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AAHKS Symposium: Patient Reported Outcome Measures: This is your New Reality

Patient-Reported Outcome Measures—What Data Do We Really Need?

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ABSTRACT

The Center for Medicaid and Medicare Services has recently announced the inclusion of several patient-reported outcome measures (PROMs), including the abbreviated Hip Disability and Osteoarthritis Outcome Score and Knee Injury and Osteoarthritis Outcome Score for joint replacement (HOOS, JR and KOOS, JR) for the purpose of quality assessment in total hip and total knee replacement (THR and TKR). Historically, Center for Medicaid and Medicare Services and other agencies have used measures of process (eg, % vaccinated) or adverse events (eg, infection rates, readmission rates) for quality assessment. However, the use of PROMs has become a priority based on stated goals by the National Quality Strategy and Institute of Medicine for a more patient-centered approach. Here, we review several general health and joint-specific PROMs, which have been extensively used in research to assess treatment efficacy and discuss their relevance to the new criteria for quality assessment, particularly for THR and TKR. Although we expect HOOS, JR and KOOS, JR to yield much useful information in the near term, these surveys are likely an interim solution. In the future, we anticipate that novel measurement platforms, such as wearable technologies or patient-specific surveys, may open new and exciting avenues of research to discover which types of data—perhaps not previously available—best represent patient quality of life and satisfaction after THR, TKR, or other orthopedic procedures.

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In accordance with the Affordable Care Act, the National Quality Strategy (NQS) and Institute of Medicine (IOM) have prioritized patient-centered, evidence-based care [1,2], driving various stakeholders, including the Center for Medicaid and Medicare Services (CMS) to implement patient-reported outcome measures (PROMs) for quality assessment [3]. Defined by the US Food and Drug Administration as “any report of the status of a patient’s health condition that comes directly from the patient [or in some cases a caregiver or surrogate], without interpretation of the patient’s response by a clinician or anyone else,” [4] PROMs have been widely used in research to determine treatment efficacy. On the other hand, CMS and other agencies have historically used measures of process (eg, % vaccinated) or adverse events (eg, infection rates, readmission rates) for quality assessment. Given NQS and IOM priorities, the identification of appropriate patient-centered measures is increasingly of interest for total hip and total knee replacement (THR and TKR), as they are major cost drivers for Medicare and because improvements in a patient’s quality of life

(pain and function) are critical for treatment success [5]. Indeed, the recently announced Comprehensive Care for Joint Replacement (CJR) model includes the voluntary reporting of patient-reported outcome (PRO) data that will be used in a composite score linking the quality of THR and TKR performance in participating hospitals to Medicaid/Medicare payment [6–8].

The CMS has determined that both general health and joint-specific PROMs are necessary for quality of care assessment for total joint arthroplasty [6–8]. The recently published CJR final rule includes the Veterans’ RAND 12 and Patient-Reported Outcome Measurement Information System (PROMIS) for general health assessment and abbreviated, joint replacement specific versions of the Hip Disability and Osteoarthritis Outcome Score, and Knee Injury and Osteoarthritis Outcome Score (HOOS, JR and KOOS, JR) or specific portions of the entire HOOS or KOOS for THR and TKR assessment [9]. The use of PROMs is certainly not new, and many surveys for assessing general and hip- or knee-related health are available. These are reviewed in the following sections. For use at the scale required for CMS, however, demands a level of optimization that allows information to be collected from potentially millions of patients efficiently and accurately. In the initial phase of the CJR model, voluntarily

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reported PRO data will be used to determine the reliability and validity of PROMs [7]. To determine adequate factors for risk adjustment for PRO data, including the comparison of performance in different hospitals to finalize the modeling for the risk adjustment methodology is an important requirement for implementation that is currently being evaluated [6–8]. PRO performance measures are anticipated to become mandatory by year 4 or 5 of the CJR [8]. Given NQS and IOM priorities, it is predictable that after successful implementation of PROMs for quality assessment, that methodologies to use the data to define clinical best practices will soon follow.

PROMS for General Health

The most popular and well-validated general health PROMs include the Short Form–36 (SF-36) [10,11] and the shorter 12-item SF-12 [12], the Veterans RAND-12 and -36 (VR-12 and VR-36) [13,14], and the National Institutes of Health (NIH) PROMIS Global Health Measure, which includes 10 items [15]. These PROMs are summarized in the following sections and in Table 1.

Short Form

First standardized in 1990, the SF-36 was developed by the RAND Corporation as part of the Medical Outcomes Study and comprises the 36 most frequently measured items that have been shown to be relevant to disease and treatment [11,16]. It is intended to be a “set of generic, coherent, and easily administered quality-of-life measures” for the assessment of care outcomes [10].

Administration of the 36 item questionnaires take about 5–10 minutes, but to decrease the time burden further, a shorter SF-12 was developed and validated [12]. Both surveys include measures of physical and mental health as assessed through a number of scales (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, mental health).

Veterans RAND

The VR-36 was developed among patients in the Veterans Administration system to improve responsiveness of SF-36 and

remove “floor” effects in patients with poor health [13,14]. It is also available in a shorter VR-12 format.

Patient-Reported Outcome Measurement Information System

The PROMIS is an NIH initiative to use increasingly widespread computer technology and item response theory to derive computer adaptive testing tools for the precise, personalized individual assessment of patient experience and outcomes at the national level [17]. It is being developed by a network of clinical and other experts at multiple primary research sites (Duke University, Stanford University, Stony Brook University, University of North Carolina, University of Pittsburgh, and University of Washington and others) and a statistical coordinating center (at Evanston Northwestern Healthcare with collaborators from University of California, Los Angeles Rehabilitation Institute of Chicago, United BioSource Corporation and Westat, Inc) in coordination with several institutes of the NIH. Among the capabilities of the computer adaptive testing tools is real-time responsiveness to patient survey answers. For example, given a particular patient response to an initial question, subsequent items can be deleted, to decrease the time burden, or changed, to make the survey more precise. PROMIS Global 10 is a static rather than computer adaptive PROM which includes 10 items from the PROMIS Global Health item bank that allows for efficient assessment of patients' general physical and mental health [15].

Joint-Specific PROMs

Patients seek hip or knee arthroplasty for a wide variety of reasons including pain, function, symptoms, quality of life, sports/recreation, activity level, expectations, and satisfaction [18–20]. Accordingly, the PROMs relevant to the assessment of THR and TKR query domains of joint health such as pain and function of the joint during activities of daily living or sports and recreation, as well as joint-related quality of life. Two of the oldest and most commonly used joint-specific PROMs include the Knee Society Score (KSS) [21] and Harris Hip Score (HHS) [22,23], but both of these are partially surgeon derived. Wholly patient-derived instruments relevant to joint arthroplasty include the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [24–26], Oxford Hip and Knee Scores [27–29], HOOS [30], KOOS [31], and their abbreviated forms, the HOOS-physical function short form (PS) [32,33] and KOOS-PS [33,34]. These joint-specific PROMs are summarized in the following sections and in Table 2.

Knee Society Score

Presented by the Knee Society in 1989, the KSS combines an assessment of the knee itself (part 1) and about patient function (part 2). Part 1 includes 7 items to be assessed by the surgeon (or other physician), whereas part 2 includes 3 items to be answered by the patient. One reason for this approach was to minimize the problem of declining scores because of overall patient infirmity, as opposed to declining knee function per se [21].

Harris Hip Score

Originally published in 1969, the HHS was intended to assess the results of hip surgery and has been used widely for the assessment of THR. Pain and function domains are queried through 8 items for the patient while absence of deformity and range of motion is assessed by the surgeon (or other physician) through 5 items [22,23].

Table 1
Patient-Reported Outcome Measures for General Health.

| General Health PROMs | Proprietary | Patient Derived | Items | Domains |
|----------------------|-------------|-----------------|-------|--|
| SF-36 | Yes | Yes | 36 | Physical function Role-physical Bodily pain General health Vitality Social functioning Role-emotional Mental health |
| SF-12 | Yes | Yes | 12 | Same as SF-36 |
| VR-36 | No | Yes | 36 | Same as SF-36 |
| VR-12 | No | Yes | 12 | Same as SF-36 |
| PROMIS Global 10 | No | Yes | 10 | General health Physical health Pain Fatigue Quality of life Mental health Social discretionary Emotional problems |

PROMs, patient-reported outcome measures; SF-36, Short Form–36; PROMIS, Patient-Reported Outcome Measurement Information System.

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