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REVIEW

Implementing patient-reported outcomes assessment in clinical practice: a review of the options and considerations

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Abstract
Purpose While clinical care is frequently directed at making patients "feel better," patients' reports on their functioning and well-being (patient-reported outcomes [PROs]) are rarely collected in routine clinical practice. The International Society for Quality of Life Research (ISOQOL) has developed a *User's Guide for Implementing Patient-Reported Outcomes Assessment in Clinical Practice*. This paper summarizes the key issues from the *User's Guide*.
Methods Using the literature, an ISOQOL team outlined considerations for using PROs in clinical practice; options for designing the intervention; and strengths, weaknesses, and resource requirements associated with each option.
Results Implementing routine PRO assessment involves a number of methodological and practical decisions, including (1) identifying the goals for collecting PROs in clinical practice, (2) selecting the patients, setting, and timing of assessments, (3) determining which questionnaire(s) to use, (4) choosing a mode for administering and scoring the questionnaire, (5) designing processes for reporting results, (6) identifying aids to facilitate score interpretation, (7) developing strategies for responding to issues identified by the questionnaires, and (8) evaluating the impact of the PRO intervention on the practice.
Conclusions Integrating PROs in clinical practice has the potential to enhance patient-centered care. The online version of the *User's Guide* will be updated periodically.

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Abbreviations

ISOQOL	International Society for Quality of Life Research
PDSA	Plan-do-study-act
PROs	Patient-reported outcomes
SIG	Special Interest Group

Introduction

Much of clinical care is directed at making patients "feel better," but patients' reports on their functioning and well-being have only rarely been collected in a standardized fashion in routine clinical practice. These data can be used along with patients' other clinical information (e.g., lab tests, imaging studies, clinic notes) to inform patient management. Recent initiatives, such as the United Kingdom's policy to encourage wider use of patient-reported outcomes (PROs) to facilitate patient–clinician communication and evaluate the quality of National Health Service care [1], have led to increased interest in using PROs for individual patient management. Research has shown that integration of PROs in clinical practice improves patient–clinician communication and in some cases, enhances patient care and outcomes [2–4]. Implementing PRO assessment in routine clinical practice to aid individual patient management involves a number of methodological and practical decisions.

To help clinicians interested in implementing PRO assessment, the International Society for Quality of Life Research (ISOQOL) has developed a *User's Guide for Implementing Patient-Reported Outcomes Assessment in Clinical Practice*. The ISOQOL Board of Directors undertook this initiative to provide a useful resource to clinicians and practitioners interested in using PROs in clinical practice. The Board approached ISOQOL's QOL in Clinical Practice Special Interest Group (SIG), given the relevance of this project to their mission, and SIG members had the opportunity to join the writing team. An initial conference call was held during which team members discussed the topics to include in the *User's Guide*, and individuals took responsibility for preparing sections. We also developed a framework of elements to include in each section: options, resources required, advantages, and disadvantages. A recently updated bibliography of papers relevant to the use of PROs in clinical practice was circulated to all team members, which supplemented other resources available to the authors for supporting literature. Each member circulated his/her draft section to the entire writing team for review and comment, the sections were combined into a single draft, and the draft was reviewed and approved by all authors, as well as the ISOQOL Board.

The resulting *User's Guide*, available at www.isoqol.org, provides detailed descriptions of the considerations, options, resource requirements, and relative advantages and disadvantages associated with the various alternatives. The document is hyperlinked to allow easy navigation through the sections. This paper provides a brief overview of the issues. The topics addressed include (1) identifying the goals for collecting PROs in clinical practice, (2) selecting the patients, setting, and timing of assessments, (3) determining which questionnaire(s) to use, (4) choosing a mode for administering and scoring the questionnaire, (5) designing processes for reporting results, (6) identifying aids to facilitate score interpretation, (7) developing strategies for responding to issues identified by the questionnaires, and (8) evaluating the impact of the PRO intervention on the practice.

Identifying the goals for collecting PROs in clinical practice

Health care providers considering the use of PROs in clinical practice need to clarify their goals and assess the resources available for implementing the intervention. PROs can be used in clinical practice for a variety of purposes, which are not mutually exclusive, so clinicians may be able to accomplish multiple objectives through implementing PRO collection.

Greenhalgh [5] proposes a taxonomy for using PROs in clinical practice. At the individual level, PROs can be used to screen for problems, monitor progress over time, and facilitate patient-centered care, with the resources required increasing with the intervention's scope. Screening involves onetime PRO assessment with feedback to clinicians, which can help identify problems that may have otherwise gone undetected but provides no information on the patient's outcomes over time. In contrast, PROs may be collected and fed back to care providers longitudinally to track patients' health over time, evaluate whether treatments are effective, and facilitate treatment modifications as needed. PRO results can be provided to the patient in addition to the clinician. This may promote patient-centered care by improving communication, enabling patients to become more involved in managing their health, and potentially leading to better patient treatment adherence. PRO data can also be used to facilitate communication in multidisciplinary clinic settings by providing a common, patient-focused frame of reference for clinicians to use in discussing progress, agreeing on, and implementing a care plan.

While not the focus of this paper, PRO data collected for individual patient management can also be aggregated across patients, appropriately adjusted for case mix variables, and used to evaluate the quality of care within a practice or to compare the quality of care across providers [6]. PRO data collected from individual patients as part of their care can be pooled and examined to identify strengths and weaknesses in care provided. If normative data are available, clinicians can compare their practice outcomes to benchmarks. Such PRO data provide information on effectiveness, rather than efficacy, and if made publicly available, enable patients and purchasers to compare providers or healthcare plans on PROs. In designing the PRO intervention, it is important to consider both the near-term and long-term goals for the data collected.

Selecting the patients, setting, and timing for assessment

In determining which patients to include in PRO assessments, it is important to consider the setting of care, the timing of assessments, and patients' ability to self-report. For example, the intervention may target all patients seen in outpatient clinics. These patients are more likely to be independent and to have discretionary time to complete PROs [7] but may not be in the greatest need of monitoring. Focusing on patients with specific conditions allows for a more targeted measurement strategy. Individuals with an identified chronic illness, whether followed in a specialty clinic or in general practice, may have greater needs for monitoring.

It is also possible to focus assessments on inpatients, either in acute or rehabilitative settings [8]. Assessing hospitalized patients may require greater resources, as they will likely require help completing questionnaires, regardless of the method of administration. The value of assessing acute care patients may be limited during their short-term stay, and without post-discharge assessments, there will be no information about the long-term benefit of hospitalization. The environment of hospitalized patients may also influence their responses [9]. In contrast, patients hospitalized in rehabilitation settings have structured schedules into which PRO assessments can be incorporated and are undergoing constant evaluation for progress.

Another consideration is how frequently patients will be asked to complete PROs. Options range from onetime only to frequent completion, with assessments tied to visits or a way to monitor patients between visits. More frequent assessment can provide a more complete picture for patients who are very symptomatic and/or in active treatment [10–14]—but if too frequent could result in greater variations in scores that are more difficult to interpret. Less frequent assessment is less burdensome and may be appropriate for generally healthy patients [15–17]. Generally, more frequent administration requires greater resources, but the upfront costs involved with implementing any PRO assessment intervention represent a large part of the resource investment [16].

In outpatient practice, PRO assessment can be linked to visits or occur between visits [11, 17]. If collected during visits, processes are required to allow patients time to complete the questionnaires, to manage data, to ensure timely review of data, and to respond to patients' identified needs [10, 13]. Alternatively, PRO assessment can occur between patient visits. This approach requires that patients have access to a website or other method, such as a telephone interactive voice response system, to complete PROs from home [18–20]. Further, a method to alert clinicians of issues requiring immediate attention needs to be in place, ideally with information directing clinicians to resources and personnel (e.g., nurses) available to help address problems [20]. Assessing PROs between visits increases the complexity of collecting the data and addressing the results but also has the greatest potential to improve patient care through greater accessibility.

Ideally, PROs are completed by patient self-report, as this provides a direct assessment of the patient's outcomes, but in some instances, patients are not capable of responding for themselves (e.g., young children, cognitively limited, too ill) [21–25]. In those instances, a proxy may complete the PRO on the patient's behalf. While proxy respondents can provide some perspective on the affected person [26], proxies may have difficulty distinguishing how the patient would respond versus the proxy's own assessment. If proxy reporting is used, the proxy needs to be identified and documented for each assessment [21].

Notably, there are potentially important interactions between the patients, setting, and timing of assessment. For example, if the target is cancer patients undergoing treatment, data collected on their first day of treatment might be affected by the uncertainty and stress of beginning therapy. Also, patient literacy levels may limit the options for mode of administration and also the frequency of assessment (e.g., if relying on live-interviewers, may need less frequent administration), as will be described in more detail later. Thus, a combination of factors must be considered to ensure that the intervention is feasible and acceptable to patients and clinicians.

Determining which questionnaire(s) to use

When determining which PRO questionnaire to use, considerations include generic versus disease-specific questionnaires, profile versus preference-based measures, single versus multi-item scales, and static versus dynamic questionnaires [11, 27–35] (Table 1). Clinician and patient

Table 1 Considerations for questionnaire selection

Element		
Generic versus disease-specific	Generic	Disease-specific
	May capture more commonly experienced health domains	May be more sensitive to specific symptoms experienced by patients
	Allow comparison to normative populations	May miss domains affecting the patient but unrelated to the disease being treated
	May not be sensitive to changes in disease-specific health domains over time	
Profile versus preference based	Profile	Preference based
	Provide multiple scores (and sometimes summary measures) across a broad range of PRO domains	Provide a single score aggregated across multiple PRO domains for an estimate of burden of disease
	Can be longer to complete	May not provide clinically relevant information on specific PRO domains affecting the patient
Single item versus multi-item	Single item	Multi-item
	Enable assessment of more PRO domains	Provide more precise and content valid measurement
	Less reliable for tracking change	More time consuming for patients to complete
Static versus dynamic	Static	Dynamic
	Feasible for paper and computer administration	Can yield shorter and equally reliable measures than static forms
	May require longer questionnaires to provide a reliable measure of a patient's health status	Require computer administration
		Only available for a limited number of domains

preferences should be balanced in selecting the questionnaire and type of PRO data to collect. PROs can include data on symptom burden, functional limitations, quality of life, health behaviors (e.g., diet, exercise, smoking), and treatment compliance. Physicians may only want to assess issues they know how to treat or manage. For patients, there may be specific symptoms and quality of life issues they want to talk to the doctor about. A number of reviews are available to guide clinicians in selecting the most appropriate measure for various conditions [36].

Other considerations in selecting the appropriate PRO questionnaire include response formats (verbal descriptor scale or numeric rating scale), focus of assessment (severity, frequency, interference, bother), and the level of psychometric evidence (validity, reliability, floor/ceiling effects, etc.) for the questionnaire in the target population. One should also consider the reference period. Shorter recall periods more accurately capture patients' actual experiences, but require either more frequent assessments (meaning more burden) or may miss important symptoms between less frequent assessments. Finally, it is important to obtain permission to use the questionnaire (if required) and pay any applicable user fees.

Choosing a mode for administering and scoring the PROs

There are various ways in which PRO data can be collected and scored, including self-, interviewer, and computer administration [37–39]. (Table 2; and interested readers are referred to the Appendix of the *User's Guide* for a summary of the literature comparing different modes of administration in terms of response rates, score distributions, and psychometrics). These options can be used to varying extents either for data collection in the clinic or outside of the clinic. If data are collected in the clinic, patients need private space to complete the PROs. Data collection outside the clinic does not require space in the clinic for questionnaire completion but does require personnel to manage the process and, for nonautomated options, data entry. Computers (including smart phones and handheld devices) are likely to be more commonly used for data collection in the future, given their increasing prevalence and many advantages, including directly integrating the PRO data in the electronic medical record and prompting automated alerts to clinicians for problematic symptoms that patients may be experiencing.

Reporting PRO results

Developing a score reporting system involves multiple steps, including (1) determining how to fit PROs into the clinical workflow, (2) identifying who will receive the reports, (3) deciding when the PRO results will be addressed, and (4) formatting PRO score reports.

First, a practice needs to determine when and how to present the results and discuss them with patients. It is useful to decide whether results will be presented within or

Table 2 Modes of administration: options, advantages, and disadvantages

Mode & setting	Advantages	Disadvantages
In person		
Paper	Have low technology requirements so can be implemented at relatively low cost	May not be appropriate for all patients (e.g., low literacy, visual disabilities)
		Potentially higher rate of missing data
		Require personnel to coordinate questionnaire completion, and assist when necessary
		Require personnel for data entry
Interview	More personal	Relatively expensive
	Enable more in-depth questioning	May create problems with socially desirable responses
	Largely circumvent issues of literacy and/or visual handicap	
Computer	Efficient data collection	Require personnel to manage the process
	Immediate scoring and simultaneous data entry into statistical database	Software needed to collect and report the PRO data
	Enable adaptive testing	Involve higher upfront costs to develop/purchase and maintain the PRO system
	Facilitate graphic score presentation	
	Possibility of linking with electronic medical record	
	Potential for automated reading and voice response	
Outside clinic		
Mail	Low technology requirements	Require personnel to manage the mailing and score instruments
	Comparatively low cost	Potentially high nonresponse rate
		Difficult to respond promptly if the patient reports serious problems
		Cannot ensure patients complete questionnaires alone
Telephone	Can be conducted by a live interviewer, which is more personal, or through an automated system	Live interviews are resource intensive, requiring both a skilled interviewer and data entry and may create problems with socially desirable responses
	Circumvent issues with literacy and physical challenges to completing questionnaires	Automated systems have higher upfront costs to develop/purchase and manage a validated, efficient tool and may be impersonal and off-putting to patients
	Can be more convenient	
		Patients may require training on the automated systems
Internet	Efficient because of immediate scoring and simultaneous data entry	Needs upfront investment to design the data collection system
		Require personnel to manage data collection over time
	Enable adaptive testing	Must ensure data security and privacy
	Facilitate graphic score presentation	Patients may require training on how to use the system
	Allow real-time feedback of results to clinicians	Not all patients have Internet access
	Enable flexible timing and can be more convenient	
	Possibility of linking to electronic medical record	

outside of the clinical workflow. If outside of the usual clinical workflow, clinical staff need to be specifically tasked with tracking changes in PRO status and addressing ongoing PRO issues which may require intervention beyond a visit (e.g., telephone follow-up) [40]. If PRO reporting is part of the clinical workflow, PRO results need to be provided to clinicians along with the other clinical data where the clinicians would expect to see them [41–44]. In paper-based clinics, PRO results would be expected in hard copy. In clinics using electronic systems, PRO results need to be integrated within the electronic medical record system, either by collecting the data electronically and linking them or adding nonelectronic PRO results to the electronic data.

Second, practices need to determine who will receive the PRO report [2, 45–48]. It may make sense for someone other than the physician to receive the reports (e.g., nurses); however, processes for addressing PRO results and coordinating care across the health care team are needed. Some practices may provide patients with their PRO results to enable patients to be active members of the care team and participate in decision making [42, 49]. Doing so requires some mechanism for getting the score reports to the patient, either via hard copy at the visit or electronic

communication prior to the appointment. Patients need sufficient context to interpret the results appropriately.

Third, practices need to decide when to address the PRO results. PRO results can be incorporated in visits if the data can be collected and scored prior to or at the time of the visit [41–45]. Having PRO data during the visit enhances patient–clinician communication and may help clarify priorities of care. Challenges include having the PRO scoring completed prior to the visit, particularly if it is not an electronic PRO with automatic scoring, and finding time within visits to address PRO results. Alternatively, PRO data can be collected prior to the visit, though this requires a mechanism for getting the results from the patient to the clinician (e.g., via mail or web-based PRO administration) [40]. Collecting data ahead of time allows more time to score nonelectronic questionnaires and provides clinicians an opportunity to prepare for the discussion. However, this option requires greater coordination to assign patients PROs outside of the clinic. If the patient reports an issue requiring immediate attention, a mechanism needs to be in place to address it. A third option is to collect the PRO data during the visit but then score it later. This option may be easier in terms of clinic workflow, but having clinicians react to results after the visit decreases their usefulness.

Fourth, formatting for PRO results presentation requires consideration [50]. The simplest option is to provide only the numeric scores. This option does not require data manipulation and may be easier to integrate into the standard workflow, but having only the numbers may make interpretation a challenge. Graphs can aid interpretation and, therefore, usability for clinicians and patients, but graphical presentation requires computer manipulation of the data. Regardless of whether the data are presented as numbers or graphs, it is possible to incorporate not only the patient's current score, but data on how the patient's score has changed over time. This option requires the ability to recall patient's previous scores but can aid interpretation by providing context. Some data show that patients prefer and are most likely to correctly interpret line graphs of means without extraneous information (e.g., error bars).

Interpreting scores

Tools to aid the interpretation of PROs vary depending on whether the patient's *current* score only has been fed back to the clinicians, or whether the clinician is presented with the *change* in the patient's score. Although different options are discussed separately later for clarity, a combination of approaches may facilitate interpretation. Furthermore, interpreting and responding to the PROs also depends on the nature of the patient's condition. For acute conditions, the expectation may be a return to or improvement in the patient's usual level of functioning, for example, following hip replacement surgery. However, for chronic conditions, the goal may be to achieve stability or a managed deterioration.

At the most basic level, guidelines can provide information on score meaning (e.g., "higher scores mean better functioning") [43, 51]; however, such approaches provide no information about the score's clinical importance or importance to the patient. Interpretation can be aided by providing cut off scores for "caseness" or levels of severity (e.g., no disability, moderate disability, severe disability) if such data are available [52–54]. This approach's usefulness depends on the sensitivity and specificity of cut offs, and predictive value will depend on the prevalence of the condition in the population being screened [55]. A more resource intensive approach to score interpretation is to have personnel review patient's scores with the patient to clarify and elaborate on problems indicated by the PROs [56].

Reference scores from research studies with similar patients, from the general population with the same condition, or from healthy populations can help by providing a benchmark [12, 57]. It is also possible to compare a given patient's scores with the scores for other patients in the practice, using the data from previously collected assessments. This approach enables comparison to average patients in the local practice. However, while reference scores provide a basis for comparison, they do not necessarily indicate what a given score represents for a particular patient. Comparison with benchmarks from group data can be problematic because of the significantly larger error of measurement in individuals [58–60].

Another approach to aid score interpretation is providing not only the patient's current scores but also how their scores have changed over time. While having the historic scores available can be helpful, guidance on the clinical importance of the changes is even more useful. It is important to distinguish between clinically relevant change and statistically significant (i.e., detectable) change [61]. Many instrument developers have worked to identify minimally clinically important differences using either statistical assessments of the distribution of scores (e.g., half a standard deviation) [62] or comparison to anchors (e.g., patient global ratings of change, clinical measures) [63] or some combination of the two approaches [64–67].

Responding to issues identified by the PRO

Another important question is how to respond to issues identified through the PRO assessments. As mentioned previously, a clinician may probe the issue through discussions with patients [11, 50]. The PRO results may be used to

help prioritize the issues that require addressing in the clinic visit and promote efficiency [14]. This approach can be time intensive, although studies have found no increased time for patient visits [68]. Clinical practices that use multidisciplinary teams can apply the varied skill sets available to tailor responses to patients' particular issues [69].

If there are published and accepted—or practice-specific—guidelines to link to the PRO results, these recommendations can be incorporated into the PRO process and may increase the ability of PRO results to affect patient care and outcomes. These guidelines may even be formalized into disease management pathways. However, there are many topics for which no clear guidance is available, and it is also important to present these recommendations in a way that does not threaten the clinician's expertise and autonomy. Whatever approach is used, training clinicians on the meaning of scores and on approaches to responding to issues raised is critical before implementing the PRO intervention. Through prolonged use of PROs or other standardized outcome measures over time, clinicians may develop tacit knowledge about the meaning of the scores and the implications for patient care [70, 71]. It may also be helpful to provide clinicians with feedback on how they responded to issues identified by PROs. It should be noted, however, that clinicians rarely act on information from one test result alone and have to integrate PRO scores with other clinical data to determine a course of action [70, 72].

Evaluating the impact of the PRO intervention on the practice

Finally, practices may want to evaluate the impact of implementing routine PRO collection in their care, using either experimental methods or quasi-experimental/quality-improvement methods [73]. For the purposes of this section, value is defined as the sum of clinical quality, service quality, and safety divided by the sum of monetary cost and time [74].

Quasi-experimental/quality-improvement designs and methods

Designs traditionally suited to explore the efficacy of conceptually neat components of clinical practice may be inadequate to study PROs in routine care [74–76]. Practices might consider quasi-experimental, observational, survey, or quality-improvement designs and methods (simple pre–post, uncontrolled designs with the goal of identifying how to implement effective changes) [74, 77–79]. These approaches have relatively lower monetary costs due to reduced personnel needs but do require expertise in quality improvement. They may require institutional support and approval, including ethics review. Sophisticated information systems can be quite useful in providing data for such studies. For example, plan-do-study-act (PDSA) requires minimal training and involves making small changes incrementally and learning from experience while doing so [75, 80]. Advantages of these approaches are that health systems and community settings may have quality-improvement programs in place. These studies provide evidence of effectiveness [77]. Disadvantages include significant risk for bias and lower internal validity due to lack of optimal experimental control [78]. Thus, it can be difficult to determine whether the particular PRO intervention resulted in an improvement [75]. Such studies are sensitive to details of implementation, organizational history, leadership, and context, which may limit generalizability to other sites [77, 81]. On the other hand, a series of case studies in different contexts could provide valuable information about how the intervention operates, which might actually be more informative than a large randomized controlled trial where generally only average effectiveness is assessed.

Traditional experimental designs and methods

Using traditional experimental designs and methods (e.g., randomized controlled trials, cluster-randomized trials) to evaluate the intervention can be quite resource intensive, with monetary needs ranging from thousands of dollars to millions of dollars, depending on the scope, duration, and complexity of the trial [81–84]. Such studies require skilled investigators and research staff, including data collection and management personnel, analysts and statisticians, project coordinators/managers, research assistants, engaged clinicians, patient advocates, and other specialists such as health economists, when appropriate. These studies require institutional support (including ethics review) and frequently require external funding. They also require a significant amount of time, not just in preparation but also to follow-up patients to detect impact. Advantages are the strong rigor, which minimize bias and provide strong internal validity of efficacy [81, 82, 84]. Still, they are subject to various biases (e.g., selection) and may have insufficient power to detect differences [82, 84]. Unless they also have a significant qualitative element built into them to observe how the intervention is implemented in practice, they also provide little information on why and how the intervention works.

Conclusion

When ISOQOL undertook this project to create a *User's Guide for Implementing Patient-Reported Outcomes*

Assessment in Clinical Practice, the intention was to provide a brief, user-friendly, and comprehensive step-by-step guide for health care providers and practices interested in using PROs to aid in their patient management. While this intervention has received recent attention in the research literature, there was little information on how to implement this approach in daily clinical practice. Specifically, there was no one resource that outlined the steps involved, the options available, the resources required, and the relative advantages and disadvantages of the alternatives. With the posting of the *User's Guide,* ISOQOL hopes to provide a valuable tool for practices interested in implementing this intervention.

The field of assessing PROs in clinical practice is continuing to develop and evolve, and we expect that the options and considerations outlined in this *User's Guide* will change over time. In particular, technology is evolving at a rapid pace and in ways that will have important implications for how data are collected and summarized. Recent years have also seen evolutions in PRO measures, with greater use of modern measurement theory and computerized adaptive testing. The practice of medicine is also changing, with emphasis on electronic medical records and more care being provided outside of visits via, for example, email. These changes will also affect whether and how PRO assessment fits into patient care.

Given these ongoing changes, we expect to update the online version of the *User's Guide* periodically to reflect developments in the field. These updates will come from several sources. First, the ISOQOL QOL in Clinical Practice SIG can take on stewardship of the *User's Guide* as part of its ongoing activities. The members of this SIG include many of the leaders in the field of using PROs in clinical practice, and this expert input will ensure that the latest information is reflected in the online *User's Guide*. Second, we invite comments from practitioners who have implemented—or are trying to implement—PROs as part of their routine care. Feedback on what has worked, and not worked, can be incorporated in the *User's Guide* and made available to others. Third, there will be opportunities for clinicians and researchers who have accessed the *User's Guide* to provide their feedback on what they found helpful and what areas would benefit from further development. All comments should be directed to info@isoqol.org.

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