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Beyond 'Consent': Amplifying Patients' Agency in the Use of their Health Data through Engagement 2.0 Interfaces

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Abstract. With (big) health data becoming increasingly useful for researchers due to enhanced modern processing and calculation possibilities (e.g. Artificial Intelligence, Whole genome sequencing), patients' agency over their data is in contention. Even though strictly speaking patients' consent is not legally required when it is used for research in the public interest, the ethically preferable alternative is to enable patients to at least express their voice regarding the use of their data. Contemporary 'Engagement 2.0' modalities such as Dynamic Consent cater to this need, but have - so far - been prototyped with only limited end-user involvement. With this paper, we want to prompt a participatory approach to the future agenda-setting on the topic of patient empowerment and the role Dynamic Consent and other Engagement 2.0 applications might play in it.

Introduction

The health research landscape has undergone a major shift over the past 15 years due to the unprecedented prevalence of multimodal real-world patient data. The potential that this big data holds is, from a research - and in particular Artificial Intelligence (AI) and Machine Learning (ML) - perspective, immense. While the EU's most prominent legal framework (General Data Protection Regulation,

GDPR) does not necessarily require patients' consent for their data to be used for research purposes, there is the clearly ethically preferred alternative of giving patients a voice in how and for which purposes their data is used.

'Engagement 2.0' applications (drawn conceptually from 'Web 2.0,' to which user-generated, dynamic interactivity is central) (Teare et al., 2015) enable various new methods of patient engagement and empowerment. One modality of Engagement 2.0 is Dynamic Consent (DC), which allows for granular consent decisions that are applied in real time, as well as interaction between patients and healthcare professionals (Prictor et al., 2020). So far, DC prototypes have mainly been used and tested within the relatively confined context of biobanks and cohort studies. Given the move towards health data being made available for research on even larger (national and international) scales, there is an increased need to look at how adapted forms of DC and other modalities of patient empowerment might be shaped against this backdrop. Even though pilot projects with interactive DC forms have been favorably appraised (e.g. Spencer et al., 2016), few efforts have been made to actively include end-users in their design. With this paper we therefore aim to prompt a multidisciplinary, multi-stakeholder discussion to shape the research agenda of patient involvement and (data) agency.

Consent as a Lawful Basis and Ethical Considerations

Consent and varieties like DC are often at the center of discussions about patient empowerment. Within the GDPR, consent from the 'data subject' (the individual whose data are processed) is one of six lawful grounds for the processing of personal data. The GDPR stipulates that consent should be given "by a clear affirmative act establishing a freely given, specific, informed and unambiguous indication of the data subject's agreement" (Recital 32). In the healthcare environment, however, several conditions for valid consent are problematic. For example, can consent to a medical procedure be considered as 'freely given' if there are few alternative options? And is it feasible or desirable to ask patients for consent every time their health data is used for secondary (research) purposes? When considering the (re)use and processing of health data for research, more appropriate lawful grounds than "consent" exist. If medical research is carried out under ethical oversight, it is presumed to be performed for the common good, i.e. in the public interest. The European Data Protection Board therefore advises that processing of health data for research be based on a public interest in the area of public health (Art. 9(2)(i) GDPR), or scientific purposes in accordance with a law (Art. 9(2)(j) GDPR).

We need to distinguish consent to (secondary) personal data processing, also, from consent to participating in a clinical trial. The latter, 'informed consent' is defined in the EU's Clinical Trial Regulation as: "a subject's free and voluntary expression of his or her willingness to participate in a particular clinical

trial", after having been informed of all relevant aspects. The aim of this 'informed consent' is to ensure the protection of two fundamental rights: the right to human dignity and the right to integrity of individuals - notably, not the right to personal data protection. While patients may give 'informed consent' to research participation, this does not entail blanket consent to all processing of their data.

To empower patients and meaningfully involve them in research while respecting their dignity, integrity, and autonomy - also without consent in its strict form - modern digital applications offer new possibilities and potential solutions.

Advanced Patient Empowerment through Engagement 2.0 Dynamic Consent applications

In different forms and shapes applications, platforms, and tools that facilitate engagement and interaction between patients, clinicians and to some extent also (clinical) researchers, already exist today. Web 2.0-based technologies allow these stakeholders to engage with one another in ways not possible before. There are electronic health records, patient portals, hospital apps,... which offer functionalities such as: consulting results/outcomes of medical tests and analyses; confirming/adjusting therapeutic relationships, stating which professionals can access data; indicating preferences for organ donation in case of decease; making appointments; and receiving and paying medical bills. Notwithstanding this relatively elaborate list of utilities that can be placed under the umbrella of 'patient empowerment', we argue that there is much more potential for them.

One functionality for which the need has grown against the backdrop of the enormous surge of health data available for secondary research purposes, is for patients to be able to express voice regarding the use of their data. An application that enables such patient-agency was first introduced within the context of biobank studies in the form of 'Dynamic Consent' (DC), which engages individuals about the use of their medical data, enabling both granular consent decisions and ongoing communication between participants and researchers (Prictor et al., 2020). DC utilizes an interactive interface that supports an individual in making autonomous decisions to alter their consent choices in real time (Kaye et al., 2015). Even though initial prototypes and real-world applications of DC have already been rolled out and overall positively assessed (Teare et al., 2015; Spencer et al., 2016) their full potential is underexplored. Current DC interfaces, and by extent other methods to improve consent, have only occasionally been developed with the participation and involvement of their envisioned end-users (Prictor et al., 2020). In their 2015 key paper, Kaye et al. elaborately describe the features that constitute 'Dynamic Consent' and how it is different from other forms of (e-)consent. They describe what makes it 'dynamic' (i.e. (re-)use of health information with knowledge and consent; possibility to

give and revoke consent in response to changing circumstances; provision of a record of all transactions and interactions in one place; modification of preferences over time) as well as what its distinct features are.

Though DC offers a valuable point of departure, we wonder what other traits, features and functionalities might be desired. Respecting patients' dignity, integrity, and autonomy can go several steps further. Involving patients in improving explanations, giving them more agency in which purposes their data can be used for, or even involving them in developing research questions are a few ways in which improved interactions between patients, clinicians and (clinical) researchers can support patient empowerment.

The specific sociomaterial conditions and intersectional particularities of individual patients, researchers, and practitioners mean that abilities and capacities differ between health technology users, and between different constellations of human and technological actors (Baraitser & Cribb, 2019; Suchman, 2020). Providing equitable agency would therefore require that participants in interface design projects are carefully selected to include a wide variety of perspectives, capabilities, knowledge bases, and behavioral patterns.

Conclusion

With big health data holding the potential to significantly improve diagnoses, treatments, prevention, medicine and medical devices, its value to research is evident. At the same time, it is important not to lose sight of the fact that this data comes from people who might want to have agency over what it is used for, by whom, and how. While consent may not be the best lawful basis for the use of health data in clinical research, we believe there are strong ethical arguments to empower patients to be more closely involved in research that uses data about them. There are several unanswered questions we hope to put on the research agenda through this paper: What is the mental model patients have of a DC tool to manage their health data used for research? What additional features might they require? How would they want to able to tailor them? In what form would they prefer communication to take place between them and researchers or clinicians? And what functionalities might allow for disadvantaged patients (e.g. with a cognitive impairment or low digital literacy) to express their voice?

To explore these questions, a participatory workshop can bring together different stakeholders to discuss possibilities and limitations of different forms of patient empowerment through online platforms. Drawing on other sectors and domains, we want to assess through a set of co-design activities 'what patient empowerment might entail, now and in the future', and what role Engagement 2.0 applications might play in this.

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