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PROsaiq: A Smart Device-Based and EMR-Integrated System for Patient-Reported Outcome Measurement in Routine Cancer Care

Pilot Project

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Abstract: The PROsaiq prototype, which is based on the use of smart devices, was developed to show the technical feasibility of a lean, low-cost electronic Patient-Reported Outcome (ePRO) system that integrated with the oncology information system MOSAIQ to provide the potential for benefits in routine patient care, and improved data for clinical research. The system was built with Free & Open Source Software and trialled for a limited number of assessments. The report describes the components used, the decisions made and the hurdles met during the project. An on-line demonstration system is available to showcase PROsaiq's functionality.

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1. Introduction

Patient-reported outcome (PRO) questionnaires measure a patient's perception of the impact of a disease and its treatment(s) [1], and, while enhancing patient-centred care generally, are particularly useful in oncology where treatment side-effects are common [2]. Initially PROs were almost exclusively collected in research [3] using a classic pen and paper approach, but the advent of electronic PRO (ePRO) systems based on tablet or web technologies has allowed their use in routine oncological practice [4], in palliative care [5] and during cancer survivorship [6]. While the stationary terminal ePRO "kiosk" approach has had its uses, widespread adaption has not resulted.

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1.1. Motivation and Challenges

Bennett et al. [7] describe improvements in patient-provider communication and patient satisfaction, efficient clinic time utilisation and increased thoroughness and accuracy of symptom assessment as incentives for using ePRO as part of clinical routine. A comprehensive literature review by an Australian group [8] confirms this and indicates that evidence for benefit in health outcomes, patient health behaviour or health system performance is weak or non-existent.

The only qualitative study into practising oncologists' attitudes and experiences regarding ePROs [9] also endorsed these benefits, but identified concerns after implementation including:

- the impact on clinic workflow and efficiency,
- cost and feasibility of implementing the technology,
- usability problems and need for assistance in certain patient populations (elderly, non-English speaking, semi-literate) and
- information overload that could overwhelm providers if not summarised and prioritised adequately.

Jagsi et al. [9] noted that for clinic workflow and efficiency,

> "PRO collection could ideally be coordinated with the use of electronic medical records in their practices, especially if patients could use tablets for automatic data transfer into medical records".

Others also stress that ePRO and electronic medical record (EMR) integration are important factors for success of PRO measurement in routine care [10, 11], they point out that converging the electronic systems provides new opportunities for comparative effectiveness research and patient-centred outcomes research. PROs measured in the routine care setting enhance decision making within the individual patient-clinician interaction. Later, when de-identified , they provide clinically integrated information to build clinical knowledge. These benefits are displayed in Table 1.

1.2. Objective

Convinced of these ePRO advantages and challenges, we formulated the following goal of this study:

> ... build a pilot system demonstrating the feasibility of a low cost ePRO system integrated with our existing EMR for routine care data collection.

The oncology information system (OIS), MOSAIQ®, was used locally (see Section 3.2), and because the result was a PRO-enriched MOSAIQ system, we titled the project "PROsaiq". We do not mind the connotation that the system is 'ordinary', 'pedestrian' or 'factual' as the technical infrastructure behind PROsaiq functions ***reliably*** and ***invisibly*** during ***every-day*** clinical practice. Though unseen, the new opportunities offered by PROsaiq are exciting.

2. Related Work

There is an active ePRO literature body, with several groups describing ePRO development, implementation and use [12–16] in a "green field" approach, which provides maximal flexibility, but requires considerable resources. Recent reviews have compared a range of academic and/or commercial ePRO systems [17, 18]. We investigated Equicare CS[1] which claims MOSAIQ integration and provides electronic survey support among other functionalities. The investigation revealed the MOSAIQ integration was only one-way, that is, it imports some MOSAIQ information to set up appropriate survivorship care plans, but the collected survey information is not returned to MOSAIQ. ePRO collection introduces new security and privacy risks that require appropriate action [19]. If the security and privacy issues are overcome, emerging evidence suggests patients trust ePRO more than paper for sensitive personal information [20].

3. Materials and Methods

3.1. Design Science

The methodology underlying this pilot project is Design Science (DS) which "creates and evaluates IT artifacts intended to solve identified organisational problems." [21]. This novel and domain–specific problem solving

Primary Benefits			
	Individual Care	-	Increased accuracy and thoroughness of symptom assessment (screening)
		-	Improved patient-provider communication
		-	Improved patient satisfaction
		-	Efficient clinic time utilisation
Secondary Benefits			
	Clinical research	-	Patient-centred outcome measures as primary or secondary endpoints in clinical trials and observational studies
		-	Enabling comparative effectiveness research through using standardised PRO sets across separate studies
	Population surveillance	-	Augmenting population level disease registries with PRO data for increased utility in areas such as quality improvement, pay-for-performance or public health.

Table 1. **Benefits of ePRO measurement in clinical practice (based on [7, 8, 10, 11])**

[1] *http://www.equicarehealth.com/products/patient-portal*

process is aimed at utilising existing IT with added components to develop useful and practical information systems. Design Science artifacts can be constructs (vocabulary, symbols), models (abstractions, representations), methods (algorithms, practices), and instantiations (implemented & prototype systems) [21, 22] which iteratively built and evaluated to develop more DS knowledge by abstraction and reflection to extend the applied DS artifacts.

Concentrating on unsolved, complex domain problems with an innovative and rigorous approach distinguishes design science from routine design, which applies established best practices to well-known problems. The approach is rigorous in being informed by existing theoretical foundations and appropriate research methodologies (e.g. evaluation strategies) [23].

We used the prototyping method [24] for our development, using classical system development activities, such as requirement analysis, design, programming, debugging, testing in an iterative development process.

3.2. MOSAIQ Oncology Information System

MOSAIQ®(Elekta, Stockholm, Sweden) is a successfully implemented [25], proprietary oncology information system incorporating electronic format for radiotherapy and chemotherapy record & verify (R&V) functions in addition to appointments, schedules, check lists, disease definition, assessments, document management and images.

There a considerable amount of customisation possible in the section designated Clinical Assessments (CAs) [26], with numerous CAs being available on installation, and additional CAs being added as required. A CA consists of either

- Data Items, which have a numerical value as seen with laboratory data, or
- Table Items, which have predefined value sets based on a classification, e.g., the ECOG performance status. The classification is expressed through a Table Title, which defines the question being assessed, and an associated set of Table Items, which hold the discrete values and the definition of each possible value.

MOSAIQ has been the sole electronic medical record (EMR) for the Radiation Oncology department since early 2011, and for Medical Oncology and Haematology outpatient care and inpatient chemotherapy delivery shortly after. It functions as a single repository for all cancer management and care in the service [27].

4. Design

Given the ever-present restriction in resources within the health system, several design principles were enunciated at the project‘s commencement. The final solution had to deliver its data using the built in MOSAIQ functionality already purchased, and additional software had to be robust, free Open Source software. Entry of ePROs on a smart device was the initial focus, with the ability to complete at any time and to dispatch when wireless access was available. Smart devices (phones, tablets) are becoming ubiquitous, hence their selection as the target platform. While the penetration of smart devices into the elderly population is less, the numbers are substantial and increasing [28].

The ability to undertake PROs on a personal computer (PC) was not initially catered for, though subsequently this ability was enabled by technological decisions. This will be valuable for home-based ePRO collection, which is planned in the future. Furthermore we did not indulge in the important questions of "which assessments?" and subsequently, "what will we do with the results?", as these questions are contingent on a functioning ecosystem.

4.1. Principles and Strategies

Table 2 summarises these design principles and corresponding strategies for the PROsaiq system. In the following subsections we provide background about the principles and explain the rationale for our selection of each strategy.

Principle	Strategy
Low cost	Use of open source components if available
Future-proof and maintainable	Use web service paradigm to loosely couple different components
Suitable ePRO interface (tablet computer)	Use of OpenRosa ecosystem
EMR integration	Use MOSAIQ‘s HL7 import mechanism

Table 2. **PROsaiq design principles and strategies**

4.1.1. Open Source Software

Free & Open Source software (FOSS) has particular advantages for the ePRO ecosystem. Commercial vendors and producers of ePRO have to sustain a marketing and sales ecosystem which adds to a product‘s expense, and prevents an individual site from refining the ePRO software to function better. We hope to show that great expenditure is not required for a ePRO system, and in fact, the development and maintenance of ePRO software is likely to cost less than one professional salary each year in total. However while managers are prepared to sign off millions on Hospital Information Systems, surprisingly they are often wary of expenditure on items in the thousands or tens of thousands.

Our pilot development consisted of a project ‘owner‘ and a single developer, who was also working as a full time resident medical officer. The developer‘s restricted time further highlights the usefulness of FOSS and precluded the green field approach described elsewhere [12–15].

For efficient development, we decided to use suitable, best-of-breed FOSS components and only develop "missing" components. We defined suitable FOSS component as:

- having the needed functionality,
- using sound development and communication practices within the FOSS project,
- being an active FOSS community with several developers and multiple users,
- having a proven track record of successful implementation, and
- providing a native web service interface (see Section 4.1.2).

The use of FOSS components reduced the required development effort, and the complete PROsaiq prototype system is available under FOSS licensing, which makes it available to any department.

4.1.2. Web Services Paradigm

All FOSS software has a culture reflected in the choice of programming language and release strategy which have overt social and technical consequences usually hidden in proprietary projects. The high level of software library re-use in FOSS projects leads to common dependency issues. Changes in dependencies can break downstream projects. As a result, all dependency updates released for improved security and efficiency have to be tested against the project. Project maintenance therefore carries a cost. While the discontinuation of a dependency or component is a risk, the FOSS paradigm permits an ePRO software team to substitute and write missing functionality. We lessened this risk by not altering the source code of any FOSS component. Any missing functionality was requested through the FOSS project‘s processes (e.g. filing a bug report or offering a software "patch" for official inclusion in the project‘s source code) or was implemented as a self-contained component which was built using the Web Services Paradigm [29].

This strategy ensures that the FOSS components used are maintainable, and future proofed by being easily replaced if discontinued or faced with a better alternative.

4.1.3. OpenRosa Ecosystem

Tablet-based measurement is the most widely used ePRO approach during clinic visits [18]. Implementing an ePRO tablet application and corresponding server exceeded the available resources for the PROsaiq prototype.

We discovered the OpenDataKit (ODK) project which was built for mobile paperless data collection in resource limited settings and utilised the original Android phone (Google G1[2]), accessing the functionality on the

[2] *http://en.wikipedia.org/wiki/HTC_Dream*

smart-phone including screen, phone, camera, GPS and data connection. It has been successfully deployed in many large scale data collections efforts in the developing world (see ODK's blog[3]) including as a tool to support home visits and clinic–based care in a Kenyan HIV treatment programme covering a two million individual catchment area [30, 31].

The OpenRosa ecosystem of components [4] was developed around the ODK project and supported by Washington University and Google [32]. The ODK tools implement the XForms-based OpenRosa standard [5]. The OpenRosa components are described below.

Survey configuration

The web application 'ODK Build' [6] was built to configure surveys for deployment in the OpenRosa ecosystem. It provides a web-based drag-and-drop user interface to visually compose surveys from individual assessments. It is intuitive and suitable for new users and simple surveys. Complex surveys should use the spreadsheet-based tool, XSLForm [7] which exposes OpenRosa's full functionality, including skip logic or sophisticated entry validation. The XSLForm format provides a concise view of extensive surveys, is similar to data dictionary specifications, and is easily shared .

Mobile data collection

Data collection occurs using the Android app 'ODK Collect' [8] which was ODK's original user interface. The app is optimised for smart-phone sized displays and supports the full set of ODK functionality including sophisticated features like barcode scanning, photography, displaying and recording multimedia content and switching interface languages.

Enketo[9] is another FOSS project which implements the data collection from a modern web browser. This provides independence from the installed operating system. Similarly to ODK Collect, Enketo does not require a constant internet collection to enable mobile data collection in areas with poor internet connectivity, and derives this ability from HTML5's offline storage feature. Enketo covers most of ODK Collect's functionality, except for some phone specific functionality.

[3] *http://opendatakit.org/blog/*
[4] *https://enketo.org/openrosa*
[5] *https://bitbucket.org/javarosa/javarosa/wiki/OpenRosaAPI*
[6] *http://opendatakit.org/use/build*
[7] *http://opendatakit.org/use/xlsform*
[8] *http://opendatakit.org/collect*
[9] *http://enketo.org*

Server-side data management

Having devised the surveys and had them completed on devices, 'ODK AGGREGATE' [10] is the central, server-based form repository that receives completed surveys. ODK AGGREGATE also has the responsibility for serving the "blank" surveys to ODK COLLECT. The "filled-in" surveys are eventually submitted for storage and processing such as visualisation, export or automatic publication to external systems. ODK AGGREGATE is implemented in programming language Java and uses the Google Web Toolkit [11].

A research group at Columbia University has developed an alternative server application called FORMHUB[12] with similar functionality. As an internet hosted data service, it provides some community functions, e.g., form sharing, not available in ODK AGGREGATE. FORMHUB is implemented in the programming language Python and uses the web framework Django [13] [12].

4.1.4. MOSAIQ Integration

As the EMR is our sole repository for clinical information, an efficient ePRO clinic work-flow and enabled research ability requires EMR integration. The HL7 (Health Level Seven) standard in its second version (HL7 V2.x) [14] is a well established and accepted international communication standard for clinical systems. MOSAIQ uses HL7 V2.x data import routinely for laboratory information as Data Items in CA. The MOSAIQ documentation describing HL7 V2.x import into CA provides minimal specific details about Table Items import ([33], Section 11.27), which was our preferred method for the import and population of ePRO surveys in MOSAIQ. The MOSAIQ HL7 import provides error and identity checking functions making it a clean and robust import method without the risk of data corruption associated with the direct database write access alternative [34]. Fortunately, discussions with the MOSAIQ Help desk revealed that Table Item import is possible.

A successfully imported assessment looks identical to a clinician-entered assessment in the CA interface. Clinical utility can be improved by processing the information into graphics. Collected data in the repository can be post-processed, whether for research, reporting, triggering clinical alerts, or for presentation in a dashboard. Interrogation of the database using Business Intelligence tools[15] is just the beginning of what can be done when the data is available.

[10] *http://opendatakit.org/use/aggregate*
[11] *http://www.gwtproject.org*
[12] *http://formhub.org*
[13] *https://www.djangoproject.com*
[14] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=185*
[15] *http://en.wikipedia.org/wiki/Business_intelligence_tools*, *e.g., Crystal Reports* *http://www.crystalreports.com/*, *Pentaho* *http://www.pentaho.com/*, *SpagoBI* *http://www.spagobi.org* *or Jaspersoft* *http://www.jaspersoft.com/*

4.2. Architecture

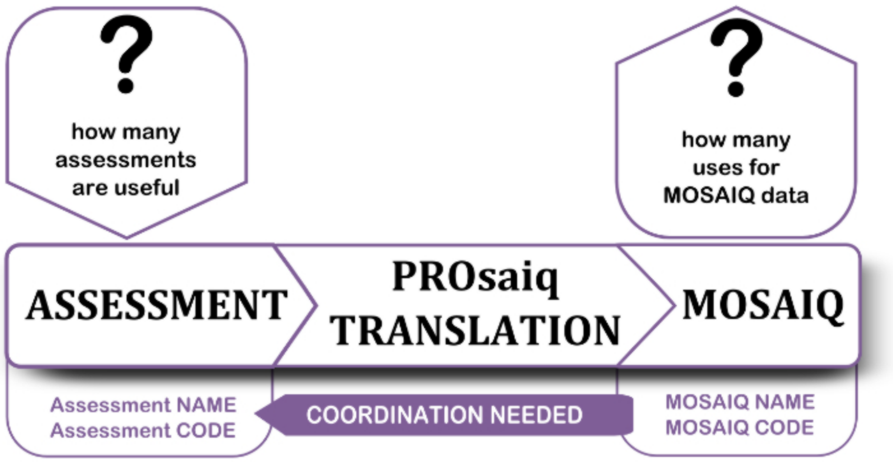

Figure 1. **The PROsaiq vision**

The overview of the project architecture (Figure 1) focuses on demonstrating that the data transfer '**pipeline**' is possible, since this is the necessary component of any ePRO system attempting to bring PRO data into a mainstream clinical repository. The need for coordination between MOSAIQ and the assessment arose from the requirement that the MOSAIQ Data/Table Items require specific names and codes which the assessment must present on transfer to MOSAIQ. The modules for additional surveys and data re-use are not the subject of this report but are presently being developed as part of a project with the Cancer Institute NSW.

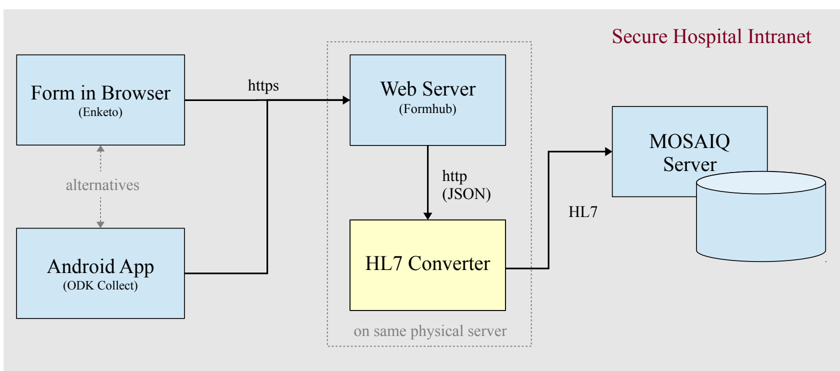

Figure 2. **PROsaiq prototype component architecture**

The detailed structure of the pilot project is described in Figure 2, and used an Android smart device using Enketo rather than ODK Collect, and Formhub rather than ODK Aggregate. These components were chosen for the pilot because the production ePRO system will accommodate PC and Apple smart devices, therefore the Enketo project based on the web browser with CSS3, Javascript and HTML5 was chosen. The selection of Formhub over ODK Aggregate was based on data transmission speed. Formhub transmits immediately, while ODK Aggregate delays submission relay for up to 15 minutes in order to conserve resources.

5. Implementation

The proposed design was implemented and a departmental demonstration allowed staff weight to enter a weight into two smart devices (Android & iOS based) and visually verify that end–to–end data transport was achieved by seeing the data in CA in MOSAIQ immediately after entry.

We have demonstrated through our pilot the technical feasibility of an ePRO for MOSAIQ which relies heavily on FOSS components. The source code[16] for the pilot HL7 converter is available under the Apache 2 license.

The easiest way of understanding the functionality of the prototype is to use it on the demonstrator web page[17]. The demonstrator ends with the generation of the HL7 message, which can be imported into a configured MOSAIQ with an operational HL7 gateway.

Each component in Figure 2 will be examined separately in details. In conjunction with the on-line demonstrator this will provide a comprehensive picture of the PROsaiq prototype features for clinicians. The details of the salient configuration steps and implementation decisions taken will assist potential developers in the PROsaiq effort.

5.1. ODK Collect App on the Android device

As a example, we implemented Cancer Care Ontario's Patient Reported Functional Status (PRFS) tool which is a multilingual version of the Eastern Cooperative Oncology Group Performance Status (ECOG PS) expressed in lay language to be completed by the patient [35]. It has been validated against the physician-reported ECOG PS and has similar survival predictability in metastatic cancer [36].

The patient uses the PRFS, which can be seen in Figure 3, to classify their activity level over the previous month by selecting one of five different response options.

16 *https://github.com/tschuler/prosaiq*
17 *http://tschuler.github.io/prosaiq/demo*

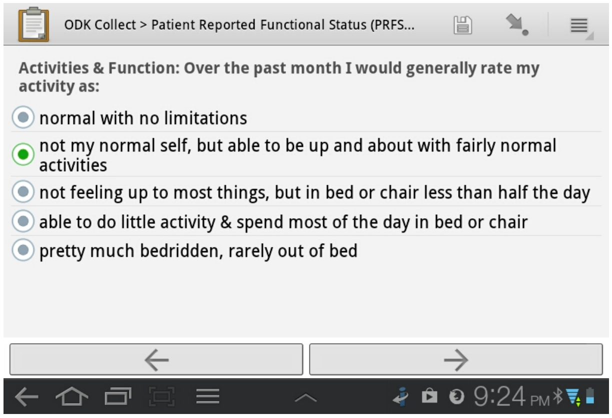

Figure 3. **ODK Collect rendering of PRFS in English.**

The second screen shot (Figure 4) demonstrates how ODK COLLECT supports multilingual ePROs. If an assessment is configured for multiple languages, the patient can switch the language via the menu at any time.

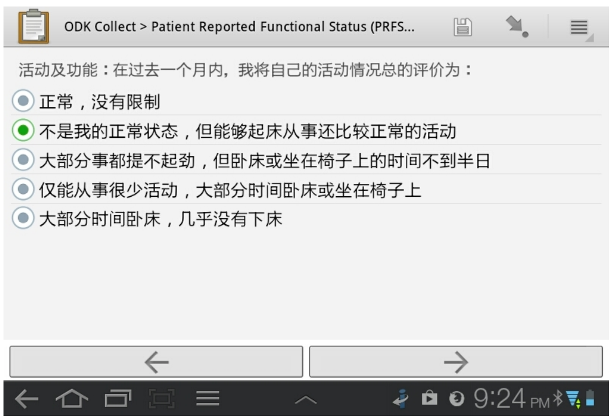

Figure 4. **ODK Collect rendering of PRFS in Chinese**

The ODK COLLECT app is configured to access an intranet installed FORMHUB instance (Section 5.3) and download the blank ePRO survey, which was configured using XSLForm tool, have the patient complete it and submitting it back to the same server. For the sake of simplicity certain ODK COLLECT user options were disabled, e.g., downloading of blank surveys is disabled via administrator settings.

5.2. Enketo Form in Browser on Android & iOS devices

The departmental demonstration used a survey asking for height and was entered by attending staff members (radiation therapists, nurses, oncologists & physicists) via ODK COLLECT on Android, and via ENKETO in a browser on iOS and Android (Figure 5). We employed validation, skip logic and dynamic calculation features (metric or imperial units). Selection of imperial or metric units adapts the interface accordingly. With metric input selected, the conversion into centimetres is displayed automatically. With imperial input selected, validation rules limit natural numbers (0–11) in the inches input field. No specific explanation of use was provided or requested, and attendants successfully completed survey with either the ODK Collect or Enketo variants.

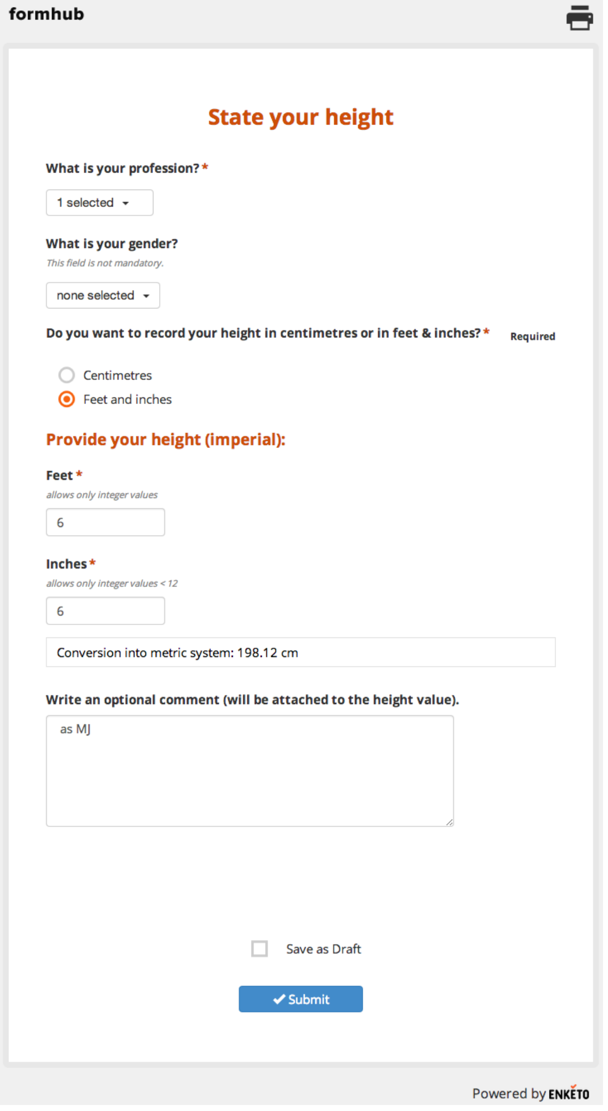

Figure 5. **Height survey rendered by Enketo, with the option to use metric or imperial measures.**

The Enketo–based ePRO pilot involved a local intranet installation to comply with security requirements. Although Enketo's core engine is FOSS, the recommended operation method is as hosted software–as–a–service, hence the documentation for local installation is very limited. We chose a Ubuntu Linux machine as the Enketo host.

5.3. Web Server

The Formhub web server received submitted ePRO data, immediately relaying submissions to the web service interface of the HL7 Converter component. Formhub's inbuilt data posting feature facilitated the relay by selection of a serialisation format and providing the URL of the relay destination.

The installation of Formhub on a local Ubuntu Linux host was smooth following the provided instructions[18]. We used the JSON serialisation format[19] and set the the relay destination in the 'Rest Services' area accordingly.

5.4. HL7 Converter

The PROsaiq HL7 converter was built to transform the ePRO submission into a HL7 message which could be imported into MOSAIQ, providing the missing link between the OpenRosa component ecosystem and MOSAIQ. In normal operation, this is a background process without user interaction. For testing and maintenance purposes, we used a graphical user interface (GUI), which can be seen in the on-line demonstrator[20] displaying the HL7 generated message.

The challenge in building the PROsaiq HL7 converter is determining the exact structure of the HL7 V2.x message necessary to populate custom CAs in MOSAIQ (Section 3.2). The international MOSAIQ user mailing list, nor Elekta's external systems interface team yielded satisfactory answers. Therefore we used a HL7 message for lab values that had been successfully imported, and experimented using the MOSAIQ documentation [33] and a freely available general HL7 V2.x reference [21]. Several iterations were required to produce a successful message populating a custom Data and Table Item CAs in MOSAIQ. It was found that we had to provide CA items with an unique identifier code.

This process is further explained in the next section. Using this identifier a mapping from the item in the OpenRosa compliant survey to the corresponding item in MOSAIQ could be established. The mapping information needs to be available to the HL7 converter and synchronisation of table item value sets needs to be ensured. This configuration has to happen prior to the first data import. In the future we envision semi-automating this process via a coordination module (see figure 1) including a round-trip completion check of the configuration.

18 *https://github.com/SEL-Columbia/formhub/wiki/Installation-and-Deployment*
19 *http://www.json.org/*
20 *http://tschuler.github.io/prosaiq/demo*
21 *http://www.corepointhealth.com/resource-center/hl7-resources*

For the programmatic validation and construction of the HL7 2.xc messages, we used the popular HAPI Java library which contains a HL7 parser and other tools [22]. The Grails web application framework [23] was used as the development environment based on combination of factors such as:

- suitability for an iterative prototyping approach
- ease of HAPI integration due to Java support
- previous Grails experience of the developer
- professional tools such as the freely available integrated development environment ‘Groovy Grails Tool Suite‘ [24]

The PROsaiq HL7 converter component data flow begins with assessment data reception in JSON format via the web service interface, where it parses the JSON data and looks up matching, pre-supplied mapping information depending on which PRO survey was submitted. These two data sources are used in an algorithm that makes HAPI calls in order to generate an in-memory representation of the HL7 message. Finally the HL7 message is serialised as a text file (see top part of figure 6) and delivered to a specified directory where the MOSAIQ HL7 interface polling mechanism seeks new messages.

5.5. MOSAIQ Server

Figure 6 shows the relationship between the HL7 message (particularly identifiers and payload data), the MOSAIQ assessment configuration interface and the run-time MOSAIQ system.

Seconds after submitting an ePRO via PROsaiq the corresponding values appear in MOSAIQ, provided the smart input device is connected to the intranet. The window in the lower right hand corner of Figure 6 shows the height CA displayed after collection (refer Section 5.2).

In order to provide an addressable target for PROsaiq, a unique identifier at item level is required. MOSAIQ‘s ‘Observation Definition’ Data Item creation window on the left of Figure 6 shows mandatory (red) and optional configuration fields. The optional ‘Code’ field requires a unique alphanumeric identifier. When creating the HL7 message, the assessment data collected by the OpenRosa ecosystem is mapped to the corresponding table in MOSAIQ via this identifier. When the identifiers match, the message can be imported (refer to ’a’ marker pair in Figure 6).

[22] *http://hl7api.sourceforge.net*
[23] *http://grails.org*
[24] *http://grails.org/products/ggts*

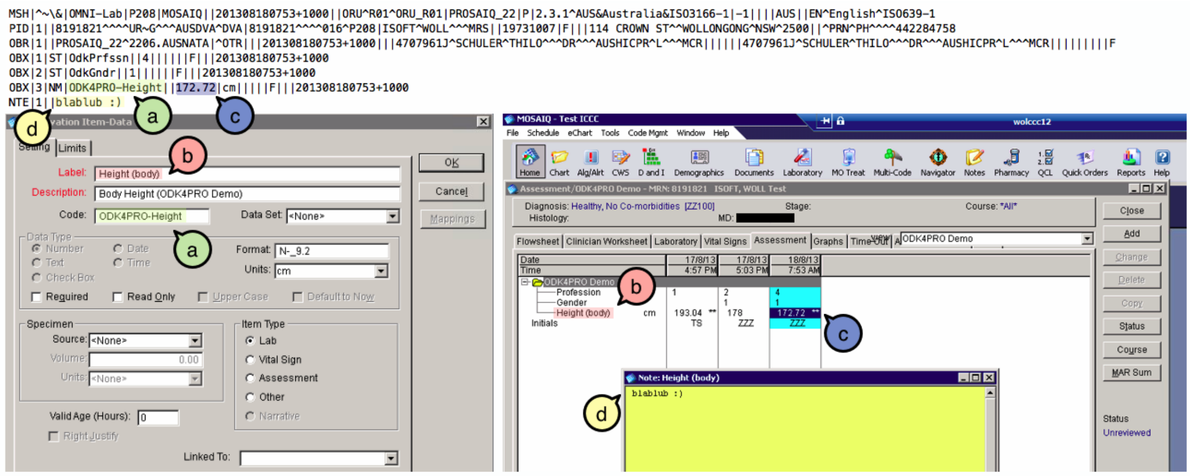

Figure 6. **Populating MOSAIQ custom CA item 'height (body)' via HL7v2 message**

Figure 6 demonstrates the interaction between the PROsaiq HL7 converter MOSAIQ using the custom CA Data Item 'height (body)' as an example. The following provides a short explanation for each marker pair:

(a) CA item identification (as described above)

(b) CA item label (its configuration and run-time display)

(c) CA item payload data (in HL7 message and its run-time display)

(d) CA item note (in HL7 message and its run-time display), some free text associated with the respective CA item.

The configuration and display of CA Table Items in MOSAIQ, such as items 'Profession' and 'Gender' in Figure 6, works in the same manner as Data Items (see above) with a single exception. At the time of data collection, the assessment requires that validation rules be in place to check that the transmitted payload number is within the value set of the Table Item to be populated.

6. Discussion

Our work makes two contributions to the ePRO community, namely :

- the demonstration of the feasibility of a lean system that enables MOSAIQ-integrated ePROs through strategic use of FOSS
- the first published report of the clinical use of the OpenRosa component ecosystem in a developed country

In contrast to previous "green field" ePRO system developments [12–14, 16] and other established solutions [17, 18, 37] this work demonstrates a particularly lean and resource-conscious process for ePRO collection, and to our knowledge, delivers the first system fully integrated with MOSAIQ, enabling the routine collection of PROs without disrupting the existing workflow. Since PROsaiq uses the HL7 standard for integration, it should generally be possible to use PROsaiq with other OISs provided they support the HL7-based data import.

The key element that enabled this lean system is the use of FOSS components from the OpenRosa ecosystem, which were originally tailored for the resource-limited settings of the developing world where being able to function without constant connectivity is a central design feature. Originally this was achieved by using the dedicated ODK Collect app, however the innovative design of Enketo provided a more comprehensive web-based solution, which also does not require constant connectivity. Thus, Enketo has fewer trade-offs for ePRO systems [19]. It is interesting that this developed world project is based on and learns from a 5 year old mobile health movement from the developing world.

While the software in FOSS projects is free, the total cost of ownership is not zero but lower in the long term, because investment in staff (either in-house or contracted) is required to safely run, adapt and maintain the FOSS components [38] which can change often. While loosely coupling various components provides opportunities in functionality, this is balanced with increased complexity. We used Formhub instead of ODK Aggregate because the near instant availability of the ePROs in MOSAIQ was deemed crucial. This decision increased complexity by exposing PROsaiq to an additional project community with different development tools and its own release cycle.

Although MOSAIQ has supported HL7 import for a long time, this has been confined to laboratory results, without applying it for other purposes in order to provide added value to patients, clinicians and researchers. This work provides a practical account of how to expand data clinical data collection into Clinical Assessments custom in MOSAIQ using a HL7 message. This knowledge did not widely exist in the MOSAIQ implementation community prior to this report.

PROsaiq offers the opportunity to additional import data into MOSAIQ from many other sources such as point-of-care measurements (e.g. pulmonary function testing), ePRO 'histories' (e.g., detailed smoking, alcohol, occupation, residential and risk factor history), and the results of genomic measurements.

PROsaiq can also function as an 'electronic Clinician Reported Outcomes' (eCRO) system. MOSAIQ does not support clinician workflow well. For example, when seeing a prostate cancer patient in follow up, to enter the side effect profile, and disease status requires the clinician to navigate to two different sites within MOSAIQ during or after the consultation. PROsaiq can be utilised within a Clinician Workflow Dashboard that presents a summary of completed ePROs and also required eCRO surveys relevant to the patient's event (e.g., if Follow

Up appointment and Prostate Cancer, then serve Prostate Cancer Follow up survey to Clinician Dashboard).

This study has limitations. The PROsaiq system has not been formally tested or routinely used in a clinical setting. The problems of identification to target an individual patient record in MOSAIQ with the HL7 message have not been solved. The PROsaiq prototype added all assessments to a single test patient. The obstacles are not technical. Available solutions include the use of the inbuilt scanner for a barcode, or provision of identifiers such as the patient's MRN (Medical Record Number), surname or date of birth for verification against the MOSAIQ entries. The PROsaiq architecture is limited in its options for the front-end GUI configuration. Although almost indefinitely complex surveys can be composed with OpenRosa, the control over screen layout is small.

7. Conclusion and Future Outlook

The PROsaiq prototype proves the technical feasibility of a lean, low-cost ePRO system that integrates with MOSAIQ, providing the potential for primary benefits in routine patient care, and secondary benefits in improved data for clinical research.

The next steps are to conduct a clinical pilot study based on the PROsaiq system, and to build the pipeline as production software. Potential focus areas of the pilot could be usability or the benefits of multilingual assessments. In terms of usability a comparison with usability scores of custom designed systems such as the MoCoMED-GRAZ system [13] would be interesting. In the midterm an extended PROsaiq system could be used in other settings such as home-based ePROs or health care professional-based assessments (e.g. rounding on a ward with patchy WIFI coverage, equipment checks by medical physicist while in the treatment bunker). In the latter use case, PROsaiq‘s robust design in terms of interrupted connectivity could provide a significant advantage. The idea of linking ePROs with clinical registries is attractive and is starting to become feasible [39]. We could integrate PROsaiq with national registries such as the emerging American NROR [40, 41] or the Australian ARORP [42] simply by generating multiple HL7 messages with different destinations. In the long term there are many open questions in the ePRO field not the least whether routine ePRO collection can contribute to better health outcomes, influence patient health behaviour, and improve overall health system performance [8].

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