European Review of Digital Administration & Law - Erdal
2023, Volume 4, Issue 1, pp. 187-200
ISSN 2724-5969 – ISBN 979-12-218-1128-5 – DOI 10.53136/9791221811285 14

*The Italian Electronic Health Record (EHR)**

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ABSTRACT The work analyses the Italian legislation governing the electronic health record (EHR). Among the other things, it dedicates particular attention to the role of this tool in the context of the Italian healthcare digitalisation; the paper also deals with the problems related to the elimination of the data subject's consent for the implementation of the EHR and it tries to highlight some possible actions for the enhancement of this tool expressly provided by the Italian National Recovery and Resilience Plan (NRRP).

1. *The Electronic Health Record (EHR) as a tool of Italian digital health*

The *Electronic Health Record* (EHR) holds a central role among Italian e-Health tools: it is 'a pillar' within the initiatives related to the pathway towards digital health and it constitutes the main enabling factor for the achievement of significant improvements in the quality of services provided in the health sector.[1]

The EHR is a digital collection of all health and socio-medical data and documents relating to a person's medical history and it is part of the broader process of dematerialisation/transfer of health records into digital format.[2] More specifically, it is an "archive of the health of the patient", which, set up by the respective Italian Regions (and Autonomous Provinces),[3] is implemented over time by the practitioners of the health professions and by the patients themselves.[4] In this sense, it is one of the clearest manifestations of the culture whereby architecture is designed to fully serve the interaction between health professionals and between patients and doctors.

At the legislative level, the EHR was officially introduced in Italy in 2012;[5] however, even before the instrument acquired "national" importance, several regions had already started project activities for the implementation of EHR systems at local levels.

The main purpose of the EHR is to create an organic information base, with continuous implementation, that favours the improvement of prevention, diagnosis, treatment and rehabilitation of patients.[6]

It enables the digital sharing of health data and documents created, integrated and updated over time by several parties; it is thus able to document patients' entire medical history, report their several health events and offer a better care process.

Thanks to the EHR, patients can trace and consult the entire history of their health life, sharing it with health professionals in order to obtain a (at least abstractly) more effective and more efficient service: it is evident, for instance, that the tool provides a valid support for the continuity of care, as it allows the

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[*] Article submitted to double-blind peer review.
The work is a joint study of the two authors; specifically, N. Posteraro is the author of paragraphs 2, 5, 8 and 9, while S. Corso is the author of paragraphs 3, 4, 6 and 7. Paragraph 1 was written by both the authors.

[1] This is the description of the EHR found on the official website: *www.fascicolosanitario.gov.it.*

[2] A process that, in Italy, was launched in 2011 with the aims of implementing the true potential of data collected, cutting the costs of managing and archiving "paper", streamlining and speeding up procedures; over time, it has also involved medical records, prescriptions and reports. N. Posteraro, *La digitalizzazione della sanità in Italia: uno sguardo al Fascicolo Sanitario Elettronico (anche alla luce del Piano Nazionale di Ripresa e Resilienza)*, in *www.federalismi.it*, 17 November 2021.

[3] The Italian EHR is therefore a model whose infrastructure is based on a national network of regional/provincial architectures (also for this reason, it is different from the English and French models, designed respectively with a mixed and centralised architecture at national level).

[4] Article 12(3) of d.l. No. 179 of 18 October 2012 (the so-called "Decreto crescita", later converted into Law No. 221 of 17 December 2012).

[5] More specifically, by Article 12 of d.l. No. 179 of 18 October 2012.

[6] See Article 12(2)(a) and (a-*bis*) of d.l. No. 179/2012; P. Guarda, *Fascicolo Sanitario Elettronico e protezione dei dati personali*, Trento, Università degli Studi di Trento, 2011, 26.

various professionals who are already in charge of a patient to be aware of the diagnostic and therapeutic initiatives carried out by their colleagues. In this sense, the EHR contributes to create an e-Health system based on the centrality of the patient.[7]

Clearly, the possibility of retracing the history of a clinical pathway is highly dependent on the fact that all the documents contained in the EHR, in addition to being easily retrievable, are correctly stored and protected from modification or alteration. This is a particularly important issue, if we consider not only that there has been a dangerous exponential increase in cyber-attacks aimed at stealing numerous health data in our country in recent years, but also that, as things stand, there is still little awareness on the part of healthcare facilities of their obligation, as data controllers, to adopt logical security measures aimed at protecting their computer systems and, consequently, the integrity of the data.[8]

The purposes of diagnosis, treatment and rehabilitation of patients are pursued by the subjects of the National Health Service (NHS) and the regional socio-health services and by all health professions;[9] those of prevention, on the other hand, are pursued (in addition to the subjects of the NHS and the regional socio-health services and by the health professions) also by the offices of the Regions and Autonomous Provinces responsible for preventive health care and by the Ministry of Health.[10]

Added to these purposes are those of international prophylaxis, pursued by the Ministry of Health.[11]

At the same time, the EHR also acts as a support for the study and the scientific research in the medical, biomedical and epidemiological fields, as well as for health planning, quality of care verification and health care evaluation.[12] For the sake of completeness, it should be pointed out that, under the current legislation, the subjects deputed to achieve the above-mentioned purposes,[13] within the limits of their respective competences attributed by law, may access the file and process the data contained therein, provided that they are deprived of identifying elements, on the assumption that, for these purposes, other than those of prevention and personal care, it is sufficient to use non-identifying information.

In this sense, the regulation of the EHR (the establishment of which therefore gives rise to a further processing of personal data, distinct from all the processing deriving from the provision of health services to the patient in relation to which the data have been acquired or produced) constitutes an emblematic application of the delicate balance

[7] The EHR is different from the Electronic Medical Record because: whereas the EHR describes the patient's entire clinical life, the electronic medical record (which can be defined as a digital document created by the healthcare facility treating a patient in order to manage his or her clinical data and to guarantee continuity in care pathway) only refers to a single episode of hospitalisation of the person concerned. However, it seems appropriate to point out that the electronic medical record also differs from the health record which collects all the clinical information relating to all the operations performed for the patient in the facility that receives him or her (and thus serves to make the processes of diagnosis and treatment of the patient within a single health facility more efficient). See A. Thiene, *Salute, riserbo e rimedio risarcitorio*, in *Rivista italiana di medicina legale*, 2015, 1421; L. Califano, *Fascicolo sanitario elettronico (EHR) e dossier sanitario: il contributo del Garante Privacy al bilanciamento tra diritto alla salute e diritto alla protezione dei dati personali*, in G. de Vergottini and C. Bottari (eds.), *La sanità elettronica*, Bologna, Bononia University Press, 2018, 29; A. Pioggia, *Il Fascicolo sanitario elettronico: opportunità e rischi dell'interoperabilità dei dati sanitari*, in R. Cavallo Perin (ed.), *L'amministrazione pubblica con i* big data*: da Torino un dibattito sull'intelligenza artificiale*, Torino, Università degli Studi di Torino, 2021, 216.

[8] Cf. E. Sorrentino and A.F. Spagnuolo, *La sanità digitale in emergenza Covid-19. Uno sguardo al fascicolo sanitario elettronico*, in *Federalismi*, 2020, as well as the data released by the Agency for Digital Italy (AGID) in the Report on ICT Expenditure in Italian Territorial Healthcare - *www.agid.gov.it/sites/default/files/repository_files/rapporto_agid_sulla_spesa_ict_nella_sanita_territoriale*). In this regard, it should be noted that, as pointed out by AGID, the Italian Public Administration more generally lacks awareness of the threat and notes the absence of local-organisational structures capable of effectively operating an incident preparation and response activity (see on this point the Three-Year Plan for Information Technology in Public Administration 2019-2021, in which the Agency has retraced some important criticalities that emerged in the Report "Italian Cyber Security Report 2014"). On this point, it should be noted that, according to the 2018 Clusit report, in the public sector in general, attacks have increased by 41%, reaching a peak of 99% in the health sector (*https://ofcs.report/wp-content/uploads/2019/03/Rapporto_Clusit_2019.pdf*) and, in the 2021 report, the growth of attacks in the health sector continues to be highlighted.

[9] Article 12(4) of d.l. No. 179/2012.

[10] Article 12(4-*bis*) of d.l. No. 179/2012.

[11] Article 12(2)(a-*ter*) and 12(4-ter) of d.l. No. 179/2012, introduced by d.l. No. 4 of 2022.

[12] Article 12(2)(b) and (c) of d.l. No. 179/2012.

[13] The Regions, the Autonomous Provinces, the Ministry of Labour and Social Policy and the Ministry of Health.

between the principle of the free circulation of data, functional to the protection of public health and the requirements of administrative efficiency, and the right to privacy, paramount to safeguard the personal dignity.[14]

The EHR, then: a) ensures undoubted advantages in terms of lightening the burden of documentation (and, therefore, considerable savings in time and expense); b) provides effective support for management and administrative activities related to care processes (as it allows, for example, administrative information such as bookings for specialist visits, prescriptions, etc., to be shared between operators); c) allows a significant reduction in medical errors (the doctor knows the patient's clinical situation in greater detail, before intervening); d) prevents health professionals from prescribing examinations that would prove unnecessary because they have already been carried out, with a consequent reduction in treatment times and an inevitable decrease in the costs that the widespread phenomenon of so-called defensive medicine actually produces in our country.

2. *Some innovations made in 2020 to the EHR regulation*

In 2020, the legislator extended the database of the HER:[15] it now also includes information on private services provided outside the NHS whose recording on patients' personal handbooks was previously left to their discretion. This is an important change, given that the care provided outside the NHS constitutes a significant part of the healthcare services, in Italy, and that, in the face of such exclusion, the patients' medical history often risked being only half known by those who had to take care of them. The reasons were mainly twofold: on the one hand, not every patient had the possibility to insert such information in his or her personal-notebook area -see *infra*-, which was often missing, since it was not envisaged by the reference Region/Autonomous Province among the so-called supplementary elements of the EHR. On the other hand, not all the patients who could make such an entry actually did so, either because they were digitally incompetent, or because they forgot, or because they had little knowledge of the tool, and/or because they were not duly informed of the possibility of actively participating in the enrichment of the information. The legislator's aim is clearly to enhance the effectiveness of the EHR by broadening the type of information processed.

The legislator then revised the rules for the implementation of the record, stipulating that it is no longer dependent on patients' free and informed consent, but rather it becomes automatic.[16] In other words, once the EHR has been activated, patients' data on their use of healthcare services will automatically be included in the digital collection.[17]

The amendment seems to give continuity and completeness to the health database: in this way, the governance and research purposes, summarily mentioned above, may perhaps be more adequately achieved (they would otherwise be -and have been so far- pursued through the processing of potentially-incomplete data).[18]

However, it will certainly be necessary to understand to what extent such an innovative context is compatible with today's legal framework for the protection of personal data: for example, it will have to be ascertained whether this type of processing -not permitted- is compatible with the GDPR, given that, pursuant to Article 9(1), it is

[14] See S. Corso, *Il fascicolo sanitario elettronico fra e-Health, privacy ed emergenza sanitaria*, in *Responsabilità Medica,* 2020, 396; A.M. Gambino, E. Maggio and V. Occorsio, *La riforma del fascicolo sanitario elettronico*, in *Diritto Mercato Tecnologia*, 2020, 2. On the impact of technology in the structures of contemporary society, see G. Biscontini *et al*., *Le tecnologie al servizio della tutela della vita e della salute e della democrazia. Una sfida possibile*, in *www.federalismi.it*, 2020; A.G. Orofino, *La semplificazione digitale*, in *Il diritto dell'economia*, No. 3, 2019, 87-112, and on the related concept of risk, A. Barone, *Il diritto del rischio*, Milano, Giuffrè, 2006.

[15] The amendments were made by d.l. No. 34 of 19 May 2020, converted, with amendments, by Law No. 77 of 17 July 2020.

[16] In particular, Article 12(3-*bis*), d.l. No. 179/2012, stated: "The EHR may be fed exclusively on the basis of the free and informed consent of the patient, who may decide whether and which data relating to his or her health should not be included in the file itself". See S. Bologna et al, *Electronic Health Record in Italy and Personal Data Protection*, in *European Journal of Health Law*, No. 23, 2016, 265 ff. This paragraph was repealed by Article 11(1)(d) of d.l. No. 34 of 19 May 2020, converted, with amendments, by Law No. 77 of 17 July 2020.

[17] This is made explicit in the updated summary sheet available on the institutional website of the GPDP, aimed at summarising the new regulations. This is the infographic of 19th June 2020, *Le novità sul FSE*, available at *www.garanteprivacy.it.*

[18] And the same applies now for international prophylactic purposes.

forbidden to process, inter alia, data relating to the health of the individual.[19] Article 9(1) of the GDPR prohibits the processing of, inter alia, data relating to a person's health; it may indeed be argued that, in such cases, one of the hypotheses set out in Article 9(2) is relevant, which is capable of derogating from the aforementioned general rule prohibiting the processing of data relating to an individual's health; however, it will always remain to be ascertained whether, in order to achieve the purposes envisaged by those hypotheses deemed applicable, the processing thus carried out is really "necessary".[20]

3. *The problem of consent*

The decision to overcome the consent requirement is in line with the statements of the Italian Data Protection Authority, which, in its provision No. 55 of 7 March 2019,[21] admitted the possible elimination of the need to acquire the data subject's consent to the feeding of the record.

The Authority's position was based on the renewed regulatory framework, following the entry into force of the General Data Protection Regulation and Legislative Decree No. 101 of 2018, adjusting the provisions contained in Legislative Decree No. 196 of 2003, the Italian Privacy Code.

The prohibition on the processing of particular categories of personal data, including data relating to health,[22] set out in Article 9(1) of the Regulation[23] is waived in the cases listed in paragraph 2 of the same article. Of these, consent is only one of the exceptions.

The processing of health data,[24] in particular, is not prohibited if it is «necessary for reasons of substantial public interest, on the basis of Union or Member State law [...]» (g); «necessary for the purposes of [treatment] [...]» (h); «necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices» (i); or necessary for the purpose of scientific research (j).[25]

[19] For example, one could refer to letter i) of paragraph 2 of the aforementioned Article 9 of the GDPR, expressly referred to by Art. 75 of the Italian Privacy Code, according to which processing is lawful if it is "necessary for reasons of public interest in the field of public health, such as protection against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products and medical devices, on the basis of Union or Member State law that provides for appropriate and specific measures to protect the rights and freedoms of data subjects, in particular professional secrecy"; but one may also consider applicable letter g) of the above-mentioned paragraph 2 of Art. 9 of the GDPR, according to which processing is permitted if it is "necessary for reasons of substantial public interest on the basis of Union or Member State law, which must be proportionate to the aim pursued, respect the essence of the right to data protection and provide for appropriate and specific measures to protect the fundamental rights and interests of the data subject". That letter g) may be relevant with regard to the processing of data contained in the EHR has recently been confirmed by Law No. 205 of 3 December 2021, converting, with amendments, d.l. No. 139 of 8 October 2021, which introduced, in Article 2-sexies of the Privacy Code, paragraph 1-*bis*.

[20] It is unclear what meaning should be attached to the adjective "necessary": see paragraph 5.

[21] See F.G. Cuttaia, *The impact of EU Regulation 2016/679 on the Italian health system*, in G. Fares (ed.), *The Protection of Personal Data Concerning Health at the European Level. A Comparative Analy*sis, Torino, Giappichelli, 2021, 195 ff., especially 200; S. Corso, *Sul trattamento dei dati relativi alla salute in ambito sanitario: l'intervento del Garante per la protezione dei dati personali*, in *Responsabilità medica*, 2019, 236.

[22] It is just worth mentioning that Directive No. 46 of 1995 did not define health data, but in 2003, the Court of Justice gave it a broad interpretation, in relation to Article 8(1) of the Directive, in the famous "Lindqvist" case. ECJ EU, 6 November 2003, Case C-101/01 (*Lindqvist*), in *Europa e diritto privato*, 2004, 1001 ff., with a note by R. Panetta, *Trasferimento all'estero di dati personali e Internet: storia breve di una difficile coabitazione*. As is well known, now, EU Reg. No. 679 of 2016 defines health-related data in Art. 4(15) as «personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status». See L.A. Bygrave and L. Tosoni, *sub* art. 4(15), in C. Kuner, L.A. Bygrave and C. Docksey (eds.), *The EU General Data Protection Regulation (GDPR). A Commentary*, Oxford, Oxford University Press, 2020, 217 ff. See also W. Schäfke-Zell, *Revisiting the definition of health data in the age of digitalized health care*, in *International Data Privacy Law*, vol. 12, No. 1, 2022, 33 ff.; A. De Franceschi, *sub* art. 4, in R. D'Orazio, G. Finocchiaro, O. Pollicino and G. Resta (eds.), *Codice della privacy e* data protection, Milano, Giuffrè, 2021, 156 ff.

[23] L. Georgieva and C. Kuner, *sub* art. 9, in C. Kuner, L.A. Bygrave and C. Docksey (eds), *The EU General Data Protection Regulation (GDPR)*, 365 ff.; A. Thiene, *sub* art. 9, in R. D'Orazio, G. Finocchiaro, O. Pollicino and G. Resta (eds.), *Codice della privacy e* data protection, 240 ff.

[24] For an analysis of various specific profiles relating to the processing of health data, see A. Thiene and S. Corso (eds.), *La protezione dei dati sanitari. Privacy e innovazione tecnologica tra salute pubblica e diritto alla riservatezza*, Napoli, Jovene, 2023; C. Perlingieri, *eHealth and Data*, in R. Senigaglia, C. Irti, and A. Bernes (eds.), *Privacy and Data Protection in Software Services*, Berlin, Springer, 2022, 127 ff.

[25] I. Rapisarda, *Ricerca scientifica e circolazione dei dati personali. Verso il definitivo superamento del para-*

In relation to the processing of personal data in the health sector, Article 75 of the Privacy Code now provides that «the processing of personal data carried out for the purpose of protecting the health and physical safety of the person concerned or of third parties or the community must be carried out in accordance with Article 9(2)(h) and (i) and (3) of the Regulation, Article 2-septies of this Code, and in compliance with the specific provisions of the sector».[26]

To this must be added what is now set forth in Article 2-*sexies*(1-*bis*) of the Privacy Code, introduced by Law No. 205 of 3 December 2021, converting, with amendments, d.l. No. 139 of 8 October 2021, containing "Urgent provisions for access to cultural, sporting and recreational activities, as well as for the organisation of public administrations and in matters of personal data protection" ("Decreto Capienze"). This provision expressly allows institutional subjects' the processing of data relating to health, without direct identification elements, for reasons of relevant public interest, i.e. pursuant to Article 9(2)(g) of the Regulation, including EHR data.

The relevant public interest, as well as the public interest in the area of public health, thus seems to act as an opening valve – also in view of the broad scope of the list of matters in which the public interest is deemed relevant in Article 2 sexies(2) – almost like a general clause, which essentially eliminates the prohibition of treatment, when the general public element occurs.

It must be said, moreover, that for a long time, perhaps even since the dawn of reflection on data protection, light has been shed on the inconsistency of considering data subjects' consent to processing as a control instrument in the circulation of data. In fact, it has been highlighted how consent is most often given without any awareness, with carelessness. And that data subjects are often unable to understand what they are consenting to, even when they try. And, furthermore, if they do understand, the choice to consent comes to be constrained, because otherwise the service connected to the processing will not be provided. Consent has come to be spoken of in terms of a "paradox". All this perhaps takes on even more marked traits in the healthcare context, if we consider that there can be no healthcare treatment in the absence of the processing of data relating to the patient's health by the doctor.[27]

Consent, therefore – to use Stefano Rodotà's words – is a "myth"[28] or a semblance of protection, at least consent understood in the sense of a legal basis for the legitimacy of personal-data processing.[29]

In order to offer protection to the person,[30] by guaranteeing the protection of personal data – especially sensitive data – other instruments, other than consent, have therefore been sought. And the choice has fallen on a series of measures and expedients, mainly of a technical nature, which have then been translated into principles and rules and which can, to a large extent, be said to be included in the concept of "security".[31]

Think of the principle of accountability,[32]

digma privatistico?, in *Europa e diritto privato*, 2021, 301 ff.; A. Bernes, *La protezione dei dati personali nell'attività di ricerca scientifica*, in *Nuove leggi civili commentate*, 2020, 175 ff.

[26] M. Di Masi, *sub* art. 75, in R. D'Orazio, G. Finocchiaro, O. Pollicino and G. Resta (eds.), *Codice della privacy e* data protection, 1233 ff.; F. Zanovello, *sub* art. 2-*septies*, *ivi*, 1051 ff.

[27] G. Finocchiaro, *Il trattamento dei dati sanitari: alcune riflessioni critiche a dieci anni dall'entrata in vigore del Codice in materia di protezione dei dati personali*, in G.F. Ferrari (ed.), *La legge sulla privacy dieci anni dopo*, Milano, Egea, 2008, 213. See also J. Hansen *et al.*, *Assessment of the EU Member States' rules on health data in the light of GDPR*, Luxembourg, Publications Office of the European Union, 2021, 28.

[28] S. Rodotà, *Elaboratori elettronici e controllo sociale*, Bologna, il Mulino, 1973, 45 ff. See also G. Buttarelli, *Banche dati e tutela della riservatezza. La privacy nella società dell'informazione. Commento analitico alle leggi 31 dicembre 1996, nn. 675 e 676 in materia di trattamento dei dati personali e alla normativa comunitaria ed internazionale*, Milano, Giuffrè, 1997, 377.

[29] A. Gentili, *La volontà nel contesto digitale: interessi del mercato e diritti delle persone*, in *Rivista trimestrale di diritto e procedura civile*, 2022, 701 ff., especially 704.

[30] The ultimate goal of all privacy legislation. For all, see P. Perlingieri, *Il diritto civile nella legalità costituzionale secondo il sistema italo-europeo delle fonti*, III, *Situazioni soggettive*[4], Napoli, Edizioni Scientifiche Italiane, 2020, 1 ff.; Id., *La persona e i suoi diritti. Problemi del diritto civile*, Napoli, Edizioni Scientifiche Italiane, 2005, and, Id., *La pubblica amministrazione e la tutela della* privacy. *Gestione e riservatezza dell'informazione nell'attività amministrativa*, *ivi*, 255 ff.

[31] See G. Finocchiaro*, Il quadro d'insieme sul Regolamento europeo sulla protezione dei dati personali*, in G. Finocchiaro (ed.), *Il nuovo Regolamento europeo sulla privacy e sulla protezione dei dati personali*, Bologna, Zanichelli, 2017, 1 ff.

[32] C. Camardi, *Liability and Accountability in the 'Digital' Relationships*, in R. Senigaglia, C. Irti and A. Bernes (eds.), *Privacy and Data Protection in Software Services*, 25 ff.; M.G. Stanzione, *La protezione dei dati personali tra «consumerizzazione» della privacy e prin-*

or the notions of privacy by design and privacy by default or pseudonymisation procedures and risk-assessment mechanisms.[33]

Security, therefore, as an obligation of the subjects, data controllers and processors.[34]

Nevertheless, with regard to the processing of health data by means of the EHR, some doubts about interpretation seem to remain.

Looking at the wording of Article 9 of the Regulation, it can be seen that the exceptional cases referred to in paragraph 2, which derogate from the prohibition expressed in paragraph 1 and which come into play in relation to the processing of data relating to health by means of the EHR, are constructed as cases for "necessary" processing. The principle of necessity, which undoubtedly also applies to the processing of so-called neutral or common data, as expressed in Article 6 of the Regulation, a fortiori applies with reference to the processing of sensitive data. Now, how the adjective "necessary" is to be understood can be debated. One might think that "necessary" means "useful" or "functional": when the processing of sensitive data is useful in the cases listed in Article 9(2), then it is not prohibited. Or one might think that "necessary" stands for "indispensable", i.e. the processing of sensitive data is not prohibited when it is indispensable for the purpose set out in the cases listed in paragraph 2 and cannot be done otherwise. However, of the two interpretations, the more convincing seems to be the second,[35] since accepting the first would deprive the prohibition set out in paragraph 1 of any real meaning - not merely emphatic: in fact, which processing of personal data does not appear useful, which is not necessary to better achieve one of those purposes? The exception would become the rule.[36]

If, however, one accepts the second interpretation, i.e. that the prohibition is only waived when the processing of data is indispensable – in this sense necessary – can it then be argued that the processing of health data by means of the EHR is the only possible way of responding to the public interests in the field of health, as indicated by law? If the answer is in the affirmative, it must also be acknowledged that other instruments could not have been used, or at least that this very instrument – the EHR – was chosen, making it more like a public-administration database than an electronic health record.

4. *Some not-encouraging data on the use of the EHR*

Despite coordination and enhancement efforts made, data on EHR implementation, use and deployment have not always been comforting. As AGID's monitoring has attested over time, all Italian regions have been "active" (in the sense that in every Italian region there has been at least one EHR activated in recent years) and each of them has then implemented the tool, equipping itself with the necessary structures to make the file operational in its own territory. However, data on the actual dissemination of the EHR have not been entirely encouraging.[37]

In general, there has been almost negligible use of the EHR by citizens in most Italian regions: for instance, according to available

cipio di accountability, in *Comparazione e diritto civile*, 2022, 1 ff.; G. Finocchiaro, *Il principio di accountability*, in R. Caterina (ed.), *GDPR tra novità e discontinuità*, in Giur. it., 2019, 2778 ff.

[33] A. Mantelero, *La gestione del rischio*, in G. Finocchiaro (ed.), *La protezione dei dati personali in Italia. Regolamento UE n. 2016/679 e d.lgs. 10 agosto 2018, n. 101*, Bologna, Zanichelli, 2019, 473 ff.; Id., *Il nuovo approccio della valutazione del rischio nella sicurezza dei dati. Valutazione d'impatto e consultazione preventiva (artt. 32-39)*, in G. Finocchiaro (ed.), *Il nuovo Regolamento europeo sulla privacy e sulla protezione dei dati personali*, 287 ff. See Article 29 Working Party, Guidelines on Data Protection Impact Assessment (DPIA) and determining whether processing is "likely to result in a high risk" for the purposes of Regulation 2016/679, 4 October 2017, WP 248 rev.01.

[34] N. Brutti, *Le figure soggettive delineate dal GDPR: la novità del data protection officer*, in E. Tosi (ed.), *Privacy Digitale. Riservatezza e protezione dei dati personali tra GDPR e nuovo Codice Privacy*, Milano, Giuffrè, 2019, 115 ff.

[35] This is all the more so when one considers the corresponding requirement in Article 6 of the Regulation. See D. Poletti, *sub* art. 6, in R. D'Orazio, G. Finocchiaro, O. Pollicino and G. Resta (eds.), *Codice della privacy e* data protection, 194 ff. Strictly interpreting the parallel criterion of Article 7 of Directive No. 46 of 1995, the Article 29 Working Party, *Opinion 6/2014 on the notion of legitimate interests of the data controller under Article 7 of Directive 95/46/EC*, 9 April 2014, WP217. In case law, see ECJ EU, 16 December 2008, Case C-524/06 (*Huber*), in *www.curia.europa.eu.*

[36] «In so far as it provides for an exception to the principle that the processing of special categories of personal data is prohibited, Article 9(2) of the GDPR must be interpreted strictly». ECJ EU, 4 July 2023, Case C-252/21 (Meta Platforms), in www.curia.europa.eu.

[37] N. Posteraro, *La digitalizzazione della sanità in Italia: uno sguardo al Fascicolo Sanitario Elettronico (anche alla luce del Piano Nazionale di Ripresa e Resilienza)*, in *www.federalismi.it. Osservatorio di diritto sanitario*, 17 November 2021.

data,[38] usage thresholds above 50 per cent were reached only in two regions in the second quarter of 2022; and only in one - Emilia-Romagna - in the fourth quarter of 2022.[39]

It is believed that the main reasons for this lack of (or in any case low) use are to be ascribed (if not exclusively, at least also) to the population's insufficient digital skills and to a certain resistance to change in daily habits (which probably depends precisely on the lack of knowledge of the technologies to be used: individuals' confidence in innovation and their ability to adapt to it are, in fact, often linked to the degree of knowledge of digital tools, both in terms of their actual potential and the risks that may arise from their use). This digital incompetence of the population evidently affects the telematic interaction between citizens and public administrations: with regard more specifically to the health sector, as revealed in a research conducted by the Osservatorio Innovazione Digitale in Sanità of the School of Management of the Politecnico di Milano,[40] eight out of ten citizens do not use web-based health services. 86 per cent of patients prefer to seek medical advice in person, 83 per cent go to counters to pay for services, and in 80 per cent of cases they pick up their reports by hand. It is therefore not surprising that, at least on the side of the patients, a tool such as the Electronic Health Record has been struggling to take off.

With regard, on the other hand, to use by licensed physicians, in 2022 there were indeed increasing percentages - compared to those recorded in 2021 - and higher percentages (compared to use by citizens). Thus, for example, it turned out that, in the second and fourth quarters of 2022, physicians in sixteen Regions and Autonomous Provinces used it, reaching percentages above 98% in only six Regions (Emilia-Romagna, Lombardy, Apulia, Sardinia, Aosta Valley, Veneto) and in the Province of Trento. In the fourth quarter of 2022, however, doctors in only two Regions (Umbria and Aosta Valley) fed it with the patient's summary health profile.[41]

On the other hand, the percentages relating to the number of healthcare workers who, out of the total of regional healthcare workers, are enabled to use the EHR, albeit to a relatively modest extent, were increasing compared to those recorded in 2021: according to the data from the fourth quarter of 2022 or referring to the last update surveyed by the individual Regions, only in eight of the Regions and Autonomous Provinces did the percentage exceed 50% (Emilia-Romagna: 66.23%; Lombardy: 100%; Piedmont: 83.65%; Apulia: 80.08; Sardinia: 95.25%; Tuscany: 100%; Veneto: 89%; Trento: 100%); in the others, it stood at decidedly low values (e.g. Abruzzo: 7.5 %; Basilicata: 10%; Campania: 30.71%; Friuli-Venezia Giulia: 23.29%; Marche: 19%; Molise: 3%; Sicily: 20.42%; Aosta Valley: 31%).[42]

It is clear, therefore, that it was from the outset an ambitious and challenging project for the Italian context (characterised, in actual terms, not only by a strong regional fragmentation, but also by a significant delay in digital growth, as the data show).

[38] See *www.fascicolosanitario.gov.it/monitoraggio*. Data are updated quarterly and, when the latest quarterly update is not available, reference is made to the latest available update.

[39] The indicator gives an account of the number of citizens who, out of the total number of patients for whom at least one report has been made available, have made at least one access to their EHR in the last 90 days of the monitored period.

[40] The results of the survey are reported as part of the online conference "Sanità digitale oltre l'emergenza: più connessi per ripartire" on 26 May 2021, organised by the Osservatorio Innovazione Digitale in Sanità of the School of Managment of the Politecnico di Milano (*www.osservatori.net/it/eventi/on-demand/convegni/convegno-risultati-ricerca-osservatorio-innovazione-digitale-sanita-convegno*).

[41] In 2021 the number of physicians and healthcare workers who, compared to the total number of licensed general practitioners and paediatricians of free choice, used the EHR in the exercise of their profession was still very low: according to the data then available, in the second quarter of 2021, only physicians in 9 Regions had used the EHR and in two of them, moreover, very low percentages were recorded (we refer, in particular, to Lazio, which reached the percentage of 22%; to Piedmont, which reached 3%; to Tuscany, which reached 10%. The results of the other 7 Regions were good: Emilia-Romagna: 100%; Friuli-Venezia Giulia: 74%; Lombardy: 100%; Apulia: 99%; Sicily: 99%; Aosta Valley: 100%; Veneto: 99%); furthermore, with respect to the total number of activated EHRs, only the physicians of 3 Regions, in the same period considered, had concretely fed it – however slightly – with the patient's synthetic health profile (and in one of the 3 – Friuli-Venezia Giulia – it had been implemented by only 1% of the physicians).

[42] In the second quarter of 2021, however, the percentage exceeded the 50% threshold in only six regions (Emilia Romagna: 60.62%; Lombardy: 100%; Piedmont: 76.2%; Apulia: 71.6%; Tuscany: 100%; Veneto: 89%); in the others, the thresholds reached were very low, or zero (Calabria: 0%; Campania: 0.74%; Friuli Venezia Giulia: 23.29%; Lazio: 0%; Sicily: 14.42; Aosta Valley: 31%).

The current national panorama was also taken into consideration by the Guidelines approved by the EHR Working Group on 25 January 2022 – to which we will return below – from which it emerged that the conception of the EHR has always appeared rather basic and its implementation characterised by only partial dissemination of services on the territory, incomplete implementation of the minimum core of documents, documental inhomogeneity, limits, shortcomings and systematic shortcomings. Moreover, an uneven feeding of the file was noted, so that, even in the Regions where the minimum core was implemented, the EHR was not then fed in the same way by all healthcare facilities. In any case, the low or incomplete feeding of the file has resulted in its inability to respond to the user's needs regarding his or her care and to provide a valid and reliable care tool for healthcare professionals.

5. *The EHR in the context of the National Recovery and Resilience Plan*

The Italian National Recovery and Resilience Plan (NRRP) highlighted that the COVID-19 pandemic has confirmed the universal value of health and its nature as a fundamental right. In particular, it pointed out that our NHS in general is able to provide adequate health outcomes and a high life expectancy at birth;[43] then, it also stressed that the pandemic has made more evident some structural criticalities of the aforesaid NHS (critical aspects that could be aggravated by the increased demand for care resulting from the demographic, epidemiological and social trends currently underway).[44]

The strategy that the NRRP pursues is therefore aimed precisely at tackling all these critical aspects in a synergetic manner. The Plan specifically devotes Mission 6 to health, allocating a total of 15.63 billion euros to it. The NRRP emphasises how the health emergency has shown, among other things, the importance of being able to count on an adequate use of the most advanced technologies and on high digital skills (as well as professional and managerial skills): the pandemic – it specifies – has highlighted how healthcare is an area that requires significant digital upgrading;[45] consistently, it allocates a large part of the aforesaid resources to improving infrastructural and technological endowments, as well as to developing skills, including digital skills of personnel.

The Plan embraces the potential of the EHR, defining it as a "cornerstone" for the provision of digital-health services and the enhancement of national clinical data:[46] from this perspective, for example, it proves relevant the part of the Plan that states that telemedicine projects proposed by the Regions on the basis of the priorities and guidelines defined by the Ministry of Health may be financed only "where they can be integrated with the electronic health record".

The main objective of the NRRP is to strengthen the EHR, in order to ensure its dissemination, homogeneity and accessibility throughout the country by patients and health workers.

In the light of what has been noted above, the part in which the Plan expressly alludes to the need to invest in (in order to improve) the digital skills of the population[47] certainly appears important; the project is destined to really take off only with the effective participation of all the stakeholders of the health ecosystem, including, first and foremost, the patients.

However, it is believed that this type of activity, while certainly appreciable, will not be sufficient to ensure the effective dissemination of the tool, given that individuals, even when they are digitally competent, will refrain from using the EHR if they are not made aware beforehand of its potential and actual functioning, with a focus on the processing of the personal data that flow into it: a recent survey conducted in 2021 by the "Osservatorio Innovazione Digitale in

[43] Despite the fact that healthcare expenditure on gross domestic product is lower than the EU average.

[44] See N. Posteraro, *Complexity and complication of the italian healthcare system: can e-health be a possible solution?*, in M. De Donno and F. Di Lascio (eds.), *Public authorities and complexity. An Italian overview*, Napoli, Jovene, 2023, 161 ff.

[45] On the relationship between the pandemic and increased digitisation of the healthcare sector, see the above-mentioned report 'Digital transformation: Shaping the future of European Healthcare', by the Deloitte Centre for Health Solutions, a Deloitte research centre specialising in healthcare issues and practices. 65% of European respondents say their organisation has increased the use of digital technologies to support the work of healthcare workers following the COVID-19 emergency; a similar percentage (66%) for Italy.

[46] See p. 17 of the Plan, which also refers to the EHR in sections other than the one strictly devoted to the Health Mission.

[47] P. 86 ff. of the Plan.

Sanità" of the Politecnico of Milan[48] shows that Italians have not a good perception of what the Electronic Health Record is and how it works. It turns out, in fact, that only 38% of the population has heard of it and only 12% is aware of having used it.[49] This would explain the mismatch, noted above, between the number of active records and the percentage of actual use of the tool (consultation and access). As things stand, adequate awareness-raising campaigns on the use of the EHR must therefore be promoted.

Equally appreciable, then, is the part in which the NRRP alludes to investment in the digital skills of medical-health personnel: investing in the training of citizens, in fact, is not enough; it is also necessary to work on the training of socio-healthcare personnel, who must actually use the tool in their work, if we consider that, at present, as highlighted earlier, the number of doctors and health-care workers who use it in their profession is still very low.

Significant from this point of view are the data from the survey – referred to above – of the "Osservatorio Innovazione Digitale in Sanità". They evidence that although 60% of specialist doctors and general practitioners have sufficient basic digital skills, mostly linked to the use of digital tools in daily life, only 4% have, to a satisfactory degree, the digital skills necessary for the medical-health profession. With regard to the digital skills of younger doctors, the findings of the survey conducted in February 2020 by the scientific task force of the *Validate*[50] project are equally relevant. The online survey – which involved a sample of 362 doctors under the age of 35 – found that only 13% of them had experience with *Big Data*, predictive models and artificial intelligence; while only 6% had experience with the *Internet of things*.

When investing in the digital skills of healthcare professionals, special attention must also be paid to the unavoidable issue of personal-data processing. This is also with a view to preventing damage resulting from data breaches in the healthcare sector: the ongoing sanctioning activity of the Italian Data Protection Authority is proof of this. In this regard, it is worth recalling the measures of 2 July and 9 July 2020, with which the Authority admonished two healthcare facilities for security breaches, albeit limited, resulting in the unlawful processing of healthcare data.[51] In the first case, a person who had requested a paper copy of his own medical record was mistakenly given that of another patient; in the second case, a patient found in his electronic health record a report on a different person. Both episodes denote the need not only to encourage the preparation of appropriate organisational measures to ensure the security of processing, but also to raise the awareness of the staff who are actually required to process such data.

6. *The EHR implementation Guidelines. Evolving perspectives*

In order to ensure that the objectives that the EU requires for the disbursement of funds are achieved within the timeframe set out in the NRRP, the EHR Implementation Guidelines were drawn up. Adopted by Decree of the Ministry of Health of 20 May 2022 and published in July of the same year, they are intended to summarise and amend all previous recommendations and become the basis for implementation up to 2026.[52]

The EHR must become – they say – the

[48] The results of the survey are reported as part of the above-mentioned online conference "Sanità digitale oltre l'emergenza: più connessi per ripartire" on 26 May 2021, organised by the "Osservatorio Innovazione Digitale in Sanità" of the School of Managment of the Politecnico di Milano.

[49] The problem of patients' lack of knowledge of the tool has already been highlighted by G. Comandè, L. Nocco and V. Peigné, *Il fascicolo sanitario elettronico: uno studio multidisciplinare*, in *Rivista italiana di medicina legale*, 2012, 105 ff. More than ten years later it does not appear that things have actually changed.

[50] The national survey was conducted in cooperation with the Associazione Segretariato Italiano Giovani Medici (SIGM) and the Istituto Superiore di Sanità. The Validate project (Value-bAsed Learning for Innovation, Digital-health, Artificial inTelligencE) aims at the definition, structuring and dissemination of specific skills and competences in the field of e-Health with particular reference to young doctors.

[51] These are decisions No. 123 and No. 141 of 2020. See decision No. 371 of 10 November 2022, in which the GPDP imposed a fine of EUR 40,000 on a healthcare facility for breach of the GDPR rules, with reference to the processing of personal data carried out by means of a health record. Without claiming to be exhaustive, see also decisions No. 27, 29, 30 and 36 of 27 January 2021, No. 45 of 11 February 2021, No. 142, 144 and 145 of 15 April 2021, No. 211 and 212 of 27 May 2021, No. 34 of 27 January 2022, and No. 200 and 201 of 26 May 2022.

[52] These Guidelines were issued pursuant to Article 12(15-*bis*) of d.l. No. 179 of 2012, as amended by d.l. No. 4 of 2022, precisely in order to enhance the EHR. S. Corso, *Le Linee guida di attuazione del fascicolo sanitario elettronico*, in *www.rivistaresponsabilitamedica.it*, 31 July 2022. The text of the Guidelines is available at *www.agid.gov.it*.

single and exclusive point of access for citizens to national health-system services. It will be an ecosystem of data-based services for healthcare professionals for the diagnosis and treatment of their patients and for increasingly personalised patient care, as well as a tool for healthcare facilities and institutions, which will be able to use the clinical information in the EHR to perform clinical-data analysis and improve healthcare-service delivery.

There are four actions envisaged by the Guidelines to strengthen the EHR: 1) guarantee homogeneous and uniform digital-health services; 2) standardise contents in terms of data and coding; 3) improve interoperability of the EHR; 4) strengthen the governance for implementing the new EHR.

For each action – i.e. services, content, architecture and governance – the Guidelines define EHR requirements and recommendations – for the the short, medium and long term – necessary to achieve the objectives set by the NRRP.

It is not possible here to review all the requirements listed in the guidelines, but it may be useful to mention some of them.

The mandatory requirements to be implemented in the short term include, as regards the standardisation of access services, managing consents to consult documents in the file, withholding specific clinical documents or types of clinical documents, and managing proxies.

Among the mandatory requirements, in addition to the evolution towards services for accessing clinical data – not only just documents – are the innovation of the EHR architecture, complete with a central clinical-data repository,[53] and the adoption of Advanced Analytics tools, also based on artificial-intelligence techniques for processing clinical data in the EHR.

Added to this, in terms of services, is access to telemedicine, for the provision of "tele-visits" by doctors, tele-assistance and tele-consultation.[54]

For health institutions, the EHR represents the knowledge base on the health status of the Italian population, at all levels of the NHS, for the definition and implementation of prevention and health-planning policies. Therefore, it will provide services – it says – to support the decisions of policy makers and the clustering of patients in relation to their respective clinical and health conditions.

Among the recommended requirements, on the other hand, is the provision to healthcare institutions, for governance purposes, of data, i.e. the knowledge base useful for governing regional and national public health policies, also through the implementation of value-based care strategies, i.e. the effectiveness and actual benefit generated on the patient by the healthcare services provided. In this context, the EHR will implement: data extraction, pseudo-anonymisation and preparatory functions that healthcare institutions can use to: organise and modulate healthcare around individual pathologies and groups of patients with similar needs; measure outcomes and costs for each patient, i.e. consistently measure value, understood as the relationship between health status and the costs of the care cycle; adopt value-based reimbursement models.

The Guidelines then illustrate the benefits for the citizen, both direct, in relation to treatment, and indirect, through the advantages enjoyed by the public administration. These include those deriving from research, which will be able to make use of EHR data, for which its enrichment with omics, genetic and epigenetic data is recommended.

The EHR will become the main information and health-education tool, with the aim of promoting health awareness among citizens. In this sense, the EHR will also realise patient empowerment in care.

The National Agency for Regional Healthcare Services (AGENAS), which is expressly recognised as the National Digital Health Agency,[55] will also contribute to achieve the objectives of the NRRP.

The legislative and technological development of the EHR will, in any case, have to reckon with the new rules of European-Union law. The reference here is to the proposal for a Regulation of the European Parliament and of the Council on the European health data space (COM(2022) 197 final), presented by the European Commission. Indeed, on 3 May 2022, the Commission launched the European Health Data Space (EHDS). This space, as stated in

[53] And it will already be completed with the Health Data Ecosystem (EDS).

[54] R. Senigaglia, *Telemedicina ed essenza fiduciaria del rapporto di cura, in Persona e mercato*, 2023, 470 ff.

[55] Article 12(15*decies*) d.l. No. 179 of 2012.

the relevant press release, will enable people to control and use their health data both in their own country and in other Member States, promote a single market for digital health services and products, and provide a coherent, reliable and efficient framework for the use of such data in research, innovation, policy-making and regulation, while respecting the Union's high standards of data protection. This is the first Common European Data Area in a specific field and is part of the European Data Strategy.[56]

It is just worth mentioning that, at the European level, a decisive impetus for data-related innovation has already been given by EU Regulation No. 868 of 2022 (Data Governance Act), especially through the regulation of data re-use and altruism. Further impetus towards enhanced data-based services will be provided by the new EU Regulation No. 2854 of 2023, on harmonised rules on fair access to and use of data (Data Act).

The introduction of these new systems - and sub-systems - of rules at the supranational level, in the area of data processing, as well as their impact on the regulation of health data, may also affect cross-border healthcare.[57]

Certainly, in the multiplication of regulatory references, the intersecting levels of sources, and the overlapping of regulated topics, one of the greatest challenges for the legislator will be to coordinate the various provisions and compose a legal framework that can guarantee certainty.

7. *The detailed discipline: the decree published in 2023*

The detailed discipline of the EHR was first laid down in the "Regulation on the electronic health record", set out in Prime Ministerial Decree No 178 of 29 September 2015, and then in the Ministry of Health Decree of 7 September 2023, entitled "Electronic Health Record 2.0" ("EHR 2.0 decree").

Published in the Official Gazette on 24 October 2023, the EHR 2.0 decree intervenes on the legal-reference framework, updating the provisions to the technological and regulatory evolution of the electronic health record.

Issued pursuant to Article 12(7), of d.l. No. 179 of 2012, it is the result of a long institutional interlocution and of multiple adjustments, as evidenced by the provisions of the Italian Data Protection Authority No. 294 of 22 August 2022 - which expressed a non-favourable opinion on the draft decree of the Ministry of Health[58] - and No. 256 of 8 June 2023, which expressed a positive opinion in relation to the draft decree on the HER.[59]

Therefore, the Prime Ministerial Decree No. 178 of 2015 ceased to be effective as of 24 October 2023 except for the provisions of Chapters III and IV,[60] which remain in force until the adoption of the further decrees[61] for the provisions on the processing "of data and

[56] S. Corso, *Lo spazio europeo dei dati sanitari: la Commissione Europea presenta la proposta di regolamento*, in *www.federalismi.it. Osservatorio di diritto sanitario*, 10 August 2022; Id., *European Health Data Space. La Commissione europea presenta la proposta di Regolamento sullo spazio europeo dei dati sanitari*, in *www.rivistaresposabilitamedica.it*, 13 June 2022; Id., *Una strategia europea per i dati, anche sanitari*, ivi, 7 March 2021. See European Commission press release, European Health Union: A European Health Data Space for people and science, 3 May 2022, in www.ec.europa.eu. On this proposal for a regulation, the European Data Protection Board (EDPB) and the European Data Protection Supervisor (EDPS) adopted a joint opinion on 12 July 2022. S. Corso, Il parere congiunto del Comitato europeo per la protezione dei dati e del Garante europeo della protezione dei dati in merito alla proposta di Regolamento sullo spazio europeo dei dati sanitari, in www.rivistaresponsabilitamedica.it, 5 September 2022.

[57] See N. Posteraro, *Cure oltre lo Stato: l'effettività del diritto alla salute alla luce del d.lgs. n. 38 del 2014*, in *www.federalismi.it*, 23 November 2016; Id., *Active international healthcare mobility and urban accessibility: the essential role of Italian cities and urban planning in the development of foreign healthcare tourism*, ivi, 13 January 2021. See European Commission Recommendation 2008/594/EC of 2 July 2008 on cross-border interoperability of electronic health record systems, and 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, COM(2008) 689 final, 4 November 2008. For particular relevance, also of a comparative nature, see the studies by F. Lupiáñez-Villanueva et al., *Study on Health Data, Digital Health and Artificial Intelligence in Healthcare*, Luxembourg, Publications Office of the European Union, 2022, and J. Hansen et al., *Assessment of the EU Member States' rules on health data in the light of GDPR.*

[58] S. Corso, *Fascicolo sanitario elettronico ed ecosistema dati sanitari. I pareri critici del Garante per la protezione dei dati personali al Ministero della salute*, in *www.rivistaresponsabilitamedica.it*, 22 september 2022.

[59] N. Posteraro, *Parere del Garante privacy sullo schema di decreto sul Fascicolo Sanitario Elettronico (FSE)*, in *www.federalismi.it, Osservatorio di diritto sanitario*, october 2023.

[60] Article 27(5), of the EHR 2.0 decree.

[61] To be issued in implementation of Article 12(7) of d.l. No. 179/2012.

documents" of the EHR for research and government purposes.[62] Thus, Articles 15-17 and Articles 18-20 of Prime Ministerial Decree No. 178/2015 are still applicable for processing for research purposes and processing for government purposes, respectively.

The EHR 2.0 decree, as announced in Article 2, identifies the contents of the EHR, the limits of the responsibilities and tasks of the parties involved in its implementation, the guarantees and security measures to be adopted in the processing of personal data with respect to the rights of the assisted person, and the modalities and different levels of access to the EHR.

The decree only partially innovates the previous discipline, maintaining in many aspects the same choices made previously.

Undoubtedly positive is the attention shown by the new provisions with regard to the identification of the data controller of the data processed by means of the EHR, since the EHR is established at the Regions and Autonomous Provinces, but may be used, for different purposes, by several entities on the basis of different legal requirements.

An important new feature of the EHR 2.0 decree is to provide liability for the persons responsible for feeding the EHR for failure to do so, or for untimely or inaccurate feeding.[63] The disposition treasures the indications expressed by the Italian Data Protection Authority, in provision No. 294 of 2022, which highlighted, as a critical point of the discipline, the absence of a real obligation to upload data and documents in the EHR, given the lack of a rule expressly providing for a liability for specific subjects.

The operations executed on the EHR are recorded. The patient can view the recordings made[64] and he is notified of the operations carried out on hir or her HER.[65]

Similarly to the previous 2015 regulation, the 2023 decree specifies that consultation of EHR data and documents, for purposes of diagnosis, treatment and rehabilitation, prevention, international prophylaxis - not for purposes of study and scientific research or health governance - is subject to the prior consent of the patient, pursuant to Article 8 of the EHR 2.0 decree, which reproduces the requirements enshrined in the GDPR: consent must be freely given, specific, informed and unambiguous as well as granular, i.e. expressed for each purpose of processing, and - for sensitive data – explicit.[66]

Another relevant issue of the EHR 2.0 decree is the actual possibility for patients to delegate other parties to access their EHR and the power to express consent to consultation.[67]

With regard to emergency access, a rule is now laid down that respects the confidentiality and self-determination of the patient. The case regulated is that of a person who has not given consent to consult the EHR, who is in a condition of physical impossibility, incapacity to act or natural incapacity, and at the same time is at serious, imminent and irreparable risk to his or her health or physical safety. In this case, health professionals and practitioners may first access the patient's summary and, only where necessary, once the inability to give consent has been verified, also the other data and documents in the EHR, limited to the time needed to provide treatment and except for those that he or she has decided to obscure.[68]

8. *The content of the EHR*

The EHR is an instrument subject to continuous feeding over time, rich in heterogeneous data and documents. In the light of the 2015 internal provisions,[69] it had to include a minimum core of elements,[70] but it also could be composed by some others integrative elements, foreseen by the individual Region/Autonomous Province.

Among the necessary elements, the patient summary and the pharmaceutical dossier were particularly important.

The pharmaceutical dossier is a section updated by the pharmacy; it makes it possible to trace (and, if necessary, to reconstruct) the patient's pharmacological history, as well as

[62] Order No 256 of 2023 emphasises the need for the revision of the rules on the processing of personal data through the EHR to be completed as soon as possible, also innovating the rules on the pursuit of health government and research purposes.
[63] Article 12(3), of the EHR 2.0 decree.
[64] Article 21 of the EHR 2.0 decree.
[65] Article 22 of the EHR 2.0 decree.
[66] European Data Protection Board, Guidelines 05/2020 on consent under Regulation 2016/679, Version 1.1, adopted on 4 May 2020, in www.edpb.europa.eu.
[67] Article 8(5) and 11(8-12) of the EHR 2.0 decree.
[68] Article 20 of the EHR 2.0 decree.
[69] Article 2(2), of the 2015 regulation.
[70] In detail, the EHR must contain the patients' identification and their administrative data, reports, first aid reports, discharge letters, and consent to organ donation.

to monitor the appropriateness of the dispensing of medicines and the fitness to treatment[71] (which can ensure that the use of medicines is optimised and can produce documented results in terms of improving the population's state of health and savings for the NHS[72]). This section has not been adequately developed, in all these years[73] and the new decree published in 2023 expunged it: the dossier will be regulated by the implementing decree of the provisions referred to in paragraph 15-quater of art. 12 d.l. n. 179/2012, as a service rendered available from EDS.

The patient summary, instead, is regulated by the EHR 2.0. decree[74] and can be qualified as a summary of the patient's medical profile drawn up by the so-called "family doctor" (or free-choice paediatrician): it is a document that provides an important support, especially in emergency situations, as it allows health professionals to gain a background on an unknown patient during a sudden and unpredictable contact; it is updated upon changes that are considered relevant to the patient's medical history.

Among the constituent elements, the "personal notebook" has a particular importance: it is a specific area in which patients may personally enter data and documents relating to their treatments.[75] This is a particularly-important additional element, which allows and ensures the active participation of the patients in the construction of their own health databases.[76] In this sense, it promotes attitudes of self-management and empowerment, which are certainly in line with the digital evolution of the citizen, made more autonomous by ICT technologies.

From this point of view, the personal notebook (that was an integrative element, during the validity of the 2015 regulation[77]) thus represents an important evolution of the relationship between the health world and the citizen-patient, since it promotes new forms of dialogue and interaction between doctor and patient, and encourages patients to use the EHR, offering them the possibility to "customize" it. In any case, the entry of data depends on the patients' ability to find them, as well as on the willingness/ability to enter them into the system; therefore, one cannot rule out the possibility that a) patients may refrain from entering because they are not fully able to navigate the platform; b) erroneous or misleading data may be entered: then, the healthcare professionals will have to assess with extreme caution the possibility to consider correct and reliable the data and documents entered in the personal notebook. The question then arises as to how useful an entry of this kind really is, given that it is not followed by a control-filtering carried out downstream by subjects previously identified and appointed for this purpose.

9. *On the right to obscure the data automatically inserted into the EHR*

Article 9 of the 2023 new decree establishes that the patient is free to conceal the data automatically included in the file that they do not wish to make visible, not even to those who are authorised to access them; this is the so-called "obscuration", which is carried out in such a way as to ensure that those authorised to access the EHR for the purposes of treatment cannot automatically become aware of the fact that the patient has made this choice and that such data exist (so-called "obscuration of the obscuration").

In this way, it should be averted the danger of an indirect influence of the current legal framework on the choices of those who prefer not to be treated, rather than disclose certain health treatments - concerning, for example, their sexual sphere -. These are reinforced measures, the rationale for which is to be found in the peculiar sensitivity of health data, which are more subject to possible misuse, even for discriminatory purposes. As noted by Italian scholarship, in fact, health data are part of the "hard core of confidentiality" – to which the right to health is linked by "an indissoluble link"[78] – and, therefore, enjoy

[71] Article 12(2-*bis*) of d.l. No. 179/2012.
[72] See Federfarma, *La farmacia italiana 2020/2021*, cit.
[73] This can be concluded reading the opinions recently disseminated by some professionals in the pharmaceutical sector (see, for example, the reflection of F. Schito, secretary general of Assofarm, in an editorial to the association's June 2021 newsletter, *Digitalizzazione, è il momento del Dossier Farmaceutico*, available at *www.assofarm.it*, as well as by what is expressly reported by Federfarma, *La farmacia italiana 2020/2021*, April 2021, in *www.federfarma.it.*
[74] Article 4.
[75] Article 5.
[76] A.M. Gambino, E. Maggio and V. Occorsio, *La riforma del fascicolo sanitario elettronico*, 5.
[77] The new decree establishes that this section of the EHR will be composed also by the data generated by medical devices and/or wearable.
[78] C. Colapietro and F. Laviola, *I trattamenti di dati per-*

special protection compared to ordinary data. For this reason, under the 2023 regulation,[79] the option to obscure EHR data must be expressly mentioned - along with the other components identified by the rule – in the information provided to patients.

Certainly, also through this action, the EHR solicits the empowerment of the patients,[80] who is called upon to take an active attitude in the management of health information concerning him or her.

The internal rules specify that the request for the obscuring of data and documents can be made both before the file is fed and afterwards:[81] therefore patients can request obscuring when they decide to undergo treatment and are made aware of the processing to be carried out and that their data will be transferred directly to the digital archive. From this point of view, the fundamental moment of prior dialogue between the doctor and the patient must therefore be enriched with new moments of information: in particular, the doctor must remind individuals that the service to be performed, if consented to, will entail the automatic inclusion of the data relating to it in the EHR; and he must at the same time remind them that they have the right to request and obtain the obscuring of the aforementioned data even before the treatment is carried out.

Finally, it should be recalled that, pursuant to the 2023 regulation, the health and socio-health data and documents governed by the regulatory provisions for the protection of HIV-positive persons, women undergoing voluntary termination of pregnancy, victims of acts of sexual violence or paedophiles who use drugs, psychotropic substances and alcohol, women who decide to give birth anonymously, as well as data and documents relating to the services offered by family-advice centres, can only be visible with the explicit consent of the interested person:[82] in this case, therefore, the active action of the individual patient, subsequent to the automatic implementation of the data in the EHR, is not aimed at hiding what is otherwise visible, but at making visible what otherwise, *ex lege*, would not be visible.

It must be considered, however, that some information may be missing from the EHR, and the gap may be, if not real, at least virtual, if the patients have exercised their right to obscure the data.[83] The healthcare professional must then be aware that the EHR can always give only a partial view of the patient's medical history.

The possible non-exhaustiveness of the visible and searchable collection of data carried out by means of this instrument therefore also implies its potential incompleteness. The doctor, therefore, cannot afford to rely entirely on the EHR, since it could prove detrimental to the patient, as decisions concerning his or her health could be taken on the basis of a partial and, on the whole, inaccurate compendium of information.[84]

sonali in ambito sanitario, in *www.dirittifondamentali.it*, No. 2, 2019, 6 ff.

[79] Article 7 and article 9(2).

[80] G. Fares, *The processing of personal data concerning health according to the EU Regulation*, in G. Fares (ed.), *The Protection of Personal Data Concerning Health at the European Level. A Comparative Analysis*, 17 ff., especially 19.

[81] Article 9(3).

[82] Article 6.

[83] V. Peigné, Il *fascicolo sanitario elettronico, verso una «trasparenza sanitaria» della persona*, in *Rivista italiana di medicina legale*, 2011, 1535 ff.

[84] S. Corso, *Il fascicolo sanitario elettronico fra e-Health, privacy ed emergenza sanitaria*, 404. The probable incompleteness of the EHR was recently reiterated by the Data Protection Authority in a recent ruling (Decision No. 294 of 2022).