SOLIDIFYING USABILITY TESTING GUIDELINES FOR eCOAs FROM THE PATIENT PERSPECTIVE

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INTRODUCTION:

Usability Testing (UT) is a qualitative and patient-centred process that 'tests the device or application usability and functionality of electronic Clinical Outcome Assessments (eCOA) formats from the patients' perspective' (Kaul et al 2021: p. 3). UT is designed to be an objective means of eliciting the patient experience with an eCOA on a user interface system. According to Aiyegbusi (2020: p. 326), 'it is … crucial that the user-friendliness and usability of the ePRO user interfaces are adequately assessed and improved throughout system development to reduce attrition rates in clinical trials and enhance their adoption post-implementation in clinical practice.'

Where an instrument has been designed specifically for electronic administration through an app on a smartphone (*de novo* electronic COAs), tablet, or any other device, UT helps to:

a. Measure operational efficiency of the eCOA system

b. Recognize any design issues of the eCOA that are likely to cause patient dissatisfaction and impede with the data collection process

c. Examine any opportunities to improve the software and the eCOA wording and design

d. And, understand how patients/participants interact with the interface and eCOA.

The patient perspective and experience are the focus of the UT process in order to validate an app or eCOA device for use among a specific patient population. This is particularly important if the questionnaires' target patient-population experience physical or visual accessibility issues due to their disease, symptoms, or common treatment side effects. Lee et al (2022) in discussing factors that are associated with the adoption and compliance of electronic patient-reported outcome measures (ePRO) with cancer patients undergoing active treatment stress the importance of patients having digital technology knowledge in order to be able to use an ePRO. In fact, Hartkopf et al (2017) highlight in their study with breast cancer and metastatic breast cancer patients in nonexposed (i.e. no exposure to electronic assessment) and exposed (i.e. after exposure to electronic assessment and whether there was preference for a tablet-based questionnaire) settings that there were quite a few barriers for implementing ePROs in clinical practice (e.g., lack of technical knowledge and experience, discomfort when using technology, etc.).

For any eCOA device or app, the richness of feedback that UT provides depends upon deploying: a) a patient-centred approach by utilizing a tailored and task-based interview script; and b) sufficient demographic variability in the tested sample to ensure successful use by patient populations that may differ in age, educational attainment, disease burden, cognitive impairment, and visual or motor impairments.

METHODS:

This paper presents qualitative findings from a UT project conducted with 14 cancer patients, split into two groups of 7, each group testing different devices (smartphone or tablet). Demographic characteristics are shown in Table 1.

We tested a *de novo* eCOA using provisioned devices (a smartphone and tablet) to determine:

a. The overall usability of the interface and how intuitive it is for patients (e.g., navigation through the questionnaire[1]);

b. Overall usability of the questionnaire along with an evaluation of its readability and clarity of content (e.g., are patients able to follow instructions or troubleshoot without needing an administrator?); can they perform the tasks required of them (e.g., enter text, select an answer on a slider scale)?

The UT interview was task-based (see Table 2) and required patients to complete a number of different tasks which allowed the interviewer to observe any challenges participants faced when they performed them. The interviewer used pre-designed and customised interview scripts for the specific devices and eCOA apps.

Participants were encouraged to verbalise challenges they faced / overall impressions while using the devices and apps, such as: comprehending questions in the instrument; answering different types of questions via the interface, such as inserting text, dates, or using sliders; and, being able to set up user profiles or access the app from the device home screen.

A qualitative analysis of the results informed the development of guidelines and recommendations based on the participants' experience.

Table 1: Patient Demographic Info (N=14 in total across devices)

Smartphone: N=7; 4 males, 3 females; Age Range of Participants= 18-75 (av age: 54.7; std dev: 16.68); Average Academic Education (years) = 12.86

Tablet: N=7; 3 males, 4 females; Age Range of Participants= 26-75 (av age: 50.5; std dev: 12.9); Average Academic Education (years) = 12.6 years

Subject #	Age (years)	Sex at Birth	Academic education (years)	Visual Impairment	Motor Impairment
SM1[2]	56-65	M	14	Refractive eye problems: Both	Tremor of the hands was noticeable
SM2	56-65	F	12	Glasses for both myopia and hyperopia	Poor circulation
SM3	56-65	M	10	Myopia and hyperopia	Tremor of the hands was noticeable
SM4	66-75	M	16	Reading and distance glasses	None
SM5	18-25	F	14	No visual impairments	Difficulty walking
SM6	66-75	M	12	Glasses for myopia and hyperopia	Tremor of the hands
SM7	56-65	F	12	Reading Glasses	None
TBL1	66-75	F	12	Glasses, refractive eye problems, both myopia and hyperopia	None
TBL2	56-65	F	14	Myopia. Wears reading glasses as well	Poor circulation
TBL3	46-56	M	14	Far sighted, wears glasses	Difficulty walking
TBL4	26-35	M	12	Myopia, glasses	Uses a motorized wheelchair
TBL5	36-45	F	12	None	Some problems walking
TBL6	46-55	F	14	Wears contacts	None
TBL7	46-55	M	10	Wears contacts	Poor circulation

Table 2: The task-based interview script elicited feedback that focused on the following areas

Demographic information

age; gender; academic education; visual/motor/language impairments

Task completion

- Accessing the devices (from a sleep mode)
- Entering/accessing the questionnaire though a specified app
- Navigating through the instrument (e.g., next/back/exit buttons)

Readability and text clarity and comprehension evaluation

All instructions and questions in the instrument were subjected to feedback to establish the ease of readability and comprehension

Responding to defined questions/tasks

- Testing 1 vertical and 2 horizontal sliders
- Selecting multiple answers from a list; selecting a single answer; selecting an answer from a set of responses; selecting a single answer from a drop-down menu
- Entering a date in the past (by accessing a calendar on the instrument); selecting time (hours and minutes appearing on screen); entering time and date
- Entering/typing text as an answer
- Selecting a number (numerical scale from a drop-down menu); entering a number answer; selecting a number from 1-10
- Selecting a number from 1-10 to assess software satisfaction
- Selecting a number from 1-10 to assess comfortability in using the software unassisted.

RESULTS:

Feedback from participants and the interviewer revealed a number of issues that were graded in terms of severity and resolved accordingly, and confirmed the utility of the patient-centred approaches deployed here in establishing and improving usability of the eCOA solution.

Overall, the patients expressed relative confidence and comfort in using the study smartphone and tablet without any remarkable differences across sex, age group, and level of education.

Participants with visual and motor challenges noted that using a small device, such as the study smartphone, was challenging and required adjustment (for example, some had to improvise by using their own phone holding devices to be able to hold the phone with one hand and complete the questionnaire with the other, or some had to place it on a table to be able to complete the questionnaire). These participants also experienced challenges with the larger tablet device due to it being difficult to grip or hold.

No problems concerning readability, text clarity, and comprehension were noted. The instructions, questions, and tasks were clearly understood by participants in both groups. In terms of device intuitiveness, the patients self-rated their frequency in using electronic devices along with their confidence levels and their frequency in using specific apps on electronic devices:

- patients indicated frequently using electronic devices (7/14 using devices all the time; 6/14 often; 1/14 sometimes) and showing confidence with the use of electronic devices (4/14 completely confident; 4/14 very confident; 4/14 somewhat confident; 2/14 a little confident)
- frequency in using specific apps on smartphones and tablets (6/14 all the time; 2/14 often; 2/14 sometimes; 4/14 rarely).

In terms of task completion, patients were also able to enter the questionnaire and navigate through the instrument successfully without any difficulties.

The primary concerns raised during UT revolved around completing specific tasks. These are summarised here:

Readability, and text clarity and comprehension evaluation:

- Some additional guidance needed around inserting dates/times (see next bullet point) but these can be resolved with a more intuitive inserting date/time task

Responding to defined questions/tasks: we highlight here specific tasks that have caused issues during UT:

- Date and time entry difficult; not intuitive or lacking critical functionality (3/7 smartphone users faced difficulties; 4/7 tablet users)
- Slider use (horizontal/vertical) & functionality:
  - Sliders in general can be challenging to use.
  - The vertical slider with a numeric scale enabled patients to make a more precise placement on the scale (see Figure 1).
  - Horizontal sliders (see Figures 1&2) (a): were more challenging to use especially for patients with hand dexterity issues.
  - Horizontal sliders (b): patients did not feel they could always place the slider where they needed it to be placed.

Figure 1: Vertical slider

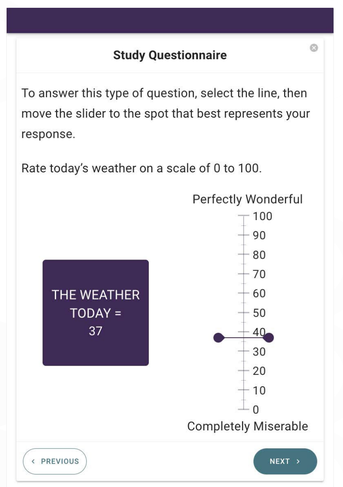


Figure 2: Horizontal slider (i)

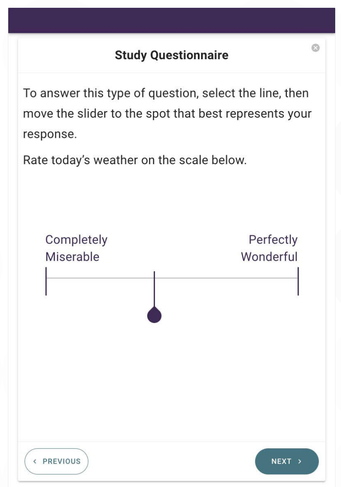
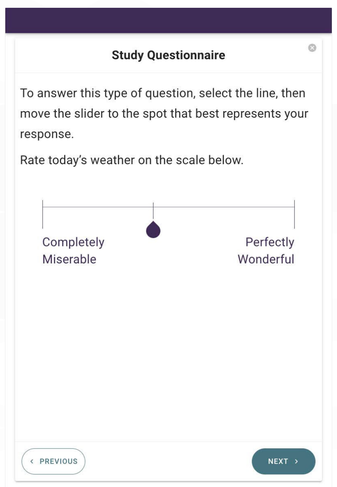


Figure 3: Horizontal slider (ii)



- Size of text too small throughout questionnaire (2/7 smartphone users; 3/7 tablet users).
- Inconsistency in settings of provisioned devices both within and across device types (e.g., screen orientation settings).
- Patients reported having to tap twice on some occasions to register their responses. This might be a device issue rather than an eCOA issue (3/7 smartphone users; 4/7 tablet users).
- Patients reported that the screen dims too quickly and they were not aware how to manage this (3/7 smartphone users; 4/7 tablet users).
- Patients commented that they would have liked a screen cover with the device so they can feel that they have a better grip of the device whilst completing the questionnaire (7/7 smartphone users; 4/7 tablet users).

CONCLUSIONS:

The essence of usability testing is the patient experience. An eCOA design needs to be tested against a small focus group of its intended users who are representative of the questionnaire's target demographic.

The assessment of the user interface and the interaction between the patient/user and the system needs to also address questions around accessibility and inclusion of various populations. Aiyebgusi (2020: p. 325) stresses that whereas there has been an increase in the ownership of electronic devices worldwide, this has not been at the same rate in developing countries vs developed countries. There has also been a narrowing in the digital divide between older and younger generations, but again that divide still exists. Thus, an important focus of UT should be in becoming more inclusive in terms of the patients/participants recruited for the testing in order to make appropriate enhancements to usability (e.g., testing in both developed and developing countries; testing with both young and old populations).

Another area of focus in UT should be on patients/participants exhibiting physical and visual accessibility challenges. The way a patient with accessibility issues experiences the completion of a trial questionnaire on an electronic device is qualitatively different than a participant without any accessibility issues. Trial devices need to accommodate the needs of all patients in order to ensure that the patient population recruited is representative and inclusive.

Usability testing overall has an important role to play in ensuring successful and effective data collection for eCOA platforms in clinical trials. As the need for electronic administration will increase further, considerations outlined here will need to become an integral part of the process.

References

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Footnotes

1 The instrument was a designed training questionnaire to help patients familiarize themselves with the different types of questions/answers they will need to complete during a clinical trial.

2 SM1 (SM stands for Smartphone); TBL1 (TBL stands for Tablet).