Implementation of OpenEHR in Combination with Clinical Terminologies: Experiences from Norway

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Abstract—**Norway is currently involved in several initiatives to adopt clinical information standards and terminologies. This paper aims to identify and discuss challenges and experiences for large-scale national implementation projects when working towards structured Electronic Health Records systems, process and decision support, and secondary use of clinical data. This paper reports from the national strategy for OpenEHR adoption in Northern Norway Regional Health Authority encouraged by the development of a national repository for OpenEHR archetypes and a national initiative to integrate clinical terminologies. The paper contributes to a qualitative longitudinal interpretive study with an effort to increase the possibility to obtain semantic interoperability (towards integrated care) and discusses Systematized Nomenclature of Medicine - Clinical Terms and other relevant clinical terminology and Clinical Information Models such as OpenEHR archetypes. Terminology and archetypes are used to structure the EHR two-folded, and we discuss a general use of information models to increase interoperability extensively. A two-folded use of terminology where terminology is integrated in archetypes, or where terminology is used to structure the Electronic Health Record system while using the hierarchical model of the terminology is discussed. Secondly, we discuss for what purpose OpenEHR is the choice of Clinical Information Model to succeed in Norwegian healthcare. We have identified some challenges and lessons learned.**

Keywords-eHealth medical records; electronic health records; web technology; e-health; interoperability; semantics; integrated care; OpenEHR; terminology; classification systems.

I. INTRODUCTION

Currently, the healthcare system is involved in a transformation process [1][2] in an attempt to overcome some of its challenges [3][4]. Researchers, governments, and international organizations, recognize the need to advance towards a healthcare system capable of integrating the different islands of expertise that conform different components of healthcare [5], accelerate the access to latest evidence [6][7][8], and use the data generated during the care process to elicit new knowledge that allows the whole system to learn from its own experiences [6][9]. Achieving this vision requires an extensive but also sound use of Information and Communication Technologies (ICT) in order to allow healthcare information to seamlessly flow across healthcare levels [6][8]. Achieving this holist healthcare system capable of learning from its own operation needs not only efficient technologies but also the ability of these technologies to exchange information without any ambiguity or loss of meaning, i.e., interoperate at a semantic level [10].

Enabling semantic interoperability (SIOp) across healthcare technological platforms is needed in order to guarantee that different stakeholders will derive the same conclusions from the same data set [10]. If SIOp is not granted across organizational boundaries, the lack of precision in specifying the meaning of the information shared may lead to misinterpretations of healthcare data jeopardizing the quality of care and hampering research outcomes. SIOp is a keystone for holistic healthcare systems that aim to integrate different areas of expertise (and, therefore, the technologies that support them), and reuse their data to generate new knowledge. During the last decades many initiatives have advanced in the development of different standards to enable SIOp [11][12][13]. However, despite the heavy investment performed, standardisation in health care has proven to be a cumbersome and difficult process [14][15].

In Norway, several projects are currently working towards realizing that vision [7][13][16]. For more than a decade, National initiatives towards shared and integrated care have been a focus area for the Norwegian health authorities [17][18]. More recently, several initiatives to enable the secondary use of clinical information were also considered strategic by the Norwegian Health authorities [7][16]. These initiatives especially emphasize the need to apply clinical information standards and terminologies for enabling interoperability across heterogeneous health information systems. However, optimal leverage of all the components needed to enable SIOp is not a trivial task, and it is currently a matter of discussion among academia, implementers, and the Norwegian health authorities.

Three main components are necessary to enable SIOp: a) reference models; b) clinical information models (CIMs) (a.k.a. Detailed Clinical Models), and c) biomedical terminologies [10]. In 2012, Norway opted for the adoption of openEHR as standard for specifying EHR information. The objective was twofold: a) providing a set of robust clinical information models (CIMs) (a.k.a. archetypes) to build the national EHR upon; b) enabling SIOp across different health information systems based on these archetypes.

The adoption of openEHR has been an effort involving many stakeholders at different health trusts and healthcare levels. After 9 years, the number of CIMs defined with openEHR is increasing creating a robust set of information models to build the EHR upon [19]. Regarding the adoption of terminologies, the national strategy has focused on ICD-10 for medical diagnosis and reimbursement, together with a more fragmented use of nursing classifications in different EHR systems for clinical purposes. In 2016, Norway joined the IHTSDO acquiring systematized nomenclature of medicine - clinical terms (SNOMED-CT). When it comes to the adoption of SNOMED-CT the first evaluations performed in collaboration with the committees involved in archetypes definition has already unveiled challenges that need to be overcome in order to fully exploit the potential of the terminology.

This paper describes the national work accomplished to support the openEHR modelling of EHR, and the evolution of systems with focus on the development of clinical value. We describe the work performed in: a) CIMs definition as archetypes by multidisciplinary teams of information architects and clinicians; b) experiences regarding the adoption of different terminologies; and c) the evaluation of the adequacy of adopting SNOMED-CT as reference terminology to annotate CIMs.

The remaining of the paper is organized as follows. The background section introduces the use of CIM and terminologies to enable SIOp, the method section describes the data gathering and synthesis performed through interviews, meetings and active participation with the national comities involved in SIOp technologies adoption. The results section shows first the status and accomplishments of the national initiatives in the definition of CIMs (openEHR archetypes). The second section is devoted to report on efforts in terminologies adoption and the current evaluation of the feasibility in adopting SNOMED-CT. The discussion explains the future challenges and raises important areas that have been identified to be critical in the success for adopting openEHR in combination with clinical terminologies for enabling SIOp.

II. BACKGROUND

A. *Clinical Information Models*

CIMs [20] are models specified in some clinical information standard to express the schema of clinical information entities processed by Health Information Systems (HIS). CIMs are used to appropriately maintain the consistency of clinical information structures inside a HIS, and to enable semantic interoperability across different systems and organizations. This makes CIMs a basic component for the appropriate management of patient data [10]. Moreover, with recent advances in data reuse strategies, CIMs are also playing an important role in defining the clinical information structures needed for architectures oriented to secondary use of data [21][22][23] and the integration of genetic reports in the EHR [24].

In the last decade, the work of different initiatives to model CIMs is leading to the definition of an extensive catalogue of models publically available. These models can be used to drive the development of HIS. Nowadays, there is a considerable diversity in the standards and approaches available to define CIMs. Examples are openEHR, CIMI, HL7 CDA and HL7 FHIR. Although most editorial teams follow similar steps, there exists no unified methodology or guideline for their definition [20]. The scope of modelling initiatives varies significantly from the local to the international level. For example, the international Clinical Knowledge Managers (CKM) and the Clinical Information Model Initiative (CIMI) define CIMs at an international level; the Norwegian CKM defines them at a national level; and the Intermountain Clinical Element Models (CEMs), were defined at intra-organizational level. The work in parallel of different initiatives has led to semantically equivalent models expressed in different information standards, a.k.a. iso-semantic models. In Norway, the openEHR open standard has been the one adopted by 3 of the 4 health regions. OpenEHR relies on a meta-model (i.e., reference model) and a constraint language (i.e., cADL) to define CIMs (referred to as archetypes in openEHR jargon) [25]. The consistent use of archetypes enables interoperability between different openEHR-based EHRs, as well as efficient reuse of data across different contexts [10][26]. Since archetypes represent a consensus over the data structures to represent clinical information, they need to be defined among the different stakeholders that will rely on the archetype to interoperate. Therefore, their definition must be carried out as a collaborative process among multidisciplinary teams of clinicians and information architects [23][27]. This collaborative definition of archetypes is achieved in web platforms where experts review and publish the archetypes that will be used to define the EHR. These platforms are known as CKMs [28][29][30][31].

In Norway, since 2012, several projects have evaluated the adoption of openEHR as standard for enabling SIOp in secondary healthcare [32]. At the moment, 3 of the 4 existing health regions rely on openEHR to enable SIOp in secondary healthcare. The national initiative that deals with archetypes definition has gradually gained a foothold in the Norwegian e-Health scene. The openEHR architecture has been used to build a national CKM. Archetypes are defined collaboratively in the CKM in order to provide vendors a library of common formal models to build their clinical information systems on. The national CKM archives information about how new archetypes are translated, modelled, and shared, and is planned to contain between 1000 to 2000 archetypes. The final aim is to build an open source repository of clinical content, based on the OpenEHR clinical information model. A precondition for success is that clinicians agree on the content of each archetype in the CKM consensus processes. Clinicians from the four Regional Health Authorities are active contributors in the process for developing archetypes. The national editorial group, and the National Administration Office of Archetypes (NRUA, from the Norwegian nasjonalt redaksjonsutvalg for arketyper) have coordinated this process.

The national CKM in Norway is responsible for the definition of reference archetypes that vendors will use to build the EHR information model on. The definition of CIMs typically encompasses two main tasks: a) the specification of the information structure in a clinical information standard such as OpenEHR; and b) the binding of the meaningful sections of the CIM to a terminology to attach unambiguous standard descriptions to them.

Archetype sections can be bound to concepts provided by standard terminologies, thus endowing archetype elements with semantics provided by standard terminologies such as ICD 10, LOINC or SNOMED-CT. This enables semantic interoperability among those HIS that rely on the same set of archetypes and terminology [33]. At present, the binding of the archetypes in the National CKM to SNOMED-CT is under evaluation. The results section reports some of the challenges found to coordinate the use of SNOMED-CT in combination with archetypes.

B. Biomedical terminologies

Clinical terminologies offer a common vocabulary for national health authorities, local researchers, and quality registers [34]. This means that in addition to being a storing device for free text data, EHRs are capable of encoding commonly occurring data using fixed lists of multiple choices for certain purposes. Thus, data becomes more comparable and computable than free text would be.

There is a wide spectrum of clinical terminologies. In nursing, the International Classification of Nursing Practice (ICNP) or Nursing Intervention Classification (NIC) and The North American Nursing Diagnosis Association (NANDA) are widely used [27][35]. Other examples are the International Statistical Classification of Diseases and Related Health Problems (ICD), the Foundational Model of Anatomy (FMA) or even general-purpose terminologies such as SNOMED-CT. There are also terminological standards for more specific domains, such as the International Classification of Functioning, Disability and Health (ICF) for rehabilitation. These terminologies have been developed, and used, to ensure consistency of meaning across time and place. On one level, nursing classifications enable day-to-day planning for local users (primary use) where clinical terminology is used to structure information (standardized care-plans) using diagnosis and interventions from NIC and NANDA, for example. In practice, the adoption of standard terminologies will enable a consistent vocabulary to describe information that is sent and received between different systems or health care deliverers. Although SIOp is the main objective, other areas benefit from the consistent use of terminologies and CIMs. The increased focus on process-oriented systems across different health care organisations presumes standardization in the form of shared terminologies and information models to enable SIOp. However, leveraging the use of CIMs and terminologies optimally with CIMs involves challenges that information architects must face at design time [36]. Examples of these challenges include decisions about what to represent as CIMs or terminology, which sections of the archetype to annotate, whether or not to use post-coordination to express clinical concepts, among others.

Archetypes can be tagged with SNOMED-CT codes adding a standard term to each of the sections and nodes of the archetype. This allows specifying the sections and contents of the archetype in a standard terminology so it can be interpreted over organisational or even trans-national borders. In this way, the information becomes interoperable for multiple purposes. Thus, it is essential that standardized terminologies for different domains can be integrated either in the archetype or in the EHR system. The use of a terminology such as SNOMED-CT, which is widely exploited, increases the semantic interoperability at several levels, both for primary and for secondary use. For example, the use of terminologies such as SNOMED-CT facilitates the integration of disparate systems by providing a common definition of clinical terms that can be used to determine when sections of different information models represent the same entity. The integration with co-existing EHR systems is especially important. Medication, laboratory results, and the care plan have to be integrated in the same view to visualize the pathway. The chart systems have a CIM for structured data elements that differs from the OpenEHR/archetype CIM intended to be used in Norway, and mapping between them demands unknown resources.

III. Materials And Methods

The research presented herein has mainly been developed in the North Norwegian Regional Health Authority in coordination with NRUA, and the Norwegian Directorate of Health. Interpretive and ethnographically oriented qualitative methods have been applied, grounded in the participation and contribution to the work accomplished [19]. The fieldwork has focus on the regional/national work accomplished, and, secondarily, on the forthcoming process where numerous archetypes will be tested as structured elements in the new process oriented EHR system. A mind map of the archetype problem/diagnosis is shown in Figure 1. During the last seven years several meetings, courses, and workshops with focus on archetypes and terminology have been covered by observations, document analysis, and interviews. Conversations, discussions, reflections, and debates from these meetings are the foundation of this work. The observations and description of on-going work have been followed by interviews with members of the regional and national initiatives. This includes six interviews on the archetype governance, 10 interviews and 180 hours of observations on the use of clinical terminology, conversations with end users of the CKM while guiding them to become users, and participants in national discussions on the consensus of archetypes. The interviews includes physicians and nurses that are active users of the CKM. The process of educating them to become CKM users has provided valuable knowledge on how to develop the learning and recruitment strategies. A summary of the data collection for the qualitative research process is presented in TABLE I.

TABLE I. An overview of the data collection. Time used, and the number for interviews of the qualitative research process.

Data source	
Interviews with contributors to the work with archetypes, and the development of new EPR.	18 open ended interviews
Participatory observation	180 hours
Participation in meetings, workshops, and informal discussions.	300 hours
Research on SNOMED compared to CIM	200 hours
Document studies: Documents from the CKM, concerning archetypes in general.	

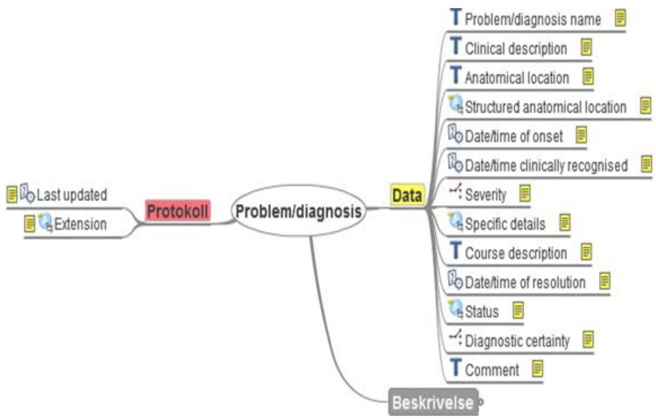

Figure 1. Illustration of the archetype Problem/Diagnosis in the form of a mind map.

IV. Results

A. Definition and governance of archetypes

During the last three years, the use of OpenEHR archetypes has grown with focus on a national anchorage in Norwegian healthcare. The initiative has developed through National ICT, and an EHR vendor that holds more than 80 % of the secondary healthcare EHR systems. From the outset, a national collaborating group is working, in coordination with the aforementioned vendor, to build a national repository of archetypes.

The National ICT, with the goal of producing high quality archetypes, established NRUA in 2013. NRUA has assigned six full/part time associates with an increasing number of collaborators in the Regional Health Authorities. There are between two and three members from each of the four regions. As an example, there is an increasing number of members from the North Norwegian Health Authority, one physician with special interest in health informatics, one nurse with a PhD in Information Systems, one ICT-advisor, two PhD students in part time positions and one project manager from the regional ICT development program where the new process oriented EHR is developed. NRUA also cooperates closely with global connections such as the international openEHR CKM [28], and vendors that cooperate with the Norwegian vendor. The vendors are important contributors with a mutual interdependency. In all, the governance work is important in local, national, and global environments. The overall goal with NRUA is to coordinate the development, and use of archetypes, on a national level, both handling translations of international archetypes as well as handling local initiatives.

The reviews are initiated by the Editorial Group, which also covers the recruitment of the reviewers to the national CKM. The Editorial Group does the further approval if the requirements are met.

The number of review iterations varies depending if the archetype was mature when imported into the Norwegian CKM, or it had to be developed from scratch.

The collaboration and coordination between the national and international CKMs is crucial and, as shown before, helps to reduce the number of review iterations needed to publish an archetype. In some cases, archetypes are imported from the international CKM into the national and published there; while in other cases, the national CKM develops an archetype needed by Norwegian implementers and later it is adopted by the international CKM. Weather archetypes are approved first on international or national CKM depends on the priories of each editorial team. The priority scale is provided in TABLE II. The scale gives an total score for each information element with a total score to coordinate the consensus work. After publication, the results of the review are collated and taken to the other CKM to accelerate the review process. One of the leaders of the international CKM stated, "*the collaboration between the international and the Norwegian CKM is one of a kind based on the national consensus process, and all activities with archetypes in Norway are followed by the international society and vice versa*". Nevertheless, since archetypes publication involves the consensus of many stakeholders with very different backgrounds, there are challenges in the coordination of reviews, and final agreement on the published archetype. She continued by saying, "neither the CKM nor the consensus process is perfect and adjustments will be necessary along the way. Changes can be related to open-source and Web based CKM/process where everything is stored open and is constantly evolving". In relation to these challenges, Christensen and Ellingsen [32] performed an evaluation in the openEHR adoption process between 2015 and 2016 identifying several organizational problems. In their study, they found that the fact of establishing the archetype editorial team (NRUA) at the same time as the implementation of the openEHR-based system that had to use those archetype originated problems. The reason is that the archetypes need to be in a published state when the EHR development starts. Otherwise, the vendor does not count on the real use case models during the implementation. One of the causes for this overlap of activities was the time needed to build a consolidated editorial team with representative reviewers had been underestimated.

TABLE II. PRIORITY SCALE FOR ARCHETYPES [37]. A SCORE MADE TO DIFFERENTIATE ARCHETYPES IN PROCESS TOWARDS CONSENSUS. THE SCORE 4-15 IS A MEANS TO PRIORITIZE. WIKI.ARKETYPER.NO (12.01.2016)

Reuse (0-3)			**Diffusion (1-3)**	**Time for testing (1-5)**	**Functional dependencies (1-2)**	**Semantic dependencies (1-2)**	**Total score (4-15)**
Search, presentation, reuse, aggregation	***Process support***	***Decision support***					
1	1	1	3	5	2	1	14

Clinicians are willing to participate in the review of archetypes but often they require that some of their working hours are reallocated for this task [32]. However, these hours are often difficult to be released since they do not depend on NRUA. A clear alignment with local leaders becomes paramount so they understand the benefits of openEHR adoption and they provide some resources in the form of review hours. In the initial stages these organizational factors caused the publication of archetypes to be slow, in fact only one archetype had been published in the first year of work of the Norwegian CKM [32]. Despite these challenges, the following years become more fruitful. During 2015, 2016 and 2017 the review process has become more mature and effective in the publication of archetypes [19]. At present, it counts on a good pool of reviewers and collaborators that have contributed to accelerate the publication of archetypes, see TABLE III. While at the beginning of 2014, NRUA first had focus on the translation of already existing archetypes and observation-archetypes such as blood pressure, body weight, nutritional risk, height, and temperature, at the time of writing, national consensus has been reached for 57 archetypes and more than 100 are in process of approval. Examples are the archetypes:

- openEHR-EHR-OBSERVATION.nutritional_risk_screening.v1;
- openEHR-EHR-OBSERVATION.blood_pressure.v1:
- openEHR-EHR-OBSERVATION.body_weight.v1.

During 2015 and 2017 more complex archetypes were defined such as:

- openEHR-EHR-INSTRUCTION.medication_order.v1;
- openEHR-EHR-EVALUATION.adverse_reaction_risk.v1.

Clinicians have been invited to participate through the national CKM after coordination between the regional groups and the secretariat at NRUA. The CKM is, as showed in Figure 2. , where the clinicians state there opinion in the text box on the right hand side. Archetypes are used as standards for the clinical content of the EHR and it was important for clinicians to have an essential role in defining and designing them. One clinician said: “It is crucial to include clinicians in this work; they have the clinical knowledge and know what is important to focus on, for the archetypes to be useful standards for clinical work.” The same clinician commented, “If others than clinicians design the archetypes, it will be troublesome to get clinicians to accept and use them”. However, as reported by Christensen and Ellingsen [32], it was not only enough to count on clinical reviewers, those reviewers needed to be trained to review archetypes using the Norwegian CKM.

TABLE III. *DISTRIBUTION OF ARCHETYPES IN EACH OF THE DIFFERENT LIFECYCLES:* PUBLISHED, IN REVIEW OR DRAFT.

Draft	149
Review	26
Published	58

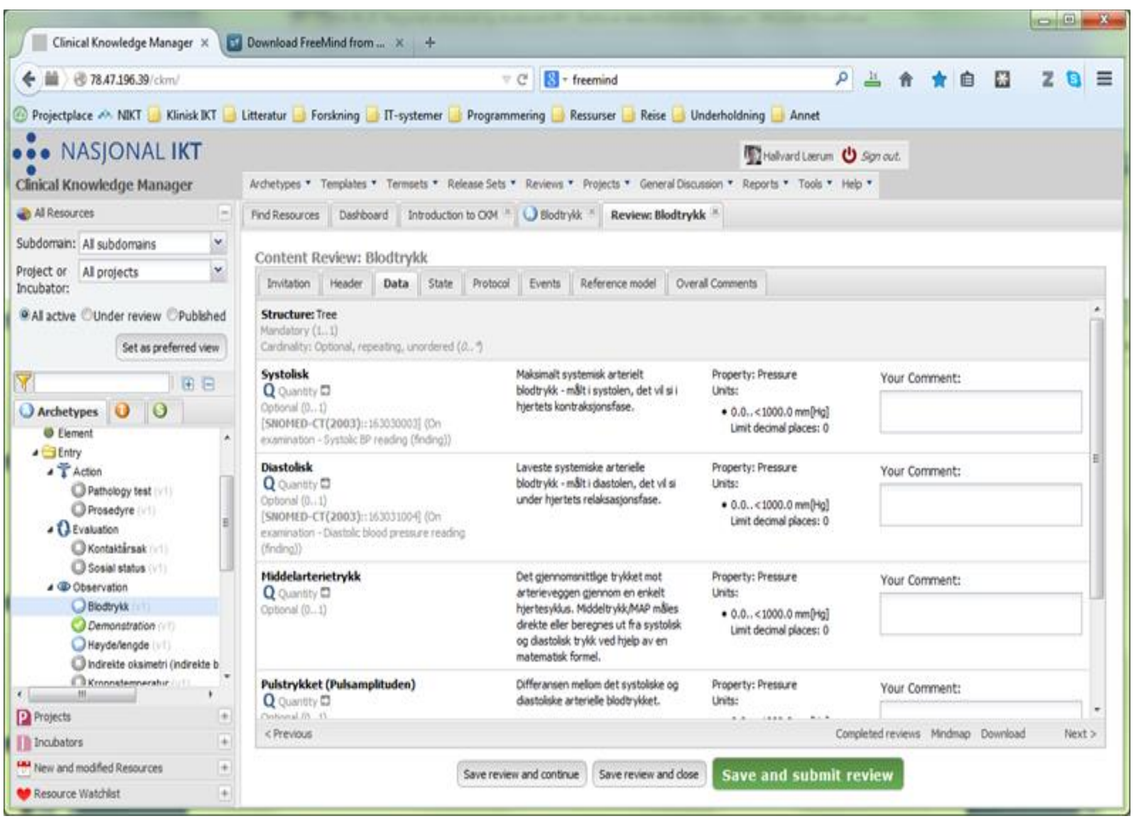

Figure 2. Screenshot of the Clinical Knowlwdge Manager where clinicians cooperate towards the consensus of archetypes.

B. The use of terminology to standardize local practice

In parallel to the adoption of openEHR as information standard, the Norwegian Directorate of Health has put focus on clinical terminology, and has engaged clinicians nationwide to explore the integration of several terminologies in the existing ICT portfolio.

Since 2005, one of the largest hospitals in Norway, Akershus University Hospital, has used an EHR that includes a module for nursing. Along the lines of standardization, the nursing care plan, including nursing classification systems were regarded as a mean for making nursing work more effectively and offering quality assurance. The classification systems are ICT-based standards integrated with the care plan. The diagnoses are represented by the international classification system NANDA, consisting of 206 nursing diagnoses [38]. The interventions are represented by the NIC system, consisting of 486 interventions. Care plans are increasingly made to replace the use of free text in the documentation, foremost to establish a common, formalized language based on the best practices. Free text documentation is whatever information nurses share about the patient in the EHR in addition to, or without, writing formalized care plans. However, the implementation of the EHR led to a systematic use of standardized care plans that gave more efficacy, transparency, and quality of documentation. The care plan has been organized in such a manner that each diagnosis, dimension, and action is firmly attached to the plan with a start and a stop date. When standardizing these plans, the nurse can easily choose several actions from a predefined list for the applicable diagnosis. By doing this, the nurse saves time, while the standardized sentences work as a quality indicator. The purpose of using terminology as a primarily means to standardized EHR systems is challenging, still terminology has been used to structure an unstructured EHR system with success.

C. The national strategy for clinical terminologies

At a national level several terminologies have been adopted and integrated in EHR systems. In the case of ICD-9 and ICD-10, they have been used in Norwegian healthcare systems from their origin with the target of coding medical diagnosis both for clinical and economical benefit. One clinical IT manager stated that the primary target behind the adoption of terminologies could have been achieved if the clinicians had used the diagnosis codes from ICD-10 to categorize the patients in the EHR. However, clinicians found it difficult to be explicit and specific early in the trajectory of the patient, since diagnosis change throughout the patient pathway. Diagnosis change and the IT systems in use need to track and categorize these changes logically to support the activity coding of clinical work. The coding of activities reflects the focus of the clinical pathway, not the diagnosis of the patient. In this sense, the adoption of archetypes becomes valuable: as a quality assurance of the completeness of the clinical terminology, to direct the clinical content of the EHR systems and other integrated systems, and to identify relevant information and give the clinicians access to this information. However, in opposition to local level, patient pathways fixed to clinical ICD diagnosis probably need to be determined on a national level, and based on national directives. This led to discussions on how to use different terminologies in combination with archetypes. A member of the regional archetype group stated: "*The archetype is not annotated but this is a subset of the SNOMED concepts available for severities. As a maximum data set, the archetype should not restrict the "standard" set of terms agreed in terminologies. However, before doing so, I think that the implications in terms of SNOMED licenses should be considered very carefully.*"

The use of standard terminologies is also considered paramount for the standardization of clinical processes. For instance, clinical pathways for cancer diagnosis are today organized from national cancer groups that have resulted in national guidelines that easily could be followed and connected to already existing patient pathway processes, standardized packages to monitor that cancer patients receive the right treatment at the applicable time. Large-scale Infrastructure projects, with increasingly more focus on integrated care, put pressure on the Norwegian Directorate of Health to focus on clinical terminologies and archetypes. Recently, there has been a growing activity in the section of e-health towards increased focus on general-purpose terminologies such as SNOMED-CT, and the International Classification of Functioning, Disability and Health (ICF). This has motivated studies on how terminologies and archetypes fit together. A selected number of experts have, through the last 6 months, recruited evaluators from all over the country. These are clinicians and information architects with special interest in the use of clinical terminology. The work started in November 2015 with the purpose to map SNOMED-CT towards the most commonly used EHR functions. At the same time ICNP will be piloted in the primary healthcare services, this has been organised by the Norwegian Nursing Association that has translated the terminology, and the Norwegian Directorate of Health acknowledges it. SNOMED-CT and ICNP are both discussed in the new national project. Other Scandinavian countries such as Sweden and Denmark have earlier allocated significant resources both to translate and get SNOMED-CT operational for clinical practice.

The national projects have focus on SNOMED-CT and attempt to advise the Ministry of Health in questions such as: should Norway become an organized users of SNOMED? How is the coverage of SNOMED-CT for the content of the clinical pathway? How is the integration of SNOMED-CT solved technically? The last question includes the use of archetypes, but also the possibility to use SNOMED directly to represent EHR content?

A national project coordinated by the Norwegian directorate of Health in 2016 had the purpose to map the clinical patient pathway with SNOMED-CT codes. A standardized breast cancer process was used with the purpose to categorize the coverage of SNOMED-CT for all the relevant clinical variables. The study revealed that despite the total number of codes in the SNOMED-CT hierarchies, more than 30 % of the breast cancer process values had no SNOMED-CT code.

D. Terminology binding of archetypes

A key aspect of archetypes is that they allow the binding of their elements to codes from an external terminology. Since the objective in Norway is to cover most clinical areas in secondary healthcare using archetypes, the adoption of SNOMED-CT as general-purpose terminology for their terminology binding has been explored. The binding of archetypes to SNOMED-CT endows them with the semantics provided by the standard terminology. This allows those systems relying on the same archetypes and SNOMED-CT to interoperate at a semantic level. Concerning the secondary use of clinical information, the adoption of SNOMED-CT facilitates the representation of clinical content with rich semantics enabling expressive queries required for phenotyping in clinical research.

In collaboration with NRUA, the combination of SNOMED-CT with archetypes has been evaluated finding several challenges [39]. At a technical level archetypes can be bound to any terminology and it is up to the archetype designer what elements of it to annotate. However, in our experiences assessing archetypes binding to SNOMED-CT, several challenges were found. Archetypes are generic data schemas to be used at a national level, however their binding to terminologies is very influenced by the different scenarios where they is used. For example, sharing the patient summary across different health platforms would require the annotation of some main sections of the archetype with SNOMED-CT. Guidelines for terminology binding can be followed at that level [36][40][41]. However, if a higher level of expressivity is needed, for example to be able to use the archetype to perform semantic queries applying reasoning over the terminology, more sections of the archetype would need to be linked to SNOMED-CT. It would be required to represent some contextual properties at a terminological level for dealing with contextual aspects such as time intervals, parties involved in an observation etc. For example, if one needs to perform a query for identifying patients diagnosed with some kind of malignant epitherial neoplasms in the last 10 years, any patient diagnosed with a subtype of such disorder should be retrieved, i.e. patients diagnosed in the last decade with adenocarcinoma of nasopharynx, carcinoma of lingual tonsil, carcinoma of the uvula etc. To enable this kind of expressive queries, first, it is required to annotate archetypes and their instances properly with an ontology-based terminology; second, it is necessary to rely on a technical infrastructure that explores the SNOMED-CT concept hierarchy; and, third, timing aspects expressed at an archetype level need to be also be considered in the query processing. SNOMED-CT covers the first two requirements but, as domain ontology, specifying precise contextual aspects such as time is out of its scope [42]. This involves that two different models (the archetype and the terminology) need to be analysed to answer such a query. The terminology can provide subsumptive (i.e. class- subclass) reasoning to identify subtypes of the disorder and the archetype query language (AQL) can help in filtering contextual aspects. However, this means operating at two different levels as proposed in [43] thus making more complex and less dynamic the definition of queries over clinical information. This challenge is not only present when querying the EHR for research purposes. In fact, the presence of iso-semantic models (CIMs defined in different standards) requires the use of semantic web architectures to guarantee that the meaning of health information is preserved across organizational boundaries to provide access decision support systems [44]. How to leverage archetypes and biomedical ontologies such as SNOMED-CT guaranteeing scalability and viability of health information architectures is currently a matter of concern for the Norwegian e-Health Directorate.

V. Discussion

A. Adoption clinical information model

Terminology standards are used on a daily basis in health care work. The combination of health information standards and terminologies is currently the preferred option to enable SIOp for sharing clinical data both for care delivery and for secondary uses (e.g., clinical research) [3]. In Norway, the availability of a structured EHR model based on archetypes is opening the door for clinicians to categorize variables for building meaningful reports, extracting data for quality registers, and performing clinical research. Structured data elements will also make it possible to organize information that supports processes and decision support inside an integrated EHR portfolio and the use of OpenEHR will provide clinicians with a more open, adaptive, and collaborative system. OpenEHR compliant data tagged with clinical terminology codes allows the interoperation of different HIS, thus enabling integrated care. In the near future, the implementation of the archetype-based system will elevate the possibilities to use the standardized information models in clinical settings. The implementation program for the new EHR has focus on clinical decision support, and mapping of CIM between different integrated systems.

B. Primary use of terminology

The integration of clinical terminology for use in EHR systems to support clinical practice has proven difficult to accomplish. With the use of archetypes, and a national governance of clinical variables through a common repository for structured data elements, there are future advantages of both semantic and interoperable character. Earlier research elaborates on how the categorical use of clinical terminology to structure nursing diagnosis and interventions in standardized nursing plans has been a success for increased quality and efficiency. However, the use of clinical terminology to categorized clinical documentation for enabling process- and decision support in the EHR portfolio is limited. The use of standardized nursing plans at a large scale in a Norwegian hospital showed clear advantages for both quality and efficiency [45]. Furthermore, when information is tagged with the purpose to categorize such as with ICD-10 and medical diagnosis, the same information becomes available for secondary purposes. On the next level, any of these tagged nodes of information could be recirculated. Archetype based elements such as blood pressure, pulse, temperature, and laboratory data can also be used for primary purposes. Different national and regional initiatives will in a close future be piloted in different implementation processes such as Helseplattformen that is a pilot for One- citizens one Journal, and the new FIKS program in the North Norwegian Health Authority [46].

C. Secondary use of terminology

At the same time, as the primary information becomes interoperable, both as single archetype/terminology or intervened, the information becomes semantically interoperable for use in secondary settings. As an illustration, all information that is tagged with the nursing classification ICNP, both diagnosis and interventions, becomes sharable for secondary use. All the nursing diagnosis and interventions would be an object for clinical research on a national or global level, which is a relatively unexploited research arena. The care plan is intended to be an interdisciplinary tool for categorizing documentation in the EHR. For this to become a success, it is important that structured information from other applications is used in the care plan. A regional implementation program will soon have focus on the integration of information models between the EHR and the EMR [46].

In the end, an increasing number of archetypes, a so far unknown number, is expected to be accessible in an open repository, and each archetype that is translated or modelled will be compared or reviewed with the purpose of being added to the global repository. For instance, the process of getting consensus on the observation archetype blood pressure started with a translation of the global standard, and ended with a new version that also is planned for the global or international repository. The increasing number of archetypes increases the possibility to use the structured data elements to extract data for other secondary purposes. The national quality registers is an example where physicians use time on extracting data form the HER manually. The same implementation program will focus on possibilities to make these processes automated using archetypes.

D. Adoption clinical information model

The diversity in standards, scope and methodology complicates the decision about adopting one standard or another for the definition of CIMs since it will influence the systems that can be deployed in the health network. Standards available are openEHR, ISO 13606, HL7 CDA, HL7 FHIR, to name a few. In Norway, although 3 of the 4 health regions rely on openEHR for secondary care. Nevertheless, many other HIS rely on different standards or no information standard at all. Therefore, in the near future it is expected to find an ecosystem where implementations based on different information models will coexist. This may add a burden for those implementers that need to adapt from one standard to another. However, it is important to notice that the most valuable resource of a CIM is not the technical specification, but the conceptual model that it contains. CIMs, beyond providing a format to express clinical information, define a way of combining clinical concepts together to build more complex conceptual structures. For example, the archetype OpenEHR-EHR-CLUSTER.symptom_sign.v1 aggregates several granular concepts such as Body site, Episodicity, Impact, etc., to build the more complex entity Symptom/Sign. This aggregation of concepts is more evident when the CIM is annotated with an international terminology. Reaching a consensus about the conceptual model of the CIM is the task that consumes most of the efforts of editorial teams since they need to coordinate professionals from different domains. Nevertheless, if the modelling work is appropriately performed, the conceptual model will be equivalent in most iso-semantic models. Consequently, once CIMs are defined in a particular standard, the conceptual model is clear and can be transformed to other representations/standards. In fact, that is the approach of the opencimi.org initiative, which pursues the definition of CIMs that can be expressed in several formats such as CEMs, HL7 CDA or OWL by defining transformation functions among them. These transformations, although complex, are technical tasks that can be accomplished with much less effort than the definition of stable conceptual models. The EU project SemanticHealthNet has provided insights to define an ontology based on the CIM conceptual model that allows the access to equivalent information hosted in repositories expressed with disparate information standards [47]. In the case of Norway, we expect several standards to be implemented in different regions and HIS. In such scenario, we believe that the common repository of published CIMs expressed as archetypes will be of paramount importance to provide the set of models approved at a national level that can drive the development of interoperable infrastructures across disparate HIS.

VI. CONCLUSION

Currently several standards and terminologies are available for the specification and annotation of CIMs, respectively. openEHR, HL7 CDA and ISO 13606 are examples of standards to define CIMs, which in most cases are annotated with standard terminologies to enable their interoperability across systems.

With the parallel national initiatives running at this time in different countries, it is starting to become visible how the organization and size of countries influences their standardization efforts. On one hand, large countries with very heterogeneous health networks are aiming for the adoption of standards that allow sharing EHR information documents extracts That is the case of Spain with ISO 13606 [48] or the US with HL7 CDA [12][49].

On the other hand, Norway is heading to the adoption of a nationwide EHR information architecture with openEHR that defines not only some relevant CIMs but also the whole EHR information structure. Three factors have influenced this direction of work. The first is the homogeneity in the market since only one vendor represents 80% of the market share in hospital. The second is the close collaboration between vendors and health authorities; this allows coordinating the definition of the whole information model of new systems. The third, and most determinant, is the body of knowledge already available in the international CKM that has fed the national CIMs definition pipeline with existing archetypes. This has accelerated their validation at a national level avoiding their definition from scratch.

At the moment, the Norwegian eHealth strategy has established a multidisciplinary community of vendors, governmental agencies and health organizations collaborating in order to define a nation-wide EHR information architecture. The knowledge management framework of OpenEHR supports to manage the national CKM. The OpenEHR governance model and the collaboration between the international and Norwegian CKM teams are proving to be effective to manage the definition of CIMs for the national eHealth strategy. On the technical side, the rich reference model provided by OpenEHR acts as a powerful modelling tool for the definition of CIMs. On the organizational side, the collaborative environment provided by the CKM is allowing to ensure the validity of the CIMs generated. As a result, the National eHealth Department is providing the health informatics community a body of standard clinical models, which allows implementers and researchers to define standard interoperable implementations on them.

The semantic interoperability gained from the use of both terminology and OpenEHR archetypes separately is a highly valuable asset. For instance, earlier studies in Norway have showed that clinical terminology has the potential to structure information of unstructured EHR systems. The ongoing national work also suggests that the combined use of archetypes and terminology further increases the semantic interoperability for connecting EHR systems on different layers of healthcare. Using for instance SNOMED “non-hierarchical” to tag the nodes of archetypes is interesting, and could be an integration advantage for vendors. It is a fact that both subjects complement each other’s capacity to reach semantic interoperable.

Another “feature” that could increase the semantic interoperability is the growing possibility to use different Clinical Information Models to extract and share information from the National repository of archetypes/ clinical variables and content. The Government and the National e-health administration has decided to use different ICT systems in the primarily and specialist healthcare for several years to come. This requires a possibility to use clinical content from the national repository using another CIM specification standard than OpenEHR to extract and use semantic interoperable information. In this sense, the clinical model defined by an archetype can be represented in another standard by defining transformation rules among OpenEHR and the other standard. This way, the archetype-based repository becomes the reference common information ‘ontology’ or conceptual model used by different vendors regardless the standard, classes, and model they implemented.

ACKNOWLEDGEMENT

Thanks to the people at North Norwegian Health Authority, the NRUA, and the National ICT for contributing with vital information to the project.

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