

# The California Joint Replacement Registry

## Selecting a Tool for Evaluating Patient-Reported Outcomes

### Executive Summary

Capturing patient-reported outcome (PRO) data is a key objective for the California Joint Replacement Registry (CJRR). CJRR staff undertook a literature review of the most commonly-used PRO questionnaires in order to inform selection of an instrument for use by the statewide registry. The Technical Working Group agreed on criteria and reviewed an earlier draft of this paper.

Criteria for chosen instrument(s):

- Meet minimum standards for validity, reliability and responsiveness
- Include summary measures of overall physical and mental health that are key predictors of patient reported outcomes
- Provide data that is useful and practical for informing clinical decision-making
- Demonstrate high-levels of responsiveness
- Minimize questionnaire length as a means to maximize response and compliance
- Aim for comparability with existing programs

A review of the research literature identified the candidate instruments listed below. The questionnaires that are highlighted stand out as the most promising potential matches for CJRR.

		<b>Instrument</b>	<b>Items</b>	<b>Assessment</b>
<b>Generic</b>	SF-12	Medical Outcomes Study 12-Item Short Form Health Survey	12	Valid, responsive and efficient
	SF-36	Medical Outcomes Study 36-Item Short Form Health Survey	36	Valid, responsive, widely-used nationally and internationally
	EuroQol	EQ-5D Index Visual Analog Scale	6	Other tools demonstrate superior psychometric properties
<b>Disease Specific</b>	WOMAC	Western Ontario and McMasters University Osteoarthritis Index	24	Valid, responsive, widely-used
	HOOS	Hip Injury and Osteoarthritis Outcome Score	42	Lengthy for registry application
	KOOS	Knee Injury and Osteoarthritis Outcome Score	42	Lengthy for registry application
	Oxford	Oxford Hip Score Oxford Knee Score	12	Valid, superior responsiveness, efficient. Not widely used in U.S.
	Knee Society	American Knee Society Score	4	Inconsistent validity
	Harris Hip Score	Harris Hip Score	8	Other tools demonstrate superior responsiveness
	AAOS Lower Limb Scale	American Academy of Orthopedic Surgeons Hip and Knee Core Scale	7	Valid, responsive, efficient, but very limited testing. No clear comparability to other instruments.

## Introduction

The California Joint Replacement Registry (CJRR) is a multi-stakeholder collaborative working to establish a voluntary, statewide Level 3 database on hip and knee replacements. In order to evaluate the long-term effectiveness of joint replacement procedures and the devices used in those procedures, the CJRR aims to capture data on patient pre-operative characteristics, prosthetic devices and patient outcomes—including revision procedures and patient assessments of pain and function.

Capturing patient-reported outcome (PRO) data is of particular interest to the CJRR stakeholders. Longitudinally tracking patient assessments of pain and function can provide insights into the effectiveness of hip and knee arthroplasty across a much broader patient population than the relatively small number of patients that suffer implant failures and require revision surgery. Perhaps most importantly, PRO data reflect the patient's perspective on the outcome of the surgery—described as “the truest end result of our care as physicians” by one orthopedic surgeon. Overall, California orthopedic surgeons have expressed strong interest in capturing PRO data; in a November 2009 survey of COA joint replacement surgeons, 90% of respondents supported the idea of a centralized process to administer PRO assessments.

Collecting PRO data has proven to be a cost-effective follow-up option as compared to post-operative visits and radiological tests. Programs to capture PRO in Sweden and England have demonstrated response rates to mail questionnaires in the 90-95% range. It is likely that new technologies will further facilitate capture of patient-reported outcomes. Within California, the orthopedic centers at Scripps, Hoag and UCSF have developed systems to routinely collect PRO information—with the latter two organizations utilizing web-based programs in their efforts.

The goal of this report is to inform the process for selecting the survey tool, or tools, to be used for capturing PRO data by the CJRR. Equally important design decisions include determining the mechanisms by which patients will be identified, contacted and administered the questionnaire. Staff will be developing these recommendations in the course of developing an overall technology infrastructure for the CJRR. The focus of this brief is solely to provide a framework for selecting the PRO *questionnaire* to be adopted by CJRR.

## Recommendations

A number of tools have been developed to measure health-related quality of life from the patient perspective. The various instruments may measure different dimensions of health (pain vs. function), and do so with varying degrees of effectiveness. It is generally recommended that researchers evaluating arthroplasty outcomes utilize both a generic and a disease-specific tool in order to capture all pertinent health dimensions.

Generic tools are designed to measure overall health and functioning, and provide the ability to compare outcomes across different populations, health conditions and methods of treatment—which in turn facilitates health policy and cost-effectiveness analyses. The SF-36, SF-12 and EuroQoL stand as the most commonly used generic tools in the orthopaedic community.

Disease- and site-specific instruments are designed to focus on the health issues related to specific conditions and procedures. In the case of arthritis, scales have been developed to evaluate joint-specific pain, function and health. The most commonly-utilized are the 24-item WOMAC, and increasingly, the 42-item HOOS and KOOS—hip and knee specific questionnaires derived from the WOMAC and designed

for use among younger, more active populations. The American Knee Society Score and the Harris Hip Score were among the first wave of questionnaires developed to assess patient pain and function, but were originally designed for administration via clinician interview.

More recently, shorter questionnaires have been developed to reduce patient burden and serve as practical alternatives to existing instruments. These include the 12-item Oxford Hip and Oxford Knee Scores for assessing site-specific joint health and which are routinely used in the United Kingdom. The seven-item AAOS Hip and Knee Core Scale was developed to complement the SF-36 and has likewise been validated, although in a single study with a relatively small sample of patients<sup>1</sup>

Recommendations are:

**I. Utilize instrument(s) that meet minimum standards for validity, reliability and responsiveness.**

Over the past two decades, a science has developed to evaluate the effectiveness of patient-reported outcome instruments for producing valid, comparable data. There is general agreement in the research community that outcome instruments should meet minimum standards in the following areas:

Validity	The instrument measures what it is supposed to (e.g. function, mental health)
Reliability	The instrument produces the same results in both an initial test and a re-test
Responsiveness	The instrument is able to detect changes in health status over time

There are a number of PRO tools being utilized in the orthopedic patient population that have undergone extensive testing and have demonstrated substantial validity, reliability and responsiveness. These candidate tools are listed in Table 5 on page 9.

**II. A generic instrument is essential for capturing key predictors of patient-reported outcomes.**

As with any outcome measure, risk adjustment for the factors that have an impact on patient-reported outcomes is vital for provider acceptance of the results. The Swedish Hip Registry has been collecting PRO data since 2001. Analyses of these data indicate that PRO results are associated with three pre-operative factors: Charnley category\*, gender and anxiety/depression.<sup>2,3</sup> Other researchers have similarly found depression (either clinical or sub-clinical) to be a strong predictor of persistent pain and suboptimal outcomes in arthroplasty patients.<sup>4</sup>

Additional research suggests that advanced age and the presence of two or more medical conditions have a significant negative correlation with patient-reported joint scores—even among patients with no joint disease. Furthermore, joint scores may decline over long periods due to change in patient age and/or medical condition, rather than any factor relating to joint replacement.<sup>5,7</sup>

Given these associations, it is recommended that measures of Charnley category, overall physical health and mental health be integrated into CJRR data collection activities. Generic instruments are among the best mechanisms for capturing the mental and physical health status indicators. The candidate generic instruments include the SF-12, the SF-36 and the EuroQol.

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\* The Charnley categories represent: A-Unilateral Joint Disease, B-Bilateral Joint Disease, and C-Multiple joint disease or intercurrent disease influencing ability to walk.

Although used by the Swedish Hip Registry, the EuroQol instrument has shown inconsistent performance in research to date. It has demonstrated validity, responsiveness and reliability in studies of rheumatoid arthritis patients.<sup>6</sup> However, in head-to-head comparisons, the EuroQol has proven less responsive than the SF-36 and SF-12.<sup>7,13</sup> It has also demonstrated other questionable properties, including a non-normal distribution and limited discriminative power.<sup>8,13</sup>

The SF-12 or SF-36 have both demonstrated strong validity, reliability and responsiveness. The SF-12 shows validity, reliability and responsiveness comparable to the SF-36 in large samples but, as might be expected, is less precise in small samples, and provides a smaller set of information than the SF-36.<sup>9,10,11</sup> For large group studies, these differences are not considered as important, because confidence intervals for group averages in health scores are largely determined by sample size.<sup>9</sup>

### III. Adopt instrument(s) that provide the most useful data for CJRR participants.

As denoted in Table 1, there are a number of potential uses of PRO data. The specific health dimensions to be measured should be determined by the value each will bring to users of the data. In addition, the scales to be reported should be easy for physicians to interpret and incorporate into their treatment decisions. For example, reporting several domain-specific scores (such as those for joint pain, joint function, overall bodily pain) may be overwhelming for physicians, and thus summary scores may prove most useful for clinical decision making.

It should also be noted that the candidate instruments measure different domains, but not all break down their scores into the specific dimensions. For example, the WOMAC provides both a summary joint score and subscales for pain, function or stiffness, while the Oxford Hip Score is reported solely as a single summary score of hip health.\*

**Table 1. Potential Uses of PRO Data for CJRR Participants**

Uses	Joint Pain	Joint Function	Summary Joint Score	Bodily Pain	Bodily Function	Summary Physical Health	Summary Mental Health
Comparing outcomes across devices			✓			✓	Risk Adjuster
Comparing outcomes across pt. characteristics			✓			✓	Risk Adjuster
Provider monitoring of self-performance			✓			✓	Risk Adjuster
Monitoring individual patient outcomes	✓	✓	✓	✓	✓	✓	✓
Comparing JR effectiveness to other diseases						✓	✓
Comparing effectiveness to other arthritis treatments	✓	✓	✓	✓	✓	✓	✓

\* Table 5 on page 9 includes the full list of candidate instruments.  
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#### **IV. Adopt instruments that demonstrate high-levels of responsiveness.**

Because CJRR’s overarching goal is to promote the use of evidence-based information to guide provider and patient decisions—as a means of driving quality and cost improvements—we propose that the key uses of PRO data are:

- Comparing outcomes across devices
- Comparing outcomes across patient characteristics
- Providing physicians with data to monitor their own professional performance compared to statewide averages

Making these comparisons requires an instrument that demonstrates high levels of *responsiveness*, or sensitivity to clinical change. Although joint replacement procedures generally produce relatively large shifts in PRO scores, highly responsive tools are more likely to detect subtle differences in outcome across various devices and patient risk factors. Moreover, if there is a desire to compare the effectiveness of joint replacement procedures to other treatments for arthritis—which result in less dramatic changes in health status—CJRR would likewise require more sensitive instruments to detect the smaller variations in treatment effect.<sup>12</sup>

Disease-specific instruments are typically better at discriminating among varying levels of orthopedic disorders and are more sensitive for assessing changes in health status among arthroplasty patients. Conversely, generic instruments are generally better at discriminating among individuals with different levels of general health and comorbidities.<sup>22,13,14,15</sup>

Virtually all of the disease-specific instruments under consideration have demonstrated high levels of responsiveness. In research that directly compared different PRO instruments:

- The Oxford Hip Score proved more responsive than the WOMAC<sup>7</sup>
- The HOOS demonstrated more responsiveness than the WOMAC for pain and symptoms subscales,<sup>16</sup> but the KOOS was comparable to the WOMAC on all dimensions.<sup>17</sup>

The generic SF-36 has also been found to compare favorably with the WOMAC tool for detecting changes in pain and function among THA patients in some studies, and researchers have suggested that fielding the SF-36 alone may provide a more efficient alternative to administering both a condition-specific and generic instrument. The caveat is that administering the SF-36 alone may not provide sufficient sensitivity for detecting more subtle changes in health status that are useful for distinguishing between different surgical techniques, non-operative treatments and patient populations.<sup>18</sup>

The Harris Hip Score was originally developed as a physician interview tool and has been widely used in clinical trials. Although it has since been validated for use as a patient-reported outcome tool,<sup>19</sup> it has been criticized for an inability to detect subtle differences in performance of two different types of hip replacement.<sup>20</sup> Overall, it appears there are several superior alternatives to the Harris Hip Score.

**V. Minimize questionnaire length as a means to maximize net response rates.**

Research has shown that shorter questionnaires improve patient compliance, response rates and quality of response.<sup>21</sup> Moreover, assessments that utilize a single-item question to represent a measurement domain demonstrate greater variability and sensitivity to change. This is because multi-item questions—in order to exhibit a similar change as single-item questions—must move by the same amount and in the same direction *in concert*.<sup>22</sup>

Brevity will be particularly important when selecting a tool for a statewide registry designed to capture data from patients receiving services across large numbers of orthopedic surgeons. The longer—and more burdensome—survey completion appears to the patient, the more active a role the surgeon needs to take on to encourage compliance. Yet, it is highly unlikely that the surgeons participating in CJRR will provide comparable levels of support for patients to complete the surveys. Minimizing the length will be necessary to achieve satisfactory response and completion rates in the proposed statewide registry. Table 2 outlines the association between questionnaire length and perceived patient burden.<sup>21</sup> Given these associations, a target cap of 24-40 questions is suggested for the CJRR instrument.

**Table 2. Patient Perceptions of Question Burden**

Question Load	Patient Perception of Burden
< 12 questions	None
> 24 questions	Start to perceive a burden; continued compliance depends on relevance, ease, logic and degree of controversy of items included.
> 50 questions	5% attrition and missed questions
> 80 questions	Fatigue sets in

Table 3 below compares the net response rates (the percentage of individuals that return the survey multiplied by the percentage of questions completed on the survey) for several questionnaires evaluated in a single study. The SF-12 garnered a better net response rate than the SF-36, while the SF-12 completion time was almost half that of the SF-36.<sup>23</sup> Meanwhile, the 12-item Oxford Knee Score achieved a better response rate and shorter completion time than the 24-item WOMAC.

**Table 3. Comparison of Net Response Rates and Completion Times of 4 PRO Questionnaires**

Instrument	Net Response Rate	Time to Complete (minutes)
SF-12	75.4%	7.7
SF-36	63%	14.2
Oxford Knee	89.4%	9.6
WOMAC	83.0%	11.7

The above research suggests there is likely to be a significant drop off in response and completion rates for longer instruments. As such, in spite of their excellent psychometric properties, the 42-item HOOS and KOOS are unlikely to be good candidates for use in a statewide registry.

## VI. Aim for Comparability with Other Programs

Ideally, CJRR’s program to track patient reported outcomes will be one of many such efforts—both nationally and internationally. It would be highly advantageous for the programs to utilize a standard instrument in order to facilitate comparison of results. At this time, no such standard exists.

Systematic reviews of outcome measures used in hip and knee replacement studies have found extensive variation in the tools administered for research purposes. The most commonly used tools for randomized clinical trials are the American Knee Society Score and the Harris Hip Score.<sup>24</sup> For cohort studies assessing the impact of knee and hip replacements on health-related quality of life, the WOMAC and/or the SF-36 are the dominant measures used.<sup>25</sup> Table 4 provides a summary of the tools used by other registry programs, including both international and local organizational registries.

Three institutions in California utilize the HOOS/KOOS with either the SF-12 or SF-36. As described above, the length of the HOOS/KOOS makes them impractical for use in the statewide registry. However the HOOS/KOOS both include the full set of WOMAC questions. As such, if the registry were to adopt the WOMAC, organizations that prefer using the HOOS/KOOS for research purposes could still calculate the WOMAC subset of questions for comparison to statewide registry scores. Similarly, because the SF-36 and SF-12 both use norm-based scoring, comparisons can be made between these two generic health surveys.<sup>26</sup>

A potential issue with the above approach is the possibility that the two instruments will produce highly divergent response rates given the differences in question load. Bias may be introduced if certain types of patients are systematically less likely to complete the longer instrument. In this case, the results for institutions calculating outcomes from a HOOS/KOOS subset would not be comparable to those calculated from the shorter WOMAC instrument.

The National Joint Registry of England and Wales utilizes the highly responsive and efficient Oxford Hip and Knee Scores<sup>7</sup>. Adopting the Oxford tools would allow comparability with another large multi-institutional registry.

**Table 4. PRO Instruments Used in Other Registry Programs**

Description	Hoag	UCSF	Scripps	Sweden	England
<b>Overall Health</b>	SF-36	SF-12	SF-12	EuroQoL	EQ-5D
<b>Hip Function and Pain</b>	HOOS	HOOS Harris Hip	HOOS Harris Hip		Oxford Hip
<b>Knee Function and Pain</b>	KOOS	KOOS Knee Society	KOOS Knee Society		Oxford Knee
<b>Activity Index</b>	Work Productivity and Activity Impairment	UCLA Activity Rating Scale			
<b>Visual Analog Scale</b>	General Health			-Pain -Satisfaction	

## VII. Incorporate an activity rating scale into patient assessments as a predictor of device survivorship.

Research indicates that post-surgical physical activity is related to risk of revision—with more intense activity levels predicting earlier implant failure.<sup>27,28,29</sup> Including an activity rating scale in CJRR’s patient outcome questionnaire would allow for capture of this predictor variable.

The literature on scales that measure patient activity levels is not nearly as fulsome as that for other patient-reported assessments. The only comparative study of activity scales concluded the UCLA Activity Scale is the most appropriate measure for arthroplasty patients (vis-a-vis the Tegner score and the Activity Rating Scale).<sup>30</sup> 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.

### Options

CJRR is the first region-wide joint registry in the U.S. to propose a system for uniformly collecting patient reported outcomes data. As such, the decision of which tool(s) to use carries particular import—potentially setting the standard for patient survey programs in other U.S. programs. Based on the above recommendations, we propose the following options for surgeon consideration:

Option	Generic	Disease Specific	Disease Burden	Activity Scale	Total Items
1	SF-12	Oxford Hip/Knee	Charnley	UCLA	26
2	SF-12	WOMAC	Charnley	UCLA	38
3	SF-36	None	Charnley	UCLA	38

**Table 5. Comparison of PRO Instruments**

Domains	Generic			Hip					Knee	
	SF-12	SF-36	Euro QoL	AAOS Lower Limb	WOMAC	Oxford Hip	Harris Hip	HOOS	Oxford Knee	KOOS
<b>Number of Items</b>	12	36	6	7	24	12	8	42	12	42
<b>Psychometric Properties</b>										
Volume of Evidence	★★	★★★	★★	★	★★★	★★★	★★	★★	★★★	★★
Validity	★★	★★	★	★★	★★	★★	★★	★★	★★	★★
Responsiveness	★★	★★	★	★★	★★	★★★	★	★★	★★★	★★
Reliability	★★	★★	★	★★	★★	★★	★	★★	★★	★★
<b>Dimensions</b>										
Summary Physical Health	✓	✓								
Summary Mental Health	✓	✓								
Summary Joint Health				✓	✓	✓	✓	✓	✓	✓
Joint Function-Daily Living					✓			✓		✓
Joint Pain				✓	✓			✓		✓
Joint Stiffness					✓			✓		✓
Joint Symptoms								✓		✓
Joint Function-Sports/Recreation								✓		✓
Joint-Related Quality of Life								✓		✓
Other Joint Symptoms										
Physical Functioning	✓	✓	✓							
Role-Physical	✓	✓	✓							
Body Pain	✓	✓	✓							
General Health	✓	✓	✓							
Vitality	✓	✓								
Social Functioning	✓	✓								
Role-Emotional	✓	✓								
Mental Health	✓	✓	✓							

**Key:** ★★★ Superior / ★★ Excellent / ★ Good

## Endnotes

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