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THE IMPLICATION FOR ORGANISATION AND GOVERNANCE THROUGH USER-DRIVEN STANDARISATION OF SEMANTIC INTEROPERABLE ELECTRONIC PATIENT RECORD SYSTEMS

Completed Research

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Abstract

The increased demand for more effective sharing of healthcare information to support complex patient pathways crossing organisational boundaries calls for semantic interoperable process-oriented Electronic Patient Record (EPR) systems. It follows the need for common standards to ensure that information is understood and interpreted consistently across various contexts.

A considerable body of literature has demonstrated that standardisation within healthcare has proven difficult to achieve. Moreover, standardisation processes have traditionally had a top-down approach, for which little attention has been paid to users' work practices.

The many failures of standardisation efforts have put focus into alternative standardisation strategies, in which one promising method is promoted through the emerging openEHR approach for standardising the content of the EPRs. A network of voluntary clinical users should have a prominent role in standardisation processes and running the process in a distributed and negotiated manner over the Internet.

In this paper, we seek to give empirical insight regarding the evolving process of developing and implementing a sematic interoperable EPR system based on the openEHR framework, and the implication for organisation and governance addressed by the evolving process. We analyse the case through an information infrastructure perspective, and claim that user-driven standardisation of semantic interoperable EPR systems has to be supported by a multi-level organisational infrastructure, in addition to governance organisations that make decisions and monitor results and performances at different healthcare levels. The organisational and governance infrastructure has to be established simultaneously, but preferably, in advance of new development projects.

Empirically, we have followed the interplay between the developing process of an EPR system based on the openEHR approach and a government-led establishment of an archetype repository.

Keywords: User-driven standardisation, Electronic patient records, organisation, governance.

1 Introduction

The increased demand for complex patient pathways crossing organisational boundaries in healthcare calls for interoperable process-oriented Electronic Patient Record (EPR) systems that are able to exchange clinical information between independent EPR systems (Helse- og omsorgsdepartementet, 2012; Pedersen et al., 2015a; Wollersheim et al., 2009). It follows that the need for common standards to ensure that information is understood and interpreted consistently across various contexts (Bowker and Star, 1999; Bygstad et al., 2015; Star and Ruhleder, 1996) accompanies the rise of distributed technologies used across wide geographical distances.

However, standardisation within healthcare has proven difficult to achieve, and a considerable body of literature has demonstrated empirically as well as analytically that organisations are different and have diverging needs. Based on several studies, standardisation processes have traditionally had a top-down approach for which little (or no) attention has been paid to users' work practices (Bowker and Star, 1999; Hanseth et al., 2012; Timmermans and Berg, 1997; Timmermans and Berg, 2003).

The many failures of standardisation efforts have put pressure on vendors, policy-makers, and public standardisation organisations to look for alternative standardisation strategies. One promising method is promoted through the emerging openEHR approach for standardising the content of the EPRs (Garde et al., 2007; Kalra, 2006). The purpose in openEHR is to promote structuration and interoperability of EPRs independent of technologies and vendors on a national and international scale. A network of voluntary clinical users should have a prominent role in standardisation processes and running the process in a distributed and negotiated manner over the Internet (Beale and Heard, 2007; Beale and Heard, 2008; Garde et al., 2007; Kalra, 2006; Pedersen et al., 2015b).

Including a broad range of users in the standardisation process and giving them the ability to be "in charge" diverges completely from the traditional top-down approaches conducted by ISO. Such an approach instead echoes large-scale open-source development projects (Christensen and Ellingsen, 2014; Ellingsen et al., 2007; Pedersen et al., 2015b), is a completely new standardisation strategy.

Although giving the users "complete" control of the standardisation processes is practically and democratically appealing, it begs many questions on how this can be accomplished in practice on a large-scale. Important questions to ask are: how will 'ordinary' clinicians request new structured elements in the EPR? Who should deal with the requests from ordinary users? How should the prioritising of structured elements be decided and who should be responsible? How should the collaboration between the stakeholders (users, openEHR users, vendors, etc.) be organised? Based on this, we pose the following research question: What are the implication for organisation and governance when dealing with user-driven standardisation processes in design and implementation of semantic interoperable EPR system?

The purpose of this paper is to provide empirical insight regarding the evolving process of developing and implementing a sematic interoperable EPR system based on the openEHR framework, and the implication for organisation and governance addressed by the evolving process.

Empirically, we have followed the development process of a new EPR system and, in particular, the development of a new surgery-planning module, based on the openEHR approach in the North Norwegian Regional Health Authority. The project started in 2012 and is to be completed by the end of 2016. The development process started out as a cooperative effort between an EPR vendor and the Northern Norway Regional Health Authority. The development process evolved into an interplay between several actors, for which we have also followed a national initiative of building a national repository of common semantic clinical data elements (openEHR archetypes) for collaborative EPR systems (Christensen and Ellingsen, 2016; Pedersen et al., 2015; Ulriksen et al., 2016).

The rest of the paper is organised as follows: Section 2 (Theory) describes the theoretical framework for the paper. Section 3 (Method) briefly introduces the empirical setting and the paper's methodological foundations, followed by an explanation of the methods for the empirical research. Section 4 (CASE) presents selected empirical findings in three vignettes, which describe the evolving process of developing and implementing a semantic interoperable EPR system in an organisational perspective. In Section 5 (Concluding Discussion), we discuss the empirical findings in relation to the theoretical framework, and provide a concluding remark.

2 Theory

In response to the goals of integrated care, standardised patient pathways, and evidence-based treatment and care, healthcare organisations have increased their focus on a semantic interoperable process-oriented EPR system that has the ability to exchange and understand clinical information and knowledge between independent EPR systems to improve healthcare service. Accordingly, semantic interoperable EPR systems presuppose standardisation in one form or another (Berg, 1999; Berg and Goorman, 1999; Bowker and Star, 1999; Bygstad et al., 2015; Pedersen et al., 2015; Timmermans and Berg, 2003). Traditionally, standardisation processes in healthcare have a top-down approach, for which users' work practices, characterised by different and diverging needs, are paid little attention and resulting in a slow diffusion of the standards (Hanseth et al., 2012). Consequently, achieving standardisation in healthcare has often proven difficult because much of the structuring of the EPR content translates into the need to also standardise related clinical routines and practices (Ellingsen et al., 2007; Timmermans and Berg, 1997). Accordingly, information systems need to be situated to the local context of use, in contrast, to align the different and diverging organisational needs to a uniform standardised EPR system (Berg, 1999; Berg and Goorman, 1999; Bowker and Star, 1999; Hanseth and Lundberg, 2001; Rolland and Monteiro, 2002).

New strategies for standardisation emerge with this perspective; user-driven standardisation is one approach. As such, an empirical example is the promising openEHR architecture promoted by the international openEHR foundation (Garde et al., 2007; Kalra, 2006). The openEHR framework offers users the technical capability to conduct standardisation and structuration of the EPR content themselves, and enables extensive flexibility that encourages users to define and introduce local clinical data elements (Beale and Heard, 2007.)

The openEHR architecture was developed by the openEHR foundations and standardised by CEN and ISO in the EN/ISO 13606 standard series. It consists of a two-level modelling approach for EPRs (Garde et al., 2007) that separates the technical design of the system and the clinical data collection using archetypes. A standardised reference information model represents the first level, whereas the openEHR archetypes, based on the reference model, represent the second level (Beale and Heard, 2007; Garde et al., 2007).

As structured data elements, archetypes can be displayed in different presentations. For example, a 'blood pressure (BP) archetype represents a description of all the information a clinician might need or has to report about a blood pressure measurement' in a patient's record. The actual blood pressure value is accompanied by additional data regarding who (who measured the BP), how (which type of equipment was used, and if the patients was sitting/bed resting), when (related to datum and time of day), and where (refers to the location on the patient's body [e.g. intra-arteria BP, right/left arm or leg etc.]) as a way of describing the context of the blood pressure measurement. Therefore, archetypes are *'metadata used to define patterns for the specific characteristics of the clinical data, for example the blood pressure, in this case'* (Kalra, 2006, p. 138). In the hands of clinical personnel or domain experts, they can be seen as generic building blocks used to construct templates, or as structures corresponding to formatted displays, documents, or reports (Beale and Heard, 2007). Accordingly, this ap-

proach promises a high degree of local customisation for users and ensures that clinical users can 'be in the driver's seat' of standardisation and structuration processes (Garde et al., 2007).

'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'(ibid, p. 336).

Skilled users are encouraged to embed internationally or nationally agreed-on archetypes in systems based on the openEHR architecture to ensure interoperability, but they are also free to define their own local archetypes (Atalag et al., 2016; Garde et al., 2007; Kalra, 2006; Silsand and Ellingsen, 2014; Ulriksen et al., 2016). Moreover, the strategy of user-driven standardisation through the openEHR framework implies developing an evolving repository of standardised/structured clinical data elements (archetypes)—a so-called Clinical Knowledge Manager (CKM)—on an international/national level, in which the clinicians need to engage in and be responsible for the production of archetypes (Atalag et al., 2016; Garde et al., 2007). Archetypes are, in a figurative sense, the 'backbone' of sematic interoperable EPR systems and a premise for supporting documentation of clinical work in local settings; they coordinate clinical activities distributed in time and space, are the basis for decision making, and serve as data for research. Moreover, building an international/national repository of archetypes is not a list of standards or a fixed product, but a living process whereby the international/national initiative creates the standards required over time and issues them in ongoing programs that include provider organisations, clinicians, vendors, and other stakeholders (Atalag et al., 2016).

In this sense, the notion of information infrastructure is increasingly used for describing the networks of technological elements and the number of developers and users involved in the evolution of an information system that supports cooperation and communication within and across, for example, health care. In this paper, we use the information infrastructure framework to investigate the standardisation process through the openEHR framework. Hence, we interpret archetypes as an evolving information-characterised by necessity of cooperation in design and used by a large community. Moreover, in infrastructure (II) an II perspective, archetypes contribute to the enabling function of a semantic interoperable EPR system, openness, and reach of scope, and are formed and exist only in relation to someone's practice (Bowker and Star, 1999; Garde et al., 2007; Hanseth and Monteiro, 1998; Star and Ruhleder, 1996).

Archetypes as information infrastructures change and grow in relation to our ever-changing health knowledge, but also in relation to the clinician's need for granularity of clinical information necessary to the context of use. This represent a continuous process of design and evolution. However, an important implication is that archetypes have to be designed in accordance to a formalised process, ensuring that the design principles from the openEHR framework are followed. The openEHR framework makes it possible to define in terms of technical incompatibilities with the international/national archetypes and may cause clinical archetypes only locally or for medical sub-fields. Consequently, local design may threaten the goal of semantic interoperability safety problems, such as overlapping concepts between healthcare domains (Garde et al., 2007; Star and Ruhleder, 1996). Important questions to ask are how the clinicians enrol wishes and requirements of new archetypes, how to prioritise the development of required archetypes, and how to govern standardised clinical information on several organisational levels. This addresses a need to investigate user-driven standaridsation process when developing and implementing a semantic interoperable EPR system, in addition to the implication for organisation and governance addressed by the evolving process. Accordingly, we analyze our data (the case description) through the lenses of an information infrastructure perspective (Atalag et al., 2016; Garde et al., 2007; Ulriksen et al., 2016).

3 Method

3.1 The Regional Project

The Northern Norway Regional Health Authority decided in 2011 to invest in new clinical ICT systems for all 11 hospitals in Northern Norway. The Regional Project was then established with a cost likely to exceed €100 million for the period 2012–2016, and it is currently one of the most ambitious healthcare-related ICT projects in Norway. A key aim of this project was to replace an existing, largely free-text-based EHR with a new archetype-based (i.e., highly structured) EPR offering extensive decision support, interoperability capabilities, and easy reuse of data for clinical research. The procurement conformed to the national Norwegian strategy of building an infrastructure for specialised healthcare based on the openEHR architecture. More than 150 clinicians from all 11 hospitals in the northern health region were invited to workshops to define their expectations and requests for a new EPR system.

The Regional Project started out in early 2012 with several workshops in parallel, in which developers and managers from the vendor, the clinicians, and the members of the Regional Project cooperated to plot the course of the system to be developed. In this paper, we have limited our focus to the development of a new surgery-planning module within the new EPR system.

DIPS, the principal vendor in the Regional project, currently holds approximately 86% of the hospital-based EHR market in Norway. During the last 25 years, it accumulated high-level expertise in developing ICT systems in this domain. Because of the domain's complexity, DIPS started to experiment with Model-Driven-Development methodology as early as 2006. This culminated in 2011 with the decision to use the openEHR architecture for its future EPR system.

3.2 Methodological approach

This study is an interpretive case study with the aim of providing insight about the key mechanisms at play during the evolving process of designing and implementing a new semantic interoperable EPR system based on the openEHR framework, and the implication for organisation and governance addressed by the process (Klein and Myers, 1999; Walsham, 1995). The epistemological foundation in interpretive research emphasises 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 (Orlikowski and Baroudi, 2002).

We have traced the development process of the new EPR system, which started with user-vendor workshops on the local level in January 2012, to the ongoing implementation in a clinical setting until May 2016. During 400 hours of observation, data were collected through qualitative interpretive methods (Klein and Myers, 1999; Walsham, 1995), in which the first author participated in workshops with the vendor and users when designing the new EHR system, software module testing, meetings and seminars on archetype strategy, and formal and informal project meetings. Twenty-six semi-structured interviews, each lasting 40–60 minutes, were conducted of developers, project managers, and clinicians. A digital voice recorder was used, and the interviews were transcribed. In addition, document studies of the ongoing project and reports from National ICT on ICT architecture and archetype strategy were performed.

The interpretive approach calls for detailed case descriptions, followed by an analysis of the data for potential analytical themes guided by the philosophical perspective of hermeneutics and the chosen theoretical framework. The hermeneutic perspective implies the consideration of the entire data collection in an iterative and interpretive process. Therefore, our analysis has been a back-and-forth process between observation, case descriptions, and the use of the relevant literature and document studies

mentioned above. Moreover, informal talks with stakeholders and research fellows have played an essential role in the interpretive process. In addition, the first author has worked as a nurse in different fields of the Norwegian healthcare service for the last 15 years. The second author has a long history of studying the implementation and use of ICT in healthcare, particularly regarding EPRs in hospitals.

Through this approach, we emphasise various viewpoints of the process to ensure deeper understandings of the ongoing process of developing and implementing semantic interoperable EPR systems in an organisational perspective. We present the data in chronological order as a case description of three vignettes.

4 Case

4.1 Vignette 1: Leaving the messy details of clinical practice to the users

As elaborated above, DIPS regarded the openEHR architecture as the perfect strategy to handle an increasingly complex healthcare market:

'Very much of what we had developed in the period 2008–2011—was good functionality, but all the screens and modules were hardcoded, and every tiny change to our software had to be done by our developers and that was an overwhelming task (. . .) [in comparison] openEHR is a very good domain model of the healthcare sector (. . .) and building a system where it is possible to model things and change structure afterwards would be very efficient for us" (system architect, DIPS).

"The profit by using the "archetype approach" is that it allows us (the developers) to live in "our own little developers' world"—though, not the developers who implement the system. (...) 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, DIPS).

Through adherence to the openEHR framework, DIPS could concentrate its efforts on developing the technical part of the new EHR while users were expected to model the clinical content of various healthcare domains through archetypes in accordance with the national strategy. In turn, the vendor's running software would process and interpret the archetypes to generate user interfaces, workflow, and process support.

In the initial phase of the development project, the clinicians were enthusiastic about the possibility of gaining flexible structured clinical information, which could be reused during clinical processes and serve as a premise for process and decision support. However, according to the openEHR approach, building software is different from traditional software design. Traditionally, the clinicians' requirements are gathered via the well-known "use case" methodology; and designs and models are built from the requirements and implementation proceeds from the design, followed by testing and deployment of the software. Through an openEHR approach, the vendor was supposed to concentrate on developing the technical part of the new EPR while the clinical content—the semantic interoperable data elements—were expected to be modelled by the clinicians.

At this stage of the development process, the vendor did not have any working software to present to the clinicians, but needed feedback from the clinicians about how the software should process archetypes dynamically into the prospective user interface. According to the developers, they would not develop a specific local functionality (e.g., in surgery planning for a local hospital), but rather generic functionality that could process archetypes and then make it possible to plan surgery tailored to the local context (Figure 1).

A developer from the vendor explained: *'We are going to build a LEGO® city, but at this stage we are making the description of how to put the single bricks [archetypes] together'.*

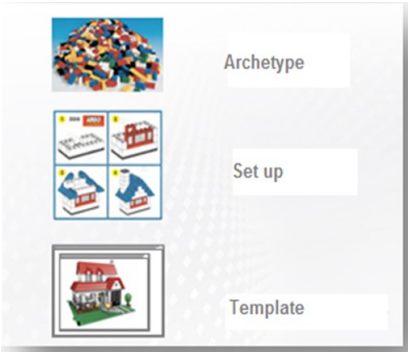

Figure 1.

Grasping the potential of a completely new technology was challenging to the clinicians, and getting the clinicians' feedback was challenging for the developers. This was necessary for technical development. Archetypes are not the EPR system's user interface, and do not decide how the system should look and behave. However, with no working archetypes to process the developed software, it was difficult for the clinicians to realise the potential of local customisation of standardised clinical data elements.

4.2 Vignette 2: Bureaucratisation: Centralisation—national governance. The vendor-led initiative

During the first year of the development process, it became clear that the new EPR would be difficult to develop and would not be fully operative without the presence of a broad range of archetypes to represent the clinical content related to the surgery-planning process. The vendor had expected the Northern Norway Regional Health Authority to organise relevant user forums for modelling archetypes. However, the management of the Regional Project realised that building a repository of archetypes would be a task too huge for the smallest health region in Norway. Accordingly, an increased understanding of the need for a broader national initiative to do this work led to the establishment of an editorial group (two full-time positions) for building and governing a national archetype repository (a so-called clinical knowledge manager) in January 2014. The initiative was developed through National ICT and the vendor. In February 2014, the editorial group launched a Norwegian CKM, aiming to govern Norwegian archetypes by the same principles as the international CKM.

The introduction of a national repository of archetypes was an important step towards sharing clinical information over organisational borders, and the archetypes were designed in accordance with the design principles from the openEHR framework. To obtain a basic catalogue of archetypes quickly, the archetype governance program saw it as effective to start the process of filling the repository with observation-type archetypes already developed and approved internationally. The intention of an evolving archetype repository was to develop archetypes through a so-called "do-ocracy", for which clinicians, allied health workers, and other experts propose which clinical information has to be defined as archetypes based on local needs—or, for example, national initiatives—as quality standards for healthcare. Moreover, the requested archetypes have to be reviewed; the editorial group covers the recruitment of the reviewers (supported by regional archetype groups) to the national clinical knowledge manager. If the requirements— such as having the right number of clinical specialists for the specific archetype— are met, the editorial group provides further approval.

However, from the vendor's point of view, the initial process of modelling nationally approved archetypes moved too slowly. The surgery-planning module combines structured data from the EPR with logistic data and resource overview data from other systems to create a schedule for surgery activities. Accordingly, the surgery-planning module needed an amount of working archetypes. In general, 10–20 archetypes are necessary for core clinical information, 100 archetypes for a primary care EPR, and

an estimated 1000–2000 archetypes are necessary to encompass the clinical content of a hospital EPR system. By November 2014, only one archetype had been approved in the Norwegian CKM, a translated and approved version of blood pressure, but no locally initiated archetypes had been approved However, in June 2016, the national repository had 43 approved archetypes and 524 in process.

The archetype concept states clearly that it is the clinician's responsibility to propose and create archetypes. Nevertheless, the vendor could not deliver an empty system requiring customers to spend years building the archetypes to use the new EPR. Consequently, the vendor took the responsibility of defining and creating the initial archetypes for the surgery-planning module in cooperation with international stakeholders and the national editorial group. However, both the vendor and the national editorial group stated that developing vendor-based archetypes was far from the ideal of national approved archetypes initiated through the 'do-ocracy'.

4.3 Vignette 3: Implementation of surgery planning—revealing the 'missing link'

As described in vignettes 1 and 2, developing an archetype-based EPR system revealed organisational dependencies and structures not established by the time the development process started. As described, the archetype development process did not follow the official channels for several reasons, and proceeded to reach the goal of a semantic interoperable process-oriented EPR system to present to the customer and the clinicians. In April 2016, the surgery-planning module was ready to be used in a real clinical setting; surgery was performed on a limited group of patients in an outpatient clinic of the University Hospital of Northern Norway. After more than four years of development and testing of the new EPR system, the implementation of the surgery-planning module into clinical practice was prolonged and welcomed by clinicians, project management, and the vendor.

So, what did the first month of clinical use reveal? As anticipated, the clinicians needed support when starting to use a new user-interface with new software functionalities to process clinical information. More disturbing were the technical problems related to the reuse of clinical information. Nevertheless, there are always initial technical problems when putting new technology into ordinary use, and the vendor improved the functionality for the next release. The local ICT department at the University Hospital established a regional resource group in 2013, but the focus of their work had been on the national archetype work. However, looking into the development and implementation process from an organisational point of view, the 'growing' archetype-based EPR system missed support from the 'domain expert' level because the regional resource group had not been organised to support the development and implementation project.

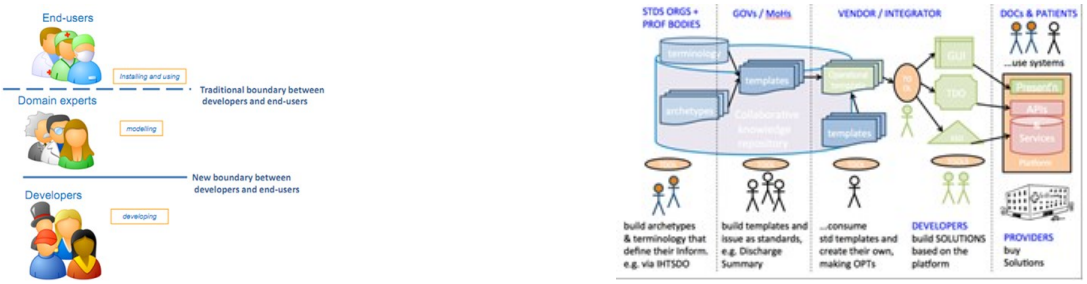

Figure 2

The intention of a user-driven standardisation process is to give the clinicians the opportunity to tailor the specification of clinical content (represented by archetypes) on local/regional/national levels. Moreover, by the time of implementation, the vendor had no tool to offer to the clinicians/domain ex-

perts, which is needed for customising the archetypes to local contexts. The clinicians had expected that they could change the archetype-based schemas in the new EPR—in terms of constraining or expanding the number of clinical variables within (templates) schemas—to fit into their local context of use. Tailoring the archetype-based schemas was not an option for the clinicians during implementation, and, accordingly, the clinicians felt misled. However, designing templates to local practices is described to be a task for the domain experts in cooperation with the clinicians. If there were no domain experts participating and no technical tools, however, the vendors took on the domain expert roles themselves.

Another concern related to the absence of domain experts was where, to whom, and how could local clinicians address needs of clinical information that could be designed as archetypes during implementation and use? During implementation, a clinician stated:

'It is ok with reuse of clinical information like blood pressure, weight, and height, but what would be of real added clinical value is if a clinical procedure, e.g. a surgery procedure, automatically initiates a list of new procedures, measures, or actions that you have to consider and make a decision in relation to the patient condition. Then, we are talking about a new dimension of process- and decision-supporting systems'.

To meet requests as described by the clinician, the needs of domain experts participating in the design and implementation process were addressed, including those from the management of the regional development project and the local implementation project at the hospital. Moreover, the national editorial group needed input from a local or regional initiative to start the design process of new archetypes to make the archetype development process the 'do-ocracy' way.

To summarise the initial clinical use of the new EPR system, the clinicians were mostly positive about the new user interfaces and functionalities. Nevertheless, the reuse of clinical information by archetypes was limited, and consequently the semantic interoperable process-oriented system was not present. However, the development and implementation process revealed implications for organisation and governance of the new EPR system.

5 Concluding discussion

The vignettes are selected 'snapshots' of the evolving and unpredictable process of developing and implementing a semantic interoperable EPR system in an organisational view. As vignette 1 described, the initial development process focused into the design of the standardised reference information model, but initiating a development process of a semantic interoperable process-oriented EPR system without the necessary standardised clinical data elements (archetypes) was a cumbersome design process. The vendor's software 'in-progress' would process and interpret archetypes to generate user interfaces, workflow, and process support. However, with no working archetypes to process, it was difficult for the clinicians to catch the potential of local customisation in accordance to different clinical needs supporting different surgery-planning processes like clinicians from different hospitals and wards represented. Moreover, the developers' needed feedback from the users to guide the development process and they had to understand the context for which the software should be used. Accordingly, the vendor used the Lego analogy to present the generic software-in-progress to the clinicians and as a way to facilitate dialogue between clinicians and developers during the development process.

Nevertheless, semantic interoperable EPR systems presuppose standardisation in one form or another (Berg, 1999; Berg and Goorman, 1999; Bowker and Star, 1999; Bygstad et al., 2015; Pedersen et al., 2015; Timmermans and Berg, 2003). In this case, archetypes are in a figurative sense the 'backbone' of the semantic interoperable EPR system 'in-progress', but a repository of archetypes has no value without software that can process archetypes for clinical use. These aspects place the development process in the same light as the philosophical dilemma—what comes first, the egg or the hen? Developing a semantic interoperable EPR system has to be seen in a relational perspective in which arche-

types and the standardised reference information model are interdependent of each other in constituting semantic interoperable EPR systems.

How did this statement influence the development process? The vendor handled the development of the standardised reference information model, as expected. This brings us to discussion the relational aspect of developing archetypes. In this paper, we interpret archetypes as an evolving information infrastructure (II) characterised by the need cooperation by a large community in design and use. In accordance with the openEHR framework, the clinician need to engage in and be responsible for the production of archetypes. Standardising clinical information becomes the responsibility of the clinicians because they represent the clinical domains in which the production of clinical information and knowledge constantly change and evolve (Atalag et al., 2016; Garde et al., 2007). Consequently, archetypes exist only in relation to a clinical domain or a clinical practice. However, as they inherit the quality of '*metadata used to define patterns for the specific characteristics of the clinical data, […]'* (Kalra, 2006, p. 138), their reach of scope is open or infinite - but they need to be formed to specific clinical practices (Bowker and Star, 1999; Garde et al., 2007; Hanseth and Monteiro, 1998; Star and Ruhleder, 1996).

Accordingly, archetypes as information infrastructures change and grow in relation to our ever-changing health knowledge, but also in relation to the clinicians' need for granularity of information to support their clinical context of use. This represents a continuous process of design and evolution. However, an important implication is that archetypes have to be designed in accordance with a formalised process, ensuring technical incompatibilities and clinical safety (preventing overlapping concepts) (Garde et al., 2007; Star and Ruhleder, 1996). This calls for an organisational structure like that described in vignette 2, establishing a national (global) repository of archetypes to design and govern archetype production.

As mentioned, archetypes exist only in relation to a clinical domain or a clinical practice, and user-driven standardisation promotes 'putting the clinicians back into the driver's seat' (Kalra, 2006). In practice, this means that the national editorial group needs input from clinical practices to adjust the design of new archetypes to local clinical needs. The intention is to develop archetypes through a so-called 'do-ocracy', in which clinicians, allied health workers, and other experts propose clinical information that should be defined as archetypes based on local needs (or, for example, national initiatives as quality standards for healthcare). The requested archetypes must be reviewed by the right number of clinical specialists through a consensus process to ensure their position as metadata, before approval. Of course, the archetypes must have a technical design in accordance with the previously mentioned formalised procedures.

However, the 'do-ocracy' and the formalised consensus process for approved archetypes involved several clinicians from different specialities and professions, which challenged the progress of the necessary archetype development process (vignette 2). Consequently, the relational perspective of the archetypes and the standardised reference information model, interdependent of each other, were again the main problem of the development process, resulting in the vendor taking responsibility for defining and creating the initial archetypes. The case revealed a network of interdependencies necessary to proceed the development process. The scenario points to the organisational structure, in which the regional level, where the Regional development project took place, was in a premature state. Consequently, the local level needs to be linked to the national (global) level, with the 'domain expert level' (regional level) in the middle, which appears as the answer to how and to whom local clinicians should give input into the archetype development process. The 'domain expert level' has to link the local needs to the global organisation (Bowker and Star, 1999; Garde et al., 2007; Star and Ruhleder, 1996).

Nevertheless, the user-driven standardisation process is not a bottom-up standardisation process only. Standardised archetypes are 'generic building blocks used to construct templates, or as structures corresponding to formatted displays, documents, or reports' within semantic interoperable EPR systems (Beale and Heard, 2007). Accordingly, taking the archetype repository into clinical use raises the

questions of who is going to do the 'template design', who will decide which templates, documents, and reports to model, and how to govern the local templates. In this case, the vendor had not released the tool that empowered the clinicians/domain experts to bring the customisation archetypes to local contexts (vignette 3). However, designing local templates addresses the need for governing the templates on a local or regional level, which makes it tempting to give the domain expert level a role in the local/regional governance as well. At this time in the Regional development and implementation project, it is not obvious how the customisation process should proceed or how to govern customised products, in addition to what and to which level customisation of archetypes and templates are necessary. Moreover, will customisation of archetypes influence the semantic interoperability of the clinical information? These questions will need to be explored through further research.

In conclusion, an important insight of the study is that developing a semantic interoperable EPR system is dependent on a well-working organisation and governing infrastructure. It is not enough to promote user-driven standardisation of semantic interoperable EPR systems as something the users can do by themselves. User-driven standardisation of semantic interoperable EPR systems addresses the need for a multi-level organisational infrastructure—a mixture of various structures, processes, and relational aspects—in addition to well-functioning governance organisations that make decisions and monitor results and performances at different healthcare levels. The multi-level organisational infrastructure has to be 'up-running' when user-driven standardisation programs are introduced.

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