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Secondary Use of Clinical Data in Healthcare Providers – an Overview on Research, Regulatory and Ethical Requirements

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Abstract. Hospital providers, physicians and researchers are interested in a cross-institutional use of their data for clinical research. This interest has led to the question whether the scientific potential of the data stored in so many different systems can be unfolded by the establishment of a cross-institutional medical data warehouse. The aim of this paper is to describe the ethical and regulatory requirements and to develop a solution architecture considering technical and organisational aspects. The present paper uses a structured approach to collect user requirements. The requirements are discussed with legal experts. The work was complemented by extended literature research. An essential requirement is the cross-institutional merging of the data. Here, aspects of data protection as the informed consent, or transparency must be considered. In addition it is essential to protect the researchers through transparency from accusations on publication bias. Technical and organisational solutions in combination of data protection, and data security enable an operation of a central medical data warehouse in compliance with the law. The usage of this infrastructure for research can contribute to an improvement of the treatment quality, and patient safety if there is an appropriate transparency. This contributes to innovation and added value of a hospital group.

Keywords: Medical Informatics/methods, Clinical Research, Ethics, Privacy of Patient Data, Outcome Assessment (Health Care) / Healthcare Benchmarking, Secondary Use.

Introduction

Healthcare providers increasingly set up controlling structures in order to establish management control systems, and health care services based on defined business performance indicators. This requires appropriate data warehouse (DWH) solutions. Simultaneously, there is an increasingly demand to evaluate medical data for external quality assurance as well as medical questions in form of registers and research databases [1-5]. Thus, the need for a usage of a joint IT infrastructure for business and clinical research purposes is obvious [6]. For the development of a central DWH

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infrastructure, it is important to consider different ethical and technical aspects as well as data protection legislations [7-12].Furthermore, many hospitals are under the authority of different German federal states and sometimes publicly-administered hospitals. As a consequence, different state-dependent data protections and hospital laws need to be considered and applied. If there is a central collection and aggregation of data in a hospital group, the data will leave the circle of access authorized physicians. A violation against ethical requirements or data protection regulations can have, next to legal consequences such as fines and criminal penalties, a not foreseeable damage to the reputation of the provider. The possibilities of an attack on the confidentiality of the data are various [13].

The aim of this work is to evaluate the user, technical, organisational and regulatory requirements of a central DWH system in a nationwide operating hospital group and to develop a solution-oriented approach under consideration of the above mentioned aspects.

1. Methods

To clearly understand the core user requirements, we decided to use a multi-phases approach. At first, user requirements were worked out via a requirement analysis to get an empirical basis. The identification of user requirements was based on recommendations and guidelines of the DAkkS [14]. Context interviews with physicians from different specialist fields were conducted. In a next step, implicit needs and user requirements were obtained from these context descriptions and information-technical requirements were deduced. In a second phase, the requirements were categorized in professional, organisational, legal, market, ethical and system requirements. With the help of expert interviews, literature research as well as an analysis of comparable projects, solution modules (work packets) were developed for each individual requirement category, and subsequently evaluated on the basis of objective criteria. On this basis, in the third phase, a solution architecture was designed. The solution architecture was then critically examined regarding the fulfillment of the formulated requirements by legal experts.

2. Results

2.1. Requirements

2.1.1. User Requirements

Many medical societies have published different structured data sets. They mostly describe a structured data set with specified vocabulary which is to be sent to independent evaluation offices and research registers [1-5]. The data sets include data structures such as process times, findings, diagnostics and measures with different vocabularies and are only partially coordinated. The physicians claim a reduction of the redundant documentation to be performed for each purpose. Furthermore, the physicians demand a possibility to merge data from different institutions and systems for research purposes. This would give them the opportunity to generate requests over

an entire patient population across all institutions in order to carry out evaluations on the basis of the merged data.

It must be possible that data sets of patients can be completed at any later point in time (follow-up, survival-statistics, cross-treatment facility). They also have to break down data on different cases in order to control the plausibility of accounting data in combination with medical information. Likewise, there are demands to be able to re-identify patients in order to inform the patients about new therapies with better prognoses. This excludes an anonymisation of the data. Requirements to administer patient-specific bio materials for research purposes do not only emerge in the field of oncology. Biobanks represent due to their need for pseudonymisation of biomedical samples an entire different range of solution requirements.

2.1.2. Information-technical Requirements

An extract-transform-load process (ETL) - with special extensions for the identity services - to unite the data from different systems is needed. Unfortunately, vendors sell information systems that use many different parametrisations which make the interface terminologies non-comparable. A key aspect is to be able to enrich the corresponding data semantically in order to establish the necessary comparability. The data must be exportable in the given data-set-format for the evaluation offices and research registries [1-5].

2.1.3. Regulatory and Ethic Requirements

In the development and operation of a data warehouse system, the protection of identity and privacy of patients is mandatory. It must be ensured that one can, at any given time, unfalsifiable understand when, where and for which purpose researchers had access to a certain date. If data is used external, i.e. in a central department, one must ensure that there can be no inference made to the real patients. In order to achieve an identification of the patients across all institutions, a pseudonymisation through an autonomous and independent department is necessary. It is important that this department is independent by any directives from the board of the hospital group (escrow holder concept) [8]. However, if too many related data is accumulated in those locations, there is a residual risk that a re-identification is possible via a profile [15]. The legal basis for data processing of non-anonymous data outside the treatment context is the consent of the patient. Thereby, the patient needs to be informed in an understandable way about the purpose of the data processing as well as their right to inspect, and their authority to delete (informed consent) [11]. This requires from a central DWH with different purpose determinations a complex declaration, and a consent management solution [16].

Previous to the processing of scientific questions on non-anonymous data, a positive vote of the ethics committee needs to be present [9,10,17]. “Authors have a duty to make publicly available the results of their research” [9]. In addition, it is essential to protect the researchers and hospitals through transparency from accusations on publication bias.

2.2. Solution Architecture

On the basis of generic data protection concepts of the TMF [8], the following solution architecture was developed (Figure 1). The solution enables, on the basis of existing systems, the complete encapsulation of all decentralized systems of the participating

hospitals. A decisive role of the architecture is that the ETL-process happens decentral in control of the hospital in charge. Thus, disease-pattern-oriented data pools (D and C) can be set up.

The connector service (A1) serves as a decision and access control instance for requests of the standardized data provided by the clinical DWH (A2). An audit-trial at the connector ensures the logging of the accesses and the retrieval for every access. In case of every data retrieval, there will be a decision enforcement point whether the owner of the request is permitted to make the request, whether the hospital is participating in the study, and whether the patient gave their consent. An organisational independent entity represents the identity-management service (IDMS) (B) for all participating hospitals. The IDMS depicts always the same pseudonym for the same patient even if the data is from different institutions. In order to make sure that there exists a positive vote from the ethics committee and that even undesirable results will be published by the researchers, an open study register is necessary (E) which is comparable to the study registers in prospective clinical studies.

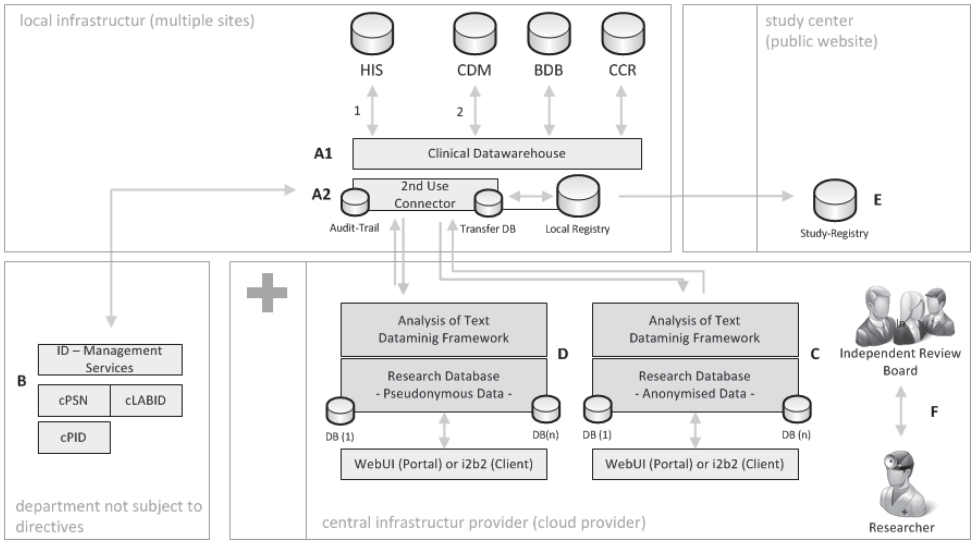

Figure 1. Solution-Architecture (HIS= Hospital Information System; CDM= Cancer Documentation System; BDB= Biobank Database; CCR= Clinical Cancer Registry; cPID/cPSN= Central Pseudonymisation Services; cLABID= Central Pseudonymisation Service for Specimen Tracking IDs)

3. Discussion

The requirement analysis for a central clinic and research DWH architecture in hospital groups displays several essential differences in the comparison of research databases from medical societies. These are the connection of business and research data, the cross institutions aggregation of medical data of a patient, the expanded data pool of different disease pattern, and possible interest conflicts of research result publications. The present solution architecture orients itself strongly on the generic data protection concept of the TMF [8]. Crucial main points are the independence of the IDMS and the decentralized data preparation via an ETL-process, which is in the responsibility of the hospitals. Hence, it is ensured that the pseudonymisation and anonymisation happens within the treatment relationship.

The combination of technical and organisational solutions enables through compliance of privacy protection and data security an operation of a central DWH system in conformity with the law. The usage of this infrastructure for research can contribute to an improvement of the treatment quality and patient safety. At European level, researchers are working on similar questions within the framework of the IMI EHR4CR [18] project. Healthcare providers must ensure that there is an appropriate transparency via a public study register. This can offer a contribution to the innovation capacity and added value of a hospital group.

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