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Digitalizing healthcare in Italy and Germany: the Electronic Health Record and m-Health regulation as key for e-Health

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Il presente contributo propone una comparazione del processo di digitalizzazione della sanità in Italia e Germania, concentrandosi su due strumenti principali: il fascicolo sanitario elettronico e la regolazione della mHealth. Nonostante le differenze strutturali tra gli ordinamenti, i due paesi presentano un livello di digitalizzazione simile e se la Germania ha di recente introdotto una normativa all'avanguardia in tema di cure digitali, l'Italia mostra invece un più avanzato livello di implementazione del FSE. L'analisi verte quindi sulle problematiche emerse nei due ordinamenti e sulla complementarità delle soluzioni adottate.

This article compares the digitalization process of healthcare in Italy and Germany focusing on two main tools: the electronic health record and the mHealth regulation. Despite structural differences, the two countries present similar levels of digitization and, whereas Germany has recently introduced cutting-edge legislation on digital care, Italy has a more advanced level of EHR implementation. The analysis therefore focuses on the issues that have emerged in the two jurisdictions and the complementarity of the solutions adopted.

Integrating mHealth into the healthcare system: the German model.- 5. Conclusion.

1. Introduction[1]

The digitalization of healthcare systems has certainly accelerated in the wake of the COVID-19 pandemic, but the willingness to undertake such a transformation was clear even before the global health crisis. In 2018, a communication by the European Commission[2] stressed the importance of adopting digital solutions in healthcare. In particular, the Commission emphasized the need to create a patient-centered healthcare model and to shift from hospital-centered systems to community-based and integrated structures.
Data play a central role in this process. The availability of reliable, good-quality data is important in several respects: first, it enables the development of medicine that is personalized and thus better responsive to patient's needs; it also enables faster scientific progress, even in fields where data are scarce, as in the field of rare diseases. For this reason, the Commission's communication emphasizes the central role that the electronic health record (EHR) must play in the digitalization process. However, the implementation of this tool still presents many problems in several member states[3]. Also, the solutions adopted are often not interoperable making it impossible to exchange data within the Union[4]. The second aspect the Commission focuses on is the use of digital tools such as wearable devices and mHealth[5] technologies, especially for treating chronic patients, since they could improve patient well-being and quality of care, while also promoting an active patient role in disease management[6].
Therefore, although the journey toward healthcare digitalization had begun well before, the outbreak of the pandemic certainly helped speed up the process. The need to provide services remotely has brought the importance of telemedicine to the forefront[7]; the central role of data has become crystal clear both at the individual level – to ensure that patients receive the most personalized care possible – and in healthcare governance[8]; finally, during the pandemic, the

mHealth sector registered a surge in the deployment of medical, well-being, and fitness apps[9].

Along with the potential and benefits that accompany digital (r-)evolution, there are also risks and issues that legislators must consider. In a 2023 report on digital health in Europe[10], the World Health Organization (WHO) recognized that the pillars around which the digitalization of health systems is built are those previously mentioned, namely electronic health record, telemedicine, mHealth, and big data. The study highlights future perspectives and key points to focus on in order to develop systems that make the most of the potential of digital tools, as well as critical issues to be resolved. The study notes the indispensability of establishing effective governance of digital health including the creation, or strengthening, of agencies and the development of clear guidelines that also aim to improve digital and health literacy. Regarding the path to the creation and implementation of electronic health records, two main obstacles - common to most EU member states - are identified: the need for funds to be allocated for the maintenance and improvement of technological infrastructure and the lack of interoperability among the technological solutions adopted in recent years. The fifth recommendation expressed by WHO, namely, to develop patient-centered and inclusive healthcare through clear policies and strategies that can integrate the latest digital technologies into the healthcare system, is very relevant. Emphasis is placed on the efforts needed to bridge the digital divide through digital inclusion strategies that inevitably rely on ensuring universal access to digital tools. In fact, WHO argues that «*digital exclusion is a major driver of inequality and can lead to poor health outcomes*».

Digital exclusion is caused by two main factors: on the one hand, the lack of skills to effectively use digital tools; and on the other hand, the unavailability of the economic resources needed to obtain access to the tools such as an adequate Internet connection and the necessary devices[11]. In studying national legislation, therefore, it will be necessary to assess whether adequate solutions have been arranged to deal with these problems.

2. Italy and Germany towards the digitalization of the

healthcare system

This paper analyzes two national cases, Italy and Germany, focusing on the legislative implementation of strategies for the digitalization of healthcare systems.

The two EU member states have a similar level of digitalization. Considering the DESI 2022 index[12], Germany stands just above the European average (52.88) and Italy just below (49.25). The DESI index has four components: digital public services, integration of digital technologies, connectivity, and human capital. The component with the largest difference is human capital, where Germany outperforms Italy by almost two points. However, if we look at the trend of this component in the two states, we see that from 2017 to the present it is virtually identical[13]. Germany in five years has improved this human capital component by 0.97 points and Italy by 0.94, thus failing to fill the existing gap. Therefore, the gap in the level of digitalization does not seem to be such as to prevent the comparison of the two countries. The two countries have different healthcare systems, a universalistic National Healthcare System in Italy and an insurance system in Germany. However, the digitalization tools mentioned above – i.e. the electronic health record, telemedicine, mHealth - are being developed in all EU member countries regardless of the type of healthcare system. Nonetheless, it should be also considered that eHealth implementation was found to be higher in countries with a national healthcare system compared to those with an insurance system[14]. The different form of state, regionalized in Italy and federal in Germany, makes the comparison between the two national paths to healthcare digitalization even more interesting, also given the central role played by Italian regions and their broad legislative autonomy in the healthcare sector[15].

In particular, it seems important to consider what solutions have been adopted in the two states, mainly considering two aspects: Italy has longer-term experience regarding the implementation of the electronic healthcare record since it was introduced more than ten years ago. During these years, many problems have emerged in the implementation of this instrument, and it is still unevenly used throughout the territory.

The German legislation only managed to introduce the EHR with the Digital Healthcare Act[16] of 2019 and, as we will see below, to date the implementation is

still very poor. By contrast, Germany has adopted extremely advanced eHealth/mHealth legislation, pioneering in the European landscape, whereas Italy has not managed to integrate these tools into its healthcare system yet and to date, the existing legislation is mainly composed of guidelines regarding telemedicine[17]. The potential of the German eHealth legislation risks being constrained in case implementation does not go hand in hand with the effective development of the electronic health record. The experience of both countries can therefore contribute to a comprehensive development of the digitalization process. On the one hand, analyzing the problems that have arisen in the implementation of the Italian electronic health record (which are not fully resolved yet) can contribute to a better evaluation of the solutions proposed and adopted in a country like Germany, which has only recently introduced this instrument. On the other hand, the introduction of a model of eHealth legislation that enables the integration of health applications within the health system might serve as a model for the advancement of digitalization in Italy.

3. The electronic health record: a key tool in the digitalization process

As anticipated, the electronic health record plays a central role in the digitalization process of healthcare systems. According to the WHO, the electronic health record (EHR) can be defined as «*real-time, patient-centered records that provide immediate and secure information to authorized users. EHRs typically contain a patient's medical history, diagnoses and treatment, medications, allergies, immunizations, as well as radiology images and laboratory results*»[18]. Normally EHRs also include patient's administrative data. By collecting health data from all providers and sometimes even from the patient himself, the EHR enables physicians to gain a better understanding of the patient's clinical situation. This allows for faster and more accurate diagnoses in the first place and, avoids duplication of examinations, it also saves money. It relieves the patient from the burden of having to select paper reports to bring to each visit and prevents documents from being lost. At the same time, the individual has quick access to all of his or her data, which increases the patient's sovereignty over them; according to some, this should result in greater awareness

of one's clinical situation. The EHR has not only played a role about individual health; it is also relevant in the area of public health and health governance. For example, it is believed that through the data collected and in an anonymized form, the development of epidemics can be predicted, and a clearer view of population needs can be obtained. In some countries[19], the EHR also collects data from wearable devices and apps, allowing patient monitoring outside hospitals through real-world data[20]. The combination, therefore, of mHealth technologies with the EHR offers a 360-degree view of the patient[21].

Despite the many advantages of its adoption, in many countries, the implementation process of this tool has encountered many difficulties, regardless of the type of healthcare system[22]. As anticipated, the Italian legal system has regulated EHR for more than a decade, while Germany has introduced it on the legislative level since 2019. The following paragraphs will outline the characteristics of this instrument in the two countries and the stage of implementation.

3.1. The electronic health record in Italy: il fascicolo sanitario elettronico (FSE)

In Italy, the nationwide introduction of the electronic health record (*Facicolo sanitario elettronico* – FSE) dates back to 2012, with Legislative Decree No. 179, but some regional projects existed even earlier.

The implementation process has been long and difficult, with several delays. Initially, June 30, 2015, was set as a deadline for regions to activate the FSE. However, meeting this deadline was impossible, first of all, because the decree defining the mandatory and optional content of the FSE was not adopted until September 2015[23]. Subsequently, one of the main problems to be solved was the interoperability among the various regional records and the harmonious development throughout the country. It should be kept in mind that the competence for the establishment and development of the FSE lies with the regions[24].

In fact, according to the constitutional text[25], health protection is a subject of shared competence between the state and the regions: it is up to the state to determine the essential levels of care (*Livelli essenziali di assistenza* – LEA) that

must be guaranteed throughout the national territory[26], while it is up to the regions to determine the concrete organization of the regional health services[27], which may also involve the provision of services in addition to those included in the essential levels. However, it is also relevant to note that IT coordination of national and regional administration data is an exclusive State competence[28].
Although the 2015 decree already expressly required interoperability between regional FSE, it was not until the end of 2018 that the National Infrastructure for Interoperability (*Infrastruttura Nazionale per l'Interoperabilità* – INI) became fully operational.
INI is designed by the Agency for Digital Italy[29] and has the main task of ensuring the interoperability of regional FSE and the identification of the assisted person through alignment with the National Registry of Assisted Persons (*Anagrafe Nazionale degli Assistiti* – ANA)[30].
Despite the time passed since the nationwide legislative introduction of FSE, many problems remain concerning both its use and interoperability. However, since the EHR is a backbone tool of the digital healthcare system, it has been placed at the center of the investments included in the National Recovery and Resilience Plan (*Piano Nazionale di Ripresa e Resilienza* – PNRR). Mission 6 of the plan, dedicated to health, was allocated 8.16 percent of the total amount, which is 15.63 billion euros. Component 2 of the mission deals specifically with innovation research and digitalization of the healthcare system and includes «*strengthening of technological infrastructure and tools for data collection, processing, analysis and simulation*», namely the FSE, among the interventions under the responsibility of the Ministry of Health.

3.1.1. Content and Functioning of FSE

Article 12 of Law Decree 179/2012 defines FSE as «*the set of health and social-health data and digital documents generated from present and past clinical events concerning the patient, also referring to services provided outside the National Healthcare Service*». The FSE should, therefore, collect all the data related to the patient's health allowing for an easy and complete reconstruction of clinical history. The article was amended in 2020[31], requiring that services performed outside the National Healthcare Service (SSN - *Servizio Sanitario Nazionale*)

also be included in the FSE. This tool performs (or should be able to perform) several functions on different levels: at the level of the patient, it should allow easy access to health data and thus a clearer knowledge of his or her health condition[32]; at the level of physicians and healthcare personnel, it allows for higher quality care and treatment, thanks to the knowledge of the patient's clinical history also concerning diagnoses, treatments and examinations performed or prescribed by other specialists; finally, the FSE also plays a role as a tool for scientific research[33] and health planning[34], through the possible use of data in anonymized form.

The content of the FSE consists of a mandatory and an optional core[35]. Mandatory parts of FSE are patient identification and administrative data; referrals; emergency room reports; discharge letters; summary health profiles; pharmaceutical records and consent or refusal to organ and tissue donation. This means that all regional health records should at least include these parts. Then, there is a list of data and documents that can supplement the record, but their presence depends on discretionary regional decisions and the level of development of the regional health file. Among the optional documents, however, we also find particularly relevant ones, such as specialist and pharmaceutical prescriptions, medical records, a list of vaccinations, diagnostic-therapeutic plans, and data to support telemonitoring activities. An optional section is called the "patient's notebook" (*Taccuino dell'assistito*), within which the patient himself or herself can directly enter data that he or she considers relevant. In this regard, it should be emphasized that these data are not certified by healthcare personnel or institutions, so they may at most have the value of notes that the patient believes may be useful. Precisely because the veracity and accuracy of these data is highly variable, in no way can the physician consider them as certain, but they can enrich the doctor-patient relationship and be a dialogical and collaborative tool.

The fact that there is such a wide discretion of the regions on the content represents the first critical profile with regard to the homogeneous development of this instrument in the country. Regions can legitimately decide to implement only the minimum core, but this potentially affects the quality of care that patients are entitled to receive, ultimately widening the already very large regional gap[36]. The concrete risk is that the digital tool will increase existing differences

between regional healthcare systems.

The creation and feeding system also changed during the pandemic period. In fact, file activation and document entry were initially contingent on patient consent, thus configuring an opt-in system. The number of active files in the various regions and their use will be analyzed in the next section, but it should already be pointed out that the opt-in system did not allow the full exploitation of the tool's potential: in fact, in December 2019, only 20 percent of FSE were active nationwide. Article 11 of law decree 34/2020, therefore, eliminated the need for patient consent for the creation and feeding of the FSE, starting from May 19, 2020. This means that, since then, FSE are created automatically for each patient, and health documents and data will be entered regardless of the patient's will. According to the joint memorandum of the Ministry of Economy and Finance and the Ministry of Health[37], it is planned to activate the FSE for patients identified with a tax code, resulting from the ANA or, pending its implementation, from the national list of the Health Card system (*Sistema Tessera Sanitaria*). Consent remains necessary only for consultation of the FSE by physicians and healthcare providers. Thus, Italy has moved from an opt-in system to a system where there is not even the possibility of opt-out.

The new mode of feeding the FSE has critical issues regarding the protection of patients' privacy and sovereignty over the management of their personal data[38]. On October 6, 2020, the Data Protection Authority issued an opinion clarifying the conditions for the legitimacy of this paradigm shift[39]. The authority points out that the problem arises mainly for data generated before the entry into force of the aforementioned decree. They can flow within the FSE even in the absence of the data subject's consent under the following conditions: that there has been an appropriate information campaign at both the national and regional levels; that a 30 days time is recognized from the moment the population was informed of the new legislation in order to object to the inclusion of these data in the FSE. Thus, a temporary and partial opt-out was configured, as it related only to data generated before May 2020.

Consent remains the legal basis for allowing FSE data to be viewed by healthcare personnel for treatment purposes and it is articulated in two aspects. First, the individual has the right not to consent to the viewing of the health record, without consequences in the provision of healthcare services. In the absence of

consent to consultation, the patient is the only one who will be able to view the contents of the FSE (except for the use of the data in anonymized form for research or health planning purposes). Second, there is a right to data obscuration (*diritto all'oscuramento dei dati*): every person has the right to make data related to a particular medical service invisible. This implies that such data will not be displayed at all, and therefore the healthcare provider will not even know that those data exist but that they have been obscured. There are also categories of data that are uploaded by default in an obscured mode, and these are data that entail additional protection such as data and documents governed by the regulations protecting people with HIV, women undergoing voluntary termination of pregnancy, victims of acts of sexual violence or pedophilia, people who use drugs, psychotropic substances and alcohol, as well as data and documents referring to services offered by family counseling centers. It is intended to avert the possibility that people would rather not undergo certain medical tests to protect their privacy on particularly sensitive issues[40]. In the near future, the impact of the new activation and feeding model in relation to the exercise of the right to blackout should be evaluated. This means that it will have to be considered whether the shift to compulsory feeding of the FSE will lead to greater distrust on the part of the population, who will cautiously prefer to obscure data[41].

While this would not completely nullify the benefits of the FSE, it would certainly largely limit them. Indeed, it would remain possible to exploit the data for research and planning purposes, and the uploaded documents could still be consulted by patients; however, the possibility for healthcare providers to have a complete and direct view of the medical history, and thus to be able to provide more personalized treatment pathways avoiding the repetition of medical examinations, would be restricted. This is why information campaigns, also suggested by the Data Protection Authority, among others, will be key. In my opinion, it would be necessary not only to get information about the functioning of the FSE and its benefits to patients, but it would be essential also to try and strengthen a doctor-patient relationship based on trust[42]. In no way should the patient feel exposed or fear that his or her data will be used for purposes other than those stated. Of course, developing public trust in this tool goes hand in hand with the need to strengthen data security against possible cyber-attacks and

data leaks[43].

A final aspect to consider is how patients can access their FSE. Currently, each region implements its own FSE and sets up its own access point, determining which credentials can be used. The existence of so many access points does not facilitate the usage of the system by citizens[44]. First, because individuals will have to search for specific information on how to access their FSE, depending on the credentials required by the region of residence. Second, in case of moving from one region to another, the methods of access change.

These issues are well-known to the legislator, which has made changes by both standardizing at the national level the credentials that can be used to access the FSE and providing for the establishment of a single access point (fascicolosanitario.gov.it)[45].

To date, however, this single point of access is not active yet, and the website serves as a mere collector of information. Thus, at present, there are many aspects of the FSE that are undergoing changes, but it is too early to assess their effects.

3.1.2. State of adoption and implementation problems of the FSE

Although more than 10 years have passed since the legislative introduction of the FSE at the national level, this instrument has not yet reached a satisfactory level of implementation, only partially deploying its potential. In this section a few data are provided, which are useful for understanding the level of nationwide diffusion as well as usage by physicians and patients.

The monitoring activity is carried out taking into account two indicators established by AgID jointly with the Ministry of Health: activation and utilization[46]. The activation indicator considers several services that contribute to the full implementation of the system.

Among the most relevant aspects are considered services for access (by patients, physicians, and healthcare providers); services for interoperability; services for laboratory report management. The most recent data, for the third quarter of 2023, show that the implementation indicator is 100 percent in 8 out of 21 regions, and the lowest level (86 percent) is found in one region only (Liguria), while in all others it exceeds 90 percent[47].

The provision, therefore, of the infrastructure necessary for the operation of the FSE is present evenly throughout the country. In terms of the total number of activations, 57,663,021 FSE were active as of November 2023[48], accounting for nearly the entire population of Italy, which was 59,030,133 as of January 2022[49]. According to the aforementioned joint memorandum of the Ministry of Economy and Finance and the Ministry of Health[50], as of December 31, 2019, only about 11 million FSE had been activated. This massive increase seems to be attributable to both the push effect toward digitalization of the pandemic and especially the new paradigm of automatic activation of FSE.

Certainly, the coverage of almost the entire population must be considered a great step forward in the direction of the full exploitation of this tool: the data on its usage are much less encouraging though. Monitoring utilization considers three categories of actors: patients, physicians, and healthcare providers. The population-related indicator reports the percentage of FSE access by citizens for whom a new document (such as a medical report) was made available in the last 90 days. Thus, it generally refers to the actual consultation of FSE by patients. Only two regions (Emilia Romagna 81% and Tuscany 56%) show a significant percentage of use. The other regions do not exceed 25% (Lazio 25%, Valle d'Aosta 20%) and for many regions either no data is reported, or it is close to 0[51].

Better results, although not fully satisfactory, come from the data on physicians' usage of the FSE. In ten regions, the share of physicians using the FSE system ranges from 90% to 100% (Emilia-Romagna, Lombardia, Marche, Piemonte, Puglia, Sardegna, Valle d'Aosta, Veneto and the autonomous province of Trento). In two regions, the share is around 70 percent. The remaining regions show a significant gap: Abruzzo has a level of use by physicians just above 20%, Tuscany is at 14% whereas for the remaining regions the percentage is either minimal or data are not available[52].

Even less positive are the figures for public healthcare authorities (*Aziende sanitarie*).

This indicator is divided into two categories: the number of healthcare authorities enabled to use the FSE and the healthcare authorities that feed FSE. This second aspect, together with the feeding of the FSE by physicians, holds the greatest significance. Feeding the FSE is an issue that logically lies upstream from citizen use. With the recent reform, as explained, the feeding will not depend on

the will of the patient, so the entire responsibility for this activity falls on the administrations' charge of uploading documents into the system.
Only two regions indicate that almost all healthcare authorities feed FSE. In six regions, the share ranges from 50% to 70%, while there are no data available for eleven regions.
It must be stressed that the unavailability of granular data makes it extremely difficult to assess the actual status of implementation. The monitoring service provided by AgID is also supposed to make detailed data available at the regional level[53]; currently, however, regional sections do not appear to be available.
Some tentative considerations may nevertheless be drawn from currently available data.
The activation of FSE for almost the entire population is a huge step toward realizing the full potential of this tool. If this aspect is combined with an effective and complete automatic feeding of FSE, under the provisions of the most recent legislation, data availability will be ensured at least for health research and governance purposes.
Lack of awareness of the FSE and its usage by the population have been considered indices of the failure of this tool in the Italian system. However, when considering the purposes of the FSE, it does not seem correct to consider this aspect as a key element in evaluating its role. The use of the FSE by patients (i.e., its consultation) should be considered an option; it represents the healthcare system's offer of an easier way to consult and store health data. However, given that the patient continues to have access to his or her data and reports even through traditional channels, the improvement in the quality of care comes first and foremost from the feeding of the FSE by healthcare facilities and its use by physicians who will be able to have a more complete view of the patient's medical history. As access to patients' data for physicians continues (rightly) to be subject to individual consent, it will be interesting to observe the response of the Italian population in the coming time. The question is whether the shift to a mandatory FSE feeding mode will be accepted with confidence at the societal level, or rather it will result in a distrustful reaction that could push patients to obscure their data in the record.
Furthermore, if patients' awareness and familiarity with the FSE are to be increased, appropriate information campaigns are needed. In my opinion, an

effective awareness-raising role could be played by family doctors, who are usually a reference and trusted figure for patients. However, it seems impossible to burden general practitioners with this task as well, given the limited number of GPs in relation to the population and, thus, the workload imposed on them[54]. Investments should also be used to improve the digital literacy of the population. This is a more general problem for Italy. In fact, as already pointed out, the DESI index identifies human capital as the weak point in Italy's digitalization process: apparently only 46% of the Italian population has basic IT skills[55].

3.2. The electronic health record in Germany: die elektronische Patientenakte (ePA)

In 2021, after decades of trial and error, the Electronic Health Record (*Elektronische Patientenakte* - ePA) was introduced in the German healthcare system. The ePA was legislatively adopted in 2020 through the Patient Data Protection Act (PDSG)[56], which amended SGB V[57].
The discussion on the opportunity of introducing the EHR started actually in the 1990s[58], and the introduction of the ePA had already been decided in the GKV Modernization Act of November 14, 2003[59]. Nonetheless, this instrument did not find any real application until January 2021, partly due to opposition over the years by *gematik*[60] itself, which is the federal agency responsible for the digitalization of the healthcare sector. Until 2019, in fact, the *gematik* was composed of 50 percent representatives of health insurance companies and service providers, which made decision-making difficult and hindered the implementation of important innovations, such as ePA[61].

3.2.1. Content and Functioning of the ePA

§341 SGB V opens with a definition of ePA, which is described as an electronic record managed by the insured and made available by health funds. This means that the insured themselves decide which data are stored or deleted in the ePA and who can access them. The emphasis on insured management of the file highlights the willingness to give a prominent role to informational self-determination and patient sovereignty. The activation mode is therefore different

from the one currently in place in Italy and similar to the one that existed before the 2020 reform. In the face of the ePA activation, two subjective positions arise: the right on the part of the insured to activate the ePA and a respective obligation on the part of the health insurance company to offer the ePA service to its clients[62].

The content of ePA is similar to what is already in place in many other states of the Union, and it is intended to be the counterpart (and in the future the substitute) of patient's paper health record. All the considerations made above about functions, usefulness and goal of the EHR/FSE also apply to the ePA. The interoperability issue has been addressed by the German legislator as well, but whereas in Italy the need is to ensure interoperability among regions, the German insurance-based system is concerned with ensuring interoperability and portability of data between different insurance funds. To ensure completeness of data, in case of change of insurance fund, data portability must still be guaranteed (§ 342 par. 2 let. d SGB V). It is also intended to make it possible for all healthcare providers to access these data, subject to patient's consent.

The content of the ePA is determined by law through § 341 para. 2 n. 1-13. The text of the norm reports that there is the possibility (and not the obligation) of including such data in the record, and this is because, as already pointed out, the patient's will plays a sovereign role. It is important to underline that, in addition to data related to patient's health conditions obtained through diagnosis, therapeutic measures, early diagnostic examinations, treatment reports, and thus generally through documents from healthcare facilities, it is also possible to include health data provided by the insured himself (§341 para.2 n. 6) as well as data from digital applications under §33a SGB V (§341 para.2 n. 9). While the possibility to insert data directly by the patient is also provided for in the Italian system, the inclusion of data from apps is not possible in the FSE and it represents a further step toward an integrated vision of digital healthcare. The provision is consistent with the desire to make mHealth an integral part of German healthcare, as it will be seen below[63].

Again, to enhance patient's sovereignty over his or her own data, a granular access authorization mechanism (*granulares Berechtigungsmanagement*) is ensured. As laid down in § 342 paragraph 2 no. 1 let. c SGB V, insured persons can give their consent not only to access all ePA data, but also to exclusive access to data under

§ 341 para. 2 n. 1, which are basically medical information from examinations and diagnosis, the treatment plan, and information for emergencies, or to data under § 341 para. 2 n. 6, namely the information provided by the patient himself. Thus, in the end the "all or nothing" principle was rejected. In the first stage, a so-called rough control (*grobgranulares Berechtigungsmanagement*) on access was provided, because the choice was simply between making all data accessible or only those in n. 1 and 6 of § 341 par. 2 SGB V; later on, detailed control (*feingranulares Berechtigungsmanagement*) was provided by allowing selection of individual documents to be made accessible to health personnel[64]. Certainly, this approach enhances the role of the patient and helps limiting concerns about sharing sensitive data. However, it also has critical aspects. First and foremost, if the patient only consents to access to certain data, the possibility for health professionals to make a truly comprehensive assessment of the situation is lost. Indeed, it would be the patient who would be able to decide what data are relevant, but he or she often lacks the relevant expertise. This could partially challenge the usefulness of ePA, the use of which could provide only a partial view of patient's status. Nonetheless, it is correct that the ultimate decision about one's sensitive data remains with the patient, not only for privacy reasons and one's most personal sphere, but also in deference to the principle of self-determination and freedom in treatment choices, even if these choices may ultimately harm individual health. On this aspect, there are no substantial differences from the Italian law. The only point of divergence is the fact that, currently, the German law does not provide for categories of data that are by default completely obscured (thus there does not seem to be a right to obscure data as explained in paragraph 3.1.1.).

3.2.2. Adoption and implementation problems

In the implementation phase, it is the responsibility of the *gematik* to formulate the technical standards for ePA functionality at every stage, including ensuring interoperability among the systems (§ 354 SGB V). The implementation process of the ePA legislation was divided into three main stages reported in § 342 SGB V. The first stage was set for January 1, 2021. From this date, the insurance funds (*Krankenkassen*) are obliged to make an ePA available to all the insured who

request it. Thus, an opt-in system was initially envisaged, the appropriateness of which, however, has been called into question by the very low uptake of ePA two years after its introduction. At this first stage, it was planned to implement only a few essential functions such as the collection of the data indicated in § 342 par. 2 and 6, i.e., strictly medical data and data provided by the insured. In addition, ePA was initially tested only in certain areas (Berlin and Westfalen-Lippe), and then by the 30th of June 2021, the system covered the whole country. Since the 1st of July, 2021, contract physicians (*Vertragsärtzte*) have been required to create the conditions for a connection to the telematic infrastructure in order to be able to use the ePA, while hospitals must be connected from January 1, 2022[65].
From the second stage, starting in January 2022, additional data can be saved on the electronic file. The detailed control over access to data, mentioned earlier, has also been introduced.
From the third stage, starting in January 2023 the insured person is given the option to make his or her data available for scientific research (§ 342 par. 2 n. 4 let. b).
This possibility is consistent with European policies that, especially in the area of health, are working to expand the possibilities for secondary use of data. In particular, the choice to make one's data available for research evokes the concept of data altruism[66], introduced by the Data Governance Act[67]. In this respect, there is a major difference from the FSE, whose data can always be used, in anonymized form, for research purposes regardless of patient's wishes.
Finally, although in the first stage, ePA use was guaranteed only through mobile devices (smartphones and tablets), by January 1, 2022 at the latest, health insurers are obliged to ensure that ePA can also be used through PCs (§ 342 par. 7 SGB V). The opposite has occurred in Italy, namely, the FSE has always been available from PCs only, and later some regions have also developed apps for mobile devices.
As said, both activation and usage of the ePA are fully voluntary, and an opt-in system was initially chosen. However, two years after the introduction of the health record and in light of the wholly unsatisfactory results, it was deemed appropriate to switch to an opt-out system. In fact, just over two years after the effective introduction of ePA into the German system, this instrument has not achieved the desired results. It is estimated that only 1 percent of the population

has requested to activate[68] it and only 6 percent of physicians is using it[69].
Several scholars have tried to identify the causes of such failure (so far), and three main factors have been identified: the activation system, the population's lack of awareness of the tool, and the general distrust of sharing sensitive data[70].
Regarding the first aspect, i.e. the opt-in mechanism, this presupposes an active role of the insured who requests activation of the record from their insurance fund. Each fund, therefore, has been able to work out its own process for requesting activation, and very often this process has not been designed to be simple, fast, and accessible to all; in fact, many funds have provided as exclusive way of activation that the subject had to physically go to the offices to request it[71].
The choice of the opt-in mechanism was consistent with the view of enhancing patient's sovereignty over his or her own data; however, to date the validity of this choice is questioned. According to this approach, everything comes through active consent: the activation of the record, the uploading of data, and the ability for healthcare providers to access it.
In light of the poor results to date, it has been proposed by several parties to move to an opt-out mechanism[72], whereby the ePA will then be set automatically for all the insured and those who do not wish to do so can actively oppose it. The 126th conference of German physicians, held in May 2022, also supported an opt-out system for the activation of ePA and indeed called for such an option to be provided for data visibility by physicians as well, i.e., they claimed for patient's consent not to be required for physician access to the health record, but rather for the patient simply to be given the option to object to such access[73].
As consequence, on Nov. 7, 2022, the shareholders' meeting mandated the *gematik* to switch to an opt-out system by the end of the term, whereby the automatic creation of the electronic file will be the default option, subject to the insured's opposition[74]. This evolution would be similar to the Italian one, but the ePA scheme would still recognize the possibility to opt out and therefore it will not be mandatory. It remains to be seen whether this change will be enough to ensure the successful implementation of ePA, since the current failure is also related to the lack of awareness of the tool among the population, as well as a general fear of sharing sensitive data.
Regarding the lack of public awareness about the existence and use of ePA and the population's distrust, it was pointed out that no effective information

campaign has been carried out, differently from what was done when the Covid tracking app (Corona-Warn-App - CWA) was introduced[75]. Interviews with the developers of the Covid tracking app show how the broad acceptance of this app by the population is based on two pillars: on the one hand, the development of the app itself was user-centered and various stakeholder groups were integrated into the development process; on the other hand, the skepticism of the population was addressed through openness and transparency and the choice was made to develop the software through an open source project[76]. In developing digital solutions, the emphasis is on technical issues, while strategic, communication, and human aspects are often neglected. However, it is precisely the difficulty in solving these issues and coping with the social aspects of digital evolution that causes the failure of key projects in digital health, such as EHR. Indeed, it has been underlined that «*the areas of acceptance, change management, demonstration of benefits, funding, project management, health-policy related goals, and implementation strategy, and basic legal conditions, data protection must be given at least as much importance at the very start of the project as technological aspects are given*»[77]. Thus, while a clear and transparent communication strategy is necessary, it alone cannot overcome public distrust and concerns about privacy.

The other aspect that certainly needs to be taken into account, as well as improved, relates to patients' motivations for using or not using ePA[78]. In fact, there has been a positive trend in patients' interest in being able to digitally monitor health data, but this benefit often fails to offset privacy and security concerns. Therefore, alongside improving technical and interoperability aspects, it is necessary to consider patients' motivations for using the electronic health record, as highlighted in several studies. In conclusion, in the absence of a multidirectional action, addressing communication, privacy, and data security, and ensuring sovereignty over one's medical data, merely introducing an opt-out mechanism for the activation of ePA might only partially achieve the desired results, and many indeed prove counterproductive.

4. Integrating mHealth into the healthcare system: the

German model

Although a central tool such as the ePA is still struggling to find full implementation, the German legal system has been pioneering, adopting a law on digital healthcare[79], whereby, in short, it introduces the possibility for physicians to prescribe the use of digital tools (such as apps) for disease management, treatment and care.

On December 19, 2019, the so-called Digital Healthcare Act (*Gesetz für eine bessere Versorgung durch Digitalisierung und Innovation - DVG*) came into effect; it made changes to SGB V and in particular introduced §33a, titled "digital health applications" (*digitale Gesundheitsanwendungen - DiGA*). The norm is the legal basis for the provision of care through digital applications, the costs of which are covered by insurance funds. In other words, apps and software that are classified as low-risk medical devices, according to the European medical device regulation[80], become part of the healthcare system and can be prescribed by physicians like a traditional therapy. Therefore, according to §33a SGB V, insured persons are entitled to be supplied with low-risk medical devices whose main function is essentially based on digital technologies and which are designed to support the detection, treatment, alleviation or compensation of injuries or disabilities. These provisions only cover apps that are on the list maintained by the German Federal Institute for Drugs and Medical Devices[81] under §139e SGB V and that have been prescribed by the doctor or psychotherapist, or are used as a result of an agreement with the insurance company.

Thus, the first point to be analyzed is the objective scope of the regulation, that is, what is meant by digital health applications, or rather which digital applications fall under this scope. In fact, the concept of digital health application is very broad and there is no single legal definition. The DVG limits its scope to applications that are classified as low-risk medical devices, namely devices that fall into risk classes I and IIa according to the MDR[82] and are used for detection, monitoring, treatment or alleviation of diseases or detection, treatment alleviation or compensation of disabilities. This implies that apps must be approved as medical devices; therefore, all those software that deal more properly with wellness and lifestyle are excluded. A DiGA can also be hardware, such as a wearable device if this works through software and collects data[83]. In

addition, such devices must be approved by the German Federal Institute for Drugs and Medical Devices and included in a specific list after a so-called "fast-track procedure"[84].

The procedure for the inclusion of a DiGA in the list maintained by the BfArM is stated in §133e SGB V and detailed in the Regulation on the Procedure and Requirements for Reviewing the Eligibility for Reimbursement of Digital Health Applications in the Statutory Health Insurance System[85]. This procedure that can be activated to own-initiative and can last maximum three months. The manufacturer has the burden of attaching evidence that: the application meets safety, functionality, and quality requirements, including interoperability of the medical device; it meets data protection requirements and ensures data security in accordance with the state of the art; it has positive care effects. Positive effects of care mean medical benefit or structural and procedural improvement in healthcare relevant to the patient. According to §14 of the Regulation, the manufacturer must submit at least the results of a systematic data evaluation on the use of the digital health application as plausible justification that a positive healthcare effect can be demonstrated in a trial.

§15 adds that the manufacturer shall submit an evaluation concept drawn up following generally accepted scientific standards that takes appropriate account of the results of the data evaluation under § 14. This requirement proved to be the most difficult to meet since it was unclear what constitutes "systematic data for use" and what are "data scientific standards". Nevertheless, producers' opinion on this "fast-track procedure" is positive because it is not static but characterized by dialogue.

During the three months, the BfArM communicates with producers by asking for clarifications and additions, in the spirit, therefore, of a cooperative procedure[86].

Sometimes it is possible that the manufacturer may not have the necessary data and studies at the beginning of the procedure to prove the benefit of the application on patient care.

In that case, it is possible to place the DiGa on the registry with a 12-months trial period (extendable up to 24 months) during which the manufacturer collects the necessary data to prove the beneficial effects of the device (§139e par. 4 SGB V).

DiGA pricing also follows a well-defined administrative process[87]. §134

authorizes the National Association of Statutory Health Insurance Funds (*GKV-Spitzenverband*) to issue binding regulations for all statutory insurance funds and to agree with the producers of digital applications on remuneration amounts. The established amount applies from the year following DiGA inclusion in the register. The price is then established through an agreement and can be modified by a subsequent agreement. If an agreement is not reached within nine months since inclusion in the registry, the setting of the price is referred to an arbitration panel (§134 par. 2 SGB V).

There are currently 55 DiGAs in the registry[88]. A large group of applications is devoted to mental health and in particular to the treatment of depression, anxiety, stress, and burnout; others deal with the treatment of chronic diseases such as diabetes, heart disease, and oncology; and others deal with alcohol and nicotine addiction. The list is user-friendly.

Next to the name of each app, it gives several indications such as the platform from which the app is downloadable (Apple App Store, Google Play Store) or whether it is a web app, the diseases for which it is indicated, the cost required by the manufacturer and which will be covered by insurance, whether medical services are required for use, the languages in which it is available, and if additional devices are needed. The physician or psychotherapist can prescribe the use of one of these apps contained in the registry, and the patient can obtain it directly from the major app platforms. It seems clear that digital literacy of physicians plays a key role, maybe even more than patient literacy. Some research has shown that currently, the knowledge of DiGAs by physicians is still very limited: according to a 2022 study, 64 percent of respondents were unaware of the possibility of using and prescribing them[89]. Moreover, some surveys have found that physicians are quite skeptical of DiGAs, and only 30 percent was planning to prescribe them[90]. In the face of mistrust from physicians, the population (especially in the 30 to 49 age group) is favorable to the use of digital medicine, especially those applications whose quality is attested at the state level[91].

Data on the age of those inclined to use digital medicine highlight a recurring problem in the area of digitalization, namely the so-called digital divide. This concept has several dimensions: first, the socioeconomic divide; second, the divide related to the digital knowledge/literacy of patients, which is often linked to age[92]. Some research has, in fact, shown that internet use is not only related to

users age. It is in fact well known that younger individuals are more accustomed to using technology, but a correlation between internet use and income has also been shown: the percentage of those who use internet at least once a day increases with income[93]. Moreover, although internet connection costs have significantly reduced over the years, this does not mean that access to digital tools is guaranteed to the entire population. On the one hand, it must be considered that Germany suffers from an urban-rural digital divide regarding fixed network broadband coverage and the share of fiber connections is still very low[94]; on the other, the usage of DiGAs almost always presupposes the possession of a smartphone. True, the portion of the population that does not own a smartphone is getting smaller and smaller, but it still exists. In 2021 the number of smartphone users in Germany reached 62.61 million[95], which means that 24.75% of the population did not own such a tool. Also, consider that it is not enough to own any type of smartphone since the use of some apps is conditional on their compatibility with the operating system. It is therefore necessary to use a smartphone that is new enough and performs well enough to support the apps.
The average price for a new smartphone in Germany is currently estimated to be around €626[96], which undoubtedly raises questions regarding the need to ensure that even the lowest income earners can purchase them. A U.S. study carried out on patients with tuberculosis found that patients who were older, male, less educated, or had lower annual incomes were less likely to own smartphones[97]. One of the challenges that policies have to address is actually be the exclusion of segments of the population from digital services; that is, it will be necessary to prevent technology from increasing social distances instead of shortening them.
The DVG covers the costs of the apps by making them an integral part of the German healthcare system, but it does not provide any mode of reimbursement, not even partial reimbursement, for the purchase of a smartphone capable of supporting the doctor-prescribed DiGA. This remains one of the knots that need to be addressed in the coming years to prevent digital medicine from widening the gap between social classes in healthcare instead of narrowing it. Alongside this, the awareness and literacy of physicians about e-Health should not be neglected, since, as seen above, they play a key role in “linking” patients and digital tools.

5. Conclusion

As a result of the pandemic, we have seen an acceleration in the digitalization process in many areas and especially in the field of healthcare. All EU member states are engaged in a digital transition of their health systems, although some are frontrunners and others are still at an early stage. Regardless of the healthcare model, the cornerstone of this process is the electronic health record as a tool to collect health data. This paper first analyzed the Italian and German models of EHR implementation and then focused on the integration of mHealth in the German healthcare system.

Despite the different timing of FSE and ePA adoption, some common trends and issues stand out. Both have similar content and functions, but different activation mechanisms, partly because of the different healthcare models. In Italy, where there is a national healthcare system, the responsibility for establishing the FSE lies with the regions, which operate by following common national guidelines. In Germany, the insurance system assigns responsibility to insurance funds, also coordinated, however, at the federal level through the "gematik". The autonomist and decentralizing tendency (toward the regions in Italy, toward the "Krankenkasse" in Germany) is thus, in both cases, balanced by coordination at the central level. It will be interesting to evaluate in the coming years which system succeeds best in ensuring effective and homogeneous development.

Both countries chose an opt-in system in the first instance, which in both cases proved unsatisfactory. In response, Italy has shifted to a mandatory FSE model, while Germany is moving towards an opt-out system. As was seen during the pandemic with tracking apps, public trust in the technological tool plays a key role in its success or failure.

Clear and consistent regulations, along with user-friendly and easily accessible technologies, are obviously indispensable, but they are not sufficient to determine the successful implementation of tools such as EHR. Even more than in any other field, in the health sector where particularly sensitive issues, fundamental rights, and conflicting interests come to the fore, the social perception of trust or distrust, of usefulness or uselessness of an innovation plays a decisive role. The features and methods of introducing digital tools must thus

be tailored to the peculiarities of the target population. For this reason, in a country like Germany where the population is very sensitive to privacy issues and cautious about disclosing sensitive personal data, the introduction of an opt-out system for ePA must be accompanied by a careful awareness campaign, based on transparency.

In Italy, the mandatory FSE model has made it possible to cover almost the entire population in a short time, but it does not mean that this solution would work in Germany as well, since it could be perceived as being too coercive and led to opposite results.

It should also always be kept in mind that the ultimate goal of digitalizing healthcare is to improve care, keeping the patient at the center of the system. It follows that patient's will and self-determination must continue to be cornerstones of the system.

The possibility, provided in both countries analyzed, to deny access to one's data cannot be questioned, as it falls under the principles of freedom of therapeutic choice and self-determination that are placed to safeguard patient's dignity. Certainly, actions are possible and necessary to ensure that patient's decisions are based on correct and complete information. In addition to traditional information campaigns, it seems appropriate to strengthen the doctor-patient relationship. However, this cannot happen at no cost and cannot imply offloading onto the shoulders of GPs also the task of educating their patients about every new technological innovation.

The goal of improving care offered to patients and making it more personalized is also pursued by the Digital Care Act, which was introduced in Germany in 2019 and effectively integrates mHealth into the healthcare system. The benefits of using these technologies are proven in relation to different diseases and situations. They benefit chronic patients the most and they are particularly effective in the fields of mental health, oncology, cardiology, etc.

To reach the full potential of using medical apps, they need to be made interoperable with the EHR. In order not to lose the potential of such advanced legislation, the German system needs more than ever to make the implementation of ePA effective and satisfactory.

A further challenge concerns the need to avoid that the delivery of quality care through digital tools ultimately leads to the exacerbation of social inequalities,

namely, the exclusion of those who neither have the skills to use these tools nor have the financial means to purchase suitable smartphones and devices. App reimbursement is certainly the first step in the right direction, but it is not enough. Close monitoring and effective actions aimed to ensure that technology reduces social distances, instead of broadening them, will be key tasks task for legislators in the coming years, from which they cannot escape if they do not want digital medicine to become synonymous of exclusionary and elitist medicine.

1. This paper will also be published in the proceedings of the 16th Annual Conference of the *Societas Iuris Public Europaei* (SIPE), Neue öffentliche Aufgaben in Spannungszeiten – New Public Tasks in Times of Tension – Nouvelles missions publiques en période de tension (Lisbon, 22-24 June 2023).
2. Communication from the commission to the European Parliament, the council, the European Economic and Social Committee, and the committee of the regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society, COM(2018) 233 final.
3. European Commission, Overview of the national laws on electronic health records in the EU Member States and their interaction with the provision of cross-border eHealth services. Final report and recommendations https://health.ec.europa.eu/system/files/2019-02/laws_report_recommendations_en_0.pdf.
4. For this reason, and in view of the importance of ensuring that health data can be exchanged across the Union, the Commission adopted a recommendation to adopt a European EHR format to facilitate cross-border interoperability: Commission Recommendation on a European Electronic Health Record exchange format (C(2019)800) of 6 February 2019. See also: M. Ferrara, *Dalla mobilità dei pazienti alla interoperabilità dei sistemi sanitari. Spunti sull'adozione di un formato europeo di scambio delle cartelle sanitarie elettroniche (Raccomandazione (UE) 2019/243)*, in *Federalismi.it*, 5, 2021, pp. 15-41.
5. mHealth (mobile health) is a specific branch of eHealth (electronic health); according to the WHO definition mHealth is a term used for medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, Personal Digital Assistants (PDAs), and other wireless devices. mHealth applications include the use of mobile devices in collecting community and clinical health data, delivery of healthcare information to practitioners, researchers, and patients, real-time monitoring of patient vital signs, and direct provision of care (mHealth programmes are sponsored by government (who.int)).
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15. See the next section for the allocation of competences between the state and regions in Italy.
16. Act to Improve Healthcare Provision through Digitalization and Innovation (Digitale-Versorgung-Gesetz – DVG), which was approved on 7 November 2019 by the Bundestag and adopted on 29 November 2019 by the Bundesrat.
17. Decree of the Ministry of Health 21.09.2022, Approval of guidelines for telemedicine services - Functional requirements and service levels; Decree of the Ministry of Health 30.09.2022, Procedures for selection of telemedicine solutions and nationwide deployment, as well as mechanisms for evaluation of regional needs proposals for minimum telemedicine services and adoption of the Guidelines for Telemedicine Services. For an overview of the implementation of telemedicine in Italy and the issues related to it see: *L. Ferraro, La telemedicina quale nuova (e problematica) frontiera del diritto alla salute*, in *Diritto dell'informazione e dell'informatica*, 4, 2022, p. 837.
18. https://www.who.int/data/gho/indicator-metadata-registry/imr-details/4791.
19. For example, the Finnish Maisa system can connect to Google Fit and Apple Health: https://www.maisa.fi/maisa/Authentication/Login?mode=stdfile&lang=britishenglish&option=hlthprivacy

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46. A description of the content and operation of monitoring is contained in Annex B of the Guidelines for the Submission of Regional Project Plans for the FSE dated March 31, 2014 (2_fse_linee_guida_dpcm_31032014.pdf (fascicolosanitario.gov.it)).
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50. See par. 3.1.1.
51. https://www.fascicolosanitario.gov.it/it/monitoraggio/bc.
52. https://www.fascicolosanitario.gov.it/it/monitoraggio/bm.
53. In fact, it is stated that «*in the specific regional section, a detailed graph is displayed in which the sum of the values entered is shown*».
54. According to the National Agency for Regional Healthcare services (Agenas) report, there are 40.250 general practitioners in Italy in 2021. The number is reduced by 2.178 compared to 2019. This means that on average there are 6.81 doctors for every 10.000 inhabitants (according to Eurostat, in Germany there are 10.3 GPs per 10.000 inhabitants), with significant differences between regions. It is also estimated that by 2025 the number of general practitioners will decrease by an additional 3632. (Agenas, *Rapporto sui medici di medicina generale*, 2021, https://www.agenas.gov.it/images/agenas/mmg/Dati_MMG_Revisione_4.0_full.pdf). Moreover, Italy has the largest share of physicians aged 55 years and over, which means that in the coming years, many of them will be reaching retirement age: see Eurostat, healthcare personnel 2021, Healthcare personnel statistics - physicians - Statistics Explained (europa.eu).
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