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Implementation of an ODM and HL7 Compliant Electronic Patient-Reported Outcome System

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Abstract. Interoperability is one of the biggest issues in health informatics despite of the huge effort invested to solve it. Clinical Data Interchange Standards Consortium (CDISC) and Health Level 7 (HL7) are two of the most recognized institutions working on this field. Several systems are becoming compliant with their standards; however, the process to accomplish it is not always straightforward. In this manuscript, we present the successful implementation of the CDISC ODM and HL7 import and export functions for "MoPat", a web-based multi-language electronic patient-reported outcomes system. The system has been evaluated and tested and is currently being used for clinical study and routine data collection, including more than 10.000 patient encounters.

Keywords. Patient-Reported Outcomes, Interoperability, Standards.

1. Introduction

The importance of electronic collection and storage of clinical research and routine data has been widely recognised in the last decades. Electronic Health Records (EHRs) improve healthcare efficiency and safety, as well as allow much simpler methods for data analysis than paper based records [1]. One of the most important advantages of the EHRs is the possibility to share the data with other systems, enabling multi-setting research frameworks where the data from several sources can be accessed, extracted and/or analysed from a single location.

Lack of interoperability between electronic healthcare routine and research electronic systems is a common issue. Normally, interoperability is pursued through the use of standards that ensure a common language for data, metadata and transport protocols. However, the great variety of standards makes it difficult to agree on common ones and their adoption is not always straightforward. The work of the Clinical Data Interchange Standards Consortium (CDISC), in particular the Standard for Operational Data Model (ODM) [2], is widely accepted in clinical research. ODM is a XML-based standard for data and metadata in clinical trials, which is system and vendor-independent and is accepted by the regulatory authorities for clinical trials such as the American Federal Drug Administration and the European Medicines Agency [3]. Besides, ODM can be used for the exchange of information between electronic data capture systems, as for example OpenClinica does [4]. Another reputed institution working on this field is

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Health Level Seven (HL7) [5], a not-for-profit, standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information.

An additional solution proposed by the health informatics consortium in order to solve the interoperability issue between health information systems (HIS) is the use of standard medical forms. Open access to medical documentation forms, item catalogues and case reported forms (CRFs) could considerable advance HIS, public health and medical research networks, however, the publication of medical forms is seldom permitted due to copyright and contractual issues [6]. In this context, the institute of medical informatics (IMI) at the university of Münster (Germany) started in 2011 the development of the Medical Data Models (MDM) [7] portal, which became the world's largest open-access registry for medical forms in 2015. The web-based portal enables viewing, discussing, rating and exporting of medical forms by healthcare professionals, as well as supports the comparison between medical data models [8].

An essential type of health records normally encapsulated in medical forms are patient-reported outcomes (PROs), defined by Deshpande as "the outcomes of a clinical intervention obtained by the patient" [9]. PROs are gaining importance for the collection of elemental clinical data for patient diagnostic and treatment, as well as for clinical research. The collection of these data has traditionally been done via paper based questionnaires, which leads to error during transcription of the data and high expenses for the health personnel. A solution for these issues is the use of electronic patient-reported outcome (ePRO) systems. EPROs lead to more accurate and complete data, improved protocol compliance, avoidance of secondary data entry errors, easier implementation of skip patterns, less administrative burden, high respondent acceptance, reduced sample size requirements, and potential cost saving [10].

Several ePROs are being developed around the world. These are though normally single purpose, they do not offer local storage capabilities or do not allow export functions to store the data in the EHRs. EPROs need to be compliant with international accepted standards so that they are able to import and export data into EHRs and research databases. The aim of this research is to implement ePRO ODM and HL7 import and export functions, enabling data transfer between mobile devices and several endpoint systems such as EHRs and research databases.

2. Methods

The University Hospital Münster (UKM) started in 2010 the development of "Mobile Patient Questionnaires" (MoPat), a web based multi-language ePRO that reduces medical practice costs with a high user acceptance[11]. The initial MoPat's use case was to capture the quality of life of patients with chronic skin diseases. Although being successfully deployed, the prototype had been stretched to its limits. Thus, the system was newly developed in 2014.

The implementation of the ODM and HL7 import and export functions started in May 2014 at the UKM and was completed in October 2015. The development was divided into four stages: First the ODM java library that would handle ODM messages; second the ODM metadata importer; third the ODM clinical data exporter and lastly, the HL7 exporter.

The ODM java libraries, as well as the import and export modules were completely developed by the Münster team and are compliant with the current ODM version: v1.3.2.

The HL7 exporter uses the HAPI library in its version 2.1 for the generation of HL7 v2.x messages. HAPI is an open-source, object-oriented HL7 parser for Java developed by the University Health Network in Toronto [12] that allows applications to easily parse text into a tree based modifiable HL7 object and vice-versa.

The development was completed with manual and semi-automatic test units. Once these were finished, the system was deployed in a production environment within the hospital network and an informal user acceptance test was conducted by clinicians at the UKM.

3. Results

The originally developed ODM java library contains all of the elements and attributes that an ODM object requires, as well as methods to add, remove and modify these.

The ODM importer allows users to select ODM files and converts them into MoPat compatible questionnaires. Examples of the ODM files compliant with MoPat are available at the MDM portal [7]. The importer reads an ODM file, verifies that it is consistent (ItemDefs and ItemRefs are defined), and transforms ItemDefs into MoPat questions. Besides, conditions that activate initially disabled questions can also be imported. The input conditions must be XPATH statements and need to include the ItemGroupData and ItemData OIDs from the answer that triggers the activation of the associated question.

The ODM importer generates an automatic mapping file for the exporter using the original ODM file as template. The MoPat administrator site allows import and removal of export templates, as well as modification of export mappings. Figure 1 presents an example of the MoPat ODM export for the Well-Being Index questionnaire.

```
1  <?xml version="1.0" encoding="UTF-8" standalone="yes"?>
2  <ODM xmlns="http://www.cdisc.org/ns/odm/v1.3" xmlns:ns2="http://www.w3.org/2000/09/xmldsig#
   " Description="WHO (Five) Well-Being Index" FileType="Snapshot" FileOID=
   "1.3.6.1.4.1.13158.101.4.141022090424" CreationDateTime="2016-02-05T12:32:01.662+01:00"
   ODMVersion="1.3">
3      <ClinicalData StudyOID="S.0000" MetaDataVersionOID="MD.0000">
4          <SubjectData SubjectKey="test">
5              <StudyEventData StudyEventOID="SE.0000">
6                  <FormData FormOID="F.0000">
7                      <ItemGroupData ItemGroupOID="IG.0001">
8                          <ItemData Value="4" ItemOID="I.1"/>
9                          <ItemData Value="1" ItemOID="I.2"/>
10                         <ItemData Value="3" ItemOID="I.3"/>
11                         <ItemData Value="2" ItemOID="I.4"/>
12                         <ItemData Value="5" ItemOID="I.5"/>
13                     </ItemGroupData>
14                 </FormData>
15             </StudyEventData>
16         </SubjectData>
17     </ClinicalData>
18 </ODM>
```

Figure 1. Example of the ODM export.

The HL7 exporter uses the HAPI library to encapsulate the questionnaire answers into an HL7 message (Figure 2). The message is securely sent to the hospital's communication server that imports the incoming messages into the EHR. The current version of the HL7 exporter contains an xml based message with the questionnaire responses and their correspondent element name within the EHR's form.

```
1 MSH|^~\&|WHO (5) Well-Being Index MS|MSH-4|MSH-5|MSH-6|20160209165159.969+0100||ORU^R01|123456|P|2.3||L
2 PID|
3 PV1||||||||||||||||||test
4 OBR|||SENDER||||201602090451
5 OBX|1|ST|||<Instance><Formname>WHO (5) Well-Being Index MS</Formname><DocumentName>WHO (5) Well-Being Index
  MS</DocumentName><cbx_A1_5/><cbx_A1_4/><cbx_A1_3/><cbx_A1_2/><cbx_A1_1/><cbx_A1_0/><cbx_A2_5/><cbx_A2_4/><cbx
  _A2_3/><cbx_A2_2/><cbx_A2_1/><cbx_A2_0/><cbx_A3_5/><cbx_A3_4/><cbx_A3_3/><cbx_A3_2/><cbx_A3_1/><cbx_A3_0/><cb
  x_A4_5/><cbx_A4_4/><cbx_A4_3/><cbx_A4_2/><cbx_A4_1/><cbx_A4_0/><cbx_A5_5/><cbx_A5_4/><cbx_A5_3/><cbx_A5_2/><c
  bx_A5_1/><cbx_A5_0/><KGZuweisung1>KG TEST</KGZuweisung1><KGZuweisung2/><KGZuweisung3/></Instance>|||||F
```

Figure 2. Example of the HL7 exporter.

Since the implementation of the MoPat ODM exporter (9th July 2015), more than 5.500 patient encounters have been exported. Since the implementation of the MoPat HL7 exporter (28th October 2015), more than 5.000 encounters have been exported.

4. Discussion

The implementation of the ODM and HL7 import and export functions enhances MoPat's interoperability with other systems and sets a methodology that similar systems could follow in order to achieve this aim.

The functionalities of the ODM importer and exporter are limited due to the standard limitations for PRO messaging: The ODM standard includes several data types not specifically meant to be questionnaire question types such as "HexBinary", "PartialDate" or "IncompleteDatetime". These datatypes were not considered for the implementation of the importer. On the other hand, MoPat includes some question types not addressed by ODM v.1.3.2. In some cases, a workaround was found to solve this issue (e.g. the Integer ODM data type is transformed into a multiple choice MoPat question when the ODM question contains a code list), but the following MoPat question types: "vertical slider", "numeric checkbox", "drop-down list" and "info text" are not supported in the current version of the importer.

Due to the lack of an ODM array type for multiple choice questions and answers, the ODM exporter needs also a workaround for these question types. The solution is to generate Boolean questions for multiple choice questions' answers. The disadvantage of this solution is that the visualization of the answers might result confusing as several answers will appear to be empty (not responded).

The HL7 MoPat exporter contains an xml based structured that has been tested with one other system: AGFA ORBIS®, a popular EHR system in Germany. The exporter is based on HL7 version 2.x. Currently, this is not the newest version of the standard as there exists a version 3, but ORBIS only compliant with version 2.x. MoPat should be tested with other systems in order to validate its HL7 exporter.

ODM needs to be revisited so that it complies with typical question types as multiple choice, sliders and pictures. Another possible improvement would be to include layout aspects within the standard specifications. Other systems that use ODM have made extensions to the standard so that it suits better to their systems [13] but this hampers interoperability if the extension is not officially released. A new version of ODM should address these issues.

A decision needs to be made when deciding on creating a new ePRO or enhancing existing ones. Some systems offer similar functionality as MoPat. For instance, limesurvey[14] offers an extensive spectrum of possibilities for multi-language online questionnaires but it does not include EHR linkage capabilities. Others such as PatientViewpoint and Patient care view are able to export the data to an EHR, but in a

single format and single language [15]. Among these, MoPat is the only ePRO that includes all of these features.

The integration of functionality to handle ODM and HL7 messages within MoPat was successfully implemented and tested. The methodology to achieve this aim could be re-used by similar systems in order to increase their interoperability, enhancing knowledge leverage and reducing operational costs and complexity. MoPat still needs to be enhanced with functionality that allows PRO data collection and export to the EHR outside of the hospital's network.

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