Designing a Framework of Components to Support Patient Engagement in Research

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Abstract. In the context of the German Medical Informatics Initiative (MII), where data reuse and data sharing are major goals, cross-site, long-term research on patient care data can only be conducted lawfully with informed patient consent. Thus, the MII consent working group developed a template form for patient information and broad consent based on work that has been done for a former biobank project. The broad consent enables the patient to consent to the use of a wide range of the documented data including research purposes. Therefore, a user-friendly tool is needed which not only supports the storage and maintenance of the patient's consents but also allows him to easily review or withdraw his consents. Furthermore, the tool should allow the patient to review the use of his data in research projects and possible publications. This is why we developed a concept of how such a tool could be integrated into the clinical and research system landscape and implemented a prototype as a proof of concept.

Keywords. Informed Consent, Patient Participation, Data Sharing, Consent Management

1. Introduction

1.1. Background

Reusing "real world data" which have been documented during patient care processes for research or other purposes in Germany either requires to be based on a national or state law or shall only be based on a patient's respective informed consent. In contrast to a typical consent in clinical trials, however, in the case of reusing clinical data from patient care the research question and type of analysis for future research usage is not yet defined and it is in the interest of the researchers to keep the definition of the field of research as broad as possible [1]. Identifying the need for such a broad consent for biobanking in Germany, researchers have initiated a consensus-based development process and in 2016 provided a template for broad consent in biobank research [2]. Further, in the context of the German Medical Informatics Initiative (MII), where data reuse and data sharing are major goals, cross-site, long-term research on patient care data can only be conducted lawfully with informed patient consent. Thus, the MII consent working group, based on the above-mentioned template for biobanking,

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developed a template form for patient information and consent, which comprises a number of predefined modules to which the patient can agree [3]. The modularity of this template, differentiating between (1) reuse of data documented during a hospital care process, (2) reuse of biomaterial for research, (3) linking hospital care data with health insurance-based outpatient data and (4) allowing to be recontacted, makes this broad consent similar to the dynamic consent [4]. Independent from small differences from the ethical perspective, both concepts at least require a user-friendly tool which not only supports the storage and maintenance of the patient's consent to the respective modules but also allows him to easily review his consent status and withdraw the consents to all or single modules whenever he likes. This illustrates the need for a dedicated personalized, digital communication interface that connects researchers and participants, placing participants at the heart of decision making [7].

On the other hand, in Germany two large networked research initiatives (MII and GBA = German Biobank Alliance) have also independently from each other identified the need for a central portal to always keep the broad public and the general medical research community informed about the use of samples respectively data within respective research projects, which are based on sample and data repositories of such initiatives [3, 6].

Focus group discussions in a GBA stakeholder workshop and with various researchers however have brought us to the decision, that patients would typically build up a "relationship" to their direct caregivers and the caring hospital, but not to any joint research network in which their samples/data might be used. Therefore, the establishment of general information portals within such initiatives (albeit they might also provide general information for patients) does not free the hospitals from the challenge to establish their local patient portal as a patient interface for twenty-first century research networks. Such a portal should, amongst other functionalities, at least facilitate a two-way communication with patients to stimulate a more engaged, informed and scientifically literate participant population where individuals can tailor and manage their own consent preferences [7].

1.2. Requirements

Considering the fact, that in Germany within the MII almost every university hospital is currently establishing so-called data integration centers (DIC) as research IT infrastructures, which in the long term shall support large-scale data sharing across all those hospitals, we see the need that respective (mostly similar) requirements which additionally focus on biomaterials-based research shall also be integrated in such an environment. A DIC shall at least integrate and provide interfaces between modules for identity management (e.g. pseudonymization, record linkage), consent management, project proposal review and project registration, as well as various types of research repositories for feasibility studies, patient recruitment support and large-scale analysis.

Thus, we envision a framework where, in order to support patients in their informed participation in upcoming research projects as donors of data and biomaterial, we will use dedicated functionalities of an EHR-linked patient portal to manage the patient's consent preferences and provide the patients with information about future usage of their data/biomaterial in respective research projects.

This patient portal shall however not only focus on such research aspects but additionally provide functionalities for communicating with care providers in the context of the respective care situation. Finally, it shall in the long run also provide a

platform for communicating patient-generated data (e.g. patient reported outcome questionnaires, but also sensor-based data generated by various types of wearables).

In order to, on the one hand provide a direct, personalized interface to the patient, but further also provide critical information and restrictions for a patient's data usage in the research context, such a patient portal needs to be closely linked to various research IT components, such as for example a consent management and an identity management platform.

2. State of the art

Kaye et al. have described active patient engagement in research processes as the usage of digital technologies to enable research partnership through a personalized, digital communication interface that connects researchers and participants, placing participants at the heart of decision making [7]. A review of the websites of major German medical research networks (e.g. the German centers for health research, the GBA and the MII) has illustrated, that those networks currently have not yet implemented such type of "two-way communication". Their typical consents directed toward patients are restricted to a one-way communication with general information about the respective disease and the possibility to query/retrieve a list of disease-specific clinical trials.

On the other hand, research about the design, implementation, evaluation and impact of patient portals has been reported already since many years, mainly focusing however on the application of such portals for patient care scenarios before/after an inpatient stay in a hospital (e.g. [8-11]) or even during an inpatient care situation [12-14]. Rarely have research scenarios also been supported by such patient portals. One very promising example, however, for a digitally supported two-way communication with patients has been established in the RUDY (Rare UK Diseases of bone, joints and blood vessels) study, encouraging patients to be actively involved at all stages of the project's development [15]. The researchers pioneer in their approach to a custom-developed electronic platform where patients can contribute information over time about their disease experience, lifestyle and clinical history. This is combined with a state-of-the-art dynamic consent model enabling tailored participation and changing consent preferences over time. Finally, the RUDY platform also supports outputs of research to be posted on the participants' secure page [5].

Within GBA and MII currently paper-based templates for a broad consent have been agreed upon. Nevertheless, the organizational structures and logistics to establish a suitable process for acquiring this modular consent from patients that are admitted to a participating university hospital still have to be defined. Even though it is obvious, that such a new process needs to be digitally supported. To our knowledge, this is the first publication which analyses the complex interactions between several IT systems (partly from the clinical context, partly research IT solutions) as components of the hospital information system infrastructure.

3. Concept

The components in the proposed framework can be divided into two categories: Clinical IT systems and research IT systems. The first one includes the Electronic

Health Record (EHR), which holds the clinical data from routine patient care, and the EHR patient portal, which serves as a web frontend for interaction with the patient. The research IT systems comprise the identity management for pseudonymization and depseudonymization, the consent management for storing and retrieving the patient's consents, the feasibility platform for checking the feasibility of studies, the data warehouse for data provision and finally the project management, which keeps track of the project proposals and the approved study projects.

There are three actors in our framework: (1) Patients, who manage their consent and inform themselves about the usage of their data using the EHR patient portal, (2) researchers, who want to use clinical data for research projects, and (3) the Use and Access Committee (UAC), which has to approve the individual research projects.

The following describes the processes that take place when a patient manages his consent with the EHR patient portal, researchers initiate research projects and the patient is finally notified about the use of his data.

The first process (Figure 1) is initiated by the patient who agrees to use the EHR patient portal: For this, the patient is given an activation link (for instance at consultation prior to the planned admission or by mail/postal letter) so he can activate his account himself. The patient identifier (PID) is created when a patient's planned admission is documented in the administration/billing system. The pseudonym (PSN) and the EHR patient portal account are created directly afterward. When the patient has activated his account and logged in to the EHR patient portal, the PSN belonging to the PID is retrieved from the identity management. Now the patient fills in his consent form in the patient portal. The resulting consent policies (CPx) and the PSN of the patient are then sent to the consent management where they are stored in the consent management database.
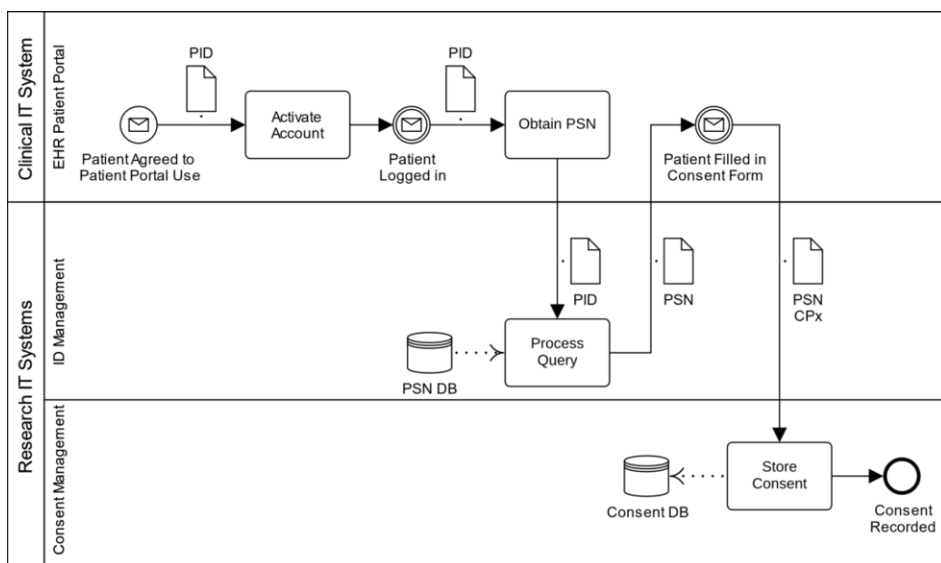

Figure 1: Swimlane diagram (BPMN model) illustrating the interaction and interfaces between the EHR Patient Portal, the ID Management and the Consent Management when a patient enters his consent policy (CPx).

In nightly data extraction, transformation and loading processes (ETL) the new medical data (MDAT) and the consent policies (CPx) are extracted from their primary systems (Figure 2). For privacy reasons, in the transformation process the PID is substituted by the PSN. Such data are then integrated and loaded into the feasibility platform.
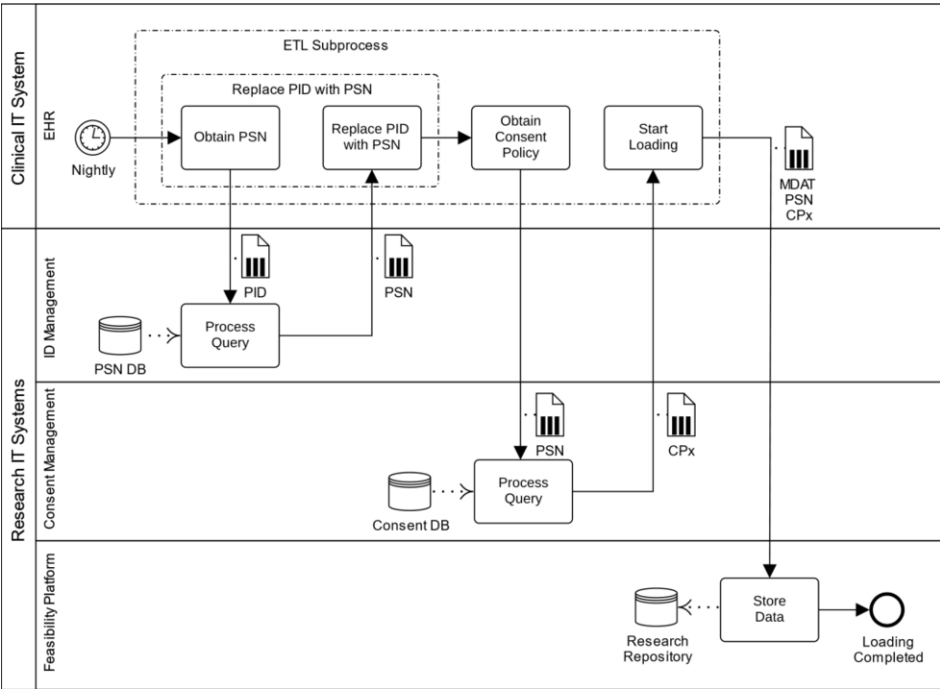

Figure 2: Swimlane diagram (BPMN model) - Every night, the new medical data (MDAT) and the consent policies (CPx) are transferred from the respective systems to the Feasibility Platform.

The third process (Figure 3) illustrates the steps from a researcher's submission of a research project proposal, its approval by a hospital's use and access committee, and the provision of the respective pseudonymized data set to the researcher. To keep track of the status of the project, it is initialized in the project management and linked with the PSN of all provided data records. Then for each PSN, the corresponding PID is retrieved from the identity management and the respective project information is stored for all those patients in the EHR patient portal. This again triggers a notification (e.g. via mail) of those patients about the new information in their portal.
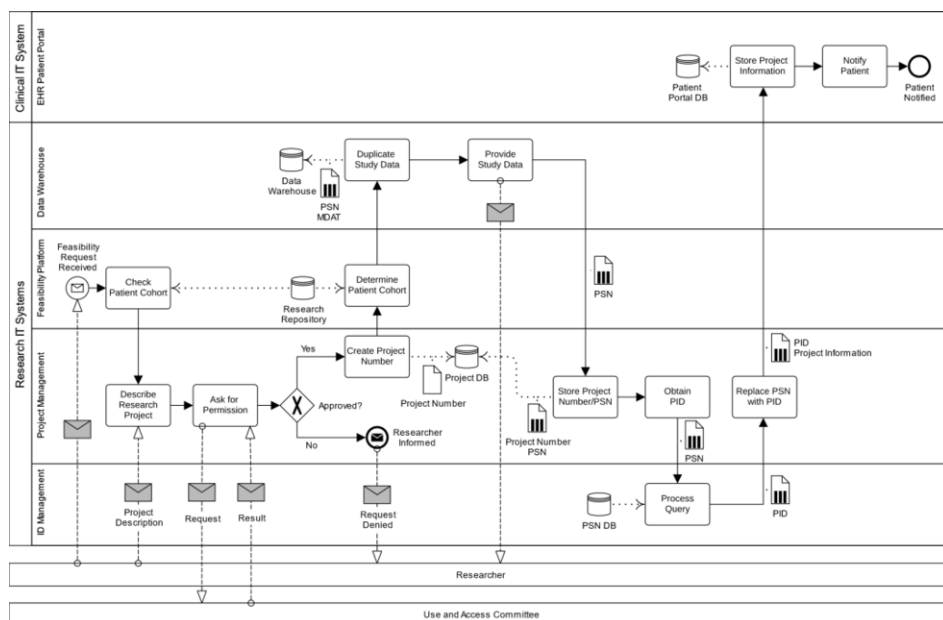
Figure 3: Swimlane diagram (BPMN model) illustrating the process steps to be pursued when a research project is submitted and approved.

Obviously, two systems store the participants in a research project: The project management and the EHR patient portal. We deliberately accepted this redundancy. When a patient uses the EHR patient portal to investigate which research projects have used his data, the EHR patient portal should respond as quickly as possible for usability reasons. If the EHR patient portal hadn't additionally stored this information, the EHR patient portal would have to contact the identity management and the project management for such a request. This would result in higher response times and make the system less user-friendly.

In addition to the main processes just described in detail, there are many other processes: For example, another goal of this framework is to notify patients about newly published manuscripts for which their data have been used. If the patient's data are published in a manuscript/literature the process is very similar to the second half of the third process described above, so we only highlight the differences: Now the researcher starts the process by informing the project management about the publication of a new manuscript. Subsequently, this system adds information about the manuscript in the project database. It also retrieves the pseudonyms of the patients to be contacted from this database using the corresponding project number. Because the EHR patient portal cannot work with pseudonyms, the project management uses the identity management to resolve the pseudonyms back into patient identifiers. Thereafter, the project management sends these patient identifiers together with information about the manuscript to the EHR patient portal. This system then stores the information in its database and notifies the patients.

4. Implementation

The patient portal has been implemented as a prototype which, at the moment, is under evaluation by potential users. The wireframe mockup (Figure 4) shows how the patient is enabled to manage his modular consent policies himself.
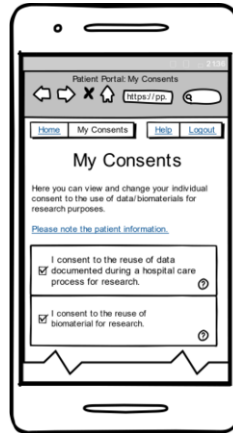

Figure 4: Wireframe prototype of the EHR patient portal web user interface.

5. Lessons learned (Discussion)

Based on the above described processes we could define a framework of interlinked software systems comprising systems from the clinical care environment (EHR system and EHR–integrated patient portal) and a hospital's research IT infrastructure. Strict consideration of data protection regulations, which require the de-identification of data sets for research purposes, can be solved by the integration and usage of the identity management system in the respective process steps.

Before such a system can be deployed for routine use, however, comprehensive usability and technology acceptance studies need to be pursued with patients as the potential system users. Further, the ethical discussion about the details of the various broad consent modules needs to be finalized with data protection officers and ethics committees. Last but not least, such a digital patient portal needs to be provided with a desktop-based access and as an app for smartphones. Even though those technologies will increasingly be applied also by elder patients, we still need to provide traditional paper-based patient information and consent forms, since there will for a long time remain a group of patients with preferences for this traditional way.

6. Conclusion

As to our knowledge, only very few of the processes we have identified and described above have yet been finally agreed upon in the standards community. Thus, it would be an important future step to discuss all those scenarios within the IHE community and work on the future development of dedicated integration profiles.

Conflict of Interest

The authors state that they have no conflict of interests.

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