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Shaping the Future of Health Law: Challenges for Public Law

Research group of the Interdisciplinary Research Centre on Health Law – CeSDirSan

Report of the research presented by the research group during the International Conference ICON•S MUNDO (July 2021)

Chair: M.A. Sandulli – F. Aperio Bella
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Introduction

by Maria Alessandra Sandulli
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In these days, and undoubtedly accelerated by the COVID-19 pandemic, the process of innovation and technology development in healthcare is evolving in such a way that we can surely say that a new chapter for national, European and global health governance has now opened.

The pandemic shed light on the urgency to focus on Information and Communication Technology as a tool to deliver services outside the hospital network, developing new forms of territorial and home care. Public Law will play a crucial role in this new framework.

In fact, if E-health plays a key role in the future of healthcare, it poses significant challenges for Public Law, concerning its safety, efficacy and desirability as a consequence of the reshaping of the doctor-patient relationship.

Further confirmation of the relevance of the phenomenon of the digitalization of healthcare services is that the PNRR (National Recovery and Resilience Plan) – which is the Italian plan in the framework of the Next Generation EU – sets out important goals concerning E-health, house assistance, remote medicine, techno-nursing, community hospitals.

The objectives of the Plan are right and proper: territorial healthcare assistance does not work out adequately and house assistance is something that cannot be dismissed. House assistance plays a major

role in improving the efficiency of a service that cannot be provided exclusively in hospitals or public structures. And the pandemic called to our attention the importance of the problem of overcrowding in hospitals. In this sense, community hospitals are also important: the wish is that patients will access these structures for minor injuries (for example domestic accidents and so on), reserving hospitals' emergency rooms only for real emergencies.

Furthermore, the PNRR focuses on the digitalization of health information, which is, at present, underdeveloped. The Electronic health record is fundamental in all those cases in which the patient is not conscious or there is an emergency that hinders the doctor to collect all the information directly from the patient.

Furthermore, the creation of an information system that collects – on a local basis – clinical data of patients is increasingly indispensable.

If the PNRR sets out important objectives, the funding and the estimated times are not sufficient. In most cases the predicted time when these innovations will be implemented is 2026. It is too late: the need for a digitalization of healthcare is of unavoidable urgency and it is not possible to wait until 2026.

All these changes in healthcare are subject of scientific research by the CeSDirSan, which I have the honor of directing, a Study Centre for Health Law founded in 2020. At CeSDirSan we discuss the implications of E-health both with law and medicine experts, in an interdisciplinary approach.

Returning to the object of this panel, before leaving the floor to the speakers, let me say a few words on relevant topics, besides those that will be addressed by the speakers.

First, telemedicine. Telemedicine represents not only a huge change in patient-doctor but also in doctor-doctor relations. With respect to the first one, telemedicine could be a powerful means in providing health services but, on the other hand, the remote interaction – and therefore a greater distance perceived than in person – could cause distrust in patients. This means must ensure adequate quality, comparable to the in-person relation. As already said, telemedicine will also impact on doctor-doctor relations: the exchange of information between medical specialists could be more immediate and easier.

Second, accessibility and sharing of information. On one hand, greater accessibility of medical information could be desirable, fostering scientific debate, but on the other hand, sometimes an excess of information may lead to disinformation. This has happened during the last year and a half in which besides a COVID-19 outbreak there has also been what the WHO calls an infodemic: an excess of information, often misleading, that caused confusion, risky behaviors and sometimes distrust in health authorities. For example, the exponential diffusion of studies in the pre-print phase, sometimes led the authorities to pursue therapies that did not prove effective in treating the disease (like hydroxychloroquine with COVID-19). Should accessibility prevail on the quality and reliability of

information? In answering this question, we cannot ignore that the scientific method requires some time to grant results, but it is the price to pay for their trustworthiness and scientificness.

Finally, let me make a final comment: as it clearly emerges from the spread of the Delta Variant, which also seems to be more resistant to the effects of the vaccines we have, in the current situation it is necessary to enhance the contact tracing and genomic sequencing of COVID detection tests. I had already pointed out in a conference on 10 June that the pandemic emergency is not over yet. Without an additional effort on tracking and sequencing we will not be able to get out of the emergency, especially in a phase in which – at least in Europe – the movement of people is starting to return to the pre-pandemic level, thanks to the summer and European football championship effects.

New health technologies and professional's liability. How public law can prevent "remote defensive medicine"?

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1. The expression "New Health Technologies" is very comprehensive and defines, in general, the provision of healthcare services through use of ICTs.

Giving some examples, it refers to the digitalization of the NHS (transformation all medical records in a digital format making the NHS paperless) and to the improvement of interoperability between IT systems in the NHS (they must 'talk to each other'). The concept involves also more complex phenomena such as Telemedicine (the provision of healthcare services at a distance through use of ICT), the use of AI for diagnostic and the use of robotic systems for direct patient care (e.g. surgery robots).

All those are eHealth tools.

2. The promotion of eHealth is an ongoing process at all levels, accelerated by the pandemic.

Institutions are facing the challenges related to ageing population, the increase in chronic diseases and limited human and financial resources. In this framework, the promotion of e-Health tools is a way to ensure health systems' sustainability. It allows innovative models of healthcare, moving away from hospital-centered systems towards integrated care, implementing personalized medicine, making it easier for citizens to have equal access to high quality care and overcoming geographical barriers.

3. Emerging digital technologies in the health sector are increasingly considered by lawmakers at all levels. Having regard to the most important EU documents on the matter, all of them emphasize the potential inadequacy in existing legal regimes in addressing new risks created by emerging digital technologies.

The first EU "eHealth action plan" of 2004 introduced the topic of e-Health as a tool to make healthcare better for European citizens and stressed that "*Another important legal issue is liability in the event of problems - such as technical malfunctions of the system, network, or provision of the service itself - that result in serious harm to a*

patient. While there are currently no specific guidelines or liability rules."[1] On 2012, the EU "eHealth Action Plan 2012-2020" maintained the same approach.[2]

Other official documents highlighted that a "*major challenge for telemedicine*" is the lack of legal clarity having regard, *inter alia*, liability.[3]

Potential inadequacy in existing legal regimes is emphasized also in other EU documents, dealing with new technologies in general. In the European Parliament resolution of 2017 about Civil Law rules on Robotics, it is stated that "*In the scenario where a robot can take autonomous decisions, the traditional rules will not suffice to give rise to legal liability for damage caused by a robot*."[4] In a more recent report on Liability for AI and other emerging digital technologies published by the European Commission, the drafters emphasized that "*A robust regulatory framework should proactively address the ethical and legal questions surrounding AI*"[5] and that the lack of legal clarity about liability might compromise the expected benefits of eHealth tools.

If the matter of eHealth entered years ago in the EU's agenda (as well as in international institution's agendas[6]), since then, we had a slow and variable uptake of digital solutions for health and care across Member States and regions.[7] Only a few Member States have clear legal frameworks.

It is not surprising bearing in mind that the Treaties let the organisation and delivery of health and social care to the responsibility of the Member States according to Art. 168 TFEU.

5. The pandemic acted as an accelerator of the spread of digital solutions for health.

The health crisis facilitated the acceptance of supply of healthcare services at a distance, because of their potential to reduce hospital congestion for patients infected with COVID-19 who do not need intensive care. Such tools were useful also for non-Covid patients (especially for chronical patients) during the suspension of "in person" treatments.

One might say that the "legal shield" for health workers at the forefront of the Covid-19 emergency contributed to such acceleration. In fact, during this pandemic, several countries, such as Italy, promulgated specific laws aiming to prevent health professionals from being targeted by legal claims.

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[1] See Communication from the Commission on e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area,(COM (2004) 356 final.

[2] See Communication from the Commission on eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century, COM(2012) 736 final.

[3] See Communication from the Commission on on telemedicine for the benefit of patients, healthcare systems and society, COM/2008/0689 final.

[4] See European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL).

[5] 2019 Report on Liability for Artificial Intelligence and other emerging digital technologies by the Expert Group on Liability and New Technologies – New Technologies Formation.

[6] The eHealth strategy of WHO World Health Organization was established on 2005

[7] "The uptake of digital solutions for health and care remained slow and varied greatly across Member States and regions" (COM(2018)233 final on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society).

It was the case both for Covid and non-Covid related treatments provided in a framework of emergency and insufficiency of available resources.

6. Having regard to the Italian legal approach to the spread of the supply of healthcare services at a distance during the pandemic, it is worth starting by saying that we use to have a very light regulatory framework compared to other European countries where systems of remote care were deeply regulated (such as France).

The only (and very generic) reference were the Guidelines of the Ministry of Health of 2014.

At the beginning of the pandemic, the use of systems of "remote healthcare" increased without express intervention of lawmakers.

In the hardest days of the "first wave" the use of Telemedicine has been informally oriented by "Interim provisions on telemedicine healthcare services during COVID-19 health emergency", enacted by the National Institute of Health (Istituto Superiore di Sanità)[8]. The document aimed at providing support for the realization of services in Telemedicine during the emergency, offering indications, identifying operational problems, and proposing solutions to proactively monitor the health conditions of both Covid and non-Covid patients.

In absence of a homogeneous legal framework, the implementation of such technologies among Regions (and even among different structures in the same Region) diverged, generating potential inequalities.

Finally, in December 2020, the Ministry of Health approved the "National Directions for the provision of Telemedicine" (Indicazioni Nazionali per l'erogazione di prestazioni di Telemedicina), an updated guidance for the use of such technologies beyond the health emergency.[9] The new Guidelines mention the "pandemic" experience as a driver of the initiative to provide for uniform and detailed guidelines at national level.

7. Beyond the pandemic, the large-scale use of eHealth tools requires addressing the challenge of liability in new technologies scenarios.

Medical malpractice in Italy crossed different phases, some scholars have spoken of "swinging malpractice"[10].

[8] Available at https://www.iss.it/documents/20126/0/Rapporto+ISS+COVID-19+n.+12+EN.pdf/14756ac0-5160-a3d8-b832-8551646ac8c7?t=1591951830300.

[9] See the agreement of 17th December 2020 of the "Conferenza permanente Stato-Regioni-Province Autonome", approving the "National Directions for the provision of Telemedicine" (Indicazioni Nazionali per l'erogazione di prestazioni di Telemedicina).

[10] C. Castronovo, Swinging malpractice. Il pendolo della responsabilità medica, in Europa e diritto privato, 2020, 3, 847 ff.

In the late '70s, thanks to the case law, we passed from physicians' immunity from liability to the «error hunting». Then, we had a growing number of litigations for malpractice, the multiplication of overlapping liability regimes and the spreading of defensive medicine.[11]

Recently, some legislative acts (2012 and 2017) took a step back, mitigating the health professional's liability and fighting defensive medicine.

New technologies bring new risks for health professionals.

Recent studies clarified that there is no room for extending some kind of legal personality to emerging digital technologies.[12] In this scenario, the principle of the "supervised autonomy of robots" implies that the human role remains crucial and that practitioners must face new sets of risks (defects or malfunctions of devices, misuse of new technologies and so on).

8. Then the question arises: how to prevent defensive medicine in new technologies scenarios?

A first solution may be to reduce liability, for instance by introducing protective legislation barring lawsuits against healthcare professionals. It may also be chosen to sanction defensive medicine, introducing specific forms of liability to reduce "defensive approach". Another path is to introduce mandatory insurance scheme[13] or even to supply the insurance system by compensation funds to protect tort victims who are entitled to compensation but whose claims cannot be satisfied. Other strategies are focused on the prevention: the training on the use of digital tools could be enhanced (bearing in mind that hospitals and structures have a duty of care to make sure health professionals receive appropriate training and exchange information about the new technologies). In fact, to give appropriate education, training and preparation for health professionals, such as doctors and care assistants, it is of the utmost importance to secure the highest degree of professional competence possible, as well as to safeguard and protect patients' health. We can also think, in the future, of new professionals clinician-informaticians. It is also possible to enact shared operating protocols to assist practitioners and to integrate models of conduct to prevent professional and organizational liability implications.

7. The choice between available strategies must be guided by the need to "resize" the role of law facing defensive medicine.

[11] Defensive medicine refers to all medical care by physicians, aimed primarily at preventing the risk of litigation (*ex multis* see R. Agarwal, A. Gupta, S. Gupta: The impact of tort reform on defensive medicine, quality of care, and physician supply: a systematic review, Health. Serv. Res. 54(4), 2019, 851 ff.,).

[12] See the already quoted 2019 Report on Liability for Artificial Intelligence, stating that "For the purposes of liability, it is not necessary to give autonomous systems a legal personality" (p. 37 ff.).

[13] Till now, the availability of liability insurance for health professionals had ambiguous effects on defensive medicine and studies demonstrated that compulsory liability insurance should not be introduced without a careful analysis of whether it is really needed (see A. Antoci, A. Fiori Maccioni, M. Galeotti, P. Russu, Defensive medicine, liability insurance and malpractice litigation in an evolutionary model, in Nonlinear Analysis: Real Word Applications 47, 2019, 414 ff., spec. 430)

It is true that streamline existing rules of liability are very important, and it is possible also to consider adaptations and amendments to existing liability rules, but we have to take into account the compliance costs related to the introduction of new rules. In addition, the diversity of emerging digital technologies and the correspondingly diverse range of risks these may pose implies that it is impossible to come up with a single solution suitable for the entire spectrum of risks. In a nutshell: one size doesn't fit all.

In conclusion, the most effective reaction to defensive medicine seems to be to focus on the restore of trust with patients. It is even more crucial having regard to the 'zero-mistake' culture of omnipotent medicine encouraged by the use of New Health Technology and the fact that ICTs enable people to become active agents in their own health journey and physicians' future is dealing with self-diagnosed cases.

The digitalization of the healthcare sector in Italy: the Electronic Health Record

by Nicola Posteraro
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University of Milan

During my presentation, I will focus in particular on the Electronic Health Record.

I decided to focus on the EHR, because it is one of the main Italian e-health tools.

E-health, as we know, is a generic term that indicates the use of information and communication technologies to support the health system; so, it includes a multiplicity of tools and actions. Among these tools, the electronic health record occupies a central place in the Italian legal system.

The EHR was introduced in 2012 and it can be defined as a collection of medical data and documents relating to a patient's medical history.

This tool can be considered as a health digital archive, a google of the patients' health; we can say that it is an example of the dematerialization process of health documentation.

It aims to create an organic information data base; a data base that promotes the improvement of the diagnosis, treatment and rehabilitation of the patients.

Every Italian citizen can decide to activate this personal tool; and when it is activated, new information of patients' clinical history are added. So, it is the main factor that assures the creation of an e-health system based on the centrality of the patient.

However, it also acts as a support for the scientific research and for the health planning, because it gives to the institutions the possibility to check the quality of the health cares.

The EHR must have some minimum elements decided by law. In particular, I would like to talk about the patient summary and the pharmaceutical dossier.

The patient summary is a synthetic overview of the patient's medical profile; it is drawn up by the family doctor and it is very useful especially in emergency situations, because in that case usually there is no time to study the patient's clinical situation before intervening. The pharmaceutical dossier, instead, is an updated section edited by the pharmacists and it is useful, too: it allows to monitor the adequacy of dispensing medicines, for example.

So, we can say that the EHR is enriched, in particular, by the pharmacists and the medical professionals who take care of the patient; however, it can also be integrated by the patient himself: the health record

can in fact consist of an additional element called "personal notebook": this is a specific area in which the patient can enter personal data and documents relating to his/her own health condition.

The EHR ensures many advantages.

For example, it ensures that social and health care takes place in a shorter time, because it eliminates many bureaucratic steps that would otherwise be necessary.

Certainly, it also ensures a lightening of the documentary burden (and, therefore, it implies a significant saving of time and costs).

Then, it ensures an improvement in the citizen's social and health assistance service: for example, it avoids unnecessary prescriptions for diagnostic tests already carried out; and it can potentially reduce the number of medical errors, because it gives to the professionals the possibility to know in detail the patient's previous medical history.

Therefore, it has a positive impact on the costs that we normally face in Italy due to the lawsuits brought by the patients against doctors and health facilities.

When we talk about the EHR, we have to consider that Italian regions play a very important role in its functioning.

In fact, the EHR is introduced by every Italian Region; so, every region rules the relative methods of its activation.

It means that the ways to activate the EHR are different from region to region and there are various differences between regions.

In 2018, in order to guarantee the full operation of the EHR in the whole country, Italian institutions created a national access portal; this website is not active yet, but it will allow users to access their EHRs from a single national access point. So, in the future, it will ensure equity and it will solve all the problems that we now have in Italy, for example when moving from one region to another.

Currently, almost all regions have reached a state of implementation of the instrument over 85%; it means that they have generally equipped all the EHRs with the needed elements.

However, only few regions have already reached the so called stage of services, a stage in which the EHR stops to be just a global data container and it becomes a control room that gives the patient the possibility to do so many things using internet (for example, patients in Emilia Romagna can book their medical check ups by using the EHR).

Now: the EHR works well if the regions set up an efficient IT system; this IT system has to be able to manage not only the relationship between the region and other facilities and health professionals, but also between one region and the others.

This is the so-called interoperability, which is an essential condition for the creation of a horizontal paradigm that facilitates the exchange of public data; let's imagine the case of a health service provided in Lombardy to a Calabrian citizen: in Italy interregional mobility is highly developed; interoperability therefore is essential for the right functioning of the tool.

This is the reason why our law-maker created a national facility to assure interoperability between regional EHRs that guarantees the exchange of data between regions.

Recently, in the period of the pandemic, our law maker revised the rules of the electronic health record; this activity confirmed that the EHR is a strategic tool for the digitalization of the Italian health system.

In particular, the law extended the database of the dossier: it now also includes information relating to services provided by private health facilities.

The law also provided that the implementation of the EHR takes place automatically; in this way, health professionals don't need the patient's consent to include new data in the digital collection.

In any case, the consent of the patient remains compulsory for the medical staff to consult the file.

Obviously, the health professionals who treat the patient can use the health file, but they are able to see and check the file only if the patient agrees.

I want to underline then that the patient may decide to ask for the data to be hidden; so these data cannot be seen neither by those who are authorized to access the file.

At the end of this short presentation, we can say that the EHR has been and it still is an ambitious and challenging project for Italy, because our country is characterized by a significant delay in digital growth.

When I say digital delay, I refer to the data spread by the Digital Economy and Society Index: it represents that Italy is in the fourth lowest place, followed by Romania, Greece and Bulgaria.

In fact, the percentage of citizens who already activated the EHR is still very low, compared to the total number of the Italian patients; and we also have to consider that not all people who activated it, are actually using it.

It depends in particular on the fact that in our country the Italian institutions didn't promote the use of the tool; but it also depends on the fact that Italian citizens do not have good digital skills: they therefore quit to use the health digital services.

It is then necessary to implement the action of raising awareness of the use of the tool; however, it is also necessary to invest in the creation and in the improvement of the citizens' digital skills.

This action will be able to solve the problems created by the *digital gap* that we have to face in our country.

Indeed, investing in the training of citizens is not enough: it is also necessary to invest in the training of health professionals, who are those that actually have to use the tool. In fact, the number of health

professionals who use the EHR is very low, now: in the first quarter of 2021, only doctors of 8 regions used the EHR; and only doctors of 3 regions implemented it.

We also have to consider that the PNRR (the Italian plan of recovery and resilience) paid attention to the EHR. In particular, the plan aims to improve, harmonize and disseminate the EHR; it defines the electronic health record as a cornerstone for the provision of digital health services and also for the enhancement of clinical data.

So, in the end, we can say that we have to see what it's going to happen in the next years; and we have to hope that it will start to work efficiently and that in the future all the related existing regional differences will be eliminated.

Data governance and Clinical risk management

by Martina Sinisi
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My short talk is about the role of health data and their use in health risk prevention and management.
In particular, I would like to focus on some specific profiles of data governance, starting from the conception of the right to health as a collective interest (as well as an individual right) as it is stated by Article 32 of the Italian Constitution.
I'm going to start by introducing the use of data to develop models of organization, care and management of clinical risk, also looking at the Covid experience; then, I'm going to move to the relationship between citizen privacy and the use (and re-use) of health data, focusing in the second part of my presentation on the new health information system. Finally, I will close with some considerations about collective interest in risk management and data transparency.
We have all seen how the flow of national and international data has affected emergency management.
In particular: they have made it possible to trace the first cases; they have made it possible to sequence the virus; they have affected governmental choices (health and economic choices).
The topic of data use in healthcare is not new. For years now, digitalization has made it possible to use the potential of big data in healthcare organizations and care delivery: for example, electronic health record and database are measures that are also strongly promoted to improve cross-border care.
This topic is very broad and has a number of related aspects. One of these is linked to the possibility that the citizen, once data have been processed by the health administration, may in turn acquire information and data relating to health organizations and the measures that have been taken.
It is clear that these data are no longer sensitive because they are already processed on a large scale. However, there seems to be a problem of control of administrative activity that may be difficult to balance with the individual right to know the data on the basis of which organizational choices have been made and which may have an impact on individual positions.
This is connected to the consideration of risk management as a collective interest and not only as a generic interest of the health administration.

The Covid health emergency has demonstrated the full potential of the use of big data: **1**. to monitor the progress of the virus and to develop, thanks to the new technologies, perspectives and solutions that are as responsive as possible to the interests of the community; **2**. to search for contacts in order to create a database capable of directing government action in adopting measures to contain Sars-Cov 2; **3.** to study the course of the disease and to identify with algorithmic models the best treatment of the disease based on the reactions observed in patients subjected to the use of off-label drugs, such as hydroxychloroquine in Covid patients (for which the administrative judge also ruled[14]).

By using available data, updated emergency management reports were issued.

This was made possible by the so-called "articulation of data" that implies the separation of information that can be traced back to the owners of the data and that those data produced.

This is in compliance with the principle of data minimization that directs its automated use to create "horizontal maps" referring to the overall population and "health planning".

It also concerns the organization from the point of view of timing. Prevention and protection must be both *reactive* and *proactive*.

It is necessary to have a good pandemic plan with which the doctor assesses the clinical needs of patients according to *urgency* and *impact*.

This is why the new Italian pandemic plan (2021-2023) is based on the different impacts of national and international risks.

It is clear that an error in the data collected results in an error in clinical risk planning, and this can amplify unexpected events (and produces consequences also in terms of responsibility).

Data have become indispensable for infection prevention and control (IPC) and health system reinforcement.

The need for national and facility-level IPC programs is claimed in the World Health Organization (WHO) Global Reference List of 100 Core Health Indicators.

Actions related to the prevention and management of SARS- Cov 2 infection through the use of data include the following:

1. Incident reporting: for the reporting of events related to the safety of patients and health workers in order to promote corrective actions;

2. Significant Event Audit (SEA) for the investigation of the most important events, with a view to preventing their repetition and to improve generally;

[14] TAR Lazio, Sez. III-quater, 20.10.2020, n. 11040; Cons. St., Sez. III, ord. 11.12. 2020, n. 7097.

3. Failure Mode and Effect Analysis - FMEA (simplified) with respect to new approaches in order to identify any dangers of "failure".

Thanks to the collaboration between the corporate networks of clinical and infectious risk, actions were guaranteed to further support the "infection control" programs aimed at the dissemination of good practices related to infection prevention and control - IPC.

European policies have stated in several occasions the importance of the digital solutions.

The European Council Conclusions of December 8, 2018, state that digital solutions play a key role in supporting the transition to new models of care.

The Commission has undertaken various actions to implement e-health (electronic health).

One of these is the cross-border sharing of health data to ensure greater access and to advance research and disease prevention.

It is important to increase the use of digital tools to improve communication and to design digital health tools that take into account quality, security, and data protection requirements (item 23).

General Data Protection Regulation (EU Regulation 679/2016) states that "*the processing of personal data should serve humanity*" and that "*the right to privacy is not an absolute right*".

Personal data can be used for "*reasons of public interest in public health*" (this is what it is stated in Art. 9 of General Data Protection Regulation).

The same regulation, however, refers to the identification of "safeguards" for the processing of health planning data to the Privacy Supervisor (national Authority). It states that Member States may keep or introduce "*additional conditions*" for the use of the data, including "*additional limitations*."

On the other hand, the fact that the citizen is part of a community with which he/she shares the general interest in collective health, would require that he/she be given the possibility to access health data (no longer sensitive) related to planning, prevention and protection activities.

This possibility has not always been there in the management of the SARS-cov 2 emergency.

For example, data on the number of people who died in the hospital; data on the number of people who died in their homes; data on the number of places actually available in the intensive care unit[15] and other information that was contained in the confidentially reports of the Scientific Technical Committee[16] had not been disclosed (or have been disclosed after a judgment).

[15] TAR Lazio, Rome, sez. I *quater*, 25.6.2020, n. 7174 e Cons. Stato, Sez. III, 8.4.2020, n. 1841. Codacons requested procedural access in accordance with the administrative law (241/90) - which requires a personal, concrete and current interest - to know the number of people who died in hospital; the number of people who died in their homes; the number of places actually available in intensive care and other information. The claim was resolved by a voluntary production of the documentation.

[16] TAR Lazio, Roma, sez. I *quater*, 22.7.2020, n. 8615. In this case a request was made for general civic access (FOIA), formally allowed to anyone and without the obligation to justify the request, to see, but the matter was set to one side.

In other words, it is believed that the health administration in its risk management activity is bound only to an interest of the national health system.

This is despite the fact that the issue of clinical risk has a strong social impact.

In health planning the circulation of data is very important because it is thanks to the reporting of so-called "sentinel events" that the health administration's actions to prevent risk are identified.

The sentinel event is the event of particular gravity that is reported and avoided in future situations thanks to clinical risk management.

This does not concern only the error of health personnel but involves the whole health organization.

I am thinking of what has happened in residential centers for the elderly. The reporting of outbreaks has allowed us to take them into account in the organization of vaccination in Italy.

It is therefore important to use the full potential of health data to protect both the public interest in correct and timely organization and, at the same time, the private interest in knowledge of the measures chosen by healthcare administration.

The Covid emergency has shown the macro-economic relevance of public health services.

For this reason, the National Recovery and Resilience Plan (NRRP) aims to provide unified responses to health risks. This is done by strengthening the New Health Information System (NSIS) and improving local data collection, processing, and production.

The health information system provides the underpinnings for decision-making and has four key functions: (i) data generation, (ii) compilation, (iii) analysis and synthesis, and (iv) communication and use.

The health information system collects data from health and other relevant sectors, analyses the data and ensures their overall quality, relevance and timeliness, and converts the data into information for health-related decision- making.

In addition to being essential for monitoring and evaluation, the information system also serves broader objectives, such as providing an alert and early warning capability, supporting patient and health facility management, enabling planning, underpinning and stimulating research, permitting health situation and trends analyses, orienting global reporting, and reinforcing communication of health challenges to diverse users.

Much is still left to the discretion of the administration, which chooses whether or not to grant the request for general civic access (FOIA).

Information is of little value if it is not available in formats that meet the needs of multiple users, like policy-makers, planners, managers, health-care providers, communities and individuals. Dissemination and communication are therefore essential attributes of the health information system.

Health planners and decision-makers need different kinds of information including:

- health determinants (like socioeconomic, environmental, behavioural and genetic factors) and the contextual within which the health system operates;
- inputs to the health system and related processes (like policy and organization, health infrastructure, facilities and equipment, costs, human and financial resources and health information systems);
- the performance or outputs of the health system (availability, accessibility, quality and use of health information and services, responsiveness of the system to user needs, and financial risk protection);
- health outcomes (like mortality, morbidity, disease outbreaks, health status, disability and wellbeing); and
- health inequities (like sex, socioeconomic status, ethnic group and geographical location).

A good health information system brings together all relevant partners to ensure that users of health information have access to reliable, authoritative, usable, understandable and comparative data.

In conclusion, the use of data for collective purposes results in benefits for health care progression and population mapping to study complex events and predictive frameworks to improve the ability to plan health services and detect emerging diseases. However, at least three aspects must be considered: (i) proportionate use of data: personal data shall be processed lawfully, fairly and in transparent manner in relation to the data subject; (ii) timely planning: implementation of predictive medicine is contingent on meaningful data acquisition and timely analysis of that data; and (iii) transparency in health care administration action in clinical risk management (benchmarks for data quality include independence, transparency, and access).

When all these aspects come together, we will be ready to meet the challenge of the digital health revolution.

ICT in medicine: rethinking of the administrative control procedures

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The introduction of telemedicine reshapes the traditional models of health care service delivery, by developing new forms of territorial and home care. The place, the timing, the persons involved, and the medical procedures themselves take different features. The limitation of physical presence, not only calls for a rethinking of the norms on liability but has also an impact on the administrative organisation, and, therefore, on administrative controls.

Italian legislation provides for both internal and external controls on health facilities. These controls mainly concern:

- the correct and sound use of the economic and human resources;
- the legitimacy of the administrative action;
- the quality and adequacy of the service provided;
- the performance of public officers and managers;

The traditional administrative control system assumes that all the activities related to health service take place in hospitals or in healthcare facilities and does not consider the employment of information communication technologies.

In order to evaluate telemedicine services, it is important to

a) develop organisational models that consider all the changes in the relational aspects implied. This can improve the ability to objectively assess the performance of telemedicine services and their results in relation to their objectives. For this reason, the Italian Minister of Health issued guidance, where different organisational models of telehealth, teleconsultation, tele cooperation, are explained.

b) The second tool is to develop instruments to enhance the long-term financial benefit of digital innovation. The employment of ICT in medicine requires a significant amount of dedicated economic resources, that are now available, thanks to the Recovery and Resilience Plan. The investment strategy, that leads to the adoption of platforms capable of supporting a new health

service model, needs to comply with the principle of balanced budget and shows savings and payback in the long run.

The impact of ICT in medicine on different types of administrative controls shows on the following aspects.

1. Service evaluation:

The healthcare system's assessment is a complex process based on the data analysis related to the performance of the offered services. It aims at identifying best practices to be implemented in different realities and issues to address. It calls for multidimensional performance evaluation systems, to catch all relevant factors that affect healthcare services delivery, by answering to all different stakeholders' needs. The Minister of Health has developed indicators to describe the performance of a Telemedicine service with respect to the following aspects:

- Size: volume of services provided
- Temporal continuity: duration and stability of the service
- Complexity: organisational complexity of the service
- Quality: standards and response performance of the service
- Efficiency: cost of the service
- Efficacy: comparison with the population of users affected by the same pathology covered by the telemedicine service, but followed in conventional mode, in terms of:
    - Reduction in mortality
    - Reduction in the incidence of re-hospitalisation
    - Reduction in the number of days spent in hospital
    - Reduction of accesses to the Emergency Room.
    - Improved quality of life
- User satisfaction (patients and caregivers). These play an important role in the evaluation of healthcare services but require particular attention when personal data and health data are collected and processed.

2. Management and financial controls

One of the main benefits expected by the development of ICT in medicine and, especially, of telemedicine, is represented by a general long term cost saving. However, the literature has highlighted the difficulty of measuring the economic value of ICT investments in health care.

Measuring effectiveness means to objectively assess improvements in health status attributable to the programme and presupposes the evaluation of final outcomes (such as years of life gained) and intermediate outcomes (such as days of disease avoided).

The Ministry of Health has developed general criteria for the implementation of a cost-effectiveness analysis of telemedicine services, through specific indicators. These are, at first, applicable ex-post, but, once the main benchmarks have been determined, they can also be used for preventive and ongoing evaluation of projects.

Among the most widely used economic evaluation methods, the following are recognised:

a. Cost-Effectiveness Analysis: it compares the costs of a programme with the non-monetary outcomes of the programme, such as 'years of life gained', 'diseases avoided' and so on;
b. Cost-benefit analysis compares costs with benefits measured in monetary terms;
c. Cost-Utility Analysis: measures benefits in terms of utility (e.g. quality-weighted life years gained, Quality-Adjusted-Life-Years - QALYs).

3. The monitoring system of Recovery and Resilience Plan

Given the specific nature of the financial instrument and in line with the recommendations of the European Commission, the Recovery and Resilience Plan provides for additional checks to the ordinary administrative controls.

The entire 'system' of verification of the Plan is inspired by the control systems of the European structural funds and is geared towards preventing, detecting, and combating serious irregularities such as fraud, corruption, and conflicts of interest, and to prevent potential cases of double financing.

The control activities focus on the actual achievement of targets and milestones, in accordance with the requirements of the European Commission, but also on the regularity of procedures and expenditures based on risk assessment and proportionate to the risks identified.

In addition, specific audit activities are foreseen to be carried out by the Audit Board of the Recovery and Resilience Plan based on the risks identified, under international control standards and which are aimed at:

- independent verification of the effectiveness of the management system (system audit)
- the regularity of expenditure procedures and costs declared (transaction audit)
- the correctness of milestones and targets reported (performance audit)

Finally, to strengthen the verification activities described above, specific protocols of understanding are concluded with the Guardia di Finanza and the competent independent authorities, including ANAC.

In order to simplify the processes of management, control, monitoring and reporting of funded projects, and, at the same time, to adhere to the principles of information, publicity and transparency prescribed by European and national legislation, the Recovery and Resilience Plan will use the "ReGiS" information system developed by the Ministry of Economy and Finance. This digital platform should provide an efficient electronic exchange of data between the various entities involved in the governance of the Plan. Each aspect of the implementation of the plan is electronically tracked by means of all the data and information on the progress of the activities, which the Responsible and Implementing Administrations manage throughout the life cycle of the initiatives. In addition, the system allows the verification of targets and milestones and provides an integrated view with the similar framework of projects being implemented with other European and national sources, and with the European Commission.
The "ReGiS" system is available to assist the units in their related activities, including control activities. Through the codification and tracking of projects funded under different national and European public instruments, the system also avoids the risk of double funding.
Finally, the system ensures the availability of supporting data for audit activities.

To conclude, the employment of ICT in medicine creates both challenges and opportunities for administrative controls.
The main challenges are the reshaping of the doctor-patient relationship and of the administrative organisation; the need for significant investments; the reshaping of existing administrative controls and the introduction of new forms of control.
The main opportunities derive from the fact that the technological infrastructures, developed to guarantee the interoperability of health databases and the electronic health record, may be exploited, in connection to the existing instruments, and to the ReGiS system, to help developing risk predictive algorithms in the control pre-investigation phase.
The Recovery and Resilience Plan states very clearly the need for risk-based and proportionate action to control the use of public resources. Indeed, the principle of risk-based inspections and controls is widely recommended by the EU Commission and by the OECD.
The development of ICT in medicine represents a unique opportunity for improving the necessary data gathering for an accurate risk prediction. This way, controls and inspections could be planned to focus on the cases that show a higher potential for deviation from the regulatory provisions, in accordance with the proportionality principle. Setting out in advance clear and transparent objectives and criteria for administrative controls should encourage synergy and cooperation between the parties involved in the

control relationship, with the effect of limiting coercive and repressive measures, enhancing compliance, and discouraging defensive attitudes and misleading behaviour.

One last caveat is in order: the adoption of new models of healthcare service evaluation requires to identify technical and organizational measures that can guarantee data protection compliance during all phases of the data gathering process.