Development and user experience testing of an electronic system for routine collection and use of electronic patient-reported outcome measures.

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Abstract

Background

Electronic collection of patient-reported outcomes (e-PROM) allows accurate recording of data. They also enable the visualization of longitudinal trends in domain-specific scores for a patient, and may improve patient-physician communication. Several commercial offerings are available but deploying them in countries like India is challenging due to language barriers and literacy levels. Additionally, costs involved remain a major problem. We propose to develop an open-source tool to serve the same purpose.

Material and Methods

After an exhaustive requirement analysis for a minimum viable product, we decided to proceed with developing the system using an open-source content management system. Additional contributed modules like Webform and Media were used to provide additional functionality. Three tiers of user roles with role-specific privileges were defined. A preliminary user experience testing was done for the patient role.

Results

All requirements identified in the requirement analysis section have been met. The system allows users with a patient role to fill in questionnaires presented to them. To ensure that diverse groups of patients can be accommodated, patients are grouped according to disease groups. Health care workers can visualize the results of the questionnaire as well as develop new questionnaires using a graphical interface. Initial user experience testing shows that 93.5% of the users (playing the role of patients) were able to use the website without additional help.

Conclusion

An open-source system to collect electronic PROM has been developed with localization in Indian languages. We aim to continue developing, validating and extending the system in the future.

Keywords: Patient-reported outcome, electronic patient-reported outcome measures, Open-source, Drupal

Introduction

Patient-reported outcomes (PRO) refer to any report of the health status of the patient's health obtained directly from the patient without any interpretation by others (of Health et al., 2009). The key elements of a PRO are that the outcome should be self-reported, and measurable in absolute or relative terms. Standardized measures to collect information on PRO are called patient-reported outcome measures (PROM). This umbrella term, in turn, can include measures that focus on understanding the quality of life (QoL), health-related quality of life (HRQoL), symptom burden (SB), and functioning (Weldring and Smith, 2013). Both

generic measures, that are applicable across a wide range of normal population, as well as disease-specific measurement instruments are currently available.

Though originally developed as a research method, increasing emphasis has been placed on the routine collection of PROs during clinical encounters (Black, 2013; Nelson et al., 2015). For diseases like cancer where treatment is often toxic (Henry et al., 2008), distressing (Carlson et al., 2004), costly (Knight et al., 2018), and time-consuming, integration of PROMs in routine clinical care makes sense as patients often have unmet needs (Sanson-Fisher et al., 2000). The National Health Services of the UK has implemented the routine collection of PROMs in some surgical disciplines as a method to assess the quality of care (Kingsley and Patel, 2017). In a recent publication, Porter et al have identified several key considerations for implementation of PROMs in routine clinical practice (Porter et al., 2016). It has been suggested that both the availability of a feedback system, where results of the PROM are available during the clinical interaction, as well as appropriate training of professionals in the interpretation of scores are vital (Porter et al., 2016).

Over the past decade, efforts have been made to administer PROM electronically. Advantages of electronic PROM (e-PROM) administration include the ability to present questions with appropriate conditional (skip) logic, reducing faulty and missing answers, implementation of computerized adaptive testing, integration of media like audio and video along with the questions for elaboration as well as integration with voice-based response systems which can widen the scope of application to populations with limited literacy (Coons et al., 2014). Furthermore, e-PROM systems allow data to be visualized in real-time at the time of clinical encounter and can be configured to provide information on time trends as well as comparisons with peer groups. Two meta-analyses have concluded that paper and electronic administration of PROM are psychometrically equivalent (Gwaltney et al., 2008; Rutherford et al., 2015). Several commercial and proprietary systems are available for e-PROM administration e.g. Assessment Center (NIH) ("Assessment Center", n.d.), Ayva (Bravado Health) ("Ayva - Bravado Health", n.d.), EPIC (EPIC Systems Corporation) ("About Us — Epic", n.d.), Patient IQ (PatientIQ) ("PatientIQ", n.d.), CHES platform(Evaluation Software Development (ESD)) ("CHES platform", n.d.) etc. An open-source project called openPRO also exists, but has seen limited development over the past few months ("goinvo/openPRO", n.d.).

In the current manuscript, we describe the design and development of an open-source tool to capture e-PROMs and display them to physicians at points of encounter. The design choices and underlying open source technologies used are described. Preliminary results of user experience testing are also presented.

Methods

Requirement Analysis

In order to use an e-PROM system clinically in our setting, we identified the following requirements for a minimum viable product:

- Should be developed using existing open source technologies to minimize development time.
- Easily installable on-premises to allow de-centralized data collection.
- Access control with different role-specific modular permissions for reading, editing, revising content and forms.
- Should allow sharing of PROMs across installations using simple configuration files.
- Ability to be delivered across diverse digital platforms, especially smartphones.
- Ability to deploy multiple types of PROM instruments simultaneously.
- Ability to target specific groups of patients with disease-specific as well as generalized PROM instruments.
- Ability to present questions one question at a time with minimal distractions.
- Ability to integrate multi-media prompts (audio/video) with text such that patients with limited literacy or reading problems can fill the questionnaires.
- Ability to present diverse response options which are touch screen friendly.
- Easily translatable into multiple Indian and other international languages and dialects. Integration with a translation management system would be preferable so that translations can be reused across sites.
- Integration with a graphical query builder such that summarized results from questionnaires can be presented for a group of patients as well as for a single patient in tabular formats and charts.
- Ability to export data for further analysis in external applications.

Software choice

After reviewing the requirements we decided to go ahead with Drupal (version 8.8.x) as the core content management system on which the platform will be developed ("Drupal - Open Source CMS", n.d.). The choice of Drupal was dictated by the fact that it is open-source and has a great eco-system of add-ons (also called modules) which can extend the functionality. The software is easily installable on a Linux server with a MySQL database backend. Not only is Drupal 8 modular and extensible, but also has the following features built-in:

1. Modular role-based permission system and a robust user authentication system.
2. Responsive design allowing usage across devices like mobiles, tablets and desktops without requiring additional theming and coding.
3. Strong support for regional languages and integration with translation management services. Currently supported Indian languages include Assamese, Bengali, Gujrati, Hindi, Kannada, Malayalam, Marathi, Odia, Nepali, Punjabi, Sindhi, Singhala, Tamil, Telugu, and Urdu ("Drupal 8 translation status — Translations", n.d.).
4. Integration with a powerful graphical database query builder (Views) which can return tabular summaries of data.
5. A separation between the front end and back end allowing content developers and site administrators to have separate work interfaces
6. An active open source community of developers backed by multiple enterprises.

In addition, we also used the following contributed modules to build the required functionality:

1. Charts: A module that allows the display of charts using data from Views ("Charts", n.d.).

2. Group: Allows creation of arbitrary groups of users with group-specific content and membership. Access control is also built-in and tiers on top of the existing access control ("Group", n.d.). Also allows integration with Views.
3. Media: Allows management, translation and embedding files and multimedia elements (e.g. audio, video) across the site ("Media", n.d.).
4. Webform: A complete form builder with support for a diverse range of form elements, skip logic, calculated fields, translation, visualization, data export along with application programming interface (API) support ("Webform", n.d.).
5. Lingotek Translation: A translation management system offering automated as well as manual translation for Drupal entities ("Lingotek Translation", n.d.).

Software deployment

The CMS was deployed on a virtual machine in the Google Cloud platform on an n1-standard-1 machine (with 1 virtual Intel Haswell CPU and 3.75 GB of memory). Ubuntu 18.04 server was installed on the machine. Standard MySQL (26), PHP (PHP: Hypertext Preprocessor(27)) and Nginx (28) packages were installed from the Ubuntu package repositories. The standard installation profile of Drupal was deployed using Composer (a PHP dependency manager)(29). The deployed website is available currently at *https://astu.pw*.

User Roles and Functionality

The site defines three types of roles with role-specific privileges and features (1):

1. Patient
2. Health Care Workers
3. Site Administrator

The group module is used to create disease (cancer) specific groups such that specific questionnaires could be targeted to specific patients. Thus patients with breast cancer would only see PROMs for breast cancer. Given the large number of patients seen in health care settings in India, it may not be possible to ensure that each and every patient gets individual attention from a health care worker while filling the PROM. Hence this arrangement should reduce the chances of patients filling in wrong questionnaires.

Each patient can view information related to the disease group they belong to. Given the rich content creation ability in the site varied types of content can be presented to the patients at a later stage of development.

Physicians and other healthcare workers have higher privileges. They can create, edit and translate questionnaires (forms) and view responses to the questionnaires filled by patients. They can additionally add patients to disease groups and create rich multimedia content for patients to view for each disease group.

Administrators are privileged to do all the tasks that the physicians can do and can administer the site functions including taking care module installation, site update and maintenance. Additionally, they can add new roles with a more limited set of privileges in the system and tweak the permission system. A super administrator role can also be defined for further fine-grained permission control.

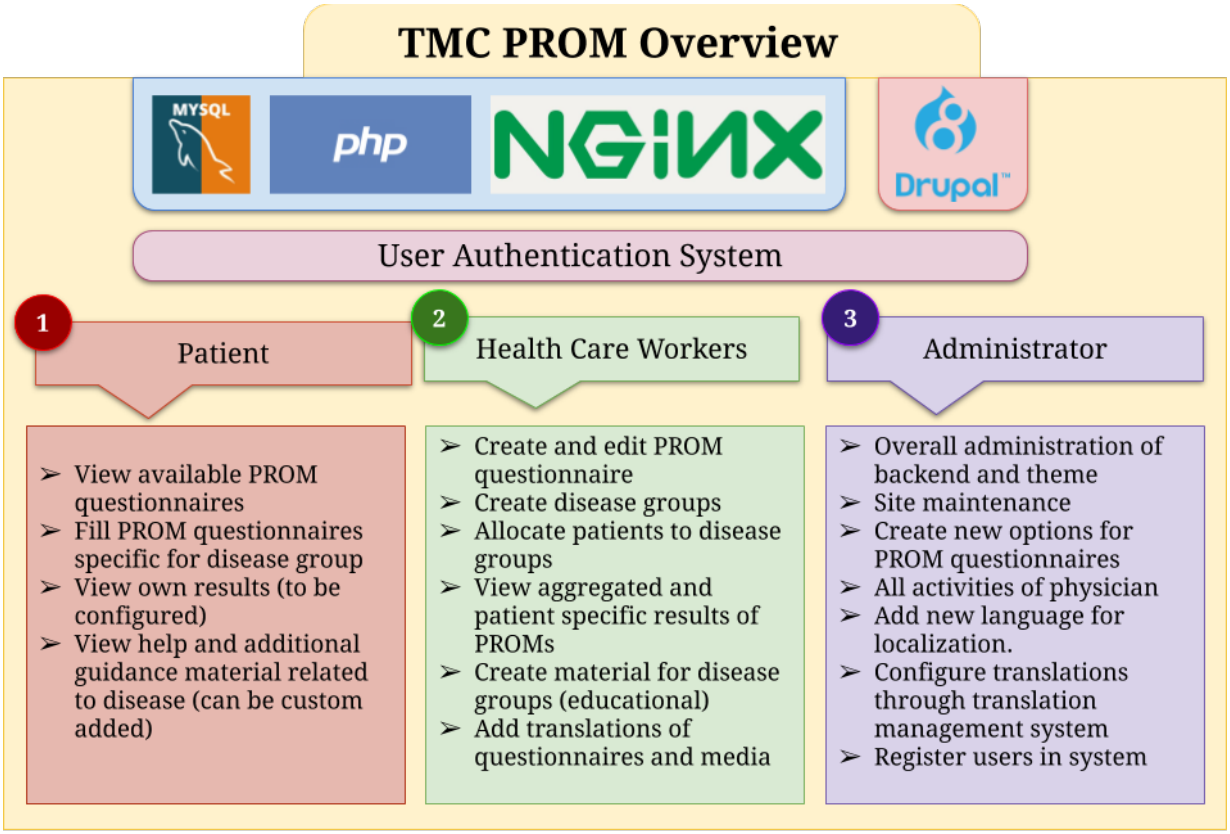

Figure 1: Overview of the Roles and Privileges available in the system

Access and Authentication

Drupal's innate authentication system relying on a username and password is used keeping in mind concerns regarding data safety and patient privacy. We plan to have an internal database of patient usernames against patient hospital unique IDs which will be maintained separately from the system. Administrators will be responsible for creating users and assigning them roles and privileges. No personal identifying information will be collected and retained in the system including patient name, age, gender etc.

Preliminary User Experience Testing

We determined that the key user of the system was the patient and we could expect that they would have a diverse range of literacy and proficiency with electronic devices. It was unlikely that a system could be designed such that users who had never used computers and smartphones could use the system without some help. However, from the patient's perspective, it was important to reduce and eliminate roadblocks on the system so that they required minimum assistance. While dedicated testing of the system would need real patients, we proceeded with an initial round of user experience testing such that some data is available as a benchmark for the planned validation studies in future. Physicians and other health care workers would usually be more proficient with the use of electronic devices but would need specific training in the site so that they can use it to maximum benefit.

To get a preliminary idea of the user experience of the website in the patient role, we invited laypersons to do a series of tasks on the website pretending to be a patient and then provide us with feedback on the tasks

performed. Social media contacts of authors were invited to participate in this testing. These were a mix of laypersons as well as physicians. We requested all participants to ask their parents and other senior family members to do the tasks if possible. The key tasks to be performed included:

1. Navigation to the website
2. Logging in to the website
3. Checking if changing the language was easy and working.
4. Find the available questionnaire
5. Fill the questionnaire
6. Fill a user experience questionnaire.

Three dummy patient accounts were created (one for each language - English, Hindi and Bengali) and assigned to the cervical cancer disease group. A document with instructions for the user experience testing was prepared in all three languages.

A dummy questionnaire was made available (a small subset of the European Organization for Research and Treatment in Cancer - EORTC quality of life (QLQ C30) questionnaire) and translated into the two Indian languages. Each question was presented in a single page and each question was accompanied with an audio prompt that allowed users to listen to the question in the language of choice. Time taken to complete the questionnaire was recorded in the system.

After the questionnaire was completed patients were automatically redirected to a user experience evaluation questionnaire. The questionnaire asked questions on whether there was any difficulty in performing the above tasks and gave the option to the user to give a free text opinion. Additionally, a few demographic questions were asked on patient age, gender, the device used for the task as well as the degree of proficiency with the use of computer or mobile.

Statistical Analysis

Descriptive analysis of the results of the user experience testing is presented. Summaries of continuous variables like time are presented using the median and interquartile range. For categorical variables frequencies are reported. Formal sample size calculations were not done and no group-wise comparisons have been performed.

Results

Website Development Status

Most of the functions identified in the requirements section have been successfully developed with minimal coding. Table 1 demonstrates the functionality achieved.

System Requirement	Development status
Easily installable on-premises to allow de-centralized data collection.	The entire configuration can be exported easily to set up the website. The CMS natively supports export and import of configurations. A Linux server running MySQL and Nginx can be easily set up even in a local area network using a virtual server or a physical server. System requirements are modest and available with most hosting providers.
Access control with different role-specific modular permissions to read, edit, revise.	Role-based permissions implemented as above (Figure 1). While currently not implemented, the system can be extended to allow further permissions based on-site in case two or more health care facilities decide to use the same system.
Should allow sharing of PROMs across installations using simple configuration files.	All patients are registered by site administrators and given an ID which is not the same as the hospital unique ID. No identifying information is collected. Webforms created on the site can be exported as YAML (YAML Ain't Markup Language) files along with cascading style sheet (CSS) based styling of the options as well as the translations. Media entities in the form will need to be exported separately. Custom options if used in the form need to be exported (can be exported together with any images used). Existing questionnaires on the site can be duplicated easily by users with appropriate permissions. Changing the question title is all that will be required if a questionnaire like the EORTC QLQ questionnaire is being deployed as the response options provided are the same.
Ability to be delivered across diverse digital platforms especially smartphones.	Theme tested with multiple device configurations especially smartphones with diverse resolutions. Testing has been done by users during user experience testing as well as through browser-based tools (Google Chrome Dev Tools and Firefox Developer Tools). Using the default responsive theme allows appropriate presentation and resizing of elements in the display.
Ability to deploy multiple types of PROM instruments simultaneously	5 different PROM questionnaires were developed on the site. The largest questionnaire had 37 questions. Custom option elements were used by each of the questionnaires. Once developed each questionnaire was made available to appropriate disease groups.
Ability to target specific groups of patients with disease-specific as well as generalized PROM instruments.	Achieved by the use of groups and building an entity relationship between the group and the form using a graphical interface. Access control implemented such that patients can view forms in their own group(s). Additional access control can be added to lock down access at webform level if required.
Ability to present questions one question at a time with minimal distractions.	Easily controllable through the use of wizard pages. One question is presented at a time. Additionally, the site elements like the main menu and header blocks are hidden using the available block visibility rules to ensure a distraction-free viewing experience to the user filling the form.
Ability to integrate multi-media prompts (audio/video) with text such that patients with limited literacy or reading problems can fill the	Media elements like audio and video can be uploaded. Language can be selected at the time of upload. Media module provides a system by which

The video in Appendix I below shows the functionality available on the site for health care workers (**??**).

The most important functionality is the visualization of the domain-specific scores obtained from the e-PROM questionnaires. These are automatically calculated and presented on the website. Each questionnaire has a dedicated page where the results of the questionnaire can be viewed easily. Graphical plots, as well as tabular summaries of the results, are presented. Additionally, the profile page of the patient also has the results of the questionnaire presented in a tabular and graphical format (Figure 3).

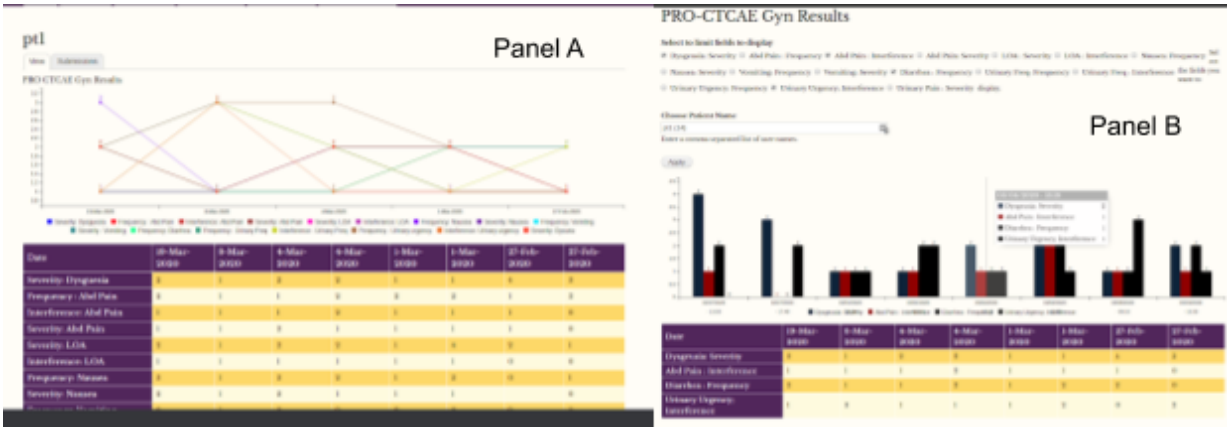

Figure 2: Panel A: Shows the results of the PROM domain scores for a single patient. Panel B : Shows the Results of PROM on the PROM result page. Note that the user can select which user to display by typing in the patient ID in the choose patient name box and limit the graph and table to display a restricted set of domain scores. The chart display can be customized. The date range can be restricted by the administrator and additional filtering options can be easily set up.

User experience testing

Out of forty-eight (48) persons who expressed interest in the user experience testing, thirty-one (31, 64.5%) persons participated in user experience testing. Of these, 74.1% (n = 23) were females, and 29% (n = 9) identified themselves as being over the age of 50 years. Most of the respondents had completed the survey on their mobile phones (71%, n = 22). Proficiency with computers and mobiles was rated as good to very good to excellent by 29% (n = 9) persons. The median time taken to navigate the test questionnaire with 5 questions was 1.2 minutes (IQR: 0.67 - 1.74 minutes).

A summary of the results is presented in the Table 2 below (2).

Question	Response Category	Number	Percentage
Were you able to go to the website easily ?	Yes	31	100.0%
	No	0	0.0%
How fast did the website load as compared to other websites you normally visit ?	Much Slower	0	0.0%
	Slower	0	0.0%
	About same speed	12	38.7%
	Faster	8	25.8%
	Much Faster	11	35.5%
Were you able to login to the website	Yes	31	100.0%
	No	0	0.0%
How many attempts did you make for logging in	One time	27	87.1%
	Two times	2	6.5%
	Three or more times	2	6.5%
Were you able to change the language easily	Yes	30	96.8%
	No	1	3.2%
Were you able to find the questionnaire easily	Yes	31	100.0%
	No	0	0.0%
Was the question easily readable in the form	Yes	31	100.0%
	No	0	0.0%
Were you able to hear the audio voice over easily	Yes	25	80.6%
	No	6	19.4%
Did audio voice over help to understand question better (missing = 1)	Definitely	11	35.5%
	Probably	10	32.3%
	Not sure	2	6.5%
	Probably Not	5	16.1%
	Definitely Not	3	9.7%
Did you need any help from anyone for completing the tasks (missing = 3)	Yes	2	6.5%
	No	29	93.5%

Table 2: Results of user experience testing questionnaire

The key feedback received from the participants included the following:

1. Changing the position of the language buttons to a more visible location (n = 1).
2. Voice quality in the audio voice-overs to be more natural (n = 2).
3. Improve the text matter in the login block to ensure that people understood that they have to log in using the information provided for them and no registration option was available (n = 1).
4. Improve the language translation to make it more colloquial (n = 2).

Discussion and Conclusions

A robust and versatile software tool could be designed which met almost all of the design objectives using an open-source content management system. This is a testament to the inherent flexibility and modularity of the system. The overall development took about 4 weeks with around 30% of the time being spent in theming and around 40% of the time devoted to developing the translated versions of the questionnaires.

At this stage, we have intentionally chosen to limit the patient-related information that the site collects especially with respect to identifying information. The system can be easily extended to collect any additional information the user desires. Additional integration with social sign-in and login modules can allow users to register and log in using their social media accounts. Two-factor authentication systems can be also implemented to improve security. Short messaging system (SMS) based login systems can be integrated to allow OTP based login. From a user experience testing, logging in possibly not essential for patients. However, some form of user authentication is necessary in order to ensure that longitudinal evaluation of user responses is possible. This can be achieved through the use of an invitation-based system which sends invites to the patient's emails. However, this would mean that the site will have to maintain a record of a patient identifier like email or phone in the system.

The results of the initial usability testing are encouraging enough to actually proceed with a full-fledged research plan for implementation of the system at ground level. Key inputs from the initial round of user testing revealed that most participants were able to access and fill the questionnaire in the expected time. As expected most participants found the audio voice-overs for the questions to be helpful. However, a more professional voice over should be employed when using for patients to convey empathy and emotional range. Additional media types like videos need to be explored.

The system offers an open-source alternative to resource-strapped health care systems in the country to implement PROM collection and usage. Questionnaire development, content development and site maintenance activities can be done using the graphical user interface. The key benefit of an e-PROM system is the ability to view patient results in real-time during a clinical encounter. The results of the patient should be ideally reviewed, discussed at the clinical encounter after the patient fills the questionnaire and appropriate supportive care offered where feasible. We plan to extend the health care worker interfaces for viewing the results further and integrate more sophisticated graphing and predictive modelling techniques in future iterations.

The system will be available for users from other centres across the country to deploy the system and implement their own version as they require. We as a group would be very happy to help and support implementation and usage. The system would be open to all interested users and we would freely provide a local copy for testing and usage without copyrighted questionnaires.

Quality of Life questionnaires from organizations like EORTC will require separate licensing agreements with the respective organizations before usage. However once the proof of licensing agreement is shown to us, we can export the form configuration easily to the user to minimize development time. The codebase of the system including the system configuration and the theme is available for reuse under a creative commons CC BY-NC license. We propose to test and extend this system further through a prospective study whereby this system will be presented to actual patients who are undergoing cancer therapy or presenting for their followup visits. The impact of this system on symptom discovery as well as the impact on patient-physician communication will be assessed in this study.

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developers of the Drupal CMS and the contributed modules, whose contribution allowed us to develop this system with minimal coding.

Supplementary Material

Rich media available at https://www.youtube.com/watch?v=nicVSi4Ch6E&feature=youtu.be

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