1. Abstract

On behalf of Nictiz, the Netherlands, a request was sent to the HL7 TSC to extend the DSTU status of the Care Provision Domain with another two years in order to have more time for implementation of Care Provision in the national infrastructure.

The Patient Care committee accepted this proposal. In addition, the HL7 International TSC accepted this extension in 2009 with two conditions: 1, that a proper evaluation would be done, 2 that Patient Care WG would move the Care Provision messages to Normative ballots in 2011. This report is about this evaluation.

The evaluation is based on a semi-structured questionnaire on which a series of interviews is based. These interviews are carried out in early 2010. In addition comments to the different HL7 communication means where selected that deal with evaluative comments of Care Provision.

Results based on N = 8 interviews, and the comments on the HL7 DSTU site show that there are several projects using Care Provision, but that there are many comments for use cases not met, or required changes in interactions, classes, topics, and usability. These items will be submitted to HL7 International Patient Care workgroup for further enhancement of the Care Provision materials before moving it to Normative.

2. Introduction

In health care more and more data is exchange electronically. With the implementation of a national or international Electronic Health Record standardization is necessary to exchange data between health care facilities. Electronic messages are used to exchange this data between health care facilities. The exchange of these messages can only be successful is there is semantic interoperability. That means that the receiver understand which data has been correctly. There are two ways this semantic interoperability can be achieved. The first is to link each existing system to all other existing systems. It is obvious that this is a costly solution [1]. The second solution is to have a standard structure of the messages that are exchanged. One of the international standards for electronic message exchange in health care is HL7.
3. Background

This section explains the background of this standard and the reason for evaluation.

3.1. HL7

HL7 is the abbreviation of Health Level Seven (HL7). HL7 is a standards development organization [2, 3]. HL7 as organisation develops and maintains an international standard for electronic exchange of messages between health care systems. HL7 provides this via a framework and set of several standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services.

HL7 v3 uses a data model that forms the base of derived models used in v3 messages. The development method of HL7 v3 is UML based. The v3 messages are a set of message formats for data exchange between software applications. The message syntax is XML. In HL7 v3 the Clinical Document Architecture is also used. This describes an exchange format for documents in the health sector, for instance a discharge order. The document syntax is XML [2, 3, 4].

HL7 was founded in the United States of America, now the organization is active in over 30 countries [3]. All these countries have a local organization that is responsible for the management of the HL7 standards, adjusting, or extending of the international standard to the local situation. The HL7 standard is developed in a democratic process by volunteers. The designed standards go through several voting rounds before they are accepted.

In The Netherlands almost all hospitals use HL7 v2: that describes a set of message formats for data exchange in hospitals. Several subversions of HL7 v2 have appeared. In the development of a national infrastructure for patient data exchange (the AORTA structure) in The Netherlands HL7 v3 is used.

3.2. Care Provision

The Care Provision domain of HL7 finds its origin in the perinatology project of Nictiz. It has been reused in CVA care, heart failure, youth health care, master plan perinatology, and e-diabetes. The care provision domain addresses information that is needed for the continuing care of individuals, populations, and other targets of care. Care Provision is the act of recording a process that defines the responsibility for supplying support to targets of care. The Care Provision domain is meant to exchange critical data about observations, diagnosis, problem list, treatment and care, medication list, allergies and intolerances and care plan, among others. Care Provision is also used for referral, acceptance, querying, and discharge letters and improves the continuity of care.

The care provision domain exists of:
- Storyboards/use cases
- D-MIM Care provision
- Care Structures
• Care Record
• Care Record query
• Care Transfer [4]
Other components are under development and specify the clinical content for specific use cases which can be included as clinical statements in the Care Record.

3.3. Reason for evaluation

On behalf of Nictiz, the Netherlands, as the major stakeholder for the Care Provision Domain, a request was sent to the HL7 TSC to extend the DSTU status with another two years in order to have more time for implementation of Care Provision in the national infrastructure.

The Patient Care workgroup has accepted the Nictiz proposal to organize these subjects better in the Normative edition 2010 or 2011. The Patient Care committee did so mainly because other stakeholders could use the extra time to get more implementation experiences.

The Technical Steering Committee (TSC) has approved in 2009 a 2 year extension (2009-2011) of the Draft Standard for Trail Use (DSTU) provided that an evaluation takes place of experiences and use and balloting will start for obtaining the normative status in 2011.

Plan is to ballot the first materials in the January 2011 ballot round. This means that the materials should be submitted at the end of November and that the Patient Care work group has to decide on it in the Sept-Oct 2010 Work Group Meeting (WGM). This research evaluates the experience and use of HL7 Care Provision.

3.4. Research question

As can be derived from the above reason of evaluation the research question is:

What is the experience and use of the Patient Care Domain of HL7?

Sub questions that can be derived from this research question are:
• What experience do users of Care Provision have?
• What appear to be the weak points of Care Provision?
• What appear to be the strong points of Care Provision?
• What are the barriers to use Care Provision?
• Where do they use Care Provision for?
• Where do they want to use Care Provision for?
• What do users implicate that needs to be improved in Patient Care?
4. Methods

This evaluation research will be a multi-method research which aims to improving the Care Provision domain. The data will be obtained in different ways. First a semi-structured questionnaire has been developed and used [5, 6, 7]. The approach is mainly qualitative for content and summative for the evaluation [5]. This questionnaire was send via e-mail to stakeholders, which are leaders or participants in projects in which Care Provision messages are applied. Based on the sent questionnaire, interviews are held. Also, data are gathered from the DSTU comments on Patient Care list, wiki and the DSTU site of HL7 International. The reports of these interviews, the results of the questionnaire and a summary of the DSTU comments are the base of this evaluation report on the HL7 Care Provision Domain.

4.1. Selection and description of participants

The population for the online questionnaire will be N users of the Care Provision domain of HL7. The population of the data gathered from the comments of the DSTU is limited to the users that placed their comment at the DSTU, or participate regularly in the HL7 Patient Care WG. The structured interviews are held with about 13 expert users. These users are selected by the co-chair of HL7 Patient Care, based on their involvement in projects and Patient Care working group. The selected expert users are:

- Keith Boone (USA, Standards Architect at GE Healthcare, USA)
- MaryAnn Juurlink (Ontario Health Informatics, owner of MAJ Associates, Canada)
- Ernst de Bel (EHR Architect at UMC St Radboud, Nijmegen, The Netherlands)
- Michael van der Zel (HIT-Architect at UMCG, RIMBAA-NL Co chair at Stichting HL7 Nederland, RIMBAA WG member at HL7)
- Michael Tan (senior project manager at NICTIZ, The Hague, The Netherlands)
- Harrie Huisman (owner of Zoombim, Hilversum. The Netherlands)
- Kai Heitmann (HL7 NL / DE, Heitmann consulting and services, Cologne, Germany)
- Gerrit Boers (Consultant, Maastricht, the Netherlands)
- Tom de Jong (NovaPro consultant, the Netherlands)
- Yvonne Pijnacker (Consultant Medical Informatics at TNO) and/or Roel Barelds
- Ewout Kramer (Furore)
- Monica Harry (GP Informatics, on behalf of Canada Infoway)
- René Spronk (Ringholm GmbH)
- Henk Hutink (Project Manager at Nictiz, Senior Project manager at Verdonk, Klooster & Associates, The Hague, The Netherlands)

Their comments based on the questionnaire, DSTU comments or project related comments of these experts have been included in this evaluation report.
4.2. Technical Information

This research is a multi method research. The overall goal of this multi method research is to get qualitative materials from both a questionnaire, interviews and DSTU comments. This approach integrates methods that isolate aspects of a phenomenon from its context, with qualitative methods that emphasize meaning and an acquaintanceship with the particulars [6]. Qualitative data collecting is used when for instance live experience is sought and to gain insight into processes and events. Qualitative research has the benefit that they can provide unexpected insights. Quantitative methods however are used for isolating and identifying the correlates associated at specific moments in time. Quantitative researchers often only see what they are looking at while the qualitative method can expand the view to elements there were not even considered before [7].

In this research at first interviews were conducted based on the semi-structured questionnaire.

4.3. Interviews with experts

The interviews were conducted via a meeting, by phone or Skype. The candidates for the interview received an invitational letter to invite them to participate. One of the candidates was not able to respond due to illness. One candidate replied that he did not know the Care Provision Model well enough to participate in the interview. A few other candidates where working on an HL7 project and wanted to wait with the participation in the interview until after the project was ended. These interviews will be done at a later stage, probably in the situation where the ballot preparation takes place.

4.4. Questionnaire development

Based on the experiences and the components of the Care Provision DSTU materials and additional topics that where entered in the last years, a set of questions was developed. These include both open and structured questions. During the first eight interviews, several questions have been added that came forth from the interviews comments and suggestions. These where added for the next upcoming interview, because the nature for this evaluation was to get as much as possible qualitative material that can help to improve the standard.

4.5. HL7 site comments

HL7 has the policy that during the DSTU period, users can give immediate feedback on a HL7 website. In additional, when something is unclear or does not properly work, it is possible to use the PC email list and submit comments to the WGMs of which formal minutes capture these discussion points. None of the comments did require immediate changes to the DSTU materials, hence these are collected for the next cycles of ballots.
5. Results

Results of the questionnaire based interviews

For the DSTU extension, the following projects / stakeholders where identified.

<table>
<thead>
<tr>
<th>The FDA is interested and plans to evaluate the Care Record message.</th>
</tr>
</thead>
<tbody>
<tr>
<td>The CDISC-HL7 project sponsored by FDA and CDISC would like to be included in the extension request for Care Record DSTU.</td>
</tr>
<tr>
<td>IHE is international, and QED and other IHE profiles using the Care Record and Care Record Query DSTUs are of interest to IHE members from the US, Canada, France and other countries.</td>
</tr>
<tr>
<td>ANSI/HITSP has selected the Care Record and Care Record Query DSTUs as well for use in Health Information Exchanges in the US.</td>
</tr>
<tr>
<td>Ministry of Health in Ontario Referral, Promise (or denial) and Care Record messages are used in the Continuing Care eHealth solution currently implemented in 5 sites: The Scarborough Hospital (TSH), In &amp; Outpatient Department Central East CCAC, Scarborough Office Central CCAC (northern Branches only) CHATS Unionville Home Society The Scarborough Hospital (TSH) – Short term Crisis Team Canadian Mental Health Association (CMHA) – Toronto Hong Fook Mental Health Association (Hong Fook) Also three provinces in Canada are looking at those topics for inclusion in the Chronic Disease Management solution.</td>
</tr>
<tr>
<td>the German VHitG in cooperation with HL7-DE has specified order messages based on patient care transfer requests.</td>
</tr>
<tr>
<td>Nictiz, the Netherlands, has specified content for using patient care messages for stroke care, perinatology and diabetes care. Several projects are in preparation or ongoing.</td>
</tr>
<tr>
<td>Samenwerkingsverband Regio Eindhoven (Netherlands) has specified message content and is piloting Care Provision in the Eindhoven region</td>
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Eight interviews have taken place. Of the eight interviews 2 where done by e-mail because of lack of time for a meeting of the interviewed expert user. The results of these interviews are summarized below.

5.1. Use of Care Provision materials

Care provision has been used for EPD development, youth health care, pathology, data exchange in perinatology and diabetes, assessment for care, querying records (IHE), Continuing Care (Ontario) the locum record for general practitioner (Dutch acronym: WDH) and as a conceptual model.

The topics were used for:
- The Care Plan topic has been used as a patient follow-up system and in a conceptual model.
- The Care record Topic has been used in development, communication and in a conceptual model.
• The Care Record Query Topic has been used to query for encounters, with associated diagnoses and procedures. In another project it has only been used in a conceptual model.
• The Care Transfer Topic has been used for consultation requests and references.
• The Adverse reaction Topic has been used for complications.
• The Allergies and intolerance Topic has been used in the development of a patient record.
• The Professional Service Topic has been used to record actions.
• The Care Composition Topic has only been used in a conceptual model.

The Canadian users of HL7v3 use different terms for several topics because those terms are better understood by the healthcare professionals. They used Clinical Summary document, Patient annotation, Patient annotation query, Patient annotation response, Allergy, Adverse reactions, Health conditions (same as health concern), Health condition summary, Referral Record – international under CDA, Discharge- international under CDA, Care summary, Clinical Observation Document, Measured Observation Record, Measured Observation list Query, Coded observation record, Care composition, Record updates, list and detail, Professional service procedure record, Professional service procedure list.

One of the interviewed only used Clinical Statement, the core part of Care Provision. That was used for measurements of general practitioners, locum general practitioners and laboratory observations.

5.2. Missed Content in Care Provision

In several of the topics items were missed:
• Allergy: it is one to have a model; the content is not so easy. You mainly want to know the severity of the reaction.
• Care plan topic: if you use the topic in a dynamic way, a lot of data can be entered in the topic without working around.
• Care record Topic: in the implementation it has been a problem that there are differences in the Clinical Statement and the Care Statement of Care Provision. This is mainly a computability problem. The exchangeability between Care Provision and CDA and the Clinical Statement pattern is complex. This should be the same in every domain. This also concerns the classes in the choice box. The content of a class in this box differs from the content in other topics that use the same class. For instance: Patient and Person and Assigned entity differ. More differences can probably be found. Also in this topic there is data that concerns the patient or person and have nothing to do with the context or condition at that moment. These data cannot be entered in the patient or person CMET’s.
• Because “scale” can have several meanings (the weighing of a person is done with a scale) a name change is advised. In Canada Assessment Scales are replaced by “assessment tools or surveys”. R-MIM addresses Assessment scales/scores.
• Medication information in Care Record/Transfer has been missed.
• A domain that concerns the multidisciplinary collaboration (where the group is the executor) should be added to Care Provision. Part of this can be fused with Care Plan, but often the patient is not present but only his file is used. Recording the report is very important. Also a topic that concerns consent is
being missed. In the response model the reason why a care provision started is missed. Also additional query topics should be added.

Several remarks on Care Provision were made. These remarks contained the following:

- Issue: medication subscriptions cannot be done in Care Statements. For now Care Statements are used with CMET’s.
- To query for encounters, with associated diagnoses and procedures. Note that the patient administration domain allows for the querying of encounters, but the corresponding result model doesn’t support associated procedures.
- There is not a good method to structure templates. The definition is often filed in spreadsheets.
- The schedules are very generic, easy for version management. But this also makes them very comprehensive, that causes a lot of input and maybe they will never be finished. Communication to care providers does not get easier by this.
- Care Statement is already difficult.
- The difference between the head counsellor, co-counsellor and the consultant are not clearly modulated.
- Once a CP is started it cannot be changed, we want a more dynamic model.
- Many problems concern the movement in HL7. Nothing is normative, so sometimes things disappear.
- Transactions across groups. In Composition the collaboration is to be found but parts are in Record.
- Care Provision consists of both content and structure (allergy is content, care plan is structure). It lacks an overview on completeness concerning content and structure. Several R-MIMs are missing.
- To capture semantics in the depth is now impossible. When data is too complicated, CDA is used now.
- There is too little attention to the importance of history, now and future. Too many details disappear.
- There are too many differences now. Exchange between Care Provision, Clinical Statement Pattern and CDA is only possible if there is a transformation. This only concerns the technical part, the content is the same.
- All changes in the Clinical Statement should be processed in the Care Provision Care Statement. This related to the consistency and improved implementability.
- In HL7 there are a lot of topics in other domains that might be more suited in Care Provision. For example not showing for an appointment is in the administrative domain, while the reason for not showing could be a health concern. Every action in an ambulance is considered an encounter, when the patients arrive in the hospital the same actions belong to the Care Provision domain.
- The R-MIMs are not connected to Care Provision. They can be reused in other domains. Care Provision is much more about structure. Care Statement is content, but the relation with Care Provision is clearly stated. But Care Statement can also be used in CDA.
- There is an inconsistency between the PatientAdministration D-MIM and the patientCare DMIM.
- There is not enough guidance on the link between generic Care Provision-based models (using Care Statements) and the very specific structures (templates) that need to be represented using it.
5.3. **Also a few recommendations were made:**

- Everything is optional now, sometimes important data is accidently left out. This can be prevented by using templates.
- On management level the choice is often made for a system that is easy to explain. HL7 is impossible to explain in an easy way. HL7 needs to be translated into software that they can understand. The HL7 documents should be written in the language of the employees.
- Abstract HL7: eg observation.code
- Programmer: can be captured in code eg vital parameters.
- Users: daily language eg blood pressure
- What is needed are people that make the translation of HL7 for ICT suppliers, users and managers. Managers do not understand what HL7v3 can do for them. A demonstration on a practical level could be useful.
- HL7 (NL) should get enough support (like in Canada) so that there will be investments in the model (Nictiz?)

5.4. **Results of the DSTU comments [8]**

Continuing Care in Ontario requested additional dynamic models in Care Provision. These include:

- a need to add 3 new trigger events (and corresponding interactions) for
  1. Suspend Care Transfer Request
  2. Resume Care Transfer Request
  3. Nullify Care Transfer Request

Oemig from Germany requested that the Assessment Scale part be upgraded and published as DSTU. Work currently approved by ballot, but not finalized.

Comments from the Dutch project for Diabetes using the Care Provision messages include requirements for querying different class attributes, e.g. method code, e.g. query for blood pressure with the patient in a sitting position.

Another requirement would be to be able to constrain generic templates.

From
Dec 05, 2008    New    Kirnak, Alean
Vaccine Forecast Decision Support would like to make use of CareRecord as a payload format for passing data to and from the service. The required input is an immunization history and other medical summary data. The output is a validated immunization history and a recommendation for vaccines to be administered. Adding the following data elements will allow CareRecord to be used for this decision support and possibly other decision support applications.

(1) Need a way to express an immunization in terms of the diseases it targets - i.e. combo vaccines need to broken into doses by disease (shots vs. doses). For instance, Vaccine Family (targeted disease) expressed by dose (as opposed to by shot - combo vaccines may have more than one)
(2) Need to be able to show 3 separate groups within substanceAdministration tag:
   a.) Reported, b.) Validated by dose, including a way to express an invalid dose c.)
   Forecasted (which may repeat for different jurisdictions)

(3) EffectiveTime needs to include effectiveTime/low, effectiveTime/optimum, and
   effectiveTime/high

(4) Need a Partial Dose flag.

(5) CareRecord should be harmonized with POIZ. Investigation shows the two stan-
   dards are already very close.

Fields needed by CareRecord include: a) confidentialityCode; b) uncertaintyCode.

A few tag names are also different but it may be better to either ignore the differ-
ences or modify POIZ, which is also in DSTU. These include:

POIZ tag names:

administerableMedication.administerableMedicine.name
administerableMedication.administerableMedicine.asMedicineManufacturer.manufacturer.id
administerableMedication.administerableMedicine.lotNumberText
administerableMedication.administerableMedicine.expirationTime

vs CareRecord tag names:

administerableMaterial.administerableMaterial.name
administerableMaterial.administerableMaterial.asMedicineManufacturer.manufacturer.id
administerableMaterial.administerableMaterial.lotNumberText
administerableMaterial.administerableMaterial.expirationTime

Sep 04, 2007       New     Boone, Keith

   Each care entry can have a "conditions" associated with it. One use for this
   is to describe the preconditions under which a substance administration is to occur
   (e.g. Tylenol 500mg, 1-2 tabs every four hours as needed for pain).

The issue I raise is that the constraints on condition are too restrictive:

1. condition.value is required, but if the only value you have is text, then this could
   be found in condition.text, and requiring condition.value gets in the way (especially
   if you want more compatibility with other HL7 standards, such as CDA Release 2).
2. condition.interpretationCode is also required, but in the above case, I find noth-
   ing in interpretationCode that SHOULD be required in the use case just provided.
6. Discussion, Conclusion and Recommendation

This evaluation of the Care Provision DSTU materials is based on the interviews with 8 experts. Some expert users where not able to participate either because of not being knowledgeable or illness. In addition, some of the interviews had to be done via electronic media as e-mail and/or Skype / phone. Also, during the first interviews issues arose that have been included into the questions for following interviews. Hence, the nature of the interviews has changed slightly during the evaluation. This potentially can lead to discrepancies in the answers. However, that is balanced due to the fact that all qualitative comments have been included and the purpose of a semi structured interview is indeed to allow for differences in questions and responses to get the maximum quality of comments.

It is clear that Care Provision fulfills a need in the health care information industry given the current implementations and projects underway. However, several suggestions have been made to improve the Care Provision materials before moving to normative balloting. The items in the results section can be handled as line items to be discussed by the HL7 International Patient Care workgroup.

- Results based on N = 8 interviews show that there are several projects using Care Provision, but that there are many comments for use cases not met, or required changes in interactions, classes, topics, and usability. These items will be submitted to HL7 International Patient Care workgroup for further enhancement of the Care Provision materials before moving it to Normative.

7. References

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