

PUBLIC COMMENT SUMMARY REPORT

Project Title: Hospital-Level 90-Day Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) for a Combined Inpatient (IP) and Outpatient (OP) Setting Measure

Dates:

The Call for Public Comment ran from September 1, 2022 to September 30, 2022.

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) contracted Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (CORE) to develop a Hospital-Level 90-Day Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) for a Combined Inpatient (IP) and Outpatient (OP) Setting Measure. The contract name is Development, Reevaluation, and Implementation of Outcome/Efficiency Measures for Hospital and Eligible Clinicians, Option Period 3. The contract number is HHSM-75FCMC18D0042, Task Order Number HHSM-75FCMC19F0001. As part of its measure development process, CORE requested interested parties submit comments on the candidate or concept measures that may be suitable for this project. This measure is a re-specification of an existing claims-based measure, Hospital-level RSCR Following THA and/or TKA, NQF 1550, to include patients undergoing elective primary THA/TKA procedures in hospital outpatient settings, for potential use in an episode payment model (EPM). The goal of the measure is to estimate a RSCR for elective primary THA and TKA procedures performed on Medicare fee-for-service (FFS) beneficiaries 65 years and older in hospital IP and OP settings.

Information About the Comments Received:

The measure developer solicited public comments by email notification to CMS listserv groups, email to relevant stakeholders and organizations, and posting on the CMS Public Comment website.

We received three responses on this topic. Specifically, from two medical associations and one medical society (American Medical Association [AMA], American Association of Hip and Knee Surgeons [AAHKS], American Society of Anesthesiologists [ASA]).

Stakeholder Comments

General Stakeholder Comments:

We received comments on various aspects of the measure. Comments focused on risk adjustment, data sources, reliability and validity, social determinants of health, and hospital setting.

Most commenters were supportive of the development of a measure that expands monitoring of complication outcomes following elective primary THA and/or TKA to the hospital outpatient setting.

Measure-Specific Stakeholder Comments:

General

There were two general comments in support of the measure.

- One commenter expressed support for measures that promote quality of care in order to improve patient outcomes, as well as this specific measure's expansion into the outpatient setting.
- One commenter expressed support for the measure as it includes patient encounters from settings previously excluded from these procedures, and that the measure will encourage care coordination and communication across specialists.

Response: We appreciate the commenters' support for the expansion of this measure to the outpatient setting. We also appreciate the commenters' support for the inclusion of encounters that had previously been excluded from measurement. We agree that assessing both inpatient and outpatient procedures will encourage coordination and communication across specialists and across the continuum of care.

Social Determinants of Health (SDOH)

There were three comments about the use of SDOH in the measure.

- One commenter supported the inclusion of race, socioeconomic, and additional SDOH factors in the measure. The commenter expressed concern that the aggregation of data may not best reflect the differences that may exist in individual settings and encouraged continued examination of SDOH in order to prevent unintended consequences on patient care.

Response: We appreciate the commenter's support for the inclusion of race, socioeconomic, and additional SDOH in the measure, as well as the commenter's feedback regarding the aggregation of data. We understand that this measure is assessing outcomes for an elective procedure with known disparities. We will continue to monitor the impact of SDOH and differences by setting moving forward to avoid potential unintended consequences in patient care.

- One commenter expressed concern over continued testing of social risk factors after assessment of clinical and demographic risk factors. The commenter suggested revision of methods used to test the data in order to elucidate more information and evaluate clinical factors in conjunction with social risk factors.

Response: We appreciate the commenter's feedback. CMS will carefully consider this feedback during potential future measure reevaluation. We note that the goal of outcomes measurement is to identify variation in the quality of health care so that hospitals can implement interventions to help improve patient outcomes. Variation in quality associated with SDOH may be indicative of differences in the quality of the care provided to vulnerable populations, so risk adjusting for these factors would obscure these disparities in care.

- One commenter recognized the opportunity this measure presents to account for race, ethnicity, and other social risk factors that can contribute to complications and that collection

and usage of data from this measure can contribute to addressing health care disparities among total joint replacement patients.

Response: We appreciate the commenter's feedback and recognition of the opportunity this measure will provide. We agree that the collection and usage of data from this measure can be used to address health care disparities among THA/TKA patients.

Setting

- One commenter requested more specific guidance of the determination of outpatient versus inpatient status.

Response: We appreciate the commenter's feedback. We will share the commenter's request for guidance with CMS.

Risk Adjustment

Two commenters expressed concern over Present on Admission (POA) codes.

- One commenter stated that the absence of POA codes on OP patients may impact the risk standardization because we do not know the impact of the absence of POA codes on the measure.
- One commenter recognized that the POA indicators are limited in outpatients claims but encouraged CMS to assess if this lack of information negatively impacts the performance of the measure.

Response: We appreciate the commenters' feedback. We recognized and fully assessed the potential impact of the absence of POA codes on OP claims throughout measure development and testing. We note no negative impacts were identified. We will continue to monitor the potential impact of the absence of POA coding has on measure performance during future measure reevaluation.

Data Sources

- One commenter expressed concern that the timeframe for testing this measure was a period mostly impacted by the COVID-19 pandemic and urged CMS to avoid using those data as they are not representative of typical care outside of a public health emergency.

Response: We appreciate the commenter's feedback. We assessed the impact of the COVID-19 pandemic on measure development. Empiric analyses and expert input both suggest that the impact was not significant, likely because THA and TKA are elective procedures. However, we will continue to explore any potential impact of COVID-19.

Volume Thresholds

- One commenter encouraged CMS to set the case minimum for the measure to 85 or greater to ensure that the minimum reliability is above 0.7.

Response: We appreciate the commenter's feedback. CMS will consider this feedback during potential future implementation planning.

Patient Selection

- One commenter asked for reconsideration of how some patients' conditions are assessed and measured; the commenter believes that, depending on patient selection criteria, there may be some issues related to complications across institutions. Patient selection criteria across different settings may have a wide range of acceptable limits, for example patients with diabetes, COPD, or CAD.

Response: We appreciate the commenter's feedback. CMS will consider this feedback during potential future implementation planning and measure monitoring.

Preliminary Recommendations

We plan to incorporate the recommendations received during public comment into the development and future implementation of our measure. Specifically:

- We will continue to assess the impact of SDOH during future measure reevaluation.
- We will continue to examine the contribution of SDOH and other factors on the measure and evaluate potential unintended consequences during future measure reevaluation.
- We will continue to assess the impact of the absence of POA coding on OP claims.
- We will continue to evaluate the impact of case minimums and minimum reliability thresholds during future measure reevaluation.
- We will ensure that CMS is aware of the public input received for any future implementation planning, including the impact of SDOH, the absence of OP POA coding, approaches to setting minimum case volume thresholds and patient selection criteria.

Overall Analysis of the Comments and Recommendations

The feedback on the measure was positive. Commenters identified several potential concerns related to SDOH, POA coding, and minimum reliability thresholds that we will address through future measure implementation planning and reevaluation. Technical Expert Panel (TEP) members reviewed the public comments and supported the recommendations, particularly noting the importance of minimum reliability thresholds and the use of SDOH/social risk factor data as a tool for care planning and to reduce the impact of these factors on THA/TKA outcomes (see Appendix A for full comment).

Public Comment Verbatim Report

Date Posted/ Received	Name, Credentials, and Organization of Commenter	Type of Organization*	Measure Set or Measure	Text of Comments
September 30, 2022	Bryan D. Springer, MD, President; American Association of Hip and Knee Surgeons	Medical associations and societies	Hospital-Level 90-Day Risk- Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) for a Combined Inpatient (IP) and Outpatient (OP) Setting Measure	<p>The American Association of Hip and Knee Surgeons (AAHKS) appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on Development of a Hospital-Level 90-Day Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) for a Combined Inpatient (IP) and Outpatient (OP) Setting Measure. AAHKS continues to support measures promoting quality of care in order to improve patient outcomes and AAHKS has supported the Hospital-Level 90-Day Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) measure and the recently proposed expansion to include 26 additional complication codes. We are generally supportive of the expansion of the Hospital-Level 90-Day Risk- RSCR Following Elective Primary THA and/or TKA for a Combined Inpatient (IP) and Outpatient (OP) Setting Measure, but we have several areas of concern regarding the combining of IP and OP into a single measure. AAHKS believes that applying quality measures to all THA/TKA patients irrespective of site of service is an important goal.</p> <p>We continue to believe that CMS should provide more specific guidance for the determination of IP versus OP status. We are unaware of what unintended consequences the removal of TKA/THA from the Inpatient Only (IPO) list has had on RSCR and believe that further clarification and guidance will ensure consistency in the claims data which are used as the basis for the measure. Additionally, because of the absence of “present on admission” (POA) diagnoses in OP patients, we believe that this difference in data may impact the risk standardization as we do not know the impact of the absence of POA diagnoses on the measure.</p> <p>As expressed in the Technical Expert Panel report, we also support the inclusion of race, socioeconomic, and additional social determinants of health (SDOH) factors in the measure. The data presented in the appendix of the Draft Measure Methodology Report demonstrate differences in RSCR for hospitals based on low/high percentage of Black patients, low/high percentage of other non-White patients, and patients with dual-eligibility. While there was near perfect</p>

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(cont'd)	(cont'd)	(cont'd)	(cont'd)	<p>correlation of RSCR with/without race, with/without adjusting for dual eligibility, and with/without adjusting for the Agency for Healthcare Quality and Research Socioeconomic Status Index (ASI), we remain concerned that this aggregation of the data does not best reflect differences that may exist in individual hospitals/communities/regions and CMS should continue to examine the contribution of these and other SDOH factors in the measure. Exclusion of such factors may have unintended consequences on patient access and care that must be prevented.</p> <p>Thank you again for the opportunity to provide comments on this measure. If you have any questions, please contact Michael Zarski at mzarski@aahks.org or Joshua Kerr at jkerr@aahks.org.</p>
September 30, 2022	James L. Madara, MD; American Medical Association	Medical associations and societies	Hospital-Level 90-Day Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) for a Combined Inpatient (IP) and Outpatient (OP) Setting Measure	<p>Dear Dr. Wallace:</p> <p>On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Hospital-Level 90-Day Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) for a Combined Inpatient (IP) and Outpatient (OP) Setting Measure.¹ The AMA strongly believes that while it is useful to understand the rate of complications for patients following THA/TKA procedures particularly for quality improvement, measures used in accountability programs, such as these, must be actionable to ensure that improvements can be driven by those held accountable and proven to be reliable and valid at the levels to which the measure is attributed.</p> <p><i>Data Sources</i></p> <p>We note that the timeframe for testing this measure was April 1, 2018, through March 31, 2021, a period mostly impacted by the COVID-19 pandemic. Since these data are likely not representative of typical care outside of a public health emergency (PHE), we urge CMS to avoid using these data when testing any measure. We strongly believe that our questions and concerns must be addressed using data from other years. Several conclusions made regarding the absence of Present on Admission (POA) indicators on outpatient claims, reliability, and validity of the measure could be flawed due to the use of data produced during the PHE.</p> <p><i>Volume Thresholds Required for Specific Signal-to-Noise Reliability Targets</i></p>

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(cont'd)	(cont'd)	(cont'd)	(cont'd)	<p>The AMA encourages the CMS to set the case minimum for this measure at 85 or greater as it ensures that the minimum reliability result is above 0.7, which we believe is necessary to ensure adequate reliability across all reporting hospitals. While the number of hospitals to which this measure would be attributed would decrease as outlined in Table 14 of the Methodology Report, CMS will still be able to include 95.5percent of all procedures and 93.8percent of all complications if this higher volume was used.</p> <p><i>Risk Adjustment</i></p> <p>While we understand the current limitation with the absence of POA indicators on outpatient claims and testing demonstrated that this additional detail may not be necessarily warranted at this time, we encourage CMS to continue to assess whether the lack of this information does not negatively impact the performance of this measure using a different timeframe outside of the PHE as well as in the future. Even though current data demonstrate that individuals receiving these procedures in the outpatient setting are generally younger and healthier, there is the potential for these characteristics to change, particularly if the emphasis is to reduce costs and leads to older and/or higher risk individuals receiving these surgeries outside of the inpatient setting, regardless of whether it is clinically appropriate. This unintended consequence must be monitored to ensure that patient safety is not compromised.</p> <p>We remain concerned that CMS continues to test social risk factors after assessment of clinical and demographic risk factors and it is unclear why this multi-step approach is preferable. On review of the Evaluation of the NQF Trial Period for Risk Adjustment for Social Risk Factors report, it is clear that the approaches to testing these data should be revised to strategies such as multi-level models or testing of social factors prior to clinical factors and that as access to new data becomes available, it may elucidate more differences that are unrelated to factors within a hospital's or physician's control (NQF, 2017). Additional testing is needed to evaluate clinical factors in conjunction with social risk factors; as opposed to the current approach that prioritizes clinical factors. We also encourage CMS to consider whether any of the social risk factors such as dual eligibility or the AHRQ SES Index score should be included regardless of whether other methods to address inequities in care are implemented such as at a program level,</p>

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(cont'd)	(cont'd)	(cont'd)	(cont'd)	<p>particularly since performance for various hospitals varied as the proportion of individuals who are more disadvantaged increased.</p> <p>The AMA urges CMS to address all of these comments and concerns prior to implementing this expanded measure in any program.</p> <p>The AMA appreciates the opportunity to provide input and thanks you for considering our recommendations. If you have any questions, please feel free to contact Margaret Garikes, Vice President, Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.</p>
September 30, 2022	Randall M Clark, MD, FASA, President; American Society of Anesthesiologists	Medical associations and societies	Hospital-Level 90-Day Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) for a Combined Inpatient (IP) and Outpatient (OP) Setting Measure	<p>On behalf of the 55,000 members of the American Society of Anesthesiologists® (ASA), I am pleased to offer feedback and comments on the Yale New Haven Health Services Corporation – Center for Outcomes Research & Evaluation (YNHHSC/CORE) Development of a Hospital-Level 90-Day Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) for a Combined Inpatient (IP) and Outpatient (OP) Setting Measure. We support the development of this combined inpatient and outpatient setting measure as it will include patient encounters from settings that were otherwise previously excluded from these procedures. Physician anesthesiologists are central to preserving patient safety and ensuring patient quality during the perioperative episode, especially as more surgeries like TKA and THA are scheduled in outpatient settings. As such, the inclusion of care settings outside of the hospital, like ambulatory surgery centers, and hospital outpatient departments will aid in reducing the burden on an already stretched healthcare system. Additionally, the use of this risk-stratified measure will better guide physicians on how to determine the most appropriate postoperative course of care. Finally, we recognize that this measure presents an opportunity to account for race, ethnicity, and social risk factors that can contribute to complications following total joint arthroplasty procedures. By collecting and using data from this measure, anesthesiologists will have information available to play a significant role in addressing health care disparities among total joint replacement patients. We ask that Yale – CORE reconsider how some patient conditions are assessed and measured. Depending on patient selection criteria, we perceive some issues related to complications across institutions, especially</p>

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(cont'd)	(cont'd)	(cont'd)	(cont'd)	<p>when comparing tertiary care centers versus community hospitals. In these scenarios, Yale – CORE should consider how co-morbidities included in the measure, such as diabetes, chronic obstructive pulmonary disease (COPD), and coronary artery disease (CAD) are variables that might impact patient outcomes and facility scoring. Patient selection criteria for hospital versus ambulatory or outpatient settings for procedures may have a wide range in acceptable limits for patient with diabetes, COPD, or CAD. A diabetes mellitus control factor within the measure for a patient with a hemoglobin A1c of 6% versus a patient with a hemoglobin A1c of 10%, COPD patients on home oxygen as opposed to managed only with inhalers, or CAD patients stented with preserved function versus not amenable to intervention with depressed ejection fraction are just a few examples of differences within patient populations. Commonly, higher risk patients are referred to hospitals where subsequent procedures are frequently performed which leads to possible complication multiplier effect for large institutions. Yale – CORE should ensure that their testing does not unfairly favor or penalize one facility over the other.</p> <p>ASA believes that this measure will encourage care coordination and communication across specialists. Although we expressed some concerns with unintended consequences of the measure above, we nonetheless feel anesthesiologists may have a potential solution to mitigate such consequences. The ASA Perioperative Surgical Home model is an approach that lends itself to a cost-effective way to provide value for these encounters. This approach leads to improved operational efficiencies, decreased resource utilization, a reduction in length of stay and readmission, and a decrease in complications and mortality-resulting in a better patient experience of care. This is accomplished through various levels of risk-assessment, stakeholder engagement, and patient education. These efforts by anesthesiologists can be enhanced by understanding how this proposed THA and TKA measure performs in their hospital and ambulatory settings and making appropriate adjustments to the perioperative team’s care coordination, quality, and safety activities.</p> <p>This measure is also an important step in creating a better understanding among health care professionals, including anesthesiologists, on how quality measures can better capture health disparities, clinical outcomes, and quality-of-life measures for patients. Recent</p>

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(cont'd)	(cont'd)	(cont'd)	(cont'd)	<p>literature and studies have allowed the health care community to better understand how individual physicians and health care professionals can reduce disparities, improve access to care, and ultimately improving health outcomes. For anesthesiologists, this has implications for nearly every surgical, therapeutic, and diagnostic procedure, including THA and TKA. Although race and ethnicity data are oftentimes self-reported and hospital- and clinician-level data may suffer from small sample sizes, we nonetheless support, when data is available, the stratification of measures by race and ethnicity. However, data is only actionable if a physicians and others have access to and plan to improve their care based upon available data. Accounting for race, ethnicity, and/or social risk factors as included in the measure, should be shared with anesthesiologists in a transparent fashion with an eye toward quality improvement.</p> <p>ASA appreciates the re-specification of this measure to include HOPDs and ASCs. With consideration of our comments on patient selection, we believe the measure will aid ultimately improve our understanding of patient complications within different settings and identify disparities that may not have otherwise been identified. Thank you for your consideration of our comments. We welcome the opportunity to speak with you further about our feedback in the future. Please contact Claire Ostarello, ASA Senior Quality and Regulatory Affairs Associate (c.ostarello@asahq.org), for questions or further information.</p>

Appendix A. Verbatim Technical Expert Panel Feedback

TEP Member 1: Thank you for sharing the public comments that were received. I certainly appreciate that these three practitioner groups provided their feedback. My feedback primarily revolves around the comments about Social Determinants of Health. The recent COVID-19 pandemic has highlighted the ongoing existence of factors that contribute to healthy outcomes. While I appreciate there are likely ongoing issues w/ data collection for social risk factors, it seems pretty clear that these SDOH/SRF are impactful to patient care and outcomes.

I have some concern over the comments about "factors within a hospital's or physician's control." I would point out that data elements related to SDOH are more than data elements to be reported on to see the impact on outcomes, but rather are also presented with data analysis to better determine appropriate planning, and course of care. The awareness to the fact that SDOH have an impact on outcomes can be addressed even prior to surgery. THA/TKA can be a very "protocol" driven procedure, especially in terms of post-operative care, but by bringing in this awareness to SDOH surgeons/hospitals can better plan for necessary care and resource utilization. Consider 2 patients planning for a TKA, same hospital, same surgeon, similar co-morbidities but patient a) is affluent, has support at home from a spouse whom if working can take time off, has readily available transportation from the spouse for appointments or outpatient therapy VS patient b) is dual-eligible, lives in subsidized housing, may also have a spouse but is u/a to take time off of work, uses public transportation to go to appointments and therefore can't readily make appointments or outpatient therapy. Planning for care after the procedure for patient A vs patient B will likely look significantly different by having the awareness of their differences that may lead to health inequities but are within a surgeon's and/or hospital's control to provide the resources necessary to reduce potential complications that may be brought about by the SDOH differences. Ultimately, while these issues may not be in their control, the surgeon/hospital can deliver care that addresses the issues.