

# Measuring patient-reported outcomes: moving from clinical trials into clinical practice

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Patient-reported outcomes (PROs) are reports coming directly from patients about how they function or feel in relation to a health condition and its therapy, without interpretation of the patient's responses by a physician or anyone else<sup>1</sup> (Box 1). PROs are increasingly used in clinical research, and their usefulness to inform clinicians' and patients' decisions about treatment alternatives is beginning to be understood.<sup>3</sup> But results of empirical testing of using PROs in clinical practice have been inconsistent, and ascertaining the circumstances under which PROs are truly helpful beyond research settings remains a challenge.

## What benefits and harms can we expect from using PRO measures in clinical practice?

The potential benefits of using PRO assessments in daily clinical practice include facilitating patient–clinician communication about issues that are important to patients, thereby promoting shared decision making; monitoring disease progression and response to treatment; identifying vulnerable patients; and enabling continuous assessment of quality of care.<sup>1,3</sup> These benefits could lead to improvement in outcomes that are important to patients.

On the other hand, the use of PROs may interfere with doctor–patient communication and patients may be concerned about who will review or use the information. Even in the absence of harm, the use of PROs would carry an opportunity cost, which is an important consideration given that administering some of the currently available measures is already burdensome, and scarce resources would be consumed in computing and reviewing PRO scores.

## What is the evidence for using PRO measures in clinical practice?

A number of systematic reviews have assessed the impact of measuring PROs in clinical practice. The most recent included 28 randomised controlled trials and the results were consistent with previous reviews: in most trials, the impact of PROs was limited.<sup>1</sup> Feedback of PROs to health professionals has, in some studies, had an impact on the *process* of care, with a less evident impact on health outcomes. In cancer clinics, feedback of PROs to health professionals has been shown to increase the frequency with which doctors discuss issues such as quality of life and symptoms with their patients, without an increase in the visit duration.<sup>4,5</sup> In one of these studies, physicians informed by PROs had greater agreement with their patients about how well the patient was functioning.<sup>5</sup> A meta-analysis showed that PRO reports of mental health status in a variety of settings resulted in a higher likelihood of diagnostic notations recorded in patients' medical records.<sup>6</sup>

There are a number of additional steps that must be taken before changes in the process of care can be translated into changes in outcome (Box 2). For instance, routine provision of feedback to health professionals may not necessarily translate into routine use of the information for all patients. Thus, those who demand evidence of improved patient-important outcomes will not be impressed simply by improvements in process. Moreover, randomised control-

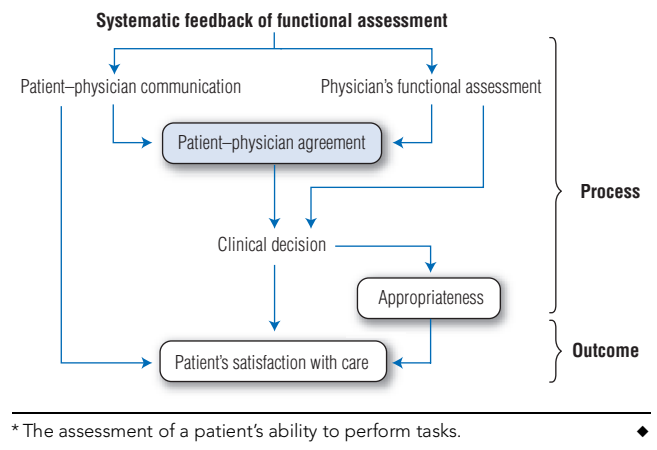
### 1 Examples of patient-reported outcome (PRO) instruments

- Medical Outcomes Study short-form health surveys (SF-36, SF-12, SF-6D): the most used family of PRO measures
- EuroQol (EQ-5D): a well known econometric preference-based measure, and one of the shortest instruments available
- McGill Pain Questionnaire: the most widely cited PRO instrument for measuring pain
- KIDSCREEN: a specific tool for PRO measurement in children and adolescents
- Patient Health Questionnaire (PHQ-9): a tool for assessing severity of depression; currently part of the "pay-for-performance" incentives scheme for primary care practitioners in the United Kingdom<sup>2</sup>
- Schedule for the Evaluation of Individual Quality of Life (SEIQoL): an individualised measure, eliciting both the content of the items and the ratings from the respondent

led trials on PROs have been highly heterogeneous in setting (primary care; specialised outpatient and inpatient clinics), participants (new and known patients; experienced and more junior clinicians), the intensity and content of the PRO intervention implemented, and diversity of outcomes reported.<sup>1</sup> This heterogeneity poses a major challenge in interpreting the evidence and in identifying the clinical contexts and strategies for measuring and reporting PRO results to clinicians that will result in improved patient outcomes.

Some additional methodological weaknesses affect these trials. Often, the investigators analysed the data as if they had randomised patients, when in fact they had randomised clinicians or groups of clinicians.<sup>1</sup> This error would bias results in favour of the intervention. Some interventions were suboptimal in the degree of training clinicians received in interpreting the results, and in the manner of

### 2 Assessing the impact of patient-reported outcomes in clinical practice: a model for feedback on functional assessment\* in clinical practice<sup>7</sup>



presentation of results to the clinicians.<sup>8</sup> Methodologically stronger trials successfully implementing feasible interventions with clear positive effects are required to provide clear direction for clinicians.

### What are the challenges for implementing PRO measures in clinical practice?

The systematic use of PRO instruments in clinical practice has the potential to bring about significant improvements in a number of relevant areas of health care. But possible barriers to implementation would need to be overcome, including scepticism about the validity and potential utility of PRO data; unfamiliarity with the interpretation of PRO information; a paucity of direct face-to-face instrument comparisons; costs of data collection; and the need for rapid data manipulation and processing.

Significant progress has been made in some of these areas. A recent review comparing common medical measurements and their associated error with PRO measurements concluded that the latter were comparable with commonly used outcome data.<sup>9</sup> The next step is to convince clinicians that this is the case and that they may reliably benefit from information derived from PROs. Researchers are also finding new, imaginative ways to help clinicians understand the magnitude of treatment impact on quality of life. One useful measure in this regard is the Minimal Important Difference (MID) — the smallest change in instrument score that patients perceive as important.<sup>10</sup> For instance, the MID for the Chronic Respiratory Questionnaire is 0.5 on a scale that ranges from 1 to 7. This means that changes smaller than 0.5 should not be considered relevant, regardless of the statistical significance of the comparison. Some authors propose linking PRO scores with expected performance profiles to facilitate interpretation of results.<sup>7</sup> The development of standardised tools relying on sound criteria<sup>11</sup> is making direct comparison between instruments and their devised purposes easier. These evaluative approaches should facilitate the selection of the most appropriate PRO for each occasion. Also, efforts are being made to develop very brief questionnaires by either shortening existing ones or applying computer-based methods to tailor the content of the instrument to each patient based on the responses provided to each previous item. This approach should reduce the burden of collecting PRO data. Finally, the development of new PROs specifically devised for use in the clinical setting might also help to overcome barriers to successful implementation.

### Where to from here?

PRO instruments used in clinical research can theoretically provide important information to guide decisions about alternative treatments. There are some grounds for optimism that the use of PROs could have a positive impact on clinical practice (specifically in improving diagnosis and recognition of problems and in patient-physician communication), but considerable work is still required before clinicians can invest resources in the process and confidently anticipate benefits for their patients.

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(Received 17 Jan 2008, accepted 26 Mar 2008)

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