The datafication of Swiss healthcare and biomedical research: ethical and legal issues and the way forward for health data governance.

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Acknowledgements

Legends say that Cortéz – the famous Spanish conquistador guiding one of the first expeditions to the New World – burned his ships upon arrival to America, in order to encourage his fellow travellers to go on rather than retracing their steps back to Spain. I suspect that there are indeed moments in life where one has to break with the past and forget about it, in order to get motivated and move on. But I am also convinced that many more are the situations where the past has to be cheered and so do the people that have been part of it. As the curtains close and this PhD comes to an end, I would thus like to take up a few lines to cheer at the many protagonists that helped give form to this play of mine.

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Executive Summary

This Thesis presents the research conducted over the course of three years on some ethical and legal challenges related to the governance of data in the Swiss healthcare and research context.

In PART 1, the background to the work conducted during the PhD is presented. Datafication – as a phenomenon – and its epistemological underpinnings are briefly outlined, to then show that they relate to the most current trends how healthcare and biomedical research are evolving. It is illustrated that the *datafication* of these two domains calls for the extensive collection, exchange and linkage of different data, thus exacerbating the challenges related to the governance of such processes. It is then argued that a great deal of such challenges are of an ethical and legal nature and a short overview them is provided. Effectively tackling such ethical and legal challenges requires adjusting governance at the international level, but it is also underlined that the national level should not be neglected, given the different shapes that the datafication of healthcare and biomedical research takes in single countries. Finally, the specific context of Switzerland is introduced, by first illustrating the most important initiatives that have lead healthcare and biomedical research to being increasingly datafied and by then sketching out the legal and ethical challenges that these have raised in terms of data governance.

In PART 2, it is delineated which questions in relation to data governance in Switzerland this PhD investigated and how it went about answering them from a methodological point of view. It is emphasised that there were three main research questions corresponding to three modules to which the original contributions constituting this PhD belong. In Module 1, the ethical issues raised by the collection and use of data through digital health tools were investigated. In Module 2, the focus was on questioning the (un)readiness of Swiss data protection law to keep up with the challenges that datafication of healthcare and biomedical research generates. In Module 3, the challenges in terms of data governance and the evolution of the Swiss health data landscape mentioned during qualitative interviews with national stakeholders were analysed. An overview of the methodological approaches followed in the three modules is also sketched out.

PART 3 contains the original manuscripts that have been written as part of the research conducted in the PhD, divided in the three modules outlined before.

In PART 4, there is an overall discussion of the research conducted in the different modules of this Thesis. With respect to the use of data collected via novel digital health tools, a range of ethical issues that are relevant both in general (e.g. the risk of stigmatisation) and more specifically to Switzerland (e.g. the personalisation of health insurance premiums via data) are extensively examined. With reference to the (un)readiness of Swiss data protection law zo face the challenges of datafication in healthcare and research, it is demonstrated that Swiss law still sticks to the outdated 'consent or anonymise' approach, which in turns contributes to creating a divide between the law-in-the-books and the law-in-action – as exemplified by the study case of data linkage. With regard to the views of expert stakeholders on the challenges raised by the datafication of Swiss healthcare and biomedical research, it is explained how a tension persists around the issue of the control of health data in Switzerland and it

is reflected on the governance changes necessary for the data landscape to evolve in an ethically acceptable fashion.

In PART 5, an overview of the limitations of the research conducted in this PhD is given.

PART 6 contains a brief conclusion, and PART 7 includes the appendices to some of the original manuscripts of this Thesis.

PART 1 – General Introduction

1. General Introduction

The research conducted as part of this PhD Thesis analyses the impact of datafication on the Swiss healthcare and biomedical research sector, in particular with respect to 1) the ethical implications of using data collected via digital health tools to personalise healthcare provision in Switzerland; 2) the question whether Swiss data protection rules on the processing of health data for research are coherent and practice-friendly; and 3) how Swiss health data governance can be improved in the future. To provide a comprehensive background to such research, in the Introduction to this Thesis I shall first reflect on the definition of our time as a 'datafied age' and on the meaning of 'datafication' as a phenomenon, drawing principally from Science and Technology Studies (Section 1.1). In this respect, my objective is to explore the epistemological underpinnings of the phenomenon of datafication, which are important to contextualise the ethical and legal issues that datafication raises in Swiss healthcare and biomedical research.

Second, I will explain how datafication has shaped healthcare and the biomedical research domain by showing that the major trends in these two fields are grounded on the same epistemological underpinnings that characterise the phenomenon of datafication (Section 1.2). In this section, I will also explain that the datafication of healthcare and biomedical research has led to the necessity – within these two fields – that the collection, exchange and linkage of data from different sources is facilitated, as this is an unavoidable requirement for datafication to deliver its promises.

Third, I will argue that the datafication of healthcare and biomedical research and the related need to facilitate the collection, exchange and linkage of data within these domains has exacerbated the problem of (health) data governance (Section 1.3). I will then present the significant role that ethics and law play in data governance and illustrate what are the main ethical and legal issues that the increasing datafication of healthcare and biomedical research has created with respect to data governance. These are: the difficulties in categorising what can be considered as 'data' for the scope of data governance (section 1.3.1.1); the growing indeterminacies related to the concept of 'consent' within data governance (Section 1.3.1.2); the question of 'change of purpose' with respect to data processing and the determination of the exact scope of rules on the 'research exemption' (Section 1.3.1.3); the issues around the idea of data ownership (Section 1.3.1.4); and the delicate interplay of confidentiality with respect to data and patient surveillance (Section 1.3.1.5). I will conclude this section by arguing why such issues related to data governance need to be tackled both at the international, but also (and especially) at the national level (Section 1.3.2).

Finally, I will move closer to the context of Switzerland and provide an overview of the concrete initiatives that have been leading the Swiss healthcare and biomedical research domains to become increasingly datafied, thereby also raising concrete challenges with respect to data governance within the country (Section 1.4). I will then sketch out some of the open legal and ethical questions in terms of data governance in the Swiss healthcare and biomedical research domains, questions which have been the object of investigation for the research presented in this Thesis (Section 1.4.1).

1.1 The datafied age and its epistemological foundations

If this section were to start by reporting a quote saying that…

> "Today in western societies more people are employed collecting, handling and distributing information than in any other occupation. […] Our society is truly an information society, our time an information age."(Mason, 1986, p. 5)

…this would not probably come as a surprise to the reader. What might perhaps be more surprising is to learn that these words do not come from a piece of writing published in the last few years. They are – in fact – the words that Mason used in a forward-thinking article written in 1986 outlining what he described as the "four ethical issues of the information age". As we are nowadays witnessing – almost four decades later than the aforementioned article – society has indeed become datafied[1] to an extent that probably even Mason could have not anticipated, thus amplifying the challenges that the author presented and whose solution, in his words, would determine "whether the kind of [datafied] society being created *is the one we want*" (Mason, 1986, p. 5) (my emphasis).

Determining in which sense it is possible to talk about today's age as a 'datafied' one is not an easy task. What does it mean – in other words – to claim that today's age is 'datafied'?

One first and most immediate answer could echo Masons' words and provide a rather *quantitative* (ac)count of the ubiquitous processes of data collection and data processing that characterize the majority of activities in modern day society. One could refer to the amount of data which are currently produced and its exponential growth,[2] or to the number of data-consuming and data-producing devices that are in circulation (Hilbert and Lopez, 2011),[3] or to the increasing value that data are sold and bought for (Hunter, 2016). Although such first answer might undoubtedly be correct, it is only partial, since it focuses on the number of data collected and on the data infrastructure in a technical sense, but it overlooks some profound cultural and epistemological changes that datafication has brought about.

A second answer thus entails looking at datafication 'as a phenomenon' that has invested our society and changed some of the premises of how the creation of knowledge is conceived, to an extent that it justifies to refer to ours as a *datafied age*[4]. From this perspective, thinking about datafication

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[1] Unless otherwise stated, the term 'data' and 'information' will be used as synonyms in the next sections talking about the phenomenon of datafication. For a distinction between the meaning of data and information - a distinction that is not univocal and changes depending on the discipline considering such distinction - from a philosophical perspective see e.g. (Floridi, 2005), especially at page 353. For a reflection on this distinction from the perspective of public health, see e.g. (Chiolero and Buckeridge, 2020).

[2] Although undoubtedly approximate, some estimates about the exponential growth have been produced by analyses commissioned by industry. See e.g. (IDC Research, 2014).

[3] For example, in 2020 there were an estimate of 3.6 billion smartphone users (Statista, 2021).

[4] The phenomenon here defined as datafication is often referred to (or coupled with) the term of Big data – which was here avoided due to its inherent conceptual vagueness – see e.g. (Favaretto *et al.*, 2020).

requires more than focusing on the increased amount of data collected and the development of data infrastructure(s). As a phenomenon, datafication presents a new paradigm thoroughly shaping today's society, something that goes beyond a mere technological dimension and it rather involves a transformation of how both the world and social action are perceived (Mayer-Schönberger and Cukier, 2013). To define what it means to claim that our age is *datafied*, I shall therefore focus primarily on this second kind of approach, thus investigating datafication 'as a phenomenon' and exploring the epistemology that it embodies.

In literature from the field of Science and Technology Studies, it has been explored how the phenomenon of datafication cannot be reduced to the availability of more tools to collect and analyse an increasing quantity of data. It has been argued that datafication rather reflects the "wider transformation of human life so that its elements can be [conceived] as a continual source of data"(Mejias and Couldry, 2019, p. 2). In other words, datafication 'as a phenomenon' refers to the shift occurred in our age, whereby most of the activities conducted by individuals and most of the events happening in the world are measurable and can be tracked,[5] thus fuelling a tendency to *understand* the world in terms of data. Such shift reflects the (re)emergence of a few epistemological convictions and ideological beliefs that are informing not only specific fields (e.g. data-science), but they are also shaping the way how government, industries and individuals perceive and model their activities. I refer to the changes to which the phenomenon of datafication is connected as mainly 'epistemological'. Whilst epistemology is a highly complicated and multifaceted term (Steup and Neta, 2005), I shall here use it in its rather etymological meaning, that is, a discourse around how knowledge and understanding are conceptualised and produced. In this respect, there are three main interconnected aspects how the phenomenon of datafication is influencing the way knowledge (in its broadest sense) is conceptualised and produced across different societal domains. For a start, the phenomenon of datafication is coupled with the idea that an observable reality exists outside the individual subjective point of view and that it can be accurately represented through data; second, it is assumed that the representation of reality through data (in order to be accurate and objective) should involve processes of *quantification* and *numerification*; third, datafication has brought about the conviction that such data can indeed lead to better understanding of the world and should thus be used to guide action. I will now explore these points more in depth, which – when taken together – might be said to characterise the epistemological underpinnings of the phenomenon of datafication as bringing about a new form of empiricism in today's age (Kitchin, 2014).

First, datafication is characterised by the conception that an objective reality exists independent of the subjects observing it and perceiving it (Mingers, 2001). Consider for example the widespread analogy of 'data as the new oil' (Hirsch, 2013), famously pictured by a front cover of 'The Economist' (Parkins, 2017) in which big-tech companies are represented as oil platforms drilling oil from an ocean (of data). This metaphorical representation reveals the assumption underlying datafication that an

[5] As opposed to the past where the measurement and recording were cumbersome activities.

objective reality exists regardless of the subjectivity perceiving it (just like oil exists before it is drilled by a company out of the ocean) and that such reality can be brought to the surface (and thus be made perceivable) by an activity of mere mining. Indeed, it has been argued that "data-intensive science clearly focuses more on the materiality of the world than the subjective constructions of this reality"(Chandler, 2015, p. 846), because of the epistemological assumption that a well-defined and external (to the subjects' perception) materiality indeed exists. This entails a degree of faith in the tools which are used to extract the data, which are thought of as capable of delivering a digital representation of a material reality. For example, when discussing the case of online platforms recording peoples' behaviour, Van Dijck observed how the data extracted are "generally considered imprints or symptoms of people's *actual* behaviours or moods, while the platforms [allowing data collection] themselves are presented merely as *neutral* facilitators" and "analysts often describe the large scale gauging of [data] as using a thermometer to measure feverish symptoms" (my emphases) (Van Dijck, 2014, p. 199). The limits of such epistemological assumption have been underscored in the sociological studies about technology (Sadowski, 2019; Amaturo and Aragona, 2021). It has highlighted that "data *mining* is a misleading name; a more apt term would be manufacturing" (emphasis in the original) (Sadowski, 2019, p. 2), since – no matter how precise – a 'thermometer' recording phenomena can only lead to a partial representation of such phenomena, due to the unavoidable limitations of any measuring instrument. Indeed, the very idea that a 'reality' exists independently of the observing/measuring subject and that representing such reality through data (derived from measurement) constitutes an act of mere neutral *discovery* is inaccurate: "even the 'discovery' of data carries an implication of human agency: If data are discovered, then someone must be doing the discovering" (Muller *et al.*, 2019, p. 4). Despite these criticisms, the first assumption of a datafied age that "the collected data are a mere reflection or rational representation of [an independently existing] reality" (Mai, 2016, p. 198) resists.

The second epistemological underpinning of datafication as a phenomenon is the idea that processes of quantification and numerification[6] are best suited to accurately and objectively represent reality through data. Quantification and numerification refer to the tendency to prioritise data which are (more) easily analysable because of their standardised nature. Indeed, it has been argued that the very process of datafying – as intended today – consists in "putting [information] in a quantified format so that it can be tabulated and analysed" (Mayer-Schönberger and Cukier, 2013, p. 78). This is because one of the objectives that is associated with the phenomenon of datafication (see below) is to turn virtually everything into data "that can be analysed for patterns and correlations" (Mai, 2016, p. 193). In line with the first feature of datafication exposed above, the preference for quantification and numerification

[6] Here, quantification and numerification are used as close synonyms to indicate the preference – in the datafied age – for structured data (organised in databases with clearly defined variables and definitions thereof) as opposed to unstructured data that require 'cleaning' (to use a word often mentioned in the data-science community) before being analysed. A good example of what quantification and numerification mean is the Google Books project, which provides online access to a plethora of books that have be scanned "in a way that allowed for full-text searching and stored the text in a way that allowed people to search for particular words or phrases across millions of books in a few seconds" (Mai, 2016, p. 193).

offers a way to *reify* reality and present data as neutral and infallible, exactly because they are said to accurately mirror an objective reality that they simply capture (Milan and Velden, 2016). The reification of reality through quantified and numerical data is an essential component of the phenomenon of datafication, whose very essence is not about having just *any* large quantity of data, but rather "about a capacity to search, aggregate, and cross-reference large data sets"(boyd and Crawford, 2012, p. 663) thus requiring data to be of quantified and numerified nature. Needless to say, this conception of data neglects the fact that process of quantification (or numerification) used to create data can never guarantee objectivity, since "like words, numbers are sign systems, and as such they are not to be confused with the object or processes they often claim to represent" (Hansen, 2015, p. 206). At the same time, quantification entails a form of reductionism, since it "reduce[s] all phenomena and means of accounting for phenomena to numbers, [thus simultaneously displacing] other less easily quantifiable albeit insightful ways of expressing phenomena" (Sharon and Zandbergen, 2017, p. 4).

The reason why – despite their inherent limits – datafication entails processes of numerification and quantification can be explained by considering the third feature of such phenomenon. Datafication is indeed characterised by the ideological conviction that quantified and numerified data can offer the basis for knowledge-creation and rational decision making. Data have to be quantified and numerified because "numerical operations are often attributed the quality of providing transparency in the sense of insight and true knowledge" (Hansen, 2015, p. 204). In this context, it is obvious to assume that the data required for the creation of 'true' knowledge need to be analysable through modern computing and automatized techniques, and thus must be a specific type of data (i.e. numerified and quantified) that conforms with such process. It is thus important to underline that the phenomenon of datafication does not simply implies the creation of *any data*: it requires the creation of data which need to be compatible with the type of analysis that they will be subject to (computer-based and increasingly automated) and thus to the purposes which they are supposed to serve.[7] In turn, the purpose of having such data is to use them to generate knowledge of an allegedly superior value ('true knowledge' – see above), due to "the widespread belief that large data sets offer a higher form of intelligence and knowledge that can generate insights that were previously impossible, with the aura of truth, objectivity, and accuracy" (boyd and Crawford, 2012, p. 663). Such belief is linked to an ideological conviction that the "widespread adoption of computers and communications systems along with easy access to electronic information will *automatically* produce a better world for human livings" (my emphasis) (Winner, 1986, p. 105).

[7] A concrete example of what this means is provided by (Hoeyer, 2016): the process of datafication of Danish healthcare entailed the development of uniformed Electronic Health Care record relying on standardises information systems, with the objective of increasing harmonisation throughout the different healthcare providers and facilitating the re-use of data in such records for secondary research. This required a modification in the very nature of how data (and thus what kind of data) is recorded in the records: for example, the space limited for healthcare professionals to write freely (free text boxes) was drastically reduced, since "free text made it more difficult to use data in the daily management of the hospital" even if there was "a decade of scholarly work demonstrating that from the clinical perspective free text is central to patient safety and care". The reduction of non-quantified/non-numerical data (i.e. the free text) in the record was deemed necessary to serve the purpose of re-analysis of the data itself.

Producing knowledge with numerified and quantified data requires the classification and evaluation of such data and – via the data – of the facts, people and behaviours which those data represent. This reflects "one goal of big data analysis [i.e.] to classify and sort people"(Mai, 2016, p. 197). In this respect, "commercial enterprises and state agencies have interests not necessarily in specific individuals, but often in large groups of people and the characteristics that these groups exhibit" (Mai, 2016, p. 197). Therefore, producing 'true knowledge' also requires to characterise and classify individuals and their behaviours based on certain features present in the data. Classification leads to 'knowing' features possessed by single individuals, but at the same time 'individuality' is conceived in a particular fashion. Individuality is seen as the combination (different from person to person) of a series of attributes that the person possesses, *exactly because* she can be classified as belonging to several specific categories of other individuals, who – although different in other respects – share at least one same feature with her. Understanding individuality in this fashion is connected with the idea that numerified and quantified data are best suited at representing people and their behaviours, which – just like anything else – are conceived as an external reality that objectively exists and can be accurately measured. Reaching 'true knowledge' about individuals by classifying them also opens up the possibility to draw normative conclusions deriving from the fact they possess certain features or adopt certain behaviours that can be documented in a numerical and quantified fashion.[8]

In conclusion, datafication can be understood as a complex phenomenon with certain specific epistemological underpinnings about what reality consists of, how it can be measured (that is, through which kind of data), and also what kind of knowledge can be produced by data created through measurement. Although such epistemological underpinnings and their concrete impact can be arguably found in different societal activities – from how public institutions operate, to how private enterprises function, from how scientific research has evolved to how individual behaviour is changing – I shall now turn to the fields which are most relevant for the scope of this Thesis. Indeed, by analysing recent trends in the healthcare and biomedical research domains I will show to what extent the epistemological underpinnings outlined above have had a concrete impact on such trends, thus justifying the claim that healthcare and biomedical research are becoming 'datafied'.

1.2 Datafied healthcare and biomedical research

In this section, I shall square the features of datafication as a phenomenon outlined above with the recent developments and the general evolution of the healthcare and biomedical research domain. In so doing, I shall argue that the major trends in these domains resonate with the epistemological underpinnings of datafication as a phenomenon, thus allowing to claim that such field are becoming

[8] To make a concrete example related to the healthcare sector and to one of the topics touched in the research conducted for this thesis, insurance apps which allow to monitor people health-related behaviour start from a supposedly objective knowledge (e.g. 10'000 steps a day are good for health), classify single individuals between those who align with such knowledge (i.e. walk 10'000 steps) and those who don't, to then reward only the former.

'datafied'. This claim is in line with previous literature, which discuss the spread of the "informational myth" (Nicolosi and Ruivenkamp, 2012, p. 309) in the biomedical field, that is, the idea that the human body (as the object of attention of both healthcare and research) can be understood as a compound of several information, which – if decoded – can lead to progress in both of this fields.

One of the major trends best representing the presence of the epistemological underpinnings of datafication in healthcare and research is 'Precision Medicine'. The latter is a medical model for both healthcare and research whose main idea is to develop "prevention and treatment strategies that take individual variability into account" (Collins and Varmus, 2015, p. 793). Whilst it is widely recognised that such approach is not new in itself, it is however stressed that "advances in genetics, and the growing availability of health data, present an opportunity to make precise personalized patient care a clinical reality" (Hodson, 2016, p. S49). The epistemological underpinnings of datafication are thus at the core at this vision: indeed, the creation and delivery of precise medical interventions is dependent on the assumption that patients' health has an objective and biological dimension that can be measured and classified through (quantified) data, which – in turn – can determine which patients should get what intervention. Indeed, according to the narrative of Precision Medicine "the ability to predict how a 'given treatment will affect a given individual' […] relies […] upon a history of aggregating patient data alongside measurements of therapeutic outcomes" (Phillips, 2020, p. 5). The vision represented by Precision Medicine embodies also to the idea that through data it is possible to create a superior form of knowledge in the medical domain. In fact, precision medicine is linked to "the dream of turning medicine into a deterministic science" (Phillips, 2020, p. 6), where by stratifying patients on the base of accurate (quantified) data it becomes possible to deliver them the best treatment, despite not having entirely resolved the central question of how "generalized knowledge [from individual patient outcomes can be applied] to a new patient who is similar in some respects and different in others" (Phillips, 2020, p. 6). The vision put forward by Precision Medicine has been incredibly influential in the healthcare and research domains, and it has also stimulated the application of the same approach to the field of public health. Here, the idea of promoting 'precision public/global health' has been advanced, its objectives being those of "propos[ing] appropriate, targeted interventions in global public health, thanks to innovation, in order to greatly improve efficacy" (Flahault *et al.*, 2017, p. 2). Even with respect to precision public health, the centrality of data is undisputed (Khoury, Iademarco and Riley, 2016), thus reflecting the same convergences with respect to datafication as in Precision Medicine.

Very similar to precision medicine is another recent trend at the crossroad of healthcare and biomedical research, namely P4 medicine. The four "Ps" giving the name to this approach stand for Predictive, Preventive, Personalized, and Participatory, thus indicating that the essence of P4 medicine is to lead to "the quantification of wellness and the demystification of disease" (Hood, 2013, p. 12) thanks to advancements in system biology and the study of the determinants of both health and disease. The ambition of P4 medicine is to study the underlying biological determinants of well-being, and exploit the knowledge produced through this research to guide interventions in the healthcare sector.

From this perspective "the whole life story may still be portrayed as information that biomedicine can decipher" and "although the whole life process of each individual is defined as complex, this whole […] is defined as potentially quantifiable, predictable and actionable" (Vogt, Hofmann and Getz, 2016b, p. 314). A complementary promise of P4 medicine is thus "to provide a quantifiable metric for wellness" (Vogt, Hofmann and Getz, 2016a, p. 404). It seems thus evident that at the centre of P4 medicine stands the conviction that human health has an objective biological basis, which can (even in this case) be quantified via data, to then tackle the prevention and treating of diseases in a pre-emptive fashion. Again, the epistemological underpinnings associated to datafication are at the forefront of this approach.

Other trends in healthcare and biomedical research that share the same centeredness on datafication and its epistemological underpinnings are Personalised Medicine and Value-Based Healthcare. The definition of Personalised Medicine is often overlapping with that of Precision Medicine – the two approaches are very similar in their essence – and it is often quite vague – with the risk that it "can be misused as a flexible void with a positive connotation that stakeholders fill with divergent meanings according to their interests and preferences" (Schleidgen *et al.*, 2013, p. 10). Personalised Medicine is often described by the succinct the motto of developing "new therapies and optimize prescribing by steering patients to the right drug at the right dose at the right time" (Hamburg and Collins, 2010, p. 301). A more precise definition has been centred on the fact that Personalised Medicine "seeks to improve stratification and timing of health care by utilizing biological information and biomarkers on the level of molecular disease pathways, genetics, proteomics as well as metabolomics" (Schleidgen *et al.*, 2013, p. 10). Whichever the definition, what rests is the centrality of data for such approach, and of the conviction that "the use of genomic and other biotechnologies to derive information about an individual that could be used to inform types of health interventions that would best suit that individual" (Savard, 2013, p. 197). The fact that individual data and measurement should be used to guide research and improve healthcare delivery is also at the base of value-based healthcare, a new approach on how to structure healthcare systems characterised by the requirement that providers focus "on enhancing the quality of their products and services and the efficiency with which they are produced" (Porter and Teisberg, 2007, p. 1104). Essential to this approach is the presence of measurements and data, which are the "vital feedback indicating what works and what does not", given that "every thriving sector of the economy harnesses this kind of information to spur learning [whereas] Health care is the outlier" (Porter and Teisberg, 2007, p. 1106). Even in this case, the parallels with the epistemological premises of datafication as described above are several. Value-Based Healthcare rests on the assumption that objective data about the 'actual' functioning of interventions can be obtained, that such data need to be processed and thus are essentially quantified/numerified in nature, so that they can serve to produce new knowledge to inform and steer care delivery.

A final example of how current healthcare and biomedical research are deeply influenced by datafication – and of how datafication blurs the boundaries between these two fields – is the idea of Learning Healthcare. Initially developed out of a report from the Institute of Medicine in the United

states, which declaimed how "care that is important is often not delivered, and care that is delivered is often not important" (Institute of Medicine, 2015, p. 8), this approach has come to represent the ambition to ensure that there is a continuous flow of knowledge from biomedical research to healthcare and vice versa. The vision offered by Learning Healthcare does indeed revolve around the idea that activities in the healthcare system can be accurately measured through numerical data, which then offer the possibility to install a continuous cycle of improvement by being analysed and producing knowledge that can be fed back into care delivery. Indeed, Learning Healthcare "focuses on exploring the potential of data collected in daily clinical practice as a source of up-to-date minimally biased population-specific knowledge, which could be implemented into clinical practice" (Budrionis and Bellika, 2016, p. 88).

As I have illustrated, all these current trends guiding the evolution of healthcare and biomedical research have datafication and its epistemological underpinnings at their very core. What is also common about them – given the centrality of data in the epistemological underpinnings that characterise them – is the need to harvest as much data as possible. This is achieved by exploiting new sources of data (such as wearables, direct-to-consumer genetic tests and the like) and by calling for the sharing of the data which are collected by the several stakeholders of the healthcare and research domain. In this respect, the desire to see medical sciences as a collective effort has reinforced the call to make data 'open', meaning that access, reuse and linkage of data should be facilitated (Boulton *et al.*, 2011). The necessity to share data is thus portrayed even as an 'ethical imperative', due to the existence of an alleged 'social contract' requiring to generate as much benefit as possible from the data that are collected by the different institutions involved in healthcare and biomedical research (Bauchner, Golub and Fontanarosa, 2016). Based on how the epistemological underpinning of datafication are adapted to these domains, favouring the re-use, sharing and linkage of data become then indispensable prerequisites and also aims to pursue. The call for 'open' data is also advanced with respect to data collected by governmental institutions (e.g. in population-based health registries) or other public health actors (e.g. public hospitals). This is because accessing and reusing such data is seen as the new form to ensure accountability, turning on its head the idea of public service created in the 20th century, which was centred on the need for a certain degree of secrecy (Hoeyer, Bauer and Pickersgill, 2019).

The fact that datafication within healthcare and research feeds on the openness and the exchange of data has been exacerbating the problem of how to govern such practices and how to balance the interests of those parties that have a stake in data reuse, sharing and linkage. I will turn to the challenges in data governance prompted by the datafication of healthcare and the biomedical domain in the next section.

1.3 Data governance of healthcare and biomedical research

In the literature, data governance is normally used in two senses. On the one hand, it is sometimes described – especially in the field of management studies – by referring to "who holds the decision rights and is held accountable for an organization's decision-making about its data assets" (Khatri and Brown,

2010, p. 149). In this meaning, data governance is intended as having a rather intra-institutional dimension, and of consisting in the sum of rules related to how a single organisation can maximize the value of the data assets that it possesses (Otto, 2011). On the other hand, the term data governance also has an inter-institutional or supra-institutional meaning. In this case, governance can be defined as – borrowing from Black's reflections on what regulation broadly means – "the intentional activity of attempting to control, order or influence the behaviour of others" (Black, 2002, p. 25) and – when applied to data – it therefore covers the sum of policies and instruments regulating the processing of data *within and between* different organisations. This broader understanding of data governance has advanced to comprise three overarching elements: rules and policies on the exchange of data; people and organisational body which make and operationalise the rules; and concrete processes that people follow to process the data (Thomas, 2006).

At the core of data governance in the context of healthcare and biomedical research is the pivotal question of how tight the conditions for the use of data should be. In this respect, easier access is depicted as beneficial to the patient, to the efficacy of healthcare and to the quality or research, but it is also described as threatening patients' privacy, patient-doctor confidentiality and health information security (Rosenbaum, 2010). In order to find a balance between these two poles, ethical and legal issues play a central role. Indeed, even if data governance is a broader concept than (legal and ethical) regulation, it is also clear that data governance mechanism should "be designed with ethical, legal and social issues (ELSI) considerations already embedded within it" (Kaye, 2011, p. 381).

1.3.1 Ethical and legal issues in data governance

In the following sub-sections, I shall present some of the most pressing legal and ethical issues with respect to data governance, focussing in particular on those that are especially relevant for the context of healthcare and biomedical research.

1.3.1.1 Categorising what 'data' are

A preliminary but thorny legal and ethical issue in the context of data governance relates to the very meaning of data as the object of governance. Indeed, determining what constitutes *data* is a precondition to understand where data governance should apply. From the perspective of information and computer ethics, it has been postulated that *data* could refer to semantic, syntactic or pragmatic level (Thouvenin, Weber and Früh, 2017) of information[9]. If conceived as being related to the semantic level of information, data would consist in their own structure, that is, the sequence of '0s' and '1s' that can be processed by a computer, or any other symbols which are used to record an external phenomenon (i.e. the letter of the alphabets in cases of interview data). If intended as being related to the semantic level, data would consist in the *meaning* that is conventionally assigned to a series of symbols that a

[9] For a more in-depth discussion of the relationship between data and information, see e.g. (Floridi, 2009).

machine or a human is capable of processing. At the pragmatic level, on the contrary, data refer to the *knowledge* that is derive-able from the meaning of the series of symbols. Whether one interpretation of 'what data are' or another is picked has a significant influence on the scope of data governance. In respect to healthcare and biomedical research, this determines – for example – whether data governance concerns the single units of information in a certain dataset (e.g. the visual representation of a patient's x-ray), whether it only relates to the meaning of those units of information (e.g. the fact that an x-ray image reveals the presence a certain fracture), or to the implications of those units of information (e.g. the fact that an x-ray suggests that a patient should be operated upon or not).

Even from the legal perspective, defining 'what data are' is particularly problematic. Traditionally, data protection law has drawn a sharp distinction between data that are personal – and thus worthy of governance and protection from the legal perspective– and data that are not – which can then be more easily freely used and exchanged. For example, the European Union has recently clarified with a specific regulation that when *non-personal* data are being processed, the main principle should be that of free-flow.[10] From the legal perspective, data governance should then just concern *personal* data, which are almost universally defined as "any information relating to an identified or identifiable person". In this respect, to qualify as worthy of protection, data should just be *relating to* a person, and such person should be *identified or identifiable*. However, the exact meaning of both requisites has generated several doubts. First, the meaning of *relating to* is normally intended as very broad, encompassing data that are *about* a person, or whose *purpose* is that of treating a person in a certain way, or whose *result* is that of influencing a person's rights or interests.[11] However, as it has been observed, basically any data satisfy at least one of these conditions (Purtova, 2018), thus making the first requisite almost redundant – since basically any information would be *relating to* a person. Second, the meaning of *identifiability* has been generally intended as the possibility that the person to whom the data are relating to can be at least singled out from a group (Zuiderveen Borgesius, 2016). Even in this case, it has been argued that the more data analysis techniques advance and the more linkable datasets exist, then virtually any information can become *relating to* a person who is – at least in principle – *identified or identifiable* (Ohm, 2009; Tene and Polonetsky, 2012). Similarly, the traditional assumption that *anonymising* personal data (i.e. eliminating the possibility to link data back to a specific person) is possible has been debunked, thus showing that anonymising data cannot be considered a panacea for reducing legal and ethical risks related to data processing (Ohm, 2009). In terms of classification of data, it is also important to underline that the widely held assumption that different categories of personal data (e.g. health data, socioeconomic data, income data) exist and that they can be easily distinguished is also

[10] Regulation (EU) 2018/1807 of the European Parliament and of the Council of 14 November 2018 on a framework for the free flow of non-personal data in the European Union. Available at: http://data.europa.eu/eli/reg/2018/1807/oj (last access 30.06.2021).

[11] Article 29 Working Party opinion 4/2007 on the concept of personal data, 20 June 2007 ('WP 136'). Available at: https://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/2007/wp136_en.pdf (last access 30.06.2021).

vanishing (Schneble, Elger and Shaw, 2020). Given these uncertainties surrounding both the ethical and the legal definition of which data are worthy of protection, the very scope of data governance is contested.

1.3.1.2 The question of consent(s)

A fundamental tenet of both data protection law and biomedical ethics with respect to data processing has always been that 'informed consent' as a justification for the use of data is of pivotal importance. In the healthcare sector, for example, the consent of the patient has traditionally been a central requirement for the treating doctors to reveal information about their patients to other people (see also Section 1.3.1.5 on confidentiality). Indeed, even for the development of electronic healthcare records – which allow different healthcare providers to easily access all the data related to a single patient – in the last few decades, the process of obtaining informed and voluntary consent was considered an invaluable ethical instrument in the beginning (Kluge, 2004). Similarly, in the research sector, the traditional approach when setting up a research project has been that of illustrating participants – whose data are used – the reason why information is processed and then collect their consent to justify the processing of data for the specific purpose of the research project. However, the creation of the first biobanks and the incremental development of large institutional datasets by healthcare providers and other organisations has increasingly called into question the centrality of consent in the healthcare and biomedical research sectors. Indeed, the very idea of a biobank is to collect biological samples and health data for a series of uses that are not pre-determinable at the moment of collection and for which then informed consent in its traditional sense is difficult to collect. In a comparable fashion, institutional health database often takes form out of the accumulation of routinely collected data (e.g. hospital databases, where the data of the patients who come to get treatment are recorded), for which often consent to do further research is not obtained. In these cases, not only would asking for specific consent for every new data usage be very expensive and troublesome, but it would also risk to become routinized for patients – thus losing its essential function of being there to meaningfully protecting autonomy (Ploug and Holm, 2013).

As a response to this situation, several different solutions have been proposed by lawyers or by ethicists. For example, it has been advanced that consent needs not be related to a specific purpose or use, but that it may also be acceptable if it is given for broad classes of uses (Helgesson, 2012). This would allow to inform people who give their data to a biobank or a databased about the general purposes (rather than the specific projects) for which their data will be used, to then collect a form of 'broad consent', and use this a justification for processing data for multiple research projects without the need to re-contact participants for each new study. Apart from the fact that the conformity of such form of consent with general principles of data protection is sometimes contested, it is also often debated whether such a 'broad' consent can act as an ethically valid substitute of traditional specific consent (Sheehan, 2011), or not – as it does not possess the same informative outreach (Hofmann, 2008; Karlsen,

Solbakk and Holm, 2011). In order to render consent for data usage an engaging – rather than static – process, proposals have also been advanced to create 'dynamic' or 'meta' consent procedures. In the former, patients whose data are used are regularly asked about their consent preferences throughout the lifetime of the dataset in which they participate, allowing them to engage repeatedly and more actively in the consent process (Kaye *et al.*, 2015; Budin-Ljøsne *et al.*, 2017). According to the model of 'meta consent', on the contrary, patients are asked about their meta-preferences concerning the *kind* of consent they would like to give for different types of data or of research, so that they can also pick what level of details they desire about the different uses of their data – allowing them also to allow certain uses of data without being asked for any consent at all (Ploug and Holm, 2015). At the opposite side of the spectrum of patients' engagement, it is also often argued that health data should be usable without any kind of patients' permission, as long as some adequate safeguards are in place and if there is a public interest justifying certain data uses. Patients should – at most – have a right to opt-out from the processing of their data (e.g. for research purposes), if certain conditions are met (Olsen, 2015). Apart from the ethical argumentations underpinning this option, there are also legal grounds supporting it. Indeed, in data protection law it is undisputed that patients' consent is but one of many legal grounds allowing for data processing, other ones being the necessity to execute a contract, the presence of an overwhelming public interest or the necessity to protect a health of the population. In this respect, legal scholars have highlighted that researchers dealing with patients data often run the risk of incurring in the so-called "'consent misconception', a scenario whereby because consent is the favoured mechanism and key ethico-legal norm in research ethics governance, it is perceived that it must also be the case for data protection purposes" even though "there are compelling reasons why […] consent may not be the appropriate lawful basis in the health research context, depending on the type of project" (Dove and Chen, 2020, p. 128,131).

The juxtaposition of different consent models for data processing and the increasing necessity to use data without the constraints that traditional consent entails have been fuelling the debate on the role that consent should play in data governance, a debate which has yet to deliver a definitive and satisfying answers for all stakeholders.

1.3.1.3 Change of purposes and research exemptions

Another legal and ethical challenge in respect to data governance is how to decline the principle of purpose limitation and how to regulate the change of purpose why data are processed. Traditionally, data protection law has been based on the principle of purpose limitation, that is, data can be processed only for specified and pre-defined goals and every change of purposes requires a new legal justification (Brouwer, 2011; WMA, 2016). Similarly, in research ethics it has always been claimed that one prerequisite for consent to data-processing is that the purposes of the research are clear to the consenter and that they do not change (Chassang and Rial-Sebbag, 2018). However, the increasing pressure to facilitate the re-use data which are routinely collected in the healthcare system and in biobanks for

secondary research purposes has highlighted that the traditional legal and ethical positions of purpose limitations are increasingly in contrast with scientific and medical needs (Forgó, Hänold and Schütze, 2017). For this reason, the necessity to find ways to go beyond the purpose limitation principle has emerged. With specific reference to biomedical research, one solution discussed in the ethical domain and already implemented in several legislations is that of creating a specific set of rules for the re-purposing of data for research objectives (Holm and Ploug, 2017; Staunton, Slokenberga and Mascalzoni, 2019). This is often referred to as the 'research exemption' or 'research exception' and it constitutes in legal rules and ethical guidelines allowing the re-use of data originally collected in a specific context (e.g. during the provision of care in a hospital) for research purposes, without the necessity to abide by the normal rules required for a change of purpose (e.g. a renewed consent or a new legal basis) (Shabani and Borry, 2018). However, both the extent and the acceptability of these specific set of rules for when the data are re-used specifically for research purposes has not been immune from criticism (Martani and Hummel, 2021). On the one hand, it could be advanced that the ethical justification for having special rules (i.e. favouring a socially beneficial re-purposing of the data, such as research) might backfire, since the research exemption could be also applicable to research whose objectives are different (e.g. market research). On the other hand, it is empirically questionable whether the presence of specific rules for the repurposing of data for research objectives actually simplifies processes for researchers, since the application of this specific rules often comes with additional safeguards that have to be put in place.

1.3.1.4 Data ownership

Another contested legal and ethical issue in the framework of data governance concerns ownership of data themselves. In ethics, the concept of data ownership is particularly ambiguous. Ownership claims towards data can be said to refer to two main issues: on the one hand, the question of who controls the access to data and their exchange; on the other hand, the question of who stands to profit from the processing of data (Mittelstadt and Floridi, 2016). However, apart from this initial distinction, ownership of data is interpreted in many different ways. As highlighted by Ballantyne, ownership is often thought in terms of private property over data, but such understanding can be misleading, as data – despite being *about* a person – are co-created by the effort of different subjects and they often concern more than one subject (e.g. genetic information also relates to the family) (Ballantyne, 2020). Moreover, whereas calls for enhancing ownership rights towards data are often made with the objective to increase data marketability, there are several ethical concerns raised in this respect, for example that making data fully marketable would entail that – if individuals sell their data – they would lose any kind of control over them, possibly in exchange of a mere small monetary compensation since data acquire value only when aggregated (Hummel, Braun and Dabrock, 2020). From a legal perspective, the idea of ownership towards data is even more contested. First, there are authors who contest the idea that any legal ownership rights towards data should exist, with arguments ranging from

the fact that propertising data (i.e. applying legal ownership rules to data) would infringe on the conception of privacy as a civic liberty, or to the fact that propertisation of data would not solve market failures concerning the exchange of data between parties with different information asymmetries in the data market.[12] Moreover, it is often argued that data, being a resource that does not get consumed even by repetitive uses, could never be subjected to legal ownership rules in a proper sense.[13] However, it is also argued that the fact that clearer legal rules on data ownership would facilitate the development of a market for data would not be undesirable, since data are already exchanged, bought and sold, but in a climate of legal uncertainty (Duch-Brown, Martens and Mueller-Langer, 2017). Specifically with respect to health data – which are considered particularly profitable – it is also argued that promoting patients' ownership would be overall beneficial and would empower them (Kish and Topol, 2015). On the other hand, it is also argued that treating data like property and thus facilitating the selling and buying of data would infringe on human dignity, since health data – like organs – would represent something related to the most intimate private sphere of individuals, and thus not tradable.

In the midst of these uncertainties about the meaning of data ownership and its desirability, the idea of data ownership remains both very appealing and also very used, especially in the healthcare and research domains: it is common to read in data transfer agreements (legal documents often used to exchange data between institutions) that the de-facto controller of a database is referred to as 'data owner'.[14]

1.3.1.5 From confidentiality to patient surveillance

Finally, the last prominent legal and ethical issue often discussed in respect to data governance concerns the changing boundaries of confidentiality. Traditionally, a fundamental principle in biomedical ethics, professional ethics and also legal regulations concerning medical professionals has been that the information revealed (e.g. during a consultation) and produced (e.g. through medical examinations) between a healthcare professionals and their patients should be treated with extreme confidentiality by the former. Indeed, "confidentiality is fundamental to the trust upon which the doctor-patient relationship is founded" (Marsh and Reynard, 2009, p. 164), since it functions as an insurance that both patients and doctors can be forthright to each other. Confidentiality never represented an absolute right, but it nevertheless generates a justified expectation that "information obtained in the course of a medical intervention will be held in confidence by the person who obtains it unless there is a very good reason for disclosing it" (Kent, 2003, p. 16). However, with digitalisation of healthcare and the increasing attention of medicine to the prevention of diseases, the relationship and the interaction

[12] See, for a review of the arguments against implementing legal ownership of data, (Purtova, 2009; Thouvenin, Weber and Fr, 2017) .

[13] But, for a very valid criticism of this view, see (Purtova, 2015).

[14] See e.g. the Data transfer agreements templates used by the Swiss Personalised Health Network, available at https://sphn.ch/services/dtua/ (last access 30.06.2021).

between healthcare professionals and their patients has come to be situated at the centre of different concurrent interests that demand access to the information emerging from this interaction. Information revealed by patients is now easily re-usable for public health surveillance and monitoring, given the benefits that can be reached through the monitoring of diseases relevant to public health. In general, datafication has exacerbated two pre-existing ethical dilemmas interlinked with the topic of confidentiality. On the one hand, the dilemma whether it should prevail the interest of patients to keep information as private as possible or the desire to allow access to all the healthcare professionals who can help provide the best care available (Siegler, 1982). On the other hand, the dilemma whether the interest of the individual to protect information about himself can trump the interest of the community to know what happens in the healthcare system (Myers *et al.*, 2008) – both in terms of public health (e.g. concerning infectious disease) and in terms of healthcare planning (e.g. knowing how prevalent non-communicable diseases are in a certain area).

Moreover, with the datafication of healthcare the transit of data from patients to healthcare professionals has become more dispersed and distributed. Multiple innovative mobile health tools have been developed for treating a range of conditions, tools which do not only allow patients to increasingly self-manage their health at home, but they also multiply the collection of new types of data (Elenko, Underwood and Zohar, 2015). Such data are available not only to the treating professionals to help their patients keep their conditions under control, but they do also pass over to the company that have developed such tools, which can use them to do further research or for other commercial purposes. In this context, "insufficient protections can lead to unauthorized use and disclosures of data, subjecting individuals to possible embarrassment, social stigma, and discrimination" (Hodge, Gostin and Jacobson, 1999, p. 1467). From the legal perspective, an open issue in this regard remains how to regulate the access to the market of such innovative medical tools, considering that, due to the technological innovations that they contain, they cannot be considered as simple tools for which only basic safety requirements needs checking (Garber, 2010; Sorenson and Drummond, 2014; Frigerio, 2016). Moreover, the exchange of data collected by such tools often happens based on complicated contractual terms, which can hardly be said to allow people to exercise autonomy and control over their data. From an ethical point of view, an additional problem related to the fact that collection and exchange of information about a patient's health condition has moved from 'the doctor's room', to the 'patient's home' is linked to the issues of responsibilisation and medicalisation. Responsibilisation is an idea that is receiving increasing support in modern healthcare, according to which health is an individual matter, since "My health is my responsibility, and I have the tools to manage it" (Swan, 2012, p. 108). Responsibilising patients for their own health presents a mix between the desire to empower them to manage their own health in a more independent and also autonomous way, but also to monitor them and increase their accountability for their (good or bad) health status (Sharon, 2017). The same digital tools that allow to share patients' data outside the traditional boundaries of confidentiality also require individuals to take care of the collection of data about their own health and to take responsible decisions

upon those data, for which they can then be hold accountable. Furthermore, the fact that patients' information is less covered by the secrecy of confidentiality is also connected to the increasing medicalisation of different lifestyle. Despite the presence of several definitions, medicalisation refers generally to the increased bearing of medicine in how different aspects of life are conceived (Hofmann, 2016). By extending the gaze of medicine beyond the moment when people are ill and looking for data on the causes of illnesses and on lifestyle (Armstrong, 1995), medicalisation in a datafied healthcare leads to the ambition of creating "a computer representation of the health status of each citizen that […] provides unified access to all information about the patient's health determinants" (Díaz-Zuccarini *et al.*, 2013, p. 13) without the necessary moderation and duty of confidentiality required by healthcare professionals. In this context, the availability and accessibility of patients' data is increasingly taken as a given, regardless of desire of either healthcare professionals or their patients to keep such data privy to them.

1.3.2 International and national data governance

Before turning to how the concrete ethical and legal challenges within data governance are shaped in the specific context of the increasingly datafied healthcare and biomedical research domain in Switzerland, I shall briefly justify why attention to the *national* dimension of data governance is justified. Indeed, I do not dispute that some of the ethical and legal issues within data governance might require to act at the international level (Kaye, 2011), but I also defend the view that several aspects of governance remain to be addressed at the national level. This is particularly true for legal and ethical issues within data governance, since ethical guidelines and data protection law remain at present time a prerogative of individual countries. Regulation (of a legal and ethical nature) of the healthcare sector and the biomedical research are often intimately linked to certain cultural and societal specificities of single countries, thus making it difficult to regulate such practices at the international level. This becomes evident by looking at a concrete case, namely the General Data Protection Regulation recently promulgated by the European Union[15]: even though this Regulation attempted to harmonise data protection law within the European Union, the legislation has actually left a lot of leverage to single states – through the presence of a high number of opening clauses, which allow national regulators to specify amply the rules within country's boundaries (Wagner and Benecke, 2016). On a similar line, a recent recommendation of the Organisation for Economic Co-operation and Development (OECD) on health data governance has also highlighted how domestic policies of single states (still) play a fundamental role (OECD, 2016), thus confirming that tackling data governance issues at the national level is still relevant. In the next sections, I will thus move to the context of Switzerland by outlining the

[15] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data. Available at: http://data.europa.eu/eli/reg/2016/679/oj (last access 30.06.2021).

process of datafication of its healthcare and biomedical research contexts and by sketching the open legal and ethical issues in respect to data governance in the country.

1.4 Swiss healthcare and biomedical research: increasing datafication and new governance challenges

Whilst the datafication of healthcare and biomedical research is an international phenomenon, it articulates itself in different fashion and it has reached different stages of developing in single national contexts. Similarly, ethical and legal challenges in data governance raised by the process of datafication in these sectors vary slightly depending on the country where datafication is taking place. Since the research conducted in this Thesis focuses on the ethical and legal challenges raised by datafication in Switzerland, in the next sections I will zoom in on the specific context of this country.

During the last 20 years, the Swiss healthcare and biomedical research context have made it a priority to transition towards becoming more datafied and digitalised. Datafication and digitalisation have become a priority also because international reports are highlighting that the availability of health data and the medical information infrastructure of the country have been lagging behind – despite the overall high quality of the healthcare system (OECD, 2013, 2015). An extensive review published by the European Observatory on Health System and Policy concerning the evolution of the Swiss healthcare system has also highlighted that two of the main areas subject to recent reforms are that of the data infrastructure and the development of e-health solutions (De Pietro *et al.*, 2015). Indeed, the decentralised structure of the Swiss healthcare system – which is actually constituted by a very complex interplay of private and public institutional actors – has traditionally favoured the fragmentation of health data in different institutions, thus requiring additional efforts for promoting datafication, which – as explained above – requires easy accessibility, exchanged and linkability of data as a necessary precondition. For this reason, the two most important policy documents of the Federal Office of Public Health highlighting general strategies on how to steer the Swiss healthcare in the future feature eminently the topic of improving the datafication of the care system and of biomedical research (Bundesamt für Gesundheit BAG, 2019; Federal Office of Public Health (FOPH), 2021). Apart from the institutional and governmental theoretical commitment to advance datafication, there have been several concrete initiatives demonstrating the national effort to make healthcare and biomedical research more datafied.

One of the most important initiatives of the Federal government in this respect has been the attempt to introduce interoperable electronic patient records all over the country. Swiss healthcare is actually the combination of the healthcare systems of the 26 Cantons (Federal States) which the country is made up of, thus making the exchange of data collected in healthcare institutions belonging to different Cantons very challenging. To remedy this problem – which made it difficult for patients who were treated in one Canton to have their medical information transmitted to the another one, if they switched to a care institution managed by a different Canton – the Federal government issued its first E-

health strategy to create interoperable electronic health records in 2007. As part of the strategy, the main goal of the government was to create the necessary health-information infrastructure to allow Swiss patients to digitally manage all health data about them, regardless of where the data in question were originally collected. Despite the implementation of this project has proceeded by fits and starts (De Pietro and Francetic, 2018), the necessary legal framework for an Electronic Patient Dossier (EPD) was passed in 2015[16] and in 2021 the first EPDs can be finally opened by citizens. The project has encountered several difficulties (concerning e.g. the certification mechanisms of the organisations managing the data infrastructure (Foppa, 2020)) and also presents several in-built limitations (including the fact that only hospital and care homes have the obligations to allow patients to open their EPDs – thus excluding General Practitioners – and that data from the EPD cannot be used for research purposes at the moment). Nevertheless, it represents a considerable piece of evidence of how the healthcare system of the country has sought to transition towards more datafication. A major principle of the EPD is that of facilitating access to data throughout the country in the conviction that better standardised and organised data will allow healthcare professionals to achieve more complete knowledge of their patients, thus improving the quality of care.[17] This aligns with the conception of structured data as a means to produce better knowledge, a fundamental feature of datafication as outlined above.

Another important initiative by the Federation to accelerate datafication has been the reform of the population cancer registries which record data about this illness all over the country. Until recently, population cancer registries could be set up by the single Cantons, but there was no obligation to do so, and the different existing registries were not harmonised. The Federal Government thus passed a law to oblige all Cantons to either set up a population cancer registry independently or to associate to one of the existing ones, in order to achieve better coverage of the whole population.[18] The law also established a mandate for healthcare professionals to report a comprehensive list of different types of cancer, it harmonised the kind of data to be collected for each cancer case in all Cantonal registries and it instituted a special organisation with the task to coordinate and supervise the collection of cancer data all over the country. A further institution, NICER (National Institute for Cancer Epidemiology and Registration),[19] is also present to help do research on cancer-related data and the law also provides the legal basis to create population-based registers on other illnesses in the future (art. 24 of the Federal Law on Cancer

[16] Law on the Electronic Patient Record. The Federal Assembly of the Swiss Confederation. Status on the 17 April 2017. Available from: https://www.fedlex.admin.ch/eli/cc/2017/203/de (last access 30.06.2021).

[17] See information at https://www.patientendossier.ch/de/bevoelkerung/informationen/nutzen/bessere-behandlungsqualitaet-und-mehr-sicherheit (last access 30.06.2021).

[18] See further information on this reform at https://www.bag.admin.ch/bag/it/home/gesetze-und-bewilligungen/gesetzgebung/gesetzgebung-mensch-gesundheit/gesetzgebung-krebsregistrierung.html (last access 30.06.2021).

[19] See the webpage of NICER for further information at https://www.nicer.org/en/home (last access 30.06.2021).

Registration[20]). At the same time, the Swiss Medical Association (Foederatio Medicorum Helveticorum - FMH) also funded a project aiming at mapping the other registers that collect medical data and health-quality data that already existed, but are scattered throughout Switzerland.[21] The project led to the creation of a portal where the existing medical and quality registries are now listed.[22] These initiatives related to medical registries also touch on another important feature of datafication discussed above, namely the tendency to promote the collection of numerified and quantified data about a phenomenon like specific illnesses or health conditions.

More recently, several federal institutions have joined forces to promote the creation of the Swiss Personalised Health Network (SPHN), a network with the objective of promoting the introduction of personalised medicine[23] in the healthcare sector and a more efficient use of health data for research.[24] The initiative has already secured funding for almost 150 million CHF,[25] and its main areas of activity are that of developing a nationally coordinated data infrastructure and improve the interoperability of the many information systems used throughout the country's medical and research institutions (Meier-Abt *et al.*, 2018). The institutions involved in the SPHN include the University hospitals, federal and cantonal universities, the Federal Office of Public Health and the Swiss National Science Foundation, but important partners remain excluded – at least for the moment – such as health insurances, private hospitals and industry (Lawrence and Selter, 2017).

Datafication of healthcare and biomedical research was also promoted by passing new laws on data protection. First, the Federal Government passed a new regulation on biomedical research in 2011 (entered into force in 2014)[26] named Human Research Act (HRA), which contained several rules to better govern the processing of data in this field. One important element of this law that was meant to incentivise the datafication of biomedical research was the implementation of a set of norms to regulate the re-use of health-related and genetic data for research purposes (art. 32-34 HRA). Such rules were meant to – for example – give more legal certainty for those projects based on retrospective research on data collected in the healthcare context (e.g. by hospitals when patients are treated) or for studies based on the re-use of data collected as part of a different research project (Rudin, 2015). Second, a comprehensive reform of the Federal Data Protection Law – which sets the general principles for data processing all over the country – has been underway, with the final version of the law set to come into

[20] Federal Law on Cancer Registration (LCR). The Federal Assembly of the Swiss Confederation. Status on the 1 January 2020 [cited 2020 March 30]. Available from: https://www.admin.ch/opc/de/classified-compilation/20121618/index.html (last access 30.06.2021).

[21] See the overview of the project at https://www.fmh.ch/themen/qualitaet-saqm/register.cfm (last access 30.06.2021).

[22] For the overview of these registries, see https://www.fmh.ch/themen/qualitaet-saqm/register/medizinische-register.cfm (last access 30.06.2021).

[23] For a reflection on how the promotion of personalised medicine is related to datafication, see Section 1.2.

[24] See further details at the webpage of SPHN at https://sphn.ch/organization/about-sphn/ (last access 30.06.2021).

[25] A recap of the funding received is to be found at https://sphn.ch/organization/about-sphn/ (last access 30.06.2021).

[26] Human Research Act (HRA). (2011). Federal Act on Research involving Human Beings. Available at: https://www.fedlex.admin.ch/eli/cc/2013/617/it (last access 30.06.2021).

force in 2022 (Rosenthal, 2020). Despite these two recent legislative changes, the Swiss data protection legal architecture for the healthcare and biomedical research sectors remain very complex. This is due to several reasons, including: 1) the Federal Data Protection Law is only applicable to the processing of data by federal institutions and private persons, whereas cantonal public organisation (such as cantonal hospitals) need to apply cantonal data protection law – given that the legislation of the activities of cantonal offices is constitutionally a competence that the Federation cannot assume; 2) if data are processed for research purposes, the rules of the HRA and the Federal Data Protection Law need to be coordinated in the application of the law.

Several initiatives to favour the datafication of healthcare and biomedical research have also come from research institutions and not directly from the government. The most important ones from a nation-wide perspective are the Swiss Learning Health System (SLHS), the Swiss Biobanking Platform (SBP) and the National Research Programme 74 (NRP 74). The SLHS is a partnership initiated by several Swiss universities to promote the creation of iterative cycles of improvement between healthcare and biomedical research (Boes *et al.*, 2017). To do so, the SLHS has been trying to establish connections between research, policy and practice by developing standards for the management of health data collected by the healthcare system, so that the latter can be used to do research, whose results are then fed-back to practice (Boes *et al.*, 2018). The SBP is a coordination centre for all the human and non-human biobanks in Switzerland that are collecting biologic material and the related datasets and it is aimed at improving the quality of biobanks, facilitating their management and coordination, and promote research based on existing data and biologic material.[27] The NRP 74 is a funding program launched by the Swiss National Science Foundation (SNSF), whose purpose was to fund research projects that could be useful for direct application in the healthcare system and to promote the use and standardisation of medical data in Switzerland.[28]

Despite not being exhaustive, the list of initiatives aimed at promoting the use of data both in the healthcare system and in healthcare research are a sign of the investment that Switzerland has been doing to datafy both of these sectors. As outlined above, the process of datafication is intimately connected with the necessity to make data more easily accessible, shareable and linkable, which in turn generates problems with respect to data governance. These have emerged also in Switzerland and in the next section I shall focus on the main open legal and ethical questions in Swiss health data governance.

1.4.1 Open legal and ethical questions in Swiss health data governance

The datafication of healthcare and biomedical research in Switzerland has exacerbated the need to revise the data governance of data in the country and raised three sets of legal and ethical questions related to data governance in the country.

[27] For further details, see the website of SBP at https://swissbiobanking.ch/ (last access 30.06.2021).

[28] Further information available online at http://www.nfp74.ch/en/Pages/Home.aspx (last access 30.06.2021).

The first prominent set of question concerns the use of data at the individual-level for the personalisation of treatment and potentially also of insurance coverage. The Swiss healthcare system has been traditionally based on a combination of the principles of community solidarity but also individual responsibility (Bircher, 2005; Biller-Andorno and Zeltner, 2015). Elements of solidarity include: 1) the fact that everyone can access healthcare services through social health insurance, since enrolment is mandatory for every resident and 2) premiums are subsidized by the government for low-earners; 3) health insurances cannot refuse to take on any individual, and 4) they cannot make profit from this kind of insurance (Quentin and Busse, 2018). At the same time, there are a lot of features of the system which are underpinned by the idea of fostering individual responsibility for health. For example, every insured person has a franchise in the health insurance (i.e. an amount she has to pay before insurance coverage starts), for any treatment there are co-payments (which are however capped annually) and there are higher co-payments for patients who fill in a prescription with a brand-name drug (when a generic version is available) (Bürgstein, 2015). In the health-policy debate, the desire to strengthen elements of personal responsibility has had a prominent role recently (Moresi-Izzo, Bankauskaite and Gericke, 2010), and it is also increasingly framed to account also for risk-taking behaviours (such as smoking) (Sax, 2017). In this respect, given the possibility that datafication offers to monitor people's lifestyle and responsibilise citizens (Davies, 2021), in Switzerland the idea has spread that financial incentives could be distributed to insured people whose behavioural choices (monitored through the sharing of health data) display a commitment towards being healthy (Stepanovic and Mettler, 2020). The attempt of some insurers to implement such reward-systems has sparked legal controversies,[29] but it has also shown that the idea that health data can be used to individualise health coverage is not simply hypothetical in the Swiss context. Given this tendency and the constantly increasing possibilities that new health tools offer to collect health data at the individual level, the first challenge for Swiss data governance is to determine whether it is ethically tenable to exploit the datafication of healthcare to influence the delicate balance between individual responsibility and solidarity in the healthcare system.

The second important set of legal and ethical questions is related to the transition of data from treatment to research and the conditions upon which such transition can happen. As it has been underlined in the literature about the digitalisation of the Swiss healthcare system, "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" (Vayena *et al.*, 2018, p. 6). This requires – however – to allow data that is collected in the clinical context (for example in electronic health records or in insurances databases containing data on the treatment reimburse to insured people) to pass over to the research context, where the data are then analysed to create new

[29] See e.g. the reaction of the Federal Data Protection and Information Commissioner to the reward system implemented by one health insurance fund available at: https://www.edoeb.admin.ch/dam/edoeb/de/dokumente/2018/Empfehlung%20Helsana.pdf.download.pdf/Empfehlung%20Helsana.pdf. (last access 30.06.2021).

knowledge and inform healthcare policy. This passage poses ethical challenges (i.e. is patients' informational self-determination threatened if their data are re-used without consent?) and also legal ones (i.e. what are the exact data protection rules to respect?). In Switzerland, re-use of routinely collected data from the healthcare system has different kind of legal and ethical oversight depending whether the data-processor is a research institution, a quality-control institution or a governmental institution (e.g. the Federal Office of Public Health) (McLennan *et al.*, 2018). More specifically, if data are re-used for research purposes the Human Research Act poses specific and complex conditions – especially in terms of consent requirements – which have been stirring much controversy (Junod and Elger, 2010). Although there have been attempts to draft legally compliant consent forms for data re-use which could be used all over the country (Salathé, 2017; Fey, 2020; Sprecher and Talanova, 2020), these have only partially succeeded and the matter remains controversial. Specifically debated is also whether (and upon which conditions) linkage of data on the same patient – but scattered across different databases – should be allowed, especially if this wants to be performed by using specific identifiers (such as the social security number) (Egger, Steck and Spoerri, 2015). Alternative linkage methods have been developed, but they present some limitations (for example the fact that they are much more time-consuming) (Schmidlin *et al.*, 2015). This situation is further complicated by the fact that population preferences towards data sharing are particularly important in the Swiss context (Mouton Dorey, Baumann and Biller-Andorno, 2018) – also because of the strong emphasis on individual freedom and political participation in the country. Such preferences express both willingness to contribute with data to research, but also concerns about privacy and other perils related to data re-use (Brall *et al.*, 2021).

A third set of question concerns the control of the existing databases and other sources of data. In Scandinavian countries or England[30], the government and other public institutions with a relatively stronger (in international comparison) centralised structure play a very prominent role in organising medical registries and other health datasets (Furu *et al.*, 2010). In Switzerland, on the contrary, the situation is more fragmented. Health databases exist but they are much more scattered, they are often the product of individual, local and temporally-limited initiatives. Both due to the opposition of data protection authorities and the resistance of single data controllers (including health insurances), merging the data from the different sources is a challenge (Zwahlen, Steck and Moser, 2020). Indeed, data controllers remain very protective of their data in Switzerland, something which according to a recent report (FORS, 2020) is due to several reasons: 1) there is a feeling that data are a strategic asset and should thus be preserved; 2) there is a fear that sharing will lead to data protection breaches, thus undermining the trust towards the institution sharing the data; 3) there is the worry that sharing data with other institutions might lead to finding flaws in the dataset shared or lead to misinterpretation of the data. Such situation opens up the possibility that legal rules (such as the aforementioned norms

[30] For further information on the English approach, see the websites of the National Health System at https://data.england.nhs.uk/dataset and https://digital.nhs.uk/services/data-registers-service#about-data-registers. Or else, see the website of Public Health England at https://ukhealthdata.org/members/public-health-england-phe/ or https://www.gov.uk/guidance/phe-data-and-analysis-tools (for all websites, last access 30.06.2021).

concerning the passage of data from care to research) are instrumentally exploited by data controllers to deny access to the data they manage. It also creates the premise for the development of a stark insider-outsider divide, whereby the managers of a certain database are much more likely to also be using it, whereas external people are encouraged to create their own data collection. This has been recently criticised on ethical grounds, by highlighting that equitable data management requires that patient data are made readily available without regards for private commercial interests (Vayena, 2017).

The research project of which this Thesis consists was indeed focused on tackling these three set of legal and ethical questions that the transition of Swiss healthcare and biomedical research to the datafied age has raised. In the next chapter, I shall turn to the specific research questions of the Thesis, the structure of the different modules in which the manuscripts forming this Thesis is organised and to the methodological approach adopted in the modules.

Abbreviations

HRA = Human Research Act

NRP 74 = National Research Program 74

SLHS = Swiss Learning Health System

SBP = Swiss Biobanking Platform

EPD = Electronic Patient Dossier

1.5 References

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PART 2 – Research question(s), structure of the Thesis and methodological overview

2. Research question(s), structure of the Thesis and methodological overview

The research conducted as part of this PhD is linked to a larger project (Elger, 2018) conducted collectively by a research team of which I have been part. The project in question is aimed at investigating how to promote the merging of health data in Switzerland. Within this broader framework, the research constituting this PhD Thesis has focused on the legal and ethical challenges that the merging of health data sources in Switzerland raises. The aim of the Thesis was thus to investigate the main ethical and legal issues emerging from the datafication of Swiss healthcare and biomedical research. More specifically, the Thesis has dealt with three overarching research questions, which represent the three modules in which this Thesis can be split (see Table 1).

Table 1. Overview of the three research questions explored in the Thesis.

Research question	**Module**
1. What are the ethical implications of the increasing availability of digital health tools allowing to collect medical data and their potential use in the Swiss healthcare system?	1
2. How well does Swiss data protection law come to terms with the datafication of Swiss healthcare and biomedical research?	2
3. What is needed to improve health data governance in Switzerland based on the perspective of stakeholders from the research and healthcare domain?	3

First, the Thesis has explored the ethical issues concerning the use of health data collected through digital health tools to potentially responsibilise individual about their health, both in general and with specific reference to Switzerland (Module 1.). Second, this PhD has investigated a set of legal issues, namely whether the current data protection rules in Switzerland about the use of health data for biomedical research and public health surveillance present any problems and how they could be improved, especially with reference to the secondary use of data (Module 2.). Third, the thesis also includes an empirical module, which draws from expert interviews with stakeholders of the Swiss research and healthcare context to investigate the a) question of health data ownership and b) the way forward for the Swiss health data landscape (Module 3.). In the following sections, I will describe the three research questions of this Thesis, illustrate its structure and provide a methodological overview of its different modules. In-depth details about methodological issues can be found in the individual articles forming the three modules. I will also limit bibliographical references to a minimum, given that extensive references to the literature can also be retrieved in the original manuscripts included in this Thesis. Lastly, it must be preliminarily noted that the various manuscripts included in this Thesis – and indeed the whole research work underpinning this Thesis – is the product of teamwork between the

author of the Thesis and different colleagues and collaborators. The invaluably important role of different colleagues, co-authors and collaborators is explained in great details in the single manuscripts, whereas in the next sections only an overview is provided.

2.1 Module I - Collecting data with digital health tools and enhancing personal responsibility for health

The first module of the research conducted as part of this Thesis focused on the ethical issues raised by the use of data collected with digital health tools for responsibilising citizens about their own health. To investigate this issue, I first conducted a scoping review and ethical analysis of the empirical literature concerning 'Digital Pills', i.e. innovative drug-device combinations that allow the collection of individual health data to help manage patients' medication adherence (Section 1.1). I then carried out a review of the existing apps present in Switzerland that allow users to share individual health data with their medical insurances in exchange for monetary compensations (Section 1.2). Finally, I wrote a theoretical article reflecting on the normative question whether data collected with digital health tools (such as Digital Pills and insurers' data sharing apps) should be used to responsibilise citizens about their own health (Section 1.3).

2.1.1 Scoping review of 'digital pills' and analysis of ethically relevant aspects

The first paper published as part of Module 1 (Martani, Geneviève, *et al.*, 2020) is a scoping review and ethical analysis of the empirical literature published about a new class of digital health tools, Digital Pills. Digital Pills consist in an ingestible sensor that can be combined with traditional medications to record data about medication adherence and other lifestyle health data. The reason for choosing this digital tool as a starting point for Module 1 was twofold. First, reviewing the literature on this specific digital tool allowed me to delve into the topic of how datafication can *practically* be implemented in the healthcare system through a specific digital health tool that collects health data at the individual level with the objective of personalising care. Second, the review focussed on a specific digital health tools that was also of interest for the Swiss context, since a prominent Swiss pharmaceutical industry had started investing in such device (Au-Yeung, 1019) and this technology was also discussed World Economic Forum held annually in Switzerland as a promising approach to personalise treatment in the future (Fox, 2019).

The first paper relied on a scoping review methodology, whose features are presented in depth in the article and here only sketched. Four methodological sources were used to provide the methodological framework for this part of the research: the guide on conducting scoping studies by Arksey and O'Malley (Arksey and O'Malley, 2005); the update of the latter by Levac and colleagues (Levac, Colquhoun and O'Brien, 2010); a guideline for the reporting of scoping reviews by Tricco and colleagues (Tricco *et al.*, 2018); and a general guidance on conducting scoping reviews by Peters and colleagues (Peters *et al.*, 2015). Specifically, this scoping study started from one main research question and a sub-question related to the former:

- *What empirical research has been done where Digital Pills have been tested to collect patients' data?*
- *What, if any, ethically relevant aspects concerning the use of this digital medicine are evident in that empirical research?*

In order to answer such research question(s), a few search engines and medical databases were searched for literature on the topic by means of a search strategy described in the manuscript. Such search lead to retrieve almost 500 items (n=475). At this point, the phase of study selection – typical of both scoping and systematic reviews – started. This included several steps: 1) identifying and removing duplicates; 2) screening retrieved items for eligibility by looking at the abstracts alone and eliminating those which appeared evidently outside the scope of the research question(s); 3) screening the remaining items by reading the whole text and eliminating the ones which were evidently not relevant to answer the research question(s); 4) screening the references of the remaining items to identify potential additional literature. Both steps which required selecting and eliminating items (either through abstract screening or full-text screening) were performed by at least two researchers independently to improve accuracy of such processes – and eventual disagreements were discussed until consensus was reached on the items to eliminate. This process led to finally include 18 items for analysis.

The successive phase of this scoping study consisted in data charting, i.e. the extraction of the information relevant to the two research questions investigated. For extracting the information related to the first question, a data extraction form was developed and used for charting data from each of the included items. An example of the data extraction form as applied to one of the included items is showed in Figure 1.

Figure 1. Example of one compiled data extraction form to collect general information on the studies included in the review.

Background information	
Author (first author, only surname)	Belknap2013
Title	Feasibility of an Ingestible Sensor-Based System forMonitoring Adherence to Tuberculosis Therapy
Year of publication	**2013**
Is the paper merely theoretical?	**no**
Study location (only the nation, e.g. USA)	**usa**
Intervention type (e.g. prospective non-randomized descriptive study)	prospective, non-randomized, descriptive study
Study population (e.g. 16 patients with tuberculosis).	30 Patients with active Tuberculosis
Aim of the study (e.g. test the safety and performance of the pill)	the safety, performance and acceptability of an ingestible sensor. [...] The primary objective was to determine the detection accuracy of the ingestible sensor system when co-administered under direct observation with active TB medications. This included the ability to correctly register when ingestions occurred (positive detection accuracy) and the ability to correctly identify the unique signatures of multiple sensors ingested simultaneously (identification accuracy). A secondary objective was to measure whether the wearable sensor would detect any false signatures. Other secondary objectives were monitoring for adverse events and obtaining feedback from providers and participants.
Specific information about the technology, the producer and the relation with the study	
Name of the producer of the technology used (Proteus digital health, etectRx etc).	Proteus digital health
Is there one (or more) author with a conflict of interest (e.g. employed by the company producing the technology, or declaring other conflict of interests)?	**Yes.** Proteus Digital Health which funded the study is also the employer of authors Kit Yee Au-Yeung PhD, Greg Moon M.D. and Lorenzo DiCarlo M.D.
Was the study explicitly funded or somehow sponsored by the company producing the technology?	**Yes, see above.**

For retrieving information about the second research question, a different approach was used. The research team first met to define what could constitute an ethically relevant issue in relation to the use of Digital Pills to collect patient data. In this respect, we started from – but then decided to go beyond it – the framework provided by Klugman and colleagues (Klugman *et al.*, 2018). Afterwards, each items included in the review was screened to look for pieces of information related to the ethically relevant issues identified, or to new ones that were found when reading the items. Each item was analysed by at least two researchers to increase validity. Moreover, a description of each ethically relevant issue (containing also a justification of why the issue in question was considered to be 'ethically relevant') was drafted and published together with the manuscript.

For both research questions, data charting was performed by at least two researchers independently – to increase accuracy – and divergences in the content of the information extracted were discussed until a consensus was reached. The information collected in this manner was then presented in the result section of the paper, where it is also possible to find further details on the methodology and on the different phases of the review.

2.1.2 Review and ethical analysis of data sharing apps provided by Swiss health insurance funds

For the paper on Swiss insurers' data-sharing apps (Martani, Shaw and Elger, 2019), we first searched the web for information concerning all the insurance companies offering basic/mandatory health insurance in Switzerland and then conducted an ethical analysis of such apps drawing from the methodological approach of casuistry. To identify the apps, a search was performed starting from the list of companies offering basic/mandatory health insurance authorised by the Federal Office of Public Health at the time when the search was performed (BAG, 2018). For each insurance, the relative website was searched for information concerning the availability of an app that would satisfy the following criteria: the app provides general incentives for promoting healthy behaviour, such as daily sport challenges or health tips; AND it provides a series of direct or indirect monetary bonuses as a reward for sharing behavioural health-related data. The full list of criteria for selecting the apps analysed as part of the second manuscript of Module 1. are summarised in Table 2.

Table 2. Inclusion criteria for selecting Swiss insurance data-sharing apps to review

Inclusion criteria to select apps to review	
1. The app is offered by an authorised health insurance according to the Federal Office of Public Health	AND
2. The app provides some kinds of tips/suggestions/incentives to promote 'healthy' behaviour (e.g. daily sport challenges, tips for healthy lifestyle).	AND
3. The app offers direct or indirect (money, discounts on the insurance premium, vouchers etc.) bonuses with a monetary value in exchange for the sharing of health-related behavioural data through the app	

Through this search strategy, we identified and included in our review five different apps, whose feature were mapped and are then presented in the relative article.

On top of reviewing such apps and their features, in the second article of Module 1. we also added a brief analysis of the ethical issues raised by the use of insurers' data-sharing apps in Switzerland. To this aim, we refrained from an analysis based on the principlism approach to bioethics (Beauchamp and Childress, 2013). Indeed, instead of asking 'What questions does the use of these apps raise with respect to beneficence, maleficence, autonomy and justice?', we preferred a bottom-up approach to ethical analysis that we elaborated drawing from casuistry (for literature references, see the manuscript). In brief, an analysis based on casuistry aims at looking at a specific situation to inductively extrapolate more general considerations that can be applicable to similar circumstances to the one under scrutiny. In our case, the specific situation was the use of insurers' data-sharing apps in the Swiss context, from which we tried to extrapolate more general considerations about the impact of digital health tools allowing to collect data at the individual level.

2.1.3 Theoretical paper on the use of health data as a parameter to responsibilise citizens about their health

The third paper (Martani and Starke, 2019) of the first module is a normative piece of research which reflects at the theoretical level on a question emerged when writing the first two papers of the same module. The question at stake in the normative paper is the following:

- Is it appropriate to use data collected with digital health tools to responsibilise individuals about their own health?

The question stemmed equally from the first as well as from the second piece of research in module one. On the one hand, Digital Pills described in the scoping review are indeed digital health tools which allow to collect data showing if an individual behaves in a 'responsible' way with respect to a very crucial health-behaviour, i.e. medication-adherence. Once such data are available, questions

on how (and for what) to use them become prominent. On the other hand, insurers' data-sharing apps allow insurance companies to collect data about 'how healthy' people behave, and the fact that they include some – albeit small – economic rewards hints at the fact that they somehow already use these data to make individuals more responsible about their health.

In terms of structure, this third paper starts with a review of the literature on the concept of responsibilisation in the healthcare domain, followed by a discussion on how digital health tools collecting data at the individual level make 'responsibilising' policies more easily enforceable, to then conclude with a rebuttal arguing why using data collected with digital health tools to responsibilise individuals about their own health would present several ethically relevant drawbacks.

2.2 Module II - Data protection law and health data processing in Switzerland: a legal analysis

The second module of the research conducted as part of this PhD focused on the legal issue whether current data protection rules in Switzerland regulating the collection and (re)use of health data are appropriate. From a methodological point of view, the legal analysis in all the four papers constituting Module 2 of the thesis drew heavily from the *dynamic approach* to legal analysis developed by Rodolfo Sacco in the framework of comparative legal studies (Sacco, 1991a, 1991b; Sacco and Rossi, 2015). In the legal analysis of this module, the main subject of study were different aspects of Swiss legislation on data protection with reference to the processing of health data. To analyse such aspects, Swiss rules were repeatedly compared with the ones present in different legal systems. For example, in the paper on secondary uses of data for research (Martani *et al.*, 2019), Swiss law was compared with rules of EU law, rules from Canada and from the United States. Or else, in the paper analysing the interaction of data protection law and biomedical research in Switzerland (Martani, Egli, *et al.*, 2020), constant comparisons with solutions offered in EU law are present. Lastly, in the paper analysing data protection aspects of Swiss cancer registry legislation (Martani *et al.*, Under Review), comparisons were drawn with the English and Finnish regulations on the same matter.

Whether comparative law as a discipline offers a fully-fledged scientific method, if it offers none, or it offers many, is still heavily debated (Reitz, 1998). In the legal analysis conducted in Module 2, I followed the line of thoughts by Hage, who observed that comparative law offers – if not a fully-fledged methodology – at least some valuable heuristic tools, which help to analyse what the (legal) solution for a societal problem is (Hage, 2011, 2014). In this respect, having chosen one specific approach to (comparative) legal analysis (i.e. the *dynamic approach* by Sacco) allows to present clearly those specific heuristic tools that guided the legal analysis constituting Module 2.

In the following paragraphs, I will describe the main heuristic tools used in the legal analysis of the different papers in Module 2 and present concrete examples of how I applied them in conducting the research for this module.

2.2.1 Considering different 'legal formants'

The first heuristic tool for doing legal analysis according to the *dynamic approach* requires researchers who want to determine what 'the law' says on a specific matter to consider as many 'legal formants' as possible. This is based on the conception that "within each legal system there co-exist different 'legal formants' which may or may not be in harmony with each other" (Sacco, 1991a, p. 30) and that only considering many of them might lead to understand 'what the law says'. Legal formants are the different sources of law, which include "statutory rules, the formulations of scholars, and the decisions of judges" but also "propositions about philosophy, politics, ideology or religion" (Sacco,

1991a, p. 32) within a certain society. In consequence, applying this heuristic tool for legal analysis means that the researcher should consider several of the sources of law on the subject matter of investigation, and not just what one single 'legal formant' (e.g. a rule contained in a statute) says.

For example, in the paper describing the three main nodes where Swiss data protection law interacts with biomedical research (Martani, Egli, *et al.*, 2020) we did not consider only the major pieces of legislation on such topic (i.e. the statutory legal formants). we also relied on some juridical decisions of Swiss courts, which have also contributed to define the legal concept of 'personal data' (i.e. the judicial legal formant). In the same manuscript, when discussing the possibility of processing personal data without consent, we also considered the function and role of Research Ethics Committees to define when the exception to the 'consent rules' provided by the legislation actually applies. In this case, Research Ethics Committees' decisions and practices function as an additional extra-statutory legal formant, which however needs to be considered to better understand the functioning of regulation.

2.2.2 Identifying operative rules

The second heuristic tool offered by the *dynamic approach* to help conduct legal analysis is the necessity to draw distinctions between "operational rules and the formulas which jurists have deemed to describe those operational rule" (Sacco, 1991b, p. 378) in order to properly understand the law on a certain subject matter. Operational rules are the norms that are actually in operation, the "working rules" and they can be opposed to "the discourse used by lawyers to describe, justify, and rationalised the rules" (Monateri, 2003, p. 582). Operational rules are often "inconsistent, empiric and responsive to obscure unconscious underlying ideas [of the practitioners who apply the rules], and in that sense, endowed with a rationality of their own" (Sacco, 1991b, p. 384). Practically, this means that – in order to provide an accurate and factual understanding of 'what the law' on a certain matter actually says – it is necessary to pay attention to how the rules set by the different legal formants are operationalised (e.g. in contracts, agreements, guidelines, and customary practices).

An example of how this heuristic tool was applied to do legal analysis can be found in the article on the law on the secondary use of data for research (Martani *et al.*, 2019). There, the analysis focused not only on the letter of the law about consent rules, but on how these have been operationalised in the various drafts elaborated in Switzerland for having a harmonised general consent form. Focusing on the operationalised rules allowed to show that – from an operational point of view – the distinction between genetic and non-genetic data theoretically set by one legal formant (the Human Research Act) had to be de facto abandoned when the rules on that matter were operationalised within consent forms.

On a similar note, in the paper on data protection rules concerning the recording of data in cancer registries (Martani *et al.*, Under Review), I demonstrated that – although the legislator claimed to have drafted rules that moved away from a consent-based model for data collection (and although the law does technically do not contain any requirement to obtain informed consent to collect data) – the operationalisation of the law creates a situation which closely resembles the one of a 'consent-based'

model. Or else, on the short contribution reflecting on the application of Human Research Act in the field of genetic research (Martani, 2021), I highlighted how a rule – Art. 34 of the Human Research Act, that is theoretically to be applied only in exceptional cases according to the letter of the law – is actually operatively utilised as if it were not exceptional.

2.2.3 Consider implicit norms underlying a certain legal system

The third heuristic tool which the *dynamic approach* provides for legal analysis is related to the concept of "mute law" (Sacco, 1995). In practice, according to the *dynamic approach* to understand 'what the law says' on a certain matter, it is not only necessary to consider different legal formants and pay attention to operational rules. It is also important to consider the underlying (and implicit) elements that influence the way different legal formants are structured, despite not being (entirely or explicitly) expressed in the letter of the law.

For example, in the article on the data protection rules relative to biomedical research in Switzerland (Martani, Egli, *et al.*, 2020), I underlined the importance of the principle of 'informational self-determination' in Swiss data protection law, although the latter is not explicitly present in the Constitution. The importance of this principle is however evident when looking at long-standing legal doctrine (and legal rulings), that have been *implicitly* deriving such principle from an interpretation of Art. 13 of the Swiss Constitution. The importance of the 'informational self-determination' is also representative of an extra-legal element, i.e. the relevance that independence and autonomy of individual citizens have in the Swiss politico-cultural context.

Or else, in the manuscript about the secondary use of data for research purposes (Martani *et al.*, 2019), the main point of the article is to question the underlying assumption which the legislator – when drafting the law – took for granted, i.e. that genetic data are more sensitive than any other health data. Such assumption reveals the implicit adherence of the Swiss regulator to the idea of genetic exceptionalism, which in modern days' datafied healthcare and biomedical research can be highly questionable. Unmasking and questioning such assumptions is an example of the concrete application of the third heuristic tool offered by the *dynamic approach*.

2.3 Module III - Qualitative analysis of semi-structured interviews with stakeholders from the Swiss health data landscape

The third module of the research conducted in this PhD project consisted in the qualitative analysis of semi-structured interviews with expert from the Swiss health data landscape. Here I will summarise the methodology used for both manuscripts belonging this module, but differentiating the specific steps of data analysis done for the two different papers. Further details and more extensive bibliographical references can – even in this case – be found in the individual manuscripts.

2.3.1 Design

This module builds on the research design elaborated for the bigger project where the research conducted for this PhD was nested (Elger, 2018). This project included conducting semi-structured interviews with expert stakeholders from the Swiss health data landscape to explore a variety of issues related to data sharing, ethics norms on data exchange, legal aspects of data linkage and infrastructural aspects about the Swiss health data framework. For collecting information on these topics, it was decided to conduct interviews with people with experience in the aforementioned areas. The design aimed at selecting experts who had mainly practical experience with the handling of data, rather than ethical or legal experts with theoretical experience in the analysis of the ethico-legal challenges related to data processing.

2.3.2 Recruiting and study sample

Experts to be interviewed were selected through a combination of purposive and snowball sampling strategies. For a start, some experts were identified by means of a systematic review conducted by our team (Geneviève *et al.*, 2019), in which Swiss projects involving the cross-institutional or cross-regional sharing or linkage of health data were identified. This allowed to single out some stakeholders with practical experience in the handling of health data. Further experts were identified through further literature research and by exploiting the academic network of the research team. Moreover, experts that were interviewed were asked to recommend further stakeholders who could be contacted, thus adding a snowball element to the recruiting strategy. In this fashion, 58 experts were identified by myself and a fellow PhD student who contributed to this part of the project, 48 of which accepted to be interviewed (22 of which were interviewed by myself and 26 by my colleague).

2.3.3 Considerations related to research ethics

An enquiry concerning the interviews conducted as part of this module was submitted to the local research ethics committee, the Ethikkommission Nordwest- und Zentralschweiz. The latter declared that such empirical study did not require ethics approval according to current Swiss regulation, that it

complied with general ethical and scientific standards and that it could thus start (EKNZ req-2017-00810).

Participants to the interviews did not sign a standard written consent form. They did, however, receive extensive information about the scope and purposes of the interviews, the ways recordings and transcriptions would be handled and the way potentially identifying information was going to be eliminated. Information was provided in writing via email when the experts were recruited and then orally before each interview. If participants did not feel at ease with some of the statements made during the interview, the possibility of checking the transcriptions and requiring the masking of certain statements was offered. To guarantee confidentiality, all potentially identifying information was masked during transcriptions (e.g. if participants referred to personal life events) and no extracts of the interviews that could lead to singling out any of the experts were published nor released.

2.3.4 Data collection

To collect data from the interviewed experts, a semi-structured interview guide was created by the team of the project were this module of the PhD thesis was nested. Both interviewers (i.e. myself and my fellow and colleague PhD student) received preliminary training in qualitative research.

As previously noted, 48 experts were interviewed. These included: 1) biomedical researchers working with different kinds of databases and with experience in linking data from different sources; 2) policymakers and people working in the public administration having roles related to data management (e.g. in the Federal Office of Public Health); and 3) other expert stakeholders working with health data (e.g. directors or managers of private or public health databases).

At a practical level, interviews were conducted in person, via phone or via video-call, depending on the experts' availability and preferences. The great majority of the interviews were one-to-one, but some experts – e.g. if they were working in the same institution – required to be interviewed together. There were thus 39 one-to-one interviews, three one-to-two interviews and one one-to-three interview. Interviews conducted in person were carried out in the offices of the experts or in a place selected by them (e.g. conference room, cafeteria etc.). The preferred language for the interview was English, which is commonly used in Switzerland as a sort of lingua franca in the academic context (Dürmüller, 1992; Andres and Watts, 1993). However, a minority of experts preferred to use their another of the official languages of Switzerland (4 Italian, 3 German and 1 French). These four elements (i.e. different mediums, different sizes of the interviews, different locations, and language variations) might have generated some divergence between the interviews. However, the choice of our research team was to accommodate as much as possible the preferences of the experts, in order to facilitate their recruiting and participation.

All interviews were tape recorded and transcribed verbatim with Maxqda version 18 and 20 (Kuckartz and Rädiker, 2019), a commonly used data-analysis software that caters also for transcriptions. The transcriptions constituted then the data on which analysis was based.

2.3.5 Data analysis

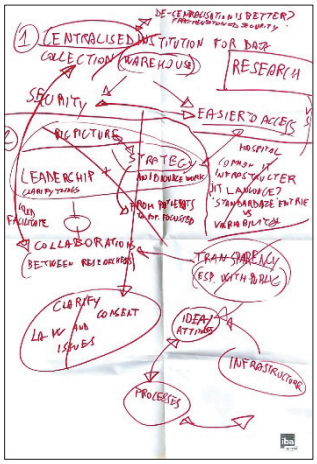
The analysis of the interview data started already during data collection, as it is common for qualitative research. Seven interviews were used as an initial sample for discussion by our research team to start identifying the overarching topics that were present in our data, a process defined by Guest and colleagues as 'segmentation' (Guest, MacQueen and Namey, 2012). More specifically, using the aforementioned software (i.e. Maxqda), different segments were assigned to certain overarching topics (e.g. 'Recommendations') based on their content. As data collection went on, 15 content-rich interviews were also discussed collectively to further categorise the different topic that were discussed by the experts into different overarching categories. I and a fellow PhD colleague used the developed categories to classify segments from all the interviews. After this process, for the two papers belonging to the thesis only the segments referring to the overarching topic of health data ownership and to the recommendations on how to improve the Swiss health data landscape and its governance were considered for the manuscript contained in this Thesis. Segments related to these two overarching topics were extracted in two different databases, which were then used for writing the two manuscripts.

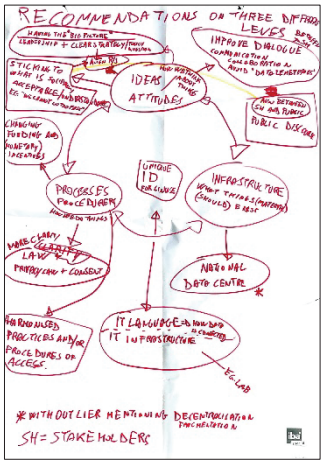
For the manuscript on data ownership (Martani, Geneviève, Elger, *et al.*, 2021), the relative dataset was analysed following thematic analysis according to the indications of Brown and Clarke (Braun and Clarke, 2006). The choice of this analytical approach was based on the fact that can be used to "provide a more detailed and nuanced account of one particular theme, or group of themes, within the data" (Braun and Clarke, 2006, p. 83) – which in this case was the topic of health data ownership. More specifically, having identified the overarching topic of health data ownership during the aforementioned process of segmentation, transcripts were further screened to retrieve all the segments relatable to this topic. All these segments then formed a dataset, in which more specific themes related to the overarching topic of data ownership were identified. These steps correspond to the phases 1 to 3 of Braun and Clarke methods, that is: 1) familiarising with the transcript; 2) identifying initial topics/codes; and 3) searching for themes. The themes identified were then reviewed, refined and collated into a map – as per phase 4 and phase 5 of Braun and Clarke's approach. The themes identified were then used to present and organise the result of the manuscript written on this topic, which were described by general reference to the content of the interviews and also with specific quotes – as prescribed by phase 6 of Braun and Clarke's methodological framework. Further details, the map of the themes and their content can be found in the methods and result sections of the relative manuscript.

For the manuscript on the evolution of the Swiss health data landscape and its governance (Martani, Geneviève, Egli, *et al.*, 2021), the methodological approach for data analysis that was followed is Applied Thematic Analysis as described by Guest and colleagues (Guest, MacQueen and Namey, 2012). In brief, this approach to thematic analysis requires – after having segmented the data and identified an overarching theme on which to focus – to start the identification of themes and codes. In this framework, themes are defined as unit of meaning observed in the data, and codes as textual

descriptions related to the semantic boundaries of a theme or a component of a theme. A list of themes and codes are first drafted by note-taking in relation to the segments considered for analysis and by discussions with the research team involved in the data analysis. Two images representing the discussions of different themes and codes are provided – they show the notes made based on the dataset and the links drawn on a blackboard when the research team met for discussion (see Figure 2).

Figure 2. Images of the blackboard sketched during the discussions by the research team to identify themes and codes.





After identifying potential themes and codes, a codebook (containing both single codes and the themes to which they belong) can start being developed. The refining of the codebook, its accuracy and its reliability can be improved by drafting for each code a schematic and systematic characterisation of the code itself. In the case of this manuscript, this was made by developing a table containing – for each code – the following information: 1) a short intuitive definition of the code; 2) a lengthier and precise definition; 3) indications on the kind of segments which the code could be applied to or NOT applied to; 4) an exemplary segment for the code in question. In Figure 3, an example of how this looked like in our analysis is presented.

Figure 3. Example of an item in the codebook.

Codename:	Data center
Full name	National data center
Brief definition	Creating some kind of centralized institution for the linking or managing of data
Full definition	These recommendations concern the idea of creating an external and neutral office, which could coordinate or help with the linking or the managing of data, rather than for single stakeholders to do everything always on their own. This center would have to serve a public function.
When to use	When stakeholders refer to the idea of creating a further institution or a "space" within an existing institution, fulfilling the role of a data center, i.e. an institution (or a space) with which people could interact to get access to data that they did not directly collect.
When NOT to use	When people speak about other infrastructural elements (e.g. we would need more labs) or when they hint at the need for more leadership.
Example:	"P: Yes, just each person has this number and every time you go to the doctor, you go to spitex, you go anywhere this is registered and you can link it. But I think it needs restrictions who has access to this because it's very sensitive data, this has to be dealt with. You can't um/ yes and it needs some centralized place where this linkage is done. I: So a centralized place for more security I guess? P: Yes, for more security. Well I guess that's more secure if only at one place."

Whilst developing the codebook in this fashion, themes and codes can be refined, merged and modified. Thereafter, the codebook can be used to go back to the segments from the interviews and assign them to a specific code or theme. During this part of the analysis process, segments are checked against the background of the interview were they were placed, in order to ensure that the context of statements was taken into consideration. Codes and themes are then presented in the manuscript describing this analysis and they are accompanied by representative quotes. Even in this case, a more thorough methodological description is present in the manuscript itself.

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PART 3 – Original contributions

3.1 Module I

3.1.1 Digital Pills: a scoping review of the empirical literature and analysis of the ethical aspects.

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Abstract

Background: Digital Pills (DP) are an innovative drug-device technology that permits to combine traditional medications with a monitoring system that automatically records data about medication adherence as well as patients' physiological data. Although DP are a promising innovation in the field of digital medicine, their use has also raised a number of ethical concerns. These ethical concerns, however, have been expressed principally from a theoretical perspective, whereas an ethical analysis with a more empirically oriented approach is lacking. There is also a lack of clarity about the empirical evidence available concerning the application of this innovative digital medicine.

Methods: To map the studies where DP have been tested on patients and discuss the ethically relevant issues evident therein, we performed a scoping review of the empirical literature concerning DP.

Results: Our search allowed us to identify 18 papers reporting on studies where DP were tested on patients. These included studies with different designs and involving patients with a variety of conditions. In the empirical literature, a number of issues with ethical relevance were evident. At the patient level, the ethical issues include users' interaction with DP, personal sphere, health-related risks and patients' benefits. At the provider level, ethically relevant issues touch upon the doctor-patient relationship and the question of data access. At the societal level, they concern the benefits to society, the quality of evidence and the dichotomy device-medicine.

Conclusions: We conclude that evidence concerning DP is not robust and that more research should be performed and study results made available to evaluate this digital medicine. Moreover, our analysis of the ethically relevant aspects within empirical literature underscores that there are concrete and specific open questions that should be tackled in the ethical discussion about this new technological solution.

Background

Healthcare is becoming a data intensive environment where a huge amount of data is both produced and consumed [1]. In this context, digital medicine is assuming an increasingly important role [2, 3]. Differently from *digital health*, a broad term that encompasses all those technical solutions related to health and medicine, such as telemedicine or electronic health records [4], the meaning of digital medicine is narrower. Specifically, digital medicine refers to "those products that are undergoing rigorous clinical validation and/or that ultimately will have a direct impact on diagnosing, preventing, monitoring or treating a disease, condition or syndrome" [5]. Digital medicine includes a wide range of devices, such as temperature-monitoring foot mats capable of automatically detecting diabetic foot ulcers or clinically validated smartphone apps for smoking cessation combined with video tutorials and nicotine replacement therapy [3]. These products share some features with traditional medications – such as the fact that they need approval from regulatory bodies before accessing the market – but they also differ from them. In fact, unlike standard medicines, the functioning of several digital medicine products relies primarily on technological elements, rather then – for instance – on new active principles, in an attempt to combine innovative technology with traditional therapy or medication [6] in what has been also defined as the emerging field of "digital therapeutics" [7].

One of the most recent and advanced technological medication developed in the field of digital medicine are digital pills (DP). DP are drug-device combinations that collect and transmit individual measurement data from patients both in the clinical and the research setting to monitor some health-related lifestyle habits and, in particular, medication-taking behaviour [8]. DP are comprised of three complementary elements: an ingestible sensor, a wearable patch and a mobile application connected to an external web server. The ingestible sensor is a small digital marker that – after being ingested by patients – is activated by the acid fluids in the stomach and releases a signal detectable by the wearable patch. The wearable patch is a plaster applied to the abdomen of the patient that records not only data about the occurred ingestion transmitted by the digital marker, but also other physiological data – such as heartbeat and daily steps. All information collected through the wearable patch is automatically transmitted to an application installed on the patients' phone. The application then uploads the data on a web-based portal, which makes it potentially accessible to the patient herself, as well as her family, and her healthcare providers. DP have been designed to integrate traditional drugs, in that the ingestible sensor can be co-encapsulated with normal medicines to allow a reliable monitoring of medication-taking behaviour and the collection of data concerning other health-related lifestyle habits [8, 9].

DP have been recognised "as a qualified method for measuring adherence in clinical trials" by an opinion of the European Medicines Agency (EMA) in 2016 [10] and at the end of 2017 the first DP combined with a traditional drug was granted market approval as a medication by the Food and Drug Administration (FDA) in the US [11]. The first DP approved as a medication consists in a combination

of this device with aripiprazole, a drug to treat mental illnesses such as schizophrenia or bipolar disorder. The review process by the FDA evaluated the evidence produced by the DP developers and decided for approval arguing that "if the [..] system fails, patients will not incur additional risk; they will continue to receive the exact treatment benefits of aripiprazole tablets without tracking. If the system works as intended and the patient chooses to share the data with the HCP [health care providers], the drug ingestion data could potentially help guide the prescribing physician on treatment interventions" [12].

After the first approval of a DP combined with a traditional drug, it is foreseeable that many other traditional medications will be *digitalised*. In particular, the developers of DP argue that digitalisation of traditional drugs would be particularly useful for the treatment of chronic illnesses, such as Type 2 diabetes, hypertension, Alzheimer's disease and hepatitis C [13]. In fact, medication-taking behaviour is often suboptimal for patients with such chronic illnesses, and finding solutions to help tackle this problem would entail both better health outcomes and great savings in terms of healthcare resources [14]. In this respect, DP have been described as a landmark advancement, since they would "pioneer a path toward improving the quality and cost of care for the millions of people suffering from uncontrolled illness" [15]. Moreover, it has been observed that DP could help improve the communication and the counselling interventions of healthcare providers thanks to the possibility of transmitting real-time reliable data about patients and their health-related behaviour [16].

The idea that traditional drugs are integrated into DP in order to automatically collect and share patients' data has also generated a great number of ethical concerns. It has been argued that collecting data through DP might affect individuals' autonomy [17], represent an unpleasant form of surveillance [18], introduce elements of coercion in the treatment of patients [19], impact on the doctor-patient relationship [18, 20], compromise privacy [21] and over-enhance the idea of responsibility for health [22]. Some authors have even compared taking DP to "swallowing a spy", which would collect and upload a huge amount of sensitive data without bringing any substantial therapeutic benefit to the patients [23]. Others consider DP as a potential first step towards a biomedical "big brother" [24].

Although the ethical issues that the use of DP might generate are extensively discussed, the literature providing ethical analysis of DP is predominantly theoretical in its nature, whereas an ethical reflection based directly on the data emerging from studies where DP have been tested is lacking. With the objective to complement the existing theoretical literature, the purpose of this scoping review is twofold. Firstly, it maps published empirical studies where DP have been tested with patients, in order to provide an overview of the available empirical evidence on this digital medicine. Secondly, it provides - in the context of those studies - a discussion on the ethics of this digital medicine based on the data from the studies were DP were tested.

Methods

To conduct this scoping review, we followed the methodological framework elaborated by Arksey and O'Malley [25] and updated by Levac et al. [26]. We also followed the recently published PRISMA-ScR checklist for reporting of scoping reviews [27].
Within this framework, our questions were:

> *"What empirical research has been done where DP have been tested to collect patients' data? What, if any, ethically relevant aspects concerning the use of this digital medicine are evident in that empirical research?"*

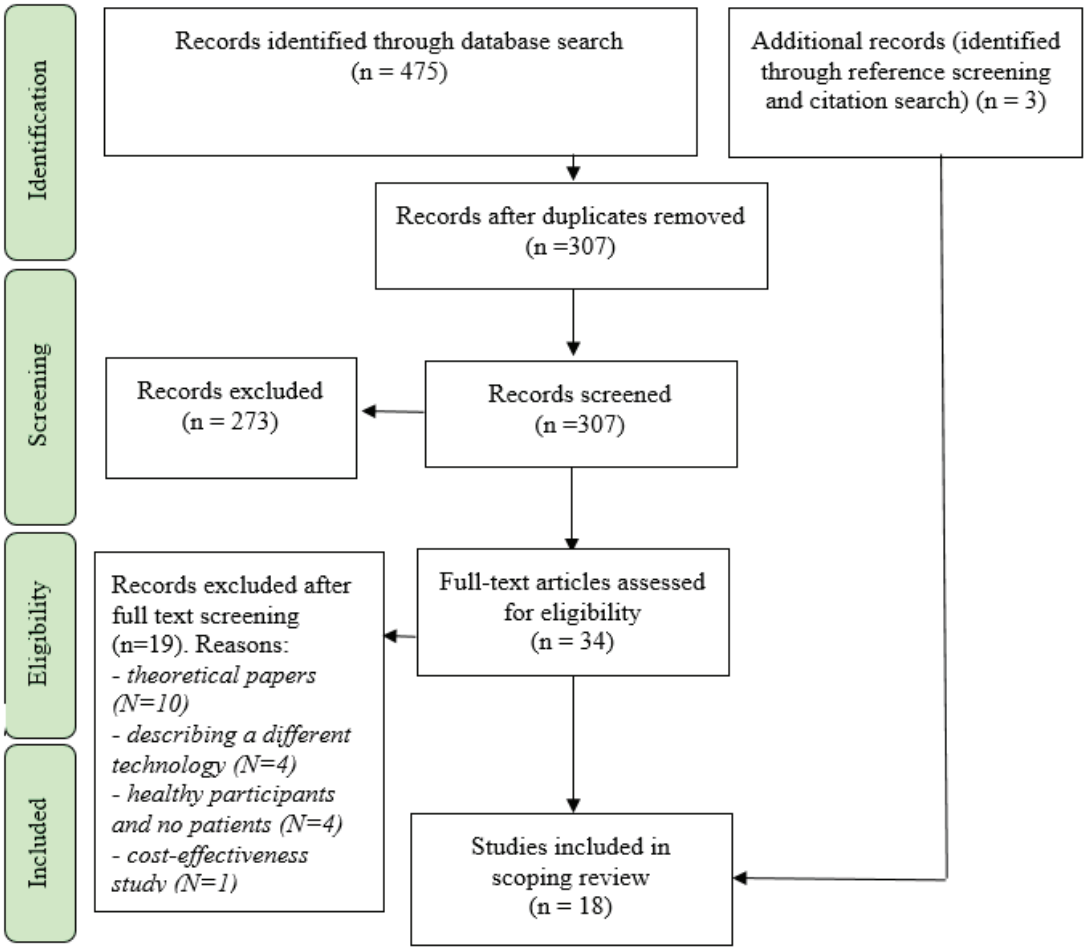
As recommended by Levac et al. [26], these questions are both broad and focused. They are broad in that they address the growing and diverse body of literature concerning DP (i.e. we decided not to limit our quest to the in-patient or out-patient setting or to the use of DP in combination with one specific traditional drug). They are also focused, in that they are limited to empirical research and considered only studies involving patients (i.e. no healthy volunteers). We were aware that much literature of a theoretical nature had been published concerning ethical issues related to DP [28]. However, we decided to focus our research question only on empirical literature since our objective was to ground an ethical analysis on the published empirical studies where DPs were tested.

Search Strategy

In order to retrieve the relevant studies where DP were used in the patient setting, we performed a literature search through four search engines, namely PubMed, CINAHL, Scopus (MEDLINE) and Embase.[1] We built our search strategy as broad as possible to find all the studies that combined the two main subject fields of our quest, namely the DP technology and the context of data collection. We limited our literature search to publications from 2010 onwards, since – through a preliminary search of the literature – we observed that the first DP prototype received official certification of safety and quality only then [29]. Our literature search was conducted on 05/09/2018 and produced 475 results (see Figure 1).

[1] [1] An example of how the search strategy was implemented in a source string to be used in the databases can be found in the supplementary material [Additional file1].

Figure 1: PRISMA flowchart of study selection



Study Selection.

Study selection was divided into three steps, as recommended by Peters et al. [30]. Firstly, duplicates were eliminated, thus reducing the number of records from 475 to 307. Secondly, a preliminary screening based on title and abstract was performed independently by two authors. After the independent abstract screening stage, there was an initial discordance with respect to which records to exclude on 33 papers (10.75%), which was solved through debate until consensus was reached. It was finally agreed to exclude 273 records, either because they were conference abstracts or they did not concern DP. The 34 records remaining after abstract screening underwent full-text assessment for eligibility, which was performed independently by AM, CP and LDG. In this case, the concordance rate between different assessors was 100%. Consequently, additional records (n=19) were excluded, either because they were theoretical papers not reporting on empirical studies with patients (n=10), or because they were describing a different digital medicine technology (n=4), or because they involved only healthy participants (n=4), or because they were cost-effectiveness studies based on hypothetical data (n=1). The final number of included records resulting from our literature search (n=15) was then complemented

by additional papers retrieved via reference screening (n=2) and citation search (n=1). In the end, the definitive number of records wherefrom data were extracted consisted of 18 papers.

Data Charting

For data charting, we decided to be comprehensive and extract both general data about the characteristics of the included studies (e.g. type of intervention, study population) and then information concerning which ethically relevant aspects were evident to the assessors. Every included record was analysed independently by two authors to enhance the accuracy and completeness of data extraction. Data concerning the general characteristics of the studies were recorded according to a data extraction form based on the PICO model, adapted to the specific features of the present review, which included studies with quite different designs. In order to chart data concerning ethically relevant aspects from the studies, we started from the framework developed by Klugman et al. [6]. In their theoretical study concerning digital medicine, Klugman et al. [6] hypothesized that ethical aspects related to DP and similar technologies can be of three natures, namely patient-related, provider-related, and society-related. Although within this framework they also provided a list of ethically relevant issues, we decided not to be bound by their framework in extracting data, since Klugman et al. [6] admit their list is only tentative. We adopted a bottom-up approach and searched for all those aspects in the included records that had an ethical dimension of a patient-related, provider-related or society-related nature. To ensure comprehensiveness and reliability of data extraction with this bottom-up approach, we met and preliminary discussed what could constitute an ethically relevant aspect. After two authors examined each paper independently, they coded all the information that they individually considered of ethical relevance. The authors then met another time to crosscheck the data they coded, they organised them according to themes and justified why they considered the different themes of ethical relevance based on a connection with one of the principle of biomedical ethics [31]. When disagreement emerged, this was solved through debate until consensus was reached. A summary of the reasoning behind the choice of themes and the justification why they were considered of ethical relevance is provided in the supplementary material [Additional File 2]. The authors then refined the specific themes and sub-themes to organise, collate and then report the ethically relevant aspects retrieved from the analysed records. These were then ordered in the categories defined by Klugman et al. [6].

Results

General features of the included studied

This scoping review resulted in the analysis of 18 papers reporting on studies where DP were used to collect individual data from patients. Table 1 illustrates and summarises the general features of the included records.

[TABLE 1 – see end of the paper]

Apart from three studies conducted in the UK and one in Switzerland, the great majority of the studies (n=14) took place in the United States.

In terms of study design, one group (n=14) of the studies were prospective and observational. Within this group, six studies were further described as "pilot" (n=4) or "feasibility" (n=2) studies, two terms that normally refer to trials which are conceived as preparatory to larger confirmatory studies [50]. Two more of this group were additionally described as exploratory, which also refers to studies with a strong tentative component. The remaining studies outside the prospective/observational group (n=4) had slightly different designs. One was a prospective and descriptive study not offering any specific analysis of the data it produced. The others were a randomised cross-over study, a post-hoc study and a human factors study.

The included studies tested DP with patients having a wide range of conditions or illnesses. In total, the 18 studies included 896 participants ranging from 5 [34] to 151 [44]. Six studies included patients with uncontrolled hypertension, where DP were co-encapsulated with different types of traditional medications belonging, for example, to the category of beta-blockers or angiotensin-converting-enzyme inhibitors. In five studies, the patient population was comprised of patients with psychiatric disorders, such as schizophrenia, bipolar disorder or depression. In these cases, DP were used in combination with antipsychotic medication, principally aripiprazole. Three studies included patients with tuberculosis (TB) and in these cases DP were combined with TB medications, such as isoniazid and rifampin. In two studies, DP were tested with patients suffering from acute fractures and they were used together with opioid medications. Two studies included patients suffering from type II diabetes, and DP were combined with metformin or sulfonylurea. Two studies also addressed patients with cardiovascular problems and DP were used in combination with furosemide or other cardiovascular medications. In the only study where the patient population consisted of patients having received kidney transplant, DP were combined with Enteric-coated mycophenolate sodium.[2]

In terms of objectives, the studies had different specific purposes, but they were normally aimed at exploring different features of the DP system, its acceptability and its accuracy. Only one compared traditional therapy with DP therapy [40], since participants were cluster randomised in three groups, one with traditional care and two with DP medications. Only one study [49] compared explicitly the accuracy of the DP in monitoring medication-taking behaviour in comparison with self-reporting by the patient.

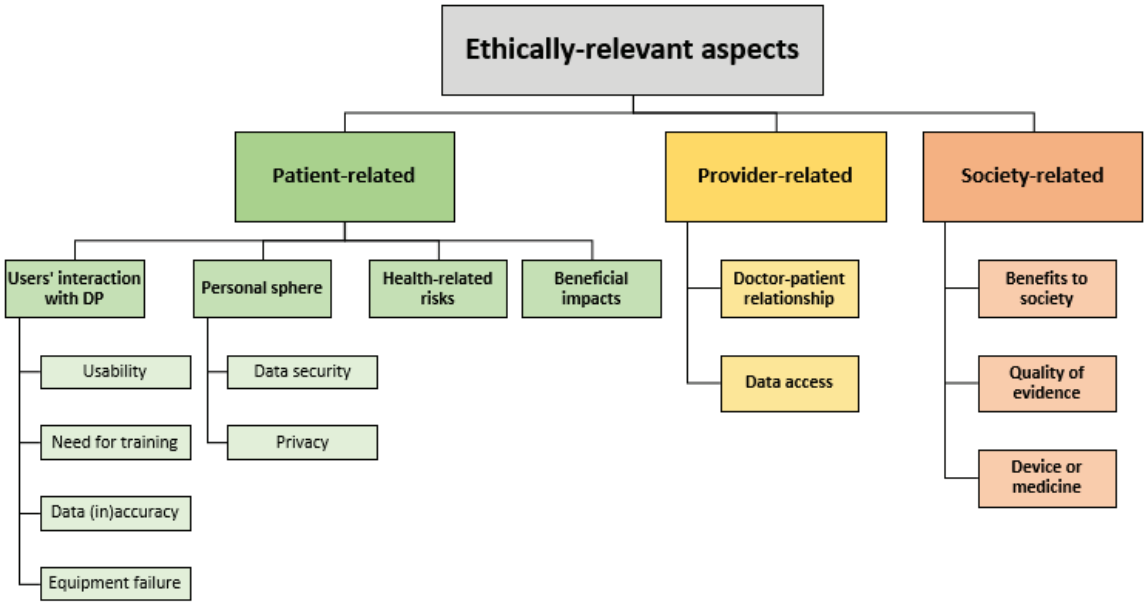
Almost every study (n=16) was approved either by a REC or an IRB. One study [45] reported that in its case ethics approval was not needed. One study [49] did not report any information concerning ethical review or approval. In many studies (n=14), at least one author was an employee or had a conflict of interest to declare concerning his relationship with the producers or developers of DP.

[2] [2] Some records contained details about more than one study and some considered more than one illness.

Ethically relevant aspects

Within the included records (n=18), a wide range of ethically relevant aspects was extracted and presented in Figure 2. As recommended by the methodological framework for conducting scoping reviews [25] and also often made in scoping reviews with an ethical scope [51], results are reported in a narrative fashion.[3]

Figure 2. Ethically relevant aspects.



Patient-related

Patient-related aspects are widely mentioned in the analysed records and they include considerations about the interaction between DP and patients, issues concerning patients' personal sphere, health-related risks and benefits of DP at the individual level.

Considerations about the interaction between DP and patients touch on different topics. Many papers (n=10) reflect on the usability of DP and generally underscore that patients give positive feedback concerning the functional aspects of this technology. For instance, one study [44] claims that "ninety-two percent (92%) of patients reported that they did not mind wearing the wearable sensor. More than 87% of patients reported having a good experience from using the ingestible [*sic*] and thought that it was easy to understand and convenient to use". Ten papers explicitly report that using DP requires some form of training for patients, who, on top of indications concerning the medicine they are taking, also

[3] [3]A detailed depiction of the distribution of ethically relevant issues – clearly organised article per article – is available in the supplementary material [Additional file 3].

need to learn how to operate the wearable patch and the mobile application. For example, one study [46] reports that "the patients received structured training at baseline (BL) and additional direct weekly support/remedial training" and that "optimal performance [of DP] depends on continuous use of the wearable sensor, which requires a patient's ability to regularly replace the sensor and pair it each time with a smartphone application". Another important issue concerning the interaction between users and this digital medicine is whether DP data accurately mirror patients' behaviour. Part of the records (n=7) tackle the issue of the accuracy of the data recorded through DP. Generally, it is underscored that the system is accurate, either by reporting how precise DP are in registering the occurred ingestion or by underscoring that false positives (i.e. DP recording ingestions although these have not occurred) were rare. Lastly, some other papers (n=7) tackle another relevant factor to consider for patients in their interaction with DP, namely the possibility to experience equipment failure. One paper, for example, stresses that data can be successfully transmitted only if the user's phone has signal [37]. Or else, in another paper [42] it is underlined that data transmission can occur successfully only if patients regularly keep their phone near them. Another study [49] also underlines the necessity for patients of contacting technical support to troubleshoot connectivity issues.

Reflections about patients' personal sphere in the studies touched upon the themes of data security and privacy. Almost all the records (n=14) explain that data collection and data transmission are safe and secure, mentioning, for example, that personal information is encrypted [38] or that a secure server is used [39]. Some papers (n=9) also refer to privacy considerations, by underlining the vast amount of personal data that is collected [34], by reporting that these data are collected in a private way as data transmission is confined to the body of patients [32], who are anyway fully aware of being monitored [44]. In one study testing DP with opioids medication given to patients suffering from acute fractures [37], it is argued that "formative interviews of study participants demonstrate their perception that the digital pill maintains patient privacy. […] This suggests that individuals with other stigmatized conditions […] may also similarly accept the data security offered through the digital pill". One study [41] underlines that, despite the close monitoring of patients' activities, "no subjects developed new onset of paranoid ideation".

The last types of ethically relevant aspects at the individual level evident in the studies are health-related risks and the benefits of DP to the health of patients. Almost all records (n=14) address issues related to potential health-risks. The majority of them simply report the adverse effects of DP, which are mostly related to local skin irritation produced by the wearable patch. For example, one study [39] underscores that "2 [patients discontinued treatment prematurely] due to skin intolerance to the APM [adhesive personal monitor, i.e. the wearable patch]" and another study [46] that "there were five TEAEs [treatment-emergent adverse events] (rash, papular rash, rash pruritic, pruritus, skin discoloration) that led to study discontinuation of four patients." Only one study [34] reports that there were no adverse events related to DP usage. One study [47] hints at the possibility that "use errors […] might lead to a patient taking a one-pill extra dose", but then claims that these cases "were rare in the validation study".

In terms of the beneficial impacts of DP, only a minority of the studies (n= 8) report them and considerations are quite disparate and cautious. For example, one study [43] says that its "findings demonstrated improved medication taking for patients", but only when these "are near their mobile device during medication dose times". Another study [40] underlines that "participants [who used DP] had significantly greater reductions in SBP [systolic blood pressure] within 4 weeks than the usual care group" and thus DP "can help patients improve their level of BP and diabetes control".

Provider-related

Two typologies of provider-related ethically relevant issues are addressed in the studies, namely the impact of DP on the doctor-patient relationship and the question of data access (i.e. who – and on what conditions – can monitor patients' data collected through DP).

Ethically relevant issues concerning the relation between healthcare professionals and patients are addressed in several studies (n=14). Some studies highlight that DP could foster patient self-care and self-management. For example, one study [43] says how DP "continuously engages with patients about the pharmacologic and non-pharmacologic therapies of their treatment plan"; another study [38] underlines that thanks to DP "digital health data […] are passively acquired to be provided automatically to patients as part of ongoing feedback on their health behaviors". Other studies, however, claim that DP require more interventions and more interaction with medical professionals since "participants preferred real-time transfer of ingestion data to their physician, especially if their physician could use their ingestion data to intervene at potential times of escalating use [of the medicine]" [37]. Other studies claim that DP are adaptable in this respect, since "assistance from a caregiver was allowed; however, patients were encouraged to use the DMS [acronym for DP] independently" [42]. Eight studies also insist on the idea that DP allow healthcare providers to receive data concerning medication adherence that is "actual" or "objective", in contrast to other methods relying on patients' information (e.g. self-reporting). For example, one study [42], although not providing any direct evidence as to the accuracy of data collected through DP, claims that DP "addresses daily adherence by detecting and registering the ingestion of *actual* doses taken by a patient, it provides an *alternative* and *objective* means of closely managing medication therapy to ensure adherence and optimal outcomes" (emphasis added). Another study [36] stresses that "digital pills […] can provide *direct* and *definitive* evidence of medication ingestion" (emphasis added).

Part of the papers (n=8) also deal with the issue of data access and discuss who can monitor patients' data and at which conditions. In all these cases, studies underline that the patient is in control of data collected through DP and that she is the only one who can determine who else (e.g. family members or healthcare providers) may access it. For example, one study [32] states that "fundamentally, the information gathered by the networked system belongs to the patient user; he or she has the right to determine whether or not and with whom to share this information."

Society-related

As far as the societal level is concerned, three types of ethically relevant issues are present. Firstly, almost the entirety of studies (n=14) mention that DP might bring about considerable societal benefits. Some (n=11) mention how DP could improve prescribing practices and medication-taking. For example, one study [45] underscores that "the information that is collected […] can be used to determine the root cause for uncontrolled hypertension during existing antihypertensive treatment, thereby providing an evidence base for appropriate prescribing recommendations, and a means for avoiding the medicine wastage". Some others (n=3) highlight that DP can help rationalise the use of healthcare resources. For example, it is reported that "the future application of the system could allow more efficient use of resources, particularly personnel" [33]. Lastly, it is hypothesised that DP might contribute to the implementation of individualised medicine (n=7). For instance, one study [43] highlights that with DP "health care providers can view patient data with the use of a patient portal, facilitating more targeted treatment and lifestyle recommendations".

Secondly, a considerable number of studies (n=11) reflect on the limited quality of the evidence they produce concerning DP, due to small sample size and lack of generalizability. For example, one study [46] describes that "most of the enrolled patients were male and black and were rated as mildly ill […] and all were capable of using the smartphone; therefore, the current results may not be generalizable to a more typical population of patients with schizophrenia". Or else, one other study [33] reckons that "the sample size for this feasibility study was small and larger studies are needed to further document the sensitivity, specificity, usability, acceptability, and cost-effectiveness of the system".

Some records (n=8) mention a third important issue at the societal level, i.e. they refer to the fact that the device-components of DP had already received official approval as medical devices, although DP not having yet been approved as medicines, i.e. when used in combination with a traditional drug for curative purposes. In fact, the first versions of the components of DP (i.e. the ingestible marker and the wearable patch) received market approval as class IIa medical devices in 2010 in the EU and they received FDA clearance in 2012 in the US [38]. On the contrary, the first DP used in combination with a traditional drug only received approval in 2017 for the US market.

Discussion

This scoping review offers an overview of published literature where DP have been tested with patients and presents systematically the ethically relevant aspects. The first important finding is that published studies are quite diverse in their design, but are predominantly explorative, non-randomised and with small numbers of participants. This suggests that the evidence publicly available concerning DP is not robust. Indeed, the lack of rigorous control and double-blind methodology in studies testing digital medicine have been described as problematic, since it exposes the validity of research results to both the placebo effect (i.e. the psychological impact of knowing to be taking the medication) and the Hawthorne effect (i.e. the impact of the observer/researcher on the behaviour of participants) [52]. Moreover, small

sample sizes and flexibility in study designs have been described as two important factors that affect substantially the validity of results [53]. It is also surprising that, although some studies explicitly test the accuracy of DP (i.e. whether the device correctly records data about medication-taking), only one of them [49] somehow compares the accuracy of DP with that of another method for assessing medication-taking, namely self-reporting. More evidence in this respect would be particularly important since, even if DP are admittedly not aimed at guaranteeing better medication adherence [54], they nevertheless constitute a system that claims to objectively monitor medication-taking behaviour. From an ethical standpoint, comparing the accuracy of DP in monitoring medication-taking behaviour with that of other traditional methods (e.g. pill counts, self-reporting) would be very important, since it could be a convincing reason to justify the closer digital surveillance and the higher privacy risks that DP entail. Another important finding is the absence of studies on specific age groups, which might have their particular features and present different sets of challenges. For example, focusing on young adults and adolescents might reveal that this age group has aesthetical concerns related to DP, something which has been observed with respect to other body devices for diabetes monitoring and treatment [55].
One further relevant finding that emerges from our results is that DP have been tested in combination with patients suffering from different illnesses. Such variety certainly demonstrates that DP may be applied in different contexts, but it also reveals that little research has been published with respect to the use of DP with every single illness. Although the core elements of this digital medicine remain the same (i.e. they monitor medication-taking behaviour), it cannot be presumed that findings concerning the use of DP with one specific illness could be equally valid for other types of diseases. Every illness presents patients and doctors with different challenges and it is should be studied more in details how DP affect those diverse situations. Moreover, we found only one study [40] that compares DP therapy including a *digitalised* traditional medication with the *non digitalised* therapy. Accurately testing whether the *digitalised* version of a medicine has better outcomes in terms of medication adherence than its *non digitalised* variant would be quite important from an ethical point of view, since it could help decide if there is a substantial interest, for example in terms of beneficence, for society to shift from traditional to *digitalised* medications.

With respect to the ethically-relevant aspects at the patient level, our results indicate that many issues related to the personal sphere of patients, especially with respect to data security, are evident in the empirical literature concerning DP. In this respect, there are two important findings to point out. First, our results show that DP are designed in a way to ensure data security and to protect privacy. However, results also suggest that the protection of the personal sphere is reduced to something that concerns mainly technical aspects (e.g. encryption, security of servers). On the contrary, the moral dimension of privacy, which is particularly relevant in the field of health data management [56], remains underappreciated. DP allow to monitor delicate aspects of people's lives – such as the fact that they are taking medications for mental disorders – thus requiring that also aspects of privacy other than data-

security are considered – such as potential loss of control over the intimate sphere and disempowerment. This is particularly important to decide on the possible future use of DP in the regular clinical context. In the latter case, protecting privacy might not be achieved simply by encrypting the data, but it would require also making sure that patients do not feel indirectly coerced to opt for DP – for example if health insurances expected the use of digitalised medications as a condition to cover treatment costs or employers as a guarantee that workers are preserving their health [57]. Second, the emphasis on privacy being protected at the technical level through encryption or the use of secure servers cannot overshadow the fact that personal aspects of private life are nevertheless monitored and thus potentially accessible to other parties. In this respect, it must be underlined that DP also collects lifestyle data, thus potentially exposing other personal behaviour. Only one study [37] reports that its participants did not express concerns about privacy in a less *technically oriented* meaning, but the study in question did not involve directly the use of DP for the treatment of chronic or stigmatising conditions. Moreover, another study [41] marginally mentions that the close monitoring of patients seems not to be linked with the development of paranoid feelings, but it does not explore in details the potential links between surveillance through DP and paranoia. Investigating this aspect would be particularly important, since – as outlined above – the clinical use of DP involves also the treatment of psychiatric disorders such as schizophrenia.

Our results further reveal that studies acknowledge how DP create a few complications for their users. The system is not always accurate because it depends on some external factors (e.g. that the battery of the wearable patch is charged) and it requires training. Considering these elements is relevant from an ethical perspective, since their impact – for example in terms of quality of life – needs to be evaluated to determine whether DP are truly beneficial for patients. If the promise of DP is to be "smart" [58], then more evidence is needed to verify whether the complications that are related to their technological components do not end up constituting a burden for patients.

Our results at the provider level reveal that two inconsistencies related to the use of DP emerge from the literature. The first concerns the doctor-patient relationship. On the one hand, studies discuss that the objective of DP is to foster self-care and reduce dependency on (and contacts with) healthcare professionals. On the other hand, it is also claimed that DP would require more interventions by health professionals, whose role seems to be idealised – as if they were practically capable of constantly monitoring patients' medication-taking data, to then promptly intervene whenever needed [18]. The presence of this dichotomy suggests that it is not clear whether DP entail an increase or a reduction of workload for doctors in the everyday provision of care. In either case, it is important to ensure that monitoring devices like DP do not compromise the communication between patients and medical professionals, and the support the latter can offer in the implementation of any treatment plans. The second inconsistency concerns data access. By looking at the ethically relevant aspects at the provider level, it emerges that many studies regard as an essential element that control over data access is retained

by patients, so that they can decide freely whether data can be shared with other parties (e.g. family members or healthcare providers). At the societal level, however, studies argue that the advancements in terms of societal beneficence – such as providing individualised care or improving medication-taking behaviour – are essentially dependent on the sharing of data between patients and other subjects. None of the records discusses how the apparent contradiction between these two claims – that patients have free choice whether they want to share their data and that societal benefits require sharing of data – can be resolved.

With respect to the societal level, the most relevant results concern, again, the quality of the empirical evidence available of DP studies. As noted by Vayena and Ienca [59], an essential element for the ethical assessment of digital medicines is the presence of significant empirical evidence concerning their functioning, their benefits and their risks. In particular, it is important that preliminary studies of a device have representative samples whose results are generalizable and have external validity, so that they can be assumed to apply to the wider public that will make use of the technology after its approval [60]. Our results show that the great majority of published DP studies acknowledge significant limitations related to small sample sizes and thus to the generalizability of results. This indicates that comprehensive evidence to thoroughly assess, for example, if the extensive use of DP can improve the cost-effectiveness of certain treatments in a given healthcare context, is lacking.

Moreover, results concerning the societal level raise two further important issues. Firstly, the question emerges whether the use of DP is beneficial from the collective perspective. In the included studies, there is emphasis on the societal benefits achievable through the digitalisation of traditional medicines. However, no concrete evidence in this sense is produced directly by the studies themselves. Societal benefits are simply mentioned as hypothetical and future outcomes of the extensive use of DP. To truly prove the cost-effectiveness of DP, a comparison would have to be made between the traditional version of a medication and its corresponded digitalised form, both in terms of outcomes and of costs [61]. During our literature search, we had retrieved one cost-comparison study concerning DP [62], but we excluded it since its findings were based on calculations using hypothetical data. The second issue concerns the repetitive mentioning of the approval of the technological components of DP as medical devices. This underlines that a societal reflection is needed to decide whether to keep this existing dichotomy, where a much different path of approval exists for medical devices in comparison to drugs. The first one is much less restrictive and it is comparable to the type of approval of washing machines, lawn mowers or videogames consoles [63]. Moreover, possibilities exist in some states to further reduce governmental control concerning approval for market access if medical devices are deemed to be substantially equivalent to previously cleared devices – such as the often criticised 510 (k) process in the US [64]. Given the profound impact on many aspects of treatment that digital devices like the ones included in DP can have, this reinforces the existing claim that the approval process of this kind of devices should be modernised [65].

Limitations

Limitations of this review include the fact that the search strategy was limited to some databases and that the relatively newness of this digital medicine entails a terminological unevenness amongst publications which makes it difficult to capture all the published work. Even DP – the name chosen for this manuscript – is not uniformly used throughout the literature. However, the fact that we complemented our initial search not only by screening the references, but also by citation search gives us confidence about some level of completeness of our review among published data. We nevertheless acknowledge that – due to the nature of the approval process for digital medicines – there could be other DP studies that are not published and hence unavailable to the team. Another limitation is the way we gathered ethically relevant issues from the included papers, which could be subjective. To increase transparency of our decision making process, we have explained our rationale in the Additional file 2. Lastly, being our focus on published work of an empirical nature, we have not included all the literature of a theoretical nature, where many ethical issues concerning DP have been thoroughly discussed, and unpublished work. Companies developing DP might not publish some of the studies they have conducted in academic journals and the authors have no resources to contact companies and get such information. Yet, the purposes of this review were indeed to explore empirical literature concerning DP and ground an ethical analysis in the elements evident directly therein, in an attempt to bridge the gap between literature reporting on studies where DP were actually tested and the theoretical literature on this digital medicine.

Conclusions

DP represent an example how digital medicine - and indeed more in general the application of technology to the field of healthcare – is a complex and divisive field of enquiry, where enthusiasm for innovation and diffidence from the ethical perspective clash. To help overcome this deadlock with respect to DP, this review has provided more clarity about the content of empirical research currently available. It has presented an overview of the empirical literature on DP and has mapped the ethically relevant issues mentioned therein, in order to discuss some aspects of new technology with a less theoretical approach. This sets the basis for future research and discussions concerning both the potential and the concerns related to a wider use of DP and the digitalisation of traditional drugs.

List of abbreviations

DP: Digital Pills

EMA: European Medicines Agency

FDA: Food and Drug Administration

REC: Research Ethics Committee

IRB: Institutional Review Board

TB: tuberculosis

ECMPS: Enteric-coated mycophenolate sodium

MDD: major depressive disorder

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of data and material

All the data were retrieved from articles from publicly available databases and it is presented in the tables and the additional material of this manuscript. The review protocol and the data extraction form are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

AM, LDG, CP and TW contributed to the design and planning of this literature search. AM, LDG, CP and TW participated in the data collection, which for this manuscript includes organisation and selection of the records retrieved through the literature search and data extraction. AM, LDG, CP, CC and TW participated in data analysis that comprised charting of the data, their classifications into ethically relevant issues and data interpretation. AM wrote the first draft of the manuscript. LDG, CP, CC and TW critically and substantially revised several versions of the manuscript and incorporated new ideas. All authors read and approved the final version of the manuscript.

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Table 1: Overview of the features of the studies

Paper ID[a]	Country	Study design	Study population	Aim(s) of the study	REC/IRB[b] Approval
Au-yeung2011 [32]	USA	3 prospective observational studies	30 patients with Tuberculosis, 8 with Heart Failure, 43 with Hypertension[c]	Evaluate the system and characterize technical performance.	Yes
Belknap2013 [33]	USA	Feasibility study: prospective and observational.	30 patients with active tuberculosis (TB)	Evaluate accuracy, safety and acceptability of the system.	Yes
Browne2015 [34]	USA	Prospective observational cohort-study	5 patients with type II diabetes	Characterize the at-home adherence patterns of patients through modern methods of visual analytics.	Yes
Browne2018 [35]	USA	Randomized cross-over study	12 patients with active tuberculosis	Address Good Manufacturing Practice methods to combine the ingestion sensor with oral medications.	Yes
Chai2017a [36][d]	USA	Prospective descriptive study	16 patient with acute fractures[e]	Report data on opioid ingestion patterns detected by DP	Yes
Chai2017b [37][d]	USA	Pilot study: Prospective, non-randomized and observational.	10 patients with acute fractures	Determine the feasibility the digital pill system to measure opioid ingestion patterns	Yes
Dicarlo2016 [38]	USA	Feasibility study: prospective, non-randomized, observational.	37 patients with hypertension	Record patterns of medication-taking, step count, daily blood pressure and weight. Study safety and acceptability of digital pills	Yes
Eisenberg2013 [39]	Switzerland	Exploratory study: open-label, non-randomised and prospective.	20 patients after kidney transplant under Enteric-coated mycophenolate sodium (ECMPS)	Evaluate the detection accuracy, usability, and safety of DP combined with ECMPS in kidney transplants.	Yes
Frias2017 [40]	USA	Pilot study: prospective, open-label, cluster-randomized (three arms).	109 adults with uncontrolled Hypertension and type II diabetes	Study the effect of digital pills on blood pressure, glycemic and lipid control, engagement, and provider decision making.	Yes
Kane2013 [41]	USA	Pilot study: observational, non randomised.	28 subjects with schizophrenia (16) or bipolar disorder (12)	Compare the detection accuracy to that of a directly observed method. Characterise safety and user satisfaction.	Yes

Kopelowicz2017 [42]	USA	Pilot study: observational, open-label and non-randomised.	49 subjects with bipolar disorder, major depressive disorder, or schizophrenia	Evaluate the functionality of an integrated call center in optimizing the use of the digital pills and assess its use.	Yes
Moorhead2017 [43]	USA	Post hoc studies based on a study following a cluster randomised design.	113 patients with uncontrolled hypertension.	Study the incremental impact of seeing versus not seeing DP medication dose reminders on medication taking and assess the safety of the digital pills with respect to possible risk of overdosing.	Yes
Naik2017 [44]	UK	Prospective registry-based observational study.	151 patients with uncontrolled hypertension[f]	Characterize patterns of medication use. Assess usability and acceptability of digital pills.	Yes
Noble2016 [45]	UK	Prospective observational study.	39 patients with uncontrolled hypertension	Report and summarise the first use of digital pills by pharmacists to establish blood pressure management recommendations.	Not required
Peters-strickland2016 [46]	USA	Phase II open-label observational study.	67 patients with schizophrenia	Assess the usability of the system, satisfaction, safety and tolerability.	Yes
Peters-strickland2018 [47]	USA	Six formative human factors studies	129 patients with confirmed diagnosis of schizophrenia, bipolar I disorder, or major depressive disorder (MDD)	Assess the safe and effective use of a system. Assess whether the three intended groups of users (patients, healthcare providers, and caregivers) can appropriately use the technology.	Yes
Rohatagi2016 [48]	USA	Phase 4 exploratory observational study: open-label and single-arm.	58 stable patients with a diagnosis of bipolar I disorder (n=35) or MDD (n=23)	Obtain descriptive feedback from patients, assess safety and summarize patient adherence	Yes
Thompson2017 [49]	UK	Prospective observational study	21 patients with either established cardiovascular disease or high multifactorial risk	Test the system in a group of patients at elevated cardiovascular risk attending a cardiac prevention and rehabilitation program	N/A

[a] First author and publication year
[b] Research Ethics Committee (REC) or Institutional Review Board (IRB)
[c]Only 40 completed the study
[d] this study used a version of the ingestible sensor and wearable patch produced by a different company.
[e] Only 15 patients completed the study.
[f] 167 patients were enrolled in the registry, but 16 were excluded from the study

3.1.2 Stay fit or get bit - Ethical issues in sharing health data with insurers' apps

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Abstract

In the framework of digital health, mobile applications with a health-related content are increasing in number and importance. A great deal of these apps are targeted to the general public and, although they differ in features and purposes, their functioning is often based on the promotion of health and the monitoring of customers' lifestyle data. Apps of this type have also recently been developed by health insurance companies. In many cases, insurers' app do not simply offer health-related recommendations to the users, but they also provide economic incentives to those customers who accept to share their behavioural data through the applications. Although such apps may contribute to the adoption of a health-conscious lifestyle, the fact that they require the sharing of dense individual data with the companies responsible for insurance coverage raises some relevant ethical issues.

This paper investigates the phenomenon of insurers' apps permitting customers to share their data in exchange for monetary rewards currently available in Switzerland. After describing the features and functioning of the apps, we present some ethically relevant aspects related to their use. More specifically, we discuss the issues of transparency of data-sharing purposes, potential discrimination amongst insured people, "quantification" of the users and finally the tension generated between solidarity and responsibility. We conclude by emphasising that these apps are becoming a new paradigm for insurers in many countries and that a thorough assessment of their ethical and societal implications is required.

Introduction

Digital health is drastically changing the context of medicine and healthcare. Although a shared and clear definition of this term is lacking [1], it has been argued that digital health encompasses mobile health, health information technologies, wearable devices, telehealth and telemedicine [2]. Although quite diverse in nature, digital health solutions share the distinctive feature that they "provide digital and objective data accessible to both caregivers and patients [thus leading] to an equal level doctor-patient relationship with shared decision-making and the democratization of care" [3].

Health apps constitute a relevant component of digital health solutions. In general, the term 'health apps' refers to all mobile applications aimed at the promotion of health through supporting self-management, generating pre-diagnosis or having other therapeutic effects [4]. A recent study on the potential and risks associated with health apps supported by the German Ministry of Health reported that there are over 100,000 apps with health-related content [5]. One of the reasons why health apps are thriving is that a great deal of them are not aimed at healthcare professionals or at patients with a specific disease, but are rather targeted for the general public [6].

In this context, health apps have recently also started to be commercialised by health insurers [7]. Many of these apps simply allow customers to deal more efficiently with their documents by digitalising some previously paper-based processes. Some others, however, belong more closely to the field of digital health because they include some functions that are strictly related to health promotion [8] and because they aim at directly engaging users with respect to their health [9]. Specifically, to promote the adoption of a healthier lifestyle, these apps allow users to share their behavioural health-related data with their insurer to better track their habits and provide them with personalised health tips [10]. The insurer often offers monetary awards or similar kinds of bonuses as incentives to share data and to try to improve health-related behaviour [10].

Although insurers' data-sharing apps aim at promoting health-conscious behaviour and at giving financial bonuses to people with an active lifestyle, the fact that they are based on the monitoring of individual behaviour and the sharing of health-related personal information also raises some legal and ethical concerns. Indeed, one of these apps was recently criticised by the Federal Data Protection and Information Commissioner (FDPIC), who recommended the revision of a few features of the app [11]. In particular, the FDPIC criticised the processing of data concerning Basic Health Insurance (BHI) together with data about Additional Health Insurance (AHI) and disapproved of the fact that economic rewards were given also to BHI subscribers. However, the idea of using apps to share behavioral health-related data with insurance providers in exchange for monetary rewards was neither questioned in principle nor investigated in depth.

In this article, we first provide an overview of the features and the functioning of insurers' apps currently available in Switzerland that offer monetary incentives in exchange for data-sharing. Then, we discuss some of the ethical issues related to the sharing of lifestyle data with insurances through these apps. Our discussion is based on an adaptation of the casuistry approach, relying both on the analysis of the apps

available on the Swiss market and on further literature review on the topic of digital health and the use of incentives to modify health-related behaviour.

Methodological approach

To further investigate the phenomenon of insurers' data-sharing apps, we searched for all the apps of this kind offered on the Swiss market. For the scope of our searched, we defined as "insurers' data-sharing apps" those mobile applications developed or offered by a health insurance company whereby the sharing of individual health-related behavioral data is awarded with a monetary reward or similar compensation. We based our definition on the official communication by the FDPIC analyzing one of these apps. According to our definition, the distinctive feature of insurers' data-sharing apps is that they provide – on top of general incentives, such as daily challenges or health tips – a series of direct or indirect monetary bonuses as a reward for sharing behavioral health-related data. In this sense, these apps are different from other health-promotion tools such as smoking cessation programs. In fact, with insurers' apps users are even more strongly motivated to share behavioral health-related data, since – on top of the promise of the long-term benefit of improving their health – they also receive a direct, readily available and more tangible monetary benefit. In this context, with the term "sharing" we refer to the transferring of data between users of the app and insurers, and not to the transferring of data between users.[1]

In order to be comprehensive, we decided to investigate the whole Swiss market, thus including insurers' data-sharing apps offered in the framework of both BHI and AHI. We did not consider health insurance plans that simply allowed for reduction of premiums upon participation in specific health promotion activities.[2] To identify insurers' data-sharing apps, we checked insurers' websites as listed by the Federal Office of Public Health [13] to establish whether they offered apps that fitted our scope of inquiry. After having identified apps that fitted our definition, we analyzed their characteristics by reading their description on the insurers' website and on the app stores (Google Play and Apple Store). We then read the terms and conditions (T&C) of the identified apps to better map their functioning. We finally discussed the features of insurers' data-sharing apps by furthering the investigation started by the FDPIC and using a casuistry approach [14, 15, 16]. Casuistry, in contrast to principlism approaches in bioethical analysis, is based on a bottom-up procedure, whereby a specific and concrete situation is investigated

[1] We use the term "sharing" and not "collecting" since in most cases these apps simply rely on data collected by other means (for example through fitness trackers). However, this same process could also be described as "secondary collection", i.e. collection from a source that had already gathered data from the data-subject.

[2] For example, "KPT Krankenkasse AG" offers an insurance plan named "active plus", where customers can obtained premium reductions if they participate to certain health promoting activities (e.g. yoga courses). To obtain the discount, customers need to provide evidence of participating in these activities and such evidence (e.g. receipts) can be also scanned and submitted via the insurance app used to submit other documents (e.g. hospital bills). In this case, however, a proper digital health component is missing, since the app is simply used as an alternative to paper transmission. One example is the ActivePlus Program [12].

to elaborate considerations, reflections and maxims of a more general validity and potentially applicable also to similar circumstances to the one analyzed [17].

Insurers' data-sharing apps in Switzerland: features and functioning

Our search was finalized in January 2019 and allowed us to identify seven different apps that could fit our definition. Upon further reading of the T&C of the identified apps, we excluded two of these for the following reasons. The app "Ignilife" [18] was indirectly sponsored by one insurance group, but it was specified that the app did not belong to the group and that the apps' producers would not share data with the insurer [19]. The app "maxyourhealth" [20] was sponsored by one insurer, but did not explicitly include a reward program allowing users to receive monetary incentives for sharing data [21]. We thus included in our analysis the five remaining insurers' data-sharing apps, whose most relevant features are presented in Table 1 and described more in depth below.

[Table 1 - see end of the manuscript]

"Helsana+" permits users to either manually "feed" the app with data about health-related behaviors (e.g. photos of outdoor activities), or link the app directly to other health-monitoring devices (such as fitness trackers). When linked to fitness trackers, the app then automatically collects data concerning the lifestyle of the insured person. In exchange for sharing behavioral data, users are awarded bonus points. Bonus points can either be used to reduce the insurance premium, or they can be redeemed as vouchers spendable with selected marketing partners. According to the insurance company, sharing data through the app can lead to savings of over 300 CHF per year [22]. It is available for both BHI and AHI subscribers, but the former can receive only up to 75 CHF discount per year.

"MyCSS" allows users – amongst other things like scanning insurance documents – to register for the "MyStep" functionality. Once activated, with "MyStep" users are not allowed to manually feed data, but they can link their fitness trackers directly to the insurer's app. The app then automatically monitors data concerning the amount of steps that customers make. As a reward, for every day that the insured person achieves specific step-thresholds (see Table 1), she receives a cash-credit. These cash-credits are transferred to the personal account of the insured person and can be redeemed as cash, for up to 146 CHF per year. MyStep is only available for AHI subscribers.

The "Active" app by Sanitas follows a very similar model to that of "Helsana+". Insured people can collect bonus points if they share individual health-related data with the app. Data-sharing can be performed either through manual feeding by the user (for example by uploading data about nutrition), or via automatic means, by linking the app to a fitness tracker. Once collected, bonus points can then be

converted in vouchers that can be spent to buy products offered by business partners. Everybody can register on the app, but only Sanitas insurees can collect bonus points.

"Benevita" is slightly different from the other apps. In order to obtain bonus points, users have to fill in a questionnaire and communicate data concerning their lifestyle habits. Depending on their questionnaires, a certain number of bonus points is assigned to customers. The number of bonus points determines the discount that users can have on their AHI premiums. Automatic collection of behavioral health-related data through linking the app with fitness trackers is possible, but it does not allow collection of points and it is simply used to create health-related challenges for the user.

SanaHealth is similar to the "Active" app in its structure, but – being a pilot project limited to 1500 users – it is less developed. Customers can share their data with the app either automatically, by connecting the app to fitness trackers, or manually, by providing single pieces of information about lifestyle habits. Through sharing, users are assigned bonus points, which can be then used to buy products from an online shop. It is downloadable for free for all customers of Sanagate, the insurance company offering it.

Ethically relevant aspects of health-data sharing though insurers' apps in exchange for monetary rewards

The widespread collection and sharing of personal health data has the potential to revolutionize healthcare. Since a link between life-habits and health outcome exists [33], apps offering the chance to contribute to the adoption of responsible health-related behaviors may lead to health improvements and beneficially affect health interventions [34]. Moreover, the use of financial incentives in this context could encourage responsible behavior by providing a tangible and short-term benefit on top of the long-term expectations of positive health outcomes.

However, the constant monitoring of behavior that insurers' data-sharing apps require also raises a number of ethical and legal questions. When analyzing one of these apps, the FDPIC already observed that there were some issues related to the legitimacy of data-linkage, the provision of consent and the payment of economic bonuses. By expanding this analysis in light of the common features of all insurers' data-sharing apps available on the Swiss market, we identified four further areas of ethical concern, which are presented here.

Transparency: what are the (true) purposes of data-sharing?

One fundamental principle of legitimate data usage is that of clearly defining the purpose for which data is collected, shared and processed [35, 36, 37]. Indeed, Swiss law explicitly defines that private institutions processing personal data are limited – with regards to the extent and the objectives of the processing activities – to those purposes that are disclosed at the moment when data is shared and consent by data subjects is obtained [38]. The importance of clearly disclosing the purposes of data

processing is especially fundamental with respect to sensitive information such as data concerning health [39].

In this regard, there seems to be an issue concerning transparency with respect to insurers' data-sharing apps, since the whole range of purposes for which users' data is processed is not equally disclosed. The common message that the insurers promoting their apps deliver is that the key purposes why data should be shared are the following: 1) improve individual health; 2) help users save some money. For example, the webpage describing and promoting the app "Active" claims that "in the medium and long term you benefit from better health. And in the short term you benefit from the bonus system of our Active app!" [40]. Similarly, "myStep" is advertised as having the objective of "Turn[ing] steps into a bonus", "reward[ing] your physical activity" and "encourag[ing] people to take more exercise and inspire them to enjoy their health"[24]. However, while these certainly represent some of the purposes of data-sharing and processing, they are certainly not the only reasons. In fact, the T&C that need to be agreed upon to use these apps explicitly specify that the purposes of data collection also include more delicate aims, such as using data for marketing purposes and forwarding data to third parties. For example, users of "Helsana+" need to accept that the insurance company "is entitled to forward user data within the context of the above-mentioned processing purposes to all companies in the Helsana Group or to third parties who process the user data for Helsana on a contractual basis" [23].

It is true that by listing the purposes of data sharing and data processing in great detail within the T&C and by requiring explicit agreement therewith, the insurers may err on the side of caution, legally speaking. However, from an ethical perspective, there appears to be a problematic lack of transparency, particularly given that often consumers do not read the fine print closely [41] and that, when confronted with documents such as T&C, people often simply click "Agree", thus giving a type of "blind" consent [42].

In this sense, there is some imbalance concerning the weight given to different types of information by the insurers providing the apps. On the one hand, the beneficial purposes of sharing and processing the data from the perspective of potential users are the main focus of all related web-pages and information sheets that describe the product and present the reasons of data sharing. On the other hand, the more delicate purposes of data sharing and data processing are remotely indicated in a document, the T&C, which – because of the nature of how consent is given for the purchase of apps – few users are likely to read. That users are not adequately informed about the purposes data will be used for seems even more problematic as the data in question is often sensitive behavioral health-related information. Insurers should be up-front about the use of data for marketing and third party reuse on the main pages as well as in the small print.

Data-driven discrimination: is it ethical that lifestyle data collected through apps is used to personalize insurance?

Another ethically relevant aspect related to insurers' data-sharing apps concerns whether favoring users who share behavioral health-related data is ethically acceptable. Some degree of differentiation amongst insured people has always been accepted in Switzerland both in the framework of BHI and (even more) in the market of AHI. In this sense, individual choices – such as deciding one's own franchise or participating in health promotion programs – have always had an influence on the amount of money paid for insurance coverage. In consequence, it could be argued that also the idea of furthering this tendency through the monitoring of users' behavioral data is acceptable, insofar as an active – and thus allegedly beneficial – lifestyle entails a premium-reduction or another economic advantage. Moreover, this idea of enhancing insured people' responsibility for their own behavior seems consistent with a recently developed definition of health as "the ability to adapt and to self-manage, in the face of social, physical and emotional challenges" [43].

In general, where to set the exact boundary between acceptable differentiations amongst insured people and illegitimate discrimination is a bone of contention [44, 45]. With respect to Swiss healthcare, it is important to draw a clear distinction between the context of BHI and AHI [46]. Despite being offered by private companies, BHI is mandatory and covers a broad range of healthcare services that is equal for everybody and defined by the law. Insurers are obliged to accept all applicants irrespective of their risk profile and – although they have some degree of freedom in setting the price for their premiums (e.g. they can offer lower premiums to people as old as 25) – insurers are not allowed to profit. AHI, on the contrary, is a market-based system, where insurers can make profit, define eligibility and establish prices and exclusion criteria. Since most of the insurers' data-sharing apps offer an economic advantage that is linked to AHI, the main issue at stake is whether - in the context of the market-oriented AHI - it is ethically acceptable for insurees to receive better economic arrangements (through discounts or rewards) if they share lifestyle data.

Even in market-oriented models of health insurance, different economic arrangements are often seen as ethically troubling if based on features upon which the insured person has no control, such as race, gender, or genetic data [47]. This is true also for Switzerland, where the law governs the disclosure of genetic data to insurers in a special way and insurers cannot – for example – ask applicants to undergo genetic testing as a condition to subscribe AHI [48]. On the contrary, differentiation based upon factors that depend on individual choices does not seem to be fundamentally unfair, especially in the framework of AHI. From an ethical standpoint, this is because a difference is often drawn between voluntary and involuntary risk-seekers: whilst a person with inherited genetic features that determine a predisposition towards certain illnesses is seen as a "victim" who deserves support, an individual that, for example, smokes is considered "faulty" and deserving (economic) disadvantages [49]. In this framework, discriminating – by awarding economic benefits – in favor of those that share data documenting their healthy lifestyle might therefore seem acceptable.

Yet there are three reasons that seem to make this form of "data-driven" discrimination ethically problematic, even in the framework of AHI. Firstly, the basic claim that discrimination based on lifestyle choices should generally be justifiable because behavior is both voluntary and a matter of free choice is highly doubtful. Not only it has long been known that un-healthy behaviors are associated to socio-economic conditions over which the individual has little control [50], but behavioral economics has also more recently demonstrated that individuals are not rational decision-makers even with respect to important issues such as health [51]. Secondly, this form of discrimination seems unfair because it interferes with the autonomy of those that have a healthy lifestyle, but refuse to share their data through insurers' apps, perhaps because of concerns related to data protection. Making economic benefits dependent on consent to share dense behavioral data through an (admittedly) fallible app seems to create pressure to share data, rather than merely incentivize to have healthy lifestyle-habits. Positive behaviors could be monitored (and incentivized) in many other manners, either less privacy-invading – such as by asking to provide receipts of fitness courses – or more reliable – such as through professional health check-ups. Thirdly and more importantly, this "data-driven" discrimination seems ethically unsound because the exact consequences of data sharing on individual coverage are not clearly outlined. In fact, the T&C of most data-sharing apps say that lifestyle data can be processed for profiling purposes through behavior analysis [23, 27, 29]. Whereas risk-profiling *per se* is a normal task for insurance companies, it seems ethically problematic that this is done retrospectively (i.e. after being insured) and on the basis of lifestyle data. The piece of legislation governing AHI (Swiss Federal Law on Insurance) already requires individuals to truthfully disclose all relevant information related to their risk profile before they sign an insurance contract, and protects insurers from deceitful non-disclosure as – if the individual lies – the insurance contract can be voided [52]. In this sense, it seems more ethically acceptable that the whole processes of profiling, risk-assessment and personalization of coverage and premium cost are done upfront in a transparent and explicit fashion, rather than being potentially open to ex-post evaluation thanks to lifestyle data. In order to be ethically sound, differentiation in economic arrangements and medical underwriting should be based on clear facts directly and consciously declared by individuals and not on complex profiling based on dense lifestyle data automatically shared through apps.

The quantified-self: are users merely what their data say they are?

At a practical level, the principle underlying the idea of rewarding insured persons for sharing some health-related data is that adopting a responsible lifestyle contributes to improving health. In this sense, granting a discount on the insurance premium or assigning other monetary bonuses are presented as incentives to adopt a healthy lifestyle. Moreover, there are also economic reasons for granting a monetary reward in exchange for data confirming the adoption of a responsible health-related behavior. Just as with discounts granted for the performance of regular health check-ups [53], the assumption is made that if insured people demonstrate they are trying to keep fit, they will be less likely to make use

of healthcare services, thus reducing their consumption of healthcare resources and deserving an economic benefit. On the other hand, people that do not share data would not have access to discounts, because the assumption is made that their undocumented lifestyle might be unhealthy, thus increasing the likelihood that they are in need of healthcare services in the future. In this sense, insurers' data-sharing apps seem to foster the idea that individuals and their health status are quantifiable through the data they produce with their self-tracking devices and apps [54].

Quantification of individuals in the context of health has sparked a polarized ethical debate [55]. On the one hand, advocates for self-quantification through tracking devices underline how this would serve the principle of beneficence. In fact, since tracking devices allegedly allow to collect objective lifestyle health-related data, the latter can be used to personalize treatment and thus improve care. On the other hand, concerns have been raised with respect to autonomy and self-tracking has been described as disempowering because it potentially allows the control and the surveillance of others who have access to the data of the tracked person.

In the context of insurers' data-sharing apps, promoting the idea that people are simply what their data say raises three issues. Firstly, it is disputable that the lifestyle data shared through the apps corresponds to the aspiration of truth and objectivity of self-tracking technology [56]. In fact, because of some inherent limitations of such apps, there is no guarantee that the few types of data shared are actually accurate. For example, the T&C of one app specify that the app "draws exercise data from third-party sources [e.g. fitness trackers] and assumes no liability for the accuracy and correctness of this information" [27]. Secondly, as the amount of data that can be shared through these apps is limited (some relevant risks factors such as smoking are not contemplated), their focus seems to be too narrow for them to be used to define such a complex concept as the health status. For example, a person could reap substantial benefits from sharing data through these apps, but also be 'hiding' other habits (such as heavy drinking), which could impose much heavier costs on the healthcare system than someone who merely does not share data or exercises less. Third, the fact that these apps share data with insurers fuels the concerns that some form of surveillance could take place, since health insurers have a vested interested in analyzing the health-related behavior of their customers.

Tension with solidarity: is it ethical to stress the "moral" side of personal responsibility?

One last remark must be made concerning the impact that insurers' data-sharing apps can have more broadly on some of the ethical foundations of healthcare as a component of the system of social security. Along with security and protection, the crucial pillars of healthcare systems in Europe are solidarity and responsibility [57, 58]. According to solidarity, people who are in specific situations of need or risk should be included in the protection given by the social security system, and the costs of the disadvantages related to their condition should be shared amongst all members of society, regardless of health status [59]. Responsibility, on the contrary, stresses that social protection cannot be indiscriminate

and that individual freedom cannot excessively go against the interests of the community. In this context, striking a socially accepted balance between individual responsibility and communal solidarity is a crucial challenge. In the Swiss healthcare system, this balance is achieved by combining the guarantee – thanks to mandatory BHI – of a large basic benefit basket for everybody, with the possibility to personalize this offer through the subscription of AHI or the selection of a BHI with higher deductibles or with managed care model at a lower premium rate [60]. Individual responsibility thus plays an important role, but it is anchored to personal preferences and objectively defined criteria, rather than to lifestyle and behavior.

Because of their features, insurers' data-sharing apps can have a substantial impact on the delicate balance between personal responsibility and solidarity in Swiss healthcare. By rewarding those who accept being monitored, these apps "moralize" the idea of responsibility, since they introduce differences – albeit minimal, since rewards have a modest economic value for the moment – between "deserving" and "undeserving" agents [61]. This latently reinforces the idea that insured persons are allowed to contribute less to the financing of healthcare because of their lifestyle. In other words, insurers' data-sharing apps stress the link between responsibility and lifestyle choices. In Switzerland, the debate concerning the extent and the role of personal responsibility for health is an open one, and whether lifestyle should be considered as an important element to limit solidarity in healthcare is often discussed [62, 63]. In this respect, although increasing responsibility for health-relevant behaviors is not ethically problematic *per se*, whether this is the right direction for the future evolution of healthcare in Switzerland is something that ought to be collectively and openly discussed, rather than being subtly introduced through mobile apps that are not clinically validated.

Careful discussion before the delicate balance between solidarity and responsibility in healthcare is modified is particularly important from an economic standpoint. An argument for justifying premium reductions according to behavioral habits could be that people – by means of adopting a healthy lifestyle – still contribute positively to the insurance model, as the savings they produce through healthy habits would offset the small economic benefits they receive. However, whether this is the case is an empirical question and, before any such system is implemented, a reliable amount of evidence regarding the real economic consequences of following specific lifestyles should be collected. A recent study exploring the impact of digital health solutions on healthcare utilization in the US, demonstrated that these are not associated with any large short-term increases or decreases in health care usage [64]. More in general, empirical evidence seems to show that, from a purely economic perspective, the adoption of what could be regarded as an "active" lifestyle actually increases health expenditure, since people have a longer life expectancy and are thus more likely to suffer from age-related chronic diseases [65]. Moreover, as outlined above, the fact remains that people could "exploit" the system to obtain monetary benefits by providing biased data or by "hiding" other unhealthy habits that are not measured (e.g. smoking). This is even more likely given that these apps are not clinically validated and that T&C often underline that use of the apps is undertaken "entirely at the user's own risk" [23].

Conclusion

Insurers' data-sharing apps are a representative and relevant technological instrument in the field of digital health. The phenomenon of insurance apps permitting to transfer health and lifestyle data in exchange for monetary rewards is thriving and apps of this kind are not exclusive of Switzerland. In 2016 Generali, the third largest insurance group in the EU [66], announced the start of the "Vitality" program [67]. The latter is based on continuous monitoring of health-related behavior of insured persons through, amongst other things, an app linked to fitness trackers. The "Vitality" program is aimed at promoting a more active lifestyle amongst insured persons and offers several monetary rewards in exchange for the sharing of health-related data. The financial benefits include, for example, a 40% discount on the purchase of a fitness device and a definite amount of bonus points for every data-upload [68]. "Vitality Health" in the UK also offers a similar program, proposing tailored insurance plans with special discounts if the person accepts to transfer personal health data through fitness tracker and regular visits [69]. The same model is offered by "Discovery" in South Africa, where sharing also entails the transferring of data concerning users' medication adherence [70].

From this article, it has emerged that insurers' data-sharing apps are presented as a way of incentivizing the adoption of a healthier lifestyle, saving money, and reducing the burden of those illnesses that are co-caused by some specific health-related behaviors. However, the use of these apps also raises a series of problematic ethical issues, particularly with regard to the issues of transparency, discrimination, the quantification of the self and the balance between responsibility and solidarity in healthcare. Moreover, in addition to some widespread skepticism concerning the use of monetary incentives to improve behavior [71], at present decisive evidence demonstrating the beneficial impact of health-related mobile applications – either in terms of clinical effectiveness or in terms of healthcare-resources consumption – is lacking [64, 72, 73, 74, 75, 76].

As society ages and the impact of chronic illnesses grows, the pressure of increasing efficiency while decreasing healthcare costs will continue to rise. In this sense, the use of data and the implementation of digital health represent powerful ingredients to help reduce costs and better allocate scarce resources [77]. However, new developments such as insurers' data-sharing apps must continue to be critically assessed and evaluated in order to protect citizens – both healthy and unhealthy – from potential discrimination and exposure to privacy risks.

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

The authors have no conflicts of interest to declare.

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Table 1. Insurers' data-sharing apps in Switzerland.

App's name	Type of data shared	How is data shared?	Rewards for data sharing	How can rewards be used?	Who benefits?
Helsana + [22] [23]	Health-related behavioral data of routine activities (e.g. steps) or time-limited activities (e.g. sport event)	1) Automatically: by linking health apps (e.g. Google fit) or fitness trackers (e.g. Garmin) to the insurance app 2) Manually: by sharing photos or scanning QR codes.	Redeemable bonus points: the amount depends on the insurance cover, and is limited per year (30.000 for AHI and 7.500 for BHI)	Bonus points can be redeemed as cash, benefits in kind, or vouchers. Up to 300 CHF can be redeemed per year.	Insured people. Even underage individuals from the age of 12 can participate upon authorization by legal representative.
myCSS (MyStep option) [24] [25]	Number of steps per day.	1) Automatically: data from a fitness tracker is synchronized with the app.	Cash credits: CHF 0.40 for every day with 10,000 or more steps; CHF 0.20 for every day with between 7,500 and 9,999 steps.	Credits are paid as cash to the insured person. Up to CHF 146 (365 days at CHF 0.40) can be redeemed.	Insured people with AHI. However, behavioral data is compared with data concerning BHI of the subscribers for marketing and statistical purposes.
Sanitas Active [26] [27]	Personal data, data about nutrition, sleep, pulse, and other routine activities (e.g. steps, minutes of cycling).	1) Automatically: by linking health apps (e.g. Google fit) or fitness trackers (e.g. Garmin) to the insurance app	Coins: the rewards depend on the achievement of daily targets or the completion of challenges.	Coins can be redeemed as vouchers to be spent with one of partner companies. Collected credits cannot be exchanged for cash.	Insured people with additional insurance.
Swica BENEVITA [28] [29]	Data concerning lifestyle habits and data from fitness trackers.	1) Automatically: data from a fitness tracker is synchronized with the app. 2) Manually: a declaration can be completed online by answering to a series of health-related questions.	Bonus points: depending **only** on the declaration, a specific amount of points is granted.	Bonus points determine the status of the user and the entitlement to a premium discount up to 15%.	Insured people.
SanaHealth [30] [31] [32]	Data concerning physical activity, eating habits, heart rate, blood pressure and sleep patterns.	1) Automatically: data from a fitness tracker or health app is synchronized with SanaHealth. 2) Manually: the person feeds single pieces of information.	Redeemable bonus points.	Bonus points can be used in a user-reserved shop ("SanaHealth-Shop") to buy a series of products.	Insured people. The app is current being develop as a pilot project limited to 1500 participants.

3.1.3 Personal responsibility for health: the impact of digitalisation.

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Abstract

Fostering personal responsibility of patients is often considered a potential remedy for the problem of resource allocation in healthcare systems. In political and ethical debates, systems of rewards and punishments based on personal responsibility have proved very divisive. However, regardless of the controversies it has sparked, the implementation of personal responsibility in concrete policies has always encountered the problem of *practical enforceability*, i.e. how causally relevant behaviour can be tracked, allowing policies of this kind to be applied in a fine-grained, economically viable and accurate fashion. In this paper, we show how this hurdle can be seemingly overcome with the advent of digitalisation in health and delineate the potential impact of digitalisation on personal responsibility for health. We discuss how digitalisation – by datafying health and making patients transparent – promises to close the loophole of *practical enforceability* by allowing to trace health-related lifestyle choices of individuals as well as their exposure to avoidable risk factors. Digitalisation in healthcare thereby reinforces what Gerald Dworkin has called the *causal* aspect of personal responsibility and strengthens the implicit syllogism that – since exposure to risk factors happens at the individual level – responsibility for health should be ascribed to the individual. We conclude by addressing the limitations of this approach and suggest that there are other ways how the potential of digitalisation can help with the allocation of resources in healthcare.

1. Introduction

Should people who contribute to their own poor health be held accountable for it? The question whether enhancing personal responsibility for health is a just policy-choice enjoys a prominent role in the political as well as the scientific debates concerning the allocation of healthcare resources[1]. The increasing importance that this argument has acquired in the last decades can be related to several factors. First, with population ageing and the incidence of non-communicable diseases increasing, healthcare services struggle to keep up with populations' health needs. Second, with scarcity of resources hitting many healthcare systems – albeit to different extents – there is an increasing need for socially accepted criteria to allocate the available money. Third, the advancements of medicine raise popular expectations to receive effective treatment with respect to an increasing number of conditions regardless of their cost – especially when those illnesses are life-threatening and affect children.[2] Fourth, research is showing that for common non-communicable diseases whose treatment significantly contributes to health expenditure - such as cardiovascular diseases, diabetes and even cancer - a few changes in lifestyle would reduce the occurrence of many of these illnesses.[3]

In this context, it is easy to understand the appeal of the idea that people who contribute to their own poor health should be personally and financially responsible for it. In England, for example, some local Clinical Commissioning Groups (the public bodies responsible for the planning and commissioning of healthcare services in England's National Health Service) have been contemplating plans to restrict free[4] elective surgery for smokers and obese patients.[5] Similarly, individual co-payments for health problems resulting from medically unnecessary cosmetic surgery, tattoo or piercing were increased in Germany,

[1] See, for example, M. Minkler, 'Personal Responsibility for Health? A Review of the Arguments and the Evidence at Century's End', *Health Education & Behavior* 26 (1999):121-140; A.M. Buyx, 'Personal responsibility for health as a rationing criterion: why we don't like it and why maybe we should', *Journal of Medical Ethics* 34 (2008):871-874; K. Sharkey & L. Gillam, 'Should patients with self-inflicted illness receive lower priority in access to healthcare resources? Mapping out the debate', *Journal of Medical Ethics* 36 (2010):661-665; A.M. Baker & L.M. Hunt LM, 'Counterproductive Consequences of a Conservative Ideology: Medicaid Expansion and Personal Responsibility Requirements', *American Journal of Public Health* 106 (2016):1181–1187.

[2] See, with respect to this point, the literature on the "rule of rescue", e.g. Bettina Schöne-Seifert: "The 'rule of rescue' in medical priority setting: Ethical plausibilities and implausibilities." *Perspectives in Moral Science* (2009):421-430.

[3] See e.g. S. Barquera, A. Pedroza-Tobías, C. Medina, L. Hernández-Barrera, K. Bibbins-Domingo, R. Lozano & A.E. Moran, 'Global overview of the epidemiology of atherosclerotic cardiovascular disease', *Archives of medical research* 46 (2015):328-38.; I. Soerjomataram, E. de Vries, E. Pukkala & J.W. Coebergh, 'Excess of cancers in Europe: A study of eleven major cancers amenable to lifestyle change', *Int. J. Cancer* 120 (2007):1336-1343; I. Soerjomataram, K. Shield, C. Marant-Micallef, J. Vignat, C. Hill, A. Rogel, G. Menvielle, L. Dossus, J.N. Ormsby, J. Rehm & L. Rushton, 'Cancers related to lifestyle and environmental factors in France in 2015', *European Journal of Cancer* 105 (2018):103-113; Y. Zheng, S.H. Ley & F.B. Hu, 'Global aetiology and epidemiology of type 2 diabetes mellitus and its complications', *Nature Reviews Endocrinology* 14 (2018):88.

[4] Free at the point of use.

[5] V. Pillutla, H. Maslen & J. Savulescu, 'Rationing elective surgery for smokers and obese patients: responsibility or prognosis?' *BMC Medical Ethics* 19 (2018), 28.

based on the Competition Reinforcement Law passed in 2007.[6] Even in Switzerland, a country where 'there is little explicit rationing of services […] [and] cost is a concern, but there has been no cost explosion'[7], rising insurance premiums and out-of-pocket spending have reinforced calls to increase personal responsibility for health. In a recent editorial of the Schweizerische Ärztezeitung, the author expressed this point strongly:

> 'People without personal responsibility are overweight, smoke and sit in front of their screen instead of doing exercise. They eat too much sugar, too much fat and few vegetables. They ignore the suggestions of the professionals and run to the doctor when they feel ill, without any second thought. And we – the slim, fit and sporty non-smokers – co-pay for that. We – the ones who take personal responsibility seriously – will be punished with ever higher insurance premiums.'[8]

The success of the idea of enhancing personal responsibility for health lies in its intuitive appeal. Holding people accountable (e.g. through requiring higher co-payments) depending on their behaviour is profoundly rooted in a certain interpretation of the liberal principle 'that the liberty of the individual must be thus far limited; he must not make himself a nuisance to other people'[9]. Following John Stuart Mill, one could thus conclude that – by voluntarily choosing an un-healthy behaviour – certain individuals are damaging the community who, as a consequence, is allowed to withdraw the support normally provided to them according to the solidarity principle. In such instances, withdrawal of support would allegedly be justified if it concerned only guilty risk-takers (such as those who do not eat healthy), since they are not allowed to pass on to their fellow citizens the negative externalities produced by their voluntarily-assumed behaviours, and not risk-carriers, such as people with a genetic predisposition.[10] Despite the many doubts that have been cast on such reasoning, the question whether it is appropriate to create policies reinforcing personal responsibility for health has enjoyed ongoing popularity, both inside academia and in the political domain.

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[6] S. Huster, 'Individual Responsibility and Paternalism in Health Law', in *New Perspectives on Paternalism and Health Care*, ed. T. Schramme (Switzerland: Springer International Publishing Switzerland, 2015), 221.

[7] N. Biller-Andorno & T. Zeltner, 'Individual responsibility and community solidarity—The Swiss Health Care system', New England Journal of Medicine 373 (2015):2194.

[8] A. Sax, 'Eigenverantwortung', Schweiz Ärzteztg 98 (2017):174. Translation from the German version. The original reads "Leute ohne Eigenverantwortung sind übergewichtig, -rauchen und sitzen vor dem Bildschirm, statt sich zu bewegen. Sie essen zu viel Zucker, zu viel Fett und zu wenig Gemüse. Sie foutieren sich um die Empfehlungen der Fachleute und rennen, wenn sie sich krank fühlen, ohne nachzudenken, zum Arzt. Und wir, die schlanken, fitten, sportbewussten Nichtraucherinnen, zahlen mit. Wir, die wir unsere Eigenverantwortung wahrnehmen, werden mit immer höheren Krankenkassenprämien bestraft".

[9] J.S. Mill, 'On Liberty. In J. S. Mill, Utilitarianism. Liberty and
Representative Government. Introduction by A. D. Lindsay' (London: J. M. Dent & Sons Ltd) 1947, 114.

[10] I. Van Hoyweghen, K. Horstman & R. Schepers, 'Genetic 'risk carriers' and lifestyle 'risk takers'. Which risks deserve our legal protection in insurance?', *Health Care Analysis* 15 (2007):179-193

In this paper, however, we do not primarily address the theoretical issue whether it is legitimate to use personal responsibility as a rationing criterion in general. Instead, we focus on the interplay between the principle of personal responsibility for health and the phenomenon of digitalisation in healthcare. First, we outline how – aside from theoretical arguments for or against this principle – implementing policies based on a strict interpretation of personal responsibility has always encountered the hurdle of *practical enforceability*. We also provide two policy examples to root the debate on a more practical level. Thereafter, we show how digitalisation supposedly offers a remedy to circumvent the hurdle of practical enforceability, since it allows to closely and accurately monitor individual behaviour, thus allegedly opening up the possibility to strengthen personal responsibility for health. Based on these considerations, we then analyse the influence of this shift on the conception of personal responsibility and argue that digitalisation stresses the *causal* aspect of this principle. Having highlighted the conceptual and practical limits of such digitally-supported inferences regarding personal responsibility, we finally plead that, beyond a mere focus on the individual, there are more promising alternatives how digitalisation can improve resources allocation in healthcare.

2. Personal responsibility for health as a rationing criterion: a practical problem.

Using personal responsibility as a criterion for allocating resources in healthcare remains a contentious idea. On the one side, arguments in favour of more personal responsibility for health underline that de-prioritising patients who contribute to their own poor health is justified on several accounts. It is argued that these patients (1) are more likely to have poor health outcomes following treatment, (2) take away limited resources from patients who are more careful about their health, (3) lack incentives to change their behaviour and (4), if not held to account, may even disincentivise other people to contribute to the financing of healthcare.[11] On the other side, opponents of the use of personal responsibility as a rationing criterion have argued that ascribing responsibility generates stigma and does not necessarily improve health-related behaviour, therapeutic outcomes or public finances.[12] Apart from arguments at these two extremes, many authors have tried to find some middle ground. For instance, it has been argued that whether responsibility is prospective (i.e. a commitment for the future) or retrospective (i.e. accountability for the past) should determine its legitimacy.[13] As an alternative

[11] Sharkey & Gillam (note 1).

[12] P. Friesen, 'Personal responsibility within health policy: unethical and ineffective', *Journal of Medical Ethics* 44(2018):53-58.

[13] E. Feiring, 'Lifestyle, responsibility and justice', *Journal of Medical Ethics* 34 (2008):33-36. The exact terminology used by Feiring is "forward-looking" and "backward-looking". However, the use of "prospective" and "retrospective" is more established in literature. For a more in-depth definition, see G. Marckmann, M. Möhrle & A. Blum, 'Gesundheitliche Eigenverantwortung', *Der Hautarzt* 55 (2004):715–20.

criterion, Harald Schmidt[14] has suggested that the degree of consequences (e.g. higher co-payment vs higher co-payment plus lower priority in waiting list) assigned to the individual would affect a policy's adequacy.

Whilst the theoretical debate concerning the legitimacy of increasing the use of personal responsibility for health as a rationing criterion has flourished, the concrete issues that implementing this principle would entail at a practical level have not received the same attention. It seems clear though that using personal responsibility in the rationing of healthcare would encounter two sets of challenges. On the one hand, it would be necessary to agree upon a list of facts, acts and situations for which responsibility can be demanded and then set the consequences for the individual when those facts, actions or situations occur. Taking the example from Germany quoted above, the policy listed unnecessary cosmetic surgery, piercing and tattoo as triggering actions, and higher co-payment as consequence. On the other hand, it would be necessary to ensure the accuracy and correctness in the concrete operationalisation of such list. We will refer to these two set of challenges as – respectively – the macro- and micro-level.

At a macro-level, the challenge consists in drafting an evidence-based and socially accepted list of actions for which personal responsibility can be demanded. This entails several questions for policymakers. First, they would need to determine which facts or actions produce a negative outcome *per se* (e.g. does smoking lead to COPD?), or – as Alena Buyx put it – 'we want to be sure that we know exactly what actions or behaviours lead to a certain condition before holding patients responsible for the consequences'.[15] In this respect, it has been suggested that there are two categories of facts and actions for which people could be held accountable.[16] On the one hand, there are traditional health-related behaviours like smoking, drinking, and unhealthy eating habits. On the other hand, there are risky behaviours such as practicing extreme sports, opting for elective surgery and driving motorcycles. Furthermore, it would be necessary to determine if those facts and actions truly determine negative consequences for the rest of the society. This would entail both purely economic considerations (e.g. are smokers really compromising public finances?[17]) and moral ones (e.g. would it be socially accepted –

[14] H. Schmidt, 'Personal responsibility in the NHS Constitution and the social determinants of health approach: competitive or complementary?', *Health Economics, Policy and Law* 4 (2009):129-138.

[15] Buyx (note 1), 873.

[16] J. Savulescu, 'Golden opportunity, reasonable risk and personal responsibility for health', *Journal of Medical Ethics* 44 (2018):59-61.

[17] This aspect might seem a trivial one but cannot be underestimated. For example, it is a common assumption that smokers' poorer health outcomes generate a higher consumption of healthcare resources, which would supposedly justify reducing their healthcare benefits or increasing their co-payments. However, this assumption is often incorrect, from a purely economic perspective. Smokers are often "cheaper" to society because their higher mortality contributes to saving the money that they would have costed the healthcare and social system had they lived longer (the so called 'survivor consumption costs', see e.g. (D.R. Rappange, W.B. Brouwer, F.F. Rutten & P.H. van Baal, 'Lifestyle intervention: from cost savings to value for money', *Journal of Public Health* 32 (2009):440-447; L.B. Russell, 'Preventing chronic disease: an important investment, but don't count on cost savings', Health Affairs 28 (2009):42-45). Of course, such purely economic considerations ought not to be

in a given society – to require higher co-payments for emergency healthcare services for drivers?).[18] Lastly and more importantly, one would need to determine objective measurements for holding people responsible for a certain fact or action. Is one cigarette a week enough to warrant higher co-payments for healthcare services? Which healthcare services exactly will be affected? Only those related to the risk-taking behaviour (e.g. lung cancer treatment for smokers)? Or more generally all services (e.g. by requiring smokers to pay higher health-insurance premiums)?

Even more complicated are the challenges at the micro-level. In this respect, implementing personal responsibility for health as a rationing criterion would require to 'single out the one decisive causal factor when it comes to individual patients'.[19] Even when a list of actions and facts and their consequences in terms of responsibility were compiled at a macro-level, the fact would remain that in the single cases it would be necessary to distinguish between those individuals where healthcare services can be rationed due to their behaviour and those where it cannot. Let us consider the example of a rule establishing higher co-payments for treating a multifactorial disease such as type II Diabetes when it is caused by unhealthy habits like exercising too little. Enforcing such a measure as a general policy would require a considerable effort to distinguish between those patients that should be held accountable (e.g. because their condition is causally related to specific eating habits) and those with whom society should be supportive (e.g. because the illness has occurred due to genetic predisposition). These micro-level challenges concerning the accurate operationalisation of personal responsibility for health as a rationing criterion have been a crucial deterrent to the implementation of policies of this kind. Indeed, an accurate and impartial operationalisation might often prove difficult and especially expensive, thus undermining one of the main objectives why personal responsibility for health would be reinforces (i.e. to save cost). As one author put it, attempts to practically implement policies based on the reinforcement of personal responsibility for health would be largely impractical because of 'the extensive time and resources that would be required to assess each individual's responsibility for a given condition'.[20] For example, with regard to cost-sharing schemes based on personal responsibility in some US states' publicly funded Medicaid program, it has been argued that the additional administrative costs incurred by tracking patients would likely exceed expected savings, rendering the implementation financially inefficient.[21]

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dominant – e.g. higher mortality of smokers should not be considered acceptable just because society saves money on their missed pensions. It is, however, important to consider such aspects before surrendering to the intuitive assumption that it is easy to select those behaviours for which personal and financial responsibility can be demanded.

[18] This aspect is also very important, and it is related to the societal determination of what is considered an acceptable risk-taking behaviour.

[19] Buyx (note 1), 873.

[20] Friesen (note 11), 53.

[21] J.B. Wishner, J. Holahan, D. Upadhyay & M. McGrath. Medicaid expansion, the private option, and personal responsibility requirements: the use of Section 1115 waivers to implement Medicaid expansion under the ACA. Urban Institute, 2015, http://www.urban.org/sites/default/files/alfresco/publication-pdfs/2000235-Medicaid-Expansion-The-Private-Option-and-Personal-Responsibility-Requirements.pdf (accessed September 10 2019). Retrieved in Baker & Hunt (note 1).

On the same line, other authors have emphasised that, from a concrete policy perspective, 'not all risky activities are taxable (e.g. sitting on the couch all day) since they are not *administratively* controllable'[22]. From now on, we will refer to this set of issues as the problem of *practically enforcing* personal responsibility for health.

3. The challenge of *practical enforceability*: two policy examples

The challenges of *practically enforcing* personal responsibility for health as a rationing criterion become even more evident when far-reaching – in terms of people impacted and money affected – policy-questions in the context of rationing are considered. To substantiate this claim, we provide two hypothetical policies: the first one concerning sub-optimal medication adherence, the second one concerning liver transplantation.

Poor medication adherence – i.e. the habit of *not* taking medication as prescribed – has been widely identified as one of the most impactful health-related behaviours - both in terms of health outcomes and financial burden to health care systems. In a famous report by the WHO of 2003[23], it was estimated that 50% of the patients worldwide do not take medications as prescribed. As a result, not only health outcomes are worse, but also considerable amounts of healthcare resources are wasted. Estimates put the cost of hospitalisations due to poor medication adherence in the range of $100 billions - in the US alone.[24] A putative policy to help tackle this problem could be that of strengthening personal responsibility. If individuals chose not to adhere to the prescribed treatment plan, personal responsibility for such a decision would come into play. The putative policy might require, for example, higher costs for follow-up treatments when individuals incur poor health outcomes as a result of sub-optimal medication adherence. Alternatively, patients could be required to stick to their medication plan as an initial and future-oriented requirement to have their costs covered by the healthcare system. Assuming that it were possible to define a threshold where patients would be considered non-adherent and assuming that the policy were socially accepted, the problem of *practical enforceability* would remain. In fact, it would often prove difficult to show – when the policy needs to be applied – which patients adhered to their medication plan as prescribed and which did not, thus becoming accountable for the poor treatment outcome. Relying on self-reporting by the patients would arguably not represent a fair and feasible solution: with health coverage at stake, lying would be encouraged and honesty punished. An alternative may be checks by medical professionals or administrative personnel verifying the

[22] K. Bærøe & C. Cappelen, 'Phase-dependent justification: the role of personal responsibility in fair healthcare', *Journal of Medical Ethics* 41 (2015):839 (emphasis added).

[23] E. Sabaté (ed), *Adherence to long-term therapies: evidence for action* (World Health Organization, 2003).

[24] L. Osterberg & T. Blaschke, 'Adherence to Medication', *New England Journal of Medicine* 353 (2005):487-497.

correctness of medication-taking behaviour, e.g. by blood or urine testing. However, this would not only be highly impractical (especially in the outpatient setting) but also financially counterproductive, if the objective of the policy were to save costs.

Another example showing the difficulty of *practically enforcing* personal responsibility is that of liver transplantation. Already in 1991, Moss and Siegler suggested that 'patients who develop ESLD [end stage liver disease] through no fault of their own (e.g., those with congenital biliary atresia or primary biliary cirrhosis) should enjoy higher priority in receiving a liver transplant than those whose liver disease results from failure to obtain treatment for alcoholism'.[25] According to the authors' proposal, general guidelines for physicians should not entail an outright ban of liver transplant for people who fail to obtain treatment for alcoholism but simply move them down in the waiting list for transplantation. Their reasoning sparked controversial debates about organ donation and substance abuse, with many subscribing to the intuition that 'entitlements to health care for a diseased condition are inversely proportional to control and responsibility'[26] – a preference that has also been corroborated by empirical research.[27] More recently, Daniel Brudney has argued in a similar vein that substance abusers are less deserving of liver transplants if they are aware of the consequences, including the fact that they may deprive someone else from receiving a necessary organ transplant.[28] Apart from any considerations about the ethical merit of such proposals, even here the question would remain though how to *practically enforce* this policy in individual cases. As has been pointed out, it is not clear how physicians could 'distinguish those among this group who could and should have taken steps to prevent liver failure from those who may have had no reason to suspect that their drinking would lead to liver failure'.[29] Whether the reason to ascribe responsibility is rooted in the awareness of the patient (i.e. is she informed about the potential consequences of her actions) or in the presence of a specific link between drinking habits and liver failure, the problem remains that both circumstances are difficult to verify. It seems that the only option would be to 'undertake intrusive investigations into the private lives of patients'.[30] If responsibility were to be ascribed on the basis of the patient's awareness of her risky conduct, medical personnel would have to collect evidence to determine such awareness. If, on the contrary, responsibility were to be ascribed on the basis of a specific link between drinking habits and liver failure, doctors would have to impose additional medical examinations (e.g. carbohydrate deficient transferrin (CDT) levels), which would be both expensive and ethically troubling (since they would not promote the welfare of the patients). In either case, this would be a problem, not only by compromising

[25] A.H. Moss & M. Siegler, 'Should alcoholics compete equally for liver transplantation?', *Jama* 265 (1991):1295-1298.

[26] W. Glannon, 'Responsibility, alcoholism, and liver transplantation', *The Journal of Medicine and Philosophy* 23 (1998):35.

[27] PA. Ubel, C. Jepson, J. Baron, T. Mohr, S. McMorrow & D.A. Asch, 'Allocation of transplantable organs: do people want to punish patients for causing their illness?', *Liver Transplantation* 7 (2001):600-607.

[28] D. Brudney, 'Are alcoholics less deserving of liver transplants?', *Hastings Center Report* 37 (2007):41-47.

[29] M. Benjamin, 'Transplantation for alcoholic liver disease: the ethical issues', *Liver Transplantation and Surgery* 3 (1997):337-342.

[30] *Ibid.*, 339.

the role of and trust in the medical personnel but especially because – at a practical level – it 'would be a very intensive and time-consuming job to determine the *real* measure of responsibility for a patient's disease'.[31]

These two examples demonstrate how *practical enforceability* would remain an obstacle to the implementation of personal responsibility in concrete policies. This is because 'on *practical* grounds, it seems very difficult, if not impossible, to measure out and determine the exact scope of people's individual freedom and responsibility'.[32] Even if theoretical and political issues concerning the appropriateness of using personal responsibility for health as a rationing criterion were set to the side, far-reaching policies would always face a thorny dilemma. Either they have to accept approximation and potential errors for those cases where it may be impossible or unreliable to verify the actual adoption of the specific health-related choices to which responsibility is linked (e.g. poor medication adherence, or drinking). Or they require a complex and often costly (especially if needed on a large scale) effort to retrospectively or prospectively check – for example through the presence of specific markers – that individuals have taken the course of action that justifies a different allocation of healthcare resources.

4. The impact of digitalisation: responsibility becoming enforceable?

Whilst the debate concerning the personal responsibility for health has become increasingly stagnant and repetitive[33], healthcare has drastically changed and has been undergoing a profound digital revolution. Digital health has been defined as 'the development of technological solutions to monitor, process and integrate vast amounts of data at the individual and population levels'.[34] At the core of the digital revolution in healthcare is a more extensive use of different types of health-related data, which can be divided into three main categories.[35] First, there is traditional patients' information – such as doctor's notes, hospital records and healthcare bills – which can be collected in electronic form and are therefore often more easily shareable and linkable. In this sense, digitalisation has mainly impacted collection and transit of information, rather than the nature of the information collected. Second, there is the category of data belonging to so called "–omics data streams", which includes genomic and proteomics data now also collectable through direct-to-consumer tests. Third, there is health-related behavioural data traceable through new technological solutions (e.g. mobile sensors on the phones, fitness devices or digital therapeutics).

[31] (W. Martens, 'Do alcoholic liver transplantation candidates merit lower medical priority than non-alcoholic candidates?', *Transplant International* 14 (2001):172 (emphasis added).

[32] Schmidt (note 13), 130 (emphasis added).

[33] Sharkey & Gillam (note 1).

[34] 'Medicine in the digital age', *Nature Medicine* 25 (2019):1.

[35] M. Swan, 'The quantified self: Fundamental disruption in big data science and biological discovery', *Big data* 1(2013):85-99.

Digitalisation, in other words, has been conveying a true 'datafication of health'.[36] This has fostered views of patients – and individuals more generally – as quantifiable entities that can be defined by the electronic information that is collected from and about them. In the medical literature, it is no minority position to claim that 'just about everything that makes a human tick can now be quantified like never before, by means of sensors, sequencing, laboratory tests and scans'.[37] At the same time, digitalisation of healthcare also largely facilitates access to medical data, making patients increasingly transparent. Through electronic health records, wearable devices and other e-health tools, information concerning a patients' health status – from their medical history and test results to data collected directly through apps and wearables – becomes much more accessible and monitorable. Unsurprisingly, this vision has also been endorsed by a large part of the industry active in the e-health sector.[38] In the most optimistic accounts, digitalisation promises 'to prevent and mitigate the physical and financial burdens of "lifestyle diseases" such as obesity, diabetes, and cardiovascular disease—conditions that derive from daily behaviours of overeating, underexercising, and smoking—by shifting their management away from hospitals and doctors and into the hands of empowered patients'.[39]

More importantly, with the datafication of health and patients becoming increasingly transparent, digitalisation seems to offer the missing link necessary to *practically enforce* personal responsibility for health. Indeed, the problem of *practical enforceability* gets drastically downsized, since patients' health status and their health-related behaviours become easily measurable and accessible through digital means. For example, the European Union has recently funded the MyHealthAvatar project, consisting of an internet-platform where citizens can upload their behavioural data (e.g. number of steps), medical records and also allow linkage to their twitter profiles, so that information can be analysed to facilitate the prediction of some non-communicable diseases.[40] Similarly, at the end of 2017, the United States approved the first pill combined with an ingestible sensor that monitors – automatically and in real-time – whether patients take their medications correctly.[41] With the rapid increase of tools of this kind, not only is it possible to 'deliver a more efficient and effective healthcare system'[42], but also to effectively monitor patients' behaviour.

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[36] M. Ruckenstein & N.D. Schüll, 'The datafication of health', *Annual Review of Anthropology* 46 (2017):261-278.

[37] L.J. Kish & E.J. Topol, 'Unpatients—why patients should own their medical data', *Nature biotechnology* 33(2015):921.

[38] N.D. Schüll, 'Data for life: Wearable technology and the design of self-care', *BioSocieties* 11 (2016):317-333.

[39] Ruckenstein and Schüll (note 35), 262.

[40] European Commission, 'MyHealthAvatar: your digital health status through an app', https://ec.europa.eu/digital-single-market/en/news/myhealthavatar-your-digital-health-status-through-app, (accessed 10 September 2019).

[41] FDA - Food and Drug Administration, 'FDA approves pill with sensor that digitally tracks if patients have ingested their medication', https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm584933.htm, (accessed 10 September 20189).

[42] E. Rich & A. Miah, 'Mobile, wearable and ingestible health technologies: towards a critical research agenda', *Health Sociology Review* 26 (2017):85.

Indeed, digitalisation makes it much more appealing to implement policies demanding personal responsibility for health because many risk factors such as a lack of exercise or an unhealthy diet can be easily, extensively and pervasively documented. In a sense, digitalisation has the potential to shift the burden of proof concerning responsibility from society to the individual. If individual-level data is available suggesting that one patient has taken poor health-related choices, this could be used as justification to demand responsibility and, more importantly, as an instrument to make it practically enforceable. The assumption is that the collected data is correct and complete and that the single person – if she wants to avoid responsibility – must prove herself that her poor lifestyle choices cannot be ascribed to her in the single case. When evidence thereof is not provided, rationing healthcare services covered by the community might become the default option. In the case of medication adherence, for example, patients could be asked to digitally monitor their medication-taking behaviour and, if it results that they miss certain doses, reimbursement of the cost for their medications could be curtailed. In the case of liver transplantation, patients could be asked to prove that they have not been purchasing large amounts of alcoholic beverages or that they have not been frequent visitors to pubs or bars.

The claim that digitalisation provides the means to *practically enforce* personal responsibility as a rationing criterion is not purely hypothetical. Although official policies and regulation of this kind do not exist yet, private actors are already deploying digital health solutions as tools to *practically enforce* personal responsibility for health. In Switzerland, for example, some major health insurance companies are offering customers the possibility to pay cheaper premiums for basic insurance – either directly through discounts or indirectly through monetary rewards – if they demonstrate the achievement of daily challenges in terms of steps or other relevant health-related behaviours.[43] Users simply have to link their fitness trackers to an app provided by the insurance and, then, those customers who are more active end up paying less for the same insurance coverage of other customers who are not as fit.

The appeal of using digital tools to *practically enforce* personal responsibility for health is fostered by the logic of personalised medicine. Although its exact definition may vary, the term 'personalised medicine' generally refers to 'a medical model using characterisation of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention'.[44] In other words, the movement of personalised medicine contends that individual health-related data should be routinely used to improve the care of patients at the individual level by making care more tailored and precise. The same logic could be extended to the use of data at the societal level to personalise and individualise resource allocation in the healthcare sector. As has been argued, 'it is assumed that more information necessarily will lead to better healthcare

[43] A. Martani, D. Shaw & B.S. Elger, 'Stay fit or get bit-ethical issues in sharing health data with insurers' apps', *Swiss medical weekly* (2019), 149.

[44] Council conclusions on personalised medicine for patients, 2015/C 421/03, https://op.europa.eu/en/publication-detail/-/publication/f416ce37-a48c-11e5-b528-01aa75ed71a1 (accessed 10 September 2019).

and economic efficiencies, both by encouraging patient engagement and self-responsibility for their health and providing healthcare services with the data they need to improve medical care and service delivery'.[45] Beyond promising to solve the practical problem of enforceability, such reasoning also affects the way personal responsibility in healthcare is construed on a conceptual level.

5. Digitalisation and causal responsibility

As digitalisation promises to make personal responsibility for health *practically enforceable*, it is important to reflect on the consequences that this can have on the conception of personal responsibility and its use as a criterion to allocate healthcare resources.

Throughout the debates about personal responsibility for healthcare rationing, several attempts have been made to disentangle its different conceptual facets. Gerald Dworkin[46], for example, distinguished between three interrelated aspects of the concept of personal responsibility, namely role-responsibility, causal-responsibility and liability-responsibility. With regard to health, role-responsibility roughly could be said to refer to a person's responsibility for her health precisely because it's *her* body, of which she has an obligation to take care. In comparison, causal responsibility describes an individual bringing about a certain health impairment as a consequence of her very behaviour. As Walter Glannon put it: 'To the extent that a person has causal control over the events that determine his healthy or diseased condition, he is causally responsible for these events as well as for this condition'.[47] Finally, liability responsibility describes the aspect of holding a person materially accountable for her actions' consequences, such as paying for her own treatment.

While the other two aspects stay largely constant, it seems that increased traceability due to digitalisation in healthcare mainly affects causal responsibility. This dimension of responsibility focusses on voluntarily assumed risks and 'implicates [that] the individual's choices and actions with regard to diet, exercise, and so forth [help] to determine his or her health status'.[48] In other words, causal responsibility underscores the factual relations between individual behaviour and its consequences, encouraging to hold patients accountable for them. Traditionally, it is particularly this aspect of personal responsibility that has often been subject to moralisation.[49] This is because the underlying claim of causal responsibility is that every individual needs 'to change his personal bad habits or quit

[45] D. Lupton, 'The digitally engaged patient: Self-monitoring and self-care in the digital health era', *Social Theory & Health* 11 (2013):260.

[46] G. Dworkin, 'Voluntary Health risks and Public Policy', *The Hastings Center Report* 11 (1981):26-31.

[47] Glannon (note 25), 33.

[48] Minkler (note 1), 122.

[49] R.C. Brown, 'Resisting Moralisation in Health Promotion', *Ethical Theory and Moral Practice* 21 (2018):997-1011.

complaining. He can either remain the problem or become the solution to it'.[50] From this perspective, linking causal responsibility to culpability, *unhealthy behaviour* equals to *bad behaviour*, a problem for which people should be held accountable.

Digitalisation seems to be closely linked to this aspect of personal responsibility and it further extends its scope. By making individual behaviours ever more traceable, digitalisation emphasises the importance of choices with respect to health outcomes – is the patient compliant with medication regime? Does she eat, sleep and drink well? Has she sought medical treatment at the appropriate time? At the same time, digitalisation advances an allegedly value-neutral conception of responsibility, according to which individuals can be held accountable when objective data confirms they have causally contributed to their poor health. In this perspective, accessible and shareable information concerning the life – both inside and outside the healthcare sector – of a patient offers a supposedly *objective* benchmark that can be used to define and treat the patient herself. Health-related data is thought of as a repository of all the events and the choices that patients have taken and that can have a – direct or indirect – influence on their health.

When the causal aspect of responsibility is emphasised, patients' data can be framed as a useful tool not only to find the most apt treatment for single patients, but also to single out patients for whom healthcare resources can be used most effectively. As others have argued, there is a – potentially unconscious or implicit – connection between notions such as personalised or individualised healthcare and responsibilisation in healthcare policy.[51] Given the wide-spread optimism regarding the objectivity of data and algorithmic decision making[52], allocating resources based on vast individually and longitudinally collected personal data can be presented as objective, unbiased and therefore even just.[53] This is consistent with the view that 'digitisation of the welfare state and e-health services is an advancement based on the assumption that more access to information is better for citizens, patients and consumers'.[54] When choices and behaviour are documented through an extensive data-collection effort, holding individuals accountable for those choices and behaviours becomes a seemingly obvious consequence.

The focus on causal responsibility within the interplay between personal responsibility and digitalisation seems to have two further implications. On the one hand, tracking causally relevant health-

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[50] J. Knowles(ed.), *Doing Better and Feeling Worse: Health in the United States* (New York: Norton, 1997). Retrieved in Minkler (note 1).

[51] R.C. Brown, 'Moral responsibility for (un) healthy behaviour', *Journal of Medical Ethics* 39 (2013):695-698.

[52] P.L., Galison, 'Algorists Dream of Objectivity', in *Possible Minds: 25 Ways of Looking at AI*, ed. J. Brockman (Penguin Publishing Group, 2019), 231 et seq.

[53] In the literature supporting the use of personal responsibility as a rationing criterion, this includes roughly two elements: 1) the idea that only actions which produce a relevant health-related outcome (either positive or negative) would be used to ascribe responsibility; 2) that only those individuals who have autonomously chosen those actions would be held responsible.

[54] A. Fotopoulou & K. O'Riordan, 'Training to self-care: fitness tracking, biopedagogy and the healthy consumer', *Health Sociology Review* 26 (2017):65.

related behaviour before the onset of a disease further extends the reach of the medical paradigm into the ordinary life of the healthy, in line with the broader phenomenon of medicalisation. In fact, the advent of the new category of 'unpatients' – defined as 'neither patients in the usual sense of being under treatment, nor nonpatients, in the sense of being [totally] free of a medically relevant condition'[55] – had already been prognosticated at the dawn of the genomics era. With digitalisation, the datafication of medicine and the possibility to use data to predict future health status, the 'sense that some, perhaps all, persons though existentially health are actually asymptomatically or pre-symptomatically ill'[56] has advanced. Secondly – and more importantly –, the reinforcement of the *behavioural* side of personal responsibility caters for a conception of health that is markedly atomistic. The public health dimension of health tends to get lost, and the latter is rather seen as the product of a series of choices by single self-caring individuals. In this perspective, persons are positioned as 'ready and willing to actively engage in their own healthcare and promote their own health, in the attempt to shift such responsibilities from the state to the individual'.[57] If it is mainly dependent on behaviour, health belongs to the domain of the individual-consumer, with the corresponding need for the (welfare) state to back-off.[58] Indeed, a transition is happening from the idea that '[m]y health is the responsibility of my physician [and my healthcare system]' to the new thinking that '[m]y health is my responsibility, and I have the tools to manage it'.[59] As a consequence, if 'health is mostly a function of how individuals choose to behave, then medical care is less important'.[60]

6. Enforcing personal responsibility: the best way of using digitalisation to improve resource allocation?

In the previous paragraphs, we have explored some of the limitations that the practical implementation of policies using personal responsibility for health as a rationing criterion has traditionally encountered. We have shown how digitalisation promises to close the loophole of *practical enforceability* by offering tools for monitoring exposure to individual risk factor, thus allowing to hold people accountable for negative health outcomes. In this sense, digitalisation corroborates the often-implicit syllogism that, since many risk factors can be tracked on an individual level and correlate with behaviour, responsibility for health should be ascribed to individuals and their choices. This narrative is in line with the twofold promise of personalised healthcare which aims at being 'a stone that kills two

[55] A.R. Jonsen, S.J. Durfy, W. Burke & A.G. Motulsky, 'The advent of the "unpatients"', *Nature medicine* 2 (1996):623.

[56] N. Rose, *The Politics of Life Itself: Biomedicine, Power, And Subjectivity in The Twenty-First Century* (Princeton, NJ: Princeton University Press, 2007).Retrieved in Schüll (note 37).

[57] Lupton (note 44), 266.

[58] Schüll (note 37).

[59] M. Swan, 'Health 2050: The realization of personalized medicine through crowdsourcing, the quantified self, and the participatory biocitizen', Journal of personalized medicine 2 (2012):108.

[60] D. Wikler, 'Who should be blamed for being sick?', *Health Education Quarterly* 14 (1987):17.

birds: its [of personalised healthcare] effectiveness is tantamount to its cost-efficiency'.[61] The emphasis on the individual, her behaviour and her own personal responsibility is thus seen as 'an important contribution to diminishing the burden of disease and financial cost'.[62] From this perspective, even population health is not seen primarily as a collective concern, but as the arithmetical sum of the effort by single citizens to self-manage their own individual health.

However, even if digitalisation seemingly allows to create the conditions to use personal responsibility as a criterion to allocate resources, there are several limitations to this proposition. The first problem concerns accuracy. Although digital tools in healthcare allow to monitor patients (and prospective patients) in a much more granular way, measurement of individual behaviours is still an infant science, frequently rendering the quality of the measured data problematic. Some medical devices – especially wearables – are often commercialised without proper scientific validation, thus raising the question whether 'it make[s] sense—and is it ethically defensible—to collect and analyse data of questionable accuracy'[63], especially if such data is then used to determine access to socially funded healthcare. While if studies on the accuracy and validity of data produced by health monitoring tools have recently picked up[64], for now, caution concerning data quality is certainly warranted. The second challenge concerns determining causal relations. On a conceptual level, inferences from human behaviour to health outcome remain challenging and often spurious - not least given the complexities of health-related behaviour and the multifactorial aetiologies of many common diseases. The two policy examples discussed in this paper are cases in point for this. With regard to alcoholism, debates about the culpability of addicted individuals in light of their socio-economic circumstances, personal history and biological disposition are long-standing and have even featured in a controversial ruling of the US Supreme Court.[65] Even concerning the supposedly easier case of medication adherence, research shows that medication adherence is as much a function of patient-doctor-interaction and the structures of a health care system as it is the responsibility of individual patients. A comprehensive literature review on the topic thus concluded that '[b]elieving that medication nonadherence is the "fault" of the patient is an uninformed and destructive model that is best abandoned'.[66] Third, even if accuracy and causality issues can be surmounted for specific instances, the question remains whether we believe allocation

[61] T. Sharon, 'Self-tracking for health and the quantified self: Re-articulating autonomy, solidarity, and authenticity in an age of personalized healthcare', *Philosophy & Technology* 30 (2017):100.

[62] *Ibid.,* 100.

[63] Sperlich B, Holmberg H Wearable, yes, but able…?: it is time for evidence-based marketing claims!
British Journal of Sports Medicine 2017;51:1240.

[64] See e.g. E.A. Chowdhury, M.J. Western, T.E. Nightingale, O.J. Peacock & D. Thompson, 'Assessment of laboratory and daily energy expenditure estimates from consumer multi-sensor physical activity monitors', *PloS one* 12 (2017); M.A. Case, H.A. Burwick, K.G. Volpp, & M. Patel, 'Accuracy of smartphone applications and wearable devices for tracking physical activity data', *Jama* 313 (2015):625-626.

[65] Traynor and McKelvey vs. Turnage. (1988).108 S. Ct. 1372. Retrieved in Glannon (note 25), 39.

[66] M. Brown & J. Bussell, 'Medication Adherence: WHO Cares?', *Mayo Clinic Proceedings* 86 (2011):312.

based on personal responsibility to be adequate and ethically justified – especially from the point of view of justice. While it is beyond this paper's scope to take a general stance here, it seems clear that any answer to this question would need to take the actual consequences of implementing such policies into account.

So, is enforcing personal responsibility for health the best use of digitalization for allocating scarce resources? While digital monitoring of risk factors such as leading a sedentary life happens at the individual level, this does not necessarily entail that assigning responsibility to the individual is an appropriate or effective strategy to improve health outcomes – or reduce overall costs. Indeed, alternative approaches for using the potential of digitalization may be better suited to improving resource allocation. Digitalisation allows, for example, to collect data of large cohorts to scale-up epidemiological studies, improve our understanding of the impact of environmental factors on health and study how to 'make avoidance of behavioural risk factors easier'.[67] Digital tools can also be used to conduct Phase IV post-marketing studies of newly approved drugs, to then decide whether it is appropriate and safe to publicly reimburse their costs or recommend their use. Finally, digitalisation can offer the tools to better target public health interventions that extend beyond the individual level such as tailoring suitable limits for pollutants.

7. Concluding remarks

Allocation of resources is an intricate matter and developing strategies to cope with scarcity remains a constant challenge for healthcare systems. In this respect, tackling individual risk-factors that contribute to non-communicable diseases constitutes an important milestone. Digitalization can indeed support this process. With appeal to personal responsibility, digitalization may be used to monitor individual behavior to single out the allegedly "undeserving", whose healthcare expenditures should not be covered by public means. However, we hope we have illustrated the problems of using digitalisation in this manner. We are aware that neither of the alternative uses of digitalization we have suggested will definitely settle the problem of resource allocation. But holding individuals accountable for their digitally monitored health most likely won't either. Ethicists, policymakers and society at large should thus revisit old debates about distributive justice in healthcare and carefully think about the way new technologies are used for resource allocation.

[67] R.C. Brown, H. Maslen & J. Savulescu, 'Responsibility, prudence and health promotion', Journal of Public Health 41 (2018):563.

8. Abbreviations

COPD= Chronic Obstructive Pulmonary Disease

FDA= Food and Drug Administration

CDT= carbohydrate deficient transferrin

9. Acknowledgments

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3.2 Module II

3.2.1 Regulating the secondary use of data for research: arguments against genetic exceptionalism

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Abstract:

As accessing, collecting and storing personal information becomes increasingly easier, the secondary use of data has the potential to make healthcare research more cost and time effective. The widespread reuse of data, however, raises important ethical and policy issues, especially because of the sensitive nature of genetic and health-related information. Regulation is thus crucial to determine the conditions upon which data can be reused. In this respect, the question emerges whether it is appropriate to endorse genetic exceptionalism and grant genetic data an exceptional status with respect to secondary use requirements. Using Swiss law as a case study, it is argued that genetic exceptionalism in secondary use regulation is not justified for three reasons. First, although genetic data have particular features, also other non-genetic data can be extremely sensitive. Second, having different regulatory requirements depending on the nature of data hinders the creation of comprehensible consent forms. Third, empirical evidence about public preferences concerning data reuse suggests that exceptional protection for genetic data alone is not justified. In this sense, it is claimed that regulation concerning data reuse should treat genetic data as important, but not exceptional.

Introduction

The considerable potential that the extensive use of data in the medical field can disclose has been extensively discussed (Costa, 2014). Not only can data be exploited at an individual level to accurately implement personalised medicine (Meier-Abt et al., 2018)[1], but it can also be extremely useful at a societal level to help develop cost-efficient healthcare policies and carry out clinical and public health research (Dugas et., 2013).

Yet, alongside with many expected beneficial impacts, the full deployment of data in the healthcare sector also raises challenging legal and ethical questions. A great deal of these is related to the high mobility and interconnectivity of information which the big data era has brought about (Mittelstadt and Floridi, 2016). In a context where technical advances make it possible for data to be stored for a long time and to move quickly and unrestrained, data can be easily shared and subsequently reused. As a consequence, the distance increases between subjects and their personal information (Nuffield Council on Bioethics, 2015). It then becomes crucial to combine the pervasive and beneficial use of data with efficacious safeguards capable of protecting sensitive personal data, such as genetic and non-genetic health data (Jensen et al., 2012).

Finding the right balance between protecting privacy and promoting beneficial use of data is particularly difficult in the case of secondary use. In contrast to primary use, where data are collected and then used for a specific aim, secondary use entails the processing of data for different purposes to those originally envisaged when information is gathered and, potentially, also the involvement of data processors other than the primary data collectors (Schlegel and Ficheur, 2017). Conducting multiple secondary analyses on the same data has the potential to reduce costs and time for research (Safran et al., 2007; Geissbuhler et al., 2013). If usage of data was limited to primary purposes, subjects' integrity and privacy would be invaded more often, as data would have to be collected from them for every single data-usage. Moreover, data collection and analysis would become lengthier and more expensive (The Danish Council of Ethics, 2015), since new datasets would have to be created every time a new aim emerges.

Secondary use of data is important because of the many purposes for which data can be reused in the healthcare sector. These include organisational, educational, public health, commercial, disease surveillance, quality measurement and forensic purposes (Safran et al., 2007; Elkin et al., 2010; Barton et al., 2011). For example, digital histology slides can be used to train pathologists and routinely collected data from hospitals can be used for quality improvement and biomedical research. Moreover, the fact that data do not have a strong tangible and physical dimension entails that multiple secondary uses of data are not mutually excluding. Whilst re-using tissues or biological material is usually[2] possible for a finite amount of times, iterative access and exploitation of the same data unit do not affect the

[1] By this term we refer to medicine which "aims to prevent, diagnose and treat diseases by taking into account individual variability of genes, environment and lifestyle for each person" (Meier-Abt et al., 2018).

[2] There are only some cases where biologic material has been reused for a high number of times. The most notable one is that of Henrietta Lacks (Lasso, 2011).

integrity of either the single piece of information or the entire dataset where it belongs. As long as the single piece of information is not erased or lost, the same data can be cumulatively used for research, public health, clinical and commercial purposes, thus generating an incentive to rely on information which has already been collected (Richter et al., 2016).

Data reuse can be also be beneficial as many health systems are promoting the idea of learning healthcare, which has been be described as the attempt to "generate and apply the best evidence for the collaborative healthcare choices of each patient and provider; to drive the process of discovery as a natural outgrowth of patient care; and to ensure innovation, quality, safety, and value in health care" (Institute of Medicine, 2007:37). In the framework of learning healthcare, reuse of data collected in the clinical setting is fundamental, as it allows to conduct a wide range of healthcare research projects, whose results can then be "*fed-back*" to the healthcare system to improve the delivery and quality of care (Budrionis and Bellika, 2016). In fact, a core component of learning healthcare is to repeatedly exploit data routinely collected at different points of the care-cycle in multiple forms – such as electronic health records, health registries or laboratory tests – to fuel the chain of healthcare improvements (Deeny and Steventon, 2015; Meystre et al., 2017).

In a recent review of projects involving the secondary use of data, Martin-Sanchez et al. (2017) identified three main categories of cutting-edge initiatives in this field. Firstly, there are projects reusing data for clinical research, where patient data previously collected at different steps of their clinical management can accelerate recruitment and reduce redundant data capture. Secondly, data are increasingly reused for different types of evaluations of health interventions, in which routine data of patients undergoing alternative treatments can be used to retrospectively compare them. Thirdly, many projects have started reusing data in the field of genomic research and research concerning the effects of the environment on health. The latter category is particularly innovative, since these kind of projects often combine the reuse of both genetic and other health related medical information. For example, the eMerge Network initiative in the United States aims at linking genetic data from multiple biorepositories with other clinical health data, which would allow to study the association of genome-wide data with phenotypes defined through the electronic medical records data (McCarty et al. 2011).

Within this context, the objective of this paper is to discuss whether granting genetic data a special status in the regulation of data reuse represents a justified policy choice. To answer such a question, this contribution delineates the prevalent regulatory frameworks at both national and international levels and then compares them with Swiss law, which represents a rare case where genetic data are given an exceptionally special status with respect to secondary use requirements. The analysis of this unique normative framework is complemented by policy considerations, whereby the problematic aspects of endorsing genetic exceptionalism in regulation concerning the reuse of data are underscored. It is finally argued that the case of Switzerland suggests that granting genetic data an exceptionally special status in terms of reuse requirements is not an appropriate policy choice.

Secondary use of data for research purposes: Switzerland's unique regulatory framework

A supportive policy environment has been described as one of the crucial elements to favour the reuse of data (Safran et al., 2007). This entails having a regulatory framework that facilitates secondary use, but also protects privacy and autonomy (Sethi and Laurie, 2013). In order to strike a balance between these two elements, regulations normally establish that research involving the secondary use of personal health information can be permitted only if consent has been obtained from data subjects, the law and/or a research ethics committee (REC) has granted an exemption or the data have been anonymised or de-identified (Lowrance, 2003). This is the case, for example, for regulation and guidelines covering the processing of data for research in the EU, the US, and in Canada (Table 1).

Table 1. Requirements for the secondary use of data for research purposes.

	Informed consent	Research exemption	Data anonymization/de-identification [a]
European Union	The use (primary or secondary) of all sensitive types of data is permitted if subjects consent. (General Data Protection Regulation [GDPR], 2018, art. 9.2(a)).	The use (primary or secondary) of all sensitive types of data is permitted if the research exemption applies. (General Data Protection Regulation [GDPR], 2018, art. 9.2(j)).[3]	The use (primary or secondary) of all types of data for research is permitted if the data are anonymous or anonymised. (General Data Protection Regulation [GDPR], 2018, recital 26).
United States	Any use of protected health information (primary or secondary) cannot be done without the explicit authorisation by data subjects (Health Insurance Portability and Accountability Act of 1996 [HIPAA] (2013), §164.508).	An Institutional Review Board (IRB) or a privacy board can allow for research involving the use (primary or secondary) of protected health information to be conducted without data subjects' authorisation (Health Insurance Portability and Accountability Act of 1996 [HIPAA] (2013), §164.512).	The requirements for the use (primary or secondary) of personal health information do not apply if data have been de-identified (Health Insurance Portability and Accountability Act of 1996 [HIPAA] (2013), §164.502).
Canada	Research involving secondary use of identifiable information requires data subjects' consent. (Tri-Council Policy Statement 2 [TCPS 2], 2018, art. 5.5A).	Research involving secondary use of identifiable information can exceptionally be conducted without consent by authorisation of a Research Ethics Board. (Tri-Council	Researchers do not need to ask for consent if research relies exclusively on the secondary use of non-identifiable health. (Tri-Council Policy Statement 2 [TCPS 2], 2018, art. 5.5B).

[3] [3]The research exemption has been given a broad scope of application by the GDPR and should facilitate the performance of research without the need to obtain consent (Shabani and Borry, 2018). However, the GDPR also presents open clauses with respect to the processing of data for research purposes. Article 9(2)j and article 89 list "research" as a legitimate ground for the processing of data and delegate to member state the possibility to define on which further terms. This openness has been used, for example, by Denmark in art. 10 of the new Data Protection Act enacted at the national level to supplement the GDPR.

		Policy Statement 2 [TCPS 2], 2018, art. 5.5A).	

[a] Definitions of anonymization or de-identification vary in different legislations (Elger and Caplan, 2006) and sometimes even within the same country.

In the framework of data processing, a hierarchy is usually established between sensitive and non-sensitive personal information. Sensitive data are granted a higher level of protection than other personal information, generally by limiting their processing – both primary and secondary – or by setting more stringent conditions for the usage or collection of such data. For example in the EU, the recent General Data Protection Regulation [GDPR] (2018) recognizes the special nature of some types of personal information and establishes a series of specific rules that must be complied with when such sensitive data are handled (Shabani and Borry, 2018).

Within this hierarchy, it is usually acknowledged that genetic and health-related information are part of that sensitive data requiring a higher level of protection, but it is not considered necessary to draw a significant distinction between genetic and non-genetic data in terms of reuse requirements. With respect to secondary use requirements in the field of research, it is common to consider genetic and other non-genetic health data as equally sensitive, and genetic data are not granted any exceptional status (Wilkinson, 2010; Kim et al., 2018).

In contrast, Swiss law sets unequal normative standards for data reuse depending on whether data are genetic or health-related. The secondary use of data for research purposes is regulated by the Human Research Act [HRA] (2014) and the Human Research Ordinance [HRO] (2014), two comprehensive pieces of law passed in 2014 at the federal level. The HRA and HRO exclusively regulate the field of biomedical research and entail a set of sector-specific rules for the processing of data in this field. From a legal point of view, these sector-specific rules function as *lex specialis*, i.e. they override the general data processing norms contained in the Federal and Cantonal data protection laws (Rütsche, 2015). The latter only have a *subsidiary* function with respect to the regulatory framework for the processing of data in the field of biomedical research set by the HRA and HRO. According to this sector-specific regulatory framework, the conditions to reuse genetic data for research purposes are stricter, whereas secondary use of non-genetic health data is subject to more relaxed legal requirements. With respect to secondary use for research, Swiss legislation follows the doctrine of genetic exceptionalism, i.e. the idea genetic information is uniquely personal and thus deserves special protection (Annas et al., 1995). Accordingly, reuse standards are different depending on the genetic or non-genetic nature of data (see Table 2).

Table 2. Requirements for legitimate secondary use of data in Switzerland.

	Secondary use of identified[a] data	Secondary use of "coded"[a] data	Anonymization[a] of data for secondary use	Secondary use of anonymous[a] information
Genetic data	Explicit consent must be obtained for every single research project (Human Research Act [HRA], 2014, art. 32.1).	Explicit consent is required, but it can cover multiple research projects (broad consent). (Human Research Act [HRA], 2014, art. 32.2)	Explicit consent is NOT required, but data subjects have right to dissent (presumed consent). (Human Research Act [HRA], 2014, art. 32.3)	No requirements.
Other health-related data	Explicit consent is required, but it can cover multiple research projects (broad consent). (Human Research Act [HRA], 2014, art. 33.1)	Explicit consent is NOT required, but data subjects have right to dissent (presumed consent). (Human Research Act [HRA], 2014, art. 33.2)	No requirements.	No requirements.

[a] The meaning of these terms in the Swiss context is clarified below in the corresponding paragraphs.

The definitions of genetic and non-genetic health data

Similarly to other national and international regulations, Swiss law presents two different definitions for genetic and health data (Table 3).

Table 3. Definition of genetic and health-related data for the purpose of data processing: a comparison between different regulations.

	Definition of health-related data	Definition of genetic data
Switzerland	*"information concerning the health or disease of a specific or identifiable person, including genetic data."* (Human Research Act [HRA], 2014, art. 3.f).	*"information on a person's genes, obtained by genetic testing*." (Human Research Act [HRA], 2014, art. 3.g).
European Union	*"personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status"* (General Data Protection Regulation [GDPR], 2018, art. 4(15)).	*"personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question"* (General Data Protection Regulation [GDPR], 2018, art. 4(13)).

United States	"*any information, including genetic information, whether oral or recorded in any form or medium, that:* *(1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and* *(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual."* (Health Insurance Portability and Accountability Act of 1996 [HIPAA] (2013), §160.103).	"*information about:* *(i) The individual's genetic tests;* *(ii) The genetic tests of family members of the individual;* *(iii) The manifestation of a disease or disorder in family members of such individual; or* *(iv) Any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by the individual or any family member of the individual."* (Health Insurance Portability and Accountability Act of 1996 [HIPAA] (2013), §160.103).
Canada	*"(a)information concerning the physical or mental health of the individual;* *(b)information concerning any health service provided to the individual;* *(c) information concerning the donation by the individual of any body part or any bodily substance of the individual or information derived from the testing or examination of a body part or bodily substance of the individual;* *(d) information that is collected in the course of providing health services to the individual; or* *(e) information that is collected incidentally to the provision of health services to the individual."* Personal Information Protection and Electronic Documents Act [PIPEDA], 2019, Part 1 Section 2).	There is no specific and uniform definition of genetic data (Walker, 2014).

According to the Human Research Act [HRA] (2014), health data include all pieces of "information concerning the health or disease of a specific or identifiable person, including genetic data" (Human Research Act [HRA], 2014, Art. 3.f). To define genetic data Swiss regulation adopts a more pragmatic approach, if compared with its international counterparts. Unlike other regulations (Table 3) the Swiss definition covers "information of a person's genes", but only when this is "obtained by genetic testing" (Human Research Act [HRA], 2014, art. 3.g). This implies that the special status granted to genetic data does not apply to all the genetic characteristics of a natural person, since, in order to qualify as "genetic" for the application of the law, data need both to satisfy a requirement about the nature of the information itself and about its source (Schweizer Bundesrat, 2009). In this sense, data concerning a person's genes whose source is not a genetic test have to be considered as normal health data, as far as reuse requirements are concerned.

Secondary use of identified genetic and non-genetic health data

The distinctive feature of identified data is that it is so rich and comprehensive that it is possible to identify data subjects by looking at the single dataset alone and without the need to rely on any additional pieces of information (Heuberger-Götsch and Burkhalter, 2014). Since in this case data subjects can be easily tracked back, reuse requirements are generally strict.

For the secondary use of identified genetic data, Swiss law establishes that informed consent needs to be both specific and explicit (Human Research Act [HRA], 2014, art. 32.1). In this case, consent must therefore be referred to clearly defined research project(s) and cannot cover broad or unspecified areas of research. Moreover, it must also be explicit, thus always requiring an affirmative action by the data subject, whose agreement cannot be presumed – for example – by using a consent form with pre-ticked boxes. Therefore, researchers willing to reuse identified genetic data need to re-contact all data subjects and obtain a renewed provision of consent for every new study involving their data. On the contrary, for non-genetic health data researchers still need to ask for explicit consent, but this does not need to be related to a specific study and can cover broad classes of research (Human Research Act [HRA], 2014, art. 33.1 HRA). This type of consent is commonly referred to as "broad" or "general" (Grady et al., 2015) and offers the advantage of being valid for a wide range of research projects, even if these do not coincide with the initial reason for data collection (Petrini, 2010). Once data subjects have provided this form of consent, there is no need for researchers to re-contact participants before any new study involving the reuse of the same set of data, as long as research lies within the area that was covered by the initial provision of consent.

Secondary use of "coded" genetic and non-genetic health data

Secondary use requirements are different if personal data are "coded". The key characteristic of "coded" data is that re-identification – although always possible – can only be achieved through the use of additional information to those present in the dataset, normally referred to as "key" or "code" (Heuberger-Götsch and Burkhalter, 2014). In the literature, a distinction is sometimes made between "coded" or "pseudonymized" data on the one hand and "reversibly anonymised" data on the other, depending on whether the key to re-identify data subjects is kept in-house by the researchers managing the dataset or is held by third parties (Elger and Caplan, 2006). Swiss definition of "coded" data, on the contrary, covers every personal information "linked to a specific person via a code" (Human Research Act [HRA], 2014, art 3.h), whether or not researchers have direct access to the key necessary to re-identify data subjects. The law requires that the "key must be stored separately from the material or data collection […] by a person to be designated in the application who is not involved in the research project" (Human Research Ordinance [HRO], 2014, art. 26.2). This resembles in part the requirements of the GDPR, which demands that the key "is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable

natural person" (General Data Protection Regulation [GDPR], 2018, art. 4(5)). In this respect, it is also important to underscore that – according to Swiss regulation – as long as the key to achieve re-identification exists, data must be regarded as "coded" data and cannot be considered "anonymised" (McLennan et al., 2018; Rütsche, 2015).

In Switzerland, for "coded" genetic data, explicit consent must be obtained, either for a specific project or also for broad classes of research (Human Research Act [HRA], 2014, art. 32.2). For "coded" non-genetic health data, on the contrary, explicit consent is not needed. If researchers provide some basic information to data subjects, consent can be implicitly presumed, as long as the data subjects have not explicitly dissented (Human Research Act [HRA], 2014, art 33.2). Researchers simply have the duty to inform the individuals whose data are to be reused of the proposed use of the data, of the right to dissent, of the measures in place to protect information and of the possibility that data are passed over to third parties (Human Research Ordinance [HRO], 2014, Art. 32). With this form of "presumed" consent (also known as "*opt-out*" model), it remains a challenge to register an eventual dissent by the data subject (Rütsche, 2015; Swissethics, 2018). In this case, the *default option* (i.e. the case where the data subject does not explicitly neither consent nor dissent to the reuse of his data) is that secondary use of "coded" data is permissible, since consent is presumed.

Secondary use of anonymised genetic and non-genetic health data

As highlighted in Table 1, anonymization is commonly recognised by many regulations as a valid alternative to consent to reuse information without infringing on data subjects' rights. This is due to the widespread regulatory assumption that anonymous data do not represent personal information (El Emam et al., 2015). This holds true also for Switzerland, where the lawmaker has established that anonymous data fall outside the scope of the HRA (Human Research Act [HRA], 2014, art. 2.2), thus implicitly allowing to conduct research on non-identifiable data, regardless of the genetic or non-genetic nature.[4]

[4] Naturally, it remains a challenge to define to what extent genetic data can truly be de-identified. In fact, although it might be difficult to re-identify data subjects from single portions of their DNA, the whole genome data of a person is so unique that it is always possible to track back the data subject. However, whether data can be considered as "de-identified" or "anonymized" depends also on the legal definition of de-identification or "anonymization". The GDPR, for example, does not directly define anonymization, but explains that "the principles of data protection should therefore not apply to anonymous information, namely information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable" (GDPR recital 26). It then adds that "to determine whether a natural person is identifiable, account should be taken of all the means reasonably likely to be used, such as singling out, either by the controller or by another person to identify the natural person directly or indirectly. To ascertain whether means are reasonably likely to be used to identify the natural person, account should be taken of all objective factors, such as the costs of and the amount of time required for identification, taking into consideration the available technology at the time of the processing and technological developments."(GDPR recital 26). From a more technical perspective, "de-identification" or "anonymization" is defined as the process of eliminating all direct identifiers and indirect (or quasi) identifiers, i.e. the metadata

However, if genetic data are collected in an identifiable form and then only subsequently anonymised, special reuse requirements apply. According to the law, anonymization consists in the deletion of "all items which, when combined, would enable the data subject to be identified without disproportionate effort" (Human Research Ordinance [HRO], 2014, art. 25.2), including – in particular – metadata such as the "name, address, date of birth and unique identification numbers" (Human Research Ordinance [HRO], 2014, art. 25.2). If genetic data are anonymised following this process, secondary use for research purposes can be performed only if data subjects have not actively expressed their dissent (Swissethics, 2017) and if researchers fulfil some information duties. The latter include the obligation to inform data subjects of their right to dissent and of the possibility that data are transferred to third parties once anonymised (Human Research Ordinance [HRO], 2014, art. 30). Moreover, since advances in medical sciences have contributed to further enhance the predictive value of genetic data, the lawmaker also requires that subjects are warned that anonymization might entail indirect consequences on their state of health, since it might impede – for example – the return of clinically relevant findings (Rütsche, 2015). Informing data subjects before their data are anonymised also offers them the last chance to withdraw their data from the research, which is not possible anymore once any link between them and their data is eliminated.

Whereas anonymization of genetic data for secondary uses is explicitly regulated, the HRA does not provide any indications as far as non-genetic health data are concerned. In consequence, it must be assumed that, with non-genetic health data, anonymization before data reuse can be performed without the necessity to consult or even inform data subjects' (Schweizer Bundesrat, 2009). In this case, the lawmaker has favoured the interest of research over individual concerns about privacy and autonomy (Rütsche, 2015).

Is it appropriate to grant genetic data an exceptionally special status? A reflection based on the Swiss experience

Switzerland represents an ideal case-study to reflect upon the implications of endorsing genetic exceptionalism for the secondary use of data. Indeed, although there have been some calls for considering implementation of regulation granting genetic data an exceptionally special status with respect to secondary use requirements for research (McGuire et al., 2008), to our best knowledge the Swiss legal system is unique in having fully endorsed this stance. Moreover, Switzerland is one of the many countries that is striving to develop a learning healthcare system. At a national level, there have been calls to favour those iterative processes of healthcare improvements by allowing the flow of data from care to research – and of knowledge from research to policy-making – which are the distinctive

related to the information collected from a data subject (i.e. name, social security number, date of birth etc.) (El Emam et al., 2015).

feature of learning healthcare (Boes et al., 2018). Facilitating the secondary use of data is, in this respect, a priority. In a call for research launched in 2015 by the Swiss National Science Foundation, it was emphasised that improving the conditions for data accessibility and re-usability is especially important to remedy to the underdeveloped sector of health service research (Swiss National Science Foundation, 2015).

When reuse regulation was implemented, the Swiss legislator relied on two arguments to justify the special status granted to genetic data with respect to secondary use requirements. First, it was claimed that genetic data, because of their high predictive value, contain extremely delicate personal information, whose handling – especially in the case of secondary uses – requires stricter and more demanding standards (Schweizer Bundesrat, 2009). Second, the legislator argued that genetic data, as they can reveal some of the most distinctive traits of a person, presents higher re-identification risks in comparison with other health data. In this sense, offering data subjects more control over their data before this can be shared and reused was deemed as a necessary measure to protect individuals' privacy (Schweizer Bundesrat, 2009). These justifications are in line with the fundamental assumption of the doctrine of genetic exceptionalism, namely that genetic data are an extraordinarily sensitive type of personal information and deserves therefore an exceptionally special status (Annas, 1995). This assumption is mainly based on considerations about privacy, confidentiality, and security, as genetic data are deemed to have a high predictive value and to entail considerable re-identification risks (Annas, 1995; McGuire et al., 2008).

In our view, however, the experience of Switzerland suggests that granting genetic data a special status with respect to secondary use requirements can be problematic both from a theoretical and a practical perspective. In particular, we argue that imposing stricter reuse requirements for genetic data neglects that also other health-related data can be particularly sensitive, it overcomplicates the drafting of comprehensible consent forms, and it is not supported by empirical evidence concerning data subjects' preferences about the reuse of their data.

Also non-genetic data can be sensitive

The claim that only genetic data have a high predictive value and poses serious re-identification risks seems to be inaccurate (Rütsche, 2010), especially in the big data era. The interpretation of genetic information is, to some extent, still an infant science and, although useful, genetic prediction has not yet become as accurate as the initial hype suggested (Jostins and Barrett, 2011). Furthermore, the application of artificial-intelligence-based approaches – such as machine learning – to the medical field has demonstrated that also routinely collected non-genetic data have the potential to predict the future health status of a person (Beam and Kohane, 2018). A recent review, for example, illustrated how machine learning can be used to enhance prognostic prediction after the onset of a mental illness based on baseline neuroimaging scans (Walter et al., 2019). Moreover, although it is true that genetic information represents a key to the identity of a person (McGuire et al., 2008), it cannot be neglected that even other

health-related data can easily allow the re-identification of data subjects. For example, in a study published in 2013, it was proved that it was relatively easy to re-identify individuals with a 95% confidence level starting simply from laboratory results, although these had been previously de-identified (Atreya et al., 2013). Similarly, in another study published in 2018, it was proved that also physical activity data with geographic and protected health information removed could be easily re-identified using machine learning without the need to rely on genetic data (Na et al., 2018).

The fact that also non-genetic health data can have a predictive value and can be re-identified does not entail that they are inherently equal to genetic data. Genetic data feature specific qualities, such as: 1) the fact that they provide information about family members; 2) that DNA sequence variations of an individual are unique and lifelong; and 3) that future developments of genetic risks prediction might multiply the information that genetic data provide. Our claim is rather that both genetic data and other health-related data can be very sensitive, albeit for different reasons. For example, a medical record containing the diagnoses of a mental disease or whether the patient is HIV positive are both very stigmatising details about a data subject, even if they would not fall under the category of genetic data. As it has been argued, "it is not always clear what intrinsic properties of the DNA molecule (e.g., DNA sequence, genetic mutation) make it more deserving of protection than other types of information contained in the medical record of an asymptomatic, at-risk person (e.g., familial history of disease, cholesterol level and high blood pressure)" (Dupras et al.,2018:2). On the same line, the National Committee on Vital and Health Statistics – an advisory body of the United States Federal government for matters concerning health data and privacy – repeatedly recommended to consider several categories of data as sensitive, including not only genetic data, but also mental health information, data about reproductive health and substance abuse (National Committee on Vital and Health Statistics, 2008 & 2010). All these categories of data concern intimate aspects of people's lives and could be similarly be misused for discriminatory purposes.

Therefore, from the perspective of data subjects' privacy, it would seem more appropriate that a distinction (if any) in regulatory requirements for secondary use were based on the degree of sensitiveness of personal data, or simply on the degree of de-identification, rather than on the genetic or non-genetic nature of the data themselves. As it has been argued, the fact that genetic data are qualitatively different does not *per se* justify exceptional protection, since *all* data subjects' information deserves in principle privacy protection (Sulmasy, 2015). The type and nature of the data is undoubtedly an important element to determine whether special protection should be granted. However, perception about the sensitiveness of data might also be influenced by elements such as: 1) whether the data are shared and reused cross border; 2) whether the data were initially collected under a strong assumption of confidentiality (e.g. medical history or notes taken during a psychotherapy); 3) what conditions there are for allowing reuse by third parties, especially industry.

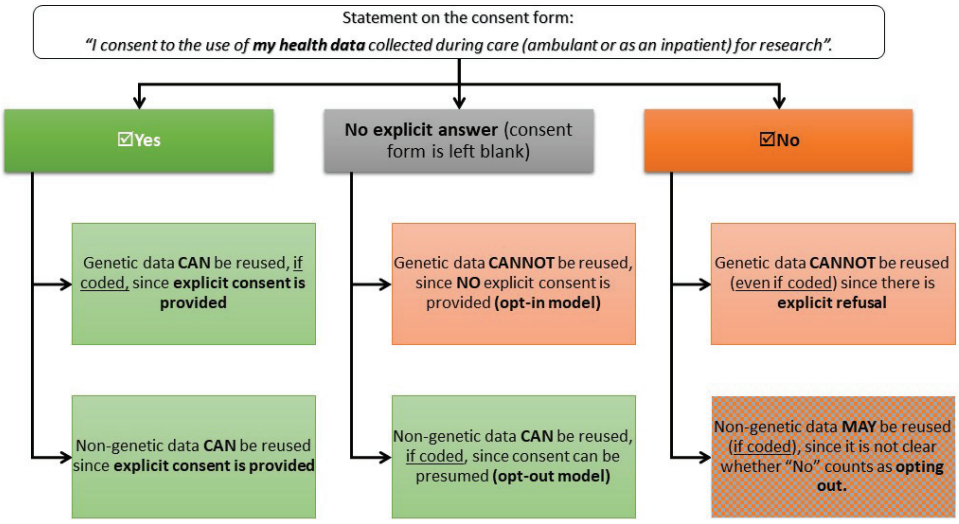
If it offers special protection to certain categories of personal data only depending on the nature of the data and not on the context or the level of de-identification, regulation might secure legal certainty, but

also produce counterintuitive consequences. For example, the GDPR offers special protection (General Data Protection Regulation [GDPR], 2018, art. 9) to health data in general regardless of the context, which implies that the mere information that a person carries glasses would receive special protection with respect to data processing (Paal and Pauly, 2018). On the contrary, data about the economic relationships would not be offered the same protection, despite being arguably quite more sensitive than the information whether one carries glasses (Paal and Pauly, 2018). Moreover, relying only on the nature of the data to determine sensitiveness has the further drawback that the definitions of different categories of data provided by the law are often quite generic and open ended, and might not correspond to the complexity of current data rich research.

Different rules for the *default option* hinder the creation of clear consent forms

Secondly, the presence of different regulatory requirements complicates the process of drafting clear and reader-friendly consent forms, thus impacting on transparency and trust in the researchers. In fact, the presence of different legal standards for the two types of data entails that a consent form should ensure that data subjects understand: 1) the difference between genetic and non-genetic health data, and 2) the different consequences that stem from not providing explicit consent. As to the first point, whereas the distinction between genetic and non-genetic data can be clear-cut from the perspective of researchers, the same does not necessarily hold true for lay people. A solution could be the elaboration of tiered consent forms, where the data subject can elicit the types of studies that they want their data to be reused for (Bunnik et al., 2013). But even if tiered consent forms were to be used, the problem would remain that patients would need to understand how the same answer on the consent form has different implications depending on the type of data it refers to, because of the diverging regulatory standards. In Switzerland, for example, *explicit* consent is required for the reuse of genetic data (opt-in model), whereas non-genetic health data can be used even without explicit consent if they are "coded", unless the subject explicitly opts out (opt-out model). This entails that the *default option* (i.e. what happens if no explicit answer is provided) for the two types of data is different, thus causing some divergence in the consequences that the same answer in the consent form has for genetic or non-genetic health data (see Figure 1).

Figure 1. Legal consequences of data subjects' replies on consent forms in Switzerland.



This decision-tree illustrates what are the consequences of the different choices that data subjects can take when compiling the consent form. Under the current national policy, patients that enter a care facility (ambulatory or hospital) should be provided with a consent form that explains them how their data collected during clinical care might be reused for research and then asks them whether they would consent to the secondary use of their data.

Indeed, in Switzerland the creation of an appropriate consent form following the regulatory requirements for the reuse of genetic and non-genetic data has proven to be a challenge. Since 2015 the Swiss Academy for Medical Sciences (SAMS), Swissethics (the umbrella organisation of all regional RECs, also responsible for coordinating and harmonising the ethical overview of research) and Unimedswiss (an organisation of all university hospitals) have been attempting to elaborate an appropriate consent form that would mirror regulatory standards. A first draft was published in 2017 (Swiss Academy of Medical Sciences, 2017), but it was soon criticized by patient organisations, single hospitals and representatives from the research community. These denounced the lack of clarity in terms and formulations and described as potentially deceptive the procedure of how consent for the reuse of non-genetic data in a "coded" form could be implied as long as the subject does not explicitly dissent (Swiss Biobanking Platform, 2018), which is a consequence of having different regulatory requirements for this kind of data. A study put this consent form to the test with some subjects and confirmed that the difference in regulatory standards between genetic and non-genetic data can be difficult to convey (De Nardi et al., 2018). The study concluded that "the fact that different levels of data protection – depending on the type of data (genetic vs. non genetic) – are legally stipulated creates a potential problem of

comprehension" (De Nardi et al., 2018:27).[5] A subsequent version for a uniform consent form to be used throughout the country was drafted as a reaction to these criticisms and it *de facto* abandoned any significant distinctions between genetic and non-genetic data, by requesting data subjects to *explicitly* consent or *explicitly* dissent for the reuse of both (Unimedswiss, 2019). This confirms that, although setting more relaxed regulatory standards for non-genetic health data is aimed at facilitating their reuse, this objective might backfire. Having different *default options* for genetic and non-genetic data comes at the price of reducing the clarity of consent forms, which is key to promote data subjects' support and participation rates, especially for those research projects aimed at improving clinical care.

Empirical evidence suggests data subjects do not support genetic exceptionalism

Setting different regulatory requirements for genetic data also seems to go against the findings of empirical research investigating data subjects' preferences concerning the secondary use of data in different countries. In the United States, a conjoint analysis study with 3064 participants exploring public preferences about reuse of electronic health information found that the nature of the data does not affect subjects' willingness to agree to the reuse of their data (Grande et al., 2013). According to this study, subjects' concerns about secondary use of their data refer to the purpose (e.g. marketing, quality improvement, research) of data reuse, rather than to the genetic or non-genetic nature of data. Despite inherent limitations of their study, the authors explicitly conclude that their "finding contrasts with the notion that patients view genetic information as particularly sensitive" and that "it may add support to the arguments against privileging genetic information, as some experts have argued" (Grande et al., 2013:1802). Another quantitative study with a sample of 2945 participants was conducted in the Unites States with the objective of exploring cancer patients' views concerning the secondary use of their health information (Grande et al., 2015). Even this study concluded that "although policymakers, clinicians, and ethicists tend to add extra protections to genetic information because of concerns over reidentification, discrimination, and the unknown significance of certain findings based on current knowledge, the cancer participants in our study were more willing to share their information when inherited genetic results were included" (Grande et al., 2015: 381). The authors hypothesise that cancer patients might be further motivated to allow the reuse of their genetic data since they realise the importance of this type of information and the benefit it might bring to society and research. A qualitative study from the United States on the views of prospective participants in research concerning data sharing went even further and it explicitly concluded that data subjects often see non-genetic medical data as more sensitive than genetic medical data (Trinidad et al., 2010). In this study, many of these prospective participants argued that non-genetic health data are often shared with healthcare

[5] [5]Translation from the original text in German. The original reads "die Tatsache, dass unterschiedliche Stufen des Datenschutzes – je nach Art der Daten (genetisch vs. nicht-genetisch) – gesetzlich vorgeschrieben sind, stellt ein potenzielles Verstehensproblem dar".

providers under the assumption that it will be treated with confidentiality, and should thus be considered even more sensitive than genetic data. Prospective participants were particularly worried about the potentially stigmatizing contents of their confidentially shared non-genetic medical records, e.g. concerning their reproductive or mental health. As far as Switzerland is concerned, a qualitative study with semi-structured interviews was conducted in 2017 to investigate the attitudes of older adults towards the sharing of genetic data (Mählmannet al., 2017). In this case, participants were split: half of them considered that the two types of data should be treated differently; the other half expressed their opposition to any differentiations between genetic and non-genetic data. Interestingly, those who were in favour of no differentiation justified such belief by mentioning the conviction that both types are equally important for the progress of medical knowledge. In general, the great majority of the participants to this study underlined their confidence that making genetic data available for research was important to contribute to the common good and to the acceleration of research.

Although not conclusive, all this empirical evidence suggests that, when it comes to secondary uses, data subjects do not feel strongly about the formulation of exceptional protection for genetic data. On the contrary, the public seem to agree that even non-genetic data should be treated as sensitive and they reveal awareness as to the importance of making genetic data available for research. Such positive attitude by the public towards research with genetic data might not be sufficient to justify an opposition to genetic exceptionalism "in general", but it provides convincing evidence against the adoption of genetic exceptionalism in regulation concerning the secondary use of data for research.

Actionable recommendations and conclusions

Designing a supportive normative framework for the reuse of data is of crucial importance for the development of a successful interaction of research and clinical care. The example of Switzerland suggests that granting genetic data an exceptionally special status does not provide a satisfactory policy choice to this aim. In Switzerland, the distinction between genetic and non-genetic health data represented an attempt to strike a balance between the interest of research in having easy access to individual data and the protection of personal privacy and autonomy. However, implementing genetic exceptionalism resulted in a multi-level regulation that is a barrier to the free flow of data between care and research without a convincing justification. Moreover, the complex Swiss reuse regulatory framework negatively impacts on normative clarity, thus not only hindering healthcare research, but also compromising individuals' understanding and control over their personal data.

Differences with respect to secondary use standards between states can already be a significant obstacle for research (Mittelstadt and Floridi, 2016) and creating further differentiation in terms of reuse requirements within a single legal system adds to this problem. Although genetic data are undoubtedly sensitive, it is also true that medical information as a whole is highly private, valuable and requires appropriate safeguards (Evans and Burke, 2008). For the context of Switzerland, this was confirmed by a recent study conducted with Swiss RECs and exploring the attitudes towards research with human

tissues, where it emerged that REC members considered clinical data in general – and not genetic data in particular – as an element whose presence required stricter consent requirements (Colledge et al., 2018) If any distinctions in terms of secondary use requirements were to be present, they should thus be based on the sensitiveness of information, rather than simply on its genetic or non-genetic nature.

In today's healthcare systems, it is crucial to strike the correct balance between protection of personal information and facilitation of data reuse for research purposes. Although this is no easy task, it is important that regulation is confronted with those practical issues that it raises and that it is note based on purely normative claims. In this sense, setting higher regulatory standards for genetic data cannot come at the price of the law being too articulated and potentially disorientating for both research institutions and data subjects. In Switzerland, dissatisfaction with the current regulatory framework has been voiced also by Swissethics and, in a recently delivered report, it has been suggested that the special status granted to genetic data is one of the most problematic aspects the legislator should revise (Swissethics, 2018). Indeed, the whole Swiss regulation concerning human research is currently under evaluation by the Federal Office of Health, and one of the key points of such evaluation concerns exactly the question whether rules concerning secondary use are appropriate (Bundesamt für Gesundheit, 2017). For this reason, it is to be hoped that Switzerland will soon align with other national and international regulations and that, with respect to secondary use requirements for research, genetic data will continue to be considered important, but not exceptional. Thereby, we do not argue that reuse requirements for genetic data should necessarily be more relaxed, but simply that legal standards should not differ between genetic and non-genetic data. Whether requirements are strict or relaxed is something that depends on the cultural and societal circumstances where legislation is enacted. In fact, any regulatory and procedural burdens have their *raison d'être*, but only when they have a good justification and the alternatives are worse. In the case of secondary use, different standards between genetic and non-genetic do not seem to be justified, since they neglect that also non-genetic health data can be very sensitive, and they are not the best alternative, since having the same standards – whether strict or relaxed – for all kinds of data would simplify the consent process, help secure the trust of data subjects and ensure that reuse of already collected data is rightfully promoted.

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Authors' contributions

AM, BE and SM conceived the initial idea of the paper. AM prepared the initial draft under the guidance of SM and BE, who continuously provided feedback and comments. LG and CPM reviewed the draft,

provided feedback about the regulation analysis, brought in additional motivations against genetic exceptionalism and finalized the discussion parts. All authors read and approved the final version of the paper.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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List of abbreviations

GDPR: General Data Protection Regulation

HIPAA: Health Insurance Portability and Accountability Act

TCPS 2: Tri-Council Policy Statement 2*:* Ethical Conduct for Research Involving Humans

PIPEDA: Personal Information Protection and Electronic Documents Act

HRA: Human Research Act

HRO: Human Research Ordinance

REC: research ethics committee

IRB: Institutional Review Board

SAMS: Swiss Academy of Medial Sciences

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3.2.2 Data protection and biomedical research in Switzerland: setting the record straight

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Abstract

Ensuring the protection of privacy and the compliance with data protection rules have become central issues for researchers active in the biomedical field. In this respect, data protection law is often perceived as very complex to interpret and thus potentially hindering the efficacious planning and implementation of new research projects. Indeed, the sophisticated legal architecture that governs data processing activities in general and biomedical research in particular might feel overwhelming for both legal practitioners and researchers.

In this context, the objective of this article is to review the interaction of data protection law and biomedical research with a predominant focus on the Swiss context. In order to facilitate a better understanding of the interplay between law and data processing in the research field, we discuss three crucial nodes of such interplay. First, the meaning of "personal" data, the requirements to classify data as "personal", "non-personal", "pseudonymised" or "anonymized" and the implications of such classifications from a legal perspective are explored. Second, the relationship between sector-specific data processing regulations for research and other laws on data protection is investigated. Third, the role of consent for data processing in the research field and its significance from a data protection perspective is examined. In conclusion, the importance of fostering reciprocal collaboration of data protection experts and biomedical researchers to facilitate the development of new projects in the future is underlined.

1. Introduction

In the last few years, concerns about the protection of personal data have become an increasingly important subject of discussion in biomedical research. Although it could be argued that data in general – and personal data in particular – have always been a central component of research, it is only recently that discussions about the appropriate data processing standards in this field have intensified. Arguably, this can due to two intertwined factors, one related to the research world and one to legal developments. On the one hand - due to the progressive digitalization of healthcare - clinics, laboratories and other medical research institutions have become data-driven environments, where the processing of large amounts data has grown exponentially. Fueled by innovative projects in fields like genomics (e.g. the human genome project [1]), neuroscience (e.g. the human brain project [2]) and by the development of precision medicine [3], the urge to accumulate vast amounts of personal data of different types has skyrocketed. This has been further intensified by the open science and open data movements in their different declinations [4]. On the other hand, there is rising awareness that the law is increasingly involved in the regulation of data processing in general and data processing for research purposes in particular. In the recent General Data Protection Regulation (GDPR) [5] by the European Union, for example, it is reasserted how research undoubtedly falls under the scope of data protection law and a specific "research exemption" has been created for the processing of data for research purposes, especially in case of secondary processing [6] (see also section 2.3). In preamble[1] 159, it is firmly asserted that: "Where personal data are processed for scientific research purposes, this Regulation should also apply […]. For the purposes of this Regulation, the processing of personal data for scientific research purposes should be interpreted in a broad manner including for example technological development and demonstration, fundamental research, applied research and privately funded research." The increasing importance of considering data protection aspects in biomedical research also holds true for Switzerland, where several projects have been initiated to facilitate the use of data for research in an ethically and legally sound fashion. For example, fostering a more comprehensive, coordinated and efficient processing of data in healthcare was one of the main objectives of the National Research Program 74 launched in 2015 by the Swiss National Science Foundation [7]. In the same spirit, the Swiss Personalised Health Network (SPHN) was recently started as a nationwide initiative with the specific mandate to leverage the potential of health-related data [8] in particular with respect to the research sector [9]. Or else, in 2016, the Swiss Biobanking Platform was initiated to facilitate the harmonization of biobanks and their research work with biological material and personal data [10]. All these initiatives are designed with particular attention to the legal ramification of data protection, probably also due to presence in Switzerland of a specific piece of law that regulates in details the processing of personal data in the research sector (the Human Research Act - HRA [11], see below). Issues related to the legal

[1] In European Law, preambles are claims attached to any approved law to indicate the motivations of the legislator in enacting such law and to indicate how it ought to be interpreted. They are not, however, legally binding.

ramifications of data protection in relation to scientific research are also likely to remain a central concern for the scientific community in the future, since a revised version of the Federal Act on Data Protection (FADP [12]) is currently being discussed [13] (for the relationship between FADP and HRA, see below).

With such increased interplay between biomedical research and data protection law, the latter is often perceived as a potential hindrance from the perspective of researchers. In international reports on the status quo of the health-data framework of Switzerland and other developed countries, it is often spoken of "legal barriers" (e.g. [14]). Indeed, even in the interviews with national stakeholders conducted as part of a project of our research team about the health-data framework in Switzerland[2] [15], a commonly expressed complaint – especially by researchers – was that navigating data protection rules is demanding. Prima facie, such observation appears to have some factual basis. In Switzerland alone there are 26 different data protection regulations (the FADP and 25 cantonal data protection laws - the cantons of Jura and Neuchatel have a common data protection bill [16]), a law on biomedical research, several other sectorial regulations containing norms about personal data processing, and even additional rules related to data processing in the criminal code (see below). It is understandable that researchers in the biomedical field might feel overwhelmed by such a complex regulatory architecture. The truth is that even for experts in the legal field the interaction between data protection rules and research poses many uncertainties [17]. In this respect, addressing difficulties concerning how to combine the potential of data-rich research projects with adequate protection of the privacy of people whose data are used (data subjects) can thus benefit from an open dialogue between the research and the legal field.

In this context, the objective of this contribution is to offer an overview of the current debate in the legal field around three nodes of data protection law that concern biomedical research. It is – according to the classification by Grant and Booth [18] – a critical review, since it aims to go beyond mere description of the reviewed literature and case law and includes a certain degree of conceptual innovation. Given space constraints, our focus is on three nodes that are considered of primary importance in the literature. Other relevant issues in the legal debate (e.g. the concepts of purpose limitation or data minimization) are only indirectly touched insofar as it is functional to the other nodes of the review. We start by tackling the topic of the meaning of personal data, since this is the primary criterion that determines whether any data protection rules apply or not – also for biomedical research. Afterwards, we discuss the presence of specific data-protection rules concerning exclusively the processing of personal data for research purposes. Finally, we turn to the topic of consent and clarify its role in data processing in general and data processing for research in particular. This review draws mainly on legal literature and legal sources (both judicial decisions and legal texts), but our intent is to address the medical and research community. Moreover, although the focus is on Switzerland – and its legal framework – this review is of interest also for a non-Swiss readership, since the three nodes discussed are central to the interaction between

[2] Manuscripts in preparation.

data protection regulation and research across borders. To help link the content of this review with the legal texts, we provide a conversion table (see Table 1) of the legal terminology discussed, to facilitate reference to original legislative acts not written in English.

Table 1. Cross-Language comparison for Switzerland of the legal terminology discussed as part of the first node.

Term in English discussed in the Review	**Correspondent in German**	**Correspondent in French**	**Correspondent in Italian**
"Personal data"	"Personendaten" or "Personenbezogene Daten"	"Données personnelles»	"Dati personali"
"Relating to"	"sich beziehen auf"[a]	"se rapporter a"[b]	"relative a"[c]
"Identified or identifiable"	"Bestimmt oder bestimmbar"	"identifiée ou identifiable"	"identificata o identificabile"

[a] As in article 3.a. of the FADP " Personendaten (Daten): alle Angaben, die sich auf eine bestimmte oder bestimmbare Person beziehen".

[b] As in article 3.a. of the FADP "données personnelles (données), toutes les informations qui se rapportent à une personne identifiée ou identifiable"

[c] As in article 3.a. of the FADP "dati personali (dati): tutte le informazioni relative a una persona identificata o identificabile"

2. Three "nodes" at the crossroad between biomedical research and data protection law

2.1 The meaning of *personal* data

Data protection law is not relevant for the processing of data *in general*, but for the processing of *personal* data in particular. This is a common trait of virtually every piece of legislation on data protection. In Switzerland, this is clearly established by, for example, the FADP (art. 3.a. [12]) and the HRA (art. 2 para. 1. e. [11]) and most of the cantonal data protection regulations.[3] For the field of biomedical research, this implies that data protection rules apply if – and only if – researchers are making use of *personal* data. Biomedical research with *non-personal* (or *anonymized*, see below) data fall outside the scope of data protection rules (for more details, see [19, p. 109]) and thus does not require, amongst other things, approval from ethics committees. The staggering difference in the regulatory

[3] Some cantons, like Zürich (Gesetz über die Information und den Datenschutz) and Basel-Stadt (Informations- und Datenschutzgesetz), have regulations that deal with the principle of transparency for public bodies and thus "information" more in general, but most of the rules therein contained are referred to personal data. Moreover, there are also some other federal regulations that contain rules which concern also non personal data (e.g. the LIH).

regime between *personal* and *non-personal* data, clearly begs the question how to distinguish between these two categories.

In the legal literature, the exact meaning of what constitutes *personal* data is extensively debated and the exact borders of this category are highly contested [17], especially after recent developments in the field of data science [20]. In regulations, *personal* data are usually defined as information relating to an identified or identifiable person. For example, the FADP states that *personal* data are "all information relating to an identified or identifiable person" (art 3.a [12]). Virtually every other cantonal data protection law contains a similar definition and even for the EU level, the GDPR (art. 4 (1) [5]) uses very similar words – with the exception that it refers only to *natural* persons. Along the same line, the HRA defines (health related) *personal* data as "information concerning the health or disease of a specific or identifiable person" (art. 3.f [11]). All these definitions are relatively open-ended and leave quite some room for interpretation by legal doctrine and by courts. In practice, to understand within a specific biomedical research project whether the data being processed are *personal*, two[4] elements are of primary importance. First, it must be determined whether data are *relating to* a person. Secondly, it must be determined whether this person is *identified or identifiable*. If both conditions are satisfied, data must be considered *personal* and data protection rules will apply.

In the context of biomedical research, it will often be clear that data *relate to* a person, since most of the data used are *about* people. However, in order to be *personal*, data must not only be *relating to* a person, but such person needs also to be *identified or identifiable*. With respect to this requirement, it is difficult from a legal point of view to give clear-cut answers. Cases where the data are relating to an *identified* person, i.e. when the identity of the person is evident from the data themselves [22, p. 34], are rather easy. If, for example, the data in a database of a research project contain directly the names or the addresses of the people whose data are processed, such data will obviously relate to an *identified* person and thus be *personal* data [19, p. 516]. Cases where data are relating to an *identifiable* person, i.e. when the identity of the person does not emerge directly from the data(set) itself, but can be derived from the context or the combination with other data, are more difficult [22, p. 34]. Whether such data can still be considered *personal* data depends on several factors, since the legal concept of *identifiability* – at least in Switzerland – is relative and not absolute [22, p. 34]. Traditionally, legal doctrine has argued that both an objective (the existence of means to re-identify) and a subjective factor (a sufficient interest by the data-processor to re-identify) need to be present, in order for data to be considered *identifiable* [23]. The relativity of the concept of *identifiability* and its dependency on context and intentions of the data-processors are also confirmed by case law. In a recent decision of the Swiss Federal Supreme Court [24], for example, the judges ruled that images of people on Google Street View are *identifiable* (and thus *personal* data), since – even if faces are blurred – the identity of the person can often be derived by the context (e.g. dresses, place where the photo was taken etc.). In another decision by the same court

[4] A third element sometimes considered is that of defining what *information* means (see e.g [21], pp. 25ss), which is normally interpreted extremely quite broadly as to include information in any form and on any support (e.g. digital, analogic).

[25], it was established that IP-addresses are data relating to an *identifiable* person, if the data-processor in the specific case has the concrete possibility to access additional information that can lead to (re-)identification of the person using the IP-address. Therefore, the relative nature of the concept of *identifiability* entails that even the same data that might be considered *non-personal* in a certain context may be deemed *personal* if the circumstances changes.

In the biomedical research context, *anonymization* represents the procedure through which data cease to be *identifiable* and thus *personal*. Indeed, rather than speaking of *non-personal* data, the term *anonymized* data is often heard in this context. From a legal perspective, *anonymization* is also defined as the procedure through which *personal* data are processed so that re-identifying the person becomes either impossible or disproportionately difficult [19, p. 512]. Article 25 of the Human Research Ordinance (HRO [26]) explains that "for the anonymization of […] health-related personal data, all items which, when combined, would enable the data subject to be identified without disproportionate effort, must be irreversibly masked or deleted. In particular, the name, address, date of birth and unique identification numbers must be masked or deleted". Since the law provides a non-exhaustive list of elements that must be deleted in order to anonymize personal data, this leaves some room for interpreting what concrete processes can be considered relevant to match the legal definition of anonymization. Although there are concerns that, due to current advances in big data analytics, the legal concept of anonymization is bound to become ever more elusive [22, p. 34], for the moment anonymization can - in practice - be treated as the flipside of identifyability (see previous paragraph). In this respect, to determine whether data are truly *anonymized* (and thus *non-personal* anymore), both the material chances of re-identification and the interest in re-identifying must be evaluated on a case-by-case fashion [19, p. 513]. This means, in turn, that the problems of relativity described above with respect to *identifiability* concerns also *anonymization*. Therefore, the classification of a certain dataset as anonymised might not be definitive: if the circumstances change and the link to the identities of individuals are re-established [19, pp. 515ss], this would turn *anonymized* data back into being classifiable as *personal*. This generates more legal uncertainty if compared to the legal situation in the U.S. where health data are considered definitively de-identified once a precise and exhaustive list of 18 personal identifiers are removed [27]. The porous differentiation between *personal* data and *anonymized* data in Switzerland also implies that even for research projects processing data that they deem *anonymized* it might be convenient not to neglect the rules of personal data processing (e.g. in terms of data security).

Pseudonymization or *coding* are also often mentioned as procedures through which data can somehow be made "less" *personal*. From a legal point of view, *coding* (and equally *pseudonymizing*) is regarded as the process through which the elements that permit to link data to the identity of a person are *reversibly* removed [19, p. 512]. For example, if a research project aims at studying mortality rates after one type of surgery based on retrospective analysis of routinely collected data from two different hospitals, researchers might merge data from the two hospitals in a unified database, remove the original

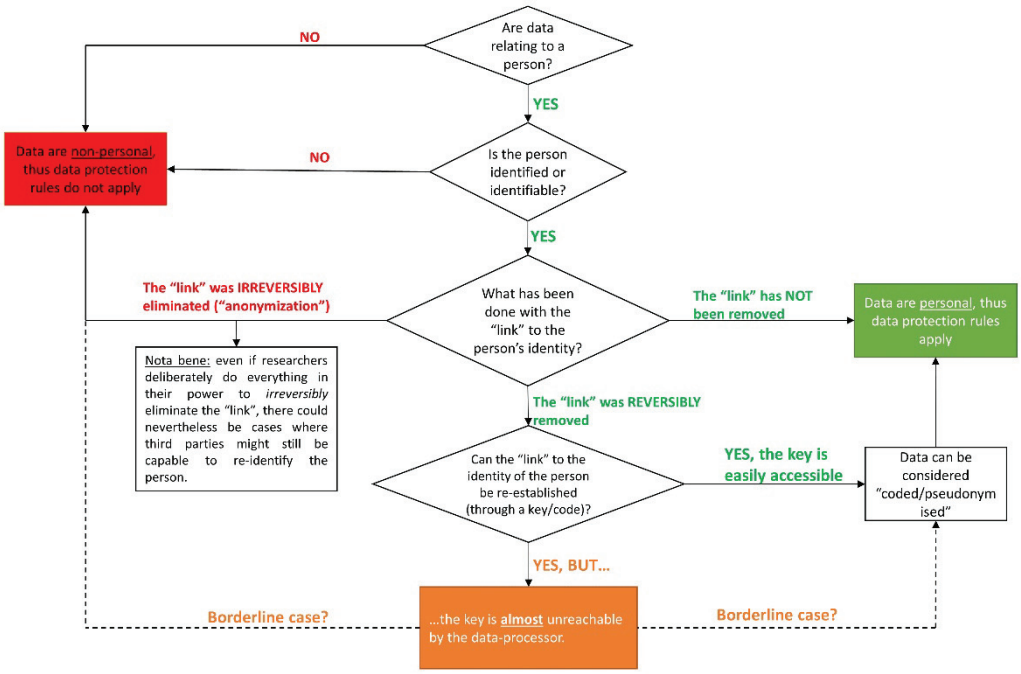
case-IDs of each single patient and substitute them with newly developed codenames. If it is possible to reverse such process and go back from the codenames to the original case-IDs of the two hospital, these data might be considered as *pseudonymised* from a legal point of view. Differently from *anonymizing* - which consists in irreversibly impeding to get back to an identifiable person, and thus renders the data *non-personal* - *coding/pseudonymizing* simply represents a way to better protect personal data and to benefit, under certain circumstances, from better conditions concerning the reuse of data for research purposes (see also last section). To refer back to the terminology of the previous sections, if data are simply *coded* or *pseudonymized*, they will still be *relating to* an *identifiable* person (and thus still be *personal* data), although only indirectly by means of a key[5]. If, on the contrary, data are *anonymized*, the key to link them back to an identifiable person either does not exist or it has been eliminated. The exact boundary between these two categories can often be blurry, especially when the key exists, but it is not directly and easily accessible to the researchers and it is not their intent to re-identify patients.[6] Moreover, it has been argued that – aside from the legal requirements – concrete practices how anonymization is technically achieved are far from uniform in Switzerland [29].

To help researchers navigate these different aspects, we summarized this section in a decision tree (see Figure 1.) that can be used to reflect whether data used in a research project are indicatively *personal* or *non-personal*.

Figure 1. Ascertaining whether the data a research-project are personal or not. A supportive decision tree.

[5] The key can be, for example, a conversion table where every code-name is associated with the original ID, or another technical device that permits to recover systematically the original ID starting from the codename.

[6] See, for example, Baeriswyl and Parli [22, pp. 35-36] where it is argued that in such cases data can be considered anonymized (non-personal) from the perspective of the researchers. The same stance is argued in [28].



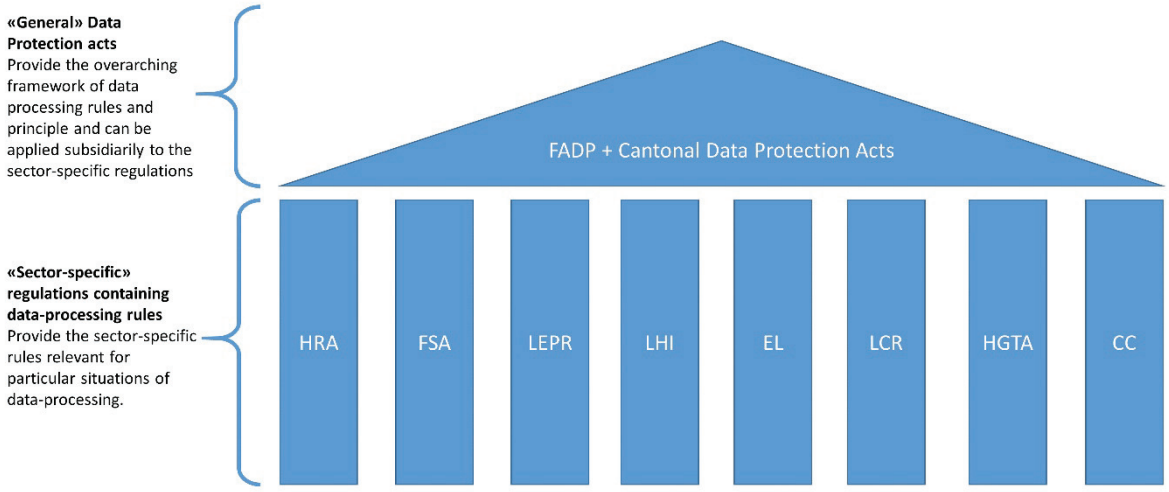
[Legend: this decision-tree has merely indicative and instructive (rather than prescriptive) purposes, since every schematization involves some degree of simplification and approximation. Specificities of each single case (such as linking possibilities) might lead to different outcomes.]

2.2 Sector-specific data protection rules for research

When they ascertain that the data in their project are *personal* and thus data protection rules apply, researchers still need to determine which specific regulatory framework they need to follow. Traditionally in Europe, data protection rules are contained in legislative acts that regulate the processing of personal data across sectors. In Switzerland, for example, the FADP contains general rules on the processing of personal data by federal bodies (e.g. federal universities) and private persons (e.g. pharmaceutical companies) and cantonal data protection regulations set the norms for the processing of data for cantonal bodies (e.g. cantonal hospitals and cantonal universities). On top of these general regulations, a number of additional data protection rules are scattered across several sectorial legislative acts (see Figure 2). The principal ones in the field of interest for this article are the HRA [11], the law on electronic patient record (LEPR [30]), the Law on Health insurance (LHI [31]), the Epidemic Law (EL [32]), the Law on Cancer Registration (LCR [33]), the Federal Statistic Act (FSA [34]) and the Federal Act on Human Genetic Testing (HGTA [35]). The HRA covers the collection and analysis of data in the field of human research. The LEPR concerns the "processing of data in the electronic patient record" (art. 1 [30]), which hospitals and nursing homes have the duty to offer [36]. The LHI contains some data protection rules concerning duties of healthcare providers and healthcare payees to transfer data to federal offices with monitoring (art. 23 and art 59a [31]) or quality control purposes (art 58b and 58c [31]). The EL has some sectorial rules applicable to "process personal data, including data concerning health, for the purpose of identifying people who are ill, potentially ill, infected, potentially infected or that expel pathogen elements with respect to public health provisions, in particular to single

out and surveil contagious illness and fight against them" (art. 58 [32]). The LCR regulates the "collection, recording and analysis of data concerning cancer illnesses" (Art. 1 [33]) for monitoring, prevention, quality development and research purposes (art. 2 [33]). The FSA delineates some data protection rules for the processing of data by the Federal Office of Statistics. The HGTA focuses on the regulation of genetic testing for the medical, employment, insurance and liability contexts and it contains some rules on the protection of genetic data. Lastly, the processing of data by healthcare professionals and researchers is also covered by the rules on confidentiality in the Criminal Code (art. 321 and art. 321bis Criminal Code [37]).

Figure 2. An overview of parts of the legislative framework concerning data processing in Switzerland.



FADP= Federal Law on Data Protection; **HRA=** Human Research Act; **FSA=** Federal Statistic Act; **LEPR=** Law on Electronic Patient Record; **LHI=** Law on Health insurance; **EL=** Epidemiology Law; **LCR=** Law on Cancer Registration; **HGTA=** the Federal Act on Human Genetic Testing; **CC=** Criminal Code.

[Legend: the image does not aim to be exhaustive, but merely indicative of the relationship between different legislative acts concerning data protection and data processing in the healthcare sector.]

For researchers, this articulated framework of data protection rules involving several legislative acts might look quite difficult to navigate. Indeed, even from a legal point of view, determining exactly which rules concerning data protection have to be followed in a single research project can be a challenge. There are, however, some general indications that can be given. One general principle of law is that *lex specialis derogat legi generali*, i.e. when two pieces of law cover the same subject matter the specific legislation derogates the more general one. In the case of data protection rules, the more general legislations are the FADP and the other cantonal data protection acts, since they all regulate the processing of data across sectors. This means that their framework can be derogated if a specific legislation covering the processing of personal data in particular sector exists. This is the case for the field of biomedical research, where the passing of the HRA in 2011 created sector-specific data protection rules that apply to the processing of personal data for biomedical research. As it has been

noted, the HRA created a proper "data protection regime" for the field of biomedical research [19, p. 808]. Data protection rules contained in the FADP and other general cantonal data protection regulations have thus a *subsidiary* function, i.e. they can be considered to supplement the rules of the HRA: in other words, the general data protection regulations remain applicable in cases where the provisions of the HRA are not exhaustive enough (see also [19, pp. 809ss]).

The presence of a sector-specific regulation containing data protection rules for the field of biomedical research has both advantages and disadvantages. A considerable advantage is that the processing of data for biomedical research purposes has its own peculiar needs and features (if compared to – for example – the processing of data for marketing purposes, or for other types of research). In this respect, having data protection rules tailored to the field of biomedical research (rather than the more general rules contained in the FADP [12]) was perceived as particularly important by the regulator [38]. Another advantage is that the presence of a specific regulation for the field of research may allow, to some extent, a harmonization of the rules throughout a country [39]. Other European countries, such as Germany, do not have a general regulation that comprehensively covers biomedical research [40], and data protection rules for this sector are scattered amongst several other laws [41]. Having a sector-specific regulation, however, also entails disadvantages. These include factors such as the coordination and the interplay with other existing regulations containing rules on data processing. We will turn to these two issues consecutively.

To determine whether a research project can benefit from the sector-specific data protection rules of the HRA, it must be determined if the project falls within the scope of this act. Art. 2 para. 1 [11] defines the scope of the HRA and states that the act "applies to research concerning human diseases and concerning the structure and function of the human body". As it has been clarified [19, p. 103], the scope of application of the HRA is based on the aim, and not directly on the type/design of the research – in contrast to an earlier draft of the HRA [42]. The scope of the HRA is then quite broad: as long as a methodology recognized by the scientific community is used to produce knowledge with the (far?) objective of improving medical standards or better understand the human body (and its subparts), the HRA will apply [19, 38]. For the HRA to apply, another important fact to consider is whether the project is using *health-related* personal data. Although a very general definition of this concept is provided in art 3.f. [11] of the HRA, the exact meaning of *health related* personal data is bound to be influenced also by technological advances and by the context in which data are processed [43]. No relevant rulings by Swiss Federal courts are present to help guide practice. Legal doctrine in Switzerland traditionally interprets the *concept of health data* as very broad, including all personal data that have a direct or indirect connection with the physical or psychological health of a person [22, p. 39]; [44, p. 56]. Moreover, as it has recently been highlighted [43], it is increasingly difficult to distinguish from "traditional" health data and new forms of (especially digitally collected) data that can be used to infer knowledge about the health status of a person. Since health data are universally considered as

particularly sensitive[7], the blurred edges of their definition are particularly problematic. In fact, determining whether or not the personal data being processed is health-related, not only determines the applicability of the HRA, but more in general triggers specific (and usually more stringent) requirements for data processing. This is because health data are considered – together with other types of data, such as those about religion or political orientation – particularly sensitive and thus deserving special protection (on the notion of *particularly sensitive data*, see e.g. [22, pp. 37ss]). For example, the FADP (Art. 4 para 5) stipulates that when personal data are processed based on consent, the latter must be explicit when particularly sensitive data – such as health data – are processed.

However, even if the scope of application of a sector-specific regulation like the HRA is clarified, some additional questions might emerge for researchers. What happens with "borderline" research projects, which may rely on innovative methodologies (e.g. mining of electronic health records), or make use of large datasets generated during clinical routine and are not aimed at singling out individual cases (e.g. retrospective registry-based studies)? What if a research project processes data from multiple sources and originally collected according to different data-protection regimes (e.g. combining data from insurances, cantonal hospitals and the Federal Office of Statistics)? How do the data processing rules of these different regimes interact? Unfortunately, such questions do not have one-size-fits-all answers from a legal perspective. Innovative healthcare service research that relies – for example – on data routinely collected is relatively underdeveloped in Switzerland [45, p. 28] and has only been recently encouraged by the scientific community (e.g. through the aforementioned NRP 74 [7]). How to combine existing rules on data protection and data processing with this type of research require the effort of both the research and the legal field to develop efficient and accepted practices. The latter should help, for example, to simplify the combination of different sectorial legal regimes and of the federal and cantonal data protection law (see e.g. [46], and, to better clarify the distinction between processing of data for research and for quality improvement purposes, see [47, 48]). Moreover, a balance should be found between easing the requirements for the processing of data for research (through the creation of a "research exemption" [6]) and the retention of ethical requirements for data processing, especially with respect to health data [49]. Lastly, particular attention should be given to the topic of consent, to which we turn in the next section.

2.3 The relevance of consent for data processing in research

Consent, especially in the field of biomedical research, has considerable importance, since it has traditionally been one of the key requirements to legitimately enroll patients in clinical studies and it is one of the cornerstones of research ethics. This is due to the fact that, historically, consent has become a fundamental precondition to justify the intrusion in the *physical* integrity of both patients and research participants [50]. When data processing techniques evolved and more research started being possible

[7] This holds true also in Switzerland, where the FADP and each cantonal regulation on data protection considers data concerning health as worth of additional protection.

without any physical contact with participants, but rather through the processing of their data, consent continued to remain a pivotal requirement, especially because of its ethical significance. Participants' protection rules like the requirement of consent were upheld, in the conviction that data processing for research entails an *intangible* (rather than physical) invasion of personal integrity [51]. Consent, thus, remained one of the central paradigms of data processing for research purposes to such an extent that, even when processing happens without traditional informed consent, it is often spoken of *presumed consent* solutions (e.g. for the collection of data in registries and the performance of epidemiological research with them in Denmark [52] and [53]).

From the legal perspective, however, the role of consent for data processing is quite different. While consent remains one fundamental instrument to protect informational self-determination[8] especially when it comes to health data (e.g. [56]), the concept may come into play at different levels. Where the law – as the GDPR at the EU-level – requires a lawful basis for any data processing, the long list of grounds that permit data processing includes not only consent, but also several alternatives, such as the necessity to perform a contract, the pursuance of a legal obligation or the protection of a vital interest of a natural person (art. 6 GDPR [5]).

In Switzerland, one has to distinguish whether personal data are being processed by a federal or cantonal body or by private persons. If personal data are processed *by private entities*, the FADP [12] does not necessarily require to obtain consent. If processing does not comply with general data protection principles, leading to a potential violation of personality rights of the data subject, it may be possible to justify such processing by obtaining consent [21, p. 350] [22, p. 165], or by a specific legislative act authorizing such data processing, or the presence of an overriding private (e.g. the execution of a contract) or public interest (e.g. the compilation of statistics) - Art. 13 FADP [12] [22, p. 172]. If personal data are processed *by federal public bodies*, a formal legislative act authorizing the processing is necessary to use personal data, consent of the person being of minor relevance [22, pp. 220ss]. In both contexts (processing by private persons or by federal public bodies), data processing for research, planning and statistics is privileged (art. 13 sec. 2 lit. e and art. 22 FADP) by the presence of less rigid conditions for data processing [22, pp. 184ss and 290ss] [44, pp. 124ss], which partly resemble the "research exemption" present at the EU level [6]. These considerations show that, from a legal perspective, the right question researchers should formulate – when they design the data protection aspects of a project – is not "Do we have consent?", but rather "Do we need consent?".

To better understand what this means in practice, it is helpful to consider a case study offered by the rules of the HRA. As specified in the previous section, the HRA represents a sector-specific set of data processing rules for biomedical research. In articles 32-35 [11], this act sets some specific conditions for the "further processing" (or secondary processing) of personal data. Further processing refers to

[8] The right to informational self-determination (informationelle Selbstbestimmung) is not directly present in the law in Switzerland, but it has been introduced into case law and has been recognized by the doctrine (e.g. [54], although sometimes in a critical fashion [55].

those cases where data are collected for a specific aim (e.g. during the provision of care), but can then potentially be re-used for research purposes. A classic example is the further processing for research purposes of routinely collected data from hospitals, which has received much attention and prompted both application (e.g. [57]) and implementation (e.g. [58]) projects. In such cases, the HRA offers multiple requirements and possibilities for further data processing (for more details see e.g. [59]). For genetic data and for non-genetic health data in an identified form (i.e. non-coded/non-pseudonymized), the requirement for further data processing is having the consent of the data-subject, in some cases even of a "general" nature (art. 32.1, 32.2 and 33.1 HRA [11]; [19, p. 484]). For the further-processing of non-genetic health data in a coded form or for the anonymization of genetic data, a different possibility permitting such data processing is the provision of information and the acknowledgment of the right to dissent (but explicit consent is not necessary [19, p. 499]). However, when provision of consent (first case) or provision of information (second case) is not possible, an alternative possibility permitting further data processing is that of receiving an *exceptional* exemption by the competent Research Ethics Committee (Art. 34 HRA [11]; see also [19, pp. 501ss]). The latter needs to ascertain that: 1) providing consent (first case) or information (second case) is impossible or disproportionately difficult; 2) no documented refusal by the subject whose data are used is available; and 3) the interests of the research project outweigh the interests of the person concerned (art. 34 HRA [11]). Since theoretically *exceptional*, it is disputed whether the application of this alternative ground for data (further) processing should become regularly used [19, 60]. In any case, this example shows how – from a purely legal perspective – consent to data processing often remains a very relevant aspect of lawful data processing, but it is not necessarily the only one. Which other alternative requirements for data processing are present is a matter for the law to settle. How (and how often) they are used within the legal limitations, is a matter for practice to develop. In this context, it should also be kept in mind that – as mentioned above – general data protection rules contained in more general data protection regulations (such as the FADP for Switzerland) may continue to apply in a *subsidiary* function.

3. Conclusion

In this contribution, we explored three intersections of data protection law and biomedical research. We first focused on the concept of personal data, which represents the most important criterion to determine whether data protection rules apply at all. We then analyzed the sector-specific data protection rules for the field of research and their interaction with more general data protection norms. Finally, we reflected on the topic of consent for data processing from a legal perspective. Our aim was to help bridge the gap between the legal and biomedical sector by providing an overview on the articulate legal debate on important elements related to the processing of data relevant for the biomedical sector. Given the complexity of such elements, we explained why there cannot be an expectation to find the exact and exhaustive rules for correct data processing in one single document – be it a legislative act, a guideline or a policy statement. This is also due to the fact that data protection and privacy are important values,

but they are not absolute and, especially with respect to research, have to be balanced with other important (legal and) ethical principle. Therefore, the establishment of such balance will require collaboration between biomedical research professionals and legal experts. This cooperative effort will be crucial for addressing the pivotal question of how to ensure adequate data protection while promoting important research in the future.

Currently, there is a discussion [61] ongoing in the legal doctrine about a renewed definition of

Anonymisation

Currently, there is a discussion [61] ongoing in the legal doctrine about a renewed definition of anonymisation of data for research purposes, one that is sufficiently nuanced and comprehensive and that takes into consideration the specific features of the research context. The proponents for developing a new definition argue that once personal identifiers are eliminated from a dataset, researchers often9 have no subjective motivations to re-identify subjects, even when re-identification remains technically (i.e., objectively) possible (by e.g., combining data from different datasets). In a similar fashion, also Voekinger et al. [27] propose a further category of data, namely pseudo-anonymised, to define all those data where every effort has been made to anonymise them, but re-identification cannot be excluded. These legal proposals should also be considered by the research community so that solutions for finding a definition of anonymisation that is both legally solid and research friendly. A good starting point for this collaboration between the legal and the research worlds is the creation of courses on data protection for the research community (see e.g., the initiative of the SPHN [62]). Another possibility for productive exchange between the research and legal community is a partnership between researchers and cantonal data protection officers, who could offer assistance for the interpretation and application of the law if they are evenly organised and properly funded [63].

Declarations

Ethics approval and consent to participate

Not applicable.

Competing interests

The authors have no conflicts of interest to declare.

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3.2.3 The devil is in the details. An analysis of patient rights in Swiss cancer registries.

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Abstract

Cancer registries are an important part of the public health infrastructure, since they allow to monitor the temporal trends of this illness as well as facilitate epidemiological research. In order to effectively set up such registries, it is necessary to create a system of data collection that permits to record health-related information from patients who are diagnosed with cancer. Given the sensitive nature of such data, it is debated whether their recording should be based on consent or whether alternative arrangements are possible (e.g. opt-out systems where information is automatically collected but patients can later withdraw). In the recent reform of the Swiss cancer registration legislation, the lawmaker set out to implement rules about the recording of data in cancer registries that would allegedly go beyond a consent-based model, in order to balance accurate registration and respect of patient rights. However, by analysing the operational norms of the new legislation and comparing them with those of other systems, it emerges that the Swiss rules *de facto* closely resemble a system of registration based on informed consent – in partial contradiction with the objective pursued by the lawmaker. In this paper we thus show how the details of a policy are crucial to determine its true nature and we highlight some critical elements – from an ethical standpoint – of the recently reformed Swiss policy on cancer registration.

1. INTRODUCTION

Given the increased digitalisation in healthcare and biomedical research, privacy rules on how to safely process personal health data have become a topic of intense ethical and legal debate. In recent years such debate has been further fuelled by the reform the promulgation and implementation of the General Data Protection Regulation (GDPR), whose impact on the processing of health data – especially for research purposes[1] – is still being discussed. This has stimulated a heated discussion on which legitimate grounds could (or should) be used to process health data, which are generally considered as particularly sensitive.

The attention towards data protection aspects around the processing of medical information is also widespread in the cancer registry community.[2–5]. Indeed, cancer registration and data protection rules interact at different levels: from the question concerning the conditions to fulfil for data on cancer to be transmitted to the registry; to the question whether data from the cancer registry can be (re)used for retrospective registry-based research. The latter is particularly developed in the Nordic countries, where cancer registries have been existing for a long time and the data therein can - under defined conditions - be used for research without ethics approval and can be linked with other routinely collected data.[6]

Switzerland has recently passed a comprehensive reform of the cancer registration system at the federal level.[7,8] The new legislation came into force in between 2018 and 2020, and it regulates in a harmonised way the collection, recording and analysis of data in cancer registries all over the country.[9] Whereas population-based cancer registries already previously existed at a regional level, the new cancer registration obliges every canton[i] to develop a homogeneous system of cancer registration. Moreover, the new law also centrally established the variables that need to be collected and created a nation-wide institution in charge of the analysis of the data.[10] One of the main objectives of the reform was also to clearly define patients' rights with respect to the recording of their data in the new system of cancer registration. Indeed, the lawmaker determined that one of the weaknesses of the pre-reform situation was that rules on patients' rights were lacking and not uniform in different parts of the country.[11]

In this paper we analyse the rules on patient rights with respect to cancer registries in Switzerland and show that the current rules *operationally* resemble a *consent-based* model – despite the objective of the lawmaker to go beyond it. Moreover, we discuss some ethically problematic aspect of the current system. To do so, we first present the different models how cancer registrations can be classified from the perspective of patients' rights. Second, we illustrate the recently implemented Swiss solution to cancer registrations, which the lawmaker defined as a compromise between a *consent-based* and a 'Scandinavian' model. Thereafter, we examine more in detail how Swiss law concretely operates and argue that – rather than being truly a compromise – it is *de facto* very similar to a *consent-based* model. From the start, we would like to underline that this paper concerns the modality how data is recorded in

[i] Switzerland is a confederation comprised of 26 states denominated *Cantons*.

cancer registries. Whether such data – once recorded – should be reused for further research (and upon which conditions) falls outside the scope of the present article.

2. TO BE OR NOT TO BE - BASED ON CONSENT? THE DIFFERENT MODELS HOW TO COLLECT PATIENTS' DATA IN CANCER REGISTRIES

One of the main points of discussion in the ethics of cancer registration is how to protect the confidentiality of the patient-doctor relationship and privacy of patients whose data is recorded.[12] Whilst this entails also the question of how to regulate access to cancer registries by third parties (e.g. researchers willing to conduct epidemiological studies), a crucial and preliminary element is to determine upon which conditions data routinely collected in the clinical context can be added to cancer registries in the first place. Recording of medical data in cancer registries can be classified from the perspective of healthcare personnel's duties or from the perspective of patients' rights. From the perspective of healthcare professionals, one can distinguish between voluntary and mandatory notification systems.[4,5] In the former, reporting by health professionals is not obligatory. In the latter, there is a clear duty for healthcare professionals to transmit data of their patients to the cancer registries, potentially enforceable through fines or other measures.

From the perspective of patients' rights, however, a slightly different classification can be outlined. On the one hand, a cancer registration system can be based on an (explicit) *consent-based* or *opt-in* model. In this case, patients are given the right to actively consent or dissent to their data being registered, thus giving them full control over their personal information. This was the case, for example, in a breast cancer registry in new Zealand until 2012.[13] This system is sometimes also called *opt-in* approach, in that patients must actively provide their consent in order for their data to be recorded, whereas the *default position* (i.e. what happens if patients do not express any preference) is that data is not collected. According to a recent study, the *consent-based* model is only present in a minority of European countries.[14] From an ethical standpoint, this system can be justified based on the idea that the informational self-determination – that is, "the ability of data subjects to shape how datafication and data-driven analytics affect their lives, to safeguard a personal sphere from others, and to weave informational ties with their environment"[15] – should be respected. Requiring people to actively consent before their data can be recorded gives them the possibility to negotiate their participation in the public sphere and its interference with the private sphere, which also lays at the core of the concept of informational self-determination.[16]

However, the *consent-based* model has generally been opposed on grounds that it undermines the mission of cancer registries to accurately monitor and improve the health of the population.[17] For example Coleman et al. claimed "the requirement that patients give written or verbal consent for data about their cancer to be entered into a registry [produces] uncontrollable selection bias and distortion of incidence data which seriously detract from the usefulness of the data collected."[18] On a similar line

Stiller argued that placing "on registries a duty to obtain permission from patients before registering them […] would be always impracticable and sometimes impossible - for example, if they have already died".[19] For these reasons, the recording of data in cancer registries is often justified not through consent, but through alternative legal bases provided by the law, such as article 8(3) of the old European data protection directive (95/46/EC)[ii] or article 9 §2 lit. h[iii] or article 9 §2 lit. i GDPR. This model is adopted – for example – by the Finnish Cancer registry, in which registration is not based on consent and thus patients do not have the right to withdraw it or to get their data out of it.[20] Or else, in the English system of cancer registration, it is the law (and not consent) that provides a justification for data to be recorded, and people are only given the right to opt-out from registration upon certain conditions.[21] One could argued that – as compared to *consent-based* model – in this case people have less control over their data at the individual level, since their ability to impede their data to enter the cancer registry is either curtailed (e.g. Finnish example) or limited (e.g. English example, data is recorded, but people can opt-out). The ethical justification of such a system can be found primarily in the objectives of cancer registries, which is that of promoting public health by allowing to monitor the impact of such disease on the population. Indeed, "[t]o be of value, data recorded must be accurate, reliable and as complete as possible",[22] something which can be hindered if the decision whether to include or not data on a certain case is left primarily to the single patient. A recent review of the literature also found that the papers reflecting on the ethics of *opt-out* systems of cancer registration (where consent is not needed, but patients have the right to withdraw their data at a later stage) mainly justify such system by appealing to its potential to guarantee that accurate and comprehensive data on cancer is recorded.[23]

3. THE SWISS "HYBRID" MODEL AND ITS RATIONALE

The choice of how to regulate patient rights in relation to cancer registration was at the center of a political debate in Switzerland, since the lawmaker has been drafting a comprehensive reform of cancer registries. Such reform led to the passing of federal law on cancer registration[7] together with an ordinance to help implement the law [8]. That the lawmaker was aware of the different models outlined above clearly emerges by looking at the accompanying documents that the Federal Council (the executive power at the Federal level who writes law-projects) publishes concerning the law-making process.[11,24] Specifically, it is explained that – in the discussion on how to regulate patients' rights with respect to the recording of their data – two models were considered. On the one hand, the lawmaker

[ii] The use of this article as a legal basis to justify recording of data in cancer registry is indicated here for example in [5].

[iii] This article is basically equal to 8(3) of the previous data protection directive and it justifies the processing of sensitive data such as health data even without consent when the "processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services".

speaks of a *Scandinavian* model based on obligatory registration based on the law. Indeed, it is acknowledged that "the best way to guarantee a complete registration of cancer illnesses is to record the data without allowing patients the right to object".[11][iv] As an alternative, the lawmaker explains that also a *consent-based* model could be implemented, which would allow "the maximal expression of the protection of patients' rights" since the latter would have to "explicitly consent to the recording of their data".[11]

After considering these two possibilities, the Swiss lawmaker claims to reject both solutions. The *Scandinavian* model is considered "in contrast with the principle of informational self-determination"[11] of patients, and thus not in conformity with fundamental rights of privacy enshrined in Art. 13 of the Swiss Federal Constitution. The *consent-based* model, on the contrary, allegedly presents the problem that it "does not however allow to guarantee a complete cancer registration".[11] Based on these considerations, the lawmaker considered neither solution viable and selected an alleged compromise. The "hybrid" Swiss model is in fact based on a duty for healthcare professionals to report all cancer cases, coupled with a so-called "right to dissent"[v] and strong informative rights for patients. In brief, healthcare workers are now obliged to report every cancer case to the competent cantonal[vi] cancer registry. Patients' explicit consent is not needed, but at the same time "if she [the patient] objects to the recording of data by the registry, the patient can refuse that [registration] in any given moment".[11] Moreover, patients enjoy particularly strong informative rights, including the need to be individually informed about the planned transmission of data to the registry. Such information is given to the patient individually by the treating physician who has the duty to communicate data to the cancer registry. To ensure that patients can reflect on cancer registration, for the first three months after they have received such information by the treating doctor, no data about their illness can be transmitted to the registry till such "time limit" (Art. 17)[8] expires. Such three-month "time limit" is present "to allow patients to whom it has just been communicated the information about cancer registration the time to decide whether to dissent to the registration of their data."[24] Indeed, the lawmaker explicitly says that "patients' rights are reinforced by the introduction of a time limit. […] in this way, the patient has an adequate time to reflect whether she wants to exercise her right to dissent. The register can proceed to record the data only after the time limit has expired in vain". The lawmaker claimed that by "giving patients a right to dissent it is possible to respect their informational self-determination"[11] and then speculated that "we can start from the assumption that the cases of dissent should remain very limited".

[iv] The original texts are available in Italian, French or German, but we translated in English this and the following relevant passages.

[v] According to the official languages of Switzerland, the law text speaks of a "Widerspruchsrecht" in German, a "droit d'opposition" in French and a "diritto di oppositzione" in Italian.

[vi] The new law establishes that several cantonal (i.e. regional) cancer registries remain in operation, but the type of data collected and the procedures for collection are now harmonised at a nation-wide level.

4. THE DEVIL IS IN THE DETAILS

As outlined in the previous section, a primary objective set out by the Swiss legislator with the cancer registration reform was to implement a system of data collection that could go beyond the limits of an *informed-consent* model based one. Indeed, it is claimed that "if registration depended on explicit patients' consent, there would be the risk of large gaps in the registration, and the aim of the new legislation would be totally called into question".[11] At the same time the legislator wanted to recognise substantial privacy rights of patients over their data. The solution developed might seem to combine the best of both worlds and thus represent a good example of the tendency to compromise, which "is deeply engrained in Swiss political culture".[25] But does the Swiss "hybrid" model truly represent a well-balanced compromise between the two extremes of a *consent-based* model and a 'Scandinavian' one[vii]?

By taking a closer look to how the Swiss "hybrid" model actually works, we argue that the answer to this question must be negative. Indeed, from the *operational* point of view, the Swiss "hybrid" model strongly resembles a *consent-based* model. To substantiate our claim, we compare the *operational* aspects of the Swiss model to an *consent-based* model, and also confront them with the solutions followed in England[21,26–28] and Finland[20,29,30] – both systems where the collection of data is NOT based on consent (see Table 1).

Table 1. Comparison of *consent-based*, Swiss, English and Finnish model.

	Can the individual *preliminary* impede that data about his illness is recorded?	**Does the healthcare worker responsible for the registration have a clear *obligation* to talk with the patient about the registration before proceeding?**	**Does the interaction with the patient concerning cancer registration have to be documented?**	**What happens if the patient says nothing?**	**Can patients require the cancellation of their data from the cancer registry?**
***Consent-based* model**	Yes, by simply not providing consent.	Yes, in order to collect the informed consent.	Yes, since the informed consent has to be documented.	Data is NOT recorded, since consent is necessary	Yes, by withdrawing consent.
Swiss model	Yes, by exercising the	Yes	Yes.	Data is recorded.	Yes, by exercising the

[vii] By 'Scandinavian' model, we here refer to those systems where the recording of data in cancer registries is NOT based on consent, and where there are limited possibilities to opt-out for patients.

	right to opposition.				right to opposition.
English model	Potentially yes, depending how quick the opt-out right is exercised.	No.	N/A	Data is recorded.	Yes, by exercising the right to opt-out.
Finnish model	No	No	N/A	Data is recorded.	No.

Firstly, according to the Swiss model patients have the possibility to completely impede the recording of any of their health data in the cancer registry. Patients can do this by exercising their "right to dissent" when the illness is diagnosed and within the 3-month time limit from the moment they are informed by their own physician of the existence of cancer registration (see below). This situation is to some extent similar to the one encountered in a *consent-based* model, in which patients might avoid the recording of their data by simply not providing their consent. Clearly, a difference between the Swiss and the consent-based model is that in the former an *active* action is required (exercising dissent) to avoid recording of the data, whereas in the latter *abstaining* from an action (i.e. abstaining from providing consent) is sufficient. But the fact remains that – unlike in a system like the Finnish one – both models allow the *individual* (through action or abstention) to prevent data recording.

Secondly, in the Swiss model there needs to be a one-to-one encounter between the healthcare worker responsible for recording data for the cancer registry and the patient. In this encounter, the doctor has to inform patients on why/how their data will be transmitted to the cancer registry and on patients' rights, including the "right to dissent". The doctor also has the duty to document the date in which such interaction occurs (e.g. on the medical record of the patient).[24,31] From such date a three-month time limit must pass before any data is transmitted to the registry, in order to allow patients enough time to reflect whether they want to exercise their right to dissent. Even in this case, the situation is very similar to a *consent-based* model, where a one-to-one encounter between the patient and the healthcare worker in charge of cancer registration has to occur. Indeed, if we consider informed consent as a process, it can conceptually be split in two phases: the *provision-of-information* phase; and the *decision-making* phase. Operatively, the *provision-of-information* phase of the Swiss model resembles exactly what would happen in a *consent-based* model. The treating doctor provides counselling to their patients, in order for them to make an informed decision concerning cancer registration. The only difference is that in a *consent-based* model, the *decision-making* phase consists in the patients choosing whether or not to provide consent. On the contrary, in the Swiss model the *decision-making* phase consists in choosing whether or not to exercise the right to dissent. Either way, the decision-making phase can end with

patients refusing participation in the cancer registry: by not-providing consent in the consent-model, or by exercising the right to dissent in the Swiss model.

Thirdly, a further similarity between the Swiss model and the consent model occurs when examining the possibility that patients whose cancer data was recorded change their mind and want to withdraw from the cancer registry. In both models this is equally possible. In a consent based model the patient might simply withdraw consent; in the Swiss model patients may exercise their right to opposition, thus obliging the cancer registry to cancel all their personal data already recorded or to anonymise them.

All in all, the only substantial difference between a consent-based and the Swiss model seems to be that – if at the end of the one-to-one encounter the patient does not express any preference – in the Swiss model the data can be recorded (after the three-month time limit), whereas in the consent-based model this is not the case. However, one wonders how likely it is that – at the end of a one-to-one encounter – patients would not make their mind up about registration. If stimulated through individual interactions – which the lawmaker describes as crucial to allow "the patient to ask questions in case of doubts"[24] – one would expect that patients then actively decide what to do about their data. Clearly, it could happen that people refuse to take an active decision at the end of the interaction, or that they decide to exercise their right to opposition, but then forget to actually send in the necessary documentation for enforcing their right in the three-month time limit which they are granted. If this happens, in the Swiss-model the data can nevertheless be transmitted to the cancer registry, whereas a *consent-based* model would not allow it (since active/explicit consent would always be required). But 'relying' on patients' forgetfulness to exercise their rights does not seem coherent with the expressed objective of the Swiss legislator to respect informational self-determination in a meaningful way.

5. CONCLUDING REMARKS

In the previous sections we explained how patient rights with respect to cancer registration can be regulated. We have presented the new Swiss law on cancer registration and argued that the way Swiss rules actually operate practically defy the purpose of the lawmaker to go beyond a *consent-based* model. The objective of this paper is not to argue for one model of cancer registration over the other, but to show the importance to have *operational* rules that are coherent with the objective the lawmaker opts for – whatever that is. If the main objective of a policymaker with respect to cancer registration is to respect individual rights and make registration dependent on individual choice, then having a pure *consent-based* model might be more straightforward. If the priority is to maximise registration, then an obligatory model with very limited individual rights might be better. In the Swiss case, it may seem at first sight that the lawmaker refused the *consent-based* model and created a balanced compromise between these two solutions. On closer inspection, *operational* rules are significantly skewed towards a *consent-based* model.

To truly implement a system based on a compromise between a *consent-based* model and one based on obligatory recording of data, other options could have been explored. For example, it would have been possible to renounce informing patients *individually* about their rights and instead promote far-reaching informative campaigns illustrating to the wider population (and not only to those already diagnosed with cancer) the scope of cancer registries and the possibility to exercise specific rights (including the right to dissent) with respect to their data. Indeed, Article 19 of the Swiss Cancer Registration Law actually establishes that "the national institute for cancer registration informs periodically the population […] in particular about: a. the nature, purpose and extent of data processing; b. patients' rights". Opting for population-based information campaigns has naturally the drawback that – if such campaigns are poorly implemented or if the public has little interest – it might be difficult to ensure that the population is genuinely informed. This risk could be mitigated by involving patient organisations (e.g. the Krebsliga in Switzerland) in setting up informative-events about the purposes, advantages and risks of the collection of data in cancer registries. Moreover, having public information campaigns would avoid individual influence by health care personnel, who – based on their own perceptions – might have a significant indirect influence on patients' choices whether to dissent or not to cancer registration. From a legal point of view, *individual* provision of information remains a pilaster of Swiss data protection law[viii], but it is generally possible to create exceptions to this principle when the collection and subsequent processing of data is provided by a sector-specific law (like in the case of cancer registration legislation), is justified by a public interest and comply with the principle of proportionality (see also art. 36 Swiss Constitution on the conditions to be fulfilled to restrict fundamental rights).

From an ethical perspective, it must also be considered that the current Swiss model – which obliges doctors to have *individual* encounters with their patients to inform them about cancer registration – might also unintentionally be the source of emotional harm. Indeed, it might be burdensome for patients to be *forced* (since their physician have a duty to try and collect the data) to reflect on cancer registration in the difficult period when the illness is detected. Moreover, if the objective of the Swiss-model is also to have a high rate of data collected, the individual encounters between patients and doctors might turn into an ambiguous situation, which can also be perceived as deceptive. Indeed, doctors have to conduct a conversation about patients' informative rights and their right to dissent registration, in the *hope* (from the point of view of the lawmaker) that patients stay silent and do not exercise the right to dissent that they have just been made aware of, so that registration may proceed.

In legal analysis it is stressed how the real functioning of a policy is often determined by how rules established in the legislation are concretely operationalised, rather than by how they are dogmatically described by the lawmaker.[32] Our analysis of Swiss rules on cancer registration has shown that there might be a difference between what the legislator sets out to do and how the rules it creates concretely

[viii]See, for example art. 19 of the new Federal Data Protection law (available at https://www.fedlex.admin.ch/eli/fga/2020/1998/de).

function. Clarity in how legal rules function is particularly important when it comes to data protection, given the interest of citizens to understand what happens with data related to them, especially when it comes to sensitive data like cancer-related information. For Switzerland, it is now important to closely monitor – as soon as reliable statistics are available, since the new Swiss model is active only since 2020 – the actual impact of the new rules on patient rights in cancer registration and on the collection of sufficiently complete and accurate cancer data, to see whether changes on the legislation are needed in the future.

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Comment on: Research projects in human genetics in Switzerland: analysis of research protocols submitted to cantonal ethics committees in 2018

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The article by Driessen and Gervasoni[1] is the last of a series of three papers recently published in the Swiss Medical Weekly, which explore the interaction between biomedical research and Research Ethics Committees (REC) in Switzerland. Previously, the article by Bergstraesser and colleagues[2] analysed several applications for ethics review sent by the University Children's Hospital Zurich to the local REC and suggested strategies to improve the drafting of applications for ethics review in the future. Then, the study by Gloy and colleagues [3] investigated – by means of document analysis and a questionnaire – how the processing of jurisdictional inquiries to Swiss RECs (i.e. requests by researchers to know whether their projects require ethical oversight) could be improved. The article by Driessen and Gervasoni, on the contrary, focussed only on research in human genetics and it provided an overview of the features of research protocols submitted and approved by RECs in 2018. Studies of this kind are important because they help understand how RECs practically operate and can help both researchers who have to interact with RECs in the future, and also RECs' members and policymakers, in that they show how the ethics review process might be improved.

Since 2014 the interaction between researchers and RECs in Switzerland is governed by Human Research Act (HRA[4]), which has also laid out important rules on how to manage personal health data in the context of research. The contribution by Driessen and Gervasoni is linked to a broader endeavour of evaluation conducted by the Federal Office of Public Health (FOPH) to monitor the implementation of the HRA, which has led to the issuing of several recommendations on how to improve this law[5]. Since it is planned for the Federal Council to soon start revising the HRA[6], we would like to point out two specific findings from the study of Driessen and Gervasoni that could be considered during such revision.

First, the article showed that 97% of the research proposals in human genetic used data in a coded form, i.e. where the identity of participants is reversibly removed from the dataset. At present, the HRA does not oblige to use data in a coded form, but for projects involving data previously collected (so called "further use") it sets different sets of rules depending whether the data are in a coded form (art. 32 para 2 HRA), "identified" (i.e. the identity of participants is NOT protected by a code or pseudonym, art. 32 para. 1 HRA) or whether they are anonymised for further use (art. 32 para. 3 HRA). Moreover, rules change also depending whether the data used in the project are exclusively genetic (art. 32 HRA), or whether they are non-genetic, but still health-related (art. 33 HRA). The fact that the study by Driessen and Gervasoni shows that the overwhelming majority of research projects use data in a coded form suggests: 1) that this is the set of rules of greatest importance during the revision process of the HRA; 2) that the different sets of rules for data in a "identified" form (art. 32 para. 1) or for the anonymization of data (art. 32 para.3) are *de facto* extremely rarely applied, and it can be considered whether they should be kept in their current form. A simplification of such rules seems to be the preferable option, as also previously recommended by Junod and Elger.[7]

Second, the study showed that a substantial proportion of the research projects based on the further use of genetic material exploit the possibility to be exempted from regular consent requirements through the

procedure laid out in art. 34 HRA. This procedure allows researchers to ask RECs to grant an exemption from the standard consent rules, if a set of conditions (e.g. the interest of conducting the research project trumps over that of the person whose data or genetic material is used) are satisfied. The current wording of the HRA states that RECs should grant such exemption only *exceptionally*, but this study shows that *de facto* this happens in a substantial number of cases. Thus, as also suggested by a report of the FOPH (recommendation number 8[5]), the exemption allowed by article 34 should be reformed. It should be recognised that the exemption can be conceded regularly and not only exceptionally, but the conditions upon which it can be granted should be further specified [7], to make sure that they are applied in a harmonised way throughout Switzerland and that the privacy of research participants is not compromised.

Declarations

Competing interests

The author has no conflicts of interest to declare.

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3.3 Module III

3.3.1 “It’s not something you can take in your hands”. Swiss experts’ perspectives on health data ownership: an interview-based study.

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Abstract

Objectives: The evolution of healthcare and biomedical research into data-rich fields has raised several questions concerning data ownership. In this paper, we aimed to analyse the perspectives of Swiss experts on the topic of health data ownership and control.

Design: In our qualitative study, we selected participants through purposive and snowball sampling. Interviews were recorded, transcribed verbatim, and then analysed thematically.

Setting: Semi-structured interviews were conducted in person, via phone or online.

Participants: We interviewed 48 experts (researchers, policy makers and other stakeholders) of the Swiss health-data framework.

Results: We identified different themes linked to data ownership. These include: 1) the data owner: data-subjects vs data-processors; 2) uncertainty about data ownership; 3) labour as a justification for data ownership; and 4) the market value of data. Our results suggest that experts from Switzerland are still divided about who should be the data owner and also about what ownership would exactly mean. There is ambivalence between the willingness to acknowledge patients as the data owners and the fact that the effort made by data-processors (e.g. researchers) to collect and manage the data entitles them to assert ownership claims towards the data themselves. Altogether, a tendency to speak about data in market terms also emerged.

Conclusions: The development of a satisfactory account of data ownership as a concept to organise the relationship between data-subjects, data-processors and data themselves is an important endeavour for Switzerland and other countries who are developing data governance in the healthcare and research domains. Setting clearer rules on who owns data and on what ownership exactly entails would be important. If this proves unfeasible, the idea that health data cannot truly *belong to* anyone could be promoted. However, this will not be easy, as data are seen as an asset to control and profit from.

1. Introduction

As healthcare is set to become an increasingly data-rich environment, the question of how to govern the medical information collected and processed represents a great challenge.[1] Appropriate governance is especially important at a time when initiatives to promote the sharing of data between countries and institutions are growing. For example, in the context of the CORBEL (Coordinated Research Infrastructures Building Enduring Life-science Services) European project, there have been efforts to establish solid principles to guide the (re)use of individual patient data from clinical trials.[2] Similarly, the discussion on how to properly govern the exchange of data between different actors has been prominent also in the United States.[3] Even single research institutions - like the UK Biobank - have dedicated particular attention to the ethics and governance of the data they manage.[4] Indeed, failing to establish appropriate and socially accepted governance for medical information can lead to significant problems.[5] For example, the Care.data project of the National Health Service (NHS), which was aimed "to extract data from NHS primary care medical records in England unless patients have purposefully opted out, in part to facilitate research",[6] proved deeply controversial also due to some fallacies in its governance.

One very important issue in the governance of health data is determining whether ownership in data exists, whom it refers to and what exactly it is.[7] Due to the lack of a commonly accepted definition, the debate on data ownership focuses on two sides of the issue: rights to *control* data and to *benefit* from them.[8] Such debate is present in the biomedical research community,[9] in the ethical domain [10] and especially in the legal field (see e.g. this review of the literature).[11] In this respect, it is often questioned whether and how data can truly 'be owned' in a legal sense,[12] and whether it is desirable to extend norms concerning other kinds of property to data.[13] Although originally focussed predominantly in the United States, the debate on the 'propertisation' (i.e. the application of property-like rules) of personal data has then progressively expanded in Europe as well.[14] This has also been fuelled by the reform of data-processing rules in the European Union brought about by the *General Data Protection Regulation* (GDPR). Indeed, the GDPR represented an effort to better define the role and powers of individuals where data come from (data-subjects, art. 4(1) GDPR) and of those who manage data collections (data controllers and data processors, art. 4(7), (8) GDPR). Some have described the GDPR as a decisive step towards the implementation of a property regime for data [15] and others have been more sceptical about this.[16]

The idea of introducing property or ownership rights in data concerning health has received particular attention. Critics note that without clear and transparent rules about ownership of patients' data, an uneven level-playing field has emerged, where the use of data in medical research is overregulated, and use of health data in the private domain is underprotected.[9] In this respect, ownership by patients has been pointed as a potential way forward to benefit both individuals and healthcare in general.[17]

Moreover, clear ownership rules concerning medical data has been proposed as one important step to capture the benefits that data can produce in healthcare.[13] Concerns have also been expressed that granting real 'property-like' rights in their data to patients might hinder important research, due to the excessive control these rights would give to individuals.[18]

The attention to the topic of health data ownership on a theoretical level is also mirrored by the increased scrutiny that this issue has received in empirical literature. In this respect, research has considered mostly the questions of who should be the owner of health data [19, 20, 21, 22, 23, 24, 25] or underlined that there is lack of (legal) clarity about rules and rights concerning data control.[26, 27, 28, 29, 30, 31] However, existing empirical research discuss this issue from a broad perspective in the context of data management and data reuse, without focussing extensively on different aspects of data ownership and its meaning.

In this paper, we explore specifically the topic of data ownership in the healthcare domain based on interviews with Swiss experts involved in the processing and sharing of medical information. Switzerland makes no exception to the international tendency of harnessing the benefits that digitalisation and the use of data in healthcare and for biomedical research can bring about. For example, in 2020 a new decentralised system of interoperable Electronic Health Records started being operative [32] to permit citizens to have more control on their data and to share them with all the medical providers from whom they receive care. Moreover, some data-sharing platforms that "enable citizens to be in control of the storage, management and access of their personal health and health-related data" have been introduced in the country.[33] The topic of data ownership has also started being debated in the legal field.[34, 35] In consequence, understanding ownership with respect to medical data is particularly relevant. The current paper is part of a broader project on the topic of health data harmonisation,[36] where we summoned experts' views and concerns related to the collection and sharing of health data in Switzerland, as well as its legal, organisational and ethical implications. In this paper, we only report findings on the topic of data ownership.

2. Methods

2.1 Ethical considerations

The cantonal ethics commission evaluated our study, stated that it fulfilled general ethical and scientific standards, posed no health hazards and did not required formal approval by them (EKNZ req-2017-00810). Structure and objectives of the study were illustrated to the prospective participants when contacted and then described again before each interview. Participants orally agreed to take part in the study, that their interviews be recorded, transcribed and used for the project after personally identifying information was eliminated. Upon request, transcripts were returned to participants to correct them and

eventually ask for the elimination of some segments, whereas checking of the findings was not planned for this part of the project. We followed the COREQ reporting guidelines.[37]

2.2 Study design

We conducted interviews with 48 experts involved in the processing, governance or collection of health related data in Switzerland. For the study, a total of 58 experts were contacted: 10 either declined the invitation or did not reply. Experts were interviewed either in person (n=36) or via phone/skype (n=12) based on their preference. Most of the interviews (n=39) were one-on-one. A few experts requested to be interviewed with members of their team for practical reasons. Thus, 9 participants were interviewed either one-to-two or one-to-three.

2.3 Sampling

We relied on purposive and snowball sampling. An initial list of potential interviewees from the three experts' groups was elaborated from the studies considered in the systematic review conducted previously by our team.[38] The objective of our sampling strategy was to include both experts on the topic of health data from a more practical side (e.g. researchers, hospital directors) and those with a more institutional perspective (e.g. policymakers, directors of health registries). Often, experts had (or had had in their career) more than one role. Interviewed participants were asked to provide recommendations so that our team could contact other experts from the Swiss context. Our sample did not include patients or members of the public, since we wanted to focus on stakeholders with first-hand experience in the management and use of medical databases. To indirectly tap into the perspective of patients, we had also contacted an individual with experience as patient think-tank director, who however declined our invitation for lack of specific expertise on the topics.

2.4 Data collection

A semi-structured interview guide was developed by the study team and pilot-tested for content and understandability. The interviews were conducted independently by either LDG or AM, two male PhD candidates with training on data collection and qualitative research methods. During one interview by AM, another PhD student came along as an observer to gather experience on the conduction of interviews, upon agreement of the interviewee. As a default, interviews were conducted in English, but the other three major official languages of Switzerland were also offered as an alternative, with some participants opting for Italian (n=4), German (n=3), or French (n=1). The interviews took place between May 2018 and September 2019. In one case, a participant asked to integrate the interview with a second conversation. The recordings lasted between 38 and 131 minutes, with a median duration of 60 minutes. Recordings were transcribed verbatim, integrated with field notes and potentially identifying information – e.g. age, exact place of work and position within the organisation/institution – was eliminated to ensure confidentiality. Overall, 10 participants were director or managers of health information databases/registries, 28 were researchers working with health data in project of national relevance, and 10 were experts from the public administration involved with health data management.

Data collection was stopped when no new issues were emerging in the interviews and it was thus deemed that data saturation had been reached.

2.5 Data analysis

To analyse the data, we relied primarily on thematic analysis [39] and were guided by the framework provided by Hansen.[40] In our analysis, we also followed the recommendations by Silverman,[41] in particular by considering both a positivistic (i.e. the idea that the content of responses conveys primarily an external "truth") and an interactionist perspective (i.e. the idea that answers also mirror the situational contingencies where they are given).

Our analysis started after the first interviews were conducted. Seven interviews were read and discussed together by AM, TW, and LDG during a series of meetings and a preliminary coding tree with themes and subthemes was developed. We used MAXQDA.18 as an analytical software to help with our analysis.[42] Afterwards, the remaining interviews were analysed individually by AM and LDG relying on the previously developed coding tree. Thereafter, a series of meetings were organised to discuss additional 15 content-rich interviews to refine the coding tree, its themes and subthemes, and to develop key findings from the data.

As this study is part of a broader project aimed at tackling several issues related to the health data framework and infrastructure in Switzerland, several broad themes and codes were identified during the data analysis. These included, for example, recommendations on how to improve health data infrastructure in Switzerland and how to promote fair data sharing practices. For this paper we relied only on the broad theme of data ownership, which emerged when asking questions about the barriers to the acquisition and sharing of health data, about the presence of regulatory barriers, or about the reasons why data-processors are hesitant to share medical data they collect. All segments related to the theme of data ownership were extracted and a topic-specific coding tree was developed, leading to the classifications presented in the results. All authors reviewed, edited and approved the specific coding tree for data ownership and participated to the analysis of the results.

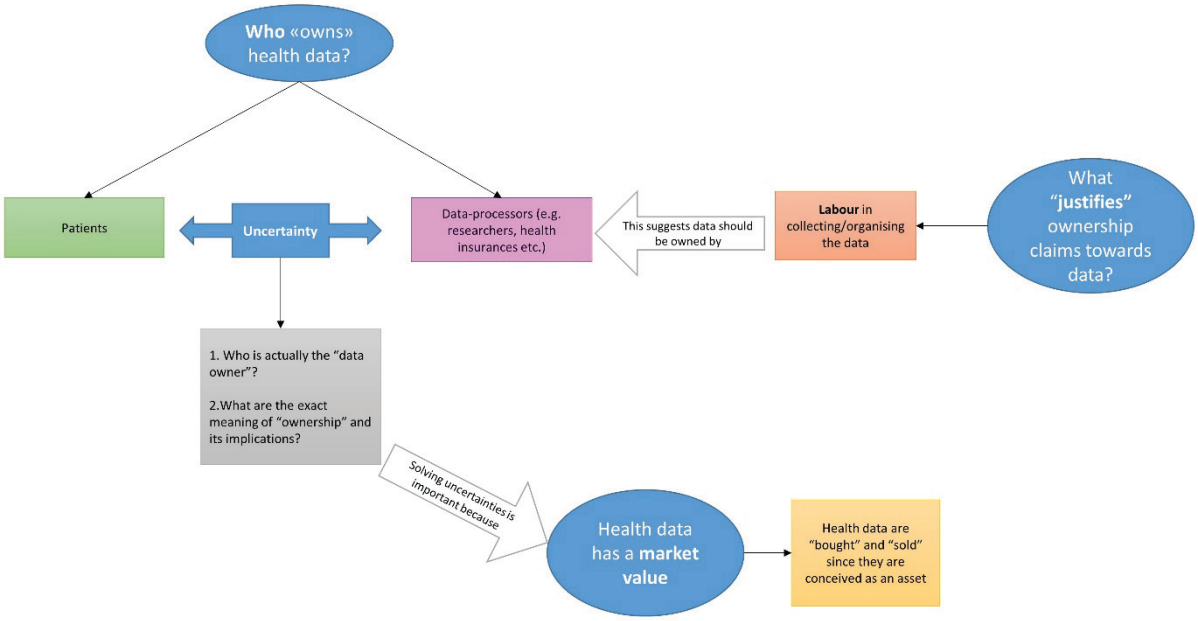
2.6 Patient and public involvement

Patient and public involvement was not part of this study. See section 'sampling' for further details.

3. Results

Four main themes concerning data ownership were identified, as presented in Figure 1.

Figure 1. Representation of the themes related to health data ownership.



3.1 The data owner: data-subjects vs data-processors

Participants often reflected on the subject of whom the ownership of data can (or should) be ascribed to. In this respect, two main potential data owners were mentioned, namely the data-processors[1] (i.e. the institutions or individuals, often researchers, who collected and/or used the medical information) or the data-subjects (i.e. the patients or, more generally, the persons to whom the health data refer).

Some experts (generally researchers) leaned towards associating ownership with the data-processors. In E1 (Table 1), for example, an expert talking about a project involving the use of medical information provided by an insurance company explained that the data belonged to the insurance company. Interestingly, experts suggesting that ownership pertains to data-processors were subtler in expressing this connection, as compared to those who argued that patients are the owners. Indeed, the former tended to speak of data-processors and data as being 'theirs', rather than using specifically terms like 'ownership', 'property', or 'belonging to'. The director of a health database (see E2 in table 1) explained that the medical centres contributing data to the database considered such data as 'theirs', but did not mention the concept of 'belonging'.

[1] In our results, the term 'data-processors' is used *in a general sense* to indicate all those institutions/individuals who practically collect and/or manage the data for a certain purpose, as opposed to data-subjects (i.e. the individuals – often patients – where the data comes from). According to the GDPR, there can be a distinction between those institutions or individuals that actually carry out the processing, and those which determine "the purposes and means of the processing" (art.4 (7) GDPR), which are named "data-controllers". We did not consider this distinction for our analysis, since it was not present in Swiss law at the moment when interviews were carried out. The distinction between data-controller and data-processor will be introduced in the near future by the reform of the Swiss Federal Act on Data Protection, which will come into force in 2022 and is referenced in the Discussion.

Other participants (including also researchers, but mainly experts involved in health registers or other health data infrastructures) indicated that health data fundamentally belong to the data-subjects, i.e. the patients or more in general the citizens from whom information is collected. As compared to those participants who sided for data ownership by the data-processors, those who argued that data are owned by patients often used firmer language (E3 in Table 1). Those who argued in favour of ownership by patients, despite their firm claims that data belong to patients, tended not to justify such claims – as if the fact that data belong to patients is self-evident and needs no further justifications. This is very different as compared to the ascription of ownership to data-processors, for which an explanation was provided (see section labour and property). Only some experts seemed to suggest that ownership by the patient has to do with 'empowering' them (E4 in Table 1).

Even those who ascribed ownership to patients seemed to be aware of the fact that – traditionally – the processors of the data (e.g. doctors, hospitals or health insurance companies) feel entitled to data ownership by default. For example, one expert expressed this idea in E5 (Table 1) and argued that this tendency has to be changed. One participant who was in favour of ownership by patients indicated that one of the reasons why data-processors might prefer to consider health information as their own property is that they see data as an asset (E6 in Table 1). Another participant argued that an additional reason why data ownership by patients is opposed by data-processors (in that case doctors) is the paternalistic conviction that patients would not be able to deal with information about their own health (E7 in Table 1)

Although in the literature the idea of common data ownership or public ownership of health data has been advanced,[43, 44] only two participants showed some sympathy for the idea that data should be open and treated as some kind of *common property*. One participant (23REngP)[2] spoke about it with reference to data collected by researchers (but see also E1) and one of them (18PGerP) with reference to data collected by governmental agencies.

Table 1. Extracts on the topic of assigning data ownership.

[2] The abbreviation gives details about the interviewee. The first number is the number of the interview, assigned chronologically according to date of conduction. The first letter refers to their positions: **R** = Researcher, **P** = policymaker or public official; **H** = High position in a health register, IT infrastructure or a relevant initiative concerning health data. Secondly, the original language of the interview is indicated: Language: **Eng** = English, **Ger** = German, **Ita** = Italian, **Fre** = French. Then the medium with which the Interview was done is indicated: P = in person, T = on the phone, S = on Skype. If a number is present thereafter, it means that two or more experts participated to the interview and the number indicates the expert from which the quotation comes – unless otherwise indicated. For example 23REngP means: 23rd interview, with a Researcher, conducted in English and in Person.

Extract Number (E)	Quotes from participants
E1	*"And I know that the [name of funding agency] now requires that all data should be on some platform. […]. But we cannot give the data, because they belong to [name of a health insurance]."* 23REngPA
E2	*P: Because it is possible that every now and then one center was not keen on transmitting **its** data because it has/ because it preferred keep them for itself and publish them in another way. We experienced this. There were a couple of centers which preferred to keep **their** data […], which told themselves: "But we have already enough data so that we can publish them […] But then I have to say that even this resistance is – typically – an initial resistance. Because some centers say "Wait a minute: Why do we need to make **our** data available to you, who then publish them?"* (emphasis added). 8HItaT
E3	*"You start actually with patients' data. So the data - first of all - belongs to the patient. […] Meaning, also for a doctor, or a researcher, the data does not belong to these people, the data belongs to the patients."* 43HEngP2
E4	*"One solution is the empowerment of the patient or the person […] And in these in [year] I have developed [name and description of a data collection system]. And this system works in the sense that it is the patient that actually is the ultimate owner of the data [...]. So basically you must have a system where the data are being owned by the patient rather than by the institutions."* 2REngT
E5	*"[B]ecause the institutions or the head of the institutions they feel the data belong to them and you can only give it to somebody with trust. And first of all you have to explain to them that the data don't belong to them."* 21HEngP
E6	*"So, they [data-processors] are not interested in sharing. They are not interested in sharing now, because they see these as a sort of// all the medical data as sort of an asset."* 27HengP
E7	*"They [the doctors collecting data] say: "It's my data, you know, I wrote this data. Sometimes there's things in these reports that the patients should not know or should not read." So this understanding that you take your patients seriously as persons who also can deal with difficult topics if you do it the right way. This is a cultural change and this is not easy to establish."* 11PEngP

3.2 Uncertainties about data ownership

Whereas many experts sided for data ownership either by the patients or by data-processors, another theme often discussed was the uncertainty related both to 'who is the data owner' and 'what is the meaning of data ownership'. In an exchange during the only one-to-three interview, it emerged how the

uncertainty as to the question 'who is the data owner' is related to a tension that exists between the fact that health data are related to patients, but the latter are often not practically in control of what happens with them (E8 Table 2). Uncertainty concerned, however, not only the question of 'who owns the data', but also what exactly the meaning and the features of ownership are. One participant, for example, explained how difficult it is to apply categories like 'property' and 'ownership' to an incorporeal item like data, since those categories are traditionally conceived for tangible objects (E9 in table 2). On a similar line, the complexity of understanding what the concepts of 'belonging' and 'ownership' actually mean when applied to data was also mentioned as a source of uncertainty (E10 in Table 2).

Table 2. Extracts on the topic of uncertainty.

Extract Number (E)	**Quotes from participants**
E8	Participant 3: "*However, this thing concerning health insurance funds actually… 'whom does the data belong' is really a question that I ask myself. Whom do they belong to, since the patient has given them and they are anonymous...to whom do they belong?"* Participant1: *They belong to the patient probably. However, the problem is that the availability of data does not depend on the patient. Because the patient does not have her own data...That's it.* Participant 2: *"Because then it is the 'data management' – do you understand? – who takes care about them [the data]...I authorize you to process my data, but if I am then not the one who manages or processes it..."* 14RItaP
E9	*"[A]t different conferences, meetings this [data ownership] is always a discussion point but it doesn't come to a solution. It ends open mostly. And I think it's, yeah... it's difficult because you have to find out what is data. It's not something like a cup or something you can take in your hands, it's not material in that perspective. So can you own it or can you get only the right to process it? It's very, very tricky."* 21HEngP
E10	Participant: *"I think this 'belonging' of data is somehow a difficult story. […] Maybe it is legally at first sight straightforward, but on second thoughts it is – I think – more complicated."* Interviewer: *"Well, theoretically yes [it is easy] but practically not so much...* Participant: *"Yes, right? And what does it mean actually 'they belong to me'?"* 36PGerT

3.3 Labour as a justification for data ownership

As different individuals may potentially make ownership claims towards the same health data, participants often reflected on what entitles to owning the data. In this respect, there was a tendency among participants to express a strict connection between labour and property, with the idea that putting

effort and energy to collect and manage health data legitimises ownership claims towards them. This connection between labour and data ownership was sometimes expressed in a very direct and strong fashion. Interestingly, even some participants who argued in favour of data ownership by the patients acknowledged (albeit with some criticism) that there is a widespread sense – especially in the field of research – that having put some effort in collecting and organising the data renders the data 'yours' (E11 and E12 in table 3). The contrast between the conviction of some participants that data have to belong to patients – on the one hand – and the fact that data-processors feel some kind of ownership due to the effort they put in organising the data was well highlighted also in another interview (E13 in Table 3).
In other cases, participants provided a more differentiated description: they did not claim explicitly that labour with respect to data entitles to be the data owner, but still creates some 'privileges' with respect to those data. In one passage, an expert referred to the fact that the work for preparing the data and passing them on should be somehow acknowledged, also in other ways than simply receiving authorship. Also, the idea of having invested time and energy in collecting or preparing health data for analysis was sometime mentioned as generating not exactly ownership, but rather some kind of 'pre-emptive' rights – i.e. the right to have a say before the health data are forwarded or used for something else (E14 and E15 in table 3).

Table 3. Extracts on the topic of labour as a justification of data ownership.

Extract Number (E)	**Quotes from participants**
E11	*"If you [as a researcher setting up everything for data collection] have the relevant data, the IT-platform, if you have all the regulations in place// you know, in [name of one project] I had to invent all of that. We do everything from 'A' to 'Z'. So, then of course you have some ownership*." 38REngP
E12	*"[T]here is too much about...it's too much often protection of your own work, of your own project, also because you have actually gained the funding - so why should I give my data which I collected by my funding and so on. […]. It is a very, it is a narrow way of thinking. 43HEngP2*→ supporter of patient data ownership, but acknowledging how data-processors justify making ownership claims.
E13	*"[B]efore - [name of P's project] some institutions and researchers said: 'These data belong to me'. They have built a biobank from patients and so. Maybe they have 200 samples or something like that in research. And then they say: 'This biobank belongs to me'. Then you have to tell them: 'No, no, no, no. Just stop. Nothing belongs to you. All the data belong to the patients and not to the institutions'. But for sure - I mean - the institution invests money, and so the institutions think: 'Oh we cannot just give out the data,*

	otherwise we have invested some money and we want to have the investment back at least'". 39HEngT
E14	*"I'm happy that you used our data, I don't need to be an author because I did not contribute as an author, but I would like to be listed as a collaborator and this is what they do. So I think this is a very good way to acknowledge and you know nowadays I mean authorships are nice to have, but it's much more important to show to others that you are participating and you have a strong network"* 26REngS
E15	*"There would have to be agreements you know… if I let you see these data, you know, are you going to give credit to the people who worked on them you know...who actually did the work of getting them [Interviewer: collecting?]…Yeah, yeah... That is something that has to be worked out… that's a lot of work you know."* 1REngP

3.4 Data have a market value

In the literature, data ownership is often discussed in relation to the development of an efficient market for data.[45] In particular, it is claimed that clarifying who the data owner is and what exact powers ownership entails would facilitate its trading. Despite the diverging opinions concerning who is the data owner and the uncertainty as to what powers ownership entails, in our interviews data were often discussed in market terms. Some participants, for example, referred to how data are now conceived as a commodity and monetised, or alluded to a health data market when discussing how data are exchanged (E16 and E17 in Table 4). One participant was quite critical of the position that giving ownership and control of their data to citizens will empower them to become active participants in the data market and trade their medical information for money (E18 in Table 4). The tendency to think about health data as a tradeable commodity was also present in some participants who spoke about data-exchange as a sort of 'barter' between researchers (E19 in Table 4).

There was only one interviewee who explicitly contrasted a market language with respect to data-exchange and referred to the fact that people might be motivated by altruism when they provide their health data, thus 'donating', rather than 'selling' them (E20 in Table 4).

Table 4. Extracts on the topics of data having a market value.

Extract Number (E)	**Quotes from participants**
E16	*"And second, probably there is now the consciousness that data are a resource. So you can make money with data, and so it's better to…well it's better to make some market with your data than just sharing them. Because we are all in a very.... big pressure for resources and so if you can have…if we can make some money with the data, we can get some more resources to work."* 28REngP

E17	*"I mean the problems you realised at first hand by seeing how everyone is very protective of what they think is a great asset. Because, you know, I mean in the US, [name of a pharma company] just paid 1.5 billion dollars for [name of a company], which is a company that bought - bought! [emphasising the word] - a million hospital record and annotated them a bit"* 27HEngP
E18	*"I have heard some people say: 'Oh wow, as soon as I have data, I will share this data - for instance - with industry, because industry is looking for data and they will pay for this data and then we can make money and we can share this money with people who share their data with us' [..]. I think it's ridiculous. It's a very poor understanding about industry"* 30REngS
E19	Interviewer: *"We usually hear that researchers are not very keen in sharing the data that they've collected.* Participant: *Yeah* Interviewer: *So do you agree with this?* Participant: *"Yeah, yeah. I mean, researchers, they want to share data usually as long as they receive data from others."* 33HEngP
E20	*"I think quite a lot of people are - how would I say that...some kind of 'want to do good'...if it comes to research, you know, if your research can explain why he is doing something and, let's say, what the purpose is and how it can help - so to say - the system…most of the people will, let's say, donate the data."* 24HEngP

Discussion

In this paper, we reported the results from our interviews with Swiss experts concerning the topic of health data ownership. In this respect, our study findings underline very diverging convictions concerning who is the data owner, possibly also because there is some uncertainty about what ownership entails. Other qualitative research had suggested that ownership of data resides either with the patients [22, 23, 24] or with the data-processors, such as local or public health authorities,[20, 21, 30] but did not investigate how to reconcile these two opposite claims. The presence of these two competing conceptions might be explained with the indeterminacy of the concepts of 'ownership' or 'belonging'. In this sense, it could be that experts siding for patients' ownership referred to the fact that data are *about* patients and *provided by* patients, and thus *theirs*. On the other hand, our study participants claiming that data-processors own the data might have thought of ownership in terms of 'having something at your disposal', which applies – with some limitations – to the relation between data processors and the data they have. Indeed, our interviews also highlighted confusion about the meaning of ownership (see discussion below). Alternatively, the divergence of opinions could be explained by the fact that participants were making *normative* (i.e. indicating how things *should be*), rather than *descriptive* (i.e.

referring to how things *are*) statements. The idea of health data being conceived as a common good or a public property – which has been discussed by some authors [43, 44] – was seldom mentioned. This might be due to the specific features of the Swiss context, where there is no national healthcare system,[46] and thus the *de facto* control over many resources in healthcare (including data) is divided between a multitude of stakeholders, rather than hold by one public entity.

Our results do not only confirm that there is lack of agreement about who the final data owner should be, but also uncertainty about what *ownership* exactly entails. This finding is particularly important, since it suggests that experts – although often referring to the idea of *ownership* of health data – are not always certain what this concept means. In general terms, ownership can be defined as "a set of relationships, granting to a person or to a group control over a specific resources vis-à-vis other people",[47] but this term assumes different connotations depending on the context in which it is used (e.g. legal vs economic). The meaning of *ownership* as applied to *data* is even more complicated, since claims of *data ownership* are not merely legal, but also have a political and philosophical scope.[48] One straightforward reason why data ownership is a complex concept is that data possess a rather intangible nature, as compared to other objects of ownership rights, and applying ownership to immaterial objects has been controversial.[49] Legal experts are indeed still very sceptical about using the (legal) concept of ownership to describe the relationship between data and the subjects that interact with them.[50] In the Swiss parliament, there was an effort to modify the Constitution to declare personal data as *property* of the individual,[51] but this modification was rejected. On the contrary, the recently reformed *Federal Act on Data Protection* [52] recognises health or genetic information as a sensitive kind of data, but it does not grant any ownership rights of a legal nature towards them. Our interviews confirm that the idea of data ownership has a certain appeal, but that there is still great uncertainty as to the exact meaning of this concept. It is possible that, if prompted with more concrete cases, our participants would have expressed less uncertainty about what they conceive as *ownership*. Nevertheless, since this concept is often used to described the control of people (be them the patients or the data-processors) over health data, its meaning should be clarified a priori. Better defining the meaning and extent of ownership entitlements has also been described as an important condition for the data market to thrive.[45]

Moreover, our study indicates how there is a widespread conviction that labour provides a justification for owning the data (or dataset) for which the work was done. This would lead to think that ownership of data should reside with the data-processors and not with the patients – since the former do most of the work to collect and use the data. The idea that labour justifies ownership claims was also shared by some experts who – in other part of their interviews – had suggested that patients should be owners (e.g. interview 38REngP). On the contrary, no explicit and extensive justifications as to why patients should own their data was provided by those who argued in favour of this. When considering the views of supporters of patient data ownership in the United States, Evans [53] explains that normally these rely

on arguments of control and of full access to one's own information. It is possible that similar motivations drove the statements of the experts in our study. In Swiss legal literature, both the possibility of assigning ownership to data-subjects – because the data originate from them - and to data-processors – because they invest in the collection, storage and use of data – have been discussed.[34] The claim that patients should own their data might be popular also because Switzerland has a long tradition of strong individual rights and citizens' control, as its political system is characterised by direct democracy (e.g. with referenda and popular initiatives). Furthermore, Switzerland is host to two of the first international examples of *data-cooperatives*, i.e. data-sharing platforms strongly leaning towards the idea of citizens' control of their data.[54] Data-cooperatives are databases "concerned with the collection, storage, maintenance, and analysis of health data" where every citizens can participate by "pay[ing] a one-time unit price (membership fee), which entitles the person to be a member and owner [of the cooperative] at the same time".[55] The existence of such initiatives in Switzerland corroborates the idea that patient ownership and control over health data is acknowledged. Nevertheless, it is surprising that no justification of the claim that patients are data owners was expressly present in our interviews. One obvious reason that would support the claim that patients are to some extent 'data owners' is the fact that they must often provide consent before their data are used – thus exercising some sort of control on the data. Indeed, informed consent of the data-subject (i.e. the patient) is considered a cornerstone of legitimate data processing from an ethical, but also legal point of view.[56] Both Swiss law and the GDPR indicate that obtaining informed consent by data-subjects is often necessary to permit the processing of medical data, which are considered as "particularly sensitive" (art. 3 of the Swiss Federal Act on Data Protection and art.9 GDPR). However, it is also true that there are many cases where data processing might proceed without patients' explicit consent and it is justified by a different lawful basis for data processing.[57] For example, if medical data are sufficiently anonymised,[3] patients' consent becomes generally irrelevant when using such data (e.g. for public health purposes).[58] Or else, even if the data are *not* anonymised, regulation often caters for 'research exemptions',[59] i.e. specific rules that allow the secondary processing of medical data for research purposes (e.g. the use of data initially collected during clinical routine to then conduct healthcare service research) without the need of the explicit consent by patients (see e.g.[60] for Switzerland). Thus, although it is true that expressing consent for data processing could be a powerful justification to claim that patients 'own' their data, it is also true that the processing of medical data does not always necessitate consent. Despite the existence of established paths to use patients' data without their permission, supporters of patient data ownership in our interviews presented their stance (i.e. that data belong to patients) in an assertive fashion – hence also the use of a 'strong' and 'resolved' language and the denouncing of the opposite position (i.e. data belongs to data-processors) as mistaken.

[3] There are doubts, however, whether data nowadays can ever be considered as truly anonymised, especially with respect to genetic data [62].

The fact that putting labour with respect to data was described as legitimising ownership claims towards such data mirrors one established philosophical and jurisprudential account of ownership, according to which by commingling labour with an object, one establishes property of it.[61] Such finding is important because it reveals that those working on acquiring or processing health data(sets) develop a sense of entitlement towards owning the data. This sense of entitlement might curb the willingness of healthcare researchers and hospitals to share data and might generate controversies between individual data-processors (e.g. researchers working at a hospital), who do the actual work for organising the data, and the institution by which they are employed, which provides the financing and the means. Moreover, if it is perceived that labour gives some degree of ownership on the data (or at least have some pre-emptive rights towards them), the rhetoric of "patient data ownership"[17] might clash with a reality where those who put an effort to collect patients' data feel they deserve to control that medical information. The need to resolve the tension between the willingness to facilitate data sharing and the feeling of data-processors of having special claims towards the data they manage was also explored by a previous study conducted with stakeholders from Africa.[63] Our study suggests that a similar attitude is present also in a wealthy country like Switzerland, where resources to collect and manage data are comparatively larger. If health data-sharing and reuse should be facilitated, there might thus be a need to reduce this feeling of entitlement that data-processors perceive, by diminishing the competition for the resources needed to create databases. This could be achieved in different ways. For example, shared priorities concerning the health data that need to be collected and managed could be elaborated at an inter-institutional level, to then distribute the effort necessary for collection and managing of such data between a multitude of actors and thus sever the sense of entitlement of single institutions. Or else, clear guidelines could be developed that explain how to access health data collected by the effort of single data-processors (e.g. hospitals) in exchange for a reasonable fee (especially since data are already seen as having a market value), but also without leaving too much discretion as to which access-requests to accept and which not. Needless to say, it is difficult to strike a balance between providing an adequate reward to data collectors and keeping data accessible, but this seems to be the right way to go.

Lastly, our results indicate that using a market language with respect to health data is already quite widespread. This confirms what theoretical literature has been suggesting for some time, namely that health data are often conceived as a commodity.[64] Commodification can be considered ethically problematic, since health data – like characteristics derived from biological material and organs – are something intimate and connected to human dignity.[65] Some authors claim that the dangerous tendency of *commodifying* data can be accelerated, if *property* rights towards them are reinforced (the so called 'propertisation of data').[66] However, whether having well defined ownership rules concerning data really increases an alarming tendency to commodify them remains to be ascertained. Our interviewers often spoke about data in market terms and as a commodity, even if in Switzerland (like in any other European country) data is not formally governed by property law and ownership of data remains ill-defined (see above). Purtova argued that it is actually the lack of explicit ownership

rules that favours the development of a more unbalanced data-market, since "maintaining the status quo where no ownership in personal data is formally assigned equals assigning ownership to the Information Industry and leaving an individual defenceless".[67] Although data can be re-used over and over again, and shared with a massive amount of parties at the same time, the fact remains that "the tricky part is in getting to the source of [data], i.e. people, in the first place".[67] A potential way to escape the market logic in data sharing and exchange could be to favour the idea of health data as a common good, which should be simply guarded by the data-processors who actually manage the data themselves.[2] A political initiative in this sense was promoted in the Swiss Parliament during the COVID-19 pandemic, with an appeal by some politicians to create the possibility for citizens to voluntarily donate their health data in the public interest, for both research purposes and public health emergency response.[68]

Limitations

This study has some limitations. First, the interviewees were experts with often limited amount of time, thus we had to adapt the study design to their needs. This led, for example, to having some one-to-two interviews and a one-to-three interview, to having to conduct some interviews in person and some via phone or Skype and to having limited time for probing questions. Second, the two data collectors have different backgrounds (AM in law and LDG in medicine), thus potentially introducing some variations in the different interviews. Third, as a qualitative interview study, we cannot exclude that responses may have tended towards socially desirable answers. Finally, ours results cannot be deemed a generalization to what other health data experts in Switzerland and elsewhere believe about data ownership.

Conclusions

In an increasing digitalised medical sector, data ownership remains a highly controversial topic. This study confirms that uncertainty still surrounds both the question of who can be considered data owner and what "ownership" exactly entails. The fact that labour was mentioned as a reason to assign ownership to data-processors (e.g. researchers) suggests that the latter feel a sense of entitlement towards the data they manage. This clashes with the opposing claim that data should be owned by patients. The contrast between the rights of patients towards their data and those of data-processors who manage them is typical of several countries (see e.g. [69] for the U.S). The findings of this study may thus be of use not only for Switzerland, but also for other countries which are trying to implement the most appropriate governance to settle this potential contrast. Indeed, there is an international endeavour to implement a form of data governance that continues protecting patients' rights and privacy towards their data, but also favours the reuse of data in biomedical research and public health. More precise definitions of data ownership rights of the different parties involved in data collection and their management would be a step forward in this direction. This would entail providing clarifications of who controls data in the different data processing activities and should thus be consulted e.g. when data are shared with third

parties. If the language of 'ownership' proves impracticable for the research sector or the use of medical data more in general, then there should be an effort to reject the idea that medical data *belong to* anyone. An alternative could be to favour the idea that these are a sort of public good, which can be *donated* by patients and guarded by data-processors, who would "have a responsibility to ensure the data are discoverable by others and accompanied by sufficient metadata for them to be found easily, understood in context and used appropriately".[2] Yet, this would also require to eradicate another tendency that our study confirmed, namely the fact that medical data are seen as an asset with market value, which – as any other resource – many parties have an interest to control and profit from.

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Competing interests

There authors have no commercial or financial interests to declare.

Authors' contributions

BE and TW conceived the study and prepared the interview guide with LDG and AM. AM and LDG conducted the interviews. All authors participated in the analysis of the data. AM and TW prepared the first draft of the manuscript. LDG and BE integrated the initial draft with comments and additions to the manuscript. AM finalised the last version of the manuscript, which was then corrected, read and approved by all authors.

Ethics approval

According to the Swiss Human Research Act, our study does not require ethical approval. This was confirmed by the cantonal ethics commission (Ethikkommission Nordwest- und Zentralschweiz - EKNZ), to which we submitted the outline of our study and which stated that it fulfilled general ethical and scientific standards, posed no health hazards and did not required formal approval by them (EKNZ req-2017-00810).

Participants' consent

Participants orally agreed to take part in the study, that their interviews be recorded, transcribed and used for the project after personally identifying information was eliminated. No personally identifying or health information are included in this study.

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Data availability statement

Interviews have been conducted under the assurance of confidentiality concerning the identity of the interviewed experts, hence potentially identifying information has been masked during transcription. Due to reasons of confidentiality, full transcripts cannot be shared - as the potential of re-identification would be relevant. Data and segments used for the following manuscript can be provided upon reasonable request and upon agreement with the authors, to ensure that ethical and legal requirements are upheld.

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3.3.1 Evolution or revolution? Recommendations to improve the Swiss health data framework

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Abstract

Background: Facilitating access to health data for public health and research purposes is an important element in the health policy agenda of many countries. Improvements in this sense can only be achieved with the development of an appropriate data infrastructure and the implementations of policies that also respect societal preferences. Switzerland is a revealing example of a country that has been struggling to achieve this aim. The objective of the study is to reflect on stakeholders' recommendations on how to improve the health data framework of this country.

Methods: We analysed the recommendations collected as part of a qualitative study including 48 expert stakeholders from Switzerland that have been working principally with health databases. Recommendations were divided in themes and subthemes according to applied thematic analysis.

Results: Stakeholders recommended several potential improvements of the health data framework in Switzerland. At the general level of mind-set and attitude, they suggested to foster the development of an explicit health data strategy, better communication and the respect of societal preferences. In terms of infrastructure, there were calls for the creation of a national data center, the improvement of IT solutions and the use of a Unique Identifier for patient data. Lastly, they recommended harmonising procedures for data access and to clarify data protection and consent rules.

Conclusion: Recommendations show several potential improvements of the health data framework, but they have to be reconciled with existing policies, infrastructures and ethico-legal limitations. Achieving a gradual implementation of the recommended solutions is the preferable way forward for Switzerland and a lesson for other countries that are also seeking to improve health data access for public health and research purposes.

1. Introduction

Promoting the use of data and fully taking advantages of digitalisation are amongst the principal challenges that healthcare systems have been facing in recent years. With data being presented as a powerful resource (often referred to as the "new oil" (1)), there is hope that health-related information collected whenever individuals come in contact with the health system can help improve both the quality of healthcare and its cost-efficiency. For example, it has been highlighted that real-world data can be used to evaluate the cost-effectiveness of drugs after their approval or to develop more targeted therapies for cancer (2). The use of routinely collected health data can also play an important role in improving public health policies in high, middle and low income countries (3). For example it has recently been shown how health-insurance-provider data and administrative data can be used to help design the vaccination strategy against SARS-CoV-2 (4). Or else, by linking individual prescription data with data on SARS-CoV-2 infection and comparing users of Nonsteroidal anti-inflammatory drugs (NSAIDs) with non-users, Danish researchers proved that NSAIDs are not associated with increased hospitalisation, ICU admission or 30-day-mortality, thus delivering policymakers and clinician a timely answer concerning an emerging infectious disease (5). The vision of *learning healthcare* is indeed based on the idea that a beneficial circle between research and care can be achieved, if data and knowledge flow iteratively between these two integrated sectors (6). A concrete consequence of the perceived relevance of medical information to improve healthcare has been the gradual introduction of electronic health records across Europe (7,8). Indeed, facilitating the cross-country exchange of electronic health records has also been one of the goals of recent recommendations by the European Union (9–11).

Harnessing the potential that health data offer has also been an important priority in the Swiss healthcare system. Switzerland is a confederation comprising 26 cantons (federal states) with extensive powers in the field of healthcare. This decentralisation – together with a tradition of direct democracy, the prominent role of private actors (e.g. insurance funds), and a high degree of corporatism (i.e. the involvement of interest groups in policymaking) – renders the Swiss healthcare system particularly complex (12). The complexity of the system is mirrored by the fragmentation of the health data infrastructure, which the government has been recently trying to remedy. Indeed, already in 2013 the Federal government released the "Health 2020" strategy, in which the objective of improving the health data framework of the country was transversally mentioned in the four pilasters of the strategy (13). At the same time, an ambitious effort to guarantee the creation of interoperable electronic health records (Electronic Patient Dossier – EPD) for the whole country has started, following the vision proposed in the Strategy document "eHealth Schweiz" (14,15). The awareness that there is a need to improve the health data framework in Switzerland has been wholly present also in the research community. In 2013 the Swiss Society of Public Health published a manifesto named "Better health data for a more efficient health system" (16), which called for improving the completeness, accessibility, linkability and comparability of data concerning health. This manifesto was also endorsed by the Swiss Learning Health System, a consortium of institutions of higher education and universities aimed at strengthening the link

between research and clinical practice (6). The message that the data-readiness of the country needs improvement has continued to resonate as a priority in the political sphere also more recently, as confirmed by the launch of the strategy "eHealth Schweiz 2.0"in 2018 (17) and by the new federal health policy for the period 2020-2030 (18).

Despite the constant commitment of the scientific and political fields in the last few years, the overall situation of the health data framework in Switzerland still faces several challenges. For example, data-controllers continue to express reluctance with respect to facilitating the combination of data from different sources (19). Moreover, the overall operationalisation and implementation of digital health remains in a developing phase (20). For example, the EPD was originally planned in 2007, but the adoption of the necessary legal framework was particularly troublesome (14). Even after legislation was approved, its concrete operationalisation was postponed mainly due to problems related to the certification of the institutions that manage the EPD.(21) Thus, while the EPD should have been available throughout Switzerland in April 2020, as of January 2021 it is available only in one region (22). Moreover – despite the many years and the considerable funding provided – several technical questions on the EPD (such as how it will be possible for doctors to retrieve information quickly from the record) still remain open (23), thus revealing how providing an interoperable data platform in the Swiss healthcare system continues to be a challenge.

Similarly, some significant incidents during the SARS-CoV-2 outbreak revealed the need of improvement in the data-readiness of the country. At the end of July 2020, the Federal Office of Public Health (FOPH) reported how data communicated by physicians suggested that most COVID-19 infections occurred in discotheques, prior to realising that this analysis was based on a mistake with subsequent correction of the number of such infections to less than 2%, as compared to families accounting for almost 30% (24). Or else, in August 2020 the announcement by the FOPH of the death of a young patient due to the virus caused a sensation, but it later was revealed that the person was in fact alive and had only mild symptoms. The error resulted from the misreading of a sign in the paper-based record concerning the patient (25), which could have been prevented if data collection had been digitalised. Such examples reveal that there is still room for improvement in how health data are collected and shared between stakeholders in Switzerland, as already highlighted in a report by the OECD a few years ago (26). These persisting difficulties generate a considerable damage, in that they severely limit the health service research that could be conducted to inform policymaking in healthcare (19,27) and they are significant obstacles to having more transparency in the health sector (12). Moreover, an under-developed and fragmented health data infrastructure represents a hindrance to the development of precision medicine within the country (28).

In this context, this manuscript presents the recommendations on how to advance the health data framework in Switzerland, which we collected in a qualitative study with Swiss stakeholders. This study is part of a broader project aimed at identifying, mapping and ordering current deficiencies of the health

data infrastructure and data culture in Switzerland and the possible solutions thereto (29). The project included also a systematic review(30) and the analysis of relevant legal (31,32) and ethical (33) issues. From the qualitative part of the project, an article on the conception of health data ownership has been written (34). In this manuscript we focus exclusively on our findings concerning the recommendations to improve the health data situation in Switzerland and we discuss their feasibility against the political and legal situation of the country.

2. Materials and Methods

The overall methodology of the qualitative side of the project of which this study is part has already been previously described (34). Here we provide a quick overview and we focus on the specific methodological approach used for data analysis of this study.

2.1 Research Team and Reflexivity

Interviews were conducted by AM and LDG, two PhD students in biomedical ethics, with previous training on qualitative research methods. The data analysis was conducted – on top of AM and LDG – by SE, a medical student, and TW and BE – both senior researchers with longstanding experience in empirical research. Given the presence of several themes in the data that concerned legal and policy aspects, FE – a lawyer specialised in data protection and experienced about the health data situation in Switzerland – was also involved in the analysis.

2.2 Design

This study is part of a multi-stage process aimed at facilitating the harmonisation of health data in Switzerland (29). As part of this project, national experts were interviewed to identify the current barriers to health data exchange and possible solutions to address them. Since the project did not involve patients or the collection of personal health-related data, it did not need ethical approval according to Swiss regulation.[1] Nevertheless, the local ethical committee was notified and it confirmed that ethical approval was not needed, that the project respected general ethical and scientific standards and that it could thus proceed (EKNZ req-2017-00810).

2.3 Settings and data collection

Experts were selected based on purposive sampling combined with snowball sampling. Purposing sampling is an established sampling strategy in qualitative research which consists in "selecting 'information rich' cases, that is individuals, groups, organizations, or behaviours that provide the greatest insight into the research question" (35). A first list of potential experts was drafted based on literature analysed for the systematic review(30) that was also conducted as part of the project. Potential experts to be interviewed were divided according to their occupation and/or expertise into three categories: 1) researchers working on projects of national importance which involved the collection and

[1] See the Human Research Act, available at: https://www.fedlex.admin.ch/eli/cc/2013/617/en [Accessed January 29, 2021].

sharing of health data from different sources; 2) policymakers and public officials involved in the health data framework; and 3) directors or administrators of institutions having a health database. Experts from the initial list were contacted via email by AM and LDG, who explained the purpose of the study and asked for availability to be interviewed. Those experts who were eventually interviewed were also asked for further recommendation as to other stakeholders that they recommended to interview (snowball sampling). In total, out of the 58 experts who were contacted, 48 agreed to be interviewed, whilst the remaining either declined or did not reply. Interviewees included 28 researchers with experience in merging health data from different sources in Switzerland, 10 individuals from policy or administrative bodies involved in the steering of health data policy (e.g. from the Federal Office of Public Health or Federal Statistical Office) and 10 stakeholders of other health databases (e.g. disease-specific registries, cancer registries, hospital databases or private health databases). Often experts covered – or had previously covered in their career – more than one role. Experts were interviewed in person or via skype/phone, according to their preference. Whereas the majority of the interviews took place in English, some experts were interviewed in Italian, German or French – official languages of the Swiss Confederation. The interviews lasted between 38 and 131 minutes, and the majority (39/48) were one-to-one. Interviews were conducted between May 2018 and September 2019 depending on experts' availability. Experts consented to participate in the study, for their interview to be recorded and transcribed verbatim, but eliminating reference to personal attributes that could lead to identification.

2.4 Qualitative analysis

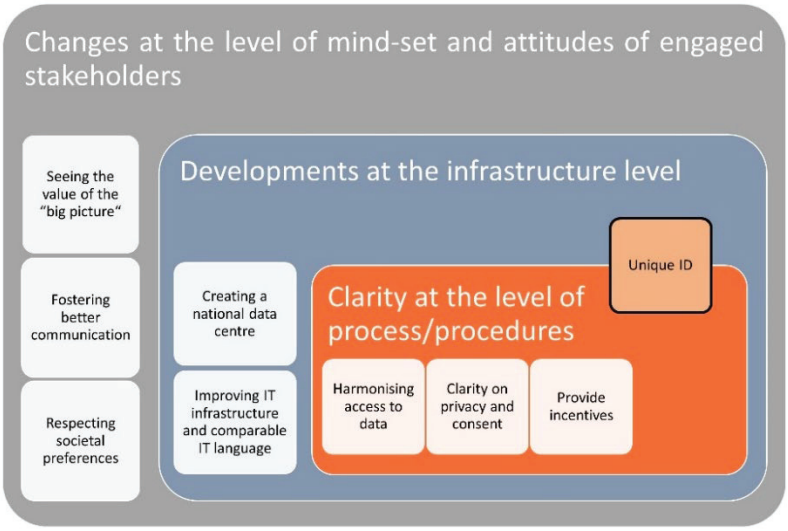
For this manuscript we relied on Applied Thematic Analysis as described by Guest et al.(36) Transcribed interviews were initially analysed by AM, LDG and TW, with the objective to identify overarching topics and to divide the transcripts in segments related to those topics - a process which Guest et al. define 'segmentation'. After this process, for this manuscript we considered only the segments that related to the overarching topic of "recommendations". These were mostly related to the last section of the interview guide we used in our project (see appendices at the end of the Thesis), in which we asked participants to provide recommendations to improve the Swiss health data landscape. Moreover, given the semi-structured nature of our interviews, additional segments containing recommendations were also present in other parts of the interviews (e.g. when participants were asked if they encountered legal or ethical challenges in their work and if they saw room for improvement). The segments containing recommendations were grouped in a new database and the following procedure was followed for analysis. First, half of the segments were read and manually annotated by AM and the other half by SE, with the objective of identifying thematically-related recommendations. The annotations were then discussed between AM, SME and TW, and a tentative coding tree – i.e. a list of codes encompassing the meaning of the different recommendations – was developed. Thereafter, a codebook was developed to help define the boundaries between codes, as recommended by Guest et al.(36) The codebook

included for each code: 1) a brief one-line intuitive definition of the code; 2) an extended and more detailed definition; 3) some notes highlighting when to use the code and when not to use it; 4) an exemplary segment for the code in question. With the coding tree and the codebook, the segments concerning recommendations were then finally assigned to the different codes by AM and SME. Each of these two authors coded half of the segments, and then checked the other half to ensure inter-coder agreement. Segments for which coders were in disagreement were discussed collectively between AM, SME, LDG, and TW until unanimous consensus was reached on the code to which the segment should be assigned. All the authors then revised this analysis, elaborated the systematisation of the codes and their organisation into categories and discussed the implications of the recommendations made by the interviewees.

3. Results

In the interviews, a series of recommendations that covered different topics and suggested different solutions were present. First, some recommendations concerned how to change the general orientation and the mind-set that lay behind the governance of health data in Switzerland. Second, other recommendations targeted more concrete developments that can be undertaken with respect to the health data infrastructure. A third set of recommendations were aimed more specifically at suggesting how to improve clarity of the processes and procedures concerning access or exchange of health data. The categories and sub-categories of recommendations are summarised in Figure 1 and then presented in more details in the sections below. All quotes presented below have been cleaned (e.g. by eliminating repetition and grammar mistakes present in the recording) and those which were originally in French, Italian or German have been translated into English.[2]

Figure 1. Overview of the recommendations and their different levels



[2] Segments were translated to English internally by our research team, which features proficient users (C1 and C2 proficiency according to the Common European Framework of Reference for Languages - CEFR) of all languages used (English, French, German, and Italian).

3.1 Changing mind-set and attitudes

A considerable amount of recommendations proposed by the interviewees highlight some changes that should be adopted by various stakeholders in how they approach the issue of health data processing and sharing, as summarised in Table 1.

Table 1. Recommendations concerning mind-set and attitudes

Recommendation	Concrete implications
Seeing the value of the "big picture"	→ a clear health data strategy must be developed: this includes agreeing on the important objectives that need to be achieved by collecting and processing health data.
Fostering better communication	→ ensure that different actors are continuously engaged in a proactive exchange: institutions and initiatives in the health data framework have to be known by all actors to coordinate efforts.
Respecting societal preferences	→ the development of the health data framework has to combine efficiency with considerations for populations preferences and attitudes.

First, one urgent concern expressed by the interviewees is that progress in the health data framework requires various stakeholders involved to think long term about the purposes and the reasons for data collection and data sharing. Having long term plans on the objectives that are to be achieved by the analysis of health-related information is thus conceived as a condition to stimulate the improvement of the health data situation in a coherent way and without wasting resources.

> *"The first reason is that data without a scientific question are useless. And I think that Switzerland needs to ask [....] the question of: "What will these data be used for?". […] If there is no scientific question, there is a lot of data being collected which are useless. And a lot of data which would be useful, which are not collected."* (Res20[3])

The importance of having a clear plan and a clear overarching idea of the final purpose as to why health data are collected is necessary for more concrete actions – such as defining standards for data collection. This element of having a "data strategy" in Switzerland was noted as such:

> *"Maybe the problem is not that there is no data. The problem is that there is no consistency about the data existing. I think we could play a big role in trying to make structural data ready for use. But for that it has to be simplified somewhere else... [gathers thoughts] ...a data strategy, so far as I know, is not existing in Switzerland."* (Pol5)

[3] The abbreviation gives details about the interviewee. The letters indicate from which group of participants the interview of the coded segment belongs. "Res" refers to researchers, "Pol" to policymakers and "Stak" to directors or administrators of an institution managing health data. The number refers to the order of the interview within that group of stakeholders. So, for example "Res20" means: 20th Interview conducted with a Researcher as interviewee.

Second, interviewees expressed that fostering communication and collaborations between the different actors involved in the health data framework is an important step to improve the situation. In the following segment, one expert mentioned the need for a much more open dialogue.

> *"Participant: [T]hose efforts [referring to initiatives working with health data] should know from each other and there should be some national exchange across those efforts [mentions the names of different initiatives]...*
>
> *Interviewer: I see. So more collaboration between all these different actors?*
>
> *Participant: Yes…and not necessarily collaboration. I think an exchange of information would already help. I mean just to know from each other. Maybe some informal meetings."* (Res2)

Exchange of information concerning, for example, the health databases already available, their content and their potential would avoid the creation of so-called 'data cemeteries'. That is, such exchange of information can address the problem of underuse of available health data.

> *"Well, for a researcher I would say: "Before starting to collect data, look around what's available". Because, ok, there is the issue of 'open data': everybody wants 'open data', but then there is some - how to say – 'schizophrenia' out there. Everybody wants open data, but nobody seems to use it. We were the first to use the data of our hospital. Nobody knew how to extract it. So we took six months with the informatics team to know how to extract the data. Now they have a team that only does that, but we had to start it. There might be lots of data, what we call - what I call – 'data cemeteries' out there, with data that might be suitable for your research."* (Res22)

The third series of recommendations in terms of general attitudes is that stakeholders working in the field of health data should work in a way that holds in high respect the preferences of the society in which they are active, their concerns and their priorities. With respect to societal preferences, some experts hinted at the importance to respect more specifically certain features of the Swiss society when designing the development of the health data infrastructure.

> *"Switzerland is Switzerland. And Switzerland is very decentralised and therefore also the databases are accordingly decentralised. Now, what we could offer is [to have a] centralised [solution], but where data is collected in a decentralised way."* (Pol4)

One expert also mentioned that these specificities of the Swiss approach could also have positive upsides

> *"In one vision, you can say it[Switzerland] is a fragmented system. You have basically the three levels: the federal level, the cantonal level and the communal level, which are the three acting levels with different characteristics and competences. […] So for me, looking*

at the global challenges we are facing in the field, I think that it's a serious advantage to be in a decentralized system. [..] It's not a surprise that Switzerland is currently becoming a very important place for blockchain. It's because of this strong, cultural and decentralized distributed approach of the people here and the way they see the world." (Res26)

3.2 Developments necessary at the infrastructure level

Many experts addressed in their recommendations the fact that the health data infrastructure should be improved from many points of views, as presented in Table 2.

Table 2. Recommendations concerning infrastructure

Recommendation	Concrete implications
Create a national data centre	→ create an institution or an organisation that is capable of coordinating and combining the requests for data access and data linkage for the healthcare and research sector.
Improve IT infrastructure and promote comparable IT language	→ invest on a IT infrastructure that allows an effective reuse of health data. Also, ensure that data from different datasets are compatible by promoting the use of standard nomenclatures and formats
Unique Patient Identifier	→ in a decentralised system like Switzerland, a unique identifier to link data concerning the same person from different sources should be enabled.

In this respect, a series of suggestions proposed the creation of an institution resembling a "national data center" in charge of managing and coordinating the different data sources available in Switzerland. Although all the features that such an institution could have and its exact architecture were not described in details, it was mentioned that one key characteristic it could have is to allow linkage of data from the different sources.

"That's why I would actually say we need a center which is allowed to link data and for the linkage you need everything which is identifying. And once the link exists, we can attach the research data and the researcher or whoever who wants to do the analysis" (Res14)

Not only would this data center facilitate linkage, but it would also facilitate sharing, in that it could evaluate the request of access to different types of data in a systematised fashion.

"There needs to be some umbrella [organisation] where you can put the data and share it just to people that have a really good research question and you have maybe some sort of a process in place how you approve those data sharing processes" (Res7)

Other recommendations suggested that the health data infrastructure should be advanced. This would entail, for example, aligning the different clinical information systems that hospitals use. According to one expert, improving the IT systems of the country would be feasible since the technical expertise in Switzerland is present.

> *"[I] also would think that actually it would be smart if all the hospitals have the same clinical information systems, the same place where they collect [their] dataset"* (Stak6)

> *"And then of course, we have to resolve a lot of logistical problems you know…the IT systems…but I think they are all solvable honestly. […] We have a lot of good IT guys in Switzerland. They know what computers are, they can do that...and I think their ideas will somehow work."* (Res23)

Expanding the IT Infrastructure in itself should however not be the only concern. One expert specifically addressed the need to align standards as well, when reflecting on the idea of creating new health registries. Similarly, other experts also mentioned the need to work on promoting comparable IT languages in the infrastructure which are already present and those which will be built.

> *"At the same time, registers are in many cases the only instrument to obtain quasi real-life evidence, aren't they? […] And the question will be then: "Must you really for every question, for every sector, for every [medical] intervention – now I am thinking really about the future – must you really then for every single thing in the future create a register?" And then also maintain it and carry it forward. Or would it not be [possible] also with a strong standardisation of health data at the source?"* (Pol6)

> *"So you have to unify, to finally unify the semantics. And then you have of course to to find a way to code data that they are shareable. They are just not shareable right now."* (Res13)

Improving and harmonising the semantics of how data are collected would allow, to some extent, to combine existing IT infrastructure without the necessity to 'revolutionise' the system. One expert made this point referring to the specific example of the electronic health record.

> *"Yeah, I think realistically right now we can't ask every major Swiss hospital to use the same electronic health record. We can't. […]. But what we could do is build a sort of under-scaffolding. So you have all the Swiss Hospitals with their different electronic health records but like we are piloting here in [Swiss city] with this, kind of behind-the-scenes, behind the façade, you could build these common language, common electronic language […] ...you could create a common language ...a common - you know - electronic processing language where you harmonize all these data, all these clinical data."* (Res1)

Many interviewees also recommended that a system to efficiently link health data from different sources should be implemented. This type of recommendation concerns both the infrastructure level (since

linking requires the appropriate technical support) and processes/procedures (since linking operations also need to follow appropriately regulated protocols). In this respect, it was highlighted that the ideal situation would be that of having a Unique Patient Identifier (UPI) for patients, so that every time data are recorded about the same person, they can be combined with data of that very patient from other databases. The use of such number would naturally have to be properly regulated.

> *"Yes, just each person has this number and every time you go to the doctor, you go to Spitex [a form of intermediate care offered in Switzerland], you go anywhere this is registered and you can link it. But I think it needs restrictions on who has access to this, because it's very sensitive data. This has to be dealt with. And it needs some centralised place where this linkage is done."* (Res9)

> *"So I think we spend too much money and time [laughing] with single different solutions [to do the linkage] and it would be also time in the health sector to get there a general way of using this [unique identification] number, a safe general way to have this number used."* (Pol3)

> *"Well [laughs] it could be much easier as for example in the Nordic countries where you can track all the…where you have the information from the whole health system together or more or less together and identifiable."* (Res6)

3.3 Clarity at the level of processes and procedures of data access

Several recommendations expressed by the experts did not focus on attitudes or generally on the infrastructure level, but they addressed more specifically improvements that could be made with respect to the mechanisms necessary to access and/or share the data (see Table 3).

Table 3. Recommendations concerning processes and procedures

Recommendation	Concrete implications
Harmonise access to data	→ ensure that access procedures to data are less fragmented and dispersed, to facilitate the identification of data sources and the transparency of the process to obtain access to such data.
Clarity on privacy and consent	→ educate researchers on the data processing legal rules and implement more broadly a simplified pathway to allow the reuse of health data without more relaxed consent requirements.
Provide incentives	→ create tools to favour the cooperation between the different institutional actors that need to collaborate in the fulfilment of the procedures for data sharing and access.

In this respect, an important recommendation referred to the need of streamlining and harmonising the concrete procedures of how data are accessed. This would entail, for example, making it clear and easy for researchers that have a project idea to know who they have to approach in an institution to inquire about the data available in such institution.

> *"Harmonisation of processes would be that every hospital, for example, implements a consulting group where a researcher can go to if he has a project in mind that he would like to request data for".* (Stak3)

In some cases, experts highlighted that harmonising access to data would also require trying to implement regulations that streamline access procedures to data, possibly with the creations of step-by-step procedures on how to collaborate in the sharing of data. In this respect, there were calls for uniformity of how regulations are practically applied, rather than a call for adding or changing the law per se.

> *"I would never want more regulations because that increases complexity. What I would like is more for people like me, clinical researchers, to have a very simple guide and very simplified information that we can look at when we are on the verge of doing such a collaboration. Even having a platform with very clear and simple steps and having the tool to share data. That would be very helpful."* (Res17)

> *"I wouldn't call it more regulations. I want just to have that the true regulations are always applied in the same way. And then if we see that certain types of projects are impossible - truly impossible - in Switzerland, then probably you need to change regulations."* (Res10)

Accessing data requires not only compiling forms and following procedures, but also complying with data processing rules and consent requirements. The need for more clear legal provisions concerning data processing rules was highlighted, for example, with respect to healthcare service research with already existing data.

> *"[A]s I said…I think the research in Switzerland...the opportunities for research, particularly for research with existing data are very narrow already. So… yes a framework that allows more and gives clear rules for this more, it makes sense of course."* (Res3)

With respect to the role of informed consent, it was argued that the possibility of using the data without the explicit permission of the patient – maintaining however the possibility for them to opt-out from processing – should be more broadly implemented.

> *"I think one is to sort out the consent process. Ideally, really ideally to cancel the 'opt-in' [i.e. that explicit patient consent is necessary to process data] and to go for an 'opt-out' as other European countries do."* (Res13)

There was also awareness that another way to improve the clarity of the rules on data processing and its interaction with privacy is to improve the education of data processors (e.g. researchers).

> *"Participant: [M]aybe we can improve...the curriculum of the researchers or health professionals so that they can really know about what are the data, how they can share them, what are the legal frameworks.*
>
> *Interviewer: So more like offering some training to these researchers*
>
> *Participant: yes, training is very important. Because when you train people early, they don't make mistakes afterwards."* (Res18)

More in general, a sense that some of the ways how ethics has been traditionally implemented into research should be re-thought – e.g. by clarifying more specifically for which research projects involving only the use of data (e.g. retrospective registry-based studies), ethical approval is not required. This would entail – as recommended by one participant – to revise the balance between privacy for the individual and the benefits that can be produced for society if health data are more easily usable.

> *"Well, I think that it would be very helpful to legally implement the value, the ethical principle that also the interest of the public can overrule the subjective rights […] under certain circumstances.[…] and I think that if we look at other countries such as Great Britain or Norway, Sweden, we could really learn a lot from them on their way to collect [health data]on a population base"* (Res4)

Lastly, a few experts mentioned also that incentives should be provided to ensure that the procedural work and the collaboration between different institutional actors in the health data framework are carried out. Such incentives could be, according to one expert, of a financial nature – e.g. to ensure that Swiss hospitals harmonise their health records.

> *"If you could require Swiss hospitals to do this [harmonise their health record systems] and you have to give them money of course to do this. Because this would be a big job and then with this undue layer of harmonized data, that all have the same meaning and speak the same language...you could create a pathway to share these data."* (Res1)

The director of a health database highlighted that incentives for institutional actors to perform all the procedural chores necessary for exchanging data could also be of a political and legal nature.

> *"It would be necessary - in my opinion - to have instruments that make such obligatoriness [to collect certain data] a true obligation. […] We [as a register] are not capable of going around Switzerland and say: "You have not send us your last data, you are lagging behind...". But we should have the instruments that allow to apply or that permit// some*

instruments that could be legal or else, that would allow these data registries to work well." (Stak1)

4. Discussion

As the debate to promote a better use of health data is still a priority in the Swiss political agenda, our study presenting recommendations on how to improve the health data framework can provide valuable insights on how to reform this sector in the future. Here we analyse experts' recommendations against the policy, societal and legal background of Switzerland to reconcile some of the swift changes proposed with the existing context of the health system in Switzerland.

A relevant finding from our interviews is the focus of many recommendations on changes that are needed in the mind-set and attitudes of the actors involved in the processing of data. Although strengthening the data infrastructure in health remains crucial (26), it is important to also secure the commitment of stakeholders, whose approach and mind-set are preconditions to develop and exploit the health data infrastructure. For example, in a study on the development of a national programme for information technology in the public health system of the United Kingdom, it was noted that "persuading" stakeholders to commit to the development of the health data framework – which was likely to produce substantial benefits only in the long run – "is at least as great a challenge as the technical one" (37). Lovis et al. made a similar point when reflecting on the Swiss situation and emphasised that "the success of eHealth projects depends on many factors besides purely technical aspects" (38). A potential solution could be that of selecting specific areas of the healthcare sector where the data infrastructure should be reinforced and where the use of data should be facilitated, and provide long-term financial incentives for such areas. For example, the Swiss Cancer Research (the most important foundation for cancer-related research in the country) has launched since 2016 specific funding for the development of projects in the field health-service research, to incentivise research relying principally on the secondary use of routinely collected data (39). Providing specific funding for projects using and/or reinforcing the health data landscape in specific areas can however also be perceived as unfairly advantaging researches with expertise on that area and indirectly limiting the freedom to pursue research in different and uncoordinated topics.

Our interviews also highlighted that having an explicit and long-term health data strategy for Switzerland - and defining what specific achievements are to be reached with such strategy – could help in changing the mind-set of relevant stakeholders. In fact, another qualitative study evaluating Canada's e-health policy underlined the importance of having a comprehensive and well-structured national strategy to favour the development of information technology in health, underlining in particular the need "to align the investment in information technology with the priorities of the health care system and of health care providers in order to accelerate adoption and achieve early return on the investment"(40). Switzerland formally has a national e-health strategy, but this is almost exclusively focused on the

introduction of nationwide interoperable EPD that needs to be offered – at least initially[4] – only in the in-patient sector (hospitals and nursing homes) (17). Such 'narrow' approach in the e-health national policy can have positive side effects, such as setting more specific objectives and parameters, rather than turning the e-health policy in a collection of general political statements.(41) However, a 'narrow' approach also runs the risks of not providing a clear long-term vision for the evolution of the whole health data framework: in the digitalisation of healthcare, the EPD is a good start, but cannot represent the final objective.(42) Moreover, the lack of a more comprehensive health data strategy could lead to ineffective multiplication of efforts. Indeed, in Switzerland there are several national initiatives aiming at improving the health data framework: firstly, the Swiss Personalised Health Network (SPHN), a consortium supported and financed by the Swiss Federal Government and other important institutional partners with the objective of promoting personalised medicine through a better use of health-related data (43); the EPD project mentioned in the introduction; the Swiss National Cohort (44); SantéPerso[5] a project focussed on precision medicine; the Swiss Data Science Center[6] developed by federal universities to bridge the gap between data science, academic research and industry; or also innovative citizen-science projects like MIDATA, a platform organised as a cooperative through which individuals can make their data available for further use[7]. However, there is little formal coordination between these initiatives (45), which could be detrimental in the long run. This limited coordination is linked to another set of recommendations expressed in our interviews, i.e. to favour communication between the different actors, who are now independently pursuing diverse efforts aimed at improving the health data situation. The SPHN recently received an additional 66.9 million CHF (equivalent to 62 million euros) of funding for the period 2021-2024 (46), and could thus take a leading role in this respect, by continuing the efforts recently initiated and by enhancing the visibility of the solutions that it is proposing (see below).

At an infrastructure level, not only a general need to improve the IT infrastructure was expressed in our interviews, but also a more specific proposition emerged. Participants insisted that a supra-institutional centre responsible for managing the procedural steps necessary for access and/or linkage should be created. Efforts in this sense are already in the pipeline: for example, the recent reform of the Cancer Registration Law has led to the creation of a national coordination center (the National Agency for Cancer Registration) operating in coordination with a national center for epidemiological research (the National Institute for Cancer Epidemiology and Registration) (47)[8]. Their competence is limited to health data concerning cancer for the moment, but Art. 24 of the same law (48) opens up the possibility to use this legal framework to also record data concerning other non-transmissible widespread or dangerous illnesses in the future. On a similar line, the Federal Statistical Office (FSO) has been recently developing an internal office to perform linkage for third-parties (e.g. researchers) between external data

[4] Other care providers (such as private medical practices) have the option of offering the EPD, but no legal obligation to do so.
[5] See https://santeperso.ch/A-propos [Accessed April 15, 2021].
[6] See https://datascience.ch/who-we-are/ [Accessed April 15, 2021].
[7] See https://www.midata.coop/en/cooperative/ [Accessed April 15, 2021].
[8] For more information see the websites of these two institutions: https://www.nacr.ch/ or https://www.nicer.org/ [Accessed January 29, 2021].

from different sources and/or data from the FSO itself[9]. This represents a form of standardisation – indeed a standardised form for applying to this service was developed(49) – and centralisation, since the service represents a unique point-of-entry for the whole country. However, both the Cancer and the FSO coordination centers are too narrow in scope as compared to the idea of a national data center envisioned by our participants. Given the de-centralised nature of the Swiss healthcare system and the fragmentation of data sources, the development of a national data center should not entail the transfer of data ownership and a centralisation of data, but it should rather act as a one-stop-shop structure to access the different sources of medical information in the country. This would facilitate the possibility of combining data coming from different institutions and help reduce – together with appropriate incentives – the fragmentation of access procedures to data (see also below). An effort in this sense is underway as part of the SPHN, which led to the adoption of a semantic interoperability framework between university hospitals[10] and is also currently creating a *Federated Query System* that would allow researchers to quickly verify what data are available according to certain search criteria within the datasets of different university hospitals.(50)

Creating a national data center is connected to the further recommendation of establishing a UPI to be transversely used every time health data from the same person are collected. The presence of such an identifier would facilitate the linkage of data from different sources, which now is often done by probabilistic linkage methods – often used effectively in the Swiss context (51), but which have some inherent limitations (52). Recording data through a UPI is common in New Zealand (53) and especially in the Nordic countries, where the UPI has proven to be very useful to facilitate health services research (54,55). For example, in Denmark every resident is assigned through the Danish Civil Registration System a UPI, which is then also used to record peoples' health data in virtually every database, thus allowing accurate linking and facilitating registry-based research (56). In Switzerland, the newly created EPD foresees the creation of an identification number assigned to the record of each patient.[11] This number is *derived from*, but also *different to* the Social Security Number normally used by citizen (e.g. for tax purposes, or to buy health insurance): connecting the EPD directly with the Social Security Number was initially planned, but then ruled out for legal reasons and for fears of potentially compromising citizens privacy (57). As a consequence, the identification number used for the EPD represents a step towards a *universal* UPI, but presents several drawbacks. First, it is difficult to exploit the linking possibilities offered by the EPD and its identification number, since the secondary processing of EPD data for research purposes could prove very controversial as the EPD was built on the idea that

[9]For more details on this service offered by the FSO, see the dedicated page at: https://www.bfs.admin.ch/bfs/de/home/dienstleistungen/datenverknuepfungen/fuer-dritte.html [Accessed January 29, 2021].
[10] For more details, see the dedicated page at: https://sphn.ch/network/projects/data-coordination-center/the-sphn-semantic-interoperability-framework/ [Accessed February 10, 2021].
[11] For more details see the dedicated page on the : https://www.zas.admin.ch/zas/it/home/partenaires-et-institutions-/unique-person-identification--upi-/identifiant-du-dossier-electronique-du-patient.html [Accessed January 29, 2021].

it would only be used for care purposes.[12] Second, the EPD identification number would cover only data recorded in the EPD itself. As offering the EPD is currently mandatory only for hospitals and nursing homes (the latter starting from 2022) and data are saved in a PDF format, there is a risk to miss out data from the outpatient sector and to have data structured in a way that make many analyses very difficult (58). Moreover, differently from countries like Estonia and Denmark where an electronic health record is automatically created (59), participation in the Swiss EPD requires the explicit consent of the patient, who can also freely decide to eliminate or hide any of the information therein recorded. To really favour the secondary use of data, a clear legal basis for the use of the same number to record and link data from the EPD and other data sources would be a necessary step. This would require adequate ethical and security measures that are approved by the population, as expressed by the recommendation to follow societal preferences. Indeed, improving health data access necessarily requires to "engage with [its] underlying political, human, and legal challenges" (60), since neglecting societal preferences, fears and hopes might backfire. This happened, for example, in Iceland when the government tried to introduce a new system of health data registration/linking (61). In this regard, it is important to note that – in the last few years – the willingness to have health data saved electronically and the trust that the institutions collecting health data respect privacy have both diminished in Switzerland, despite remaining generally high (62). The origin of such decreased trust should be investigated.

At the ethical and regulatory level, another important set of recommendations concerned the clarification of the role of consent and of data protection legislation for the processing of health data. Swiss legal and ethical standards already provide for a research exemption (i.e. special rules for data processing for research or statistical purposes) and for exceptions concerning consent, which allow the secondary use of data through general consent (e.g. a consent for covering broad areas of research, rather than simply one specific project) or even without consent in some cases (31). However, there is disagreement in the Swiss legal field to what extent these exemptions can be implemented in practice without compromising individual rights (63,64). Moreover, the fact that experts recommended clarifications on such topics shows that – although these exceptions exist in the letter of the law – their concrete implementation still necessitates improvements. In particular when data are combined from (or linked between) different sources, many questions about the actual operational functioning of the law remain open (65). For example, the legal conditions for using medical data routinely collected by health insurances to conduct health services research theoretically exist (66), but it is unclear how to design such research projects in a legally compliant fashion. Uncertainty on the concrete operationalisation of legal rules concerning the reuse of data can create a catch-22 situation: when researchers plan studies involving the secondary use of data from other institutions (e.g. health insurances), "funding agencies routinely request a guarantee that data access should be possible, while data owners [from those institutions] often may not be able or

[12] The Swiss federal council recently suggested that research using EPD data could be performed according to Swiss law on human research (https://www.parlament.ch/de/ratsbetrieb/suche-curia-vista/geschaeft?AffairId=20194136 [Accessed January 29, 2021]), but this possibility remains controversial.

willing to give such a guarantee [until] funding is available"(45). To help solve these issues, ethics committees and data protection commissioners should be more actively involved to establish concrete operational rules that, once followed, guarantee compliance with data protection requirements. This would also allow to keep up with the new ethical and legal questions generated by the increasing availability of novel forms of health data (e.g. those generate by fitness devices or mobile applications). Although ethics committees can have difficulties in approaching innovative projects involving processing of health-related data(67) and cantonal data protection commissioners struggle with underfunding (68), it is necessary for data processors (e.g. researchers) to coordinate with these actors, who are *de facto* in charge of applying the law on health data processing.

Compliance with consent norms and data protection rules when re-using data would also be facilitated by reducing the fragmentation of procedures to access the different sources of health information (69). This can be achieved in several ways: for example, by securing that every institution storing health data possesses a clear access-point that external stakeholders can easily find and contact, if they wish to collect data from that source. Else, common and shared requirements could be established, indicating what the necessary procedures (e.g. security requirements, permission necessary by cantonal data protection officers, etc.) are for accessing data in a legally and ethically compliant fashion. Efforts in this sense have already started, with the drafting of legal agreement templates by the SPHN[13], aimed at standardising the documentation necessary for data-exchange between institutions. However, the use of such documentation was primarily designed for the exchange of data between *academic* institutions, thus excluding important sources of health data in Switzerland, such as health insurances. Such documents could thus be further developed as to become easily usable also in other contexts. The creation of a comprehensive national data center could also contribute to this aim, as it could offer a unique transit-station, where all bureaucratic steps necessary to access data from the different institutions could be channelled and more efficiently solved. Such center should also be adequately structured and financed, so that its functioning is expedite and efficient.

4.1 Next steps and knowledge transfer

The findings of this study add to the evidence produced recently in Switzerland to suggest the way forward for the health data landscape (see e.g. (45)), which is one of the main priorities in the vision for the Swiss healthcare in the next decade (18). The further step for our research team is to present the findings to a group of stakeholders during a workshop, in order for them to reflect on the recommendations, refine them and – if possible – find a consensus on the main priorities for the future of the Swiss context. The insights presented in this study and in the project where it is embedded(29) are also going to inform the knowledge transfer activities of the National Research Program (NRP) 74(70). The NRP 74 was launched in 2015 on initiative of the Swiss Government and the Swiss National Science Foundation to fund projects aiming at "making healthcare smarter" and then selected 34 projects

[13] These are available at: https://sphn.ch/services/dtua/ [Accessed January 29, 2021].

- including the one where this study belongs - to help reach this aim. To ensure that the research by NRP 74 funded projects reaches policymakers and other relevant stakeholders, the NRP 74 created a synthesis process aimed at summarising and condensing the evidence produced by all 34 selected projects (71,72). Such synthesis process includes a specific section on the topic of health data, into which our team is feeding the insights produced by our research. This will lead to the creation of policy briefs that will be delivered to relevant stakeholders and discussed at a final symposium planned for mid-2022 (71).

4.2 Limitations

This study has some limitations. Firstly, and more importantly, it includes the view of a plurality of stakeholders, but it does not consider other important actors which are involved in the governance of health data in Switzerland – such as data protection commissioners, health insurance companies and the public. This limitation was due to choices made for the design of the project where this study is nested and it thus requires to integrate its fundings with those of other studies considering the perspectives of different stakeholders (for citizens' perspectives in the use of data, see e.g. (73,74)). Also, participants were selected non-randomly, which underlines the non-generalizability of our findings. Moreover, we cannot exclude that some of the responses in our interviews were influenced by social desirability, especially considering that participants were aware that this study was part of a project by an institute specialised in biomedical ethics.

5. Conclusion

Improving the health data framework of a country is a lengthy and long-term endeavour with no silver-bullet solutions. It is however a worthy endeavour, since a solid and well-functioning health data infrastructure is an important element for evidence-based policymaking and for appropriate public health interventions. With this study, we presented and analysed the inputs from stakeholders who have an interest in improving the situation in Switzerland and who are thus motivated to find solutions that are both effective, but also practical. We have explored the proposed recommendations and have discussed their feasibility, showing that progress cannot be revolutionary, but rather evolutionary, in that new proposals have to be reconciled with the pre-existing infrastructural, legal and ethical backgrounds. Rather than a swift change, a gradual development of the health data framework appears preferable. Our study is thus particularly useful as a reference to steer policymaking at a national level. However, it is also an important source of information for other countries that are transitioning towards a more digitalised healthcare and that might profit from the experience of Switzerland and from the recommendations expressed by our stakeholders. Countries which are further ahead in the development of an effective system of health data exchange also obtain a competitive advantage for their health system and their researchers, as the case of Denmark shows (75). Learning from the experiences of nations that are successful in improving health data usage as well as nations which still face challenges is equally important. Indeed, for achieving progress in each single country, it is necessary to find the

appropriate compromise between the system of health data exchange that researchers and public health practitioners ideally desire, the preferences of society at large and the pre-existing data infrastructure and organisation of healthcare services.

6. Additional information

6.1 Conflict of Interest

AM, LDG, SME, TW and BSE have no conflict of interest to declare. FE is affiliated with the Swiss Institute of Bioinformatics (SIB), a non-profit organization predominantly publicly funded that is dedicated to biological and biomedical data science and that collaborates with the SPHN.

6.2 Author Contributions

BSE and TW conceived the study and prepared the interview guide with LDG and AM. Data were collected by AM and LDG. AM, TW and SME prepared the first draft of the manuscript. BSE, LDG and FE integrated the initial draft with comments and additions to the manuscript. FE provided additional review concerning the legal and policy aspects. AM finalised the last version of the manuscript, which was then further corrected, and approved by all authors.

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6.4 Abbreviations

EPD= Electronic Patient Dossier

UPI= Unique Patient Identifier

FOPH= Federal Office of Public Health

SPHN= Swiss Personalized Health Network

FSO= Federal Statistical Office

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6.6 Data availability statement

The de-identified dataset used for this manuscript is available upon reasonable request to the corresponding author upon reasonable request to the corresponding author. Full transcripts cannot be shared to keep the risk of re-identification of participants low, as it was guaranteed to the interviewees upon participation.

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PART 4 – General discussion

4. General Discussion

In the following sections, I will provide an overall discussion of the research conducted as part of this Thesis, its implication for practice and some lines for further research on the topics investigated in the different manuscripts. Whilst the Discussion is formally divided along the lines of the three main Modules which this Thesis consists of, the observations and reflections in the three parts of the discussion draw consistently from the entirety of the research conducted as part of this PhD.

4.1 The temptation of using health data for personalising care (and its financing)

Similar to other countries, Switzerland has also experienced in the last few years an increasing pressure to make its healthcare more efficient. This has been fuelled both by the general increase of healthcare costs (and the connected need to control them), and by the narrative of personalising and individualising the provision of care. Such debates have been increasingly focussed on the topic of health data processing, since better use of data is thought of being capable to help understand where care resources need to be invested at the societal level, but also to provide at the individual level the best available care to single patients – based on their genetic makeup and their (datafied) medical history.

Indeed, even in Switzerland there is a latent expectation that better data usage combined with (and facilitated by) the spread of digital health tools (like the ones studied in the two reviews of this Thesis) can be a panacea for better quality of care, more patients' empowerment and financial efficiency. This expectation is particularly linked to the vision that digital health tools will increasingly allow data capture to be capillary enough as to account for variations (in terms of care needs) that happen at the individual level, so as to fulfil the objective of Precision Medicine to provide 'the right treatment to the right patient at the right time'. Monitor relevant health-related behaviours (such as medication taking), personalising (through the offer of incentives in exchange for data sharing) insurance coverage and responsibilising individuals based on the behaviours that emerge from the data they deliver appear in this respect logical and desirable consequences. However, the research conducted as part of Module 1 of this Thesis has provided evidence as to the ethical problems associated with this logic. In particular, it has been explored how digital health tools – whether they are used for collecting data about medication adherence or to allow the sharing of data in exchange of discounts on health insurance premiums – sidestep and neglect several ethically relevant issues related to data usage in care.

4.1.1 The problem of data accuracy

First, I have showed that the use of digital health tools to collect individual data to personalise care is confronted with a problematic assumption about the objectivity of the data that such tools allow to collect and analyse. Both with insurers' data sharing apps (Martani, Shaw and Elger, 2019) and with Digital Pills (Martani *et al.*, 2020), these digital health tools allow to collect data which are then used to

draw conclusions about people's behaviour: in the case of insurers' data sharing apps, the data are used to determine who has a 'healthy' lifestyle and can thus receive certain financial benefits; in the case of Digital Pills, data are used to determine which patients actually adhere to appropriate medication-taking indications. Drawing conclusions from this kind of data can have concrete consequences on single individuals: both their finances (if they receive the financial benefits) and their relationship with healthcare professionals[1] (if it turns out that patients do not take medications as prescribed) can be impacted. Due to such concrete impacts, it would be crucial that the data which drive the conclusions are valid, reliable and accurate. In fact, the whole point of monitoring behaviour through digital health tools instead of – for example – relying on self-reporting (e.g. patients compiling a daily form in which they indicate if and when they have taken their medications) is that digital health tools promise to deliver more accurate and reliable data. However, in both digital health tools studied within this Thesis, serious limitations concerning the objectivity of the data collected were revealed. In the case of insurers' data-sharing apps, the data collected to determine which insured person 'lives a healthier lifestyle' are very limited (e.g. smoking behaviour is not included) and insurers themselves admit the fallibility of their apps with respect to the types of data actually collected. Similarly, analysing Digital Pills has also showed that this digital health tool has several concrete limitations in respect to the objectivity of the data that it collects, ranging from the fact that patients need to accurately wear the patch on their abdomen, to the fact that connectivity must be secured to ensure accurate and real-time data transmission. It has been observed elsewhere how assuming that digital health tools offer accurate data is problematic (Sperlich and Holmberg, 2017). In their research, Pink and colleagues (Pink *et al.*, 2018) studied cases of what they call "broken data", i.e. concrete situations showing that there are several problems in assuming that digital health tools allow accurate data collection. Cases of "broken data" can be caused by simple (but common) factors, such as the fact that individuals might forget about battery duration of the digital health tool or neglect connectivity issues. The problems related to the (false) assumption that digital health tools allow to collect accurate and objective data has also been highlighted by Jeanningross and McFall (Jeanningros and McFall, 2020). The authors observed that data collected through digital health tools in the context of insurance are often skewed due to simple fact that often individuals drop out from using such tools, thus raising "questions about whether self-tracking data is clinically, epidemiologically and actuarially reliable enough to assess or price individual health risk" (Jeanningros and McFall, 2020, p. 12). On a similar line, Raber and colleagues also flagged the problem of accuracy of data collected by many digital tools "because large trials validating these devices are lacking" (Raber, McCarthy and Yeh, 2019, p. 1768). One might argue that the problem of data accuracy is simply technological, and that it is simply necessary to improve digital health tools in order for data to be finally objective in a near future. However, as rightly pointed out by Davies (Davies, 2021), assuming that the problem of objectivity of the data can be solved by more pervasive technological

[1] A recent study started investigating the inflence of data-collecting digital health tools on the patient-doctor relationship (Jongsma *et al.*, 2021).

monitoring would generate a sort of catch-22 problem: the (in)accuracy that many digital health tools now present (just like other methods to collect individual data, such as self-reporting by patients) can only be solved at the price of increasing the surveillance features of such tools. However, this would in turn also raise additional issues related to the respect of privacy and autonomy. In other words, the more accurate and precise digital tools become, the more they are likely to incur in opposition due to the increased gaze that they would permit into people's private lives.

4.1.2 More individual data, more individual empowerment?

A second set of ethical questions raised by the collection of health data through the digital health tools studied in this Thesis relates to autonomy and patients' empowerment. With respect to both typologies of digital health tools that were reviewed, there was the claim that the data such tolls allow to collect would permit patients to take control of their health-related behaviour in general (insurers' data-sharing apps) and medication-taking behaviour specifically (Digital Pills). However, the claim that these digital health tools reinforce patients' empowerment and autonomy is at odds with many of the practical features of such devices. In the case of insurers' data-sharing apps, contractual terms that users need to accept to download the apps allow insurers to share data with a variety of different partners, thus reducing – rather than reinvigorating – individuals' control over their own data (Martani, Shaw and Elger, 2019). With Digital Pills, reviewing their features showed that there is an inherent contradiction in their functioning: these digital health tools promise to guarantee that collected data are under the control of the patients, but at the same time it is claimed that – to realise the full beneficial potential of such tools – data *need to* be shared with other stakeholders (e.g. the treating physicians, who can thus monitor whether their patients are taking medicines as prescribed) (Martani *et al.*, 2020). In the literature it has already been discussed that data-driven digital health tools present an apparently irreconcilable dichotomy between patients' empowerment and liberation (since they allow patients to 'take care of themselves') and disempowerment and surveillance, in that they invite "an increased control of others - health promoters, friends and followers, and even the internalized health promoter of one's own super ego - over oneself" (Sharon, 2017, p. 99). This contradiction inherent to the practice of collecting individual health data through digital tools has also been discussed by Lupton, who argued that the narrative of patient engagement is used in this realm to "construct the figure of what I term 'the digitally engaged patient'" (Lupton, 2013, p. 258), who is expected to take more control of her own health by constantly being monitored, thus ironically transforming 'empowerment and autonomy' in a set of obligations.

4.1.3 Datafying responsibility for health

Thirdly, the papers included in Module 1 – and especially in the theoretical manuscript (Martani and Starke, 2019) – have showed that the idea of using the datafication as a means to promote personal responsibility for health presents a further set of ethical problems. In studies (Becker, 2010) about the

basic feature of social security systems across Europe (of which healthcare is an important component), it has been observed that they all have a combination of elements reflecting the principle of societal solidarity (e.g. by guaranteeing access to care to the needy) and of individual responsibility (e.g. by requiring co-payments for the provision of certain services). This holds true also for Switzerland, where the organisation and financing of the healthcare system embodies both the principle of solidarity and responsibility (Biller-Andorno and Zeltner, 2015). In countries like Switzerland, where healthcare is based on (publicly regulated and mandatory) insurance[2] – rather than on a national health system funded through taxation – the balance between solidarity elements and responsibility aspects is particularly delicate. Indeed, the fact that people directly pay insurance premiums, that there is a franchise (before the basic mandatory health insurance starts covering health expenses) and that people often have to claim personally their health expenses from the insurance (rather than the system being automatic) contributes to render people particularly sensitive towards the idea of individual responsibility with respect to health. This is confirmed in annual surveys on public attitudes toward the Swiss healthcare system, which have shown that there has a been a constant increase in the preference of citizens for reinforcing personal responsibility for health in the last few years (a trend only partially inverted by the COVID pandemic) (Interpharma, 2021). This inclination towards the idea that the organisation of the healthcare system should foster the personal responsibility suggests that the narrative of using data collected through digital health tools to demand citizens more (financial) responsibility for their health (e.g. by modelling insurance premiums based on such data) could gain traction. As other studies have indicated, personalising health insurance based on extensive data availability can be appealing for insures, since such data would allow "to drill down to the level of individual [in terms of risk-assessment and pricing]" thus introducing "the hypothetical prospect of a risk 'pool of one'" (McFall, Meyers and Hoyweghen, 2020, p. 2). This is particularly attractive for insurance companies active in the field of healthcare or life insurance since "instead of a 'health snapshot'[…] self-tracking data promises a continuously updated status report" (Krüger and Ní Bhroin, 2020, p. 100) of the health condition of individual subscribers. The idea of pricing insurance (and thus – in a system like Switzerland – contributions to the general financing of healthcare) based on individualised and continuously updated data of each single person might sound tempting also from an ethical perspective. One might argue that individualising the calculation of risk based on data from each single person – rather than on group of individuals with similar features – could be *fairer*, since it would ensure that only people who actually and continuously act in a similar way have to pay the same amount, rather than making health-savvy people pay as much as people who are less careful about their health. However, as highlighted elsewhere in this Thesis (Martani and Starke, 2019), this appeal to fairness is only hypothetical, given the problems concerning data accuracy already discussed and also because of the often unclear causal relationship

[2] When I reflect on health insurance in this paragraph, I refer to the European notion of social health insurance (heavily regulated by the state, usually mandatory and often heavily financed by the state as to ensure that premiums are paid according to income), rather than the 'American' notion of private health insurances.

between certain behaviours (documentable through digital health tools) and poor(er) health outcomes. At the same time, whether such risks can actually materialise may be contested. In the field of health insurance (in Switzerland as well as in other European states where healthcare is insurance-based) differentiations in pricing and coverage are heavily regulated, both in order to maintain a certain level of solidarity in the healthcare system and avoid discrimination. For this reason, it might be claimed that the threat of 'individualised insurance' permitted by the collection of data through digital health tools is merely hypothetical. This is somewhat true at the moment, but it must also be acknowledged – with an eye to the future – that this danger cannot be ruled out. As Krüger and Ni Bhroin rightly observed when commenting the increasing integration of digital health tools in insurance plans "[o]nce notions of worth and merit have permeated ideas of health care, the foundation of health insurance as a *common good* and its predication on the notion of solidarity is eroded and replaced by competition" (Krüger and Ní Bhroin, 2020, p. 102) (my emphasis). If we consider the two digital health tools reviewed in Module 1, the step between monitoring lifestyle to provide small financial bonuses (or collecting data about medication adherence) and demanding responsibility when the collected data document a 'poor' healthcare-related behaviour is not big. For this reason, it is important to consider the rebuttals raised in the theoretical paper of Module 1 (Martani and Starke, 2019), in which the assumption that data collected through digital health tools *should* be used to enforce personal responsibility for health is confuted. Such rebuttals are particularly relevant for a society like Switzerland, both because of the traditional inclination to be sensitive towards arguments about responsibilisation in the healthcare domain, but also because the narrative of personalised medicine has been picking up recently (see Section 5.3 for more details). In this respect, the collection of data through digital health tools "is expected to play a significant role in the move toward 'personalised health care'" (Sharon, 2017, p. 94) by providing 1) healthcare professionals with additional individual information to deal with patients in a more personalised manner and 2) the healthcare system with granular data to organise a more efficient use of its resources (Lupton, 2013). In this passage to a personalised (data-based) medicine – which has been defined as the transition from mechanical to informational medicine (Nettleton, 2004) – it appears logical to accept that "if people have the opportunity to make healthy choices [and if data prove that], it is sometimes reasonable to hold them responsible for choosing not to" (Davies and Savulescu, 2019, p. 140). In the case of Digital Pills, this would entail that data about poor medication adherence could be used (together with other evidence) to show that patients had the opportunity to make healthy choices, but they did not take it, thus allowing insurances to refrain from reimbursing treatment. However, if this happened, not only would it raise the ethical challenges mentioned above, but it would also endanger the collective and social character that health insurances (and healthcare systems as a whole) nowadays have across Europe. To prevent this from happening – both in Switzerland and abroad – it might soon be necessary to adapt regulation on the use of data collected through digital health tools, as to protect from new potential forms of discrimination that may derive from such (McFall, 2019).

4.1.4 The risk of stigmatisation

The last ethical problem related to the collection of data through digital tools concerns the 'stigmatisation' that can originate from the selection of the behaviours to datafy. Indeed, documenting – through data – the fact that certain people adopt some selected behaviours is not an objective or neutral action. As highlighted in the Introduction, assuming that data are simply a neutral representation of an objective reality is not accurate. Data are never simply 'discovered': they are always co-created by the different stakeholders involved in their generation (e.g. patients and doctors co-generate the patients' healthcare records) and the content of data is highly influenced by the tools used for data-collection – and such tools are designed according to the (subjective and potentially value-laden) aims of the designers. In this sense, a tool like Digital Pills is not simply 'reporting objective data about medication-adherence': Digital Pills are measuring the complex phenomenon of medication-taking behaviour based on a binary benchmark – namely whether patients ingest or do not ingesting the pill – levelling out all the other different elements that could be measured with respect to this behaviour (e.g. whether the drug was not taken due to forgetfulness or in order to avoid side effects). In so doing, Digital Pills do not simply allow to collect data about medication adherence: they allow to measure one specific aspect of this multifaceted behaviour, thus fostering the identification of two clear distinct categories of individuals based on this benchmark, namely those who can document abidance by the indications of healthcare professions and those who cannot. Similarly, insurers' data-sharing apps are not simply collecting data about fitness, but they are (through the selection of the kinds of health data that they collect – e.g. number of steps) setting a specific standard of fitness. With either of those tools, there is thus an implicit value-laden judgment about which behaviours are 'preferable', as clearly evident in the case of insurers' data sharing apps, which give small monetary rewards for sharing data showing adherence to certain behavioural patterns. In this way, also this digital health tool reinforces a distinction between 'the healthy' (according to the insurers' own standards) and 'the unhealthy'. Can these divisions and distinctions that Digital Pills and insurers' data-sharing apps create lead to the stigmatisation of those categories of users that they help single out? Drawing from Goffman (Goffman, 2009) and further literature, Ploug and colleagues (Ploug, Holm and Gjerris, 2015) highlighted that in public health there can be a fine line between the classical definition of stigmatisation (which is based on the act of attributing a person with a discreditable trait) and the act of 'de-normalising' certain behaviours considered as dangerous towards health. The collection of specific data that permit to single out particular groups of the population (e.g. those who do not take medications as prescribed, or those who do not have an active lifestyle) seems to represent a valid example standing at the very boundary between these the classical definition of stigmatisation and de-normalisation. Indeed, distinguishing (by means of a digital tool and the data that are collected therewith) certain individuals from others (e.g. those who take medicine according to their prescriptions and those who do not) highlights the relevance of a certain behaviour to the definition of the 'normal' health-savvy patient and the 'deviant' one. The risk that the de-normalisation of certain behaviours brought to the surface by the collection of certain data turns into

proper stigmatisation is substantial. Elsewhere, it has already been argued that the collection of data revealing a certain health-related behaviour can indeed lead to stigmatisation of the group engaging in such behaviour (Ploug and Holm, 2017). In the case of data collected through digital tools such as the ones analysed in Module 1, the risk of stigmatisation seems particularly considerable. Indeed, such tools allow to collect data about behaviours which are already in a bad light – such as adopting a sedentary lifestyle and not taking medications as prescribed. With particular reference to medication adherence, the risk of stigmatisation is even more serious, since poor medication adherence often concerns people with several conditions under a multidrug regimen (Marcum and Gellad, 2012) and thus in a situation of particular vulnerability. A review on medication adherence has highlighted that a key to improve it is the "creation of an encouraging, 'blame-free' environment" (Brown and Bussell, 2011, p. 309), and singling out of patients whose digitally collected data show poor adherence would hardly help in this respect. The risk of potential stigmatisation holds also with respect to insurers' data sharing apps: by providing financial rewards for (certain) behaviours, this digital tool promotes a narrative pushing "people to lead healthier lives, as accomplishing this would benefit both the service providers – by lowering their indemnity rates – and the customers, who would be able to enjoy more balanced daily lives" (Tanninen, Lehtonen and Ruckenstein, 2021, p. 455). From this perspective, those who do not provide data showing the adherence to the pattern of behaviour recommended by the apps can be perceived as self-serving individuals who are damaging their own and also societal welfare. To avoid that these risks of stigmatisation materialise, it will be important to regulate accurately the use of data collected with digital health tools in the context of insurance. At the same time, it might be necessary to put higher threshold for the entrance to the market of such tools, as highlighted in particular in the manuscript on Digital Pills (Martani *et al.*, 2020).

4.2 Persisting inadequacies in data protection law for the processing of health data

In Module 2 of this PhD Thesis, the focus has been on several aspect of Swiss law concerning the protection of data at the crossroad between the healthcare and biomedical research domain. Across the different points dealt in the four manuscripts included in Module 2, there are two main findings on which I shall focus in the following section, since they characterise the approach of Swiss law to data protection in these domains at a general and overarching level. The first one is the latent persistency in Swiss law related to data processing in the healthcare and (especially) biomedical research domain of the 'consent or anonymise' approach. The second one is the distance between the law-in-the-books (i.e. how regulation reads and how legal experts dogmatically interpret it) and the law-in-action (i.e. how the law is actually applied and interpreted by practitioners) with respect to data protection issues. I will address these points separately and then reflect on the concrete problem of how to regulate the data-linkage, a case-study which exemplifies both the limits of the 'consent or anonymise' approach and of the distance

between the law-in-the-books and the law-in-action in Swiss data protection law for the processing of health data.

4.2.1 The influence of the 'consent or anonymise' approach

In Switzerland, individual informed consent is still perceived as a central element for justifying the use of personal data in both healthcare and the research domain. For example, the recently implemented law providing the legal basis for the creation of the Electronic Patient Dossier[3] – where it will be possible to electronically collect all health data about a single patient regardless – establishes that opening up such digitalised health record can be done only with the consent of the patient, who can then also decide which healthcare providers have access to individual piece of data in the record. Similarly, also in the research context the centrality of consent is evident throughout Swiss law: in the articles of the Human Research Act which regulate the secondary use of health data for research purposes, patient consent (whether 'specific' or 'general/broad') remains usually a prerequisite, which can only be *exceptionally* waived by Research Ethics Committees (Martani, 2021a). When consent is not available, it is widely held in the legal community that anonymization of data is the second best alternative for justifying the lawful processing of health data. For example, when commenting the Human Research Act, van Spyk highlights that the law favours research done with anonymised data, in that research with such data is outside the scope of the Human Research Act, thus avoiding the otherwise central requirement of obtaining consent (van Spyk, 2015). These examples show how Swiss data protection rules for the healthcare and research domains are still anchored to the 'consent or anonymise' approach. This term was first used in a report of the British Academy of Medical Sciences to refer to the widespread (but – in the opinion of the authors of the report – misleading) opinion in the biomedical field that health data can be legally processed (especially in the research context) only if consent is available or if the data are anonymised (Academy of Medical Sciences and Souhami, 2006). According to this approach "consent [is] a necessary requirement for using data for research and [it is regarded] as a panacea that alone sufficiently addresses the concerns around data use" and "where [consent] is not possible, anonymisation of data has emerged as the default" (Sethi and Laurie, 2013, p. 175). This approach has been heavily criticised internationally, since "obtaining meaningful consent or irreversibly anonymising data is impracticable or impossible for a great deal of data-intensive medical research" (Mostert *et al.*, 2016, p. 958), but it is still deeply enshrined in Swiss legislation and in the general approach of Swiss data protection law towards the regulation of health data processing. Even in the revised federal law on data protection which is set to come into force in 2022, this approach is substantially unaltered (Rosenthal, 2020).

On the one hand, the centrality of 'consent' in data processing rules is not surprising in Switzerland, given the strong emphasis in the Swiss legal domain on individual autonomy and self-

[3] See the Introduction for further details on this initiative.

determination, which is also reaffirmed in article 13 of the Swiss Constitution.[4] Due to the importance of autonomy and self-determination, it appears logical that anonymization is considered the principal alternative to consent for legitimate data usage: the assumption is that individual control over the processing of data can be given up only when the data in question are not personal anymore, and thus risk to autonomy and self-determination are not present. However, there are several reasons why the persistency of the 'consent or anonymise' approach in Swiss data protection law is problematic. For a start, the focus on the duality proposed by the 'consent or anonymise' approach may lead – in current datafied healthcare and medical research – to "(over)stretching [the] concepts of consent or anonymisation in order to sustain their central role" (Mostert *et al.*, 2016, p. 959). And there are some signs that in the Swiss context the over-stretching of both concepts is indeed happening. For example, as explored in one of the studies contained in this Thesis (Martani *et al.*, 2019), the conditions for the reuse of data for research purposes contained in the HRA delineate de facto three types of consent ('specific', 'broad/general', and a form of 'presumed consent') as conditions for legal data processing. As argued elsewhere, this multiplication of the models of consent creates the risk that the concept of consent becomes a sort of 'empty shell', whose features can then be freely modulated so that the concept of 'consent' loses any distinctive features (Martani, 2021b). Similarly, also the concept of anonymization is undergoing some degree of overstretching. In Switzerland there are no accepted and shared standards concerning the concrete procedures that data need to undergo before they can be considered anonymised. Thus, the standards for anonymising data vary, something which may cast doubts whether the definition of anonymisation is overstretched. For example, it is common that retrospective studies with data from health insurances may process the data without consent or ethics approval under the assumption that this is permissible because these data can be considered anonymous.[5] This practice is accepted by Swiss Research Ethics Committees, but – in absence of explicit and clear criteria of anonymisation – sometimes doubts are raised on whether these data can be considered anonymous and can thus sidestep the requirement to undergo formal ethical approval and to collect consent by data subjects (von Mandach, Hsli, and Swiss Academy for Perinatal Pharmacology SAPP, 2021).

Technically, Swiss law already contains a provision which allows to escape the 'consent or anonymise' approach. In fact, art. 34 of the HRA permits to conduct research on already-existing data sources (e.g. hospital databases) without the need to either collect consent or anonymise data by requiring RECs to concede a waiver if[6]: 1) it is impossible or disproportionately difficult to obtain consent; 2) no documented refusal (by the data subjects whose data are processed) is available; and 3)

[4] As per the English translation provided by Swiss authorities, art. 13 of the Constitution reads: "Every person has the right to privacy in their private and family life and in their home, and in relation to their mail and telecommunications. Every person has the right to be protected against the misuse of their personal data." An electronic version of the English translation of the Constitution can be found at https://www.fedlex.admin.ch/eli/cc/1999/404/en (last access 30.06.2021).

[5] See e.g. the study by Spoendlin and colleagues (Spoendlin *et al.*, 2021) or that by Bähler and colleagues (Bähler *et al.*, 2021).

[6] The conditions are cumulative.

the interests of research outweigh the individual interest of the people whose data are used. However, the rule is defined as applicable only in *exceptional* circumstances, both directly in the law and in the doctrinal interpretation thereof, indicating that regulators and also legal interpreters do not really approve of this 'third way' outside the 'consent or anonymise' approach. At the same time, in practice the exception of art. 34 is *regularly* (rather than *exceptionally*) applied,[7] which signals the tendency (once rules are operationalised) to abandon the duality of the 'consent or anonymise' approach. For the future, it would be necessary to make regulators and the legal community more aware of such discrepancy between the law-in-the-books and how it is then applied, in order to find a workable solution to find a consistent alternative to the 'consent or anonymise' approach. Until this is done, there will be a continuing distance between the letter of the law (still stuck with a preference for the 'consent or anonymise' approach) and its concrete application (in which alternatives are emerging). If the distance between the letter of the law and its concrete application remains, this will fuel an irreconcilable opposition between data protection lawyers and data processors (e.g. researchers), a problem which is further explored in the next paragraphs.

4.2.2 The distance between data protection law-in-the-books and data protection law-in-action

The second relevant general finding emerging throughout the research conducted in Module 2 of this Thesis concerns the high level of abstractedness of the legal debate about data protection and the distance between the law-in-the-books and law-in-action with respect to data protection rules related to health data processing. The general tendency of data protection law to magnify the gap between law-in-the-books and law-in-action has been described in the literature (Koops, 2014). In the Swiss context, this transpires from several specific provisions of data protection regulation. For example, it appears evident when looking at the rules for data re-use in the research context contained in articles 32 and 33 of the HRA. As explained in this Thesis (Martani *et al.*, 2019), such articles design a very eloquent network of rules, which however does not adequately mirror the actual practices of data reuse. Although two of the five rules contained in these articles concern the secondary processing of 'identified' data (i.e. data which have been neither coded, nor pseudonymised), these rules are almost never applicable, since in research projects data are normally *at least* coded (i.e. direct identifiers are masked by a code or pseudonym). This was recently confirmed by a review of protocols for human genetics research submitted to RECs in 2018, which observed that none of the 122 protocols analysed planned the use of 'identified' data. As highlighted in a commentary to that article included in Module 2 of this Thesis (Martani, 2021a), this indicates that rules about the processing of 'identified' data are practically *dead letter*, since – despite existing – they are hardly ever applied, since research projects normally at least code/pseudonymise the data they use. The fact that these rules remain in existence despite having little

[7] A recent review of all project in human genetics submitted for ethics review confirms that this rule is applied far more often than *exceptionally.* See (Driessen and Gervasoni, 2021).

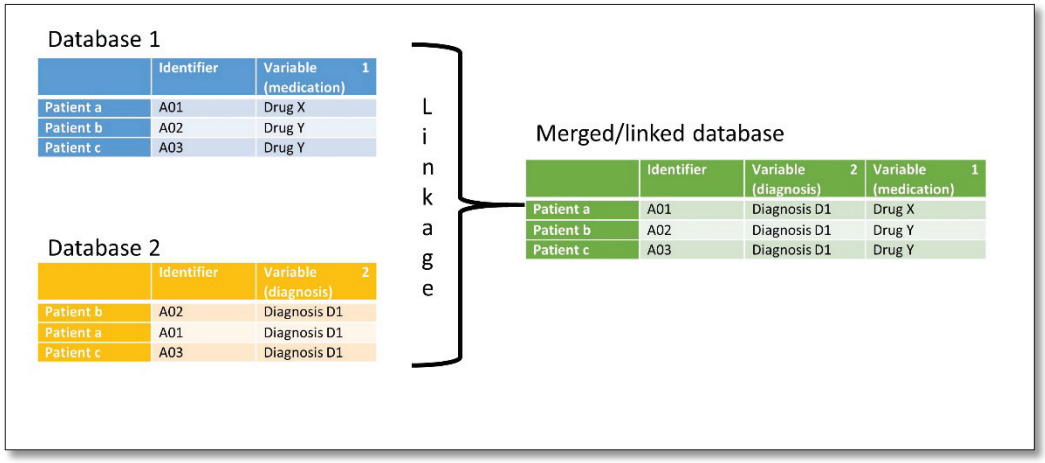
practical relevance can thus simply create confusion, since non-legal experts might not be comfortable in interpreting the exact field of application of this complex network of norms. Another example showing the distance between the law in the books and the law in action comes from cancer registration, as explained in one of the manuscripts included in this Thesis (Martani *et al.*, Under Review). Although in the reform of data protection rules for population-based cancer registration so much attention was dedicated by the regulator to go beyond a 'consent model', the new regulation established a set of operational rules that de-facto replicates a situation very similar to the one where informed consent would be formally needed – see the relative manuscript for further details (Martani *et al.*, Under Review). Even in this case, it thus appears that there is a significant distance between how the rules about health data usage are envisioned by the legislator, and how they then actually operate in practice. For the future, it would thus be desirable that legal rules are reformed as to account for the actual practices of how health data are collected and used in Switzerland, rather than beginning from dogmatic standpoints, to then elaborate rules which are either inapplicable in concrete projects (re)using, or rules that practically operate almost in a diverging way as compared to the (declared) intention of the regulator. To promote such approach, there is certainly the need of a more profound exchange between legal experts in data protection and practitioners from the research and healthcare fields. The development of expertise at the intersection between these two categories of stakeholders that the Swiss Institute for Bioinformatics[8] is pursuing could represent a first step in the right direction.

4.2.3 Regulating data-linkage: a case study of the limits of Swiss data protection law

A relevant and final case-study that condenses both the findings highlighted above (i.e. the problematic focus of Swiss data protection law on the 'consent or anonymise' approach and the distance of the legal rules in the books from actual practices of data processing) and that simultaneously shows where legal discussion about health data usage could move in the future is that of data linkage. In this context, I shall refer to linkage as the process through which different data points relative to the same individual – but scattered in different datasets – are merged. Given the persisted fragmentation of the Swiss data landscape (see Section 4.3), linkage would offer the opportunity to combine several data sources and thus merge more data points about a certain pool of patients, in order to do research or monitor the quality of healthcare delivery. Performing data linkage requires the use of direct or indirect identifiers, i.e. information which allows to combine the data points present in two separate databases that are relative to the same person. In Figure 1, it is illustrated how, starting from 2 databases containing different types of data (about diagnoses and about medication), linkage through a certain identifiers permit to create a linked/merged database in which – for each individual – both variables are present, thus allowing to see if patients with the same diagnoses are prescribed different drugs.

[8] For an overview of this institution, see their webpage at https://www.sib.swiss/ (last access 30.06.2021).

Figure 1.



The more the identifier used to merge different databases is un-ambiguous, the more linkage is reliable. Names are not – for example – reliable identifiers, since there could be spelling mistakes, errors in transliteration (if the name is originally spelled in another alphabet) or cases of homonymy. A more reliable identifier is the use of social security numbers, since these are unique for each person living in specific county and they are often recorded automatically (e.g. by scanning social security cards, rather than by manual input). Social security numbers are routinely used as identifiers to perform data linkage in the Nordic countries, something which has allowed these contexts to be considered particularly advanced in terms of public health and health-related research (Rosén, 2002). In Switzerland – on the contrary – both the performance of data linkage in general, and the use of social security number as identifiers to permit data linkage are very difficult due to widespread legal opposition (Biaggini, 2012; Schmidlin *et al.*, 2015). The premises of the legal opposition to linkage in general and to the use of social security numbers to this aim can be roughly summarised as follows: linkage in general is disapproved as it increases the data-points available for a specific individual, hence increasing the risk of re-identifying individuals (Huber, 2015); the use of social security numbers as identifiers to allow linkage is opposed, because the latter unambiguously identify a specific person, thus necessarily representing a form of 'pure' (re)identification leading to potential privacy risks (Basin, 2017). Both these arguments show an implicit adherence to the idea that anonymization (intended as non-re-identifiability) remains at the core of data protection law in Switzerland and that the legal discussion is in part distanced from a practice/operational-approach, as I will argue in the following two paragraphs.

Opposing data linkage at a general level reflects the commitment of the Swiss data protection framework to the 'consent or anonymise' approach, whereby – if individual consent is not available – anonymization (in the sense of limiting re-identifiability) is perceived as the only alternative for lawful data processing. However, this approach and the conception of anonymization that it puts forward

neglects that de-identification – in the digital era – is a chimera. Re-identification (intended as the process of discovering the identity of the person to whom a specific data point refers, thus turn such data point back into 'personal data' worthy of protection) is nowadays basically always possible, at least in theory. Hence, sticking to anonymisation (intended as the effort through which re-identifiability is impeded) as a central parameter for lawful data processing produces two negative consequences. First, it reduces legal uncertainty, since it renders anonymization an extremely volatile concept, thus making the definition of certain data as anonymous dependent on a case-by-case decision, which represents a great hindrance, for example, for researchers. Second, the fact that 'what count as anonymization' is currently determined by applying the so-called reasonableness standard (i.e. data are considered anonymised as long as it can expected that in the single case re-identification has become reasonably impossible, since it would require a disproportionate effort (El Emam and Alvarez, 2015)) does de facto relinquish the determination of the 'practical/operational' meaning of the legal requirements for anonymisation to case-by-case agreement, which are dependent on the goodwill and the negotiating powers of the parties involved. As long as anonymization is considered in these terms, data linkage will be opposed in principle, since any linkage does – by definition – increase the number of data-points relatable to a single individual, thus making the data more (reasonably) re-identifiable (and thus less anonymised). This is however problematic, because it renders the performance of data linkage subject to legal uncertainty and to the single agreements of the parties involved in each attempt at linking data from different sources. In order to move away from this deadlock, the legal debate should reconsider its attitudes towards data-linkage, for example by providing a clearer definition – even just for certain fields of research – of what constitutes *sufficient* anonymization (possibly also with a list of concrete parameters), so that operations of linkage that respect such definition will stop being considered as privacy threatening *by default*. One further point that should be integrated in the legal debate to overcome the principled opposition to data linkage is that in fields like epidemiological research, even if linkage might always increase the *objective* risk of re-identification, there is never (on part of the researchers) a *subjective* aim to re-identify patients, but rather to obtain generalisable knowledge.

The opposition towards the use of the social security number as the basis to link datasets shows, on the contrary, the persisting resistance of the legal debate to address data protection issues from an operational and practice-oriented perspective. To take an operational and practice-oriented approach towards this issue, it would first be necessary to look at how data linkage is already currently performed in Switzerland. By doing so, it would first be evident that the Federal Office of Statistics already performs linkage on behalf of third parties also by using unique identifiers derived from the social security number, both internally and on behalf of external researchers (but only when data from the office itself are part of the databases to be linked) and that the existing well-defined legal boundaries allow to do so without major threats to the personal sphere (FORS, 2020). Second, it would also emerge that in the research field data linkage is also already done, often by means of probabilistic methods, such as a specific method of probabilistic linkage elaborated by the University of Bern (Schmidlin *et al.*,

2015). With this latter methodology, a series of identifiers (such as name, residential details, etc.) from the different datasets to be linked are masked and encrypted through different procedures, to then be sent (from the centres holding the different databases) to a third party that matches probabilistically data from the original databases by delivering a link table containing site IDs (e.g. by saying which string of data points in one database has to be combined with a string of data in the another dataset that is related to the same person). To do the linking in this fashion, a number of data-points for each patient have to be present in each database (e.g. name, residential details, etc.), which are then masked and combined to allow for this probabilistic linkage. What is often missed, is that the data-points (from the databases to be combined) used for performing probabilistic linkage actually work as identifiers, just like the social security number would. From this perspective, it seems obvious that if the social security numbers were used (after having been masked and encrypted) instead of the different data-points used in probabilistic linkage (e.g. name, residential details, etc.), only one (instead of several) identifier would be necessary. The suggested approach is not exempt from several privacy problems (e.g. the social security number could be considered a particularly sensitive data-point[9]) and it is not meant to suggest an easy way out. But it shows that this could be the direction towards which the legal debate should move: namely, it should face that any data linkage requires the use of some form of (masked and encrypted) identifiers, and thus the principled opposition towards the use of use of social security numbers has its own downsides also in terms of privacy. Indeed, if social security numbers (with the appropriate data security measures and encryption standards) were used, not only could they facilitate linkage and make it more accurate, less expensive and time-consuming[10], but the use of other (also sensitive) data-points which are currently used for probabilistic linkage could be avoided, and the only identifier to mask/encrypt would be the social security number itself.

Abandoning the general aversion to data linkage based on the traditional conception of anonymization and grounding the debate on using the social security number for linkage purposes on the concrete and existing alternatives how linkage is already done could both be fruitful points of departures to move ahead the legal debate about data usage in healthcare and biomedical research. However – as far as the knowledge of the author goes – they are not yet part of mainstream legal discussions in the country. This underlines the persisting misalignment of legal experts on data protection and other stakeholders in the healthcare and research sector that actually manage the data, something that emerged also in the interviews constituting Module 3, where many interviewees of the latter category expressed frustration with respect to how the law works. A very recent report on data linkage in Switzerland (FORS, 2020) has provided some useful first steps to improve the situation, and it could be used as a first basis for developing more practice-oriented data protection rules in the healthcare and research domains.

[9] But also name and residential details could be considered equally sensitive.

[10] The probabilistic method previously illustrated is – by admission of its own creators – very demanding.

4.3 Controlling the data(bases): negotiating progressive changes

In Module 3 of this Thesis, the perspective of different stakeholders from the Swiss health data landscape on the topic of data ownership and on the potential evolution of the Swiss health data framework in the future was explored. In general, there are several relevant insights that arose within the empirical part of this PhD. Here I will reflect in particular on the issue of control over health data and on the future actions that can be taken at a policy and societal level to deal with data governance in the healthcare and biomedical research sector.

4.3.1 Who 'owns' data in Switzerland?

In the Swiss context, the question of control or ownership over data remains particularly controversial. As highlighted in the Introduction, authors (Mittelstadt and Floridi, 2016) suggested that the issue of data ownership and control can be considered from two different perspectives: 1) the power to control access and usage of data; and 2) the entitlement to control the value generated through data access and usage. In Switzerland, the issue of ownership and control is very complicated in both perspectives, in particular due to a present struggle at the legal, political and societal level between the ideas of *individual* and *institutional* control of data. By *individual* control, I refer to the idea that single persons should be in charge of deciding on (almost) every aspect of the uses of health data about them. By *institutional* control, I refer to the idea that institutions (be them care institutions, governmental or research institutions) who practically collect and manage databases should steer decisions about the usage of the data at their disposal.

The idea of *individual* control is particularly rooted in the Swiss context, given the value given to the notions of autonomy and individual self-determination in the country. As discussed above, this transpires particularly from the legal system, which in the context of data protection law still gives primary importance to the role of informed consent for data processing. Compared to the legal approach of countries like Denmark – where in the healthcare and research context "privacy protection is primarily based on trust in governance and data security structures" (Hartlev, 2015, p. 751) – the Swiss legal apparatus still supports the view that privacy protection is at best secured at the individual level by granting control to single citizens on their data. Further evidence of the tendency to delegate the protection of privacy to individuals is the fact that data protection authorities[11] have – comparatively speaking, in respect with the powers that they have in EU countries – little powers, something which the new data protection legislation will try to partly change (Rosenthal, 2020). As highlighted above, the idea of individual control over health data is also evident in the governance of the newly created Electronic Patient Dossiers[12], where patients do not only have the freedom to decide whether to open or not their electronic healthcare records, but they can also decide for each piece of information which

[11] In Switzerland, there is both a Federal data protection authority as well as Cantonal ones, but especially the latter struggle with underfunding and understaffing (Rudin, 2018).

[12] See the Introduction for further details on the Electronic Patient Dossier.

categories of healthcare personnel can access it. Another sign of the preference for *individual* control is the presence in Switzerland of two of the most important examples (in international comparison) of health data cooperatives (Riso *et al.*, 2017). These are institutions which allow citizens to store and control their health data in a specifically designed data infrastructure – as if data were currencies deposited in a bank – and they are based on the governance model of cooperatives – where account holders are also shareholders of the institution itself. These health data cooperatives (called MIDATA and Healthbank) promote the notions of individual data ownership[13] and of "tak[ing] ownership of your data"[14], something which reflects and reinforces the idea that both decisions around access to data and control of the value generated through data usage should be a matter of individual choice. The study on ownership included in these Thesis (Martani, Geneviève, Elger, *et al.*, 2021) shows that also among stakeholders the perception that individuals (should) own their data is well-rooted.

The idea of *institutional* control is – however – equally strong in Switzerland. As it has been shown in the study of ownership in this Thesis (Martani, Geneviève, Elger, *et al.*, 2021), this is probably related to the extensive effort that is still required in the country to set up extensive (health) databases. Given such effort, institutions act in a protective way towards their data-assets, both in the sense that they want to keep control over them and derive benefit from them. As highlighted in a publication on the difficulties in conducting healthcare services research in Switzerland by using already existing data sources, Swiss institutional data-holders are commonly reluctant to relinquish control of the data they *de facto* possess (Zwahlen, Steck and Moser, 2020). For example, when the Federal Office of Public Health tries to collect more data from health insurances in order to provide a better oversight of the healthcare system, insurers often tend to resist such attempts (santésuisse, 2017). Similarly, hospitals are normally not keen on sharing extensive data that they collect whilst providing care with health insurances (H+ Gli Ospedali Svizzeri, 2011). With respect to data collected by researchers, our own interviews (Martani, Geneviève, Elger, *et al.*, 2021) have shown that there also is some resistance in sharing data in an open and extensive fashion. In future studies, it would be relevant to try and investigate the difficult topic of the extent to which institutions are weary about sharing their datasets: 1) because of concrete legal uncertainty concerning what they are allowed to do with their data; or 2) due to potential of data breaches and data leakage; or 3) in reason of a protective attitude towards their data and what they might reveal (e.g. overtreatment patterns, or other irrational uses of medical services).

To solve this apparently incompatible conundrum, whereby both the idea of *individual* and *institutional* control over data coexist, in Switzerland there has recently been insistence on the narrative of Personalised Medicine. As explained in the Introduction of this Thesis, Personalised Medicine is an approach to healthcare based on the idea of using health data to do research that promotes the development of individually-tailored treatment, to then provide them in routine medical care. In the

[13] See the mentioning of the idea of ownership on the webpage of the MIDATA platform at https://www.midata.coop/en/cooperative/ (last access 30.06.2021).
[14] Quote taken from the website of Healthbank at https://www.healthbank.coop/#how-it-works (last access 30.06.2021).

Swiss context, many of the initiatives that have been launched to facilitate health data usage embrace this sort of narrative. For example, the Swiss Personalised Health Network - despite having 'personalised' in its very name – is an initiative primarily focussed on the "development, implementation and validation of coordinated data infrastructures in order to make health-relevant data interoperable and shareable for research in Switzerland"[15]. Another initiative in the French speaking region named SantéPerso also embraces the narrative of Personalised Medicine, but at the same time focuses much of its attention on the debate around data usage.[16] Adopting the narrative of Personalised Medicine has thus been a tactic to promote data usage in the Swiss context, since it permits to 'justify' the expanded use of data by institution (e.g. research centres) – thus aligning with the idea of *institutional* control of data – but at the same time with the final objective of bringing data-analysis back to patients by improving individualised forms of treatment – thus embedding also the perspective of *individual* control. It is not by chance that two of the projects supported by Swiss Personalised Health Network and SantéPerso were aiming at developing better consent procedures in order to combine *individual* control over data usage and *institutional* necessities to have more data available for them.[17] Even in the academic domain, the study of societal attitudes to make their health data more available is often studied and framed along the narrative of Personalised Medicine (Brall *et al.*, 2021).

Whether continuing with the narrative of Personalised Medicine will represent the key to solve the contraposition between the *individual* and *institutional* idea of control over data remains an open question for the moment. Two remarks can however already be made in this respect. First, the narrative of Personalised Medicine has been so far relatively vague and largely promissory. This means that the willingness of the population to compromise on their *individual* control over data in exchange of receiving the benefits of data usage (in terms of better and more individualised care) might be let down, unless Personalised Medicine starts offering some concrete and large-scale changes to the provision of care.[18] Second, the narrative of Personalised Medicine hardly addresses the central issue of trust in the context of health data processing. Indeed, processing data within the healthcare and research system of a country requires a diffuse sentiment of trust towards both governance models and institutional actors exchanging data. When data start circulating in great amounts, it often becomes so difficult to disentangle different data processors and their individual responsibility, and a general feeling of trust in those data processors 'as a whole' and especially in their oversight becomes crucial[19]. In this respect,

[15] Quote taken from the webpage of SPHN available at https://sphn.ch/ (last access 30.06.2021).
[16] See the description of such initiative on their website at https://santeperso.ch/A-propos (last access 30.06.2021).
[17] For the project supported by the SPHN see https://sphn.ch/seminar-training/e-general-consent-development-and-implementation-of-a-nationwide-harmonized-interactive-electronic-general-consent/ (last access 30.06.2021).. For the broject supported bySantéPerso see https://santeperso.ch/Applications-concretes/Smartconsent-une-nouvelle-forme-de-consentement-des-patients-pour-la-recherche (last access 30.06.2021).
[18] Some concrete examples of how personalised medicine works are presented in a dedicated Swiss portal, but these remain relatively niche examples. See https://naturalsciences.ch/personalized-health-explained/personalisierte_gesundheit_und_medizin_heute_und_morgen/m_glichkeiten_heute (last access 30.06.2021).
[19] For example, Hoeyer has highlighted that in Denmark – which is a country where data can be easily exchanged – the data of an individual person are used up to 100'000 thousand times every year by different actors to perform different kinds of

there is much room for progress in Switzerland. An important annual national survey analysing the perspectives of the population on e-health topics (Golder *et al.*, 2021) showed that in 2021 there is still a considerable section of the population suspicious towards the exchange of health data in the context of care (between different healthcare professionals) and even more with respect to providing data for research purposes. In this respect, more effort should be done – also at an institutional and political level – to analyse the reasons for such resistance and reinforce trust in the data governance and oversight mechanism in the Swiss healthcare and research context. Moreover, it should be secured that there are no scandals concerning undiligent or negligent data usage in these sectors. In early 2021, the online platform mandated by the Federal Office of Public Health to manage the creation of online records of vaccination data had to be shut down (srf, 2021) after it was revealed that the platform presented several significant problems in its infrastructure – e.g. it was possible to register as a health professional without proper identification and access peoples' vaccination data (Fichter, Seemann and Rock, 2021). If the trust in the population wants to be secured in the future, public institutions have to set the example and avoid sloppy management of any relevant data infrastructure that they promote.

4.3.2 Future actions to advance the health data landscape

On top on working on improving trust in data governance and oversight mechanism, to secure the development of a better health data infrastructure in Switzerland in the future there is one additional important step that could be taken. Currently, Health 2030 (Bundesamt für Gesundheit BAG, 2019) – the most recent document highlighting the national strategy concerning the development in the Swiss healthcare context in the next 10 years – sets the advancement of digitalisation and datafication of healthcare as one of its four main components. However, what still seems to be missing – as highlighted also in one of the articles included in this Thesis (Martani, Geneviève, Egli, *et al.*, 2021) – is a clear vision of the concrete aims for which digitalisation and datafication should be developed, and thus the direction towards which such developments should go. Is the objective of datafication that of facilitating research? If so which kind of research (e.g. epidemiological research, healthcare services research, cost-efficiency studies, or clinical studies, etc.)? Is it to reduce over- and under-use of healthcare researchers in the care sector and thus contrast the constantly rising healthcare costs, which make of the Swiss systems one of the most expensive in the world? Is it that of improving public health surveillance? Whilst more than one of these objectives can be picked, it would be important to indicate a clear vision of where datafication should lead. Some single initiatives have their own outlook. The e-health strategy first approved in 2007 (see Introduction for more details) which envisioned the creation of interoperable Electronic Patient Dossier all over the country offered a relatively clear vision of where datafication should lead, but it also lacked in many other respects (e.g. the integration with existing hospital clinical information systems and the usability of documents saved in the Electronic Patient Dossier in the context

analysis (Hoeyer, 2016). In such context, only a general sense of trust in data governance and oversight mechanisms can ensure that citizens do not worry about the use of their data.

of care and potentially research). The Swiss Personalised Health Network is also goal-oriented (but see above the discussion on the problem of the vagueness of the promise of Personalised Medicine), but it has at least presently a short expiry date (indeed, funding is only available until 2024). Apart from the particular objectives of these single initiatives, a general and shared vision of what overarching objectives the datafication of Swiss healthcare and research domain should serve are absent. Developing something like a clear health data strategy – and creating a narrative of why datafication should be supported[20] – would facilitate communication and coordination between the different initiative that have been started by different stakeholders in the Swiss context, another need identified by one of the manuscripts of this Thesis (Martani, Geneviève, Egli, *et al.*, 2021).

An interesting input to help delineate a data strategy for the healthcare and biomedical research domain has been put forward in the Swiss Federal parliament in the last few years. With a postulate titled "Better use of health data for a high quality and efficient healthcare", the Parliament gave a mandate to the Federal Office of Public Health to provide a report indicating what steps need to be taken to facilitate the use of data for developing a quality-driven and efficient healthcare (Humbel, 2015). Another important recent input from the political level has been that of thoroughly reforming the system of population-based cancer registries,[21] which has also set the basis for the collection and processing of a specific set of health data (i.e. cancer related) for some well-defined purposes (more accurate public health surveillance, better statistics and possibly also the establishment of more population-based registries). If initiatives like these are followed up and supported in the long-term, they may allow not only to develop a concrete vision of why the health data infrastructure needs to be improved. They will also (and probably more importantly) allow to develop the appropriate expertise to conduct research that is aimed at orientating healthcare policy and improve healthcare services,[22] thus also contributing to overcome the resistance of the population in respect to the use of healthcare data. Moreover, this will also help to reduce institutional resistance to exchange data with other stakeholders, which is now often based on the suspicion that data can be used for reciprocal control and for 'eating up' each other market spaces or – in the case of researchers – to advance own careers by using data collected with a great effort by other groups (Geneviève *et al.*, 2021). This might be facilitated by the current COVID-19 epidemic, which has shown the weaknesses of the Swiss health data infrastructure (Martani, Geneviève, Egli, *et al.*, 2021) and has created more political support for the idea that data should be more easily exchanged for the benefit of the Swiss healthcare and research system (Bellaïche, 2020).

[20] For example, Denmark, the EU and the UK have recently elaborated specific narratives of why the datafication of their healthcare and research domain should be further developed, all named "Data saves lives". For Denmark see (Copenhagen Healthtech Cluster, 2017). For the UK see the following website https://understandingpatientdata.org.uk/animations (last access 30.06.2021). For the EU see the following webpage https://datasaveslives.eu/ (last access 30.06.2021).

[21] See the Introduction for more details.

[22] For example, it is now being discussed how to develop a dynamic community of healthcare services researches at the national level. See the initiative promoted at a recent conference at the website https://hsrconference.ch/ (last access 30.06.2021).

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PART 5 – Overview of the limitations

5.1 Overview of the limitations

The research conducted as part of this Thesis has some limitations. In general, it must be acknowledged that the subject of investigation of the Thesis is particularly ample and constantly evolving. Data governance, the ethical and legal issues that it raises and also the very meaning of what count as 'data' are all broad and blurry concepts. The research conducted in this PhD did not expand on the exact definition of such concepts: it has, for example, taken as a given that data governance concerns primarily inter-institutional policies, although – as explained in the introduction – the same term often refers also to intra-institutional policies. Moreover, the research of this PhD has focused on the debate and the problems of the Swiss data context, thus adopting a rather national perspective. However, as also mentioned in the introduction – there are also several fundamental aspects of the debate about ethical and legal use of data in healthcare and (especially) research which have an international dimension. The specific limitations of the different modules of this Thesis are briefly sketched out here below. More limitations to the single paper included in this Thesis are also contained in the individual manuscripts.

5.1.1 Limitations of Module 1.

There are several limitations to Module 1. Whereas the general objective is to investigate the ethical issues raised by the use of data collected at the individual with digital health tools, the research conducted in the Module focuses on two very specific digital health tools. Since the field of digital health is constantly changing and very ample, the ethical issues that the use of data collected via these tools might vary substantial depending on the tools under investigation. Similarly, the context where these digital tools are used also influences the ethical issues that they raise. For example, when commenting on the increasing practice of health insurance to personalise premiums based on individual health data, Tanninen and colleagues (Tanninen, Lehtonen and Ruckenstein, 2021, p. 450) rightly observe that "local contexts and historical continuities are equally important. Finns are provided universal health care at very low cost, and the general welfare system guarantees a decent basic income for citizens exposed to economic vulnerability; thus, private health and life insurance policies are often regarded as forms of extra security". For these reasons, the ethical issues analysed in this module are not generalisable to *any* digital health tool, nor are they generalisable to *any* context where the digital tools are used.

5.1.2 Limitations of Module 2.

The major limitations of Module 2 concern the approach adopted for legal analysis and the scope of the legal analysis itself. With respect to the first issue, it must be acknowledged that the *dynamic approach* used in this Thesis is one but many ways to analyse the law, and it has several limitations. These include the fact that it draws on a specific view of 'what the law' is that is hugely influenced by legal anthropology and that it put forwards a very broad understanding of the scope of legal analysis (including, for example, also certain sources of law – such as political and cultural factors – that are considered to be 'beyond' the scope of legal analysis by many).[1] With respect to the second issues, this Thesis approached a very multifaceted and sophisticated field of law, namely data protection. As it has been argued elsewhere, data protection rules are so relevant in our datafied society that data protection law is almost becoming the 'law of everything' (Purtova, 2018). This implies that data protection rules are often scattered between different pieces of primary and second legislation, often with cross-references between them, and sometimes with sector-specific norms that derogate to more general ones. Due to time constraints, the research of this module has focused only on particular issues within the vast realm of data protection rules relevant for the healthcare and research domain. Many other relevant issues in the legal debate around data protection were not extensively addressed (e.g. the complex interaction of cantonal and federal data protection legislation), and only some parts of the complex legislative architecture of data protection in Switzerland were analysed - e.g. the rules on professional secrecy of healthcare professionals were only briefly mentioned in one of the paper of Module 2 (Martani *et al.*, 2020).

5.1.3 Limitations of Module 3.

There are several limitations also to Module 3. For a start, since both manuscript rely on qualitative interviews and qualitative analysis with a sample of participants identified through purposive and snowball sampling, its findings are not generalisable. Second, the interviews were conducted by 2 researchers with different educational background, a fact which – given the semi-structured nature of the interview guide – might have led to explore more in-depth different topics during the conversations with participants. Furthermore, it is not possible to exclude that some of the responses given by interviewees were containing socially desirable answers. Lastly, there was some variability in how data collection was performed. For example, some interviews were conducted as one-to-one conversations, but a minority consisted in one-

[1] For an extensive reflection of how broad should be the scope of legal analysis, see (Legrand, 2017).

to-two or one-to-three interviews. Or else, some interviews were conducted in person, some via phone and others via video-call. Our research team accepted the variability that this might entail, in order to favour participation by experts (e.g. by allowing them to be interviewed together with colleagues working at the same institution, when they requested to do so).

5.1.4 References

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PART 6 – Conclusion

6. Conclusion

In the research conducted as part of this PhD Thesis, I have attempted to shed some light on a few ethical and legal issues raised by the datafication of Swiss healthcare and biomedical research. In so doing, I have tried both to improve the knowledge of some areas of data governance and also to suggest a series of concrete improvements that could be made therein.

In respect to the use of data collected via digital health tools, I have investigated the concrete ethical issues that they raise, and I have warned against the tendency to utilise such data to personalise health insurance coverage and access to healthcare services. Since the use of data collected through digital health tools of a similar or a different nature (e.g. digital contact tracing apps to help contain infectious diseases) will likely remain a relevant topic in the future, it is important to continue questioning the ethical implications that this can have. Particular attention should be dedicated to the impact on privacy that collecting data through these tools has, whether it can be simply secured by means of technical measures (e.g. by encrypting data) and whether innovative approaches such as 'privacy by design' can truly be implemented.[1]

Given the central role that data protection law plays in data governance, I have dedicated a substantial part of my research to study the former. Whereas changing the overall set-up of Swiss data protection away from the outdated 'consent or anonymise' approach remains – despite desirable – very difficult,[2] there are other small modifications that can be readily implemented. First, this Thesis has highlighted the need to simplify the complex multi-layered rules for the secondary use of health and genetic data for research purposes. Second, I have highlighted the need of the legal community to engage more openly in discussions with practitioners from the healthcare and research domain, to help ensure a better degree of reciprocal understanding of the different views on the issues at stake in health data processing. This would help ensure that the law-in-the-books and the law-in-action start converging, thus facilitating both the work of data protection lawyers and of healthcare professionals and researchers that deal with personal data. It would also contribute to overcome the current frustration with the law expressed by several stakeholders of the healthcare and research sector, as emerged during the interviews conducted as part of this Thesis.

Changing some aspects of the law is part of the challenges that lie ahead in the future, as the process of datafication of Swiss healthcare and biomedical research goes ahead. Empirical data collected in Module 3 of this Thesis has shown that improving the health data landscape would require also infrastructural changes and socio-cultural changes in how control over data is perceived and exercised. Of note, I have also considered the lack of a clear, long-term and shared vision of the ends towards which the health data landscape should develop. It is true that in the Swiss context countless initiatives have been launched to improve health data usage and that the ambition to improve personalised care is

[1] For a reflection on the concrete challenges of implementing privacy by design see (Spiekermann, 2012).
[2] At least in the short term. For a reflection on how difficult it is to move to a 'new generation' of data protection law, see (Martani and Hummel, 2021).

shared by many of them. But it has also emerged that such initiatives lack coordination and reciprocal knowledge, with the concrete risk of duplicating efforts and – even worse – of pursuing incompatible goals. I have also highlighted that a problem of using Personalised Medicine as a flagship concept to promote the development of a health data infrastructure and encourage society to open up about data usage can be a double-edged sword: on the one hand, promising personalised care aligns with the preference for individualisation of the Swiss population and it is a concept broad enough to be usable to stimulate the provision of data in different contexts; on the other hand, its vagueness risks generating high and diverging expectations about 'what will come' (if data are made more easily available), thus potentially triggering frustration and discontent in case the promised benefits (e.g. in terms of care) do not materialise in a substantive way.

Given that the datafication of healthcare and biomedical research – both in Switzerland and abroad – is bound to continue (and likely intensify) in the future, it is to be hoped that ethicists will continue to monitor and potentially readdress such developments – like I have attempted to do in this Thesis.

6.1 References

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PART 7 – Appendices

7.1 Appendices relative to 3.1.1

Additional File 1. Search strategy implemented in a search string for PubMed.

Additional File 2. List of Themes and justification of their ethical relevance

Additional File 3. List of Coded Sources and Themes, By Source – Thematic table of sources.

Additional file 1.

Search strategy implemented in a search string for PubMed

((("digital" AND "medicine offering") OR ("smart pill") OR (digital health feedback system[tw]) OR ("digital" AND "adherence-assessment" AND "device") OR ("ingestible" AND "sensor") OR ("Ingestion event" AND "monitoring") OR ("sensor enabled" AND "medicine*") OR ("Abilify" AND "MyCite") OR ("proteus" AND "digital health") OR ("drug-device" AND "combination") OR (“digital” AND “pill”)
AND
("data" OR "information" OR "measur*" OR "collect*" OR "record*" OR "monitor*" OR "detect" OR "register*")

Additional File 2. List of Themes and justification of their ethical relevance.

Ethically relevant issue[a]	Domain to which it is pertinent	Bioethical principles to which it is connected	Reason for considering this an "ethically relevant issue"
Beneficial impacts	Patient-related	Beneficence	The "beneficial impacts" - that are listed or mentioned in the studies - help define what the advantages for patients who use DP are. Put it differently, highlighting the beneficial impacts contributes to answer the question: "What is the benefit for patients if they use DP?"
Benefits to society	Society-related	Justice	"Benefits to society" are linked to justice since the adoption of a new technology in the field of medicine is also addressed to solve problems at the collective level, especially concerning better use of resources. For example, in the case of DP, one of the reasons why they were developed is to tackle poor medication-adherence, which is causing severe problems at a societal level, especially due to waste of resources. With this issue, we wanted to look for insights to the question: "What does society stands to benefit from the introduction of DP?"
Data access	Provider-related	Autonomy	We concluded that considerations about the access to the data that patients produce by ingesting DP affect patients' autonomy, in that they reveal information about their behaviour to the healthcare provider. In other words, issues concerning data access are relevant to autonomy since they determine to what extent patient's health related behaviour is monitored and can also be steered.
Data (in)accuracy	Patient-related	Beneficence	The level of accuracy of one of the main functions of DP (namely monitoring medicine taking behaviour) is quite an important issue concerning the beneficence for the patient. In fact, "how accurate DP are" is a factor that helps to determine the overall benefit that patients might derive from using them.
Data security	Patient-related	Autonomy	"Data security" is closely linked to autonomy. The data DP collect (mediation taking behaviour and other lifestyle data such as heartbeat and steps made) are sensitive health-related data. The level of security and the measures taken to achieve it, are thus two important elements to determine how these data about the intimate sphere of the patient are safeguarded from potential intrusion of third non-authorised parties.
Device or medicine	Society-related	Justice	Issues concerning the approval of DP by a public authority (e.g. FDA) are important to reflect on societal questions concerning appropriateness of the procedures used to approve these product. This is particularly interesting for a technology such as DP, which are a medical device to be integrated with a drug (thus – to some extent – blurring the boundaries between these two categories). Moreover, the process of approval of a medical device or a drug – as a matter of fact – determine the level of safety and

			effectiveness that society deems acceptable to allow a product on the market, which might vary with time and with technological advancement.
Doctor-patient relationship	Provider-related	Beneficence	At the same time the "doctor patient relationship" also concerns the principle of beneficence. For example, if DP reduce the number of visits to GPs, this might have a negative impact on the welfare of the patient. At the same time, reducing visits to GPs might also have positive impacts if – for example – this reduction requires less travelling to the healthcare facility and the quality (and length) of the fewer visits is improved.
Equipment failure	Patient-related	Non-maleficence	"Equipment failure" is an issue that plays an important role with respect to the principle of non-maleficence. In fact, if a device is *per se* accurate and effective, but at the same time subjects to malfunctions, this might result damaging to the well-being of the patient.
Health-related risks	Patient-related	Non-maleficence	"Health related risks", especially in terms of potential adverse reactions, are relevant to consider for the principle of non-maleficence to avoid negative health outcomes for patients.
Need for training	Patient-related	Autonomy	The presence or absence of a "need for training" might have an impact on autonomy at least in two ways. On the one hand, more training needed means that patients require more support in operating the device and then exercise their autonomy with respect to the treatment. On the other day, the presence of training might also help patients expand their autonomy, in that after the training they might become less dependent on, for example, their doctor.
Privacy	Patient-related	Autonomy	"Privacy" is strictly related to autonomy, since the intrusion in the personal and intimate sphere of a patients impacts on his freedom to act freely – especially with respect to the healthcare provider.
Quality of evidence	Society-related	Justice	The "quality of the evidence" concerning a the performance of a health technology is a key feature to reflect, for example, whether that technology should be financed in the publicly-funded health system, or if can be used by health insurances to adjust coverage.
Usability	Patient-related	Beneficence	"Usability" is closely linked to beneficence, since a device that is non-user-friendly can compromise its usefulness for the patients and impact on patients' welfare.

[a] alphabetical order

Additional File 3. List of Coded Sources and Themes, By Source

Patient-related ethically relevant issues

Included records[a]	USABILITY	NEED FOR TRAINING	DATA INACCURACY	EQUIPMENT FAILURE	DATA SECURITY	PRIVACY	HEALTH RELATED RISKS	BENEFICIAL IMPACTS
AU-YEUNG2011 [30]			X		X	X	X	X
BELKNAP2013 [31]	X		X		X	X	X	
BROWNE2015 [32]				X	X	X		
BROWNE2018 [33]			X		X		X	X
CHAI2017A [34]	X	X	X	X				
CHAI2017B [35]	X	X	X	X	X	X	X	
DICARLO2016 [36]		X			X		X	X
EISENBERG2013 [37]		X	X	X	X	X	X	
FRIAS2017 [38]	X	X				X	X	X
KANE2013 [39]	X	X	X		X	X	X	
KOPELOWICZ2017 [40]				X	X	X	X	X
MOORHEAD2017 [41]		X			X			X
NAIK2017 [42]	X				X	X	X	X
NOBLE2016 [43]					X			X
PETERS-STRICKLAND2016 [44]	X	X			X		X	
PETERS-STRICKLAND2018 [45]	X	X			X		X	
ROHATAGI2016 [46]	X			X			X	
THOMPSON2017 [47]	X	X		X			X	
TOTAL	**10**	**10**	**7**	**7**	**14**	**9**	**14**	**8**

[a] first author and year of publication

Provider-related ethically relevant issues

Included records[a]	DOCTOR-PATIENT RELATONSHIP	ACCESS TO DATA
AU-YEUNG2011 [30]	X	X
BELKNAP2013 [31]		
BROWNE2015 [32]	X	
BROWNE2018 [33]		X
CHAI2017A [34]	X	
CHAI2017B [35]	X	
DICARLO2016 [36]	X	
EISENBERG2013 [37]	X	
FRIAS2017 [38]	X	
KANE2013 [39]		
KOPELOWICZ2017 [40]	X	X
MOORHEAD2017 [41]	X	X
NAIK2017 [42]		X
NOBLE2016 [43]	X	X
PETERS-STRICKLAND2016 [44]	X	
PETERS-STRICKLAND2018 [45]	X	
ROHATAGI2016 [46]	X	X
THOMPSON2017 [47]	X	X
TOTAL	**14**	**8**

[a] first author and year of publication

Society-related ethically relevant issues

Included records[a]	BENEFITS TO SOCIETY	QUALITY OF EVIDENCE	DEVICE OR MEDICINE
AU-YEUNG2011 [30]	X	X	
BELKNAP2013 [31]	X	X	
BROWNE2015 [32]	X	X	X
BROWNE2018 [33]	X		X
CHAI2017A [34]	X	X	X
CHAI2017B [35]	X	X	
CARLO2016 [36]	X		X
EISENBERG2013 [37]	X		X
FRIAS2017 [38]	X	X	
KANE2013 [39]	X	X	X
KOPELOWICZ2017 [40]			
MOORHEAD2017 [41]	X	X	
NAIK2017 [42]	X		X
NOBLE2016 [43]	X		X
PETERS-STRICKLAND2016 [44]		X	
PETERS-STRICKLAND2018 [45]		X	
ROHATAGI2016 [46]	X		
THOMPSON2017 [47]		X	
TOTAL	**14**	**11**	**8**

[a] first author and year of publication

7.2 Appendix relative to 3.3.2

Interview Guide – SMAASH NRP-74 project

Let me begin by asking you some questions on your professional/research domain.

Q1. Could you please walk me through your professional/research activity in relation to health data?

Q2. Could you tell me more on your most recent project which currently involves the collection and sharing of health data?

Q3. Could you tell me more about these data collections you are using? Which institution provided them?
What additional types of data are being used?

Can you please describe how you acquired such data?

Q4. What is your opinion on data sharing for your project?

Q5. Have you experienced barriers towards the acquisition and/or sharing of such data?
What were these barriers and how were they addressed?

Q6. If using multiple data collections (referring to Q3):

Concerning the databases/registries you are currently working with, how did you manage to link these data sources to your data?

Q7. Have you experienced OR are you anticipating barriers towards the analysis of those data for your project? Could you elaborate more on these challenges? How were these addressed?

I would like now to switch gears and move towards legal and ethical considerations concerning data collection and data sharing and would love to learn your perspectives on those:

Q8. Do you consider informed consent for data collection/sharing? What is your strategy for obtaining it or justification for not obtaining it?

Q9. For your project, did you ever experience any legal/regulatory challenges? What were these challenges?

Did you abide to any existing national/international regulatory and ethical guidelines pertaining to your professional/research activities? If yes, which ones? How did they influence your project?

Do you see any room for improvement and if yes, what exactly?

Q10. We usually hear that institutions as well as individual researchers are not keen in sharing health

data. What is your opinion on this?

Q11. In the context of your project, do you feel comfortable sharing the data you collected directly or after the first analyses, and can you explain why?

In your opinion, under what conditions would third parties be allowed to use your data?

If you agree that there are conditions under which third parties can gain access, who should these third parties be?

Q12. In light of our interesting discussion, do you have any specific recommendations you would like to make which will help to improve the health data situation in Switzerland?

Q13. Do you have any question or comment that you would like to add before we end our discussion?

It has been a pleasure knowing more about you and your research/professional activities in regard to health data. We thank you for your participation and time.

Note: Only main questions are present here. These were integrated by a series of probes developed during the data collection process.