Socio-technical Requirements for Expert Users to Design Structured User-Interfaces for OpenEHR-based Electronic Health Records

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***Abstract*—The paper addresses socio-technical challenges when expert users design structured user interfaces in openEHR-based Electronic Health Records (EHRs). Structuring healthcare data enables extracting and reusing clinical information for both primary and secondary purposes, contributing to the goal of creating a digital society across multiple social arenas. We use an action research approach to follow an empirical project, developing an openEHR-based registry form, and trying out the initial methodology for designing structured user interfaces in a health organization. The aim of the paper is to describe and discuss socio-technical challenges related to expert users designing openEHR-based forms. The findings relate to 1) the complex design tools 2) the compromise between instant benefit and long-term requirements 3) the need for extensive governance for user-designed software, and 4) the importance of contextualization.**

Keywords- structured EHR; openEHR; arcetypes; structured form design; action research.

I. INTRODUCTION

There are extensive ambitions of reusing data from EHRs, both for clinical use and for secondary purposes, like registries, research, and management. However, one of the main problems when it comes to exchange and reuse of health data is that most of the content in EHRs is recorded as free-text information.

A promising strategy of exploiting health data across different contexts is to structure the clinical information recorded in EHRs through openEHR-based clinical variables (archetypes) [1][2]. This way, the clinical information is recorded as standardized data, in relation to the context it is registered. Hence, such standards can be extracted and reused for both primary and secondary purposes contributing to the goal of creating a digital society across multiple social arenas. The Norwegian vendor DIPS AS is currently developing an openEHR-based EHR system called "DIPS Arena" [3], to comply with the expectations of exchange and reuse of health data in the Norwegian healthcare sector. A core principle of the openEHR specification is that clinical users are in charge of structuring the content of the EHR, i.e., the archetype standards. Furthermore, expert users should be in charge of designing user interfaces, e.g. (forms, templates for notes and documents) where the archetypes are embedded [1]. To be defined as an expert user, a combination of clinical background, technical understanding and knowledge about openEHR is required.

However, previous attempts of healthcare organizations structuring openEHR-based archetypes and forms revealed that this work was more demanding than expected [4]. The main challenges were related to: how to structure clinical variables in terms of high quality archetypes as basis for the structured form, how to make these forms more user friendly than the original paper based ones, and the importance of including a number of clinicians from specific medical specialties' in the standardization work [4].

There exist development methodologies for creating terminologies and ontologies [5]-[7]. In addition, an archetype modelling methodology has recently been released [8]. Some papers describe experiences with using structured data, standardized through the openEHR approach [2][9]-[10]. Still, a comprehensive and formal methodology for modelling structured openEHR-based user interfaces does not exist. It is of great importance to establish a methodology for developing and designing structured user interfaces, since the openEHR ambition gives the expert users a specific role as designers in the process.

However, a methodology is in progress, based on an empirical project in the North Norwegian Health Region. This project is part of the regional program The Future Systems in the Clinic (in Norwegian: Fremtidens Systemer i Klinikken, FRESK) [11]. The program is responsible for implementing a portfolio of new clinical Information and

Communications Technology (ICT) systems in the health region, in which a new openEHR-based EHR system, DIPS Arena, is one of the core systems.

In this paper, we have focused on the development of a structured openEHR-based form, conducted by expert users. The form is supposed to collect and transfer clinical patient data from the EHR to the Norwegian Registry for Spine Surgery (NORspine). During the process of developing the openEHR-based form and the initial framing of the methodology, socio-technical challenges emerged related to the expert users' role in the design process.

This study has followed the empirical project through an action research approach [12][13]. To analyze and discuss the empirical findings in order to answer the research question, we lean on the design principles of Information Infrastructure (II) and Infrastructuring theory [14]-[18].

The aim of the paper is to describe and discuss the socio-technical challenges related to expert users designing openEHR-based forms, in terms of designing clinical variables as archetypes, programming the queries and designing the lay out of the form. Hence, we ask the following research question: Which socio-technical challenges are addressed when expert users design openEHR-based forms?

The rest of the paper is structured as follows: Section 2 presents the action research approach, and data collection. Section 3 describes the design tools, the design process of the registry form, and summarizes the methodology for designing openEHR-based user interfaces. In section 4 we address key socio-technical challenges when dealing with infrastructural complexity in design, this includes working with advanced openEHR design tools, the role of the expert users, and the technical complexity of designing structured forms. Section 5 presents a brief concluding summary of the paper.

II. Background

The empirical project started in January 2019, when NORspine approached the FRESK program for collaboration. NORspine set a proposal of transforming their paper-based registry form into an openEHR-based data entry form, and implement it into DIPS Arena. NORspine aims at improving the quality of surgical treatment for degenerative disorders in the cervical and lumbar spine [22]. The purpose of implementing the registry form into the EHR was to raise the registration rate from today's 64% to the national goal of above 80%, and which will raise the quality of the registry's recommendation for the spine surgery service [22].

Today, clinical information within the EHR is mainly recorded as free-text descriptions. Hence, the clinicians have to make double registrations on most of the data reported to registries [23]. This generates a risk that parts of the patient information end up in the registry only, since there is no connection between the registry form and the EHR system. Today surgeons fill out a paper-based form, and then a secretary or a nurse upload the recorded data into an electronic form in the registry's web-portal. Double registration of patient data is a time consuming process taking up an extensive amount of the healthcare personnel's time. Therefore, it is anticipated that automatically extracting and exporting clinical data recorded as part of the EHR documentation process to the registry form, will be a key means to improve the coverage rate, increase the quality of the registry, and reduce the time spent on documentation [22].

The FRESK program accepted the proposal from the spinal surgeons, and the structured EHR team of expert users got the assignment. The request from NORspine implied automatically extracting and exporting clinical data recorded as part of the EHR documentation process to the registry. Accordingly, the clinical information had to be structured as archetypes in accordance to DIPS Arena as an openEHR–based system. The development of the openEHR-based form was done in close collaboration with the vendor DIPS AS, and the National Administration of Archetypes (In Norwegian: Nasjonalt Redaksjons Utvalg for Arketyper NRUA). NRUA is responsible for the library of nationally approved archetypes, in terms of developing new archetypes on request from clinical communities, translating archetypes from international archetype libraries, and running public review rounds with numerous clinicians involved to approve new or translated archetypes [4].

An openEHR-based EHR system is not an 'off-the-shelf' product. In accordance with the openEHR specification, the healthcare organizations and clinicians are expected to take part in the customization process of designing archetypes, templates and forms for their organizations, as well as tailoring clinical process- and decisions support functionalities to their needs [1][8]. The North Norwegian Health Region is committed to the openEHR framework and do their fair share of customization of the EHR system. Several stakeholders are involved: expert users, clinicians, system vendors, ICT consultants, and archetype experts. The expert users have both clinical and technical competence in addition to extensive knowledge on openEHR, which is necessary for using the design tools and understand the capabilities, benefits, and consequences when changes are made in the archetypes, templates and forms.

III. Method

We have used a qualitative action research approach to follow the emerging process of developing a methodology for expert users in healthcare organization designing structured user interfaces [12][13][19][20]. Action research requires close collaboration between researchers and clinicians, and it is an iterative research process within a given context [12].

Creswell [21] has defined three elements of action research design. 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 action research as the main method of studying practice and organizational development, contributing to a 'co-constructive' learning process for health personnel, developers, and researchers [21]. In this research project, the first and second author participated in the practical work of developing the openEHR-based form, and the outlining of the methodology. In this regard, they had an 'insider' role as expert users and experienced researchers. 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 have been used as recommendations for the ongoing process [14]. Third, for data collection and analysis, we used II theory to identify the socio-technical challenges. The last two authors have many years of experience from research on ICT in healthcare in general, and on openEHR research in particular. In this study, these authors had an 'outsider' role, in terms of balancing the insider perspectives and contributing in framing the research.

TABLE I. OVERVIEW OF THE DATA COLLECTION

Participatory observations in the design process	
Participated in: • Mapping variables to archetypes • Designing archetypes • Designing templates (OET/OPT) and forms	*Meetings/workshops with:* • The vendor • Clinicians • Project management • Members of Open Q-reg registry • NRUA
In total 320 hours	**In total 50 hours**

We present an overview of the data collection from January - August 2019 in Table I.

IV. CASE – THE DESIGN PROCESS

The findings presented in this section is detected by following the evolving methodology for developing openEHR-based user interfaces.

A. *The Design Tools*

Two expert users (the first two authors) in FRESK transformed the existing paper-based spinal surgery registry form into an archetype-based registry form for DIPS Arena. To design the archetype-based form, it was necessary to use four different (ICT) programs: Electronic mind map (XMind), Ocean Informatics Archetype Editor, Ocean Informatics Template Designer [24] and a specific Form Designer provided by DIPS AS. The mind map was used to get an overview of the variables in the paper-based form. The Archetype Editor and the Template Designer were used to design archetypes and align and constrain them into a template for this specific use case. Then, the Form Designer was used for further configuration of the template into the registry form as representing the user interface for clinicians. It took long time, extensive training and in-depth knowledge about the openEHR design principles to learn how to use the design tools and how the different design steps related to each other. These steps are described in detail in the following sections.

B. *Mapping Variables and Archetypes*

The first step was to insert the variables from the existing paper-based registry form into the electronic mind map (XMind). This provided an overview of all the variables in use in relation to e.g. if there was an overlap of variables, and the coherence between them (see Figure 1).

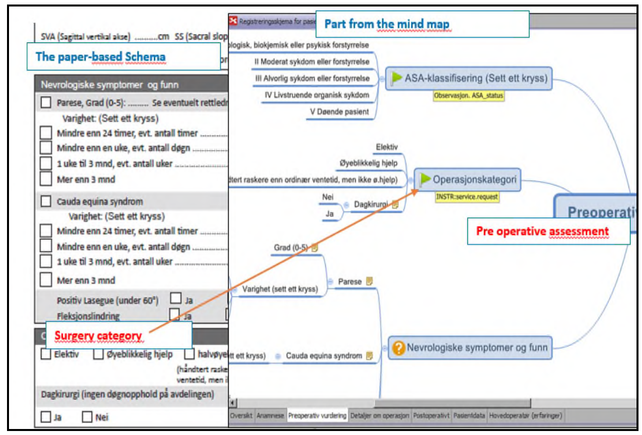

Figure 1. Mapping the variables in XMind

Given the request for automatically extracting and exporting clinical data recorded as part of the EHR documentation process, it was necessary to categorize the variables in relation to where they first emerged in the clinical documentation process (pre, per, or postoperative), and to assess the potential for reuse. In the present documentation process, information was stored in different documents, e.g., outpatient clinic notes, evaluation notes, surgery notes, and discharge notes. In addition, the registry form was not part of the documentation process.

The expert users collaborated closely with clinicians to understand their current use of the clinical documents. For example, when and where did they record the clinical information, what was the coherence between different variables in the registry form, and the relation between clinical needs of specific and unambiguous information.
Then, the expert users made suggestions for which archetype to replace with each of the variable, and discussed the proposal with NRUA and DIPS AS in several meetings.

One important finding from this process was that the variables used in the registry form were aggregated compared to clinical information used for documenting treatment and care. For example, the variable 'other endocrine diseases' used in the register form, covers all kind of endocrine diseases, except from diabetes. However, in clinical practice, 'other endocrine diseases' is too generic to use when documenting assessments, treatments and care.

The different granulation levels will complicate the potential for automatically reusing information about endocrine diseases into the registry form. Hence, differences in the granulation level of registry variables and clinical information was important to consider during the replacement. One suggested way of complying with this problem was to link together the diagnose codes for all endocrine diseases recorded in the EHR and map the linked codes to the specific category in the registry form.

C. Use National Archetypes or Develop Local Ones

After mapping the variables to archetypes, the next step was to decide whether to use archetypes from the national openEHR-library, or design local archetypes for this specific use case. It is preferable to use national approved archetypes to ensure semantic interoperability of clinical information. However, the first version of DIPS Arena did not offer functionality for advanced reuse of clinical information between different documents in the clinical process. In addition, the healthcare organization has not yet started to structure clinical documents as archetype-based notes, e.g., the admission notes, the physicians' daily notes and discharge letters. Accordingly, at this point of the design process, it was not possible to reuse clinical information from different documents to the registry form.

Another factor for using local archetypes was that national approved archetypes are complex standards designed as maximum dataset. This demand for extensive adjustments of the archetypes when using them in the templates - or forms, to comply with specific contextual requirements, e.g., the registry form. For example, the openEHR 'problem diagnosis archetype' is used for recording details about an identified health problem or diagnosis. The registry form asks for the name of the diagnosis only, comparing with the problem/diagnosis archetype that has 13 data elements, e.g., anatomical location, date/time for debut and clinical description to make a comprehensive description of the medical problem and diagnosis. Accordingly, it would be time consuming for the clinicians to fill in information requested in all the 13 data elements when only one data element is required in the form.

In relation to the current limited reuse of archetypes from the clinical process, and the complexity of constraining national archetypes to the registry form, the decision of designing local archetypes to the first version of the registry form was made. This decision was made in agreement with advisors from the vendor and NRUA. In addition, using local archetypes was expected to speed up the design process since they are less complex than the national ones. After a short development process, the first version of the form was presented to the clinicians. They provided feedback about the first version of the electronic form to the expert users, and approved the layout.

A disadvantage of using local archetypes was that some of the archetypes, e.g., (radiological examination) contained several clinical elements with the potential of being reused as autonomous archetypes. However, since the elements were part of a larger archetype, it was possible to reuse the whole archetype only.

D. Coherence between the Design Tools

To design local archetypes, the Ocean Informatics' Archetype Editor was used. The Archetype Editor has a given set of data types used to design clinical variables as data elements in an archetype (Figure 2). There is a coherence between the data type chosen to represent the variables/data elements in an archetype, the possibilities for configuration of the variables/data elements in the DIPS' Form Designer and finally the options of how to display the variables in the form. For example, some data types could generate variables as radio buttons in the Form Designer, while other data types could not.

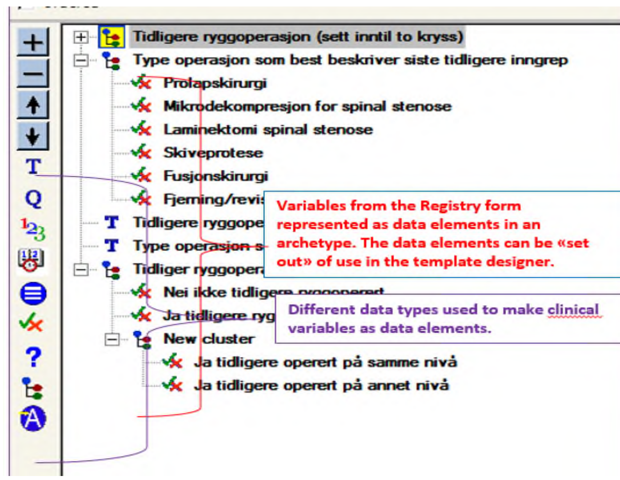

Figure 2. The different data elements for designing variables in an archetype using the Archetype designer.

In addition, if the goal was to create a drop-down menu where users could select one variable from the list only, then the data type 'Text' had to be used. Moreover, the drop-down menu for clinical variables had to be added as a list of 'internal codes' when designing the archetype, or as a 'value set' in the archetype when using the Template Designer. If it was uncertain how the variable would be used in the form, it was possible to design different data elements e.g., both 'Boolean' and 'Text' elements representing the same variable.

E. Assembling the Archetypes to a Template

When every variable in the registry form were represented as archetypes, they were assembled in a template by using Ocean Informatics' Template Designer. In the Template Designer, it was possible to constrain the archetypes in terms of making data elements/variables inaccessible. For instance, the national archetype for American Society of Anesthesiologists risk (ASA) score, containing 11 stages, was used in the form. However, in the registry form, the variable ASA score was defined by five different ASA stages only. Therefore, six stages had to be defined as inaccessible in the template. If archetypes were constrained in the template (Template Designer), and it became necessary to make some of the inaccessible data elements available later, it required creating a new template. After conducting all necessary configurations in the Template Designer, the template was exported to the Form Designer.

The final steps of configuring the form was done in the DIPS' Form Designer, this included adding dependencies between variables to define the relations amongst them, adding calculations, etc. In example, a field in the form addressed medication, and asked if the patient is using anticoagulation regularly. If the answer was 'no', then the option to answer 'yes' disappeared. If this was wrong, you just clicked 'no', and the option 'yes' appeared again. If you answered 'yes', you got more options, e.g., a drop-down list of different kind of anticoagulation medications (made as 'internal codes' in the archetype) to specify the answer. Another example was, if you filled in weight and height, then BMI was automatically calculated. During the process of adding dependencies, it became important to create a system for storing and managing the dependencies, annotations and calculations, to be able to update or check them if something did not work as anticipated, or if changes were made in the template/form. Making change to an archetype required the need for making changes in the calculations, annotations and dependencies where the archetype was used.

When configuring the form in the Form Designer, it was very important to work in close collaboration with the spinal surgeons. The archetype-based form was designed similar to the web-based form, in terms of dependencies amongst variables and options in drop-down menus etc. However, based on feedback from the surgeons, it was necessary to change some of the dependencies and displays in the form. For example, in the paper-based form, the surgeons explained that the list of options related to 'other diseases' was used as a reminder to help them remember to ask for all the different diseases when filling in the form. Therefore, they wanted to see all the options in the electronic form. Dependencies hiding the list of options made it more cumbersome for the surgeons to fill in the form, as 'the reminders' then were hidden.

The vendor had made a technical user manual for the Form Designer. However, the design process addressed a need for expanding the user manual with instructions aimed for the expert user role.

F. *The Methodology for Structuring an EHR Form*

Table II summarizes the evolving methodology for designing openEHR-based user interfaces.

TABLE II. METHODOLOGY FOR STRUCTURING AN EHR FORM

Tasks	Collaborating partners	Responsible part
Archetype work		
Mapping archetypes and existing variables	Expert users, NRUA, clinicians,	Expert users
Decide to using local or national archetypes	Expert users, NRUA, Vendor	Expert users
Designing local archetypes	Expert users, NRUA, Vendor, clinicians,	Expert users
Template Design		
Design a template from the archetypes	Expert users, Vendor, NRUA	Expert users
Constrain archetypes if needed	Clinicians	Expert users
Forms design		
Upload template to the Form Designer	Expert users	Vendor/ICT department
Define dependencies, annotations, calculations etc. between archetypes	Expert users, clinicians, Vendor and/or ICT consultants in health organizations	Vendor/ICT department

V. DISCUSSION

In the design process, we described the evolving empirical process of designing an openEHR-based EHR form. As mentioned earlier, structuring the spinal surgery form was very useful for uncovering challenges associated with structuring openEHR-based user interfaces in a 'real-life' setting. The design process addressed several socio-technical challenges. We will now discuss four of them; 1) the complex design tools, 2) the tension between instant benefit and long-time requirements, 3) the need for extensive governance for user designed software and 4) the importance of contextualization.

A. *The Complex Design Tools*

The four design tools available for the expert users are quite complex to use. Everyone can download the mind map tool and the tools from Ocean Informatics. However, behind the scenes, using the tools requires extensive training of the expert users. In an infrastructuring perspective, it is not enough that the expert users have knowledge about using the design tools only. They also need extensive knowledge on the different possibilities and limitations in both designing archetypes and templates, and how designing them affects the design possibilities in the user interfaces. Each step conducted in each of the different tools are interdependent to make the overall infrastructure evolve [19].

In addition, even if the design of archetypes, template and form is of high quality, the final step of the design process needs to end with a user-friendly display of the form. Accordingly, it is necessary to include clinical expertise and technical competence as well. This demand for expert users taking the role as translators between ICT and clinical practice to establish an II were knowledge from these two installed bases are merged.

B. Tension between Instant Benefit and Long-term Requirements

There is an inherent tension between 'quick-and-dirty' design, and designing for long-term use. The case describes why local archetypes were used extensively, despite the recommendation of using national approved archetypes. There is a constant negotiation between the importance of an efficient design process, were the clinicians can see early results of a structured form, and the need for robust archetypes as basis for future use. Design for instant usefulness is in accordance with the II design principle of bootstrapping, where users get access to working software as early as possible in the design process, to motivate them to continue in contributing to the work [17]. However, the consequence of 'quick-and-dirty' design can be that long-time usefulness is compromised by for instance extensively constraining the archetypes in the template. Another use-case may demand for briefly constraining an archetype thus, designing a new template is necessary. This demands for extensive work with the form to redesign annotations, calculations and dependencies related to the archetype. Hence, extensively constraining of archetypes in a template decreases the possibility for long-time usefulness.

However, designing for long time use to ensure future needs related to the design principle of adaptability [17]and can generate a risk of designing local archetypes too flexible like in the empirical case where different data elements represented the same clinical variable. To this end, if these archetypes are reused in several EHR systems and one organization decides to use the data element 'Text' and another organization uses use 'Boolean' for the same variable, the consequence is that the clinical variable is not interpreted as the same archetype. Accordingly, the reuse potential is severely compromised.

C. The Requirement for Extensive Governance for User Designed Software

User-designed software like variables, forms, and dependencies requires extensive governance. The complex infrastructuring process [18][19] of form design expresses the need for interaction between different actors with dissimilar competences [4]. Structuring user interfaces is a complex infrastructuring process in relation to, e.g., making changes to archetypes, and how that effects the templates and forms were they are used. The infrastructuring process also demands for setting up a shared repository for storing and retrieving both local and national archetypes to be used for structuring the EHR. In addition, governing a structured EHR addresses the need for training the actors involved, to get an overall understanding and knowledge about archetypes, templates and forms, in terms of where archetypes are used and reused, as well as what consequences changes or constraints generates.

Scaling the structured form to a structured EHR will increase the need for control over archetypes, templates and forms implemented in the EHR, and the accompanying dependencies, annotations and calculations. This requires an extensive ICT governance organization unit within the healthcare organization. Establishing an extensive governance organization relates to the design principle of building on the installed base in where existing systems, actors and governance need to be part of the process [17].

D. Contextualization is a Complex, but Necessary Dealing.

Nationally approved archetypes are developed through a thorough design process managed by high-qualified expert users in NRUA. These archetypes are developed as maximum datasets to be useful in any clinical context and for different clinical specialties. National approved archetypes constitute the basis for semantic interoperability in openEHR-based systems. This adheres to the II design principle of standardization, and the importance of communicating through defined clinical standards [17]. However, as maximum datasets, these archetypes need to be contextualized, i.e., constrained and tailored to specific use contexts. In line with the openEHR specification, the configurations must be done by local health care organizations. As the case describes, configuration of archetypes, templates and forms is complicated and requires a combination of different skills, such as clinical insight, archetype competence and expertise in ICT/programming. A related contextualization is also found between local archetypes in the EHR form and NORspine. Here some apparently similar data, for instance 'other endocrine diseases' have different granularity. This illustrates that data traveling across settings needs to be contextualized to make the infrastructure grow [17].

VI. CONCLUSION

To summarize, this paper has described and discussed socio-technical requirements, detected when following the design of a registry form and the emerging methodology for designing structured user interfaces by expert users.

From this study, we found:

1) The expert user role demands a thorough understanding of the complex design tools. It also requires extensive training over a longer period of time, in order to create high quality archetypes, templates and forms.
2) It is important to find a balance between an efficient design process and the need for robust archetypes as a basis for the infrastructuring process.
3) Structured user interfaces demand for establishing extensive governance at different organizational levels.
4) It is essential to contextualize national high quality complex archetypes to different local contexts, in order to make them useful for clinical practice. This must be done in collaboration with clinicians and local governance organizations.

The infrastructuring process of designing regional openEHR-based user interfaces is a complex process, which demands for several socio-technical requirements to succeed. Hence, it is important to establish a 'scaffolding' organization, in terms of governance and extensive training programs to make it possible for expert users to be in charge of the infrastructuring processes of designing user interfaces. This is an ongoing process in the health region and, accordingly, it is necessary to do more research in this field.

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