Patient-Reported Functional Outcomes:

How to Collect and Report Risk-Adjusted Musculoskeletal Patient-Reported Functional Outcome Data in an Orthopaedic Practice in California

White Paper
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Executive Summary and Recommendations

The purpose of this white paper is to educate COA members about key issues to consider when making decisions about adopting standardized processes for collecting PRO data from patients with musculoskeletal conditions of the shoulder, hand, spine, ankle and foot[1]. It is not designed to be an exhaustive study of PRO instruments and methodologies for administering, interpreting and analyzing PRO data; there are several existing white papers (Cella, 2012, Deutsch, 2012, Aaronson, 2011), as well as many peer-reviewed journal articles that can provide more detailed information on the topics discussed.

Rather, this paper draws from these many sources, as well as from many personal communications with experts on the cutting edge of this rapidly developing field, and synthesizes information into what is intended to be a practical resource containing summaries of the most salient issues for assisting COA and its members in embarking on more widespread adoption of PRO data collection and analysis processes.

Adoption of these processes is critical for improving physician patient management, continuous quality improvement (CQI) monitoring of interventions, and more generally as the field moves toward patient-centered care. It is critical for COA members to take a lead in defining processes and models before payors make their own determinations and mandates.

Below we provide several recommendations based on the information collected for this white paper.

For individual practices: We recommend beginning to put processes in place for collecting PRO data in the office setting. In general, this will involve the following steps:

1. Selecting a general and disease-specific short PRO instrument(s) (Tables 1-5; e.g., SF-12, UCLA Activity Index) already available on one of the PRO-specific software tools (Tables 6-7; e.g., OBERD, SOCRATES, SOS).
2. Checking for instrument licensure requirements (most software tools expect the user to do so).
3. Developing a data collection/tracking protocol(s) that includes:
   - when instruments should be administered (e.g., pre-operative, 1-month post operative),
   - their mode of administration (e.g., ipad in office; smartphone application; online survey)

[1] Knee and hip replacements were not included so as not to replicate what is covered under the American Joint Replacement Registry (AJRR) and the California Joint Replacement Registry (CJRR). Instruments available for non-reconstructive knee (e.g., sports-knee instruments) and hip injuries are listed when they are included as part of PRO-specific software tools (Table 7).

4. Preparing a data management and storage plan.
5. Preparing a data analysis plan.
6. Preparing a data reporting plan.

This can be a complicated process and should be tailored for each practice. ETR is an agency in northern California that has the capacity and expertise to act as a consultant in this process (see also the COA website under Practice Management Resources – PRO/Quality Measurement). Clinicians also should consider the possibility of participating in a demonstration project to establish a base of California orthopaedic PRO data for risk adjustment model development (see Section IX).

For the COA and sub-specialty fields: We recommend: (1) working with a consulting organization to identify a small set of general and disease-specific PRO instruments to recommend as region-specific standards for use across California; and (2) collaborating with an organization to establish a data center in which early adopters of PRO integration into clinical practice can pool their data for a demonstration project. Such a demonstration project would serve to: (a) provide data for beginning to establish normative values and risk adjustment models; and (b) demonstrate to non-early adopters the value of collecting PRO data, including the identification of effective clinical practices and ability to show patient-centered value to payors.

These recommendations encourage the staged implementation of PRO integration across the state and would enable COA to set standards and determine normative values/risk adjustment models rather than waiting for government agencies and payors to do so.

(I) Purpose

This paper was commissioned by the California Orthopaedic Association (COA) with the goal of providing recommendations on practical, cost-effective processes and standards to encourage more widespread, consistent use of patient-reported outcome (PRO) instruments by COA members working in shoulder, hand, spine, foot and ankle sub-specialties across California. Specifically, the objectives are to: (1) educate COA members about the importance of beginning to collect PRO data from their patients; (2) identify the most appropriate, standardized, validated instruments for assessing PROs in patients with musculoskeletal conditions within the named sub-specialties; (3) identify processes and software tools by which these instruments can be administered routinely in clinical practice settings, both pre- and post-procedures; (4) identify PRO data flow issues – i.e., compatibility and integration with Electronic Medical Record/Electronic Health Record (EMR/HER) systems; and (5) educate COA members about issues surrounding interpretation and analysis of PRO data in a risk-adjusted manner.

(II) Significance/Background

Patient-reported outcomes (PROs), also called patient-reported functional outcomes (see Table 1), are being recognized widely as critical tools to improve care management by enabling clinical providers to continually assess the results of their interventions for the purpose of continuous quality improvement (CQI) (Cella et al., 2012).

Historically, PROs were used routinely in controlled research studies as part of developing evidence-based practices. Now, their promise in helping clinicians ensure they are providing interventions likely to result in the best outcomes for patients, adjusted for various risk profiles, is driving the identification, development and study of standardized tools most appropriate for specific disease areas. PRO data collection is a critical component of patient-centered medical care, and is being recognized as a key early indicator of intervention success (Franklin et al., 2012).

Furthermore, federal regulators recently have shown interest in expanding the measures they require for assessing levels of payments to providers (differential reimbursements). Upcoming 2014 changes from the Affordable Care Act and proposed payment policy changes from the Centers for Medicare and Medicaid Services (CMS) have implications regarding required PRO data collection within the next two to three years.

Specifically, CMS plans to begin requiring that providers obtain pre- and post-procedure PRO measurements (Clark, 2012); currently they require only the Hospital Consumer Assessment of Healthcare Providers and Systems (H-CAHPS) scores, which report on outcomes measuring patient satisfaction and perceptions of care domains (e.g., was a hospital bell call answered in a

timely manner) rather than on functional outcome domains (e.g., how well the patient can now climb stairs). In addition, there is a developing movement among private payors (insurance companies) to tie providers‟ payments to patients‟ functional outcomes.

In the wake of this movement, it‟s critical that orthopaedic surgeons begin implementing the routine collection of the most appropriate PRO data for their sub-specialties. In particular, providers need to identify the most appropriate, standardized, validated instruments for assessing PROs for their subspecialties; identify processes and software tools by which these instruments can be administered routinely and with high rates of compliance in their clinical practice settings, both pre- and post-procedures; and appropriately interpret and analyze PRO data, taking into account clinically important differences and underlying risk profiles (e.g., age, weight, activity level, comorbidities) of patients (Appleby, 2012; Deutsch, et al., 2012; AAOS, 2013).

To date, the routine collection, monitoring and analysis of PRO data using standardized tools has not been widely adopted in the sub-specialty areas focused on musculoskeletal conditions of the shoulder, hand, spine, foot and ankle, either within research trials or clinical practice settings. In the mid-1990s, the American Academy of Orthopaedic Surgeons (AAOS) began an initiative to bring together existing, validated PRO instruments and develop new ones for various sub-specialty areas, and promote their use by orthopaedic practices. The group of instruments was called the Musculoskeletal Outcome Data Evaluation and Management System, or MODEMS.

In addition, AAOS began a normative data study for MODEMS instruments to provide mean scores for general, healthy populations against which clinicians could compare their own patients‟ and practice scores (Hunsaker et al., 2002). Unfortunately, in 2000 the MODEMS initiative was halted due to a variety of issues related to lack of use of the instruments, lack of clear processes and protocols to follow for administering and reporting data, extremely poor follow-up response (compliance) rates, and financial failure (Saleh et al., 2004). Another barrier likely was the state of technology and electronic appointment and health record systems at the time of the initiative, both of which have advanced greatly in the past dozen years.

In the past decade, pilot studies have been conducted to test new standardized PRO measures, and to test the feasibility of incorporating PRO data collection systems into medical practices, and, in particular, into electronic health information systems. For example, a group at Johns Hopkins School of Public Health concluded that it was feasible to collect PRO data in a clinical setting based on results of a study using a newly designed web-based software tool (“Patient Viewpoint”) to collect data from breast and prostate cancer patients (Snyder et al., 2012). The tool doesn‟t directly link to an EMR, but generates a data file that can be imported into an EMR. A study is ongoing to investigate using this web-based tool to collect PRO data in the context of CQI.

In another study, researchers at the University of Utah have been investigating the validity of PRO measures from patients before and after undergoing ankle/foot surgery, using a system currently being developed by a multi-center project funded by the National Institutes of Health (NIH) called the Patient Reported Outcomes Management Information System, or PROMIS (Hung et al., 2011, 2012). While the instruments are being refined to improve their sensitivity, compliance rates for post-procedure PRO measures remain relatively low at 45(Saltzman and Abidi, 2013). In yet another example, PROMIS was adopted by the Robert H. Lurie Comprehensive Cancer Center at Northwestern University after a 2-year process involving many IT and other process and institutional barriers (Rothrock, 2013).

Currently, The Dartmouth Institute for Health Policy and Clinical Practice (TDI) is working with Dynamic Clinical Systems (DCS) (refer to Table 6) to establish systems for collecting PROs for cardiac and hip- and knee-replacement patients; however, given the steep cost and setup structures, their system is geared for large institutions. Finally, in the past few years, a joint initiative between the COA, Pacific Business Group on Health (PBGH) and California HealthCare Foundation (CHCF) created the California Joint Replacement Registry (CJRR), which collects patient-reported outcomes in addition to traditional clinical registry data on hip and knee replacement surgeries. It is one of the few level 3 registries in existence (CJRR, 2010).

To date, most large, successful PRO data collection efforts in the field have fallen under the umbrella (and financial support) of funded research studies and within large (more than 15 surgeons) practices. Even for these, there have been barriers to implementation, including the need for IT programming resources; resources dedicated to tracking patients to obtain follow-up PRO measurements and ensure reasonable compliance rates (data collection response rates); obtaining buy-in by patients and surgeons/clinical staff; and clear guidelines and plans for scoring, interpreting, analyzing and using PRO data.

The purpose of this white paper is to provide information that facilitates the extension of the use of PRO data beyond research/clinic trial settings and into orthopaedic clinical practice settings, with a particular focus on musculoskeletal surgical interventions of the shoulder, hand, spine, foot and ankle. This is accomplished by: (1) identifying appropriate, valid, low-burden (e.g., short) PRO instruments for each sub-specialty; (2) identifying processes and cost-effective and compatible (i.e., with electronic health systems) software tools that can be used to administer these instruments; and (3) providing guidelines about how these data may be used and analyzed in a risk-adjusted manner.

(III) Definitions and Terms

PRO – Patient-reported outcome, or patient-reported functional outcome
PROM – Patient-reported outcome measure (instrument)
Small-medium practice – fewer than 15 surgeons
Large practice – more than 15 surgeons

(IV) Why Standardized, Widespread PRO Data Collection by Orthopaedic Practices Is Important

As discussed above, the integration of PRO data collection into routine clinical practices is being recognized as essential within the movement toward patient-centered approaches to medical care (Cella et al., 2012; Deutsch et al., 2012). Specifically, PRO data can be used to: (1) help guide individual clinicians and patients dynamically through treatment pathways; (2) help clinicians conduct practice-wide monitoring of interventions for continuous quality improvement (CQI); (3) help surgeons across a given orthopaedic sub-specialty and geographic region (e.g., California) monitor interventions (if data are pooled across practices in Registries or Data Centers); and (4) demonstrate value to payors, especially in preparation for upcoming mandates to do so using PRO measures.

PRO data could be presented to patients at each visit, and their total score and various subscale/subdomain scores could be examined for aspects of recovery that may need further attention. For example, one study found that post-surgery care may be guided by specific symptoms measured on the Disabilities of the Arm, Shoulder and Hand (DASH) Outcome Measure that were addressable in the post-surgery period (Plummer, 2013). In this way, CQI processes are combined with patient-centered care.

Registries historically have collected limited data on device failure rates and revisions. The scope of traditional registries is being expanded to include PROs, so that the success of interventions can be monitored across different patient populations (e.g., CJRR). Evidence is emerging that the patient voice is key to earlier detection of intervention success and problems (Franklin et al., 2012).

COA members can take a lead in directing the movement towards patient-centered care, especially as it is incorporated into future payor mandates, by making choices now to integrate into their practices the routine administration of selected standard PRO instruments, at standardized time intervals via standardized processes (i.e., using protocols for introducing PROs to patients, gaining buy-in from patients and clinic staff, obtaining high follow-up compliance rates). Through routine data collection of PROs, they also can begin amassing pools of data through data centers, in order to establish normative benchmarks and create statistical models for

risk adjustment of scores within sub-specialty areas. The latter is critical for making fair assessments/comparisons of quality of care based on actual improvements in functioning of patients, while accounting for the clinical risk factors (e.g., multiple comorbidities, baseline functional status) different patients who are candidates for the same musculoskeletal surgery present with prior to any intervention (see section below on risk-adjusted analyses).

(V) How to Collect PRO Data: What Instruments to Use

1. *Introduction*

Combining generic health assessment PROs with condition-specific PROs is recommended (Cella et al., 2012; Deustch et al., 2012; Aaronson et al., 2011). The more disease-specific a PRO, the more sensitive it will be to change (i.e., responsive). On the other hand, the more general a PRO (e.g., the PROMIS general physical function form), the more results can be compared to other population results. Experts in the field of PROs, including PROs used in orthopaedic practices, recommend the use of both a general health assessment tool and a disease-specific tool when assessing patient-reported functional outcomes (Cella et al., 2012; CJRR, 2010).

The full PRO instrument as it was developed and validated must be used in its entirety to maintain the integrity (i.e., validity, reliability) of the measure. Historically, across the field, despite the many PRO instruments developed and validated for sub-specialty areas in orthopaedics (see Tables 2-5), many variations of similar instruments have been implemented. Variations are made for a variety of reasons, including patient response burden. However, variations lead to problems with validity and comparability of scores. Currently, very few PROs are consistently used in the orthopaedic sub-specialty areas of interest (shoulder, hand, spine, foot, ankle) in clinical settings, and there is no standard set of instruments and procedures (e.g., follow-up intervals) that has been adopted or endorsed by associations. There also are no registries set up for these areas.

2. *Criteria for Instrument Inclusion*

COA PRO Task Force members expressed interest in identifying emerging tools that were in various states of validation. The criteria for inclusion of PRO instruments in the summary tables were therefore as follows:

a. Instruments identified in literature review of peer-reviewed journal articles on PROs in the above-named orthopaedic sub-specialties, and/or (in limited cases) listed on association websites or used in registries

b. Instruments recommended by COA Task Force members within shoulder, hand, spine, foot, ankle sub-specialties OR included in major software tool systems specializing in orthopaedic PROs (e.g., OBERD, SOCRATES)

3. *General Health Assessment PRO Instruments*

Table 1 presents information on validated patient-reported general health assessments most commonly used in orthopaedics. The SF-36, SF-12 and EQ-5D are the most commonly used generic tools in the orthopaedic community (CJRR, 2010). More recently, the VR-36 and the VR-12, which were developed by the Veterans Administration based on the SF questionnaires and are in the public domain, are being adopted by major PRO software tool companies (SOCRATES, OBERD).

In addition, the CJRR recommends incorporating an activity rating scale into patient assessments. The only comparative study of activity scales concluded that the UCLA Activity Scale is the most appropriate measure for arthroplasty patients. The single item UCLA scale asks patients to rate their activity level from 1 to 10, with 1 defined as "no physical activity" and 10 defined as "regular participation in impact sports." The UCLA scale has demonstrated construct validity, excellent reliability and the best completion rates (CJRR, 2010). The full scale is shown as a sample instrument in Appendix B.

4. *Disease/Region-Specific PRO Instruments for Orthopaedic Sub-Specialties of Shoulder, Spine, Hand, Foot, Ankle*

Tables 2–5 present a mix of disease and anatomical region-specific PRO instruments by sub-specialty. Key information on instrument domains (i.e., constructs), response burden (i.e., length), availability within software tools, etc., is provided. The foot/ankle "FFI-R" instrument is shown as a sample in Appendix B.

5. *A Solution to the Lack of Standardization in Instruments: NIH-PROMIS*

The NIH-funded Patient Reported Outcomes Measurement Information System (PROMIS) multi-site project began in 2004 with a primary goal of constructing item banks from which to create *standardized, valid, reliable* fixed-length short PRO instruments and variable-length "computer adapted tests" (CATs) (see below for explanation) across a comprehensive set of health domains. It also seeks to establish normative values for clinical and general populations.

The item banks were developed based on exhaustive review and testing of "legacy scales" – i.e., already existing valid, reliable PRO instruments across the medical fields, including orthopaedics. The motivation for the development of PROMIS came in part from the high variability in existing instruments (even those of the same name) that were being used across studies and clinical populations to measure PROs. This lack of standards makes it difficult to compare outcomes across studies and populations, something PROMIS hopes to remedy.

From its item banks, PROMIS has created and tested, and continues to create and test, multiple fixed-length "short form" instruments across a variety of domains, including physical functioning, pain and mental functioning. It also has created and tested, and continues to create and test, variable-length CATs. PROMIS CATs are computer programs designed to ask individual patients with specific medical problems requiring intervention only the items most relevant to them given their answers to previous questions about functioning. They tend to be less burdensome (shorter), but are more difficult to set up, especially in a clinical setting. There currently are a number of ongoing studies across the country of the performance of PROMIS instruments – both short forms and CATs – in specific clinical populations.

The only studies of the PROMIS system for use in orthopaedic clinical settings identified thus far come out of a team of researchers at the University of Utah. They recently published two papers on their work. One showed the results of a Lower Extremity CAT (LE CAT) they developed, which performed better than two "legacy" foot and ankle PRO scales (FFI and spFAAM) (Hung, et al., 2011; Hung, et al., 2012; Hung, 2013). Furthermore, they found that their initial division of the PROMIS physical function item bank into upper and lower extremity (UE and LE) sets worked well for lower but not for upper extremity, and so are currently revising the banks. Concurrently, the PROMIS team created smaller upper and lower extremity physical functioning banks from which they created a LE and UE short form, each containing only 8 items. These have been tested, are currently undergoing more tests, and will be available on the site for free (as all PROMIS instruments and CATs are) within the next 2 months (Rothrock, 2013). Also important to note, is the existence of a general health assessment instrument, the PROMIS-10 Global (which has been adopted by The Dartmouth Institute"s PRO section).

The full PROMIS system with CATs is currently only in use in large research institutions (e.g. Northwestern University Robert H. Lurie Comprehensive Cancer Center) and is not recommended as feasible for use in orthopaedic practice settings in the foreseeable future. However, the short form instruments compiled by PROMIS should not be ruled out as candidates for use in a clinical practice setting, especially given their short length, validity and lack of any required fees.

PROMIS short form instruments currently are compatible with the EPIC 2012 EMR. However, in order to utilize them, a local IT EPIC team member person needs to access the PRO code and make it available after the clinician decides which short forms s/he wants made available to patients through the MyChart portal. Once specifications are set up, patients are emailed at regular intervals with a link for completing the form(s). (Rothrock, 2013). PROMIS currently is in negotiations with EPIC to integrate their CAT programs into EPIC 2014.

6. *FOTO – Focus on Therapeutic Outcomes Inc. – PRO Instruments, Software and Registries for Physical Therapy Rehabilitation for Musculoskeletal Conditions*

For more than a decade, the field of physical therapy rehabilitation has been adapting, administering and collecting routine baseline and follow-up data on PROs for patients with various musculoskeletal conditions. For example, the company FOTO has adapted numerous existing orthopaedic sub-specialty PRO instruments (e.g., the DASH) to maximize their validity for patients with musculoskeletal conditions presenting for physical therapy rehabilitation services (both post-surgical and not post-surgical). FOTO also provides web-based software tools for entering and analyzing these data in a risk-adjusted manner. They are an approved registry for data entry into the CMS Physician Quality Reporting System (PQRS). FOTO"s chief scientist, who passed away last year, developed risk adjustment models using the large datasets resulting from PT providers across the country submitting PRO data through their registry.

While they have developed a complete system for collecting, monitoring and risk-adjusting PRO data from patients with musculoskeletal conditions for the sub-specialties named above, these systems were developed and therefore validly apply only to patient populations undergoing PT rehabilitation. To apply to orthopaedic surgical patients, the instruments would need to be adjusted back to the forms in which they were originally validated for orthopaedic surgical patients, which would require minor programming resources by FOTO. Additionally, the risk adjustment models would have to be newly constructed with data from surgical patient populations (see Risk Adjustment section below).

(VI) How to Collect PRO Data: Software Tools for Administering PRO Instruments

1. *Introduction*

In the last decade, rapid changes in technology have moved the administration of PRO instruments away from paper/pencil methods to various electronic methods. Many of the validated PRO instruments described/listed in section (V) are available in electronic format through various PRO data-collection software packages. Furthermore, studies have demonstrated that most instruments retain their validity across modes of administration (Cella, 2012)

2. *Software Tools for Administering PRO Instruments*

Tables 6 and 7 present information on major software tools available for administration of the orthopaedic PRO instruments identified above, including information about cost and compatibility with EMRs. Software tools were included based on whether they currently incorporated or indicated they would incorporate PRO instruments from the orthopaedic sub-

specialties of interest. Some large companies were excluded because their focus was not PROs and their systems were complex and/or costly (e.g., ORTECH).

OBERD and SOCRATES appear to be most promising for adoption in orthopaedic clinical settings at this time, given their flexibility and extensive focus on PRO instruments for the named orthopaedic sub-specialties. Additionally, OBERD is currently working on developing risk-adjustment models for various PROs, with the recognition that these may need to be tailored to different patient populations defined by factors such as geographic region as well as clinical presentation (Plummer, 2013).

OBERD uses a web-based portal for patient data entry. It integrates into a practice‟s appointment system, so that appointments can trigger emails to patients with web links to the patient portal data entry system. Data also can be entered on tablets in the waiting room, or by staff calling patients to collect data at times that align with the appointment system or are pre-determined by the clinician at the time of PRO process setup. The application and data reside on the OBERD server, and data can be exported into comma-separated data files that can be read by spreadsheets and common statistical programs. OBERD also has modules that offer analysis capabilities and reports. Data are always owned by the practice, and data transfers are all via HIPAA-compliant transfer protocols. OBERD has tools to assist clinicians in obtaining follow-up PRO data from patients, such as dashboards that notify clinicians when patients are missing certain follow-up measures. To date, OBERD‟s clients are medium to large practices.

SOCRATES differs from most PRO software administration tools in that the PRO data entry occurs only on the practice‟s local server where the PRO administration application is installed. This means that patient PRO data are never accessible by SOCRATES; it also may mean more IT support is required within the practice. It‟s important to note that having PRO data reside on the clinician‟s server is not necessarily more secure than having it reside on a software company‟s server, given the high level of HIPAA-compliant security (e.g., HL7 transfer protocols) involved when PRO applications and data entry are run through a company‟s server. However, many clinicians do still prefer to know that access to their data occurs only through their local server (Giveans, 2013). To data, SOCRATES clients range from small to large practices.

3. *Compatibility with EMRs*

No commercial software tools for administering orthopaedic PROs were found that are fully integrated into an EMR system in the sense that PRO data can be entered through an EMR patient portal. As described above, the NIH-PROMIS system recently was fully integrated into Northwestern University‟s Robert H. Lurie Comprehensive Cancer Center EMR (EPIC) MyChart patient portal after a 2-year process, and this was made possible through NIH collaborative research funding.

Thus, in reality, compatibility at this time refers to the ability of a PRO software tool to make transfers into or out of (or both – i.e., bi-directional transfers) their system to other analysis software programs and/or EMRs. This ability will depend on the EMR as well, and whether it stores clinical data in separate data fields or as PDF "pictures" of a written patient chart (Plummer, 2013; Giveans, 2013). For example, OBERD has bi-directional integration with Allscripts, with PRO data from OBERD being uploaded directly into Allscripts, or clinical data from Allscripts being uploaded into OBERD for integration with PRO data.

The OBERD and SOCRATES PRO software tools can merge PRO data from multiple practices in a blinded manner – an important consideration for COA and other associations if they wish to form data consortiums for the purposes of creating normative benchmarks and risk adjustment models for practices with similar characteristics.

(VII) How to Collect PRO Data: Implementation Processes for the Clinic

Many issues need to be addressed to maximize the usefulness of PRO data once a decision is made to collect it in a clinical practice. The major issues include (1) timing of PRO administrations; (2) physical locations and modes of PRO administration; (3) procedures for maximizing compliance rates; (4) procedures for transferring and storing data; and (5) procedures for analyzing and interpreting data. Considerations for addressing the first four of these issues are described in this section. It's important to note that many orthopaedic surgeons successfully implementing PRO data collection processes in their practices utilized consultants to help them set up protocols for addressing these implementation issues (Giveans, 2013; Snyder et al., 2012; Aaronson et al., 2011).

1. *Timing of PRO Data Collection*

Timing of data collection should be decided based on the question(s) being addressed, the purpose of collecting the data, and the interventions for which PROs are being assessed. For example, protocols for dynamic patient-centered care and CQI of hip-replacement procedures might require 6- and 12-week follow up, while protocols for research studies of long-term effects of a particular TJR might require follow-up every 6 months thereafter for several years (Giveans, 2013).

2. *Location and Mode of PRO Data Collection*

There are benefits and drawbacks to administering PRO instruments in the clinic waiting room or the patient's home. When completing surveys in the waiting room patients may feel some anxiety relating to their appointment and uncertainty about privacy, among other issues. On the other hand, there are barriers to patients completing surveys at home, including access to technology and motivation, which may impact response (compliance) rates (Cella et al., 2012).

Many software tools have built-in modules for emailing patients web links to PRO instrument portals; these may be triggered by appointment systems or at pre-defined intervals.

Tablet and smartphone applications are emerging as a new, promising mode for data collection. Phone interviews by staff sometimes are used but may incur biased responses due to patients feeling "social desirability" pressures to answer questions in a more positive way than they might otherwise. One study that used a newly-developed PRO web tool (PatientViewpoint) to administer PROMIS instruments and import results into an EMR found that 86% of questionnaires were completed out of the office setting (e.g., at home); they also found that missing data were less common when questionnaires were *not* completed in the office, where there often were time constraints around completing the surveys (Snyder et al., 2012).

In reality, to maximize compliance rates, a combination of locations and modes often is utilized. This is further described in the next section.

3. *Maximizing Patient Compliance (Response) Rates*

In the past, compliance (return) rates for paper/pencil PRO instruments sent to patients through the mail were 25% or less. More recently, average compliance rates appear to be around 50% when web links are emailed to patients (Giveans, 2013; Plummer, 2013). However, there are instances of clinicians achieving compliance rates in the 90% range. The key to achieving these rates appears to be patients' awareness that they will be asked for their assessments of their own functional outcomes, and why – i.e., patient education.

One consultant in Minnesota, who assists orthopaedic practices in setting up processes for collecting PRO data (including determining appropriate instruments, timing of data collection, modes of data collection, protocols for achieving high compliance rates, scoring, interpretation and analysis of data), has found that surgeons who themselves take the time to educate patients about the importance of PRO data and how it will be used in their own care, as well as for improving interventions for future patients, achieve 90-100% compliance rates. He advises those interested in achieving higher rates to create an office culture among all staff members that emphasizes the importance of the patient's report of her/his own functional outcomes.

For example, during the first meeting with the surgeon when diagnoses and treatment plans are discussed, if the surgeon also talks with the patient about the importance of tracking his/her reported functional outcomes, compliance rates will be much higher. Some clients achieve 100% baseline compliance on their PRO measures because the patient is not seen for an initial visit until the PRO form is filled out. Finally, supplementing patient education with tracking protocols for office staff and even surgeons to make follow-up reminder phone calls to patients can improve compliance rates. It should be noted that problems with social desirability biases may be encountered when surgeons make these follow-up calls.

4. *Examples of PRO Use in Orthopaedic Practice Settings*

OrthoCarolina is a large (>25 surgeons) multi-site practice that uses the OBERD PRO software administration system. OBERD reports that their average compliance rates are 70-80%. However, the rate varies greatly across individual surgeons, with the most successful surgeons using scripts for themselves and their office staff when educating patients about the importance of completing PRO measures.

In contrast, a large orthopaedic practice in Minnesota achieves only a 48% compliance rate from patients who have email addresses, and a 25% compliance rate for patients without email to whom PRO surveys are sent in the mail. The compliance rates of this practice are the result of almost no patient education regarding PROs (Giveans, 2013).

(VIII) How to Interpret and Analyze PRO Data

There are several methods for analyzing and utilizing PRO data. These include: (1) examination of change scores from pre-surgery to post-surgery within individual patients or across patients (for total scores and domain subscale scores); (2) comparing post-surgical scores of patients to those of a similar population with similar clinical profiles (either from a surgeon‟s own practice or from a normative population if available); and (3) combining these and comparing change scores of individual patients to those of patients with similar profiles from the practice or from available normative population studies.

1. *Pre-post Surgery Changes in PRO Scores and Minimum Clinically Important Differences (MCID)*

In a CQI process, a clinician might examine whether a group of patients who received a given intervention showed improvements in mean PRO scores from pre-surgery to a certain time interval post-surgery. With a sample size of at least 25, a clinician could reasonably examine whether there was a statistically significant change in mean reported PRO scores from pre- to post-surgery. However, whether this difference is *clinically significant* in terms of meaningful improvements to patient functioning also should be examined; for example, does the change represent a shift from inability to ability to climb stairs independently.

A number of orthopaedic sub-specialty PRO instruments have undergone studies to define Minimum Clinically Important Differences (MCIDs) (also called Minimally Important Differences, or MID), which can be very useful in assessing the meaning of changes in PRO scores from pre- to post-surgical intervention. MCIDs can be determined in multiple ways, including anchor-based methods, in which PRO scores are correlated to external anchor measures that are interpretable, and data-based methods that look for clear cutpoints in scores (Cella et al., 2012). Unfortunately, there are no standards for determining MCIDs, and those that

have been determined are vastly under-utilized in favor of simple statistical significance (Giveans, 2013; Plummer, 2013)

Finally, examining the specific instrument domains in which change is seen and not seen may provide information that, in conjunction with clinical data, can help guide treatment paths post-surgery. In particular, as noted above, one study using the DASH found key PRO domains (e.g., absence of tingling, absence of stiffness) for a certain class of patients were largely addressable with medication and certain physical therapy post-surgically (Plummer, 2013).

2. *Within-Practice Comparison of PRO Scores to Groups of Patients with Similar Profiles*

Some PRO software tools (e.g., OBERD) have modules to enable clinicians to compare visually (e.g., in a scatterplot) patient scores to those of patients with similar profiles. In OBERD, the classification of profiles is based on clinical factors determined by the clinician.

3. *Comparison of PRO Scores/Change Scores to Normative Population Values*

One way to monitor quality of a practice‟s intervention using PRO data is by comparing individual patient or mean practice scores to normative values determined for similar patient populations. Unfortunately, as can be seen in Tables 2-5, very few normative values have been determined for the existing, validated PRO instruments for the named orthopaedic sub-specialties, especially for a range of clinical populations. As with the determination of risk-adjustment models, normative population values require large quantities of data pooled from multiple practices with similar patient and even geographic characteristics (Plummer, 2013).

COA can take a lead in establishing normative population values for patients in California, whose demographic and risk profiles likely vary from those of patients in other states. AAOS‟s normative study for the MODEMS instruments discussed above only established normative values for healthy populations.

(IX) Risk Adjustment of Scores

Risk adjustment of PRO scores is critical to enable fair comparisons of patient outcomes given the wide range of health risk factors – e.g., comorbidities – of patients undergoing a given orthopaedic procedure. The AAOS and others are highly recommending to CMS the use of appropriate risk adjustment models when assessing provider outcome scores (see section (I) above). Several steps must be accomplished to enable risk adjustment of PRO scores:

1. A group of candidate risk factors that have been found empirically in prior studies to be associated with patient outcomes for a given orthopaedic procedure must be identified. These will include demographic factors such as age and gender, as well as clinical factors

such as number of comorbidities. For example, for ankle and foot conditions, an important factor for predictive risk-adjustment models may be the simple American Society of Anesthesiologists (ASA) class (Egol et al., 2006).

2. A predictive regression model, in which the dependent variable is the PRO score of interest and the independent variables are the candidate risk factors, must be estimated using a large dataset that includes patients spanning a variety of risk levels expected in the populations to which the model will be applied. Risk-adjustment models are not one size fits all. In particular, there is evidence that risk-adjustment models (i.e., the risk factors included, but most especially the exact formulas derived from the regression coefficients) may differ by geographic region and medical condition being examined. That is, while there may be a common core of risk factors that are predictive of PROs following orthopaedic surgical procedures, the relative influence of the factors, and therefore specific risk-adjustment formulas (regression "beta coefficients") would be expected to differ across differing clinical populations. Thus, risk-adjustment models ideally should be tailored to populations categorized by presenting condition, geographic location and so forth (Plummer, 2013). The predictive model usually is estimated on a subset of the population, called the "training dataset," and then calibrated and assessed for the quality of its predictions on the remainder of the data.
3. The expected score of a patient is calculated using the predictive regression model from step 2. This is subtracted from the patient"s actual score. If the result is negative, the patient did worse than expected in comparison to a patient with similar risk factors (e.g., comorbidities). If the result is positive, the patient did better than expected given her/his risk factors.

Thus far no specific risk adjustment models were identified for the orthopaedic sub-specialties (Bozick, 2013; Rothrock 2013; Plummer 2013; Giveans 2013; Bozick 2013; Soohoo, 2013). The following is a summary of the work being conducted in this emerging area. Of particular interest are the specific variables/factors currently being used in existing risk adjustment models for other areas.

Some cutting edge work is being done in the area of risk adjustment in England, where the National Health Service (NHS) Northwest provided a small grant to a team led by a shoulder/elbow surgeon (Bibhas Roy) and a software company to create PROMS 2.0, a system developed to "go beyond the National PROMs collection" to collect and analyze PROMs, using risk-adjusted models. They currently have funding to apply the system at various sites in northwest England. A list of the risk factors they use for adjusting scores is shown in Appendix A. It includes information such as severity of disease, comorbidities, smoking status and BMI.

As discussed above, in the United States, the physical/occupational therapy community has developed models for risk-adjusting their PROs for assessing outcomes from rehabilitation processes. These instruments and their risk adjustment models were created by FOTO (Focus on Therapeutic Outcomes, Inc.) and are currently recommended by the CMS PQRS for use in reporting to registries. The variables used in their risk adjustment models are Functional Status Score at Admission, patient age, symptom acuity, surgical history, gender, and number of comorbidities and level of fear-avoidance. A description of how these variables are defined is provided in Appendix A.

In a white paper for the National Quality Forum (NQF) (Deutsch et al., 2012) the following factors are listed as important for inclusion in risk adjustment models: demographic characteristics (e.g., age, gender), diagnosis, severity of illness, comorbidities, and baseline scores that affect outcomes

Tables

Table 1: Summary Matrix Table_Selected[1] General Health Status Patient Reported Outcome Instruments

Scale	Instrument Name	Source/How to Obtain/URL	Constructs included Outcomes	Validity/ Reliability[2]	Subscales (# of items)	MCID[2]	Use by Registries/ Ortho Associations[3]
SF-12v2	Medical Outcomes Study	Ware http://www.qualitymetric.com/WhatWeDo/SFHealthSurveys/tabid/184/Default.aspx	General Health	Yes	**12 items** short form Physical and Mental Components	Unknown	CJRR UCSF SCRIPPS
SF-36v2	Medical Outcomes Study	Ware http://www.qualitymetric.com/WhatWeDo/SFHealthSurveys/tabid/184/Default.aspx	General Health	Yes	**36v2 items; 8 domains** of health: physical function, physical role, bodily pain, general health, vitality, social functioning, emotional role and mental health	Unknown	CJRR Hoag
EQ-5D	EuorQol	http://www.euroqol.org/eq-5d-products/how-to-obtain-eq-5d.html	General Health	Yes (EuorQol)	**5 dimensions/items** (mobility; self-care; being able to carry out one's usual activities; pain; and anxiety)	Yes http://www.euroqol.org/about-eq-5d/population-norms.html	CJRR Sweden England
PROMIS-10	PROMIS-10 Global Health	http://tdiprm.dartmouth.edu/overview.php	General Health	Yes (TDI Dartmouth)	**10 items**	Unknown	Dartmouth
HAQ,MHAQ	Stanford Health Assessment Questionnaire	Public Access http://patienteducation.stanford.edu/research/haq20.pdf;	Generic; General Health	Yes; Uhlig et al. 2006; Bruce and Fries, 2003	**HAQ-20 items:** **HAQ-DI 8 items** The 2-page HAQ contains the HAQ Disability Index (HAQ-DI), the HAQ visual analog (VAS) pain scale, and the VAS patient global health scale	Unknown	
VR-36 VR-12	Veterans Rand 36	Public Access http://www.chqoer.research.va.gov/docs/VR12.pdf	Quality of Life	Yes	VR-12; VR36 The 12 items in the questionnaire correspond to eight principal physical and mental health domains	Unknown	

Scale	Instrument Name	Source/How to Obtain/URL	Constructs included Outcomes	Validity/ Reliability[2]	Subscales (# of items)	MCID[2]	Use by Registries/ Ortho Associations[3]
					including *general health perceptions; physical functioning; role limitations due to physical and emotional problems; bodily pain; energy-fatigue, social functioning and mental health.*.		
SMFA (MFA)	Short Musculoskeletal Functional Assessment	Swiontkowski Public Access http://www.ortho.umn.edu/research/home.html http://www.ortho.umn.edu/prod/groups/med/@pub/@med/documents/asset/med_97193.pdf	General orthopaedic; general health and function	Yes	**46 items; two parts**: the dysfunction index with 34 items and the bother index with 12 items. The dysfunction index assesses the patients' perceptions of the amount of difficulty they have in the performance of certain functions (25 items) and how often the patients have difficulty when performing certain functions (9 items). The dysfunction items are grouped into four categories: daily activities, emotional status, function of the arm and hand, and mobility.	Unknown	
UCLA Activity Score	UCLA Activity Rating Scale	http://www.boulderorthopedics.com/Portals/294/Skins/BOU/pdfs/UCLA%20Activity%20Score.pdf	Activity Level Lower extremity	Yes	**10 items**	Unknown	CJRR UCSF

[1] Selected PROs included based on COA PRO Task Force Member input and availability of score as ePRO on OBERD and SOCRATES (refer to table 7).
[2] Smith (2012)
[3] As reported in literature searches on websites and from personal communication from COA PRO Task Force Member input.

Table 2: Summary Matrix Table of Selected[1] Patient Reported Outcome Instruments by Orthopaedic Sub-Specialty: Shoulder

Scale	Instrument Name	Developer/ How to Obtain/ URL	Constructs included Outcomes	Validity/ Reliability[1]	Subscales (# of items)	MCID[1]	Use by Registries/ Ortho Associations[2]
*ASES	American Shoulder and Elbow Scale/ American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form	Richards et. al Public Access http://www.midsouthorthopaedic.com/patient_forms/American_Shoulder_and_Elbow_Surgeon.pdf	Shoulder disorder outcomes assessment Patient and clinician parts	Yes	**10 items pASES** patient self-evaluation of pain, instability and ADL	Yes	ASES (American Shoulder and Elbow Surgeons)
*CM	Constant Shoulder Score/Constant Murley Score	Constant and Murley	Shoulder disorder treatment outcomes	Yes	**10 items;** Pain, mobility, ADL, strength	Unknown	European Society for Surgery of Shoulder/Elbow; German Society of Shoulder/Elbow Surgeons
*SST	Simple Shoulder Test	Public Access	Before and after shoulder treatment assessment	Yes	**12 items;** function related to pain, strength, range of motion	Yes	
DASH Quick DASH	Disabilities of the arm, shoulder, and hand questionnaire	Public Access http://www.dash.iwh.on.ca/ http://www.orthopaedicscore.com/	Outcome instrument to measure physical function and symptoms of upper extremity	Yes	**30 items Quick DASH 11**	Yes	AAOS Institute of Work and Health (WH)
OIS	Oxford Instability Score	Public access http://phi.uhce.ox.ac.uk/ox_scores.php	Assesses shoulder instability		**12 items**		
OSS	Oxford Shoulder Score	Public access http://phi.uhce.ox.ac.uk/ox_scores.php	Quality of life shoulder surgery outcomes specifically arthritis or rotator cuff injuries	Yes	**12 items** Pain (40; daily function (8)	Yes	

[1] Selected PROs included based on COA PRO Task Force Member input and availability of score as ePRO on OBERD and SOCRATES (refer to Table 7).
[2] Angst (2011)
[3] As reported in literature searches on websites and from personal communication from COA PRO Task Force Member input.
* COA PRO Task Force Member recommendation.

Table 3: Summary Matrix Table of Selected[1] Patient Reported Outcome Instruments by Orthopaedic Sub-Specialty: Hand_Wrist

Scale	Instrument Name	Developer/ How to Obtain/URL	Constructs included Outcomes	Validity/ Reliability[2]	Subscales (# of items)	MCID [2]	Use by Registries/ Ortho Associations[3]
*DASH Quick DASH	Disabilities of the arm, shoulder, and hand questionnaire	http://www.dash.iwh.on.ca/	Physical function and symptoms of upper extremity	Yes	30 items Quick Dash 11 items;	Yes	AAOS
*BCTQ	Katz-Levine Boston Carpel Tunnel Syndrome Questionnaire	Boston Carpel Tunnel Syndrome http://encompass-chiro.com/clients/1924/documents/Carpal%20Tunnel.pdf	Symptoms and functions	Yes	2 sub-scales; Function (11); symptoms (8)	Yes	AAOS
*MHQ	Michigan Hand Outcomes Questionnaire	http://sitemaker.umich.edu/mhq/overview	Conditions/injury to hand/wrist	Yes	**37; 6 sub scales** overall hand function; activities of daily living (ADLs); pain; work performance; aesthetics; patient satisfaction with hand function. Demographic section asking about patients' age, ethnic background, and socioeconomic status.	Yes	AAOS
PRWE	Patient-Rated Wrist Evaluation	http://www.srs-mcmaster.ca/Portals/20/pdf/research_resources/PRWE_PRWHEUserManual_Dec2007.pdf	Wrist pain & disability	Yes	**15 items; 3 subscales** Pain (5); specific functional tasks (6); usual activity/self care (4)	Yes-	

[1] Selected PROs included based on COA PRO Task Force Member input and availability of score as ePRO on OBERD and SOCRATES (refer to Table 7).
[2] Badalamente (2013)
[3] As reported in literature searches on websites and from personal communication from COA PRO Task Force Member input.
* COA PRO Task Force Member recommendation.

Table 4: Summary Matrix Table of Selected[1] Patient Reported Outcome Instruments by Orthopaedic Sub-Specialty: Spine

Scale	Instrument Name	Developer/ How to Obtain/ URL (if available)	Constructs included Outcomes	Validity/ Reliability[2]	Subscales (# of items)	MCID[2]	Use by Registries/ Ortho Associations[3]
*SRS-22	Scoliosis Research Society 22 Questionnaire	Asher (2003) http://www.srs.org/professionals/SRS_outcomes/srs-22_sample.pdf	Clinical evaluation of health related quality of life for idiopathic scoliosis	Yes	**22 items; 5 domains** Function/activity (5); pain (5); self image/appearance (5); mental health* (5), and satisfaction with management. *Mental health domain adapted from SF-36 (with permission)	Yes	Scoliosis Research Society
*NDI	Neck Disability Index Vernon & Mior Cervical Spine Score	Vernon & Mior Public Access http://www.scientificspine.com/spine-scores/neck-disability-index_%28ndi%29.html	Generalized neck pain, radiculopathy	Yes	**10 items;** General neck disability related to recreation, sleeping, driving, work, concentration, headaches, reading, , lifting, self-care, pain intensity	Unknown	Cervical Research Society
CSOQ	Cervical Spine Outcomes Questionnaire	BenDebba et al.	Cervical spine surgery	Yes	**35 items; 6 domains** Health care utilization; physical symptoms; psychological distress; physiological distress; functional disability; shoulder/arm pain severity; neck severity	Yes	
ODI	Oswestry Disability Index Oswestry Low Back Pain Disability Questionnaire	O'Brien Public Access http://www.mapi-trust.org/services/questionnairelicensing/catalog-questionnaires/266-odi Version 2.1a	Generalized back pain	Yes	**10 items; subscales** Pain intensity; personal care, lifting, walking, sitting, standing, sleeping, sex life, social like and travel	Yes	AAOS (adapted original versions)
*Modified ODI	Modified Oswestry Disability Index	Fritz & Irgang Public Access	Generalized back pain	Yes	**10 items; subscales** Pain intensity; personal care, lifting, walking, sitting, standing, sleeping, **fluctuation in pain intensity*, social like and travel	Yes	North American Spine Society (NASS)
RMDQ	Roland-Morris Disability Questionnaire	Roland & Fairbank	Generalized back pain; low back pain	Yes	**24 items; 12 categories** Pain intensity; self-care; social like; walking; sitting; standing; sleeping; bending; stairs; appetite; general activity; house	Yes	

[1] Selected PROs included based on COA PRO Task Force Member input and availability of score as ePRO on OBERD and SOCRATES (refer to Table 7).
[2] McCormick (2012); Fritz (2001)
[3] As reported in literature searches on websites and from personal communication from COA PRO Task Force Member input.
* COA PRO Task Force Member recommendation.

Table 5: Summary Matrix Table of Selected[1]Patient Reported Outcome Instruments by Orthopaedic Sub-Specialty: Ankle_Foot

Scale	Instrument Name	Developer/ How to Obtain/ URL	Constructs/ Outcomes	Validity/ Reliability[2]	Subscales (# of items)	MCID[2]	Use by Registries/ Ortho Associations[3]
AAOS-FAM	Lower Limb outcomes assessment: Foot and Ankle Module	AAOS http://www.aaos.org/research/outcomes/outcomes_lower.asp	Evaluate patient perception of foot health and measure surgical outcomes	Yes	**25; 5 sub scales** Pain (9); foot function (6); stiffness and swelling (2); giving way (3); shoe comfort (5)	Yes	AAOS
ATRS	Achilles tendon rupture score	Katarina Nilsson-Helander, MD	Strength, fatigue, stiffness, pain, activities of daily living, walking surfaces, uphill, running, jumping, physical	Yes	**10; 5 subscales**	Unknown	
FAAM (spFAAM)	Foot and Ankle Ability Measure-(Sports Scale)	Not official site—access to instrument: http://www.teamworkstherapy.com/pdf/Foot%20and%20Ankle%20Ability%20Measure.pdf	Comprehensive assessment of physical performance among patients with leg, foot and ankle musculoskeletal disorders	Yes	**21; 2 subscales:** Activities of Daily Living (21); Sports subscales (8)	Unknown	
FAOS	Foot and Ankle Outcomes Score	www.koos.nu	Evaluate symptoms and functional limitation in patients w/ generalized foot and ankle disorders	Yes	**5 subscales**; Pain (9); other symptoms (7); activities of daily living (17), sports/rec. activities (5); foot/ankle QOL (4)	Unknown	
FFI-R	Revised Foot Function Index	http://www.jfootankleres.com/content/6/1/5 http://www.jfootankleres.com/content/6/1/5/additional	Assess foot-related health and quality of life	Yes	**34 or 68 items (long form); 4 subscales**: Pain/stiffness (19); social/emotional (19); disability (20); activity limitation (10)	Unknown	

Scale	Instrument Name	Developer/ How to Obtain/ URL	Constructs/ Outcomes	Validity/ Reliability[2]	Subscales (# of items)	MCID[2]	Use by Registries/ Ortho Associations[3]
FHSQ	Foot Health Status Questionnaire	Bennett, PJ http://fhsq.homestead.com/ Available to all interested practitioners; computer program developed to assist practitioners with the analysis of results.	Measure foot health related to quality of life	Yes	**13; 4 subscales** Foot pain (4); foot function 4); footwear (3); general foot health (2)	Yes	

[1] Selected PROs included based on COA PRO Task Force Member input and availability of score as ePRO on OBERD/SOCRATES (refer to Table 7).
[2] Martin (2007); Riskowski (2011)
[3] As reported in literature searches on websites and from personal communication from COA PRO Task Force Member input.
* COA PRO Task Force Member recommendation.

Table 6: Summary Matrix Table of Selected[1] Software_Systems to Collect Patient Reported Outcomes

Software Name/ Company	Contact Info/URL/Cost	Data Collection methods	Use by Registry or orthopaedic associations/hospitals/clinical practices/in clinical trials	Compatibility with Ortho EMRs	What software is used for basic data reporting
Computer-based Health Evaluation System (CHES) Innsbruck Medical University	http://www.ches.at Gerhard Rumpold, Associate Prof., PhD, Msc Innsbruck Medical University Dept. Medical Psychology Speckbacherstrasse 23 A-6020 Innsbruck http://www.i-med.ac.at/medpsy/struktur/cl.html License: Free version for non-commercial use; full functionality; not supporting Client–server Settings; proprietary license for Client–server Setting The price depends on the amount of plugins, the duration, the purpose (research, clinical use) and the number of licenses. They charge between 500 and 22,000€.	Web-based	Mostly being used in Europe. One user in Vancouver for Gynecology. In final stages of the project to further develop and disseminate the software	Interface to clinical information systems (HL7): In order to exchange medical and socio-demographic data between CHES and clinical information systems (CIS) a HL7-interface is available.	Graphical presentation of results: results are presented as colored graphs in real time. The graphical output (see Figure 2) links PRO to the course of disease and treatment and in addition specific medical interventions can be easily incorporated and displayed. Results can be displayed optionally in a longitudinal or cross-sectional setup. Flag System: Based on reference values from literature or previously collected data, the Flag System allows for the quick identification of patients with clinically relevant problems, using cut-off scores or score distributions. Clinical Report Generator: CHES supports the automatic generation of clinical reports, including questionnaire results represented using charts as well as clinical data. For interoperability, reports can be stored as Portable Document Files (PDF). Data Export/Import: Socio-demographic, clinical and questionnaire data can be exported to different file formats and imported from files, e.g., SPSS or MS Excel.
cPRO University of Washington's Clinical Informatics Research Group	http://cprohealth.org https://sites.google.com/a/uw.edu/cpro/ The software is open source and free.	Web-based		The system interfaces with Electronic Medical Record systems via an open-source Mirth HL7 transport layer, to communicate summarized reports and discrete data.	A research data access tool is provided as a way for researchers to download granular data from the database for subsequent statistical. The data access tool provides a basic overview of patients enrolled and recent sessions. The researcher can then choose a date range and look at a variety of views of the data. All views can be returned as HTML or delimited text files to make it easy to import into an analysis package. There is the ability to output raw data.
E-Kiosk AutomationMed	http://www.automationmed.com/index.php/products-2/e-kiosk http://www.emedoutcomes.org/index.php/ekiosk-frequent-questions Dr. Goldstein 401-864-4468	Computer Kiosk or tablet	Dr Goldstein is an orthopedic surgeon that created this program for his office. It came out of MODEMS created by the Academy.	Integrates with EMR and legacy billing HIPPA compliant O DBC Compliant Hl7	Data is stored locally on server. Immediate scoring and graphing for patient and doctor feedback. Built in call back reporting and administrating data mining. Outcomes Administration allows the Physician or Researcher to query their own database of validated Outcomes Measures utilizing multiple parameters. These include age, sex, race, Insurance carrier, etc. Data can then be evaluated utilizing simple statistical methods which allow the user to examine data on a local level. Their own patient norms may be

Software Name/ Company	Contact Info/URL/Cost	Data Collection methods	Use by Registry or orthopaedic associations/hospitals/clinical practices/in clinical trials	Compatibility with Ortho EMRs	What software is used for basic data reporting
	$5000 with the EMR bring an extra expense				easily compared to individual patients, or local norms may be compared to national normative data. Data output is native in SQL database or XML. Data can be outputted as simple text and printed if desired.
Focus on Therapeutic Outcomes Inc.	http://www.fotoinc.com/ **Judy Holder** **Director of Provider Relations** Phone: 800.482.3686 ext. 238 Email: judyholder@fotoinc.com Set up fee: There is a one-time set up fee of $250 per clinic. (The set up fee is invoiced at the time that the signed FOTO Business and License Agreement is submitted to FOTO.) Monthly Fee: Per clinic: $50 Per clinician: $25 This fee is the same for full time and part time clinicians, but it does not include assistants. (The monthly fee is invoiced for the first time one month after the initiation of the contract) Private Practice Section Members of the American Physical Therapy Association FOTO gives a $10 / month off the clinic fee	Web-based			
Integrated Survey System (ISS) DCS – Dynamic Clinical Systems	http://dynamicclinical.com/solutions/data-collection-outcomes-management/ Morrie Bailey EVP Business Dev 617-381-4333 Morrie.bailey@dynamicclinical.com One Time setup fee for first clinical area $15,000, the each area after is $7500. Yearly subscription $4500 for first 10	Web-based	Darthmouth College, Unv. of W Virginia. Mainly in big universities	Yes. They are HL7 compliant and as long as the EMR is too, they can push and pull data.	There are some basic reports (process of care, patient status reports and some aggregate reports) built in, but most of their clients just want the raw data. The database is fielded and searchable with 350 different variables Data can be outputted for Analytical software. DCS has an analytical team that analyze data on a fee-for-service basis.

Software Name/ Company	Contact Info/URL/Cost	Data Collection methods	Use by Registry or orthopaedic associations/hospitals/clinical practices/in clinical trials	Compatibility with Ortho EMRs	What software is used for basic data reporting
	users				
OrthoIllustrated Surgical Outcome System (SOS) Arthrex Inc.	**Morgan K. Rouleau** Surgical Outcomes System Manager Office: (800) 933-7001, Ext. 1969 Cell: (239) 249-4521 Morgan.Rouleau@arthrex.com https://www.orthoillustrated.com/sos/ https://www.orthoillustrated.com/pated/docs/SOS-Brochure.pdf $150/surgeon/month	Web-based Patients are notified via e-mail at predefined time milestones and asked to submit health questions online to a central registry	Has a built in registry. Over 70 enrolled surgeons and over 4100 enrolled patients	Not currently but discussions are in the works.	To help visualize the results and findings, the system provides a graphical representation of the scores with the option to configure custom reports based on variable selection such as age, gender, etc. It is also possible to compare the results between different devices and/or techniques. The **Patient Analysis** panel provides a graphical representation of the outcome data. By default, selecting a case in the Current Patients panel generates three different chart lines: • One line that represents the surgeon's data of a single selected patient • One line that represents the surgeon's average data of patients enrolled in the same study • One line that represents the global average data of all patients enrolled in SOS in the same study Additional chart lines can be added to represent custom data that can be configured via filters. The data can be filtered by variable selection such as gender, surgical technique, etc. The data can be exported and saved as needed.
Orthopaedic Scores	http://www.orthopaedicscore.com/	Web-based		NA	All data is exported as a csv file.
Outcome Based Electronic Research Database (OBERD) Universal Research Solutions	http://www.universalresearchsolutions.com/ http://www.oberd.com/specialties/ One time setup fee $1,800 per provider; Yearly subscription $3000-$4000 depending on modules; bulk discounts offered	Web-based, email, tablet, portal, staff can call in and report data, working on VOIP system	Western Ortho Forum adopting them; Rothman Institute, and others	Nexgen, Allscripts, SRS In the pipeline: GE, Cerner, EPIC	Built in reporting. Module called Data Mining and Visualization tools Working on developing risk adjustment models. Yes can analyze. Can also output raw data and analyze with any software you want
Patient Reported Outcomes/PRO Marshall Steele	https://www.marshallsteele.com/ServiceLineAnalytics/patient_reported_outcomes.asp *Judy E. Jones*, Vice President	Ipad	Yes. Hospitals, medical centers, orthopedic institutes, clinics	Right now it's a separate platform. It is in development to be able to integrate with major EMR.	Built in Aggregate and Patient Level reports. Analysis is built in. Custom reports can be made for dr. They are working on adding Risk Adjust for enhancement in

Software Name/ Company	Contact Info/URL/Cost	Data Collection methods	Use by Registry or orthopaedic associations/hospitals/clinical practices/in clinical trials	Compatibility with Ortho EMRs	What software is used for basic data reporting
	Stryker Performance 2101 E. Coast Highway, Suite 260 Corona Del Mar, CA 92625 949-718-4561 Office 949-433-4137 Mobile Judy.jones@stryker.com https://www.marshallsteele.com/ServiceLineAnalytics/PRO_Insert.pdf $1000 to set up per practice. Includes software set up and training staff. 2nd office is $400 Ipads leased at $500 per ipad. Number of ipads needed depends on number of doctors in on same days, etc. Can't use own ipad because of security issues. Two Types of pricing: **Per Survey:** $15 a survey **Price per surgeon:** 1st surgeon: $300/month 2-4th surgeon: $250/month 5th-10th surgeon: $200 >10 surgeon: $150/month			HIPPA compliant Ipads have 3 levels of security	2013. Raw data can be exported and would be encrypted.
QC Manager Boundary Medical	http://www.boundarymedical.com/ Link to brochure: http://www.boundarymedical.com/PDFs/Outcome%20Enterprise(tm)%20QC%20Manager%2004-09.pdf Ron Mercado 410-374-4290 $100/month subscription based	Web-based	Minnesota, Florida Medical, Hawkins, Syracuse – Focus on independent clinics	EMR interfaces are extra fee. # of clients…Nextgen, greenway, talked to epic, It's doable, cost is per system	Built in reporting. Follow from day 0 to whenever you want. Data extracting for use by third-party biostatistics packages
Socrates Orthopaedic Outcomes Software Ortholink Pty Ltd	http://www.socratesortho.com/ Russell Giveans **Initial Cost** Single Surgeon: $7000	Web-based	Demographic data (name, DOB, Gender, ID numbers, address details) as well as some details of surgery - date, side,	Templates can be created to enable operation reports, examination reports, summaries etc to be automatically generated from the fields	The program has a statistical package included which will calculate basic statistics for either the entire data base or subsets of. All variables on the database can be exported in their raw form either the complete database or sub sets. Data can then interface with Excel or any of the major statistical packages for more sophisticated analysis - cross correlations, group

Software Name/ Company	Contact Info/URL/Cost	Data Collection methods	Use by Registry or orthopaedic associations/hospitals/clinical practices/in clinical trials	Compatibility with Ortho EMRs	What software is used for basic data reporting
	2 Surgeons same site: $11000 3 surgeons same site: $14000 More than 3: Price on Application **Annual License Fee:** Single surgeon: $1400 2 surgeons: $2100 3 surgeons: $2800 More than 3: Price on Application		surgeon and hospital name as well as details of diagnosis and procedures and codes can be imported and updated on an ongoing basis from most EMR's	entered on the program. HIPAA issues: Since the database is hosted in the user site there are no concerns about data security relating to 3rd parties. There are other features built in to the database base to ensure compliance, audit trails, strong passwords, administrator rights to select who can enter and view data for which user etc.	comparisons etc.
Tonic Health Tonic Solutions	http://www.tonicforhealth.com/ 303-699-6884 if you have more questions. Free and Paid Versions available: http://www.tonicforhealth.com/how-much-does-tonic-cost.html **Free Version: Build and deploy** surveys of up to 10 questions **Pay per survey:** Unlimited surveys with unlimited questions. Starts at $1 per survey and then goes down in price the more volume you have. There is a minimum of $2000 a year	Ipad app	UCSF, UCLA, UC Irvine, UC Davis, UC San Diego, Kaiser Permanente The Mayo Clinic The Department of Veterans Affairs Medstar Georgetown University Hospital Joslin Diabetes Center Palo Alto Medical Foundation Athena Breast Health Network	Paid version: can export data to EHR via HL7 or backend database of your choosing. **Free version:** export data to an excel file HIPPA compliant	Has full reporting on all your patients. Scoring is done in real time. Backend analytics basic. You can download the data into excel/csv file and then pop into whatever software you want.

[1] Selected software included based on ability to incorporate PRO instruments from orthopaedic sub-specialties of interest and for use primarily in clinical settings (vs. primarily research setting). Information/pricing subject to change.

Table 7: Orthopaedic Patient Reported Outcome Measures by Sub-Specialty Available as ePROs[1]

Instrument[2]	OBERD	SOCRATES Orthopaedic Outcomes Software	OrthoIllustrated Surgical Outcome System (SOS)	Orthopaedic Scores.com	Boundary Medical	Integrated Survey System (ISS)	Marshall Steele	E-Kiosk	Computer-based Health Evaluation System (CHES) **	cPRO**	Tonic Solutions **
GENERAL HEALTH											
Euroqol EQ-5D		✓									
Global Rating of Change (GROC)		✓									
Pain & Normal VAS		✓									
Pain Visual Analogue Score 0 -100		✓									
Patient Satisfaction and Expectations Met Survey		✓									
Activities of Daily Living	✓										
SF-12	✓		✓					✓			
SF-36	✓							✓			
Veterans Rand 12 and 36		✓									
FOOT/ANKLE											
AAOS-FAM- Lower Limb Outcomes assessment: Foot and Ankle Module											
AFAOS – American Foot and Ankle outcome score		✓		✓	✓	✓	✓				
AOFAS- Ankle Hind foot scale; Ankle Mid-foot scale	✓										
FAAM; spFAAM- Foot and Ankle Ability Measure (Sports scale)	✓	✓									
FADI – Foot and Ankle Disability Index				✓							
FAOS- Foot and Ankle Outcome Score		✓									
FFI_R- Revised Foot Function Index	✓		✓								
FHSQ- Foot Health Status Questionnaire											
MOX Foot		✓									

Instrument[2]	OBERD	SOCRATES Orthopaedic Outcomes Software	OrthoIllustrated Surgical Outcome System (SOS)	Orthopaedic Scores.com	Boundary Medical	Integrated Survey System (ISS)	Marshall Steele	E-Kiosk	Computer-based Health Evaluation System (CHES) **	cPRO**	Tonic Solutions **
Oxford Children's foot		✓									
Oxford Foot and Ankle Score	✓										
UCLA Activity		✓									
HAND/WRIST											
DASH- Disability of Arm, Shoulder, and Hand	✓	✓		✓	✓	✓	✓	✓			
Kerlan Jobe score		✓									
Mayo Wrist Score	✓	✓	✓	✓	✓	✓	✓				
MHQ - Michigan Hand Outcomes Questionnaire				✓	✓	✓	✓				
PRWE- Patient-Rated Wrist Evaluation	✓	✓									
Quick DASH	✓	✓		✓	✓	✓	✓				
SHOULDER/ELBOW											
ASES- American Shoulder and Elbow Scale/American Shoulder and Elbow Evaluation Form	✓	✓	✓	✓	✓	✓	✓	✓			
Constant Score – (CM) Constant (Murley) Score)	✓	✓	✓	✓	✓	✓	✓	✓			
DASH - Disability of Arm, Shoulder, and Hand	✓	✓		✓	✓	✓	✓				
Flex 36 Shoulder rating		✓									
L'Insalata		✓									
Mayo Elbow scores	✓	✓	✓		✓	✓	✓				
MISS - Melbourne Instability Shoulder Score		✓									
OES - Oxford Elbow Score	✓	✓			✓	✓	✓				
OSIS - Oxford instability Score	✓			✓	✓	✓	✓				
OSS - Oxford Shoulder Score	✓	✓		✓	✓	✓	✓				
PREE - Patient Rated Elbow Evaluation formerly PRFEQ		✓	✓								

Instrument[2]	OBERD	SOCRATES Orthopaedic Outcomes Software	OrthoIllustrated Surgical Outcome System (SOS)	Orthopaedic Scores.com	Boundary Medical	Integrated Survey System (ISS)	Marshall Steele	E-Kiosk	Computer-based Health Evaluation System (CHES) **	cPRO**	Tonic Solutions **
PENN Shoulder Score	✓	✓									
RC-QoL - Quality of Life outcome tool full spectrum of rotator cuff disease				✓							
Quick DASH	✓	✓		✓	✓	✓	✓				
Rowe Score/Modified Rowe Score- shoulder instability	✓	✓		✓	✓	✓	✓				
Sane- Visual analogue normal score		✓	✓								
Shoulder Activity score		✓									
SPADI - Shoulder Pain and Disability Index		✓									
Somos Activity Duty Shoulder Score		✓									
Somos Biceps Function Score		✓									
SST - Simple Shoulder Test	✓	✓	✓								
UCLA Shoulder Score	✓	✓		✓				✓			
WOOS- Western Ontario Osteoarthritis Visual analogue score		✓			✓			✓			
WORC - Western Ontario Rotator Cuff Visual analogue score		✓						✓			
WOSI - Western Ontario Instability Visual analogue score		✓		✓	✓	✓	✓	✓			
SPINE											
Back Pain Index	✓			✓	✓	✓	✓				
Japanese Orthopedic Association Cervical Myelopathy Evaluation		✓									
JOA - Japanese Orthopedic Association Scale		✓									
MDI -Myelopathy Disability Index											

Instrument[2]	OBERD	SOCRATES Orthopaedic Outcomes Software	OrthoIllustrated Surgical Outcome System (SOS)	Orthopaedic Scores.com	Boundary Medical	Integrated Survey System (ISS)	Marshall Steele	E-Kiosk	Computer-based Health Evaluation System (CHES) **	cPRO**	Tonic Solutions **
M-ODI- Modified Oswestry Disability Index	✓			✓							
NDI - Neck Disability Index—cervical spine specific	✓							✓			
Neurogenic Claudication Outcome		✓									
ODI- Oswestry Disability Index	✓			✓	✓	✓	✓	✓			
ODOM Back & Neck		✓									
RMDQ - Roland-Morris Disability Questionnaire		✓									
Sciatica Frequency and Bothersome Index		✓									
Scoliosis Research Society score SRS 22		✓									
Scoliosis Research Society score SRS 30		✓									
Tampa kinesphobia score		✓									
VAS back & leg		✓									
VAS Neck & arm		✓									
Vernon & Moir neck disability index		✓		✓							
Zung Sel-rated Depression Scale		✓									
Zurich Claudication Questionnaire		✓						✓			
HIP											
Ceramic Hip Noise	✓		✓								
Harris HIP Score (HHS)	✓			✓	✓	✓					
HOS - Hip Outcome Score			✓								
HOOS - Hip Outcome and Osteoarthritis Score	✓			✓	✓	✓					
iHOT-12 --International Hip Outcome Tool-Short Version			✓								

Instrument[2]	OBERD	SOCRATES Orthopaedic Outcomes Software	OrthoIllustrated Surgical Outcome System (SOS)	Orthopaedic Scores.com	Boundary Medical	Integrated Survey System (ISS)	Marshall Steele	E-Kiosk	Computer-based Health Evaluation System (CHES) **	cPRO**	Tonic Solutions **
M-HHS - Modified Harris hip Score			✓								
Oxford Hip Score	✓			✓	✓	✓					
WOMAC Hip				✓	✓	✓					
KNEE											
Brittberg/Perston Score		✓									
Hamstrings Questionnaire		✓									
IDKC - International Knee Documentation Committee	✓	✓									
IDKC - International Knee Documentation Committee- pediatric version	✓	✓		✓	✓	✓					
KOOS - Knee Injury & Osteoarthritis Outcome	✓	✓	✓	✓	✓	✓		✓			
KSS - Knee Society Score	✓	✓		✓	✓	✓					
Kujala patellofemoral score		✓									
Lysholm		✓									
Marx Activity Score		✓	✓								
Modified Cincinnati	✓			✓	✓	✓					
Oxford Knee Score		✓	✓	✓	✓	✓					
Quality of Life Assessment in ACL Deficiency		✓									
Tegner Lysholm Knee Scoring Scale	✓	✓		✓	✓	✓					
UCLA Activity		✓									
Visual analogue pain, activity and expectation score		✓									
WOMAC Knee		✓		✓	✓	✓					
WOMET- Western Ontario Meniscal Evaluation		✓									

[1] Selected software included based on ability to incorporate PRO instruments from orthopaedic sub-specialties of interest and for use primarily in clinical settings (vs. primarily research setting). Information/pricing subject to change.
✓ = instrument ready
*Most have a process for adding scores or customizing for a fee.
** Surveys must be built by user
[2] Licensing to use must be obtained by clinician.

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APPENDIX A

Risk Adjustment Variables Used for FOTO PT/OT Orthopaedic Rehabilitation Patient-Reported Functional Outcome Instruments

1. Gender: male vs. female

2. Symptom Onset (symptom acuity): the number of calendar days between date of onset of symptoms and date of initial evaluation. Coded as 0 to 7 days, 8 to 14 days, 15 to 21 days, 22 to 90 days, 91 days to 6 months, and over 6 months.

3. Age in years.

4. Surgery: surgical history, coded as no surgery for the primary condition being treated vs. 1 or more surgical procedures for the primary condition being treated.

5. Payer: source of payment for the therapy services, coded as PPO (Preferred Provider Organization), Indemnity (fee-for-service) plans, Litigation (patient is involved with an attorney to settle the claim and identify who is responsible for the treatment), Medicaid, Medicare Part A, Medicare Part B, Patient (patient private pay), HMO (Health Maintenance Organization), and Other.

6. Number of Functional Comorbid Conditions (FCI): Dianne L. Groll et al (The development of a comorbidity index with physical function as the outcome. J Clin Epidemiol 2005;58:595-602) developed a list of comorbid conditions related to physical functioning. Simply sum the number of comorbid conditions present and use the quartile of the number of comorbid conditions (coded as none, 1, 2 or 3, or 4 or more comorbid conditions) as the risk adjustment variable, which is a proxy for condition severity. The comorbid conditions include a history of arthritis (rheumatoid or osteoarthritis), osteoporosis, asthma, chronic obstructive pulmonary disease, angina, congestive heart failure, heart attack, neurological disease, stroke or TIA, peripheral vascular disease, diabetes types I and II, upper gastrointestinal disease, depression, anxiety or panic disorders, visual impairment, hearing impairment, degenerative disc disease, and obesity and/or body mass index >30.

7. Fear-Avoidance Beliefs of Physical Activities: Gordon Waddell et al (A fear-avoidance beliefs questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. Pain 1993;52(2):157-168) developed a survey that assesses the level of fear of performing physical activities. Four items are used: „Physical activity makes my pain worse"; „Physical activity might harm me"; „I should not do physical activities which (might) make my pain worse"; and „I cannot do physical activities which (might) make my pain worse". The second item was edited to eliminate the reference to the back. Responses are 0 (Completely disagree), 1, 2, 3 (Unsure), 4, 5, 6 (Completely agree). The patient answers all four items by

selecting a 0 to 6 response. Responses are summed. Total summative scores run from 0 to 24. Level of fear is dichotomized on the median as low fear (summative scores 0 to 13) vs. high fear (summative scores 14 to 24). FABQ is only assessed in patients who have pain. So, if you want to risk-adjust on level of fear, assess whether the patient has pain.

8. Intake FS Measure: Only for predicting risk-adjusted discharge FS measure. The intake FS measure is entered from the Scoring Algorithm table. (Focus on Therapeutics, Inc., 2012).

Risk Adjustment Variables Used for U.K. PROM System

Factor Definition Coefficient Standard Error

Q1 score Patient"s pre-operative questionnaire score 0.285 0.011

Q1 score (squared) Patient"s pre-operative questionnaire score, squared -0.173 0.016

Age Patient"s age 0.006 0.0009

Age (squared) Patient"s age, squared 0.00004 0.000007

Sex: Female Takes value 1 if patient is female, 0 if not -0.017 0.002

Ethnicity: Asian Takes value 1 if patient is of Asian ethnicity, 0 if not -0.059 0.021

Ethnicity: Black Takes value 1 if patient is of Black ethnicity, 0 if not -0.056 0.017

Ethnicity: Not given Takes value 1 if patient"s ethnicity is not given through HES, 0 if not 0.023 0.004

IMD (Deprivation) The IMD (Deprivation) 2004 score for the area the patient lives in -0.001 0.0001

Assisted at Q1 Takes value 1 if patient was assisted in completing preoperative questionnaire, 0 if not 0.013 0.003

Assisted at Q2 Takes value 1 if patient was assisted in completing postoperative questionnaire, 0 if not -0.098 0.005

Disabled at Q1 Takes value 1 if patient considers themselves to have a disability, 0 if not -0.066 0.002

HRG Code H80 Takes value 1 if the main HRG assigned to patient"s spell was H80 (v3.5), 0 if not 0.056 0.025

HRG Code H81 Takes value 1 if the main HRG assigned to patient"s spell was H81 (v3.5), 0 if not 0.065 0.025

Previous Surgery: Yes Takes value 1 if patient has had previous surgery on their hip, 0 if not -0.037 0.006

PRC: High blood pressure Takes value 1 if patient has high blood pressure, 0 if not 0.017 0.004

PRC: Poor circulation Takes value 1 if patient has poor circulation, 0 if not -0.048 0.006

PRC: Diabetes Takes value 1 if patient has diabetes, 0 if not 0.021 0.006

PRC: Nervous system diseases Takes value 1 if patient has nervous system diseases, 0 if not -0.050 0.013

PRC: Cancer Takes value 1 if patient has (had) cancer, 0 if not 0.020 0.006

PRC: Depression Takes value 1 if patient has depression, 0 if not -0.103 0.006

PRC: Arthritis Takes value 1 if patient has arthritis, 0 if not -0.015 0.003

Patient has 1 HESRC Takes value 1 if patient has one HES-reported comorbidity, 0 if not -0.023 0.003

Patient has 2 HESRC Takes value 1 if patient has two HES-reported comorbidities, 0 if not -0.053 0.007

Patient has 3 HESRC Takes value 1 if patient has three or more HES-reported comorbidities, 0 if not -0.060 0.017

Patient has 2 PRCs Takes value 1 if patient has self-reported exactly two comorbidities, 0 if not -0.027 0.005

Patient has 3 PRCs Takes value 1 if patient has self-reported exactly three comorbidities, 0 if not -0.047 0.008

Patient has 4 PRCs Takes value 1 if patient has self-reported four or more comorbidities, 0 if not -0.080 0.014

Symptom period (1-5 yrs) Takes value 1 if patient has experienced symptoms for between 1 and 5 years, 0 if not -0.012 0.003

Symptom period (6-10 yrs) Takes value 1 if patient has experienced symptoms for between 6 and 10 years, 0 if not -0.028 0.005

Symptom period (10+ yrs) Takes value 1 if patient has experienced symptoms for more than 10 years, 0 if not -0.027 0.005

Constant term 0.562 0.040

PRC = Patient Reported Comorbidity

HESRC = HES Reported Comorbidity

Patient Reported Outcome Measures (PROMs) in England: The case-mix adjustment methodology Department of Health. 11 April 2012; accessed at: http://static.squarespace.com/static/509ad012e4b0592f670ebb81/t/5120d83ee4b02be7eddb7bb8/1361107006899/Risk%20Adjustment%20Considerations%20%E2%80%93%20PROMs%202.pdf

Appendix B
Sample PRO Instruments

- **UCLA Activity Scale**
- **Revised FFI-R short form**

UCLA Activity Score	**Hip ID:**
	Study Hip: Left Right
	Examination Date (MM/DD/YY): / /
	Subject Initials: |____|____|____|
	Medical Record Number:

Interval: _____

Check one box that best describes current activity level.

1: Wholly Inactive, dependent on others, and can not leave residence 2:

Mostly Inactive or restricted to minimum activities of daily living

3: Sometimes participates in mild activities, such as walking, limited housework and limited

shopping 4: Regularly Participates in mild activities

5: Sometimes participates in moderate activities such as swimming or could do unlimited housework or

shopping 6: Regularly participates in moderate activities

7: Regularly participates in active events such as bicycling

8: Regularly participates in active events, such as golf or bowling

9: Sometimes participates in impact sports such as jogging, tennis, skiing, acrobatics, ballet, heavy labor or

backpacking 10: Regularly participates in impact sports

Revised FOOT FUNCTION INDEX (FFI-R) Short Form

Subject ID: [_____]_____]_____]_____]
[Date: [___]___] / [___]___] / [___]___]___]

PAIN

PLEASE READ BEFORE ANSWERING.

- Please circle the number that indicates how bad your foot pain was in each of the following situations during the past week.
- For example, when asked how severe your foot pain was at its worst, if you feel "No pain," circle the number 1 and if you felt "Severe pain," circle the number 4.
- If, for some items, the question does not apply, circle the number 5.
- Please provide an answer for every item.

1. DURING THE PAST WEEK, HOW SEVERE WAS YOUR FOOT PAIN:

	No Pain	Mild pain	Moderate pain	Severe pain	
1. Before you get up in the morning?	1	2	3	4	
2. When you first stood without shoes?	1	2	3	4	
3. When you stood wearing shoes?	1	2	3	4	
4 When you walked wearing shoes?	1	2	3	4	
5. When you stood wearing custom shoe inserts? . .	1	2	3	4	5 = do not use inserts
6. When you walked wearing custom shoe inserts? .	1	2	3	4	5= do not use inserts
7. At the end of a typical day?	1	2	3	4	

Subject ID:

[_____]_____]_____]_____]

STIFFNESS

PLEASE READ BEFORE ANSWERING.

- Please circle the number that indicates how bad your foot stiffness was in each of the following situations during the past week.
- For example, when asked how severe your foot stiffness was at its worst, if you feel "No stiffness," circle the number 1 and if you felt "Severe stiffness," circle the number 4.
- If, for some items, the question does not apply, circle the number 5.
- Please provide an answer for every item.

1. DURING THE PAST WEEK, HOW SEVERE WAS YOUR FOOT STIFFNESS:

	No stiffness	Mild stiffness	Moderate stiffness	Severe stiffness
8. Before you get up in the morning?	1	2	3	4
9. When you stood without shoes?	1	2	3	4
10. When you walked without shoes?	1	2	3	4
11. When you stood wearing shoes?	1	2	3	4
12. When you walked wearing shoes?	1	2	3	4
13. When you walked wearing custom shoe inserts? .	1	2	3	4
14. Before you went to sleep at night?	1	2	3	4

Subject ID:

[_____]_____]_____]_____]

DIFFICULTY

PLEASE READ BEFORE ANSWERING.

- Please circle the number that indicates how much difficulty you had performing each activity because of your foot problems during the past week.
- For example, when asked how much difficulty your foot problems caused when walking around the house, if you had "No difficulty," circle the number 1 and if it was " Severe difficulty," circle the number 4.
- If, for some items, the question does not apply, circle the number 5.
- Please provide an answer for every item.

2. DURING THE PAST WEEK, HOW MUCH DIFFICULTY DID YOUR FOOT PROBLEMS CAUSE YOU:

	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty
15. Walking outside on uneven ground?	1	2	3	4
16. Walking four or more blocks?	1	2	3	4
17. Climbing stairs?	1	2	3	4
18. Descending stairs?	1	2	3	4
19. Standing on tip toes?	1	2	3	4
20. When you carried or lifted objects weighing more than five pounds?	1	2	3	4
21. Getting out of a chair?	1	2	3	4

22. Walking fast?	1	2	3	4

Subject ID:

[_____]_____]_____]_____]

3. (cont.) DURING THE PAST WEEK, HOW MUCH DIFFICULTY DID YOUR FOOT PROBLEMS CAUSE YOU:

	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty
23. Running?	1	2	3	4
24. Keeping your balance?	1	2	3	4
25. Walking with assistive devices?	1	2	3	4

Subject ID:

[_____]_____]_____]_____]

ACTIVITY LIMITATION

PLEASE READ BEFORE ANSWERING.

- Please circle the number that indicates how often you performed each of these activities in the past week because of your feet.
- For example, when asked how often you used a cane indoors because of foot problems, if you used one "None of the time," circle the number 1 and if you used one "All of the time," circle the number 4.
- If, for some items, the question does not apply, circle the number 5.
- Please provide an answer for every item.

4. DURING THE PAST WEEK, HOW MUCH OF THE TIME DID YOU:

	None of the time	Some of the time	Most of the time	All of the time	
26. Stay indoors most of the day because of foot problems?	1	2	3	4	
27. Limit your outdoor activities because of foot problems?	1	2	3	4	5= No outdoor activities
28. Limit your leisure/sport activities because of foot problems?	1	2	3	4	5 = Do not play sports

Subject ID:

[_____]_____]_____]_____]

SOCIAL ISSUES

PLEASE READ BEFORE ANSWERING.

- Please circle the number that indicates how often you experienced the following feelings in the past week because of your feet.
- For example, when asked how often you felt a fear of falling because of foot problems, if you felt fear "None of the time," circle the number 1 and if you felt fear "All of the time," circle the number 4.
- If, for some items, the question does not apply, circle the number 5.
- Please provide an answer for every item.

5. DURING THE PAST WEEK, HOW MUCH OF THE TIME DID YOU EXPERIENCE:

	None of the time	Some the time	Most the time	All of the time	
29. Embarrassment due to footwear?	1	2	3	4	
30. Feeling awful because of foot problem?	1	2	3	4	
31. Limit social activities due to foot problems? . .	1	2	3	4	
32. Difficulty participating in social activities due to footwear?	1	2	3	4	_____
33. Burden of taking medication to control foot pain?	1	2	3	4	_____
34. Concern about limited work around the house?.	1	2	3	4	_____

SUBJECT COMMENTS:

Please comment about:

1. Were the directions clear?

2. Were any of the questions difficult to understand?

3. Were any of the questions unclear? If yes, which ones and why?

4. Did any of the questions make you uncomfortable? If yes, which ones and why?

5. Are there any issues about your feet that were not asked or that you would add to the questionnaire? If yes, which issues?

6. Did you have any problems with this questionnaire that you would like to mention? If yes, which problems?

Thank you for participating in this study.

Pain score: _____
Stiffness score: _____
Difficulty score: _____
Activity score: _____
Social score: _____
Cumulative score: _____