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Donor's support tool: Enabling informed secondary use of patient's biomaterial and personal data

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ABSTRACT

Purpose: Biomedical research is being catalyzed by the vast amount of data rapidly collected through the application of information technologies (IT). Despite IT advances, the methods for involving patients and citizens in biomedical research remain static, paper-based and organized around national boundaries and anachronistic legal frameworks. The purpose of this paper is to study the current practices for obtaining consent for biobanking and the legal requirements for reusing the available biomaterial and data in EU and finally to present a novel tool to this direction enabling the secondary use of data and biomaterial.
Method: We review existing European legislation for secondary use of patient's biomaterial and data for research, identify types and scopes of consent, formal requirements for consent, and consider their implications for implementing electronic consent tools. To this direction, we proceed further to develop a modular tool, named Donor's Support Tool (DST), designed to connect researchers with participants, and to promote engagement, informed participation and individual decision making.
Results: To identify the advantages of our solution we compare our tool with six other relevant approaches. The results show that our tool scores higher than the other tools in functionality, security and intelligence whereas it is the only one free and open-source. In addition, the potential of our solution is shown by a proof of concept deployment in an existing clinical setting, where it was really appreciated, as streamlining the relevant workflow.

1. Introduction

Recent reports by the eHealth Task Force [1] and by the European Alliance for personalized medicine [2] focus on redesigning health in Europe to achieve a vision of affordable, more personalized and less intrusive care, ultimately increasing the quality of life as well as lowering mortality. Such a vision to a large part, depends on the application of information technology, the effective use of data and biomaterial and requires a radical redesign of e-health to meet these challenges. Among others, three important levers for change have been identified: "*liberate the data*", "*connect up everything*" and "*my data, my decisions*". Fully capturing, integrating, linking participants and exploring health data will have a tremendous impact on improving the integrated diagnosis, treatment and prevention of diseases in individuals. In addition, it will allow the secondary use of healthcare data for research, thereby transforming the ways of providing healthcare [3]. However despite the potential advantages of the above vision, specific technological, legal and policy barriers have significantly delayed the implementation and uptake of such a redesigned healthcare system within Europe.

Particularly, in realizing the vision of personalized medicine, the secondary use of patients' biomaterial and data is very important, as innovative research techniques could reveal interesting biomarkers that were hitherto overlooked. At the same time, rules pertaining to the processing of personal data as well as biomaterial have to be complied with irrespective of how divergent such rules may be. Although the rules for the processing of personal data are more or less legally harmonized in the EU by the Data Protection Directive [4] (now to be replaced by the General Data Protection Regulation [5] by May 2018), the secondary usage of bio-specimen and associated data lack a harmonized and sometimes coherent legal framework. This includes the fact that the

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requirements of valid informed consent for research with biospecimens differ from country to country. This is also coupled with the fact that there is a margin of variation in the national implementation of the Data Protection Directive regarding the validity, scope and format of informed consent. As such, complying with varying legal norms from different jurisdictions is a considerable hurdle for cross-border research, where data and biomaterial are going to be exchanged across national frontiers.

A discussion on consent is important here because it is the gateway to patients having control over their biomaterial and data, and a number of regulations require that informed consent is a prerequisite for any biomedical research involving humans. This is the case for example, in clinical trials [6], or other research use of human biomaterial and related data [7]. Thus obtaining informed consent is generally practiced by the scientific community in medical research, and there are widespread checklists and tools for generating Consent Forms [8]. To safeguard the patient's autonomy, it is postulated that consent should be specific regarding, for example, the purpose of the planned research or the timeframe for usage of the biomaterial. This has led to the devevelopment of approaches such as "tiered" and "layered" consent that allow patients to agree to a specified use of their material for research, while placing restrictions on types of research they do not wish to be performed [9,10]. However, as indicated by the term "biobank", which represents a scientific service infrastructure meant for sample storage and exchange, a donor's specific ("narrow") consent may hamper exchangeability of banked specimens. This will in turn hamper research and hence medical progress that could benefit future patients [7,11]. For this reason, a number of commentators, such as Taupitz and Weigel have argued that a broad consent regime would be preferable for biobanks [12].

Other approaches, which aim at balancing the two positions of specific and broad consents have also emerged, including the notion of *dynamic consent* [13–15]. Dynamic consent frameworks offer an interactive personalized interface that allows participants to engage as much or as little as they choose, and to alter their consent choices in real-time. A number of projects have focused on developing IT systems for dynamic consent, such as EnCoRe [16], BIOSHARE [17], Reg4All [18]. However, the complexity of these solutions limits their immediate applicability in current clinical practice.

This paper focuses on the research activities within the recently concluded EU FP 7, the p-medicine project [19], for enabling the secondary usage of both patients' data and biomaterial. In this project, an infrastructure was created to facilitate the translation from current medical practice to personalized medicine. Part of the project's objectives includes ensuring privacy, non-discrimination, while aligning access policies to maximize protection of and benefits to the patients.

In this paper, we elaborate on current practices for obtaining consent for biobanking and the legal requirements for reusing the available biomaterial and data. We review existing European legislation for secondary use of patients' biomaterial and data for research, we identify types, scope and formal requirements for consent and their implications when developing electronic consent tools. Against this background, we propose and describe a modular IT tool named "Donor's Support Tool", whose three modules are designed to be attached to existing biobanks and personal health record systems and to enable citizens to actively provide and update their consent according to applicable national laws. Among the advantages of our solution are the simplicity and the generality that allow for a quick deployment of the tool and its modular adaptation in various contexts, national laws, biobanks and patient communication systems. At the same time, we recognize that technology is not the only limiting factor against the secondary use of patients' biomaterial and data. Medical practice and culture, regulation as well as citizens' awareness also play some roles.

The remainder of this paper is structured as follows: Section 2 identifies the legal requirements for secondary use of patients' biomaterials and data, while Section 3 presents the implementation of the Donor's Support Tool as a novel, modular tool enabling the secondary use of patients' biomaterial and data. Section 4 discusses the proof of concept deployment of the tool in a clinical setting and compares it with other relevant approaches. Finally, Section 5 concludes this paper and presents plans for further initiatives in this direction.

2. Legal requirements for secondary use of patients' biomaterial and data for research

The legal landscape for the secondary use of biomaterial and data in the EU is complex. There is no harmonized European regulation that covers both the processing of biosamples and associated (personal) data at the same time. Different regimes apply to each. At present the use of personal data, as mentioned earlier, enjoys the more harmonized framework. Thus, though there are still differences in the Member States' implementations of the Data Protection Directive (including with regard to the scope and formal requirements for valid informed consent), the General Data Protection Regulation may be expected to reduce the amount of fragmentation in in many areas. Even so, as Article 89 (2) of the new Regulation suggests, there may still be national peculiarities in the area of derogations by the Member States in the field of research. It remains to be seen what these derogations will be and whether they will result to varying frameworks in the states [20]. But in any case, certain underlying principles are clear and will remain the starting point for any processing of personal data. These include the need for a legal basis for the processing, of which one may be the informed consent of the data subject, as well as the prohibition on further processing that is incompatible with the original purpose. Thus, secondary use of data is generally limited by the original purpose for which the data was collected. An exception is where Member States implement national regulations that allow processing of personal data in the public interest such as research, without consent, and subject to the provision of suitable safeguards (Art. 8 (4) Data Protection Directive [1]).

In this regard, some Member States have enacted specific laws on biobanks or health research that specify rules regarding the collection, storage and use of biomaterial and data [21]. In the Member States where there is no such specific regulation, it must be considered whether data protection rules apply for biosamples – which enjoy a complicated dual status as biomaterial and (potential or in some views, actual) data. In this respect, one school of thought sees biomaterial as carriers of personal data, thereby necessitating the application of general data protection law in the absence of a more specific law on the processing of identifiable biomaterial [22]. This approach arguably is reflected e.g. in the publication of the Danish Data Protection Authority, which states that biobanks are covered by the Act on Processing of Personal Data [22].

In contrast, another school of thought believes that human samples are not personal data, because the information contained in the material must first be extracted before it can be regarded as personal data [23]. Be that as it may, it is arguable that the use of biomaterial should mirror limitations and protections seen in the area of data protection, since biomaterial is at the very least a carrier of personal data. The doctrine of analogical application of written legal regulations applicable in the German legal system could be cited as an example here of how this mirroring should be applied. The doctrine holds that where there is a non-regulated case, which is similar to a regulated case and requires (in particular for reasons of equivalence and justice) identical legal consequence, the