

Impact of Patient-Reported Outcomes on Clinical Practice

This working document is part of a [series](#) developed by the NIH Health Care Systems Research Collaboratory [Patient-Reported Outcomes \(PRO\) Core](#) to provide and develop strategies, tools, and resources related to the measurement, collection, and analysis of patient-generated health information, including patient-reported outcomes data. This work was supported by a cooperative agreement (U54 AT007748) from the NIH Common Fund for the NIH Health Care Systems Research Collaboratory. The views presented here are solely the responsibility of the authors and do not necessarily represent the official views of the NIH.

Background

To provide value to decision makers, pragmatic trials should assess endpoints that are meaningful to relevant stakeholders. Often times the most meaningful outcomes can be measured only through patient self-report. Measuring such patient-reported outcomes (PROs) can be challenging for large pragmatic trials that rely on the electronic health record for data, because PROs are not routinely collected as part of clinical care. One of the considerations for increasing the availability of PROs in pragmatic trials is the value PROs can provide to clinicians and their patients. Currently, there is mixed evidence about the effects of PROs on clinical care. Most empirical studies accessing the routine use of PROs in the clinical setting are in the area of clinical oncology, although we have also included evidence from other fields. These studies have evaluated the extent to which PROs (1) improve patient-provider communication, clinical decision-making, and patient satisfaction; (2) enhance patient outcomes; and (3) help ensure better quality of care from a healthcare systems perspective. This article examines the available evidence to understand when PROs have the potential to provide significant value to patient care.

Impact of PROs on Patient–Provider Communication, Clinical Decision-Making and Patient Satisfaction

Patient Satisfaction and Patient–Provider Communication

Two recent systematic reviews offer supporting evidence for the use of PROs in clinics to improve patient–provider communication and patient satisfaction [1,2]. In the review by Kotronoulas et al. [2] focused on cancer care, 9 studies reported that patients were generally satisfied with care and communication with providers, citing greater satisfaction with emotional support, satisfaction with follow up care by oncology nurses as opposed to general practitioners and improved communication with physicians. However, only one demonstrated a statistically significant positive effect on patient–provider communication, reported in patients undergoing palliative care chemotherapy. In that study [3], authors reported that health-related quality-of-

life (HRQOL) issues were discussed significantly more frequently in the PRO intervention group receiving HRQOL questionnaires prior to consultation compared with the control group that did not receive questionnaires (frequency [standard deviation]: 4.5 [2.3] vs 3.7 [1.9], respectively [$P=.01$]). Similarly, authors Howell et al. [4], cite 18 studies that evaluated the effect of PROs on patient satisfaction, which established a positive association, but noted that the effects were statistically insignificant and attributed to potential ceiling effects observed in both the control and intervention groups due to high baseline satisfaction scores.

The review by Chen et al. [1], cited 27 studies, including 16 randomized controlled trials (RCTs) and 9 observational studies that addressed both patient satisfaction and patient-provider communication. Sixteen studies reported specifically on the impact of PROs on patient satisfaction. Of these, 13 reported at least a moderate improvement in patient satisfaction. For example, one study reported that 96% of patients found the use of PROs helpful and would recommend their use to others [5]. Three of the 13 studies examined by Chen et al. did not show a significant effect on patient satisfaction. Of those, 1 study [6] noted high baseline patient satisfaction, which then had a negative impact on the ability to distinguish a significant effect between the PRO intervention arm (electronic PRO completion with provider review of report) and the control arm (paper-pencil PRO, no provider review) in the follow-up period. Twenty-three studies cited by Chen et al. [1], reported on the impact of PROs on patient-provider communication, 21 of which reported a significant improvement in patient-provider communication (e.g., a 50% increase in communication between patients and oncologists in the PRO intervention arm), 1 reported no improvement, and 1 reported a negative effect on communication, potentially due to high baseline satisfaction resulting in a ceiling effect [1].

In a literature review of 52 randomized controlled trials (RTC's), Carlier et al. examined effect of routine outcome monitoring (ROM) and feedback on physical or mental health status, and found consistently positive effects on communication between patients and clinicians in both the long and short term [8]: patient feedback helped the patient and clinician communicate more frequently and effectively with each other, particularly in the field of mental health. Similarly, in a structured review of 38 controlled clinical trials to determine the effect of PRO measures in routine practice, Marshall et al. suggest that PRO measures are an effective method of enhancing communication in the health care setting and that physicians are more likely to discuss HRQOL with patients when they have access to that information [9].

Clinical Decision Making

In the field of mental health, psychiatrists may use PRO measurement-based care to support clinical decision-making. The use of standard measures (such as the Patient Health Questionnaire-9 [PHQ-9] for depression) is an increasingly common way to guide clinical decisions for patients with depression in both primary care and specialty mental health

practices [10,11]. In a study by Simon et al. [12], researchers found that response to item 9 of the PHQ-9 for depression (“thoughts that you would be better off dead, or of hurting yourself in some way”) identified outpatients at increased risk of suicide risk and suicide death. For this high-risk group, additional structured assessments are indicated to better inform clinical decisions.

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In a study in China, Guo et al. [13], compared usual care to measurement-based care using the 16-item Quick Inventory of Depressive Symptomatology–Self-Report (QIDS-SR) and the Frequency, Intensity, and Burden of Side Effects Rating scale, and found that psychiatrists were better able to individualize treatment decisions for major depression when they used PRO measures. Additionally, the PHQ-9 has been used to evaluate potential overprescribing of antidepressant medication for mild depression [14]: of the 7,051 patients who completed a baseline PHQ-9 and initiated antidepressant therapy in 2011 at 4 large health care systems, 85% of them reported moderate or severe depression at the time, indicating and that prescribing antidepressants for minimal or mild depressions is less common than suggested in previous reports.

Impact of PROs on Patient Care, Outcomes and Treatment Monitoring

Patient Care

Boyce et al. [15] conducted a systematic review of 16 qualitative studies that asked healthcare professionals in a variety of healthcare settings including primary care, hospital care, and hospice care to evaluate the impact of PROs on patient care. They found that, overall, professionals felt that collecting PROs had the potential to improve the process of care, namely communication, education, care planning, and disease monitoring. Healthcare professionals also felt that PROs help to build patient confidence, manage patient expectations, and reaffirm patient responsibility for their own care. However, there were mixed opinions regarding the association between PROs and improvements in patient care. PROs were viewed as a tool to support clinical decision-making as well as research and auditing, but many said that the measures had no clinical value since the data provided no new information. These professionals also identified some negative effects of using PROs for patient care, such as invasion of patient privacy, patient distress, myopic focus of consultation, and degradation of patient–clinician relationship, such as setting unrealistic expectations of clinicians. In their review of PRO measures in routine clinical practice, Marshall et al. found that PRO results substantially impacted some processes of care, such as the diagnosis of a mental health condition [9]. Carlier et al. had similar findings in the field of mental health: patient feedback led to faster diagnoses and more complete screenings [8].

Patient Outcomes

In terms of the impact of PROs on patient outcomes in clinical settings, the literature contains mixed reports. A scoping review assessing patient and clinical practice outcomes in routine cancer clinical practice [9] identified 6 studies that evaluated the impact of routine HRQOL instrument use on overall patient well-being. Authors found only 1 study that reported a significant overall positive effect. In that study [16], researchers found that patients in the intervention arm receiving routine HRQOL assessments showed a clinically significant improvement in patient well-being (>7 points) over patients in the attention-control (no PRO feedback to physicians) and control arms (no PRO assessment). Four studies cited in the review reported no significant effect on patient outcomes, and 1 pediatric study reported improved well-being in children 5 to 7 years of age but not in those 0 to 4 years of age.

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In the review by Kotronoulas et al. [2], which also examined whether the inclusion of PROs in clinical oncology practice was associated with improved patient outcomes in the cancer population, 26 studies (including 4 non-RCTs) found that, overall, small to moderate improvement in symptom control was observed. Reduced symptom severity and prevalence were reported in 7 studies, with fewer threshold events and less symptom interference reported. Reductions in symptom events and interference for functioning, distress, pain, and fatigue were especially noteworthy. No significant effects on HRQOL were observed in 9 of the studies; however, 1 study reported deteriorated quality of life (QOL) in the intervention group receiving a structured QOL diary compared with standard of care. Another study reported improvements in scores after treatment when the QOL was discussed during follow-up consultations [17].

Some have argued that although PROs are useful in improving processes of care, they have little impact on health status and outcomes [18,19]; however, this may be dependent on the context and the goals of PRO measures [9]. For example, in many studies, the health status of patients with certain mental health conditions has improved with the associated use of PRO measures [8,9]. In the study on measurement-based care for major depression [13], investigators found that measurement-based care could be integrated into clinical practice to improve patient outcomes and increase the speed of achieving a response to therapy and remission from depression.

Monitoring of Treatment Responses

Some evidence exists for the use of PROs to increase monitoring activities of treatment responses. Eleven of the 27 studies cited in the review by Chen et al. [1] reported on monitoring of treatment responses. All 11 found a modest-to-strong positive effect of PROs on monitoring. This effect was strongest on the monitoring of patient symptoms, side effects, and toxicity in patients after outpatient chemotherapy. In one example, participants were asked to report on symptom prevalence; the study found that 67% of those that responded exceeded the severity

threshold at least once, prompting an auto-generated alert report faxed to their physician [20]. In the field of mental health, PROs have been linked to better monitoring and more rapid adjustment of treatment [8].

In the field of ophthalmology, there has been a recent surge in vision- and eye-specific PROs; however, concepts such as vision-related QOL, visual function, and functional vision are often conflated, complicating the interpretation of these PROs [21]. In pediatric ophthalmology, there are few vision-specific PROs suitable for children, and generic health-related PROs are used instead. These PROs are suitable from distinguishing children with visual impairment from their fully-sighted counterparts, but are not useful in elucidating the nuances between children with the same ophthalmologic condition or for detecting changes over time [21]. Findings from the field of cataract surgery support the use of disease-specific measures of QOL, as they have been shown to be more sensitive and informative than general QOL measures in patients after cataract removal [7].

Impact of PROs on the Healthcare System

Evidence is limited regarding the impact of PROs on the healthcare system more broadly. Results from the review by Kotronoulas et al. [2], which examined the impact of PROs on health services outcomes, found that out of 5 studies meeting review criteria, 4 reported that PROs produced minimal changes in patient health service utilization when PROs were used as a prompt for follow-up care. The single supportive study [22] stated an improved frequency of patient–provider interactions among women with breast cancer who received routine screening for psychological distress using PROs, when compared with women who received basic psychosocial follow-up care after hospitalization for initial treatment.

In the review by Chen et al. [1], which evaluated the effect of routine collection of PROs in patients seeking general care, authors reported a weak or nonexistent effect of PRO interventions on the healthcare system overall. Of the cited 27 empirical studies, none provided sufficient evidence to support effective quality improvement, transparency, accountability, public reporting, or improved healthcare system performance (e.g., quality improvement monitoring). Thirteen of the 27 studies provided at least modest evidence to support improvements in the coordinated management of patient care. Additionally, there were anecdotal examples of a positive effect of PROs on patient management. An example given in Santana et al. [23] was of a patient experiencing severe knee pain identified by PRO data. After reviewing the data, clinicians ordered x-rays, prescribed analgesia, and referred the patient to a rheumatologist.

Evidence is lacking for a cost-benefit impact of PROs on patient safety and clinical burden [2]. A study by Hubbard et al. [24] demonstrated that the routine collection of single-item PRO measures did not heavily affect the length of clinic visits according to healthcare providers who participated in the study. Of the 83 oncology care providers surveyed online, 90% reported that administering the symptom assessment questionnaire (SAQ) did not change the length of the clinic visit or increase clinic burden.

Conclusions and Future Directions

PROs continue to gain in popularity, and stakeholders in the healthcare community are calling for the routine collection of these measures to support patient care as well as future quality improvement or comparative effectiveness research initiatives. While the majority of literature cited for this study came from the oncology setting and may not be applicable for all conditions, the available literature to date supports the potential of PROs for improving patient satisfaction with care, better patient–provider communication, treatment monitoring, and detection of new problems. However, there is little evidence to date to support the impact of PROs on clinical decision-making, healthcare services outcomes, or changes in the healthcare system overall.

The routine collection of PROs in a clinical setting will require a significant culture change, and healthcare systems should anticipate a substantial investment in technology and training. As healthcare administrators, government agencies, and other stakeholders continue to search for opportunities to improve patient care and provide healthcare services more effectively, careful consideration should be given before implementing long-term routine PRO data collection strategies at the healthcare systems level.

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