



REVIEW ARTICLE

Patient Reported Outcomes Measurement Information System (PROMIS) in the upper extremity: the future of outcomes reporting?



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Patient reported outcomes (PROs) serve an integral role in clinical research by helping to determine the impact of clinical care as experienced by the patient. With recent initiatives in health care policy and pay for performance, outcome reporting is now recognized as a policy-driven requirement in addition to a clinical research tool. For outcome measures to satisfy these regulatory requirements and provide value in understanding disease outcomes, they must be responsive and efficient. Recent research has uncovered certain concerns regarding traditional PROs in patients with upper extremity disability and injury. These include lack of consensus regarding selection of PROs for a given diagnoses, inconsistent techniques of administration of the same PROs, and the administrative burden to patients and providers of completing these forms. To address these limitations, emphasis has been placed on streamlining the outcomes reporting process, and, as a result, the National Institutes of Health (NIH) created the Patient Reported Outcomes Measurement Information System (PROMIS). PROMIS forms were created to comprehensively and efficiently measure outcomes across multiple disease states, including orthopedics. These tools exist in computer adaptive testing and short forms with the intention of more efficiently measuring outcomes compared with legacy PROs. The goals of this review are to highlight the main components of PROMIS reporting tools and identify recent use of the scores in the upper extremity literature. The review will also highlight the research and health policy potentials and limitations of implementing PROMIS into everyday orthopedic practice.

Level of evidence: Narrative Review

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clinical care as experienced by the patient. With recent initiatives in health care policy and pay for performance, outcome reporting is now recognized as a policy-driven requirement in addition to a clinical research tool. For outcome measures to satisfy these regulatory requirements and provide value in understanding disease outcomes, they must be responsive and efficient to administer for patients and clinicians alike.

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Recent research has uncovered certain concerns regarding traditional PROs in patients with upper extremity disability and injury. Many commonly used forms were created without appropriate statistical validation²⁰ and have become adopted into everyday use for largely historical reasons.²⁰ Moreover, many PROs display ceiling effects that limit their use for patients who continue to be active as they age.¹ Finally, multiple recent studies indicate that widespread variability exists in the particular PROs used in different studies of the same diagnosis,^{3,10} thereby significantly limiting the relevance of translatability of many of these high-impact studies.

In addition to concerns over PRO appropriateness and validity, there have been some challenges in efficiently administering these forms to patients in increasingly busy clinical settings. Multiple studies have highlighted these challenges resulting from certain patient characteristics,¹⁷ constraints in patient time, “survey fatigue,” and also from time constraints and administrative/cost burdens for providers.

In the face of these challenges and limitations, the National Institutes of Health (NIH) embarked on a mission to streamline the outcomes reporting practice across all of medicine. This initiative, the Patient-Reported Outcomes Measurement Information System, or PROMIS, focused on creating PROs that were applicable to the general population and that could be administered and scored in a standardized manner (normalized to match the average person based on 2000 US Census demographics). These forms further were designed in two administration formats—short form (SF) and computer adaptive testing (CAT). In the SF versions (which could be administered electronically or through a paper version), a subset of questions from the comprehensive item bank was selected for administration (typically 4, 6, or 8 questions). In the CAT version, a computer algorithm selected successive questions to be answered based on responses to preceding questions. For example, if a patient responded that he or she was unable to walk 1 block, the next question might assess the patient’s ability to stand rather than whether or not the patient could walk 1 mile. CAT theoretically allows for more efficient form administration without sacrificing responsiveness given the ability to ask algorithm-selected questions from a large question bank.

This review documents the origin and rationale behind CAT used in NIH PROMIS and reviews recent literature attempting to use PROMIS scores in studies of musculoskeletal disease specifically in patients with upper extremity injury and disability. Finally, potential benefits and limitations of incorporating PROMIS testing in everyday use are discussed.

Origins of NIH PROMIS

In 2002, the NIH Director announced an initiative to improve the practice of outcome reporting in the medical sciences.^{3,18} The goal of this initiative would be to facilitate a more efficient, and therefore, practical method of collecting and monitoring PROs after disease treatment and intervention. Such

a system would entail standardized scores that were normalized and focused on function domain, such as lower extremity physical function (PF), and pain interference, rather than diagnosis (eg, anterior cruciate ligament tear, shoulder instability). Through this format, outcome scores could be easily compared across different clinical and research scenarios. Thus, PROMIS was officially launched in 2004 as part of the NIH Roadmap for Medical Research Initiative. The initial development team incorporated 6 primary research institutions, a steering committee, and a statistical center, with the goal of developing a framework based on the 3 tenets of PF, mental health, and social function, as proclaimed by the World Health Organization.

The committee established 5 subdomains to focus on item-bank creation: PF, social function, pain, fatigue, and emotional distress. Existing literature was used to construct item banks to be used for both the SF and CAT versions of the resulting tools.³ Finally, PROMIS includes a Global Health domain, which includes broad items addressing PF, pain, fatigue, emotional distress, and social health to elicit a quality of life health indicator from participants. The complete domain map and component listing is maintained up-to-date on the PROMIS Web site.¹²

PF domains in NIH PROMIS

PF comprises 1 of the 5 physical health profile domains, along with pain intensity, pain interference, fatigue, and sleep disturbance. The PF domain is intended to measure disability, or function below the population mean, and fitness, or function above the mean.⁷

The PF domain of PROMIS is intended to encompass self-reported abilities and capabilities ranging from activities of daily living and self-care to higher-level athletic activities (eg, running extended distances). However, actual measurement of these tasks is not performed within the confines of the form. Therefore, the forms may be applicable to all patient types, regardless of their disability or recovery point from injury or treatment. Subdomains within the PF domain address mobility (lower extremity) and upper extremity components.

Currently, PROMIS forms may be administered as a SF or using CAT. The SF consists of a discrete set of questions and exists in multiple forms (eg, 4, 6, or 8 questions). From the larger item bank, questions were analyzed to determine which were the most robust, and the most relevant and efficient questions were included in the SF.¹⁶ The SF provides the benefit of allowing clinicians to administer the same discrete set of questions many times along a treatment course.

A second method of administration is through CAT. In CAT, a sophisticated algorithm selects the question to be answered based on the response of the prior question. This technique is used extensively in education testing (eg, GMAT administration). For example, in a form assessing lower extremity function, if a patient answered “without any difficulty”

to the question, “Can you walk one mile without difficulty,” the next question might be “Can you run one mile without difficulty.” If the answer to the original question was “unable to,” then the next question in the algorithm might be “Can you walk one block without difficulty.” Extensive literature has validated CAT as a method for delivering scores and results in a more efficient manner compared with conventional testing methods, without loss of accuracy or comprehensiveness. The CAT method provides a means of increasing questionnaire responsiveness without sacrificing brevity of the form. SFs tend to require more items to achieve the same level of responsiveness as a CAT questionnaire.^{2,4,8,15}

For the PF assessment, the total item bank includes 121 questions (as of the time this report was submitted). Multiple SFs are available. The most up-to-date form includes 10 questions to be completed in its entirety by responders. The alternative method of administration is the CAT version, which has been reported to require between 4 and 5 questions in initial validation studies in the upper extremity.^{1,11}

PROMIS forms are scored according to the concept of item response theory. In item response theory, the score is based on a sophisticated algorithm that compares individual question responses with the performance of the overall population on a given measure. Therefore, each question is weighted distinctly to produce a scaled scoring system as opposed to equal weighting through a Likert model. The individual score represents a T score against normative population data, with a score of 50 representing the mean score for the reference population and each standard deviation represented by 10 points. In this way, the PF instruments are able to quantify increments and decrements of function from the mean.

When determining the most appropriate method of administration, the researcher must consider logistics with regards to the study and to the patient. From a study perspective, the technological capabilities of the assessment systems must be considered to determine whether a CAT can be reliably administered. Moreover, the patient’s capacity must also be considered with regards to the number of questions that can be answered as well as the medium (paper vs. electronic) of the survey.

Correlation of the SF and CAT assessments to the comprehensive question bank is not equivalent. Although PROMIS researchers have found that scores are reasonably consistent between SFs and the CAT format of questionnaire, the CAT version is generally more highly correlated with the full bank due to the increased responsiveness of the CAT version.¹⁴ However, the correlation of the SF to the comprehensive bank increases with an increasing number of questions defined in the SF. Research personnel should consider these factors when planning study designs. It is important to note that the PF item bank is designed to represent only 1 specific domain. For example, although many traditional questionnaires address pain and PF, the PROMIS PF bank contains only questions specific to function. However, there are other CATs within PROMIS that are designed to address pain or emotional impact, if such information is needed.¹

A number of SF versions of PF assessments are available. SFs with a lower number of questions will have decreased correlation with the full bank compared with SFs with a higher number of questions. This is due to the increased responsiveness with forms that have higher number of questions. Researchers must determine which forms are appropriate for their particular patient population. Moreover, different versions may appear online as forms are updated, and the researcher must be aware of these different versions before study commencement.

PROMIS validation with general health measures

A number of different studies have begun to report data on PROMIS use in research trials, particularly in validation efforts against legacy PROs or general health scores such as the Disabilities of the Arm, Shoulder and Hand (DASH) and the 36-Item SF Health Survey.

Correlation between PROMIS and general upper extremity health scores

Multiple studies have compared PROMIS score reporting against reporting of established, general health (non-disease-specific) outcome scores. Many of these studies have attempted to validate PROMIS with upper extremity scores such as the DASH and the 11-item version of DASH (QuickDASH). These studies have had 2 goals: to establish a correlation between results of the 2 types of measures and to test the hypothesis of the PROMIS requiring shorter administration time than conventional outcome scores.

A recent study by Doring et al⁶ attempted to validate PROMIS PF Upper Extremity CAT with the QuickDASH with regards to correlation and presence or absence of floor and ceiling effects. The study consisted of 84 patients from an upper extremity clinic, and the authors found strong correlation between PROMIS CAT and the QuickDASH. Moreover, the administration time of the PROMIS CAT was only 70 seconds compared with 116 seconds for the QuickDASH. The findings of this study were somewhat limited, however, because it included a heterogeneous patient population without validation of outcomes with functional recovery. Therefore, whether the forms could be used to monitor functional recovery after injury or treatment within any specific patient population remains unknown. It did, however, report no ceiling or floor effects with PROMIS outcomes.

In a separate study by the same principle investigator, the PF CAT (without segregation into the upper extremity score) had only moderate correlation with the QuickDASH in a cohort of 93 patients seen in the upper extremity clinic.¹³ That there was moderate correlation, despite not being focused on the upper extremity, indicates nonphysiologic affects of the included questions (eg, psychological disposition) may factor into the outcome scores of patients after injury. To that

point, the authors noted that in states of higher degrees of disability, the QuickDASH correlated more strongly with the PROMIS Depression and Pain Interference scores.

In a study by Tyser et al,¹⁹ 134 patients with upper extremity injury (excluding shoulder) completed the PROMIS PF CAT and the DASH assessment. The authors reported a decreased number of questions required to complete the PROMIS PF CAT (mean of 5 questions; range, 4-12 questions) compared with the 30-question DASH form. This equated to an average time to completion of 57 seconds for the PF CAT compared with 262 seconds for the DASH. Moreover, the authors reported that the instruments were highly correlated, at $r = 0.726$, which is a higher correlation than that found by Overbeek et al¹³ between the PF CAT and the QuickDASH. However, the study by Tyser et al¹⁹ also was a cross-sectional study without any longitudinal follow-up or focus of diagnosis in the patient cohort.

Correlation of PROMIS to joint-specific PROs

Recent studies have begun to correlate PROMIS scores with joint-specific PROs in the upper extremity. In a recent study by Morgan et al,¹¹ the PROMIS PF CAT was correlated with the Constant Shoulder Scores (CSS) and to the generic upper extremity scores of the DASH and the Short Musculoskeletal Functional Assessment (SMFA) in 47 patients with displaced proximal humeral fracture. All patients were aged older than 60 years. The authors reported that patients only required an average of 4 questions to complete the PF CAT compared with 6 for the CSS and 30 for the DASH. Despite requiring fewer questions on average than the CSS (4 vs. 6 questions), the PF CAT actually took longer to complete than the CSS (98 vs 91 seconds), although the difference was not statistically significant. The PF CAT had a correlation of $r = 0.52$ with the CSS, which was lower than the correlation between the PF CAT and the DASH and SMFA.

In another recently published study by Beckmann et al,¹ the PROMIS PF CAT was administered to 187 patients with rotator cuff tendinitis, partial-thickness tear, or full-thickness tear. The PF CAT was correlated to the Simple Shoulder Test (SST) and to the American Shoulder and Elbow Surgeons (ASES) Shoulder Assessment score. The authors similarly found a decreased number of questions required by the PF CAT (4.3) compared with the fixed-length surveys of the ASES (11 questions) and the SST (12 questions). The PF CAT had a higher correlation with the SST ($r = 0.635$) than with the ASES ($r = 0.581$). The authors also reported low ceiling effects of 0.53% and floor effects of 3.2% when using PF CAT.

Potential advantages of PROMIS compared with traditional outcomes reporting

Use of PROMIS scores for research and clinical outcomes tracking may have several advantages over use of traditional outcome measures and PROs. This may be especially true

when managing patients with upper extremity injury, for whom functional recovery and resolution of pain are of essential importance to patients. Given the correlational strength between the upper extremity subdomain of the PF CAT to traditional PROs, along with the decreased time to completion for the score, there may be significant benefit in using the PF-upper extremity CAT for clinical research studies going forwards. This may save time in the office for clinicians and patients.

Secondly, and arguably more importantly, transition to PROMIS incorporation will allow clinicians to speak a “common language” with regards to outcome reporting. This will allow for enhanced comparison potential among different clinical trials. Currently, there is significant disparity in outcome reporting practices, even in high-impact orthopedic literature.¹⁰ Transitioning to a common outcome metric will improve the overall quality of literature for upper extremity disease and treatment.

Finally, successful implementation of PROMIS reporting has the potential to significantly lighten the burden of time required to filling out outcome reporting scores. Whether through a SF or CAT, PROMIS will likely save time for patients and clinicians. Moreover, scores are reported on a 0-100 scale, with 50 representing the mean. Therefore, score reporting becomes more efficient from a time-administration perspective as well as from a reporting standardization perspective.

Limitations of PROMIS for upper extremity conditions

Even though PROMIS may be more efficient to administer in patients with upper extremity disability compared with traditional outcome measures, several limitations exist. Studies that have demonstrated decreased time to completion for PROMIS scores have typically focused on the CAT version of the form.^{1,6,11,13,19} Similar benefits may exist when the SF is used, but there likely will be a decrease in responsiveness, especially if using the shorter versions of these forms.

A second limitation exists regarding actual administration of the PROMIS CAT tools. Because CAT must be administered electronically, it will require researchers to use electronic outcome reporting tools to administer these forms. Investigators without the infrastructure to transition to this medium or to support it will experience challenges in attempting to use the CAT forms. Moreover, not all electronic health records support PROMIS CAT integration at this time, and those that do may not provide support for all the different PROMIS forms. This may again force researchers to rely on SF versions of PROMIS rather than the more powerful CAT option.

To date, there has been a paucity of data regarding PROMIS outcomes in athletes with upper extremity injuries. At this time, sport-specific metrics are not included in PF question banks. Most items in the main banks are focused on activities of daily living or moderate-intensity activities, and prior

trials have indicated that a significant concern for ceiling effect exists in using the PROMIS PF forms.⁹ However, this structure is consistent with the overall goal of PROMIS, which is to focus outcome testing on the general population. Further research and validation trials are therefore required to determine the true ceiling effect of PROMIS upper extremity forms when dealing with very active individuals and athletes. With expansion of PROMIS to include assessment of these individuals, the item bank may have to similarly expand. This may require additional responses in order to become sensitive enough to detect changes in athletes, thereby limiting the efficiency of PROMIS CAT compared with sport-specific PROs such as the Kerlan Jobe Orthopaedic Clinic score.⁵

Finally, as newer versions and subsequent validations of PROMIS become available, there may be unforeseen challenges in implementing a nonstatic outcome reporting system. The outcomes of studies with different PROMIS versions may no longer be relevant as newer versions are released. This may be mitigated with scoring conversion systems between one PROMIS form version to and subsequent PROMIS form versions. Moreover, the multitude of options available for SFs also creates additional heterogeneity with outcomes reporting using PROMIS. Therefore, PROMIS engineers must work to maintain uniform reporting standards as the tool is iterated and expanded.

Conclusion

NIH PROMIS measures represent a potential improvement to the current practice of measuring PROs. Deficiencies with current outcomes reporting practices includes a lack of consensus regarding which PRO to administer as well as significant administrative burdens required for widespread use. However, additional validation testing must be performed before PROMIS measures can be fully adopted. This includes longitudinal treatment response testing as well as incorporation of measures or modifications to detect changes in the performance of active individuals and athletes. Moreover, given the role of the NIH in the development of PROMIS, the question remains whether and how the international community will incorporate PROMIS into clinical and research use.

Disclaimer

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