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Localizing the HL7 Personal Health Monitoring Record for Danish Telemedicine

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Abstract. Telemedicine holds a promise of lowering cost in health care and improving the life quality of chronic ill patients by allowing monitoring in the home. The *Personal Health Monitoring Record* (PHMR) is an international HL7 standard data format for encoding measurements made by devices in the home. However, the standard needs localization to national requirements in order to facilitate semantic interoperability between clinical systems. In this paper, we report experiences and decisions from the current effort to localize PHMR in Denmark, and highlight issues relevant for any adoption of the standard.

Introduction

Denmark, as many other countries, is facing a challenge in health care due to a population with longer expected lifetimes, increased frequency of chronic diseases, and a relative drop in the work-capable population. Telemedicine, here interpreted as remotely monitoring patients' vital signs in their homes, is seen as a path to lower costs and increased life quality. A typical scenario is a diabetes patient that several times as day measures her glucose level using a device in the home that transfers measured values to a regional hospital for review by clinicians. This saves visits to the out-patient clinic and still allows early detection of health related problems.

Denmark has moved a long way in terms of IT support for clinical work. All major public hospitals and 95% of general practitioners (GPs) are using electronic health record systems. However, connecting the home or individual patient to this infrastructure is challenging. There have been numerous telemedicine projects but generally the developed software architectures can be classified as "stovepipe systems" as each project typically develops their own dedicated client system for the home, proprietary databases and storage formats, and a dedicated application for clinicians. The result is a lack of integration with other clinical systems, missed opportunities for reuse, and generally the systems are not supported once the project funding ceases. To remedy this situation, the five Danish Regions (public institutions that govern Danish public hospitals which are by far the most important health care providers in Denmark) have decided to develop a common infrastructure.

In this paper, we report central issues and experience regarding defining a common data format for storing telemedical measurements. The Danish Regions have decided to localize the Personal Healthcare Monitoring Report (PHMR) [1], a HL7 Clinical Document Architecture (CDA) [2] template, for use in Denmark. While the localization process is still ongoing and our focus is a Danish context the lessons learned so far will be valuable for other countries adopting PHMR.

1. Methods

The process leading up to the decision for adopting the PHMR format and localizing it for Denmark has been a long one. In Denmark, MedCom, a publicly funded non-profit organization, controls standardization of clinical information systems. Since 1995 it has had success in establishing electronic exchange formats. These formats have not been based upon HL7 standards but mostly on Danish OIOXML formats (a nationally developed XML dialect initially created for exchanging information between public authorities) partly because the HL7 formats were much less mature when MedCom started. As the use of PHMR has been discussed by various stakeholders, including regional and national authorities for healthcare IT, research groups at universities, as well as commercial companies, MedCom formed a *PHMR Localization Committee* (PLC) [3] during November 2013 with the mandate to draft a first release of a Danish PHMR localization.

A main technical contributor to the process is the Net4Care project [4, 5], which was a research project based on an action research agenda [6]. From 2010 onwards, Net4Care developed and still maintains an open-source software framework based upon software ecosystem principles. The focus was on supporting rapid development of home monitoring applications by small-medium sized businesses (SMB)—and the project hypothesized a future where clinical systems migrated to PHMR and XDS.b. The Net4Care framework became widely used for experimentation and learning by SMBs and numerous presentations were made for Danish Regions and healthcare providers. Its demonstration of how these standards could be used in practice and the technical insights gained in the project thus strengthened the argumentation to move towards international standards.

2. Results

The PHMR draft [1] dictates to great detail how to use HL7's Clinical Document Architecture (CDA) to represent measurements of vital signs. Still, there are several open issues that must be handled before two IT systems can unambiguously understand a PHMR document. Below we discuss the central issues that any national or regional use of PHMR must consider. A premise of this work is the choice to require CDA level 3 [2,§3.4] which makes the PHMR machine processable as opposed to only supporting human readable contents.

2.1. Establish Unique OIDs

A central way that HL7 assigns unique meaning to entities is through the use of ISO/IEC Object Identifiers (OID), a sequence of non-negative integers separated by periods. For instance, the OID to identify HL7 itself is 2.16.840.1.113883. OIDs are essentially a tree, and one may request a unique root OID from a registration authority and define branches and leaves by adding subnodes.

As a PHMR document must identify many objects, like national and regional organizations (e.g. hospitals, GPs, etc.), and registers and standards (e.g. Danish National Register of Persons which assigns unique identities to all citizens), a Danish authority must identify and maintain such a list of OIDs and register a root OID. In Denmark, it was decided to register the root OID at HL7's OID registry [7] as PHMR is a HL7 standard. Furthermore, MedCom is responsible for defining and main-taining the OID list in collaboration with National standards to avoid duplicated OIDs.

2.2. Clinical Code System

The CDA standard defines structure and contents of a data format for storing clinical data but has wisely refrained from dictating clinical semantics. Semantics, instead, is defined by *codes and vocabularies* [2, §8].

For instance, a measurement of a weight is represented by a *physical quantity* in HL7 (value, unit), such as 72.6 kg, but to uniquely identify it as a body weight measurement, a reference is made to a *code in a vocabulary*. Thus, in

```
<observation classCode="0BS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.1.31"/>
    <templateId root="2.16.840.1.113883.10.20.9.8"/>
    <code code="8341-0" codeSystem="2.16.840.1.113883.6.1"
        displayName="Dry body weight Measured"/>
        <value unit="kg" value="72.6" xsi:type="PQ"/>
</observation>
```

the measured value is 72.6 kg and the code identifying the actual type of measurement is 8341-0 in vocabulary 2.16.840.1.113883.6.1. Looking up the latter OID you will find the LOINC [8] system. Again, by going to the search.loinc.org web site, you can lookup the 8341-0 code to find that it is indeed a weight measurement. In Denmark, it has been decided to use the Danish NPU terminology as this is <u>www.labterm.dk</u> hosted by the Danish Sundhedsstyrelse (health care authority).

2.3. Context of Measurement

The aspect of reviewing measurements made by a patient without any supervision by clinical trained personnel raises concerns for the clinicians responsible for the treatment. The question is how to judge the credibility of measurements made by the patient. This has in a Danish setting prompted a wish to add *context* to measurements. The required context includes how data has been *provisioned*, specifically whether scalar values like weight has been recorded either through electronic transmission or by manual entering of values, as well as how the *authoring context* was, specifically whether a patient made the measurements all by himself, aided by a home caregiver, or made by a trained clinician. The PHMR has entries that cover some aspects. The Author field [1, §2.13.2] represents the creator of the document, and the dataEnterer field [1, §2.13.3] represents the person who transferred the information from other sources into the document, while the Informant field [1, §2.13.4] is the source of the information. Thus, with a more precise definition of what is meant by these fields specifically in a Danish telemedical setting would enable the context to be deduced. As an example if Mr. Hansen measures his blood pressure aided by his home caregiver Miss Jensen using a device of type X—the Author could be device X, dataEnterer Miss Jensen, and Informant Mr. Hansen.

However, these fields cannot be used for defining the other dimension, how data is provisioned. Furthermore, these fields are global for all contained measurements in the PHMR document. And finally, the actual understanding of the context hinges on specific interpretations of more general fields in the PHMR, which is a very volatile proposal: Odds are that different systems will interpret the fields differently.

Therefore, the PLC has decided to use another feature of the CDA specification, the methodCode. According to IHE [9]: The methodCode element may be the specific method used to make an observation when this information is not already precoordinated with the observation code.

The PLC is presently working on a proposal with defining branch OIDs for two dimensions of methodCodes: One for author context (who was involved in making the measurement), and one for the data provision (which means were used to transfer the value to the document), and define a code system for each dimension. This entails the values as well as the codes. At present the envisioned values are: Author context (by patient himself/herself; aided by home nurse; by clinician)—Data provision (by electronic trans- mission; manually entered). As an example of the use of methodCode, the XML below shows a weight measurement using codes to define the context as *measured by the citizen* ("Målt af borger"), and *automatically provisioned* ("Måling overført automatisk").

One may note that this is not in strict accordance with the PHMR V1.1 DSTU's CONF-414 which states only one methodCode may be present in an observation section. A potential solution is to combine the two dimensions into a single set of codes, but this obviously scales poorly. We have adopted to keep this small deviation as the official XSD schemas for CDA and POCD MT000040 that we can find all allow an unbounded set of methodCodes.

2.4. Other Issues

Several other issues have been discussed in the PLC. One issue is regarding the interpretation of the Author field. In [1, §2.13.2] the author element is defined as: The author element represents the creator of the clinical document.

The question, however, is *who* is the author for a document containing medical measurements made in the home by a patient? At least three interpretations are viable: the measuring device, the patient, or a physician involved in the prescription or authenticating. The PLC has decided that the person finalizing the document (typically a disease management professional) will be viewed as the author in a telemedicine setting.

Another issue regards device information. The Regions (representing the clinicians) express this information as important with regards to interpretation of measured values. For instance, a sudden change in mean glucose level for a patient may simply be due to a change from one device to another that is slightly differently calibrated. Also, the date of last calibration is important information. However, the PHMR for- mat is relatively weak in structuring these data. Basically, only tags are provided, two manufacturerModelName and softwareName, which just contain unstructured text. Thus the PHMR document structure has no means to enforce the presence of calibration information.

3. Discussion

A recent study of semantic interoperability [10] exemplified that real-world CDA documents are often still only semi-structured. In Denmark, the Regions aim at fully machine processable documents and strive for a common format for telemedical data after years of telemedicine projects that ended in proprietary formats. Also a decision has been made to depart from the line of national standards in favor of an international standard. This decision is mostly economically grounded: The Regions want to allow bids from all of Europe for greater competitions, and it actually is also a wish expressed by Danish providers as building software systems using international standards opens for a broader international market.

In parallel with the PLC work, our research group has developed an open source Java component, inspired by Green CDA, to allow quickly constructing proper Danish PHMR. It is available on BitBucket: <u>https://bitbucket.org/4s/net4care-phmr-builder</u>.

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