Bridging the HL7 Template – 13606 Archetype gap with Detailed Clinical Models

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Abstract

The idea of two level modeling has been taken up in healthcare information systems development. There is ongoing debate which approach should be taken. From the premise that there is a lack of clinician's time available, and the need for semantic interoperability, harmonization efforts are important. The question this paper addresses is whether Detailed Clinical Models (DCM) can bridge the gap between existing approaches. As methodology, a bottom up approach in multi-level comparison of existing content and modeling is used. Results indicate that it is feasible to compare and reuse DCM with clinical content from one approach to the other, when specific limitations are taken into account and precise analysis of each data-item is carried out. In particular the HL7 templates, the ISO/CEN 13606 and OpenEHR archetypes reveal more commonalties than differences. The linkage of DCM to terminologies suggests that data-items can be linked to concepts present in multiple terminologies. This work concludes that it is feasible to model a multitude of precise items of clinical information in the format of DCM and that transformations between different approaches are possible without loss of meaning. However, a set of single or combined clinical items and assessment scales have been tested. Larger groupings of clinical information might bring up more challenges.

Keywords: *archetypes, templates, information modeling, detailed clinical models, concept representation*

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Introduction

Huge efforts are ongoing in the specification of clinical data elements. In particular clinicians, regulatory agencies, health statisticians, institutions for quality control, among others, invest in clinical data standards [1, 2, 3, 4]. The idea of two level modeling has been taken up in healthcare information systems development [5]. Two level modeling is in particular of interest for the electronic health record, the electronic exchange of patient data for continuity of care, and aggregation purposes.

There is ongoing debate whether one approach should be taken, or that alternatives are equivalent. Most efforts consist of data item specification, definitions of each element, and unique coding to determine the semantics. In particular the interaction between the information model and the terminology model is of interest because several standards that model information, such as the Health Level Seven (HL7) [6] and the ISO 13606 [7] apply external terminologies like Snomed CT [8], LOINC [9] or others. These clinical information models, templates, archetypes, clinical data elements, and Detailed Clinical Models (DCM) aim at three parts [10]:

1) Formalizing, organizing, structuring or standardizing clinical data elements to allow semantic interoperability,
2) Modeling these data elements independently of the technical implementation itself, and
3) Applying these data elements and models in different technical implementations [11], such as electronic health records, electronic messages, data warehouses / data repositories, and clinical decision support systems [12].

A fourth area of concern of such models is quality control and governance. The latter is not content oriented, but establishes what quality measures are necessary and how the ongoing maintenance is guaranteed for current and future use.

The question this paper addresses is whether Detailed Clinical Models (DCM) can bridge the gap between HL7 templates and 13606 archetypes and allow specification of concepts for use in both HL7 and 13606 standards.

Methods

In existing comparisons between HL7 templates (TM) and 13606 archetypes object model (AOM), the comparison is based on the 'whole' approach, including the full extent of the reference information models used [13, 14]. Blobel discusses different architectural components against which the standards can be compared [13]. We discuss the information view only. Bointner and Duftschmid compare the TM and AOM models and find many differences e.g. in inheritance of characteristics, definition of semantics of reference model instances rendering them incompatible [14]. Their findings are consistent with earlier discussions in the standards organizations themselves. However, we see this as the effect of object modeling using a top down approach that is based on the whole standard, and starts with the Reference Information Model downwards.

When the starting point is the clinical relevant concept such as represented in the scientific literature and/or in clinical practice documentation, records and guidelines, the comparability can be improved. This however, requires a bottom up approach on the conceptual level. One example of such comparison is presented by Cuggia et al, where they compare the Apgar score representations in both HL7 v3 and OpenEHR archetype [15].

In the CEN/ISO mirror panel of NEN, the Netherlands, the two approaches HL7 v3 and 13606 have been part of ongoing

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debate for many years. Based on a bottom up approach we were able to further disentangle the clinical concept modeling from the technical modeling and to identify adequate levels of equivalence [16]. This allows comparing data element – by data element based on review of medical knowledge on the specific topic. The underlying assumption is that data elements that medically must be similar for safe patient care should remain the same despite the applied modeling and despite their technical representation.

In other words: if a patient has a coronary heart disease, a receiver of information should not see diabetes type 2 in the problem list. Or, if a Glasgow Coma Scale (GCS) is assessed, or a body temperature is measured, then the results of such observations must be exchanged without loss of meaning, leading to appropriate care by the receiver of information.

In order to bypass all technical constraints that might block a full comparison, the Detailed Clinical Modeling approach [10] has been taken to model a Top 10 of frequently used clinical concepts (height, length, temperature, pulse, respiration, blood pressure, Apgar score, Barthel index, Braden scale and Glasgow Coma Scale). Six are variable based; four are assessment scales with a well established meaning.

We identified these levels of comparison as appropriate:

1. Data types; that is the use of different types of data such as free text, (coded) value sets and physical quantities, [17] including their units of measurements [18].
2. Encoding; that is the manner in which each approach refers to external terminologies [8, 9] for the semantics of each data element.
3. Concepts; that is the level of the clinical concept, the unit of thought.
4. Meaning is created by combining concepts, including component data elements and linking this with the context and knowledge for use in health care.
5. Electronic communication, i.e. the exchange of clinical data between systems, which is a technical level.
6. Cooperation, which discusses expectations based on exchange of information, which is an organizational level.
7. Workflow around the data elements and concepts.
8. Agreements between stakeholders.
9. Maintenance and management of the instances of models.

For this comparative analysis the Top 10 of frequently used clinical concepts where modeled in Unified Modeling Language, are represented in HL7 v3 via a mapping to the Clinical Statement Pattern, and are also modeled into an archetype using an archetype editor.

In the analysis, the search is for equivalence on the level of information modeling, applying rules from data element standards, terminology standards and information model standards. In addition, where appropriate, we applied specific knowledge about the content. E.g. when a scale is represented, the psychometric measures of reliability and validity require that scientific rules are applied as well.

Materials

Results indicate that it is feasible to compare and reuse information models for single or combined clinical data elements and for assessment scale from one approach to the other. This works when specific limitations are taken into account and precise analysis of each data-item is carried out. In particular the HL7 template approach and the ISO/CEN 13606 and OpenEHR archetypes reveal more commonalties than differences. When compared against DCMs, it becomes even easier to transform from one to the other formalism.

In the area of data types, level 1 comparison, DCM, HL7 v3 and ISO/CEN 13606 use the ISO 21090 standard for data types. All examples show that the data types as expressed in the DCM could be expressed in both the HL7 v3 Clinical Statement Pattern (CSP), TM and in the AOM (Table 1).

Table 1. Data type level: example blood pressure	
Clinical knowledge	Clear understanding is clinically important, e.g. 120 80 37 68 only make sense as 120 / 80 mm Hg 37 OC, and 68 /min
DCM	Data type PQ, unit mm Hg
HL7 v3 message using ISO 21090	<value xsi:type="PQ" value="165" unit="mm[Hg]"/>
OpenEHR archetype Partly ISO 21090	value matches { C_DV_QUANTITY < property = … units = <"mm[Hg]"> > }

For encoding data elements, level 2, DCM, HL7 v3 and archetypes can refer to external terminologies, or use internal coding. In order to achieve interoperability however, only the external codes offer equivalence. E.g. HL7 internal vocabulary deals with the mechanics of the messaging, where an archetype uses an internal numerical order for each element, called ontology. Latter has no reference to external ontologies in the medical domain. The linkage of DCM to terminologies suggests that to some extent data-items can be linked to terms present in multiple terminologies. Table 2 gives some examples of data element coding from the Top 10 of items, represented in DCM and mapping to TM and AOM.

Table 2. Coding level: blood pressure	
Clinical knowledge	Systolic Blood Pressure: The maximum pressure that is build in the aorta when the left ventricle contracts.
DCM	Blood pressure as Observable Entity, using both Snomed CT and LOINC codes as presented above.
HL7 v3 message using	SNOMED CT <code code="271649006" codeSystem="2.16.840.1.113883.6.96" displayName=" systolic blood pressure"/> LOINC: <code code="8480-6" codeSystem="2.16.840.1.113883.6.1" displayName=" BP Systolic "/>
OpenEHR archetype	ontology > ["at0004"] = < text = <"systolic"> description = <"the systemic arterial blood pressure in systolic phase"> term_binding = < ["SNOMED-CT"] = < items = < ["at0004"] = <[SNOMED-CT(2003)::163030003]>

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On the concept level 3, Cuggia et al (2009) [15] illustrated that the Apgar Score can be expressed in both the TM and AOM formats. Similarly, the Glasgow Coma Sale (GCS) can be modeled. The GCS consists of three categories: eye opening, best motor response and best verbal response. The GCS is scored by documenting the number representing the best response that could be observed with the patient. Here DCM, in which concepts can be represented by one or multiple individual data elements, potentially ensure uniformity across standards concerning composition, format and structure. See Table 3 for the concept level comparison of the Glasgow Coma Scale.

Table 3. Concept level: example Glasgow Coma Scale

Clinical knowledge	This scale is used to measure the level of consciousness of a patient with respect to verbal, motor and eye movement reactions. It has a total score summated from the three underlying observations.
DCM	Each data element is described as is the relationship between data elements. The derivation into the total score is expressed and class models can be drawn, including defining the hierarchical relationships.
HL7 v3 message using	Class representation for each of the score items and component relationships to identify hierarchical relationship with total score. Each class represented for instance by a LOINC and/or Snomed CT code: LOINC 9269-2 Glasgow Score Total, SNOMED CT 281395000: GCS eye opening sub score.
OpenEHR archetype	Node representation does allow identifying the three observations as a single data item and the total score. Also the fact that the total score is derived is defined. Each can be linked to an external code system as illustrated in table 2.

Level 4 Meaning. Figure 1 illustrates HL7 v3 classes forming the context for GCS, including the total score and the underlying components of Eye Opening, Motor and Verbal. In the code attribute the codes from external code systems can be specified. In the example LOINC codes are used, but also other codes can be included as synonyms. Figure 2 similarly represents (excerpts from) the GCS in AOM formalism.

Meaning is about the interaction between the (often intrinsic) knowledge model of clinical concepts, the information model representing it in technology, and the terminology model revealing its semantics. Both Standards do have a generic structure where concepts fit. In HL7 v3 this is the so called Clinical Statement Pattern (CSP). This is a RIM derived choice box pattern allowing 1 – n data elements to be represented and linked together with the component relationship. Figure 1 is in fact a roll out of that CSP. Similarly, the 13606 standard has the Entry component (Figure 3). DCM examples for e.g. blood pressure and GCS apply a full class diagram in which the concept is modeled, each component is represented in a class, each value is represented as a class diagram and the set of values and the code bindings are both represented in classes. An example is presented in Figure 4.

This full modeling allows a full mapping to either a HL7 CSP / TM and to an Entry in AOM.

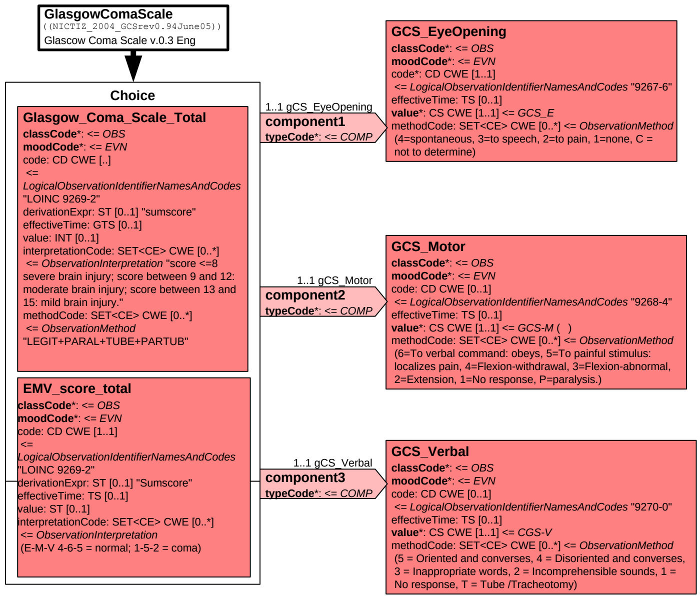

Figure 1. HL7 v3 representation of Glasgow Coma Scale.

```
ELEMENT[at0034] matches {-- E= Opening of Eyes
        value matches {
        1|[local::at0036], -- No  reaction (etc.)
ELEMENT[at0041] matches {-- M=Best motor reaction
        value matches {
        1|[local::at0043],    -- none (etc. enumeration)
ELEMENT[at0049] matches {-- V= Best verbal reaction
        value matches {
        3|[local::at0053],    -- Inadequate
ELEMENT[at0033] occurrences matches {0..1} matches {-- Total score
        value matches {
DV_COUNT matches {magnitude matches {|3..15|}
```

Figure 2: Glasgow Coma Scale concepts as in AOM.

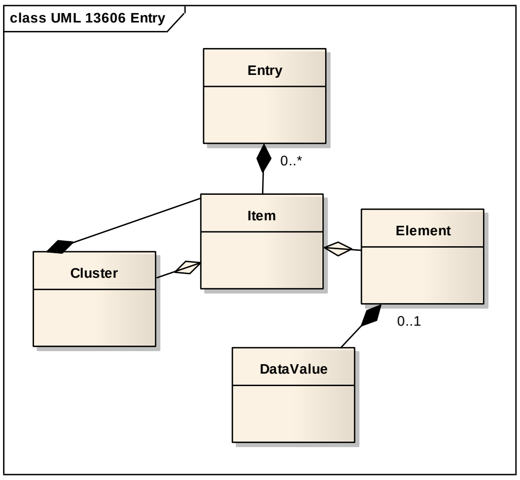

Figure 3. Entry part of 13606 RIM.

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The entry level in 13606 RIM seems to equal the CSP function in HL7 v3 Models. Comparing this reveals a difference of the Reference Models between 13606 RIM and HL7 RIM. The first is, although generic, representing the 'whole' picture, where the HL7 v3 RIM requires a second step to create a so called Domain Message Information Model, of which the CSP is an example. Thus if we are to compare how a concept fits in the overall model, the 13606 Entry is the equivalent level to deal with a single data element or a concept (e.g. one (set of) observation(s) as CSP in HL7 v3 or one (or more) item(s) in 13606). This way the same level of comparison is achieved between TM and AOM. Concepts partly get their meaning from the structure they are embedded, which cannot lead to full 100% comparability of the reference models differ.

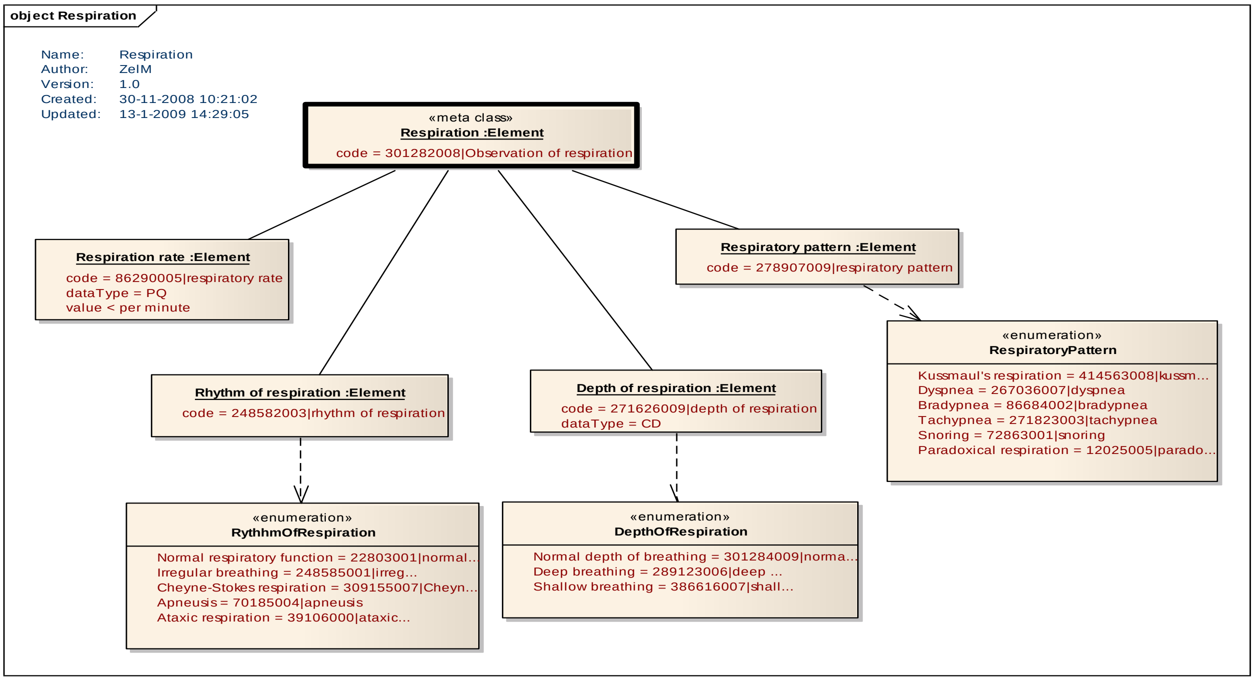

Figure 4. DCM model of respiration.

In HL7 v3 it is possible to represent the step in workflow (level 7) for each data element via the HL7 moodCode attribute that is inherited in each instance from the HL7 v3 RIM Act class. For instance, it is possible to order a blood pressure measurement (HL7 RQO or request mood), plan it (HL7 INT or intent mood) and document it (HL7 EVN or Event mood). In AOM such a workflow definition or modeling of a care process is absent. In DCM, the actual use of data elements, e.g. their creation, the phase in a care process and where relevant more aspects of workflow are expressed. Also general guidelines for the correct interpretation of values are included, offering the option for appropriate follow up.

Levels 5, 6, 8 and 9 would require a technical, organizational and managerial discussion, which is out of scope for this study. It is a more human and organizational issue to discuss the technical tools to be used, the cooperation between care professionals, getting agreement on formalisms and maintenance issues. However, on level 7 of comparing TM and AOM, it is possible to model processes and determine workflow support. For instance in health care it is quite common that particular observations are requested, planned and carried out. For observations this can lead to entering a value (score, text, value from list) into the EHR and exchange that.

Discussion and Conclusion

This work proves that it is feasible to model items of clinical information in the format of DCM and that transformations between different approaches are possible without loss of meaning. In particular, DCM expresses clinical concepts that can be represented in TM and AOM. However, the sample of data elements that has been tested includes single data elements or small scale groupings of elements and assessment scales. Larger data sets and groupings of clinical information might bring up more challenges, and perhaps reveal potential conflicts between the terminology model and information model.

The comparison from a bottom up approach following the levels indicated reveals many commonalties. At the first level of data type specification we find no differences, as long as the standards themselves adhere to ISO 21090. When the standards create additional data types, they will render semantic interoperability hard to achieve.

At the second level of coding, we see agreement between TM and AOM in the option to bind individual clinical data elements to codes from external terminologies. In table 2 we see a difference in the Snomed CT code applied for blood pressure systolic. However, this is partly a matter of choice. In the HL7 example, which is similar to the DCM, the Snomed code for Observable Entity is used, referring to a field name in EHR. In the archetype example the clinical finding code is used, pointing to the actual finding on examination and the

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value entered. This illustrates the depth of knowledge necessary to model clinical information and to options that have to be set for actual implementation. It can be argued here that the AOM is more accurate in using the clinical finding, compared to the HL7 example. However, DCM, TM and AOM allow any choice. It can be recommended to use guidelines for code use such as Terminfo in HL7 [6] to sort this out. A difference between TM and DCM and AOM is that the latter currently does not support multiple external code systems as synonyms in the definition.

At the third level of concept, TM, AOM and DCM can define all relevant data elements, their relationships, their binding to coding, and the derivation of results. Although the representation formalism does look different, and obviously is handled different in an EHR system or an HL7 v3 XML message, the concept representation in DCM, TM and AOM remains intact for the clinical concept aspects. Only the hierarchical aspect cannot be defined in AOM itself, and needs some external mechanism. Class models applied in DCM would serve as such.

Meaning, level four of our comparison, is often discussed from the viewpoint of the reference information model of 13606 and/or HL7 v3. In fact HL7 v3 RIM is a generic structure with building blocks requiring a domain specific modeling exercise before it becomes meaningful. One format in HL7 is the CSP [6] that is used in several HL7 domain message information models or D-MIMs and message models derived from that. In the 13606, the RIM does represent the whole model used for the EHR communication [7]. The exercise with DCM examples Glasgow Coma Scale en blood pressure illustrate that these can be modeled against either the CSP in HL7 v3 and the Entry class in 13606. From this bottom up approach the commonalties become apparent, although it is not a 100% fit. Differences still remain in the hierarchical representation of concepts and in the workflow options that are both present in HL7 v3 and currently not in the AOM.

Comparisons of standards work can have different approaches, depending on the focus of the researcher carrying this out. With the bottom up approach is it feasible to stay very close to the original clinical concepts and relate these to terminologies, and different information models. Criteria from terminology use, information models, and the clinical knowledge need attention in order to get the necessary quality on the details. Use of DCM seems to bridge the gap to some extent at the very granular level indeed. However, transforming DCM into HL7 v3 TM and 13606 AOM does require transformations and careful attention for adequate concept representation and prevention of loss of meaning on the clinical side and appropriate application of the formalisms on the technical side. The overall approach is very promising; it reveals proof for the validity and the core asset of DCM: allowing specification of semantics and reuse of investments, independent of technology or standard.

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