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Operational Data Model Conversion to ResearchKit

Iñaki Soto-Rey, Sophia Geßner, Martin Dugas

Institute of Medical Informatics, University of Münster, Germany

Abstract

The increasing use of electronic health information systems brings up an unresolved issue: the lack of interoperability between these systems. The Clinical Data Interchange Standards Consortium's Operational Data Model (ODM) is an xml based standard for the exchange of clinical data and metadata. The University of Münster has been using ODM to store medical forms in a web based metadata registry called Portal of Medical Data Models, which includes a complete set of tools to transform ODM forms into other formats. One kind of medical form is the Patient Reported Outcome, a trending type due to its easy integration with mobile data capture systems. ResearchKit is a development framework that allows the easy creation of these for iOS devices; unfortunately its current interoperability is limited. This research proposes a mapping between ODM and ResearchKit and presents the successful implementation of a converter for ODM into JSON based ResearchKit readable files.

Keywords:

Patient Reported Outcome Measures, Metadata, Health Information Systems.

Introduction

With the increase of electronic health information systems (HIS) in place, a problem arises: the interchange of information between these, formally called "interoperability". This is still one of the biggest issues in Medical Informatics despite of the several initiatives pursuing a solution [1]. One of the most recognised institutions working on this field is the Clinical Data Interchange Standards Consortium (CDISC), a non-profit organisation which aims to enable HIS interoperability through vendor-neutral, platform-independent and freely available data standards [2].

The CDISC Operational Data Model (ODM) proposes a format for exchanging and storing clinical data and metadata. This xml based standard is compliant with the American Federal Drug Administration (FDA) submission guidelines for metadata [3]. ODM is widely spread and it is supported by numerous HIS. Hume et. al. reviewed 69 publications that describe several uses of ODM [4].

An example of the use and potential of ODM is the Medical Data Models (MDM) web portal[1]. The MDM project started in 2011 at the University of Münster with the purpose of enabling form based metadata exchange [5]. The web based portal developed by the Münster team contains, to date, more than 250,000 items encapsulated in more than 10,000 ODM medical forms, together with the so-called "ODMToolbox", a set of tools to generate, modify and transform ODM forms. The portal allows users to easily visualise, rate, comment and download medical forms, originally created, semantically annotated (using Unified Medical Language) and stored as ODM XML files, in several languages and formats such as PDF (with and without comments), CDA, CSV, FHIR (as JSON and XML format), Macro-XML, REDCap, SQL, SPSS, ADL, R and XLSX [6]. Furthermore, the portal also includes tools such as the so-called "ODMEdit", a tool to create medical forms in ODM; once the forms are created, they can either be downloaded or directly uploaded to the MDM portal [7] and the "ODMSummary", which allows the comparison of multiple semantically anotated medical forms in a web based tool with a high usability score [8]. In constant evolution, new forms and functionalities are regularly being included to the MDM portal, which became in 2015 the world's largest open-access metadata registry.

One popular type of medical form are Patient Reported Outcomes (PROs), defined by the FDA as "measurements of any aspect of a patient's health status that come directly from the patient (i.e., without the interpretation of the patient's responses by a physician or anyone else)" [9]. PROs are useful for the better understanding of clinical cases and the detection of patients' life quality issues, but their use and interpretation must be carefully handled [10]. Regarding their benefits for clinical research, PROs have proven to be helpful when assessing patient trial eligibility and the efficacy of new treatments and therapeutic procedures [11]. Traditional paper based collection of PROs is though cumbersome and prone to error when, for example, the collected data needs to be manually introduced in a HIS.

Electronic HIS and especially mobile based HIS offer a great opportunity for the collection of PROs. Electronic PRO 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 user acceptance, reduced sample size requirements, and potential cost saving when compared to paper based collection of PROs [12].

As several ePROs are being developed around the world, the second most important mobile device operating system after android, iOS [13], has started its own initiative to support the creation of new ePROS with a development framework: ResearchKit[2] (RK). RK allows developers to easily create ePROs with a standard user interface, optimised for all iOS based mobile devices. RK can be freely downloaded from GitHub[3] (an online repository for open source projects) [14] and built with Xcode[4]. RK supports not only the collection of classic PROs containing traditional PRO questions (multiple choice, free text, numerical, etc.) but also other functions like a utility to provide information about the study and give consent re-

[1] http://medical-data-models.org/

[2] http://researchkit.org/

[3] https://github.com/

[4] https://developer.apple.com/xcode/

motely; or information collection from several tasks available in mobile devices such as location, reaction time, balance, distance walked and multi-media records (audio, photo and video). These innovative measurements open a new spectrum of possibilities for clinical data collection and research, some of which are already starting to be used in clinical studies [15].

Unfortunately, the current version of RK does not support clinical standard formats, which hampers the exchange of information with other systems and the automatic inclusion of PROs, by for example re-using medical forms from repositories such as MDM.

The purpose of this research is to investigate the feasibility of a transformation from ODM forms into RK questionnaires and the development of a converter between these two formats, which should be integrated within the ODMToolbox of the MDM portal.

Methods

The first step was the investigation of the RK application programming interface (API) and the suggestion of a mapping between ODM and RK. For this, the ODM 1.3.2 specification was taken as reference and a list of the elements conforming ODM's hierarchy was built. With this list, matches for every element were defined based on RK's API and the RK items best representing ODM's attributes and classes were listed next to their ODM homologs.

The second step involved the development of the ODMtoResearchKit converter, which was fulfilled using Java programming language and NetBeans[5] as integrated development environment. During the development, some of the initially suggested mapped items were corrected.

The versions of the standard and software supported by the converter are ODM v1.3.2 and RK on its last update on GitHub (to date 853 forks), together with AppCore (81 forks), a model built on top of RK that includes important features not initially included in RK such as: dashboard with progress graphs; data storage back end; JSON serialization and deserialization and integration with Sage Bionetworks' Bridge service [16]. For the manipulation of ODM forms, a Java library developed by the University of Münster in 2014 was used [17]. This library allows users to generate an ODM Java object from an XML based ODM form, which facilitates its manipulation with a Java based program for its conversion into other formats.

The functionality tests were performed using ODM samples from the MDM portal, converting them into RK JSON and importing them with the sample application available in RK's source code and the open source application developed by the Icahn School of Medicine at Mount Sinai: "Asthma Health" [6], which uses RK and AppCore and is able to import JSON files as questionnaires.

Results

The result of the mapping between ODM forms and a RK based questionnaires can be visualised in Table 1.

Table 1– Mapping between ODM elements and their equivalent ResearchKit questionnaire items

ODM Object	ResearchKit Mapping
Study	ORKInstructionStep
OID	ORKInstructionStep.Identifier
StudyName	ORKInstructionStep.Title
StudyDescription	ORKInstructionStep.Text
StudyEventDef	*Not applicable*
Name	*Not applicable*
OID	*Not applicable*
Repeating	*Not applicable*
Description	ORKFormStep.Title
ItemRef mit ItemOID	ORKFormStep.formItems
Mandatory	ORKFormStep.optional
ItemDef	ORKFormItem
DataType	ORKFormItem.answerFormat
text	ORKTextAnswerFormat
Length	ORKTextAnswerFormat.maximumlength
integer	ORKQuestionTypeInteger (ORKNumericAnswerFormat)
float	ORKQuestionTypeDecimal (ORKNumericAnswerFormat)
GE	ORKNumericAnswerFormat.minimum
LE	ORKNumericAnswerFormat.maximum
MeasurementUnit	ORKNumericAnswerFormat.unit
date	ORKDateAnswerFormat
YYYY-MM-DD	ORKDateAnswerFormat.style
GE	ORKDateAnswerFormat.minimumDate
LE	ORKDateAnswerFormat.maximumDate
time	ORKTimeOfDayAnswerFormat
datetime	ORKQuestionTypeDateAndTime
intervalDatetime	ORKTimeIntervalAnswerFormat
boolean	ORKBooleanAnswerFormat
Integer with CodeListItems	ORKTextChoiceAnswerFormat
ORKQuestionTypeSingleChoice	ORKTextChoiceAnswerFormat.style
CodeListRef mit CodeListOID	ORKTextChoiceAnswerFormat.textchoices
OID	ORKFormItem.identifier
Description	*Not applicable*
Question	ORKFormItem.text
Alias	*Not applicable*
mandatory	ORKFormItem.optional task (id<ORKTask>)
CodeListItem	ORKTextChoice
CodedValue	ORKTextChoice.value
TranslatedText	ORKTextChoice.text oder ORKTextChoice.detailText
ItemDef	ORKStep
OID	ORKStep.identifier ORKStep.restorable
Mandatory	ORKStep.optional
Name	ORKStep.title
Question	ORKStep.text
FormDef	ORKStep.task

The RK question types not visualised in the table and the ODM elements marked with "*Not applicable*" could not be mapped and will be analysed in the discussion.

[5] https://netbeans.org/

[6] http://apps.icahn.mssm.edu/asthma/

The converter developed contains two main functionalities: One enables users to upload an ODM file in a very basic webpage deployed locally using Tomcat[7]. This basic system imports the (ODM) file and generates a JSON file that is stored locally and visualised on the webpage. This functionality was mainly developed and used for local tests. The second and main functionality is the integration within the previously introduced ODMToolbox of the MDM portal. Figure 1 represents the common workflow to use the ODMtoResearchKit converter: (1) A registered user of the MDM portal searches for a desired medical form using the MeSH-based MDM searching tool and accesses to the form. (2) The user hovers over "Download" on the left part of the display and selects "ResearchKit (JSON)". The downloaded .zip file contains the medical form in RK JSON format, as well as the license information and a JSON document with the form's metadata. (3) The user copies the downloaded form into the resources folder of the RK-based ePRO and includes the file in the source code.

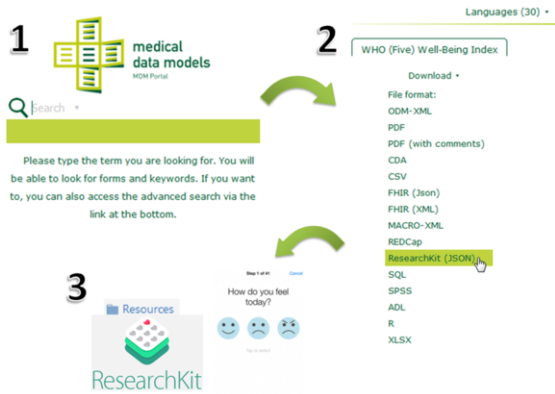

Figure 1 – Process steps to be followed in order to find a desired data model in MDM, download it in RK JSON format and include it in a RK-based ePRO.

The ODM to RK converter generates JSON files with a structure readable by any application that includes both RK and AppCore (Figure 2). In RK JSON, a questionnaire is defined as a task (RKTask). A task includes one to several questions named "steps", as well as an identifier and a name. The steps are defined as single JSON objects and are encapsulated in a JSON array. Every step contains an identifier, a question text and an answer format and, depending on the answer format, other elements such as range limits for numerical questions or answer choices for multiple answer choice questions. It is also possible to decide whether a question has to be answered or not with the option "optional task", which can also be imported from ODM's "mandatory" field.

```
{
    "identifier":"F.0000",
    "name":"WHO (Five) Well-Being Index",
    "_class":"RKTask",
    "steps": [
              {
              "identifier":"I.1001",
              "question":"I have felt cheerful and in good spirits",
              "answerFormat":{
                   "options":[
                        {
                        "shortText":"All of the time",
                        "_class":"RKAnswerOption"
                        },
                        {
                        "shortText":"Most of the time",
                        "_class":"RKAnswerOption"
                        },
                        {
                        "shortText":"More than half of the time",
                        "_class":"RKAnswerOption"
                        },
                        ...
                   ]
              }
              }
              ]
}
```

Figure 2 – Example of the first question and three first answers of the Well-Being Index questionnaire in ResearchKit JSON format, generated using the developed converter.

As RK does not support multilingual questions yet, the language of the items converted from MDM portal into RK JSON files will be the language selected for the visualisation of the form in the MDM portal. Multilingual functions for RK have been suggested and are part of the development roadmap.

The converter was positively tested using several PROs contained in the MDM portal, downloading them as RK JSON files and importing them with Asthma Health, a RK-based application available online, that includes AppCore to import RK JSON files [18].

Discussion

The converter developed is able to generate RK readable JSON files from an ODM file. With this tool, the more than 130 PROs and 9.000 medical forms available in the MDM portal can be easily downloaded and imported by RK-based apps. Besides, the test suite server developed is useful for local functionality testing and could be re-used by future converters.

Some limitations need to be pointed out: RK does not include or use a standard for using medical forms; it just provides a framework that facilitates the development of new ePROS. Thus, a mapping between ODM and the RK questionnaire structure is not straightforward. Likewise, ODM is not PRO oriented and it does not include some useful question types supported by RK.

These are the ODM item types not supported by RK:

- hexBinary | base64Binary | hexFloat | base64Float
- partialDate | partialTime | partialDatetime
- durationDatetime
- incompleteDatetime | incompleteDate | incompleteTime
- URI.

RK question types not supported by ODM:

- ContinuousScale

[7] http://tomcat.apache.org/

- Email
- HealthKitCharacteristicType
- HealthKitQuantityType
- Location
- TextScale
- Multi-media (Audio, video and photo)

Together with the activities supported by RK (and not by ODM):

- CountdownStep
- Fitness
- TowerOfHanoiStep
- WalkingTask

ODM v1.3.2 includes a possibility to represent multiple-choice questions using code lists. On the other hand, it cannot be defined if several of the choices contained in a code list could be answered. This represents a limitation when convertors from ODM metadata into PRO based formats are developed, as it is an essential characteristic of classic PRO questionnaires. In practical terms, this means that a conversion between ODM and PRO formats requires post-conversion handling for this kind of questions.

RK is meant to be used by ePROs created for a single study. Thus, an element that represents a study within the JSON structure is not needed (as there will only be one). ODM on the other hand, includes a great amount of information about the study that, due to RK's limitation, will be lost when generating RK compliant JSON files with this converter.

RK includes mainly user interface capabilities; it needs AppCore for useful features such as serialisation and deserialization of JSON files. Although AppCore functionality is soon to be included in RK, to date, a RK-based ePRO would need AppCore in order to import JSON based questionnaires.

There are several systems available for the electronic collection of PROs. The most simple ones are electronic online survey systems such as LimeSurvey [19], which offer a wide variety of languages and configuration options for the easy creation and customisation of surveys, but are normally just used for anonymous collection of simple data as data privacy may be an issue. Other systems are also multi-language and web-based, but are so far only developed to be used in a clinical setting, restricting their use with the a web clip installed in a mobile device [20]. Some other ePROs just provide an application developed compliant with several operating systems and devices, but they are normally developed for a single purpose [21], [22]. Another notorious example is REDCap: a methodology and a software solution for the rapid development and deployment of electronic data capture tools to support clinical and translational research though intuitive electronic case report forms and metadata import functions [23]. Other projects like C3PRO propose a working framework for the exchange of information between ePROs and different HIS though medical standards [24], but they are focused on clinical data, and not on metadata and import of medical forms. The great availability of systems in place should be taken into account when a new one is requested.

RK is only compliant with iOS devices. Another project that uses RK as basis and provides a similar framework for Android devices is ResearchStack[8]. We decided to develop firstly the ODM to RK converter, since RK represents the original framework compared to ResearchStack. Furthermore there are currently more initiatives using ResearchKit to conduct research and, most importantly, after a short look into ResearchStack's source code, one can observe that ResearchStack has preserved RK's structure and functionalities, which suggests that the JSON files generated by the ODMtoResearchKit converter could also be importable by ResearchStack based ePROs.

Electronic PROs have surpassed the possibilities of PROs. Modifications on traditional PROs should be considered so that they include new question types and tasks available only on electronic devices (previously mentioned). To the knowledge of the authors, there are no official guidelines for these question types and tasks to be included as part of PROs yet. Likewise, ODM should include some of these useful question types and tasks in order to update it to the new ePROs, as well as a solution for the multiple choice questions previously explained. RK should consider the possibility to select a different graphic interface and survey languages. As soon as this functionality is available, a small update on the ODMtoResearchKit converter needs to be carried out so that the JSON files generated contain the elements in various languages. The MDM portal contains, to date, more than 130 PROs. This number is thought to be low compared to the total amount of data models included in the portal. The most important reason for this is the lack of licence free PROs. A feature to include non-licence free PROs in the MDM portal could be developed so that only users with rights to use these kind of PROs could download them. The converter could be enhanced with a library to manipulate RK objects in Java, which would facilitate the export in different formats (swift or objective-c code for example) and further tests are needed to demonstrate the compatibility with ResearchStack.

Conclusion

A mapping between ODM and RK questionnaires was suggested and a converter for ODM forms into RK readable JSON forms developed. With this converter integrated within the MDM portal, more than 130 PROs and 10,000 medical forms contained in it can be easily imported by RK-based ePROs. Further work should include a Java based RK questionnaire library and tests to demonstrate the generated JSON files' compliance with ResearchStack.

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Address for correspondence

Inaki.SotoRey@uni-muenster.de