

August 11, 2010

Lein Han, Ph.D.
Government Task Leader
Centers for Medicare and Medicaid Services
7500 Security Boulevard, Mail Stop S3-02-01
Baltimore, MD 21244-1850

Laura Grosso, Ph.D.
Associate Research Scientist
Yale/Yale New Haven Hospital
Center for Outcomes Research and Evaluation (CORE)
1 Church Street, Suite 200
New Haven, CT 06510-3330
E-mail (hipknee@yale.edu)

Dear Dr. Han and Dr. Grosso,

The American Association of Hip and Knee Surgeons (AAHKS) appreciates this opportunity to comment on the two measures currently in development by the Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE): (1) Complications following Elective Total Hip or Knee Replacement (the Complications Measure); and (2) 30-Day All-Cause Readmission following Elective Total Hip or Knee Replacement (the Readmission Measure).

AAHKS is a national association of orthopedic surgeons formed to provide leadership in advocacy, education and research to achieve excellence in hip and knee patient care. AAHKS is committed to quality and improving the care of our patients. Our organization has recently decided to commit significant resources to the development of outpatient quality measures for arthroplasty patients. AAHKS also recognizes the need for quality measures regarding inpatient care and acknowledges the significant resources and effort which CMS has devoted to these proposed inpatient measures. Furthermore we appreciate the complexities of data collection and risk adjustment and understand the complexities of data collection. We support the concept of this project and want to partner with CMS to improve inpatient care for our arthroplasty patients. We do have a variety of concerns with the two proposed measures which will be delineated in this document. Of greatest concern is that these measures would have the unintended consequences of decreased patient access to arthroplasty for those at higher risk of complications and readmission.

I. Comments on Complications following Elective Total Hip or Knee Replacement

AAHKS has significant concerns regarding the risk adjustment proposed in the Complications Measure. Based on our understanding of the information presented in the Complication Measure, the risk adjustment in the draft would be best suited for determining risk of medical complications. The Complication Measure lists nine inclusion complications, including 1) acute myocardial infarction; 2) pneumonia; 3) sepsis/septicemia; 4) pulmonary embolism; 5) wound infection; 6) surgical site bleeding; 7) death; 8) periprosthetic joint infection; and 9) mechanical complication. We are also under the impression that using the proposed risk adjustment would account for less than 50% of variance seen in these complications and 30-day readmission rates.

Among these complications, half are directly related to the procedure (*i.e.*, surgical site bleeding, wound infection, periprosthetic joint infection, mechanical complications). However, there is no risk adjustment to capture patient variance relating to these surgical complications (*e.g.*, obesity, preoperative deformity, functional status, quality of bone). In particular obesity and preoperative deformity are risk factors well known to orthopedic surgeons. Arthroplasty on patients with significant hip or knee deformity is a more complex surgical procedure (more release of soft tissues; possible need for specialized implants and augments) and such patients are at higher risk of surgical complications. Furthermore, we know of no surgeon who prefers to operate on an obese patient as compared to a thin patient. Surgeons are well aware of the increased risk of wound healing problems, infection, thromboembolic complications and readmission in the obese patient. Without more robust risk adjustment access to arthroplasty for such patients will decrease. AAHKS believes that such patient and limb specific factors need to be included in the risk adjustment for these Complications Measures.

Although it is critical that risk adjustment consider patient-specific measures that influence surgical complications, there are currently no risk adjustment administrative codes related to surgical factors that influence outcome. AAHKS recognizes the difficulty of using non-administrative claims data to develop quality measures. Accordingly, we urge CMS to develop ICD-9 codes that would capture the very meaningful data relating to the complexity of the patient's orthopedic issues and deformity. AAHKS would like to help CMS develop ICD-9 codes to address these risk factors and believe such codes could be developed in a time-efficient manner. Although we agree that the measures currently listed in the Complication Measure could be immediately reported, we strongly recommend holding the more direct surgical complications measurements until the significance of obesity and limb specific factors is understood and taken into account for risk adjustment.

In addition to the risk adjustment factors discussed above, studies demonstrate that socioeconomic status is an independent predictor of outcomes.¹ AAHKS recognizes that the

¹ SooHoo NF, Lieberman JR, Ko CY, Zingmond DS. Factors predicting complication rates following total knee replacement. *J Bone Joint Surg Am.* 2006. 88(3):480-5.; SooHoo NF, Farnig E, Lieberman JR, Chambers L, Zingmond DS. Factors That Predict Short-term Complication Rates After Total Hip Arthroplasty. *Clin Orthop Rel Res* (2010) 468:2363-2371.

CORE group agreed to perform *subsequent* additional analysis to determine the potential impact of socioeconomic status on the hospital's risk standardized outcome rates and, if necessary, to consider adjusting the measure by social economic status. We strongly believe that risk adjustment should account for the patient's socioeconomic status and measures should not be released without such inclusion. In particular, we are concerned by contradictory nature of the statement in the Complication Measure that:

“Preliminary analyses demonstrated that although [socioeconomic status] is a significant predictor of adverse outcomes at the patient level, it does not affect overall hospital performance in the risk-adjustment complications model... Given our preliminary findings, we do not expect to stratify by such factors.”

We respectfully ask that if a factor (*i.e.*, socioeconomic status) is “a significant predictor of adverse outcomes,” what is the rationale demonstrating that it does not affect the Complication Measure model? If it has an affect on adverse outcomes, necessarily, it must be accounted for in the model. AAHKS requests a detailed explanation of the CORE group's rationale for this exclusion. We understand that the National Quality Forum (NQF) does not allow for risk adjustment for quality measures based on disparities in care. However the reality is that socioeconomic factors do influence the outcomes of elective THA/TKA. We have significant concerns that without proper risk adjustment of socioeconomic status, those patients with poor socioeconomic risk will have less access to care as the incentive will be for hospitals and surgeons to not perform elective surgery on these patients.

Lastly, AAHKS is concerned that variability in coding among providers will confound this data and inaccurately disadvantage certain providers based on factors not related to the quality of the care received by the patient. The variability in coding among providers has been documented in the medical literature.² While AAHKS recognizes that a certain degree of variability in coding among providers is inevitable, if CMS endeavors to use this data in public reporting and Medicare's pay-for-reporting program, it is critical that this variability be accounted for in some manner. This could range from provider outreach and education to studying the variability more closely for coding these complications and using this information to inform whether differences observed via the Complication Measure accurately reflect the quality of care.

II. Comments on 30-Day All-Cause Readmission following Elective Total Hip or Knee Replacement

AAHKS is concerned that the Readmission Measure endeavors to take too broad a sweep of data to produce meaningful results. We understand that the measure will look to “all cause” readmissions. However, it is entirely unclear how such a broad metric bears any real nexus to a specific population of patients receiving a particular treatment (*i.e.*, elective total hip

² Sony T, Skinner J et al. Regional Variations in Diagnostic Practices; N Engl J Med. 2010 Jul 1;363(1):45-53. Epub 2010 May 12.

or knee replacement). Much of the hospital care that could affect readmission rates is generic to any type of elective surgery. By narrowing the population to those patients receiving elective total hip and knee replacement, the Readmission Measure unnecessarily introduces population-specific bias into the data. If YNHHS/CORE is interested in the quality of care for patients receiving elective total hip and knee replacement, it should endeavor to study readmissions that are related to the specific procedure. If YNHHS/CORE is interested in the overall quality of care received by a patient following elective surgery, the patient population should be substantially broadened to include large groups of like procedures to contribute to the measure. While an "all cause" approach presents a relatively easy way to approach the development of a quality measure, it does a disservice to the ultimate goal of the project; that is, to produce a real snapshot of the quality of care received by the patient. There must be some nexus between the readmission and the care received at the hospital for the particular procedure.

In addition to introducing unnecessary confounders into the project, AAHKS also questions the utility of the data proposed by the Readmission Measure. Even if the data were reflective of quality of care, the failure to collect specific information that are related to hip and knee arthroplasty results in hospitals not receiving feedback sufficiently specific to improve practices. Improvement of the quality of care is the goal vis-à-vis quality measures, and we have concerns that this generic approach does not further that goal.

In either case, we request that CMS carefully study and account for the influence of such confounding factors such as obesity, preoperative limb deformity and socioeconomic status on the rate of readmission, and consider developing some exclusionary criteria for injuries clearly unrelated to the prior care (*e.g.*, automobile accidents).

III. American Joint Replacement Registry

AAHKA strongly recommends that CMS specify that participation in the American Joint Replacement Registry (AJRR) be a quality measure for THA/TKA. The AJRR was recently founded and is an independent board formed to operate the joint registry. Provider participation in this registry is critical to improving outcomes, because the joint registry will allow the tracking of implant performance and identify problems, if any exist, with specific products. The correct time to enter a patient in the joint registry is after the index procedure; therefore, including participation in the joint registry as a hospital quality metric is appropriate. AAHKS has been a supporter of AJRR from its onset, and feels very strongly the joint registry is essential to decreasing the revision burden. A quality measure directed to participation in the AJRR would greatly enhance the data on suboptimal clinical outcomes, and further CMS' goal to enhance the quality of care for Medicare beneficiaries. We urge CMS to consider this; data from countries with joint registries show a decrease in the revision burden. This would have a significant impact on quality of care for Americans and decrease healthcare costs.

IV. Closing Thoughts

AAHKS expresses its appreciation to YNHHS/CORE and CMS for its full consideration of these comments. AAHKS looks forward to working with YNHHS/CORE and CMS to further refine these measures and develop additional ICD-9 codes to help make the data more robust and the measures more meaningful. Finally, we would be pleased to discuss these comments with you in greater detail. Please feel free contact me at occonnor.mary@mayo.edu or 904-953-0713.

Sincerely,



Mary I. O'Connor MD
President
American Association of Hip and Knee Surgeons

cc: Robert A. Hall, MEd, CAE, Executive Director, AAHKS

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