

# Utilizing IHE-based Electronic Health Record Systems for Secondary Use

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## Keywords

Electronic health record, data retrieval, secondary use, integrating the healthcare enterprise

## Summary

**Objectives:** Due to the increasing adoption of Electronic Health Records (EHRs) for primary use, the number of electronic documents stored in such systems will soar in the near future. In order to benefit from this development in secondary fields such as medical research, it is important to define requirements for the secondary use of EHR data. Furthermore, analyses of the extent to which an IHE (Integrating the Healthcare Enterprise)-based architecture would fulfill these requirements could provide further information on upcoming obstacles for the secondary use of EHRs.

**Methods:** A catalog of eight core requirements for secondary use of EHR data was de-

duced from the published literature, the risk analysis of the IHE profile MPQ (Multi-Patient Queries) and the analysis of relevant questions. The IHE-based architecture for cross-domain, patient-centered document sharing was extended to a cross-patient architecture.

**Results:** We propose an IHE-based architecture for cross-patient and cross-domain secondary use of EHR data. Evaluation of this architecture concerning the eight core requirements revealed positive fulfillment of six and the partial fulfillment of two requirements.

**Conclusions:** Although not regarded as a primary goal in modern electronic healthcare, the re-use of existing electronic medical documents in EHRs for research and other fields of secondary application holds enormous potential for the future. Further research in this respect is necessary.

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## 1. Introduction

### 1.1 Rationale

Electronic health records (EHRs) are gaining increasing importance in modern health care. A number of countries have adopted these EHRs as new participants in health information exchange to aid physicians in their daily work and reduce costs by using existing information about the pa-

tient instead of producing new information by repeated laboratory testing or radiological examinations [1, 2].

The project ELGA is the nation-wide implementation of electronic health records in Austria. The aim is to allow time- and location-independent access to relevant health information for authorized physicians and also for patients. According to the ELGA feasibility study [3], the electronic health record should increase the

quality of health care as well as enhance the efficiency and effectiveness of the Austrian health care system.

Along with access to existing health information for patient treatment, the possibility to reuse this information for secondary purposes could serve as a major impetus for medical research, decision-making in health policies, and quality assurance in health care.

The international initiative known as Integrating the Healthcare Enterprise (IHE) aims to cover the concepts required for integrated communication in health care within a number of frameworks and profiles by the use of established standards. Through several national initiatives (e.g. France, Germany, United Kingdom, Netherlands, Austria, Switzerland, etc.) which facilitate and promote these activities within and across their countries, IHE is gaining importance in Europe.

For Austria IHE has special relevance according to the feasibility study for implementing the electronic health record in the Austrian health system [3]. In this study the IHE profile XDS (Cross-Enterprise Document Sharing) [4] is recommended to serve as the central concept for collecting, storing and sharing medical documents within the Austrian ELGA project. It is based on an actor named Document Source which stores medical documents to a Document Repository, and an actor Document Consumer which retrieves documents from there after querying a (central) Document Registry which stores document metadata.

For primary use of health data, XDS contains the necessary elements for document sharing. However, the patient-centered design of XDS makes it inappropriate for cross-patient secondary use. The XDS transaction Registry Stored Query requires a mandatory patient ID to be valid. For example, it would be necessary to know all

registered patients to query for a specific document type if one merely wanted to know how many documents of the specified type are stored in the system within a certain period of time.

For purposes such as that mentioned earlier, IHE published a profile named MPQ (Multi-Patient Queries) [5] as a supplement for trial implementation, which addresses cross-patient document retrieval. However, it omits certain relevant aspects of secondary use.

The rationale for the present study was to find ways to further benefit from secondary use of health information while preserving and protecting the patients' interests. Furthermore, existing IHE-based architectures for electronic health records should remain untouched as far as possible.

## 1.2 Related Work

The potential of using large repositories of routinely collected data was discovered more than 15 years ago (e. g. by Safran for clinical data [6, 7]). Bain et al. [8], as another example, described the potential advantages of the use of routine data in 1997. They mention low costs, the big size of the database, population coverage, time period coverage, and the breadth and diversity of the recorded items as the principal advantages.

The large repositories are gold mines but have their limitations and are frequently not fit for secondary use [8]. EHR data is usually collected during the treatment of a patient and not for the purpose of research. Therefore, integration and most notably data quality issues, including the understanding of the data collection process, must be given careful attention [9].

Authors of current publications (e.g. [10–14]) dealing with secondary-use applications of EHRs agree about the enormous potential of EHRs in terms of contributing to progress in medical research, as well as their limitations. The articles mainly focus on actual application rather than the architectural set-up of the system for secondary use. Hanauer et al. [10] used an analytical approach based on an algorithm originally developed for the analysis of gene expression data. The authors conclude that

the use of “-omics”-based methods for the generation of hypotheses could be helpful for further research and analysis of EHR data. Willison et al. [11] consider the ethical aspects and the willingness of patients with stigmatizing health conditions (e.g. HIV) to make their health information accessible for secondary use as compared to a control group. The authors found that it was necessary to take individual aspects into account when obtaining the patients' consent. Moreover, a generally high level of trust in medical research was registered in the study. Tannen et al. [12] conclude that the use of EHR data might produce valid results to check the therapeutic effectiveness of drugs.

A small number of articles focus on the requirements to be fulfilled by a framework for secondary use (e.g. [13, 14]); these constitute the basis of our considerations. Certain elementary requirements for a system of cross-patient and cross-institutional secondary use of EHRs are described in [13], but no purpose-specific architecture is presented. Safran et al. [14] define six recommendations for successful adoption of a national framework for secondary use of health information, but mainly focus on political and social aspects of the system. Their recommendations are the following:

- Introduction of transparent policies and practices for secondary use of health data
- Focus on data control ownership – not on data ownership
- Consensus on privacy, policy and security
- Public awareness
- Comprehensive scope
- National leadership

## 2. Objective

The main objective of the present paper is to propose and evaluate an IHE-based architecture for secondary use of EHR data for medical research, decision-making in health politics, and quality assurance methods. Two prerequisites were deemed necessary to achieve this objective:

1. Analysis of the IHE profile MPQ (Multi-Patient Queries) [5] concerning its suitability for secondary use

2. The development of a catalog of requirements for secondary use of EHR data

## 3. Methods

### 3.1 Identification of Requirements for Secondary Use of EHR Data

The recent scientific literature was searched in order to develop a catalog of requirements and create a preliminary informative basis. Only a small number of pertinent articles were found. Articles like [13] and [14] were helpful but not specific enough for our investigation in respect of architecture because of their rather general assumptions. We decided to formulate exemplary questions that would arise in the context of secondary use, as we believed these would enable us to formulate specific and more adequate requirements for a system of secondary use of EHR data.

#### 3.1.1 What Security Measures Should One Consider?

The authors of [13] state that security and data privacy are elementary concerns when using health data. Especially the secondary use of such documents is a challenging issue because the secondary user (e.g. researcher) is not directly involved in the patient's treatment. As a result, anonymization or pseudonymization of health data is a key requirement in order to fulfill legal regulations. Especially in the EU, differences may exist between the local regulations of member countries and normative EU guidelines. According to [15], an exemplary conflict exists between the Austrian Data Protection Act DSG 2000 and the Data Protection Directive 95/46/EC of the European Union. The Austrian Data Protection Act distinguishes between individual-related, indirect-individual-related and non-individual-related data, whereas the European directive does not consider the indirect form of individual-related data. The problem is that the Austrian government permits the use of indirect-individual-related data (e.g. pseudonyms) for research purposes without the approval of the Austrian Data Protection Commission.

Anonymization would ensure compliance with European statutory requirements and avoid legal discrepancies, but would render patient recruitment and outcome-oriented research impossible. Patient recruitment and outcome-oriented research would require pseudonymization rather than anonymization. The discrepancy described above leads to another requirement indicated in [14], namely the necessity to define and control specific transparent policies for secondary use of health data. The placement of controls on the compliance with these policies also enhances the patients' empowerment in terms of their sensitization to the risks and benefits of secondary use of their health information.

### 3.1.2 How Should Data Be Formatted for Secondary Use?

Another core requirement for integrated care as well as secondary use is the use of harmonized standards for medical documents themselves as well as for communication between the members of the shared system in order to achieve interoperability [16]. Concerning communication, the IHE profiles XDS for general document sharing and XCA for cross-domain document retrieval in a federated EHR-approach provide a solid and standard basis. A number of options exist for the documents themselves, such as the openEHR model, the model of CEN 13606 or HL7 CDA (Clinical Document Architecture) Release 2. For a number of projects such as the Austrian ELGA project and the German VHiT Initiative for Intersectoral Communication, HL7 CDA Release 2 was chosen as the document format. HL7 CDA is based on XML and is structured in three levels. Level 3 is most thoroughly structured: it provides a means of referencing text elements by the use of certain codes such as ICD (International Classification of Diseases) or LOINC (Logical Observation Identifiers Names and Codes). Thus, CDA R2 Level 3 is fully structured in contrast to lower level CDA documents or even PDF documents and is therefore suitable for secondary use [17] and constitutes the format of choice for our approach.

### 3.1.3 Which User Groups Use the System and What Are Their Demands?

As mentioned in [13], different users will participate in a secondary use scenario. To define user groups (roles) as indicated in the MPQ Profile [5], we identified those who could benefit from such a system. These are primarily medical researchers, health policy makers and health reporters. Medical researchers require access to detailed medical documents in order to generate new hypotheses or establish associations between specific clinical problems. In contrast, health policy makers and health reporters usually need a small portion, or an aggregated form of the data to draw their conclusions. One such example would be the number of documents containing a specific diagnosis and stored in a certain period of time.

We therefore delineated two user groups (roles): the first are researchers who need access to detailed data while the second are health policy makers/health reporters who need aggregated information.

### 3.1.4 How Could the Queries Be Formulated?

In cases of queries for documents, the transactions defined and technologies used by the different IHE profiles fulfill the requirements for secondary use. It should be possible to perform a cross-patient search for certain document metadata such as the type of document or the date of its creation, which is necessary to retrieve the desired documents for subsequent evaluation. A more challenging task – though actually not the main subject of this paper – is to query the contents of the retrieved documents. This task would be facilitated by the use of the XML-based HL7 CDA format. An exemplary tool for querying the contents of the document would be XQuery, a query language for XML documents defined by W3C. With XQuery it is possible to formulate query statements à la SQL on XML documents and receive the results in a structured form (such as a list). The parameters chosen for the query should be appropriate to select the documents. A terminology service should be available to facilitate

this choice of search terms. EQL – a declarative query language developed for openEHR-based EHRs – was introduced recently. EQL tries to overcome the disadvantages of the direct use of XQuery and could be used for any archetype-based information system [18].

## 3.2 Analysis of the IHE Profile MPQ (Multi-Patient Queries)

The IHE profile MPQ [5] was published as a supplement for trial implementation to permit cross-patient retrieval of documents stored within an XDS-based document sharing domain. In contrast to XDS, the MPQ profile permits formulation of a transaction named Multi-Patient Query to allow retrieval of documents without requiring a patient identifier (e.g. by time of its creation, type of document or other valid XDS parameters). We decided to choose MPQ for our further investigations because of the intended use. Other rather inappropriate profiles are mentioned in Section 5 of this paper.

A number of questions concerning implementation are still open because of the profile's trial status. We decided to conduct a basic security and risk evaluation to address the risks and the level of security MPQ can provide. We followed the risk analysis procedure recommended by the Austrian Handbook for Information Security [19], which divides the process of risk analysis into eight steps and is similar to the German BSI Standard 100-3 [20].

The risk analysis will be summarized here for reasons of brevity. The analysis showed that the missing and undefined mechanism for anonymization in MPQ is the greatest security risk. Data policies will have to be defined and enforced (e.g. defined structure of passwords, time intervals for password change, smartcards, biometric systems) in order to resolve the problem of unauthorized access.

## 3.3 Catalog of Requirements for a System for Secondary Use of EHR Data

By combination of the requirements taken from the articles [13] and [14], the answers

given to the questions above and the analysis of the IHE profile MPQ we compiled the following catalog of eight core requirements for secondary use of EHR data:

1. Use of standards and terminologies to permit structured and consistent acquisition of documents and enhance evaluability (derived from 3.1.2, 3.1.4)
2. Possibility of cross-patient and cross-domain retrieval of documents (see 3.1.2, 3.2)
3. Selection of documents by different metadata parameters (e.g. time of creation, type of document) (see 3.1.4)
4. Possibility to anonymize the retrieved documents (see 3.1.1, 3.2, [13])
5. Possibility to formulate queries within the retrieved documents (derived from 3.1.4)
6. Assignment of user groups (roles) to restrain access to data (see 3.1.3, [5], [13])
7. Definition of and compliance with different transparent policies for secondary use of health data (see 3.3, [14])
8. Sensitization within the population (possible risks and advantages) (derived from [14])

### 3.4 Architecture for Patient-centered Cross-domain Document Retrieval

As a precondition for the development of a cross-patient and cross-domain architecture for secondary use of health data, we first considered a patient-centered architecture for primary use (document sharing) of health data. We combined information on the intended architecture of the Austrian ELGA project [21] and the architectural white paper for cross-community federated information exchange by IHE [22].

As mentioned above, a federal approach is chosen. In other words, each Affinity Domain (e.g. federal state, hospital networks) possesses its own IHE-based architecture for document sharing (XDS) and patient identification (PIX), and the domains are interconnected within a national domain. These Affinity Domains are connected by gateways derived from the IHE profile XCA (Cross-Community Access). To permit patient-centered cross-domain retrieval of

documents, the patient IDs have to run through an identity mapping process in the central patient index (CPI) in order to find the corresponding patient ID. This index serves as the linking table for the different local patient IDs a single patient may have in different Affinity Domains. The following example explains the process of mapping and lookup of patient IDs inside the CPI: the local patient IDs a single patient "John Miller" may have in several Affinity Domains (e.g. local patient ID = '123' for Affinity Domain 1, local patient ID = '456' for Affinity Domain 2) are inserted into the CPI and mapped to the patient's central patient ID inside the CPI (e.g. central patient ID 'c987' = patient ID '123' in Affinity Domain 1 = patient ID '456' in Affinity Domain 2) using additional attributes like the patient's social security number, name, gender, date of birth or address. Now, if an actor inside Affinity Domain 1 wants to retrieve Information for patient "John Miller" from Affinity Domain 2, the actor queries the CPI for the patient's ID for Affinity Domain 2 by use of its' known local ID '123'. The CPI checks for the corresponding entry and returns the patient ID '456' for patient "John Miller" in Affinity Domain 2.

Authorization checking of the document consumers is achieved through an authorization system connected to an index that contains all health service providers (GDA index), as well as to the CPI. A portal enables the patient to view his or her personal health documents or the audited actions.

### 3.5 Migration to the Cross-patient Architecture

The pure profile MPQ is not capable of fulfilling the formulated eight core requirements for secondary use of EHR data. As only requirements 1 and 3 can be met, surrounding constructions are needed for MPQ.

Based on the patient-centered architecture, the requirements not covered by MPQ were taken into account for creating or migrating to the cross-patient architecture. This was done to extend the patient-centered architecture and thus cover a maxi-

mum number of requirements. The necessary components are the following:

- Insertion of an Affinity Domain "Secondary use"
- Insertion of a patient independent transaction for XCA Cross Gateway Query
- Insertion of an anonymization mechanism (within national domain)
- Extension of the GDA Index by secondary users
- Insertion of mechanisms for policy enforcement and policy control
- Extension of an authorization system to consider patient consent for secondary use and identify the role of secondary users and their authorizations
- Insertion of a database for anonymized documents into Affinity Domain "Secondary use"

## 4. Results

### 4.1 Design of an Architecture for Cross-patient and Cross-domain Secondary Use

To design the architecture for cross-patient and cross-domain secondary use, the patient-centered architecture was extended to include the necessary components for cross-patient use mentioned above and thus provide the required functionality.

► Figure 1 shows that an integration of an Affinity Domain for secondary use does not directly affect the other Affinity Domains in the scenario. The only domain that has to be extended and adapted is the national domain (inserted components are highlighted within the dashed rectangle).

The most noticeable changes concern the added service for anonymization within the national domain to anonymize the transferred metadata and documents and the PEP (Policy Enforcement Point) at the gateway of the "Secondary use" Affinity Domain.

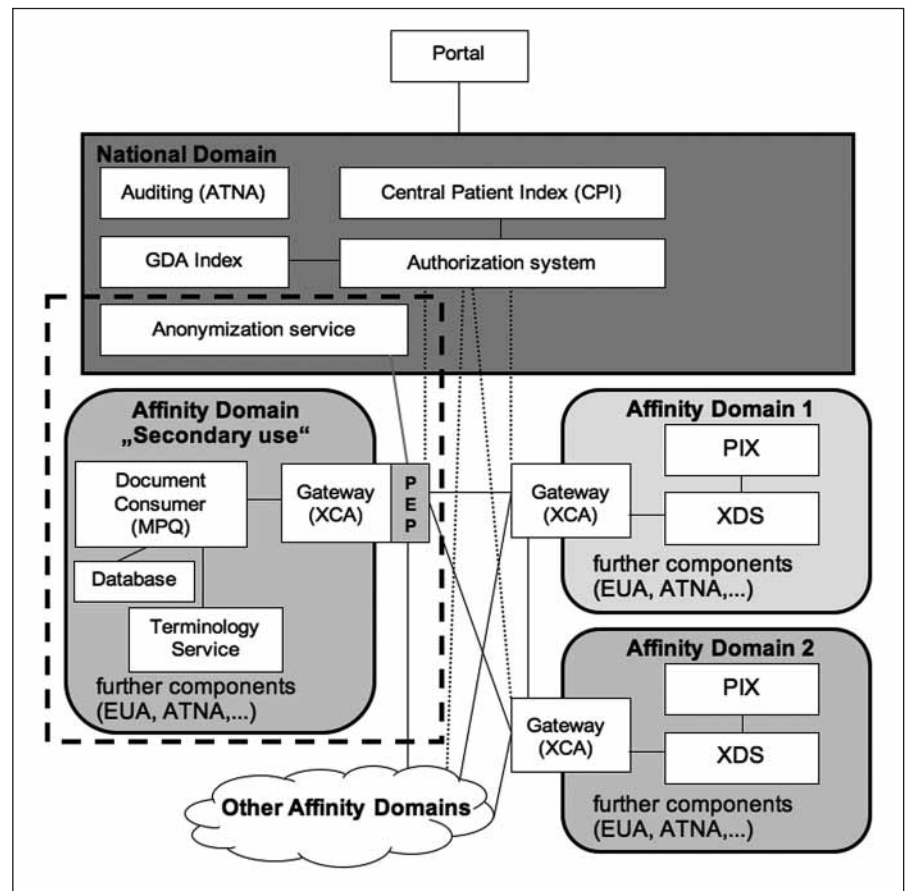
The reason for using only one Affinity Domain "Secondary use" is based on the use of anonymization instead of pseudonymization in our approach. To create a separate Affinity Domain for every study would increase effort for administration and reduce usability of the stored docu-



ments caused by the separate data pools. The use of anonymization instead of pseudonymization makes reidentification impossible, even with only one Affinity Domain. For use of pseudonymization, multiple instances of the basic Affinity Domain “Secondary use” would be necessary to prevent reidentification.

To allow retrieval of only HL7 CDA R2 Level 3 documents the consumer’s document query contains the corresponding format code (e.g. format code ‘CDAR2L3’) for the document type. By using this parameter, only documents usable for the proposed architecture are retrieved.

The PEP is intended to enforce policies for secondary use and serves as a watchdog. It is connected to the authorization system to check the legitimacy of a request after the latter is sent by the “Secondary use” Affinity Domain and also checks whether the format code corresponds to the only one allowed in our approach. The PEP is out of reach for the Document Consumer of MPQ so that he or she can never access non-anonymized data. Whenever responses arrive at the PEP, it directs the non-anonymized data to the anonymization service, which removes all personal information (e.g. patient’s name, name of physician, social security number) from the affected XML-elements within the HL7 CDA R2 Level 3 document and returns it to the PEP, which forwards the anonymized data to the gateway. However, it should be noted that spelling mistakes in affected text elements or multimedia content could probably be problematic for an anonymization mechanism. By this approach the gateway itself can be left untouched. The Document Consumer receives the documents and can store them inside a database. The Document Consumer also has to be supported by a terminology service to cope with the large spectrum of medical terms and code systems to facilitate appropriate formulation of queries. This terminology service could support different steps of query formulation and query execution to further assist the secondary user with the correct selection of parameters to optimize results. The service could map a certain description (e.g. name of disease, name of laboratory parameter) to different terminologies (e.g. ICD-10,



**Fig. 1** Architecture for patient-centered and cross-domain use, extended to include components for cross-patient secondary use (dashed rectangle)

LOINC, SNOMED CT, MeSH) and also map between them.

With regard to performance and efficiency of queries on the retrieved, anonymized and stored documents inside the Affinity Domain “Secondary use” the database plays an important role. In this respect an XML-database could be appropriate for the storage of the anonymized and XML-based HL7 CDA R2 documents, which would also allow queries using XQuery as mentioned in Section 3.1.4.

## 4.2 Evaluation of the Architecture for Cross-patient and Cross-domain Secondary Use

To evaluate the architecture shown in ►Figure 1 the eight core requirements formulated earlier were applied. ►Table 1 shows the results of the evaluation. Six of eight requirements could be fulfilled. Re-

quirements 7 and 8 require activities that exceed the possibilities of the architecture. For requirement 7 the architecture is only able to check compliance with different policies. The definition of the policies is incumbent upon the respective statutory authorities. The characteristic that allows at least partial fulfillment of requirement 8 is the fact that the patients can view their data and all the audited handling of their documents that has been performed by primary and secondary users.

A limitation of the architecture exists in terms of usable document standards: it is intended for use with HL7 CDA R2 Level 3 documents because they are widely accepted and they form a good basis for secondary use based on their high level of structuring, although other documents based on the models of openEHR or CEN 13606 (as mentioned in Section 3.1.2) would also be applicable.

**Table 1** Evaluation of the architecture for cross-patient and cross-domain secondary use of EHR data

Requirement	Fulfillment
1. Use of standards and terminologies to permit structured and consistent acquisition of documents and enhance evaluability	yes
2. Possibility of cross-patient and cross-domain retrieval of documents	yes
3. Selection of documents by different parameters (e.g. time of creation, type of document)	yes
4. Possibility to anonymize the retrieved documents	yes
5. Possibility to formulate queries within the retrieved documents	yes
6. Assignment of user groups (roles) to restrain access to data	yes
7. Definition of and compliance with different transparent policies for secondary use of health data	partially
8. Sensitization within the population (possible risks and advantages)	partially

## 5. Discussion

We formulated eight core requirements that an architecture for the secondary use of EHR data has to fulfill, and introduced an approach for a possible IHE-based architecture for secondary use of EHR data.

Although a few assumptions were taken from the Austrian ELGA project, the approach may be used in other countries as well. The analyses carried out in this study show that IHE-based architectures such as the architecture intended for ELGA are not yet plug-and-play ready for secondary use because of their patient-centered nature, but may constitute an acceptable basis for prospective scenarios of secondary use. As described above, extensions and adaptations have to be performed on patient-centered IHE-based architectures in order to render routine data reusable. Along with the use of the actors and transactions of the IHE profile MPQ, new components like an anonymization service have to be inserted and existing components such as authorization systems adapted.

A weakness in terms of the possible potential of the developed architecture lies in the use of legally safeguarded anonymization instead of pseudonymization. Pseudonymization would facilitate answers to more complex questions such as the efficacy of drugs or other questions that need a kind of pretest-posttest comparison because of the usable reference of the corresponding patients' pseudonyms, whereas anonymization would only facilitate

answers to questions concerning trends and numbers. In this respect, Pommerein has described different possible scenarios for procedures of anonymization and pseudonymization that are appropriate for medical research networks [23]. Other popular approaches for data anonymization are *k*-anonymity [24] and *l*-diversity [25]. However, it must be carefully evaluated which method is suitable for a specific scenario to avoid attacks by exploiting a lack of diversity within sensitive attributes.

Other notable IHE profiles concerning information gathering include QED (Query for Existing Data) [26] and CM (Care Management) [27]. Although these profiles are lacking multi patient capabilities they implement enhanced search functionalities for clinical documents. Furthermore, IHE is currently developing another framework named the Quality Research and Public Health (QRPH) Technical Framework to deal with aspects of research and quality assurance. A part of this framework is formed by the supplement Clinical Research Document (CRD) [28] which permits retrieval, filling in, and storage of certain forms for clinical studies. However, our aim is to reuse the documents routinely created by physicians and stored in EHRs and not to use separate mechanisms for collection of data as CRD does. This renders the QRPH Technical Framework inappropriate for our purposes, but probably useful for conducting multicenter clinical studies.

A very important prerequisite for secondary use is standardization and correct composition of the documents. As mentioned above, standardized formats such as HL7 CDA R2 are necessary to facilitate integrated care [29]. Especially the correct composition of documents needs selective attention because increased standardization and structuring goes hand in hand with increased complexity at the point of composing a document.

With this fact in mind, another factor influencing the quality of documents becomes evident: the cooperation of documenting physicians. Physicians must be aware of the fact that the quality of their daily documentation will directly influence progress in medicine and affect the health status of entire populations. The possibility of reusing stored documents for research purposes would enhance the physicians' acceptance of structured documentation, as Prokosch et al. point out in [30]. Nevertheless, physicians are entitled to the best possible support, as they are confronted with the increasing complexity of structured documentation. Amongst other aspects, Dogac et al. [31] propose the use of an ontology for correct assignment of document metadata in order to avoid accidental inconsistencies in metadata.

Although not included in the scope of this paper, the formulation and use of templates and archetypes for the composition of documents in terms of standardization would further enhance the capabilities of a secondary use framework.

## 6. Conclusions

The coverage of population is part of public health care. Kukafka et al. [32] use the core functions assessment, policy development and assurance to evaluate EHRs concerning their ability to support public health. The architecture for secondary use designed in this paper would address the coverage of population and at least some elements of the core functions of public health mentioned above.

Should secondary use become a primary goal in terms of EHRs? It should definitely be regarded as a very important goal in electronic health care, second only to the

general interoperability in electronic health care. Further research will disclose the actual impact of secondary use of routine data on the health care system as a whole in terms of early identification of trends and the discovery of new associations.

Future research activities definitely have to include concepts to handle the large amount of clinical terms for the composition of highly structured medical documents like HL7 CDA R2 Level 3. This will improve quality of medical documentation in general and facilitate the selection of relevant documents for a certain problem in primary use, with the side effect of enhancing the possibilities of secondary use.

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