Structuring the Electronic Patient Record; an Easy Way to Improve Data Usability?

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Abstract. In this paper, a qualitative trailing research approach is used, combined with information infrastructure theory to conduct a formative evaluation on an empirical project in North Norway. In this project parts of the clinical information in the electronic health record (EHR) were structured as openEHR archetypes to enable automatic reuse of data from the EHR system to a national medical quality registry. We explore the design-challenges when structuring clinical information for different purposes. Hence, we ask the following research question: What are the premises for reusing clinical information for both primary and secondary purposes? The paper aim to contribute with empirical results and discuss the importance of understanding the prerequisites and implications of reusing clinical information for a duality of purposes. As results we outline three important issues to address. 1) the demand for attaching context when reusing variables, 2) how to ensure reusing the right data, and 3) the challenges of granulating the variables. Lessons learned indicates that governance and competence are the most important prerequisites for improving data usability by structuring clinical information.

Introduction

Over the last years, building global healthcare frameworks to improve clinical data usability have gained increased attention. In line with this, there are extensive

ambitions of reusing data from Electronic Health Records (EHRs), both for clinical use and for secondary purposes, like registries, research, and management (Greenhalgh et al., 2009; Häyrinen et al., 2008; Min et al., 2018). In Norway, gathering information from national medical quality registries is particularly important, since they are regarded as means to improve health systems and the quality of patients' treatment and care (HOD, 2020).

Today one of the main problems when it comes to exchange and reuse of health data is that most of the EHR content is registered as free-text information (Severinsen et al., 2020; Häyrinen et al., 2008). To comply with this, vendors, healthcare providers and even government programs have promoted and purchased solutions to solve interoperability between different health information systems (HIS). However, the flow of clinical data is not yet solved, and the outcome and expectations to improved data usability is still a "work in progress".

Previous research has investigated different approaches like HL7 FHIR (HL7, 2014), and openEHR (Beale, and Heard, 2008; OpenEHR, 2019) for designing standardized and structured information models (Bernstein, 2009), and how these approaches can solve the need for exchanging clinical information within and between systems. However, the primary purpose of clinical documentation is about collecting, assessing, and using clinical information in point of time, and recording information for colleagues taking over the patients on the next shift. A change in focus is needed for information to be used outside the context of patient's treatment and care, and reused for secondary purposes (Häyrinen et al., 2008). In another study, the duality of purposes was found to create tensions because the demand to generate data for secondary purposes led to more work of creating data for healthcare professionals (Greenhalgh et al., 2009). Still, there is limited knowledge about how exchange of clinical information within and between systems depends on the origin of the information, namely the primary purposes. How does the need for improving data usability play out in the existing clinical documentation practices?

One promising way to reuse free-text data from EHR systems is AI methods like Natural Language Processing (NLP). This has been tested, but so far been rather unsuccessful due to the variety and heterogeneity of the EHR content (Lee and Yoon, 2017; Malm-Nicolaisen et al., 2019). A different strategy for automatically exchanging healthcare data across different context is to standardize the clinical information in the EHR. We used a qualitative trailing research approach to follow and participated in one such standardization process in the North Norwegian health region between November 2018 and June 2020. In this project standardizing clinical information in the EHR to achieve semantic interoperability, was done using the rich information models of openEHR archetypes (Beale and Heard, 2008; OpenEHR, 2019). The goal of the project was to design an electronic registry form for the EHR system. The form was modelled by using clinical standards aimed to extract specific registry information from the EHR's database

and automatically exchange the information to the national spine and neck registry, NORspine (Silsand et al., 2019).

During this design process, several socio-technical challenges occurred. Hence, we connected the empirical findings with the theoretical framework of information infrastructures (Bowker and Star, 2000; Hanseth and Lundberg, 2001). This framework contributes with a specific perspective on understanding the complexity of design and an implementation process from both organisational, structural, technological, and human perspectives to be successful. In addition, the framework points out that designers should 'build upon the existing installed base', in this case the present clinical documentation process.

The empirical project was a collaboration between the regional program for implementing regional ICT systems (FRESK), and neurosurgeons working both at the hospital, and as leaders of NOR spine. We explore the design-challenges when structuring clinical information for different purposes and outlines three important issues to address. Hence, we ask the following research question: What are the premises for reusing clinical information for both primary and secondary purposes? The paper aim to contribute with empirical results and discuss the importance of understanding the prerequisites and implications of reusing clinical information for a duality of purposes.

Background

Today, the documentation of treatment and care is mainly free-text descriptions, recorded retrospectively. Related to neurosurgery normally surgeons fill in a paper-based form after the surgery is conducted. Then, the surgeons need to go back and forth in the EHR system to gather all the relevant information. When the paper-based form is completed, a nurse logs in to the registry's web-based portal and transfer the information into the portal (Silsand et al., 2019). The time and resource demanding double documentation, and lack of reuse and exchange within and between different systems reflects the limited maturity of the existing EHR systems in Norway (HOD, 2015).

In November 2018, a collaboration between FRESK (Norwegian abbreviation), and NORspine (Norwegian abbreviation), was established. The purpose was to design an openEHR-based form to implement in the new EHR system. The aim of the design was automatically reusing clinical data from the clinical documents in the EHR to fill out the registry form, and automatically exchanging the data in the form to NORspine. Reuse of data would limit the need for double documentation. An indirect goal of reusing clinical information into the registry was to raise the coverage rate of the registry from todays about 70 % to the national goal of above 80%. The purpose of raising the coverage rate was to improve the quality of surgical treatment for spine surgery (Solberg et al., 2021), by raising the quality on information and knowledge of outcomes of different types of back surgeries. The

goal was to enable using registry data as a risk calculator for clinical decision support for spine surgery and minimize data errors by automating the process (Solberg et al., 2021).

The surgery form will be implemented in the new EHR system, DIPS Arena. This system is built in accordance with the openEHR specification, a promising framework to improve semantic interoperability for clinical data, including open specifications for designing clinical information models (archetypes) and software to designing them, in addition to an open clinical knowledge manager (CKM) for cooperation design and governance of the archetypes information (Beale and Heard, 2008; OpenEHR, 2019). An important principle of openEHR is that both clinical professionals and health informatics experts are involved in designing clinical standards (archetypes) to improve the usability of the clinical content. In Norway design and governance of archetypes are mainly done at a national level to ensure high quality and usability (Beale and Heard, 2008; OpenEHR, 2019). An archetype is a computable specification of the data points and groups of a specific clinical topic, e.g., 'problem/diagnosis'. Archetypes are defined as constraint structures based on the openEHR reference model, which holds the contextual meta-data in health records, and ensure that it do not need to be redefined in each archetype (Ulriksen et al., 2017; Chen et al., 2009). These archetypes can be used by national and local e-health programs, building as openEHR templates. Templates are a means of building clinical data sets to specific use cases, e.g., a registry form, composed of elements from one or more archetypes constrained for a particular setting e.g., National registry forms (Beale and Heard, 2008; OpenEHR, 2019). The template is uploaded in a software program, often developed by the EHR vendor, in where the final outline of the users' specifications and user interface is modelled.

Method

This study was conducted as formative evaluation research in collaboration with FRESK (2017-2022). Formative evaluation research is a rigorous assessment process designed to identify potential and actual influences on the progress and effectiveness of implementation efforts (Stetler et al., 2006). In that perspective, the study was closely related to a trailing research approach because it required close collaboration between researchers, clinicians and stakeholders in the FRESK project as well as the vendor and the clinical ICT department. The data collection was an iterative process within the given context of the empirical project (Baskerville and Myers, 2004).

Creswell, (2003) has defined three elements of trailing research design, which has inspired the outline of this study. First, the science-theoretical perspective, in where we used II as a theoretical lens, to discuss, understand and give recommendations to the empirical process. Second, the research strategy, in where we describe

formative evaluation research as the main method of studying practice and organizational development, contributing to a 'co-constructive' learning process (Baskerville and Myers, 2004) for health personnel, developers, and researchers (Creswell, 2003). Working in close collaboration with the empirical program, the preliminary findings were discussed and presented to the project managers, vendors and users involved. In addition, preliminary findings were used as recommendations for the ongoing process (Hanseth et al., 1996). The two first authors had each a 50% position in the design team of the project related to developing archetypes, templates and forms in FRESK. Since the two first authors had a double role in the project and there was a risk of being too close to the empirical program it was important to discuss the data with both the third author, who has over 10 years of experience from research on both ICT in healthcare in general and openEHR in specific. Third, data analysis, we used II theory and particularly the design principles of standardization, bootstrapping and adoptability outlined by Hanseth and Lundberg (2001) to identify the socio-technical challenges.

Data collection and analysis

Data was collected between November 2018 and June 2020, and included 420 hours of participatory observations, and 60 hours of meetings and workshops with different actors in the process (see table I).

Table I. Overview of the data collection

Participatory observations in the design process	
Participated in:	*Meetings/workshops with:*
• Mapping variables to archetypes • Designing archetypes • Designing templates (OET/OPT) and forms	• The vendor • Clinicians • Project management • Members of NORspine registry • NRUA
In total 420 hours	In total 60 hours

The data analysis followed a hermeneutic approach, characterized by simultaneous data collection and analysis (Baskerville and Myers, 2004). The objective of analysing collected data was to organize and structure the gathered material, to generate an understanding of how the socio-technical interdependencies influence the evolving empirical process (Klein and Myers, 1999). The data was analysed through the lenses of the II framework and its design principles.

The overall objective of conducting formative evaluation research is to bring knowledge back to the ongoing empirical processes in order to strengthen opportunities and understand any challenges so that adjustments can be made (Finne et al.,1995; Stetler et al., 2006). In this study, this was done by discussing and presenting the preliminary findings from the analyses repeatedly. We had

meetings with stakeholders; both the EHR vendor, the national archetype governance, the regional EHR governance, the spine surgeons, and members of the FRESK program.

Results

Structuring the NORspine form was one of the fist efforts where a health region in Norway participated actively in designing a standardized form by using the openEHR approach. In addition, the standardization implied reusing information for a secondary purpose. Following the design process from a paper-form to an electronic archetype-based one revealed necessary premises for improving usability of clinical data in a real-world context (Silsand et al., 2019). In this paper, three important issues for understanding the premises for reusing clinical information are presented: 1) the demand for attaching context to structured clinical variables; 2) the challenge of reusing correct clinical variables; 3) the challenges of balancing the variables to the correct granulation level.

1) Reuse of structured clinical information needs to include information about the context in which the information first occurred. For instance, if the value of a blood pressure (BP) is reused, it is not enough to reuse the systolic and diastolic values like 120/80. A clinician needs to have information of the patient's status when the reused BP was taken, e.g., was the patient treated for acute illness, or was the BP taken before or after haemodialysis? Was the patient sitting or lying, what instrument was used for measuring BP etc. It is the additional contextual information the clinicians receive that enables him to assess if the variable has clinical significance for a new clinical setting. Archetypes are examples of information models that includes relevant contextual meta information to ensure correct and valid reuse. Archetypes to reuse must be designed including skilled health information experts, in accordance with the openEHR specification, to ensure high quality information models.

2) Reusing the correct information is another important issue. For example, a patient may have conducted three surgeries in the same submission period, the main surgery of spinal fusion surgery a follow-up surgery cause by unforeseen postoperative complications and a knee surgery. Then it is of great importance that the information e.g., the variable "operation duration" is reused only from the main surgery into the registry form to represent the correct information addressed by the purpose of the registry. Consequently, reuse of information addresses governance of the queries that enable automatically utilization of data for several purposes (see figure 1).
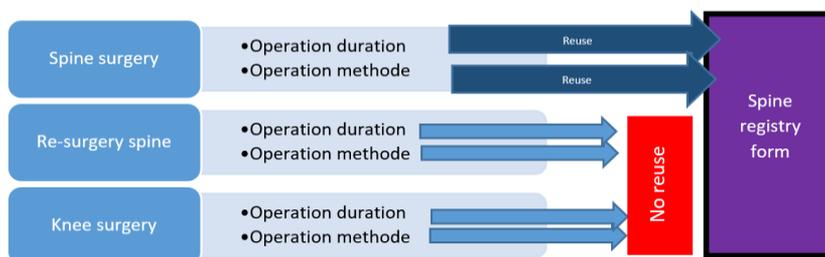
Figure 1. Reuse of the right information

3) Reuse of information from primary to secondary purpose includes dealing with transfer of archetype standards of different granulation levels. Within the EHR, clinical information about the patient's present and past conditions is specified for primary purposes, but the NORspine's form askes for information about diseases and illness on an aggregated level. For instance, the registry form asks for "endocrine diseases" as one aggregated variable. However, for a clinical purpose recorded in the EHR, "endocrine diseases" is too generic, and give very limited instructions and information for clinicians on how to follow up treatment and care for the patient. The clinicians need to know the specific disease since a patient is treated differently if she has Diabetes 1 or if she has Cushing disease. Hence for a primary purpose, it is necessary to specify which specific endocrine disease the patient have. Therefore, reuse of data demands for complex mappings between "endocrine diseases" and all the different endocrine diseases registered in the EHR system (see figure 2). There are several examples of different needs of granulation levels of structured clinical information related to utilizing data for primary and secondary purposes. As a result, an extensive web of mapped variables, that must be updated and governed, is necessary to comply with different goals of reused information (see figure 2).
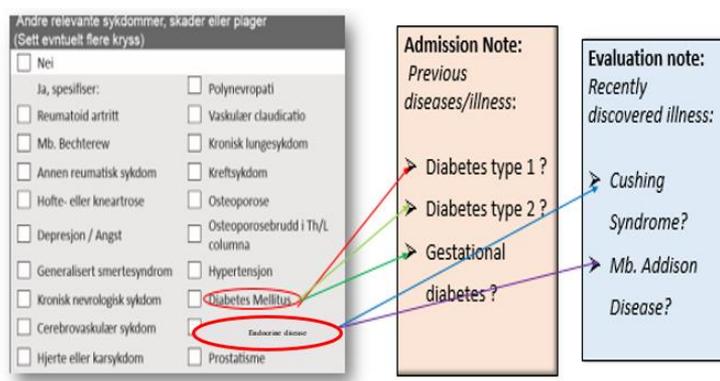

Figure 2. Different granulation levels of clinical information

To summarize the design of a standardized form to enable automatically reuse and exchange of clinical information; standardizing clinical information is the most important means to improve usability of clinical data, but also the main challenge.

Concluding Discussion

There is an extensive amount of attention directed towards reuse of healthcare data within and between EHR systems, both for primary treatment purposes and secondary purposes like registries, research, quality improvement and clinical decision support. In this project we have followed the steps of the activities in the empirical project, in were structuring the clinical information within the EHR was the given approach for enabling automatically reuse of clinical data. In this paper, three important issues have been outlined for understanding the premises for reusing clinical information for primary and secondary purposes: 1) the demand for attaching context to structured clinical variables; 2) the challenge of reusing the correct clinical variables; 3) the challenges of connecting the variables to the correct granulation level.

The overall lessoned learned from this study is that automatically reuse of clinical data is complex and challenging. The study has followed the empirical project from its early beginning in 2018 until it was put on hold in 2020 [1], and a broad range of socio-technical issues (which is not part of the scope for this paper) have influenced the design and implementation process. Designing standards based on the need from a registry form, represent a limited part of structuring an EHR system. Nevertheless, knowledge from previous work (Silsand et al., 2019, Severinsen et al., 2020) supported by II design theory (Hanset and Lundberg, 2001) underscores that a complex process as standardizing the EHR system needs to start with focusing on a limited part of the process. First, to gain instant profits early in the design processes, where users get access to working software can motivate them to continue contributing to the work. On the other hand, there is limited knowledge about the practical implications for all the stakeholders involved, when structuring clinical information for enabling automatically reuse for both primary and secondary purposes. Accordingly, for the stakeholders in the empirical project it was important to gain knowledge, highlight challenges, and to ensure that the step in the evolving design process was compliable with both short-term and long-term goals of structuring the EHR system (Hanseth and Lundberg, 2001). With this formative evaluation study, the research team has contributed to this process.

The three issues presented in the result section, is all about ensuring that the right clinical data is available for the right clinician or purpose at the right time. Because at any stage weather the data is recorded for a primary or reused for a secondary

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[1] The collaboration between the empirical project and NORspine was put on hold due to delays in the implementation of the new EHR system caused by the Covid-19 pandemic.

purpose, the data need to be characterized in terms of completeness, correctness, and precision relative to purpose. Accordingly, these the three issues are relevant when understanding the premises of reuse, and the understanding of each of the premises need to be compared with each other. Based on these issues we go on and summarize implications for design.

First, structuring clinical information for a duality of purposes demands for high design competence when designing information models (e.g., archetypes), as well as designing templates and forms. A duality of purposes demands for the correct use and granulation level of the clinical information models, through the step of templates and forms, and between different forms used for different purposes in different contexts. Accordingly, structuring an EHR is an extensive process which requires a team of competent resources to succeed.

Second, it is important to establish high quality governance of clinical information models, templates and forms in different organizational levels such as in this case the health region, the national archetype organization, NORspine, and the vendor. Governance includes an overview of the interconnections and queries between variables in the EHR, and where they are used for secondary purposes. Changing an archetype has consequences wherever this archetype is used both related to the forms that uses it, as well as the clinical process and exchange between healthcare levels. In addition, to understand the coherence between structured clinical information models, how they relate to the design levels of templates and forms, and consequences when upgrading on different design levels are needed.

Third, structuring the clinical information in EHR system is an important means to reach the goal of improved usability of clinical data for different purposes, but both the means and the goal rest heavily on competence and governance to carry out the structuration process. So far, there is a national governance for archetypes, however the necessary requirements for governance within the health regions and the hospitals has not yet been established by the empirical project.

Finally, our study has so far only stirred the surface, and the aspects in the introduction about collecting data, interoperability within and between systems, and using data for primary and secondary purposes need to be further explored.

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