for the Verification of the Essential Levels of Care (Comitato permanente per la verifica dell'erogazione dei Livelli Essenziali di Assistenza), called, for short, Lea Committee (Comitato Lea).[66] As of 2018, all regions have adopted the Guidelines through their own resolutions.

However, the inclusion of telemedicine in the "Lea" cannot be derived from this provision. As known, guidelines are an example of *soft law*.[67] This type of acts, which encompasses, together with guidelines, codes of conduct, good practices, standards and so on, is aimed at harmonizing actions and behaviors in certain sectors, especially those characterized by a high rate of innovation and technical-scientific complexity, but, unlike laws and other regulatory sources, are not legally binding. Therefore, the aforementioned provision of the State-Regions Agreement was a way to give some kind of binding force to a *soft law* act.[68]

Nor does the fact that subsequent National Directions of 2020 stated that the national/regional regulatory framework governing access to the various essential levels of care applies to all healthcare services delivered remotely determines this inclusion. Indeed, they aim to define a framework for the supply of telemedicine services particularly as to their economic quantification. They do not grant a right to have telemedicine services.

The idea of digital "Lea" is perhaps *in nuce* in the Ministerial Decree of September 21, 2022, defining, as already said, the guidelines regarding telemedicine functional requirements and service levels, where the concept of "minimum services" appears. The Decree states that the minimum services to be provided by the regional telemedicine infrastructure are as follows: televisit, teleconsultation,[69] telemonitoring and telecare.

However, it cannot be said that this Decree embodies the "Lea".

The Italian Constitutional Court, in particular in decisions 88/2003 and 134/2006, has clearly defined the process for determining them. Given their strong impact on the exercise of functions in matters assigned to the legislative and administrative powers of regions and autonomous provinces, the Court has ruled that the choices concerning them are made, at least in general outlines, by State law, which must determine appropriate procedures and precise formal acts for further specification and articulation.

nel Servizio sanitario nazionale, in R. Balduzzi and G. Carpani (eds.), *Manuale di diritto sanitario*, Bologna, il Mulino, 2013, 13 *et seq*.; R. Ferrara, *Il diritto alla salute: i principi costituzionali*, in *Trattato di biodiritto*, directed by S. Rodotà, P. Zatti, vol. V, R. Ferrara (ed.), *Salute e sanità*, Milan, Giuffrè, 2010, 3 *et seq*.; Id., *L'ordinamento della Sanità*, Turin, Giappichelli, 2020, 39 *et seq*.; Id., *Salute (diritto alla)*, in *Digesto delle Discipline Pubblicistiche*, vol. XIII, Turin, Utet giuridica, 1997, 513 *et seq*.; D. Morana, *La salute nella Costituzione italiana. Profili sistematici*, Milan, Giuffrè, 2002; B. Pezzini, *Principi costituzionali e politica nella Sanità: il contributo della giurisprudenza costituzionale alla definizione del diritto sociale alla salute*, in C.E. Gallo and B. Pezzini (eds.), *Profili attuali del diritto alla salute*, Milan, Giuffrè, 1998, 1 *et seq*.; M. Luciani, voce *Salute* (diritto alla salute – dir. cost.), in *Enc. giur.*, Roma, Treccani, 1991, vol. XXVII; Id., *Il diritto costituzionale alla salute*, in *Diritto e Società*, 1980, 769 et seq.; B. Caravita, *La disciplina costituzionale della salute*, in *Diritto e Società*, 1984, 21 *et seq*.

[65] In these terms E. Balboni, *Livelli essenziali: il nuovo nome dell'eguaglianza? Evoluzione dei diritti sociali, sussidiarietà e società del benessere*, in E. Balboni, B. Baroni, A. Mattioni and G. Pastori (eds.), *Il sistema integrato dei servizi sociali. Commento alla legge n. 328 del 2000 e ai provvedimenti attuativi dopo la riforma del Titolo V della Costituzione*, Milan, Giuffrè, 2003, 27 et seq.

[66] The State-Regions Agreement of 23 March 2005 established at the Ministry of Health the Lea Committee (Comitato Lea), which is entrusted with the task of verifying the provision of the essential levels of care under conditions of appropriateness and efficiency in the use of resources, as well as the congruity between the services to be supplied and the resources made available by the National Health Service.

[67] On the use of *soft law* as a regulatory method in the field of e-Health see M. Campagna, *Public and private participation in digitalised healthcare*, in this issue of *Erdal*.

[68] See M. Campagna, *Linee guida per la Telemedicina: considerazioni alla luce dell'emergenza Covid-19*, 610; C. Botrugno, *La diffusione dei modelli di cura a distanza: verso un "diritto alla telesalute"?*, 173.

[69] Teleconsultation concerns the relationship between professionals.

Moreover, the procedure must respect the principle of loyal cooperation, deemed a "constitutionally necessary principle".[70] The provision of health services is not unilaterally imposed by the State, but must be agreed upon in certain aspects with the regions, which are responsible for the planning and organization of health services in the territory, up to their actual supply through their regional healthcare systems.[71]

The procedure for identifying the essential levels of healthcare has most recently been regulated by article 1, par. 553 *et seq*., Law 208/2015: according to it, they are defined and updated by Decree of the President of the Council of Ministers on the basis of an Agreement achieved in the State-Regions Conference. At present, the "Lea" have been determined by the Decree of the President of the Council of Ministers of January 12, 2017.

The aforementioned Ministerial decree of September 2022 regarding telemedicine is merely a ministerial-level transposition of guidelines, without any underlying State-Regions Agreement, a procedural aspect that, as seen, is very significant.[72] On the basis of these arguments, it cannot yet be said that telemedicine is the object of a right, granted through the "Lea".

From this point of view, it may also be interesting to note the fact that, according to the same Decree of September 2022, no new or additional burdens on public finance arise from its implementation (art. 2). The planned activities are carried out with the human, instrumental, and financial resources available under current legislation, and there is no special economic appropriation designed to guarantee the provision of telemedicine services.

5.3 *Telemedicine and healthcare organization. Implications for the principle of equality*

Further observations concern the huge organizational effort required by the implementation of digital health. It is sufficient to think of the slowdowns that have marked the history of telemedicine, as well as other digital tools, like the electronic health record.

The organizational commitment is exceedingly complex as it involves integrating innovative modes of care with traditional ones.[73]

Organizational issues are all the more relevant insofar as the level of guarantee of the right to health is not only a matter of services provided. The effectiveness of the right is affected by organizational choices: as some scholars have pointed out, the fulfillment of subjective legal situations – rights or interests – "appears historically and politically subordinate to the organizational moment".[74]

Quite often, inequalities in health protection depend on organizational choices and dynamics. Emblematic in this regard are the disparities between the different Italian regional health systems and, in particular, the differences between Northern and Southern healthcare.

Will the recently approved guidelines on telemedicine be enough to ensure homogeneity in the delivery of remote services?

For sure, they represent an important step in supporting from a technical and functioning

[70] For this statement see Constitutional Court decision n. 98/2007.

[71] For the application of these principles see Constitutional Court decision no. 114/2022.

[72] Similar comments were made with reference to the "Guidelines for the Implementation of the Electronic Health Record" ("Linee guida per l'attuazione del Fascicolo sanitario elettronico") adopted by Decree of the Ministry of Health of 20 May 2022: see N. Maccabiani, *Tra coordinamento informativo e livelli essenziali delle prestazioni: il caso del Fascicolo Sanitario Elettronico*, in *federalismi.it*, 2023, 12, 250. In the present case, moreover, the decree was issued after hearing the Permanent Conference for Relations between the State, Regions and Autonomous Provinces of Trento and Bolzano and not on the basis of an agreement with it. The subject of criticism, therefore, was the degree of collaboration between State and territorial autonomies, which was not in accordance with the Constitutional jurisprudence and the legislative approach to the essential levels.

[73] M. Campagna, *Linee guida per la Telemedicina: considerazioni alla luce dell'emergenza Covid-19*, cit., 610; C. Botrugno, *La diffusione dei modelli di cura a distanza: verso un "diritto alla telesalute"?,* 609.

[74] In these terms see G. Corso, *I diritti sociali nella Costituzione italiana*, in *Rivista trimestrale di diritto pubblico*, 1981, 3, 762. On the impact of organization on the right to health and, more in general, on the right to social services, one may refer to V. Molaschi, *La rilevanza dell'organizzazione dei servizi pubblici sull'effettività dei diritti sociali*, in M. Renna, C. Micciché and P. Pantalone (eds.), *La partecipazione dei cittadini all'organizzazione dei servizi sociali. Il caso della metropoli milanese*, Napoli, Editoriale Scientifica, 2020, 27 *et seq*.; Id., *Programmazione e organizzazione dell'equità in sanità. L'organizzazione come "veicolo" di eguaglianza*, in *BioLaw Journal – Rivista di BioDiritto*, 2019, 2, 51.

point of view regions and autonomous provinces for the definition and implementation of project initiatives on telemedicine services within a common framework. From this perspective, it is significant that they have been acknowledged in a decree, which is not a *soft law* act, as the previous guidelines were: this means that precisely with a view to ensuring greater uniformity it has been decided to give more stringent guidance with greater constraint.

However, the problems concerning the uneven distribution of infrastructure and resources between the various Italian regions still remain, with consequences in terms of digital divide. This could heighten once again the already-existing inequalities that characterize the different national territorial areas, with repercussions on the guarantee of the right to healthcare.[75]

Moreover, the NRRP intervention in the field of telemedicine mostly consists of funding telemedicine projects proposed by regions: the Plan deservedly rewards the regional "spirit of initiative". However, this policy could reveal some points of "weakness": the risk that the already-more-virtuous and technologically-advanced regions could take advantage of the measure and that the others, more in difficulty, could once again fall behind.[76]

In this regard, it should be noted that, according to the Report on the status of implementation of the National Recovery and Resilience Plan of May 31, 2023, the goals inherent in telemedicine have been subsequently specified by providing for at least one project per region by 2023 (considering both the projects that will be implemented in the single region and those that may be developed within consortia between regions).

A push, however, in the direction of greater "digital uniformity" in healthcare will come from the National Telemedicine Platform. The latter, in fact, promoting the adoption of telemedicine organizational and process best practices, is aimed at bridging the gap between territorial disparities. In addition, it will achieve greater integration between regional health services and better interoperability with central systems deployed nationwide, thereby improving the accessibility and quality of healthcare delivery.

[75] On these issues see, more in general, A. Morelli, *Il diritto alla salute nell'era digitale: profili costituzionalistici* (18 December, 2012), in *mediaLAWS*, http://medialaes.eu, paragraph 4.

[76] According to L. Ferraro, *La telemedicina quale nuova (e problematica) frontiera del diritto alla salute*, 850-51, it is interesting to note that, based on the mapping of experiences done by the Ministry of Health (dated 2018 and updated in 2021), although the best data on activated telemedicine experiences concern the North of Italy, there is not an excessive gap compared to the South. The data, both positive and negative, varied across different areas of the Country. The Ministry of Health document can be found at the following link: www.salute.gov.it/imgs/C_17_pagineAree_2515_2_file.pdf.