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

September 2024

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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, Base Period. The CORE contract number HHSM-75FCMC18D0042, Task Order HHSM-75FCMC24F0042. As part of its measure development process, CORE convenes groups of stakeholders and 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 includes both Medicare Fee-for-Service (FFS) and Medicare Advantage (MA) beneficiaries. The measure development will include defining a sepsis cohort for use within the readmission measure, identifying risk variables to include within the risk model, risk model testing and 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 its first meeting held on September 26th, 2024.

Measure 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	Hospital Research and Development Division Lead
Onyinye Oyeka, PhD	Project Lead
Kerry McDowell, M.S.Ed., M.Phil.Ed.	Project Manager
Alexandrea Stupakevich, MPH	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
Lisa Suter, MD	Senior Project Director
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

Participant and Credentials	Title	Organization, State
Mitchell Levy, MD, MCCM	Systemwide Director, Critical Care Medicine	Brown University Health, Providence, RI
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, ACSN-BC, CCNS, CCRN, FCNS, FCCM, FAAN	Clinical Nurse Specialist	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 Meeting

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.

CORE held its first TEP meeting on September 26th, 2024 (Appendix A).

TEP Overview

Prior to the first TEP meeting, CORE provided TEP members with detailed meeting materials outlining the background on readmission measures, the background and approach of the sepsis readmission measure, sepsis coding guidelines, proposed sepsis cohort definition, presentation slides, and questions to serve as the focus of discussion. The goals of the TEP meeting were to solicit feedback from the TEP on defining a sepsis cohort for use in the readmission measure and on the approach to risk-adjustment for the measure.

The following bullets represent a **high-level summary** of what was 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)

Readmission Measures Methodology

- CORE noted the sepsis readmission measure specifications and methodology are similar to
  CMS's risk-adjusted 30-day All-Cause Unplanned Readmission Measures, and provided an overview of the cohort, outcome, risk adjustment, and measure score.
- CORE posed the following discussion question to the TEP*:* ***Do you have any questions about the readmission measure methodology?***

TEP Feedback:

- TEP members affirmed their understanding of the readmission measure methodology and CORE answered questions about the following topics: (1) the planned readmission algorithm (PRA), (2) the 30-day all-cause readmission, (3) the use of claims-based codes to identify the sepsis population, (4) CMS sepsis coding guidelines, (5) details about the sepsis cohort and measure attribution for hospital transfers.

Sepsis Readmission Measure Development and Cohort Definition

- CORE noted that the goals for defining the sepsis cohort included defining a broad sepsis readmission measure cohort that: (1) aligned with the approach used in other existing readmission measures; (2) avoids overlap with other readmission cohorts; and (3) accounts for differences between patients with severe and non-severe sepsis.
- CORE made recommendations for the cohort definition based on extensive literature review and environmental scan of existing sepsis measures based on claims data and findings from the exploratory analyses assessing the sepsis cases captured in the pneumonia readmission measure. CORE's proposed recommendation included:
  - Excluding the sepsis cases that are already captured in the pneumonia readmission cohort (pneumonia with non-severe sepsis) to avoid overlap with the pneumonia readmission measure;
  - Keeping sepsis cases that are coded as severe sepsis as well as those that are non-severe in the readmission measure cohort to capture the broad spectrum of sepsis cases ; and
- CORE detailed the definition of the proposed cohort.

- Combine the following sepsis categories which exclude the pneumonia cohort overlap and maintain both patients with sepsis and patients with severe sepsis in the cohort:
  - Principal discharge diagnosis of sepsis and secondary diagnosis of severe sepsis coded as present on admission (POA);
  - Principal discharge diagnosis of sepsis and no secondary diagnosis of severe sepsis;
  - Principal discharge diagnosis of sepsis and secondary diagnosis of pneumonia, and secondary diagnosis of severe sepsis coded as POA.

- CORE posed the following discussion questions to the TEP:
  - **Do you have any concerns with the proposed cohort and rationale?**
  - **Do you agree with our approach to adjust for the severity of sepsis using a binary indicator?**

TEP Feedback

- Overall, TEP members supported the proposed sepsis readmission measure **cohort and rationale** and noted agreement with the following points.
  - The approach of avoiding overlap with the pneumonia readmission cohort.
  - The sepsis and severe sepsis clinical scenarios and the sepsis readmission measure cohort descriptions were clinically relevant and reflective of personal and clinical experiences with sepsis.
- TEP members also agreed with the proposed approach to **adjust for the severity of sepsis** using a binary indicator and noted the following:
  - Accounting for severity of illness through stratification or risk adjustment is key to differentiating sepsis, severe sepsis, and septic shock. TEP members recommended incorporating codes for end-organ dysfunction in risk adjustment, in addition to incorporating codes for severe sepsis.
  - All TEP members were eager to learn more details about risk-adjustment for the severity of sepsis to be discussed at the next TEP meeting.
- All TEP members agreed on the importance of sepsis measure development and acknowledged the challenges associated with sepsis.

Recommendations/Rationale

- TEP members made recommendations to further **refine the sepsis readmission measure cohort:**
  - Considerations need to be made for how providers code sepsis, , given that the sepsis condition tends to be used frequently, while oftentimes it may not be reflective of the patient's actual medical experience of sepsis.
  - Given hospital variations in sepsis coding practices, consider that the measure may favor those hospitals with more resources for clinical documentation and coding (because sepsis tends to be under-coded).
  - Consider the inclusion of variables such as infection site and organ dysfunction (e.g., low platelets, worsening kidney or liver function, a drop in blood pressure, etc.) to distinguish severe sepsis from sepsis.

- TEP members offered specific suggestions regarding the approach to **risk adjustment**:
    - Incorporate a three-level categorical indicator to adjust for the severity of sepsis (sepsis, severe sepsis, and septic shock).
    - Consider organ failure POA as a risk factor in the model.
- TEP members highlighted the importance of applying an equity lens to the sepsis readmission measure, noting that disaggregated measure reporting (e.g., stratification by race/ethnicity, payer) can identify disparities in sepsis care and outcomes.

Exceptions

- TEP members highlighted the issue of heterogeneity of sepsis , noting the difference between sepsis alone and severe sepsis is the presence of organ dysfunction. They suggested reviewing hospital diagnosis codes to verify if the patient is coded for other organ dysfunction to confirm the presence of severe sepsis (versus sepsis that is not coded as severe).
- TEP members shared concerns about clarifying the specific population that is captured with codes for sepsis that is a specified as severe

Further Insights

- TEP members shared that the Center for Disease Control and Prevention (CDC) is working on the development of a community-onset sepsis mortality measure (an electronic clinical quality measure [eCQM]); this measure will be relying on an electronic health record (EHR)-based identification for both sepsis and risk adjustment variables.
- TEP members underscored the need for hospitals to improve transparency with patients about the diagnosis of sepsis and healthcare-acquired infections (HAI).
- TEP members expressed interest in how claims-based measures fit into CMS strategy of advancing digital quality measures.

Next Steps

- TEP members are invited to send emails with additional feedback or questions to: alexandra.stupakevich@yale.edu
- TEP members will be asked to complete a brief survey on your experience in this meeting.
- CORE will provide CMS with a summary of TEP input for consideration.
- Outreach to schedule the next TEP meeting is expected in November and will occur in December.
    - The next meeting will review risk variable selection.
- CORE thanked participants for sharing their thoughts and valuable insights.

Ongoing Reevaluation

The project team will consolidate the feedback received at the September 26th, 2024, TEP meeting with the feedback received.

Appendix A. TEP Call Schedule

TEP Meeting #1

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

Appendix B. Detailed Summary of Base Period TEP Meeting

Sepsis Readmission Measure Technical Expert Panel (TEP) Meeting #1 Minutes

Thursday, September 26, 2024, 10:00 AM – 12:00 PM ET

Participants

- **Technical Expert Panel (TEP) Participants:** Rosie Bartel, David Classen, Sara Cosgrove, Steven Coffee, Sarah Doernberg, Tom Ehelian, Stephen Goins, Michael Klompas, Chanu Rhee, Dorothy Winningham
- **Yale New Haven Health Services Corporation — Center for Outcomes Research and Evaluation (YNHHSC/CORE):** Katie Balestracci**,** Laura Barrett (X4 Health), Patricia Faraone Nogelo, Ladan Golestaneh, Jackie Grady, Roisin Healy, Erin Joyce, Zhenqiu Lin, Kasia Lipska, Jon Niederhauser, Onyinye Oyeka, Lucy Pereira, Doris Peter, Allie Stupakevich, Zhen Tan, Mariel Thottam, Yahui Tian
- **Centers for Medicare & Medicaid Services (CMS):** Raquel Myers

TEP Action Items

- Reviewing and sending any suggested edits to the meeting summary;
- Completing a brief survey about their experience during this meeting; and
- Reaching out via email if they have any questions and watching their email for future project updates.

CORE Action Items

- Sharing a summary of today's meeting for TEP review in the coming weeks; and
- Considering TEP feedback during the measure development process.

Detailed Discussion Summary

- Ms. Mariel Thottam welcomed the TEP members, introduced herself 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.
- Ms. Thottam acknowledged that CMS staff may be joining the call.
- Ms. Thottam 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 members' participation and their willingness to provide input about the proposed measure.
- TEP members introduced themselves and shared their preferred name, location, relevant background, or interest in the sepsis TEP, and disclosed any Conflicts of Interest (COI).
    - Rosie Bartel (Chilton, WI) is a survivor of septic shock 15 times due to a Methicillin-resistant Staphylococcus aureus (MRSA) from a healthcare-acquired infection (HAI)

following a knee replacement. She is very familiar with sepsis and experienced severe septic shock with severe complications (e.g., intubation, coma); has a very strong personal interest in sepsis research and studies; no COI.
    - David Classen (Salt Lake City, UT) is an infectious disease physician and medical informaticist at the University of Utah and works with a federally funded patient safety organization. His interests focus on the intersection of health information technology (IT), infectious disease, and complications. He has built measures around complications and artificial intelligence (AI) methods to predict complications; no COI.
    - Sara Cosgrove (Baltimore, MD) is an infectious disease physician and the Medical Director of the Department of Antimicrobial Stewardship at John Hopkins Hospital. She has a strong interest in sepsis, septic shock, and the link to antibiotic interventions. The focus of her work is to ensure the best possible outcomes for patients while ensuring appropriate antibiotic use; no COI.
    - Steven Coffee is an active Colonel in the US Air Force and serves as a patient activist and advocate. His son's experience with septic shock led to his strong interest in wanting to understand how providers and patients can partner to improve health care. He is cofounder of Patient Safety US, which is a chapter of the World Health Organization (WHO); no COI.
    - Tom Ehelian (Dallas, TX) is also a sepsis survivor and shared that his interest in this measure stems from having had sepsis.
    - Steven Goins (Albany, NY) is a research scientist and leads the Sepsis Analytic team for the New York (NY) State Sepsis Care Improvement Initiative at the NY State Department of Health; his work involves outcome measure development for public reporting; no COI.
    - Michael Klompas (Boston, MA) is an infectious disease physician at Brigham and Women's Hospital and is a researcher on surveillance, prevention, and management of Sepsis.
    - Chanu Rhee (Boston, MA) is an infectious disease and critical care physician at Brigham and Women's Hospital. He is a researcher on sepsis surveillance, epidemiology, and quality improvement (QI) measures. He disclosed that his organization contracted with the Centers for Disease Control and Prevention (CDC) to develop a community onset sepsis mortality measure.
    - Dorothy Winningham (Atlanta, GA) is a member of Health Quality Innovators Patient and Family Advisory Board; her interest in sepsis stems from her brother's admission to the emergency department (ED), and she suggested to the hospital that he had sepsis; he was indeed diagnosed with sepsis and her close friend also has sepsis.

Review & Approval of TEP Charter

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

Introduction to Readmission Measures

- Dr. Oyeka introduced the readmission measures, noting that the readmission of patients represents an important, expensive, and often preventable adverse outcome. She shared the following details:

    - Readmission following a condition/procedure is a signal of both perioperative complications and suboptimal transitional care.
    - Readmission measures help hospitals to focus on patient safety during all aspects of care, while also enhancing the quality of care provided during the transition from discharge to outpatient settings.
    - CORE developed, and CMS implemented, risk-adjusted 30-day all-cause readmission measures for several conditions (e.g., Heart Failure [HF], Pneumonia, Acute Myocardial Infraction [AMI], Coronary Artery Bypass Graft [CABG], Chronic Obstructive Pulmonary Disease [COPD], Total Hip Arthroplasty/Total Knee Arthroplasty [THA/TKA]).
- Dr. Oyeka provided an overview of the readmission measures noting their similar measure specifications.
    - The readmission measures apply to short-term acute care hospitals including Critical Access Hospitals (CAHs).
    - The outcome is all-cause readmissions within 30 days after discharge from the initial hospitalization for a specific condition/procedure.
    - The cohort includes Medicare Fee for Service (FFS), and Medicare Advantage (MA) patients aged 65 and older; the measure relies on specific condition based cohort criteria. Demographics and comorbidities are used for risk adjustment to adjust for differences in patient case mix.
    - The measure score is reported as the risk-standardized readmission rate (RSRR) which is the ratio of predicted/expected readmissions multiplied by the national observed readmission rate.
- Dr. Oyeka clarified that the readmission measure outcome is unplanned readmissions for any cause within 30 days of discharge from the index admission.
    - The readmission measure outcome is a dichotomous outcome whereby readmission is counted if a patient has one or more unplanned admissions 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 and any unplanned admission is considered an outcome regardless of cause, because from the patient's perspective, an unplanned readmission for any cause is an adverse event. Planned readmissions like elective admissions for procedures or staged surgical interventions are not counted and there is an algorithm used to account for planned readmissions.
- Dr. Oyeka explained that the readmission measure score is calculated for each hospital, as the ratio of a hospital's "predicted number of readmissions" and "expected number of readmissions" within 30 days. Specifically, the ratio of the "predicted" over "expected" readmission is multiplied by the national rate to calculate the RSRR.
- Dr. Oyeka detailed the process for categorizing hospital performance based on the estimate of each hospital's RSRR and the corresponding 95% interval estimate.
    - Hospitals are assigned to a performance category by comparing each hospital's RSRR interval estimate to the national observed readmission rate; performance is categorized as "No different than U.S. national rate," "Worse than U.S. national rate," and "Better than U.S. national rate."

Discussion Session #1

- Ms. Thottam presented the discussion question in reaction to the general readmission measure methodology for the first TEP round robin session:

Question #1: Do you have any questions about the readmission measure methodology?

- A TEP member asked for clarification on the calculation of case mix for risk adjustment.
  - Dr. Oyeka noted the risk variable selection process uses Medicare claims data 12 months prior to, and at index hospitalization, as additional risk variables to adjust for the patient case mix at each hospital.
- Another TEP member asked for more details about the planned readmission algorithm.
  - Dr. Oyeka explained that the planned readmission algorithm is used for all the readmission measures to ensure the measure outcome is not capturing planned readmissions.
  - Ms. Jackie Grady added that the goal of the planned readmission algorithm is to identify through claims whether a readmission would have been planned (subsequent admission) based on the index admission. It looks at a series of procedures and if they could be potentially planned, along with looking at the admission diagnosis to determine (through claims) the likelihood that the readmission is planned.
  - Dr. Zhenqiu Lin clarified that elective procedures without an acute diagnosis are considered planned readmissions. Details of the planned readmission algorithm are outlined in the article to which this link refers: https://pubmed.ncbi.nlm.nih.gov/26149225/.
- A TEP member asked about delineating a readmission solely based on sepsis from another condition.
  - Dr. Oyeka clarified the measure captures unplanned readmissions for all causes, not only sepsis. For example, if you were hospitalized for sepsis, then discharged from the hospital, and then readmitted for any reason within 30 days, it is deemed a readmission.
- A different TEP member asked if the case mix methodology for sepsis readmission measure was the same as is used for the other readmission measures. They also asked for clarification about the data source (administrative and/or clinical data).
  - Dr. Oyeka confirmed that only administrative (claims data) were used for the case mix methodology. The next TEP meeting will include an in-depth discussion of case mix and the risk variable selection process.
- A TEP member asked if the 30-day all-cause readmission measures capture the outcomes of other diffuse conditions/diagnosis, and how that compares to the proposed sepsis measure, given sepsis is a diffuse diagnosis (e.g., community onset, hospital or post-surgical onset, severe sepsis, septic shock, etc.). They asked about information on the frequency of readmission for sepsis patients, and how often the readmission is related to the previous episode of sepsis.
  - Dr. Oyeka acknowledged the complexity of capturing the wide range of sepsis patients and noted the background and approach used to define the sepsis cohort (e.g., the principal discharge diagnoses) will be discussed in more detail later in the TEP presentation.

    - Another TEP member asked if the cohort is Medicare ages 65 and older and does not include the End-Stage Renal Disease (ESRD) and Medicare disability eligible population.
    - Dr. Oyeka confirmed the cohort only includes the Medicare FFS patients aged 65 years and older.
    - Another TEP member shared a paper by another TEP member on reasons for readmission following a sepsis hospitalization: https://pubmed.ncbi.nlm.nih.gov/25756444/.
- Another TEP member asked about the grading (what is captured) and if it would be diagnosed differently or alongside the sepsis event if it occurred during the sepsis readmission period and it was a terminal disease.
    - Dr. Oyeka noted the measure will capture all readmissions following the index hospital stay, and if the patient returns back to the hospital for any reason it will be counted as a readmission.
    - Dr. Lin confirmed that we do count them if the readmission is within the 30-day period; we anticipate there will be instances of patients who are readmitted, for example, due to a car accident. CORE expects the variation in readmissions will not be disproportionately higher for any particular event and any individual hospital. Also, the expectation and goal is not a zero readmission rate for hospitals, rather we know that hospitals will have room for improvement.

Sepsis Readmission Measure Development

- Dr. Oyeka noted the focus of today's TEP is defining the cohort and identifying the inclusion and exclusion criteria as the first step of the Sepsis Readmission Measure development process. She continued reviewing the steps of the measure development process and the timeline for TEP meetings and input.

Sepsis Readmission Measure Cohort Definition

- Dr. Oyeka provided the background on sepsis which underscores the complexity of post-sepsis care and the need for strategies to improve outcomes for sepsis survivors.
    - Sepsis is a life-threatening condition characterized by a dysregulated response to infection or injury. Sepsis studies show that 1.7 million adults develop sepsis and 350,000 die as a result each year. Studies on the 30-day readmission rate following sepsis hospitalization range from 17% to 26%.
    - The frequency of readmission highlights the need for a Sepsis Readmission Measure to encourage hospitals to prioritize patient safety, encourage effective hospital collaboration, and provide proper discharge planning and follow-up care to reduce the risk of readmission.
- Dr. Oyeka highlighted the goals for defining a broad Sepsis Readmission Measure cohort: (1) align the approach as much as possible with the other existing readmission measures, (2) avoid overlap with other readmission cohorts, and (3) account for differences between patients with severe and non-severe sepsis.
- Dr. Oyeka noted that the CORE team's approach to the Sepsis Readmission cohort included the review of existing sepsis measures and literature for risk-adjusting for the severity of sepsis with a focus on claims-based measure that is as broad as possible; while the exploratory analyses included the following:

  - Review of sepsis coding guidelines, initial cohort definition, estimate of cohort size, and observed outcomes (unplanned readmissions);
  - Examine the overlap of the existing pneumonia readmission cohort that has sepsis patients included;
  - For this analysis CORE used the data source of the Hospital-Wide Readmission measure and Medicare FFS administrative claims (Part A) data from July 1, 2021, to June 30, 2023; the dataset includes all admissions with sepsis as the principal discharge diagnosis.
- Dr. Oyeka highlighted the key cohort consideration of avoiding overlap with other readmission measure cohorts. Thus, the initial analysis examined the magnitude of overlap of the sepsis patients that are included in the pneumonia readmission measure cohort. The pneumonia readmission cohort currently includes admissions for patients discharged from the hospital with:
  - Principal discharge diagnosis of pneumonia, OR
  - Principal discharge diagnosis of sepsis (that is not severe), AND
  - Secondary diagnosis of pneumonia coded as present on admission (POA) but without a secondary diagnosis of severe sepsis coded as POA.
    - Sepsis patients were included in the pneumonia cohort to capture sicker pneumonia patients, so the pneumonia readmission measure includes patients with sepsis and pneumonia but not severe sepsis.
  - A TEP member asked if out-of-hospital deaths within 30 days of discharge are excluded.
    - Dr. Lin noted they were not excluded because some of these patients could still have readmissions, and we generally avoid using 'event' to define the cohort. Potentially they could pose a competing risk issue, and the CORE team is actively evaluating this issue.
  - Dr. Oyeka noted that to estimate the cohort size, CORE examined the volume of Sepsis International Classification of Diseases, Tenth Revision (ICD-10) codes in the dataset. There was a total of 892,052 sepsis ICD-10 codes and the associated observed unplanned readmission rate within 30 days was 16.6%.
  - After determining the size of the cohorts, CORE further analyzed the data to determine the overlap of the sepsis cases in the readmission cohort by creating mutually exclusive subgroups based on the severity of sepsis, and pneumonia complexity. The four subgroups are the following:
    1. Severe sepsis patients only, which included admissions associated with a principal discharge diagnosis of sepsis and a secondary diagnosis of severe sepsis coded as POA;
    2. Non-severe sepsis patients only, that is admissions associated with a principal discharge diagnosis of sepsis and no secondary diagnosis of severe sepsis;
    3. Pneumonia with severe sepsis patients (patients excluded from Pneumonia Readmission), that is, principal discharge diagnosis of sepsis, and a secondary diagnosis of pneumonia coded as POA, and secondary diagnosis of severe sepsis coded as POA; and
    4. Pneumonia with non-severe sepsis (patients Included in Pneumonia Readmission), admissions associated with a principal discharge diagnosis of sepsis, and a secondary diagnosis of pneumonia coded as POA, and no secondary diagnosis of severe sepsis coded as POA.

- Dr. Oyeka described the analysis of the frequency of sepsis ICD-10 codes and the 30-day unplanned readmission rates across the sepsis subgroups. Findings revealed that approximately 24% of all sepsis codes (210,300) were included in the pneumonia readmission cohort and the severe sepsis subgroups had higher unplanned readmission rates.
    - CORE recommends excluding the sepsis cases that are in the pneumonia readmission cohort (category 4 above) to ensure that the sepsis cohort does not overlap and to avoid the potential of double counting patients in both cohorts.
    - To define a broad cohort that adequately captures a wide range of sepsis patients to include both sepsis and severe sepsis cases, CORE examined the outcomes associated with each sepsis category (removing the overlap with the pneumonia readmission measure) for 30-day mortality, discharge to hospice, and discharge to a skilled nursing facility (SNF).
    - The analysis showed that mortality rate and discharges to non-acute care settings are higher for groups with severe sepsis compared to the non-severe sepsis group.
    - The analysis of the prevalence of other medical conditions (secondary discharge diagnosis) showed that patients with severe sepsis were more likely to have higher rates of other significant medical conditions compared to the non-severe sepsis group.
        - Given the goal to develop a broad measure, CORE recommends keeping the sepsis and severe sepsis groups in the Sepsis Readmission Measure cohort.
- CORE proposes the final cohort will keep severe sepsis admissions to capture a broader cohort of sepsis patients and the measure will need to account for the clinical risk of these patients. To ensure fair and accurate hospital results, CORE will use a thorough approach to risk variable selection to account for the severity of illness; the recommended approach is to incorporate a binary indicator to distinguish severe sepsis from non-severe sepsis in the risk model.
- Dr. Oyeka presented details about the proposed Sepsis Readmission Measure cohort.
    - Combine the following sepsis categories which exclude the pneumonia cohort overlap and maintain both patients with sepsis and patients with severe sepsis in the cohort:
        - Principal discharge diagnosis of sepsis and secondary diagnosis of severe sepsis coded as (POA);
        - Principal discharge diagnosis of sepsis and no secondary diagnosis of severe sepsis;
        - Principal discharge diagnosis of sepsis and secondary diagnosis of pneumonia; and secondary diagnosis of severe sepsis coded as POA.
    - In summary, the proposed sepsis cohort does not overlap with the pneumonia readmission cohort; it prevents the potential to double penalize or reward hospitals for patients included in the pneumonia cohort; and retaining the severe sepsis in the cohort ensures that the measure is more inclusive and is aligned with the approach of existing sepsis measures and research studies.
    - Dr. Oyeka described the proposed detailed sepsis cohort inclusion and exclusion criteria.

Discussion Session #2

- Ms. Thottam presented the discussion questions for the second TEP round robin session:

Questions #2:
Do you have any concerns with the proposed cohort and rationale?
Do you agree with our approach to adjust for the severity of sepsis using a binary indicator?

- A TEP member confirmed no concerns about the cohort and rationale; they agreed with the approach of adjusting for sepsis severity using the binary indicators; CORE has done a good job of looking at things that may be connected to sepsis as a secondary indicator for readmission. They reflected upon seeing herself in many of the sepsis scenarios that were presented thus far and noted that when you have personally gone through sepsis, you know when it is severe and when it is not severe. They thanked and commended the CORE team on the careful approach to the sepsis measure.
- Another TEP member expressed appreciation for the measure overview. Regarding the proposed cohort and rationale, she noted most hospitals, because of the Severe Sepsis and Septic Shock Early Management Bundle Measure (SEP-1), are focused on severe sepsis and septic shock; however, the patients with these diagnoses are likely to have an infection causing a problem. They noted some concerns about the specific population that is captured with just a sepsis code. Sepsis gets assigned to people with relative ease, but it is oftentimes not what is happening with the patient during the hospital stay. There should be more explanation of the patient population that is captured when the code is only sepsis, and not severe sepsis or septic shock. They also asked for clarification on adjusting for the severity of sepsis and if this means the reports are stratified (e.g., a separate assessment for sepsis versus severe sepsis).
    - Dr. Oyeka clarified that the literature indicates that the clinical care for sepsis compared to severe sepsis patients is somewhat different. If it appears that we have two separate populations in the cohort, the risk variable identification and selection process will inform how this measure is working for all the patients included in the cohort.
    - Dr. Lin added that severe sepsis may be associated with higher readmission rates, and it is important to account for that (and patients with other comorbidities), particularly when a hospital has more severe sepsis cases. We will investigate if the risk variables are sufficient to account for patients who may potentially have higher post-readmission risk.
- Another TEP member concurred with previous comments on the need for further explanation of the sepsis readmission patient population; they also emphasized the importance of looking at the measure through the equity lens because when this is applied, we may see shocking results.
    - Dr. Oyeka noted the measure results are not currently stratified by payer or race and ethnicity.
    - Dr. Lin added that as part of measure development, the measure will go through the consensus building endorsement (CBE) process and equity issues will be evaluated and then reported back to the TEP members at a future TEP meeting.

- Another TEP member had no comments on the measure approach.
- A different TEP member commented that they feel the measure is representative of quite a range and applicable and agreed with the indicators.
- Another TEP member agreed with the need for further explanation of the patient population and asked if index admissions do not include transfers in or out and do include admissions from another acute care facility in the measure.
    - Dr. Oyeka explained that the measure is attributed to the hospital that ultimately discharges the patient. For example, if a patient is transferred from hospital A to hospital B and hospital B treats and discharges the patient, then the measure is attributed to hospital B.
    - The same TEP member noted the importance of understanding the differences in the patient population between sepsis and severe sepsis and suggested sensitivity analysis to ensure that the model performance is appropriate for both groups. Secondly, they recommended a three-level categorical indicator rather than a binary indicator. NY State collects data on the severe sepsis and septic shock populations and consistently finds that septic shock patients have much higher mortality rates (even when compared to severe sepsis) and they would expect the same for hospital readmissions. They recommended to further split the cohort out between severe sepsis and septic shock.
    - Dr. Lin agreed with the importance of accounting for patient risk and ensuring careful evaluation of the risk model to sufficiently account for differences in risk. The model must work well with all the patient groups and not favor some patients. CORE plans to assess if the model calibrates better with binary or three-level indicators.
- Another TEP member offered several comments. Firstly, it would be very helpful to have the slides in advance to absorb the complex information in preparation for the meeting. Secondly, they echoed previous comments about the variation in sepsis and the likely implications for readmission rates. Sepsis is really a mix of different kinds of infections (e.g., pneumonia, urinary tract infections [UTI], abdominal abscesses, skin soft tissue infections, etc.) and different kinds of organ dysfunctions (such as low platelets, worsening kidney or liver function, a drop in blood pressure) and these can be combined in a thousand different ways. Mortality rates for different sepsis syndromes have an enormous range between 2% – 40%, and the same variability can be expected for the readmission risk across those categories. The distribution of those different kinds of infections and organ dysfunctions will vary across hospitals and lumping it all into one syndrome of sepsis will lose the complexity of the sepsis syndrome as well as the drivers of readmission. It is critical to distinguish septic shock from severe sepsis and sepsis (within each of these, there is much variability). They suggested the inclusion of variables such as infection site and organ dysfunctions to tease apart these important contributors. Lastly, they highlighted the variability between hospitals in coding methods, noting the difference between sepsis alone and severe sepsis is the presence of organ dysfunctions, thus we should look at the codes to verify if the patient is coded for other organ dysfunctions to confirm the presence of severe sepsis (versus sepsis).
    - Another TEP member commented that organ failure is a call out they wanted to make in connection with severe sepsis or septic shock because organ failure has been an outcome for them.
    - Dr. Oyeka acknowledged the valid concerns, noting that this measure (and other clams-based measures) does rely on the claims codes to identify the sepsis

population. CMS has guidelines specifically for sepsis that CORE uses to identify the population for the measure. She acknowledged the concerns and challenges, and the CORE team will consider these recommendations as the measure is developed.
    - Dr. Lin acknowledged the complexities and offered to hold a follow-up discussion as helpful. He agreed with the heterogeneity of sepsis and noted some of this can be mitigated through risk adjustment, by comparing the hospital's rate given their particular patient case mix (compare the expected rate to actual performance) to account for the severity of sepsis across hospitals.
    - The same TEP member noted that a follow-up discussion could focus on the methodology of the case mix adjustment and the extent to which it is sensitive to sources of variability.
    - Dr. Lin confirmed that CORE will investigate the case mix adjustment results of the patient characteristic outcome distribution and variation across hospitals by subgroups to share with the TEP for input.
    - Ms. Thottam appreciated the important concerns and noted the meeting materials were sent to TEP members before the meeting. CORE will aim to make it clearer to the TEP members when the slide deck and questions are added to the meeting invitation. The measure team plans to bring more deep discussion on case mix and risk variable selection for the next TEP meeting.
- Another TEP member agreed with most of CORE's approach for the measure, especially given the constraint of using only claims data, noting the measure will not be perfect for obvious reasons. He agreed with avoiding overlap with the pneumonia cohort. Regarding variability, he highlighted the need to be aware of it and that the measure may favor hospitals that have more resources to put into clinical documentation and coding because sepsis tends to be under-coded. The Septic Shock (Sepsis-3) definition notes that sepsis is organ dysfunction caused by a dysregulated response to infection, which aligns with the information presented by CORE showing that many of the sepsis patients had codes for organ dysfunction (e.g., renal failure). While they agreed with stratification or risk adjustment for sepsis, severe sepsis, and septic shock, it may introduce bias in favor of the hospital that does better coding. They asked if CORE was planning to include organ failure present on admission (POA) codes as additional risk factors.
    - Dr. Oyeka noted the details of the risk variable selection process are still in discussion and that CORE's empirical process will be very transparent and shared with the TEP for input.
    - Dr. Lin confirmed that CORE will explore the data to identify other information that may contribute to the risk prediction, such as severe sepsis with or without organ failure. He agreed that although the measure will never be perfect; we can mitigate these issues to be fair to all hospitals.
    - The same TEP member asked if septic shock codes are included in the severe sepsis code.
    - Dr. Lin confirmed that severe sepsis with septic shock is included.
- A different TEP member noted agreement with the measure approach information presented and previous discussion and shared about a friend's experience of having post-surgical sepsis with multiple admissions at two different hospitals. She asked for clarification about the process of verifying hospital claims codes for the sepsis diagnosis.
    - Dr. Oyeka explained that CMS has clear sepsis coding guidelines. When the patient presents to the hospital, they code for sepsis and if the hospital is aware of the other

infection, they are required to code that as well. If the patient has severe sepsis POA, the coding guidelines state to code sepsis and code the severe sepsis as a secondary diagnosis; severe sepsis cannot be coded as a primary diagnosis. We rely on the hospital to ensure the patients are coded appropriately, and these codes are used to determine the population for this measure.
    - Dr. Lin suggested that the first hospital coded the patient as sepsis and did not inform the patient of the diagnosis. In this example, we can assume that the first hospital coded sepsis correctly and then the patient had a readmission. This measure will capture situations like this, whereas the first hospital did not provide proper treatment resulting in an unplanned readmission.
- Another TEP member shared about the development of a community-onset sepsis mortality measure which is an electronic clinical quality measure (eCQM). This is an electronic health record (EHR)-based identification for both sepsis and risk adjustment. He asked about the messaging of these two measures (Sepsis Readmission and Community-Onset Sepsis Mortality). They both focus on sepsis; however, the methodologies and sepsis definitions will be entirely different; a thoughtful approach to messaging for all of us is key.
    - Dr. Lin supported and encouraged the sepsis mortality measure to capture different aspects of health care (acute care phase) from the readmission measure (post-acute care planning); the CDC measure is complementary, a needed balancing measure.
- Another TEP member asked if the confidence intervals were available for the 30-day observed unplanned readmission rates (on slide 32) to inform variability across hospitals.
    - Dr. Oyeka confirmed that the confidence intervals were not calculated.
    - Dr. Lin noted the variability in hospitals and confidence intervals will be discussed in detail at subsequent TEP meetings.
- Another TEP member reflected on previous comments, noting that they had MRSA following a knee replacement, and they were admitted for MRSA and then had multiple readmissions. Over time they realized they were experiencing sepsis. Once they had severe sepsis, they also experienced organ failure, intubation, and a coma. During this period, the hospital never said that they had sepsis, yet that was what was happening. Hospitals need to be honest with patients about the hospital acquired infections (HAI) and sepsis.
    - Dr. Oyeka appreciated the important observations and noted that one of the goals of this measure is to ensure that hospitals are providing the best possible care for hospitalized patients and proper discharge planning (e.g., transitional care, patient education, etc.) to reduce readmissions.
- Another TEP member asked if this measure is focusing on readmissions following a POA sepsis hospitalization, not readmissions following hospital-onset sepsis.
    - Dr. Lin responded that the measure focuses on readmissions following a POA sepsis hospitalization.
- A different TEP member asked about where this measure fits within CMS's overarching framework of advancing clinical quality measures based on EHR data rather than claims data.
    - Another TEP member agreed with the question and expressed interest in knowing CMS's rationale for how claims-based measures fit into the larger CMS strategy.

    - Dr. Lin noted the CORE team would convey this question to CMS and share comments at the next TEP meeting.
    - The same TEP member noted the advantage of the EHR-based clinical measures is they remove some of the variability in coding differences. eCQMs capture the presence of codes for sepsis and organ dysfunction at the same time to accurately distinguish the sepsis syndromes (e.g., sepsis, severe sepsis, and septic shock).
    - Dr. Lin agreed with the advantage of the EHR-based clinical measures and cautioned that EHR data were not specifically designed to support measure data collection, and some variation will exist with EHR systems.
    - Another TEP member noted agreement with the advantages of eCQMs.
- Another TEP member asked for clarification on the rationale for the exclusion criteria of a COVID-19 and whether it will be retained in the future.
    - Dr. Oyeka noted the COVID-19 exclusion is a CMS policy and some of these datasets used are reflective of COVID-19 or COVID-19-adjacent time periods. This exclusion could potentially be dropped in the future, but it would be at the direction of CMS.
    - Dr. Lin noted the CORE team would follow-up with CMS for any updates on the COVID-19 exclusion criteria.

Next Steps

- On behalf of CORE, Ms. Thottam thanked the TEP participants for their time and valuable feedback. She noted their continued feedback was welcome and encouraged TEP members to send emails with additional feedback or questions to: alexandra.stupakevich@yale.edu
- Ms. Thottam 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 measure specifications.
- Ms. Thottam noted next steps and thanked participants for sharing their thoughts and noted understanding of and appreciation for the complexity of this conversation.