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An e-consent-based shared EHR system architecture for integrated healthcare networks

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ABSTRACT

Objectives: Virtual integration of distributed patient data promises advantages over a consolidated health record, but raises questions mainly about practicability and authorization concepts. Our work aims on specification and development of a virtual shared health record architecture using a patient-centred integration and authorization model.

Methods: A literature survey summarizes considerations of current architectural approaches. Complemented by a methodical analysis in two regional settings, a formal architecture model was specified and implemented.

Results: Results presented in this paper are a survey of architectural approaches for shared health records and an architecture model for a virtual shared EHR, which combines a patient-centred integration policy with provider-oriented document management. An electronic consent system assures, that access to the shared record remains under control of the patient. A corresponding system prototype has been developed and is currently being introduced and evaluated in a regional setting.

Conclusion: The proposed architecture is capable of partly replacing message-based communications. Operating highly available provider repositories for the virtual shared EHR requires advanced technology and probably means additional costs for care providers. Acceptance of the proposed architecture depends on transparently embedding document validation and digital signature into the work processes. The paradigm shift from paper-based messaging to a "pull model" needs further evaluation.

1. Introduction

Several studies in various clinical settings illustrate needs for a better continuity of care and for improvements in documentation, communication, and coordination (cf. [1–3]). Adoptions of the shared care paradigm in regional healthcare networks demand shared, patient-centred documentation, and lead to new architectural approaches supporting cross-institutional cooperation. The European Commission and the CEN e-Health Standardization Focus Group state the necessity of coordinated and interoperable electronic health services and recommend a Europe-wide e-Health platform [4,5]. However, a smooth cross-institutional interoperability of health information systems currently remains as a major challenge both on functional and on semantic level [6,7].

A shared electronic healthcare record (shared EHR) for integrated care contains "... information regarding the health status of a subject of care in computer processable form, stored and transmitted securely, and accessible by multiple authorised users" [8]. Development of shared EHRs already has a long history. The technology of the GEHR and Synapses projects [9] (1992–1999) can be seen as a first mature approach to a federated healthcare record. Specification and deployment of a generic cross-institutional ICT architecture for

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regional healthcare networks were the tasks of the PICNIC project [10]. A peer-to-peer architecture for decentralized, open healthcare networks, which uses information mediation and a sophisticated patient ID management method, is currently developed in the ARTEMIS project [11]. This list is far from complete, but represents a trend towards provider-based integration approaches, which can be seen as an opposite to patient-centred approaches [12]. Current implementations of such personal health records (PHRs), i.e. electronic health records edited and managed by the patients themselves, are assessed to be of only limited utility for healthcare providers [13,14]. Nevertheless, an integration approach based on PHRs may reduce complexity of establishing a shared EHR [15,16].

In this paper we intend to show, that a patient-centred approach offers a privacy-preserving and controlled way for the consolidation of health information to a shared EHR. We propose an e-consent information system component [17,18], which stores a patient's consent about particular healthcare affairs and will be a key element towards a novel quality of health information services. This e-consent system will allow the patient to explicitly express her/his agreement for an information transaction. Privacy issues often are considered as a knock-out factor when trying to establish advanced information services in healthcare.

2. Methods

To keep track of the application field, various published approaches and projects implementing a shared EHR have been analysed. The conducted analysis method adopts the ISO reference model for open distributed processing (RM-ODP) and decomposes a system's architecture into different perspectives. For each perspective, several architectural considerations have been identified and classified, resulting in a survey of shared EHR aspects and a vocabulary for further reasoning.

The literature-based survey was complemented with methodical process analyses in two regional healthcare networks regarding cross-institutional communication. The MOSAIK-M framework and tool environment [19] was used, which supports modelling, simulation, and animation of information and communication systems in medicine. The first process analysis concentrates on the exemplary scenario of thyroid disease care in an integrated care setting and led to a basic understanding of the requirements concerning the use of a shared EHR system in a regional healthcare network. The second process analysis focuses on the Braunschweig Medical Centre as a regional provider for external medical services like laboratory and pathology analysis. To support the deployment of a shared EHR in this setting, a cost analysis was conducted. At first, an *As-is-model* of the current paper-based messaging processes was developed. Subsequently, the As-is-model was transformed into a *To-be-model* including the shared EHR concepts. Simulations of both models were used to compare the process durations and costs of the As-is-model and the To-be-model.

From literature survey and process analysis, a shared EHR architecture model was synthesized. The model has been concretised with an advanced prototype system, which is currently being evaluated in the European funded project INCA (INtelligent Control Assistant for diabetes, http://www.ist-inca.org) and in the above mentioned project setting in Braunschweig.

The remainder of this paper is organized as follows. Firstly, the results from literature analysis are summarized. Based on these findings, the approach of an e-consent based shared EHR is presented and the notion of an e-consent object is specified. An information management strategy is outlined and, finally, the results of this paper are discussed.

3. Results

3.1. *Architectural considerations for a shared EHR*

Table 1 classifies various aspects of a shared EHR based on the results of the analysis of EHR approaches and projects. The survey separately covers three of the five RM-ODP viewpoints. Each section distinguishes between several design considerations of a shared EHR, which are summarized as follows.

From the enterprise viewpoint, the objective of a shared EHR can be categorised by its strategies for long-term mainte-

Table 1 – Architectural considerations of a shared EHR

Enterprise viewpoint	
Long-term maintenance	Provider-centered; commercial/consumer-oriented service provider; national/regional government
Redundancy	Redundant copies; singular authority without redundancy
Content responsibility	Healthcare provider; patient; regulated by law or mandatory policy
Federation scope	Enterprise-bounded; trans-sectoral; local; regional; national
Information viewpoint	
Shared information model	Federated schema; domain-specific information model; ontology-driven knowledge representation
Content	Event summaries; continuity of care records; provider documentation; self-entered health data
Instance level	Referential integrity; concept representation and surrogate keys
Computational viewpoint	
Integration model	Data-oriented integration Materialized integration Information mediation Process-oriented integration Record-level registries Document-level registries

nance, redundancy model, content responsibility and scope of federation. Long-term maintenance of shared and authenticated documents is a prerequisite for a longitudinal EHR, because it ensures reliable and available information sources. These services may be provided by healthcare facilities itself, commercially oriented service providers or national/regional government. The redundancy criterion distinguishes a shared EHR as an additional information source from a shared EHR as the single authoritative source of documentation for all care providers. Responsibility for the content of a shared EHR affects the integrity of the information: only legislation or a mandatory policy guarantees, that a patient's shared EHR will comprise a homogeneous and reliable content. At last, the federation scope may range from only an improved access to information within an enterprise up to a national data repository ensuring continuity of care. Of course, not all of these characteristics can be arbitrarily combined. With relation to [12], we can identify three major architectural styles:

- A *provider-centered EHR* is initiated from healthcare providers and is normally motivated by economic incentives. These approaches are mostly bound to local or trans-sectoral federation scopes.
- A *patient-driven EHR* fosters patient empowerment and addresses continuity of care and a consolidated life-long health record. PHRs are a first step in this direction, though they currently lack of interoperability and support by care providers.
- A *platform-based EHR* requires the initiative of a regional or national player to set up a communication infrastructure based on broadly accepted standards. Many countries have started e-Health programmes or have released strategic plans (see for instance [4]) for building e-Health platforms.

Shabo introduces a new architectural style based on *independent health record banks* (IHRB) [12]. It represents the vision of a lifelong EHR based on future ethical and medico-legal regulations. IHRBs are a new kind of business entities proposed to replace the healthcare providers as authoritative record keepers.

From the information viewpoint, recent trends towards interoperable information systems indicate three different approaches of achieving semantic interoperability: establishing a federated schema, developing and improving domain specific information models, and ontology-driven approaches. A federated schema will facilitate interoperability through well-defined and commonly agreed semantics, but will normally result in rather inflexible data structures, because any refinement of the information model requires changes for all participating parties. Domain specific information models like HL7's RIM-based models allow for a more flexible representation of domain concepts, but also require agreements upon shared structures [20]. These models are typically based on reference information models, meaning a separation of data structures from domain knowledge by templates or archetypes. This enables maintenance of information models at runtime principally without needs to change software components [21]. In ontology-driven approaches, formally specified knowledge supports the interoperability of heterogeneous information models. Using ontologies as consensual knowledge across enterprise boundaries has been proposed to support integration via concept mapping, either on metadata level [22] or on the information level [23].

Another issue is the content of the common information model. A shared EHR may provide only event summaries or information about the current health status, mainly addressed to support continuity of care like for instance ASTM's CCR [24]. On the other hand, integration of various medical records to a consolidated (virtual) repository principally offers a detailed insight into a patient's health affairs, but makes the retrieval of useful information more difficult. Furthermore, valuable information often comes directly from the patient, in terms of self-entered data or vital signs from telemedical scenarios.

The instance level of a shared EHR deals with the integration of data items. A main issue is the preservation of referential integrity within federated information repositories, which is addressed by a universal healthcare identifier or an enterprise master patient index. Regarding concept representation, different coding practices and various classification systems require terminology mapping services like the UMLS Metathesaurus or establishment of a convergent terminology like the Kaiser Permanente CMT [25].

From a functional perspective, data-oriented and process-oriented integration models can be identified. From a data-oriented view, materialized integration is usually operated with a central repository on national or regional level. In contrast, a mediator-based approach is capable of integrating various sources on demand. It can be defined as an architecture, which translates global queries to the local resources and integrates local results to a virtual view on a comprehensive EHR. Typical process-oriented approaches are service-oriented architectures, which split the integration task between information sources and consumers. A predominant service-oriented model is the registry/repository integration pattern: a registry holds metadata about a patient's health information, which may be distributed among several repositories [26]. We can distinguish between registries holding metadata only about locations of a patient's medical record (record-level registries) and registries holding fine-grained metadata about documents, which are stored in the various repositories (document-level registries).

3.2. *Approaching a virtual shared EHR*

A conventional approach to a shared EHR is the materialized integration. EHR extracts are exported from care provider systems to centralized storage structures using a jointly agreed information model. This simplifies integration and retrieval of patient data and allows for a smooth scalability meeting the respective needs: an integrator-based strategy may be applied locally, regionally, nationally, or may even be built as a cascade of several integrator components linking up from local to national level. However, the integrator model also has disadvantages. Trusted organizational structures have to be established, which keep the authoritative record or a copy of the record for a patient's life. The concentration of a large amount of patient-related data also raises privacy issues. For example, a national consolidated repository in Germany is currently declined by the healthcare self-administration [27]. As

an alternative, virtual integration approaches benefit from the provider's liability of long-term record keeping. In an idealistic virtual integration model, patient data remains solely in digital archives at point of care and is accessed only on demand. But some issues also constrain practicability of the virtual model:

- Responsibility for patient-centered information integration is shifted from the information provider to the information consumer and may require more effort than in the integrator model. Depending on the architecture, indexing and retrieval systems have to deal with locating various resources, integrating heterogeneous information models, and mapping different patient identifiers.
- The care provider has to guarantee long-termed, permanent and liable availability of information, which may require outsourcing to an external service provider.
- Completeness of a virtually integrated patient record will not be achieved, because the decision about publication of documents is left to discretion of the respective healthcare facility.

Nevertheless, the virtual approach is to be seen as a migration path from isolated repositories to regional health records. Operating expense of virtual integration can be reduced with an appropriate infrastructure providing universal healthcare identifiers, authentication and authorization services, and mediating services.

In the following proposal of a virtual shared EHR system, each participating care provider (additionally) manages an electronic archive and is responsible for medico-legal archival storage. Electronic information transactions across institutional boundaries require the interacting systems to prove the patient's consent. As shown in Fig. 1, we postulate four autonomously operating, but interlinked systems to facilitate a virtual shared EHR based on these principles. The boxes with dashed lines represent a possible instantiation of these generic components.

In contrast to integrator-based approaches, the system only registers references on data stored at several provider repositories. Without a patient's permission and her/his collated references, an integration of data to a virtual EHR cannot be accomplished. The proposed integration strategy can be achieved by extending a PHR system with a registry and an e-consent component. The e-consent extension empowers the patient to control cross-institutional transmission of her/his data. It stores digitally signed artefacts, which are issued by the patient and certify the holder to be involved in the care process with particular privileges. Together with the provider repository depicted in Fig. 2, this part of the architecture corresponds to Coiera and Clarke's gatekeeper model [17].

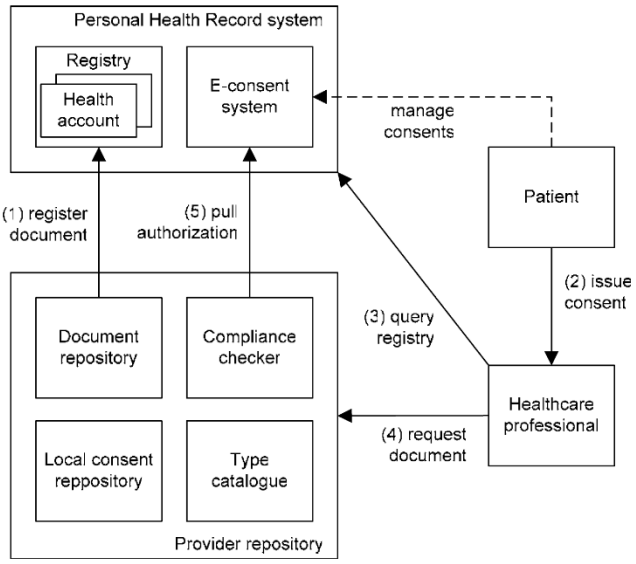

Fig. 2 – Collaboration diagram of the proposed virtual shared EHR system.

Each time the provider repository is being accessed, it checks the authentication of the requester, which is verified through the public key infrastructure and depends on structural roles assigned by attribute authorities. The authorization information has to be pulled online from the e-consent system, because the patient is free of revoking her/his consent.

3.2.1. *Contribution*

Basic requirement for contribution to a patient's shared EHR is a valid e-consent, which is registered in the local consent registry and includes the contribution privilege. Normally, the e-consent is issued by the patient during consultation and is valid for a certain time. It should be noticed, that a locally stored e-consent represents a local copy, whereas the authoritative original is held only in the e-consent system. Consent revocation therefore means deleting the attribute certificate in the e-consent system, thus all former local copies will implicitly loose significance. We suggest the following policy for contributing documents to the shared EHR:

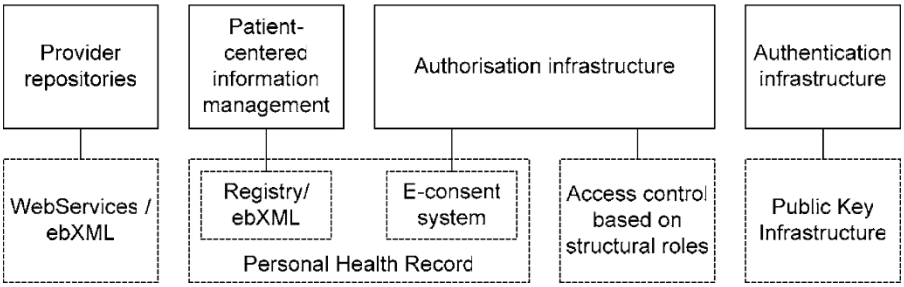

Fig. 1 – Generic components of a virtual shared EHR system.

- the type of document is assumed to be of interest for users of the shared EHR (which should be regulated by a mandatory policy);
- the document has passed the internal validation process;
- the document is digitally signed;
- an entitled user explicitly mandates contribution of the document.

To register a document, the network address of the PHR is extracted from the locally stored e-consent object and a registration request is transmitted to the registry (1). If this request is authorized, the PHR registers a descriptor to the patient's health account, which references the regarding document in the provider repository and contains metadata for retrieval.

3.2.2. *Retrieval*

Whenever access to information from the shared EHR is required, a health professional queries the PHR registry for a list of documents of interest. Similar to contribution, basic requirement for information retrieval is an e-consent object pertaining to the patient (2). The health professional obtains a set of document references from the registry (3), which may be constrained by the privileges stored within the e-consent object. Finally, the client system requests desired documents directly from the provider repositories (4), which again will check compliance to the e-consent system (5).

3.2.3. *Client integration*

The shared EHR may be used by health professionals as an additional tool within the care process. Furthermore, for a smooth integration into client systems, a publish/subscribe method is suggested, which will assign the PHR an active role within the communication process. A subscription module of the PHR may be used by client systems to register for particular information entry events and is bound to a health professional's current involvement into the care process, which is proven by an active e-consent. The subscription mechanism allows for various communication processes, e.g. for notification of results of a temporary transfer of care. For a description of suitable mechanisms we refer to [28], which in detail presents an active update approach as an extension of the Synapses Federated EHR Server.

3.3. *Outline of an a-consent object*

The e-consent object is a digital equivalent of a contract between a patient and either a health professional or an organization and comprises a vector of several attribute/value pairs. It carries a digital signature of the patient stating unambiguously her/his consent. It should state at least the following facts:

- Issuer of consent, normally the patient or a custodian;
- Subject of care, i.e. the patient;
- Grantee of consent, which is a health professional or an institutional entity as a whole;
- Relationship subject/grantee, i.e. explicit statement about involvement in care process;
- Logical network address of PHR registry for contribution to and retrieval from the shared EHR;
- Validity period of consent, which should state a rather short-timed validity;
- Target of consent, which states general and specific inclusion and exclusion criteria for concerning information items;
- Authorized operations upon information items, e.g. permitted access methods and especially the privilege to contribute to the patient's shared EHR.

Some situations require an extension of this e-consent model, because traditionally many consultations are conducted under temporary transfer of care without the need for the patient to denote her/his consent again. A prominent example is the disposition of blood samples or tissue to a laboratory. To cover this case, we allow delegation of an e-consent. When a health professional or an institutional entity h holds an active e-consent which includes the permission to delegate the contribution and/or retrieval privilege, and there exists an active e-consent stating the delegation of the contribution and/or retrieval privilege from h to another health professional h', h' shall also be permitted to apply the delegated privilege. i.e. the delegating e-consent object is issued by the referring health professional, not by the patient.

3.4. *Information model*

Clinical documents fulfil medico-legal conditions, which are required for liable processing of medical data across enterprise boundaries: a document represents a closed and persistent unit of inter-related data, can be legally authenticated, and is maintained within the authoring institution for the purpose of long-term storage [29]. The HL7 Clinical Document Architecture currently seems to be one of the most suitable approaches for the formal representation of persistent clinical documents, especially because the development of domain specific information models currently receives broad support of organizations and industry in the field of health information systems. To enable semantic interoperability of those applications connected to the shared EHR, the elaboration of CDA R2 entry level templates for transmitted documents is required. We additionally introduce type catalogues (see Fig. 2), which can be used to display a transmitted document only, if no further computerized processing of the document is required. A type catalogue is located at the provider repository and supplies a document requester with information about structure and presentation of provided documents, i.e. with an XML schema and an XML to HTML transformation.

3.5. *Information management strategy and evaluation*

The proposed architecture is a vision of a future, transinstitutional information system, which can only be approached step by step. For a regional setting, a migration path has been developed and instantiated in form of a pilot project, leading from the initial, unconnected situation to a virtual shared EHR. The migration path is depicted in Fig. 3.

In a first phase, a virtual organization of care providers is established by identifying cooperating facilities within a region. The affiliation phase also includes advertising strate-

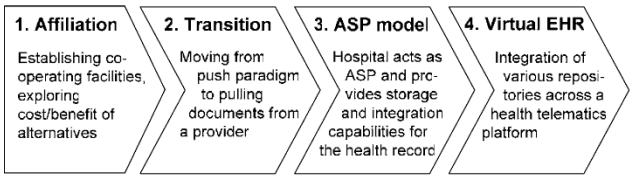

Fig. 3 – Proposed migration path to a virtual EHR for a regional setting.

gies, which have to consider costs and benefits of various future phases for the participating parties.

For a second phase, we consider a smooth transition from the traditional message-based push paradigm (sending data to the receiver) to the pull paradigm (retrieving information when required). We can think of the provider repositories as a communication platform, which will make documents available to further authorized users. An initial project setting in Germany comprises the Braunschweig Medical Centre, two further hospitals of the region, and several cooperating practices. The medical facilities have been electronically connected to the Braunschweig Medical Centre using a pull model, thus they can obtain referral results either directly from the repository via web browser or benefit from an automatic upload into their clinical information system. The main research question arising from the design of this phase is the effect of a missing trigger event: the documents a requestor is interested in are no longer transmitted in paper-based form and thus cannot trigger the working processes in the usual way. The evaluation especially measures the delay between availability of an electronic document and its usage and compares it with the delay occurring in the former paper-based messaging process. A first assessment shows a moderate usage of the electronic retrieval function, mainly in order to benefit from the timely transmission and the opportunity of a subsequent electronic data processing.

In the third phase, the Braunschweig Medical Centre is intended to act as an application service provider due to its well equipped technical infrastructure. It will provide long-term storage capabilities for cooperating facilities and registry functionalities to realise a small regional shared EHR. For the last phase, a health telematics infrastructure is required, which will provide a communication and security infrastructure and standardized interfaces to connect several provider repositories to a PHR.

4. Discussion and conclusion

This paper proposes a shared EHR architecture using provider repositories to access distributed EHR resources. In conjunction with an e-consent system and an authentication infrastructure, access to provider repositories is checked for compliance to explicitly expressed consent of the patient. Many of the privacy concerns regarding cross-institutional document repositories can thus be omitted. The virtual integration approach has also some challenges, which currently constrain deployment of the proposed architecture. Provider repositories have to guarantee high availability to offer reliable access to documents, which requires an advanced and probably expensive infrastructure within the healthcare network. Documents, which are released to a repository, have to be provided for a long-term period similar to their paper-based equivalents. Currently unresolved questions regarding long-term storage and the substitution of paper-based signature with its digital equivalent may force many users to print out documents from the shared EHR.

Furthermore, a common infrastructure for managing referential integrity has to be established. This may be achieved by a universal healthcare identifier in combination with patient and health professional cards. An alternative solution using a master patient index will cause a high effort for the user when releasing and querying documents. Also the semantic interoperability remains a major issue. The HL7 Clinical Document Architecture provides a helpful common syntax for information exchange in the presented project, but will not eliminate the need for commonly agreed information models beyond the HL7 Reference Information Model.

Finally, acceptance of the proposed architecture depends on transparently embedding document validation and digital signature into clinical routine without disarranging well accepted working processes. Another issue of a virtual EHR is the practicability of moving from paper-based messaging to the pull paradigm. The currently conducted evaluation in the Braunschweig pilot project is supposed to produce a valuable statement on these subjects.

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