Transparent bodies, transparent health? Wearable technologies and the future use of the electronic patient dossier

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Introduction

Recent technological developments in medical sciences have been determining the progressive "datafication" of the healthcare system. Data is collected and used by healthcare practitioners to additionally inform decisions concerning treatment. Healthcare providers rely on data for organisational purposes and for the implementation of management solutions. Government and public institutions draw on patients' data to create evidence based policy. Individuals themselves have become curious producers and hungry consumers of data which concerns their own health and can help manage their medical decisions. Altogether, the demand and the offer of data in the healthcare sector have both increased and the governance of data has acquired primary importance in this field.

One of the main consequences of the datafication of the healthcare domain has been the emergence of the idea of an all-encompassing transparency of patients. In broad terms, the term "transparency" is used as an effective conceptual tool to describe the more profound insight on the health and medical status of a patient, offered by data she directly collects or that she indirectly produces (e.g. by receiving a medical diagnosis or by monitoring her lifestyle activities through health apps). Transparency is therefore conceived as both a consequence of datafication, as well as the cause for demanding further collection and analysis of medical information. For example, the idea of implementing unique electronic patient dossiers (EPDs, \url{patientendossier.ch}) is both the consequence of the desire to put in order the already existing multiple data elements (e.g. medical history, diagnosis, imaging etc) related to a single patients, but has also been the pretext to argue for further collection of health related data from wearables such as fitness trackers or other wearable medical devices.

Although there might seem to be a basic shared understanding of patients' transparency in this context, the exact definition and the exact implications of this concept are still a bone of contention. With this document the authors would like to offer a perspective on the topic, which is informed by the condensed output of a week of work and academic exchange on the issue of "The Transparent Patient" during the Autumn Academy of 2019 by Academia Engelberg. In the first part, the authors will offer some preliminary terminological classification concerning the meaning of transparency and the definition of data in this context. In the second part, some reflection on the potential implications on patients' transparency - with a specific focus on wearable technologies as a representative case study - are presented. The third part provides a conclusive summary with several actionable propositions concerning the topic. A short methodological section, in which we provide a rapid overview on the process of elaborating the output presented in this document, will conclude this protocol.

Definitions

Types of Data

We define **health data** as any data that describes the health condition of a person. Examples of health conditions are the absence or presence of an illness, quality of life, or status of bodily functions. Data such as names or addresses are of a more general nature and only important in so far as to relate the health data to a specific person. Since health data identifies a person by definition, health data is a subclass of **personal data**.

Many classifications of health data have been proposed (see Figure \ref{fig:data}), such as **structured** and **unstructured** health data, which could denote a standardized demographic questionnaire on the one hand and an electronic health record with reports from different practitioners, bills, or interview transcripts on the other (Safran 2007) Other classification schemes have been based on the use of the data, such as **primary use** (e.g. a cardiogram for the patient to diagnose heart problems) versus **secondary use** (e.g. the cardiogram might be compared to others in a statistical analysis of a population)(\cite[Datamark Insights]{noauthor_electronic_2019}).

For the discussion of wearable technology, we will make use of yet another classification of data, namely **formal** and **informal health data**. This conceptualization correlates with the primary and secondary dichotomy, yet is not defined via the *use*, but via *acquisition* of the data. Intuitively, we call data that has been usually generated by the patient him- or herself in a nonprofessional (not necessarily inaccurate) manner, such as facebook posts, weight tracking, sleep data, or pulse tracking as informal health data. Conversely, formal data denotes data that has typically been recorded by medical professionals, such as a cardiogram or an MRI scan. Health data from wearable devices are a subclass of informal data (excluding among other facebook posts or weight tracking), which are worn by the patient and track a certain health condition continuously.

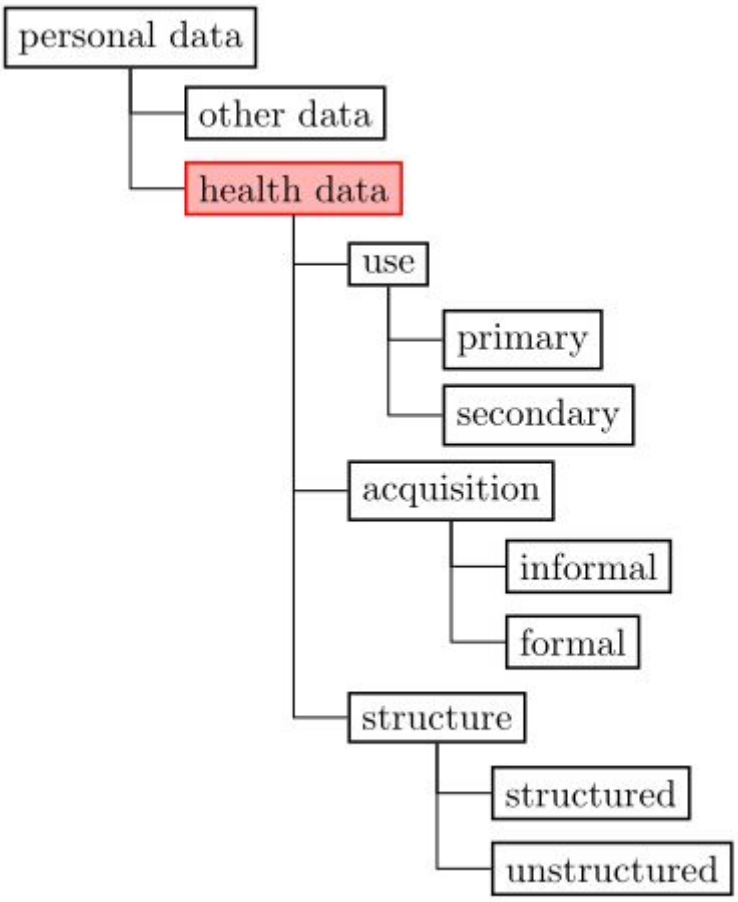


Figure 1: Classification of personal data based on different criteria that are used in this paper.

Transparency

Despite its vagueness, the concept of transparency takes a central role in the discussion around the digitization of health data, specifically in the EPD. After outlining the relational nature of transparency, we will propose a fourfold definition based on the agents to which transparency is granted.

Transparency is commonly understood as insight of any kind into an object. Colloquially, transparency can refer to any degree of insight, a view which we will also adopt for this protocol. It should be noted that - from a logical point of view - 'transparent' is an absolute adjective, i.e. it does not come in degrees. In a more pragmatic perspective, however, transparency can be also considered as a progressive element.

In the context of healthcare, transparency usually denotes the accessibility of qualitative or quantitative health data to a person or a group of people. In this sense, transparency is a dual concept involving the observer and the observed. Hence, we want to stress the relational nature of transparency, which is evident when it is considered from the perspective of accessibility: the patient is transparent *to whom*?

In this sense, we propose to distinguish four fundamental aspects of transparency: 1) transparency to the patient him- or herself; 2) transparency to healthcare professionals or medical institution; 3) 3rd party institutions; 4) the general public (see Table 1).

Table 1: Our proposed threefold definition of transparency of the patient.

To whom?	Examples	Underlying aims
To the patient	Patient and the people with whom the patient shares the data	Improve self-knowledge and promote self-care; responsibility
To healthcare professionals and medical institutions	GPs, hospitals, psychiatrists	Facilitate accessibility to data especially in case of patients' mobility. Promote better care.
To 3rd party institutions	23andMe, research labs	Facilitate research, generate market value
To the general public	Facebook friends, general public, neighbors	Foster sharing culture, comparison with others

Firstly, informal health data is currently being produced at an increasing speed and offers patients an unprecedented wealth of information on themselves. Generally speaking, having more and more accessible data offer the opportunities to have a more detailed and nuanced insight into their health condition. Patients can directly and personally look at data, which traditionally would only be accessible to medical professionals (e.g. testing) or where medical professionals would, at least, mediate between the patient and the data. Moreover, patients can also become more transparent to themselves by producing additional data concerning their health without the mediation of any third persons (e.g. wearable technologies or health apps).

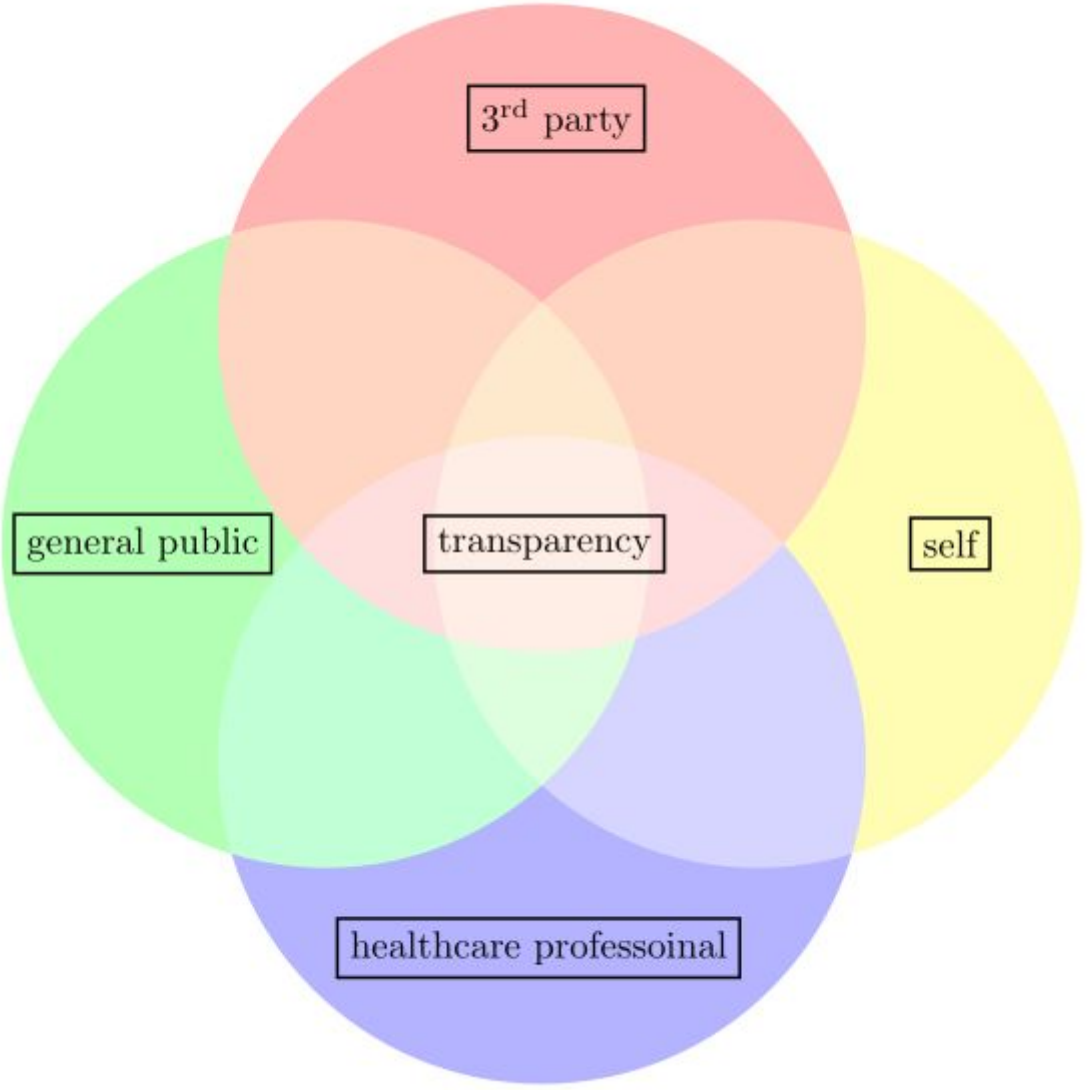
Secondly, transparency can refer to the healthcare professional or the medical institution which has access to patients' data during the provision of care or when conducting research. Usually -- with the relevant exceptions of wearables or over the counter medication -- there are professionals or a healthcare institution involved both in the production and the access to data. Examples include that of a pharmacy receiving a prescription and providing the corresponding medication, a GP with years worth of health files of a patient or a laboratory with samples of all people who underwent a specific test. In this sense, there could be even cases where a patient might be transparent primarily (or even exclusively) to others (i.e. the healthcare professionals), but not to him- or herself. For example, patients might conduct certain tests leading to the production of some data about them which they require not to be informed about.

Thirdly, it must be emphasized that patients more often reveal data -- and thus become transparent -- not to their primary care facility (such as their GP) but also to third party companies. These might include, for instance, 23andMe for the context of genetic data or PatientsLikeMe, for healthcare more in general. Transparency with respect to these institutions -- whose goals and interests might often conflict with those of the patients -- require specific attention, especially in terms of regulatory framework.

Fourthly and lastly, patients can become transparent with respect to the general public and to their fellow citizens. Traditionally, there has not been a great deal of patients' transparency with respect to other citizens, since patients and their doctors have always acted as gatekeepers of the patients' health related information. However, the possibility to share data on a larger scale, as well as the interest of policymakers to have data in order to implement evidence based policies, have fostered a more societal dimension of transparency. Moreover, the possibility that social networks offer to

connect directly with other citizens has also opened up the possibility of information concerning the health status of a person to be directly accessed by close or distant fellow citizens. This aspect is particularly important considering the many concerns of patients about stigmatising or intimate health data being somehow accessible to their neighbors or acquaintances. It should be noted that the sharing to the general public often involves also a 3rd party company, especially if sharing happens over the internet.

Naturally, these different levels of transparency overlap in a certain sense (Figure 2). For example, the data from a smart watch with a proprietary software will automatically not only be transparent to the user, but also to the company. Similarly,a lab report could only be transparent to the medical professional and the lab (the 3rd party). Including also the patient in the latter example would then create the overlap of three of the named aspects of transparency. We acknowledge that there are many interdependencies between the different aspects we have identified, each of which could be elaborated further. In this work, we try to study only the primary aspects and develop some concepts related to them.



Consequences and challenges

One of the main challenges that come along with the growing importance of health data collected through the constant monitoring of individuals through wearable technologies such as smart watches or fitbit armbands (informal health data from wearables) \cite{al-azwani} is how the different aspects of transparency are handled. With the advent of smartphones and the internet of things, citizen science projects have emerged worldwide. This has stressed the importance of data collected in this way as being relevant to close a gap in knowledge between formal data and no data at all. Traditionally, informal health data from wearables has not been available and -- now that it is present -- it promises to offer a more comprehensive picture of the health status of patients \cite{fisch}. The public discourse around the potential of this data has particularly been influenced by the notion of "data philanthropy", first put forward by the UNGP (Ajana 2017:9 ajana_digital_2017). Data philanthropy promotes the idea of "data sharing as public benefit" and thus highlights its potential in the process of working towards the greater social good. In the course of this development, the incentive to nudge individuals into giving away their personal data has massively increased . Furthermore, medical research nowadays often uses data from commercially available sensor enabled devices in order to come up with models that are able - amongst other things - to detect early signs of heart diseases.

According to the classification above, we propose an overview of the consequences these developments have on transparency. As outlined before, there is a certain dialectic between the different forms of transparency, which is also mirrored by the fact that consequences often concern more than one of those categories.

Data extraction and the myth of objectivity

More encompassing and better structured EPDs would allow for a more individually tailored healthcare for the individual and cut administrative hours for the healthcare practitioners. However, we are faced with certain difficulties when we consider the extraction of such data for other purposes - mainly research. Data mining in specific healthcare contexts happens for pre-defined purposes - a cardiogram at a local GP is generated with a different intention than counting steps or hours of sleep. Health data that is currently uploaded in EPDs is often unstructured - it is not standardised and the effort required to extract this data and then make it comparable and interoperable is high \cite{martinez}. But the matter gets even more complicated once we introduce informal data from wearable devices to the EPDs. If EPDs - with our without the inclusion of data collected from wearable devices - were opened up for research, a number of additional questions would arise: these would concern ownership and accuracy, but also the meaningfulness of this data - since extracting data from its original context often compromises its concrete meaning (Markham 2013 markham_undermining_2013). Furthermore, as research in the field of Critical Data Studies (CDS) has shown, there exists an underlying assumption concerning the objectivity and truthfulness of data gathered from everyday devices - among medical professionals and users alike. Big Data, according to CDS, has been defined as a "cultural, technological, and scholarly phenomenon" (boyd and Crawford 2012:663 boyd_critical_2012) that is characterised by the interplay of technology and analysis, as well as mythology: "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" (ibid boyd_critical_2012). There have been numerous efforts recently to understand the belief that all measurable things are true. These efforts have all problematized data mining processes (Drucker 2013 drucker_performative_2013; Gillespie 2014 gillespie_relevance_2014; Kitchin and Dodge 2011 kitchin_code/space:_2011; Montfort et al. 2012 montfort_10_2012; Neyland 2015 neyland_organizing_2015). Thus, the false syllogism of "raw", informal data from everyday life as objective and "true" data feeds into a broader narrative of objectivity, quantification and rationalization of the human body and its functioning. The underlying assumption of this narrative is the following: the more transparency (in terms of numbers) we achieve, the more we know.

Patients as quantifiable entities

Furthermore the "datafication of health" (Ruckenstein and Schüll, 2017) have fostered the aspiration that patients – and individuals as a whole – are quantifiable entities that can be defined by the electronic information that is collected from and about them. Behind this evolution, there is the hidden claim that large amounts of data are capable of exhaustively defining individuals, their behaviour and, thus, their health – which is conceived as the mathematical sum of their whole data, either performed by a doctor or simply with the help of algorithms. Patients' health profiles are not any more the product of the personal patient-doctor relationship, but rather the result of the large amount of longitudinal, allegedly objective and fully accessible electronic data collected during the patients' entire life. Other elements of life - such as cultural contexts, life-changing events and social status for example - are not mirrored in those accounts, and thus challenges any holistic claims of such records.

The "unpatient"

Constant monitoring of individuals dilutes the boundaries between health and illness. Being under constant "surveillance" without actually being diagnosed, creates a new category of humans interacting with technology, that of the "**UN-PATIENT**". S/he is always on the verge of potentially developing a disease or discovering an illness. 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" (Jonsen et al, 1996:623) – 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 ore pre-symptomatically ill" (Rose, 2007. Retrieved in Schüll 2016) has advanced.

Whose responsibility?

An increasing transparency on all levels challenges **notions of responsibility.** Not only does an allegedly increasing understanding of oneself, based on the additional data individuals now have accessible to themselves, lead to an increased pressure for self-responsibility, but also the individual responsibility to help "society as a whole", by contributing my personal data to research directly or to add it to existing patient dossiers which can then potentially be accessed by research institutions. If personal data from everyday monitoring devices is added to patient dossiers, the new, allegedly "more complete" picture of the individual can potentially be used against him/her: a permanent control of medication intake or "healthy" behaviour can be used to reinforce the argument of personal responsibility. The individual will increasingly be held accountable for his/her bad health. It goes without saying that the use of individual-level data as a way to enforce personal responsibility for health raises a number of ethical and legal issues, from questions about surveillance and privacy,

to epistemic issues about the accuracy of the data collected \ref{case2015}. It also ignores cultural contexts, social statuses, the impact of certain life events and unequal statuses of health literacy amongst patients. We ultimately need to ask, whether data should become the new paradigm according to which individuals, their lifestyle and their health-related choices are assessed. Especially when population health, as an outcome, is then 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. The many issues where a collective effort can be much more effective to tackle individual risk factors than the responsibilisation of the single person, will then be glossed over.

Changing doctor-patient relationships

Transparency of patients also challenges the traditional tenets of the doctor-patient relationship. This is because digital health tools including as wearable technologies "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 democratisation of care" \cite{mesko2017}. When data is produced and accessed directly and primarily by the patient, and then passed over to the doctor only at a later stage, the conditions are created for more patient-empowerment. At the same time, however, health related data is often ambiguous and difficult to interpret and the assistance of a medical professional is nevertheless required. Moreover, despite the instances where patients are required to self-care about their health have increased \cite{lupton2013}, a great deal of medical services are still offered by medical professionals, thus still requiring the interaction of patients and doctors. This generates two sets of challenges. On the one hand, patients - having direct access to their own data - might feel they "know better" than their doctors and when recommendations by doctors do not match the pre-existing convincement of patients, the latter might lose their trust in medical professionals. On the other hand, trust within the doctor-patient relationship might be strained also by doctors themselves, who might doubt patients' honesty when the allegedly "objective" data collected through wearables contradicts what patients say. Lastly, the question emerges of how informed consent to medical treatment and its requirements will evolve. In a context where medical care is often provided remotely and through wearable devices, personal interaction between the patient and their doctors can diminish. Consent is thus often required remotely and electronically and it risks resembling a "click-through" procedure (similar to that of accepting Terms & Conditions in a digital environment), rather than mirroring a sincere agreement between the person providing and the one receiving care.

Focus on new technology glosses over systemic problems

Whereas the potential "to do good" with the additional data gathered from sensor enabled monitoring devices in health care models worldwide, the focus on this new technology also narrows down debates about **larger economic and/or political framework** in which it is implemented. Having more data available doesn't lead to more efficient healthcare system if it lacks healthcare facilities in the first place, if it is unable to provide an encompassing social security system or if the existing facilities lack the digital solutions to share data amongst themselves. Making comprehensive use of wearable technology in the healthcare system might be difficult without an all encompassing strategy to promote health literacy.

Challenges for notions of privacy

This development has **serious implications on an existing understanding of privacy.** "Privacy is perceived as being too individualistic, too narrow and too implicated in outdated liberal assumptions about individual rights and discourses of subjectivity" (Ajana 2017:14 ajana_digital_2017). Casting

the concept as opposed to a "collective good and as a hindrance to realizing the ideal and assumed benefits of open knowledge, open data and transparent information" (ibid. ajana_digital_2017), probably aides in speeding up technological innovations, but simultaneously disguises their social value and their role in functioning democracies.

Negotiating different kinds of knowledge

Engaging with technology in or on the body means having to negotiate two or more often rather diverging narratives. Making sense of data of the body (the individual's perception, his/her own feelings and the way he/she makes sense of the signals s/he gets from his/her body) and "unbodied data" (Smith and Vonthethoff 2017 smith_health_2017) - which is data of, but not directly from the body, is a rather complex task. The latter is shown back to the individual either on a tiny device or on the screen of a smartphone or computer, which involves a sensory dimension (actual touch) as well as a certain capacity to "read" the data. This negotiation of different narratives can be a confusing endeavour - for the healthy as well as for the ill user/patient/un-patient.

Actionable propositions

The tendency to engage with wearable technologies to individually monitor one's own health increases - and it has become a huge market. However, only a small number of those devices are approved as medical devices, and they often get on the market without proper scientific validation \cite{sperlich}. There should be a clear effort by healthcare practitioners to encourage the use of more reliable devices over others. As of now, the inclusion of "everyday data" from wearable technology into EPD in Switzerland is not necessarily encouraged, but it is technically possible [ref]. Given the many uncertainties related to the data produced through wearable technologies, the authors are sceptical about their unconditional inclusion in medical records and about the reliance on this data in the provision of care. Although this data might be sufficiently accurate for the commercial sector, the authors are wary about its extensive use in the medical context, especially as long as wearable technologies receive appropriate validation as reliable medical devices and their market is more properly regulated.

In the light of new technological developments in this field and their potential benefits, we recommend, however, not to rule out the use of wearables or to oppose it as a matter of principle. Rather, we suggest to allow their use in the provision of care, but to ensure that the focus of medical professionals is kept on the individual and his/her experiences *with* the technology. Thus, in the context of rehabilitation and in that of prevention, there should be space for discussing the experience patients have with these transparency-promoting technologies and ensure that the attention is maintained on the patients and its well-being, rather than on the technology *per se*. This includes drawing particular attention to the elements of individuals' lives that are not visible in the raw data, including life-changing events, social status and cultural contexts. We thus recommend that the potential of data collection, which new technologies offer, does not result in neglecting the "missing elements" which technologies cannot (yet) capture, and that the latter are included in a patient's dossier - be it physical or electronic.

Another important actionable proposal which we recommend is that patients' empowerment and control over their own data is promoted by the use of a "physical" and "tangible" element for data management. In particular, we recommend that - if EPD are implemented and data gathered from wearable devices is uploaded on them - a card or a key is offered as a physical element necessary for accessing the data. We believe this could be a helpful element to convey the feeling of control rather

than monitoring. Moreover, this physical element would be often needed anyway, if any form of multi-factor authentication is used for accessing the EPD - in the same way as it is used, for example, for home-banking.

A further important element is that of continuously ensuring user-friendliness of all systems associated with wearable technologies, other data-collection tools (e.g health apps) and also EPDs. The importance of user friendliness for EPD systems has been extensively confirmed \cite{mcginn2011}. Moreover, with respect to the EPD, we also believe it would be important to promote the creation of a dashboard. On this dashboard people could see their latest health data as well as what kind of research is currently done, which 1) pertains to their conditions, to which 2) they could contribute by providing their data or to which 3) they would volunteer further data such as surveys or interviews.

Lastly, we would like to stress the relevance of promoting the narrative that data collection and data use in the healthcare sectors should primarily be favored in order to allow doctors to spend more time with (and draw attention to) patients. Actually talking with the patient rather than completing bureaucratic chores - such as asking for the upteenth time for some health related data - would represent a tangible way of how patients can consent to more data sharing. Needless to say, we subscribe to the view that having access to patients' medical history, their longitudinal data collected through wearables and previous medical exams should be used specifically to free up time to use for the personal relationship with the patient, and not to further reduce it (for example by assigning even more patients to the same doctor).

For the upload on data - including that from wearables - on the electronic patient record, doctors should insist on the fact that having a complete and updated medical history is part of their duty to provide good clinical care. They should be honest about the risks of having information in a more centralised database (data breaches usually affect large portions of databases), but they should also remind the patients, that the alternative is not that of total security either - especially on the individual level: paper files can be accessed or stolen and privacy violation can still happen. On a similar note it should be emphasized, that the unstandardized and/or unqualified handling of data (e.g. emailing or faxing, having paper lying around, databases on private servers, etc.) can be equally disastrous for the individual.

Also, healthcare professionals should underline that transparency and access to patients' data is a constituting part of the therapeutic relationship in healthcare. This relationship entails a certain "invasion" of the physical (the patients' body) and also non-physical (patients' data) life of a patient. The reason why this "invasion" is considered acceptable is funded in two main arguments: the duty of the doctor to promote the interest of the patient and the agreement of the patient. This should work in a similar way both for the invasion of the physical sphere, as well as of the non-physical sphere. Healthcare professions should then just underline, that getting patients data and accessing it is part of their care relationship with the patient and not an addition to it.

Notes on the authors' methodology

This protocol is the outcome of a week of work and academic exchange on the topic of "The Transparent Patient" during the Autumn Academy 2019 by Academia Engelberg. The authors of this protocol were initially grouped together by the organisers with regard to the content of the essays they submitted as part of the application process for participating in the Academy. The authors have different academic background and expertise, which include anthropology, philosophy of science, law, bioethics and computational and physical chemistry. From the perspective of the authors, this variety of backgrounds represented both a challenge and an enrichment to the discussion that led to this protocol.

To elaborate the protocol the authors worked together for three consecutive days of the academy. In the first day, they reflected together on the general topic and summarised their initial perspectives based on previous knowledge and on the inputs they received from each other. These initial perspectives were then formally summarised in the form of bullet points and a first unstructured document containing them was drafted. In the evening, each author reflected on this first document and added additional thoughts and bullet points. On the second day, the bullet points were ordered, the general objective and structure of the protocol was defined and the content of each of its sections was agreed upon. Thereafter, each author worked individually on one of the sections for a defined time-slot of 30 minutes. After the end of the time-slot, each author turned to a different section and continued elaborating the ideas developed by the other author previously working on the same section. This process was repeated for each section of the draft of the protocol till the end of the day. The authors then gathered together and discussed the draft of the protocol. Terminological inconsistencies were clarified and disagreement concerning the content was resolved through discussion. On the third day, the authors met again to refine the definitive structure of the protocol. A section of the protocol was then assigned to each author, who worked individually for the first part of the afternoon to improve and expand the protocol. At the end of the day the authors met again and collectively reviewed the whole protocol and agreed on the definitive version of the document.