

Digital health: meeting the ethical and policy challenges

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Summary

Digital health encompasses a wide range of novel digital technologies related to health and medicine. Such technologies rely on recent advances in the collection and analysis of ever increasing amounts of data from both patients and healthy citizens. Along with new opportunities, however, come new ethical and policy challenges. These range from the need to adapt current evidence-based standards, to issues of privacy, oversight, accountability and public trust as well as national and international data governance and management. This review illustrates key issues and challenges facing the rapidly unfolding digital health paradigm and reflects on the impact of big data in medical research and clinical practice both internationally and in Switzerland. It concludes by emphasising five conditions that will be crucial to fulfil in order to foster innovation and fair benefit sharing in digital health.

Keywords: digital health, personalised health, digital ethics, data governance

Introduction

Digital health is a rapidly expanding medical field premised on the availability of ever increasing amounts of data about people's lifestyles, habits, clinical histories and pathophysiological characteristics. According to the US Food and Drugs Administration (FDA) "[t]he broad scope of digital health includes categories such as mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine" [1]. These categories rely heavily on human health data. Conventionally, the collection of health data is mediated by officially licensed medical devices, such as diagnostic instruments or genome sequencers, operated by health professionals in clinical environments and under strict regulatory conditions. Moreover, clinical data are typically stored in public health registries, at hospitals or in the archives of individual physicians. Digital health, in turn, entails connecting health-related data, including data generated by patients themselves, and harnessing the medical potential of technological tools of common usage, such as smartphones, wellness bands, apps, social media and sensing devices disseminated in our dwelling environ-

ment. Most of these tools are not initially conceived for medical use and are not marketed as medical devices. Notably, however, some prominent digital health technologies already cut across the rigid distinction between licensed and ordinary gadgets, and the latter have also started to receive official designation as medical devices (see table 1) [16]. But digital health is not limited to ordinary technology, nor to ordinary-turned-medical technologies. Certain digital health tools present entirely novel features, as in the case of digital pills that, thanks to a microcircuit activated upon contact with liquids in the patient's stomach, can tell an external sensor whether and when a patient has taken his or her medication.

The defining feature of digital health, however, has to do with data rather than technology. What is distinctive about digital health in this respect, is that – typically through wearable, portable, ingestible or otherwise implantable devices – it generates a “seamless flow of critical medical data between patients, their families and their physicians” [17]. The ambition of digital health is therefore aptly described as generating a *circulation of data* from patients (patient-generated data), to devices and/or health professionals (who analyse and make sense of the data), and then back to devices that eventually provide the patient with information regarding their health status and how to manage it.

To this aim, phenotypic and behavioural information, as well as data about socioeconomic status and dwelling environment, need to be collected. Information posted on social media can also turn out to be potentially relevant to both individual and population health [18, 19]. Digital health thus inhabits what has been recently labelled an “evolving health data ecosystem” [20], a space that also includes data gathered by healthcare services, such as electronic health records, genetic or genomic data, diagnostic data, claims data and the like. According to some, given their volume, complexity, variety and propensity to be analysed through data-mining techniques, such data qualify as big data [21] or, more precisely, as biomedical big data [22–24]. This expanded set of health-relevant data is expected to occasion huge progress in medicine, for example by helping people monitor their health status, assisting patients in coping with their conditions, inferring health-related issues earlier on, personalising treatment to individual patients'

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characteristics, improving outcomes, reducing costs and inefficiencies, and also boosting medical discovery and accelerating drug development. Admittedly, there are significant expectations of digital health and there is strong interest on the part of numerous stakeholders in promoting it and seeing it flourish. At the same time, for digital health to materialise several ethical and policy challenges need to be overcome [25].

To review these challenges, a multidisciplinary symposium was held at the University of Zurich (UZH) on 1 December 2016. The symposium, convened by UZH's Health Ethics and Policy Lab (now based at ETH Zurich), brought together different perspectives from national and international experts regarding the challenges that accompany the development of digital health. Participants included scientists, ethicists and lawyers, representative of national research institutions such as the SAMS (Swiss Academy of Medical Sciences) and the SNSF (Swiss National Science Foundation), as well as policy specialists from international organizations such as the OECD (Organization for Economic Co-operation and Development) and the WHO (World Health Organization).

Three key challenges impinging on the development of digital health were identified and discussed:

1. How does digital health fare with respect to the demands of evidence-based medicine?
2. How can public trust in digital health be generated and sustained

3. What policy gaps can and should be addressed through global policy instruments and what instead require specific initiative in the Swiss context?

Here, we provide key considerations on the above three questions, based both on the discussions held at the symposium and further literature review. These considerations are of relevance to scientists, ethicists and public health experts, as well as developers and policy makers interested in assessing the impact of big data in medical research and clinical practice, both internationally and in Switzerland.

Digital health and the quest for evidence

The clinical development of digital health applications is premised on the creation of very large data collections recording sensitive personal data. In the public sector, examples include: the 100K genomes cohort in the UK, which aims to sequence the genome of one hundred thousand NHS cancer patients by 2017; the All of Us cohort of the Precision Medicine Initiative in the US, which will collect samples, and phenotypic and clinical data from one million Americans; or the Million Veteran Program, which currently constitutes the largest genomic database in the world and also includes lifestyle information and access to electronic health records for research purposes [26]. Besides these large-scale public initiatives, the private sector is also collecting huge amounts of phenotypic and genetic data from users of health-related services and products. For example, as of June 2015, the genetic testing compa-

Table 1: Examples of licensed and unlicensed digital health technologies.

Company	Product	Type	Year of license	Licensing body	Description
Licensed					
AdhereTech, Inc.	Smart Pill Bottle [2]	Wireless pill bottle		FDA, CE, ISO	Smart wireless pill bottle capable of alerting patients to missed doses.
Airstrip Technologies	AirStrip ONE® [3, 4]	Mobile app	2014	FDA	Provides an interoperable platform that simplifies clinicians' and patients' access to diverse health data.
AliveCor, Inc.	Kardia Mobile [5, 6]	Wireless pad	2016	FDA	Portable electrocardiogram device displaying results on a smartphone. It can detect cardiac anomalies such as arrhythmia.
Blue Spark Technologies, Inc.	TempTraq® [7, 8]	Disposable patch	Blue Spark Technologies, Inc.	TempTraq® [7, 8]	Disposable patch
Natural Cycles	Natural Cycles [9]	Wireless thermometer	2017	CE, ISO	App to keep track of ovulation and period, associated with a smart thermometer to determine fertile days. It can be used as a contraceptive.
Proteus Digital Health	Proteus Discover [10, 11]	Ingestible sensor, wearable sensor and mobile app	2014	FDA	An ingestible sensor mounted on a pill, which, when swallowed, sends a signal to devices keeping track of compliance with prescriptions.
Not licensed					
Butterfly Network, Inc [12].		Compact ultrasound			Portable ultrasound machines trained through deep learning algorithms.
Fitbit, Inc.	Fitbit Aria™ [13]	Wi-Fi smart scale			Used in conjunction with an app, it tracks body mass index, weight, body fat percentage and lean mass.
Happify, Inc.	Happify™ [14]	Mental health app			Smartphone app aimed at alleviating stress and negative thoughts through techniques in the form of games and exercises.
MyFitnessPal, Inc.	MyFitnessPal [15]	Calorie counter app			Free app to keep track of calorie intake. It is said to help users who want to lose weight.

ny 23&Me had collected and genotyped DNA from more than one million costumers [27]. In June 2016, the US-based healthcare provider and insurer Kaiser Permanente announced the constitution of a research biobank pulling electronic health records, DNA and behavioural and environmental information from 500 000 people [28]. Finally, end-users of digital health devices such as heart monitoring apps or fitness gadgets also contribute vast amounts of data to service providers. Such data can be cross-linked to other existing large-scale repositories both for research purposes and for developing new digital health services to users and professionals alike.

The evidence base for digital health

Mining large-scale data repositories creates challenges regarding data management, privacy protection and oversight mechanisms. Other challenges, however, relate more directly to the composition of such repositories and to the tools employed to mine the data they contain. For instance, the use of convenience samples to populate precision medicine and precision public health cohorts can bias the sample compositions and compromise the representativeness of target populations [29, 30]. Such issues can affect the quality of the evidence derived from digital health research and employed in digital health-based interventions, both at the individual and at the population level. Taking into account ethnicity, age, sex, socioeconomic status and geographical distribution in recruiting research participants thus seems crucial to ensure the generalisability of research findings. Similarly, the representativeness of the datasets employed for product development and the robustness of analytic tools to mine such datasets can affect the development of effective digital health services and devices by private companies.

There seems to be room for precompetitive research in this area in order to at least create standards and possibly reference datasets to enhance reproducibility. Meanwhile, progress in regulatory science should enable better assessments of evidence for safety, efficacy and cost-effectiveness. In both cases, policy stimulus appears crucial to achieve tangible results. As for more user-oriented digital health applications, as with products and services developed outside the realm of licensed devices, there is the need to enhance transparency and accountability by adopting forms of sector-specific self-regulation and adhering to robust corporate responsibility schemes.

Data variety is also a key issue in digital health. For example, although genetics can be extremely informative from a medical point of view, with a few notable exceptions the contribution of genetic variation to most common chronic conditions is either unknown or relatively small. Instead, other types of information, such as levels of physical activity, diet and socioeconomic factors, are better suited for predicting the risk of developing a chronic disease [31]. Therefore, to harness the full potential of data mining and predictive analytics in digital health, genomic data alone are insufficient [32, 33].

Novel modes of evidence generation could take into account multidimensional and unstructured data along with conventional clinical measures. For example, in health outcomes research or assessment of long-term effects of drugs and interventions, pragmatic trial designs are raising con-

siderable interest. Such studies employ less restrictive inclusion criteria than traditional clinical trials and allow for concomitant morbidities and medications. Such models rely on “real-world data” collected from actual patients [34] – data that would simply not be available in randomised controlled trials. Real world data include medical records, data from portable devices and social media, as well as environmental and socioeconomic data. Other than saving on the high costs of randomised controlled trials, pragmatic trials based on real world data promise to be more representative of real populations. At least when risks are deemed reasonably low, real-world evidence obtained through pragmatic designs could thus be used in support of regulatory decisions about the safety and efficacy of digital health devices and applications. Moreover, real-world evidence could also be employed to retrospectively assess digital health applications that reached the market without being cleared by regulatory agencies.

The technologies that are enabling extensive data collection and the development of digital health can be applied to both individual and population health issues, contributing to the emerging fields of precision medicine and precision public health, respectively [35–38]. Both the former and the latter promise more tailored interventions in their respective domains, progress in the understanding of disease causes and outcomes, along with reduced costs and improved access to effective healthcare. Both precision medicine and precision public health have specific sets of ethical implications [39, 40]. In such areas, larger, more representative and diverse databases are expected to tackle very well-known issues of external validity that afflict randomized controlled trials [41, 42]. Yet this prospect is affected by the challenges discussed above. Moreover, the use of artificial intelligence (AI) and deep learning [43] to mine such large data repositories has led many to think that digital health can dispense with mechanistic explanations and hypothesis-driven research, replacing them with mere algorithm-guided searches for correlations between phenomena in large-scale observational studies [44–47]. It has been noted, however, that even if those methods prove effective in establishing robust correlations, controlled interventional, randomised trials on stratified patient cohorts will still be necessary to establish the safety and clinical utility of novel therapies or public health interventions [48].

Ethical and policy challenges in digital health

Privacy and security

Most of the debate about big data uses for health purposes has focused on privacy. As more data sources become available and advanced analytics can be applied for various purposes, protecting privacy is undoubtedly a complex challenge. What contributes to this complexity is that standard mechanisms of protection such as anonymisation, notice and consent are excessively stretched in this environment of new capabilities. Consent for data uses can hardly include the exhaustive list of all possible future data uses [49]. In turn, anonymisation technologies, even if robust, still leave re-identification in the realm of possibility if enough resources were to be devoted to it. Data security has also been a challenge, with cyber attacks, hacking of databases and data kidnapping being reported frequent-

ly. Incidents of data breaches and “kidnapping” (data held by hackers for ransom) are on the rise. According to the Breach Portal of the Health and Human Services (HHS) Office of Civil Rights, millions of healthcare records have been affected to date. In May 2017, healthcare databases in one hundred countries faced a ransomware attack claiming a ransom of \$300 in bitcoin to unlock affected machines [50]. The UK’s Information Commissioner’s Office notes that the health sector accounts for most of the data incidents reported to them. These incidents, along with growing public concerns about big data affecting most aspects of contemporary life, have contributed to a bleak picture of the future of privacy [51]. Understandably, such a picture does not create an environment conducive to the demands of digital health, namely easier data circulation between individuals, devices and institutions. Against this background, the public needs to be reassured that robust security measures are mandated and enforced through clearly articulated policies. Concerns can be addressed with the adoption of appropriate technologies, monitoring and evaluation of security systems, transparency and accountability mechanisms such as legal remedies and compensation for privacy harms resulting from security breaches. Security will continue to evolve, but the big data approach will continue to demand more technical skills, responsive policies and regulatory oversight.

Trust

Essentially what is at stake is the creation of a culture of trust that will enable all stakeholders in the big data ecosystem to benefit from the development of digital health [52]. In particular, public trust in health data uses is of paramount importance. The recent case of the care.data in the UK serves as a good example of how mistrust on the part of the public can derail large-scale data initiatives (see table 2). But trustworthy digital health activities require more than privacy protection. Elements of trust include transparency, accountability, benefit sharing and certainly more clarity about data ownership and data control. What is important here is the realisation that trust cannot only be built through achieving just one element, but rather through a concerted effort to promote all of its elements. Therefore, trustworthiness cannot merely be achieved by innovative consent models offering more or less control of data uses. Rather, consent innovation has to also be accompanied by clarity on how individuals and communities will benefit from digital health developments, by oversight mechanisms that protect common interests and by accountability mechanisms that can sustain public scrutiny.

Accountability

With automated data mining for decisions of clinical or public health relevance becoming one of the most promising features of digital health, accountability is of critical importance. In particular, the adoption of these new tools requires relevant adaptations in existing accountability standards. For instance, in the field of digital epidemiology, data mining can be used to analyse free, unstructured text from social networks in order to make predictions about the spread of infectious diseases [34]. Moreover, mobile technologies can be used to target specific populations with health-related information that can help contain the spread of infectious diseases. These new approaches can increase the speed and accuracy of health dynamics monitoring, leading to more targeted and effective interventions. However, premature reliance on such innovative tools could lead to an inappropriate use of public resources, unnecessary public alarm and individual harm from dispensable medications [55]. Similarly, it is anticipated that medical practice will increasingly be aided by AI algorithms for diagnosis, treatment decisions and surgical procedures [55, 56]. Progress in such areas is expected to greatly improve the quality of healthcare provision for individual patients. Such tools can range from simply providing assistance to practitioners, to possibly one day being fully autonomous from human supervision [57]. Indeed, increasing sophistication could lead to more accuracy. However, as more AI-guided tools become autonomous, fewer human operators are able to override their decisions. Hence, AI-guided medical devices have the potential to jeopardise current norms of professional accountability in clinical practice, making it more complicated to trace responsibility back to individual practitioners. It is therefore crucial that *ad hoc*, robust evidence standards are elaborated to guide the adoption of digital health technologies in clinical practice [58, 59].

Governance approaches in the development of digital health

Global perspective

The strong technological component of digital health does not imply that innovation in this area will affect only the most affluent countries. Recent figures published by the Global Observatory on eHealth of the WHO show that health systems in most countries increasingly rely on data [60]. In fact, the decreasing cost of digital technologies is making it possible also for low- and middle-income countries to adopt telehealth, mHealth, eLearning, electronic health records and big data. EHealth initiatives are underway in 83% of WHO Member States, and 90% of them

Table 2: Case study overview: care.data National Health Service (NHS) England [53, 54].

NHS launched care.data in 2013 as an initiative to collect and store patient data from GPs (general practitioners) around the country in the Health and Social Care Information Centre database (HSCIC; now NHS Digital).
HSCIS already collected hospital data. Analysing GPs data as well was supposed to improve outcomes and customer service, as well as to further understanding of diseases and treatments.
Despite initial endorsement by various professional societies, strong public reactions against the initiative were triggered by concerns about privacy, lack of transparency regarding data access and the involvement of commercial entities.
Reports by the National Data Guardian and the Care Quality Commission that highlighted that inadequacies in transparency and privacy led to the discontinuation of care.data.
The reports emphasised that citizens should be able to exercise their “right to know how their data are safeguarded. They should be included in conversations about the potential benefits that responsible use of their information can bring. They must be offered a clear choice about whether they want to allow their information to be part of this.”
Lessons learned: in order to build public trust in the use of health and care data, initiatives need to meet criteria of trustworthiness, transparency, open communication and a clear sense of the distribution of benefits.

have an eHealth strategy. Different forms of digital health and digital health technology, however, present different patterns of global distribution, with telemedicine being more widely spread than electronic health records, which are more commonly used than big data in healthcare settings. Therefore, despite the fact that digital health represents a global phenomenon, it is adopted and implemented differently across the globe.

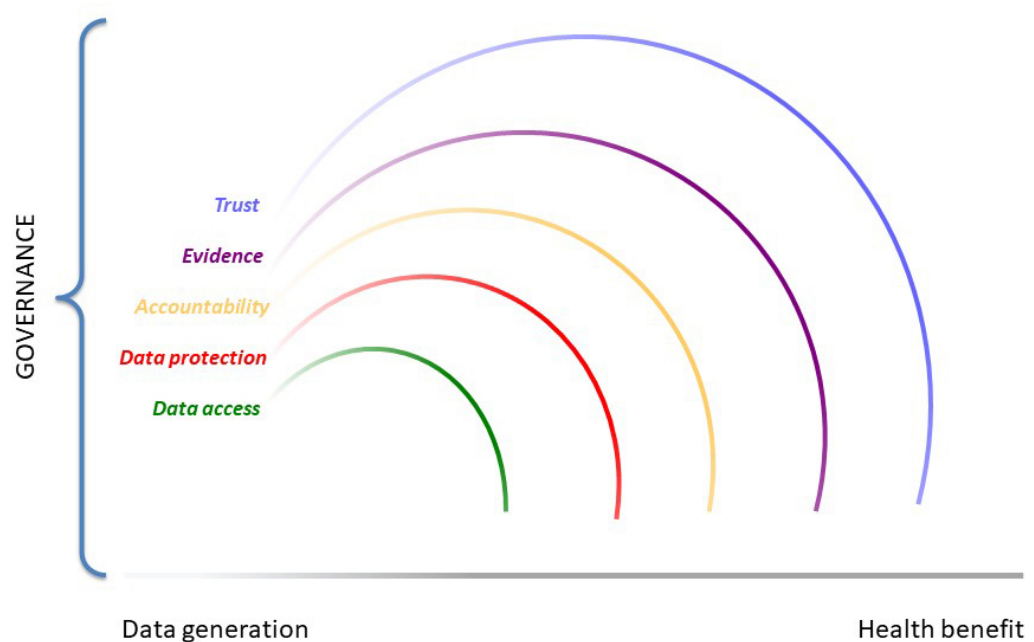
Not surprisingly, from a global perspective the governance of health data appears patchy, with only about half of WHO countries having specific privacy protections in place for personal health data. Robust national data governance frameworks tailored to the needs of real populations are thus considered a precondition for digital health to deliver sustained health benefits and to meet global health objectives such as universal health coverage. In addition, the development of international interoperability standards should continue in order to improve the capacity to monitor health needs and to deliver more effective interventions.

International policy organisations have addressed data governance issues for digital health from a global perspective. The OECD, for instance, has published a set of recommendations for health data governance [61]. Besides endorsing the idea that better health information systems and more efficient data use can improve healthcare provi-

sion, the OECD focuses on ways to maximise the usability of data for public policy, ensuring that health data processing serves the public interest, and secures public trust in data-driven health systems. To this aim, the OECD highlights several areas of intervention, including: promoting public engagement of a wide array of stakeholders; fostering collaboration to enhance interoperability and data sharing; providing clear information to individual data subjects; ensuring appropriate informed consent procedures; pursuing accurate review of data access and data processing requests; promoting transparency through public information about data use; and adopting effective control and safeguard mechanisms to protect personal data.

At the European level, the recently promulgated General Data Protection Regulation [62], which replaced the Data Protection Directive of 1995, aims at creating a more homogeneous legal framework in European Union Member States for the governance of personal data, including personal health data. This new framework stresses the importance of explicit consent to data processing, but recognises that explicit consent is not always possible in the domain of scientific research, in which data originally collected for one project are likely to be re-used by multiple researchers for purposes unrelated to the initial one. The GDPR also recognises that data processing can take place without consent if there is a pressing public health need to be ad-

Figure 1: Conditions of innovation in digital health. This graph describes the conditions for innovation in digital health, for both licensed and non-licensed products and applications. Along the continuum from data generation to health impact, several conditions need to be fulfilled for digital health applications to have a tangible effect on individual and public health. To begin with, sufficient amounts of health data about individuals, as well as other types of data helpful to the detection, treatment and monitoring of health conditions in peoples and populations, need to be accessible to developers. Secondly, digital health products need to comply with data protection and privacy requirements in the countries in which they operate. Third, accountability mechanisms should be in place to trace responsibility for data uses and their consequences on individuals, families and communities. Accountability also ensures transparent communication of health relevant information to data subjects. Fourth, solid evidence of safety and efficacy should back medical claims of digital health products. More rigidly enforced evidentiary standards – including cost-effectiveness requirements – will foreseeably apply to digital health products seeking license from national regulatory agencies (such as the FDA or EMA). Yet, also non-licensed products can and should have sufficient evidentiary bases. Only the fulfilment of all such conditions creates trust in developers and regulators of digital health products and is conducive to fair benefit sharing of digital health innovation.



dressed. Similarly, certain informational rights such as the right to have one's data erased can be limited in the name of public health emergencies, while certain sensitive data – like genetic data, for instance – can enjoy special protections set by individual member states. At any rate, the governance of data processing for research purposes and the processing of data from health registries remain subject to national rules. In terms of governance, the GDPR puts the burden of demonstrating compliance with its provisions entirely on the shoulders of data controllers, thus considerably raising the bar of accountability demands in comparison with the previous data protection directive. Governance should enable digital health innovation to address the challenges discussed above, which include not only accountability but also privacy, quality of evidence, data access and sharing, and ultimately trust. Essentially, these are five key conditions that can determine whether digital health innovation can lead to health benefit (fig. 1). It remains to be seen whether, and how, a global governance approach can achieve this. For any approach it will be crucial to ensure that all stakeholders are involved and engaged. In this respect, the emphasis that the WHO puts on public participation and engagement of broad arrays of stakeholders aptly recognises the need to ensure that digital health serves the public interest and facilitates patients' engagement in health-related decisions.

The Swiss context

The development of digital health faces similar challenges in most developed countries. However, individual countries face these challenges to different degrees depending on the quality of their IT infrastructure, regulatory frameworks, healthcare systems and so on. Currently, a number of significant developments mark a turning point for digital health in Switzerland. First, the enactment of the Swiss electronic patient dossier legislation [63], on 15 April 2017, is an important step toward further digitalisation in the country's healthcare sector. The dossier, a voluntary electronic collection of personal medical documents, is designed to provide healthcare professionals with easier access to patient information, thus improving the safety and accuracy of diagnosis, with the ultimate goal of a positive impact on patient treatment and care. Whereas some Swiss regions have already put digital patient dossiers in place (see for instance the Geneva health information exchange *e-toile* [64], or the project *dossier patient partagé - Infomed* in the canton of Valais [65]), no provider has been officially certified to date, and both the legal and organisational prerequisites are being gradually implemented this year with a view to have the system running by mid-2018. Even though Switzerland benefited from the insights of major ongoing eHealth projects in Europe [66], the process towards more centralisation of national digital health policy-making has been slow and non-linear [67, 68]. Nevertheless, the electronic patient dossier has overcome various political and organisational hurdles and can help advance other digital health services and initiatives, such as the cross-border harmonisation of e-medication records [69]. One crucial factor for the development of digital health is data accessibility. Ideally, data should be made available for further research uses that promise progress in individual or population health, and research and clinical institutions should be willing to open up their patients' data for

that aim. Despite repeated appeals on the importance of data access, however, this practice is still implemented to an insufficient degree. Some barriers to data sharing are more regulatory in nature, such as the inability of data subjects to truly consent to uses that are not foreseeable at the moment of data collection. Some others are more organisational, as in the case of institutions that are reluctant to share data for liability issues. Currently existing patient data are collected through diverse technological systems and with variations in the consent that authorises further uses.

The second important development in Switzerland aims to address this issue through the proposal of a national broad consent template. Spearheaded by the Swiss Academy of Medical Sciences, a so-called "general consent" has been developed after extensive consultation with various stakeholders. The aim of this broad consent is to harmonise the conditions under which further data uses can take place. The model of broad consent has been highly debated in the bioethics literature, however, and commentaries range from full approval to complete rejection [70–73]. Broad consent may not be the ultimate solution to conducting ethical secondary uses of data. However, if accompanied by robust oversight and accountability systems it can be a pragmatic solution that facilitates ethical digital health research [74].

The third relevant development in Switzerland is the launch of the Swiss Personalized Health Network (SPHN) [75] – a national initiative designed to build the necessary infrastructure to improve the utilisation of health-related data for research and innovation. The development of digital health, as that of other data-driven activities, depends on the development of appropriate technical standards to make data securely exchangeable and efficiently computable. Accordingly, the SPHN aims to develop interoperability standards that will enhance data accessibility for research uses in Switzerland. The SPHN's vision on data governance is based on an ethics framework including four principles: respect for persons, data fairness, privacy, and accountability. Such a soft law instrument, while indicating the direction for improving data sharing, is also flexible enough to adapt to stakeholders' organisational needs.

Public engagement

Citizens and patients are increasingly becoming the driving forces behind digital health developments [76, 77]. The extensive adoption and sustainability of health data exchange thus depend upon information technology that facilitates patient engagement and the earning of public trust [78]. To build on the support of the public, it should be made clear that digital health is a tool for citizens and professionals alike [79–81]. This is a condition for fostering trust around digital health [82]. Furthermore, public policy needs take into account the digital divide and the capacity of citizens to engage with e-health [83–86]. And whereas it is certainly important to promote collaboration among healthcare professionals and institutions, other agents, such as start-ups and the industry in general, ought to be included in the country's digital health transformation with mechanisms to incentivise partnership, investments and data sharing [87–89]. This can take the form of public/private partnerships [90], such as the Digital Switzerland Initiative [91] and the Opendata.ch Foundation [92].

Other innovative models to leverage private initiatives and foster public engagement are emerging. In Switzerland, the MIDATA cooperative is a case in point [93]. MIDATA offers data subjects the possibility of storing health data from different sources and leaves it to the data subjects to decide collectively on data access requests [94, 95]. All data contributors are equal shareholders of the cooperative, which is a not-for-profit entity and will re-invest any potential income generated by granting access to its data. This unique model is already active in digital health-related projects in Switzerland and will promote the inclusion of patient-generated data that are needed to develop digital health into clinical applications.

Conclusion

Innovation in digital health faces several ethical and policy challenges. We have argued that, for digital health products and applications to produce tangible innovation and health impacts, be it at the individual or at the population level, five conditions need to be met. First, data are of paramount importance for digital health: access to sufficient amounts of data is thus a primary condition for the development of innovative diagnostic, therapeutic and monitoring tools in this area. Second, alignment with existing legal provisions regarding data protection, data security and privacy are key to digital health innovation. Legal frameworks can thus have a major impact in facilitating or hindering progress in this field. Nonetheless, legal provisions do not address the full range of ethical issues in data processing. Nor do they cover the full spectrum of legitimate concerns of data subjects. Third, robust and transparent accountability mechanisms should ensure the precise identification of responsibility for data uses and their consequences on individuals, families and communities. What is more, accountability also sets up mechanisms for communicating health relevant information to data subjects. Fourth, evidence of safety and efficacy is a significant condition for the success of digital health. Licensed digital health products and applications will have to go through extensive assessment processes and will have to meet cost-effectiveness requirement before they can be reimbursed by insurers and public healthcare systems. This does not, however, mean that unlicensed products and applications can lack some form of evidence to back up their claims. Fulfilling these requirements will foster the fifth condition for digital health innovation, that is, trust in both developers and regulators, which in turn will facilitate the uptake of digital health by healthcare providers and lead to fair benefit sharing of digital health innovation.

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