THE DIGITALIZATION OF THE NATIONAL HEALTH SERVICE IN THE PRISM OF "VARIABLE SPEED" BETWEEN TECHNOLOGICAL PROGRESS AND ADMINISTRATIVE INNOVATION

LA DIGITALIZACIÓN DEL SERVICIO NACIONAL DE SALUD BAJO EL PRISMA DE LA "VELOCIDAD VARIABLE" ENTRE EL PROGRESO TECNOLÓGICO Y LA INNOVACIÓN ADMINISTRATIVA

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RESUMEN: En Italia, el proceso de transformación digital de las administraciones públicas está todavía inacabado. La dificultad de su aplicación viene dada por la gran velocidad de los avances científicos y tecnológicos frente a la lentitud de la normativa y de las administraciones públicas para aplicar los cambios. De hecho, existen muchos riesgos en el proceso de transición digital: la vulnerabilidad de los sistemas, terreno fértil para los ataques de piratas informáticos; la protección inadecuada de la privacidad de los usuarios con la consiguiente dispersión de datos sensibles; la exclusión del uso de los servicios de categorías frágiles (como las personas mayores, los indigentes o los discapacitados). De ahí el peligro de que aumenten las desigualdades sociales, ya muy marcadas en nuestro país.

Todo esto se aplica también al sector sanitario en el que la transición a lo digital es aún más difícil debido a la gran organización y delicadeza del bien protegido.

La necesidad de transferir los servicios de salud pública del mundo real al virtual ha sufrido una fuerte aceleración con la pandemia de Covid-19, durante la cual la inadecuación digital se reveló en todo su dramatismo en la compleja operación de contención de la infección.

El refuerzo del presupuesto plurianual por parte de Europa y la consecuente N.R.R.P del Estado representan una oportunidad sin precedentes para crear un Sistema de Salud innovador, inclusivo, equitativo y sostenible basado en la Salud Pública Digital. Sin embargo, para que el N.R.R.P no sea un Libro de Sueños sino un verdadero Plan de desarrollo y crecimiento, es necesario utilizar ingentes créditos para una reorganización administrativa profunda y estructural que haga efectivo ese derecho a la "buena administración" consagrado en el art. 41 de la Carta de los Derechos Fundamentales de la Unión Europea y obtener, de este modo, beneficios en términos de protección de la salud y salvaguardia de los presupuestos públicos.

PALABRAS CLAVE: Salud pública digital; organización administrativa; acción terapéutica; Inteligencia Artificial (IA); buena Administración; idoneidad administrativa.

ABSTRACT: *In Italy, the digital transformation process of public administrations is still unfinished today. The difficulty of implementation is given by a high-speed scientific and technological progress compared to the slow pace of regulations and public administrations to implement the changes. In fact, there are many risks in the digital transition process: the vulnerability of systems, fertile ground for hacker attacks; inadequate protection of users' privacy with consequent dispersion of sensitive data; the exclusion from the use of the services of fragile categories (such as the elderly, the indigent or the disabled). Hence, the danger of increasing social inequalities which are already very marked in our country.*

All this also applies to the health sector in which the transition to digital is even more difficult due to the big-organization and delicacy of the protected asset.

The need to transfer public health services from the real world to the virtual one has undergone a strong acceleration with the Covid-19 pandemic, during which digital inadequacy was revealed in all its drama in the complex operation to contain the infection.

The strengthening of the multiannual budget by Europe and the consequent N.R.R.P of the State represent an unprecedented opportunity to create an innovative, inclusive, equitable and sustainable Health System based on Digital Public Health. However, in order for the N.R.R.P is not a Book of Dreams but a real Plan for development and growth, it is necessary to use the huge appropriations for a profound and structural administrative reorganization in order to make effective that right to "good administration" engraved in art. 41 of the Charter of Fundamental Rights of the European Union and obtain, in this way, benefits in terms of health protection and the safeguarding of public budgets.

KEY WORDS: *Digital public health; administrative organization; therapeutic action; Artificial Intelligence (IA); good Administration; administrative appropriatness.*

SUMARIO.- I. THE REGULATION OF "DIGITAL HEALTHCARE" BETWEEN DIFFERENTIATED REGIONALISM AND IDEAS OF CENTRALIZATION.- II. DIGITAL SERVICES IN THE HEALTHCARE ADMINISTRATIVE ORGANIZATION.- III. SOME DIGITAL TOOLS OF THERAPEUTIC ACTION.- IV. N.R.R.P. OPPORTUNITY FOR THE "GOOD ADMINISTRATION" OF HEALTH CARE.- V. SCIENTIFIC AND TECHNOLOGICAL PROGRESS AS A TOOL FOR A NEW CLINICAL AND ADMINISTRATIVE APPROPRIATENESS.

I. THE REGULATION OF "DIGITAL HEALTHCARE" BETWEEN DIFFERENTIATED REGIONALISM AND IDEAS OF CENTRALIZATION.

As is known, digital administration[1] develops in a threefold dimension: that of the procedure, the traditional way of acting *ius imperii* of the p.a. and, therefore, of the consequent administrative provision[2]; that of public contracts, where telematic procedures should help make the awarding of contracts more efficient and the choice of contractor more transparent[3]; that of public services, to which it is necessary to improve access and guarantee use of the service itself without limits of time and space of the provision[4].

The object of this investigation concerns the third of the aforementioned dimensions with reference to a sector, that of Health, which needs a massive renewal intervention, useful for overcoming all the fragility and weaknesses that the Health System - modeled for many years on need to contain public spending - has manifested during and after the pandemic[5]. From a clinical point of view, in fact, it is necessary to modernize the traditional model to react to deep-rooted critical issues such as the aging of the population, resistance to antibiotic treatments, the increase in chronic diseases, as well as to deal with any new epidemics or pandemics.

1 This term (or e-government) means "the use of information and communication technologies (ICT) in administrative processes through which the PA intends to make the action of the public administration more efficient, improving on the one hand, the quality of the public services supplied to the citizens and decreasing on the other hand the costs for the community». Refer www.qualitapa.gov.it.

2 Refer to the monographs of Cavallo Perin, R. e Galetta, D.U. (a cura di): *Il diritto dell'amministrazione pubblica digitale*, Giappichelli, Torino 2020; Previti L., *La decisione amministrativa robotica,* editoriale scientifica, Napoli 2022; refer also Follieri, F.: "Decisione amministrativa e atto vincolato", *Federalismi.it*, 7/2017.

3 Di Lascio, F.: "Appalti elettronici e aggregati", in Clarich, M. (a cura di): *Commentario al Codice dei Contratti pubblici*, Giappichelli, Torino 2019, *sub* art. 55-58, p. 441; Racca, G.: "La modellazione digitale per l'integrità, l'efficienza e l'innovazione nei contratti pubblici", *Ist. fed.*, n. 3/2019, p. 739; Cresta, S.: "Procedure elettroniche e strumenti di acquisto telematici nel nuovo Codice dei Contratti pubblici", *Urb. App.*, 2016, p. 981.

4 Cammarota G.: "Servizi pubblici online e partecipazione migliorativa", in Civitarese Matteucci, S. e Torchia, L. (a cura di): *La Tecnificazione*, Firenze University Press, 2016, pp. 113 ss.

5 On the criticisms identified during the pandemic and on how to act to improve in the future, refer Pioggia, A.: "La sanità italiana di fronte alla pandemia. Un banco di prova che offre una lezione per il futuro", *Diritto pubblico*, 2/2020, p. 385.

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The digitization, as a tool for administrative simplification[6], is a goal identified for some time in the reforming ideas of the supranational and internal legislator. In fact, on both levels, there is an overabundance of regulations and programmatic documents that aim to dematerialize all public services, with the aim of making them faster, without compromising their efficiency[7].

However, in Italy the digital transformation process is still far from complete. In general, the difficulty of implementation is given by a high speed scientific and technological progress compared to the slow pace of the regulations and the capacity of the public administration to implement the changes. In fact, there are many risks inherent in the digital transition process, such as the vulnerability of systems, inadequate protection of user privacy, the exclusion from the use of services of fragile categories, such as the elderly or the disabled for example. Hence, the danger of exacerbating social inequalities (cultural, educational, economic) which in our country are already very marked[8].

What has been said is even more true in the health sector in which the macro-organisation, together with the extreme importance and delicacy of the asset being protected, increases the difficulty and caution in introducing technological innovations, so as to make the already complex transition to digital.

6 Orofino, A.G.: "La semplificazione digitale", *Il diritto dell'economia*, n. 100, 3/2019, 87; on the *e-governement* in general, reference is, without claiming to be exhaustive, to Marchetti, B.: Voce "Amministrazione digitale", *Enciclopedia del Diritto, Funzioni amministrative*, directed by Mattarella, B.G. e Ramajoli, M., Giuffrè, Milano 2022, p. 75; Galetta, D.U.: "Open-Government, open-data e azione amministrativa", *Istituzioni del Federalismo*, 3/2019, pp. 663-683; Profiti, F.S.: *Lo stato di attuazione dell'e-Government in Italia*, in Centro Tocqueville-Action, 20/2008. Merloni, F. (a cura di): *Introduzione all'e-Government. Pubbliche amministrazioni e società dell'informazione*, Giappichelli, Torino 2005; Vesperini, G. (a cura di): *L'e-Government*, Giuffrè, Milano 2004; Bombardelli B.: "Informatica pubblica, e-Government e sviluppo sostenibile", *Riv. it., dir. pubbl. com.*, 5/2002, p. 991; Zaffaroni, F.: "L'informatizzazione della pubblica amministrazione", *Foro amm.*, 7-8/1996, p. 2516.

7 Refer, in addition to the bibliography already mentioned, to Duni, G.: "Amministrazione digitale", *Enciclopedia del diritto*, Annali, I, 2007, 13; Duni, G.: *L'amministrazione digitale. Il diritto amministrativo nella evoluzione telematica*, Giuffrè, Milano 2008; Carloni, E. (a cura di): *Codice dell'Amministrazione digitale. Commento al D.lgs. 7 marzo 2005, n. 82*, Maggioli, Santarcangelo di Romagna, 2005; B. Carotti, B.: "La digitalizzazione", in Mattarella, B.G. - D'alterio, E. (a cura di): *La riforma della pubblica amministrazione. Commento alla legge 124/2015 (Madia) e ai decreti attuativi*, Il sole 24 Ore, Milano 2017; Masucci, A.: "Il documento amministrativo informatico", in Arena, G. – Bombardelli, M. – Guerra, M.P. – Masucci, A. (a cura di): *La documentazione amministrativa. Certezze, semplificazione e informatizzazione nel d.P.R. 28 dicembre 2000, n. 445*, Maggioli, Santarcangelo di Romagna 2001, p. 173; Masucci, A.: "Documento informatico e sottoscrizione elettronica", *Riv. it. dir. pubbl. com.*, 2004, p. 541; Masucci, A.: *L'atto amministrativo informatico. Primi lineamenti di una ricostruzione*, Jovene, Napoli 1993; M. L. Maddalena, M.: "La digitalizzazione della vita dell'amministrazione e del processo", in AA.VV.: *L'Italia che cambia: dalla riforma dei contratti pubblici alla riforma della pubblica amministrazione*, in *Atti del LXII Convegno di studi di scienza dell'amministrazione*, Varenna, 22-24 settembre 2016, Giuffrè, Milano 2017.

8 Piras, P.: "Innovazione tecnologica e divario digitale", *Il diritto dell'economia*, n. 108 (2/2022), p. 111, which highlights all the reasons underlying digital inequality, identifying them in the infrastructural lack of connection, in the impossibility of access due to costs, in territorial (north/south), gender, age and social disparities. Refer also *Studi economici dell'OCSE: Italia 2021*, in www.oecd.org, in which it is highlighted that the digital divide in Italy is much more marked than in other countries and therefore calls for an acceleration of the digital transition.

Certainly, the need to transfer public services from the real world to the virtual one has undergone a strong acceleration with the Covid-19 pandemic during which digital inadequacy was revealed in all its drama given the ineffectiveness (at least initially) of the measures adopted to contain the infection.

In fact, it was in the midst of the emergency that the need to regulate "Digital Health" (in the European context Digital Health or e-Healt), a term which generically indicates the use of information and telecommunications technologies, regained strength (ICT) for the benefit of human health[9] or, as it has been defined in the medical literature, the set of digital technologies in order to support and deliver health services in support of the well-being of individuals, who are not necessarily sick[10]. Furthermore, the term "digital healthcare" also refers to the application of digital technology to healthcare processes as a whole intended to achieve objectives such as the cost-quality ratio of services, reduction of differences between the various territories and improvement of the quality perceived by the citizen[11].

At the European level, it notes the recommendation (EU) 2019/243 with the primary purpose of introducing and enhancing digital technologies in the health sector[12]. An objective sculpted, most recently, in the ambitious "EU4Healt Program 2021-2027", aimed at the recovery of the health systems of the member countries[13]. Specifically, the European project is articulated on four crucial points: disease prevention, crisis preparation, attention paid to health systems and their personnel, digital implementation. All in compliance with the general objectives set forth in art. 3 of EU Regulation 2021/522 and with the ultimate aim of laying the foundations for a strong and solid European Health Union. The program will

9 *Word Healt Organization*. In WHA 58.28 del 2005, l'*e-Health* was defined "the cost-effective and secure use of information and communication technologies in support of health and health-related fields, including health-care services, health surveillance, health literature, and health education, knowledge and research". Si veda www.blogsalutedigitale.it.

10 Trifirò, G. – Crisafulli, S. – Puglisi, G. – Racagni, G. – Pani, L.: *Terapie digitali come farmaci?*, in Gussoni G. (a cura di), *Terapie digitali, una opportunità per l'Italia?*, 1/2021, Passoni editore, p. 144.

11 PRESIDENZA DEL CONSIGLIO DEI MINISTRI: *Strategia per la crescita digitale 2014-2020*, 3 marzo 2015, p. 89, on www.agid.gov.it.

12 In one of its passages we read "Digital solutions connected to health applications or wearable devices, combined with a system that allows citizens to securely access their health data, could allow patients suffering from chronic diseases, such as diabetes, or cancer, to monitor their symptoms from home and quickly share them with their clinical teams. This should reduce the number of visits to health care facilities for monitoring. Digital technologies can also help identify the need for a change in care earlier, thereby reducing the number of hospital admissions due to complications. Better management of chronic disease in the community, combined with a reduction in duplication of health care interventions (such as exams) would not only make systems more sustainable but would also improve the general quality of life and health care provided to citizens and reduce the costs associated with health care for individuals and families".

13 Equipped with a *budget* di 5,1 billion euros, this is the largest program ever implemented by funding EU countries, health organizations to enhance the quality and safety of European citizens' health, support EU health systems in the fight against threats of a cross-border nature and improve the EU's response capacity and resilience to possible future crises.

be largely implemented by the European Health and Digital Executive Agency - HaDEA, which went into operation on 1 April 2021.

In the Italian regulatory context, just think of the innovations in the field of electronic health records by the d.l. 19 May 2020, no. 34 (so-called relaunch decree) converted with amendments by law 17 July 2020, n. 77; or again to the profuse commitment to implement the application of telemedicine with the general objective of providing a unified national reference and guaranteeing an adequate use in the national context[14].

It being understood that these aspects, concerning the modernization of the healthcare organization, will be dealt with in more detail in the following paragraph, it should be noted first of all that all the ambitious reform programmes, including the P.N.R.R. to which a specific discussion is reserved in the continuation of this contribution, they go in the direction of a centralization of health matters, in a path opposite to that differentiated regionalism which during the pandemic has exasperated the variable speed system, the primary cause of inequalities.

As a result of the operational difficulties encountered in dealing with the emergency, the idea of centralizing health matters has come back strong; a suggestion (for the moment) which, if over the years it has become increasingly evanescent in consideration of the regulatory history of the National Health Service which has always been oriented towards corporate[15], today it regains strength due to the centripetal forces not so much of the State, but of the European Union in a new matter which, by combining healthcare with information technology, takes the name of "digital healthcare".

As for the State, briefly, it is the constitutional provision that attributes it exclusive legislative competence in the matter of "statistical and IT coordination of data from the state, regional and local administration" (Article 117, paragraph II, letter r). This competence is essential with a view to adapting the healthcare organization to technological evolution, an aspect in which many regions are backward and inert[16].

As for the European Union, in more detail, it is true that the supranational coordination aimed at facilitating cooperation between the individual Member States in health policies does not require a necessary and perfect harmonization

14 MINISTERO DELLA SALUTE, *Telemedicina. Linee di indirizzo nazionali*, in www.agid.gov.it.

15 Implemented with the well-known regulatory stratification: by law 23 december 1978 n. 833 establishing the National Health Service, to the reforms implemented with legislative decree 502/1992 and with legislative decree 517/1993, up to legislative decree 229/1999.

16 Catelani, E.: "Nuove tecnologie e tutela del diritto della salute: potenzialità e limiti dell'uso della Blockhain", *Federalismi.it*, n. 4/2022, p. 216.

of the internal disciplines for which the States themselves remain responsible[17], but it is also true that from the Lisbon Treaty onwards, the health matter has been the subject of an ever-increasing number of acts, interventions and directives, in coherence and enhancement of that *Healt in all policies* approach engraved in the various articles of the TFUE[18].

Therefore, in the vast and complex matter of "digital health", it does not seem to be that far from an invocation in terms of competence of health policies by the European Union, relying on the principle of vertical subsidiarity pursuant to art. 5, paragraph III, of the TUE[19].

Centralization would break down the "dividing walls" currently placed at the borders of the regions, creating a system capable of uniformly enhancing the use of digital technologies, interconnection and instantaneous retrieval of data on the national territory and fruitful collaboration, both online and in terms of patient mobility, between the various healthcare facilities throughout the country. The risk to be avoided, certainly, is that already recognized of leveling down health protection reaching the point of normalizing, and therefore losing, some regional centers of excellence, today placed to guarantee the entire population[20].

II. DIGITAL SERVICES IN THE HEALTHCARE ADMINISTRATIVE ORGANIZATION

In healthcare, even before in other sectors of public administration, the teachings of that authoritative administrative doctrine are valid and current according to which the organizational component is decisive for adequate action in

17 Racca, G.M. - Cavallo Perin, R.: "Organizzazioni sanitarie e contratti pubblici in Europa: modelli organizzativi per la qualità in un sistema di concorrenza", in Pioggia, A. - Civitarese Matteucci, S. – Racca, G.M. – Dugato, M., Maggioli, Rimini 2011, pp. 193-215; On the roles of the European Union and States in social matters, refer Balduzzi, R.: "Unione europea e diritti sociali: per una nuova sinergia tra Europa del diritto ed Europa della politica", *Federalismi.it*.

18 The approach *One Health*, according to the definition provided by the Institute of Health, it consists of "a health model based on the integration of different disciplines, based on the recognition that human health, animal health and ecosystem health are inextricably linked. It is officially recognized by the European Commission, by the Italian Ministry of Health, and by all international organizations as a relevant strategy in all sectors that benefit from the collaboration between different disciplines (doctors, veterinarians, environmentalists, economists, sociologists, etc.)". On this point, www.iss.it/one-health. As for European legislation, Health, mentioned in art. 9 TFUE, is a legal asset subject to protection in many sectors: the internal market (art. 114, points 3 and 6 TFUE), the environment (art. 191, point 1 TFUE), consumer protection (art. 169 point 1 TFUE), social affairs (art. 153 point 1 letter a) TFUE).

19 For an exhaustive reconstruction of the principle of subsidiarity, both in its vertical and horizontal sense, refer D'Orsogna: *Programmazione strategica e attività decisionale della Pubblica Amministrazione*, Giappichelli, Torino 2001, pp. 55 ss, spec. 57 where it is noted that in areas of non-exclusive competence, the Union intervenes only if, and to the extent that, it can achieve the objectives of the envisaged action when the same cannot be achieved by the Member States. It follows that, through the law, the residual nature of the State's competence emerges in those matters which, due to the nature, consistency and relevance of the interests involved, impose an intervention by the central powers.

20 Catelani, E.: "Nuove tecnologie e tutela del diritto della salute: potenzialità e limiti dell'uso della Blockhain", cit., p. 216.

terms of good performance[21]. In summary, health treatment is first "organization" and then "activity"[22], two fundamental and inseparable moments in the protection of health: only a profitable mixture between them guarantees the achievement of the institutional purpose, as a protected and constitutionally guaranteed interest.

As for healthcare organization, today the criteria of economy, effectiveness and efficiency must be adapted to modern society, the digital one: all public administrations are unable to keep up with the rapid and incessant pace of technological progress, thus generating "a rift between innovation technological and administrative innovation"[23] clearly visible in the health administration where, in recent times, the introduction of technology has taken place very slowly and, in any case, more on the medical-diagnostic front than on the purely organizational one: a valid example is the Electronic Health Record which, despite having found for some time in the national regulatory framework[24], it has not had the expected application[25] so much so that it is subject to important changes by the aforementioned emergency legislation (legislative decree no. 34/2020, converted with amendments by law no. 77/2020).

Among the relevant innovations, in the first place a massive extension on an objective and subjective level of the documents that fall within the FSE, since it is now fed with data on clinical events both by the health professions of the National Health Service and the regional social and health services, both by professionals working in the private sector and by the patient himself independently according to his own will and ability to take initiative[26]. In this way, a profitable connection is created, hitherto missing, between the public and private systems.

Furthermore, it is envisaged that the EHR is established and fed without the prior consent of the interested party (which is now relevant only for treatment purposes)[27] which implies a considerable acceleration and implementation in the

21 Nigro, M.: *Studi sulla funzione organizzatrice della pubblica amministrazione*, Giuffré, Milano 1996.

22 Villamena, S.: "La c.d. legge Gelli-Bianco. Fra strategia di prevenzione di rischio e responsabilità amministrative", 2 gennaio 2019, *Federalismi.it*.

23 Contaldo, A.: "Telemedicina e Fascicolo Sanitario Elettronico", in AA.VV.: *Responsabilità sanitaria, rischio clinico e valore della persona*, diretto da G. Cassano, Tomo I, Maggioli, Santarcangelo di Romagna 2022, 158 according to which, in computerizing and automating the administrative procedure, it is not enough to translate the traditional system of this within the digital context, but it is necessary to think critically about the articulation of the administration from an organizational point of view.

24 The Electronic Health Record was instituted with d.l. 18 october 2012, converted with amendments into law 17 December 2012, n. 221 which, in art. 12, defines it as "the set of data and digital documents of a health and social-health type generated by present and past clinical events, concerning the patient".

25 Refer to the monitoring activities of the AgID and the Ministry of Health concerning two distinct groups of indicators: Implementation and Use on www.fascicolosanitarioelettronico.gov.it which shows that, at the beginning of the pandemic, the ESF was used by a few regions and activated only by 20% of the population.

26 Art. 11, co. 1, lett. c) of l.d. 34/2020 which completely rewrites the third paragraph of the art. 12 of law 179/2012.

27 This occurred due to the express repeal, by the aforementioned legislative decree 34/2020 (art. 11, paragraph 1, letter b), of paragraph 3-bis of art. 12 of the legislative decree 179/2012 which required

use of data, so much so that measures have also been envisaged to strengthen the National Interoperability Infrastructure (INI) for the management of the ESF index at a national level in order to guarantee the concrete "portability" of the electronic file in cases of interregional mobility of patients.

The Ministry of Health also intervenes to improve the organizational set-up of the complex health system in terms of electronic health records with the publication of the Guidelines for the implementation of this digital tool[28] which are intertwined with the objectives sculpted in the N.R.R.P.: ESF used and fed by 85% of general practitioners by 2025 and adopted and used by all Regions by 2026. In fact, to this end, the Regions and autonomous provinces are been called, within three months of the publication of the guidelines, to present "adaptation plans to update their systems and to receive the financial resources necessary to implement them"[29]. To date, the ESF implementation program seems to be proceeding quite quickly, if one looks at some data published by the Ministry[30].

In essence, the intent of the emergency Legislator was to create a single and well-harmonized system in the national context in a centralizing logic of health data management capable of guaranteeing continuity in the treatment path of the individual patient and, at the at the same time, a simplification, dematerialization and speed of communication based on clinical documents, with undoubted benefits in terms of health administrative appropriateness[31].

Another tool of digital health that can be referred to the organization is Telemedicine, understood as a way of providing health care services through the use of Information and Communication Technologies (ICT) in the cases in which the health professional and the patient (but also two or more healthcare professionals) are physically distant[32]. These are techniques for the transmission of

the patient's consent to feed the electronic health record. In doctrine, on the issue of digital health and informed consent, refer Morana, D. – Balduzzi, T. – Morganti, F.: "La salute "intelligente": e-Healt, consenso informato e principio di non discriminazione", 28 dicembre 2022, in *Federalismi.it*.

28 The guidelines have been established by the d.m. 20 May 2022 pursuant to art. 12, paragraph 15-bis of the legislative decree 179/2012, converted with amendments into law 221/2012.

29 Guidelines for the Implementation of the Electronic Health Record, 27 March 2022 in www.gazzettaufficiale.it.

30 MINISTERO PER L'INNOVAZIONE TECNOLOGICA E LA TRANSIZIONE DIGITALE, *Pnrr: Fascicolo Sanitario Elettronico, al via implementazione in tutte le Regioni*, in www.innovazione.gov.it.. where it is reported, as regards the ESF funding, that in just seven months Basilicata went from 27% of available documents to 95%, Campania from 1.5% to 53% and Piedmont from 50% to 80%.

31 Contaldo, A.: "Telemedicina e Fascicolo Sanitario Elettronico", in AA.VV.: *Responsabilità sanitaria, rischio clinico e valore della persona*, cit., p. 161.

32 In distant times, the WHO provided an exhaustive definition of it, stating that Telemedicine is «the provision of health services, in which distance is a critical factor, by all health professionals who use information and communication technologies for exchange of valuable information for the diagnosis, treatment and prevention of disease and injury, research and evaluation, and for the continuing education of health professionals, all in the interest of promoting the health of individuals and their communities» in 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, Geneva, 1997.

data and information of a medical nature, in the form of texts, images, sounds and anything else necessary for the prevention, diagnosis, therapeutic treatment and control of the patient.

The impact of the remote service is evident which, by making information move instead of people, revolutionizes the healthcare sector and the doctor-patient relationship. However, despite a strong and constant commitment by the European institutions to the implementation of the use of technologies in Health[33], the recourse to them, in fact, has always been limited on the national territory because it is limited to the initiative of small businesses which have found it enormously difficult to establish themselves on the health care market[34].

During the pandemic, remote communication techniques have proven to be an effective and safe alternative to face-to-face visits, so that the Government has intervened by dictating the guidelines on the subject with the general objective of providing a single national reference for a effective planning and adequate use of Telemedicine in the national context[35].

Furthermore, the N.R.R.P. aims to create a national platform for Telemedicine services in order to make it a structured service within the National Health System. Specifically, the purpose of the platform is to create a fundamental level of interoperability capable of guaranteeing common standards on telemedicine services developed by the Regions. In this regard, the N.R.R.P. finances research projects on digital technologies in the field of health and assistance that focus on the provision of remote services and benefits, in line with the goal well expressed in Mission 6, Component 1, according to which the house must become the first place of care.

Certainly the aforementioned measures give substance to ambitious objectives not only of overcoming some clinical criticalities (such as the aging of the population or the increase in chronic diseases), but also of achieving a more flexible, resilient

33 There are many EU initiatives on this point: among the most important, the Communication of the European Commission Electronic health - improving the healthcare of European citizens: action plan for a European area of electronic health of 30 April 2004; Decision no. 1350/2007/EC establishing the second Community action program in the field of Health (2008-2013); Regulation (EU) 282/2014 of the European Parliament and of the Council on the establishment of the third Union action program in the field of Health (2014-2020); the Action Plan (2012-2020) launched by the European Commission in December 2012; to this is added, more recently, the Recommendation (EU) 2019/243 of 6 February 2019 and the *EU4Healt Program 2021-2027*, already mentioned in the previous paragraph.

34 Contaldo, A.: "Telemedicina e Fascicolo Sanitario Elettronico", AA.VV..: *Responsabilità sanitaria, rischio clinico e valore della persona*, cit., 156, which highlights the lack of trust on a triple level: that of the healthcare professional in the effectiveness of new working methods, that of the patient in these treatment solutions and in contact with the hospital structures and that of the economy in general which does not invest in the new businesses. This is so true, continues the author, that the second Community action program in the field of Health is based precisely on this awareness and therefore aims to support the Member States by providing them with elements capable of creating trust and thus favoring acceptance of telemedicine service.

35 MINISTERO DELLA SALUTE, *Telemedicina. Linee di indirizzo nazionali*, in www.agid.gov.it.

and sustainable system. In fact, the project of firmly linking the patient's residence with the healthcare environment can bring benefits not only in terms of health protection, but also in terms of safeguarding public budgets, thus becoming an advantage not only for patients, but also for for the whole community[36].

However, to guarantee adequate services performed with telemedicine, a valid basic strategy is needed to create sustainable preconditions from an economic, managerial and organizational point of view. The risk that the effectiveness of the services on the national territory differs further, rather than conforming to the objective of the NRRP, is very high. In this sense, a valid tool to help avoid this danger could be identified in *management*: in fact, the need to develop project management skills and invest in professional figures oriented towards this has already been recognized. Envisaging, rooting and implementing project managers within healthcare companies is a necessary condition for improving the organization and laying concrete foundations for the implementation of digital programs in the healthcare sector[37].

III. SOME DIGITAL TOOLS OF THERAPEUTIC ACTION

By shifting the attention from the level of organization to that of action, the deepening of "digital health" moves to the theme of Artificial Intelligence (AI), generally defined at a supranational level as the set of "systems that show a intelligent behavior by analyzing one's environment and performing actions, with a certain degree of autonomy, to achieve specific objectives"[38].

Even at a national level, its importance is recognized with particular reference to Health, which represents, in fact, one of the priority sectors in which the State undertakes to invest in order to achieve high quality healthcare[39].

36 Borghini, A. – Paone, S.: "Investimento in telemedicina: dalla progettazione all'attuazione", in AA.VV.: *Telemedicina e intelligenza artificiale a supporto dell'assistenza territoriale. Linee guida organizzative contenenti il modello digitale per l'attuazione dell'assistenza domiciliare*, Monitor, 44/2022, Elementi di analisi e osservazione del sistema salute, 10, in www.agenas.gov.it.

37 Zangrandi, A. – Fanelli, S.: "Impatti organizzativi: cosa significa la telemedicina nei reparti, nelle professioni e nelle continuità assistenziali", in AA.VV.: *Telemedicina e intelligenza artificiale a supporto dell'assistenza territoriale. Linee guida organizzative contenenti il modello digitale per l'attuazione dell'assistenza domiciliare*, cit., 35.

38 EUROPEAN COMMISSION, *Communication from the Commission, Artificial intelligence for Europe, COM 2018/237 final*, Bruxelles, 25.04.2018, in www.eur-lex.europa.eu, which already in 2018, as regards AI for the benefit of health, highlighted that "in Denmark, AI helps save lives by allowing emergency services to diagnose cardiac arrests or other pathologies based on the sound of the caller's voice . In Austria, it helps radiologists locate tumors more accurately by instantly comparing x-rays with a large amount of other medical data." In doctrine, please refer to the insights of Picozza E: "Politica, diritto amministrativo and Artificial Intelligence", *Giur. It.*, 2019, 1761.

39 Refer *Programma strategico Intelligenza Artificiale 2022-2024*, in www.innovazione.gov.it, in which, with regard to the "health and well-being" sector, we read: "In the field of healthcare, artificial intelligence applications stimulate product and process innovation by exchanging and aggregating information currently dispersed in a multitude of public and largely underused databases. Artificial intelligence applications will help meet the new needs resulting from the aging of the Italian population. Furthermore, they will have a

The maximum expression of AI applied to the medical field is represented by digital therapies (DTx), defined as "technologies that offer therapeutic interventions that are guided by high-quality software programs, based on scientific evidence obtained through methodologically rigorous and confirmatory clinical trials, to prevent, manage or treat a broad spectrum of physical, mental and behavioral conditions"[40]. Each digital therapy can take the form of an App downloaded on a smartphone or tablet or with devices wearable by the patient (wereable devices). As has been noted in medical doctrine, while in the classic drug the active ingredient is the chemical or biological molecule, in digital therapy the active ingredient is the algorithm, as the element responsible for both the positive and negative clinical effect[41]. From a legal point of view, the algorithm is the element that is not properly "responsible" but certainly "determinant" of the clinical effect and this circumstance opens up many reflections on the subject of responsibility which, inevitably, will expand both on an objective and on a the subjective one. On an objective level, because the hypotheses of malfunction of the device and, therefore, of erroneous action/decision of the machine will also fall within the context of medical liability; on a subjective level because not typically healthcare professional figures will become further centers of imputation of responsibility.

Naturally, the crux is the clinical effectiveness of digital therapies, difficult to guarantee in the short term in a system that is complex (given the macro-organisation), extremely delicate (given the protected asset) and currently underdeveloped for rapid implementation of technology.

On this last aspect, in fact, therapeutic digitization requires several rigorous clinical studies that can generate solid scientific evidence in a timely manner. However, there are many obstacles that overlap such a goal. First of all, to date, there is no specific and punctual legislation on digital therapies that guarantees the safety and quality of the data collected. In fact, the regulatory reference at a supranational level is Regulation (EU) 2017/745[42] which generally concerns medical devices and, as specifically provided for digital therapies, establishes that they must comply with some essential requirements to guarantee safety, efficacy

significant impact on the population at risk of serious diseases such as degenerative, oncological and viral diseases and will increase the social inclusion of disadvantaged groups. Some examples of applications are: medical devices and services in screening and diagnostic areas such as omics and medical imaging, new drugs and vaccines, people monitoring and treatment, patient care support (diagnosis and prognosis), and predictive models health care needs".

40 Gussoni, G.: "Executive Summary", in Gussoni, G. (a cura di): *Terapie digitali: un'opportunità per l'Italia*, 1/2021, Passoni, Milano 2021, 3.

41 Da Ros, L. – Recchia, G. – Gussoni, G.: "Perché un volume sulle terapie digitali per l'Italia", Gussoni, G. (a cura di): *Terapie digitali: un'opportunità per l'Italia*, cit., 10.

42 Regulation on medical devices of 5 April 2017 amending Directive 2001/83 EC, Regulation (EC) n. 178/2002 and Regulation (EC) 1223/2009 and repealing Directives 90/385 EEC and 93/42 CEE, at www.eur-lex.europa.eu.

and quality based on international standards[43]. On the national scene, there are mostly programmatic documents that simply mention in a declamatory tone the possible examples of application of AI in the health sector, such as robotics in surgery, virtual nursing assistance, support for diagnostic imaging[44]. However, as regards the regulatory provisions, only recently, also due to the late entry into force of the Regulation (May 21, 2021), has the transposition of the european source begun through art. 15 of the law of 22 April 2021, n. 53[45], but certainly the peculiarity of digital therapies imposes a more in-depth regulatory framework than the one currently in force[46]. In essence, to date, there is a gap between the recent programmatic documents and the regulatory provisions which precludes, at least in the short term, the effectiveness of a transition to digital.

Furthermore, on a practical level, the guarantees of security in access and reliability in the identification of users are lacking. Until satisfactory standards are reached, AI tools (but also other digital health tools such as the FSE and Telemedicine) will never find adequate application. In this respect, biometric recognition and the use of Blockchain technology are being tested, as digitization tools not characteristic of the healthcare sector, but applicable to it[47].

Yet another difficulty in implementing AI lies in the current method of training operators which is, from an objective point of view, still based on traditional models and, from a subjective point of view, limited to a few professionals compared to the range of skills that opens up in the face of digitization. Added to this is the need for the involvement of specific figures to support the structures for monitoring the use of therapies and solving any technical problems that may arise. In essence, an adequate healthcare digitization and, in particular, a good application of AI, cannot be separated from a profitable mix of knowledge given by the coexistence, within each healthcare company, of various professional figures.

Finally, there is a lack of patient involvement, as a subject who is an integral part of the digital therapy implementation process: in fact, a further and fundamental

43 For an exhaustive reconstruction of the regulatory framework in terms of digital therapies, please refer to Ravizza, A. – Caiani, E. – Santoro, E. – Stefanelli, S. – Sternini, F.: "Come gestire gli aspetti regolatori per le terapie digitali", in Gussoni, G. (a cura di), *Terapie digitali: un'opportunità per l'Italia,* cit., 15.

44 Aperio Bella, F.: "L'accesso alle tecnologie innovative nel settore salute tra universalità e limiti organizzativi (con una postilla sull'emergenza sanitaria)", *PA Persona e Amministrazione*, 1/2020, p. 230.

45 On "*Delega al Governo per il recepimento delle direttive e l'attuazione degli altri atti dell'Unione europea"*.

46 On these aspects, please refer, in more detail, to Gussoni, G.: *Executive Summary*, in Gussoni, G. (a cura di): *Terapie digitali: un'opportunità per l'Italia,* cit., p. 3.

47 Aperio Bella, F.: "L'accesso alle tecnologie innovative nel settore salute tra universalità e limiti organizzativi (con una postilla sull'emergenza sanitaria)", cit., 226; Bellomo, G.: "Biometria e digitalizzazione nella pubblica amministrazione", at Civitarese Matteucci, S. – Torchia, L. (a cura di): *La Tecnificazione*, cit., 59. On Blockchain tecnology, Carullo, G.: "Dati, banche dati, Blockchain e interoperabilità dei sistemi informatici nel settore pubblico", at Cavallo Perin, R. – Galetta, D.U. (a cura di): *Il diritto dell'amministrazione pubblica digitale*, cit., 202 ss. Furthermore, with reference to the Blockchain in the Health sector, refer to the exhaustive considerations of Catelani, E.: "Nuove tecnologie e tutela del diritto della salute: potenzialità e limiti dell'uso della Blockchain", cit., 219.

aspect for the diffusion and effectiveness of digital therapies is the information and awareness of patients through initiatives that can know them about the potential health benefits. Only the patient's effective collaboration in the use of the digital tool can generate a successful outcome of the therapy (think of the patient who does not monitor the app or does not wear the devices). Also in this aspect it is necessary to involve technical figures with good communication skills who, although external to the healthcare organization, operate in a credible, reliable, engaging way and free from the logic of profit.

From such an assumption it follows that, in introducing technology, the human component must not be neglected: machines must not replace people, but be at their service. In this regard, the principle of "non-exclusivity of the algorithmic decision" is also applicable to the health sector[48] according to which in every decision-making process the human contribution must always be guaranteed in order to validate or deny the automatic decision. It is therefore necessary to increase the staff otherwise there is the risk of sterilizing the substantial appropriations. In other words, the implementation of the programmed objectives must involve a reflection by the health administration of a structural nature on the human resources that will have to manage the new services (community homes, community hospitals) and the new digital tools of care; therefore, a trend reversal compared to the recent past is desirable, aimed at enhancing the stable recruitment of doctors, nurses and paramedical personnel, but also of new professional figures with skills that go beyond the purely health field, in order to maintain, on an ongoing basis, the efficient management of the services and tools created thanks to European funds[49].

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48 Council of State, sixth section, n. 8472 of 13 december 2019. In doctrine, Simoncini, A.: "L'algoritmo incostituzionale: intelligenza artificiale e il futuro delle libertà", *BioLaw Journal, Rivista di Biodiritto*, n. 1/2019, 79.

49 Just to give an example, the OECD has been reporting for some time that in Italy the number of nurses is well below the European average. See the report, Italy among the last in Europe for the number of nurses, at www.quodianosanità.it.

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IV. N.R.R.P. OPPORTUNITY FOR THE "GOOD ADMINISTRATION" OF HEALTH CARE

The digital transition path has historically encountered many obstacles which have led to its failure to be implemented since, when changes affect social rights, there is always a certain reluctance in public administrations to implement them even when this is possible with unchanged legislation.

Digitization brings with it many dangers that compromise the guarantee of constitutionally guaranteed rights: one of these dangers is the potential "not neutrality" in the use of technological tools connected to the dispersion of data which, in the health sector, are detached from sensitive data and assume their own definition by the European Regulation 679/2016 (GDPR)[50]. In this regard, it should be noted that the e-Healt tools analyzed above, based on messaging services, geolocation, bluetooth technology and so on, require the patient to enter personal data with the possibility of constant access by health and economic operators. In this system, data and information continuously feed databases useful for scientific research, generating an unlimited volume of data on the network. The issue is complex because confidentiality is not guaranteed simply by strict secrecy of the information but, more in depth, by the transparency of the information held by public and private entities in contact with the interested party, who has the right to access and modify data concerning him[51].

Some studies have found a picture that, between insecure communication protocols and omissions on privacy policies by some Apps, can be considered an alarm bell for the security of personal data[52]. So, despite an overabundance of supranational and national legislation on the protection of personal data[53], and although the GDPR can be considered an advanced regulatory tool[54], the difficulty

50 Covino, F. : "Uso della tecnologia e protezione dei dati personali sulla salute tra pandemia e normalità", cit., 57.

51 Covino, F. : "Uso della tecnologia e protezione dei dati personali sulla salute tra pandemia e normalità"; Colapietro, C. : "Trasparenza e democrazia: conoscenze e/è potere", in Califano, L. – Colapietro, C. (a cura di), *Le nuove frontiere della trasparenza nell'ordinamento costituzionale*, Editoriale scientifica, Napoli 2014, 30.

52 Capilli, G.: "Dati sanitari nell'era digitale. Verso uno spazio europeo dei dati sanitari", at AA.VV.: *Responsabilità sanitaria, rischio clinico e valore della persona*, cit., p. 56, which reads that "in 23% of cases, user data transmissions took place on unsafe protocols, 28% of the app did not provide privacy policies, while 47% of user data transmissions complied with the rules privacy policy".

53 For an exhaustive reconstruction, refer again to Capilli, G.: "Dati sanitari nell'era digitale. Verso uno spazio europeo dei dati sanitari", in AA.VV.: *Responsabilità sanitaria, rischio clinico e valore della persona*, cit., 51.

54 Covino, F.: "Uso della tecnologia e protezione dei dati personali sulla salute tra pandemia e normalità", cit., according to which the regulatory system as a whole is solid and effective in guaranteeing the protection of health data.

remains to raise the level of protection of confidentiality on a practical level in order to avoid violations on the dissemination of personal and sensitive data. In other words, if the use of the most modern technologies is possible today, it is not equally possible to provide adequate guarantees on the protection of personal data that are not based on rules (general and abstract plan) but on the technology itself (punctual and concrete plan)[55]. And until this gap is filled, the same clinical effectiveness of digital tools will remain compromised which, by their nature, require (as already noted) the effective collaboration of the patient.

Furthermore, the vulnerability of databases does not only involve a privacy problem but also a cybersecurity problem: in fact, there have already been several hacker attacks on hospital facilities. The problem is not insignificant given the operational paralysis of the structures until the ransom is paid or, in any case, the regular functioning of the computer system is restored. Therefore, the technology that will be put in place must also be oriented towards sterilizing the effects of these new "digital robberies" by modernizing the current IT systems, now obviously obsolete and, therefore, vulnerable.

A further pitfall of digitization, as anticipated, is the increase in inequality and the marginalization of fragile categories. The concrete risk is that the use of technologies in healthcare, instead of guaranteeing equity in access to treatment, goes in the opposite direction, exacerbating the digital divide with consequential prejudice to the effectiveness of the right to health and also in disregard of the principle of equality pursuant to art. 3 of Constitution.

The commitments and programs aimed at containing the gap and social inequalities that the unequal use of technology creates are now present both on the European and national scene; however, they are destined to remain a dead letter if targeted digital literacy policies are not followed, aimed at increasing trust in technology and, consequently, its use.

That said, the pandemic - in the more traditional vision of crisis as an opportunity - was an opportunity to resume and accelerate the digitization process of public administrations. As is now known, in fact, Europe has strengthened its multiannual budget in order to face the economic crisis generated by the Covid-19 pandemic: the strategic fundamental principles of the *NextGenerationEU*[56] have been

55 Some solutions are only being studied and tested. In this regard, refer to Casalicchio, E. – Filetti, S. – Grigolo, S. – Mancini, L.V. – Mei, A. – Pagnotta, G. – Ravizza, A. – Spognardi, A. – Stefanelli, A.: "Privacy e cybersecurity nell'ambito delle terapie digitali", in Gussoni, G. (a cura di), *Terapie digitali, una opportunità per l'Italia*, cit., 51.

56 About complete text, www.next-generation-eu.europa.eu.

implemented by Italy in the National Recovery and Resilience Plan, a complex programmatic tool with dual regulatory relevance[57].

In mission 6 of the N.R.R.P. called "Health", and for which the sum of 15.63 billion euros was allocated out of the total 191.5 billion that Italy received[58], the planned interventions concern two macro-components: the first is related to "Proximity networks, structures and Telemedicine for territorial health care"; the second pertains to "Innovation, research and digitization of the national health service".

It's evident, already from the name, how the two components intertwine in the analysis dedicated to technological tools. At a synthetic overview, the investment concerns a threefold dimension: the Electronic Health Record in order to guarantee its "dissemination, completion, homogeneity and accessibility"[59]; the strengthening of the health information system with the main but not exclusive objective of expanding the ability to detect the state of health of the population as a response to new pandemics or emerging diseases[60]; the strengthening of the health information system with the main but not exclusive objective of expanding the ability to detect the state of health of the population as a response to new pandemics or emerging diseases[61].

The sums allocated for each measure are identified in the quantum on a six-monthly and ex ante basis and the disbursement takes place upon achievement of the goals and objectives set for each measure (whether it is an investment or a reform)[62].

57 De Luongo, D.: "Contributo allo studio dei rapporti fra Piano Nazionale di Ripresa e Resilienza e sistema delle fonti statali: dinamiche, condizionamenti e prospettive", *Osservatorio sulle fonti*, n. 3/2022, to which reference is made for a study of the N.R.R.P. from the point of view of the classification within the context of state sources. To this end, see also Clarich, M.: "Il Piano di Ripresa e Resilienza tra diritto europeo e nazionale: un tentativo di inquadramento giuridico", *Astrid Rassegna*, 2021, 341.

58 To the resources allocated with the N.R.R.P. those allocated with the REACT-EU (European resources to be spent in the three-year period 2021-2023) and those allocated to the Complementary Fund must be added. The total allocated for Mission 6 is €. 20.23 billion with the general objective of strengthening prevention and health services in the area, modernizing and digitizing the health system and guaranteeing equal access to treatment. The disbursement of the sums takes place upon the achievement of the goals and objectives set for each measure (whether it is an investment or a reform), a moment upon which the allocation of resources is subject, determined ex ante on a six-monthly basis.

59 Terms used, albeit in a widespread way, within the document. For the complete consultation, refer www.governo.it.

60 This is an upgrading of the infrastructure belonging to the Ministry of Health for the monitoring of the LEA and the planning of health care services for the population, originally envisaged in art. 87 of the Law of 23 December 2000, n. 388, containing "Provisions for the preparation of the annual and long-term state budget" (2001 Finance Law).

61 For further information on "Mission 6" as a whole, please refer to Pioggia, A.: "La sanità nel Piano Nazionale di Ripresa e Resilienza", *Giorn. Dir. Amm.*, 2022, 2, p.165 ss; an overall reconstruction is also carried out by Posteraro, N.: "Il Fascicolo sanitario elettronico", at Bontempi, V. (a cura di): *Lo stato digitale nel Piano Nazionale di Ripresa e Resilienza*, Romatre-press, 2022, 87.

62 Until now, expectations have been met: in general, in the first half of 2022 Italy has achieved its objectives as has been ascertained at European level; in the second half of the year the program for implementing the objectives proceeded even faster than in the original schedules. In terms of health, the first objective

Of course, the N.R.R.P. represents recognition by Europe of Italy's ability to identify valid measures to reorganize public administrations and restart the economy. In this sense, it is an opportunity for the modernization of public administrations: in fact, in the first place, with the huge allocations foreseen, there is a change of direction with respect to the historical and disheartening tendency of the national legislator to include in the systems public reorganization regulations, which as such contain one or more items of expenditure, the so-called "financial invariance clause" generally expressed in the footnote "without new or greater burdens for public finance". If the intent is to implement the precept pursuant to art. 81, third paragraph, of the Constitution[63], in practice the financial invariance clause can frustrate the implementation of the regulatory provisions, given that the public administrations cannot resort to an increase in human and instrumental resources compared to those available at the time the law enters into force. The financial invariance clause has not spared even the health sector: historically, in fact, attempts have been made to revolutionize public health through wide-ranging regulatory systems that have proclaimed important innovations, but without implementing the economic resources[64]. Nor has the orientation of the constitutional jurisprudence, endorsed by the accounting one, had any effect, according to which "the criterion of invariance of the financial charges is established with regard to the overall effects of the provision and does not involve *in itself* the foreclosure of a possible increase in expenditure provided that this burden is "neutralized" with a compensation of other provisions producing savings or higher income"[65].

From the abandonment of the financial invariance, it follows consequently that the N.R.R.P. could be the key to reaching that model of digital administration which in Italy has never found concrete application due to the historical absence of an IT culture, a traditional inadequacy of administrative structures and, in general, a strong reluctance to change on the part of public employees[66]. Public personnel were not specialized in the use of IT systems and, upstream, there was no strategic

achieved is the reform of the IRCCS (Scientific Hospitalization and Care Institutes): these are 51 hospitals (21 public and 30 private) that provide innovative treatments, also guaranteeing an increase in therapeutic quality through collaborations external. The second objective concerned the launch of public tenders for 1.4 billion euros for digitization and was achieved with the stipulation of Consip contracts on 21 December 2022 which includes the digitization of CUPs (Single Booking Centers), new platforms, telemedicine and digital medical record. For such contracts, seewww.consip.it.

63 "Each law which imposes new or greater burdens on the State provides the means to meet them".

64 Think of the art. 18 of the law of 8 March 2017, n. 24 (so-called Gelli-Bianco law) or art. 7 of the law of 22 December 2017, n. 219 which, even in terms of end-of-life choices, "hides" within it multiple items of expenditure for public administrations with reference to the Advance Treatment Provisions.

65 Constitutional Court, 16 may 2014, n. 132, at www.cortecostituzionale.it; in the accounting jurisprudence, see C. Conti, Basilicata, n. 39/PAR of 14 september 2016 and C. Conti, Abruzzo, n. 127/2017/PAR where it is noted that "the financial constraint of the expenditure constitutes the alter ego of the obligation of financial coverage codified in art. 81, fourth paragraph, of the Constitution. The objective pursued is identical: the protection of public finance balances".

66 Losano, M.G.: *Corso di informatica giuridica. II) Il diritto pubblico dell'informatica*, Einaudi, Torino 1969, p. 243.

cost/benefit evaluation plan related to the digitization of the public sector[67]. If this was the case in the 70s of the last century, today little or nothing seems to have changed: in fact, Italy is still in a state of IT backwardness as demonstrated by the analysis conducted by the European Union in the years 2014-2019 on the degree of digitization of households, businesses and the state[68].

For this reason, with the solid foundation made up of the huge European funds, the public administration is now called to act in the awareness of the aforementioned risks in order to overcome its inefficiencies in accordance with the principle of good performance pursuant to art. 97 of the Constitution[69] and lay the foundations for a change which, by focusing on technological innovation, leads to the safe and equal use of digital services. In this way, the relationship between citizens and administration is improved, as a precondition for "good administration", understood as a citizen's right according to the more modern and supranational vision enshrined in art. 41 of the Charter of Fundamental Rights of the European Union[70].

The same N.R.R.P expressly refers to "good administration", qualifying it as the main axis for the implementation of a program of reforms and investments aimed at eliminating the bureaucratic constraints that compromise the speed, effectiveness and efficiency of the administrative action.

67 Predieri, A.: *Gli elaboratori elettronici nell'amministrazione dello Stato*, Il Mulino, Bologna 1971, p. 45.

68 Italy ranked fifth from last among European countries. In this regard, Losano, M.G.: "La lunga marcia dell'informatica nelle istituzioni italiane", in Cavallo Perin, R. – Galetta, D.U. (a cura di): *Il diritto dell'amministrazione pubblica digitale*, XXIV, which, in the exhaustive analysis on information technology, is expressed in terms of "evolution made more of intentions than of achievements".

69 Police, A: "Principi e azione amministrativa", at Scoca, F.G. (a cura di): *Diritto amministrativo*, V, Giappichelli, Torino 2017, p.191.

70 L'art. 41 "overturns" the good administration from the duty of the p.a. to the right of the citizen. In the first meaning, Falzone, G.: *Il dovere di buona amministrazione*, Giuffré, Milano 1953, p. 129. In the second, however, reference is made to the considerations of Zito, A.: "Il "diritto ad una buona amministrazione" nella Carta dei diritti fondamentali dell'Unione europea e nell'ordinamento interno", *RIDPC*, 2002, p. 433; Marzuoli, C.: "Carta europea dei diritti fondamentali, "amministrazione" e soggetti di diritto: dai principi sul potere ai diritti dei soggetti", at Vettori, G. (a cura di): *Carta europea e diritti dei privati*, Cedam, Padova 2002, p. 255; Cassese, S.: "Il diritto ad una buona amministrazione", Relazione alla Giornata sul diritto alla buona amministrazione, Barcellona 2009, in www.irpa.eu, which expresses itself on the evolution of the principle that leads it to be a right: first a principle for the effectiveness of the public administration, then a functional principle for the enjoyment of citizens' rights; Ferrara, R.: "L'interesse pubblico al buon andamento delle pubbliche amministrazioni: tra forma e sostanza", *Dir. e proc. amm.*, 2010, 31; Celone, C.: "Il diritto alla buona amministrazione, tra ordinamento europeo ed italiano", *Il diritto dell'economia*, 2016, p. 669; Perfetti, L.: "Diritto ad una buona amministrazione, determinazione dell'interesse pubblico ed equità", *RIDPC*, 2010, p.789; Cassese, S. – Galetta, D.U.: "Il diritto ad una buona amministrazione nei procedimenti amministrativi oggi (anche alla luce delle discussioni sull'ambito din applicazione dell'art. 41 della carta dei Diritti dell'UE)", in Pierro, M.C. (a cura di): *Il diritto ad una buona amministrazione nei procedimenti tributari*, Giuffré, Milano 2019, 1; Galetta, D.U.: "Digitalizzazione e diritto ad una buona amministrazione (Il procedimento amministrativo, fra diritto UE e tecnologie ITC)", in Cavallo Perin, R. – Galetta, D.U. (a cura di): *Il diritto dell'amministrazione pubblica digitale*, *c.w.*, 85; Ponti, B.: "Le diverse declinazioni della "buona amministrazione" nel PNRR", in AA.VV.: *Il PNRR come motore del cambiamento dell'amministrazione*, in *Istituzioni del Federalismo*, 2, aprile-giugno 2022, 401.

The objective of Mission 6 is to ensure "an effective improvement of the National Health System" by providing resources to be allocated and implemented by 2026: a short time if compared to the complexity of the health sector and the high degree of innovation that is aimed at to introduce. The challenge is complex because it is not just a matter of mere forecasting and giving of money, but a combination of high professionalism, constant commitment and loyal institutional collaboration is needed aimed at a profound structural change in the public administration.

V. SCIENTIFIC AND TECHNOLOGICAL PROGRESS AS A TOOL FOR A NEW CLINICAL AND ADMINISTRATIVE APPROPRIATENESS

Scientific and technological progress as a tool for a new clinical and administrative appropriateness[71]. The autonomy of the patient with respect to the professional (as opposed to the previous subordination) has favored the establishment of a symmetrical relationship which, over time, has become conflictual. And in fact, statistics have always demonstrated a counterintuitive phenomenon of direct proportionality between therapeutic success and the increase in litigation: people live longer, they heal more frequently, however health disputes increase[72]. The cause has been recognized in the advancement of science and technology that increases people's expectation of the final result: healing. The increase in litigation generated, in the first decade of the 2000s, phenomena of defensive medicine, i.e. conduct by health professionals aimed at avoiding the advancement of claims for compensation (even specious) by patients rather than focused on the protection of Health[73]. Hence, the "slippery slope" made up of disproportionate costs for the national health service[74], increase in insurance premiums for professionals, flight

71 In fact, the *Patient's Bill of Rights* dates back to 1973, the first document that values correct and complete information to the patient as a necessary condition for respecting his decision-making autonomy regarding diagnosis, treatment and prognosis. In this regard, Cataldi, R. – Storani, P. – Romanelli, F. – Vagnoni, S. - Albertazzi, L.: *La responsabilità sanitaria pubblica e privata*, Maggioli, 2013, p. 10.

72 Aleo, S. - De Matteis, R. – Vecchio, G. (a cura di): *La responsabilità in ambito sanitario*, Cedam, Padova 2014.

73 As early as 1994, in the USA it was stated that defensive medicine "occurs when doctors prescribe tests, diagnostic procedures or visits, or avoid high-risk patients or treatments, mainly (but not exclusively) to reduce their exposure to a liability judgment for malpractice. When doctors prescribe extra tests or procedures, they practice positive defensive medicine: when they avoid certain patients or treatments, they practice negative defensive medicine. Thus, the Office Of Technology Assessment. In Europe, the study of the phenomenon followed and, with particular reference to the Italian context, the first research was carried out in the period July - November 2008 by the Federico Stella Study Center on criminal justice and criminal policy of the Catholic University of the Sacred Heart of Milan with the title "Progetto di riforma in materia di responsabilità penale nell'ambito dell'attività sanitaria e gestione del contenzioso legato al rischio clinico". Another research, also from 2008, was that carried out in the medical field by the Order of the Provincial Council of Doctors and Dentists of Rome limited to the territory of the Capital, with the title "La medicina difensiva in Italia in un quadro comparato: problemi, evidenze e conseguenze", at www.art.torvergata.it. In the following years, the same Order conducted the first national research on the subject, entitled "Chi si difende da chi? E perché? I dati della prima ricerca nazionale sulla medicina difensiva" and the related results were made public on 23 November 2010.

74 Defensive medicine has come to create a hole in the state budget of about 13 million euros. On such research the doctrine is endless: please refer, without claiming to be exhaustive, to Barresi, R. – Battaglino, A. - Calabrese, A. – Lomastro, L. – Maffione, G. – Natoli, V. – Parente, E. – Quazzico, A.: *Impatto sociale,*

of doctors abroad and abandonment of some areas of responsibility by insurance companies. In this context, in the second decade of this century, the great public health reforms were grafted which concerned, with the dual *ratio* of health protection and the rationalization of public spending, both the health organization and the system of responsibility, but whose effects were not really disruptive.

Today, scientific and technological progress is changing its face: the same technology that in the past was the cause of the conflict between doctor and patient and, subsequently, of all the negative consequences mentioned above, is being relied upon in this post-pandemic moment to restore that "therapeutic alliance" functional to the effectiveness of health and the safeguarding of public finances, in summary to the good performance of the public administration.

The challenge undertaken lies in finally realizing the transition from the analogue state to the digital state in order to allow the public administration to keep up with technological progress and, in this way, promote the protection of health in its broadest sense[75] and, more generally, the economic and social development of the country.

The digital tool in the specific health sector could reasonably lead to a significant increase in the efficiency of the entire system, under the dual but inseparable aspect of organization and action: on organization, for example, waiting lists could be reduced , guarantee data interoperability, increase the availability of beds in the structures and, therefore, favor patient turnover; moreover, the transition to digital would be useful for rationalizing the workload of healthcare professionals which, especially in the midst of the emergency, has increased dramatically with consequent organizational chaos and lowering of the quality of services[76]. As for

economico e giuridico della pratica della medicina difensiva in Italia e negli Stati Uniti, in Programma Scienziati in Azienda, XII edizione, Stresa 26 September 2011 -16 July 2012, 1° Project Work of Fondazione Studi Stresa; Parravicini, M.C.: "Medicina difensiva" e Genovese, U.: "La medicina difensiva vista dal medico legale", both in *Bollettino OMC e OMI* n. 2/2011, in www.assimedici.it; Guerra, G.: "La medicina difensiva: fenomeno moderno dalle radici antiche, in Salute e diritto Politiche sanitarie", Vol.14, n. 4, october – december 2013, *www.politiche.sanitarie.it*; Confalonieri, N.: "Rapporto medico-paziente: i pericoli della medicina difensiva", *www.cineas.it*; Capozzi, A.: *Lotta alla medicina difensiva*, Edizioni Ecolab, 2016, p. 43, at www.diritto.it.

75 That is to say of "psycho-physical well-being of the person", as defined already in 1946 by the WHO. On the broad and polysemantic value that the fundamental right to health assumes in our legal system, refer to Posteraro N.: "La "reviviscenza" dell'istituto della difesa civica alla luce della legge Gelli-Bianco: il Difensore civico regionale quale garante del diritto alla salute", Osservatorio di diritto sanitario, Federalismi.it, 21 march 2018. On the evolution of the notion of "health" and on the identification of the content of the related right, refer to Pioggia, A.: *Diritto sanitario e dei servizi sociali*, seconda edizione, Giappichelli, Torino 2017, p.19 ss; Gallo, C.E. – Pezzini, B.: *Profili attuali del diritto alla salute*, Giuffrè, Milano 1998; Luciani, M.: voce "Salute", *Enciclopedia Giuridica* XXVII, Roma 1991; Vincenti Amato, P.: "Articolo 32", in Commentario alla Costituzione diretto da Branca, G., Bologna-Roma 1976; Santilli, M. – Giusti, M.: "Tutela della salute", in Enciclopedia Giuridica, XXVII, Roma 1991; Cocconi, M.: *Il diritto alla tutela della salute*, Cedam, Padova 1998; Aicardi, N.: "La sanità", in Cassese, S. (a cura di): *Trattato di diritto amministrativo*, Giuffré, Milano 2003; De Vincenti, C. - Finocchi Ghersi, R. – Tardiola, A.: *La sanità in Italia: organizzazione, governo, regolazione e mercato*, Il Mulino, Bologna 2010; Cavasino, E.: *La flessibilità del diritto alla salute*, Editoriale Scientifica, Napoli 2013.

76 With reference to the usefulness of digital healthcare to guarantee assistance to the population during the pandemic, refer ISS Covid-19 Report n. 12/2020 - Interim indications for telemedicine assistance services

the action, digitization could improve the effectiveness of many therapies to be implemented with a minimum sacrifice on the part of patients, limited at most to monitoring apps, wearing devices, communicating remotely; a collaboration that is certainly simpler than the current sacrifices in terms of mobility and hospitalization which also affect the psycho-physical state of one's family members. Furthermore, as stated by the WHO, digitization represents the answer to the need to implement and make access to healthcare more equitable and to the need to reduce healthcare costs[77].

Noble objectives, those mentioned above, for which, however, the allocation of sums, albeit large, is not a guarantee of results because digitization is not just a matter of "transition of current procedures into digital format", which would amount to a simple "change of form", but requires "a profound reorganization of the structures and an equally radical re-engineering of the procedures"[78].

What is needed, therefore, is a structural and systemic change of the public administration, as well as a revision of the reference legislation that governs its organization and action[79]. As for the administrative transformation, the long process has already been started thanks to the above-mentioned programs envisaged in the N.R.R.P.[80]: all the key points of the recent welfare reform[81] redesign the health organization with the aim of strengthening it, creating a structured system with multiple services adapted to the needs of patients, their families, as well as health professionals and to be guaranteed in full efficiency in ordinary life, not only in any future emergency situations.

during the COVID-19 health emergency, at www.iss.it.

77 World Healt Organization: *What do you need to know about digital health system*, 2020. Also, for a program of action in the immediate future, see *Global strategy on digital health 2020-2025*, in www.who.int.

78 Torchia, L: "L'amministrazione presa sul serio e l'attuazione del PNRR", *Astrid Rassegna* 2021, n. 6-7 according to which it is more correct to express oneself in terms of "digital transformation" rather than "digital transition".

79 Così Piperata, G.: "PNRR e pubblica amministrazione: attuazione, riforme, cambiamenti", in AA.VV.: *Il PNRR come motore del cambiamento dell'amministrazione*, in *Istituzioni del Federalismo*, cit., 317.

80 For a general analysis on the implementation of the N.R.R.P., Dugato, M.: "L'intervento pubblico per l'inclusione, la coesione, l'innovazione e la sostenibilità ed il ruolo del servizio pubblico locale nel Piano nazionale di ripresa e resilienza", *Munus*, 2022, p.1 ss; Catelani, E.: "P.N.R.R. e ordinamento costituzionale. Un'introduzione", *Rivista AIC*, 3/2022; Lupo, N.: "Il PNRR e i poteri dello Stato", *Astrid Rassegna*, 2022; Fiorentino, L.: "Il Piano di ripresa. Un'occasione per cambiare l'amministrazione", *Giorn. dir. amm.*, 2021, 689 ss; Cerulli Irelli, V. - Giurickovic Dato, A.: "Sugli interventi normativi necessari per l'attuazione del Piano Nazionale di Ripresa e Resilienza", *Astrid Rassegna*, 2021, 245.

81 Community houses, community hospitals, integrated home care, the 116117 operations center, the territorial operations center, the care continuity unit, the palliative care network, the family and community nurse, services for the health of minors, women, couples and families and telemedicine: these are the pillars of the reform regulated by decree 23 may 2022, n. 77. At www.pnrr.salute.gov.it we read: "The reform of territorial assistance defines a new organizational model of the National Health System which aims at health care closer to people and at overcoming inequalities. The new institutional and organizational set-up of primary health care will allow the country to achieve adequate quality standards of care, in line with the best European practices".

As for the legislation in support of organization and action, attention must be paid to the European and national dimension: at the European level, underlining the importance of a centralizing design in the governance of technological innovation in public health, the the need for an acceleration in the definition of a unitary regulatory system and a shared European strategy in order to achieve adequate levels of efficiency for health protection, guaranteed in a uniform way in order to overcome any form of inequality[82].

On the national level, however, a relevant aspect is the connection between the LEA and digital health services[83]: as is well known, in fact, the basic services that the National Health System must ensure in a fair way to all citizens must be identified in the same way as the principle of appropriateness by virtue of which the Health System only takes care of the services that can be considered effective from a clinical point of view based on scientific evidence (clinical appropriateness) and which, other services being equal, are less expensive (organizational appropriateness)[84].

Given this, today the difficulty lies precisely in including the most technologically advanced medical services in the LEA, given their high cost and the probable lack of scientific solidity given by their innovative nature. In this sense, the aspect relating to the definition of the LEAs and their continuous updating will therefore be important to ensure that the National Health System proceeds hand in hand with scientific and technological progress, guaranteeing an administrative organization and a therapeutic action effectively marked the effective use of digital tools, with associated guarantees of fairness. In essence, it is a fundamental step to allow the health administration to exercise its function appropriately, in a process of modernization of the concept of appropriateness which, as supported by the most careful and modern doctrine, should not refer only to the result, but to the *modus operandi* of the public administration[85].

82 Aperio Bella, F.: "L'accesso alle tecnologie innovative nel settore salute trà universalità e limiti organizzativi (con una postilla sull'emergenza sanitaria)", *PA Persona e Amministrazione*, 2020, 245.

83 The tool used to define the Essential Levels of Assistance was the d.p.c.m. january 12, 2017 indexed "*Definizione e aggiornamento dei livelli essenziali di assistenza, di cui all'art. 1, comma 7, del decreto legislativo 30 dicembre 1992, n. 502*".

84 For an analysis of the appropriateness in healthcare, Aperio Bella, F.: "L'accesso alle tecnologie innovative nel settore salute trà universalità e limiti organizzativi (con una postilla sull'emergenza sanitaria)", *PA Persona e Amministrazione*, p. 230 ss, hich refers, for a general analysis on the principle to Antonelli, V.: "La garanzia dei livelli essenziali di assistenza nei primi 40 anni del Servizio sanitario nazionale: dall'uniformità all'appropriatezza", *Federalismi.it*, 2018.

85 Giani, L.: "L'amministrazione tra appropriatezza dell'organizzazione e risultato: spunti per una rilettura del dialogo tra territorio, autorità e diritti", *Nuove Autonomie*, 3/2021, p. 551 who, at the end of his reflections, highlights how it is simplistic to limit appropriateness to result indicators, but it is necessary to refer it to the action that is its prerequisite, therefore the same appropriateness cannot disregard the enhancement of the organizational system and skills.

Furthermore, the inclusion and continuous updating of digital health services in the LEAs, the result of the joint commitment between the Government and the Regions, is a must if one thinks of the universalistic aspirations and equity in access to care that have always characterized the Health Service National. In this regard, it is desirable to enhance the principle of loyal collaboration between the various levels of government, as a necessary precondition for the creation of an inclusive, innovative, fair and sustainable health system based on Digital Public Health[86].

86 The words of warning uttered in 2019 by the then President of the Constitutional Court are current who, dedicating a large part of his speech to the aforementioned principle, conclusively stated: «*In such a situation, if there is a constitutional principle that deserves particular emphasis and particular attention is precisely that of "loyal collaboration" - the institutional aspect of solidarity - to which even the jurisprudence of the Constitutional Court never tires of returning, so that the action and energies of the entire national community converge towards a single, shared objective*». Cartabia, M.: "L'attività della Corte Costituzionale nel 2019", 28 april 2020, at *www.cortecostituzionale.it.*

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