The futures of eHealth – introducing the social, legal and ethical challenges

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Looking into the futures of eHealth? The title of this publication might seem quite presumptuous at first. Its objective, however, is to serve a much more modest purpose, in that it strives to take a look at potential, likely, desired, anticipated or feared futures of digital health technologies and practices. When analysing the opportunities and risks associated with them as well as the social, legal and ethical challenges they might pose, what we also see in the process are the expectations and promises projected onto them.

eHealth or "digital health", according to the World Health Organization's European Office, "involves a broad group of activities that use electronic means to deliver health-related information, resources and services: it is the use of information and communication technologies for health" (World Health Organization 2017). As far as current developments and technological solutions are concerned, the WHO has further identified the following areas:

- Electronic health records and interoperability of data;
- Mobile health or mHealth;
- Telehealth, where a patient can consult with a healthcare worker using Skype or even a regular telephone;
- Wearable technologies (fitness trackers, medical devices, etc.) and
- Technologies to support integrated care (WHO 2017).

Looking into the futures of anything always involves creating narratives. Rather unsurprisingly, the WHO's definition characterises the role of technology use as entailing "strengthening health systems and health information systems" (World Health Organization 2017), a narrative of opportunity. These promises of eHealth are embedded in and reflective of much larger discourses that are often associated with (digital) technologies, which are mainly seen as a remedy to existing social problems. These discourses often centre around terms such as "empowerment", "democratic potential", "unifying cross-border force", "special care for vulnerable groups" or "bridging distances". And, indeed, there is an abundance of opportunities in digital health solutions that are directly associated with these technologies and practices.

From a *patient perspective*, eHealth makes the promises of improved access to medical services or of individualised medicine via targeted treatments (e.g. patient-specific cancer therapies). It is characterised as enabling patients' self-management and helping them to reach informed decisions.

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From a *medical perspective*, one of the opportunities associated with eHealth is that it will speed up the process of implementing medical research findings in healthcare practices, involving all relevant fields from diagnostics and therapies to technological devices and decision-making processes. Among the objectives - and the promises - of digital healthcare are that it will bring about generally improved patient outcomes while enhancing safety and reducing medical error. Telemedical services are expected to facilitate healthcare delivery and provide access to medical expertise in rural areas, across nations or even across continents. eHealth is expected to help reduce expenses and to solve major problems associated with an aging population or rare and chronic diseases. Furthermore, the implementation of innovative data analytics methods into health systems should allow for developments such as predictive diagnostics – anticipating future ailments and allowing timely intervention – and "individualised precision medicine".

These last points – precision, prediction and individualisation – also raise hopes and expectations from a *research perspective*, hopes that are mainly associated with the well-known promises of "Big Data" (e.g. Mayer-Schönberger/Cukier 2013) for research processes and scientific evidence. These promises, however, have sparked considerable criticism in recent years, since they often assume a "more objective" type of knowledge. Data-rich environments imply gaining access to all the data there is (not just to medical data but also to social and cultural information on individuals) and analysing it via efficient machine learning methods (so-called artificial intelligence). This idea of a universal representation of all potentially relevant factors has been persuasively applied in various fields such as genomics, biomarkers, biosocial parameters or gene-environment interaction. Experiments and causality-based research, it has been claimed, will become obsolete and be succeeded by correlation, salient patterns or computer simulations. This promise expands to creating probability-based knowledge about future scenarios in the above-mentioned field of predictive diagnostics.

Of course, the debates also give voice to critical discourses concerning the risks associated with "the invasion and loss of privacy", "surveillance and control" or "automation" accompanied by the feared "loss of human agency"; this begs the question of how we can ensure that patients receive good care via these technologies, how the technologies can help doctors and medical professionals and how we can prevent them from causing harm or violating individual freedoms. Also, there are many additional challenges, including the cost of the equipment, the lack of necessary infrastructure, and the need to train doctors, medical staff and also patients. The positive effects of digital health are directly linked to media and data literacy as well as to technology acceptance.

Finding answers to these issues is highly complex and involves both social and cultural as well as legal questions and challenges that in many instances are highly interwoven with each other.

SOCIAL AND CULTURAL CHALLENGES AND QUESTIONS

As scholars consider developments in the field of eHealth as part of the extensive social and cultural transformations brought about by digitalisation, a more nuanced picture is emerging. Among the most relevant questions and pressing issues are:

(1) The tendency towards *universal datafication*: the seemingly all-encompassing collection of data in all areas of life is leading to a structural loss of privacy, a value that is deeply rooted in Western modernity. It has been succeeded and challenged by a much more fluid understanding of what is private and what is public, which is particularly relevant for the highly sensitive area of information on health (Nissenbaum 2010). Besides obviously medically relevant data (such as biochemical and genetic information), it is a wide range of data on social and cultural parameters (such as group affiliation, location and movement, consumer behaviour etc.) that are being taken into account when making correlation-based assertions about their relevance for an individual's present and future health. Given all the digital traces we leave in our everyday lives, virtually any piece of information might become medically relevant. Once the data is there, it is very difficult not to use it. The risks are obvious and pertain to issues such as data protection and confidentiality, a tendency to overdiagnosis, or the danger of producing "false" knowledge either involuntarily through chance correlations or even deliberately by outright manipulation of data.

(2) The tendency towards a *universal valorisation of data*: one of the most serious side effects of data collection by communication and tracking devices is that is large and powerful technology companies that gain easy access to them. It is a truism that sensitive data – including medically relevant data – are essential for the new business models that have emerged around virtually all types of personal data. Once the data is there, it is difficult not to make money with it. Monetising personal data has become a norm, both for companies and their users, who appreciate the "free" services they offer. Strangely, as part of this norm, being transparent about your own data has been established as the default. Consequently, protecting your own personal data becomes an opt-in and might eventually be offered to you as an additional service that you either can or cannot afford. An increasing commercialisation of health data risks reinforcing social and economic divides if the affluent are able to pay for any service they want and keep their data private and secure in the process while the less affluent either pay with their data (e.g. when a discount is given to patients when they make their data transparent) or are paid off when "donating" their data. This may not only be a problem within national health services but also on a global scale, for instance, if richer countries "extract" medically relevant data from poorer regions of the world with more lenient data protection legislation or greater economic need.

(3) Does eHealth lead to a more *personalised* or to more *de-personalised healthcare*? Does it foster *patient autonomy* or is it means of *patient surveillance* and *control*? For both questions, the picture is very complex and the answers are never either/or. Data is becoming central in diagnostics and patient therapy because they promise to provide more effective, individualised care. But at the same time, there is a real risk that patients may no longer be regarded holistically but as mere bearers of medically (ir)relevant data, which is the product of (self-)monitoring and automated data analysis. These tendencies might even lead to an increased de-personalisation of individual patients by reducing the quantity and quality of human contact in doctor-patient relationships. Closely interwoven with this development is the focus on the individual: digital health does not just make medical expert knowledge more available and accessible; with devices such as self-trackers or electronic diagnostic tools, it can also empower patients and ensure a higher degree of autonomy. At the same time, the flipside of this higher degree of self-determination is a potentially ubiquitous culture of medical (self-)surveillance, with control not only being exercised from without but from within: it becomes the individual's responsibility to stay healthy by looking after and optimising his or her own lifestyle, nutrition or level of exercise.

GENERAL LEGAL RESEARCH PERSPECTIVES

(1) The central legal challenge surrounding eHealth is legal uncertainty, which has multiple origins. Health law – which regulates patients' rights to healthcare, health insurances and healthcare professions – has traditionally been regarded as *a complex field of law*. It is challenging to interweave innovation and technological progress in the healthcare field with existing health law. This is evident internationally in initiatives to regulate the use of electronic health records. For example, in Germany, where healthcare is provided by a large number of private and public actors, enabling the seamless use of electronic health records is a tedious process. The complexity of health law is also evident in the reimbursement of telemedicine. EU law mandates that cross-border telemedical services be reimbursed when they are also covered by the patient's national health insurance. However, it can be difficult for patients to find out what their insurance coverage for telemedical services is. Expanding the range of reimbursable telemedical services so that they are on a par with in-person medical services would foster the adoption of telemedicine.

The complexity of health law is also reflected in the discussion on informed consent, and questions arise as to whether users of eHealth services are sufficiently informed about how their data is processed by eHealth technology providers. However, users of eHealth technologies, who are often patients, must in many cases give multiple different permissions, each of which has a distinct legal significance: consent to processing personal data,

to disclosing information subject to professional secrecy, to receiving treatment and to taking part in medical research, including clinical trials. Furthermore, the conditions for giving consent depend on the purpose of data processing and the jurisdiction in question.

(2) Existing *legal frameworks may not fit seamlessly with novel technologies*. For example, the standard for liability is different depending on whether the damage is caused by hardware, software or a healthcare professional. As a consequence, users of eHealth apps that bring together multiple technologies and services may find it difficult to determine what their rights are when something goes wrong. Even though the Medical Device Regulation applies to software with a specific medical purpose (Art. 2 (1)), wellness apps fall outside its scope, which may require attention from the field of consumer law.

(3) Often *existing laws may be silent* with respect to eHealth technologies, such as telemedicine, mHealth or AI-based applications. New legislation may prove necessary to increase their adoption or to ensure their safe use. For example, Russia, Brazil, the US and Germany have recently changed their legislation on telemedicine, and AI regulation has been subject to heated global debate. In some situations, existing laws may not even cover certain ethical challenges associated with eHealth technology. For example, the use and sale of anonymised health data may be perfectly legal but nevertheless raise ethical problems, for example, in terms of how they may inform insurance or marketing policies.

(4) Legal uncertainty increases whenever eHealth is applied in *a cross-border context*. In the EU, both health law and tort and contract law are not harmonised, and may differ dramatically between EU member states. In Germany, the relevant legislation is at least partly a state matter. Given that the healthcare systems across the EU are very diverse, patients, healthcare professionals and service providers operate in a very complex legal landscape, especially when services are offered across member states' borders. Furthermore, eHealth is an international phenomenon, and technologies such as telemedicine make it possible to treat patients who may be located on other continents. As a consequence, it is difficult to introduce eHealth products and services on an international scale without substantial investment to ensure legal compliance.

(5) *Harmonisation of legislation is not a panacea* for legal uncertainty, as can be seen from the General Data Protection Regulation (GDPR), which came into force in 2018. The digitalisation of healthcare, the popularity of mHealth applications and the prevalence of self-tracking technologies are all powered by processing health data, which is deemed sensitive under the GDPR (Art. 9). However, the GDPR does not fully harmonise the law on data protection in Europe. In fact, its rules on processing health data contain several references to national legislation. For example, professional confidentiality requirements for healthcare professionals remain regulated on the national level and are often subject to different standards of liability. In the EU, the legislation on healthcare remains in the competence of member states and is hence outside the scope of EU law.

However, even within this very heterogeneous legal landscape, many of the challenges associated with eHealth are similar across the world. Engagement in interdisciplinary, comparative dialogue with an international focus is a step towards alleviating the legal uncertainties associated with eHealth. This may enable eHealth providers to operate in the current, complex legal landscape and help to regulate the use of future eHealth technologies in a manner that is legally, socially and ethically sustainable. Through dialogue, we can learn from solutions adopted in other countries and identify the best regulatory and policy measures for eHealth.

Researchers from various countries and disciplines discussed these issues at the international and interdisciplinary conference "The Futures of eHealth. Social, Legal and Ethical Challenges", which was held on 29 and 30 April 2019 in Berlin, Germany. This publication identifies and details the social, legal and ethical opportunities, risks, benefits and challenges of innovative digital health technologies.

OVERVIEW OF THE CONTRIBUTIONS

The first section provides an overview of *Current Challenges in eHealth*. Arguing that mobile health applications blur traditional sector boundaries and consequently challenge research on health ethics, the *META research group* concludes in their paper that a "responsible, socially and globally sustainable and user-centric innovation" is of prime concern in order to uphold values such as patient empowerment, democratisation and procedural improvements in health and health care. *Valeska Cappel* and *Karolin Kappler* also focus on mobile health applications and shed light on potential lines of conflict in their development, implementation and diffusion by comparing the underlying conventions, investments in form and practices of different stakeholders. From a legal perspective, *Trix Mulder* looks at the principle of informed consent in the context of European data protection laws. She argues that the privacy policies of health apps and wearables are not always clear on the purposes for processing, which can result in the loss of purpose limitation as a safeguard for data protection. *Thomas Christian Bächle* looks at the ethical challenges that arise with innovations in the field of digital health, namely around developments such as universal data collection, machine learning analytics (so-called AI) and automated decision-making. These entail complex questions on shared agency and distributed responsibility as well as patient autonomy and social sorting.

The second section focuses on the *Uses and Perceptions of eHealth Applications*. *Freya Sukalla and Veronika Karnowski* analyse the portrayal of mental well-being apps in the smartphone app market, which are often categorised using keywords such as lifestyle instead of health, fitness or medicine. They find that these apps and the ways they are represented implicitly promote the idea of sole individual responsibility for well-being

and mental health, which leads them to conclude that this may have serious negative implications, including exacerbating stigmatisation. *Isabell Koinig and Sandra Diehl* look at wearable and self-tracking technologies in the context of lifelogging, personal fitness and empowerment. In particular, they ask to what degree evaluations of an advertisement for a wearable product are influenced by individuals' attitudes towards fitness and their interest in new technologies. While self-tracking clearly articulates power structures, the authors frame the concept of empowerment in the context of marketing: how can it be made known to people that new technologies in the field of eHealth can be beneficial for their health? *Galit Madar, Azi Lev-On and Nachman Ash* analyse the changing images of family physicians as perceived by their patients who use eHealth systems, as well as patients' perceptions of their interactions with their physicians in an Israeli context. Their findings indicate that physicians believe that the introduction of eHealth systems significantly transformed what we term the professional, interpersonal, and therapeutic aspects of their image as family physicians. The section concludes with a summary – authored by *Niklas Trinkhaus – of Btihaj Ajana's* keynote entitled "Self-management for better health? Reflections on the self-tracking culture", which she delivered at the conference on 30 April 2019 in Berlin. She argues that while the growing self-tracking culture was expected to be part of the solution to severe problems in the public health sector, the promises of a personalised, participatory and preventive approach towards health cannot live up to expectations. Even though some benefits and positive outcomes of self-tracking can be identified, she warns of excessive optimism regarding the potential of self-tracking technologies.

The third section, *Technology and Innovation in Context*, begins with *Martin Stojanov's* study on second-order data interoperability in public health, which highlights the challenges of repurposing web-based data and measures that need to be undertaken to ensure interoperability. *Anastasiya Kiseleva* discusses the transparency of AI-made decisions in healthcare, stressing the importance and need for legislative measures that maintain trust in AI-facilitated medical treatment. *Irma Klünker's* report on the Markets for eHealth panel discussion features the perspectives of innovators and entrepreneurs operating in the eHealth sector. The panel raised awareness about the challenges entrepreneurs face in Germany and the UK when introducing eHealth services to the market, such as the complexity of the healthcare sector and the struggle to acquire funding and ensure legal compliance, especially with respect to data. The challenges of eHealth are global, and the panel discussion curated by Asia eHealth Information Network (AeHIN) on the international perspectives brought understanding of the efforts to adopt eHealth technology in Asia, South America and Africa and Europe. The report on the panel, written by *Niklas Trinkhaus*, identifies interoperability, international cooperation and the prevention of abuses of health data as important challenges in the development of eHealth when seeking to achieve the UN goal of *universal health coverage*.

The section *eHealth in Practice* presents international case studies on the various ways digital health technologies are being used, detailing social contexts, challenges and benefits. *Daniela Rudner, Lynda Toussaint and Nao Sipula* introduce Unjani Clinic, a social franchising initiative in South Africa that has created a primary healthcare container clinic network in underserved areas. In particular, they highlight the role of electronic health records and telehealth as technological solutions applied in this project. *Manisha Mantri, R. Rajamenakshi and Gaur Sunder* look at the extensive digitisation of the health sector and highlight major issues in the debate on policies, regulations and technical standards. With respect to data privacy, they argue that additional attention must be given to the handling of patients' health data, including both legal and ethical aspects, and they explore the initiatives on policies, regulations and technical standards. *Arun Shroff* discusses a diagnostic tool that enables the early detection of diabetic retinopathy (DR) using so-called artificial intelligence that is being deployed and tested in India. DR is a serious eye-disease that affects over 148 million people worldwide and can lead to vision impairment and vision loss if it is not detected and treated early enough. It is argued that this method of automatically screening retinal images offers an effective alternative to human diagnosticians, since there are not enough specialists worldwide to screen everyone at risk. The paper outlines the objectives of the project as well as the challenges faced.

The section begins with *Stefaan Callens'* review of the current and upcoming legal challenges in eHealth that call for regulatory initiatives by the EU: transparency in the multiparty processing of health data, clinical assessment of health technologies, enablement of multiparty, interstate cooperation and information exchange for the provision of telemonitoring services, removing legal obstacles of the adoption of cross-border medicine and ensuring pro-competitiveness of big data and AI. In her paper on the secondary use of data in the context of medical research, *Paola Aurucci* discusses the complex interplay of data protection law and clinical trial regulations, both of which address the use of health related data. The power of EU member states to enact stricter legislation in connection with sensitive data may lead to situations in which medical research is undertaken in considerable uncertainty about how to process health-related data in a legally compliant manner.

Mikhail Zhuravlev reviews the recent Russian legislation on eHealth, which addresses the use of electronic health records and telemedicine. In Russia, the criteria for giving informed consent for the processing of health data are strict, formal and burdensome to meet in the context of eHealth. Besides the legislation on the processing of health data, other legislative solutions also have an impact on the adoption of eHealth technology. *Lauren Tonti* investigates the conditions under which telemental health is reimbursed in France, Australia and the Netherlands, stressing the importance of parity – the reimbursement of telemental care services on a par with face-to-face health care. She highlights the need to codify parity policies in law.

Especially in countries with large rural populations, telehealth can facilitate access to healthcare. Of all the legal norms addressing telemedicine, those that directly prohibit or limit long-distance treatment have the most pronounced effect on its adoption. *Alina Wernick* and *Irma Klünker* review the historical background and current status of the prohibitions and limitations on long-distance treatment in Germany and in the US, arguing in favour of evidence-based regulation that ensures the delivery of safe medical care in view of the advances of telemedical technology. *Mariana Canto* discusses the development of a telehealth policy in Brazil and the challenges in regulating data protection, privacy and cybersecurity of telehealth as well as the conditions for accessing it, bearing in mind the social and economic aspects of telehealth delivery.

Our publication ends with a collection of *#eHealthFutures2040* predictions shared by our conference participants. Whereas the conference presentations looked a few years ahead into the future developments of eHealth, the conference participants were asked to share their predictions about eHealth in 2040.

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The editors want to thank all participants for making the conference an insightful, multifaceted and prolific event. In particular, our thanks go to the presenters for their efforts in offering their contributions for publication in this edited volume. This ensures that their valuable research results can be shared with a broader public.

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