

TOM: Treatment Outcome Monitor - a web-based tool designed specifically for clinics with limited resources

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Introduction

Current evidence for treating cancer is almost entirely from the experience in high-income countries, with 90% of trials and more than 80% of participants coming from these countries [1]. This is despite the fact that it is predicted that three-quarters of the 13 million people who die from cancer globally in 2030 will be from low- and middle-income countries (LMICs) [2]. Globalization of clinical trials has improved slightly in the last decade, but many geographic regions have not benefited from these efforts – for example, Africa accounts for both 25% of the world’s disease burden and 17% of the world’s population, but hosts less than 2% of global clinical trials [3]. Beyond trials, cancer research (e.g. retrospective data analysis, which can provide useful understanding of diverse patient population) is also predominantly from high-income countries, with the volume of radiotherapy research output positively correlated with GDP [4].

There are many reasons for these disparities in cancer research [5]. One challenge that clinics in LMICs experience is a lack of infrastructure; this includes the use of electronic medical records (EMRs) for managing and recording patient follow-up [6]. Although known to offer improvements in patient management, the adoption of EMR is hindered in many countries (e.g. in sub-Saharan Africa) by the poor level of technological development, lack of required computer skills, and limited resources [6].

In response to this background, we initiated the TOM (Treatment Outcome Monitor) project. This project aimed to create a light-weight digital solution that can easily record patient visit data, that is designed in collaboration with future end-users in resource-limited clinics, and is responsive to their unique needs, focused on outcome studies.

Here we report the output of this project in terms of user interfaces and user feedback. This information will be useful to other software developers when creating tools for a similar user group.

Methods

This software was developed in a series of extended sprints, with continual feedback from potential users, 4 major focus group meetings, and a final usability evaluation.

Key functions of the software include creation of customized toxicity questionnaires using standard libraries, cloud-based operation to allow patients to report symptoms and toxicities remotely and in real time, and exporting features for clinical researchers to compile population outcome data and seamlessly use in modeling and outcome analyses.


User instructions

Instructions for use were generated for the following tasks, shown in the following figures.

1. How to create a questionnaire
2. How to add questions to a questionnaire
3. How to re-order questions on the questionnaire page
4. How to remove questions from a questionnaire
5. How to print a questionnaire
6. How to send answer questionnaire (for staff completion)
7. How to request the patient to answer the questionnaire
8. How to view a patient's history (minimal patient details, questionnaire completion status)
9. How to close/archive a questionnaire




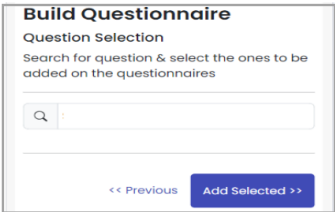
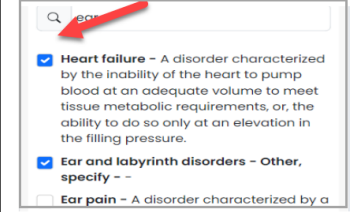
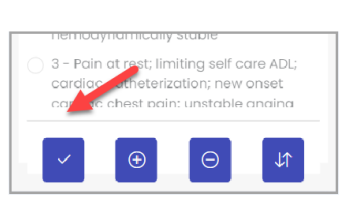
These instructions were used to support the user testing.

Figure 1. How to create a questionnaire



How to create a Questionnaire

Create a Follow Up Assessment that can be sent to the patient

 <p>1 Select "My Questionnaires"</p>	 <p>2 Select "Create New Questionnaire".</p>	 <p>3 Name your questionnaire and add details such as a description. You will also select your Questionnaire Library on this screen (CTCAE or PRO-CTCAE)</p>
 <p>4 Search for key words to retrieve questions that can be added to the assessment.</p>	 <p>5 Select the questions you want to add to the questionnaire and click "Add Selected"</p>	 <p>6 Review the Questionnaire for completeness and select the check icon to finalize the questionnaire.</p>

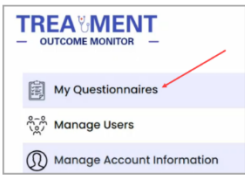
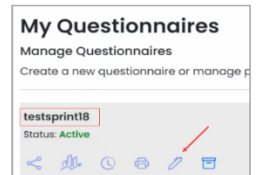
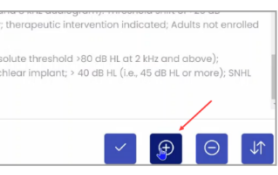
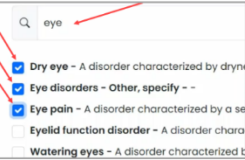
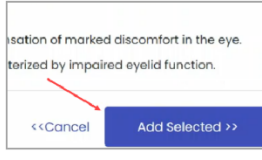
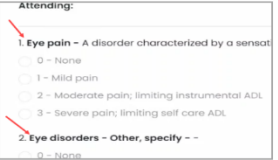
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Figure 2. How to add questions to a questionnaire

NEW!

How to add questions to a questionnaire

Using the Edit icon to add more questions to the questionnaire

 <p>1 Select "My Questionnaires"</p>	 <p>2 Select the "Pen" icon to edit a questionnaire</p>	 <p>3 Select the "+" symbol to edit and add questions</p>
 <p>4 Search for topic in library, and select as many responses as needed.</p>	 <p>5 Select the "Add selected" button to add response(s)</p>	 <p>6 The Questionnaire preview page would display the responses that have been added.</p>

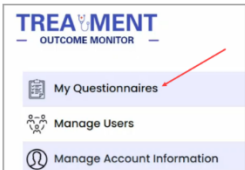
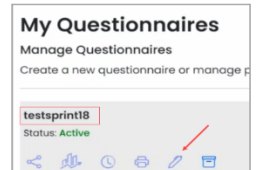
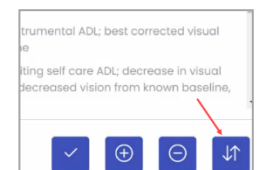
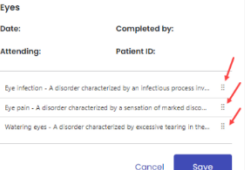
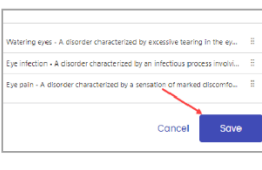
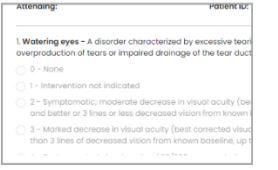
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Figure 3. How to re-order questions on the questionnaire page

NEW!

How to re-order questions on the questionnaire Page

Using the "re-order" icon to rearrange questions on the screen.

 <p>1 Select "My Questionnaires"</p>	 <p>2 Select the "Pen" icon to edit a questionnaire</p>	 <p>3 Select the "re-order" symbol to move the questions up or down</p>
 <p>4 Use the icon on the right to re-order questions by moving up or down.</p>	 <p>5 Select the "Save" button.</p>	 <p>6 The Questionnaire preview page shows the questions in modified order.</p>

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Figure 4. How to remove questions from a questionnaire



How to remove questions from a questionnaire

Using the "-" icon to remove questions on the screen.

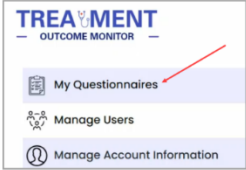
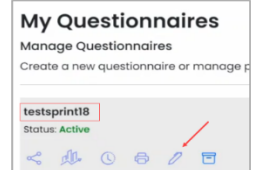
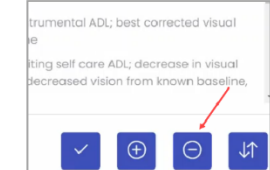
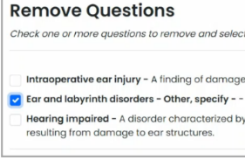
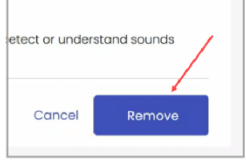
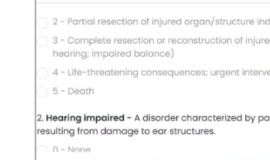
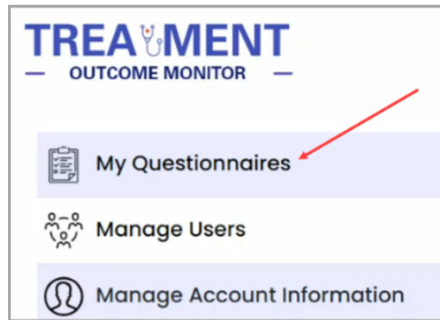
 <p>1 Select "My Questionnaires"</p>	 <p>2 Select the "Pen" icon to edit a questionnaire</p>	 <p>3 Select the minus "-" symbol to edit and add questions</p>
 <p>4 Select the question(s) to remove.</p>	 <p>5 Select the "Remove" button.</p>	 <p>6 The Questionnaire preview page shows that the question has been removed.</p>

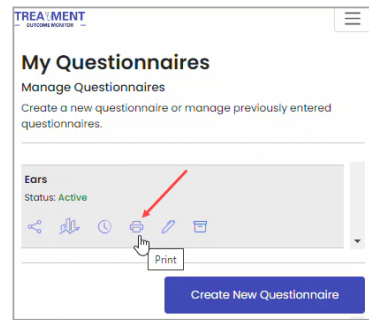
Figure 5. How to print a questionnaire

How to Print a Questionnaire.

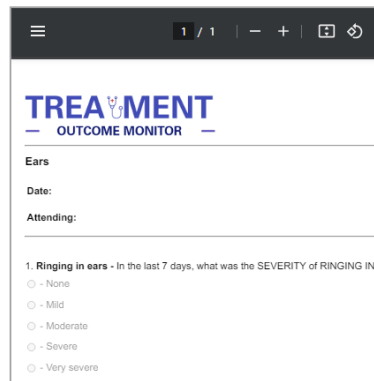
Using the "Print" icon to download the questionnaire.



1 Select "My Questionnaires"




2 Select the "Print" icon to print a questionnaire



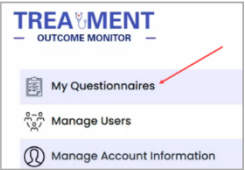
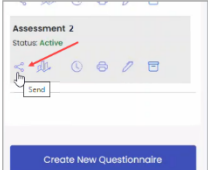
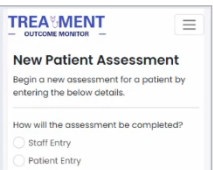
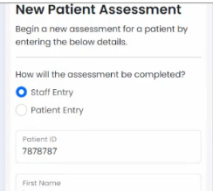

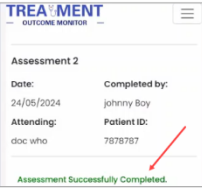
3 A copy of the Questionnaire would be downloaded in a new tab

Figure 6. How to send answer questionnaire (for staff completion)




How to send the questionnaire. (Staff Entry)

Using the "Send" icon to send the questionnaire to a Staff

 <p>1 Select "My Questionnaires"</p>	 <p>2 Select the "Send" icon to send the questionnaire</p>	 <p>3 Select to send questionnaire, either as a "Staff Entry" or a "Patient Entry".</p>
 <p>4 For "Staff Entry", enter the patient details and select the "Enter Assessment" Button</p>	 <p>5 The staff is brought to the assessment page, staff provides the response, and selects the "Submit Assessment" button</p>	 <p>6 Staff will view the message "Assessment Successfully Completed."</p>

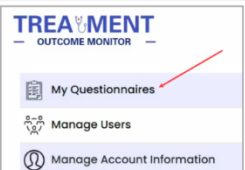
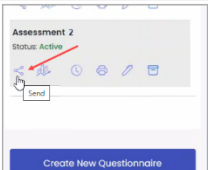
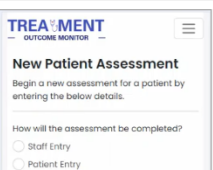
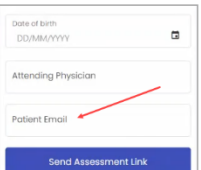
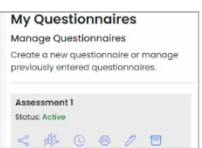
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Figure 7. How to request the patient to answer the questionnaire



How to send the questionnaire. (Patient Entry)

Using the "Send" icon to send the questionnaire to a Patient.

 <p>1 Select "My Questionnaires"</p>	 <p>2 Select the "Send" icon to send the questionnaire</p>	 <p>3 Select to send questionnaire, either as an "Staff Entry" or a "Patient Entry".</p>
 <p>4 For "Patient Entry", enter the patient details and select the "Enter Assessment" Button</p>	 <p>5 Ensure the patient email address is accurate, and select the "Send Assessment Link" button</p>	 <p>6 A link to the questionnaire is sent to the patient's email to complete the assessment. The system directs user back to the "My Questionnaires" page.</p>

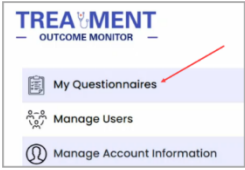
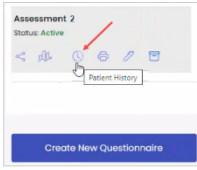
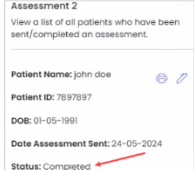
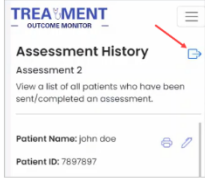
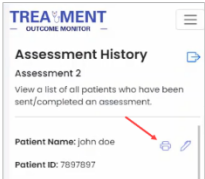
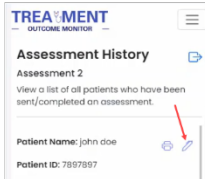
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Figure 9. How to view a patient's history (minimal patient details, questionnaire completion status)



How to view a patients history.

Using the "Patient History" icon.

 <p>1 Select "My Questionnaires"</p>	 <p>2 Select the Clock icon to view the list of all patients who have been sent that assessment</p>	 <p>3 The Assessment History page shows patient details and if Assessment Status is Completed (Submitted), Pending (Not Submitted), or Expired (not completed within 14 days).</p>
 <p>4 Select the "Export All" icon to download all the questionnaire history to an excel spreadsheet.</p>	 <p>5 Select the "Print" icon to print the specific questionnaire and Patient answers if it has been submitted/provided.</p>	 <p>6 Select the "pencil" icon for changes to the Patient Name, Patient ID, and DOB fields only.</p>

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Figure 10. How to close/archive a questionnaire

How to close / Archive a questionnaire

Using the "Inactivate" icon to close a questionnaire

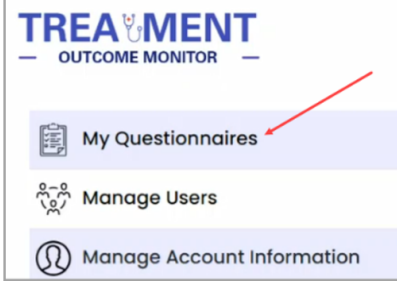
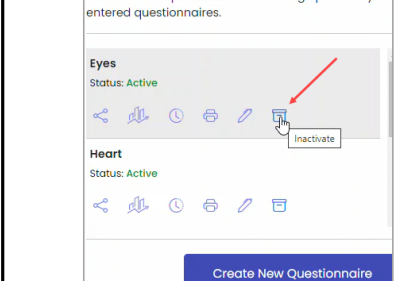
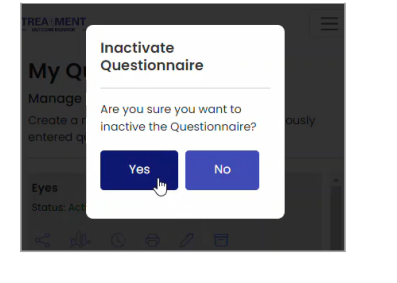
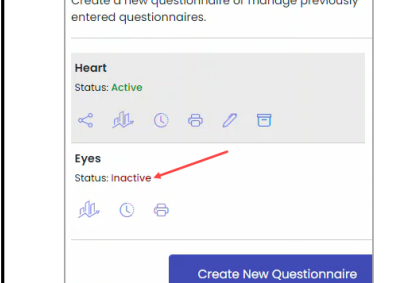

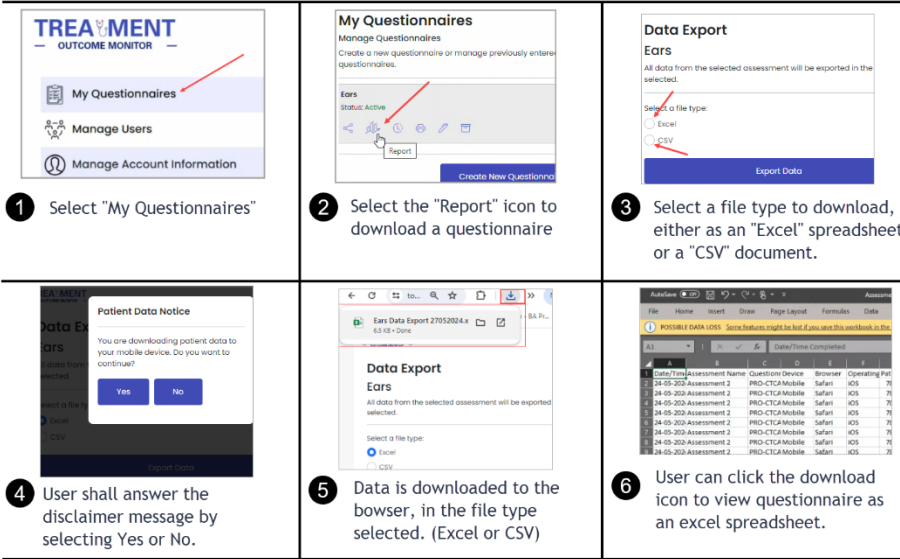
 <p>TREATMENT OUTCOME MONITOR</p> <p>My Questionnaires</p> <p>Manage Users</p> <p>Manage Account Information</p>	 <p>Create a new questionnaire or manage previously entered questionnaires.</p> <p>Eyes Status: Active</p> <p>Heart Status: Active</p> <p>Create New Questionnaire</p>
<p>1 Select "My Questionnaires"</p>	<p>2 Select the "Trash can" icon to close / inactivate a questionnaire in "Draft" status.</p>
 <p>Inactivate Questionnaire</p> <p>Are you sure you want to inactivate the Questionnaire?</p> <p>Yes No</p>	 <p>Create a new questionnaire or manage previously entered questionnaires.</p> <p>Heart Status: Active</p> <p>Eyes Status: Inactive</p> <p>Create New Questionnaire</p>
<p>3 User shall answer the warning message by selecting Yes or No, to make the questionnaire inactive.</p>	<p>4 The Questionnaire preview page would display the questionnaire with status of "Inactive".</p>

Figure 10. How to export data



How to download a questionnaire

Using the "Report" icon to download a questionnaire.



- 1 Select "My Questionnaires"
- 2 Select the "Report" icon to download a questionnaire
- 3 Select a file type to download, either as an "Excel" spreadsheet or a "CSV" document.
- 4 User shall answer the disclaimer message by selecting Yes or No.
- 5 Data is downloaded to the browser, in the file type selected. (Excel or CSV)
- 6 User can click the download icon to view questionnaire as an excel spreadsheet.

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Usability testing

A research version of the TOM software was made available on invitation, with a user code. The user group members then asked colleagues to use the software. After completing each task, they were asked to score the task using the following metric:

- How confident are you that you completed this task correctly?
1 (not confident) 2 3 4 5 (very confident)
- How easy was this task to complete?
1 (very difficult) 2 3 4 5 (very easy)

Results

Lessons learned during feedback sessions

The feedback sessions included demonstrations of partially completed sections of the software, generally followed by open discussion. Some key points that were brought up by the team include:

- Internet connectivity. Allow for questionnaires to be printed out in advance, so they can be completed even if internet connectivity is lost
- Patient return. Many patients do not return for follow up visits. Many do have cell phones with email and/or text ability. TOM needs function to send messages to patients.
- Web-based solution. Build a web-based solution as potentially cheaper to maintain than smartphone applications.
- Question database. Patient Reported Outcome (PRO) and Common Terminology Criteria for Adverse Events (CTCAE) question/scoring databases were incorporated into version 1.

The following features were discussed as useful, but reserved for version 2:

- Questions. The ability to customize questions.
- Languages. The ability to work with different languages

User instructions

User instructions are reproduced in the Appendix.

User feedback

Feedback surveys were completed by 6 radiation oncology professionals, 4 oncologists, 1 oncology surgeon, and 1 medical physicist. Five users gave 4 or 5 for all tasks (ease of use and confidence). One user gave 3s for 6 tasks and 4s for 3 tasks for confidence. For confidence that user gave 3s for 3 tasks and 4s for 6 tasks. Overall, the tasks were scored 4 or 5 for 92% of responses (99/108).

Conclusions

A prototype system was developed and successfully tested. The next step is to clinically deploy TOM in partner sites such that it can be used for clinical data collection.

References

1. Heneghan, C., et al., *Evidence for non-communicable diseases: analysis of Cochrane reviews and randomised trials by World Bank classification*. *BMJ Open*, 2013. **3**(7): p. e003298.
2. The, L., *GLOBOCAN 2018: counting the toll of cancer*. *The Lancet*, 2018. **392**(10152): p. 985.
3. Ibraheem, A., et al., *Cancer Clinical Trials in Africa—An Untapped Opportunity: Recommendations From AORTIC 2019 Conference Special Interest Group in Clinical Trials*. *JCO Global Oncology*, 2021(7): p. 1358-1363.
4. Aggarwal, A., et al., *Radiation Therapy Research: A Global Analysis 2001-2015*. *International Journal of Radiation Oncology*Biography*Physics*, 2018. **101**(4): p. 767-778.
5. Grover, S., et al., *Clinical trials in low and middle-income countries — Successes and challenges*. *Gynecologic Oncology Reports*, 2017. **19**: p. 5-9.
6. Odekunle, F.F., R.O. Odekunle, and S. Shankar, *Why sub-Saharan Africa lags in electronic health record adoption and possible strategies to increase its adoption in this region*. *International journal of health sciences*, 2017. **11**(4): p. 59-64.