Summary of Technical Expert Panel (TEP): Sepsis Readmission Measure

June 2025

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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 a sepsis readmission measure. The CORE contract name is Development, Reevaluation, and Implementation of Outcome/Efficiency Measures for Hospital and Eligible Clinicians, Option Period 1. The CORE contract number HHSM-75FCMC18D0042, Task Order HHSM-75FCMC24F0042. As part of its measure development process, CORE convenes groups of stakeholders and a technical expert panel (TEP) who contribute direction and thoughtful input to the measure developer during measure development and maintenance.

The goal of this project is to develop a sepsis readmission measure in alignment with CMS publicly reported readmissions measures and including both Medicare Fee-for-Service (FFS) and Medicare Advantage (MA) beneficiaries. The measure development will include defining a sepsis cohort appropriate for this readmission measure, identifying risk variables to include within the risk model, risk model testing, measure score reliability and validation testing, and measure specification finalization.

The CORE measure development team is comprised of clinicians, measure development experts and experts in quality measurement. The TEP currently includes 14 individuals, ranging from experts in patient safety and quality, clinicians, and patient/family/caregivers.

This report summarizes the feedback and recommendations provided by the TEP during two meetings: 1) the first meeting held on September 26, 2024; and 2) the second meeting held on December 12, 2024.

Measure Development Team

The CORE Sepsis Readmission Measure Team is led by Dr. Onyinye Oyeka, and overseen by Senior Project Director and Contract Director, Dr. Lisa Suter and Hospital Research and Development Division Lead, Dr. Ladan Golestaneh. See below for the full list of CORE team members on the measure development team.

Name	Role
Lisa Suter, MD	Senior Project Director and Contract Director
Ladan Golestaneh, MD, MS, FASN	Hospital Research and Development Division Lead
Onyinye Oyeka, PhD	Project Lead
Kerry McDowell, M.S.Ed., M.Phil.Ed.	Project Manager
Alexandra Stupakevich, MPH	Project Coordinator
Jon Niederhauser, MPH, MSW	Project Coordinator and Stakeholder Engagement Team Lead
Jacelyn O'Neill-Lee, BA	Project Coordinator
Lucy Pereira, BA	Research Support
Zhen Tan, MS	Analyst
Yahui Tian, PhD	Analyst
Kasia Lipska, MD, MHS	Clinical Subject Matter Expert
Jacqueline Grady, MS	Technical Subject Matter Expert
Zhenqiu Lin, PhD	Senior Director, Healthcare Analytics
Roisin Healy, BA	Person and Family Engagement Team Coordinator

Name	Role
Mariel Thottam, MS, BCBA	Stakeholder Engagement Team Lead
Thushara John, MHA, MA	Stakeholder Engagement Team Lead
Patricia Faraone Nogelo, PhD, MSW, LCSW	Stakeholder Engagement Research Scientist
Erin Joyce, BA	Stakeholder Engagement Division Supervisor

Technical Expert Panel

In alignment with the CMS Measures Management System, and under the guidance of CMS, CORE convened a TEP for the development of the sepsis readmission measure. The role of the TEP is to provide recommendations and feedback on specific aspects of the measure development details presented to them.

Participant and Credentials	Title	Organization, State
Rosie Bartel, MA	Patient	PFANetwork, PFCCPartners, Chilton, WI
David Classen, MD, MS	Physician	University of Utah School of Medicine, VA SLC, Pascal Metrics Salt Lake City, UT
Steven L. Coffee, MA, EM CQSL	Patient Caregiver	Head2HeartConnections LLC, Patients for Patient Safety US Dumfries VA
Sara Cosgrove, MD, MS	Professor of Medicine, Division of Infectious Disease	Johns Hopkins University School of Medicine Baltimore, MD
Sarah Doernberg, MD, MAS	Professor of Clinical Medicine, Division of Infectious Disease	University of California, San Francisco, San Francisco, CA
Tom Ehelian	Patient	Dallas, TX
Stephen Goins, MS	Research Scientist	New York State Department of Health, New York, NY
Cindy Hou, DO, FIDSA	Chief Medical Officer	Sepsis Alliance, San Diego, CA
Michael Klompas, MD, MPH	Physician	Brigham & Women's Hospital and Harvard Medical School Boston, MA
Mitchell Levy, MD, MCCM	Systemwide Director, Critical Care Medicine	Brown University Health, Providence, RI

Participant and Credentials	Title	Organization, State
Hallie Prescott, MD, MSc	Associate Professor of Internal Medicine, Division of Pulmonary Critical Care	University of Michigan; Veterans Affairs Ann Arbor Healthcare System, Ann Arbor, MI
Chanu Rhee, MD, MPH, FIDSA, FSHEA	Associate Professor of Population Medicine and Medicine	Brigham & Women's Hospital, Harvard Medical School and Harvard Pilgrim Health Care Institute Boston, MA
Maureen Seckel, APRN, MSN, ACNS-BC, CCNS, CCRN, FCNS, FCCM, FAAN	Clinical Nurse Specialist	Consultant, Retired Christiana Care Newark, DE
Dorothy Winningham	Patient Advocate	Bonaire, Georgia

Specific Responsibilities of the TEP members

Specific responsibilities of TEP members include:

- Complete and submit all nomination materials, including the TEP Nomination Form, letter of interest, disclosure of conflicts of interests, and curriculum vitae;
- Review background materials provided by CORE prior to each TEP meeting;
- Attend and actively participate in the TEP in-person meeting and/or teleconference meeting(s);
- Provide input and feedback to CORE on key clinical, methodological, and other decisions;
- Provide feedback to CORE on key policy or other non-technical issues;
- Review the TEP summary report prior to public release; and
- Be available to discuss recommendations and perspectives following group TEP meetings and public release of the TEP summary report.

CORE provides an agenda and background materials before every meeting for TEP members to review. TEP members are generally expected to attend a majority of meetings, and to review and comment on materials for the meetings they cannot attend. CORE then summarizes member comments and recommendations in a report that will be publicly posted on CMS's website.

TEP Meetings

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

Second TEP Meeting Overview

Prior to the second TEP meeting, TEP members received:

- TEP presentation materials
- Background on readmission measures

- Sepsis readmission measure risk variable results
- Sepsis readmission measure cohort and International Classification of Diseases, Tenth Revision (ICD-10) codes
- Results of analysis exploring whether and how to account for the competing risk of mortality in the sepsis readmission measure
- Results of analysis of hospital-level coding variation of sepsis and any association with the outcome

The goals of the TEP meeting were to solicit feedback from the TEP on the risk variable selection process which includes an empiric and clinical approach, and on the appropriateness of candidate risk variables selected.

The following bullets represent a **high-level summary** of what was presented and discussed during the TEP meeting. For a detailed meeting summary, refer to the full minutes of the meeting in Appendix B.

Summary of TEP Input (including both Zoom and written responses)

Recap of Previous Meeting

- CORE summarized CMS's risk-adjusted 30-day All-Cause Unplanned Readmission Measures and noted the similarities in the measure specifications and methodology with the sepsis readmission measure.
- CORE reviewed the response to TEP feedback from the previous meeting including examining the competing risk of mortality and hospital-level coding variation of sepsis, summarized the current project goals, and discussed the details of the risk variable selection process and the candidate risk variables.

Risk Variable Selection Process

- CORE described the guiding principles of the risk variable selection process:
  - Consistent approach with other readmission measures;
  - Use of individual ICD-10 codes rather than groups of related codes;
  - Combine variables that are highly correlated; and
  - Consider additional variables or grouping of variables if not selected.
- CORE noted that diagnosis codes in the 12 months prior to the index hospitalization and secondary diagnosis codes that are present on admission (POA) during the index hospitalization are used as potential risk variables for risk adjustment. Codes related to social determinants of health (SDOH) are not included in the risk model at this stage but will be examined after adjustments are made to the model based on clinical comorbidity. An analysis examining model performance across social risk factors will be conducted.
- CORE detailed the steps in the risk variable selection process resulting in the 159 final variables in the model and the rationale for the inclusion of additional risk variables (forced into the model). Risk variables that were forced into the model based on TEP member feedback from TEP meeting 1 and clinical review of the codes included:
  - Pathogenicity of the sepsis organism;
  - Immunocompromised status; and
  - Surrogate markers of severe sepsis
- CORE posed the following discussion questions to the TEP:

- **Are there any parts of the process that need to be clarified?**
- **Do you have any feedback on the process?**

TEP Feedback:

- Overall, TEP members supported the risk variable selection process, and the empiric data-driven approach combined with clinical input and face validity.
- TEP members agreed with the approach of identifying individual codes versus the use of an existing classification system or clinical rationale alone.

Risk Variable Selection Results

- CORE reviewed the risk variable selection results and summarized the process of risk variable selection as follows:
  - Applying the frequency thresholds to the 35,407 index and pre-index codes resulted in 470 (index) + 192 (pre-index) codes being available for selection.
  - Combining identical pre-index and index codes if they were statistically significantly associated with the outcome (readmission) and the difference in odds ratio was less than 0.2, and combining codes that were highly correlated (correlation coefficient ≥0.8), resulted in 652 codes remaining for risk variable selection.
  - Bootstrapping and applying the significance threshold of 95%, and including clinically relevant codes, resulted in the final 159 risk variables.
- CORE reviewed the codes and confirmed the risk variable selection process identified codes that adjust for the severity of sepsis by capturing indicators of severe sepsis (e.g., acute respiratory failure with hypoxia, severe sepsis with septic shock).
- CORE posed the following discussion questions to the TEP:
  - **Do you feel that the risk variables selected up to this point make sense (you would expect them to be associated with greater or lesser risk of readmission for patients hospitalized for sepsis)?**

TEP Feedback:

- Overall, TEP members supported the risk variables selected, noting that the list is inclusive of expected variables associated with readmission.
- TEP members asked for clarification about various diagnoses that may or may not be included in the risk variable list.
- Overall, the TEP agreed with the approach to examine the influence of social determinants of health (SDOH) after accounting for clinical comorbidities.
- TEP members were very interested in how the final risk model will work to predict readmission (e.g., C-statistic) and how it compares to other condition-specific measure risk models.

Recommendations/Rationale

- TEP members recommended the investigation of the Severe Sepsis and Septic Shock Management Bundle (SEP-1) process measure in validity testing.
- TEP members were interested in exploring the influence of social drivers on readmission risk prediction, after accounting for clinical comorbidities.

Exceptions

- TEP members noted some concern with the consistency of present on admission (POA) coding between hospitals.

- While TEP members acknowledged the limitations of claims data, they also noted the ability to look at the prior 12 months of claims, in addition to the index admission codes, as strengths of the risk model.

Model Testing Results

- CORE reviewed the sepsis readmission measure model testing results and discussed the process of determining how well the predicted risk of readmission from the model agrees with observed readmission rates across risk deciles using the validation dataset.
    - The calibration plot showed that the observed and predicted readmission rates are closely aligned across all deciles, suggesting good calibration overall.
    - In summary, the results show the model is reliable for predicting 30-day readmission rates across the sepsis population.
- CORE posed the following discussion questions to the TEP:
    - **Are there additional risk variables that you think should be considered?**

TEP Recommendations/Rationale

- TEP members supported the consideration of additional social risk variables, such as economics, distance from the healthcare facility, and literacy.

Third TEP Meeting Overview

Prior to the third TEP meeting, TEP members received materials which included:

- Sepsis definitions
- A description of the utilization of Present On Admission Indicators
- Examination of the utility of using the Severe Sepsis and Septic Shock Management Bundle (SEP-1) to Validate the Sepsis Readmission Measure
- Model testing and key terms
- Reliability, validity, and social risk factor testing and key terms

The goals of the TEP meeting were to present updates since the TEP 2 meeting (feedback taken from TEP 2 and highlight analyses completed) and solicit TEP input on model performance and measure performance testing including reliability, validity, and social risk factor analyses for the Sepsis Readmission measure.

The following bullets represent a **high-level summary** of what was presented and discussed during the third TEP meeting. For a detailed meeting summary, refer to the full minutes of the meeting in Appendix C.

Summary of TEP Input (including both Zoom)

Recap from Prior TEP Meetings

- CORE summarized prior TEP meetings.
- CORE recapped that the second meeting focused on reviewing the risk variables selected for the final risk model which includes 161 variables including age.

Model Testing Results

- CORE reviewed the risk model performance results. These analyses used two years of Medicare data (fee-for-service [FFS] and Medicare Advantage [MA]) for patients hospitalized for sepsis.

The data were randomly split into two datasets: a development dataset for risk model development and a validation dataset for validating the model.
    - The C-statistic for the risk model using development data was 0.65 and likewise was 0.65 using validation data; this C-statistic is comparable to other readmission measures.
    - The predictive ability in both datasets showed a wide range in observed outcomes suggesting the model differentiates between those at low- vs high-risk of readmission.
    - The overfitting results were close to 0 and 1, indicating the model parameters perform well with "new" data.
    - Lastly, the calibration plots showed good alignment between the observed and predicted readmission rates, indicating the model is well-calibrated in both datasets.
- In response to prior TEP feedback regarding heterogeneity of sepsis as a syndrome of disorders, and heterogeneity in the way for which it is billed by providers, CORE also assessed the model performance among important subgroups.
    - Calibration results showed that the model is well calibrated for important sub-populations: patients with severe sepsis versus non-severe sepsis and for patients with septic shock versus without (based on International Classification of Diseases, 10th Revision, Clinical Modification [ICD-10 CM] codes).
    - CORE summarized that the model performance results suggest that the risk variables and overall risk model appropriately adjust for patient-level risk factors (e.g., case mix).

- CORE posed the following discussion questions to the TEP:
    - **What feedback do you have on the model performance results?**
    - **What concerns do you have about the model testing results, if any?**

TEP Feedback:

- One TEP member noted reservations about the C-statistic of 0.65, observing that it falls below the general C-statistic range (0.70 – 0.75) for mortality measures.

Reliability and Validity Testing Results

- CORE presented the reliability and validity testing results. Key findings included:
    - The distribution of Sepsis Readmission measure scores suggests a quality gap in performance.
    - Reliability testing showed that the measure meets the consensus threshold (minimum >= 0.6) for public reporting, with acceptable split-half reliability for hospitals with at least 25 cases.
    - Validity was evaluated by comparing the Sepsis Readmission measure scores with other related quality measures, the Centers for Medicare & Medicaid Services (CMS) Overall Hospital Quality Star Rating. Results supported construct validity, showing expected negative correlations, because they show higher readmission risk among those hospitals with lower Overall Hospital Quality Star Rating.
- CORE posed the following discussion questions to the TEP:
    - **What feedback do you have regarding the measure score reliability and validity results? What concerns do you, if any?**

TEP Feedback:

- Overall, TEP members expressed support for the measure's reliability and validity testing findings, noting the validity testing appropriately seeks expected correlations with related quality measures (e.g., other readmission measures, patient satisfaction survey tools).

Recommendation and Rationale

- One TEP member recommended further evaluation of the measure's construct validity using process measures that may be conceptually linked to lower readmission risk such as timeliness of follow-up care after discharge.
    - CORE noted that these process measures are not available at the national level.
- One TEP member noted that further exploration of the relationship between Severe Sepsis and Septic Shock Management Bundle (SEP-1) and the Sepsis Readmission measure may help enhance understanding of validity testing and results.
    - CORE highlighted that the two measures reflect distinct aspects of care. SEP-1 assesses early and timely sepsis treatment, while the Sepsis Readmission measure focuses on discharge planning and coordination of post-discharge ambulatory care— making any relationship between them challenging to interpret.
    - Other TEP members agreed with the approach to not focus on the relationship between the Severe Sepsis and Septic Shock Management Bundle (SEP-1) and the Sepsis Readmission measure.

Social Risk Factor Testing

- CORE reviewed social risk factor testing and explained that the contribution of social risk factors (SRF) to the model was assessed after clinical risk factors were added, because clinical factors may already capture or mediate all or part of the association with the outcome. Specifically, CORE examined: prevalence of the SRFs, their association with unadjusted outcomes at the patient level, the risk estimate of each of two social risk factors when added to the regression model on the outcome of sepsis readmission, correlation between the Sepsis Readmission measure score calculates with and without dual eligibility (DE) and High Area Deprivation Index (ADI), and the association between hospital performance on the Sepsis Readmission measure and the proportion of patients with DE and ADI.
- CORE summarized the social risk factor testing results.
    - Patients with social risk factors (DE/high ADI) in the sepsis readmission cohort had higher unadjusted readmission rates.
    - In a multivariable model that sufficiently accounts for clinical risks, the results were as follows:
        - Adjusted odds ratios showed that DE patients had higher odds of readmission compared to patients who were not dually eligible. Patients residing in high ADI neighborhoods had similar risk of readmission compared with patients residing in low ADI neighborhoods. The adjusted odds ratio was not statistically significant.
        - Hospital measure scores calculated with and without each DE and ADI were highly correlated.
        - Hospitals with the highest proportion of patients with DE and with ADI performed comparably on the Sepsis Readmission measure to hospitals with relatively a smaller proportion of these patients.

        - The risk model performed sufficiently for each patient with DE and high ADI.
- Based on the results of social risk factor testing, CMS determined that adjustment using clinical risk factors alone is sufficient.
- CORE posed the following discussion questions to the TEP:
    - **Please provide feedback on the social risk factor testing results.**

TEP Feedback:

- Some TEP members supported the social risk factor testing results and the decision to adjust for clinical risk factors alone (no adjustment for social determinants of health [DE/high AD]).
- The TEP members agreed that both community-level factors, such as ADI, as well as more specific patient-level data (e.g., food insecurity, housing instability, transportation, etc.) may influence the prediction of readmission risk and other health outcomes, however, these data are not reliably and consistently captured for analysis.

Recommendation and Rationale

- One TEP member recommended exploring the use of patient-level health-related social needs (such as food insecurity, housing instability, transportation challenges, education, and difficulty paying for medical bills) to better understand their impact on the sepsis readmission measure.
    - CORE acknowledged TEP member feedback but noted challenges with data limitation.

Sepsis Readmission Measure Summary and Voting

- CORE highlighted the key aspects of the Sepsis Readmission measure.
    - Importance: Captures 30-day all-cause readmissions following sepsis hospitalization, the distribution of measure scores reveals a quality gap.
    - Reliability: Split-half testing result meets the Consensus Based Entity (CBE) threshold of 0.6 for hospitals with at least 25 admissions over (two years of data).
    - Validity: Demonstrates good model performance across key subpopulations; social risk factor testing showed that the risk model that adjusts for clinical variables appropriately captures the impact of DE and ADI; and good construct validity through correlations with similar quality measures.
    - Usability: Hospitals are provided with detailed patient-level data and results are publicly reported and compared to the national average for patients, consumers, and the public.
- CORE posed the following discussion questions to the TEP:
    - **Please provide feedback on the Sepsis Readmission measure.**
    - **Face Validity vote: On a scale from 1 – 6, rate the following statement: Do you think that the sepsis readmission measure as specified, can distinguish between better and/or worse performance across hospitals?**

TEP Feedback

- Overall, TEP members noted agreement with the importance of the Sepsis Readmission measure and supported the approaches of reliability, validity, and usability.
- TEP members acknowledged the thoughtful measure development efforts and conveyed support for the Sepsis Readmission measure, especially given the challenge with using claims-based data to predict readmission risk.
- Nine of 10 TEP members agreed the Sepsis Readmission measure can distinguish between better and/or worse performance across hospitals.

- 3 TEP members strongly agreed, 3 TEP members moderately agreed, 3 TEP members somewhat agreed, and 1 TEP member somewhat disagreed.

Appendix A. TEP Call Schedule

TEP Meeting #1

Thursday, September 26th, 2024, 11:00AM – 1:00PM EST (Zoom teleconference)

TEP Meeting #2

Thursday, December 12th, 2024, 1:00 – 3:00PM EST (Zoom teleconference)

TEP Meeting #3

Monday, April 14th, 2025, 2:00 – 4:00 PM ET

Appendix B. Detailed Summary of Base Period TEP Meeting #2

Sepsis Readmission Measure Technical Expert Panel (TEP)

Meeting #2 Minutes

Thursday, December 12th, 2024, 1:00 – 3:00 PM ET

Participants:

- **Technical Expert Panel (TEP) Participants:** Rosie Bartel, David Classen, Sara Cosgrove, Sarah Doernberg, Tom Ehelian, Stephen Goins, Cindy Hou, Michael Klompas, Mitchell Levy, Hallie Prescott, Chanu Rhee, Maureen Seckel, Dorothy Winningham
- **Yale New Haven Health Services Corporation — Center for Outcomes Research and Evaluation (YNHHSC/CORE):** Patricia Faraone Nogelo, Ladan Golestaneh, Jackie Grady, Kasia Lipska, Roisin Healy, Jon Niederhauser, Onyinye Oyeka, Lucy Pereira, Allie Stupakevich, Zhen Tan, Yahui Tian, Lisa Suter
- **Centers for Medicare & Medicaid Services (CMS):** Melissa Hager, Ngozi Uzokwe

TEP Action Items

- Review and send any suggested edits to the meeting summary;
- Complete a brief survey about their experience during this meeting; and
- Reach out via email if TEP members have any questions or further feedback.

CORE Action Items

- Share a summary of the meeting minutes for TEP review; and
- Consider TEP feedback during the measure development process.

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 a sepsis readmission measure.
- As the organizer of this TEP, CORE convenes groups of stakeholders and experts who contribute direction and thoughtful input during measure development. The purpose of this TEP is to assemble a group with diverse perspectives and expertise to advise on conceptual, technical, and implementation considerations for this measure.

Detailed Discussion Summary

Welcome & Introductions

- Mr. Jon Niederhauser welcomed the TEP members, introduced himself as a CORE Stakeholder Engagement Lead, provided instructions about the meeting controls for closed captioning, provided participation guidelines and discussion decorum, shared details about the specific CMS funding source supporting this work, and reminded members about the confidentiality of meeting materials and discussion.
- Mr. Niederhauser acknowledged that CMS staff may be joining the call.
- Mr. Niederhauser reviewed the agenda, provided an overview of CORE, and introduced the Sepsis Readmission Measure Project Team.

- Dr. Onyinye Oyeka introduced herself as the team lead for the sepsis readmission measure project and expressed the project team's appreciation for the TEP's participation and their willingness to provide valuable input about the sepsis readmission measure.
- TEP members who were unable to participate in the first TEP meeting introduced themselves and shared their preferred name, affiliation/role, connection/interest in this project (optional), and disclosed any Conflicts of Interest (COI):
    - Sarah Doernberg is a professor of medicine at the University of California, San Francisco, and specializes in infectious diseases, particularly focused on transplant patients; served as Medical Director of the Antibiotic Stewardship Program at the University of California, San Francisco, and conducts clinical research related to antimicrobial resistance; no COI.
    - Mitchell Levy is a professor of medicine at Brown University and has been involved in work related to sepsis for 25 years; no COI.
    - Hallie Prescott is a pulmonary critical care physician at the University of Michigan, Veterans Affairs Ann Arbor Healthcare System; serves as co-chair of the Surviving Sepsis Campaign Guidelines and leads a statewide sepsis initiative in MI; no COI.
    - Maureen Seckel is a former critical care clinical nurse specialist and sepsis coordinator at Christiana Care and is currently in preferment status and consulting in critical care and sepsis. She has been very involved with sepsis for 20 years; no COI.

Review & Approval of TEP Charter

- Mr. Niederhauser reviewed the TEP role and Charter, noting the purpose of the TEP is to gain stakeholder input on measure development and increase transparency. He reviewed the TEP member responsibilities and confirmed the TEP's approval of the TEP Charter.

Recap of Previous Meeting

- Dr. Oyeka reviewed the purpose of readmission measures.
- Dr. Oyeka provided an overview of the readmission measures noting their similar measure specifications to the sepsis readmission measure.
- Dr. Oyeka reviewed measure specifications.
    - The measure score is reported as a risk-standardized readmission rate (RSRR) which is the ratio of predicted over expected readmissions, multiplied by the national observed readmission rate.
    - Dr. Oyeka defined the sepsis readmission measure outcome as <u>unplanned readmissions for any cause</u> within 30 days of discharge from the index admission.
        - Only an unplanned inpatient admission to a short-term acute care hospital can qualify as a readmission.
        - All unplanned readmissions are considered an outcome, regardless of cause.
        - Planned readmissions are <u>not</u> counted.
    - Dr. Oyeka detailed the finalized sepsis readmission measure cohort based on TEP input:
        - Medicare Fee-for-service (FFS) and Medicare Advantage (MA) patients, aged 65 and over, admitted to a non-federal short-term acute-care hospital:
            - with a principal discharge diagnosis of sepsis, including post-procedural sepsis;
            - discharged alive; and
            - not transferred to another acute care facility.

        - The sepsis readmission measure will exclude admissions for patients:
            - discharged against medical advice (AMA);
            - discharged to hospice;
            - without at least 30 days post-discharge enrollment; or
            - admissions within 30 days of discharge from an index admission, for that same condition.
        - The cohort will include patients with a principal diagnosis of sepsis and a secondary diagnosis of pneumonia coded as present on admission (POA) but without a secondary diagnosis of severe sepsis coded as POA (due to overlap with pneumonia readmission measure cohort); and with a principal diagnosis code of COVID-19 (International Classification of Diseases, 10th Revision, Clinical Modification [ICD-10-CM] code U07.1) or with a secondary diagnosis code of COVID-19 coded as POA on the index admission claim.
- Dr. Oyeka reviewed the response to TEP feedback and briefly summarized the findings from supplemental analyses following the TEP #1 meeting, which included examining the competing risk of mortality and hospital-level coding variation of sepsis. Details of the analyses and findings were shared with the TEP prior to the TEP #2 meeting and the findings from the analyses support that mortality and hospital-level coding variation of sepsis are unlikely to have substantive effect on the measure results.
- Dr. Oyeka noted that the current meeting goals include reviewing the risk variable selection process and final risk variables and assessing how the risk model addresses TEP concerns. The main considerations for discussion include how the risk model accounts for severity of sepsis, organ dysfunction/failure, and site of infection.

Risk Variable Selection Process

- Dr. Oyeka reviewed background information of the risk variable selection process.
- She noted that the guiding principles of risk variable selection include:
    - Consistent approach with other readmission measures;
    - Use of individual ICD-10 codes rather than groups of related codes;
    - Combine variables that are highly correlated; and
    - Consider additional variables or grouping of variables if not selected.
- Risk variable selection process includes the following steps:
    1) Identify a measurement period;
    2) Identify ICD-10 codes from patient medical claims (secondary diagnosis codes present on admission (POA) during the index hospitalization and history codes, that is, diagnoses codes from the past 12 months prior to the index hospitalization);
    3) Apply frequency thresholds to the identified ICD-10 codes from step 2 to cut down the number of codes to be considered (including ICD-10 codes that appear ≥0.5% for index codes and ≥ 2.5% for history codes);
    4) Combine ICD-10 codes that are highly correlated;
    5) Identify variables that meet a frequency threshold of significance (ICD-10 codes that are consistently significantly associated with the outcome 95% of the time) through bootstrapping;
    6) Consider additional risk variables (e.g., history of COVID, MA indicator, etc.).

- Dr. Oyeka explained that through the initial bootstrapping process, 200 variables met the threshold for significance of 80%, which is the threshold used for risk variable selection for most readmission measures. CORE additionally evaluated variables that are clinically relevant and associated with the outcome based on TEP feedback (e.g., pathogenicity of sepsis organism). The bootstrapping process was repeated and the C-statistic (a statistical method that assesses model performance) was derived. Based on the C-statistic, the threshold of significance was adjusted to 95% because there wasn't much difference in model performance using a 95% versus 80% significance threshold. At this threshold, 149 variables met the criteria for selection including an indicator for frailty (Multiple Chronic Condition frailty). Variables that fell below the threshold were reviewed by clinical subject matter experts (SMEs) and 10 additional variables were deemed clinically relevant based on clinical review and responsive to TEP feedback during TEP meeting # 1. Altogether, 159 variables were selected as the final risk variables for the sepsis readmission measure (excludes age).
- Dr. Oyeka summarized the rationale for the additional risk variables forced in the model.
    - Pathogenicity of organism: Because sepsis due to pathogenically aggressive organisms may place a patient at higher risk of readmission compared to non-specific or less pathogenic organisms, the following sepsis diagnoses were included:
        - Sepsis due to streptococcus
        - Sepsis due to staphylococcus
        - Sepsis due to E. coli
        - Sepsis due to enterococcus
        - Sepsis due to haemophilus
        - Salmonella sepsis
        - Sepsis, unspecified organism
        - Sepsis due to pseudomonas
        - Other sepsis specified
        - Other gram-negative sepsis
        - Fungal sepsis
        - Gram-negative sepsis, unspecified
    - Immunocompromised status: patients who become immunocompromised as a result of conditions or medications that interfere with normal immune function may also have a higher risk of sepsis readmission. Thus, neutropenia and a transplant status indicator comprised of the following types of transplants: kidney, heart, lung, liver, bone marrow, pancreas, stem cell, was included.
    - Surrogate markers of severe sepsis: Based on TEP feedback, markers of severe sepsis resulting in acute organ dysfunction, were also included: acidosis, fluid overload, hypoxemia, and hypotension.

Discussion Session #1

- Mr. Niederhauser presented the discussion questions in reaction to the risk variable selection process for the first TEP session:

Questions #1:

Are there any parts of the process that need to be clarified?
Do you have any feedback on the process?

- A TEP member asked about how Multiple Chronic Condition (MCC) frailty is identified and if it is a specific code or an algorithm?
    - Dr. Kasia Lipska replied explaining that the MCC frailty indicator is a composite indicator designed for risk adjustment, encompassing Conditions of Categories (CC) and durable medical equipment (DME) codes that serve as markers of disability and frailty.
    - Dr. Suter noted that, along with DME (e.g., canes, walkers, wheelchairs, etc.), these code groups are also used as part of the algorithm that defines frailty:

Complications or comorbidities	Code	Complications or comorbidities	Code
Protein-Calorie Malnutrition	CC21	Pressure Ulcer of Skin with Partial Thickness Skin Loss	CC159
Quadriplegia	CC70	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	CC160
Paraplegia	CC71	Chronic Ulcer of Skin, Except Pressure	CC161
Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	CC73	Amputation Status, Lower Limb/Amputation Complications	CC189
Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	CC157	Amputation Status, Upper Limb	CC190
Pressure Ulcer of Skin with Full Thickness Skin Loss	CC158	-	-

- The same TEP member asked for more information about the rationale for using individual versus group codes and existing comorbidity categories (e.g., Elixhauser or Charlson Comorbidity Index).
    - Dr. Lisa Suter summarized that CORE has explored different approaches for grouping International Classification of Diseases, Ninth Revision (ICD-9) and ICD-10 codes, with over 20 years of building measures for CMS. Generally, the best approach has been to use a combination of empiric data-driven approaches with clinical input and face validity (e.g., forcing in frailty). CORE recently reselected risk variables using individual ICD-10 codes because this approach improved the ability to account for patient severity and risk when patients present to the hospital over the previously used grouped codes. This was an extensive process to evaluate multiple approaches and compare model performance, overfit, etc. TEP (clinicians and methodologists) input guided the process of selecting certain individual codes as opposed to grouped codes.
- Another TEP member asked about the definition of neutropenia for the immunocompromised population and if this is a code or based on a lab value, and if it is required to be at a certain level and/or for a certain duration.
    - Dr. Lipska explained this measure is a claims-based measure. Neutropenia is defined based on ICD-10 code.
- A TEP member noted strong support for the evidence-based approach to the identification of codes instead of using an existing classification system or clinical rationale alone. Even with this additional level of detail, there is some variation in patient severity of illness that will not be captured. For example, fungal sepsis/infection predicts severity, while at the same time, there is

a big difference in the likely impact of candida vs fusariosis fungal infections. They asked about available data on comparing this approach (using codes) to classical bedside physiological parameters (e.g., Acute Physiologic Assessment and Chronic Health Evaluation [APACHE]) or measures of severity of illness based on clinical values, such as lab results.
    - Dr. Suter commented on the historical background of initially building the CMS readmission measures using claims data. There was controversy over using administrative claims, and CORE compared them to clinically abstracted medical record data. She noted that claims data are their own data type, while they represent some clinical aspects, there is no one-to-one correlation to detailed clinical information. More recently, with the availability of electronic health record (EHR) data, CORE has explored adding clinical risk factors (e.g., vital signs, lab values) to measure specifications. Hybrid measures (those defined using both claims and EHR/clinical data) improved the risk prediction for mortality and complication measures but had almost no impact on improving the prediction of readmission risk because there is only a portion of readmission that is related to clinical risk. Readmission is complex, given the relation to care coordination and other factors such as access to care and social determinants of health (SDOH).
    - Dr. Suter added that the readmission measures are stratified based on the assignment of payments by dual eligibility (Medicare and Medicaid) to account for socio-economic status (SES), while not forcing SES into the risk model. That said, CMS has requested to keep the sepsis readmission measure a claims-based measure to minimize burden on hospitals. As EHR-based reporting evolves and data is easily leveraged for measurement, CMS may consider moving to a digital measure environment for the readmission measures.
    - The same TEP member noted appreciation for Dr. Suter's point about the importance of care coordination and social factors in driving readmissions. They asked if CORE has been able to incorporate measures or proxies for these into the risk-adjustment strategy.
    - Dr. Suter confirmed this often happens when defining the candidate variable pool prior to selection. Because care coordination is under the control of the hospital (and reflects quality of care), we do not risk adjust for those factors. We consider clinical comorbidities first, then look at the incremental influence of social drivers on readmission risk prediction after accounting for clinical comorbidities.
- The same TEP member asked about proxies for social factors (income, education, language fluency, health literacy, distance to care, etc.).
    - Dr. Lipska replied this is an important question. To avoid setting different expectations for patients with adverse SDOH, CORE is very careful about inclusion of social risk factors into the model. We test the influence of these factors, but do not routinely include them for adjustments. Hospitals can also work to mitigate the impact of social risk factors on the risk of readmission.
    - Dr. Suter added that CORE considers clinical comorbidities first, then looks at the incremental influence of social drivers on readmission risk prediction after accounting for clinical comorbidities.
- A different TEP member asked for clarification about which conditions (e.g., amputee) are included in the readmission measure.

    - Dr. Oyeka clarified that the measure is capturing any readmission within 30 days of the index admission. For example, if a patient had an initial hospital admission of sepsis and was then readmitted for any reason within 30 days, it would be captured in the measure. She explained risk adjustment aims for readmission rates compared across hospitals that are fair (e.g., adjusting for types of patients treated at hospitals) by using comorbidities at admission or prior conditions to determine the patient risk.
- Another TEP member asked if CORE has tried any machine learning (ML) or artificial intelligence (AI) strategies to see if they identify a different set of codes or combinations of codes that collectively are more significant than any of them on their own.
    - Another TEP member asked about the inclusion of AI in sepsis treatment.
    - Dr. Suter replied CORE has looked at ML techniques (pre-pandemic, actually), but to ensure full transparency consistent with CMS's measurement requirements, CORE did not pursue that work further at that time. CORE has been exploring this again as methods become more transparent.
    - Dr. Golestaneh added we did not use AI or machine-learning, but the bootstrapping method (multivariate) could be counted as a supervised learning method.
- A TEP member asked if CORE has considered prior healthcare utilization as a risk factor (e.g., adjusting for whether or not a patient was hospitalized, or the number of hospitalizations during a look back period).
    - Dr. Ladan Golestaneh noted CORE adjusted for codes used during hospitalizations within 1 year prior to index admission.
    - Dr. Suter added that we do not specifically adjust for the number of prior admissions, as this can reflect both patient-level and community/health system- level influences.
- A different TEP member asked if there was a clinical review process to potentially exclude any of the 159 final risk variables in the model or if it was solely determined using empiric statistical methods.
    - Dr. Oyeka confirmed that CORE considered adjusting for procedures such as mechanical ventilation or Continuous Renal Replacement Therapy (CRRT) and decided not to because although these procedures are markers for severity, they are also markers of quality of care received from the hospital and it is expected that hospitals will do these procedures.
    - Dr. Golestaneh noted CORE wanted to avoid variables that were potentially in the causal pathway to avoid over-adjusting for care quality between hospitals.

Risk Variable Selection Results

- Dr. Oyeka described the risk variable selection process.
    - Frequency thresholds are applied to 35,407 index and pre-index codes resulting in 470 (index) + 192 (pre-index) codes remaining.
    - Combine identical codes in pre-index and index based on their association with the outcome and difference in odd ratio (less than 0.2) and codes that are highly correlated (correlation coefficient ≥0.8), resulting in 652 codes.
    - Bootstrapping and significance thresholds are applied, and include clinically relevant codes, resulting in the final 159 risk variables.
- Dr. Oyeka reviewed the risk variable selection results, noting the location of the various codes in the attachment provided to the TEP members: “Sepsis Readmission Risk Variable Results.”

- ICD-10 codes within the sepsis cohort that meet frequency thresholds
  - Index admission (470 codes): secondary diagnoses POA (Tab 2a)
  - Pre-index (192 codes): inpatient and outpatient diagnosis codes (principal and secondary) 12 months prior to the index admission (Tab 2b)
  - Comparison of frequencies for MA vs FFS patients (Tab 8, 9)
- Combining codes
  - Pairs of codes that are highly correlated (Tab 4)
  - Odds ratios for all variables identified up to this step (Tab 3)
  - Codes identical in pre-index and index that meet criteria for combining (Tab 5)
- Bootstrapping results
  - Percent of the 1,000 bootstrapping samples within which each variable was significant (Tab 6)

- Dr. Oyeka reviewed the most frequent (top 20) index admission and pre-index admission variables and confirmed the risk variable selection process adjusts for the severity of sepsis by capturing those codes indicative of severe sepsis (e.g., acute respiratory failure with hypoxia, severe sepsis with septic shock).

Discussion Session #2

- Mr. Niederhauser presented the discussion question in reaction to the risk variables for sepsis readmission:

Question #2:

Do you feel that the risk variables* selected up to this point make sense (you would expect them to be associated with greater or lesser risk of readmission for patients hospitalized for sepsis)?

- A TEP member noted agreement from the patient perspective with the risk variable list and noted that the diagnoses were reflective of the many and varied conditions experienced by sepsis patients; they noted that the list is transparent and thorough.
- Another TEP member stated the list of diagnoses is unsurprising and asked if the Severe Sepsis/Septic Shock (SEP-1) measure variables correlate with readmission (e.g., if a patient does not receive the SEP-1 treatment bundle and appropriate therapy, readmission risk may increase).
  - Dr. Suter acknowledged the great suggestion and noted that CORE could investigate the SEP-1 measure in validity testing. If there is poor sepsis management, the patient may die and anyone who is discharged with sepsis has a survivor effect, so there may be some complicated dynamics depending on the range of performance across the SEP-1 measure results.
- A TEP member expressed appreciation to CORE for the thoughtful efforts and asked if CORE has explored substance use disorder as a comorbidity associated with sepsis readmission.
  - Dr. Oyeka noted substance use disorder did not meet the significance threshold for inclusion in the final risk variables.
  - Dr. Golestaneh confirmed endocarditis is on the risk variable list and perhaps acting as a surrogate for intravenous drug use.
- Another TEP member asked why nicotine and gastroesophageal reflux disease (GERD) seem to be protective against readmission. They also commented that having urogenital candidiasis is not particularly a risk factor but may be a surrogate marker for more severe illness burden. They

also remarked that neutropenia as a risk variable will capture a heterogenous group of people (e.g., benign neutropenia, neutropenia because of sepsis, etc.), and the risks in this group will be different depending on the cause of neutropenia. They recommended capturing chemotherapy-induced neutropenia, specifically. Lastly, they agreed with the approach to consider adjustment of SDOH after accounting for clinical comorbidities in the model and asked about how best to control for hospital differences in care provided for chronic illness management.

- Dr. Lipska clarified that we do not want to adjust for the processes of inpatient care, but we do want to adjust for case mix and severity of sepsis. Thus, we were very careful to use diagnostic codes that are either in the history for the patient or present on admission (POA) (when the patient arrives with sepsis).
- These data are from claims; thus, they may act differently from clinical risk factors, and some may carry other information. For example, a claim for GERD may represent a longitudinal relationship between the patient and a physician who is able to code for "non-urgent ambulatory sensitive diagnoses," which may be protective.
- Dr. Golestaneh agreed with the importance of granularity for the cause of neutropenia; we were more concerned with adjusting across hospitals. For example, if a hospital had a disproportionate number of cancer patients getting chemotherapy, we wanted to make sure that we would adjust for that.
- Mr. Niederhauser confirmed CORE will follow up about the chemotherapy-induced neutropenia code.
- A different TEP member commented they have always thought of protective odds ratios for certain comorbidities as potentially being related to the fact that clinicians/hospitals typically code for more serious conditions, so if they are coding for things like GERD, then they probably did not have too many serious conditions; at least that is the explanation for how some Leithauser comorbidities have a protective association for mortality. They noted that this, of course, highlights the problem and limitation of relying on claims-based data.

- Another TEP member asked if sepsis patients with an electrocardiogram (ECG) are included in the sepsis readmission measure cohort.
  - Dr. Suter clarified most of the risk variables are diagnoses or procedures; ECG is not a risk variable in the final model. Claims data captures heart failure codes but do not capture ejection fraction or clinical measures of different diagnoses.
  - Dr. Golestaneh confirmed heart failure and severe heart failure are on the risk variable list.
- A TEP member asked if these are adjusted or crude odds. They also asked about history codes (signs and symptoms), such as fever, chest pain - unspecified, abdominal pain, and the potential impact on sepsis readmission.
  - Dr. Oyeka confirmed these are crude odds. She clarified the history (signs and symptoms) codes along with the patient's other comorbidities, impacting the patient's readmission risk.
- A different TEP member asked if 'protein-calorie malnutrition-severe' is on the list and if dysphagia or stroke/cerebrovascular accident are included; they noted that these are some conditions that are foreseen in patients who are readmitted to our hospital.
  - Dr. Suter confirmed these codes are included in the list.

- The same TEP member noted 'pleural effusion' is at the top with severe chronic comorbidity but also elsewhere on the list with 'pleural effusion, not otherwise specified.' They asked if these should be combined or not.
    - Dr. Golestaneh replied this is a good callout and stated that CORE combined codes empirically based on frequency of co-occurrence and based on strong correlation.
    - The same TEP member asked if there are any obesity ICD-10 codes on this list (greater BMI - greater risk of general readmission).
        - Dr. Golestaneh confirmed obesity coded at the index admission was on the list.
    - The same TEP member asked if the model has different variables based on community hospital vs academic hospital.
        - Dr. Lipska noted the model is the same for all types of acute short-term hospitals.
- A TEP member noted that the approach for choosing codes is systematic and rigorous, however stated that we should not use these codes in medical terms because they are proxies for other factors that are unmeasured, which does not undermine their appropriateness/utility for this task. They expressed some concern about accuracy of coding overall and of consistency between hospitals in the use of POA codes. For example, the completeness of adjusting for SDOH (pre-existing factor) will vary and the capacity to clearly say for a diagnosis what is POA or not is sometimes subjective. The noted, for example, which adjusting for diabetes, there is mild and severe, and even though there are different codes for some of this, it does not capture the full spectrum. There is nuance to social factors and the codes that are used. They noted that the proof will be in how well this predicts readmission.
    - Dr. Suter noted the inclusion of the codes for all encounters for 12 months prior counters some aspects of coding variability (allows for capture of a more complete set of risk factors for each patient).
    - The same TEP member asked about inclusion of social factors in the model. They noted that things like language, income, literacy, etc. are "POA," as it were, and stated that it was unclear to them why they would not be included in the model. They stated that it seems unreasonable to expect hospitals to "fix" all these.
    - Dr. Oyeka stated the Z codes that are not included (in the model) can be found in the appendix slides.
    - The same TEP member suggested that the 'saving grace' is that some of the medical diagnoses may be proxies for some of these social factors in unexpected ways.
    - Dr. Golestaneh noted CORE examined model performance separately for patients residing in disadvantaged neighborhoods using Area Deprivation Index (ADI) and patients dually eligible for Medicare and Medicaid for this reason.
- The same TEP member asked if CORE adjusts for the length of the index admission.
    - Dr. Golestaneh noted that CORE does not adjust for length of stay; it would be part of the causal pathway.
    - Dr. Lipska replied that CORE tries to stick to risk factors that are present prior to or at the time of admission and not during admission because diagnoses during admission can be affected by processes of care.
- The same TEP member asked for clarification about acute diagnosis and the causal pathway.

    - Dr. Lipska noted that the codes included in risk adjustment were POA, otherwise there was a risk of adjusting for inpatient events that are in the causal pathway.
- Another TEP member asked if kidney stones with or without hydronephrosis are on the risk variable list.
    - Dr. Golestaneh clarified unspecified hydronephrosis is on the list but the history of calculus of kidney did not meet the threshold.
- A TEP member agreed with previous comments that these data are partially medical and partially artifacts related to patient interactions with the healthcare system. They noted appreciation for the systematic and robust approach that was taken; they were interested in seeing how well the model works overall to predict readmission.
    - The same TEP member stated there is a lot baked into these codes; they are serving as a marker for a lot of things (including absence of more severe comorbidities). They wondered how well the final risk model works (e.g., C-statistic), and how it compares to risk models for the other condition-specific risk models. They noted that it is really difficult to predict readmission and readmission risk models generally do not perform as well as mortality.
    - Dr. Golestaneh noted CORE is in the process of performing these analyses.
- Another TEP member noted that they often see cancer patients readmitted at their hospital and expected to see more cancer diagnoses on the list. They agreed with previous comments on the limitations of codes (e.g., diabetes) and asked about the amount of variability in the codes (e.g., severity of illness, comorbidities).
    - Dr. Suter clarified the overall use of POA codes has increased and then plateaued across hospitals. Originally, POA coding was restricted to the conditions that were incentivized by payment withholds, such as hospital-acquired infections (HAIs) and pressure ulcers. More recently, most hospitals take a very formal POA coding approach, and while there may be variation across hospitals, there is less within-hospital variation. She noted that when the first readmission measures were created, model performance in predicting readmission risk was similar when using claims data and data derived from medical records.
    - Dr. Suter also noted clinical comorbidities only account for a small proportion of the risk of readmission, unlike mortality (risk models with high C-statistic range of 0.80 – 0.90). The C-statistic is much lower for the readmission measures (0.60 – 0.65). In response to this feedback CORE will pull prior POA analysis to share with the TEP. Lastly, she noted that it is important to recognize that when codes are aggregated at the hospital level it tends to remove some of the variation compared to an individual patient or diagnosis.
    - The same TEP member commented that the inclusion of Medicare data and the ability to look at the prior 12 months of claims, in addition to index admission codes, are strengths of the risk variable model.
    - The same TEP member noted the antineoplastic induced pancytopenia code is on the list.
    - Dr. Lipska noted that D70. 1 - agranulocytosis secondary to cancer chemotherapy did not meet the frequency threshold.

- A different TEP member expressed appreciation for the statistical analysis and discussion. They asked about the risk variables used in adjusting the pneumonia readmission measure (pneumonia is a similar readmission diagnosis that is seen at their hospital).
    - Dr. Oyeka confirmed CORE will follow up on providing this information.
- Another TEP member noted, as a caregiver, that they think the codes ranking is great, particularly with the #1 having to do with renal conditions.
- A TEP member noted the use of the chat [function during the meeting] was very helpful and requested that CORE share chat comments with the TEP members.

Model Testing Results

- Dr. Oyeka reviewed the sepsis readmission measure model testing results.
    - Evaluated how well the predicted risk of readmission using the risk model agrees with observed readmission rates across risk deciles using the validation dataset.
        - Medicare FFS and MA data from January 2022 through December 2023.
        - Validation cohort size was 662,000 patients.
    - The calibration plot shows that the observed and predicted readmission rates are closely aligned across all deciles, suggesting good calibration overall.
    - The conclusion is that the model is reliable for predicting 30-day readmission rates across the sepsis population.

Discussion Session #3

- Mr. Niederhauser presented the discussion question querying about additional risk variables:

Question #3:

Are there additional variables that you think should be considered?

- A TEP member agreed with previous comment about the importance of including social risk factors in the model, such as economics, distance from the healthcare facility, and literacy.
    - Dr. Suter agreed with the importance of social risk factors. She clarified the reason these SDOH variables are not in the model is because we are trying to define the expected level of readmission for every hospital based on their group of patients, and each risk variable contributes an expected readmission rate. For example, if we added literacy into the model, (low literacy is associated with higher readmission rates in the US), then the model will allow hospitals to get "extra credit," and they will be expected to have higher readmission rates for those patients with lower health literacy. CORE first creates the best clinical comorbidity model and then explores the influence of social risk factors and assesses disparities. CMS traditionally, and specifically for readmission, has chosen to stratify the assignment of payment based on factors such as dual eligibility (an indicator of low SES), addressing disadvantaged hospitals.
- Another TEP member asked if discharge setting following the index hospitalization influences patients' risk of readmission and if this can be tracked.
    - Dr. Suter noted it may influence the risk of readmission but this is within the control of the hospital and reflects quality of care. Although it may reflect access to care and community factors, it is not included in the model. CORE can investigate this with future exploration of SDOH.

Next Steps

- On behalf of CORE, Mr. Niederhauser thanked the TEP participants for their time and valuable feedback. He noted their continued feedback was welcome, and encouraged TEP members to send emails with additional feedback or questions to: alexandra.stupakevich@yale.edu
- Mr. Niederhauser noted the next steps for CORE's Sepsis Readmission Team including:
    - Sharing a summary of today's meeting for TEP review in the coming weeks; and
    - Utilizing TEP feedback to inform the final list of risk variables.
- Mr. Niederhauser noted the next steps for the TEP members include:
    - Review the summary of today's meeting in the coming weeks.
    - Respond to communications in January for scheduling the next TEP meeting, expected in February 2025. (The next TEP meeting will review final risk variables, model performance, reliability and validity testing, and social risk factor testing.)
- Mr. Niederhauser noted that TEP members will be asked to complete a brief post-meeting survey.
- Mr. Niederhauser thanked participants for sharing their thoughts and noted understanding of and appreciation for the complexity of this conversation.

Appendix C. Detailed Summary of Base Period TEP Meeting #3

Date:
Monday, April 14th, 2025, 2:00 – 4:00 PM ET

Participants:

- **Technical Expert Panel (TEP) Participants:** Rosie Bartel, David Classen, Steven Coffee, Sara Cosgrove, Sarah Doernberg, Tom Ehelian, Cindy Hou, Hallie Prescott, Chanu Rhee, Maureen Seckel, Dorothy Winningham
- **Yale New Haven Health Services Corporation — Center for Outcomes Research and Evaluation (YNHHSC/CORE):** Katie Balestracci**,** Floraine Evardo, Ladan Golestaneh, Roisin Healy, Thushara John, Shuyi Lang, Zhenqiu Lin, Kerry McDowell, Jacelyn O'Neill-Lee, Jon Niederhauser, Onyinye Oyeka, Lisa Suter, Zhen Tan
- **Centers for Medicare & Medicaid Services (CMS):** Melissa Hager, Ngozi Uzokwe

Administrative Items

TEP Action Items

- Review and send the CORE team any suggested edits to the meeting summary;
- Complete a brief survey about their experience during this meeting; and
- Reach out via email if TEP members have any questions or further feedback.

CORE Action Items

- Share a summary of the meeting minutes for TEP review; and
- Consider TEP feedback during the measure development process.

Detailed Discussion Summary

Welcome & Introductions

- Mr. Jon Niederhauser welcomed the TEP members, introduced himself as a CORE Stakeholder Engagement Lead, provided meeting guidelines, shared details about the specific CMS funding source supporting this work, and reminded members about the confidentiality of meeting materials, discussion, and voting decisions.
- Mr. Niederhauser acknowledged that CMS staff may be joining the call.
- Mr. Niederhauser reviewed the agenda and briefly introduced the Sepsis Readmission measure project team.
- Dr. Onyinye Oyeka introduced herself as the team lead for the Sepsis Readmission measure project and expressed the project team's appreciation for the TEP's participation and their willingness to provide valuable input about the Sepsis Readmission measure.

Recap from Prior TEP Meetings

- Dr. Oyeka provided a recap of the prior TEP meetings and the Sepsis Readmission measure development activities.
- The main topic of today's TEP (third) is to share test results that describe model performance, measure score reliability and validity, and social risk factor analysis.

Model Testing Results

- Dr. Oyeka reviewed the key metrics for risk variable model testing including C-statistic, predictive ability, calibration plots, and overfitting. She noted that testing data included Medicare fee-for-service (FFS) and Medicare Advantage (MA) hospitalizations for sepsis from January 1, 2022, to December 31, 2023. She noted that the data were randomly divided into development and validation datasets; the development set was used to develop and refine the risk model, while the validation set was used to assess the model's performance.
    - The C-statistic calculated using the development dataset is 0.65, and the C-statistic using the validation data set is 0.65.
    - The predictive ability showed that there is a wide range in observed outcomes in both datasets indicating that the model differentiates well between low risk from high-risk patients.
    - The overfitting results are very close to 0 and 1, indicating that the model performs well in the validation dataset.
    - The calibration plots for both the development and validation datasets showed that the model is well calibrated.
- Dr. Oyeka also shared model performance test results for important sub-populations, patients with severe sepsis and septic shock, based on International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) in response to TEP feedback and concerns regarding the heterogeneity of sepsis.
    - The calibration plots showed that the model is well calibrated for these sub-populations of patients.
- Dr. Oyeka summarized the key findings of the model testing results.
    - Model performance statistics suggest the risk variables and risk model are appropriately adjusting for patient-level risk factors (e.g., case mix).
    - The model is well-calibrated for important sub-populations: patients with severe sepsis and septic shock, respectively.

Discussion Session #1

Question #1:

What feedback do you have on the model performance results?
What concerns do you have about the model testing results, if any?

- A TEP member expressed support for CORE's measure development work and noted the C-statistic of 0.65 would not be considered particularly strong. They acknowledged the challenges with predicting readmission. They noted that for mortality measures we want the C-statistic to be higher (a range between 0.70 and 0.75 or higher). They asked about the C-statistic standard for other readmission measures.
    - Dr. Oyeka confirmed that CORE compared the C-statistic with other readmission measures, especially the hospital-wide readmission (HWR) measure, which showed that the C-statistic ranged between 0.64 and 0.68. The C-statistic for the Sepsis Readmission Measure falls within this range, aligning with the performance of other readmission measures.
    - Dr. Zhenqiu Lin pointed out that even when clinical data (e.g., electronic health record [EHR]) is combined with claims data, improving the C-statistic for readmission measures

remains challenging. In contrast, mortality measures often achieve a C-statistic of 0.80 or higher. Other research shows that predicting readmission outcomes using patient-level risk factors is challenging.

Measure Score, Reliability, and Validity Testing Results

- The Sepsis Readmission measure hospital scores (risk-standardized readmission rates [RSRRs]) showed variation, suggesting a quality gap in performance. Detailed results for the measure scores are the following:
    - The RSRR for hospitals with >= 1 admission ranged from 12.9% to 24.9%; the 25th percentile was 17.5% and the 75th percentile was 18.5%.
    - RSRR for hospitals with >= 25 admissions also ranged from 12.9% to 24.9%; the 25th percentile was 17.3% and the 75th percentile was 18.9%.
        - To assess reliability, CORE used the split-half testing approach. To test for validity, CORE assessed the correlation of the Sepsis Readmission measure to other similar quality measures that capture related aspects of care-measure components in the Overall Hospital Quality Star Rating. These measures included: Readmission measure group score with and without the Hospital-Wide Readmission measure;
        - Overall summary score across all measure domains in the Overall Hospital Quality Star Rating with and without the readmission group;
        - Patient experience group score
    - Because the Overall Hospital Quality Star Rating and the other quality measures within it are assessed on a higher score is better scale but the sepsis readmission measure is assessed on a lower score is better scale, CORE hypothesized that the sepsis readmission measure would be negatively correlated with Overall Hospital Quality Star Rating measures.
- Dr. Oyeka reviewed the reliability and validity testing approaches and results.
- Dr. Oyeka summarized that the measure is sufficiently reliable for a publicly reported measure and detailed the following:
    - For hospitals with a minimum case volume of 25, the split-half reliability was 0.6, which meets current threshold set by the Consensus Based Entity (CBE) (endorsement process contractor [Battelle]).
- Dr. Oyeka noted the validity testing shows construct validity with the measure components in the Overall Hospital Quality Star Rating and the overall summary score with the associations in the expected direction.

Discussion Session #2

Question #2:

What feedback do you have regarding the measure score reliability and validity results?
What concerns do you, if any?

- A TEP member noted support for CORE's great work on the Sepsis Readmission measure. They asked about the measure validation process using the patient experience information and if all patients in the hospital receive the patient experience survey.
    - Dr. Oyeka clarified that the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey is administered to a sample of patients and typically receives a

low response rate. The goal is to examine the association (correlation) between patient-reported experience and the Sepsis Readmission measure among those who completed the HCAHPS survey.
    - Dr. Lisa Suter noted the inherent imperfections in quality measures but expressed hope that CORE's thorough development and testing of the Sepsis Readmission measure would instill confidence and reassurance among the TEP. While validating outcome measures is not always straightforward, CORE aims to triangulate using multiple other measures to assess whether the measure performs as expected and to identify any signals that might suggest inconsistencies with assumptions about quality. The results suggest reasonable confidence in the measure's performance. While all measures have limitations, input from the TEP is essential to help minimize flaws and reduce the risk of unintended negative consequences. At the same time, CORE acknowledges that no measure will ever be perfect.
    - Dr. Ladan Golestaneh noted that hospitals with strong patient survey responses tend to also perform well on the Sepsis Readmission measure at the health-center level.
- Another TEP member expressed support for the measure's reliability and validity findings, noting that the validity testing appropriately seeks expected correlations with related quality metrics (e.g., other readmission measures, patient satisfaction). They inquired whether CORE had considered examining care processes that may be conceptually linked to lower readmission risk, such as the timeliness of follow-up care after discharge.
    - Dr. Golestaneh noted the question is well-founded and insightful. She agreed on the importance of measuring the time to the first post-discharge clinic appointment or whether prescribed medications have been successfully obtained.
    - Dr. Suter acknowledged this important topic and noted that while there may be process measures available for subgroups of hospitals that could be leveraged for analyses, but that national-level data are not available. CORE does not have the ability to capture granular factors, such as issues with medication access or confirmation that the primary care provider received the hospital discharge summary. CORE will consider approaches to incorporating analyses related to care processes.
- A TEP member asked if CORE assessed correlation with the Severe Sepsis and Septic Shock Management Bundle (SEP-1).
    - Dr. Oyeka explained that CORE did not examine the relationship between SEP-1 and the Sepsis Readmission measure because the relationship between them is unclear. SEP-1 focuses on timeliness and early treatment of sepsis and the underlying infection, while the readmission measure centers on discharge planning and transitions to post-acute ambulatory care—which constitute distinct phases of care. As a result, the correlation between the two measures would be difficult to interpret; strong performance on one measure does not guarantee strong performance on the other.
    - Another TEP member noted agreement with not focusing on the relationship between SEP-1 and readmissions for the reasons Dr. Oyeka stated. They also noted that whether or not SEP-1 truly improves sepsis outcomes at all remains unclear and controversial. They shared a recent study with similar conclusions: https://jamanetwork.com/journals/jama/articleabstract/2819425?widget=personalizedcontent&previousarticle=283170.

    - Several TEP members expressed agreement with not focusing on the relationship between SEP-1 and readmissions.
- The same TEP member asked if CORE assessed the relationship between the Sepsis Readmission measure and mortality.
    - Drs. Golestaneh and Oyeka confirmed that CORE examined 30-day post-discharge mortality after an index hospitalization with sepsis and found no remarkable differences in timing of mortality across hospitals. The analysis also showed no correlation between mortality post-discharge and 30-day readmission across hospitals.
    - The same TEP member suggested that a hospital could look more favorable if patients died within the 30 days following the hospital discharge.
        - Dr. Golestaneh agreed and confirmed the analysis showed no evidence of differential bias related to patient death across the health systems.
    - Another TEP member commented that the sickest patients include intensive care unit (ICU) patients and those who have died never complete their admission stay in the hospital and are thus not included in the denominator of the measure.
        - Dr. Golestaneh confirmed the accuracy of this definition.
    - A different TEP member asked for clarification on measuring mortality with sepsis during the index admission (in-hospital death).
        - Dr. Oyeka clarified that if a patient dies while in the hospital, they are not included in the Sepsis Readmission measure.
        - Dr. Lin referenced a previous TEP discussion highlighting that a mortality measure capturing in-hospital mortality would serve as an important balancing measure.

Social Risk Factor Testing

- Dr. Oyeka noted that CORE evaluated social risk factors after the selection of clinical risk factors because clinical risk factors can overlap in their contribution to risk of the outcome. CORE focused on Dual Eligibility (DE)and High Area Deprivation Index (ADI), a cut-off of 85th percentile or greater to indicate high ADI.
- Dr. Oyeka summarized the social risk factor testing results.
    - Proportion and distribution of patients with DE and ADI: Hospitals varied in the social risk profiles of the patients they serve with the median percentage of DE patients at 21.26% and an interquartile range (IQR) of 15.66% to 29.53%. The median percentage of patients residing in high ADI neighborhoods was 8.81% and the IQR was 1.54% to 27.42%.
    - Unadjusted readmission rates: Patients with DE and patients with high ADI in the Sepsis Readmission cohort had higher readmission rates compared with patients without these social risk factors.
    - Adjusted odds ratios: DE patients had approximately 8% higher odds of readmission following an index hospitalization with sepsis compared to patients who were not dual-eligible. In contrast, patients residing in high ADI neighborhoods had similar risk of readmission compared with patients residing in low ADI neighborhoods. The odds ratio (1.002) was not statistically significant. Hospital measure scores calculated with and without the DE and ADI included in the risk model are highly correlated (0.98), indicating that inclusion of the social risk factors in the risk model has no substantial

impact on hospital-level measure scores. This also indicates that the clinical risk factors already in the model may capture much of the variation that the social risk factor variables would explain.
    - Hospitals with relatively higher proportion of patients with social risk factors performed as well as hospitals with relatively fewer patients with social risk factors.
    - Calibration plots showed that the model is well calibrated for patients with social risk factors.
- Given the social risk factor testing results, and because doing so would hold hospitals that serve these patients to a different standard, CMS has decided not to adjust for social risk factors (DE/high ADI).

Discussion Session #3

Question #3:

Please provide feedback on the social risk factor testing results.

- A TEP member referenced a U.S. Department of Defense (DoD) report on disparities in care based on social needs. The report indicated that traditional social determinants of health were not highly predictive, whereas health-related social needs, such as food insecurity, housing instability, transportation challenges, education, literacy, and difficulty paying for medical bills were more strongly associated with outcomes. As such, they were not surprised by CORE's findings that social risk factors did not contribute to differences in the model. They noted that they would anticipate greater variation in the risk score when comparing models that included health-related social needs to those that did not. The DoD report concluded that while addressing broad social determinants of health is nearly impossible, more targeted health-related social needs may have a greater impact on outcomes. They plan to share the DoD report with the group when it is available for distribution.
    - Dr. Suter noted that ADI includes community-level factors and even though they narrow down to a few blocks in radius, they are not patient level, whereas social needs such as food insecurity and housing instability are at the patient level. There are both individual and community barriers that may impact the outcomes.
    - Dr. Golestaneh commented that although health-related social needs are patient-level data, there are also community components (for example, someone who lives in food desert) that may affect the outcome.
    - Another TEP member commented that individuals make up communities.
    - Dr. Lin agreed that patient-level data are more predictive than community-level factors.
    - The same TEP member noted agreement with CORE's decision not to adjust for social risk factors (DE and ADI) and recommended adjusting for health-related social needs, but acknowledged such data are unavailable.

Sepsis Readmission Measure Summary

- Dr. Oyeka highlighted the key points of the Sepsis Readmission measure:
    - Importance: The measure captures an important, patient-centered outcome of all-cause readmissions within 30 days from discharge of hospitalization for sepsis.
    - Reliability: The analysis shows the measure meets the reliability threshold (0.6) for hospitals with at least 25 admissions (2 years of data).
    - Validity:

        - Good model performance (C-statistic, overfitting indices, risk-decile plots), including for important subpopulations.
        - Testing of social risk factor variables (DE/high ADI) suggests sufficient adjustment when incorporating clinical risk variables into the multivariate model.
        - There is evidence of construct validity shown through correlations with other similar quality measures.
    - Usability:
        - Hospitals will be provided with patient-level information for admissions that meet the measure criteria, and patients/consumers/public will be shown the results in comparison to the national average.

Discussion Session #4

- Mr. Niederhauser presented the survey question, rating scale, and instructions for the TEP members to provide feedback on the Sepsis Readmission measure.

Question #4:

On a scale from 1 – 6, rate the following statement: Do you think that the Sepsis Readmission measure as specified, can distinguish between better and/or worse performance across hospitals?

- **Rating: 1=Strongly Disagree, 2=Moderately Disagree, 3=Somewhat Disagree, 4=Somewhat Agree, 5=Moderately Agree, and 6=Strongly Agree**

TEP Face Validity Voting and Discussion:

- The detailed results from the Sepsis Readmission measure survey (n = 10) are the following:

Rating	Count	%
1 = Strongly Disagree	0	0
2 = Moderately Disagree	0	0
3 = Somewhat Disagree	1	10%
4 = Somewhat Agree	3	30%
5 = Moderately Agree	3	30%
6 = Strongly Agree	3	30%

- A TEP member explained their rationale for the rating of Somewhat Agree (4). They expressed support for the measure and acknowledged the constraints inherent in relying solely on claims-based data without access to more granular information (e.g., clinical or EHR data). Their primary concern stemmed from the C-statistic of 0.65 which, while consistent with other readmission measures, they stated is not an impressive score for predictive performance. They believe it likely indicates there are other factors outside the current model that influence a patient's risk of readmission.

- Another TEP member agreed with the previous comments about the rationale for the rating of Somewhat Agree (4). They noted support of the measure and think that it is a good measure but mentioned the limitation of predictive performance for readmission risk.

Measure Development Cycle and Wrap-up

- Dr. Oyeka thanked the TEP members for being an integral part of the Sepsis Readmission measure development journey and reviewed the iterative measure development cycle:
    - Measure conceptualization; measure specification; measure testing; measure implementation; measure use, continuing evaluation/refinement, and maintenance.
- Dr. Oyeka confirmed the Sepsis Readmission measure will be submitted for Consensus-Based Equity (CBE) endorsement in November 2025.

TEP Feedback:

- Another TEP member acknowledged CORE's thoughtful efforts in developing the Sepsis Readmission measure and asked if the measure has been finalized. They also asked if CORE would have the opportunity to make recommendations to CMS about potential measure adoption and limitations.
    - Dr. Oyeka confirmed that CORE briefs CMS after each TEP meeting, summarizing key concerns and recommendations. While CORE facilitates this process, CMS makes final decisions about the measure. The measure may undergo respecification and retesting in the future and potentially convene another TEP for input on improvements. Feedback from today's TEP will be included in updates to CMS.
    - Dr. Lin confirmed that the Sepsis Readmission measure will also undergo review through the CBE process to gather additional feedback.
- A TEP member asked if the goal for the measure includes pay for reporting in 2026 and then pay for performance down the line.
    - Dr. Suter noted that CORE is unaware of CMS's plans, however, CORE can notify the TEP when CMS public announcements are shared.

Next Steps

- On behalf of CORE, Mr. Niederhauser thanked the TEP participants for their time and valuable insights. He noted their continued feedback was welcome and encouraged TEP members to send emails with additional feedback or questions to: Jon.niederhaser@yale.edu
- Mr. Niederhauser noted TEP members will be asked to review the summary of today's meeting and complete a post-meeting survey over the next week. The survey will be a combination of:
    - A debrief survey, collecting your experience of this TEP meeting.
    - A measure-specific series of questions, to receive more feedback on the Sepsis Readmission measure specifications.