

# ELECTRONIC PATIENT-REPORTED OUTCOME COLLECTION SYSTEMS IN ORTHOPAEDIC CLINICAL PRACTICE

Vincent A. Lizzio, MD

Mihir S. Dekhne, MS

Eric C. Makhni, MD, MBA

*Investigation performed at Henry Ford Health System, Detroit, Michigan*

## Abstract

» The recent emphasis on the electronic collection of patient health information has catalyzed the development of numerous platforms for capturing electronic patient-reported outcome measures (EPROMs).

» There are several important considerations for selecting the most appropriate PROM for each orthopaedic practice.

» In this article, we evaluate various aspects of PROMs, examine the challenges and obstacles that are associated with routine collection, and review 6 commonly used electronic collection systems for orthopaedic clinical practice.

Traditionally, clinical outcome measures in medicine primarily have been rooted in objective data, such as readmission rate, complications, and mortality. However, as medicine continues to transition toward patient-centered care models, modern health-care models are placing a greater emphasis on a patient's satisfaction and perception of his or her own health<sup>1,2</sup>. For this reason, many providers are beginning to incorporate patient-reported outcome collection into their clinical practice.

Patient-reported outcomes are defined as information that is collected directly from a patient that is not otherwise adjusted or modified by a health-care provider. This information often is collected by means of patient-reported outcome measures (PROMs), which are questionnaires that are completed by patients; PROMs quantitatively evaluate and score various aspects of health status<sup>3</sup>. The field of orthopaedic surgery is uniquely positioned to be an industry leader for the routine collection of PROMs in clinical practice.

The most common aspects of health that are evaluated by PROMs, including physical function, pain, and satisfaction, all are relevant to the diagnoses and procedures that are encountered in clinical practice. Unfortunately, routine PROM collection in a high-volume ambulatory orthopaedic setting is difficult unless the collection is administered, scored, and recorded electronically<sup>4</sup>. Thus, electronic collection systems are vital for the routine collection of PROMs.

## Outcome Collection in Orthopaedics

Traditionally, the most common outcomes that are collected in the field of orthopaedic surgery include strength, range of motion, imaging, and adverse events. These are all objective outcomes that can be collected and measured without patient input.

Conversely, PROMs, which require input from patients, assess patient-reported pain, physical function, and satisfaction<sup>5</sup>. These outcomes are more relevant than clinician-defined outcomes because they are derived from the perspective of the

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patient. A wide variety of PROMs are described in the orthopaedic literature. These include anatomic-specific questionnaires (e.g., regarding knees, shoulders, etc.<sup>6,7</sup>), disease or condition-specific questionnaires (e.g., the Hip disability and Osteoarthritis Outcome Score<sup>8</sup>), and questionnaires that assess general health (e.g., the EuroQol 5 Dimensions [EQ-5D] and the Short Form Health Survey-12 [SF-12]<sup>9</sup>).

**The Ideal Patient-Reported Outcome Measure**

With so many options of PROMs available, which one is ideal for the ambulatory orthopaedic clinic? There are several important considerations when selecting the most appropriate PROM to collect for each orthopaedic practice.

**Standardization**

It is important to review the literature for standard or common PROMs that are used for each specialty or specific condition that may be encountered in clinical practice. The large variety of PROMs that are available in the orthopaedic literature makes it difficult to interpret and compare findings from studies that utilize different outcome measures. As consensus PROMs emerge for each specialty, it is ideal to use these PROMs so that research findings are more often applicable to a provider’s orthopaedic practice. A list of commonly used PROMs for each joint can be found in Table I. For example, the American Shoulder and Elbow Surgeons (ASES) Shoulder Score is commonly used for shoulder injuries<sup>10</sup>.

**Validity and Reliability**

PROMs should be proven valid and reliable for both clinical and research purposes<sup>11</sup>. Validity is the ability to measure what the PROM intends to measure, whereas reliability is the consistency and repeatability of the PROM measurements. Deficiencies in either of these characteristics compromise the utility of PROM data. Prior to implementing PROMs into clinical practice, these

TABLE I Commonly Used PROMs for Each Joint*	
Shoulder <sup>10</sup>	American Shoulder and Elbow Surgeons Shoulder Score Constant-Murley score Disabilities of the Arm, Shoulder and Hand (DASH) Shoulder Pain and Disability Index (SPADI) Simple Shoulder Test (SST) Western Ontario Rotator Cuff (WORC) index
Elbow <sup>37,38</sup>	Elbow Self-Assessment Score (ESAS) Disabilities of the Arm, Shoulder and Hand (DASH) Oxford Elbow Score (OES)
Wrist/hand <sup>39</sup>	Disabilities of the Arm, Shoulder and Hand (DASH) Gartland and Werley score Patient-Rated Wrist Evaluation (PRWE)
Hip <sup>40</sup>	Harris hip score (HHS) Hip disability and Osteoarthritis Outcome Score (HOOS and HOOS, JR) Oxford Hip Score (OHS)
Knee <sup>7,40,41</sup>	International Knee Documentation Committee (IKDC) questionnaire Lysholm knee score Knee injury and Osteoarthritis Outcome Score (KOOS and KOOS, JR [KOOS for Joint Replacement]) Knee Society Score (KSS) Oxford Knee Score (OKS)
Foot/ankle <sup>42</sup>	Foot and Ankle Ability Measure (FAAM) Foot and Ankle Disability Index (FADI) Foot Function Index (FFI)
Spine <sup>43</sup>	Cervical Spine Outcomes Questionnaire (CSOQ) Japanese Orthopaedic Association (JOA) myelopathy scale Myelopathy Disability Index Neck Disability Index (NDI) Oswestry Disability Index (ODI) Quebec Back Pain Disability Scale Roland Morris Disability Questionnaire
*PROMs = patient-reported outcome measures.	

properties should be investigated in the scientific literature; the original development of the specific PROMs as well as studies investigating the psychometric properties for their intended purpose should be evaluated<sup>12</sup>.

**Generalizability**

Questionnaires that can be applied indiscriminately to all patients, regardless of the anatomic location or nature of the injury, have substantial advantages over otherwise specific outcome measures. An example of this type of form is the Patient-Reported Outcomes Measure-

ment Information System (PROMIS)<sup>13</sup>. These questionnaires can be used to quantitatively compare the impact of various interventions across a range of health problems, orthopaedic or otherwise. The forms also can be normalized against a healthy control population. From a practical standpoint, routine PROM collection is made substantially easier by avoiding a customized series of questionnaires for each individual patient.

However, there are some disadvantages to utilizing generic PROMs when assessing specific orthopaedic

conditions. For example, in order to be applicable across a broad range of health problems, PROMs may sacrifice the ability to detect small changes in clinical functioning for specific patient populations. These obstacles can be overcome if adequate responsiveness for condition-specific orthopaedic populations can be demonstrated with generic PROMs.

#### **Actionability**

PROMs should be actionable and influence clinical decision-making<sup>14</sup>. Therefore, if PROMs are collected in a clinic, they should be scored and calculated before being reviewed by a provider and shared with the patient. PROMs may help to identify the patients who would most likely improve with surgical intervention<sup>15</sup>. Although it may not be feasible to implement real-time scoring for every single patient encounter, patients may become complacent in PROM collection if their scores are not being included in some capacity in clinical decision-making.

#### **Feasibility**

Routine collection of PROMs in the orthopaedic clinic must be implemented in a way that does not cause delays or otherwise interfere with patient care.

#### **The Administration of PROMs in the Clinical Setting**

Traditional pencil-and-paper administration of PROMs requires manual calculations and the recording of scores into electronic medical records (EMRs). This method is cumbersome and provides numerous opportunities for human error.

The administration of electronic PROMs (EPROMs) is becoming a more frequent method for data collection, especially in an increasingly technology-literate population. Electronic data collection offers several advantages over traditional pencil-and-paper formats and provides substantial improvement for nearly all of the aforementioned characteristics that are associated with ideal questionnaires.

#### **Advantages of EPROM**

##### **Administration**

One of the biggest innovations that has been made possible by EPROM administration is the ability to utilize computerized adaptive testing (CAT). Traditional questionnaires are administered on paper, which means that each patient receives the same number, type, and order of questions, regardless of his or her individual responses. The problem with this format is that many questions may not be particularly relevant to a specific patient. These inefficiencies have a negative impact on psychometric properties, namely time to completion, reliability, and floor and ceiling effects<sup>16</sup>.

CAT forms overcome these challenges by dynamically adjusting survey questions based on previous responses<sup>17</sup>. Consequently, every patient receives a unique questionnaire that can produce a final score in as few questions as possible. This has resulted in superior psychometric properties in comparison with standard forms for a variety of orthopaedic conditions<sup>18-23</sup>. Because this customized line of questioning functions with advanced algorithms, CAT forms must be administered electronically.

Another quality of electronic administration is decreased patient and provider burden (e.g., it minimizes the time and effort that are required by the patient to complete a questionnaire). By requiring fewer questions to calculate a final score, CAT forms take less time for the patient to complete<sup>23-27</sup>. This results in high rates of patient compliance and, theoretically, fewer delays in the clinic<sup>27,28</sup>.

Remote administration of EPROMs is considerably more practical than remote administration of paper forms. The process of preparing paper-based PROMs for the mail is quite cumbersome, and asking patients to go through the effort of returning completed forms places an unrealistically high burden on them. By comparison, electronic mail is quick, efficient, and easy to track. E-mailing EPROMs to patients prior to clinic visits can further minimize disruptions in workflow.

Additionally, with the recent rise of “virtual visits” in lieu of standard clinic visits, providers must administer PROMs remotely in an efficient manner. Recently, new methods of electronic delivery have been established for compatibility with mobile phones, including SMS (short message service) text-messaging services<sup>29</sup>.

EPROM scores can be calculated instantly, which allows for the opportunity to immediately produce score reports and provide real-time feedback to patients. These scores can be tied into patient EMRs in the same way as laboratory values and can be presented over time with use of graphic illustrations<sup>14</sup>. This feedback not only keeps the patient engaged in his or her health status, but also gives the provider immediate quantitative data for real-time clinical decision-making.

Lastly, on a technical level, EPROMs improve the quality of data by preventing patients from skipping questions or providing ambiguous responses<sup>4</sup>. EPROMs also bypass the manual recording of paper responses, a step that can result in human error and can compromise the integrity of the original data.

#### **Examples of EPROM Platforms for Orthopaedic Practice**

The recent emphasis on electronic collection of patient health information in the modern health-care system, combined with a concerted movement toward value-based care, has catalyzed the development of numerous HIPAA (Health Insurance Portability and Accountability Act of 1986)-compliant platforms for capturing EPROMs. The most popular EPROM collection platforms that are used in the field of orthopaedic surgery include EMRs, OBERD, SOS, SOCRATES, RED-Cap, and Mosio (Table II).

#### **EMRs**

Collection of EPROMs via EMRs (e.g., Epic and Cerner) represents the simplest means of integrating patient outcomes and care. For example, Epic is a health-care

TABLE II Common Platforms for EPROM Administration in Orthopaedic Practice\*

	Electronic Data Capture System					
	EMRs	OBERD	SOS	SOCRATES	REDCap	Mosio
Vendor	Varied	Universal Research Solutions	Arthrex	Ortholink	Vanderbilt University	Mosio
Commercial or noncommercial	Commercial	Commercial	Commercial	Commercial	Noncommercial	Commercial
Data collection methods	Web-based, smartphone	Web-based, e-mail, tablet, portal, staff-administered surveys	Web-based, e-mail at predefined time points	Web-based, scannable forms	Web-based, e-mail	Text messaging
Security measures	Centralized, encrypted storage	Centralized, encrypted storage	Centralized, encrypted storage	Dependent on local server	Dependent on local server	Centralized, encrypted storage
Integration with electronic health records	Yes	Yes	Yes	No	Yes	No
Qualified clinical data entry	No	Yes	Yes	No	No	No
Basic data reporting	Built-in summaries and visualization	Built-in datamining and visualization	Built-in visualization and customizable reporting	Built-in package for basic statistics	Built-in autoscoring or export to statistical package	Export to statistical package or REDCap
Additional features	Easiest integration with current health-care practices	Direct reporting of MIPS to CMS	Contribution to global registry and comparison of individual patient scores with deidentified averages	Modules for anatomic-specific problems that can be further customized	Access to user-created, prebuilt PROs in Consortium library	2-way messaging interface; can interface with REDCap

\*EPROM = electronic patient-reported outcome measure, MIPS = Merit-based Incentive Payment System, CMS = Centers for Medicare & Medicaid Services, and PROs = patient-reported outcomes.

software that was developed and is supported by Epic Systems. As one of the largest providers of health-care information technology nationally, Epic is primarily used by hospitals and health systems to organize, store, and share EMRs. Since 2012, a limited number of CAT questionnaires and short forms that measure pain, fatigue, and physical functioning, which have a major impact on quality of life, have been made available to physicians via PROMIS through Epic’s App Orchard program<sup>30</sup>. As with all commercial platforms, App Orchard requires an annual licensing agreement for use in a clinic. With Epic, physicians can assign measures to patients, view individual responses over time, and aggregate scores across patients in conjunction with clinical information. Patient access to measures is limited to web-based and smartphone platforms, while clinical staff can gain access through the Epic Hyperspace system.

In general, the advantages of recording EPROMs via EMRs include direct flow into the point of care as well as the reduced technological and operational barriers that are associated with

integrating EPROMs. Disadvantages include the limited number of questionnaires that are available to providers.

**Outcomes-Based Electronic Research Database**

OBERD, an acronym for outcomes-based electronic research database, is a cloud-based commercial software system that was developed and is supported by Universal Research Solutions<sup>31</sup>. For use in clinics, OBERD requires a licensing agreement with a yearly subscription fee per provider. Currently supporting over 2.5 million patients and 7 million outcome forms, OBERD can integrate with EMR programs and allows users to choose National Institutes of Health (NIH) PROMIS CAT forms from an extensive library, configure forms for delivery on a specific timeline, optimize forms for automatic e-reminders, brand forms specific to their institution, and deliver forms directly to patients via smartphone or tablet. Although collected data are owned by the practice, both the OBERD software and the collected data reside on a central server from which data can be exported to numerous statistical programs or to

the provider via HIPAA-compliant protocols. OBERD also has a central Musculoskeletal Outcomes Shared Platform registry that allows for national comparison across any number of variables (e.g., patient demographics, outcomes, satisfaction, and costs). OBERD is a Qualified Clinical Data Registry, which means that collected data can be used for a Merit-based Incentive Payment System (MIPS) that reports to the Centers for Medicare & Medicaid Services (CMS). However, due to subscription and implementation costs, the use of OBERD is limited to medium-to-large practices.

**Surgical Outcomes System**

The Surgical Outcomes System, also known as SOS, is a cloud-based commercial data collection platform that was developed by Arthrex<sup>32</sup>. As a commercial platform, SOS charges providers a monthly fee. SOS can accept data that are generated from an EMR as well as from other clinicians who are participating in the Medicare Electronic Health Record (EHR) Incentive Program or the Medicare Quality Payment Program (including MIPS). SOS

automatically e-mails PROM surveys, along with “core registry” outcome measures (e.g., PROMIS 10 and a visual analog scale [VAS]), which are aligned with the recommendations of the American Academy of Orthopaedic Surgeons (AAOS) and orthopaedic specialty societies, to patients at predefined time points. Of note, SOS also facilitates comparative analysis on individual outcomes, site outcomes, and the global deidentified average for different surgical procedures. These features permit providers to leverage outcomes for marketing and provide evidence for successful treatment outcomes. The global registry also can provide health plans with the ability to collect outcomes data across multiple sites, aggregate averages and benchmarks, assess cost-effectiveness of interventions, and measure key performance indicators.

#### **Standardized Orthopaedic Clinical Research and Treatment Evaluation Software**

SOCRATES, the Standardized Orthopaedic Clinical Research and Treatment Evaluation Software, is a commercial platform that was developed by OrthoLink<sup>33</sup>. SOCRATES, a smaller platform than both OBERD and SOS, collects and stores data locally at the clinical facility where the PROM administration application is installed. While this ensures that patient data are only accessible to those with access to the clinical server, it has the disadvantage of placing the burden of security on the clinical practice. Within practices, SOCRATES can be used as a simple audit system to track procedures, as a tool to assess patient outcomes for selected procedures, and as a research tool for clinical trials and research. Clinicians can access >80 outcomes scores and patient surveys that can be filled in online or with use of scannable forms. Surgeons can record intraoperative complications, concomitant therapy, and clinical examination details with use of common templates; and users can export collected data into EMR systems. However, SOCRATES does not provide qualified clinical data entry.

#### **Research Electronic Data Capture**

The Research Electronic Data Capture system, known as REDCap, is a non-commercial web-based application for building and managing surveys that was developed by Vanderbilt University<sup>34</sup>. REDCap is specifically geared to support online or offline data capture for research studies; it functions and collects data locally, although REDCap also can interface with Vanderbilt servers for specialized autoscoring and CAT functionality. One of the main advantages of REDCap is that the data collection system is free, although REDCap does require an institutional license agreement as well as membership in the REDCap Consortium. Presently, the REDCap Consortium is composed of 3,081 active institutional partners in 127 countries<sup>35</sup>; users can access and share prebuilt PROMs. Users also can build simple custom forms using various question types and instruments. Additionally, the software can provide basic statistics; however, it is not capable of performing advanced statistical analysis.

#### **Mosio**

Mosio, which was developed by a company of the same name, is a mobile messaging software that allows providers to reach patients using a 2-way text-messaging interface<sup>36</sup>. As with other commercial services, Mosio charges a monthly fee. Unlike other platforms, however, Mosio automates PROM collection through text messaging. Providers can create personalized interactions with automated messages, pre-scheduled automated follow-ups, and customized messages. HIPAA compliance is ensured through the assignment of a unique personal code (an mPIN) to each patient, and collected data are hosted on centralized commercial servers. While Mosio does not directly interface with an EMR, it has the ability to interface with REDCap; the 2 systems can be integrated so that the provider can access all of the data and surveys from within REDCap without having to interact with Mosio. Mosio delivers REDCap surveys via text to the patient

or, alternatively, can import data from administered surveys into REDCap. Mosio also can identify incomplete data within REDCap and remind patients to complete surveys. However, as with REDCap, users may need to build custom forms if the existing forms that are available through the consortium are insufficient.

#### **Choosing a Platform**

Although the above services are commonly employed within orthopaedic clinical practices, they represent only a small number of the many commercial and noncommercial software platforms that are available today. Other platforms include the new AAOS registry platform (RegistryInsights) and the new International Cartilage Regeneration & Joint Preservation Society (ICRS) registry platform (Ortech Systems). Each of these platforms offers a variety of features, costs, and infrastructure considerations that are not included herein. Providers should assess and choose an appropriate platform based on individual needs.

#### **Implementing Routine EPROM Collection: Workflow Considerations**

An efficient EPROM administration system allows for the massive collection of PROMs from all patients who come to the ambulatory orthopaedic clinic. However, there are several aspects of routine EPROM collection that must be considered in order to prevent disruptions in clinical workflow.

When establishing an electronic collection system, 1 of the primary goals is to minimize the effort that is required from both the patient and the provider. The patient burden, which has been discussed above, involves time-to-completion and length-of-questionnaire considerations. The burden on the provider often is associated with 2 aspects of each patient encounter: (1) Does the patient need to complete PROMs? and (2) Which specific forms will the patient be asked to complete?

In our practice, we utilize REDCap to capture data on all operative and

nonoperative patients who come to our sports medicine clinics. Prior to being taken back to the examination room, patients are asked to complete a series of EPROMs on electronic tablets while in the waiting area. Since every patient receives EPROMs at every visit, the effort of determining which patients need EPROMs is eliminated.

Furthermore, we distribute PROMIS CAT questionnaires to all patients, regardless of the anatomic area or nature of their injury. This is possible because PROMIS CAT forms are not specific to a single condition or disease and can be administered to patients across all fields of medicine. Because every patient receives the same set of questionnaires at every visit, the provider burden is effectively minimized.

### Overview

EPROM collection is becoming increasingly important in an era of patient-centered medicine, especially for routine collection in high-volume orthopaedic clinics. Although the routine collection of PROMs certainly requires effort on the part of the provider, electronic administration using the aforementioned platforms that utilize CAT forms makes these systems feasible for busy clinical practices. Electronic collection also has the benefit of providing immediate quantitative feedback from the patient's perspective, which can assist in clinical decision-making. Ultimately, EPROM collection has the potential to substantially enhance patient engagement in the field of orthopaedic surgery.

Vincent A. Lizzio, MD<sup>1</sup>,  
Mihir S. Dekhne, MS<sup>2</sup>,  
Eric C. Makhni, MD, MBA<sup>1</sup>

<sup>1</sup>Department of Orthopedics, Henry Ford Health System, Detroit, Michigan

<sup>2</sup>Harvard Medical School, Boston, Massachusetts

E-mail address for E.C. Makhni:  
emakhni1@hfhs.org

ORCID iD for V.A. Lizzio:  
[0000-0001-6657-4515](https://orcid.org/0000-0001-6657-4515)

ORCID iD for M.S. Dekhne:  
[0000-0002-0546-5566](https://orcid.org/0000-0002-0546-5566)  
ORCID iD for E.C. Makhni:  
[0000-0003-4408-1175](https://orcid.org/0000-0003-4408-1175)

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