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Structuring Electronic Patient Record Data, a Smart Way to Extract Registry Information?

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Abstract. The paper reports from one of the first efforts to generate data for a national register by automatically reusing data recorded in the clinical documentation process. Today, the process of reporting to national registries implies filling out a paper-based or electronic form as the final step of documenting patients' treatment. The registries' forms are hence not part of the patients' Electronic Patient Record (EPR). Therefore, the Norwegian Directorate for e-health has established a program for developing a shared infrastructure for 51 national registers, aiming to improve the utilization and quality of the reported health data. We argue that the quality of the registries' data rests heavily on an understanding of today's practice and how and when to capture the data. This paper describes the initial work of facilitating automatic reuse of standardized clinical data recorded from the EPR to the Norwegian registry for spine surgery. The empirical setting is the regional FRESK (Future systems in the clinic) program (2017-2022), in the North Norwegian Health Region.

Introduction

In Norway, the government is investing heavily in 3.-4. generation Electronic Patient Record systems (EPRs), offering process - and decision support, and reuse of data for the purposes of quality assurance, research, and management (Ministry

of Health and Care Services, 2012; Pedersen et al., 2015). Related to this, different medical specialties have established quality registries to monitor the outcome of their treatments. There are for instance registries for hip replacements, coronary surgery, spine surgery etc. Overall, there are 51 different registries in Norway.

Today, clinical data is recorded in EPR systems, but there exist no automatic reuse of the data to national registries. The present way of reporting to the registries reflects a touted problem of todays' EPR systems, where the documentation of treatment and care is mainly free-text descriptions recorded retrospectively.

On this backdrop, the Norwegian Directorate for e-health has established a program for developing a shared infrastructure for the registers (NDE, 2018). The aim of the Health Data Program (not introduced) is to improve the quality and utilization of health data, simplify reporting to the national health registers and to make data management safer. So far, in establishing an infrastructure that facilitates the utilization of data from different registries, the primary focus has been on the platform and how the connected variables accompanying different registries should be standardized (NDE, 2018). However, we believe that the quality of the registries rests heavily on the input from the EPRs and knowledge of clinical work processes, i.e. when clinical information is recorded and how clinical information can be extracted for secondary purposes.

The research questions posed are therefore: a) How to design a registry form based on reuse of clinical information? b) How should the clinicians participate in the design process?

The case reports from one of the first efforts of automatically generate data for a register purpose by reusing clinical data recorded during the medical treatment and care processes. The overall goal of the project is to integrate primary and secondary data to eliminate double documentation work, to raise the contribution rate for the registry, and minimize data errors by automating the process. The aim of the first phase of the project is to design and integrate an electronic registry form within an openEHR based EPR system used in hospitals in the North Norwegian Health Region, in which clinical data is to be reused for a secondary registry.
We use the theoretical framework of information infrastructures (Bowker and Star 2000; Ulriksen et al, 2017; Silsand and Ellingsen 2016; Hanseth and Lundberg, 2001). This framework contribute with a specific perspective on how designers should 'build upon the existing installed base', in terms of the present clinical documentation process.

Method

The study adheres to a qualitative action research approach, with the objective of contributing to a co-constructive learning process for healthcare personnel, developers, and stakeholders, as well as for the researchers (Baskerville and Myers, 2004). The data was collected through close participation in the design processes

related to developing archetypes and forms (see Table I), and will be complemented by interviews, discussions and document studies (Klein and Myers, 1999).

Table I. Data collection from November 2018 to March 2019

Participatory observation	**Meetings/workshops with:**
• Participated in the design process • Mapping variables to archetypes • Design archetypes • Designing templates (OET/OPT) and the form **In total 320 hour.**	• The vendor • Clinicians • Project management • Members of OpenQ-reg Registry • NRUA **In total 50 hours**

Empirically, we draw on the regional FRESK (Future systems in the clinic) program (2017-2022), in the North Norwegian Health Region. This program includes implementing a regional open platform based EPR system, and structuring the clinical information system through the openEHR approach, using archetypes as clinical standards (Christensen and Ellingsen, 2016; Atalag, 2016).

Case

The Norwegian registry for spine surgery (NORspine) aims at improving the quality of surgical treatment for degenerative disorders in the cervical and lumbar spine (Solberg and Olsen, 2017). In 2017, the coverage rate to the registry was only 70, 2 %. Accordingly, it is of great interest to raise this level, and include more data into the registry. Automatically extracting clinical data recorded as part of the EPR documentation process, and exporting the data to the registry is anticipated as a key means to improve the coverage rate and quality for the NORspine registry. Accordingly, the separation of reporting to registries from the clinical documentation process is pointed out as a main reason for the contribution rate lower than the ambition (Solberg and Olsen, 2017).

1) The clinical documentation process

Today, healthcare personnel in the health region mainly uses free-text in the EPR to document treatment and care given during the clinical processes. For clinical

purposes, these free text documents are effective for internal knowledge sharing, and support of the daily work, but unsuitable for reusing information within and across EPR systems, to enable clinical decision support (CDS), quality improvement, health monitoring, management, and research.

In the current clinical documentation process, information is stored in several steps and connected documents, e.g. outpatient clinic notes, evaluation notes, surgery notes and discharge notes. In addition, the registry form is not part of the clinical documentation process in the EPR system. Therefore, reporting to national registries implied filling out a paper-based- or an electronic form as the final and separate step of documenting the patients' treatment. Either a physician, or a secretary, based on the physician's instructions, did this. Hence, the separation of the clinical documentation process and reporting to registries increased the clinicians' documentation work. Especially when work was hectic, or in weekends and vacations when fewer clinicians were at work, the reporting to registries was neglected. In addition, there was a risk that part of the information like the patients medication or thrombosis prophylaxis was recorded only in the registry form, and this could cause clinical complications for the patients (Solberg and Olsen, 2017).

2) Designing a structured electronic registry form and integrating it to an openEHR based EPR

In the North Norwegian Health Authority, the implementation of DIPS Arena was expected to enable reuse of EPR data. The system was developed in accordance to the openEHR architecture, using archetypes as flexible information models for structuring clinical data, to enable reuse of information within and between systems. The innovative aspect of the openEHR approach comes from separating the system's generic reference model from the clinical information layer, which implies that the archetypes are developed 'outside' the technical system (Atalag et al., 2016). Each archetype represents a description of a maximum dataset of one clinical concept (e.g. blood pressure), and the information is thoroughly described to be useful in every imaginable clinical use context.

OpenEHR based EPR systems are "empty" systems where the users need to determine and design up-front the archetypes representing the clinical information they expect to create and record during clinical processes. In accordance to the openEHR specification, transforming clinical concepts to archetypes implies an increased level of abstraction because the openEHR idea is aimed at producing an understanding of how information systems can support the creation of information during a generic care delivery process (Beale and Heard, 2007). The development of archetypes is given to clinical communities as a bottom-up standardization approach. To support clinical communities in developing archetypes, the openEHR community provided a web-based tool called the Clinical Knowledge Manager (CKM), whereby healthcare personnel and experienced clinical experts could

develop, publish, use and govern the information models. In Norway, a national initiative was established in 2014 to lead this work. When developing the form for the NORspine registry, the first effort was to understand how archetypes could support the need for exchanging variables from the EPR system to the registry and simultaneously support the documentation of the clinical spinal surgery process.

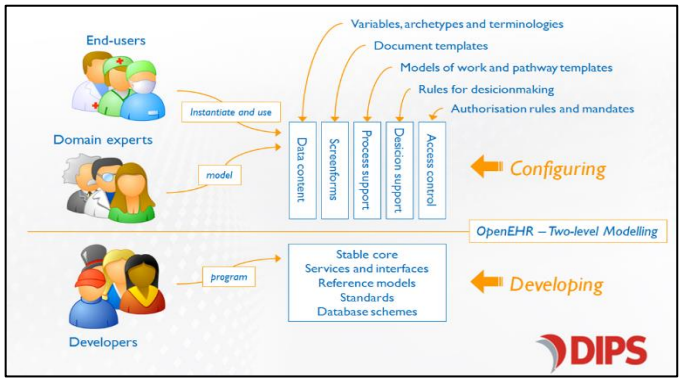

Figure 1. The openEHR platform approach

3) Capturing the variables from steps in the clinical process

In November 2018, the design team in the FRESK Program started to collaborate with NORspine to design a structured registration form to be implemented in the EPR system. The spinal surgeons "ordered" an electronic form that automatically extracted data from different parts of the clinical documentation process and reused the data in the registry form.

The case description is limited to the design process of structuring the registry form by using archetypes, and do not describe the work of transferring data from the EPR to the registry (not finalized). Structuring the registry form for spinal surgery was the first time that standardization work in this scale was done by domain experts (the design team in FRESK) (see Fig. 1), and the first effort in the health region of shifting from unstructured to structured documentation by using archetypes in the EPR system.

In the first phase of the standardization work, the most reasonable course of action was discussed. The point of departure was placing the variables of the existing form into an electronic mind map to have an overview of the relation between archetypes and the registry's variables, and an overview of where in the clinical documentation process the different variables occurred. The information was categorized as preoperative-, per operative – and postoperative information, in addition to a general category of administrative information. The categorization gave directions for which archetypes to include in which documents corresponding to the different steps of the clinical documentation process. In doing so, the design team collaborated closely with the clinicians to understand their current use of the

documents. For example, when and where do they record the clinical information, what are the logic relation between different variables in the registry form, and the relation between clinical needs of specific and unambiguous information compared to the use of more generic variables in the registry form.

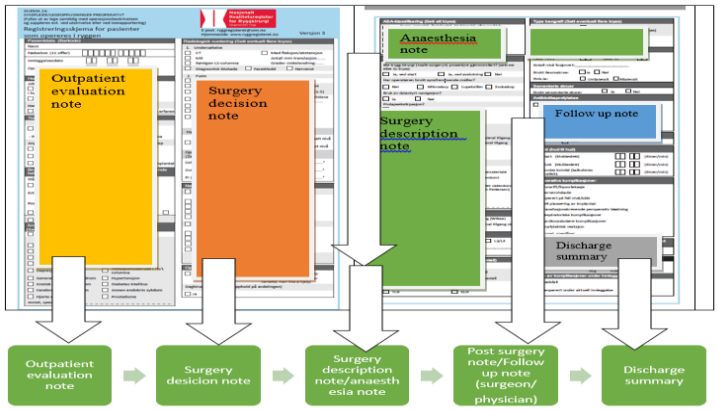

Figure 2. Clinical variables to be included in different clinical notes.

Even if this seemed to be to most appropriate way of starting the design process, the present use of free-text to record clinical information influenced the design process because there was no structured data represented as archetypes to reuse. In addition, the implementation of the new EPR system was in the initial phase, doing stepwise implementation of clinical functionality, but by the time no functionality supporting the surgery process necessary to underpin reuse of information to the registry form. Accordingly, the design process had to change course of action, and a next best decision was made in collaboration with the clinicians towards implementing an electronic registry form in the EPR. In this first version of the form, reuse of clinical information (variables) from the clinical documentation process was not possible as described above, and the clinicians still needed to fill in the form manually. The benefit of the first version was related to 1) including the form in the EPR, and 2) implementing a reminder in the EPR system giving the surgeons the decision to start creating the registry form when medical codes for spinal surgery was recorded. Hence, the vendor had to map the medical procedure codes for spinal surgery and the form. Even if the first version was far from the overall goal of automatically reuse of clinical information, the clinicians saw it as a leap forward compared to the existing form and registration process. With the new form, all documentation – both for clinical as well as registry purposes, is recorded in the EPR, which means that all information is available in the same

system, addressing the before mentioned misunderstandings related to recording data in the registry form only.

4) Structuring clinical information for primary and secondary purposes

In parallel with designing the first version, the design team started to develop a more advanced version of the form using national reusable archetypes as an attempt to produce valuable data for both primary and secondary purposes. Balancing such needs raised some design challenges in relation to structuring clinical information. In example, clinical variables for the registry was often defined much more generic compared to variables defined to support clinical purposes. An example illustrated this: In the registry form, a variable is defined as "other endocrine diseases", and it serves the registry's need for information. However, this definition was too generic to support clinical needs, and the variable had to be defined and granulated to all the specific endocrine diseases to be useful for clinical purposes. Taking into account that the registry form was the end point of the clinical documentation process within the EPR, structuring clinical information had to be based on the primary purpose of supporting daily work and knowledge sharing. Accordingly, the categories containing more than one disease needed to be structured in several separated archetypes. Then it was necessary to do an underlying mapping of all the diseases related to different categories in the registry form, e.g. "other endocrine diseases".

Concluding discussion

Designing structured registry forms as part of the EPR, where variables are automatically generated from the clinical documentation process, raised three issues to be discussed related to: 1) the tension between data for primary and secondary purposes, 2) adjust the progression of the design process to the installed base, 3) the clinicians' expectations and participation in the design process.

1) The tension between data for primary and secondary purposes addresses a need for translation work required to produce valuable data for both purposes. On the one hand, the primarily purpose is to record the patient's status in point of time, and on the other hand structured elements must also inherent capabilities for secondary use e.g. registry specific information or information important later in the process. This is a complex and time-consuming task that needs to be solved. As described in the case, clinical data is often defined in different terms and levels of granulation in the clinical documents vs registry variables. Even if the variables of the first version of the NORspine form was developed to support the registry purposes, it is of importance to take into account the primary purposes of clinical information when designing the variables, which is to support daily work and knowledge sharing. In accordance to developing an information infrastructure, the design process has to produce variables that technically and socially can support prospective needs of a growing II (Hanseth and Lundberg, 2001). Therefore, it is necessary to dig into the complex process of standardization, for example deciding

which clinical information is necessary to standardize, defining where in the clinical process the standardized information first occur, and where can the information be reused as it is or need an quality approval. There are several issues related to standardization. In addition, governance of the standards and of reuse of information is a complex topic in it selves.

2) In relation to the progression of the design process, it is important to balance the design process to the installed base, in this case represented by the present system, existing documentation practice and absence of structured clinical information. In addition, the stepwise implementation of the new EPR also set directions for the progress of designing the registry form. To comply with the premises from the installed base, the design process was tailored to be in sync with the implementation progress of DIPS Arena. The difficult question to answer is, what is possible to achieve when changing from using unstructured, free-text notes to a structured clinical documentation practice enabling reuse of information and exchange to secondary purposes? Because there is a balance between the prospective goal, and the progression and necessary changes of the socio-technical system, to reach the goal. Nevertheless, when developing an II, it is of importance to come up with a solution that persuade the clinicians to adopt, even if the solution (the registry form) is in its premature state (Hanseth and Lundberg, 2001). This bring the discussion over to the next issue, how to comply with the clinicians' expectations and participation in the design process.

3) In this case, the clinicians had initiated the cooperation of designing the new form, and they were informed about the stepwise progress towards automatically reuse of clinical information. More interesting is the upcoming work of designing the next version of the form, where information from the clinical documentation process is to be defined and developed. It is of importance that clinicians find the use of structures notes meaningful to prevent them for continuing using only the free-text field in the notes, accordingly, there has to be some instant profits. Reuse of already recorded information into other documents and forms is a "carrot" that the clinicians themselves long for, in addition to using the data for quality improvements on site, as well as generation of a future knowledge basis as part of advanced clinical decision support.

There are unsolved issues related to the implementation of the new form, which also point to the need for clinical participation. Based on previous research, implementation of new forms, tools etc. in clinical practice influence organisational - and workflow processes (Silsand and Ellingsen, 2016). Accordingly, there will be tensions related to the existent practice of using the paper-based form and the implementation of the new electronic form that need to be recognized and solved.

Finally, the quality of reliable and unambiguous data into national registries rests heavily on the input. Therefore, the focus to improve the utilization and quality of health data at a national level, needs to start with structuring the clinical documentations processes, and addresses the need for more research on the discussed issues.

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