An EHR Prototype Using Structured ISO/EN 13606 Documents to Respond to Identified Clinical Information Needs of Diabetes Specialists: A Controlled Study on Feasibility and Impact

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Abstract

Cross-institutional longitudinal Electronic Health Records (EHR), as introduced in Austria at the moment, increase the challenge of information overload of healthcare professionals. We developed an innovative cross-institutional EHR query prototype that offers extended query options, including searching for specific information items or sets of information items. The available query options were derived from a systematic analysis of information needs of diabetes specialists during patient encounters. The prototype operates in an IHE-XDS-based environment where ISO/EN 13606-structured documents are available.

We conducted a controlled study with seven diabetes specialists to assess the feasibility and impact of this EHR query prototype on efficient retrieving of patient information to answer typical clinical questions. The controlled study showed that the specialists were quicker and more successful (measured in percentage of expected information items found) in finding patient information compared to the standard full-document search options. The participants also appreciated the extended query options.

Introduction

Today's healthcare professionals can access an ever-increasing amount of patient-related information and clinical knowledge, one of the most-promising applications being the Electronic Health Record (EHR) that is defined as the lifelong, patient-centered, institution-independent representation of all health-related data of a patient[1]. While the broad availability of clinical information is normally perceived as beneficial for the quality of care, there are also concerns that a lifelong cross-institutional EHR may lead to information overload, as important information may be hidden in the huge amount of information of a longitudinal patient history[2-3]. In general, information overload occurs when "information received becomes a hindrance rather than a help, even though the information is potentially useful"[4].

In Austria, a cross-institutional EHR is currently being introduced that will allow information exchange between all healthcare institutions such as hospitals, outpatient clinics, private practices and nursing homes. The Austrian EHR architecture is based on (i) the Cross Document Exchange Profile of Integrating the Healthcare Enterprise (IHE-XDS)[5] that specifies a framework for the exchange of EHR documents from various institutions and (ii) the HL7 Clinical Document Architecture (CDA)[6-7]. The availability of all patient-related information, independent of the location of the data, supports the vision of a patient-centered shared electronic health record[8]. However, EHR introduction in Austria is being slowed down, among other things, by fears of healthcare professionals regarding information overload and the legal consequences of overlooking important information in the EHR (for example, overlooking allergy information from an older discharge letter)[9].

Considering the standard search options for documents of different healthcare organizations within the IHE-XDS framework[5], these concerns are not completely unrealistic. These IHE-XDS standard queries exclusively refer to document metadata (for example, patient ID, provider ID, document type, date of document creation) and always return complete documents as the smallest unit of information. If physicians are, for example, interested in a series of measurements for an individual item (for example, insulin therapy of the last 12 months or HbA1c values of the last 6 months), they must manually locate the corresponding values in the retrieved documents of the desired time period. A pure metadata-based search thus leaves some room for optimization regarding the efficient search for information that is relevant in a particular treatment situation, particularly when searching for information within documents from different healthcare institutions. Within one healthcare institution, a physician usually has sufficient search tools available for searching within structured or unstructured information and documents in the local EHR. However, this is not the case in the Austrian IHE-XDS based cross-institutional EHR system, which only allows for searching and exchanging of complete documents.

Our basic assumption is that physicians using cross-institutional EHR systems need extended search options to fulfill their information needs and to address the challenge of information overload. Instead of relying on document metadata only, these extended search options should allow to search for specific content within structured EHR documents. This would give the physicians the possibility to search for specific information items (for example, HbA1c values or allergy information) in all documents within the Austrian national EHR system independent of the institution where the documents are located.

In today's heterogeneous world of health information technology, with many different EHR systems on the market, the employment of EHR standards is a prerequisite for interoperability[10]. ISO/EN 13606[11], Health Level Seven (HL7) Clinical Document Architecture (CDA)[12] and openEHR[13] are the currently most important standards for the specification of the contents of structured EHRs. All three aforementioned standards support the so-called "dual-model approach", which uses separate information and knowledge layers to model EHR contents.

This dual-model approach combines a static reference model with so-called archetypes (resp. templates in HL7 diction). Archetypes represent EHR contents[14] by means of standardized, computer-processable specifications. They are expressed in the Archetype Definition Language[15] and specify individual EHR contents by constraining the reference model[16]. As an example, an archetype specifying EHR content "blood pressure" defines, among other things, the structure of its content "systolic blood pressure" (compare Figure 1).

```
archetype (adl_version=1.4) openEHR-EHR-OBSERVATION.blood_pressure.v1
[...]
        OBSERVATION[at0000] matches {           -- Blood Pressure
        [...]
                ELEMENT[at0004] occurrences matches {0..1} matches {      -- Systolic
                        value matches {
                                C_DV_QUANTITY <
                                        property = <[openehr::125]>
                                        list = < [...]
                                                units = <"mm[Hg]">
                                                magnitude = <|0.0..<1000.0|>
                                                precision = <|0|>
        [...]
        }
```

Figure 1: Fragment of an archetype, specifying a blood pressure measurement. Adapted from [17].

Within the project "EHR Arche – Archetype-based Electronic Health Records" (http://www.meduniwien.ac.at/msi/arche), we developed an EHR prototype that offers an extended search for specific information items of distributed structured archetype-based documents within an IHE-XDS-based environment[18]. As an exemplary medical application domain, we chose the treatment of diabetes mellitus (DM) patients.

This EHR Arche prototype responds to clinical information needs of diabetes specialists that we identified using a combination of literature review, guideline analysis, observations of patient encounters and interviews with clinicians[19]. We identified 446 distinct information items (such as "recent blood pressure", "smoking habits" or "recent medication") and structured them in nine categories. Based on these data, ten clinical situations (such as "initial medical interview" or "routine check-up") and the related information items could be described[19]. The 446 identified information needs were then represented by 128 ISO/EN 13606 archetypes[20]. The IHE-XDS-conform EHR Arche prototype was then implemented and now offers extended search options for these information items in structured ISO/EN 13606 document (for more details of the prototype, see below).

Our expectation was that these extended search options are beneficial for responding to the identified information needs of the diabetes specialists. To evaluate this assumption, we conducted an evaluation study regarding feasibility and impact on time effort and quality of information retrieval. The objective of this paper is to report on the results of this evaluation.

Background: The EHR Arche prototype

Architecture of the EHR Arche prototype

Our objective was to use existing IHE-XDS actors and interfaces[5] wherever possible. We therefore prepared an IHE-XDS-based architecture (compare Figure 2) that comprised the following actors[18]:

(a) Document Repository Actor that persistently and securely stores clinical documents

(b) Document Registry Actor that manages a standardized set of metadata for each registered medical document

(c) Document Consumer Actor that allows to query and retrieve both unstructured (PDF) and structured archetype-based documents, allowing to search both for individual information items and for combinations of items

(d) Document Crawler Actor that processes the queries sent by the Document Consumer and then uses either a standard XDS document query to retrieve a full PDF document or an extended content-based query to retrieve distinct information items from archetype-based documents

(e) Archetype Repository that contains the 128 ISO/EN archetypes corresponding to the identified information items for diabetes specialists

The prototype is available at: http://ehrarchenew.dyndns.org:8080/ehrArcheConsumer.

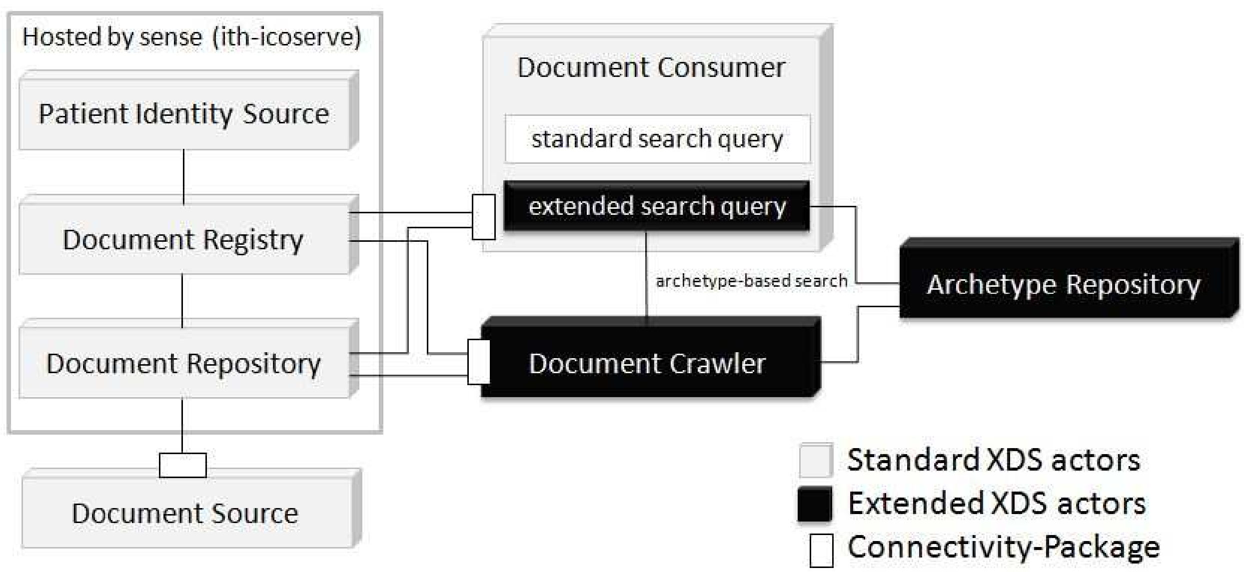

Figure 2: Architecture of the EHR Arche prototype, combining standard and extended IHE-XDS actors.

User interface for standard and extended search within the EHR

The Document Consumer of the EHR Arche prototype contains two parts:

1. A standard search interface for querying documents by using standardized IHE-XDS document metadata such as author of document, creation date or document type. The search retrieves PDF documents (such as discharge letters or laboratory results) from the lifelong cross-institutional EHR, corresponding to the selected metadata. The user than can browse through the PDF documents to identify the needed information. This standard search interface represents the way physicians search within the Austrian EHR system already today.
2. An extended search interface (Figure 3) for searching for specific information items or pre-defined collections of information items. These pre-defined queries reflect the 446 information needs when treating diabetes patients, as analyzed in a previous study[19]. The information items are internally referred to via codes of a

terminology (for the proof-of-concept, we used a local terminology), to which corresponding archetype nodes were mapped within the archetype ontology section. This indirection enables a future search for synonymous information items and a search for different archetype nodes (e.g. also based on reference models of different EHR standards) that semantically correspond to the same information item. Figure 4 shows how the retrieved results (that is, the specific information items) are presented to the user. This extended search option is new and not yet available for the Austrian EHR system.

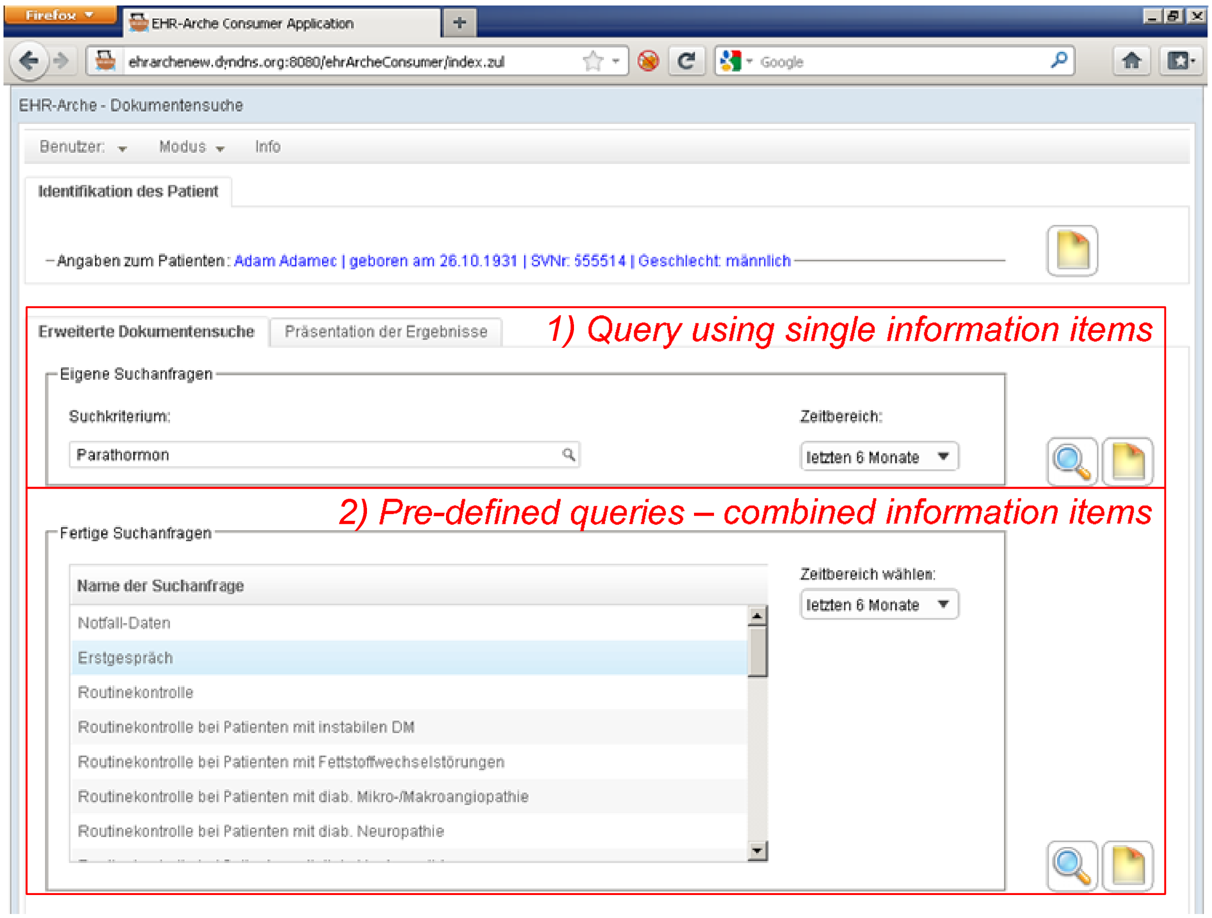

Figure 3: Frontend of the EHR Arche extended search interface: The user can choose whether to search for clinical information based on single information items (1). These single information items reflect the identified 446 information needs, for example, “medication” or “smoking” or “HbA1c” or “parathormone”. Alternatively, the user can use pre-defined queries that search for a combination of information items (2). For example, “Erstgespräch” (= initial medical interview) includes around 200 information items that are of interest during a first encounter with a diabetes patient, while “Routinekontrolle” (=routine check-up) contains 42 information items. In both cases, the age of the document where the information is contained can be determined (for example “letzte 6 Monate = last six months”).

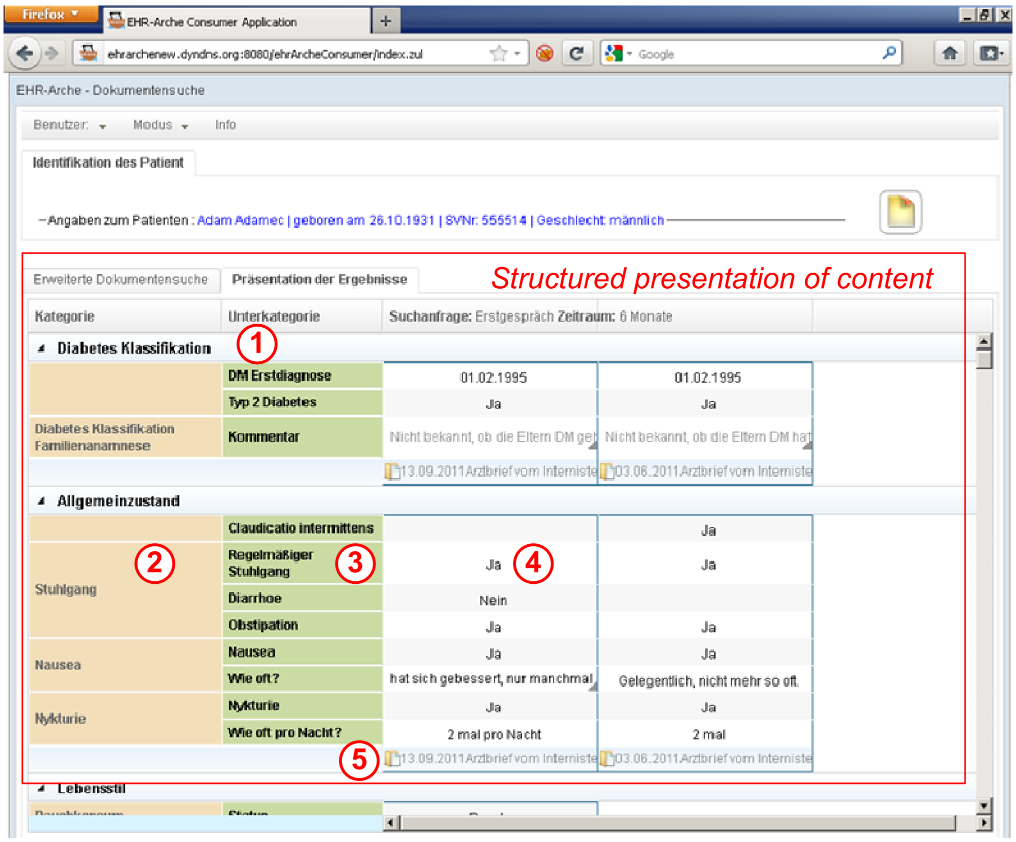

Figure 4: Frontend of the extended result presentation: Each line stands for an information item. The information items (3) are organized into logically connected groups (2). Each column represents a single document which contains the given information item. For each document, the value of the information item is displayed (4), either in qualitative or quantitative form. It is also possible to retrieve and display the full document by clicking on the document name (5).

Methods

Our evaluation questions were as follows:

1. Is using the extended search interface more successful in fulfilling clinical information needs than the standard search interface? Thus, is searching for information items in structured documents more successful than searching in full-text (PDF) documents only?
2. Does the extended search interface help to more quickly fulfill clinical information needs than the standard search interface?
3. How satisfied are the users with the extended document query interface? Do they feel it better responds to their information needs? Is the overall approach feasible?

Study design

We conducted a controlled study combining a formative and a summative evaluation. Success (study question 1) was measured by percentage of expected information types found, efficiency (question 2) was measured by time to answers within 20 min., and user satisfaction (question 3) was measured through a standardized survey. We thus used methodical triangulation, combining observations, interviews and a survey, to systematically aggregate different perspectives of the investigated object[21].

A medical expert prepared realistic test cases of two diabetes mellitus patients with related numerous complications and therapeutic interventions. For each patient, around 60 documents were prepared, such as discharge letters from various institutions (for example, from an internist, a neurologist, a dermatologist and a general practitioner) and reports of various examinations (for example, lab results and patient self-measurements). Each document was made available both in unstructured form (PDF document) as well as in identical form as structured, archetype-based document (ISO/EN 13606).

For each patient, we prepared a clinical scenario describing a typical doctor's consultation: a routine check-up of an unknown diabetes patient. Each scenario comprised five clinical questions that the physician typically may want to respond. The clinical questions were derived from typical information needs analysis of diabetes specialists[19] and comprised questions on:

1. Family history
2. Overview on general disease status and medication
3. Specific clinical questions related to individual problems and further treatments. Example: "The dermatologist suggests a debridement on both feet with an accompanying antibiotic therapy. The patient tells you that she poorly tolerated the last antibiotic therapy, but she doesn't know the name of the medicament."

For each clinical question, we defined a gold standard that presented the best available answer that could be obtained based on the available EHR data. For the example (3.) given above, the gold standard is: "Drug intolerance to Cephalexin/Ospexin", this information being contained in the discharge letter from Oct. 5, 2010. Some clinical questions could only be answered by more than one information item – for example, questions on the last medication of the patient. Altogether, the first patient case scenario comprised five clinical questions with the expected answers comprising 30 information items; the second patient case scenario comprised five clinical questions with the expected answers comprising 27 information items.

Seven diabetes specialists from Vienna and Tyrol with specialization in diabetes mellitus participated in the study. Six of them came from the diabetes outpatient clinics of four different hospitals and one from a private practice. We organized a two-hour appointment with each of these participants.

Study flow

First, each participant was given an introduction to the study and a training session on the EHR Arche prototype. Then the first patient case scenario was presented and the pre-defined clinical questions were asked. We asked the participant to find the correct answer to each question by using the EHR Arche prototype. For one patient case scenario, the participant was asked to use the standard search interface that only allows searching and retrieving PDF documents. For the other scenario, the participant was asked to use the extended search interface that allowed searching for individual information items from the structured EHR documents. The order of scenarios was changed for each participant. Interfaces and scenarios were not tied, but balanced to minimize order effects (see Table 1). Overall, as we had seven participants, we performed 14 scenarios: seven cases with the extended search and seven cases with the standard search.

Each participant was monitored by one observer while trying to solve the patient cases. The observer documented the found answers to the clinical questions. The time for answering the questions in each scenario was limited to 20 minutes to reflect a typical clinical encounter in the chosen clinical setting.

After finishing both scenarios, the participants answered a short written survey to document their first impressions of using structured documents to answer clinical questions. This survey polled participants on their assessment of searching and accessing information, on usability and on user friendliness. Overall, the survey comprised 16 closed questions on a 4-point Likert scale. In addition, we conducted a semi-structured expert interview with each participant to discuss questions of usefulness and feasibility as well as ideas for improvement. These interviews where audio-recorded and transcribed.

Data analysis

The survey results and the answers to the clinical questions were analyzed using quantitative descriptive data analysis. Performances (success rate of finding the answers to the clinical questions) between extended search and standard search were compared using the Wilcoxon-Mann-Whitney U test with alpha set to 5%. The interviews and field notes from the observations were analyzed using inductive summative content analysis.

Results

Five of the participants reported being very familiar with using the computer, two participants reported having medium familiarity. All seven participants stated having great interest in eHealth issues and health information exchange.

Success of finding information

Using the extended search, all participants were able to answer all clinical questions correctly within the time limit of 20 minutes. Using the standard search, the overall performance was lower with around 80% success rate (Table 1), meaning that 20% of the expected information items could not be found within the time limit. The differences between extended search and standard search are significant for both patient scenarios (p=0.007 resp. p=0.002).

Table 1: Success in finding the expected information items and ability to answer the clinical questions. Overall, seven physicians participated. Patient A: 30 information items to be found. Patient B: 27 information items to be found.

	Success rate using extended search	*Success rate using standard search*
Participant No. 1	*100% (patient A)*	*88.9% (patient B)*
Participant No. 2	*100% (patient A)*	*88.9% (patient B)*
Participant No. 3	*100% (patient A)*	*74.1% (patient B)*
Participant No. 4	*100% (patient A)*	*77.8% (patient B)*
Participant No. 5	*100% (patient B)*	*100% (patient A)*
Participant No. 6	*100% (patient B)*	*66.7.% (patient A)*
Participant No. 7	*100% (patient B)*	*70% (patient A)*
Mean performance rate	*Patient A: 100%* *Patient B: 100%*	*Patient A: 78.9%* *Patient B: 82.4%*

Time needed for answering the clinical questions

When using the extended search, all participants were able to find the correct answers to the clinical questions within the given time frame of 20 minutes. Answering all questions took the participants between 10 and 14 minutes for the first patient case scenario and between 8 and 12 minutes for the second patient case scenario.

When using the standard search, only one participant (No. 5, see Table 1) was able to find the correct answers to all clinical questions in the given time frame. The others had to stop the search after 20 minutes.

Search patterns when searching for clinical information (results from observations)

While observing the participants when using the metadata-based query, all participants started retrieving the most recent 3 – 4 documents from the EHR (7 cases). In addition, depending on the clinical question, they also searched for older documents within certain clinical areas (for example, dermatology results) (5 cases) or they went through all older documents in chronological order until they found the needed information (2 cases). We observed that participants were quite used to scrolling quickly through PDF documents to find specific requested information items (6 cases). The need to open and close many PDF documents was found cumbersome by participants (5 cases) and participants expressed not being able to capture the complete content of a PDF document in a short time (4 cases). One user used the search functionality in Adobe Reader to search for information in the PDF documents.

While observing the participants when using the extended query, we found that participants combined pre-defined queries (7 cases) with the search for individual information items (6 cases). One problem for the participants was to recognize cases where information items were contained identically in several documents (4 cases). In other cases, participants had difficulties identifying in which documents the found information items were contained, especially in cases where several items for one document were presented (4 cases). Regarding usability, 23 suggestions were retrieved from the observations to improve the user interface of the prototype, such as showing only one information item in cases where identical items are contained in several documents, or highlighting the date of an information item.

Participant's assessment of the extended search options (results from user survey)

The following numbers show the answers of the seven participants to the written standardized survey:

1. The extended search is simple and self-explaining to use: n=1 partly agree, n=6 fully agree
2. The extended search is more intuitive than the standard search: n=6 fully agree, n=1 no answer.
3. The extended search is more complicated than the standard search: n=7 fully disagree
4. The extended search is quicker than the standard search: n=7 fully agree
5. Medical data found in the extended search are clearly presented: n=4 partly agree, n=3 fully agree.
6. Medical data found in the standard search are clearly presented: n=3 partly disagree, n=4 fully disagree
7. The pre-defined queries are useful to obtain an overview about a clinical situation: n=7 fully agree
8. Information overload is better manageable with the extended search: n=7 fully agree
9. Information overload is better manageable with the standard search: n=7 fully disagree
10. It makes sense to further develop software tools to support searching in clinical documents: n=7 fully agree
11. I would like to have access to a longitudinal electronic record of my patients: n=1 partly agree, n=6 fully agree

Overall participants' assessment of the feasibility of the chosen approach (results from the interviews)

When discussing the metadata-based standard query options, the participants stated that it is difficult to find needed information because a great amount of data is normally not retrievable due to the large number of documents (n=2). They also stated that it is often unclear whether found information is complete (n=1). One participant stated that it is very time-consuming to retrieve information from full-text documents (n=1) and three participants stated that discharge letters from different institutions are often structured differently, making information retrieval more difficult (n=3).

Regarding the extended query, the participants stated that the extended search was intuitive in use and worked well (n=5) and that it helps to respond to their personal needs (n=4). The experts especially found the pre-defined queries very helpful (n=7). However, they also wanted to have the possibility to adapt the pre-defined query to their specific needs (n=4). The participants found it legally important to be sure that the presented information items are complete and correct (n=3). The good response time (n=4) and the design of the pre-defined queries (n=3) were positively mentioned. The participants made nineteen suggestions to improve the user interface. Three participants expressed their interest in using the tool as soon as it is available in routine care.

Discussion

Already in 2004, Godlee et al discussed the future of health information management[22]. They cited a report demanding that people accessing health information "should be given the chance to say what they want rather than simply be sent information". This simple idea was the basis for the EHR Arche prototype: Instead of simply providing a set of documents that physicians need to go through by hand, physicians now have the opportunity to state their information need in the form of a query and to get the specific information responding to this need.

The usage of archetypes within health information systems has been discussed for some years now and research has been conducted on the question on how to define archetypes and how to use them for documentation. However, as far as we know, our study is the first attempt to map systematically identified information needs to archetypes and to use these archetypes to develop a query interface allowing searching for (sets of) information items.

The EHR Arche prototype was found to be sufficiently stable and performant. In the survey, and confirmed by the interviews, all participants appreciated the concept of extended search and preferred the extended search opportunity over the (quite familiar) metadata-based standard query options that retrieve single documents and not specific information items.

We have focused on the setting "diabetes mellitus treatment". We included diabetes specialists from several hospitals as well as internists to ensure that the results not only reflect the situation in one institution. Most participants reported being quite familiar with computers; this may explain why they did not have greater difficulties in handling the unfamiliar prototype. We tried to create realistic, yet complex patient scenarios. The scenarios were developed based on observed clinical encounters and should thus reflect typical complex cases in an outpatient clinical setting.

While we have focused on the setting "diabetes mellitus treatment", the overall approach and architecture seem to be generalizable to other clinical settings, although we did not investigate this yet. We developed the EHR Arche application in a way that it can handle any list of information items and queries as well as any list of related archetypes.

The time needed to develop the pre-defined queries was quite high. We expect that the information needs in a specific clinical situation do not differ much at different healthcare institutions, which would mean that the pre-defined queries of one site can be re-used (perhaps in a slightly adapted form) at another site. However, this still needs to be further verified. In addition, it is unclear whether it is possible to identify specific information needs in a more general clinical setting such as at a general practitioner.

The time needed to answer the clinical questions of the scenarios by using the standard search was much longer (> 20 minutes) than when using the EHR Arche prototype (8 – 14 minutes). In addition, the success rate was much lower (around 80% versus 100%). At first glance, these results may not be too surprising, as searching in structured documents may intuitively be considered to be more efficient. However, using a query editor to search in structured documents is unfamiliar and may be considered complicated and even more time-consuming than simply retrieving PDF documents. In addition, presenting long lists of information items separated from their context may be regarded as risky, not informative and may even lead to an increased feeling of information overload. The results of our study, however, do not support these concerns. On the contrary, our participants found querying structured documents based on identified information needs useful and more efficient.

We observed that, in the standard search, all participants first focused on the most recent 3 – 4 clinical documents when searching for information, sometimes additionally retrieving selected older documents. Participants confirmed that this is the usual way of searching within a large number of EHR documents given the time constraint of a typical clinical encounter. This approach is successful to retrieve most recent information (when using the standard search, we had a success rate of around 80%), but clearly tends to fail in cases where the course of a disease needs to be analyzed over a longer time period or where older information (for example, older information from the family history or an old clinical note on a medication allergy) needs to be retrieved. Participants stated that focusing on the 3 – 4 most recent documents often leaves them unsure whether further important information may be contained in other documents which they did not find time to look at. On the contrary, when using the extended query, they seem to feel more secure, as they can retrieve all information from the last few months or years, so the danger of overlooking older information is reduced.

Some research has been conducted on the possibility to conduct free-text searches in EHR documents[23]. This approach gives the user the freedom to search for any information that is needed. However, these approaches have two major weaknesses: First, they do not support identified information needs, for example by offering pre-defined queries. Our tool comprised this kind of specific, pre-defined queries. Second, free-text search does not take into account the semantic context of an information item. For example, a user who wants to search for elevated blood pressure (> 140/90 mmHg) can principally do so in archetype-based structured documents, but not through a free-text search. For this, dual-model approaches of structured documents are needed and have thus been used in our EHR Arche project.

Conclusion

Our results show that, in a cross-institutional EHR setting, diabetes specialists who need specific information to respond to clinical information needs appreciate the possibility of searching for specific information items, compared to searching in full-text documents. This mapping of information needs to archetype-based documents also leads to quicker and more successful information retrieval. Further work is needed to make more structured documents available so that this extended search support can be introduced in routine care. In Austria, most EHR documents currently are unstructured PDF documents.

Another research task is the development of a methodology for analyzing information needs for specific settings (outside diabetes care) and to transform these needs into related queries and archetypes, so that other clinical areas outside diabetes can also be supported in the future. Finally, a field study needs to be conducted to investigate whether the promising results of this laboratory study can be transferred into routine care.

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