

March 31, 2015

Acting Administrator Andy Slavitt  
Centers for Medicare & Medicaid Services (CMS)  
Department of Health and Human Services  
Attention: CMS-1600-P  
P.O. Box 8013  
Baltimore, MD 21244-8013

*Subject: CMS Request for Public Comments on development of clinical quality measures using data from electronic health records for use by providers in CMS quality reporting programs, in particular functional status assessments for total hip or knee replacements. Contract name "Electronic Clinical Quality Measures Development and Maintenance for Eligible Professionals. Contract # HHSM-500-2013-13011/HHSM-500-T0001.*

The American Joint Replacement Registry (AJRR) appreciates the opportunity to review and comment on the CMS initiative to evaluate the Electronic Clinical Quality Measures (eCQMs) titled "Functional Status Assessment and Improvement for Patients Who Received a Total Hip Replacement (THR) or Total Knee Replacement (TKR)".

The AJRR, as the nation's largest hip and knee arthroplasty registry, believes that these are vitally important measures for evaluating quality and appropriately gauging the impact of total joint replacement on the lives of our patients. We also commend the CMS that, rather than just relying on administrative data based measures, your organization is considering, for the first time, clinical/patient-reported measures to assess provider performance in THR and TKR.

We have had the opportunity to review the proposed measures and have the following comments.

### **Selection of factors for risk-adjustment**

We believe it is critically important to assess functional status in order to properly establish the value of THA and TKA. An equally critical component of functional status assessment is accounting for both medical and orthopaedic-related comorbidities as risk adjusters and/or risk modifiers. As part of this effort initiated by the CMS, we favor prioritization of the development of the risk adjustment models. Some of the data elements proposed by Mathematica are either currently collected or will be collected by

the AJRR. The AJRR is thus uniquely positioned to assist with the development of orthopaedic risk adjustment models. Table 1 (potential risk-adjustment variables) in the Mathematica document provides a comprehensive list of factors that influence the likelihood of complications or the longer-term outcomes after joint replacement surgery. We propose to extend the potential list of risk-adjustment variables to include other comorbidities previously shown to be associated with arthroplasty outcomes, e.g., metastatic cancer, pulmonary circulation disorders/COPD, renal disease, and heart failure (Bozic 2013; Bozic 2012; Huddleston 2009; Kurtz 2010; Singh 2011; Singh and Lewallen 2010). We also recognize that factors that influence clinical outcomes or attained functional status are not necessarily the same factors that influence improvement in functional outcomes, and that there are significant differences between THA and TKA. We therefore hope that the list of potential risk-adjustment variables in Table 1 is extended to include factors previously shown to be associated with functional status, pain and quality of life in THA and TKA, such as musculoskeletal conditions in other joints, back pain or surgical approach, and implant characteristics. One of the primary missions of the AJRR is to identify these factors, and we look forward to collaborating with the CMS in development of valid risk adjustment models.

### **Regarding Specific Outcome Measures**

We agree with the choice of non-proprietary scoring systems that measure general health (VR-12 and Patient Reported Outcomes Measurement Information System [PROMIS-10] as well as joint- and disease- specific outcomes (Hip disability and Osteoarthritis Outcome Score [HOOS] and Knee injury and Osteoarthritis Outcome Score [KOOS]).

- It appears from the documentation that any single measure would be sufficient for the measurement of functional outcomes. For example, for TKR, a PROMIS-10, VR-12 or KOOS score would be acceptable measures.

We feel that a comprehensive evaluation of the patient undergoing joint replacement should include BOTH a general health status measure (PROMIS-10 or VR-12) AND a joint-specific measure (HOOS or KOOS, depending on the joint). Global measures are helpful for comparing the effectiveness of joint replacement to interventions for other diseases and to other treatments for osteoarthritis. However, global measures alone may fail to capture joint-specific changes, which are vital to documenting how patients respond to total joint replacement. For example, the overall health of a woman with chronic obstructive pulmonary disease (COPD) may affect her ability to walk, but her successful knee replacement would tolerate walking if not for her COPD.

- When calculating scores to be used for comparison, we recommend using the Delta (change in score) as opposed to the absolute change. This will at least allow for better comparison until an appropriate risk adjustment model is calculated. This is not entirely clear in the "Improvement Notation Section".
- It appears that the recommended PROMs would be used in their entirety; e.g., the complete KOOS and all its subscales rather than, say, the 7-item KOOS— Physical Function Shortform (KOOS-PS) and/or the 9-item KOOS Pain subscale. A note at the bottom of page 6 under "Guidance" reads, "The intent of this measure is for a patient to have all applicable subscale scores for a particular tool (eg, the VR-12 physical health score and the mental health score if the patient received the VR-12)."

We are in favor of robust data collection, but also mindful of the burden survey collection places on both patients and physicians. We have some concern that comprehensive evaluations may lead to incomplete or hastily completed forms and thus not truly reflect patient outcomes (Singh 2010). Consideration could be given to the use of the short form HOOS— Physical Function Shortform (HOOS-PS) and KOOS-PS measures. Both of these have been validated in the literature and like the PROMIS-10 and VR-12 provide a relatively quick and accurate assessment of a patient's function following total joint arthroplasty. Alternatively, the 7-item HOOS-PS or KOOS-PS could be paired with its respective 9-item Pain subscale (16 items in all), rather than using the full-length HOOS/KOOS.

- Unless CMS recommends the use of outcomes measures that evaluate physical function *only*, (eg, KOOS-PS), we recommend that the name of this quality measure be modified to reflect the multiple domains captured by the recommended surveys. In addition to function, these include emotional and mental health, pain, social functioning, and more. Examples of alternative titles for this measure include:
  - Health Status Assessment
  - Health Impact Assessment
  - Disease Impact Assessment
  - Disease Status Assessment
  - Patient Impact Assessment
  - Patient Status Assessment

## METHODOLOGICAL COMMENTS

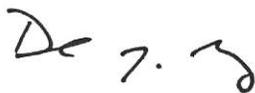
Since this represents the first CMS effort to use patient-reported outcome measures for performance assessment, we hope that CMS will devote sufficient resources to studying the issues related to overlap/interaction among measures, feasibility of data collection in various healthcare settings, appropriate risk adjustment methods, and fairness.

- It is unclear how the measures will be used to compare providers, and if they will be aggregated at the hospital level as well
- **Risk-adjustment issues:** Average change in functional status assessment certainly offers advantages to minimize the effects of unmeasured patient-level confounders if they do not vary over time. Yet selection bias and confounding may arise by time-varying factors, e.g., events that occur between pre-surgical and postsurgical assessments (e.g, surgery in other joints). The table of risk-adjustment variables is very comprehensive, but it remains to be seen which of these variables are worth considering as confounders for average change in functional status or simply stratification variables at the provider level. This concern also requires consideration of how/when the risk-adjustment variables will be measured; e.g., anytime, before surgery or both before and after surgery assessment. We believe that the change in functional status assessment score is distinct from other administrative data-based performance measures (RSRR, RSCR) and requires careful consideration of potential confounders at the patient and provider level. We also suggest, to the extent possible, avoidance of neighborhood-level measures.
- **Selection bias due to issues related to selective-reporting/under-reporting:** We understand that the CMS will use the measures to compare quality across providers and/or hospitals. Since the proposed measures are not collected universally, we believe an ongoing evaluation of selection bias is essential, both in terms of differences across hospitals as well as within hospitals. For example, patients who are less likely to benefit from surgery may be selectively excluded from the pool of patients with both pre- and post-surgery assessments, leaving a biased sample of patients with complete data (i.e., cherry-picking). Similarly, variation across hospitals in terms of data collection, scoring methodology, and risk adjustment are important methodological factors that may limit the utility of these measures.

- **Evaluation of response bias:** Although the analysis dataset will be limited to patients who provide both baseline and follow-up scores, we believe it is important to compare the scores and characteristics of responders and non-responders (those who complete only preoperative assessments) to assess potential for selection bias.
- **Clinical and technical feasibility:** Although all of the proposed measures are scientifically acceptable, we have concerns with respect to clinical and technical feasibility. So far, their use has been confined to the setting of small-scale research studies. Very few hospitals are currently collecting these measures as part of clinical practice. Therefore, the feasibility of implementation and reliability on a wider scale (e.g., small versus large volume hospitals) remains to be evaluated. This concern also encompasses most of the proposed clinical risk adjustment variables.
- **Alignment of measures:** During the development and testing phase, we believe it is important to assess the alignment of existing THA-TKA-related CMS measures (RSRR, RSCR) with the proposed functional assessment measures. Discrepancies between measures are likely and may result in confusion. If there are discrepancies, the reasons will need to be evaluated.

The AJRR appreciates this opportunity to provide input on the measure specifications and we look forward to continuing to work with CMS and providing guidance and input on issues applicable to registries, specifically Qualified Clinical Data Registries. If you have any questions regarding our comments, please do not hesitate to contact our Executive Director, Jeffrey P. Knezovich, CAE at (847) 430-5036 or at [knezovich@ajrr.net](mailto:knezovich@ajrr.net).

Sincerely,



Daniel J. Berry, MD  
Chairman  
American Joint Replacement Registry

cc: Jeffrey P. Knezovich, CAE, Executive Director  
David G. Lewallen, MD, Medical Director

## References

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