Current Concepts Review

Meaningful Clinical Applications of Patient-Reported Outcome Measures in Orthopaedics

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- Patient-reported outcome measures (PROMs) comprise valuable data, when combined with traditional clinical information, for patient-centered health outcome assessment.
- While PROMs form the foundation of orthopaedic clinical research, they are invaluable tools for clinical care.
- PROMs play a critical role in shared decision-making with patients, as they are quantitative measures of patient health (function, pain, and satisfaction).
- PROMs should be incorporated into routine postoperative care for effective clinical monitoring and understanding of the response to surgery.
- PROMs can be additionally utilized for meaningful clinical research, predictive analytics, and value-based care delivery pathways.

Patient-reported outcome measures (PROMs) represent one of the most relevant clinical outcomes for reporting patient health states. PROMs are validated questionnaires completed by the patient that quantitatively report health (i.e., general health, quality of life, physical function, mental health, and pain). PROMs can also be specific to a particular diagnosis or patient cohort. Because they are completed by the patient—as opposed to the clinician—they represent a patient-centered perspective on his or her health and are therefore very valuable as a clinical outcome tool. As outlined by Porter[1], health-care value can be improved through either a reduction in costs (denominator) or improvement in quality and outcomes (numerator). As the demand to provide improved health-care value grows, there is interest in maximizing the numerator of the value equation (outcomes), highlighting the importance of PROMs.

Despite their importance in clinical orthopaedics, PROMs are still not routinely collected by surgeons. In a recent study, it was estimated that only 35% of orthopaedic practices collected PROMs[2]. There are numerous well-documented barriers to effective PROM administration and collection[3]. These include administrative, logistical, and financial constraints. Once these barriers are overcome, orthopaedic providers are able to incorporate PROMs into a number of high-quality applications, as outlined in this Current Concepts Review. These 5 applications include shared decision-making (SDM), postoperative care, meaningful clinical research, value-based care delivery, and quality assurance (Fig. 1). This review includes numerous clinical examples to illustrate these concepts.

Integrating PROMs into Routine Clinical Care

To maximize the utilization and clinical application of PROMs, they must be administered and collected as a part of routine clinical care—for both surgical and nonsurgical patients. A variety of techniques and cost estimates for successful PROM collection have been outlined, depending on the individual

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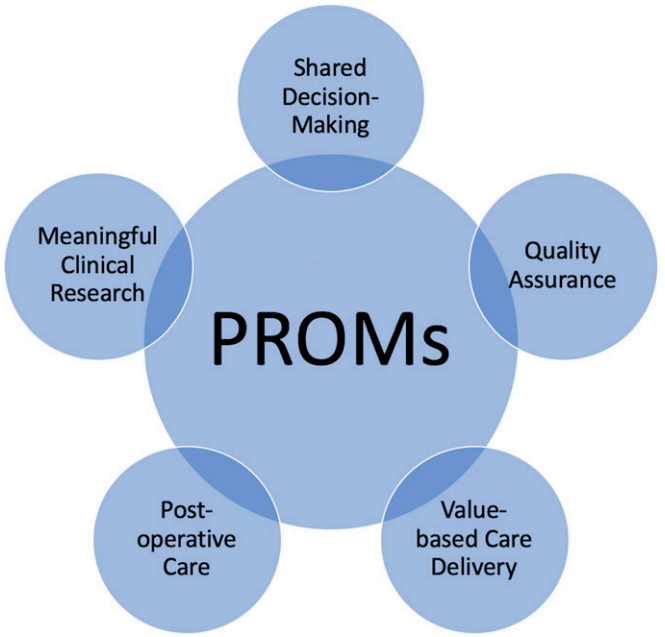


Fig. 1
Applications of PROMs.

practice characteristics[3-6]. However, there are discrete best practices (Table I) that guide implementation.

Successful PROM administration relies on a streamlined workflow and careful selection of questionnaires. From a workflow perspective, it is ideal to incorporate PROM administration into the existing workflow. The addition of personnel or processes can lead to unsustainable expenses or delays that are frustrating to both patient and provider. Numerous PROM platforms with varying levels of cost and electronic medical record (EMR) integration exist, allowing orthopaedic groups of all sizes an opportunity to collect PROMs[7]. Most electronic PROM platforms support remote delivery, allowing patients to complete questionnaires by email, tablet or computer, and even text message. Therefore, encouraging patients to complete forms prior to the scheduled appointment reduces the burden on staff during the clinic session[8]. Ideally, PROMs are completed prior to entering the examination room, so that they are available for reference during the clinical encounter[3,9].

Great care must be taken when selecting which PROMs to administer. First and foremost, they should be chosen with the patient and/or diagnosis in mind. Each individual PROM contains specific components (e.g., function, pain, and mental health) that should be considered. To minimize survey respondent fatigue, PROMs should take <5 minutes to complete[10,11]. However, PROMs that a patient can complete remotely at home (e.g., prior to the office visit) may make a longer questionnaire tolerable. In the research context, PROMs are chosen according to the relevant surgical procedure and typically consist of a number of disease-specific "legacy" PROMs. However, it is challenging to administer PROMs according to diagnosis and have them available during the clinical evaluation, as patients are often scheduled without a clear diagnosis. Moreover, administering numerous legacy PROMs can be lengthy, thereby reducing the response rate[12]. Ideally, collection techniques should be streamlined with respect to modality (i.e., telephone, electronic, and in person) as much as possible, as PROM scores may be affected by the method of collection[13].

The alternative to diagnosis-specific PROMs is domain PROMs. While these are not specific to a particular diagnosis, they do measure important health states, such as physical function, mental health, and pain. Because they are not tied to an individual diagnosis, they can be easily administered in an automated fashion on the basis of certain appointment parameters (e.g., the anatomic location of the pain, injury, or symptom). Moreover, automatic assignment facilitates previsit PROMs, as they can be assigned to patients without the determination of a particular diagnosis (which itself typically requires clinical evaluation).

Recently, the National Institutes of Health Patient-Reported Outcomes Measurement Information System (PROMIS) tools have gained attention in the orthopaedic literature, as they are domain-specific PROMs that exist in both standard survey form ("short form") as well as dynamic, computer adaptive test (CAT) form[14]. The CAT versions have been demonstrated in numerous studies to be more efficient to administer than traditional legacy PROMs, without any

TABLE I Best Practices for Successful Collection of Ambulatory PROMs

Consideration	Action Plan*
Workflow	Incorporate PROM collection into existing clinical workflow; large practices may require additional FTE support for operational oversight and quality control
PROM administration	Must be electronic. Remote collection prior to, or in-office collection on, check-in for ambulatory visit; PROMs must be completed prior to clinical evaluation
Patient selection	Ideally all ambulatory patients (surgical and nonsurgical)
Provider participation	All providers should participate
PROM selection	Standardize across division and/or department, and ideally <5 to 10 minutes should be required for completion (i.e., as short as possible)

*FTE = full-time equivalent.

meaningful psychometric compromise[15-19]. These forms rely on item response theory to deliver questions in a dynamic and efficient manner—drawing from questions found in numerous existing questionnaires—allowing them to be easily be administered in <5 minutes[11]. Standardized scoring of PROMIS forms[14] further simplifies the analysis and utilization of these metrics, as a score of 50 represents that of a reference population. Each standard deviation is equivalent to 10 points. Therefore, a patient scoring 60 on PROMIS Physical Function would demonstrate 1 standard deviation of additional physical function compared with the reference population, while a patient scoring 60 on Pain Interference (impact of pain on quality of life) would have 1 standard deviation of additional symptom severity compared with the reference population.

Regardless of which specific PROMs are utilized, it is important that the selection is standardized across a division or department as much as possible. Heterogeneity across individual providers can lead to confusion among support staff as well as increase the complexity of algorithms used for automatic form assignment. Moreover, standardization can improve the quality of PROM data, as the same measures are collected over time, regardless of the provider seen, and therefore are available for longitudinal monitoring. Such a strategy does not preclude utilization of necessary PROMs for clinical studies or registries; the provider can still leverage research staff to conduct these efforts outside the standard operating pathways.

Finally, to be useful, the results from PROM questionnaires must be available for review in real time and during the clinical encounter with the orthopaedic provider. The provider must also be able to track these outcomes over time to determine the appropriateness of care. Therefore, electronic forms should be utilized, with results available immediately for review. Numerous electronic platforms exist, including free software solutions as well as options integrated into the EMR. Figure 2 demonstrates a patient PROM dashboard as depicted in a PROM platform through the EMR (Epic).

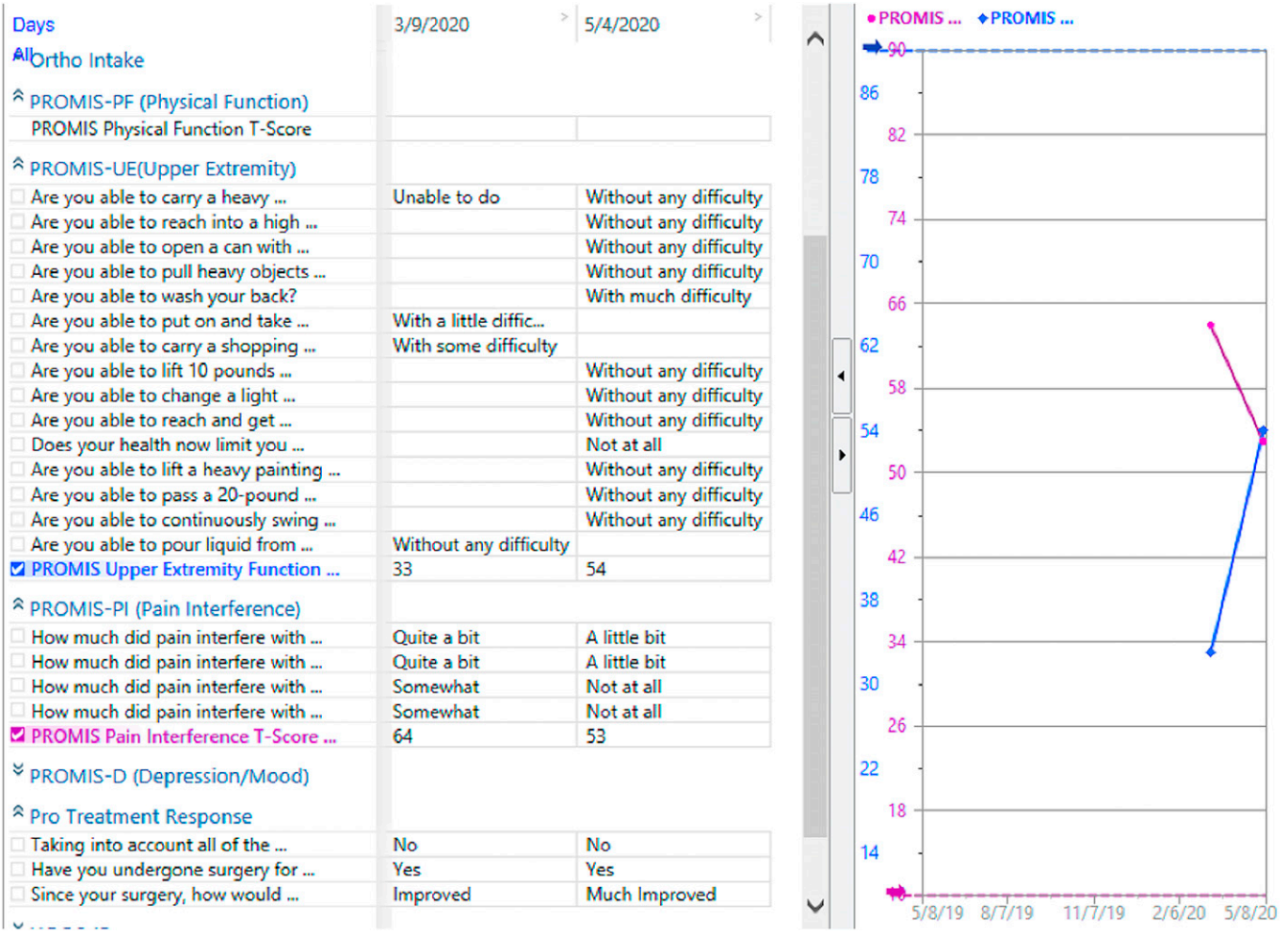


Fig. 2

The PROM dashboard for a patient after upper-extremity surgery. In this example, the patient has PROM scores depicted through the electronic medical record (Epic). Dashboards such as these allow orthopaedic providers an overview of the patient's functional and symptomatic (pain) trends with time.

Using PROMs for Shared Decision-Making

Once PROMs are integrated into routine clinical care, they are available for SDM with patients. SDM refers to the process of making treatment plans with patients through a consensus approach with patient and provider, such that critical information—risks, benefits, indications, and expected outcomes—is presented to the patient, who then makes an informed decision regarding his or her care. Participation in SDM may minimize the risk of patient dissatisfaction and provide medicolegal protection to providers[20].

PROMs are key components of SDM and can be incorporated into surgical decision-making discussions. The ultimate goal is to optimize patient selection for surgery and standardize appropriate criteria. Even in established procedures, such as total joint replacement, as many as 33% may be avoidable[21]. This underscores the importance of comprehensive preoperative discussions regarding patient expectations from surgery, as patients who are functioning well and wish to improve on this may experience variable results and satisfaction. Therefore, incorporation of PROMs may help to standardize selection criteria, leading to lower numbers of inappropriately performed surgeries and higher postoperative satisfaction rates.

Baseline PROMs allow patients and providers a quantitative assessment of a patient's true functional and pain levels in relation to reference populations. With this information, the provider can accurately counsel the patient with regard to his or her true level of impairment. For example, if a patient has a PROMIS Physical Function score of 60 and Pain Interference score of 40, they are likely in relatively good health compared with most patients who have already recovered from surgery[22]. It is logical to see, therefore, that undergoing surgery that results in a lower functional outcome postoperatively is likely to be associated with patient dissatisfaction.

Numerous studies of patients treated in foot-and-ankle clinics[23,24] have identified threshold physical function scores that predict achievement of a minimal clinically important difference (MCID). Similar findings have been reported among patients undergoing total hip and knee replacement[25,26]. In these studies, patients with preoperative functional scores above the determined thresholds were unlikely to improve meaningfully following surgery, in contrast to those under the thresholds. By applying these criteria to surgical decision-making, surgeons can optimize patient selection and, subsequently, postoperative outcomes. As an extension of this concept, advanced analytical tools (such as machine learning) may be able to predict postoperative outcomes incorporating not only preoperative PROM data but also other patient characteristics and comorbidities[9]. These predictive tools can be incorporated into the EMR and can be extremely valuable for SDM conversations.

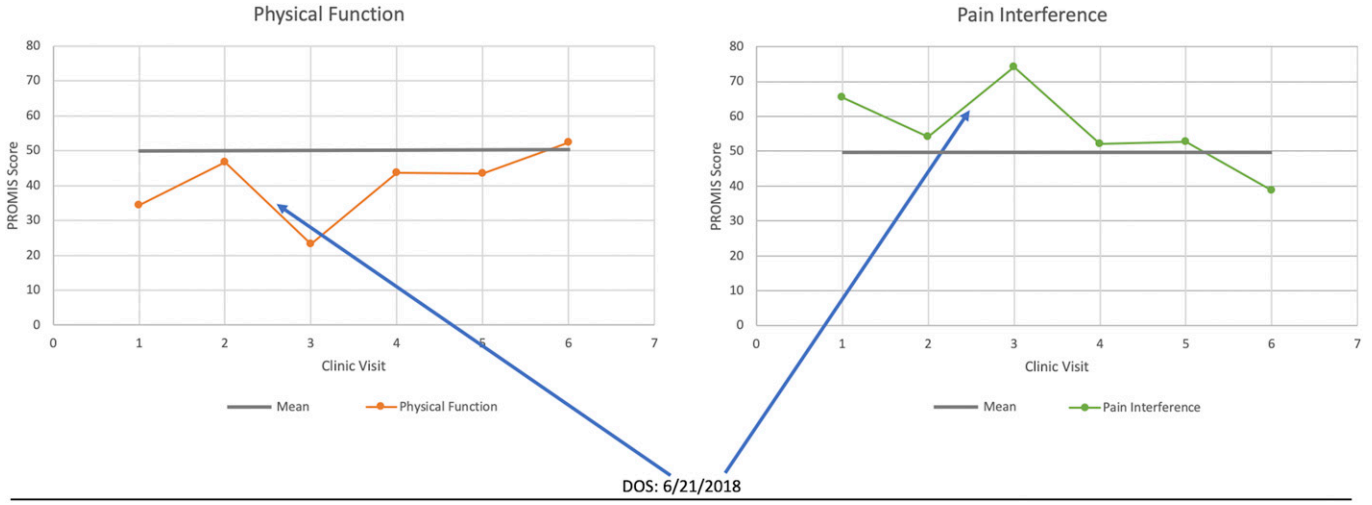
Successful recovery from most orthopaedic surgeries requires an understanding of the importance of (narcotic) pain medication weaning, physical therapy augmented with a home exercise program, and basic knowledge of inciting events that may signal a postoperative complication (e.g. wound complication, neurovascular abnormalities, or a sudden change in functional capacity). PROMs may help to identify patients who lack awareness or ownership of their medical care. These patients may be at risk for failing to improve following surgery. One commonly utilized questionnaire that measures this patient engagement is the Patient Activation Measure (PAM)[27]. In patients undergoing total hip and knee arthroplasty, those with higher PAM scores preoperatively exhibited greater mental health and satisfaction scores, as well as better pain relief, postoperatively compared with patients with lower PAM scores. These tools can be used to introduce preoperative coaching and education for those who score poorly, thus improving the likelihood of a successful postoperative result.

Streamlining Postoperative Care and Monitoring

Ultimately, the goal of most typical orthopaedic surgeries is to improve the health domains of pain and physical function, among others. Therefore, PROMs can quantitatively assess the impact of surgery on these domains by simply comparing preoperative and postoperative outcome scores. Unfortunately, when postoperative PROMs are collected for clinical registries or research projects, these scores are typically collected and reported without real-time review with the patient.

Postoperative PROMs should be reviewed with patients throughout their recovery process and during each postoperative appointment (Fig. 3). Review of these scores will visually and quantitatively illustrate to patients where they are in their recovery, as well as how much further they may be expected to recover. Moreover, it provides surgeons with quantitative data that assess the patient's health states in comparison with similar counterparts. Patients who do not demonstrate appropriate improvement in PROMs may warrant further investigation. For example, early and suboptimal plateauing of scores following tendon repair (e.g., rotator cuff), in conjunction with physical examination findings, may indicate the need for diagnostic imaging to rule out retear or failure of the repair. Similarly, patients who are performing very well postoperatively in the setting of a suboptimal objective outcomes (rotator cuff retear, nonanatomic fracture healing, etc.) may not require corrective intervention (Fig. 4). In this example, a 63-year-old patient with a rotator cuff retear may warrant consideration for reverse shoulder arthroplasty; however, if postoperative PROM scores demonstrate substantial improvement, the decision to undergo surgery can be safely deferred. Only with real-time collection and review can surgeons incorporate PROMs into these types of decision-making.

Routine postoperative PROM collection can also make delivery of care more efficient. It has been demonstrated that patients experience most improvement by 3 months and 6 months following total knee replacement[22]. In patients who achieve meaningful improvement at 3 months postoperatively, the case could be made to subsequently transition to remote monitoring with PROM surveillance, thereby decreasing the cost of care to patients and payers, while reducing low-value ambulatory visits for providers. Conversely, patients undergoing reverse shoulder arthroplasty may experience a lengthier recovery spanning 1 to 2 years, thereby justifying continued follow-up during this time period[28]. Patients with an unexpected decline in PROM scores postoperatively would warrant prompt workup for possible



Visit	Date	Physical Function	Pain Interference
Pre Op	5/21/2018	34.40	65.50
Pre Op	6/18/2018	46.60	54.10
2 week	6/29/2018	23.20	74.10
6 week	8/3/2018	43.70	52.20
3 month	8/24/2018	43.50	52.70
6 month	12/21/2018	52.30	38.70

Fig. 3

Sample PROM tracking before and after surgery. In this example, PROMIS Physical Function CAT and Pain Interference CAT scores were tracked in a patient who had anterior cruciate ligament reconstruction from the time of presentation through postoperative recovery. These graphs are used to illustrate the functional and pain recovery of patients throughout the care process. DOS = date of surgery.

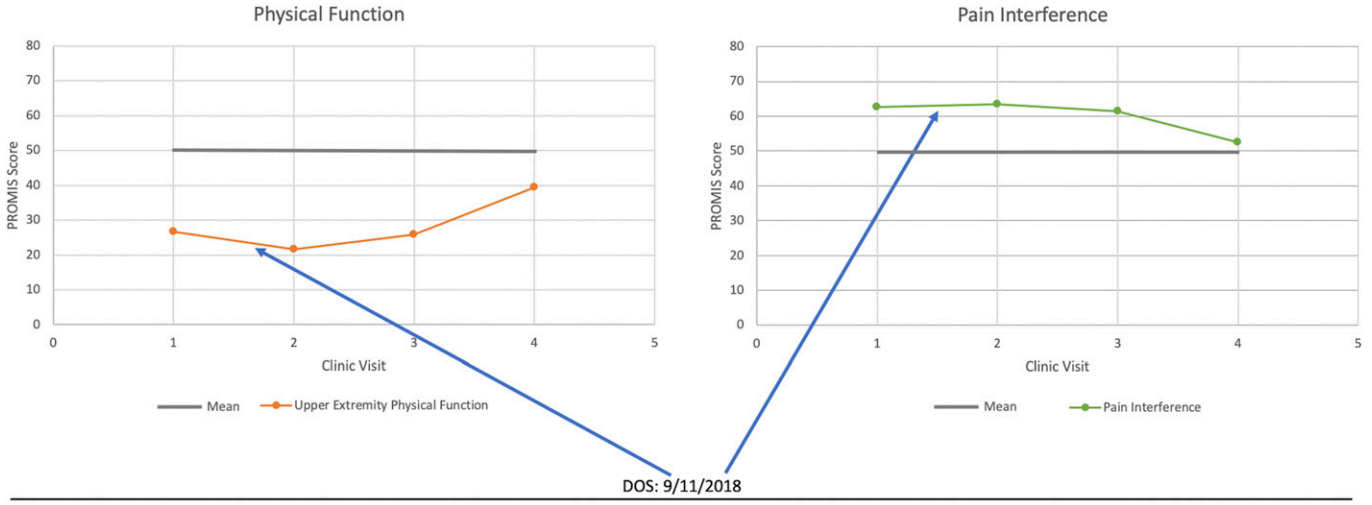
causes (e.g., hardware compromise, infection, or repair failure). However, adoption of PROMs for remote monitoring and/or decision-making should be tailored to the individual clinical scenario and in consideration of the need for traditional clinical assessment, such as history, physical examination, and imaging.

Performing Meaningful Clinical Research

PROMs comprise valuable data, combined with traditional clinical information, for patient-centered health outcome assessment. Ideal PROMs chosen for research purposes are responsive (score changes associated with health state changes), reliable (consistent), and valid (accurate)[29]. Moreover, they should demonstrate favorable (<5%) floor and ceiling effects, which are defined as the proportion of responders who score the lowest and highest possible score, respectively. Substantial floor or ceiling effects demonstrate poor sensitivity for a given condition, as many patients score similarly (at the floor and ceiling values) but clinically may be different. Recently, the American Academy of Orthopaedic Surgeons released a list of joint-specific PROMs recommended for use, as recommended by the Quality Outcomes Data Work Group[30].

Data from PROMs are most valuable when aggregated on a large scale. As health care in the United States is largely decentralized, clinical registries have emerged as valuable tools in examining clinical outcomes on large, multicenter scales. Indeed, registries may be more feasible in countries with nationalized health-care systems, with many focusing on hip and knee arthroplasty[31]. In the United States, despite the presence of a multipayer infrastructure, there have been several joint replacement registries. Some of these are regional, such as the Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI)[32], while others are geographically diverse, such as the Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement (FORCE-TJR) registry[33,34]. PROMs comprise the fundamental functional outcome metric in these registries and complement other outcomes, such as readmission rates, complications, and implant survival[34].

When PROM collection is coordinated across a department or multiple centers (i.e., with standardization of which PROMs are collected), the magnitude of input data facilitates high-quality clinical research. In particular, research focusing on the achievement of the MCID and the substantial clinical benefit (SCB) has been particularly impactful when the efficacy of treatment is considered. The MCID is defined as the minimal change in the PROM score that denotes a meaningful clinical improvement[35], while the SCB is the score change that denotes a considerable clinical improvement[36]. These assessments are performed when changes in PROM scores are compared with anchor questions that denote perception of improvement following surgery, as reported by the patient. Therefore, it is essential to include these anchor questions in routine postoperative PROM questionnaires.



Visit	Date	Upper Extremity Physical Function	Pain Interference
Pre Op	8/17/2018	26.60	62.70
6 week	10/19/2018	21.60	63.40
3 month	12/3/2018	25.90	61.50
6 month	1/25/2019	39.50	52.60

Fig. 4

Sample PROM tracking in a 63-year-old patient, a physical therapist with a massive rotator cuff tear, who wished to avoid shoulder arthroplasty and was managed with rotator cuff repair. In this example, PROMIS Upper Extremity Physical Function CAT and Pain Interference CAT scores were tracked before and after rotator cuff repair. Despite having a retear of the repaired tendon, the patient experienced substantial improvements in both domains. After discussion with the patient of this PROM improvement, the patient wished to forego revision surgery (reverse shoulder arthroplasty). DOS = date of surgery.

Similarly, the Patient Acceptable Symptomatic State (PASS) question allows the patient to report whether his or her current level of symptoms is satisfactory. The PASS is presented as, "Taking into account all of the activity you have during your daily life, your level of pain, and also your functional impairment, do you consider that the current state of your foot and ankle is satisfactory?" and is answered as yes or no[37]. This can be used as an important benchmark by which to correlate with traditional PROM scores. For example, in a recent study of hip arthroscopy patients by Kivlan and colleagues[38], the study team found that the PASS cutoff for the International Hip Outcome Tool (iHOT)-12 score was 75.2, and that patients who achieved this threshold PROM score or greater had a satisfaction rate of nearly 90% compared with 61% for patients under this threshold. Another study by Nwachukwu et al.[39] comprehensively documented cutoff scores for commonly utilized hip arthroscopy PROMs for achieving not only the PASS but also the MCID and SCB. By including benchmark questions in postoperative PROM questionnaires, surgeons can continue to align PROM scores with patient satisfaction.

These measures have also begun to play an important role in understanding how social determinants of health (SDH) affect outcomes following surgery[40]. In a recent study of nearly 122,000 patients undergoing total joint replacement, the study team found that patients with lower socioeconomic status reported worse PROM scores following surgery[41]. Similar findings have been reported for patients undergoing wrist fracture surgery[42]. The PASS questionnaire has also been used to associate SDH with PROM scores[37], thereby providing surgeons with additional tools for helping patients understand postoperative outcomes and expectations within this context. While these investigations are still in their infancy, continued exploration of PROMs in the context of SDH and measures of meaningful clinical improvement may be integral in future efforts to provide patient-centered care.

Clinical research that focuses on achievement of the PASS, MCID, and SCB—on the individual patient level—directly benefits SDM. The machine learning algorithms that calculate these likelihoods depend on large amounts of data, and the models improve as data continue to be incorporated. Therefore, coordination among data centers and clinical practices—in particular with regard to the selection and standardization of PROMs—maximizes the power of these predictive models.

Use of PROMs to Improve Health-Care Value

Considerable efforts have been placed on improving the value of health-care delivery in orthopaedics. As mentioned earlier, value can be enhanced by improving outcomes (numerator) or decreasing cost (denominator). With the passage of the Affordable Care Act in 2010, alternative payment models such as bundled payment programs have emerged with the goal of increasing value by reducing the cost of care of commonly performed surgeries (in particular, total hip and knee replacement)[43].

Even though bundled payment programs largely focus on containing costs, clinical outcomes must still be assessed. Numerous outcomes, including complication, readmission, and reoperation rates, are available for use; however, PROMs are also included in these assessments[44] as a core metric. Linking outcome metrics such as PROMs with cost initiatives allows for focused efforts addressing both sides of the value equation. A singular focus on either cost or outcomes alone would be unlikely to produce a sustainable and high-quality delivery platform. To date, there is a relative scarcity of literature that investigates the impact of bundled payment programs on PROMs. One recent study by Finch and colleagues[45] found that patients in bundled payment programs had slightly lower PROM improvements than did patients in hospitals with nonbundled payment programs. These differences were not deemed to be clinically meaningful. While further evidence is needed to determine what impact—if any—bundled payment programs have on PROMs, the actual act of measuring PROMs in a formalized structure promotes continued analysis on patient-centered outcomes.

Traditional bundled payment programs are "episodic" and focus on a discrete surgical event. However, they focus only on surgical patients, and there remains an incentive to perform surgery (which in turn, triggers payment). Patients may continue to be dissatisfied with postoperative outcomes in a bundled-surgery model if their preoperative care was not optimized or if they were poor surgical candidates to begin with, regardless of the financial savings from the program. To address this challenge, condition-based bundled programs have been developed. In these programs, reimbursement is "bundled" at the time of diagnosis (as opposed to at the time of surgery), in order to promote multidisciplinary best practices for nonoperative care. This facilitates treatment by specialties such as nutrition, weight loss, and mental health—all of which contribute to patient mental and functional health[46]. Condition-based bundles utilize PROMs as a central component in navigating care pathways, with special attention to the change in PROMs with successive treatment efforts.

Assessing Quality Using PROMs

PROMs can be powerful tools for measuring quality. In most cases, patients undergoing elective surgery demonstrate impairments from both physical function and pain preoperatively, thus justifying the need for surgical treatment. As seen in many examples, patients who have physical function scores above certain thresholds fail to have meaningful clinical improvement following surgery[23-26]. Therefore, PROMs obtained before and after surgery can be examined to assess patient selection and treatment efficacy. The demonstrable responsiveness of PROMs can be used as a proxy for appropriate surgical selection and treatment[47,48]. Moreover, providers or teams that are outliers can be examined on a granular level in order to address any deficiencies that may be present.

In addition to reporting patient health states, PROMs can be used to deliver high-quality care by influencing processes and best practices. These patient-reported outcome-process measures (PRO-PMs) guide treatment according to PROM scores. For example, when patients with depression are considered, the relevant PROM would be the Patient Health Questionnaire (PHQ-9). The PRO-PM therefore would be the percentage of patients who meet certain diagnostic and PROM criteria with subsequent improvements in PHQ-9 scores within 6 months of treatment[49,50].

Finally, PROMs can be very powerful in performing risk stratification among patient cohorts. For example, the FORCE-TJR registry was able to associate body mass index values with 30-day readmission rates, an analysis that would not have been possible with standard coding capabilities[33]. Similar analysis from this registry was performed using PROMs (Short Form [SF]-36) and the smoking status of patients. Risk stratification can help to normalize preoperative and postoperative PROM data from clinicians who are practicing in diverse geographic or practice settings.

Overview

PROMs represent a valuable tool for patient-centered health-state assessment in orthopaedics that can serve as a foundation for clinical research. However, implementing PROM collection, along with real-time review of patients, in the ambulatory setting has many logistical, financial, and administrative challenges. Overcoming these challenges allows providers to incorporate these tools into routine clinical care as well as into meaningful research, value, and quality initiatives. Perhaps the most important role of PROMs is as a facilitator of SDM with patients along with postinterventional monitoring. Successful incorporation of PROMs into daily practice can improve not only outcomes but also quality and value. ■

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