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Implementing Modular Research Consents Using IHE Advanced Patient Privacy Consents

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Abstract. The re-use of healthcare information for biomedical research is increasing and with it the importance of a consent management framework implementing computable consents. Based on requirements concerning a consent representation the Advanced Patient Privacy Consents (APPC) Profile of Integrating the Healthcare Enterprise (IHE) is evaluated and mapped to these requirements. As IHE APPC was developed for computable patient consents, the mapping of consents for research projects is possible by re-using the elements defined. Compared to other approaches like gICS, approaches using APPC can be based on commercial software products and integrated into IHE environments. IHE APPC was already successfully used in EHR projects like INFOPAT. For interoperability reasons IT platforms intending to support biomedical research including clinical data, research data, biomaterial and imaging data, IHE APPC seems to be an appropriate standard to choose.

Keywords. Consent, research, IT infrastructure, IHE, standardization

1. Introduction

With the spreading re-use of healthcare information for secondary use purposes like biomedical research, the importance of a computable representation of consents is increasing [1-4]. First, this results from legal requirements for informed consents especially for re-using data for research [5]. Further, using paper is no solution since checking paper-based consent forms manually before allowing the use of data delays the process and is error-prone. Scanning paper-based consents can only be part of the solution in case it is required for legal reasons. Thus, an electronic representation with automated consent processing is necessary.

In terms of consent there are different possible approaches. Broad consent is often desirable since the specific use cannot be precisely defined beforehand. However, informed consent, as requested by the government [5], has to be specific about the intended use. This requirement can be met by a combination of broad consent and specific consent for specific uses – so called dynamic consent.

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For interoperability reasons, computable consent should be based on open and internationally accepted standards. IHE defined in the IHE Advanced Patient Privacy Consents (APPC) Profile how to implement consent documents for health information exchange scenarios in patient care based on eXtensible Access Control Markup Language (XACML) [6].

The objective of this work is to show how the IHE Profile APPC can be used to define consents for different – especially retrospective – research topics (e.g. oncologic research projects, cardiologic research projects) as modules.

2. Methods

First, the requirements concerning the computable representation of consents are described. Afterwards, the IHE Profile APPC is explained.

2.1. Requirements

The requirements are retrieved from experts via unstructured interviews and legal documents.

A computable representation of consents needs to be able to reference different data types (1) (e.g. clinical data, patient reported outcomes, genomic data, imaging data, biomaterial). It also requires the possibility to define policies for access to all these kinds of data including biomaterial (2). Further, the intended use of the data needs to be specified (3) (e.g. use for specific trial, use for recruitment, re-contacting the patient) [5]. Not only intended use can limit the use of data, but also the time of validity of a consent (4) is often used for obtaining informed consents. Legislation requires that consents can be withdrawn at any time (5) [1, 3, 5]. As computable representations should be binary (permit/deny), the policies need to be fine-grained (6). But patients also sign multiple consent forms for different studies or purposes of use. Thus, a solution has to allow for several interacting consents to be manageable (7) [1, 3]. Since signatures according to law (e.g. in Germany) are required, it is necessary to archive the signed consent form and link it to its computable representation (8). Consent representations should be policy-based to allow for automatic computation when access to certain by the user previously specified data is requested (9) [1, 3].

2.2. Advanced Patient Privacy Consents

The IHE Profile APPC, like all IHE Profiles describes a number of use cases the profile is designed to support. Use cases include (1) consenting to access to health information based on the facility which is trying to access that information, (2) consenting to access based on a specific diagnosis with an XDS folder per diagnosis code, (3) denial to sharing of specific information based on the consent, (4) denial to sharing of information with a specific organization based on the consent and (5) denial to sharing of a specific document based on the consent.

APPC is a so-called Content Profile, meaning it defines the content of a specific document (i.e. consent document). The document consists of at least one root policy set. The root policy set can reference zero to many policy sets or individual policies, while each policy set has exactly one target. A policy contains zero or more rules.

A target may have zero to many subjects, resources, actions and environments. The subjects represent the actors (e.g. healthcare organization, individual physician) requesting access to data. Resources are the objects that are requested to be accessed (e.g. specific patients' data, data from a specific facility). An action describes the transaction to be performed with a certain data type. The environment allows for access to be granted only for e.g. a specific time period (see **Figure 1)** [6, 7].

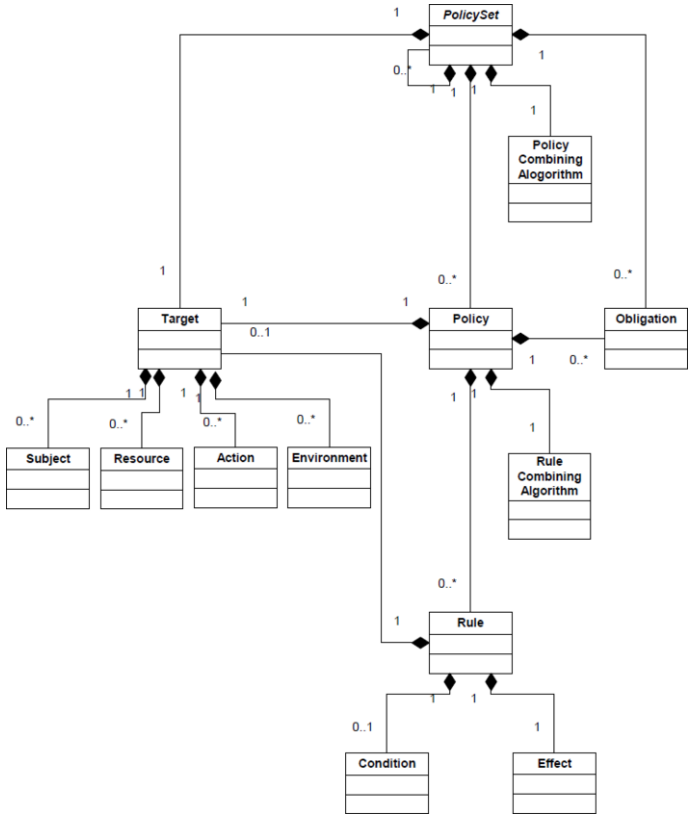

Figure 1 - Policy language model according to APPC / XACML 2.0 Core [8]

2.3. Mapping of requirements to APPC

Mapping the requirements to an APPC compliant solution was done by two experts sequentially. For each of the requirements a possible solution in APPC was investigated to be able to fully implement the respective requirement.

3. Results

The requirements as implemented using IHE APPC are summarized in Table 1. Different data types are referenced in APPC as resources. E.g. lab results are documents from a specific facility (i.e. laboratory). Biomaterial and imaging data is referenced the same way. The intended use for data is specified in subjects (e.g. a specific study, research in

general). The validity of specific consents is defined in environments. Withdrawing the consent is solved in APPC by removing the relevant policies and/or policy sets from the consent document. Fine-grained policies and the management of interacting policies is done using rules, policies and policy sets. Breaking down consents to rules allows for an atomization of consents and thus fine-grained policies. As consents are managed fine-grained interacting consents can be identified and implemented. In case consents contradict each other, it has to be defined whether there is a general ruling of deny overrides or permit overrides, depending on an opt-in or opt-out strategy.

Table 1. The mapping of requirements for modular research consents to the solution with IHE APPC.

Requirement	APPC solution
(1) Reference different data types	As resource
(2) Policy for each data type	Policy specified for data type
(3) Purpose of use	In subject
(4) Time period of validity	In environment
(5) Withdrawal	Deleting policy (set)
(6) Fine-grained policies	Rules, policies, policy sets
(7) Interacting consents manageable	Rules, policies, policy sets
(8) Link from signed form to computable representation	IHE XDS Provide and Register Document Set with Document Addendum Option

4. Discussion

IHE APPC seems to be capable of expression of modular research consents from scratch. However, there are different approaches to implementing computable research consents like gICS [1, 3]. gICS in contrast to IHE APPC uses modules (APPC: policy sets), policies (APPC: policies and rules) and a consent template. Since the consent template is a template to derive consent forms from, the same would be possible with APPC.

The INFOPAT project [9] implemented the consent management for the Personal Cross-Enterprise Health Record using IHE APPC [7, 10]. Consent was mainly implemented for access and upload of data in a care setting. For transmission of data from the PEHR to a regional research platform [11], consent based on APPC was implemented using a policy: Pseudonymized transmission of data from a PEHR to the research platform using a binary option of yes or no. Therefore, this approach cannot fully be compared to using IHE APPC for complex research consents.

Computable consents, also called eConsent, are not only about IT. Mostly, it is about processes to design informed consent forms (human-readable and computable) and policies accordingly. Knowledge about the intention of text in informed consent forms is required to define the correct policies. Thus, Bahls et al. propose to re-use text snippets as often as possible for similar research purposes, since policies can also be re-used [1].

IHE APPC is successfully implemented in several commercial products (see *https://connectathon-results.ihe.net/).* That makes it easier to use products already on the market also for research EHRs, knowing the topic of consents is addressed and interoperable already.

The analysis of IHE APPC provided does not only apply to fully paper-free eConsent. However, for fully paper-free and functional eConsent the consent document

needs to be supplemented by a digital signature and an XDS environment for storing signed consents.

5. Conclusion

The informed consent forms as needed for research purposes in the Medical Informatics Funding Scheme of the German Federal Ministry for Education and Research (*ger:* BMBF) can be implemented based on international, open standards (i.e. IHE APPC). In the future, we will implement consents based on IHE APPC in the HiGHmed project [12] and will evaluate the usability in use cases where patient consent and data privacy are relevant.

References

[1] T. Bahls, W. Liedtke, L. Geidel and M. Langanke, Ethics Meets IT, Aspects and Elements of Computer-based Informed Consent Processing, *Individualized Medicine. Ethical, Economical and Historical Perspectives*, Springer International Publishing, 2015, 209-229.

[2] B. Schreiweis, G. Schneider, T. Eichner, B. Bergh and O. Heinze, Health Information Research Platform (HIReP) - An Architecture Pattern, *Stud Health Technol Inform* **205**(2014), 773-777.

[3] M. Bialke, T. Bahls, C. Havemann, J. Piegsa, K. Weitmann, T. Wegner and W. Hoffmann, MOSAIC--A Modular Approach to Data Management in Epidemiological Studies, *Methods Inf Med* **54**(2015), 364-371.

[4] G. Schneider, B. Schreiweis, R. Pahontu, T. Eichner and B. Bergh. Towards a Holistic Biomedical Information Platform for Primary and Secondary Use Settings. *Stud Health Technol Inform* **223**(2016), 54-62.

[5] European Union. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). Official Journal of the European Union 59(2016): 1-88.

[6] Integrating the Healthcare Enterprise. IHE IT Infrastructure - Technical Framework Supplement - Advanced Patient Privacy Consents (APPC). IHE, 2016.

[7] O. Heinze and B. Bergh. A model for consent-based privilege management in personal electronic health records, *Stud Health Technol Inform* **205**(2014), 413-417.

[8] OASIS. eXtensible Access Control Markup Language 2 (XACML) Version 2.0 In: Moses T, (ed.). OASIS, 2005.

[9] INFOPAT e.V. INFOPAT. www.infopat.eu [last access: 20.10.2017]

[10] N. Weiss, L.S. Aguduri, N. Yuksekogul, B. Schreiweis, A. Brandner, T. Bronsch, P. Pensold, K.E. Stein, B. Bergh and O. Heinze, Implementing PEHR: Design and Integration of a Consent Creator Service, *Stud Health Technol Inform* **228**(2016), 167-171.

[11] B. Schreiweis, T. Bronsch, K.E. Stein, S. Nost, L.S. Aguduri, A. Brandner, P. Pensold, N. Weiss, N. Yuksekogul, B. Bergh and O. Heinze, An Architecture for the Integration of Clinical Data from a PEHR in a Regional Research Platform, *Stud Health Technol Inform* **228**(2016), 272-276.

[12] HiGHmed. HiGHmed - Heidelberg-Göttingen-Hannover Medical Informatics. website: https://highmed.org/ [last access: 20.10.2017]