

Integrating Patient-reported Outcomes Into Orthopaedic Clinical Practice

Proof of Concept From FORCE-TJR

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Abstract

Background Good orthopaedic care requires a knowledge of the patient's history of musculoskeletal pain and associated limitations in daily function. Standardized measures of patient-reported outcomes (PROs) can provide this information. Integrating PROs into routine orthopaedic patient visits can provide key information to monitor changes in symptom severity over time, support shared clinical care decisions, and assess treatment effectiveness for quality initiatives and value-based reimbursement.

Where Are We Now? Although standardized, validated PRO surveys are routinely used in clinical and comparative effectiveness research, they are not consistently or efficiently collected in clinical practice.

Where Do We Need to Go? Ideally, PROs need to be collected directly from patients before their surgeon visit so the data are readily available to the surgeon and patient at the time of the office visit. In addition, PROs should be integrated in the electronic health record to monitor patient status over time.

How Do We Get There? PRO integration in clinical practice requires minor modifications to the office flow,

some additional staff to facilitate collection, and the technical infrastructure to score, process, and store the responses. We document successful office procedures for collecting PROs in one busy orthopaedic clinic and some suggested methods to extend this model to the Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement (FORCE-TJR) consortium of 121 surgeons where the process is centralized and staff obtained consent to send the PRO directly to the patient's home. Both methods are options for the broader adoption of office-based PROs.

Introduction

Musculoskeletal and orthopaedic conditions are among the most common chronic health challenges in the United States [2]. Symptomatic osteoarthritis affects one in five adults older than 18 years and one in two adults older than 65 years. Advanced arthritis can result in severe pain and a marked limitation in function, often associated with lost work time among the US adult population [2]. Between 2001 and 2005, an estimated 77 million arthritis-related ambulatory physician visits occurred [10]. Patients seek medical care to relieve pain and improve functional limitations due to the arthritic condition. As there is no cure for arthritis, current medical treatment focuses on controlling the patient's arthritic symptoms in an attempt to help the patient maintain activities of daily life and those necessary for his or her desired vocational and recreational pursuits.

When nonsurgical treatments fail to control severe knee and hip arthritic pain, and physical function becomes sufficiently limited, patients will often seek the advice of an orthopaedic surgeon. Patient and surgeon may opt for an

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elective surgery such as total joint arthroplasty because it effectively relieves pain and improves physical function in patients with advanced arthritis. The patient's history of progressive joint pain and associated limitations in daily function are central to planning orthopaedic care. Thus, integrating standardized patient-reported outcomes (PROs) into routine orthopaedic patient visits would provide key information to monitor changes in symptom severity over time, support clinical care decisions, and assess treatment effectiveness.

In this paper, we discuss the current status of routine use of PROs in the orthopaedic office, a model for integration and use of PRO data in patient care, and a vision as to how orthopaedic practices may achieve this goal and overcome challenges that arise in the process. In doing so, we present lessons learned from two successful models of PRO implementation in busy clinical practices at UMass Memorial Health Care and the Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement (FORCE-TJR) national surgeon network.

Where Are We Now?

PROs are validated patient questionnaires to determine the patient's assessment of their health status. In orthopaedic care, PROs assess joint pain, stiffness, and physical function, in addition to emotional health and general well-being. PROs have been used extensively in clinical research, including orthopaedic research, and are important to comparative effectiveness research [1]. However, today PROs are not consistently or efficiently used in clinical practice.

Current Medical Records Do Not Include PROs

Traditionally, data collected in the orthopaedic office include history, physical examination, and radiographic evaluation. The history includes specific questions to quantify the patient's joint pain, stiffness, and functional limitations associated with these symptoms. Questions assess the severity of the joint pain during various activities, the distance the patient can walk, and the success of medical or nonoperative treatment in reducing the patient's pain and improving the patient's function. The physical examination consists of reviewing the patient's gait, atrophy of the surrounding musculature, palpation of the affected joint for tenderness, joint effusion, restricted or painful active or passive motion, or malalignment or shortening of the limb. Radiographs are examined to evaluate the degree of joint space narrowing, the presence of osteophytes, and other evidence to determine the stage

of the arthritic condition. It is worth noting that the radiographic extent of the arthritic disease does not always correlate with the symptoms the patient reports. These data are documented in the medical record by the surgeon and office staff. However, the patient does not routinely document symptoms in the paper chart or electronic health record.

Current Office PROs Are Inefficient and Not Integrated With the Electronic Health Record

Use of PROs in clinical practice has been problematic due to outdated collection methods, typically pencil and paper, that result in inefficient practice. Sometimes surveys are filled out by the surgeon, an office staff, or the patient after hours. The data are then entered manually into a computer database and scored using statistical models. This process can be time consuming and inefficient and the data are not available to the surgeon at the time of the office visit. In addition, if the patient completes the survey with the surgeon or nurse, the possibility of bias is introduced as the patient may underreport symptoms in an effort to "please" the surgeon [5].

To our knowledge, even in practices with electronic health records, patient-reported measures of pain and function are rarely collected and, if they are collected, are not incorporated in the routine information stored in the electronic health record. Current electronic health records are tools to capture clinician notes and interpretations of laboratory and radiographic tests. There is little precedent for the patient to directly record symptoms in the office medical record because of Health Insurance Portability and Accountability Act concerns and because the traditional office flow does not allow access. When patients do have access to the medical record through a patient portal, the patient has "read only" permission so cannot enter data. While emerging technology allows the patient to self-register and respond to history and administrative questions, we are unaware of clinical settings where the patient directly records symptoms in the medical record. Because office records are not designed to accommodate direct entry by patients, the orthopaedic office that chooses to capture PROs must design and integrate a parallel PRO data collection system. These data needs must be tailored to the specific electronic health record and can be costly.

Finally, the orthopaedic office typically sees dozens of patients in a session requiring a tight, efficient process to assure timely and patient-centered care. It is critical that the PRO collection process does not negatively affect the office flow or interfere with clinician or patient experience. Ideally, for the PRO data to be useful, the information must be gathered and scored in advance of the surgeon visit and

available for discussion with the patient to inform patient care decisions. While there are few examples of this model, the UMass Memorial Arthritis and Joint Replacement Center has had a functioning system since 2007. Lessons learned from this model were extrapolated to collect PROs in the national surgeon consortium in the federally funded research registry FORCE-TJR [6]. This paper will draw on these examples while highlighting the generalizable infrastructure needs to integrate PRO use for patient and surgeon decision making in the orthopaedic clinical practice.

Where Do We Need to Go?

Ideally, PROs will be collected directly from the patient in advance of the surgeon visit, and with limited disturbance to the clinic routine, the data will be readily available to the surgeon and patient at the office visit and integrated in the electronic health record to monitor patient status over time. Dedicating effort to collect PROs can be well worth the investment as the PRO data can expedite the time dedicated to collecting the patient history and allow more time for patient-surgeon review of the data to make care decisions. To achieve this goal, standardized PROs must be consistently collected before the surgeon appointment and the infrastructure must produce trended data over time.

Real-time Data to Improve Efficiency

The office scheduling system can determine which patients should complete the PRO before the office visit. For example, the surgeon may collect PROs on all new patients to document the baseline pain and physical limitations and administer followup PROs to assess changes in symptoms over time in response to treatment. Collecting timely PRO data before the office visit can be accomplished through two general approaches. The first approach asks the patient to complete and return a paper or electronic PRO survey during the week before the visit. On return, the survey must be scored and results available in the medical record at the time of the patient appointment. This process adds work to the office staff as the surveys must be distributed, collected, and scored in advance of the visit.

The second approach asks the patient to complete surveys on computers (or tablets) while in the office waiting room. The computer can capture and score the data, making it available at the time the patient meets with the surgeon. The most efficient process for administering office PROs is through computerized adaptive testing (CAT) using item response theory [11]. The CAT survey offers two distinct advantages. First, the CAT version of the survey is shorter because the computer selects each

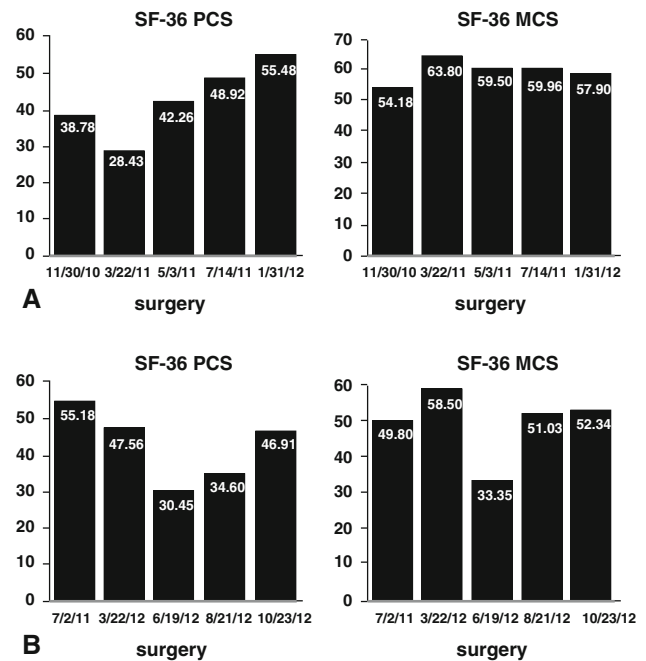


Fig. 1A–B Two examples of SF-36 physical and mental component summary score trends over time are shown. (A) Physical function shows a decline before THA and significant improvement to the national norm by 10 months after surgery. Emotional health remains strong throughout. (B) Physical function declines before TKA and improves significantly by the 4-month postoperative visit. Emotional health declined with preoperative pain but is at the national norm after surgery. PCS = physical component summary; MCS = mental component summary.

question from an item bank based on the response to the prior question. For example, if the patient reports severe pain when walking in the home, no further questions will be asked about pain when walking longer distances. Second, the survey is scored immediately and summaries are available for the clinic. However, to employ CAT surveys, the PRO must be completed on a web-based computer connected to the survey item bank. This can be a challenge in some office settings and requires annual fees for use. Alternately, the surgeon can collect full PROs on the office computer and use a scoring program to synthesize the data.

Next, the scored data should be integrated with prior measures so that the trend in pain and physical limitations can be readily assessed. When a PRO symptom trend over time shows improvement or decline, the surgeon is immediately aware that a change in treatment is warranted (Fig. 1). Data available at the office visit allow the patient and the orthopaedic surgeon to focus on changes in symptoms and use the data for shared decision making with regard to treatment. The data can support decisions both for surgical and nonsurgical care.

The availability of PRO data should improve surgeon efficiency. As the surgeon reviews the PRO data before entering the examination room, he/she knows the patient's

physical function and pain status. This process saves time by reducing the number of questions the surgeon needs to ask regarding the patient's history and the surgeon can focus the visit on the validation of the patient's physical function score and pain summary.

Trended Data Facilitate Quality Care and Value Decisions

The PRO data are very valuable to the patient, surgeon, and clinical system. To the patient, trended symptom scores over time may guide the patient's decisions. For the surgeon, the PROs assess relative effects of both surgical and nonoperative treatments and can inform treatment recommendations. Finally, when the PRO data are aggregated across similar patients within the orthopaedic practice, the clinical system can use these aggregate outcomes to inform patient care pathways and monitor quality. For example, if all patients with primary TKA complete pre- and postoperative PROs, the hospital system will have a profile of the level of pain and functional disability among patients selected for TKA and after recovery. These data are useful in demonstrating appropriate patient selection for TKA, uniform quality to the hospital, and surgical value to purchasers.

Minimal Disturbance to Office Routine

PROs should be collected efficiently so the regular functioning of a busy clinical practice is not disrupted. The process should not burden the already busy office staff, the surgeon, or the patient. To accomplish this, PROs can be collected outside the normal clinical patient flow through improved use of the patient's preexamination room time. Successful processes utilize a dedicated private space that contains computers (or tablets) and a clerk assigned to the PRO process. The process of obtaining PROs should be invisible to the surgeon. It should not slow down patient flow at check-in, delay patient entry into the examination room, increase the amount of time spent in the examination room, or increase the turnover time between patients.

One of the challenges, particularly in the case of small practices, is that a computerized PRO assessment requires an information system infrastructure that may not already be in place (computers, internet), as well as a financial investment (computers, software) and time commitment (learning curve). However, there are real benefits in collecting PROs in using the data for patient care and assessment of outcomes that will have to be considered when making the investment. Increasingly, insurers and quality-monitoring agencies value aggregated data to

demonstrate high-quality care and appropriate patient selection.

The challenges of using PRO data collected in the office for research or quality assessment include possible patient selection bias and data "missingness." When PROs are collected in the office, real-time data are available to guide the patient assessment, but no data are collected on patients who do not return for followup. Patients with excellent results may not see a need to return to the office. It is also possible that patients who have experienced adverse events after surgery choose to be treated at a different location. In both of these situations, PROs will not be available. Specific steps to address this critical issue must be part of any broad-based approach to acquiring PRO data to have any hope of the data derived from these approaches reflecting actual patients' results. As is true with any research based on medical record data, including clinic-based research on revision or infection rates, PRO research based on patients from a single clinic may not be representative of the national population.

Standardized PROs

There is a need to standardize which PROs are recorded for orthopaedic patients. At a minimum, reliable and previously validated PROs that produce independent measures of pain and physical function should be utilized. While PROs that meet these criteria may not be the shortest surveys, surgical care is designed to relieve pain and the surgeon will want an independent assessment of pain relief. While functional improvement is likely and desirable, gains in physical function are dependent on factors beyond successful surgery, such as patient motivation and the absence of comorbid conditions that limit function. Thus, the surgeon will benefit from PROs that distinguish change in pain from function. Both general health status PROs and joint-specific measures can assess pain and function. PROs that include general health measures such as the SF-12 physical component summary or joint-specific measures such as the WOMAC and the Hip and Knee Disability and Osteoarthritis Outcome Scores (HOOS or KOOS, respectively) are examples of surveys that distinguish the severity of pain from joint-specific or global functional limitations [3].

How Do We Get There?

Our experience at the UMass Memorial Arthritis and Joint Replacement Center, and our extrapolation of this model to the national FORCE-TJR surgeon network, offers insight into the steps necessary to successfully implement PROs in a busy orthopaedic clinic.

The implementation of PROs in clinic in most cases will require minor modifications of patient flow and new technical infrastructure to accommodate the collection of PROs so that data are readily available to surgeons. This will necessitate the allocation of a space with computer(s) (or tablets), a dedicated clerk to guide the patient through the PRO survey process, and the information technology infrastructure to collect, store, and process the responses.

In 2007, we implemented this PRO collection system in the UMass Memorial Arthritis and Joint Replacement Center ambulatory clinic. This system integrates PRO data with the clinical history and physical examination information to support patient-centered health care in practice and to track aggregate outcomes for longitudinal quality monitoring and outcomes research. In addition, the system was designed to combine PRO data and clinical measures as part of the patient health record to satisfy clinician and research demands for data.

The office flow for patients was modified to assure successful collection of real-time PRO scores to provide actionable and objective data to the surgeon and patient during the examination (Fig. 2). After registration, the patient is directed to a survey room equipped with desktop personal computers to complete his/her symptom surveys before the office visit. An office clerk opens the appropriate survey within the host system using the patients' personal record identification. The host system is connected with the QualityMetric Dynamic SF-36 that uses CAT technology to gain the same quantitative information as a paper survey but using fewer questions. This system automatically scores the results providing real-time feedback. The type of survey completed depends on the physician's need and the reason for the patient visit (ie, preoperative, postoperative). Scores from the survey are immediately available as a patient report of his/her symptoms and a clinician report displays the last four scores over past visits. The patient receives his/her personal copy of the individual symptom report before the physician visit.

When the patient enters the examination room, the clinical staff collects and enters a combination of other sign and symptom metrics such as pain location, history, and vital signs in the host system. The system is designed to perform medical calculations such as BMI so the information is made available to the physician at the time of the visit. When nurses have completed their intake, these data are available for the physician to review before entering the examination room. Because both the physician and patient have the results from the symptom surveys, the discussion of the patient's current health can be focused on important changes, either improvement or decline, and treatments modified as needed.

Patient and clinical data are stored in a structured database from which real-time symptom trends can be produced using query, search, and analysis functions. In

addition, the available records can be shared with interdisciplinary clinical and research teams (with institutional review board approval). Finally, the system is interoperable with other systems across multiple platforms, applications, and devices. The results can be stored in an electronic health record as a text report (similar to a radiographic dictation) or as categorical data if the electronic health record system allows.

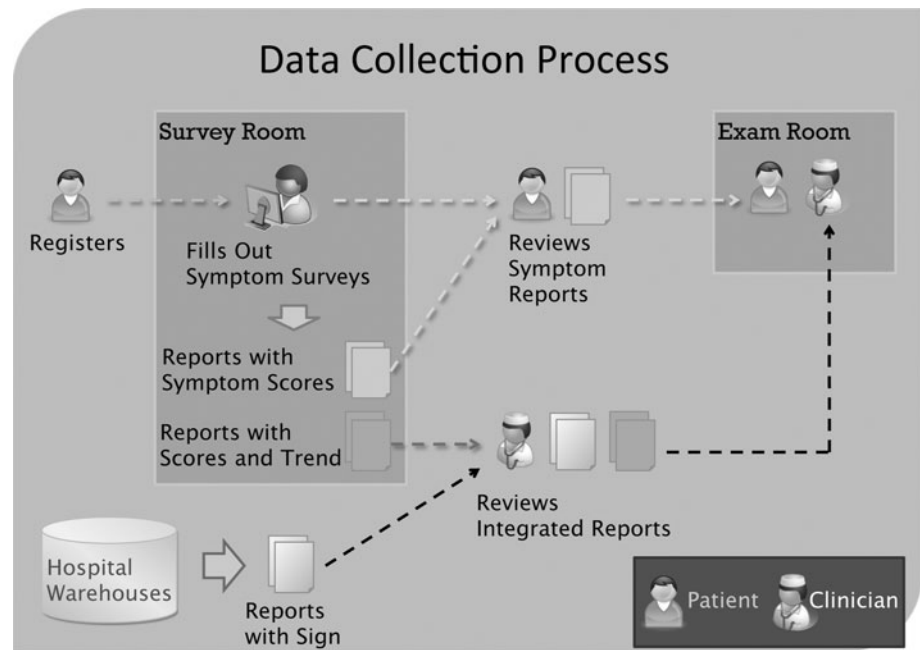
Periodic clinical outcomes for quality monitoring and research can be obtained by programming surveillance reports. With institutional review board approval, we extract longitudinal data on research participants from our PRO database. Periodic surveillance reports generated from the system are capable of tracking aggregate patient health conditions and identifying opportunities for innovation and research to improve outcomes.

The PRO system was designed and tested from 2004 to 2006 and has been in continuous use in this busy clinical practice environment since that time. During development, a time study determined that the average patient spends 10 minutes in the survey room. This time reduces idle wait time after registration and does not prolong the visit or alter the clinician flow. Up to 20% of patients will request assistance with the survey, but it is rare that the patient cannot complete the computer-based surveys. Patients who do not speak English complete paper surveys in Spanish or Portuguese, the most commonly spoken non-English languages in our region. On the computer, patients need only click to respond to questions as the clerk navigates the patient to the appropriate survey. As of today, more than 1,000,000 item measures have been collected from more than 45,000 patients with 500,000 PROs. At UMass Memorial Health Care, the PRO system has been extended successfully to the Spine Clinic and to the Hand and Upper Extremity Clinic.

This PRO process works seamlessly for patients who visit the office for individual patient care. However, patients who cancel or miss scheduled visits will not have complete data and this is a potential limitation to generating aggregate quality and research data. To address this issue, the computer system generates lists of patients who are missing followup data at key time points (eg, 12 months after total joint arthroplasty) so that paper surveys can be mailed to their home. It is important to obtain data from the patients who do not return to the office as this group will include patients with very successful outcomes and those who became ill or sought care at another office. In either case, it is important to assure representative data of all patients for the aggregate PRO data used for quality improvement and to demonstrate value to purchasers.

Ideally, standardized PROs are collected directly from all patients after total joint arthroplasty independent of their location of care. UMass Memorial Arthritis and Joint

Fig. 2 A diagram illustrates the data collection process in the office.



Replacement Center supplements the local office-based PRO collection with mailed surveys to patients who do not return to the office. The registry identifies patients who are 8 months postsurgery but do not have a 6-month PRO assessment in the database and mails PROs to the patients' homes. If the survey is not returned, a telephone call is placed to encourage the patient to return the PRO. This process augments data capture to minimize missing surveys and potential bias. National registries that collect data from hospitals only to estimate revision rates must assure that all hospitals participate or some revisions will be missed. Recently, a subset of national registries (England and Wales, New Zealand) began to collect PROs directly from patients [9]. However, this process has different challenges and limitations. For instance, the PRO mailed to the home is not available to the surgeon at the time of the office visit to guide decision making and patient return rates to date have been around 40% [7, 8].

Extending the PRO Process to a National Network of Private Orthopaedic Offices

Evidence that this PRO system can be extrapolated to other settings is now available. The University of Massachusetts Medical School is the lead for the national research registry FORCE-TJR [5]. Based on the UMass Memorial Health Care model, PROs are now collected from all patients with total joint arthroplasty of 121 surgeons in 22 US states. Because these offices do not have the computer infrastructure or a clerk to facilitate PRO collection, the centralized FORCE-TJR staff calls patients when they schedule surgery

and obtains consent to send the PRO directly to the patient's home. The patient signs the consent and completes the PRO through a web-based survey or on paper. Six and 12 months after total joint arthroplasty, and annually thereafter, PROs are mailed or emailed to the patient directly, with subsequent mailed and telephone reminders to assure optimal response rates. To date, more than 11,000 patients have completed the PROs and the scored data are stored in the national FORCE-TJR registry and returned to the treating surgeon through a secure MD website. The strength of this system is that PROs are delivered and collected on a consistent timeline and stored without any effort at the orthopaedic office. In addition, the surgeon has the PRO data to inform care decisions. However, depending on when the patient returns the survey, it is possible that the scored data may be posted on the MD website after the patient's office visit so may not be available to support the office decisions.

Discussion

The Institute of Medicine's Vision for medical care in the 21st century includes the use of information technology to support patient-centered evidence-based decisions [4]. The UMass Memorial Arthritis and Joint Replacement Center designed and implemented a software platform to integrate PRO assessments of pain and physical function in a high-volume clinical practice. These innovations have improved the efficiency of the practice and provide actionable objective data, such as the results of past treatments, allowing patient and surgeon to make a shared decision regarding treatment.

The feasibility of integrating computer-based PROs in clinical practice is supported by years of successful integration in a high-volume arthritis and joint arthroplasty practice and the recent extrapolation to serve the national consortium of surgeons in the FORCE-TJR research registry. Our model supports collecting PRO data and integrating it with clinical data as part of a patient health record. We found that patients are comfortable with computer surveys in the clinic, which challenges traditional thinking about older adults' computer use to manage health information. PROs provide valuable objective data for the surgeon-patient discussion in the examination room. Trended data inform patient and surgeon clinical decisions and offer a rich data resource to help improve patient outcomes in both clinical practice and research. Finally, hospitals and surgeons can use the PRO data to document symptom severity that supports surgical care, as well as the recovery of function and pain relief after surgery. Payer emphasis on value of surgical care can use PRO data to document the benefits to patients and balance that with the cost of care.

In the future, as the majority of adults carry tablets or smartphones, it is possible that PRO surveys will be completed on personal tablets or telephones and returned electronically to the electronic health record or orthopaedic office database. As the prevalence of chronic musculoskeletal conditions among aging adults grows, orthopaedic offices will benefit by use of patient-reported symptom data to track changes in pain and functional limitations over time to support both surgical and nonsurgical patient care decisions.

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