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Using Detailed Clinical Models to bridge the gap between clinicians and HIT

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Abstract. Two level object modelling has been introduced in recent health care IT standards, such as Health Level 7 version 3, CEN/ISO 13606 and OpenEHR. Generic functions of electronic health records and electronic messages can be developed in such a way that they become independent of the clinical data, but allow its data management. Clinical data are elicited from clinicians and modelled in the form of clinical statements or archetypes. Such clinical statements or archetypes can be standardized and inserted into the technology upon choice of clinicians. This allows flexibility in development using collections of standardized models. Detailed clinical models (DCM) thus make clinical data explicit, allowing its use in multiple standards and multiple technologies. This paper presents an overview of work for DCM including a workshop in Brisbane in 2007 and project proposals for HL7, CEN and ISO joint standardization work.

Keywords. Standards, Computerized Patient Records, Vocabulary, Controlled

1. Introduction to Detailed Clinical Modelling

Recently we see many efforts to standardize clinical data so it can be deployed in different health care information technologies (HIT). Clinicians, regulatory agencies, organisations responsible for health statistics and institutions for quality control, among others, have a vast interest in clinical data standards. Also standards organisations on national and international levels have recently shown an interest in this work. This interest exists in particular for agreed purposes such as statistical reporting, the deployment of clinical data for continuity of care, and personal health records and electronic patient records. However, we already see an explosive growth of such initiatives and developments, each with its own purpose and methods applied, with different levels of quality and usefulness.

The Detailed Clinical Model (DCM) workshop of August 25 2007 in Brisbane, Australia, followed up on current discussions within the health informatics Technical Committees of CEN and ISO, HL7 and *Open*EHR. These discussions especially concern the area of archetypes (CEN), templates (HL7) and care information models (Netherlands). All care information models, clinical templates, archetypes, (technical) templates, clinical fragments, reusable bits, detailed clinical models and more synonyms aim at three parts: 1) formalising, structuring or standardizing clinical data elements, 2) Modelling these independently of the technical implementation, and 3) applying them in different technical representations, such as electronic health records, electronic messages and data warehouses or data repositories. A fourth area of concern is quality control of these three parts. This paper reports on the main results of the workshop, and on current work underway in the different standards organisations.

2. Background of Detailed Clinical Models

According to Huff et al, clinical information models describe the structure of clinical data that are stored in electronic patient records, sent between clinical systems, and referenced in decision support rules [1]. Rector et al where among the first that modelled the electronic patient record [2]. They separated the clinical observation models and the meta-information about these observations [2]. Additionally, Johnson found that traditional modelling approaches of clinical data lead to complex schema's consisting of hundreds of entities and representing a rich set of constraints about the patient care domain [3]. This is not efficient in electronic patient records. Johnson thus transformed these complex models into a generic schema resulting in a small database of a dozen tables which is efficient for patient-oriented queries and is highly flexible in adapting to the changing information needs of a health care institution [3]. With respect to DCM, Johnson found that, in particular, changes involving the collection of new data elements where accommodated via this generic model [3].

Beale describes how small constraint models of domain concepts – archetypes – can be added to the knowledge environment, significantly improving interoperability, software economics and quality of care for electronic patient records [4,5]. The core approach is the two level modelling in which a reference model guiding system development and archetypes defining clinical content are separated out. The CEN 13606 series, OpenEHR and HL7 v3 CDA and Care Provision messages use this two level modelling approach [6, 7, 8].

There exist examples of DCM development and use. Huff et al describe several tools that where developed to use and maintain DCM, including tools to guide consistent interface development, data entry screens, clinical reports and decision support modules [1]. Parker et al describe the use of detailed clinical models in the SAGE project for clinical guideline representation and exchange [9]. They argue that common detailed clinical models give precise semantics and make the task of mapping between models manageable [9]. They have applied HL7 RIM artefacts, in particular the observation class and attributes to specify guideline content [9]. Parker et al envision a standard method for creating and sharing detailed clinical models to bring us closer to semantic interoperability [9]. De Bel describes the development of an HL7 v3 compliant electronic patient record system in which the database is configured against the HL7 reference information model [10]. This system allows DCM to be integrated in the electronic patient record, speeding up development, querying and definition of user interfaces. Ocean informatics is developing a set of tools for archetype development and a repository for maintenance [11]. Other tools are under development for complete electronic patient record systems. Van der Kooij et al evaluated a series of instances of Detailed Clinical Models www.zorginformatiemodel.nl) from projects carried out by the Dutch National ICT Institute for Health Care (NICTIZ) [12]. In this evaluation knowledge was determined that serves as quality criteria for DCM [12]. Items include version management, aim of scoring instrument for target populations, appropriate application of the instruments, interpretation guidelines for results, e.g. what is the significance of scores, copyright issues, among others [12].

3. Summary of Detailed Clinical Model Workshop outcomes

The workshop revealed four areas of further work in standardisation: 1) clinician involvement, 2) agnostic modelling, 3) quality criteria for DCM, and 4) repository to store and find DCM internationally [13]. Each of these areas is described briefly.

3.1. Involve clinicians in Detailed Clinical Model development

It is important to involve clinicians in the work of requirements setting. Evaluations of electronic health record systems show consequently that this is a core part for success (e.g. van Gennip and Talmon, [14] and subsequent studies beyond the scope of this paper). Especially the core component: 'clinical information' must be developed with clinician involvement.

Hoy et al describe the Scottish project where the focus is on clinician's information needs in specific areas of concern: e.g. complete assessment of motor functioning, family history or activities of daily living, urine continence and so on [15]. They argue that the need identified is the development of context-specific domain models as the basis for standard components for building clinical information systems. Thus, there is a need to structure information around discrete clinical concepts in a way that supports system development and interoperability. Hoy et al state that the process by which clinicians formalise objects in the world and actions that change them in ways that allow developing systems to help us achieve our goals are the main driver behind current standardisation [15].

The panel recommends the following plan:

- Develop teaching modules for engaging clinicians in standards work
- Set up a review process for engagement of clinicians, determination of clinical usefulness and quality
- Establish guidance for using existing guidelines and protocols for modelling (in practice these guidelines are usually not specific enough on data element level).
- Raise clinical content capture to professional organisational responsibility
- Model evaluation criteria readable by the average clinician

3.2. Modelling Detailed Clinical Models agnostically from technology

The different standards try to achieve – at the conceptual level – the same: construct models of clinical artefacts that are reusable over patients, time, location, purpose. In the experience of the Dutch projects with Care Information Models, the most time consuming part of this is to collect, analyse and organise the clinical content. In addition: clinical expertise is scarcely available. Therefore it is imperative to develop an agnostic modelling approach where all the clinical effort is respected and the technical representations and implementations are sorted out from there.

Benson presented an example project in which such a more or less agnostic modelling has been applied using UML as representation format [16]. Currently HL7 uses the R-MIM format, which is an UML dialect, and XML. OpenEHR uses the ADL and software to express the models, and can deal with XML as well. Benson showed that standard UML format can be used and might be a helpful starting point from which XML, R-MIM and ADL can be derived [16]. Grieve includes further comments on the

constraint formalisms that can convert the Detailed Clinical Models into the technical representations needed for the implementation [17].

The focus thus moves to a three step modelling approach with feedback loops as illustrated in Figure 1:

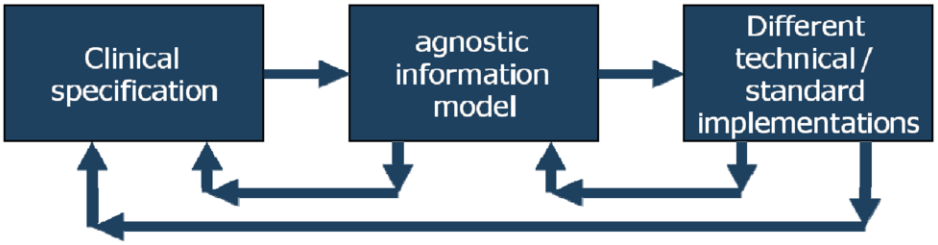

Figure 1. From clinical domain via agnostic modelling to technical implementation.

The panel recommended to:

- Continue with the current different formats to develop Detailed Clinical Models, based on acceptance of the different Standard Reference Information Models.
- Determine in near future a sharable formalism for DCM
- Develop tooling that help capture clinical knowledge.
- Limit the discussion between HL7 v3 and CEN 13606 / openEHR to the real EHR content, such as CDA and Care Provision
- Support ongoing work to bridge the controversy, although this will be hard and expectations need to be managed.

3.3. Detailed Clinical Model Repository

Garde presented his ideas on a repository for Detailed Clinical Models [18]. He argues that at present, there are several repositories available, but often from a project based approach, using various formats and formalisms. According to Garde, if we are going to harmonise the different materials that are out there, we need to be able to find each others materials [18]. Examples of repositories in different formats, but with similar intentions of sharing reusable quality clinical content exist. There are several requirements for the formalisms used and thus for the repository to facilitate finding the right materials, partly based on materials from the Detailed Clinical Models website [19]. Thus, the idea brought forward is to establish a standard repository of clinical content that can function similarly to the power adapter we all use travelling around the world. The panel recommends the following plan:

- Organise an international repository for Detailed Clinical Model content management
- Set up governance processes around this repository
- Apply a comprehensive (internationally relevant) clinical content management system

- Look at existing organisations such as IHTSDO, HL7, CEN and ISO for procedures to organise this.

3.4. Quality criteria for Detailed Clinical Models

Goossen – Baremans developed a set of quality criteria that guide the development of the Dutch Detailed Clinical Models (called Care Information Models) [20]. These care information models have been developed since 2003 for a Dutch national project for information exchange in stroke care, which was carried out on behalf of NICTIZ [21]. Recommendations of participants of a workshop in 2005 in the Netherlands have been incorporated into the current approach to set quality criteria [12, 20].

A full Detailed Clinical Model expression should consist of 18 desirable components [12, 20]. Concept name and version management are considered important meta information. Meta data are relevant for identification of the detailed clinical model, usages, definitional, administrative and relationships among concepts. During the workshop participants agreed that the following meta-information must be considered:

- Establish meta information of DCM using ISO IS 11179 [21].
- Check and review the clinical content of the DCM, e.g. based on meta-analysis and levels of confidence if and when available.
- Language and translation of DCM: change of language should not change the model, thus model on conceptual level.
- Vocabulary binding, using binding of name (variable and code) and value (code) pairs based on a slot approach to allow synonym terms and codes to be used in the DCM based on relationships.

4. Ongoing projects in standardisation of DCM

On a national scale, several health organisations and national health informatics strategies focus on developing sets of templates, archetypes and so on. There is put a lot of effort in DCM. Examples include Australia, Canada, Scotland, the Netherlands, UK, among others. Denmark and Sweden are considering starting this kind of work. Therefore, there is now sufficient interest to move to international standardisation work.

4.1. HL7 v3 DCM creation and repository

HL7 accepted a proposal to actually create DCM and align this with different working groups within the HL7 organisation. The intent of the HL7 workgroup patient care project proposal is to create and maintain in a repository a set of detailed clinical models that can be transformed from a generic model into EHR profile, HL7 templates, and V3 Clinical Statements, Clinical Document Architecture and Care Provision messages for referral and record exchange. These DCM's should also function in the ISO/CEN 13606 and OpenEHR series of standards and tools. The HL7 DCM project builds further on past and existing efforts on archetype development from OpenEHR and CEN 13606, HL7 template initiatives, HL7 Clinical Statement and R-MIM development, and clinical domain expressions in different health care associations with

the workgroup name Clinical Interoperability Council. The purpose is to organize clinical content in such a manner that it becomes multi useable in different standards and different technologies, thus supporting both the Joint work of HL7 CEN and ISO and semantic interoperability between systems.

Ongoing work is currently to flesh out the Glasgow Coma Scale with respect to background, name value pairs and vocabulary and modelling. This is already informing HL7 v3 generic models for assessment scales.

4.2. ISO New Work Item Proposal DCM

ISO TC 215 Working Group 1 has an interest and requested a New Work Item Proposal on DCM. The focus here will probably be on a 4 part standard development covering the four areas of the Brisbane workshop. At the time of writing the proposal still has to be written and voted upon, but lines of discussion have gone the following way: The NWIP will focus on a 4 part standard, each covering one aspect of the above four topics from the Brisbane Workshop:

Facilitate clinical involvement in information requirement gathering and standards setting. Potentially this includes input, process and outcome parameters leading to identification and specification of name value pairs and appropriate terminology and coding for that. This will also include criteria for review of quality of information in DCM by stakeholders and governance issues.

Define modelling requirements, guidelines and principles, including the linking of DCM to ISO data types standard, IHTSDO (Snomed CT) work, and other ISO and CEN materials. UML is considered as the formalism to apply for DCM. This part will link DCM to 13606 series and 18308 (EHR) and HL7 CDA and Care Provision among others, in order to facilitate tooling that makes the process automatable according to that which is depicted in figure 1.

Establish quality criteria for DCM and the collection of DCM into fully clinical documents, record messages or clinical templates. The first being the clinical details and the latter their combination in recognizable and clinically relevant formats. These would include the meta information requirements following ISO 11179.

Formulate criteria for DCM repositories, including meta information to allow indexing and finding what is needed for interoperability projects.

5. Discussion and Conclusions

Participants of this workshop on Detailed Clinical Models were members from ISO, CEN, HL7, *open*EHR and other groups. There was a general understanding of these 35 experts that it is important to take this work on DCM further. The four action areas identified include clinician involvement, quality of detailed clinical models, representation formalisms and establishing and maintaining repositories. Since then, presentations and discussions under the Joint Working Group umbrella of HL7 CEN and ISO has illustrated a strong interest and continuation of the preparations. Both HL7 and ISO are looking at project proposals and some work is actually taking place.

During the Brisbane work shop participants discussed the question whether we can get one representation model for DCM that covers all of the requirements for different standards and different technical developments. Will DCM support GUI design, database design, EHR design, message design, algorithm design, rule-based DSS

design? That is not answered yet and can only be addressed via testing. True semantic interoperability however goes beyond the individual variable and terminology bound to it. The context of healthcare requires more in depth approaches. On top of this intrinsic need, the pragmatics of resources – always necessary for their primary task of caring for patients – requires that we spare clinicians. Clinicians should not have to worry about all the technical nuances. However, they would need to be able to verify and control the quality of content in order to trust the EHR and the message content presented to them. Semantic interoperability starts with standards, but ends with a clinician making the right decision based on stored or communicated information.

Consensus is emerging on the representation of Detailed Clinical Models being standards and technology independent. Existing examples of models made for similar purpose include the *openEHR* archetypes, HL7 R-MIMs / (technical) templates and other HL7 or local materials, but most are standard or technology bound. One particular concern with the development is whether DCM can build upon the existing work, not limiting it. The uptake among modellers and developers is crucial for the success.

The outcomes of this workshop are relevant for joint standards work of ISO, CEN, HL7 and *open*EHR, but also of many clinical communities wishing to use EHR and messages for better patient care based on evidence to achieve quality care and appropriate patient outcomes. The current projects both on local, national and international level focus on achieving this in the near future.

References

[1] Huff SM, Rocha RA, Coyle JF, Narus SP. (2004). Integrating detailed clinical models into application development tools. *Medinfo. 2004*;11(2004) 1058-1062.

[2] Rector, A.L, Nowlan, W.A, Kay, S., Goble, C.A., Howkins, T.J. A Framework for Modelling the Electronic Medical Record. *Methods of information in medicine*, **32** (1993) 109-119.

[3] Johnson SB. (1996). Generic data modeling for clinical repositories. *J Am Med Inform Assoc*. (1996) 328-339.

[4] Beale, T (2000). *Archetypes Constraint-based Domain Models for Futureproof Information Systems.* Web documents. Accessed 13 January 2008. http://www.openehr.org/publications/archetypes/archetypes_beale_web_2000.pdf

[5] Beale T. (2003). Archetypes and the EHR. *Stud Health Technol Inform*.;**96** (2003) 238-244.

[6] CEN TC 251 (2007). *EN 13606*. Brussels, CEN.

[7] OpenEHR. *Web documents*: http://www.OpenEHR.org/ Accessed 8 July 2008

[8] Health Level 7. *Standards*. WWW documents. http://www.hl7.org/ Accessed 8 July 2008.

[9] Parker CG, Rocha RA, Campbell JR, Tu SW, Huff SM. Detailed clinical models for sharable, executable guidelines. *Medinfo. 2004*;11,(2004) 145-8.

[10] Bel, E de (2005). Ontwikkeling van een Elektronisch Patiëntendossier op basis van HL7 V3. *HL7 Magazine* (2005), 3. [In Dutch]

[11] Ocean informatics. *Product range. Web documents:* http://oceaninformatics.biz/CMS/index.php Accessed 8 October 2007

[12] Kooij Judith van der, William T.F. Goossen, Anneke T.M. Goossen-Baremans, Nelleke Plaisier. Evaluation of Documents that Integrate Knowledge, Terminology and Information Models. In: Park HA, Murray P, Delaney C (Eds). *Consumer-Centered Computer-Supported Care for Healthy People. Proceedings of NI2006*. Amsterdam etc. IOS Press. (2006) Pp. 519-522. Studies in Health Technology and Informatics, volume 122.

[13] Goossen WTF. Detailed Clinical Models: Report of a Workshop in Brisbane, August 25, 2007. Amersfoort, Results 4 Care, the Netherlands (2008).

[14] Gennip EMSJ van en Talmon JL (Eds.) *Assessment and evaluation of information technologies in Medicine*. Amsterdam, IOS Press (1995).

[15] Hoy D, Hardiker NR, McNicoll IT, Westwell P. (2007). A feasibility study on clinical templates for the national health service in Scotland. *Stud Health Technol Inform*. **129** (2007) 770-774.

[16] Benson T . UML modelling for clinical data. *Presentation materials for DCM workshop in Brisbane, August 25, 2007.*
[17] Grieve G (2007). Presentation on CEN 13606 and HL7 v3 modeling. *Presentation materials for DCM workshop in Brisbane, August 25, 2007*.
[18] Garde S (2007). A repository of repositories. *Presentation materials for DCM workshop in Brisbane, August 25, 2007*.
[19]. Detailed Clinical Models (DCM) (2008). Website. Visited Jan 13, 2008. http://detailedclinicalmodels.org/wiki/index.php?title=Main_Page).
[20] Goossen-Baremans ATM (2007). Quality Criteria for Detailed Clinical Models. *Presentation materials* for DCM workshop in Brisbane, August 25, 2007.
[21] Goossen WTF. Model once, use multiple times: reusing HL7 domain models from one domain to the other. In: Fieschi M, Coiera E & Jack Li, YC: (Eds). *Proceedings of the 11th World Congress on Medical Informatics Medinfo 2004*. Amsterdam IOS Press, (2004) 366-370.
[22] ISO (2004). *ISO/IEC 11179 metadata registry*. Geneva, ISO.