Summary Report of Technical Expert Panel (TEP) Meeting October 2, 2018: Measure of Hospital-Level 90-day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Isolated Coronary Artery Bypass Graft (CABG) Surgery

November 2, 2018

Prepared by:
Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (YNHHSC/CORE)

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The materials within this document do not represent final measure specifications for the Hospital-Level (All-Cause) 90-day CABG Mortality Measure

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Background

The Centers for Medicare & Medicaid Services (CMS) has contracted with Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (CORE) to develop quality measures of hospital performance. The contract name is Development, Reevaluation, and Implementation of Outcome/Efficiency Measures for Hospital and Eligible Clinicians. The contract number is HHSM-500-2013-13018I, Task Order HHSM-500-T0001. Under this contract, CORE is developing a hospital-level 90-Day, all-cause, risk-standardized mortality rate (RSMR) measure following isolated coronary artery bypass graft (CABG) surgery intended for potential use with various Centers for Medicare and Medicaid Innovation (CMMI) payment models, as appropriate. The primary goal is to re-specify an existing claims-based outcome measure, 30-day Risk-Standardized Mortality for Isolated CABG Surgery, for use across a range of payment models. To accomplish this, CORE will change the current measure that captures death occurring within 30 days after surgery to capture death up to 90 days after surgery.

CORE is obtaining expert and stakeholder input on the proposed measure. The CORE measure team is comprised of experts in quality outcomes measurement and measure development. As is standard with all measure development processes, CORE has convened a technical expert panel (TEP) of clinicians, patient advocates, and other stakeholders. Collectively, the TEP members brought expertise in performance measurement, quality and patient safety, and coding and informatics.

This report summarizes the feedback and recommendations received from the TEP during the first and second TEP meeting. The report will be updated to include feedback and recommendations from future meetings as they occur.

CORE Measure Development Team

Dr. Khurram Nasir is leading the measure development team. Dr. Nasir is a Clinical Investigator, cardiologist and Associate Professor of Cardiovascular Medicine at Yale School of Medicine. Dr. Nasir is also the Director of Population Health and Health System Improvement and Research at CORE. The remainder of the CORE internal measure development team provides a range of expertise in outcome measure development, health services research, clinical medicine, statistics, and measurement methodology. See Appendix A for the full list of members for the CORE measure development team.

The Technical Expert Panel

In alignment with the CMS's Measures Management System (MMS), and under the guidance of CMS, CORE held a 30-day public call for nominations and convened a TEP for the development of the 90-day CABG Mortality Measure. CORE solicited potential TEP members via emails to individuals and organizations recommended by the measure development team and stakeholder groups, as well as email blasts sent to CMS physician and hospital email listservs, and through a posting on CMS's website. The TEP is composed of 12 members, listed in Table 1.

The role of the TEP is to provide feedback and recommendations on key methodological and clinical decisions. The appointment term for the TEP is from April 2018 to March 2019.

Specific Responsibilities of the TEP Members

- Complete and submit all nomination materials, including the TEP Nomination Form, statement of interest, and curriculum vitae.
- Review background materials provided by CORE prior to each TEP meeting.
- Participate in TEP conference calls.
- Provide input on key clinical and methodological decisions.
- Provide feedback to CORE on key policy or other non-technical issues.
- Review the TEP summary report prior to public release.
- Be available to discuss recommendations following submission of the measures to CMS.

Table 1. TEP Member Name, Affiliation, and Location

Name	Title	Organization, Location
Vinay Badhwar, MD, FACS, FACC	Chair, Public Reporting Task Force, STS; Professor & Chair, Department of Cardiovascular and Thoracic Surgery, West Virginia University	The Society of Thoracic Surgeons (STS) and West Virginia University, Morgantown, WV
Araceli Carrera, DNP, RN, NP-C	Cardiothoracic Nurse Practitioner	New York Presbyterian Hospital Queens, Flushing, NY
Lee Fleisher, MD	Professor of Medicine; Chair of Anesthesiology and Critical Care	Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA
Renante Ignacio, MD, FACP, AGSF, CMD	Medical Director	AMDA – The Society for Post-Acute and Long-Term Care Medicine, Columbia, MD
Alexander Iribarne, MD, MS	Assistant Professor, Surgery, Geisel School of Medicine at Dartmouth; Assistant Professor, Health Policy and Clinical Practice, The Dartmouth Institute; Cardiac Surgeon; Director of Cardiac Surgical Research	Geisel School of Medicine at Dartmouth and Dartmouth-Hitchcock Medical Center, Lebanon, NH
Cristina Lisa	Patient	Ringwood, NJ
Jeffrey Jacobs, MD	Chair, Workforce on National Databases, STS; Professor, Surgery & Pediatrics, Johns Hopkins University; Deputy Director, Johns Hopkins All Children's Heart Institute	The Society of Thoracic Surgeons and Johns Hopkins All Children's Heart Institute, Saint Petersburg, FL and Johns Hopkins University, Baltimore, MD

Name	Title	Organization, Location
Michael Mack, MD, FACC	Cardiothoracic Surgeon; Medical Director of Cardiothoracic Surgery	Baylor Scott & White Health, Plano, TX
Sean O'Brien, MS, PhD	Statistical Director, STS; Associate Professor, Biostatistics, Duke University	The Society of Thoracic Surgeons and Duke University, Durham, NC
Lawrence Sadwin	Patient	Warren, RI
David Shahian, MD	Chair, Council of Quality, Research & Patient Safety, STS; Vice President of Massachusetts General Hospital Center for Quality and Safety; Professor, Surgery, Harvard University	The Society of Thoracic Surgeons and Massachusetts General Hospital Center for Quality and Safety, Boston, MA and Harvard University, Cambridge, MA
Joyce Sinclair	Family Caregiver	Waldwick, NJ

Technical Expert Panel Meetings

CORE held its first TEP meeting on May 21, 2018 and its second TEP meeting on October 2, 2018 (see Appendix B for the TEP meeting schedule). This summary report contains summaries of both the May 2018 and October 2, 2018 TEP meetings.

TEP meetings follow a structured format consisting of the presentation of key issues identified during measure development, as well as CORE's proposed approaches to addressing the issues, followed by an open discussion of these issues by the TEP members.

First Technical Expert Panel Meeting Overview (May 21, 2018)

Prior to the first TEP meeting, TEP members received detailed meeting materials outlining the existing 30-day measure, 90-day mortality measure concept and development approach, as well as an introduction to the risk model development.

During the first TEP meeting, CORE solicited feedback from the TEP about the overall measure concept, measure development approach, and risk model development. TEP members provided general support for a measure of 90-day mortality that focuses on isolated CABG procedures pending further risk variable analyses. TEP members felt that the change to a 90-day outcome period required further exploration to ensure adequate case mix adjustment.

The following bullets represent a **high-level summary** of what was discussed during the first TEP meeting. For further details, please see Appendix D.

Review of TEP Role and Charter

- CORE Presentation of the TEP Charter to TEP Members
    - CORE reviewed the TEP Charter, which included TEP's objectives and member responsibilities.
- TEP Feedback
    - The TEP approved the TEP Charter without modifications.

Measure Concept and Overview

- CORE Presentation to the TEP on the 90-Day CABG Mortality Measure Concept and Development
    - CORE provided a brief overview of the data source, measure outcome, measure cohort, and risk adjustment model of the existing 30-day CABG mortality measure. CORE discussed the rationale and goals of re-specifying the 30-day mortality measure to a 90-day outcome period.
    - CORE reviewed the measure concept for the 90-day CABG mortality measure, which included capturing the effects of perioperative care beyond 30 days, the effects of the post-discharge care, and the impact of cost reductions on patient care.

- CORE outlined the approach to the measure development. CORE noted that the 30-day CABG framework will be used to extend the outcome period to 90-days, reselect risk variables, and assess model performance, measure reliability, and measure validity.

- TEP Feedback
  - Several TEP members noted that re-specification to a 90-day measurement period would help analyze the post-discharge period.
  - Several TEP members discussed the robustness of claims variables as compared to clinical variables in a registry database.
  - During the discussion, similar performance in outcome predictions between STS registry data and CORE CABG readmission measure was noted.
  - One TEP member raised the concern of whether deaths occurring in the extended time frame, especially from 30- to 90-day time period might be less likely due to the original CABG surgery.
  - One TEP member asked if Medicare Advantage plan data were included in the claims data. CORE noted that the claims data only incorporates Medicare fee-for-service (FFS) beneficiaries.
  - TEP members highlighted that certain conditions, social risk factors, and utilization of services, such as rehabilitation, will have greater impact on mortality as the time frame is extended further beyond the index admission and existing 30-day time frame, and emphasized the importance of reviewing these variables.
  - Some TEP members asked whether the new model developed will be cross validated in other cohorts such as the STS registry.

- Summary
  - While some TEP members raised concerns regarding potential limitation of claims-based measures to accurately capture clinical risk and severity, overall the TEP members were supportive of the measure concept (90-day CABG, all-cause mortality), the current measure development approach, and the measure's potential value as a balancing measure for use in alternative payment programs to ensure patient outcomes are not adversely impacted by cost reductions.

Risk Model Development and Candidate Risk Variables Overview

- CORE Presentation to the TEP on Risk Model Development and Candidate Variables
  - CORE reviewed the approach to identifying candidate risk variables derived from the index admissions, inpatient Part A and Part B physician data from any admission in the 12 months prior to admission, and outpatient hospital care.
  - CORE explained that risk model development will examine Condition Categories (CCs) to account for clinical risks. CORE noted which social risk factors are available in the claims data, including the proportion of African-American

patients, low Agency for Healthcare Research & Quality socioeconomic score index (AHRQ SES), and dual eligibility for Medicare and Medicaid.

- TEP Feedback
    - Several TEP members highlighted the importance of social determinants of health (such as socioeconomic factors, dual eligibility, distance to the hospital performing the index CABG) and conditions associated with frailty which would likely be associated with a higher risk of all-cause mortality in the proposed timeframe of 90-days post isolated CABG.
    - Two TEP members encouraged CORE to explore the impact of the urgency of surgery; the TEP recommend various approaches, including the timing of procedure, presence or absence of shock, and pre-operative use of interventions such as percutaneous coronary interventions (PCIs) and intra-aortic balloon pumps (IABP) for circulatory support.
    - One TEP member recommended looking at a non-parsimonious model and comparing the existing 30-day CABG mortality measure risk model to include as many risk variables as possible and measure the overlap between the 30-day and 90-day measures.
    - TEP members provided suggestions for additional candidate risk variables for consideration and suggested additional analyses to help understand the relationship of risk variables to the outcome.
- Summary
    - TEP members generally supported the risk model development and the approach to identifying candidate risk variables, with additional suggestions. CORE agreed to additionally investigate the impact of social risk factors, frailty as a variable in the risk model, as well as carefully assessing claims-based variables that may potentially capture urgency of the CABG procedure (See Appendix D).

A detailed summary of TEP Meeting 1 is available in Appendix D.

Second Technical Expert Panel Meeting Overview (October 2, 2018)

Prior to the first TEP meeting, TEP members received detailed meeting materials outlining the existing 30-day measure, 90-day mortality development approach, risk model and measure results, reliability and validity testing, social risk analyses, and readmission analyses.

During the second TEP meeting, CORE solicited feedback from the TEP about the overall 90-day CABG measure results, testing results, and risk model performance. We also received TEP input on the impact of social risks on the 90-day CABG mortality measure results and additional analyses based upon prior TEP input. TEP members provided general support for a measure of 90-day CABG mortality risk model development approach. TEP members requested additional opportunity for feedback to reach consensus on the social risk and readmission analyses questions. CORE responded by incorporating additional questions into the TEP face validity survey administered after the meeting.

The following bullets represent a **high-level summary** of what was discussed during the second TEP meeting. For further details, please see Appendix D.

Approach to 90-Day CABG Mortality Measure Development Overview

- CORE presentation to the TEP on the 90-Day CABG Mortality Measure Development
    - CORE reiterated the approach to the measure development. CORE recapped that the 30-day CABG framework was used to extend the outcome period to 90-days; reselect risk variables; and assess model performance, measure reliability, and measure validity.

Risk Model and Measure Results Overview

- CORE presentation to the TEP on the 90-day CABG mortality measure risk model and measure results
    - CORE provided an overview of the risk model development for the 90-day CABG mortality measure.
    - CORE presented the final risk model variables, adding that specific variables with clinical relevance, such as markers of frailty, were forced into the model. The logistic regression results had similar risk factor distribution and odds ratios in both the Development Sample and Validation Sample.
    - CORE reviewed the distribution of the hospital-level RSMRs in the Validation Sample that supported opportunities for hospitals to improve RSMRs over the 90-day time period.
- TEP Feedback
    - Several TEP members supported the overall risk model development approach and final risk variable list.
    - Several TEP members suggested not to describe the 90-day CABG model as parsimonious, due to the number of risk variables added. CORE acknowledged this feedback and incorporated it into documents going forward.

- Several TEP members questioned the clinical significance, of certain risk variables, such as benign neoplasm, disorders of lipid metabolism, and gastrointestinal disorders, in the final risk model. CORE explained that diagnostic claims may or may not directly correlate with clinical diagnoses for risk prediction. However, when aggregated across all patients at a hospital, claims offer robust risk predictions that has been shown to be highly correlated to risk prediction using medical record and registry data. In addition, the process of risk variable selection used stepwise logistic regression performed in up to 1,000 "bootstrapped" samples. Only those variables significantly associated with mortality in at least 80% of samples were selected, ensuring that only very strong predictive variables were selected and then augmented by forcing in markers of frailty.
- One TEP member was surprised that the new 90-day model risk variable intra-aortic balloon pump (IABP) was not a part of the 30-day CABG mortality measure. CORE responded that this risk variable was only identified by this TEP for consideration; all CMS measures are updated annually, and any lessons learned from this measure development project will be communicated and, if appropriate, applied to the 30-day measure.

- Summary
  - TEP members generally supported the risk model development approach and final risk variables.

Reliability and Validity Testing Overview

- CORE presentation to the TEP on the 90-day CABG mortality measure reliability and validity testing results
  - CORE provided an overview of the reliability and validity testing employed in the 90-day CABG mortality measure. The two approaches to reliability testing were test/retest and signal-to-noise ratio reliability (SNR). The intraclass correlation coefficient (ICC), used to evaluate the degree of agreement between the RSMRs within the two randomly selected samples was 0.53, indicating a moderate measure reliability, similar to or higher than other CMS claims-based outcome measures. The SNR score mean of the 90-day CABG mortality measure was 0.82, indicating good reliability.
  - CORE summarized that 90-day CABG mortality measure validity testing used the National Quality Forum (NQF)-endorsed Society of Thoracic Surgeons' (STS') CABG Composite Hospital Star ratings. Results presented hospitals with the lowest overall 1-star rating by STS composite measure had the highest 90-day mortality of 5.89%, the average hospitals with 2-star rating had a mortality rate of 4.57%, and those with 3-star rating indicating the highest quality had the lowest mortality rate of 3.71%.
- TEP Feedback

- Several TEP members commented on the high SNR score, as the results were higher than expected. CORE clarified that the NQF-based SNR generally yields high reliability estimates, which is consistent with other claims-based measures.
- One TEP member suggested CORE include a statement about the measurement window used to calculate the SNR prior to reporting on the measure.

- Summary
  - While some TEP members were surprised by the high SNR score, overall the TEP members supported the reliability and validity of the measure.

Social Risk Analyses Overview

- CORE presentation to the TEP on the Impact of Social Risk on 90-Day CABG Mortality Measure Results
  - CORE reviewed the analyses to assess the impact of social risk factors on the hospital risk-standardized mortality rate (RSMRs), which focused on three variables as an indicator of socioeconomic status – dual eligibility status, African-American race, and the AHRQ SES index.
  - CORE presented the hospital RSMRs by social risk, highlighting that the AHRQ SES index demonstrated the greatest disparities.
  - CORE presented the Spearman Correlation Coefficients comparing RSMRs with and without including social risk adjustment, noting the correlation coefficients were greater than 0.99, almost a 1:1 correlation.
- TEP Feedback
  - One TEP member supported including social risk in the 90-Day CABG risk-adjustment model. Other TEP members indicated they did not support including social risk in the model.
  - Two TEP members suggested using the Net Reclassification Index (NRI) to assess the social risk impact on the 90-day CABG mortality measure versus using C-statistics.
  - One TEP member proposed considering social risk variables as candidate variables. CORE noted that, since many social risk factors are correlated to clinical comorbidities, CORE first adjusts for clinical comorbidity and then considers social risk after adequate clinical risk adjustment has been achieved.
  - One TEP member suggested including behavioral risk factors, such as smoking and medication compliance in the risk model but recognized that these factors might be difficult to capture in claims data. CORE acknowledged the valuable feedback, agreeing that meaningful assessment of such risk factors is challenging.
- Summary

- There was no TEP consensus on how to incorporate social risk in the measure specifications, although the TEP acknowledged the importance of considering social risk in a 90-day outcome measure.

Analyses Assessing the Impact of Patients Readmitted to Other Hospitals

- CORE presentation to the TEP on Analyses Assessing the Impact of Patients Readmitted to Other Hospitals on Measure Results
  - CORE presented the potential impact of unplanned readmission during the 90-day period after CABG surgery on mortality. Results demonstrated that patients who were readmitted during the 90-day post-CABG to the index hospital, the hospital that performed the CABG had a lower average observed mortality rate of 5.37%, compared to patients readmitted to non-index hospitals, that had a mortality rate of 6.17%.
  - CORE noted this measure is intended for use in a 90-day model where the hospital is theoretically responsible for both payments and care in the 90-day period. Based on this, CORE proposed keeping patients readmitted to non-index hospitals in the measure cohort to ensure the index hospital is both aware of all patients and encouraged to improve outcomes for all patients.
- TEP Feedback
  - One TEP member highlighted concern of penalizing index hospitals if a patient was readmitted to a non-index hospital during the 90-day period that does not provide high-quality care for readmitted patients. A few other TEP members agreed.
  - Several TEP members agreed with not excluding readmitted patients to the non-index hospitals from the performance measure.
  - Several TEP members suggested monitoring readmissions during a 90-day time-period as an alternative to excluding these patients.
- Summary
  - While some TEP members showed concern about patients readmitted to non-index hospitals in the 90-day period after CABG surgery, a majority of TEP members agreed with including these patients in performance measure.

Overall Summary of Second TEP Meeting

The TEP provided general support of the measure but expressed some concern about how social risk was considered in the measure and/or the payment model in which the measure was used. In order to assess the measure's face validity and gain clarity about the TEP's input on how to handle social risk and patients readmitted to non-index hospitals, we added questions to the planned measure face validity survey that will be included in the measure methodology report for future public comment (see Appendix C for face validity survey results).

Next Steps

Additional TEP Work and TEP Meeting

CORE will survey the TEP regarding measure acceptability and validity after the second TEP meeting. CORE will obtain 30 days of public comment feedback this Fall/Winter 2018. TEP members will be notified of the public comment period.

Conclusion

TEP feedback of CORE's approach to measure development will inform the development of measure specifications. CORE will continue to engage and seek input from the TEP as the measure is developed.

Appendix A. CORE Measure Development Team

Table 2. Center for Outcomes Research and Evaluation (CORE) Team Members

Name	Role
Khurram Nasir, MD, MBBS, MPH, MSc	Project Lead Clinical Investigator Director of Population Health & Health System Improvement and Research, CORE Associate Professor, Cardiovascular Medicine, Yale University School of Medicine
Lisa Suter, MD	Division Director, New Measure Division, CORE Associate Director, Quality Measurement Programs, CORE Associate Professor of Medicine (Section of Rheumatology), Yale School of Medicine
Haikun Bao, MS, PhD	Lead Analyst
Yongfei Wang, MS	Supporting Analyst
Jacqueline Grady, MS	Analytic Leadership Associate Director of Data Management and Analytics, CORE
Lynette Lines, MS, PMP	Project Manager
Andreina Jimenez, MPH	Task Coordinator
Shani Legore, BA	Research Support
Nina Brandi, BS	Research Support
Karen Dorsey, MD, PhD	Associate Director, Quality Measurement Programs, CORE Associate Research Scientist in Department of Pediatrics, Yale University
Susannah Bernheim, MD, MHS	Director of Quality Measurement, CORE Assistant Clinical Professor, General Internal Medicine, Yale School of Medicine
Harlan Krumholz, MD, SM	Senior Advisor and Director, CORE Clinical Investigator, Cardiologist and Harold H. Hines, Jr. Professor of Medicine at Yale School of Medicine and Yale School of Public Health

Appendix B. Technical Expert Panel Call Schedule

TEP Meeting #1

Monday, May 21, 2018 – 4:00-6:00 PM ET (Location: Teleconference/Webinar)

TEP Meeting #2

Tuesday, October 2, 2018 – 4:30-6:30 PM ET (Location: Teleconference/Webinar)

Appendix C. Detailed Summary: Feedback from Post-TEP E-mail

Detailed Summary TEP Meeting 1: Feedback from Post-TEP E-mail (May 21, 2018)

9 out of 12 TEP members provided feedback during the TEP call. Additional comments via email response have not been received.

Detailed Summary TEP Meeting 2: Feedback from Post-TEP E-mail (October 2, 2018)

By email, CORE sought input on the modified face validity survey, that included feedback on how to address social risk and patients readmitted to non-index hospitals. The Technical Expert Panel (TEP) rated the following statements using a six-point scale (All questions used the following response options, except statement three below: 1=Strongly Disagree, 2=Moderately Disagree, 3=Somewhat Disagree, 4=Somewhat Agree, 5=Moderately Agree, and 6=Strongly Agree):

1. The 90-Day CABG Mortality Measure, as specified, will be able to distinguish between better and worse quality of hospitals for the purposes of measuring quality. As specified indicates with no consideration for social risk and inclusion of all readmitted patients, regardless of where they were readmitted (CABG performing versus non-CABG performing hospital). 7 of 9 (78%) responding TEP members somewhat agreed or moderately agreed with this statement; 2 of 9 members moderately disagreed with this statement.
2. The 90-Day CABG Mortality Measure, modified to include the social risk (Agency for Healthcare Research and Quality [AHRQ] Socioeconomic Status [SES] index) will be able to distinguish between better and worse quality hospitals for the purposes of measuring quality. 9 of 9 responding TEP members somewhat agreed, moderately agreed, or strongly agreed with this statement; 0 TEP members strongly disagreed with this statement.
3. Regardless of how you responded to the prior two statements, please indicate whether and how you think CMS should consider the social risk (AHRQ SES) in the measure specifications of this measure. 5 of 9 (56%) responding TEP members favored accounting for social risk (AHRQ SES) by including it in the risk adjustment model; 4 out of 9 favored accounting social risk (AHRQ SES) by stratifying measure results by social risk; 0 favored some other approach to including social risk (AHRQ SES) in the measure specifications; and 0 favored not including social risk (AHRQ SES) in the measure specifications.
4. The 90-Day CABG Mortality Measure should INCLUDE all patients readmitted within 90 days after isolated CABG surgery, regardless of whether they were readmitted to the hospital that performed the index CABG procedure or another hospital. This is how the measure is currently specified. 7 of 9 (78%) responding TEP members somewhat agreed or strongly agreed with this statement; 2 of 9 TEP members moderately disagreed with this statement.

Appendix D. Detailed Summary of Technical Expert Panel Meetings

Detailed Summary of TEP Meeting 1 (May 21, 2018)

Welcome and Introductions

- CORE welcomed everyone to the first TEP meeting. CORE oriented TEP members to GoToMeeting and the previously distributed TEP materials. CORE reminded the TEP members that the meeting was recorded, and the minutes will be distributed for TEP member review following the meeting and any TEP members can provide additional feedback via email.
- CORE reminded all attendees that the TEP conversations and materials are to be kept confidential. CORE also reminded everyone that all TEP members represent themselves, not the organizations that nominated them.
- CORE informed the TEP members that this work is funded through a contract with the Centers for Medicare and Medicaid Innovation Center (CMMI). CORE also stated that members of the Center for Medicare and Medicaid (CMS) and CMMI are listening in on this call.
- CORE reviewed the agenda and stated that the focus of this meeting was to review and seek input on the approach to the measure concept and development of the proposed measure cohort and outcome. CORE stated that there will be time at the end to address any outstanding questions and review the next steps.
- CORE introduced the director of the CORE team. The director introduced everyone to CORE, including a brief overview of CORE's mission. CORE stated that this meeting is just one way for TEP members to provide input, TEP members can also provide input on this measure via email.
- CORE stated that their mission is to improve health and healthcare through targeted research combining scholarship and policy to positively impact people's lives. Further information can be found on CORE's website. CORE also clarified that members of CMS and CMMI are on the call, listening to TEP members' input.
- CORE introduced the 90-Day CABG mortality measure development team members and the working group members, who are also aiding in the re-specification of this measure.
- Each TEP member introduced themselves, including relevant experience and contributions to this panel. TEP members also disclosed relevant conflicts of interest, which included several members with experience developing, implementing, and evaluating quality measures for the Society of Thoracic Surgeons.

Review of TEP Role, Charter, and Guiding Principles of Measure Development

- CORE explained the purpose of convening the TEP, to gain stakeholder input and increase transparency during measure development. CORE explained TEP member responsibilities, including reviewing materials, attending TEP meetings, providing input

on key features of the measure, reviewing the TEP summary report, and maintaining confidentiality of materials and meeting discussions.

- CORE asked all TEP members if they had any proposed changes to the TEP charter and if all TEP members approved the TEP charter. No TEP members proposed changes to the TEP charter, and the charter was approved.
- CORE provided the TEP members with an overview of how TEP member feedback will be obtained throughout the meeting. CORE then introduced the team lead.
- CORE thanked the TEP members for their participation and contributions to the re-specification of this measure.
- CORE reminded the TEP members that the goal for this TEP is to seek their input on the development of a hospital-level, 90-day, all-cause, risk-standardized mortality measure following isolated CABG surgery, for potential use with alternative payment models. CORE clarified that the development of this measure is not starting from the beginning; CORE will be re-specifying the existing hospital-level, 30-day, all-cause, risk-standardized mortality measure following isolated CABG surgery.

Brief Overview of Existing 30-day CABG Mortality Measure

- CORE provided the TEP with a brief background of the existing 30-day CABG mortality measure that CORE is re-specifying to a 90-day CABG mortality measure.
    - CORE explained that the existing 30-day CABG mortality measure was developed in 2012 alongside the 30-day CABG readmission measure in collaboration with the Society of Thoracic Surgeons' (STS) registry-based 30-day CABG readmission measure. During this original development, CORE obtained feedback from members of STS, a diverse TEP, and a public comment period. The 30-day CABG mortality measure was endorsed by the National Quality Forum (NQF) in 2014 and CMS began publicly reporting this measure in 2015.
    - CORE explained that the existing 30-day CABG mortality measure uses a wide range of administrative claims data without increasing burden on the hospitals. CORE also explained that the outcome was chosen as all-cause mortality instead of CABG-specific mortality because the cause of death might be unreliably recorded, it is often not possible to identify related versus unrelated deaths, any death related to the hospitalization is important to the patient and focusing on merely CABG-related deaths might miss the goal to improve overall hospital care.
    - CORE explained the 30-day CABG mortality measure cohort includes patients ages 65 and older who received a qualifying isolated CABG procedure at an acute care facility. Patients with simultaneous valve or other major cardiac procedures are not included because they have a higher associated mortality risk.
    - CORE presented the risk variables, including age and gender, included in the 30-day CABG mortality measure risk model. CORE explained that the candidate risk variables were identified using the index admission with comorbidities identified from the index admission secondary diagnosis. As well as 12 months of pre-index

inpatient Part A data, Part B physician data, and outpatient hospital data. To avoid adjusting for complications of care, CORE utilized an algorithm that captures whether the code might represent a complication of care and the code was present in the patient record over the past 12 months.

Overview of Proposed 90-day CABG Mortality Measure Concept & Development

- CORE Presentation to the TEP
    - CORE provided an overview of the proposed measure concept and development for re-specification of the 90-day CABG mortality measure. CORE explained that CMMI has contracted with CORE to re-specify the existing 30-day CABG mortality measure to capture a 90-day measurement period that can be used across a range of alternative payment models.
    - CORE explained that in addition to the goals of evaluating quality of care for CABG patients, informing consumers, and increasing transparency, CORE believes that a 90-day CABG mortality measure will capture the effects of perioperative care beyond 30 days that may require a mix of postoperative care and medical comorbidity management. This provides a further opportunity to enhance the excellent improvements in care in the last decade for CABG recipients. Also, this measure can be used as a balancing measure for use in alternative payment programs to ensure patient outcomes do not suffer adversely in response to cost reductions.
    - CORE clarified that following final selection of the 90-day risk variables, CORE will follow the approach developed for the 30-day mortality measure to assess model performance, measure reliability, and measure validity. Throughout this work, CORE will continue to seek feedback from the TEP, the Technical Work Group, and a public comment period.
    - CORE asked the TEP members what feedback they have on the overall measure concept (90-day CABG, all-cause mortality) and the measure development approach.
- TEP Feedback
    - A TEP member thinks measuring all-cause mortality is a reasonable approach, as it is too complicated to identify CABG-specific mortality.
    - A TEP member agrees with the previous TEP member and wanted to discuss the variable inclusions, including the timing of PCI, home stability, and other objective criteria that might impact readmission, mortality, and morbidity.
    - A TEP member stated that they felt a 90-day measurement period will allow us to look into the post-discharge period.
    - A TEP member asked for clarification on what data were used, whether it is all claims data or if there is any clinical database, like the STS registry, that is also used.
        - CORE confirmed this (claims-only data) is correct.

        - The same TEP member asked if Medicare Advantage plans are included in this dataset.
        - CORE clarified that Medicare Advantage is not currently incorporated in this measure dataset but stated that CORE will consider incorporating Medicare Advantage plans if that data becomes available. The current measure includes Medicare FFS beneficiaries only.
        - The same TEP member also asked how robust the clinical variables are in the claims data versus a registry.
        - CORE stated that when CORE and STS created their CABG readmission measures, they were comparable in their performance. CORE noted although claims provide different information than specific test results might in terms of risk adjustment, when a claims-based risk model is chosen, informed by clinical input and driven by analytic results, the performance of risk prediction is very similar to the clinical risk prediction compared to clinical or registry-based data. CORE clarified that the existing 30-day CABG mortality measure was validated against state-based registry data, but the measure was not validated against the larger STS dataset.
    - A TEP member agreed with the summary provided by CORE. They were involved in the original development of the 30-day CABG mortality measure and said CORE was very receptive to input from stakeholders. They confirmed that there was a very high correlation between the STS readmission measure (based upon gold-standard registry data) and CORE CABG readmission measure.
    - A TEP member asked what the change in mortality is between 30-day and 90-day mortality.
        - CORE clarified that 90-day CABG mortality is about 50% higher than 30-day CABG mortality.
    - A TEP member felt that the re-specification approach is reasonable and asked whether the measure will be tested using one versus three years of data, because they feel this is an important determinant of the measure's statistical reliability and usefulness. This TEP member questioned why CORE planned to use a parsimonious approach to measure development, expressing a concern that it is not desirable or relevant in this context. They recommended looking at a non-parsimonious model and compare to the existing 30-day CABG mortality measure risk model to include as many risk variables as possible and measure the overlap between the 30- and 90-day measures. Then, the focus can be on evaluating the risk variables that do not overlap.
        - CORE explained that a decision has not yet been made about the measurement period for testing, a one or three-year period, clarifying that the existing 30-day CABG mortality measure is tested over a three-year measurement period that provides a more stable risk model and captures more patients. CORE clarified that the reliability of the 90-day

measure will specifically be tested to determine the measurement period, acknowledging that a three-year time period might not make it as easy for hospitals to improve year to year, but would increase sample size, precision, and stability.

- CORE commented on the parsimonious risk model question of this TEP member, explaining that with a measure like CABG mortality that has low outcome rates, adding too many risk variables into the model can result in a risk model that does not converge. CORE will try to balance the most robust statistical model, the shortest time period, and usability across as many settings as possible. CORE will work with the TEP in developing this measure, keeping these things in mind.

- A TEP member felt that this measure will have a neutral to positive effect on the patient.
- A TEP member said looking farther away from the 30-day post CABG surgery timeframe increases the importance of the risk variables that are chosen and their effect on mortality. They also asked if this measure will account for patients that are readmitted within the 90-day time frame and eventually die related to the readmission, not the index admission.
    - CORE responded that we are considering the implications of pushing out the measurement period. We acknowledged this is a concern, but the assumption is that anything that happens in that 90-day period is likely influenced by the CABG surgery and perioperative care and discharge planning. CORE previously made the decision to not identify the related and unrelated deaths, providing an example of a patient that dies in a car accident leaving the hospital because their blood pressure dropped from improper care received in the hospital. CORE stated that deaths within 90-days would likely result in a readmission and would likely be related to the CABG surgery. CORE stated that separating the cause of related and unrelated deaths would be difficult, but it is something that CORE could look into.
    - The same TEP member said that they think most causes of death are related within a 30-day time period. But, extending to the 90-day time period, a death might be less likely to be related to the original CABG surgery. The TEP member stated that they wanted CORE to keep this possibility in mind and asked if this model will be tested against the STS registry, to determine the correlation.
    - CORE said, although we do not have a formal plan for validation of this measure against registry data, CORE and CMS are interested in all input and ideas from TEP members concerning options for validation. We are open to many different options of validation and are interested in considering public information about hospital performance.

- A TEP member agrees that expanding this measure to capture a 90-day time frame will decrease adverse events for patients.
- A TEP member questioned how cardiac rehabilitation might be accounted for in the 90-day measure.
    - CORE explained that CMS's alternative payment models include multiple different arenas of care, forcing them to work together. The purpose of this measure is to ensure patient outcomes do not suffer when cost is decreased.
    - The same TEP member agreed with this approach.
- A TEP member suggested that we account for death caused by other procedures that occur within the 90-day period following the CABG surgery.
- A TEP member said that since we are not attributing these mortality cases on an individual basis, but at the hospital level, they are less concerned about the individual cases that might be an issue.
    - A TEP member asked for clarification.
    - A TEP member clarified that it would be good to look at how the statistical model behaves instead of including everything that might clinically relate, since this measure tests for hospital-level results.
    - CORE clarified that members of CMMI are on the call right now and they are taking note on the concerns of the TEP members. CORE also asked TEP members to consider how this measure could best be utilized.

Introduction to Risk Model Development

- CORE Presentation to the TEP
    - CORE provided an overview of risk model development for the 90-day CABG mortality measure. CORE explained that this will be similar to the development of the 30-day CABG mortality risk model. The current goal for the development of this risk model is to create a parsimonious model, including all the clinically relevant variables associated with 90-day CABG mortality. We want to illuminate the differences in the quality of care provided to patients and develop an optimal clinical risk model first, then assess any impact of social risk.
    - CORE explained that the candidate risk variables will be derived from the comorbidities, identified from the index admission secondary diagnosis and 12 months of pre-index inpatient Part A data, Part B physician data, and outpatient hospital data. Potential complications of care will not be included as risk adjusters. For developing the measure, we will start with grouping the majority of ICD-10 codes into clinically relevant diagnostic groups and conditions, which are part of the CMS Hierarchical Condition Categories (HCCs).
    - CORE explained that the next step of the development of the risk model will include a bivariate analysis to examine the strength and direction of the clinical conditions with the 90-day mortality window. Then, we will examine the

frequency that these candidate variables will be pulled into the proposed model during bootstrap iterations to select final risk variables. The final list of comorbid conditions (risk variables) will be selected through a clinical analysis of what additional elements we need to consider based on the results of the statistical input. Once the risk model is finalized, we will assess the model performance in various settings and explore the impact of social risk.

- CORE showed the TEP members the risk variables used for the 30-day CABG mortality measure as example risk variables but reminded the TEP that the final risk variables for the 90-day CABG mortality measure will likely not be the same as the 30-day list.
- CORE asked the TEP members what feedback they have on risk model development or what other variables we should consider.

- TEP Feedback
  - A TEP member asked how we plan to include social determinants at the 90-day measurement period beyond merely the statistical significance of certain risk factors. The TEP member thinks this will be more important to consider for a 90-day time frame versus a 30-day time period.
    - CORE explained that we want to start with a good clinical model and then look at social risk factors. CORE agreed that expanding to the 90-day time period brings up different issues of access to care, but we want to create the best clinical risk model, then look at the social risk factors. CORE also explained the social risk factors that are available in claims data, including dual eligibility, African-American versus not African-American (but no other race labels), and AHRQ SES (broken down by zip codes). CORE will be evaluating these social risk factors for inclusion in the risk model. CORE also stated that we are open to other suggestions, which we can note, and CMS might be able to use it in another way, if we are unable to use these social determinants in this 90-day CABG mortality measure.
    - The same TEP member asked about our ability to look at dual-eligibility status based on the recent Medicaid expansion.
    - **Action Item:** CORE will look at a state-level analysis in relation to dual-eligibility. CORE will also examine bivariate relationships of social risk factors with the measure outcome.
  - A TEP member asked if frailty is being used as a risk variable.
    - CORE said that we appreciate this TEP member's input and will look to their expertise as we look at specific risk factors.
    - **Action Item:** CORE will look into including frailty as a variable in this risk model.
    - The same TEP member stated that there are many available validated tools, like the clinical frailty index.

- A TEP member echoed other TEP members stating the importance of evaluating social risk factors. They also want us to consider, now that we are looking at a 90-day time period instead of a 30-day time period, the timing of PCI compared in comparison to CABG surgery. They question what the impact of this procedure would be and asked if this could be explored.
    - CORE asked for clarification about the clinical scenario that this TEP member explained, if they were talking about a situation where a surgeon started to treat the patient with a PCI, then realized they could not use this procedure and used the CABG surgery as a rescue situation.
    - The same TEP member clarified that this description is accurate and added another scenario where for example most of the vessels have already been stented, leaving very little to graft and a situation in which the patient might get a CABG but their short-term outcome is still limited.
- A TEP member asked if diabetes is included in the list of risk factors for the 90-day CABG mortality measure.
    - CORE clarified that diabetes is included under the category endocrine diseases and obesity.
    - The same TEP member asked whether certain vascular diseases will be separately evaluated, based on their different impacts on mortality.
    - CORE clarified that this is included under the vascular disease variable. They also clarified that this list is the 30-day CABG mortality measure risk variable risk and does not capture all the potential risk variables that could be used in the 90-day risk model.
    - **Action Item:** CORE will share the list of ICD-10 codes, within each CC variable that we are considering including in the 90-day risk model with the TEP members. CORE will look at peri-operative timing of associated procedure (such as left ventricular assist devices and PCIs).
- A TEP member asked if low health literacy would be considered a risk factor, which could potentially lead to adverse events later on.
    - CORE clarified that they think this is important to consider, but we would not have access to this type of information through the claims data. They clarified that we are open to suggestions from any TEP members in relation to how we can access this risk factor to test in our measure.
- A TEP member said that one of the strongest indicators in the STS registry is the urgency of presentation and they suggested that this variable should be considered. The TEP member said that acute myocardial infarction (AMI) might partially affect this, the STS registry has this variable, and we might be able to track this in claims. The same TEP member also wanted to echo the importance of socioeconomic factors, especially for the 90-day expansion time period. They suggested thinking about access to care, specifically the distance between patient home zip code and hospital zip code.

        - CORE asked how we would capture the difference between urgent, emergent, and elective.
        - The same TEP member said that they think emergent is within 24 hours but clarified that this should be separated from patients that are admitted within 24 hours of surgery for an elective procedure. The TEP member expressed that they are unsure how to capture this but suggested looking at patients with an index admission diagnosis of acute MI, versus patients who are admitted to the hospital and have surgery within 24-48 hours, versus patients who have an index admission diagnosis of coronary artery disease, which implies an elective admission versus an emergent case.
    - A TEP member asked how transfer status might relate to this conversation about urgency of procedure in this measure.
        - CORE clarified that this measure will approach transfer status the same way that the 30-day CABG mortality measure approaches transfer status. CORE explained an example where the patient is admitted to a hospital for AMI, then transferred and received the CABG procedure at the second hospital, so the hospital that performed the CABG procedure is assigned the outcome. CORE said that there is a code for urgency of CABG in the claims data, which in our experience is not consistently or accurately captured. CORE encouraged TEP members to provide us with more suggestions on how to capture urgency of CABG surgery.
        - **Action Item:** CORE will look into the potential for capturing urgency of CABG surgery from the claims data, including the use of AMI codes and admission type and/or urgency indicators. CORE will also look at distance from patient residence zip code to the zip code of the hospital performing the index CABG procedure as a candidate risk variable.
    - A TEP member clarified that the STS definition of urgency is a clinical definition, not based on time, which makes it difficult to link a timing aspect with urgency. The TEP member also suggested looking at timing of a cardiac catheter in relation to the CABG procedure, if the CABG procedure follows soon after the cardiac catheter it is likely an emergent procedure.

Next Steps

- CORE reviewed the future measure development work for TEP members. The TEP members will be expected to review and discuss the measure scores and preliminary testing results at the second TEP meeting. CORE will distribute meeting materials and specific topic questions to consider prior to the next TEP meeting.
- CORE reviewed the immediate next steps, that CORE will distribute TEP minutes following this meeting and will draft a TEP summary report that will be publicly posted on the CMS website, which the TEP members will have the opportunity to review before public posting. The next TEP meeting will likely occur later in the summer.

- CORE asked if there are any other concerns or questions that anyone wants to raise.
    - A TEP member asked about the planned use of this measure and how long the development of this measure will take.
        - CORE explained that the goal of this measure is to re-specify the existing 30-day CABG mortality measure to a 90-day measurement period, including reevaluating the risk model. CORE stated that CMS has asked CORE to re-specify this measure in order to capture a broad spectrum of potential alternative payment models, but there is not yet a specific payment model this measure is meant for, so there is not yet a specific timeline for implementation of this measure. CORE reminded the TEP of the deliverables that will be produced based on our work with the TEP, outlined by the task coordinator. CORE stated that this measure will also have a document describing the measure specifications and risk model variables as well as a public comment period.
        - The same TEP member asked if there are any other TEP's working on this project in parallel.
        - CORE clarified that each measure has its own TEP, so this is the only TEP working on this measure.
    - A TEP member asked how many patients were used to calculate the mortality rates.
        - CORE clarified that a sample of about 138,000 patients was used to calculate the mortality rates.
        - The same TEP member suggested discussion lives, patients, or people instead of mortality rates because it is more impactful.
- CORE thanked all the TEP members and stated that any additional comments or concerns can be directed to cms90daycabgmortality@yale.edu.

Detailed Summary of TEP Meeting 2 (October 2, 2018)

Welcome and Introductions

- CORE welcomed everyone to the second technical expert panel (TEP) meeting. CORE oriented TEP members to GoToMeeting alongside the teleconference and the previously distributed TEP materials. CORE reminded the TEP members that the meeting was recorded, and the minutes will be distributed for TEP member review following the meeting and any TEP members can provide additional feedback via email. CORE acknowledged TEP members who were not present, or had to leave the call early, would be asked for feedback on the discussion via email, as well.
- CORE reminded all attendees that the TEP conversations and materials are to be kept confidential. CORE also reminded everyone that all TEP members represent themselves, not the organizations that nominated them.
- CORE informed the TEP members that this work is funded through a contract with the Center for Medicare and Medicaid (CMS) and the Centers for Medicare and Medicaid Innovation Center (CMMI).
- CORE provided an overview of the agenda items:
    - Review 90-day CABG development approach;
    - Review risk model and measure results;
    - Review reliability and validity testing results;
    - Review social risk analyses;
    - Review analyses performed at request of TEP regarding readmitted patients;
    - Highlight next steps.
- CORE briefly discussed the round-robin approach to solicit feedback from TEP members. Then, CORE introduced the team lead.

Approach to 90-day CABG Mortality Measure Development

- CORE thanked TEP members for their participation and insights on the 90-day CABG mortality measure development.
- CORE noted that the meeting discussion is a preview of the results contained in the forthcoming methodology report as well as additional analyses on social risks and readmissions.
- CORE reiterated that CMS has contracted with CORE to develop a hospital-level, 90-day, all-cause, risk-standardized mortality measure following isolated CABG surgery, for potential use with alternative payment models. CORE reiterated that the development of this measure is not starting from the beginning; CORE will be re-specifying the existing hospital-level, 30-day, all-cause, risk-standardized mortality measure following isolated CABG surgery.

- CORE noted the rationale for and approach to measure development, such as extending the outcome period to 90 days and reselecting risk variables and noted that CORE's approach built on the existing 30-day measure.
- CORE highlighted the excellent engagement and feedback from the TEP and Clinical Work Group (CWG) members and emphasized the desire to continue collaborating throughout the measure development process. CORE also reminded TEP members that CORE will be obtaining public comments on the final measure specification soon.

Risk Model and Measure Results

- CORE Presentation to the TEP
    - CORE provided an overview of the risk model development for the 90-day CABG mortality measure. CORE reiterated that the overall approach was similar to the development of 30-day CABG mortality measure.
    - CORE explained the goal of the 90-day CABG mortality measure was to develop a parsimonious model that included clinically relevant variables associated with 90-day mortality. Specifically, CORE focused on adjusting for case mix differences based on the clinical status of the patient at the time of presentation, to illuminate the differences in quality of care. After adequately accounting for clinical comorbidity, CORE assessed the impact of social risk on measure results.
    - CORE noted the candidate risk variables were identified using the index admission with comorbidities identified from the index admission secondary diagnoses, as well as 12 months of pre-index inpatient Part A data, Part B physician data, and outpatient hospital data. To avoid adjusting for complications of care, CORE utilized an algorithm to identify potential complications of care. CORE updated this algorithm, which has been used in existing CMS measures, to include present on admission (POA) codes to more accurately capture the patient status on admission to the hospital in the risk model.
    - CORE used Condition Categories (CCs), which are part of the CMS's Hierarchical Condition Categories (HCC) map, to group ICD-9-CM and ICD-10-CM codes into clinically relevant CCs. CORE noted a team of CORE clinicians reviewed the clinically relevant CCs and excluded those that were not relevant to the Medicare population or that were not clinically relevant to the mortality outcome, for example, female infertility or attention deficit disorder. Clinically relevant CCs were further combined into clinically coherent CC groupings.
    - CORE indicated that the candidate risk variables were reviewed by the Technical Work Group and in the previous TEP meeting, which resulted in variable refinement and the addition of factors such as presentation from emergency department and preoperative use of circulatory support tools (for example, intra-aortic balloon pumps [IABP]). After variables selection, a random 50% sample of July 2014 to June 2017 data were used to develop the model

(Development Sample) and the other 50% sample, to test the model (Validation Sample).

- CORE noted for final risk variable selection, a modified approach to stepwise logistic regression was performed to run a bootstrap of 1,000 samples for the Development Sample. Then, the percentage of times that each of the candidate variable was significantly associated with mortality ($p < 0.001$) in each of the 1,000 repeated samples was calculated for each candidate variable. Thereafter, results were reviewed by CORE and a decision was made to retain risk adjustment variables above an 80% cutoff due to stable association with risk of mortality and clinical relevance. Consistent with CMS's other measures, CORE then forced in markers of frailty into the final model.
- CORE presented the final risk variables selected for the 90-day CABG mortality measure, noting the similarities to the 30-day CABG mortality measure.
- CORE then explained the hierarchical logistic regression model approach calculates the hospital-level mortality rates, accounts for patient case mix, clustering of patients within hospitals, and calculates hospital-specific risk-standardized mortality rates (RSMRs) which are obtained as ratios of the predicted number of deaths over the expected deaths multiplied by the national unadjusted rate.
- CORE presented logistic regression results, including the odds ratios and frequencies, for the final risk model variables in the 90-day CABG mortality measure in the Development sample. Although not shown, the risk factors distribution and the odds ratios yielded similar results in the Validation Sample across the three-year (July 2014 – June 2017) timeframe, supporting model stability.
- CORE highlighted that the overall patient-level model performance was similar in both the Development and Validation Samples based on the model C-statistics of 0.766 and 0.772, respectively. CORE further noted that model performance was also assessed by evaluating overfitting indices (0.00806, 1.0099), which indicated no evidence of model overfitting.
- CORE reviewed the graphical distribution of the hospital-level RSMRs for the Development Sample, which had an overall median RSMR of 4.7, a 25th percentile of 4.1, and a 75th percentile of 5.5. CORE added this indicates further opportunities for hospitals to improve RSMRs over the 90-day time-period.
- CORE asked the TEP members what feedback they have on the overall risk model development approach.

- TEP Feedback
  - A TEP member asked the rationale for developing a parsimonious model and further inquired on how CORE defines a parsimonious model.

        - CORE stated that, given the size of claims data, including too many risk variables may decrease the model convergence or lead to model overfitting.
        - The same TEP member indicated that the current model did not seem parsimonious and asked CORE to avoid using that term; another TEP agreed with his assessment.
        - CORE thanked the TEP member for flagging his concerns and stated that it was important to be reminded by the TEP and other stakeholders of how terminologies, such as parsimony, could be interpreted. CORE expressed this feedback was helpful for future measure communications.
    - A TEP member supported the overall risk model development approach. The TEP member stated his surprise that the new 90-day model risk variable IABP was not a part of the 30-day CABG mortality measure. The TEP member acknowledged the good work done by the CORE team.
        - CORE responded that this risk variable was only identified by this TEP for consideration; all CMS measures are updated annually, and any lessons learned from this measure development project will be communicated and, if appropriate, applied to the 30-day measure.
    - A TEP member noted the excellent start to the model development. The TEP member commented on the relevance of benign neoplasm as a risk variable, acknowledging the data element evidence to support its inclusion in the model. The TEP member recognized the painstaking process in deciding which risk variables to include and level of contribution.
        - CORE explained that diagnostic claims may or may not directly correlate with clinical diagnoses for risk prediction. However, when aggregated across all patients at a hospital, claims offer robust risk prediction that has been shown to be highly correlated to risk prediction using medical record and registry data. In addition, the process of risk variable selection used stepwise logistic regression performed in up to 1,000 "bootstrapped" samples. Only those variables significantly associated with mortality in at least 80% of samples were selected, ensuring that only very strong predictive variables were selected and then augmented by forcing in markers of frailty.
    - A TEP member agreed with previous TEP members that supported the 90-day model approach and noted the risk variable list looked comprehensive and representative of all possible patients.
    - A TEP member had nothing additional to contribute.
    - A TEP member agreed with previous TEP members. The TEP member noted that renal failure is such a strong predictor for CABG and asked if there were any additional renal codes besides dialysis status and acute renal failure that should be considered in the model.

- The same TEP member suggested that renal insufficiency variables may be useful in the model.
- A TEP member noted that the final risk variable list looked complete. However, the TEP member inquired if CORE considered adding atrial fibrillation, second or third-degree heart block, and ejection fraction as risk variables in the 90-day model or were these only in the 30-day model.
    - CORE stated there are several acute indications of cardiorespiratory failure, shock, and congestive heart failure (CHF) included in the model. CORE added that arrhythmias were investigated as a candidate but did not make the greater than 80 percent cutoff.
    - The same TEP member asked if CHF patients would be grouped with low ejection fraction patients.
    - CORE clarified that claim-based data does not represent exact clinical information. CORE highlighted that claims-based measures use claims codes that represent a combined predictive ability that might not be as specific as registry-based measures or EHR-based measures.
    - The same TEP member thanked CORE.
- A TEP member congratulated CORE on a work well done, and asked if risk variables with odds ratio less than one are protective of 90-day CABG mortality.
    - CORE confirmed.
- The same TEP member noted concern with the clinical significance and representation of certain risk variables, such as benign neoplasm, disorders of lipid metabolism, hypertensive heart disease, and gastrointestinal disorders. The TEP member asked how these variables would be protective of 90-day CABG mortality and what that meant in terms of the model.
    - CORE reiterated that claims data does not always reflect clinical data or scenarios in the same way and acknowledged that claims data are a unique data variable. CORE explained that in claims-based measures less severe coding may indicate an absence of more severe codes. CORE further noted that CMS performs annual re-evaluation on all their claims-based measures to monitor the codes usability and functionality in risk models and to ensure that coding changes don't result in measure changes.
    - The same TEP member proposed CORE develop a summary highlighting CORE's prior statement, in terms of the usability of claims data in risk model development, before the 90-day CABG measure becomes public. The TEP member noted that it would be easy for an outside party with less expertise on claims data to misinterpret some of the risk variables included in the model and their clinical relevance.
    - CORE acknowledged that this TEP member's feedback was helpful.

        - The same TEP member asked if a one-year look-back period was implemented for hospitalization prior to CABG admission.
        - CORE clarified that the claims data used were from 12 months prior and all the way up to and including CABG admission in the development of the risk model.
        - The same TEP member asked if all the hospitals evaluated had a median mortality rate of 4.7% at 90-days for isolated CABG.
        - CORE confirmed this was correct.
    - A TEP member noted the 90-day risk model seemed consistent with other claims-based measures developed by CORE and had no concerns about the methodology or selection of risk variables. The TEP member indicated disapproval of labeling the model as parsimonious and added that it was not a relevant or desirable objective.

Reliability and Validity Testing

- CORE Presentation to the TEP
    - CORE provided an overview of the reliability and validity testing employed in the 90-day CABG mortality measure. CORE first explained the two approaches to reliability testing – test/retest and signal-to-noise ratio (SNR) reliability.
    - CORE explained that the test/retest approach involved randomly splitting patients in each hospital into two equal samples: Development and Validation Sample. Then, within each sample, the RSMRs were calculated for the individual hospitals. The intraclass correlation coefficient (ICC), used to evaluate the degree of agreement between the RSMRs within the two randomly selected samples, was 0.53 indicating moderate measure score reliability.
    - CORE noted that as recommended by the National Quality Forum(NQF), signal-to-noise ratio (SNR) reliability was also assessed. CORE showed the TEP a graphical representation of hospitals and their reliability scores. CORE added that scores ranged from 0-1, with a higher ratio denoting a better SNR. The median score of the 90-day CABG mortality measure was 0.84, indicating good reliability.
    - CORE summarized that the NQF-endorsed Society of Thoracic Surgeons' (STS') CABG Composite Hospital Star Rating is calculated by combining 11 measures of quality, divided into four broad domains. The four domains include risk-adjusted 30-day mortality, risk-adjusted major complications, the percent of CABG procedures that use internal mammary (or internal thoracic) artery for bypass grafting, and the percentage of patients prescribed with preventative medications at discharge. Then, the composite score is used to group hospitals into three-star ratings – 1 star is considered poor, 2 stars is considered average, and 3 stars is considered good.

- CORE reviewed the face validity of the measure and explained the graph that showed 3% of hospitals on the STS CABG composite star rating had 1-star ratings, 9% had 3-star ratings, and 88% had 2-star ratings.
- CORE further explained that the graph clearly highlights that the hospitals with the lowest overall 1-star rating by the STS CABG composite star rating had the highest 90-day mortality of 5.89%, average hospitals with a 2-star rating had a mortality rate of 4.57%, and hospitals with a 3-star rating indicating the highest quality had the lowest mortality rate (3.71%).

- TEP Feedback
  - A TEP member asked why the SNR mean of 0.82 was so high.
    - CORE clarified that the NQF-based SNR generally yields high reliability estimates, which is consistent with other claims-based measures. CORE highlighted the contrast between the SNR and the split-half reliability approach, which yields a lower reliability estimates and is more conservative. CORE added that in the 90-day CABG model, there is a volume-restricted analysis of a minimum of 25 sample cases, which is the same cut-off used for the 30-day measure.
  - A TEP member expressed concern that the SNR was surprisingly high. The TEP member noted that this outcome might be due to a large signal variation in the distribution of RSMRs across hospitals or the fact that the overall aggregated mortality rate is higher in this measure than an STS-based CABG mortality measure, for example. The TEP member proposed that CORE should include a statement about the measurement window used to calculate the SNR ahead of reporting on the measure. The TEP member further explained that although the current ratio is calculated using data over a three-year period, if the 90-day mortality measure ultimately gets reported based on a one-year measurement window, then that should be the relevant timeframe used to estimate SNR.
    - CORE thanked the TEP member for this insight and noted that, while any implementation of the measure by CMS has not yet been decided, isolated CABG because mortality rates are low and there are fewer hospitals performing CABG procedures, a three-year reporting timeframe is likely. CORE concurs that any decision to implement the measure using a different measurement period should account for the potential impact on the measure result reliability.

Social Risk Analyses

- CORE Presentation to the TEP
  - CORE reviewed the analyses to assess the impact of social risk factors on the hospital-level risk-standardized mortality rates (RSMRs). CORE stated that CORE focused on three variables as an indicator of socioeconomic status – dual eligibility status, African-American race, and the Agency for Healthcare Research and Quality socioeconomic status (AHRQ SES) index. CORE noted that the AHRQ

SES is based on a beneficiary's nine-digit zip code of residence and uses identifiers, such as percentage of people in the labor force who are employed, other wealth measures, and education level.

- CORE presented the hospital RSMRs by social risk, explaining that hospitals were divided based on whether they had the lowest number of dual eligible patients (bottom quartile) or a higher number based on the highest, or top, quartile. This same approach was used to classify hospitals by African-American race and AHRQ SES index. CORE noted that the median and interquartile range of the hospital RSMRs were similar in those who had the lowest and highest proportion of dual eligible or African-American patients.
- In contrast, the AHRQ SES index analysis showed more noticeable differences, with a median hospital-level RSMR of 4.4% and 5.1% for the lowest proportion of low SES participants (bottom quartile of AHRQ SES index) and highest proportion of low SES participants (top quartile of AHRQ SES index), respectively.
- CORE presented the model C-statistics and Spearman Correlation Coefficients with and without social risk adjustment. CORE highlighted that, similar to the 30-day mortality measure, the social risk variables had little impact on the C-statistics.
- CORE presented the Spearman Correlation Coefficients, with and without social risk adjustment models, noting the correlation coefficients were greater than 0.99.
- CORE asked TEP members what feedback they had on the social risk factor impact on the 90-day CABG all-cause mortality outcome within both the high and low social economic status groups and whether it should be included in the model.

- TEP Feedback
  - A TEP member stated that while they disapproved of including social risk factors in a 30-day CABG mortality measure, they support including social risk factors in the 90-day CABG mortality measure, adding that social factors could impact survival. The TEP member voiced concerns with using correlation coefficients and proposed CORE use a Net Reclassification Index (NRI) to analyze how many hospitals' performance categories were changed by the inclusion and exclusion of social risk.
    - CORE asked for clarification on whether this TEP member advocated for or against including social risk in the risk-adjustment model, or if hospitals should be stratified by low versus high SES population.
    - The same TEP member clarified that CORE should run additional analyses using the NRI, and then based on those results seriously consider including social risk in the 90-day model.
  - A TEP member expressed concern for individuals with low SES. The TEP member stated their ambivalence as to whether hospitals should be liable or not for

patients' outcomes after 90 days, especially if a patient decided to practice risky behaviors, such as smoking, that caused them to be readmitted.

- CORE reminded the TEP that this 90-day measure is intended for use in payment models that span a 90-day period. CORE added that to avoid hospitals trimming costs after 30 days, which could reflect negatively on patient outcomes, it is important that hospitals are responsible for costs and patient outcomes during that 90-day period. CORE acknowledged that there are many reasons for disparate results of social risk factors and it is helpful to receive feedback from patient TEP members in terms of how to represent those factors in a payment model.

- A TEP member agreed with the previous TEP member regarding using NRI as opposed to the C-statistics in evaluating impact of social risk factors. The TEP member noted support of the AHRQ SES index, adding that the nine-digit level makes it more robust. In addition, they favored hospital stratification over risk-adjustment and proposed CORE employ the former to track more changes over time.
  - CORE thanked the TEP member for their feedback.
- A TEP member stated that the selected variables related to social risk impact on RSMR are not due to inadequate adjustment. The TEP member added that a reasonable approach to thinking about inclusion of variables is to recognize that the goal of covariate adjustment is to replicate randomization of patients in hospitals, and as a result, understanding the underlying observed empirical associations between covariates and patient outcomes is not necessary. The TEP member further explained that the variables would be adjusted for during the randomization process. The TEP member proposed that CORE treat the variables as covariates and not to label them as social risk variables and see if they would be included or excluded based on the >80% cutoff criteria for risk adjustment.
- A TEP member noted concern with the lack of inclusion of behavioral risk factors in the risk model and recognized that these factors might be difficult to measure.
  - CORE acknowledged the great feedback, indicating that addressing that level of detail is challenging in measure development. CORE added that hospitals should be accountable for outcomes in the 90-day period and should be held responsible to identify and treat behavioral risk factors in advance, as possible.
- A TEP member voiced support for including the AHRQ SES index in the 90-day CABG mortality model, and added that social determinants of health become more important during a 90-day window.
- A TEP member highlighted that irrespective of the various studies conducted on adjusting for socioeconomic status, there is no conclusion on a right or wrong approach. The TEP member supported conducting more analyses for the 90-day measure to justify adjusting or not for socioeconomic status, adding that the analyses results provided are thorough.

        - CORE acknowledged this feedback was helpful in highlighting the importance of the social risk variables and how to appropriately account for them in the model.
    - A TEP member noted that social risk factors have a great impact on individuals with lower SES and leads to poor patient outcome, and suggested that it might be beneficial for patients who had cardiac surgery to have an open communication follow-up with healthcare providers.
    - A TEP member noted that non-affluent post-CABG patients tend to be inundated with multiple comorbidities, medications, and experience increased readmissions compared to their counterparts. The TEP member suggested adding polypharmacy as a risk variable as it relates comorbidity and mortality management.
        - CORE thanked the TEP member for their feedback.

Analyses Assessing the Impact of Patients Readmitted to Other Hospitals

- CORE Presentation to the TEP
    - CORE reviewed the potential impact of readmission on mortality in the 90-day CABG mortality measure. CORE examined 90-day readmissions and observed mortality at the index hospital (CABG-performing) versus non-index hospital to address stakeholders' concerns about the potential impact of readmission on the 90-day CABG mortality outcome. CORE presented results of the percentage of patients who were readmitted to index and non-index hospitals between 0-30 days, 31-60 days, 61-90 days, and overall 0-90 days. The mortality rates were highest in the first 30 days, declining over the 90-day period. CORE highlighted that patients readmitted to the index hospital that performed the initial CABG had a lower observed mortality rate, 5.37 percent, compared to patients readmitted to the non-index hospital, 6.15 percent.
    - CORE noted that considering this measure is intended for use in 90-day model where the hospital is responsible for payment in that period, we propose keeping patients readmitted to the non-index hospitals in the measure to ensure the index hospital is responsible for improvement of care for patients.
    - CORE asked TEP members for their feedback on these analyses.
- TEP Feedback
    - In the context of these analyses, a TEP member inquired if distance from the index hospital might explain this finding. The TEP member asked if distance from patient's home was considered as a candidate variable in the risk adjustment model. The TEP member asked if distance might be a surrogate for SES.
        - CORE noted the great question, responding that distance was considered as a candidate variable but did not meet the 80 percent criteria in the bootstrapped samples of the development model to make it to the final risk adjustment model.

        - The same TEP member inquired if distance was considered for the readmission model or mortality model.
        - CORE confirmed distance was considered in the mortality model.
        - CORE clarified distance yielded only 2 percent of the iterations in the bootstrap analysis, which was low for inclusion in the model. CORE highlighted that there is a strong relationship between readmission at a non-index hospital and higher mortality rate. CORE recognized that there are numerous reasons for readmission at an index versus non-index hospital, including distance, but that it is difficult to distinguish whether these factors were producing this finding or whether it reflected poorer quality of care. CORE reiterated that, in a 90-day payment model, it seems reasonable to keep these patients in the measure, so the accountable hospital is aware of and can improve care for all patients.
        - The same TEP member agreed with CORE's proposal, noting concern with adding readmission in the current model because there were too many potential explanations that couldn't be accounted for at this time. The TEP member noted CORE should continue to track 90-day readmission trends over time.
    - A TEP member noted concern about penalizing index hospitals if a patient was readmitted to a non-index hospital, addressing possible underlying reasons, such as distance or severity of readmission, which makes things more complicated.
        - CORE asked for clarification as to whether their concern was that patients who are readmitted to a non-index hospital should be or should not be in the measure.
        - The same TEP member clarified that the index hospital should not be liable for patients who were readmitted to non-index hospitals. The TEP member noted that more information is necessary to draw such conclusions. The TEP member asked if an unrelated incident that leads to a readmission should be the index hospital's responsibility.
        - CORE clarified that readmissions are not currently accounted for in the 90-day mortality measure. CORE noted that this measure is intended for use in a payment model. CORE added that by measuring patient mortality outcomes this will encourage hospitals to work more collaboratively and potentially change clinical practice to provide a better safety net for hospitals seeing readmitted patients.
        - The same TEP member agreed with CORE, noting agreement with previous TEP member on the importance of monitoring readmissions during those 90-day period.
    - A TEP member disapproved of including readmitted patients to non-index hospitals in the 90-day CABG mortality measure and disagrees that index hospitals should be penalized if the non-index hospital does not provide high

quality care for readmitted patients. The TEP member noted that as the measurement window extends beyond 30-days, it is challenging to have patients readmitted to index hospital because of accessibility, bed availability, and other factors. The TEP member added that patients are more likely to be admitted to the emergency room at a community hospital or a hospital that lacks a cardiac surgery division. The TEP member stated that CABG patients who are readmitted to non-index hospitals experience higher mortality because those hospitals lack the systems to care for those patients. By including those patients in the model, this increases the pressure on hospitals to follow-up with medical issues post-operatively that could be managed at a smaller hospital. The TEP member indicated that in an ideal world, index and non-index hospitals should work collaboratively to improve systems of care, but in reality, that might not be feasible. The TEP member highlighted the complexity in capturing patients who have multiple readmissions that might get shuffled between index and non-index hospitals.

    - CORE commented that this issue of readmission needs to be further investigated between the 30- to 90-day timeframe. CORE illuminated that emerging literature support the idea of patients who are readmitted beyond 30-days to non-index hospitals present with complex medical conditions, whereas those who have surgical readmissions return to the index admission. CORE asked if this TEP member had thoughts on the issue of gaming, essentially if it was possible for index hospitals to purposely avoid seeing readmitted patients.
    - The same TEP member noted that gaming might be possible, but hopes that cardiac surgeons, with increased attention to individual and hospital-level mortality public reporting, would not try to defer patients from returning to the index hospital. The TEP member reiterated disapproval of including non-index readmission in the model because of the added pressure to bring all readmitted patients back to the index hospital, which might lead to bed availability issues, especially when considering there are other patients with competing illness severity and complications.

- A TEP member agreed with the previous TEP member that patients who were readmitted to the non-index hospital should not be included in the measure.
- A TEP member noted approval of including patients who were readmitted to a non-index hospital in the 90-day CABG mortality measure. The TEP member added that index hospitals have a responsibility to coordinate care with referring physicians to ensure adequate post-operative care, which extends to 90-days. The TEP member highlighted that since the threshold for readmission varies by hospitals and is closely related to the threshold for admission period, it is difficult to exclude patients because they come from an area where readmissions are more prevalent. The TEP member also indicated that there is a significant gaming

potential, in that index hospitals might defer patients to a community physician to avoid including them in their 90-day mortality report.

- A TEP member indicated that both the index and non-index hospitals should be liable for readmitted patients, as the 90-day all-cause readmission can prompt both types of hospitals to improve quality of care, coordination of care, and increase surveillance for CABG patients.
- A TEP member noted conflict as to whether patients who were readmitted to a non-index hospital should be included in the 90-day CABG mortality measure, because there are pros and cons to inclusion and exclusion.
    - CORE indicated the goal of convening the TEP is obtain feedback on the measure and to highlight the tradeoffs to make the best recommendations moving forward. CORE added that by understanding the tradeoffs, TEP members can develop an opinion one way or the other.
- A TEP member noted the issue of whether to include readmitted patients in the measure is an inherent limitation of a 90-day all-cause mortality measure that doesn't have statistically appropriate or simple solution. The TEP member voiced approval of including patients who were readmitted to a non-index hospital in the 90-day CABG mortality measure because excluding them could introduce bias. The TEP member challenged CORE to analyze a hospital's outcome that included only patients treated and readmitted at that hospital. The TEP member pondered if community-level covariates that would be associated with the type of care available in a patient's community could be captured as this might enhance quality of care.

Next Steps

- CORE reviewed next steps for the 90-day CABG mortality measure. CORE highlighted that TEP members will receive a face validity survey, due a week following receipt of the email with the survey link. CORE will distribute meeting materials and notify TEP members of the upcoming 30-day public comment period this fall.
- CORE added that in the public comment introductory document, questions on the readmission and social risk issues will be highlighted. CORE noted that the detailed introductory document provides an overview and approach of the measure development, TEP members feedback, and empirical results. CORE asked TEP members for feedback on how to present questions relating to the readmission and social risk issues for public comment.
    - A TEP member asked if TEP members will be convened after the public comment period ends to decide on the final 90-day CABG mortality model.
        - CORE clarified that the intention is to communicate with the TEP throughout the public comment process to solicit feedback and CORE will solicit TEP input on the results of public comment, but this may be via email and surveys, rather than a call.

- A TEP member noted that the issues surrounding whether to include social risk and readmission were still unresolved and asked how will TEP members come to a consensus on these issues to finalize the model.
    - CORE highlighted that it depends on how consensus is defined. CORE noted that it was important to create a measure that all stakeholders are comfortable with, but it was challenging to have everyone agree unanimously. CORE indicated there are other steps in this measure before a final decision is made about the model, such as public comment and NQF review. CORE added these various stakeholder engagement activities provide CMS an opportunity to decide the implementation and usability of the measure. CORE expressed that it was important to be transparent with TEP members about the strongest consensus and where there are still unresolved questions.
    - The same TEP member asked if given supporting analyses on social risk and readmission, would CMS be the one to ultimately evaluate and decide to include these factors in the model.
    - CORE noted that in the face validity survey, the questions on social risk, for example, will be more concrete to solicit feedback from TEP members and to gain insight into the measure's overall accessibility and ability to evaluate quality of care.
    - The same TEP member noted that similar questions about non-index versus index hospitals and readmission could be included in the survey as well. The TEP member shared a personal account of a CABG patient who was readmitted to a non-index, small community hospital that lacked cardiac surgery and highlighted, as a cardiac surgeon at the index hospital, his concerns with the patient outcome because of lack of bed availability to transfer said patient. The TEP member added that such challenges should be considered when developing the 90-day mortality model.

- CORE asked TEP members if they had any specific feedback on public comment or the TEP's face validity survey, noting TEP members could share feedback via email at cms90daycabgmortality@yale.edu.
    - A TEP member noted that it would be helpful if CORE provided additional analyses on the ratio of index versus non-index hospital readmission variability across hospitals, and added that an increase in variation across hospitals would be concerning. The TEP member also highlighted the need to understand the SNR hospital sample size distribution to evaluate reliability of the measure.
    - A TEP member thanked CORE for their refreshing treatment of the patient community. The TEP member noted that the efficiency in having information in advance and answering of questions in a timely manner was extremely helpful.
        - CORE thanked the TEP member for his valuable feedback and noted that CORE was grateful that they found their experience helpful.

- CORE thanked all TEP members and indicated that CORE would expand the face validity survey to include questions clarifying the TEP input on social risk and the question of readmitted patients.