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Design and Implementation of an Informed Consent Process for a Standardized Health Information Exchange Solution on the Example of the Lower Saxony Bank of Health

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Abstract

Objective Multicenter medical treatment requires health related data to be available across institutions. Since health information exchange solutions are emergent, fulfillment of privacy needs, including patients' informed consent, is vital for successful data exchange. Methods We designed a software supported consent process for the recently founded Lower Saxony Bank of Health (LSBH) with regard to particularities of German law. To implement the application, web technologies and well-described interfaces to IHE XDS profile components have been used. Results A two staged process has been developed. A special consent application creates a customized form containing all orally given constraints defined by the patient. The form is printed out and signed by the patient while an electronic policy is created and registered at the LSBH.
Conclusion The process completely reflects a conventional informed consent procedure but increases simplicity, clarity and understandability of the consent form. Technical and legal restrictions in Germany create a media split becoming a media crack in some environments. Availability of signature cards could improve the process by making it completely electronic.

Keywords:

Health Information Systems, Community Networks, Health Communication, Electronic Health Records, XDS, XDR, IHE.

Introduction

Due to the constantly increasing distribution of health care services, new ways of data access across independent providers are necessary. Special health information exchange (HIE) networks called bank of health[1, 2], independent health record bank[3, 4], health record bank[5] or health information bank[6] try to address these needs and provide patient centered medical data across institutions. Building on these concepts and further developing the idea of a health bank requires consideration of privacy needs, local regulations and a variety of software systems by a variety of service providers. Even procedural changes have to be integrated into different kinds of service providers, ranging from stationary treating hospitals through ambulatory services to care takers and even the patients themselves.

The recently founded Lower Saxony Bank of Health (LSBH) [7], located in the metropolitan area of Braunschweig, Lower Saxony (Germany), addresses all these requirements and forms a format agnostic, standardized and expandable HIE solution based on international standards. Moreover, the LSBH aims at providing a distributed electronic patient record.

Medical data is regarded to be the most sensitive personal data of all, and thus needs to be secured and protected most in HIE systems. About 71% of potential users are concerned about privacy and safety [8]. Although consent / permission is identified as one of the main security fields by the Health Information Security and Privacy Collaboration [9], less than half of patient-care-specific data transfer cases in European countries are explicitly granted by patient consent. Thereof, only about a quarter are written informed consents [10]. Until now, in Germany, electronic transfer of medical data was primarily limited to laboratory data, but emerging communication solutions like the LSBH are clarifying the need for reliable consent processes.

Reflecting the patient's intention is possible in various ways and concrete implementations are strongly linked to national eHealth strategies and privacy laws. Related work on electronic informed consent processes mainly focus on operations and procedures [11-13]. An informed consent process for transfer of medical data is not addressed. While in Austria over two thirds of patient data storage and transfer is done without any consent [10], Finnish law requires a written consent to store, access and provide medical data in a national electronic health record archive [14]. Where consent is required, two different approaches do exist. In Scotland giving the patient opportunity to reject is regarded as sufficient (opt out) whereas Belgium, France, Spain and other countries require an explicit agreement (opt in) defined in their eHealth strategies and laws [15]. German national and federal state laws restrict transfer of personal data to cases with written permission. This applies to data used for medical care processes across several health care providers, as well as for research purposes, whereas one basic principle of LSBH permits medical data use for research. If medical data are transmitted to a singular specific receiver like a doctors letter in ambulatory care, no explicit consent is needed. Implementing these requirements into an applicable consent process is the aim of this paper.

Methods

Conceptual design and establishment of the LSBH was closely accompanied by creation of a refined data security and privacy concept regarding all national and federal regulations and laws. Building upon these, the structural and procedural design has been developed.

LSBH concept and structure

Technically, the LSBH is implemented as an IHE Cross-Enterprise Document Sharing (XDS) affinity domain. A central community node directs communication of several local nodes. It provides a Master Patient Index (MPI) by implementing the IHE profiles Patient Identifier Cross-Referencing (PIX) and Patient Demographics Query (PDQ). All available medical documents are encapsulated into HL7 CDA - if not originally in CDA format - and indexed at the XDS Registry linked to the MPI which delivers the patient identity feed. Using only an index ensures that there are no central copies of sensitive medical data. Directed communication is achieved by implementation of the IHE Cross-enterprise Document Reliable Interchange profile (XDR). Additionally, the community node provides modules for Security Policy Administration (SAML/XACML) and Audit Trail & Node Authentication (ATNA). Extended services are hosted as applications on an application node. An example is the consent application we developed. A component overview is shown in Figure 1.

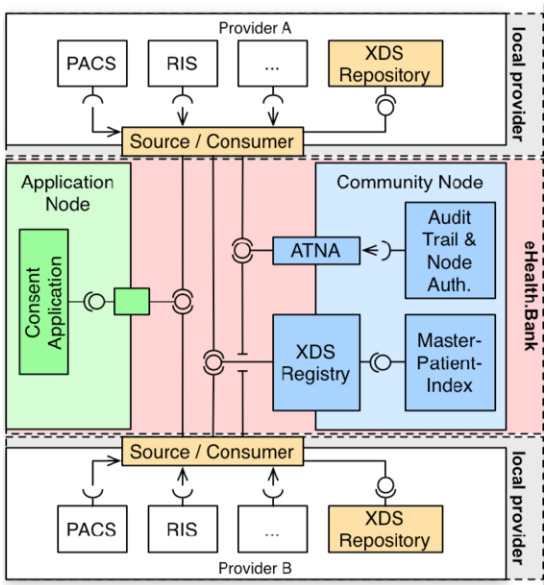

Figure 1 – LSBH component overview showing local node (orange), community node (blue) & application node (green). Central components maintained by the LSBH (red frame)

Access restrictions and privacy enforcement

The strict separation of referencing and storage facilitates a maximum of privacy. Every single access is secured by an encrypted hardware VPN tunnel and a distinct public key infrastructure for all participating nodes, and is logged by the ATNA module. Heuristic intrusion detection algorithms monitor activities and prevent unauthorized access.

Stored documents and references are secured by technical representations of the patient's consent implemented with SAML/XACML. Creating these policies is the main purpose of the developed consent application. Since creating policy documents should be a central service of the LSBH, every provider has to be able to integrate an appropriate application into local workflows and procedures. Therefore the consent application was developed with web technologies and is provided as a web application on a central application node hosted by the LSBH. Access to the application is controlled by client certificates and a signed URL containing the local user context, a patient identifier, case details and the signature. Additionally, validity of the URL is time-limited.

Results

German law demands distinct privacy concepts for all kinds of personal and especially medical data. Through the federative organization of Germany, each state has its own privacy regulations in addition to the common ones. Accordingly, medical data has to be stored by, and may be processed only by, the owner or author. This especially applies to an undirected communication. The patient has to have complete control over who provides his or her medical data and who is able to see it when, where and for how long. Even differentiation of document types has to be possible.

Design of informed consent form

The paper-based consent form has been created with mentioned privacy requirements and choices in mind. Apart from general information about services provided by the eHealth Bank, it specifies:

1. the right to register data at the LSBH registry by the issuing health care service provider,
2. the right to retrieve data with special refinements for
   a. the time since data was made accessible,
   b. the other health care providers from which data can be retrieved and
   c. which document types can be accessed.

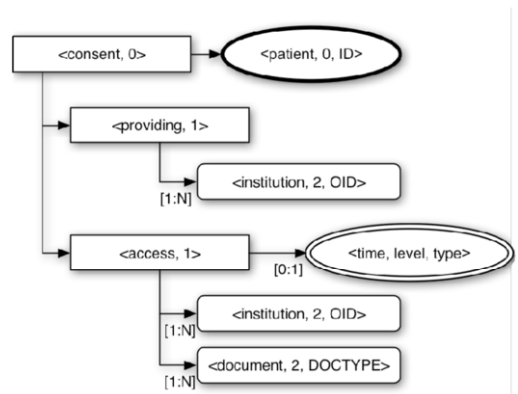

Figure 2 - Content of a consent form as GN-DTD

The content of a consent form in graphical notation for document type definition (GN-DTD, [16]) is shown in Figure 2. The full consent is valid for 56 days and can be revoked or changed at any time.

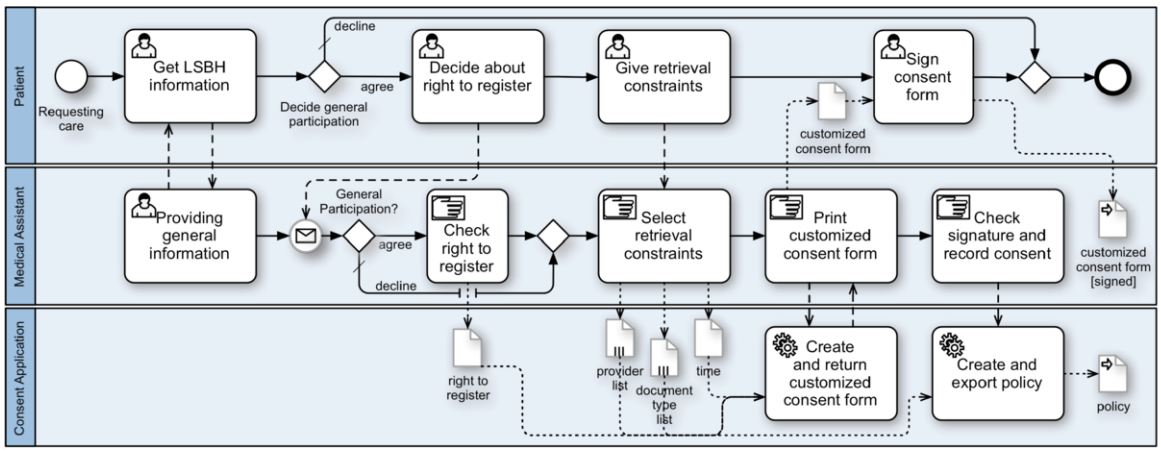

Figure 3 - Complete consent process

Consent process

The patient requesting medical care at the first visit to a health care provider usually authorizes document registration and storage. Consent creation, therefore, has to be integrated into existing admission processes while meeting the following requirements:

1. facilitation of all choices and consent restrictions,
2. integration into existing admission workflows, and
3. lawful signature of consent. [17]

Addressing the patient's right to choice is possible by creating an interactive application reflecting all agreement points as well as possible options for included health care provider, document types and time limits. According to German law, an informed consent has to be either signed by hand on a paper-based form or by an adequate electronic signature mechanism. Since patients currently have little chance to create a qualified (appropriate) electronic signature, a media split between signed and electronically created consent is necessary. This, on the other hand, integrates well into general practitioners' and medical centers' workflows insofar as consents are given to the patient in paper-based form.

The process, as indicated, begins with a patient arriving at a health care provider. A medical assistant informs the patient of services provided by the LSBH and gives general information about the consent process. If the patient wants to give access to previously registered documents or wants the health care provider to be able to register new documents, the medical assistant opens the consent application. First, the patient decides whether the health care provider has the right to register documents. If granted, the medical assistant checks the corresponding option and asks for the patient's retrieval constraints timeframe, providers and medical document subject types. The consent application creates a paper form reflecting the patient's choices. The form is printed and manually signed by the patient. If done so, the medical assistant checks the signature and, if valid, checks the respective button. This triggers the consent application to create a valid LSBH policy and to register access rights for the health care provider. The paper-based consent form is archived locally for later inspection by the LSBH. The complete consent process is displayed in Figure 3.

Consent application

As the process shows, creation of the consent form and registration of the policy is done by the consent application. Since a broad variety of health care providers should be able to use services offered by the LSBH, access to applications needs to be independent of local systems. At the same time, a good integration into admission workflows by utilizing existing user context has to be achieved. Therefore, the consent application has been developed as a web based application. It has to be called with valid user data, allowing access only from software components giving a valid patient context. This way, both security of access and continuation of context are ensured. Local software components only need to create a valid URL.

The front end is reduced to a single page in order to minimize the number of necessary clicks. All information about the selected user and possible choices are organized into sections. Section one shows general patient demographics. Section two allows checking whether to allow registration of documents or not. Section three contains two multi-selectable combo boxes, one for the health care provider allowed to a receive data, and one for the allowed document types. Time constraints can be entered either by clicking predefined buttons from "6 month" to "6 years" or by selecting a specific date. By default all combo boxes are collapsed, allowing all institutions and all documents with no time limit. A final section shows a summary of chosen options in textual form and two buttons to print the consent form and register the policy. Figure 4 shows a screenshot of the interface in default LSBH style.

Since a seamless integration into local software components is intended, the style of the application might be determined by user context.

The paper-based consent form is created by a special stylesheet for print, disabling all visual attributes and removing unnecessary content. Thus, the built-in print function of the browser or web container can be used. The resulting consent form is shown in Figure 5.

The application is written in PHP building the general frame. HTML with Javascript and jQuery [18] is used for advanced user interface design. The core application validates the URL and selects and customizes page snippet templates. User input handling and appropriate interface reflection is done client-

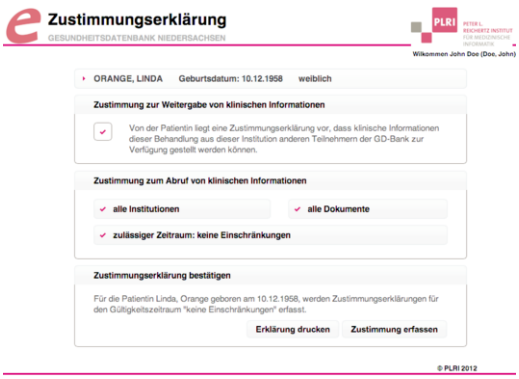

Figure 4 - Screenshot of the consent application [German]

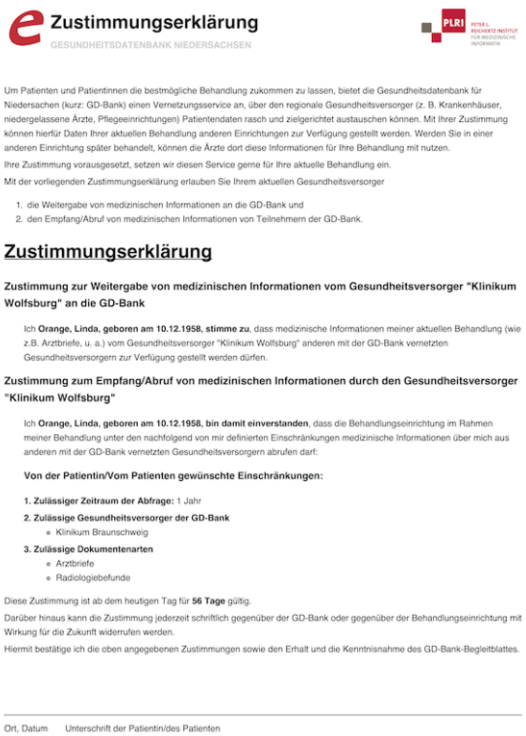

Figure 5 – Paper-based consent form created by the consent application [German].

side. Both on-screen and printed output are themed with respective CSS definitions. Input fields are only accessible if customization is intended. The interface is compatible with mobile browsers but constructing and calling the respective URL still has to be implemented into preceding applications. Enhancing the application with a patient-initiated query functionality would cause a security risk and is therefore not intended.

Discussion

Derived from German regulations, ascertaining the patient's will and obtaining an informed consent is crucial to all health data exchanging systems. The respective forms have to be understandable, clear and complete. Optimizing the consent form's content is an easy way to enhance clarity.

Sustaining local workflows

The overall consent process has been designed with regard to greatest flexibility in terms of health care providers' processes. By making the application accessible from every step of a workflow, both patient admission on arrival and consent creation during care are possible. Simply constructing a URL and calling a web application facilitates easy integration into existing software components and thus the preservation of user context.

Weaknesses of the current process

Technical restrictions and regulations from the LSBH system as a whole are creating some limitations for the consent process and embedded application.

If a health care provider archives medical documents and informed consent forms electronically, the produced paper-based consent form has to be scanned and converted into an appropriate archiving format. This transcription with change of storage media (*media crack*, [19, p160]) is not a specific problem of the LSBH consent process. All informed consent forms for medical operations and procedures are currently paper-based in Germany. Appropriate electronic signature methods do exist but are not applicable, due to the lack of accessible signature keys. Potential signature cards like the new German identity card or the electronic health card are not capable of creating qualified electronic signatures, yet.

Due to security reasons, the process currently is intended to be executed synchronously. If a consent form is created and printed, it has to be signed and accepted as valid in short order. That means, saving a "pending" consent and accepting it later is not supported. If the time limited URL of an open consent application expires, the process has to be triggered again from the source system. However, refinements can be simply selected again to represent the printed consent form.

Further development

As soon as the creation of electronic signatures is widely available, the consent process could be completely electronic. The integration of mobile devices for reviewing the informed consent form would solve both the media crack as well as the need for a synchronous process. A valid security context could be created and maintained for as long as the patient reads the agreement.

Conclusion

We designed and implemented a first-pass solution for an electronically supported informed consent creation process. A two-staged procedure ensures creation of a clearly understandable and customized consent form.

German legal and technical regulations restrict completely electronic mapping of the process. As soon as creation of qualified electronic signatures is widely available through existing signature cards like the German health card or the new ID-card, a fully electronic representation eliminating the media crack is considered.

Limitations

The LSBH currently (as of March. 2013) is in early testing stages. Enabling communication of two regional hospitals is in progress, so no real-world tests could be run. However, the process was developed with direct involvement of the future connected health care service provider.

Many technical and legal particularities apply specifically to Germany. A similar process in other countries may face different requirements.

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