

The PROMIS of electronic patient-reported outcomes

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Abstract

Paper-based questionnaires are in widespread use for patient-reported outcomes, but they can be an inefficient way of collecting patient data. Electronic patient-reported outcomes are of wide interest and have the potential to drastically change patient data collection for the better. In particular, computer-adaptive tests can reduce the question burden for everyone involved. The US National Institutes of Health has funded the development of the Patient-Reported Outcome Measurement Information System. This exciting technology is being employed in many disciplines, including orthopaedic research.

Paper vs. electronic data collection

Most patient-reported outcome measurement tools (PROMs) were designed for paper-based collection of patient-reported outcomes (PROs). However, “question fatigue” can be a problem with this format, especially because patients are often tasked with completing more than one measure at follow-up visits to the clinic. Collecting and analysing paper questionnaires also presents logistical and cost problems to researchers.¹

Electronic patient-reported outcomes (ePROs) have therefore been suggested as an improvement. A report from the International Society for Pharmacoeconomics and Outcomes Research PRO Mixed Modes Task Force stated, “Advantages of using electronic data collection include less subject burden, avoidance of secondary data entry errors, easier implementation of skip patterns, date and time stamping, reminders/alerts, edit checks, and more accurate and complete data.”² A systematic review and meta-analysis of studies conducted between 2007 and 2013 found that “PROMs administered on paper are quantitatively comparable with measures administered on an electronic device.”³ However, ePROs have some potential disadvantages, including the costs associated with a custom-built

platform.⁴ Others critique the difficulties in reaching the correct patient population. For example, can a 95-year-old patient really be tech savvy? Collecting patient data also immediately brings issues of security, privacy, and confidentiality to the fore.⁵

ePROs are still relatively new, and, as with all new technologies, not everyone will be an early adopter.⁶ So, is the implementation of ePROs in a busy hospital feasible? One study examined the introduction of ePRO systems in two orthopaedic clinical practices.⁷ Patient completion rates were 93% and 95% in the two clinics. For comparison, annual paper-based completion rates were as low as 30.6% for patients undergoing total joint arthroplasty at a single academic medical centre in San Francisco.⁸ Thus, the authors conclude that “an electronic system to capture PRO in real time is feasible without any major disruption to the clinical work flow.”⁷

Creating a powerful and validated ePRO platform

With all of these issues in mind, government-funded organisations worldwide have invested in developing standardised and usable patient-reported outcome instruments.^{9,10} In 2004, the US National Institutes of Health began developing the comprehensive Patient-Reported



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Outcome Measurement Information System (PROMIS®).¹⁰ This initiative aims to substantially improve the standards for assessing self-reported health status. Over 300 measures of physical, mental, and social health are available for use in the general population (adults and children) and individuals with chronic conditions.¹¹ The PROMIS measures have been tested and validated in large reference populations, making them suitable for research on different health conditions.¹²

The PROMIS initiative has generated a reliable and, oftentimes, more sensitive system than traditional PROs, customised to the patient, which poses fewer questions.^{13–17} A systematic review of legacy patient-reported outcome measures to PROMIS in an orthopaedic setting stated that PROMIS measures “can be administered quicker and applied to a broader patient population while remaining highly reliable”.¹⁸

PROMIS utilises item response theory. In short, after the first test question (item), all following items are based on the answer to the preceding question. For example, if a person says they cannot walk 15 metres without pain, it is clear that pain interferes with their life and there is therefore no need to ask any questions related to hiking or contact sports. All subsequent questioning is meant to calibrate just how bad their pain interference is. Can they walk 5 metres without pain? Are they able to get out of bed? It is then possible to rapidly pinpoint where the patient is on the pain interference scale. Compare this method to traditional PROMs, where every question must be asked and answered in order to arrive at a final score for the patient.

PROMIS PROs can be delivered using computer-adaptive tests (CATs), which are individually tailored electronic questionnaires (Figure 1). CATs are focused on a single domain

and utilise item response theory, so the next question administered from the question bank depends on the previous answers given by the patient.⁴ Questions continue to be posed until the patient’s score for the domain in question has been identified or the maximum number of questions has been reached. For example, the PROMIS Physical Function CAT contains a maximum of 12 questions, but typically, fewer questions are needed to identify the patient’s score – oftentimes just 5 to 7.

A common PROMIS metric enables the results of different measures to be compared and simplifies interpretation of the score.¹⁹ A PROMIS score for a patient is correlated to a specific level of ability, for example, lifting a cup to your mouth or running 10 miles.¹⁴

Clinical research and CATs

Using CATs, instead of traditional PROMs, which may contain numerous questions, may help increase patient compliance. Because a respondent’s current state of health and satisfaction is recorded quickly and precisely, surgeons can track their patients’ progress interactively and more regularly than is possible from scheduled clinical visits alone.²⁰ This may also help improve the patient’s experience and therefore patient satisfaction.

An example: using PROMIS CATs for orthopaedic clinical research

At Smith & Nephew, we are currently investigating using a PROMIS ePRO app in orthopaedic clinical research. If ePROs deliver on their promise, there is great potential that they

can be used in the many clinical studies that we run or fund, which can give us greater insight into how patients feel about their new medical device.

Smith & Nephew conducted a 4-month prospective cohort study to determine the usability, reliability, and validity of PROMIS CATs for patients undergoing total knee arthroplasty (TKA). In this study, TKA patients completed

PROMIS CATs on pain behaviour, pain interference, physical function, and depression pre- and post-operatively. The study also examined user experience and clinician satisfaction with the digital platform. Eighty-seven TKA patients were enrolled from five UK sites and one US site between January 2018 and April 2018. Although the results have

not yet been published, preliminary findings indicate high levels of patient engagement and satisfaction with the app, as well as high levels of completion of the PROMIS CAT surveys.²¹ One of the clinical investigators, Professor Iain McNamara of Norfolk and Norwich University Hospitals NHS Foundation Trust (UK), speaking about the study noted: “Traditional PRO collection is time-consuming and often burdensome for both patients and healthcare professionals. Using mobile technology is a significant improvement over standard care, providing the patient with an easy-to-use tool to report their progress and enabling surgeons to track patient recovery closely. Moreover, the PRO data collection is seamless, and enables us to also evaluate our hospital’s performance”.²²

Conclusion

Only time will tell if ePROs deliver on their promise to transform clinical research but early indications are positive. One thing is certain, this is certainly not the last time that you will hear about ePROs.

Disclaimers

The opinions expressed in this article are the author’s own and not necessarily shared by his employer or EMWA.

Conflicts of interest

The author is employed by Smith & Nephew.



Figure 1. An example question from a CAT



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