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Alessandro Bernes
Shaira Thobani *Editors*

Digitalisation in Health Care between New Technologies, Data and Research

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Editors

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Preface

As the principal investigator of PRIN 2022 PNRR "Privacy-Aware Data Sharing model for Health data" (PADS4Health), I am particularly honoured to introduce and present this conference, together with my colleague Prof. Shaira Thobani, head of the research unit at the University of Turin.

I must say that this conference aims at being not only an occasion of interdisciplinary dialogue, but also an opportunity for interprofessional conversation, looking at the distinguished speakers who will take turns and whom I thank again sincerely.

In these few opening remarks, I would like to highlight some legal aspects of digital health (eHealth), a broad and all-encompassing term that includes telemedicine, medical robotics, processing of personal data in healthcare for both treatment and scientific research purposes, etc.

First of all, let me clarify the context in which our conference and, in general, our project are taking place.

The healthcare system has been profoundly revolutionised with the advent of the digital age. In the medical field, however, digitisation is much more than a technical process: on the one hand, it certainly involves new technologies and algorithms, including artificial intelligence systems; on the other hand, it has a significant impact on healthcare practices and services at the organisational level, on the actual performance of diagnosis and intervention, and on the rights of individuals, first and foremost the right to health and the right to data protection.

Electronic health records, biomedical imaging, wearable devices, biobanks, medical apps, surgical robots, as well as application of telemedicine and remote monitoring systems are just examples of the elements that are contributing, at a particularly accelerated rate (as demonstrated by the pandemic experience, with the so-called Green Pass), to increase the availability of electronic health data. The arising issue leans on the correct use of health (personal) data for multiple purposes and its protection, which is now increasingly scattered and fragmented among a flood of regulatory measures, which are even more technical and analytical.

One particular aspect to consider is scientific and statistical research, which is essential not only for healthcare but also for science. Research studies can be retrospective or prospective, but in any case, they necessarily require data, personal data,

and "sensitive" data (recte "special categories of personal data", as art. 9 GDPR says). In other terms, research today is data centric.

Scientific research is also the primary driver of societal change, with direct repercussions on the whole community and the quality of life of its members, as well as for future generations. The interests underlying scientific activities are balanced with the rights and principles of the individual recognised by the legal system, from both public and private perspectives, which are today recognised also at the constitutional level. The right to data protection, for example, is not an absolute prerogative, but must be considered in light of its social function and balanced with other fundamental rights, in accordance with the principle of proportionality (recital no. 4, GDPR).

Proportionality should often be considered by looking at the means for collecting, processing, and sharing health data that are capable of reconciling individual rights with supra-individual interests. For example, Mission 6 of the Italian National Recovery and Resilience Plan (NRRP), inspired by the principles of "proximity, innovation, and equality", says that health policies should be oriented towards strengthening and enhancing existing infrastructure, such as electronic health records and electronic medical records, which are included in a broader national health data ecosystem. This update—labelled EHR 2.0—is accompanied by the removal of consent regarding the processing of health data: from a "consent-based" vision, in which the individual grants or refuses the transfer of their data, the paradigm shift moves to a more participatory control, in which the individual could intervene directly and immediately in the circulation of their data.

Looking only at the national landscape would certainly be short-sighted. The solution for balancing different fundamental rights and principles can only be achieved through convergent regulation at the supranational level.

As a different model of health data circulation is taking shape, data flow is even more "controlled" rather than "free".

I would like to highlight one of the objectives of the Regulation (EU) 2025/327 of the European Parliament and of the Council of February 11, 2025, on the European Health Data Space, which also aims to enhance cross-border healthcare services, as well as supporting scientific progress in the medical field. The aim is to reduce the scope of regulatory burden and constraints on the (free) flow of data stored in electronic systems. Strengthening the right to portability, consolidating the right of revocation, and reorganising data management systems, based on a functional criterion that reflects the intended use of the data, reflect the idea of a regulated market together with a state intervention.

In this regard, I would like to mention an interesting decision by the Italian Data Protection Authority (no. 465 of September 28, 2023), relating to the PRIMAGE project, with regard to a prior consultation pursuant to Article 110 of the Privacy Code. Here, the legal basis for the transfer of health data in the context of medical, biomedical, and epidemiological research falling within the scope of the EU Horizon project was considered to be the same EU legislation governing the European funding framework programme rather than the consent of the data subject.

Our project fits into this context, which is certainly complex and which I leave to the speakers of the first session to unravel.

The PADS4Health project should be considered for its interdisciplinary path, involving not only law professors but also computer scientists, oncologists, and haematologists. Through a joint action, the goal of the project is to identify a variety of models for facilitating the sharing of health data for scientific research purposes.

Many models could be based on Personal Information Management Systems (PIMS) and Personal Data Store (PDS), well-known—but not widely used—software technologies that allow personal data to be stored in a personal cloud, thus enabling at the same time immediate access to personal data by the data subject and the possibility of selectively granting access to third-party requesters, whether they are medical staff or researchers.

The implications of such models with regard to the GDPR are clear, acting as technical, organisational, and security measures, in compliance with the principles of transparency and security, guaranteeing the practical exercise of individual rights, including those of access, erasure, and portability established by the Regulation. Furthermore, in line with the NRRP objective of seeing the EHR as the single and exclusive point of access for citizens to NHS services, a PDS also seems to be able to easily serve as the main access point for health data sharing.

Let me also say that the most recent EU Regulation refers to these technologies in several places, in accordance with accountability, data protection by design, and so on. This is the case of the Data Governance Act with reference to data intermediaries. Moreover, the EHDS Regulation recognises them as an element that can be linked to the health record and electronic patient record system, to better promote the secondary use of health data. Indeed, it seems clear that a PDS could be the first step towards the creation of a federated data-sharing platform, as well as a concrete application, at least in public administration, of the once-only principle, whereby citizens only provide their data to public authorities once.

Another main issue related to digitalisation in healthcare can be seen in the convergence of various regulatory subsystems, from personal data protection to intellectual property and from contract law to liability law.

It is precisely the latter, which will be explored in depth in the second session, that poses the legal problem of the risk that eHealth technologies could become a means of undermining the therapeutic alliance, which is an immediate corollary of the doctor–patient relationship.

Understanding how the AI system works (the so-called explainability) is far from incapable of influencing and jeopardising not only the health of the individual, but also the operation of the private autonomy and the configurability of the patient's informed consent to medical treatment. Trusting an "opaque" system leads to a new configuration of the doctor–patient relationship, characterised by "machine paternalism" (according to the logic that "computers know best)", which knows everything and decides everything.

In this sense, Article 7, paragraph 3, of the Italian draft law no. 1146-B/2024 on AI states that "the data subject has the right to be informed about the use of artificial intelligence technologies and the advantages, in terms of diagnosis and treatment,

deriving from the use of new technologies, as well as to receive information on the decision-making logic used", but paragraph 5 is careful to emphasise that "artificial intelligence systems in healthcare are a support in the processes of prevention, diagnosis, treatment, and therapeutic choice, without prejudice to the final decision, which is always left to medical professionals".

The next steps are to identify the conditions for comprehensible as well as comprehensive information on AI, as well as proportionate, reasonable, and appropriate use of "smart" medical devices, which do not sacrifice certain aspects of our humanity, for medicine "with" machines and not "of" machines.

It is therefore a question not so much of whether to inform or what to inform, but how to inform. In this regard, too, it is clear that technology, and in particular PIMS/PDS, can offer effective support for the protection of individuals.

The awareness—which I would say is still to be fully acquired—is that it is humans who build technology and that it is never a neutral tool.

I would like to thank all the speakers, moderators, and participants and wish you a successful conference.

Venice, Italy Alessandro Bernes

Preface

The project that gave rise to this conference was, first and foremost, a valuable opportunity for us lawyers to engage in dialogue and, above all, to listen to what experts from other fields have to say.

Meetings between legal professionals and experts in the medical and healthcare fields often result in a clash between the former, who invoke the need to safeguard and protect healthcare data, and the latter, who call for greater freedom of action, free from bureaucratic constraints, for purposes that are also in the general interest. Among other things, this conference attempts to provide an initial response to these questions.

We are at an important turning point, in which the European legislator has taken an explicit position on the opportunity and necessity of fully exploiting the potential of data, including in the healthcare field. However, this is not an easy paradigm shift: first of all, the European legislator cannot go back on its word, and, after years of adopting a restrictive position on the processing of personal data, emphasising the risks rather than the benefits, it must be cautious in abandoning the safeguards that have characterised its work to date. Secondly, there is a major problem of trust: after raising awareness of the risks of data processing, citizens need to be reassured that the new direction towards a greater use of data will not be at the expense of their rights and interests, and this is also a delicate operation.

Another area where it is important to build trust is that of artificial intelligence systems. The meeting between lawyers and IT specialists, made possible by this project, is essential in order to make an informed assessment of the adequacy of the regulatory framework established by the European legislator. The use of artificial intelligence systems in the healthcare sector raises delicate issues of liability: these are not new issues, and lawyers are already accustomed to dealing with risk-based liability systems, but it is clear that this requires an understanding of the technical side of the phenomenon. What is new are the kinds of interactions that such systems can have with human beings: here too, it is essential to know how these systems function to understand the actual scope of the anthropocentric principle, which has been repeatedly affirmed by the European legislator.

The following lectures therefore seek to clarify how the transition is taking place, critically outlining its contours in a critical manner. I join Prof. Alessandro Bernes in thanking the colleagues who will participate in this meeting, and I now give the floor to the speakers.

Turin, Italy Shaira Thobani

About the Book

The book aims to collect the written essays of the keynote speakers who have been part of the event titled "Digitalisation in Health Care Between New Technologies, Data and Research", a conference that was held at Ca' Foscari University of Venice on November 29 and 30, 2024.

The initiative was born as an interdisciplinary workshop, as well as an opportunity for interprofessional dialogue, not only between academics.

The healthcare system has been profoundly revolutionised with the advent of the digital age. In the medical field, however, digitalisation is much more than a technical process: on the one hand, it involves technologies and algorithms, including AI systems; on the other hand, it has a significant impact on health practices and services at an organisational level, on the concrete performance of diagnosis and intervention, and on the rights of natural persons, first and foremost the right to health and the right to data protection.

This study was carried out within the Privacy-Aware Data Sharing model for Health data (PADS4Health) and received funding from the European Union NextGenerationEU, National Recovery and Resilience Plan (NRRP), Mission 4, Component 2, and Investiment 1.1 Fondo per il Programma Nazionale di Ricerca e Progetti di Rilevante Interesse Nazionale (PRIN), CUP N. H53D23010880001. This manuscript reflects only the authors' views and opinions; neither the European Union nor the European Commission can be considered responsible for them.

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Closing Remarks

Stefano Campostrini

The richness of the presentations and contributions to this conference has been undeniably substantial. I would like to thank my colleagues who organized it, both for their efforts and for choosing such a relevant topic. In these final reflections, I will not attempt to summarize individual contributions—for obvious reasons of brevity and my own limitations—but instead offer some contextual elements to reinforce the importance of the subject and the challenges ahead. The various contributions have highlighted these challenges, and due to their scope, I believe no one aimed to solve them definitively.

As a good statistician, let me begin with some numbers. At the start of this millennium, in the Veneto region (where this conference is being held), there were just over 300,000 elderly people (according to the most recent legal definition, over 75 years old). About 365,000. Much of the socio-healthcare system was designed and planned around these figures. Today, that number has nearly doubled (well over 600,000), and the real challenge will emerge soon—in just over a decade—when the baby boomer generation will mostly be over 75. Forecasts indicate that in the 2040s, Veneto will count over one million residents aged over 75 [1].

These figures alone are staggering. But to grasp the full magnitude of the challenge facing our socio-healthcare systems [2], we need more context. The demographic transition we are experiencing is not just about the increase in life expectancy and the growing number of elderly and very elderly people. A parallel phenomenon—the sharp decline in birth rates—is significantly increasing the old-age dependency ratio. Without delving into details, consider this a few years ago, 500,000 elderly people "weighed" on a population of nearly five million in Veneto. The one million elderly forecast for 2040 will weigh on a population of just over four million.

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Another contextual consideration, relevant to the healthcare world, concerns the so-called epidemiological transition. Over the last century, we have moved from mortality (and morbidity) largely due to infectious diseases to over 80% of deaths and illnesses now being caused by non-communicable diseases (as defined by WHO)—which I prefer to call, using a term more common in healthcare, chronic diseases [3]. This term better reflects the fundamental difference between infectious and chronic diseases. For the former, healthcare intervention focuses on the acute phase, resolving the issue relatively quickly or, as in the past, the patient passed away rapidly. With chronic diseases, the onset marks the beginning of a long-term co-existence, often spanning decades, and typically involving multiple conditions (comorbidity). This has a clear impact both on the healthcare system's burden and the types of services required; and beyond hospital care, there is an increasing demand for community-based, health, and social-healthcare services.

Considering that these services are mostly needed in the advanced stages of chronic disease—usually beyond the age of 75—and combining this with the projected increase in the elderly population, we face a challenge of such magnitude that the current system of service provision cannot sustainably meet future demand. Individual demand is increasing, and so is the number of individuals with such needs.

I do not wish to add further gloomy notes to this scenario, which I dare to describe as a "perfect storm." (Please forgive my tone: I try to be as clear as possible, also terminologically, especially so that political and technical decision-makers realize the need to tackle these problems *hic et nunc*.) But there are more challenges: climate change, which already negatively impacts health; globalization, which—as we saw during the recent pandemic—removes borders for pathogens; migration, which presents both benefits (given demographic realities) to the society but also strains to healthcare systems.

Let me mention one last issue that, particularly in the Italian environment, contributes negatively to the perfect storm: the crisis in the healthcare workforce [4]. To the casual observer, this may appear as a crisis among doctors. But while some issues of planning and specialty imbalance exist there, the real crisis concerns nursing. In the context of healthcare's technological transformation, nursing is even more critical. We are now also seeing signs of strain in the lowest tier of the healthcare workforce hierarchy—social-healthcare workers—who are increasingly essential, especially in elderly care. Today, we seem to face a "vocational crisis" (though I argue this is misleading, since structural factors have made these professions less attractive, beyond simple spiritual or ethical considerations). Looking ahead, demographics are not in our favor: even if we succeed in making these jobs attractive again, the percentage of young people entering them will apply to a shrinking base. The cohort of young adults choosing careers in 2030–2040 will be nearly half the size it was in the early 2000s.

So, we complete the perfect storm scenario: rising demand and declining supply. The fundamental challenge for researchers and policymakers is thus to identify potential solutions.

The first option, in Italy, is to be rejected outright for constitutional reasons (thanks to the beautiful Article 32): offering full services only to some, while cutting back for others.

A second, more likely scenario is to lower the quality or breadth of services for everyone. Unfortunately, this is what we are already witnessing. In the absence of decisive reform, this path will be fully realized. In my view, this approach should also be rejected, as it fosters social tension (already detectable today) and deepens health inequalities. It may preserve formal adherence to the principles of equity and universal access (as enshrined in Article 32), but in substance, it undermines them.

In this perfect storm, the idea that new technologies might offer a panacea—a third solution—is incorrect or, at best, partial. For several reasons:

First (briefly, as it could get out of the scope of the present intervention) is the financial aspect. Technologies, especially when first introduced, often increase service costs. Efficiency gains (which alone cannot solve our challenges) only appear in the medium term and only if implementation is done correctly. Introducing technology en masse could initially worsen the healthcare system's financial sustainability.

Second is the organizational challenge. New technologies are useless without organizational changes. While technological innovation is already widespread in healthcare, organizational innovation is still in its infancy. There are successful examples where technological and organizational changes have been combined effectively—improving both impact and sustainability [5], but much has to be studied and implemented.

This leads to the third, and most relevant for this conference: the legal and regulatory dimension. It is inconceivable to implement technological and organizational innovations in a highly regulated system like healthcare without also changing its legal and regulatory framework.

In short, adopting more technology as an "exit strategy" without addressing these three aspects is like pouring new wine into old wineskins, as the Gospel warns.

If we do indeed need new wine—and I believe we do, urgently—we must also build new wineskins.

This is especially delicate in healthcare, which has a unique trait: it cannot stop to be fixed; it must change while in motion. As the pandemic showed, even short-term shutdowns carry enormous health and social costs. We must therefore maintain the old system temporarily, while experimenting with new models.

This has implications not only for systems (organizational and regulatory) but also for research. It has long been assumed that medical and technological research could run in parallel. Recently, it's become clear they must work together. The same now applies to organizational research: innovation in healthcare management must go hand-in-hand with technological, clinical, and procedural innovation.

After this contextual preamble, I believe the relevance of legal reflection is clearer. Legal norms are, in my view, an essential part of the healthcare system's organizational architecture. If this architecture must be fundamentally redesigned—as outlined above—legal contributions are key. A further challenge to my legal colleagues: in the past, law followed change. One experimented, consolidated, then

regulated. Today, that sequence may no longer be viable. Given the magnitude and speed of change (in society, technology, and organization), law may need to accompany change, not follow it. Take this as a provocation from an outsider.

Finally, let me briefly reflect on some specific legal challenges that I see from my particular (and admittedly biased) perspective on healthcare systems. As a statistician, I have always dealt with data. Early in my career, I learned how closely data quality is tied to organizational structures. One early (unpublished) study of mine examined the quality of hospital records. It was poor. With the introduction of diagnosis-related groups—which linked those records to administrative and financial functions—data quality improved substantially, as did their use in epidemiological research. In short, data-regulation-organization forms an inseparable triad in healthcare.

This brings us to current technologies that could positively transform healthcare systems. Many hinge on data. Take the most disruptive innovation today: Artificial Intelligence. Despite its flashy name, AI is simply a highly advanced (not necessarily intelligent) use of large-scale data.

Success in healthcare AI (see [6, 7]) depends on how we handle the data-organization-regulation triad. AI is powerful, but also deeply invasive. Like any tool or procedure in healthcare, it must be tested, its organizational role defined, and it must be regulated.

But digitalization is not just AI. It includes the advanced use of digital tools to transform service delivery. One notable example is the virtual hospital [8], already operating in some areas. Through advanced technology and data—and a radically different organization—more patients can be treated at home, avoiding travel and hospital stays. This reduces costs for the system while improving patient experience. Is it technology? Of course. But what is truly striking is the organizational innovation. Nurses, for instance, remain the primary front line, but now serve many more patients. A brilliant way to optimize a scarce resource, as my economist colleagues would say.

Again, all this relies on sophisticated data use.

A final, slightly polemical but constructive note. If we agree that today's challenges demand disruptive approaches—in technology *and* organization—then legal frameworks must evolve as well. They too must adopt a disruptive mindset.

This is the challenge I leave to my legal colleagues (whose presentations here suggest they are more than capable). I confess some frustration (here comes the polemic) with the excessive restrictions on data use—especially for research—we face today, particularly in Europe, and even more so in Italy. Please don't misunderstand me: I fully support privacy and sensitive data protection. I simply believe we may be able to find alternatives to the default "it can't be done." Perhaps we need new wineskins for privacy and data use as well.

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