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A Consent Tool for Secondary Use of Biomedical Data

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Abstract. To pursue scientific goals with patient data usually requires informed consent from the data subjects. Such a consent constitutes a contract between the research institute and the patient. Several issues must be included in the consent to be valid, for example, how the data is processed and stored as well as specifics of the research questions for which the data is going to be used. Here, we describe the development and the implementation of a user-friendly IT solution that supports the process-oriented obtainment of consents. Current solutions often focus only on the benefits for the researcher. Our solution intends to add value to all participants and to reduce paperwork to a minimum. The consent Tool was evaluated by a usability test using the UEQ Method (User Experience Questionnaire) and received positive feedback – both efficiency and originality were rated above the average UEQ-Benchmark. Nevertheless, the lack of compatibility with the technical infrastructure of the hospital was a significant shortcoming. Hence, although there is a general interest in digitized solutions in the healthcare sector, there are still many hurdles to implement them and roll them out.

Keywords. General consent; informed consent; data protection; clinical trials.

1. Introduction

Research projects in the biomedical domain often require routine health data, i.e., data that is collected in the context of medical treatments. To pursue certain scientific goals with such data usually requires informed consent from the data subjects. Such a consent constitutes a contract between the research institute and the patient. Several issues must be included in the consent to be valid, for example, how the data is processed and stored as well as specifics of the research questions for which the data is going to be used. One consent type that is often used is the general consent, as it allows to formulate very broad research questions [1].

Even if the informed consent contract is not signed, there is still the possibility that using the data for research might be legal. A mechanism that leads to such an unintuitive consequence is the right of objection. In some constellations, it is present as a contract clause that requires explicit objection (see Section Results). In other words, a data subject must either explicitly agree or explicitly object (by a legally valid signature) to the usage of her data [2]. Such a knowledge is often not present in data subjects, as they often have only a vague image of what informed consent implies, and decisions or actions based on such images are sometimes referred to as “empty performative” [3].

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In Switzerland, the political agenda for future healthcare is called "Strategy eHealth 2.0", which has the vision to provide a better, more secure, and more efficient healthcare system. One ingredient in that strategy is to enhance informational self-determination, which avoids "empty performative" decisions. It is assumed that informed and conscious decisions regarding one's own health data contributes to an increased quality of treatment: patient safety is enhanced, and efficiency is achieved through health literacy [4]. To facilitate such a self-determination, paper-based consent and ad-hoc elicitation of the consent should be replaced by a digitized consent workflow that supports the information needs of the data subjects with a user-friendly and digestible annotation of the digitized consent template [5]. Current solutions often focus only on the benefits for the researcher. Our solution intends to add value to all participants and to reduce paperwork to a minimum.

2. Methods

For obtaining the necessary information, we investigated how the consent is practically completed and collected within medical research projects. For that purpose, we collaborated with the university hospital Bern (Insel), which also took the role of our main stakeholder in this project. We divided our target group into two parts: on the one hand, researchers as processors and administrators of the consent; and on the other hand, the patients, as signatories and consumers of the consent. We performed a literature search for gaining an overview on existing types of informed consent together with their pros and cons. We divided this into two subtasks, a general search in search engines (e.g., Google) and a targeted search in scientific databases (e.g., Google Scholar, PubMed etc.), covering literature from the last 20 years. The following search terms were used: "general consent", "clinical trial consent", "efficiency". In addition to that, we conducted two semi-structured online- interviews with our stakeholder, each lasted about 1.5 hours.

The gathered requirements served as the basis for an AdobeXD-mockup, which allowed us to discuss potential adaptations for implementing the prototype. We gathered feedback on the mockup based on a live-web-demo, taking notes on the recommendations of our stakeholder. It was then decided that the solution should be a user-friendly web-based application (according to the Nielsen-Usability-Heuristics: e.g., "user control and freedom", "flexibility and efficiency of use" amongst others) to ensure platform independency. The implementation was done in five scrum sprints and was based on the following technology stack: vue.js for the frontend and node.js for the backend with mongoDB as a database. For receiving feedback with respect to our solution, we conducted a usability-test with the UEQ Method.

3. Results

Concerning the types of consents, one can first distinguish between general and informed consent. General consent is mostly used in research projects where there is no active involvement of the data subjects, e.g., the research can be carried out solely by relying on previously collected data. Informed consent is used when an active participation of the data subject (e.g., in a clinical trial) is required. Our stakeholder wanted us to focus on the general consent for this project. Regarding the ingredients of

such a consent, we relied on the draft template of the Swiss Academy of Medical Sciences (SAMW ASSM) [6].

Besides the content of the general consent, three further issues had to be solved: the consequences of (not) consenting, data security requirements, and digital signatures. Table 1 summarizes the consequences of consenting, refusing or ignoring the consent contract. The most striking case is ignoring the consent for anonymized non-genetic data and samples, which allows their usage. With respect to data security, we referred again to the SAMW ASSM recommendations, e.g., related to revocations or the history of changes in the consent status. Finally, regarding the digital signature we relied on the Swiss Code of Obligations, which stated that only the "qualified electronical signature" is considered equivalent to a handwritten signature. To ensure this, a certificate-based digital ID issued by accredited trust services is required. In addition to the integrity of the document and the assignment to a person, a time stamp is added here as confirmation of the existence of the document at a specific point in time. To make our prototype more flexible, we relied only on a simple electronic signature and waived the legally valid one.

General Consent signed?	Encrypted genetic data and samples	Encrypted non-genetic data and samples	Anonymized, genetic data and samples	Anonymized, non-genetic data and samples	Anonymously collected data and samples
"Yes"	✓	✓	✓	✓	✓
"No"	✗	✗	✗	✗	✓
"No Answer"	✗	✗	✗	✓	✓

Table 1 Consent matrix for the further use of data/samples

For the implementation of our prototype, we created a BPMN process diagram (not shown here) to consider the conventional consent process involving the data subject, the researcher, and the ethics committee. Once research questions and design are described, the research institute must a request to the local ethics committee. Only after passing critical aspects like the adequacy of the purposes, data security, data protection, study design and added value for medicine in general, is a project allowed to start. After the required study population has been defined, institutes can start to contact suitable candidates. This is mostly done when a patient visits a medical facility in case of a routine examination or due to other medical reasons. They are made aware of the possibility of data usage for research purposes – but since patients came to the facility for another reason, they often don't pay particular attention to it. After their visit, they receive a letter including the form to sign.

Our prototype is designed to annotate all the relevant parts in the digitized consent template to convey their contents and reasons. Thereby, all relevant information is provided in a digestible manner. Further, our prototype allows interactions between patients and the researcher in case something remains unclear or questions beyond the consent are posed. Researchers could draft the documents which are required by the ethical committee digitally and redirect it to them on the same platform. Based on the draft, they could send the document to suitable patients who on the other hand can view it at home at their leisure. Complex terms are explained in a sort of dictionary which can be fed by researchers to avoid "empty performative" actions.

Results from the usability-test show: in comparison to the UEQs Benchmarking dataset (>20'000 persons, >450 studies), our consent tool received above average ratings for attractiveness and transparency and even better ratings for efficiency and originality.

Only stimulation was rated below average. In addition to that, 3 out of 5 researchers rated the digitized version of consenting as highly safe and informative.

4. Discussion

We have found few existing solutions for digitally obtaining consents. There are, for instance, an EU driven research project which tried to formulate a proof-of-concept for consents and the solution E-ConsentPro from the German company Thieme, which we didn't test in depth however [7]. Hence, both economically and politically the matter is still in its infancy and should receive more attention. Interestingly, this is also due to the fact that the digital equivalent of a handwritten signature is not fully clarified. Even though the Swiss law indeed describes one possible variation of that signature, real-life examples are scarce, as there is a lack of microeconomic network effects.

Originally, our tool was implemented to increase efficiency of the consent process, but the lack of compatibility with the technical infrastructure of the hospital was a significant shortcoming. As it was unclear whether the initially increased efficiency would be eaten up by the additional administrative burden and manual transfer of data, the tool has not been used in practice yet. Hence, although there is a general interest in digitized solutions in the healthcare sector, there are still many hurdles to implement them and roll them out. For example, most clinical trials are multicentric studies which are conducted at several sites – each with their own clinical information systems – which lacks a universally applicable data format to avoid data disruptions. HL7 FHIR knows a resource, which could be further developed to address this interoperability issue [8].

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