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Developing large-scale Electronic Patient Records conforming to the openEHR architecture

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Abstract

This paper focuses on one of the first efforts to implement large-scale Electronic Patient Records (EPRs) in Western hospitals conforming to the international openEHR architecture. A key aim with the openEHR architecture is to offer clinical users the possibility to define structured content of the EPR themselves. This is supposed to contribute to interoperability across various health care systems. The paper contributes with empirical insight in the first two years of the process and argues that establishing working systems in this area entails huge socio-technical challenges to make such systems work.

Keywords: openEHR; archetypes, large-scale projects, Electronic Patient Records

1. Introduction

Current Electronic Patient Record systems (EPRs) are generally characterised by a clinical content that is made up of free text [1]. This makes it hard to use the content for nothing more than registering and looking up patient information [2]. This is increasingly a problem as treatment and care of diseases frequently is coordinated across different service levels in health care, which requires that information about patients can be easily compared,

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analysed and reused along the patient's illness trajectory across different service levels. Accordingly it does not come as a surprise that structuring the content of the EPR is considered crucial interoperability between different information systems in health care.

Still at the same time, structuring of the EPR has proven extremely difficult to achieve and contains many failed efforts [3,4]. One reason is that structuring requires standardisation of the structured elements – a standardization, which up to now typically has been enforced on the users in a top-down manner, i.e. by international and national standardisation organisations. As an interesting alternative, we look into the emerging new international openEHR architecture [5,6] that offers clinical users the opportunity to structure and share the EPR content across various use contexts solely based on their own interest and effort. Through this architecture, the users decide how they want to structure the EPR, which basically puts them in the role as lead-users [7]. The openEHR has been tested in many medical informatics research projects with considerable success, but there have been limited experience with real large-scale implementations [8–10]. This makes our study particularly relevant as Norway's largest EPR vendor currently is developing its EPR portfolio conforming to this architecture.

This is our point of departure when we ask the following research question: What characterizes the openEHR approach in structuring clinical content of the EPR? How useful is it and what are the challenges? And what kind of users is necessary?

Empirically we report from a large-scale EPR project 2012-2016 in the Northern Norwegian Regional Health Authority. A key aim of this project was to replace an existing, largely free-text-based EPR with a new archetype-based (i.e., highly structured). In the remainder of this paper, we begin by elaborating on the openEHR architecture. After that we elaborate on our methodological approach. Next, we describe the large-scale EPR project followed by three empirical vignettes from the local, regional and national health care level respectively. Finally we provide a concluding discussion.

2. The openEHR architecture

The openEHR architecture is envisioned to ensure interoperability and reuse of information by offering clinicians the responsibility for defining the structured elements of the EPR, i.e. its clinical content in an ever-changing clinical sector. Systems conforming to the openEHR architecture are considered to be "more open, adaptive and collaborative than ever before [11]. They are based on standardized information models, shared clinical content models and open sourced core components". The openEHR architecture was developed by the openEHR foundations and standardized by CEN and ISO in the EN/ISO 13606 standard series [10]. It consists of a so-called two-level modeling approach for EPRs [6,10] that separates the technical design of the system and clinical concerns. This means that information systems designers basically can focus on the technical side (the underlying information model etc.) and experienced clinicians can focus on the clinical side (i.e. defining the EPR's structured clinical content).

In the two-level modeling approach, a standardized reference model represents the first level, which is a generic model for all kinds of health information [12,13]. This means that a general-purpose set of data structures store different types of clinical information without changes to the underlying information model. For example, a blood result from the laboratory and a blood pressure reading would be stored in the same general-purpose data structure. This ensures to keep the information model small and manageable for information systems designers as well as it is easy to add new types of clinical information as the health care field evolves.

OpenEHR *archetypes* represent the second level [6,14]. An archetype represents a single clinical concept, say "blood pressure" and defines the content and shape of data that needs to be stored for the blood pressure concept [12]. For instance, "in the case of a blood pressure measurement, the information model must have capability to capture blood pressure values (systolic and diastolic), clinical context such as sitting or lying and cuff size" [15]. This implies that an archetype represents a maximum definition of a clinical concept. "A blood pressure archetype for example represents a description of all the information a clinician might want or has to report about a blood pressure measurement" [6].

The actual blood pressure value would typically be accompanied by additional data on whom, how, when and where as a way of describing the context around the blood pressure measurement. Archetypes are therefore "metadata used to define patterns for the specific characteristics of the clinical data" [16].

Fortunately not every archetype needs to be developed from scratch. On the international level, almost 600 archetypes have been agreed upon and are organised in the openEHR's Clinical Knowledge Manager (CKM) (http://www.openehr.org/ckm). Archetypes can be downloaded and adjusted from the CKM to be used in different national, regional and local contexts. The above-mentioned adjustments means that each clinical context and user domain wouldn't necessary need all the metadata that comes with an archetype. Therefore, so-called templates can be defined and applied in order to tailor the archetypes for certain clinical situations. This may imply to compose archetypes into larger structures - often corresponding to screen forms, documents or reports [14]. Furthermore, templates may also be used to impose further "local constraints on Archetypes, including removing or mandating optional sections, and may define default values" [15].

Through the OpenEHR approach, skilled users can easily extend and adapt clinical content and archetypes as a way of customizing systems to their local needs [6,10]. In this regard, archetypes can be seen as generic building blocks in the hands of clinical personnel or domain experts:

A fundamental aim of the archetype approach (...) is to empower domain experts to create and change the knowledge inherent in archetypes, thus controlling the way EHRs are built up using designed structures to express the required clinical data and assuring that all necessary constraints on the values of record components are observed [6].

However, a key challenge (and perhaps somewhat overlooked) is that despite the availability of some international archetypes, developing, adapting and using archetypes do not appear out of thin air. Their definition and use require consensus on the maximum definition, which typically presupposes a negotiated process. It requires also agreement on how a specific template should tailor or delimit the scope of the archetype at a certain health care level. The socio-technical challenges around these issues are exactly what is the focus in this paper.

3. Method

Our study sites include the three health care levels in Norway. The University Hospital of Northern Norway represents the local level. The North Norwegian Health Authority represents the regional level and the National ICT (institution responsible for coordinating ICT-related initiatives in the specialised health care services in Norway) represents the national level.

The study is based on an interpretative research tradition [17,18], where reality is socially constructed among the participants. The epistemological belief in interpretive research emphasizes the understanding of social processes by getting involved inside the world of those generating them, and not by hypothetical deductions or predefined variables. The approach also assumes that social realities are not discovered, but interpreted, meaning that a phenomenon is looked at from different viewpoints.

In line with an interpretive approach, the authors have collected the empirical data on a local, regional and national health care level by participant observation, document studies, and formal semi-structured interviews with stakeholders involved in the openEHR architecture and archetype development. The data collection started in January 2012 and is still ongoing.

4. The BigInvestment project

After a prolonged bid for tendering process, the North Norwegian Health Authority decided in 2011 to invest in new clinical ICT systems from BigVendor for all 11 hospitals in North Norway. The BigInvestment project was established for the 2012-2016 period. Moreover, it is estimated to cost 82 million EURO, which currently makes BigInvestment one of the most ambitious healthcare- related ICT projects in Norway. The Northern Norway Regional Health Authority employs about 12,500 person-years. The University Hospital of Northern Norway (UNN) is by far the largest of the 11 hospitals and has around 6,200 employees and 600 beds.

The involved vendor (BigVendor) in the project started approximately five or six years ago to use a model-driven architecture, which culminated in 2011 by its decision to use the openEHR architecture. The vendor's decision also conformed to the National Norwegian strategy on using archetypes.

By committing to the openEHR architecture and the use of archetypes, BigVendor started to use the open source library from Ocean Informatics (https://oceaninformatics.com). The motivation for using the openEHR architecture was the clear separation of technical and clinical concerns. According to the BigVendor, this would make it less resource demanding to maintain the system after it was developed. Consider the following statement:

"The profit by using the archetype approach is that it allows us to live in our own little developers' world (...) the designers don't need so much clinical contextual knowledge, and the domain experts don't need extended technical skills—but we have to know a little bit of each other's domains. (Manager, BigVendor)

5. The local level - developing an openEHR based EPR

The vendor started the development process in the spring of 2012, with the aim of carving out a completely new EPR conforming to the openEHR architecture. This included a lot of interaction with the future users. However this turned out to be a bit more complicated than anticipated for the developers, as they always had to make sure that their software was able to support the openEHR framework.

"....It is a technically advanced system with a dramatically higher degree of complexity than before... We are not going to develop specific local functionality in for example surgery planning, but rather generic functionality that makes surgery planning possible."

Some demonstrations for the users of what the new software possibly could do, was very impressive as the vendor could illustrate how a structured element could be created on the fly in the EPR's text editor and then could be easily reused for instance in the patient's medication chart. Still, the actual development process took much more time than BigVendor had anticipated, and several times it was necessary to work out more technical solutions before the specific user requirements could be taken into account. In this way, the users were not presented pieces of working software, but rather the building blocks that could be used for including the archetypes and templates the user might want when the EPR was ready to be put into real use. As a result, the users (particularly the physicians) became less motivated for taking part in the workshops and their participation and engagement decreased.

In October 2013 the new EPR was ready to be piloted and tested at the university hospital. The users were happy with the new interface and how the data was displayed. They considered the screen layout to be a major improvement since they had to open six different windows to display the same amount and type of information in former EPR implementations.

Many users thought that the new EPR developed was complete in a sense that they got a structured EPR, but this was not the case. Although the EPR focused on physicians' work settings, data had yet not been structured, and hence data reuse was not possible. BigVendor had defined only a small number of archetypes to exemplify how these would work in the EPR. These were archetypes of clinical observations, like blood pressure, weight and height, data that surgeons register in the surgery order form. Particular archetypes necessary to set up workflows had not yet been defined, and hence workflow support was missing. Further work on defining archetypes would have to be done by the hospitals themselves, which is accordance with the openEHR philosophy.

6. The regional level – the need for consensus building among users

The experiences from the pilot test illustrated that some archetypes had to be integrated into the system already from the start. The period of demonstrating how to make archetypes "on the fly" was definitely over as one of the key developers recalled:

"In the early phase, we appreciated the huge positive demo effect of adding archetypes dynamically on the screen, but after a while you realise that there must be rules for what you are allowed to put into the documents "

Basically an archetype had to be agreed on within a group of users that was expected to use, share and reuse the archetype. This meant that for archetypes to be created and used among the hospitals in the northern health region, clinical personnel from the 11 hospitals had to come to some agreement on how a given archetype should look like.

In this process, the Health Authority Northern Norway established a dedicated track to standardise the deployment, government and support of the future system as well. This involved 18 working groups, consisting of 70 health care personnel, to address various degree of standardisation. The personnel were selected from the hospitals in the region and from different professions to ensure that different perspectives were addressed. This process is currently on going, but it is still not clear how this shall be done on a robust and lasting scale.

Overall the Health Authority Northern Norway came to the conclusion that to develop and maintain archetypes from scratch was an enormously cumbersome task and that this should be done by one of the other more resourceful health regions. Consequently the Western Norway Regional Health Authority undertook this responsibility.

Despite having the resources, also the Western Norway Regional Health Authority experienced challenges in the governance of archetypes. An illustrative example was presented on BigVendor's user forum by one of the project leaders of the archetype development: Two different groups where commissioned to work on the development of an archetype for "tobacco use" and ended up with two very different archetypes. In one case, the archetypes had three first-level attributes: "Do you smoke", "How much tobacco per day" and "Passive smoking". In the other case, the archetypes had five first-level attributes: "Do you smoke (no)", Do you smoke (yes)", "health condition", "functional level" and "family health history". And to make things worse, none of these archetypes were compatible with openEHR's archetype on "tobacco use". This clearly illustrated that some larger consensus among the involved stakeholders was needed.

7. The national level - governance

For National ICT it was clear that a national governance of archetypes was necessary. An important task of governing the archetype development for Norway would be twofold. First and foremost it was important to coordinate the development of new archetypes based on suggestions and validation from different stakeholders in the health care field. Second, as almost 600 archetypes existed already in the openEHR's Clinical Knowledge Manager (CKM), they should also take care of the translation of many of the international archetypes into Norwegian language and Norwegian context.

A key point for National ICT was to reuse the work that the openEHR organisation had done already on the development of archetypes. Thus it was considered crucial not to start from scratch, but to build on the existing international experiences. In a project report from National ICT it was stated:

"There are forces that take the process [the work on archetypes] in the wrong direction, such as the development of national repositories/CKM cf Sweden and Australia instead of consolidating the international development of archetypes" [19].

To gain some experience on the use of archetypes, the National ICT planned to develop around 35 archetypes. In this process, the participants realized that it was necessary to have considerable experience to work with this both in a clinical and technical sense. It was also essential to know what could be found in openEHR's repository (CKM) and what could be found in other national repositories, such as in Australia, NHS or Sweden. In this regard, the project group found that the NHS had done a lot of work relating to bind archetypes to clinical terminologies (such as SNOMED). Furthermore the group also found that some archetypes from the Australian NEHTA repository were more developed archetypes as compared to the openEHR repository as these had been through more commenting among the stakeholders and had been through several rounds of negotiations. In these cases, the Australian repository was taken as a starting point [19]

Still it was necessary to make specific translations to the Norwegian context and as many as 9 out of 35 archetypes was adjusted. For example the group found that for the archetype for "risk for illness" was necessary to introduce the quantitative concepts of "absolute risk" and "relative risk" as openEHR in their archetype only had a classification of 4 categories from low to high risk and that was according to the project group insufficient.

8. Concluding discussion

The new openEHR architecture is promoted as being very flexible for the users as they may take charge of the process of defining structured content in the EPR. And to be true, the first demonstrations of what the new EPR

could do were very impressive: Archetypes could be defined, used and reused at a moment's notice by the user him/herself. In this way, the new EPR had clearly showed its technical potential.

However when we turn to the organizational side, things turn out to be more complicated. While archetypes can be easily defined, one always has to consider at which level the archetypes will be used and shared. For instance, at the regional level, clinical personnel at this level has to negotiate and compromise on how an archetype at this level should look like. This is far from easy as our example of "tobacco use" suggests. Similarly, the effort of National ICT in Norway to use archetypes from international repositories of archetypes (i.e. CKMs), indicates that there are little coherence among the existing repositories. Some of CKMs had very good quality in certain areas (Australia on maturity and consensus building) and UK on terminology bindings. This turned out to be the case for the Norwegian repository as well. Several of the chosen international archetypes had to be adjusted when designed for a Norwegian context.

Overall, there is no such thing as a best way of structuring clinical content. What increasingly seems to be crucial is to engage clinical users in the process. This would definitely be a major challenge as also our data illustrates. The commitment of users extend as far as they can get results within a relatively short timeframe. In addition, the actual designing of the archetypes appeared to require a lot of experience, both in clinical and technical senses. A major challenge would then be to motivate the users to engage actively in archetype design, not for a project period, but rather as an ongoing process as part of their clinical work. However given, the experience necessary to design complex archetypes, it is still an open question on how *many* users should be involved, what *competence* they should possess and how a long-lasting organization should be set up.

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