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Patient-reported outcomes in clinical practice: using standards to break down barriers

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"PROs have great potential to improve the quality of patient care by informing clinical practice at several levels."

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While it seems obvious that medical care has always focused on the patient, recent efforts have been directed at formally integrating the patient's 'voice' into clinical care. One of the main approaches for incorporating patient perspectives in clinical practice is the use of patient-reported outcomes (PROs) [1–3]. PROs are defined by the US FDA as *"any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else"* [4]. Practically speaking, PROs are generally measured using questionnaires, through which patients report on their health and outcomes. There are a variety of categories of PROs, such as those evaluating health-related quality of life and symptoms, mental health, satisfaction with care, and utility measures [5].

Greenhalgh provides a useful taxonomy describing the various ways that PROs can be utilized in clinical practice [6]. To define the different clinical practice applications of PROs, Greenhalgh differentiates whether the data came from an individual patient or from groups of patients, and whether the data are applied to an individual patient–clinician encounter or to the care of a group of patients. In this overview, we focus on PRO data applied to individual patient–clinician (physician, nurse or other carer) encounters in the context of routine patient care. Specifically, we describe how aggregated data from clinical trials and observational studies can provide useful information to an individual patient's care; and how a single patient's PRO data may be used to aid his/her own care. We first briefly describe these two PRO applications, highlighting the potential benefits of each, then summarize key barriers to clinical implementation of PROs, and finally briefly discuss how current research aims to address these barriers through greater standardization of PRO methods and increased guidance to clinicians.

Describing the applications

■ Using group-level PRO data to inform individual patient care

PROs have traditionally been measured in clinical trials and observational studies to evaluate impacts on patient functioning and well-being. The PRO data collected from these studies can be applied to an individual patient's care, and because PROs represent the patients' perspective, they provide unique value in informing patient–clinician decision making [7]. Specifically, PRO findings can help clinicians and patients select the 'best treatment' by providing information on how treatment alternatives compare in terms of both their benefits and risks. Even when the treatment decision is based predominantly on consideration of outcomes such as survival rates, PROs can still provide a useful description of the patient experience, informing

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the patient and clinician about the impact of treatment on functioning and well-being. A related use of PROs is in the systematic description of tumor-related toxicities or adverse-event reporting, such as that provided by the patient-reported version of the Common Terminology Criteria used to report adverse events in oncology clinical trials [8]. Although clearly not universally so, aggregated PRO data from clinical trials have been shown to be valued by clinicians [9], understood by patients [10], and influential to medical decision making [2].

■ Using an individual's PRO data to inform his/her care

Another way that PRO data can be used to inform individual patient care is to have patients complete PRO questionnaires and provide the results to their clinical team. One-time PRO completion can be used to screen for conditions that the patient is less likely to spontaneously report (such as mental distress), or PRO data could be collected longitudinally to allow the clinical team to monitor patient progress over time (such as detecting a worsening condition requiring intervention). Research evaluating these PRO applications has consistently shown a benefit in clinician–patient communication [11], with some studies demonstrating improvement in problem detection, patient management and outcomes [12].

Barriers to clinical implementation

Even though group- and individual-level PRO data have the potential to inform and improve the care of individual patients, there are several barriers preventing their optimal clinical use. Several of these challenges involve variation in PRO methodology, including a lack of standardization of PRO instrument use, varying conventions for PRO questionnaire scoring and interpretation, and inconsistency in reporting PRO results from clinical trials [13]. Specifically, a wide variety of PRO measures have been developed to assess an array of outcomes. This diversity of PRO measures can contribute to a lack of clinician familiarity with any one particular approach and, hence, lack of confidence in the interpretation of PRO scores. As a result, clinicians often lack an intuitive understanding of whether scores constitute a clinical concern and whether a change in PRO scores is clinically meaningful [9]. If a clinician does not understand the meaning of a PRO score, he/she is unlikely to be able to integrate the PRO results effectively in clinical practice. As a result, clinicians may question the implicit value of PROs for patient care [9,14].

The interpretation challenges resulting from the multitude of PRO measures used are exacerbated by the differing conventions for instrument scoring across measures. Depending on the measures, higher scores may reflect 'better' or 'worse' patient status. Some measures (e.g., Patient-Reported Outcomes Measurement Information System [PROMIS] and European Organization for Research and Treatment of Cancer [EORTC] Quality of Life Questionnaire [QLQ-C30]) have used the convention that higher scores represent more of what is being measured, such that higher scores are better for domains such as physical functioning but worse for other domains such as sleep disturbance. Further, some measures linearly transform scores, such that the best and worst scores are the highest and lowest scores possible (e.g., the short-form health survey, SF-36®), while other measures norm to the general population. As a result, a clinician cannot easily translate knowledge about one PRO instrument's scoring system to a different measure. Qualitative research has shown that clinicians (and patients) would prefer score meaning to be consistent (e.g., higher always better) [15].

> "Increased standardization of PRO methods and application, coupled with increased guidance to clinicians on how to utilize PROs optimally, promise to further facilitate valid and valuable application of PROs in the real clinical world."

Finally, clinicians face a lack of consistency in how PRO results from randomized controlled trials (RCTs) are reported in the literature. In a cross-sectional review of 794 RCT reports, authors used a variety of strategies for summarizing PRO findings. For example, means or medians were the most commonly used (64% of RCTs), with less frequent estimates of average change from baseline (37%), or the proportion of patients achieving a predefined minimally clinically significant change (12%) [13]. Qualitative research shows such variation to be confusing to clinicians and a barrier to knowledge translation [9].

Recent efforts to address these challenges

Despite these commonly cited barriers, research also shows that a substantive number of clinicians endorse, and would like to improve, the use of PROs in practice [9,14]. A variety of research efforts may help clinicians achieve this goal. First, recent initiatives have recognized the need for more consistent use of PRO measures. For example, the PROMIS initiative aims to provide standardized items and scoring algorithms for PROs that are efficiently obtained and are reliable and valid across multiple clinical settings [16]. Another initiative seeks to identify a common

set of PRO measures that can be used across oncology clinical trials to allow consistent evaluation and between-study comparisons of PRO domains [17]. Second, the variation in PRO scoring (e.g., higher scores indicating better outcomes on some measures and worse outcomes on others) could be addressed by the development of scoring conventions to be used across measures. Ongoing research is exploring clinicians' preferences for both group- and individual-level data presentation to facilitate their understanding and application of PROs.

Third, in response to the identified need for consistent reporting of PROs in clinical studies [13], a Task Force of the International Society for Quality of Life Research (ISOQOL) has recently collaborated with the Consolidated Standards of Reporting Trials (CONSORT) group to develop improved guidance for the reporting of PROs in clinical trials [18]. Greater consistency in how PROs are scored and reported will help increase clinicians' familiarity with each type of use, such that increased confidence is achieved in the application of PROs in both settings.

In addition to research efforts aimed at improved standardization of methods, knowledge translation research may also enhance the use of PROs. In the case of aggregate data from trials, research exploring how to optimally integrate PRO data into clinical decision aids, or other patient- or clinician-education strategies, will enhance the translation of clinical trial findings to the patient–clinician interface. For example, an ISOQOL working group is updating a User's Guide [19] to reading and applying PRO studies reported in the literature. In the case of individual-level PROs, research identifying strategies for convenient and systematic collection of the data (e.g., web-based applications that allow patients to complete questionnaires at home) is now in progress [15]. Including these data in the patient's electronic medical record allows seamless integration of the PRO data with other laboratory findings, enables alerts for important changes in scores, and facilitates tracking of patients over time. In addition, increased guidance for clinicians on how to incorporate individual PRO assessments in their clinical practice aims to improve the effectiveness of this intervention [20].

In summary, PROs have great potential to improve the quality of patient care by informing clinical practice at several levels. Increased standardization of PRO methods and application, coupled with increased guidance to clinicians on how to utilize PROs optimally, promise to further facilitate valid and valuable application of PROs in the real clinical world.

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