Lessons Learnt from a Qualitative Study for Best Practice ePRO Implementation in Oncology Clinical Trials

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BACKGROUND

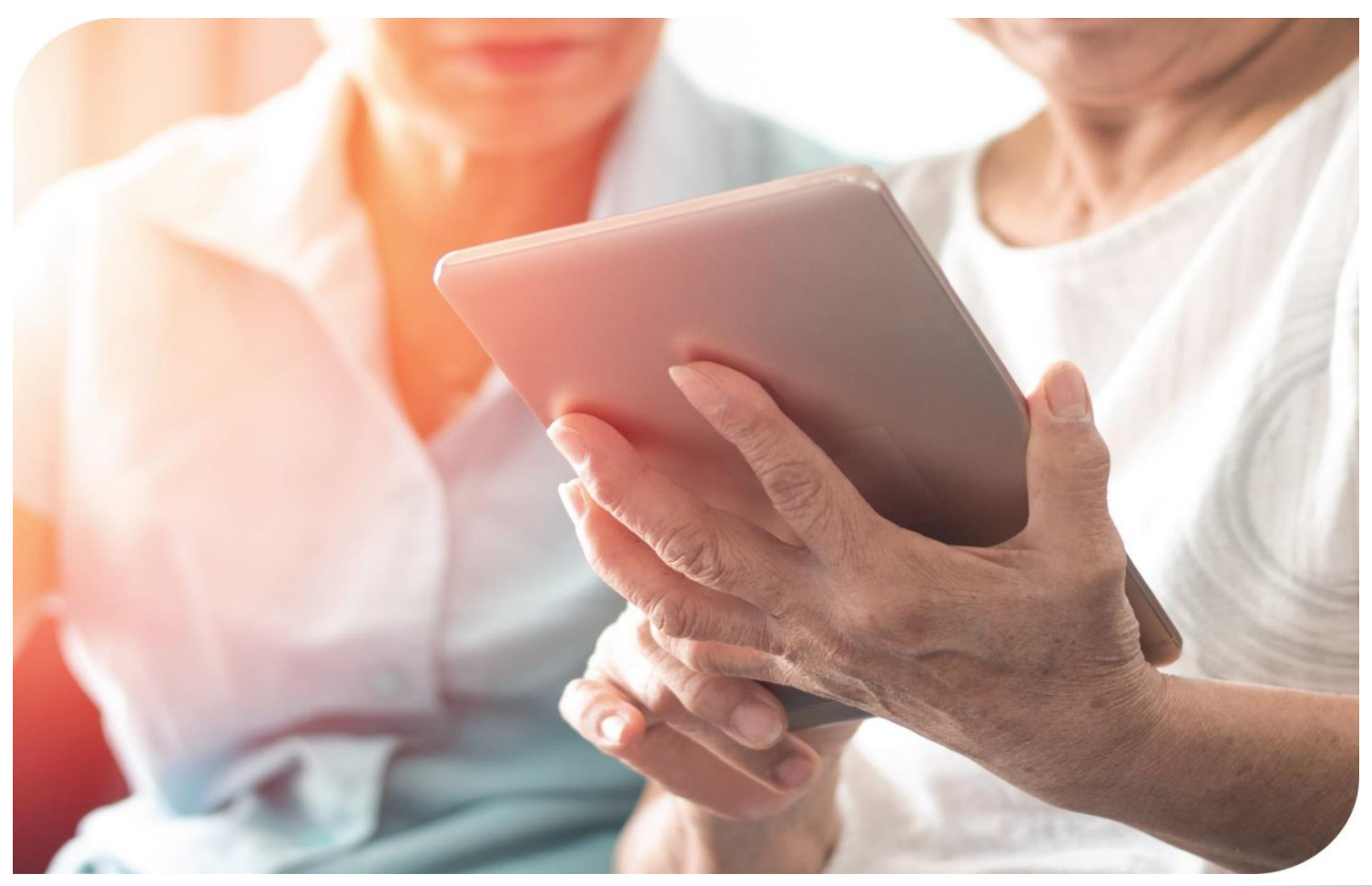
- In oncology the patient's voice is critical to ensuring the development and provision of patient-centric healthcare.
- The importance of utilizing PROMs in drug development has been emphasized by regulatory agencies (e.g., FDA) [1]; they are now routinely implemented as endpoints in oncology trials to measure disease symptoms, side effects, physical function and health-related quality of life [2], and increasingly used in labelling claims. [3]
- Implementing PROMs electronically represents a robust solution for collecting patient-reported data, at site-based visits and outside the clinical setting. ePROMs enable improved data quality due to inbuilt branching (to eliminate conflicting entries) and edit checks to eliminate invalid or missing responses; and improved data integrity including transparent attributability due to electronic signature and contemporaneousness due to completion windows, reminders, and time stamped entries.
- However, ePROMs may be influenced uniquely by the impact of the disease and treatment on the patient; for example, due to deteriorating health and/or cognitive difficulties.[4] Given the benefits offered by electronic measurement, it is imperative to understand the use of ePROM technologies in this disease population and if device functionality is 'fit for purpose' for oncology studies.

Aims

1) **Qualitatively investigate the challenges experienced by oncology patients that affect device use for recording ePROMs.**
2) **Use this qualitative data to inform recommendations for industry best practice of ePROM implementation in oncology clinical trials.**

PROMs: Patient Reported Outcome Measures;
ePROMs: electronic Patient Reported Outcome Measures

METHODS



Sample: 7 participants (3 males), aged 30-68 years (*Mean:* 54.75) who had undergone or were currently undergoing cancer treatment. All reported digital use of a smartphone and/or tablet.

Interviews: Semi-structured 1-to-1 interviews lasting ~90 mins. Participants were given a tablet and smartphone with Signant Health's TrialMax solution installed to interact with.

Analysis: Interview video recordings underwent thematic analysis.

RESULTS

EMERGING THEMES WITH IMPLICATIONS FOR DEVICE USE:

Peripheral neuropathy of the hands: 57%

"Sometimes you just cannot use your hands…that can last for a day or two… it wouldn't be a problem though… you're not so bad that there is nothing you can do that whole 24 hour period"

"The numbness in the fingers makes precise actions very difficult and frustrating."

"I prefer to use a phone…you don't want to do…writing and it's more easy to tap"

Fatigue and/or concentration issues : 86%

"Since I've had cancer, my reactions and things have slowed down… it's the illness and the treatment"

"I did find it difficult to concentrate cause it does make you very tired… it probably reduced my interaction with the phone"

- When asked about experiencing 'chemobrain' 29% said yes (n=2).
- No readability issues with the information on the devices were reported.

Time-point in treatment cycle/regime: 71%

"On the first session I was very ill, you have it every two weeks the chemo, but after a certain period you get to adapt to it…I could still text I just couldn't really hold a conversation"

"I did have a bit of problems with it but that was just in the early days if you had told me to do this everyday it would be like 'oh no', but I think I would have found some way of doing it though, so no no it wouldn't be a hardship"

SUGGESTED SOLUTIONS TO IMPROVE USABILITY:

"Save it and go back to it...if you are not a well person like I wasn't"

"The bigger the buttons, the better"

"I think you should be able to go in when you can…sometimes you cannot do things in set times"

Participants had a positive attitude towards ePROMs (preferred to paper). Caregivers assisting/completing on the patient's behalf was not a favoured solution (due to not wanting to worry their partner or for them to know how bad they were feeling). Voice assistants tended not to be a popular solution, there were mixed views on stylus use, and BYOD was mentioned as preferred/easier.

CONCLUSIONS

Findings suggest that the following recommendations for best practice of ePROM implementation in oncology clinical trials would optimize electronic solutions for this therapeutic population, and have the potential to improve data quality:

a) Utilize larger, well-spaced buttons.
b) Present all question text and response options together to reduce the reliance on participants needing to remember the question recall period.
c) Enable some flexibility in the time window that participants complete the eDiary/questionnaire.
d) Allow users to pause a survey/questionnaire and return to complete at a later point.
e) Provide a stylus so that patients have this option.
f) If suitable, implement PROMs on the participant's own device via an app/web-based solution (BYOD).
g) Automated completion reminders.
h) Being sensitive that participants may prefer to not complete PROMs, rather than asking for caregiver assistance.
i) Simple approaches for PIN reset and to access simple quick reference guides.

REFERENCES

[1] Fiero et al. (2019). *Lancet Oncology*.
[2] Basch et al. (2012). *Journal of Clinical Oncology*.
[3] Gnanasakthy et al. (2019). *Value in Health*.
[4] EMA (2014). Appendix 2 to the guideline on the evaluation of anticancer medicinal products in man

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