The Electronic Health Record in Italy: Its Potential and Further Adoption

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Purpose and organisation of the document

The COVID-19 pandemic clearly demonstrated how **digital health**[1] is now an essential part of any healthcare system, an innovative approach to the management of healthcare in society, and a vital tool in the search for better healthcare solutions. The current health crisis has led to a significant increase in the adoption of new care pathways and digital technologies. These facts have been acknowledged and addressed in Italy in the 2021 Official Guidelines issued by the Ministry of Health, which defined the following actions of fundamental importance[2]:

1 The **launch of an initiative to spread the use of technological solutions in the healthcare services**, including telemedicine and telecare, electronic medical records, artificial intelligence platforms, point-of-care diagnostics, and platforms aimed at patients' empowerment and at health education for the citizens.

2 The **promotion of the use of analytical and quantitative tools** to support healthcare planning, in order to make tools available for the collection of data and information related to disease prevention and healthcare planning, providing prompt care, and to anticipate new epidemiological scenarios.

3 The **development of a new health information system** that will supportthe Regions and the Ministry of Health in carrying outtheir duties.

4 To make the **Electronic Health Record more effective and complete**, supporting health research through which it will be possible to develop innovative clinical applications, making new treatments and more effective care and assistance paths available to patients, creating the conditions for improved healthcare.

A further opportunity for the development of digital health has been given by the Next Generation EU Recovery Fund assigned to Italy which, given the current situation, is placing a lot of importance on the development of digital health.

In particular, based on the information currently available, Italy is expected to allocate part of the funds to promoting the use of the Electronic Health Record (EHR), consistently with the weight given to this topic in the recent Law Decree No. 22 of 1 March 2021, which has made the President of the Council and the Interministerial Committee for Digital Transition directly responsible for management of EHRs[3]. However, to be compliant with the requirements defined by the European Commission, it will be mandatory to define in details the solutions to fund and implement, in order to support the evolution of digital healthcare[4]. In this context, this document analyses the opportunities for the evolution and the expansion of the use of the EHR in Italy.

To this end, the document consists of two sections: the first gives a definition of the Electronic Health Record and analyses the current level of adoption in Italy; the second presents the opportunities that exist to expand the use of EHRs and proposes a series of actions to make the most of these opportunities.

The document is based on the findings of the working groups held in February and March 2021, with representatives of HIMSS Italian Community (which coordinated the drafting of this document), SIMM (Italian Society of Leadership and Management in Medicine), AUSL of Romagna, IRST IRCCS Dino Amadori, the Autonomous Province of Trento and Trentino Salute 4.0, the Regional Agency of Healthcare in Tuscany, the Toscana Life Sciences Foundation, and Roche. The document has been presented to the Ministry of health and the Ministry for technological innovation and digital transition in Italy.

[1] For details on the status of the current implementation of digital health in Italy, please refer to Annex 1.
[2] www.quotidianosanita.it/governo-e-parlamento/articolo.php?articolo_id=94327
[3] www.agendadigitale.eu/sanita/sanita-digitale-piattaforme-dati-e-fascicolo-elettronico-pilastri-strategici-per-il-nuovo-governo/
[4] www.agendadigitale.eu/sanita/una-sanita-basata-sui-dati-per-non-vaccinare-a-caso-e-curare-meglio/

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The Electronic Health Record in Italy: Definition and level of adoption

L'Agenzia per l'Italia Digitale (The Agency for Digital Italy) - AgiD[6] defines the Electronic Health Record (EHR)[7] as "A tool the general public can use to track and consult their entire health history, sharing it with professionals for a more effective and efficient health service", in order to give "the patient greater freedom in their choice of treatment and the ability to share the information with healthcare professionals by giving them access to this data".

The goal of the EHR is to facilitate:

- The **prevention**, diagnosis, and treatment of disease, and clinical rehabilitation;

- Study and **scientific research** in the field of medicine, biomedicine, and epidemiology; and

- Healthcare planning, the **assessment of the quality of care** being provided, and the overall standard of healthcare.

As prescribed in Article 12, Law Decree No. 179 of 18 October 2012, "Further urgent measures to promote its use throughout the country"[8] the Electronic Health Record is being introduced in the provinces and autonomous regions in compliance with current legislation on the protection of personal data. In line with the requirements of the President of the Council of Ministers Decree No. 178 issued on

29 September 2015: Regulations on Electronic Health Records[9], the EHR contains a set of digital data and documents related to a patient's medical history.

AgID and the Ministry of Health, in agreement with the regions, defined a series of indicators that will make it possible to track trends in adoption of EHR in Italy. In particular, the tracking will measure two distinct groups of indicators: implementation and use (distinguishing between doctors, citizens and healthcare providers).

Looking at the level of **implementation**[10] the initiative seems to be progressing well, albeit with some inconsistency between the various regions. In particular, five regions have reached a level of 100% implementation. Of the remaining regions only three have an implementation level below 90%, and only one below 50%.

Looking at the **usage indicators**, there are considerable **differences between the various parties** that have been analysed. In particular, a general picture emerges of reluctance by doctors[11] and the general public[12] to make use of EHRs (albeit in contrast to high percentages of people with an active EHR in some regions). Better results were found for Hospitals and Local Health Authorities[13], although some regions still have levels of usage close to zero.

The aforementioned indicators demonstrate that, by virtue of the very recent adoption of EHRs in some regions and, more importantly, its limited general use, **the EHR cannot yet be considered as a practical tool, capable of playing a substantial role in supporting clinical decisions, or as an instrument of governance, as was also underlined by the research by the Digital Innovation in Healthcare Observatory of Politecnico di Milano**[14]. The next section presents a series of opportunities for extending the coverage of EHRs and the proposals for projects that could be launched in the field to make the most of these opportunities.

[6] www.fascicolosanitario.gov.it/il-fascicolo-sanitario-elettronico
[7] Per un'analisi di dettaglio degli aspetti definitori del FSE e del relativo livello di utilizzo si rimanda all'Allegato 2.
[8] www.gazzettaufficiale.it/eli/id/2012/12/18/12A13277/sg
[9] www.gazzettaufficiale.it/eli/id/2015/11/11/15G00192/sg
[10] www.fascicolosanitario.gov.it/monitoraggio/a
[11] www.fascicolosanitario.gov.it/monitoraggio/bm
[12] www.fascicolosanitario.gov.it/monitoraggio/bc
[13] www.fascicolosanitario.gov.it/monitoraggio/ba
[14] www.agendadigitale.eu/sanita/una-sanita-migliore-grazie-ai-dati-polimi-ecco-ipassi-per-una-svolta/

3

Electronic Health Record in Italy: Further Adoption...

The development opportunities described below emerged from working group discussions and aim at maximizing the potential of the EHR in the fields of prevention and diagnosis, research and governance.
In particular, they are pragmatic initiatives, actionable by the various actors involved, to maximise existing opportunities.

Currently, EHRs, in the field of **patient care**, are only partially valued. However, the EHRs could be a real decision support tool, making it possible to record and share the entire clinical history of the patient. There are two other equally important roles it can play. For **clinical research**, the use of EHRs would allow the creation of a National Health Repository, which could be a source of reliable real world data for medical research and for the development of Artificial Intelligence systems in healthcare, as recent reports on the topic clearly highlight[15]. Furthermore, in terms of **governance**, the EHR should overcome the current approach, based on ex-post information flows and on information debts, evolving towards a platform capable of collating, both at regional and national level, **near real-time information** on appointments and the provision of care. An example is the Data Warehouse used by the Tuscany Region to monitor the demand and provision of health services in the management of the COVID pandemic.
To make the most of the opportunities described above, a series of initiatives must be actioned, as outlined below.

Action 1:

Real interoperability of regional EHR solutions

The current situation highlights significant problems related to the level of adoption of EHR in the regions.

At the central level, the Interoperability National Infrastructure (Infrastruttura Nazionale per l'Interoperabilità – INI)[16], makes it possible for regions to publish health documents and data from the regional EHRs on the national index. However, it is still the case that there are incompatibilities between the various solutions in use and, in many cases, a lack of adherence to the specifications for integration required by the INI. These aspects limit the possibility of exchanging data between regions. In particular, the main inconsistencies concern:

- **Methods of managing the Electronic Health Record:** some regions use proprietary protocols to share Electronic Clinical Document (ECD), while other regions use standard protocols (for example, the XDS protocol). Furthermore, some regions require direct integration of the EHR with departmental systems of the healthcare providers, while other regions require integration only between enterprise repositories and the EHR. Finally some regions manage ECDs in different ways (in some cases, ECDs are stored at the facility that produced them and are only referenced in the EHR as a log and, in other cases, the EHR are used to manage their own ECD archives).

- **The formats used to store data in the EHRs:** some regions currently use structured formats (e.g., CDA2), others only PDF documents, and other regions use a range of other formats. The specifications defined by INI recommend the use of PDFs with CDA2 attachments, or CDA2 exclusively. This second option, however, does not define the style sheet that should be used, making further incompatibility likely. Similarly, there is a wide variation in the type

of digital signatures used to sign documents (PADES, CADES, XADES, etc.)

- **Data and metadata encoding:** the regions also use different encodings. The type of data and metadata encoding used for clinical data in the healthcare system in Italy is inconsistent and patchy.

The inconsistencies described above, in addition to reducing the effectiveness of the EHR as a tool, make it difficult for healthcare organizations operating across multiple regions to manage the integration of EHRs. In fact, they have to deal with integration protocols that are often not compatible, resulting in reduced efficiency and delays in providing access to EHRs.

To overcome these issues, a series of initiatives have already been launched at national level, which include the allocation of resources aimed at adapting cross-regional solutions, with the disbursement of funding based on the results obtained[17]. For this to be successful, it would be necessary to improve the existing initiatives and extend the work of the coordination groups between the state and the regions, so that they can monitor and direct the regional initiatives. Particular attention should be paid to:

[15] www.fsk.it/top-news/intelligenza-artificiale-sanita-e-ricerca-biomedica-in-ital-ia-proposta-di-repository-sanitario-nazionale/
[16] www.fascicolosanitario.gov.it/interoperabilit%C3%A0-del-fse
[17] www.quotidianosanita.it/regioni-e-asl/articolo.php?articolo_id=78423

- **ECD formats and metadata**, including the publication of specifications, to be made binding for suppliers, for new applications, and adopting of standard encoding with a vision oriented to integrate clinical processes

- **Signature formats should be adapted**, to cover all clinical requirements, not just single documents as in the current configuration.

- **There must be a single, standardised integration methodology** for all stages of the document management path.

In parallel, the regions should commit themselves to the adaptation of these solutions by making use of the tools and resources that are available at the central level.

Action 2:

Extending the functional coverage of the EHR

Another item to be addressed, is the need to **increase the amount of information included in the EHR**, in order to ensure that it contains a complete record of the patient's medical history, which would make it a useful tool also to **support the integration of data between hospitals and other healthcare sites**. The EHR could, in fact, be a very important and effective link between the different nodes of the healthcare system that are responsible for managing patients' health needs.

It would be necessary to insist on closer integration with the IT systems used by individual health workers and establishments (GPs, clinics, etc.), and require that the private sector is also obliged to publish on the EHRs . Legislative Decree No. 34/2020 - „Urgent health measures, support for workers and the economy, as well as social policies following the epidemiological crisis of COVID-19", amended by Law No.77[18] of 17 July 2020, seems to be pointing in this direction, and also covers non-accredited, private clinics to feed the regional EHRs.

Initially, in order to **increase integration with the IT systems used by independent healthcare providers**, the regions should put more pressure on them and closely monitor the level of implementation, in order to be able to intervene promptly to solve any issues. At the same time, the regions could encourage the use of the EHR by using it as a way of enabling access to added value services that would be able to respond quickly to present or future needs that will emerge due to the increasing use of digital health systems. An example is given by the issue of digital communication between doctors and patients, which would require the adoption of certified communication platforms.

[18] www.gazzettaufficiale.it/eli/id/2020/05/19/20G00052/sg

However, despite the fact that, according to data from the Digital Innovation in Healthcare Observatory of Politecnico di Milano, in Italy 37% of hospital doctors and 44% of GPs are interested in using platforms of this type, they are currently being used by only 10% and 18% respectively. The EHR could become the reference platform for doctor-patient communication providing doctors, who currently complain about the immaturity of the applications offered by the market, with a ready-to-use solution. Furthermore, **in order to make the EHR a useful tool for doctors**, and therefore, of greater interest at the central level, it would be necessary to:

- make the EHR the principal tool for exchanging information between healthcare providers through regulations that would make the use of other alternative channels less attractive;
- as a first step, address the adoption and use of **the Patient Summary and the Pharmaceutical Dossier**, the use of which is currently very limited in many regions, despite legislation on this matter being already in place.

Finally, still at the central level, it would be necessary **to encourage the use of self-reported health notes** (named "Taccuino") by the patients, with the intention of giving the patients the power to contribute to the management of their own EHR. Empowering the patients in this way, would enable them to engage those involved in their healthcare to contribute as well to the feeding of the EHR.

Integration with private suppliers would require, at the central level, the implementation of the aforementioned Legislative Decree, defining clear and easy methods for integration. The regions would then be responsible for verifying the effective implementation of the integration process.

Action 3:

Increase the use of the EHR by the public

The success of the EHR also inevitably depends on increasing its adoption by the general public and GPs. As we have already seen, EHR is still not being widely used, especially in certain regions. The increase in use of the EHR by the public is also essential to reach the goal, as set by the Ministry for technological innovation and for the digital transition, of achieving full digital citizenship by 2026.[19]

The regions should work towards making the EHR more **"tailored to the patient"**, initially by making a range of methods to access the data generally available. In particular, it would be useful to encourage the use of apps as strategic channels of access: apps are more manageable by a broader section of the public (such as the elderly, many of whom still don't use computers). In parallel, it would be necessary to incentivise the adoption of strong authentication systems, with special emphasis on SPID (the Italian Public Digital Identity System), in order to be able to extend the scope of those authorised to use the EHR.

Furthermore, the regions should work towards transforming **the digital platforms of the EHR into fundamental points of access to digital health services for the public**, by making them the preferred channel for viewing their own clinical information (not only reports, but also images) and for booking healthcare appointments and making payments, taking advantage of the room for improvement in the solutions currently available. (According to data from the Digital Innovation in Healthcare Observatory, currently only 23% of people use the Internet or apps to book appointments, and only 19% use them to pay for healthcare services). One of the regions setting an example in this area is the Autonomous Province of Trento[20] which, in 2012, launched the Cartella Clinica del Cittadino (Citizens' Medical Record) – TreC - initiative: the system, a network which connects the general public, medical doctors GPs, hospitals, test laboratories, and healthcare institutions, provides the residents of the Province of Trento with a range of services (e.g., health profile forms, appointment bookings, etc).

In parallel, it would be necessary to intervene in order to heavily **promote the interoperability of the EHR** with all the parties that produce and manage health documents relating to the general public (such as, for example, gyms, that issue certificates of suitability for sporting activity). Besides, the EHR, which currently is already used to record all data related to COVID-19, could also be used as a vaccine passport, thereby avoiding the necessity of creating of an additional instrument, which would only result in duplication and further complexity. Also, the current data management methods could be improved, by not archiving the COVID-19 vaccine information stored on the EHR as a PDF document, but by using a single tool, based on tried and tested algorithms, to manage and even update information (such as the validity period of a patient's vaccination coverage), that would make it possible to find out immediately if the patient meets certain requirements.

Attention is also being paid to these issues at strategy level, in the document „Linee di programma della Sanità regionale per il 2021" (Programmes for Regional Healthcare in 2021), that has the goal of making the public more aware of electronic health records as a secure method of storing and updating health documents[21].

[19] www.finanza.repubblica.it/News/2021/03/25/digitalizzazione_colao_piena_cittadi-nanza_digitale_entro_il_2026-109/
[20] www.trec.trentinosalute.net/home
[21] www.quotidianosanita.it/regioni-e-asl/articolo.php?articolo_id=94288

Action 4:

Improve and integrate digital solutions for medical data

The EHR could also act as **a single point of reference for telemedicine services**, allowing, for example, data to be collected from sensors and monitoring devices, making it readily available for both clinical and research purposes.

For this to succeed, it would be necessary, first and foremost, at central level, to draw up a specific legislation aimed at making it mandatory for the manufacturers of devices to make data eventually collected available, initially to the person from whom data is collected, and only later to the National Health System.

Furthermore, at the regional level, initiatives aimed at creating digital health ecosystems would be needed to make it possible for data and functions to be managed centrally at a regional level, thereby making it possible to exploit the full potential of the EHR.

Action 5:

Data and privacy management

It would be necessary to solve, at central level, issues related to data protection, moving from a restrictive application of the GDPR to an approach compliant with the regulation but also **flexible enough to allow secondary use of health data**, critical to add value and inform decisions. The patients should be able to provide a thorough and strategic consent to the use of their health data. Such a change in the approach would bring obvious benefits, overcoming the current limitations, which considerably restrict the opportunity to reuse data to inform decisions related to prevention and treatment, medical research and governance.

At a central level, this would require the definition of a strategy for secondary use of data that is consistent with the provisions of the European Commission which, on 25 November 2020, proposed new rules on data governance, the Data Governance Regulation Act[22]. To this end, it would be initially useful to encourage adherence to a set of common guidelines that provide general authorisation, and to define under what conditions the EHR data can be consulted for secondary purposes (e.g. in Finland[23]). This would avoid the need to consult the Italian Data Protection Authority (Garante della Privacy) for authorisation for each new initiative, saving time and resources. Furthermore, the regions should incentivise healthcare providers to adopt technological solutions that make it possible to manage public consent digitally and in real time.

Further initiatives could draw inspiration from what has already been achieved in other European countries. In particular, in France[24,25] a national body was set up to manage a data lake

created for research purposes by the French Data Protection Authority and the Ministry of Health. This would also involve making information available to the public on how the data will be analysed and provide, directly, the authorisation for public or private bodies that intend to carry out research using the data lake. On this topic, in Italy an agreement was drawn up between the Ministry of Health and Cineca aimed at creating a national data lake containing anonymised and pseudonymised data collected by the her, potentially available for secondary use in the context of research and for the application of Artificial Intelligence tools, aiming at a better management of the National Healthcare System[26]. However, the initiative does not yet include the Italian Data Protection Authority and this could lead, in subsequent stages, to compliance issues.

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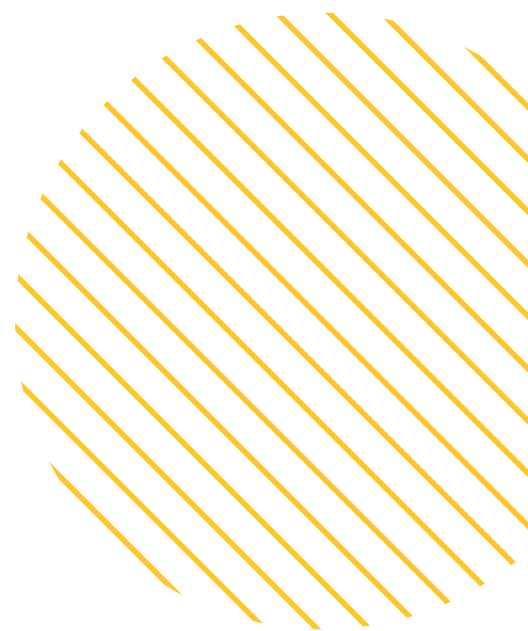
[22] www.eur-lex.europa.eu/legal-content/IT/TXT/PDF/?uri=CELEX:52020PC0767&from=EN
[23] www.stm.fi/en/secondary-use-of-health-and-social-data
[24] www.drees.solidarites-sante.gouv.fr/article/plateforme-des-donnees-de-sante
[25] www.health-data-hub.fr/
[26] www.agendadigitale.eu/sanita/fascicolo-sanitario-elettronico-2021/

Conclusions

In conclusion, it is clear that the EHR has **the potential to greatly expand the use of digital health** in Italy and its implementation and expansion should be a common goal for all those involved in the healthcare system. However, to exploit this potential, people need to be **steered away from the notion that the EHR is just a regulatory item**, leaded by compliance issues to the regulations on data management. The privacy compliance cannot be considered as the point of departure and arrival, but it must, instead, be a support to the will to think in terms of digital services capable of responding to the actual needs of groups of users (the public, patients, GP/paediatricians, specialists, etc). A debate should be launched on this topic, involving political decision-makers on one hand and technicians on the other, in order to come up with a **pragmatic action plan** (for which the actions described in this document could be considered as a starting point) to be implemented in the short or medium term.

Current status and ways forward for the development of digital health in Italy
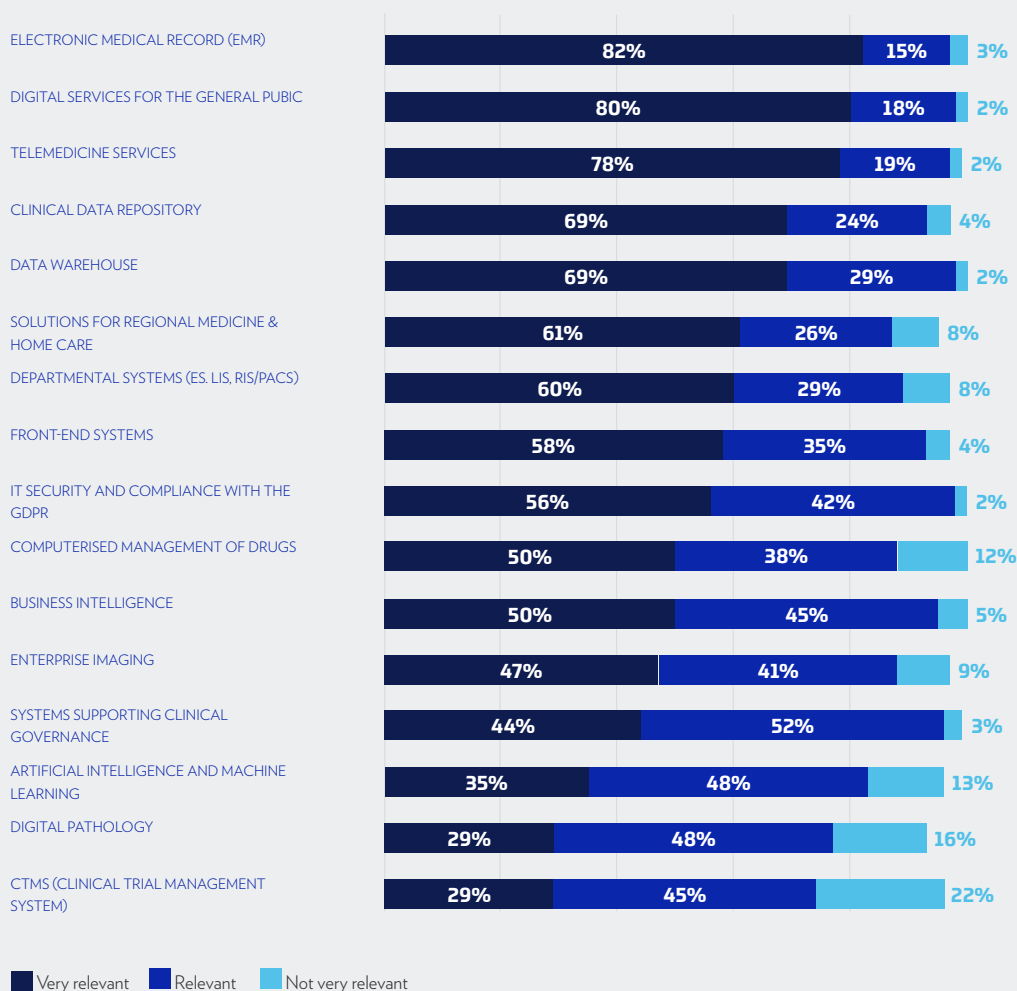
The COVID-19 pandemic has clearly demonstrated how **digital health** is now an essential part of any healthcare system, an innovative approach to the management of health in society, and a fundamental tool in order to find better healthcare solutions. The current health crisis has, in fact, led to a significant increase in the adoption of new care pathways and digital technologies[1]. These facts have been acknowledged and addressed in the 2021 Official Guidelines issued by the Ministry of Health, which has been described as being of fundamental importance[2]:

- An initiative to **raise awareness of the use of technology** in the healthcare services, such as telemedicine and tele-care, electronic medical records, A.I. platforms, point-of-care diagnostics and platforms for the empowerment of patients and patient healthcare education, must be launched.

- **Analytical tools must be improved** and their use expanded in support of health planning, in order to make these tools available for the collection of useful data and information on prevention and planning, providing prompt care, and for the anticipation of new epidemiological scenarios.

- The **expansion of a new system of health information** that will support the regions and the Ministry of Health in the course of their duties.

- Making the **Electronic Health Record more comprehensive and effective** in promoting research into healthcare, through which it will be possible to produce innovative clinical applications, that will offer patients new and more effective healthcare pathways.

In dealing with the practical use of data, reference can be made to the results of the research carried out by the Digital Innovation in Healthcare Observatory of the Politecnico di Milano[3].

Figure 1 **Relevance of digital innovation for strategic innovation and healthcare expenditure budgets**

	Very relevant	Relevant	Not very relevant
ELECTRONIC MEDICAL RECORD (EMR)	82%	15%	3%
DIGITAL SERVICES FOR THE GENERAL PUBIC	80%	18%	2%
TELEMEDICINE SERVICES	78%	19%	2%
CLINICAL DATA REPOSITORY	69%	24%	4%
DATA WAREHOUSE	69%	29%	2%
SOLUTIONS FOR REGIONAL MEDICINE & HOME CARE	61%	26%	8%
DEPARTMENTAL SYSTEMS (ES. LIS, RIS/PACS)	60%	29%	8%
FRONT-END SYSTEMS	58%	35%	4%
IT SECURITY AND COMPLIANCE WITH THE GDPR	56%	42%	2%
COMPUTERISED MANAGEMENT OF DRUGS	50%	38%	12%
BUSINESS INTELLIGENCE	50%	45%	5%
ENTERPRISE IMAGING	47%	41%	9%
SYSTEMS SUPPORTING CLINICAL GOVERNANCE	44%	52%	3%
ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING	35%	48%	13%
DIGITAL PATHOLOGY	29%	48%	16%
CTMS (CLINICAL TRIAL MANAGEMENT SYSTEM)	29%	45%	22%

The Digital Innovation in Healthcare Observatory of the Politecnico di Milano

The data confirmed that the impact of the **pandemic** has generated **a positive change in the perception** by the Health Authorities of the importance of the various aspects of digital health. Unlike in previous years, the use of **telemedicine services** was given a very high importance. Investment in this area has increased considerably (from 48% in 2019 to 78% in 2020). This is also confirmed by analysing the opinion of GPs and specialists on telemedicine services. In fact, as many as 62% of general practitioners and 36% of medical specialists stated that they had changed their opinion on the effectiveness of telemedicine following the health crisis, and now look upon it more positively.
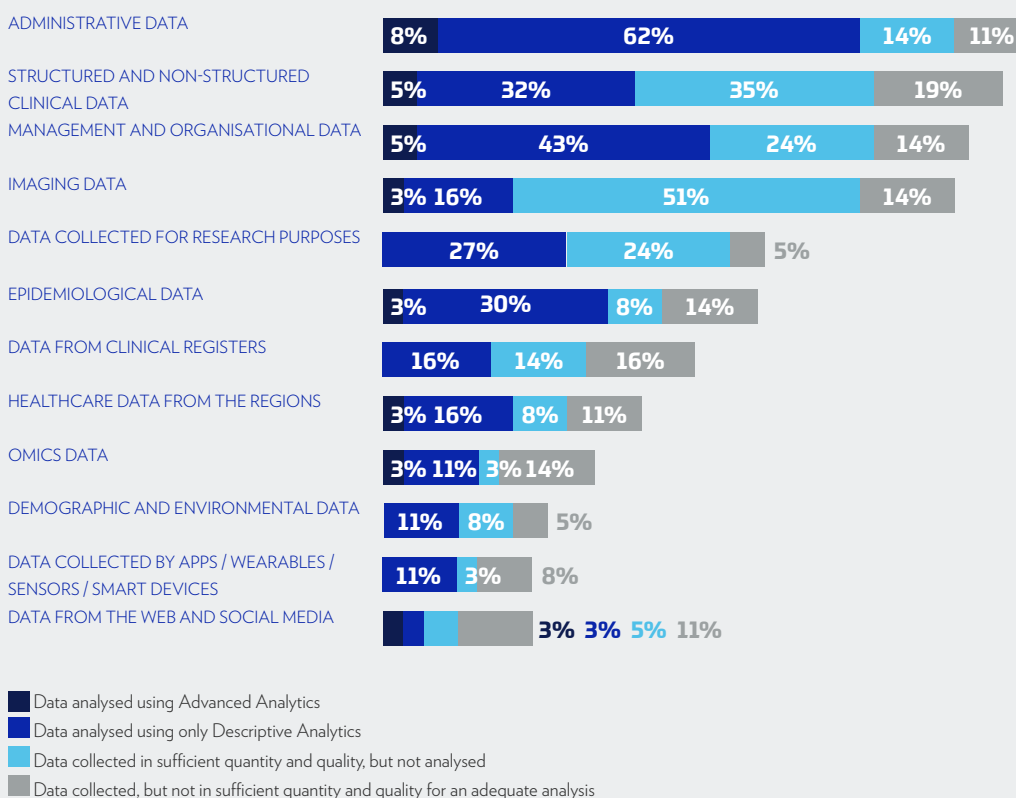
[1] www.agendadigitale.eu/sanita/assistenza-sanitaria-e-nuovi-servizi-digitali-il-nodo-dellinteroperabilita-dei-sistemi-regionali/
[2] www.quotidianosanita.it/governo-e-parlamento/articolo.php?articolo_id=94327
[3] Osservatorio Innovazione Digitale in Sanità – "Connected Care": i servizi digitali al cittadino nel percorso di prevenzione e cura

Furthermore, particular attention is being paid to the **Electronic Medical Record** (indicated as relevant for 82% of those surveyed) and digital services for the general public (relevant for 80% of those surveyed). The interest shown in **Electronic Medical Records** demonstrates how the management, integration, and proper use of data is acquiring increasing importance. This has also been confirmed to be relevant to clinical data repositories and data warehouses. From this point of view, the most advanced techniques related to the improvement in the collection of data (e.g., Artificial Intelligence and Machine Learning) are still considered to be less important, perhaps because they seem to be immature technologies that will only become really useful in the future. Analysing in detail the current status of the improvement in the use of data (Figure 2) shows how the main types of data collected and analysed by the Italian healthcare bodies are administrative data, structured and unstructured clinical data, imaging data, and data collected for research purposes. On the other hand, less progress has been made in the use of epidemiological data, data from clinical records, health data from the regions, and omics data. Fewer than a quarter of the samples collected and analysed were demographic and environmental data, the data collected by smart devices (e.g., apps, wearables, sensors, etc.) and data from the web and social media.

Figura 2 **The level of progress in the collection, management, and exploitation of data by Italian healthcare bodies, 2020**

ADMINISTRATIVE DATA: 8% | 62% | 14% | 11%

STRUCTURED AND NON-STRUCTURED CLINICAL DATA: 5% | 32% | 35% | 19%

MANAGEMENT AND ORGANISATIONAL DATA: 5% | 43% | 24% | 14%

IMAGING DATA: 3% | 16% | 51% | 14%

DATA COLLECTED FOR RESEARCH PURPOSES: 27% | 24% | 5%

EPIDEMIOLOGICAL DATA: 3% | 30% | 8% | 14%

DATA FROM CLINICAL REGISTERS: 16% | 14% | 16%

HEALTHCARE DATA FROM THE REGIONS: 3% | 16% | 8% | 11%

OMICS DATA: 3% | 11% | 3% | 14%

DEMOGRAPHIC AND ENVIRONMENTAL DATA: 11% | 8% | 5%

DATA COLLECTED BY APPS / WEARABLES / SENSORS / SMART DEVICES: 11% | 3% | 8%

DATA FROM THE WEB AND SOCIAL MEDIA: 3% | 3% | 5% | 11%

■ Data analysed using Advanced Analytics
■ Data analysed using only Descriptive Analytics
■ Data collected in sufficient quantity and quality, but not analysed
■ Data collected, but not in sufficient quantity and quality for an adequate analysis

The Digital Innovation in Healthcare Observatory of the Milan Polytechnic

Looking at **digital services aimed at the public**, it is of interest to analyse how much they actually use digital channels.
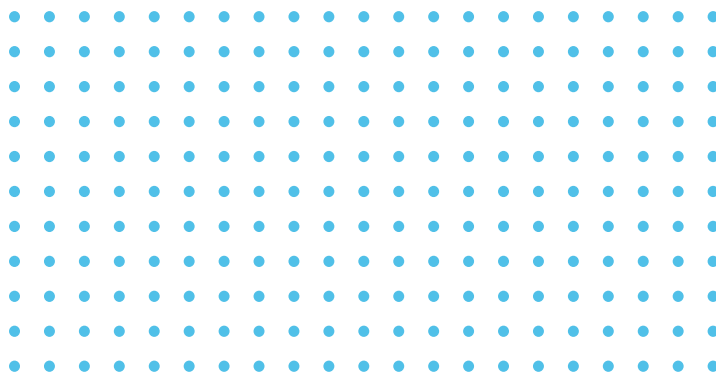
The COVID-19emergency has certainly helped to encourage the general public to experiment and increase their use of digital services, especially to avoid having to go in person to a health facility. However, there are still several limitations preventing the further adoption of these services.

Even if more than 60% more of the public than in the past did access these healthcare services and intend to use the associated digital services in the future, digital tools are used almost exclusively by the 35 to 44-year-old age group, who are more confident using digital technologies. In this age-group, 32% of those who booked a service online used the website, 25% paid using a digital payment method, and 42% of those who accessed their reports did so digitally. Much lower percentages are found in the older age groups (over 55).

The items just described testify to the fact that there is, in general, fertile ground for the development of digital health in Italy.

However, to take full advantage of this opportunity we need a strong commitment from everyone involved and the implementation of a common national strategy. In this context, it could be interesting to review the recommendations that emerged from the Consensus Conference held by CERGAS (Centre for Research on Health and Social Care Management)[4] of the SDA Bocconi School of Management.

Their recommendations focus on three main topics: governance, evaluation and service models.

At the **governance level** it is crucial to have a strategy that is capable of following up on the recent guidelines issued at central level, defining a national framework, to be updated regularly, based on standardised technology, planning processes, and methods to assess the impact these technologies are having. To this effect, uniform objectives should be defined at the central level and calibrated based on specificities at the regional level and promote scientific-health coordination at the national level by providing for on-going monitoring. Finally, the identification of priorities must be inspired by adopting a realistic approach and aim for the consolidation of services that are already available and the expansion of solutions that have already proved themselves to be valid.

Furthermore, **digital technologies** cannot be immune from robust evaluation, identifying new methodologies capable of producing timely and up-to-date evidence to support decision makers. Closely connected is the issue of pricing. In the initial phase, the acceptance of telemedicine services is often tied to the adoption of the payment parity model, i.e., charging the same rates as those charged for in-person care. However, these pricing methods do not consider the value generated, not being linked to a multidimensional assessment process. Finally, for all digital solutions, and more specifically for apps, high dropout rates have been observed increasing rapidly over time, since even the best innovations fail if used in a discontinuous or improper way.

4 Chronic diseases: now the cure is being carried out using digital technologies" | Consensus Conference Group (lavoce.info)

Looking instead at **the service models**, it is evident that the value of introducing innovative digital solutions is substantiated in the transformation of care pathways, generating a need for the continuous redesign of organisational models and processes to allow access to the services. To this effect, appropriate organisational models must be used to be included in medical-care processes and suitable digital solutions, making it possible to customise care pathways, especially in the regions, and to allow the full exploitation of the multiple modes of delivery that are available (physical, web platforms, apps, etc). Furthermore, human capital is essential to support the digital transformation of the system and must be improved, given the essential relationship between technology, people, and skills.

It is imperative to work on acceptance by both patients and professionals, through ad hoc educational processes and by developing their skills. This process can be facilitated by urging the universities to develop courses for healthcare professionals, at the level of a degree program, and through the creation of training centres for interdisciplinary care workers, healthcare and welfare workers, and psychologists).

Finally, the adoption of digital technologies must preserve the unity of the business to allow it to guarantee the integration of healthcare models, equal access to care for all, and resource optimisation for all patients.
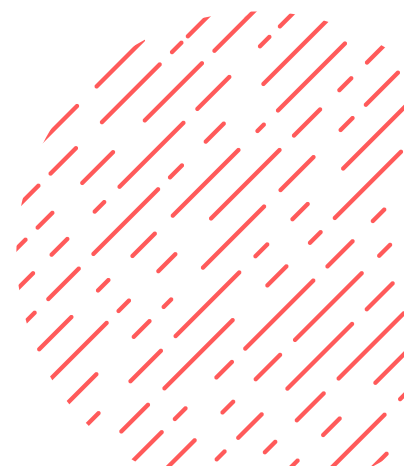
ANNEX 1

The Electronic Health Record in Italy: Definition and level of adoption

L'Agenzia per l'Italia Digitale (The Agency for Digital Italy - AgiD)[1] defines the Electronic Health Record (EHR) as "A tool the citizen can use to track and consult their entire health history, sharing it with professionals for a more effective and efficient health service", in order to give „the patient greater freedom in the choice of treatment and the ability to share the information by giving healthcare professionals access to this data". In this sense, the citizen is placed at the heart of the system and they can keep track of any medical action that concerns them, consistent with the conditions set down by the patient the first time they access their EHR (persons authorised to access, information that is to be kept private, etc).

In detail, the main objectives of the EHR can be summarised as follows:

- To facilitate patient care
- To offer a service that can facilitate the integration of a range of professional skills
- To provide a consistent information base.

In order to ensure an overall improvement in services:

- For the prevention, diagnosis, and treatment of disease, and clinical rehabilitation
- Study and scientific research in the field of medicine, biomedicine, and epidemiology.
- Health planning, the assessment of the quality of treatment, and evaluation of healthcare being provided.

As stated in Article 12, Decree Law No. 179 of 18 October 2012, "Further urgent measures to promote its use throughout the country"[2] the Electronic Health Record is being introduced in the regions and autonomous provinces, in compliance with current legislation on the protection of personal data.

In line with Presidential Decree Law No. 178 from the Council of Ministers, of the 29th of September 2015, "Regulations on Electronic Health Records",[3] the EHR will contain a set of health and socio-health digital data and documents related to a patient's present and past clinical events. A „minimum core" of data and documents to be considered mandatory are to be defined, along with a series of additional items to make the EHR more useful, but which shall remain optional and will depend on decisions taken at regional level.

The minimum core of data and documents requested in the dossier consists of:

- Identification and administrative data concerning the patient
- Reports
- Emergency reports
- Discharge letters
- Patient summary
- Pharmaceutical dossier
- Patient's consent or refusal to donate organs or tissue.

Among these items, the **Patient Summary** is of particular importance. This contains, in addition to data identifying the patient and their doctor, all the clinical data describing the patient's status such as, for example, the list of relevant problems, diagnoses, allergies, drug therapies for any chronic diseases, and all the information that is essential to ensure the care of the patient.

**Supplementary data in the dossier that is not mandatory includes:**

- Prescriptions (issued by specialists, pharmacies, etc.)
- Appointments (specialist, hospitalisation, etc.)
- Medical records
- Well-baby visits
- Home care: patient charts, health plans and medical records
- Diagnostic-therapeutic plans
- Residential and semi-residential care: complete health assessment form
- Drugs dispensed
- Vaccinations
- Provision of specialist care
- Emergency services provided (118 calls and emergency treatment)
- Inpatient hospital care
- Medical certificates
- Patient's personal notebook (a private section in the EHR in which the patient can, in complete autonomy and using the access methods set down at the regional level, enter the data and the documents they deem most appropriate, including any care pathway undertaken outside the National Health Service).
- Reports relating to the services provided by the continuity of care service
- Self-certifications
- Participation in clinical trials
- Exemptions
- Prosthetic services
- Data supporting telemonitoring
- Data supporting the management of integrated diagnostic/therapeutic pathways.
- Other documents relevant to the patient's care pathways.

[1] www.fascicolosanitario.gov.it/il-fascicolo-sanitario-elettronico
[2] www.gazzettaufficiale.it/eli/id/2012/12/18/12A13277/sg
[3] www.gazzettaufficiale.it/eli/id/2015/11/11/15G00192/sg

AgID and the Ministry of Health, in order to verify the progress and status of implementation of the Electronic Health Record in the country (EHR) and in agreement with the regions, have defined a series of indicators that make it possible to track overall progress. Specifically, the monitoring is divided into two distinct groups of indicators: **implementation and usage**.

The indicators will be used to track the state of progress of the implementation of the Regional Electronic Health Record (EHR) and will show the average usage of individual services envisaged by the plan: enabling components, services providing access to the public, services providing access to GPs/paediatricians, services providing access to health companies, services for the interoperability of the EHR, services for the management of laboratory reports, and services for the management of a comprehensive health profile.

The following figure shows the level of implementation of EHRs in the Italian regions and autonomous provinces (Data from the 4th quarter of 2020).

Figure 3 **"Implementation" indicators for all regions[4]**
Data from the 4th quarter of 2020
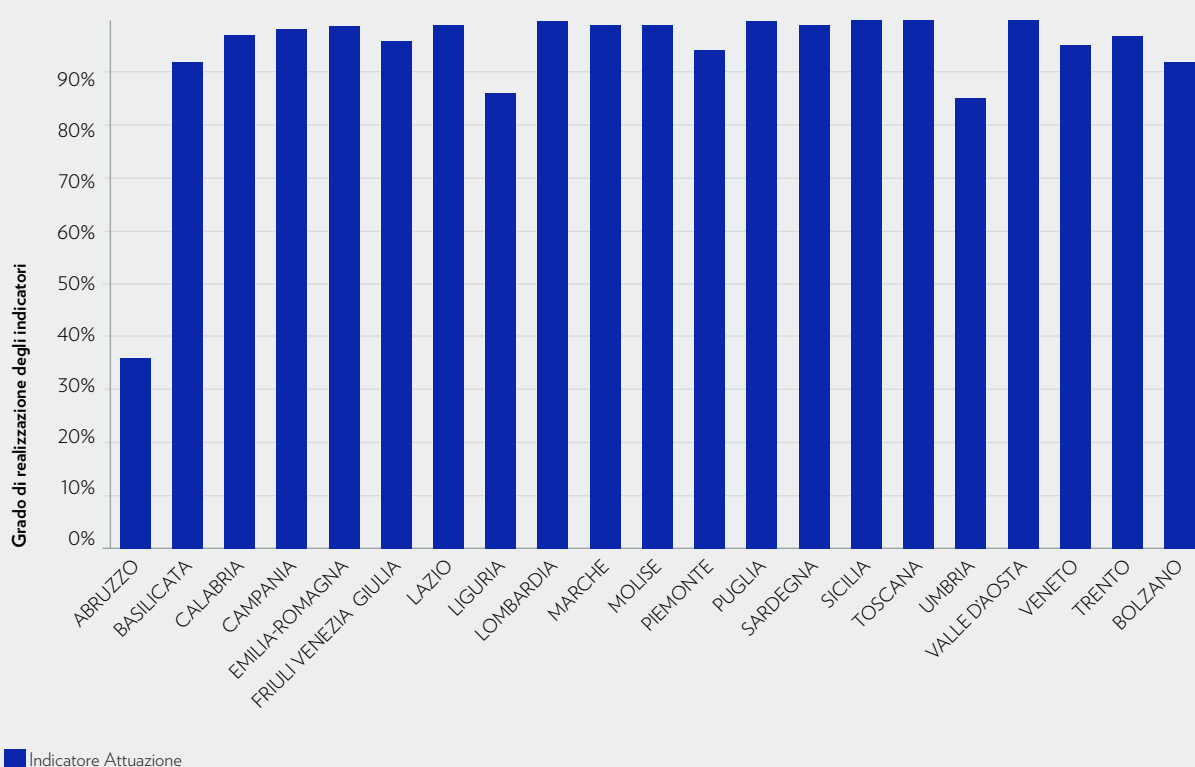
As can be seen in the diagram, the level of implementation is quite advanced, albeit with **some discrepancies** between different regions. In particular, five regions have reached a 100% level of implementation. Of the remaining regions, only three have a level of implementation below 90%, of which only one is lower than 50%.

[4] www.fascicolosanitario.gov.it/monitoraggio/a

The second type of monitoring is aimed at tracking the level of EHR use across the country by the public, doctors, and healthcare providers.
In particular, the indicators highlight:

Doctors
The number of GPs/paediatricians who have used EHRs compared to the total number of GP/paediatricians that are qualified to use EHRs, and the number of the Patient Summaries compiled by the GPs/paediatricians compared to the total number of activated EHRs.

The public
Number of people receiving care (by which we mean those residing in an Italian region who have registered with a GP/paediatrician) and who have given consent for their EHR to be used, compared to the total number of those receiving care in the region and the number of people receiving care that have accessed their EHR at least once compared to the total number of patients for whom at least one report has been made available in the last 90 days.

Healthcare Organisations
The number of healthcare workers qualified to use EHRs, compared to the total number of healthcare workers in the company, and the number of digitised and structured reports made available in the EHR, compared to the total of reports produced by the healthcare company (taking into account only laboratory reports).

The following figure shows a summary of the level of use by GPs/paediatricians, in the regions in terms of access to and provision of EHRs.

Figure 4 **"Doctors' use" indicator for all regions[5]**
Data from the 4th quarter of 2020



DOCTORS WHO HAVE USED EHRS

DOCTORS WHO PROVIDE EHRS
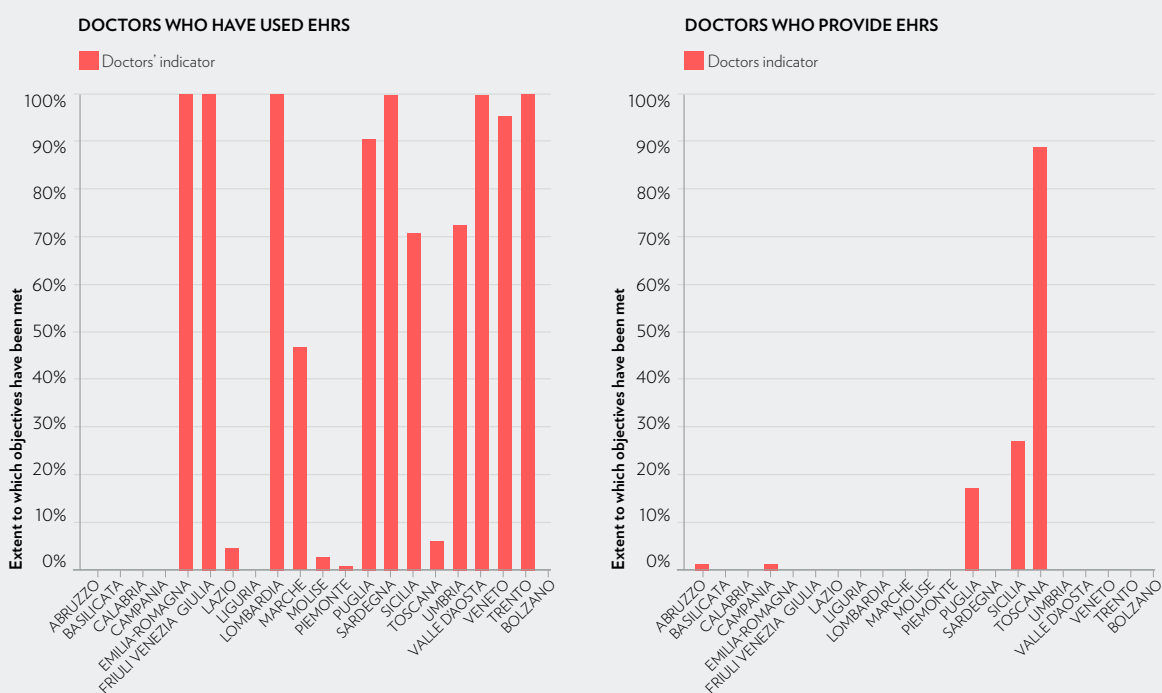
[5] www.fascicolosanitario.gov.it/monitoraggio/bm

Even though many regions still have levels of usage close to zero, a reasonable level of EHR use has been recorded by GPs/paediatricians, but the general lack of penetration is evident (with the exception of Val d'Aosta) with respect to the provision of EHRs.

The following figure shows a summary of the level of use by the public in terms of those who activated their EHR and those who used the EHR in the 4th quarter of 2020.

Figure 5 **"Use by the public" indicator for all regions[6]**
Data from the 4th quarter of 2020

DOCTORS WHO HAVE USED EHRS

DOCTORS WHO PROVIDE EHRS
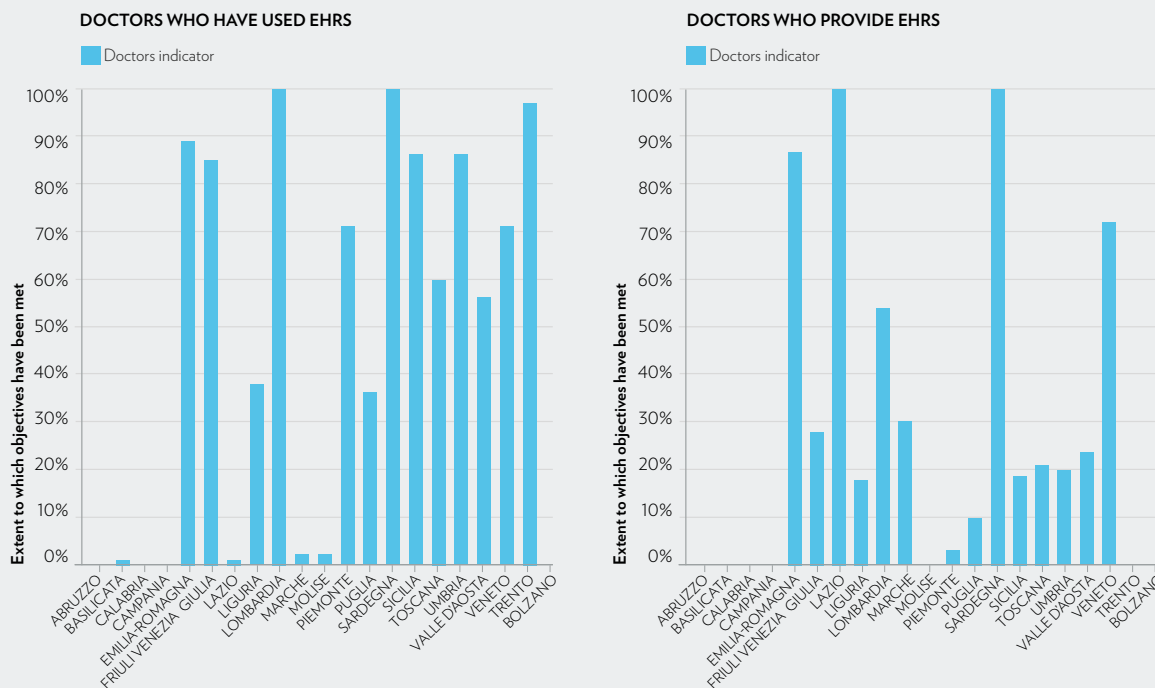
There has been a general immaturity in the level of actual use of the EHR by the public, despite there being a good percentage of people with active EHRs.

Finally, the following figure shows a summary of the level of use by health authorities in terms of providers that are authorised to make use of EHRs and health authorities that provide EHRs.
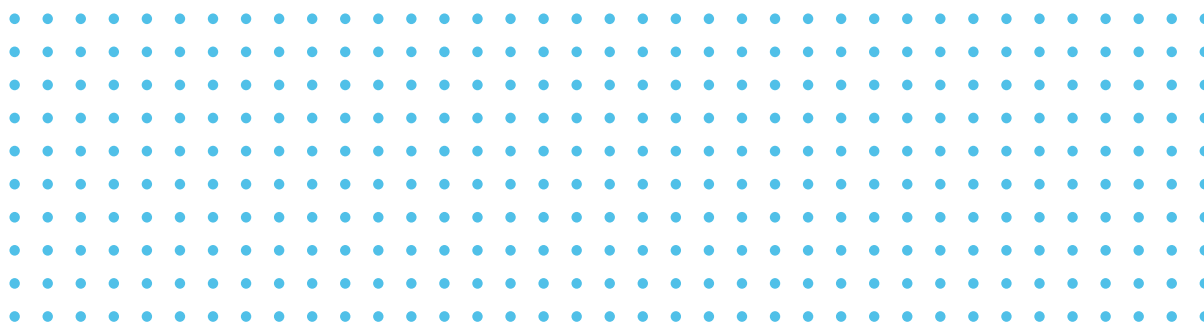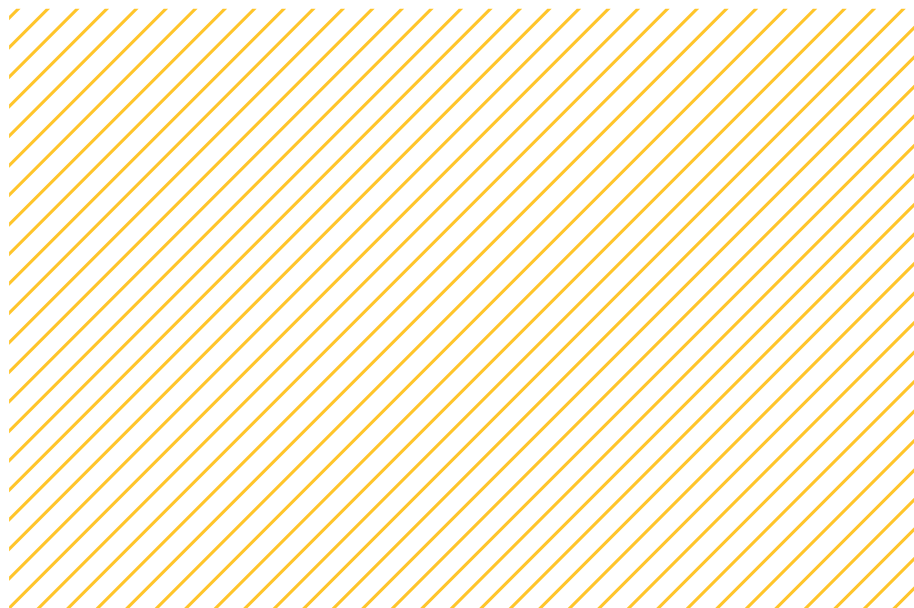

[6] www.fascicolosanitario.gov.it/monitoraggio/bc

Figure 6 **"Usage by Healthcare Providers" indicator for all regions**[7]
Data from the 4th quarter of 2020

DOCTORS WHO HAVE USED EHRS

■ Healthcare Providers Indicator

DOCTORS WHO PROVIDE EHRS

■ Healthcare Providers Indicator
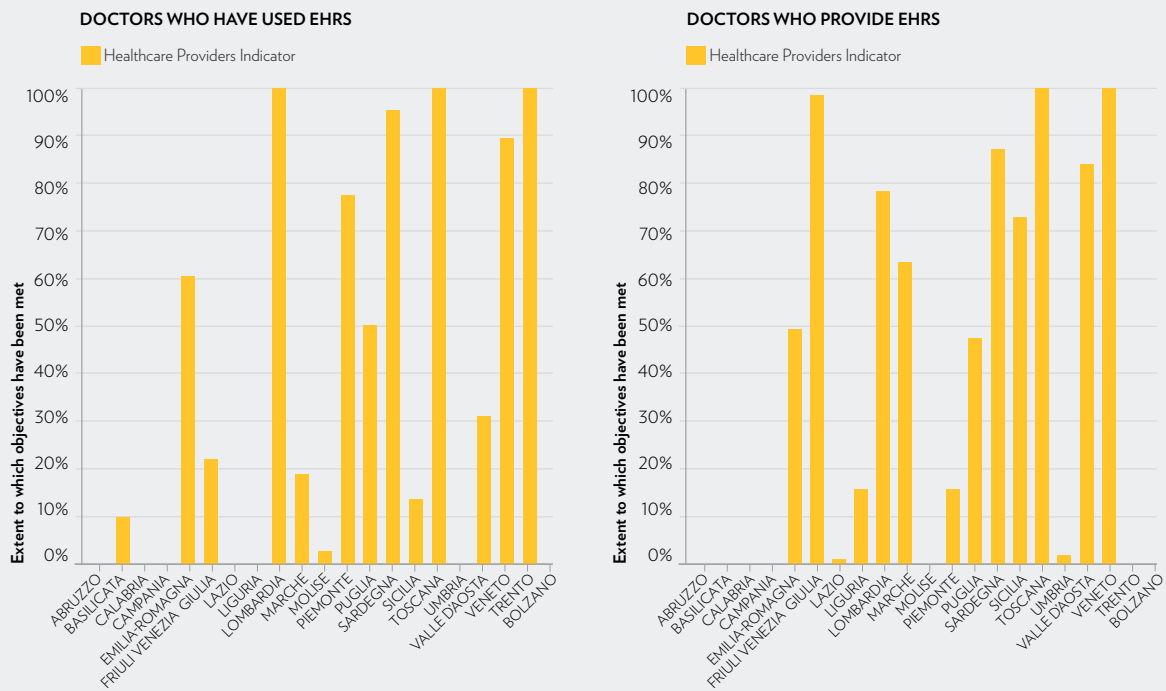
Overall, the results appear to be better than the previous ones, albeit with regions with levels that are still close to zero, along with a few of regions in which adoption is much higher.

The indicators above show how, by virtue of the obvious low levels of adoption and, above all, of use, the EHR cannot yet be considered as a tool capable of taking on the role of support for clinical decisions and governance.

[7] www.fascicolosanitario.gov.it/monitoraggio/ba

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www.himss.org/membership-participation/himss-italian-community-italian-healthcare-professionals

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