

Equitable Integration of Patient-Reported Outcomes Into Clinical Practice—Opportunities, Challenges, and a Roadmap for Implementation

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ABSTRACT

Patient-reported outcome measures (PROMs) provide a standardized assessment from the patient about their own health status. Although originally developed as research tools, PROMs can be used in clinical care to complement objective functional measures (eg, range of motion) and are increasingly integrated to guide treatment decisions and predict outcomes. In some situations, when PROMs are used during clinical care they can improve patient mortality, outcomes, engagement, well-being, and patient-physician communication. Guidance on how PROMs should be communicated with patients continued to be developed. However, PROM use may have unintended consequences, such as when used implemented without accounting for confounding factors (eg, psychological and social health) or in perpetuating healthcare disparities when used imprecisely (eg, lack of linguistic or cultural validation). In this review, we describe the current state of PROM use in orthopaedic surgery, highlight opportunities and challenges of PROM use in clinical care, and provide a roadmap to support orthopaedic surgery practices in incorporating PROMs into routine care to equitably improve patient health.

Evidence-based medicine and the tracking of outcomes can be traced back to as early as the 1850s with Florence Nightingale. Nightingale was an English field nurse whose work during and after the Crimean War helped lay the foundation for evidence-based medicine. Observing seven times more soldiers dying from disease than from battle wounds, she called for an investigation. Through the implementation of improved nutrition and hygiene standards, Nightingale was able to markedly reduce all-cause mortality. In the 1910s, Ernest Codman, an orthopaedic surgeon, built on this work with the concept of the “end result,” the idea that every surgeon should follow patients long enough to determine whether a treatment was successful and if not, to inquire why. Codman underscored the importance of documenting outcomes to prevent similar complications in the future and to

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improve care quality and efficiency. As orthopaedic surgeons began following Codman's end result principle, objective measures to assess outcomes such as mortality and range of motion became standard of care.

Objective measures in orthopaedic surgery may not always align with the patient's perspective. For example, a patient may survive a procedure and have moderate range of motion yet be unable to return to work as a manual laborer. To capture the patient's perspective of their function, surgeons began developing and incorporating patient reported outcome measures (PROMs) into clinical research towards the end of the 20th century. It was around this time that many commonly used PROMs were developed. Correspondingly, PROM use in research has continued to increase over time. A review of ClinicalTrials.gov demonstrated an almost doubling of PROM use between the years 2004 to 2007 and 2007–2013.¹ In the orthopaedic literature, PROM use has demonstrated similar trends.² These trends may be attributable to top-down encouragement and regulation. For example in 2009, the US FDA released guidance on the evaluation of PROMs used to support medical product labeling claims.³ Following suit in 2017, the Medicare Evidence Development and Coverage Advisory Committee recommended that quality-of-life measures should be included as health outcomes in research.⁴ In orthopaedic surgery, for example, PROMs are being integrated into hospital-level quality measurement as part of process measurement for total hip and total knee arthroplasty (TKR). Specifically, the Centers for Medicare and Medicaid Services adopted the total hip and TKR patient-reported outcome-based performance measure which will transition from voluntary to mandatory reporting in 2027 for reimbursement determination in the 2028 fiscal year.⁵

A variety of types of PROMs exist including generic health-related quality-of-life PROMs (eg, the Short Form 36), disease-specific or diagnosis-specific PROMs (eg, the Boston Carpal Tunnel Questionnaire), and those that are region specific (eg, the American Shoulder and Elbow Society score). Most of these PROMs were developed for paper-and-pencil administration; however, with the increasing use of technology and electronic health record systems, many PROMs have been adapted for electronic administration. Some PROMs (eg, the Patient-Reported Outcomes Measurement Information System [PROMIS]) are developed specifically for electronic use and leverage computerized adaptive testing, which reduces the number of questions required as questions asked are based on previous responses.

Mechanisms by Which Patient-Reported Outcome Measures Can Enhance Clinical Care?

Although most commonly used in research settings, PROM data are being increasingly collected and used to improve clinical care. The use of PROMs in clinical care has demonstrated benefits for multiple stakeholder groups on many levels—the individual level (eg, use between patients and clinicians to inform decisions), the system level (eg, use on a health system level for quality improvement), and the population level (eg, use on a population health level to identify vulnerable patient groups).⁶ Although the principles and benefits of PROM use are recognized at each level, this review focuses specifically on the use of PROMs to improve clinical care at the micro/individual level. This review correspondingly frames the discussion of PROM-related opportunities using the conceptual model set forth by Greenhalgh et al⁷ that details the causal pathways by which the provision of PROM information to surgeons improves patient satisfaction, experience, and outcomes.

Multiple studies have thus far demonstrated that the provision of PROM information to physicians improves patient outcomes and patient satisfaction and experience^{8–10} (Figure 1 A → G and H). Although the causal mechanisms by which PROMs improve outcomes, satisfaction and experience are continued areas of investigation, the common hypotheses include changes in communication, the ability to monitor treatment response, the detection of unrecognized issues, and changes in patient health behavior and clinical management (Figure 1).

Changes in Surgeon-Patient Communication

Physician-patient communication has been demonstrated to improve the patient experience and satisfaction and is likely a common mechanism by which the provision, review, and discussion of PROM information improves outcomes, satisfaction, and experience. Bernstein et al¹¹ conducted a study to evaluate the efficacy of PROM use as a part of routine clinical care on patient experience. The authors demonstrated that when PROMs were used (as compared with a cohort of patients in whom PROMs were not used), patients were more likely to rate the clinician higher on a 0 to 10 scale and recommend the provider to another patient. This may, in part, be due to changes in communication as patients in this study noted that providers explained health information in a more understandable manner.

Figure 1

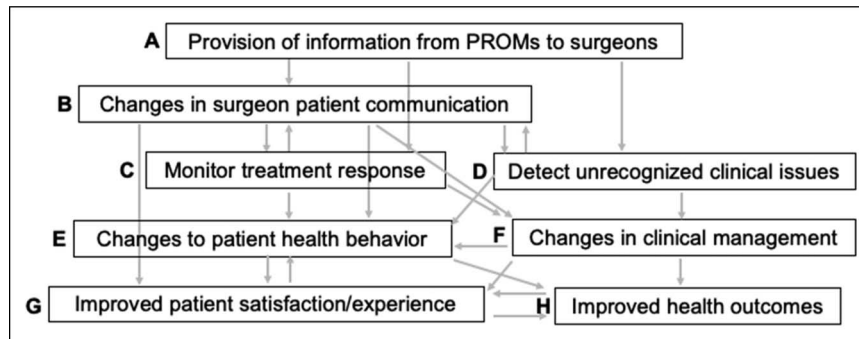


Diagram showing the conceptual model of the provision of PROM information to physicians and its effect on communication, treatment, and patient outcomes. Adapted from Greenhalgh J et al. The use of patient-reported outcome measures in routine clinical practice: lack of impact or lack of theory? *Soc Sci Med* 1982. 2005 with permission. PROM = patient-reported outcome measures. Adaptations are themselves works protected by copyright. So to publish this adaptation, authorization must be obtained both from the owner of the copyright in the original work and from the owner of copyright in the translation or adaptation.

Among patients undergoing TKR, Jayakumar et al¹² demonstrated that an intervention consisting of personalized outcome estimations using PROMs resulted in improved patient satisfaction and functional outcomes. Similarly, although a causal mechanism cannot be concluded, patients in this study noted improved decision quality and levels of shared decision making, which may be proxies for surgeon-patient communication. Sambare et al⁹ detail the incorporation of PROMs into shared decision-making models that helps to ensure that outcomes that matter to patients are being taken into consideration when discussing treatment options. In addition, these data can be used to provide estimates of achieving meaningful improvements in quality of life, function, and/or pain to patients. PROM scores have been demonstrated to provide guidance related to complication risk, postoperative hospital length of stay, and timing of return to work thus improving surgeon-patient communication.^{13,14}

Monitoring of Treatment Response

As many orthopaedic interventions (surgical or medical) may have adverse outcomes, monitoring of a patient's treatment response is another mechanism by which PROM information may result in changes to management or patient behavior which may downstream improve outcomes, satisfaction, and/or experience. In the evaluation of overall survival in those receiving treatment of advanced cancers, Basch et al¹⁵ demonstrated that the integration of patient-reported outcomes into the routine care of patients receiving treatment of advanced cancers was associated with increased survival compared with usual care in a randomized controlled trial. The authors postulated that early responsiveness to

patient symptoms that may have prevented adverse downstream consequences was one mechanism by which this effect occurred.

Detection of Unrecognized Clinical Issues

A third mechanism by which PROM information may change outcomes is that they may allow for recognition of previously unknown clinical issues. Many PROM tools are designed specially to measure psychosocial constructs (eg, PROMIS-Depression). Furthermore, scores on some PROMs that aim to measure non-psychosocial constructs (eg, physical function) may be highly influenced by a patient's psychosocial health. As such, PROMs may represent a means by which to identify psychosocial health (eg, depression, anxiety) that may alter treatment plans (eg, referral to social work).¹⁶ For example, Cochrane et al¹⁶ demonstrated that screening with PROMIS instruments identified hand surgical patients who may benefit from depression treatment.

Changes in Patient Health Behavior

As noted previously, the information obtained from PROMs may improve surgeon-patient communication and allow for the identification of unknown issues that may subsequently lead to downstream changes in patient health behavior. Although examples of patient behavior change in response to PROMs are limited, one example includes reduction of emergency department visits.¹⁵ Furthermore, PROMs developed to measure medication adherence may be deployed and can identify patients with poor adherence who may benefit from additional support for improved engagement in health management behaviors.¹⁷

Improvements in Clinical Management

Another possible causal pathway by which the information from PROMs may improve care is related to changes in clinical management. For example, Jayakumar et al¹² noted differential rates of TKR between an intervention cohort in which personalized outcome estimations using PROMs were implemented compared with a control cohort. Although not powered for this outcome and not statistically significant, those in the intervention cohort underwent TKR at a rate of 23% as compared with a rate of 12%. In addition, the investigation by Basch et al,¹⁵ in which the integration of patient-reported outcomes into routine care of patient receiving treatment of advanced cancers was associated with increased survival, demonstrated that nurses responded to symptom alerts 77% of the time with discrete clinical interventions (eg, supportive medications, changes in chemotherapy doses).

What Are the Challenges of Using Patient-Reported Outcome Measures to Enhance Clinical Care in Orthopaedic Surgery?

Despite these demonstrated benefits, several challenges limit the wide-scale implementation of PROMs in orthopaedic surgery (Figure 2). These challenges present in a variety of ways and are faced by multiple stakeholders—the patient, the healthcare professional, and the healthcare system.

1. Patient-level challenges: Although studies have demonstrated that patients perceive benefits from PROM collection and utilization,^{18,19} barriers exist. An ethnographic study of patients in an orthopaedic specialty clinic completing PROMs identified platform design, print literacy, health literacy, technology literacy, language proficiency, physical functioning, vision, cognitive functioning, and time as patient-level barriers to the completion of PROMs.²⁰ In a cohort of patients being treated for at least one chronic health condition, Philpot et al²¹ demonstrated through focus groups and a Delphi technique that the greatest barriers to PROM use were the length and complexity of the survey, lack of opportunity to voice concerns, survey detracting from patient-focused visit, and concerns related to security of personal health information. A 2020 review of barriers to PROM use in routine cancer care demonstrated that the most frequently cited patient-level barriers were time

requirements, challenges in completing surveys, perceived irrelevance, concerns about compromising the doctor-patient relationship, and privacy concerns, in descending order.²² Notably these barriers are not mutually exclusive of those raised by healthcare professionals and the system itself.

2. Healthcare professional-level challenges: In the orthopaedic surgery literature, there has been more investigation of health professional and surgeon-level barriers to PROM collection and use. Snyder et al,²³ in a multi-institutional survey of surgeons and care teams, noted that barriers to PROM collection and use include the difficulties with integration into clinical workflows, PROM accessibility limitations, issues with patient engagement and compliance, concerns about patients' ability to represent their health in outcomes, and lack of consistency across providers. A qualitative study of orthopaedic surgeons evaluating why PROM results are not being used in clinical care²⁴ and stakeholder interviews conducted by the American Academy of Orthopaedic Surgeons (AAOS) in collaboration with a PROM Workgroup,²⁵ identified analogous themes. Similar to patient-level barriers, the time requirement to collect, interpret, and use PRO data is the most frequently cited barrier.²² This is followed by difficulty in interpreting and integrating results and concerns regarding the validity and actionability of PROM data. A 2023 survey of the AAOS fellowship evaluating barriers to PROM collection and utilization demonstrated that the greatest barriers included concerns about staff burden, challenges in patients completing PROMs, PROMs being too costly to implement, lack of clarity about which PROMs to use, and lack of financial incentives (*unpublished data*).
3. System-level challenges: System-level barriers raise challenges in the collection and use of PROMs at point of care as well. The most frequently cited barriers include those related to the lack of integration of PROM data into clinical workflows, inadequate resources and infrastructure, and the lack of incentives and guidance on PROM collection and use.²² Notably, many of these barriers were similarly identified by stakeholders in the AAOS PROM Workgroup interviews,²⁵ and furthermore, solutions to many of these barriers

Figure 2

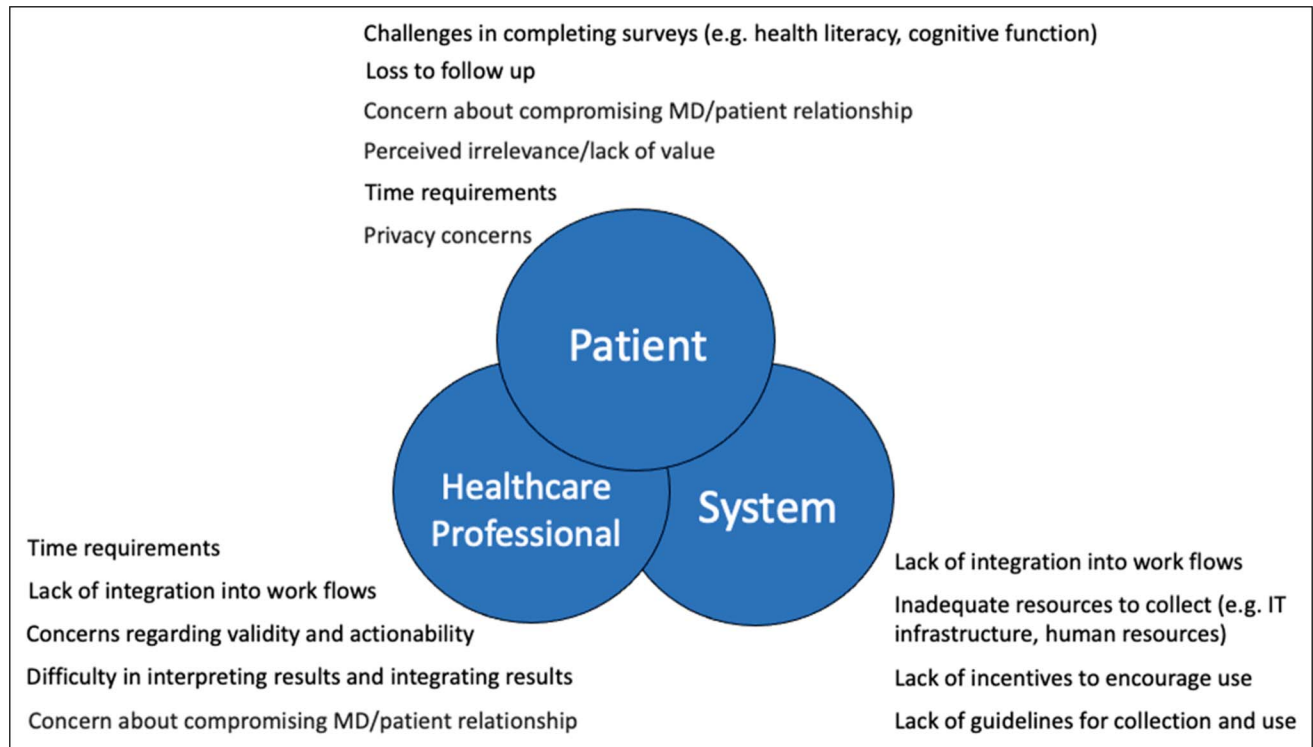


Diagram showing barriers to PROM collection and utilization summarized by stakeholder. Reused with permission from Shapiro LM et al. Patient-reported outcome measures—How to get the most out of them and mitigate healthcare disparities. *AAOS ICL*. 2023 with permission (pending). PROM = patient-reported outcome measures

simultaneously mitigate barriers cited by patients and healthcare professionals.

What Are the Potential Unintended Consequences of Using Patient-Reported Outcome Measures to Enhance Clinical Care?

Like all interventions, there can be biases in the way in which or in whom an intervention is provided and in addition, adverse effects from the intervention itself. Proactive acknowledgment of potential unintended consequences of PROM use that may result in disparities in patients achieving the benefits of PROMs can inform processes to mitigate these risks. As the recognition of the benefits of PROMs grows, patients will benefit from effort to ensure they are equally available to all patients.²⁶ For example, are PROMs accessible to and understood by all patients? Do physicians use PROM data similarly with all patients? Two mechanisms by which PROM collection and use may perpetuate or introduce healthcare disparities include (1) nonresponse bias (eg, inequitable collection of PROM data) and (2) inequitable implementation of PROMs.

Nonresponse Bias (eg, Inequitable Collection of Patient-Reported Outcome Measure Data)

Multiple studies, in a variety of orthopaedic subspecialties, demonstrate a nonresponse bias (eg, non-random discrepancies in who does not complete PROMs) based on several factors. Schamber et al²⁷ demonstrated that PROM completion rates for total joint arthroplasty patients were markedly lower among patients who are Hispanic or Black, have Medicare or Medicaid, and those who are age older than 75 years. Patients with multiple of the aforementioned risk factors were also less likely to complete PROMs. Stirling et al²⁸ noted that younger age, increasing social deprivation, higher comorbid status, worse preoperative PROM score, and unemployment were predictors of not completing postoperative PROMs. Others have noted the presence of language barriers, cognitive limitations, psychiatric diagnoses, and sight differences to be associated with nonresponse to PROMs.²⁹ A retrospective review of more than 16,000 elective total joint arthroplasty patients noted that patients who were women, Black, Hispanic, less educated, Medicaid insured, or from lower-income neighborhoods as well as those who spoke non-English languages or required an

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interpreter were less likely to complete PROMs.³⁰ It is unknown whether these nonresponders perform similarly to responders and thus the conclusions that can be drawn regarding the benefits of PROMs and the application of study results to all patients is not clear.

An example of this phenomenon is the lack of diversity of patients included in randomized controlled trials, some of which inform clinical practice guidelines. For example, orthopaedic surgery literature reports that race and ethnicity are reported less than 9% of the time in clinical trials, and when reported, minority groups are underrepresented relative to their representation in the US Census.³¹ Similar data have been demonstrated in the randomized controlled trials published in orthopaedic subspecialty journals.³² A follow-up study evaluating the linguistic and cultural diversity of the patients included in randomized controlled orthopaedic trials demonstrated that only 14% of studies reported participant language (*unpublished data*). Furthermore, this investigation noted that only 7% of studies used translated PROMs and 2% used culturally adapted PROMs. Randomized controlled trials, that provide the highest level of evidence and are considered the benchmark for assessing causal associations, are used to support strong clinical practice guidelines. Clinical practice guidelines summarize the best available evidence, and despite being discussed with patients of all backgrounds to guide treatment, there is similarly a notable lack of diversity in studies from which these are developed.³³ For example, a review evaluating the literature and patient population used to develop the clinical practice guidelines for distal radius fractures demonstrated that more than 90% of studies lacked information regarding language, race, or ethnicity of the study population (*unpublished data*). The lack of inclusion of diverse patients in research is often attributed to language barriers and the paucity of appropriately validated instruments for underrepresented patients.^{7,34} Although the consequences of these phenomena are not clear, appropriate use and the validation of PROMs for underrepresented patients may help prevent biased measurements of health states and symptoms and the misapplication of results to populations excluded from evidence development.

Inequitable Implementation of Patient-Reported Outcome Measure Data

Appropriate PROM implementation requires that a PROM is validated for use in the population in which it is being applied. Content validity, the ability of a PROM to measure a specific construct (eg, physical function, depression) in a specific population (eg, Spanish-speaking

patients), is considered a fundamental measurement property in the evaluation of PROMs.³⁵ As such, if a PROM was developed and validated in patients who speak English and live in the United States, it may not be appropriate to apply it to patients who speak Spanish and/or live in another country. To equitably implement and ensure accurate and meaningful application of PROMs, it is foundational to understand the population in which the PROM was developed. Notably, there is a paucity of demographic information of populations studied and inclusion of underrepresented patients in the many of the PROM development studies.^{34,36} The transparent reporting of these details is critical, especially as a growing body of work demonstrates that outcomes and PROM scores vary across patients with different demographics (eg, language spoken, cultural identification, race).^{37,38} A detailed discussion of the development and psychometric validation of PROMs is outside the scope of this review. However, PROM users should consider both the relevance and measurement properties of specific PROMs for diverse patients.

What Are the Necessary Steps in Transitioning Patient-Reported Outcome Measures From Research to Clinical Care?

There are multiple opportunities for PROMs to be integrated during clinical care. We describe a process with a focus on health equity (Figure 3). This four-step process incorporates the perspectives of multiple stakeholders to improve the chances of adoption and prevent inequities in PROM utilization.

The first step of PROM integration into clinical care is establishing a team of key stakeholders (Figure 1, “Getting started”). It is foundational to involve as many stakeholder representatives as needed before implementing change. For example, medical assistants who may be helping to collect data or information technology staff who may be iterating workflows should be consulted early. It is also important to gauge the context and its readiness for change. For example, the adaptations to current systems may be minimal or may be great. The AAOS has created the AAOS PROMs Utilization Scoring Tool that can be used to understand how well one’s practice is performing on PROM utilization and serve as a road map to assist in successfully implementing a PROM program.²⁵ It is equally important to understand and define not only the purpose for measurement but also the population(s) and condition(s) being measured. For example, if a large percentage of the population speaks

Figure 3

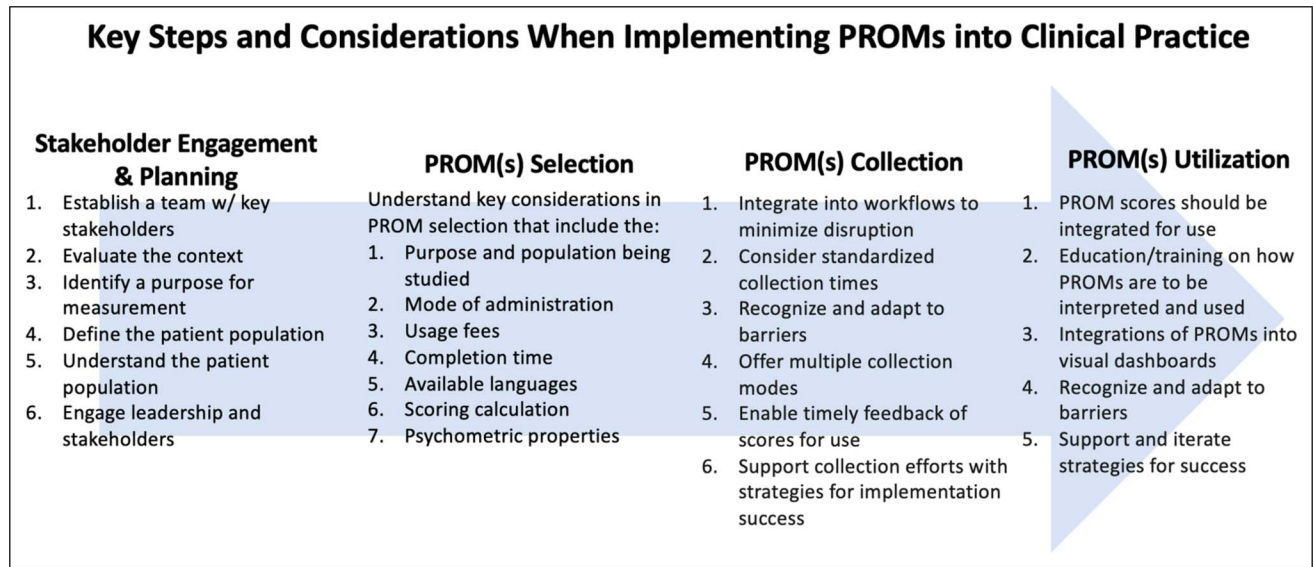


Diagram showing key steps and considerations when implementing PROMs into clinical practice. Adapted from Al Sayah et al. A multilevel approach for the use of routinely collected patient-reported outcome measures (PROMs) data in healthcare systems. *J Patient Rep Outcomes*. 2021 with permission under a Creative Commons Attribution 4.0 International License (<http://creativecommons.org/licenses/by/4.0/>). PROM = patient-reported outcome measures. Adaptations are themselves works protected by copyright. So to publish this adaptation, authorization must be obtained both from the owner of the copyright in the original work and from the owner of copyright in the translation or adaptation.

Spanish, a PROM adapted for Spanish-speaking patients should be used. Engaging stakeholders who are direct users (eg, surgeons and patients) by educating them on the benefits of PROM collection may also improve implementation success.

The transition of appropriate PROM use into clinical care requires adequate resources and leadership support. Time and financial barriers are frequently noted in the use of the PROMs at point of care.³⁹ Even more extensive resources are needed when patients do not speak English, are less health literate, or have cognitive impairments, for example. Although the time and cost associated with creating PROM collection and utilization systems can be substantial, the resources may be warranted because PROM use continues to demonstrate improvements in clinical care and patient experience. Having leadership that ideologically and financially supports the integration of PROMs into clinical care and it committed to health equity is a critical step moving forward.

How Can I Integrate Patient-Reported Outcome Measures to Support My Practice and Enhance Patient Care?

After engaging with stakeholders and gaining an understanding of the context, the next steps include selecting,

collecting, and using PROMs (Figure 3, “Selecting a PROM(s)” to “Using a PROM(s)”). To incorporate PROMs into one’s practice, thoughtful PROM selection, guided by the purpose and patient population, is important. The integration of multiple PROMs for specific conditions (eg, the Boston Carpal Tunnel Questionnaire for patients with carpal tunnel and the QuickDASH for patients with distal radius fractures) may pose logistical challenges that one should be aware of before implementation. It is similarly important to understand the mode(s) or administration and, when possible, offer multiple options to optimize equitable use of PROMs. Although text-messaging patients PROM forms to complete before clinic may increase participation, this participation may be skewed toward a specific demographic.⁴⁰ Similarly, being cognizant of patient-specific concerns (eg, health literacy, cognitive or visual impairments) and adapting/providing PROMs as necessary can increase participation rates and ensure the benefits of PROM use are realized for the greatest number of patients. Although the details are outside the scope of this work, understanding the psychometric properties (eg, validity, reliability, responsiveness) of chosen PROMs can ensure that the scores obtained are valid for the patient at hand. Finally, understanding the completion time required for each PROM used can be helpful in redesigning and/or fitting PROM collection into current workflows.

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After PROMs have been selected, it is important to integrate the collection and utilization of scores into routine workflows to minimize staff and patient burden. This may be implemented by the collection of PROMs before patient visits (either at home or in the waiting room). Standardizing collection can help streamline the process. For example, collecting the same PROM at specified time points may decrease confusion and collection burden. Many technology systems can help automate this process and further, make PROMs available for point of care use. Continuous evaluation and improvement efforts can assist in understanding gaps in participation. Obtaining feedback from surgeons and/or clinic staff and evaluating the data itself can inform iterations to the collection and/or utilization process. Such evaluations should focus on minimizing disparities (eg, evaluating from which patient populations are we missing the greatest amount of data).

After the collection of PROMs, scores should be available to healthcare professionals and patients in a timely manner. Feedback and the integration of PROM scores (whether it be through the use of graphic displays, comparisons with previous scores) should be intuitive, easy to understand, and incorporated within workflows. Although work is still underway to understand how PROMs can be best integrated into clinical care (eg, display type, risk adjustment), it is most critical that healthcare professionals understand the scores and how they can be used. For example, PROMs may assist in shared decision-making discussions to help patients understand their risk or they may be used to identify patients who may need further social support (particularly those measuring psychosocial health). Education and/or clinical decision support can assist healthcare professionals in understanding meaningful PROM changes and/or a specific patient's PROM score relative to a cohort-matched average.

As the improvements in patient-centered care through the integration of PROMs grow, PROM collection and use should be carried out in a thoughtful manner in order for the greatest number of patients to experience these benefits. Although many challenges exist to the equitable collection and use of PROMs in patient care, the process laid forth provides guidance to overcome such barriers to obtain the increasingly recognized benefits.

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