Introduction

The American Association of Hip and Knee Surgeons (AAHKS) has a strong commitment to improving quality of care for patients undergoing lower extremity total joint replacement. In 2010, AAHKS and the American Association of Orthopaedic Surgeons (AAOS) collaborated on plans to develop physician performance measures to address the care of patients undergoing a total knee replacement. In 2011, AAHKS formed a work group including representatives from AAOS, The Knee Society, the American Physical Therapy Association and the Pacific Business Group on Health to develop performance measures through the independent development process of the American Medical Association-convened Physician Consortium for Performance Improvement (PCPI). The total knee arthroplasty (TKA) process measures addressing the quality of care of patients undergoing the procedure were approved for use in 2013 and have been included in Medicare’s Physician Quality Reporting System (PQRS) since 2014. During 2015, AAHKS and its collaborators began work on developing physician performance measures for total hip arthroplasty (THA). The THA measures will include both process of care measures and patient-reported outcome measures.

In addition, AAHKS and AAOS have developed relationships with both the Centers for Medicare & Medicaid Services (CMS) and Yale New Haven Health Services Corporation and the Center for Outcomes Research and Evaluation (YNHHSC/CORE). Recently, AAHKS and AAOS have been working closely with YNHHSC/CORE to identify patient-reported outcome instruments that will not only provide appropriate assessment of outcomes but that allow data to be easily collected from patients.

Beginning in 2016, CMS is proposing to implement and test a new payment model called Comprehensive Care for Joint Replacement (CCJR). According to the proposed rule, the intent of the new payment model “is to promote quality and financial accountability for episodes of care surrounding lower-extremity joint replacement.” CCJR will include the use of patient-reported outcome measures. There are many hip and knee patient outcome scoring systems available, but there has been no national consensus as to which system should be routinely used. The proposed CCJR rule also includes a list a candidate risk variables for lower extremity joint replacement. In the past, critical orthopaedic related risk variables have not been included in risk assessment for total joint arthroplasty patients.

On August 31, 2015, AAHKS convened a Patient Reported Outcomes Summit for Total Joint Arthroplasty in Baltimore, Maryland. Representatives from orthopaedic organizations (AAHKS, AAOS, The Hip Society, The Knee Society, and American Joint Replacement Registry), CMS, YNHHSC/CORE, National Committee for Quality Assurance (NCQA), Mathematica, CECity, and Blue Cross Blue Shield Association 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.

Participants

See Attachment A for Participant List.

Summit Presentations

The Summit began with several presentations introducing the current quality landscape for total joint replacement. Jay Lieberman, MD, AAHKS President, presented the past quality measure development work organized by AAHKS regarding total knee arthroplasty and the current measure development work regarding total hip arthroplasty.

Lisa Suter, MD, Associate Director, Quality Measurement Program, YNHHSC/CORE, introduced their work as CMS contractors. They are developing risk-adjusted hospital-based patient reported outcome-based performance measures (PRO-PMs) for patients undergoing total hip and knee arthroplasties. Their work and recommendations from the Technical Expert Panel (TEP) have influenced the proposed patient-reported outcome data collection requirement for the CCJR.

Stephen Lyman, PhD, Director, Health Care Research Institute, The Hospital for Special Surgery shared the work that he and colleagues completed on the evaluation of the HOOS and KOOS instruments. They found the instruments could be shortened and remain valid with only six questions on the HOOS, JR, and seven questions on the KOOS, JR.

Patricia Franklin, MD, Director Clinical and Outcomes Research, Department of Orthopedics and Physical Rehabilitation, University of Massachusetts Medical School, presented the orthopaedic patient outcomes and risk adjustment findings of the Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement and Quality Improvement (FORCE-TJR).

In the afternoon, Kate Goodrich, MD, Director, Quality Measurement and Value-Based Incentives Group, Center for Clinical Standards and Quality, CMS, provided the CMS perspective on patient reported outcomes and value-based purchasing.

Break Out Sessions

Each participant was assigned to one of three breakout groups. The group reviewed the information outlined in the proposed rule and determined the optimal THA PROMS, TKA PROMS or THA/TKA Risk Variables.

THA Patient-Reported Outcome Measure Instruments
The group suggested that approximately twenty survey questions would be appropriate and would not be a burden to patients or the physicians. It would be important to ensure that the general/mental health survey be completed prior to surgery during the preoperative visit, as well as the post-operative visit. The group discussed the merits of using PROMIS Global 10 vs VR 12, noting that the VR 12 may need to be adjusted for THA patients. The PROMIS 10 survey collects all the necessary information in ten questions including questions number four and ten that address the important mental health issues. NIH has invested heavily into the development of PROMIS 10 and it is a non-proprietary survey instrument.

To address the specific hip issues, the group evaluated the HOOS, Jr. and determined that HOOS, Jr., along with the four HOOS quality of life (QOL) questions would be appropriate.

The group also discussed potentially including the Single Assessment Numeric Evaluation (SANE) score.

The group recommended that HOOS, Jr. (all ten questions including QOL) and the PROMIS Global 10 would address all the necessary patient reported outcomes. In addition, the group decided to ask the Summit participants if the SANE Score question should be included.

**TKA Patient-Reported Outcome Measure Instruments**

The group discussed the Oxford knee and hip scores. Due to the interest of some orthopaedic surgeons in using the Oxford scores, it was important to address why the Oxford knee and hip scores were not recommended by the YNHHSC/CORE Technical Expert Panel (TEP). The TEP had not recommended the Oxford scores because they are proprietary instruments.

The group discussed the merits of two approaches including the KOOS JR. or a “hybrid” approach. There were concerns expressed regarding the validation of the KOOS, Jr. instrument. The group considered the benefits of using VR-12 and the KOOS pain questions. It was also suggested that they recommend a subset of eight of the VR-12 questions and a subset of KOOS, the nine pain questions. The group also thought questions related to low back pain and pain in the non-operative lower extremity joints, as identified in the FORCE-TJR findings, were important to include.

Upon further discussion, it was recognized that many facilities were already collecting data on the PROMIS Global 10 instrument, and there is not sufficient justification to require those facilities to switch to the VR-12.

The group recommended using **either** VR-12 or PROMIS Global 10 for the general health instrument. In addition the nine KOOS pain questions plus the two questions regarding low back pain and pain in the non-operative lower extremity joints should be used to address the specific knee issues.

**Candidate Risk Variables**

The list of candidate risk variables from the CMS proposed rule was reviewed. There were concerns expressed regarding the list being too long and the need to identify a smaller list that would not be a burden for the surgeon to collect. It was noted that while many variables can be collected by ICD codes/administrative data, some key variables cannot, as coding is not always complete and accurate for certain conditions, such as obesity. The group identified a list of “must have” variables, future variables and variables that should not be included (see Table).
<table>
<thead>
<tr>
<th>Must Have Variables</th>
<th>Wish List for Future Variables</th>
<th>Not Needed Variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI – Height and Weight, continuous variable</td>
<td>Socioeconomic Status</td>
<td>Mode of collection</td>
</tr>
<tr>
<td>Race/ Ethnicity</td>
<td>Literacy</td>
<td>ASA</td>
</tr>
<tr>
<td>Smoking Status (This is being collected as part of meaningful use)</td>
<td>Marital Status/Live in Status</td>
<td>ROM – too difficult to collect</td>
</tr>
<tr>
<td>Preoperative use of narcotics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Charlson Score or Health Status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Back pain/Pain in non-operative lower extremity joint</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In addition, the group identified that the following patients should be excluded from the requirements of the CCJR: current fractures, prior ORIF, prior fractures with deformities, joint revisions, tumor, and previous infection. These exclusions would obviate the need for additional risk adjustment.

**CONSENSUS RECOMMENDATIONS**

The discussion leader for each group presented the findings of their group and Kevin Bozic, MD, Chair, Council on Quality and Research, AAOS, moderated a discussion in order to obtain participant consensus on the patient-reported outcome measure and risk variables.

*Patient Reported Outcome Measure Instruments*

CMS should require the use of only one general heath questionnaire for the proposed patient reported outcome measure. It is recommended that CMS allows hospitals to use **either** the VR-12 **OR** the PROMIS-Global 10 instrument. Both instruments evaluate physical and emotional health. In addition, both instruments have a minimal number of questions (ten or fourteen) which is important to the orthopaedic community. The group acknowledged that the PROMIS 10 tool is a new instrument and may not have the legacy data that VR-12 has available. However, the NIH has made a significant investment in the PROMIS surveys and many facilities are starting to collect the PROMIS 10 data. It would be redundant for CMS to require both general health PRO instruments. It is recommended that either the PROMIS 10 **OR** the VR-12 instruments be used to collect general health information.

It is recommended 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, orthopedic surgeons and their staff because of the overall length of the instruments. The meeting participants 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 regarding the number of questions the patients will be required to answer in order to complete the instrument. Many surgeons do not collect PROM data currently and it is unreasonable to expect them to begin collecting such extensive data right away. The consensus of the Summit participants was that HOOS, JR. (six questions) and KOOS, JR (seven questions) instruments should be used as the disease-specific patient survey instruments.
CMS should use a staged approach in selecting the candidate risk variables as some variables are more clinically relevant and are easier to collect at the present time. A priority list of risk variables, future desired list of risk variables and risk variables that should not be included are identified below along with information on how the data elements should be collected. It is essential that risk adjusted data be collected or access to care for certain patients will be limited in the future.

**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 a 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

Planned Follow-up

A letter outlining the consensus of the group was drafted in response to the CMS proposed CCJR rule within the week and shared with the participating organizations. The participants hoped that all orthopaedic organizations will support the consensus of the group and that CMS will consider the thoughtful recommendations of the orthopaedic organizations. The letter was co-signed by AAHKS, AAOS, AJRR, The Hip Society, and The Knee Society and included as an attachment with the CCJR comments to CMS. In the future, the orthopaedic organizations recommend a partnership with CMS and YNHSC/CORE in future development and refinement of all performance measures and payment models related to lower extremity joint replacements.

AAHKS will incorporate these recommendations for patient-reported outcomes in the drafting of the total hip arthroplasty performance measures.

There may be a follow up meeting held in the fall to continue the discussion.
Attendee List

Kevin Bozic, MD, Chair, Council on Research and Quality, AAOS
Deborah Cummins, PHD, Director of Research and Scientific Affairs, AAOS
Kerri Fei, Clinical Value Portfolio Manager, Center for Clinical Value, Blue Cross Blue Shield Association
Patricia D Franklin MD, MBA, MPH, Department of Orthopedics and Physical Rehabilitation, University of Massachusetts Medical School
Mark Froimson, MD, 3rd Vice President, AAHKS
Kate Goodrich, MD, MHS Director, Quality Measurement and Value-Based Incentives Group, CMS Center for Clinical Standards and Quality
Karen Hackett, CEO, AAOS
Brian Hall, Epstein Becker & Green
David Halsey, MD, 2nd Vice President, AAHKS
Simone Karp, Chief Business Officer, CECity.com, Inc
Joshua Kerr, Director of Advocacy and International Activities, AAHKS
Jeffrey Knezovich, Executive Director, AJRR
Becky Kresowik, Project Consultant, AAHKS
Jay Lieberman, MD, President, AAHKS
Zhenqui Lin, PhD, Yale/CORE
Steve Lyman, PhD, Director, Healthcare Research Institute, Hospital for Special Surgery
Wendy Marinkovich, Managing Director, Center for Clinical Value, Blue Cross Blue Shield Association
David R. Mauerhan, MD, Member, Advocacy Council, AAHKS
Charles Nelson, MD, The Knee Society
Vincent D. Pellegrini, Jr., MD, The Hip Society
Anthony Rankin, MD, Board of Directors, AJRR
Stephanie Rodriguez, Senior Healthcare Analyst, National Committee for Quality Assurance
Lynn Shapiro Snyder, Epstein Becker & Green
Lisa Suter, MD, Yale/CORE
David Teuscher, MD, President, AAOS
Jenna Williams-Bader, MPH, Assistant Director, NCQA (on behalf of Mathematica)
Adolph J. Yates Jr., MD, Member, Advocacy Council, AAHKS
Mike Zarski, Executive Director, AAHKS