AAHKS AMERICAN ASSOCIATION OF HIP AND KNEE SURGEONS
AAOS American Association of Orthopaedic Surgeons
AJRR American Joint Replacement Registry
Improving Orthopaedic Care Through Data

Orthopaedic Headquarters | 9400 West Higgins Road | Rosemont, Illinois | 60018-4976

THIS IS A JOINT COMMUNICATION FROM THE AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS, THE AMERICAN JOINT REPLACEMENT REGISTRY, THE HIP SOCIETY, THE KNEE SOCIETY, AND THE AMERICAN ASSOCIATION OF HIP AND KNEE SURGEONS

September 8, 2015

Mr. Andy Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5516-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services

Dear Administrator Slavitt:

The American Association of Hip and Knee Surgeons (AAHKS) appreciates the opportunity to provide comments on the Comprehensive Care for Joint Replacement Payment Model.

On August 31, 2015, AAHKS convened a Patient Reported Outcomes Summit for Total Joint Arthroplasty in Baltimore, Maryland. Representatives from orthopaedic organizations (AAHKS, American Association of Orthopaedic Surgeons, The Hip Society, The Knee Society, and American Joint Replacement Registry), Centers for Medicare & Medicaid Services (CMS), Yale-New Haven Health Services Corporation Center for Outcomes Research and Evaluation (Yale/CORE), private payors and other stakeholders participated in the Summit. The Summit's goal was to obtain a consensus regarding the patient-reported outcomes (PRO) and risk variables suitable for total hip and knee arthroplasty performance measures.

After review of the proposed rule and the discussion of the Summit participants, the comments and rationale below reflect the consensus recommendations of the represented orthopaedic organizations:

1. We propose that CMS require the use of only one general heath questionnaire for the proposed patient reported outcome measure. We recommend that CMS allow hospitals to use either the VR-12 **or** the PROMIS-10 – Global instrument.

2. We also recommend that a disease-specific instrument be used as part of the proposed patient reported outcome measure. The HOOS and KOOS instruments, as outlined in the CMS proposed rule, would be a substantial burden to patients, orthopaedic surgeons and their staff because of the overall length of the instrument. We recommend that the KOOS, JR. instrument be used for total knee arthroplasty (TKA) patients and the HOOS, JR. instrument be used for total hip arthroplasty (THA) patients. We will describe this instrument in detail below.

3. We recommend a staged approach of the candidate risk variables as we suggest that some variables are more clinically relevant and are easier to collect at the present time. We have outlined below our priority list of risk variables, our future desired list of risk variables and risk variables that we recommend should not be included. It is essential that risk adjusted data be collected or access to care for certain patients will be limited in the future.

<u>Patient Reported Outcome (PRO) Measure</u>

The Summit participants discussed both the PROMIS Global instrument and the VR-12 instrument. Both instruments evaluate physical and emotional health. In addition, both instruments have a minimal number of questions (10 or 14) which is important to the orthopaedic community. The group acknowledges that the PROMIS tool is a new instrument and may not have the legacy data that VR-12 has available. However, the National Institutes of Health (NIH) has made a significant investment in the PROMIS surveys and many facilities are starting to collect the PROMIS Global data. It would be redundant for CMS to require both general health PRO instruments. It is recommended that either the PROMIS Global or the VR-12 instruments be used to collect general health information.

The meeting participants also had a lengthy discussion regarding the appropriate disease-specific patient survey instruments for lower extremity joint replacement. In reality, the collection of post-operative patient surveys will be the responsibility of the orthopaedic surgeon and his/her staff. Orthopaedic surgeons are concerned about the number of questions the patients will be required to answer in order to complete the instrument. The HOOS and KOOS instruments, as outlined in the CMS proposed rule, would be a substantial burden to patients, orthopaedic surgeons and their staff. Many surgeons do not collect PRO measure (PROM) data at all at this time and it is unreasonable to expect them to begin collecting such an extensive data set at this

time. The consensus of the Summit participants is that HOOS, JR. and KOOS, JR instruments should be used for the PRO measures.

The HOOS, JR. and KOOS, JR. surveys are short-forms developed using an evaluation of the data obtained from the Hospital for Special Surgery joint replacement registry. A cohort of patients undergoing unilateral THA and TKA who completed both pre-operative and 2 year post-operative HOOS and KOOS hip and knee specific PROMs were identified for the development and validation of these new joint replacement specific short-forms. All HOOS and KOOS items were first assessed for relevance (pre-arthroplasty patients were asked to rate the importance of each item), difficulty (based on pre-operative scores in patients undergoing joint arthroplasty), redundancy (5 Pain domain items on both the HOOS and KOOS overlap with Activities of Daily Living and/or Sports & Recreation items), and missingness (items in which more than 10% of respondents skipped the item were excluded). Remaining items were assessed using a Rasch modeling approach to reduce the full HOOS and KOOS to a unidimensional survey of hip or knee "health" comprised of 12 items most relevant and difficult for pre-operative patients undergoing hip and knee arthroplasty. A final Rasch model was performed that reduced the 12 hip items to 6 items (HOOS, JR.) and the 12 knee items to 7 items (KOOS, JR).

In addition to the HSS validation cohort the FORCE-TJR registry was also used to validate these new PROMs. Internal consistency was high for both HOOS, JR. (Cronbach's alpha 0.84) and KOOS, JR. (0.85). The new surveys were highly responsive to joint replacement (standardized response means of 1.7 to 2.4) and there was near-perfect correlation with both the pain and activities of daily living/function domains of the full HOOS/KOOS and the WOMAC (Spearman's correlations 0.80-0.94).

The validation of these 2 new short-form joint-specific surveys was presented at the 2015 AAOS Annual Meeting (HOOS, JR.) and the 2015 International Society of Arthroplasty Registries Annual Meeting (KOOS, JR.). Both publications are currently under review at *Clinical Orthopaedics and Related Research*.

The HOOS, JR. and KOOS, JR. surveys represent efficient and reliable short-form alternatives to the full HOOS and KOOS surveys. We believe the forms should be used for the patient reported outcome measures. We believe that this type of data collection is an evolutionary process and the orthopaedic community is prepared to collect more extensive patient data if deemed necessary in the future.

Risk Variables

The Summit participants reviewed the list of candidate risk variables identified in the proposed rule. There was consensus on a priority list of risk variables, a future desired list of risk variables and variables that should not be included. Some of the variables will require additional data collection.

Priority List of Risk Variables

- Body Mass Index – The actual height and weight should be recorded. The BMI should not be captured from the administrative data. The height and weight are currently being recorded in many electronic health records (EHR).
- Race/Ethnicity – Race/ethnicity should be a patient-reported variable and may be recorded in the EHR.
- Smoking Status – Smoking status may be reported through administrative data but additional information may be provided from the EHR.
- Age – Age is reported in administrative data.
- Sex- Sex is reported in administrative data.
- Back Pain – Back pain would be a patient-reported variable and recorded in the EHR. It has been noted to influence outcomes of joint replacement patients.[1,2]
- Pain in Non-operative Lower Extremity Joint – Pain in a non-operative lower extremity joint would be patient-reported variable and recorded in the EHR. It has been noted that pain in other extremities can influence the outcome of a total joint replacement.[1,2]
- Health Risk Status – The actual comorbidities that should be included need further investigation. Both the Charlson morbidity index and the Elixhauser morbidity measure may identify appropriate comorbid conditions. In order to identify the patient's comorbid conditions, it is recommended that all inpatient and outpatient diagnosis codes for the prior year be evaluated.
- Depression/Mental Health Status - The PROMIS Global or VR-12 will collect this variable, as well as the administrative data.
- Chronic Narcotic or Pre-operative Narcotic Use – This variable affects patient outcomes and requires additional consideration. The information should be available in the EHR.
- Socioeconomic Status – This variable affects patient outcomes and requires additional consideration. Further evaluation is required regarding how the data could be collected.

Future Desired List of Risk Variables

- Literacy
- Marital Status
- Live-in Home Support

Risk Variables to Not Include

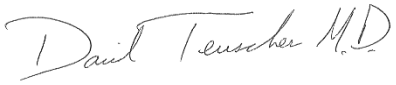
- ASA score
- ROM
- Mode of PROM collection

We appreciate this opportunity to provide these comments to CMS on behalf of the participating organizations in the Patient Reported Outcomes Summit for Total Joint Arthroplasty. For

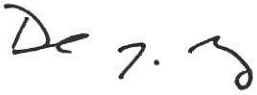
questions or to discuss these comments further, please contact me at (323) 442-8117 or jrlieber@usc.edu.

Sincerely,

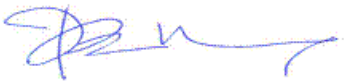
Jay R. Lieberman, MD
President, American Association of Hip and Knee Surgeons



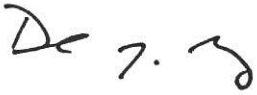
David Teuscher, MD
President, American Association of Orthopaedic Surgeons



Daniel J. Berry, MD
President, The Hip Society



Thomas P. Vail, MD
President, The Knee Society



Daniel J. Berry, MD
Chair, American Joint Replacement Registry Board of Directors

Attachments:

HOOS, JR.

KOOS, JR.

HOOS, JR. HIP SURVEY

INSTRUCTIONS: This survey asks for your view about your hip. This information will help us keep track of how you feel about your hip and how well you are able to do your usual activities.
Answer every question by ticking the appropriate box, only one box for each question. If you are unsure about how to answer a question, please give the best answer you can.

Pain
What amount of hip pain have you experienced the **last week** during the following activities?

1. Going up or down stairs

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

2. Walking on an uneven surface

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Function, daily living
The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your hip.

3. Rising from sitting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

4. Bending to floor/pick up an object

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

5. Lying in bed (turning over, maintaining hip position)

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

6. Sitting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

KOOS, JR. KNEE SURVEY

INSTRUCTIONS: This survey asks for your view about your knee. This information will help us keep track of how you feel about your knee and how well you are able to do your usual activities. Answer every question by ticking the appropriate box, only one box for each question. If you are unsure about how to answer a question, please give the best answer you can.

Stiffness

The following question concerns the amount of joint stiffness you have experienced during the **last week** in your knee. Stiffness is a sensation of restriction or slowness in the ease with which you move your knee joint.

1. How severe is your knee stiffness after first wakening in the morning?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Pain

What amount of knee pain have you experienced the **last week** during the following activities?

2. Twisting/pivoting on your knee

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

3. Straightening knee fully

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

4. Going up or down stairs

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

5. Standing upright

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Function, daily living

The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your knee.

6. Rising from sitting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

7. Bending to floor/pick up an object

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

[1]Ayers DC, Li W, Oatis C, Rosal MC, Franklin PD. *Patient-reported outcomes after total knee replacement vary on the basis of preoperative coexisting disease in the lumbar spine and other nonoperatively treated joints: the need for a musculoskeletal comorbidity index.* J Bone Joint Surg Am. 2013 Oct 16;95(20):1833-7. doi: 10.2106/JBJS.L.01007.

[2] Ayers DC, Li W, Oatis C, Rosal MC, Franklin PD. *Patient-reported outcomes after total knee replacement vary on the basis of preoperative coexisting disease in the lumbar spine and other nonoperatively treated joints: the need for a musculoskeletal comorbidity index.* J Bone Joint Surg Am. 2013 Oct 16;95(20):1833-7. doi: 10.2106/JBJS.L.01007.