Center for Clinical Standards and Quality (CCSQ)
Centers for Medicare & Medicaid Services (CMS)

Summary of Sepsis Technical Expert Panel (TEP) Evaluation of Measures

Patient Safety Measure Development and Maintenance

5/25/2021

Version # 2

IMPAQ INTERNATIONAL LLC

SUBMITTED TO

Centers for Medicare & Medicaid Services (CMS)
Center for Clinical Standards and Quality (CCSQ)

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PROJECT

Patient Safety Measure Development and Maintenance
Contract Number: 75FCMC18D0027

TASK & DELIVERABLE

Chapter 4: Quality Measure Development and Reevaluation
Deliverable 4.3 Summary of TEP Evaluation of Measures
Sepsis

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The materials presented in this document do not represent final measure specifications for the Sepsis outcome measure

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Background

The Centers for Medicare & Medicaid Services (CMS) has contracted with IMPAQ International to develop and maintain patient safety measures of hospital harm for implementation in CMS programs. The contract name is Measure & Instrument Development and Support (MIDS) Patient Safety Measure Development and Maintenance. The contract number is 75FCMC18D0027. As part of its measure development process, IMPAQ convenes groups of stakeholders and experts who contribute direction and thoughtful input to the measure developer during measure development and maintenance.

IMPAQ is obtaining expert and stakeholder input to inform the development of a sepsis outcome measure. This report summarizes the feedback and recommendations made by the Technical Expert Panel (TEP) during the meetings to discuss the sepsis outcome measure. The report will be updated to include feedback and recommendations from future meetings as they occur.

MEASURE DEVELOPMENT PROJECT TEAM

The Patient Safety Measure Development and Maintenance project team is comprised of staff from IMPAQ, UC Davis, and Kennell & Associates. In preparation for the development of a sepsis outcome measure, Dr. Allison Russo, Christina Superina, and the Kennell team worked with Dr. Jacqueline Stocking, Dr. Patrick Romano, and the UC Davis team to summarize the findings from the information gathering report for presenting with the TEP to guide the initial discussions. Presenters and moderators for the TEP meetings were Dr. Christian Sandrock, Dr. Patrick Romano, and Dr. Jacqueline Stocking of UC Davis.

Dr. Christian Sandrock, MD, MPH, is a practicing physician at UC Davis Health and a clinical subject matter expert (SME) for the project team on sepsis. Dr. Jacqueline Stocking, PhD, MBA, MSN, RN, a critical care nurse at UC Davis Health and is the clinical director for the project team. Dr. Patrick Romano, MD, MPH, leads the measure development task for the project.

A full list of the staff supporting this work is listed in Appendix B.

Overview of the Technical Expert Panel

In alignment with the CMS Measures Management System Blueprint, the project team convened a Technical Expert Panel (TEP) to provide guidance on the development of a sepsis outcome measure. The role of the TEP is to provide guidance on key methodological and clinical decisions. The Sepsis TEP is comprised of 17 individuals representing a variety of viewpoints and backgrounds, including experience in critical care, acute care, and emergency care as well as expertise in sepsis morbidity and mortality, electronic health record (EHR) systems, quality improvement, and risk adjustment. Two TEP members represent patient/caregiver perspectives. The full TEP membership is listed in Appendix A. In addition to the TEP, the project team convened an additional group of experts for a Technical Advisory Group (TAG) to further inform the TEP and the measure developer on specific relevant topics for the measure development process.

TEP PURPOSE & OBJECTIVES

The TEP is comprised of individuals with knowledge of sepsis morbidity and mortality. The overarching goals of the TEP are to provide information, support, feedback, and perspective to the IMPAQ team on the development, specification, testing maintenance, re-evaluation, and implementation of a sepsis outcome measure for possible future use in CMS programs. The TEP's role is to provide input and advice to the measure developer on the information gathering, measure development, testing, maintenance and re-evaluation of a sepsis outcome measure.

The TEP will:

- Review pre-meeting materials and provide written feedback
- Discuss feedback and revisions during virtual meetings along with other relevant topics
- Review and comment on meeting minutes and associated post-meeting documents along with any follow-up action items

TAG PUPOSE & OBJECTIVES

The TAG is comprised of individuals with knowledge of sepsis morbidity and mortality as well as measure development including risk adjustment methodologies. The TAG's role is to provide input to the measure developer and the TEP for consideration in the discussions throughout the measure development process.

Technical Expert Panel Meeting #1

January 22, 2019 3:30 PM ET

SUMMARY OF PRESENTATION

The IMPAQ team convened the first TEP meeting to introduce the TEP members to the project, discuss the significance and background of a sepsis outcome measure, and solicit TEP input on the approach to measure development. Prior to the meeting, the IMPAQ team provided the TEP members with the presentation slide deck and background materials for review and preparation for discussion. During the meeting, the TEP members introduced themselves, announced any personal disclosures, and ratified the TEP charter. The TEP then engaged in discussion around the topics as presented by the IMPAQ team, noting their support for the creation of a new measure over the adoption of the current sepsis measure created by the New York State Department of Health (NYSDOH). The TEP discussed advantages and disadvantages of the various existing sepsis definitions and the types of outcomes to consider for the measure. The TEP did not have time to discuss the TEP's preferred timeframe or end point for the measure.

Attendance:

TEP Members: Ian Barbash, Rosie Bartel, Marisha Burden, David Classen, Sara Cosgrove, Michael Klompas, Tiffany Osborn, Patricia Posa, Gregory Schmidt, Maureen Seckel, Sean Townsend, Donald Yealy, Sameer Kadri (non-voting[1]), Cristin Mount (non-voting), Runa Gokhale (federal observing[2]), Anthony Fiore (federal observing)

Not Present: Jean Proehl, Robert Panzer, Steven Coffee

CMS: Annese Abdullah-Mclaughlin

IMPAQ: Kendall Hall, Mike Sacca, Anna Michie, Stacie Schilling, Bo Feng, Maggie Lohnes, Hannah Klein, Molly Mantus

Kennell: Allison Russo, Christina Superina, Courtney Colahan

UC Davis: Patrick Romano, Christian Sandrock, Jacqueline Stocking, Meghan Weyrich

[1] Non-voting members are included in the discussion, but do not vote due to conflicts with their other work.

[2] Federal observing members are included on the TEP for knowledge sharing purposes across federal agencies, but do not provide guidance to the measure developer and do not vote with the TEP.

SUMMARY OF TEP DISCUSSION

1. **Significance & Background:** Dr. Christian Sandrock introduced the topic of sepsis, highlighting that it is a severe disease and has a significant impact on patient outcomes, cost, and hospitalizations. Dr. Sandrock then introduced the existing process measure for sepsis, SEP-1. SEP-1 is a currently NQF endorsed (NQF #0500) measure that includes both 3-hour and 6-hour components and does not include transfer patients. SEP-1 was designed to align with the Surviving Sepsis Campaign guidelines. It is an all-or-nothing measure, meaning in order to be compliant, all components must be met. The information on SEP-1 was provided merely for background. The TEP was convened to develop and test a new sepsis outcomes measure.

2. **Analytic Framework & Research Questions:** For context, Dr. Sandrock explained the IMPAQ team's approach to this work, including the questions considered during the information gathering phase. The team explored various research questions to look at where the impact of sepsis occurred, differences in clinical definitions, and differences in the prognostic effects of risk factors in patients with and without organ failure. The team also considered the impact of interventions such as antimicrobials, the impact of interventions on morbidity and mortality, and the impact of patient risk factors on sepsis-related outcomes.

3. **Existing Measure for Sepsis Mortality: NYSDOH Risk-Adjusted Sepsis Mortality Measure:** Dr. Sandrock briefly introduced the NYSDOH measure (currently NQF endorsed #3215), noting that it is an inpatient risk-adjusted mortality measure that focuses on adult patients. It uses the Sepsis-2 definition which includes both severe sepsis and septic shock, both on admission or at any time during the patient's hospital stay. The numerator is the number of inpatient mortalities; the denominator is all patients with a diagnosis of severe sepsis or septic shock. The measure excludes transfers and patients with an advanced directive or those who were transferred to hospice. The data source includes EHR, paper medical records, claims, and registry data. This measure was the most comprehensive sepsis measure the project team found.

    a. **Advantages:** The NYSDOH measure is risk-adjusted; NQF-endorsed; has fewer data elements than SEP-1 and uses the Sepsis-2 definition, which is consistent with what many hospitals are currently using. It is also used in conjunction with four other New York State process measures, which allows for alignment.

    b. **Concerns:** The NYSDOH measure focuses on in-hospital mortality rather than 30-day mortality; does not include morbidity, which often occurs with severe sepsis and sepsis shock; the denominator allows for both prospective and retrospective identification of cases, which can cause variability in data; many data elements that are not aligned with SEP-1, which causes extra work for

facilities; and requires sample that is significantly higher than what is required for SEP-1.

c. **TEP Input:** Dr. Sandrock asked for the TEP discussion to focus on whether to adopt the NYSDOH measure, adapt the NYSDOH measure, or develop a de novo measure. Dr. Patrick Romano opened the discussion to the TEP, calling on the additional experts from the NYSDOH to assist in providing more information about the measure and reminded the panel that the task at hand is to develop a measure of sepsis either claims- based or as an eCQM.

    i. Dr. Donald Yealy asked to clarify if the NY measure considers the four phenotypes of sepsis in the risk adjustment. He shared the rates of mortality vary greatly depending on which of the four sepsis phenotypes are considered. A high proportion of sigma phenotypes will have awful outcomes, regardless of the process of care. The phenotypes can be identified using surveillance approaches, which can be considered as the team develops this new measure.

    ii. Dr. Michael Klompas echoed Dr. Yealy's point about the importance of risk adjustment. Dr. Klompas found that the risk adjustment has substantial influence on the ranking of hospitals for measures of sepsis mortality. Dr. Klompas has seen a big change in diagnosis coding for sepsis and currently a wide variability in coding because of the change. For hospitals with more complete coding, the measure will capture milder cases. A hospital farther along in improving their coding will have a larger mortality rate than a hospital that is lagging behind. If the risk adjustment uses more clinical data, this will lead to a substantial change in the impression of mortality. Dr. Klompas strongly encouraged the group to consider other ways to capture sepsis patients given the dynamic flux in coding right now.

    iii. Dr. Sandrock asked for a discussion on the burden and quality related to pursuing a claims-based measure versus an eCQM.

    iv. Dr. Tiffany Osborn agreed with Dr. Klompas' note on the coding discrepancies and asked the panel if there is another database available.

        1. Dr. Klompas cited the NYSDOH's use of using charts to confirm diagnosis from database. The patients that did not meet clinical criteria for sepsis and didn't earn a sepsis code are missed.

2. Dr. Osborn agreed that using the definition of sepsis alone will not capture all patients. New York has the State Planning and Research Cooperative Systems Database, but there is not a national database available for this purpose.

v. Dr. Osborn agreed with Dr. Klompas and emphasized variance in definitions may lead to discrepancies across facilities for patients with the same condition as well as variances in the reporting of patients with sepsis. The State Planning and Research Cooperative Systems Database looks at whether sepsis patients were reported.

vi. Dr. Classen voiced support for eCQMs, noting actionability as one of the advantages and asked if a feasibility analysis has been conducted for converting the NYSDOH measure to an eCQM.

1. Dr. Ian Barbash added it will be important to consider how specification of the measure elements impacts safety-net hospitals with fewer resources for data collection and automation.

d. Additional Expert Input: Additional expert opinion supported the TEP discussion around the preferred approach for development of a sepsis outcome measure.

i. Experts on the NYSDOH measure shared their perspective on the measure, providing additional context for the TEP's discussion. These additional experts highlighted the fact that the measure is based on abstracted data rather than claims data and not all variables may adaptable into an eCQM. Additionally, the current NQF endorsed measure does not include the adjustments the team has made to the risk adjustment methodology through the annual update and continues to use the SEP-2 definition. Experts also shared concerns that the measure may not be generalizable enough for CMS' needs since it was based on data available in New York State.

ii. Another TAG member also supported the TEP's discussion around the importance of risk adjustment for the measure. They highlighted the importance of continuously evaluating the risk adjustment variables of the measure, looking at other ways to collect them rather than data abstraction, and the time frame used to account for discharges to hospice.

iii. Another TAG member supported the approach of pursuing a hybrid sepsis measure which would include components pulled from the EHR as well as administrative data.

4. **Definition of Sepsis:** Dr. Sandrock introduced the topic of sepsis definitions for the next portion of the discussion. Dr. Sandrock asked the panel to keep in mind: 1) from a clinical perspective, is one definition preferred, and 2) from a measure development perspective, is one more feasible? Additionally, he prefaced the discussion with a note that the project team may choose to base the measure on EHR data and/or claims data based on feasibility analysis.

    a. **Sepsis-2:** CMS currently uses the Sepsis-2 definition for the SEP-1 bundle measure. Sepsis-2 evolved from the Sepsis-1 definition and has three components: sepsis, severe sepsis, and septic shock. The Sepsis-2 definition of "sepsis" is patients with suspected or documented infection and greater than or equal to two SIRS criteria.

    b. **Sepsis-3:** Sepsis-3 contains two components: sepsis and septic shock and uses the SOFA and qSOFA score to identify patients. The Sepsis-3 definition includes patients with suspected or documented infection and an acute increase of greater than or equal to two SOFA points.

    c. **CDC Adult Sepsis Event (ASE):** The ASE definition was developed based on Sepsis-3 and uses an eSOFA score to be able to identify sepsis patients for CDC surveillance. The ASE definition of "sepsis" is patients with presumed infection and organ dysfunction within the time period of two calendar days before and after the collection of a blood culture.

    d. TEP Input: Dr. Sandrock asked the TEP to consider the various advantages and disadvantages of each definition.

        i. Dr. Klompas shared his inclination to use the definition that is already optimized for electronic implementation. Additionally, aligning with the ASE definition and the CDC's surveillance approach would show consistent messaging from the federal government.

        ii. Dr. Classen reiterated that a measure based on EHR data would be more accurate and more actionable than one based on administrative data. It would also simplify the way hospitals measure sepsis for diagnosis, recognition, and public reporting.

        iii. Dr. Romano prompted the TEP for any concerns that using a more recent, narrower definition would result in missed opportunities for early

intervention for patients that meet the Sepsis-2 definition but not the Sepsis-3 definition.

iv. Dr. Yealy agreed with this concern particularly from the emergency medicine standpoint because emergency medicine providers see patients in more varying and more nascent states. Dr. Yearly preferred a focus on sensitivity rather than specificity because of the uncertainty that a more specific approach will improve the overall health of patients who are affected by a dysregulated response.

v. Dr. Sean Townsend echoed Dr. Yealy's remarks and added that the government is also endorsing Sepsis-2 and Sepsis-1, so avoiding cognitive dissonance might be a challenge. Dr. Townsend shared a concern with how sepsis can be detected clinically as the Sepsis-3/ qSOFA definition of sepsis captures patients who are already quite ill. He added that Sepsis-3 or ASE might be best for an outcome measure, but noted the clinical value of early detection measures using Sepsis-2.

vi. Dr. Gregory Schmidt emphasized the purpose of this new measure, which is not to develop an early detection tool. He supported a definition focused on specificity so that the measure captures a sepsis-related outcome rather than the symptoms that allow for early detection of sepsis.

vii. Dr. Townsend agreed with Dr. Klompas and Dr. Schmidt and stated that for a sepsis mortality outcome measure, Sepsis-3 or ASE might be the right definition.

viii. Dr. Klompas echoed Dr. Schmidt's point and believed a focus on Sepsis-3 or ASE criteria does not mean that patients with early or mild sepsis are ignored.

ix. Dr. Cristin Mount agreed that the goal is more about creating a quality measure for patients already diagnosed and understood the point about avoiding multiple definitions.

x. Dr. Osborn shared that across departments there are different approaches to identifying sepsis. From her experience in both the ICU and the ED, ICU cases rely more on specificity, whereas emergency cases look more at sensitivity for identifying and treating sepsis. Dr. Osborn added that the team should also consider the definition from the *Surviving Sepsis Campaign* in the 2016 guidelines. The campaign used the Sepsis-4 definition and included septic shock. The Sepsis-3 definition

can be confusing because it can classify a patient who is hypertensive and on two vasopressors as having sepsis rather than septic shock.

xi. Dr. Osborn agreed that the group should consider severity in the definition. The previous outcome measure used "severe sepsis" to account for concerns with sensitivity and specificity.

e. Additional Expert Input:

i. One TAG member supported the TEP's comments that the group should include severity in the definition of sepsis for the new outcome measure.

5. **Category of Outcome Measure:** Dr. Sandrock opened the discussion with the option to pursue a sepsis outcome measure on mortality alone versus morbidity and mortality. He asked the TEP to consider the importance of the comorbidities that patients face when surviving sepsis and require interventions such as mechanical ventilation or renal replacement therapy, and whether the measure should use an endpoint of survivability. He also asked the panel to consider the reliability, validity, and feasibility of measuring morbidity. The NYSDOH measure focused on mortality and NYSDOH is considering making adjustments to the measure to focus on combined mortality and morbidity in the future.

a. TEP Input:

i. Dr. Schmidt asked if the Sepsis outcome measure will be confounded by patients who are put on palliative care and counted as discharged and are therefore not included in mortality statistics.

ii. Dr. Osborn commented her support for merging the CDC electronic surveillance definition and a clinical definition.

iii. Dr. Klompas suggested that the primary outcome of the measure this group is developing could be death or discharge to hospice, and then the remaining patients (e.g. patients on mechanical ventilation, patients on dialysis, etc.) could be classified. It is difficult to know how to define morbidity, especially when a lot of variability in the way it is managed and captured in medical records is expected. If morbidity is included, it should be a secondary measure rather than being part of the primary measure.

iv. Dr. Classen found both inpatient and 30-day mortality in EHR data, but added that morbidity is much more difficult to define and find in the EHR.

v. Dr. Schmidt said some morbidity measures might be easy to define in the EHR, with the increment in creatinine value on day 3 as one example. This is fairly disconnected from mortality, but might be harder to game than mortality.

vi. Dr. Townsend felt it is hard to conceptualize what we mean by morbidity and asked if risk adjusting for morbidity, how does one do that?

b. Additional Expert Input:

i. Experts on the NYSDOH measure added context on the measure's approach to patients that are discharged to palliative care. The NYSDOH measure treats the outcome of discharge to palliative care and/or in hospital hospice as a mortality event outcome in the risk adjustment because of the great variability across facilities that was impacting the outlier rates. They found the 30-day post discharge to hospice data showed a mortality rate of about 80%. They also shared that the all-cause 30-day mortality approach avoids the issue of confounding the measure with patients who are counted as discharged when they were really discharged to hospice.

ii. One TAG member supported the suggestion of a merged definition and suggested the TEP considers improving optimization of CDC criteria and potentially more harmonization of the organ dysfunction criteria with the SEP-1 measure (or Sepsis-3 criteria).

iii. One TAG member did not support a nonspecific definition that captures patients who may not have sepsis at all and forces protocolized care on them.

SUMMARY OF TEP PREFERENCE POLLING RESULTS

The TEP members were asked to indicate their preference on three questions, with the option to either decide during the meeting or send their preferences via email after the meeting. Post-meeting preference polling concluded on January 24, 2020. The results of the preference polling are as follows:

Exhibit 1: TEP Preference Polling Results

Preference Polling Question	TEP Preference Polling Results
Please select your preference for adapting the NYSDOH measure or developing a de novo sepsis measure.	70% Pursue de novo measure option (7 votes) 30% Adapt NQF #3215 (NYSDOH measure) (3 votes)
Which definition of sepsis do you recommend pursuing?	55% CDC Adult Sepsis Event (6 votes) 45% Sepsis-2 (5 votes) 0% Sepsis-3 (0 votes)
Which type of outcome do you recommend for measure development?	73% Mortality alone (8 votes) 27% Morbidity and Mortality (combined) (3 votes)

CONCLUSIONS AND NEXT STEPS

Because of time constraints, the TEP did not discuss the measure time frame. This will be discussed during the second TEP meeting. Following the TEP meeting, the MIDS Patient Safety team produced the meeting summary notes. IMPAQ plans to collect availability for the second TEP meeting in the coming weeks, aiming for March to hold the second TEP meeting. During the second TEP meeting, IMPAQ plans to focus on measure concepts, including the numerator and denominator; whether the measure should capture sepsis present on admission, sepsis not present on admission, or both; potential variables for risk adjustment; risk factors used in clinical criteria tools; and data challenges.

Technical Expert Panel Meeting #2

May 11, 2021, 2:30 PM ET

SUMMARY OF PRESENTATION

The IMPAQ team convened the second TEP meeting to review previous recommendations and decisions from the TEP and CMS regarding measure development, discuss key points related to measure design, and solicit TEP input on these key points. Prior to the meeting, the IMPAQ team provided the TEP members with the presentation slide deck and background materials for review and preparation for discussion. During the meeting, the TEP members introduced themselves and shared any new personal disclosures. The TEP then engaged in discussion around the topics as presented by the IMPAQ team, including the time window for outcome ascertainment; handling community-acquired vs. hospital-acquired sepsis; defining the denominator using SIRS criteria, suspected infection, and organ dysfunction; and how to handle specific exclusions and transferred patients.

Attendance:

TEP Members: Ian Barbash, Rosie Bartel, Marisha Burden, David Classen, Sara Cosgrove, Michael Klompas, Tiffany Osborn, Robert Panzer, Patricia Posa, Gregory Schmidt, Maureen Seckel, Sean Townsend, Donald Yealy, Sameer Kadri (non-voting[3]), Runa Gokhale (federal observing[4]) and Anthony Fiore (federal observing[4]).

Not Present: Jean Proehl, Steven Coffee, Cristin Mount (non-voting)

CMS: Annese Abdullah-Mclaughlin

IMPAQ: Kendall Hall, Anna Michie, Hannah Klein, Leah Dillard, Stacie Schilling, Bo Feng, Mia Nievera, Michelle Lefebvre, Katie Magoulick

Kennell: Christina Superina, Courtney Colahan

UC Davis: Patrick Romano, Christian Sandrock, Garth Utter, Jacqueline Stocking, Monika Ray, Meghan Weyrich

[3] Non-voting members are included in the discussion, but do not vote due to conflicts with their other work.

[4] Federal observing members are included on the TEP for knowledge sharing purposes across federal agencies, but do not provide guidance to the measure developer and do not vote with the TEP.

SUMMARY OF TEP DISCUSSION

1. **Previous Recommendations and Decisions:** Dr. Christian Sandrock reviewed the TEP input from the first TEP meeting and decisions made by CMS regarding measure design, including developing a risk-adjusted, hybrid mortality outcome measure, broadly aligning with the SEP-1 bundle, employing a 30-day time window for outcome ascertainment and focused on community-acquired sepsis.

2. **Time Window:** Dr. Patrick Romano explained that, based largely on experience of New York State and CMS, we determined this measure would be best served by setting a specific time window from the start of the encounter (at admission or ED presentation, whichever comes first). He summarized the results of empirical analysis exploring a variety of possible time windows using Medicare claims data. Empirical evidence supports a 30-day time window, with both survival curves flattening and hazard functions (i.e., the daily risk of death) dropping to baseline levels around 30-days from presentation. Dr. Romano notes that a 30-day time window is consistent with the time window used by other CMS mortality measures, including heart attack, stroke, pneumonia, COPD, and heart failure.

    a. **TEP Input:**

        i. Dr. Klompas said that the proposed approach was reasonable but noted potential feasibility issues related to hospitals to tracking data after discharge.

            1. Dr. Romano indicated that we are proposing to use the linked Social Security Administration eligibility file, which contains the confirmed date of death. This process removes any burden or feasibility issues.

3. **Community-Acquired vs Hospital-Acquired Sepsis:** Dr. Romano reviewed the rate of hospital-acquired versus community-acquired sepsis among Medicare beneficiaries and the corresponding rates of in-hospital deaths. He reviewed the characteristics of patients with hospital-acquired sepsis (evenly divided between medical and surgical patients, long hospital stays) and noted that many of these cases occur among patients being admitted with conditions such as cancer or severe cardiovascular disease and that sepsis develops late in the hospital stay. Dr. Romano reviewed some of the challenges with measuring hospital-acquired sepsis, including when to start the 30-day window, and noted that the Sepsis-1 process bundle is limited to community-acquired sepsis. For these reasons, the IMPAQ team recommends focusing current efforts on community-acquired sepsis and deferring hospital-acquired sepsis mortality to a separate measure with a separate risk adjustment approach.

a. **TEP Input:**

i. Dr. Panzer supported the proposed strategy and shared that his institution is in a Vizient collaborative on sepsis, and they're focused on the inpatient units (particularly those not treating AMI or stroke patients) as they are not as well-tuned to identify sepsis, compared to the ED.

ii. Dr. Cosgrove also supported the proposed approach but noted the importance of messaging around this to ensure that the public doesn't perceive a lack of concern from CMS about patients with hospital-acquired sepsis.

iii. Dr. Schmidt also supported the recommendation and added that many patients with hospital-acquired sepsis have issues around goals of care and their outcomes may depend substantially on the culture of end-of-life care at a particular institution as much as sepsis management processes.

4. **Denominator Definition:** Dr. Romano summarized the issues related to the denominator definition. We are proposing a hybrid approach using structured fields from the electronic health record combined with ICD-10-CM coded diagnoses from the claims record. Using structured fields eliminates the need for manual abstraction, but places constraints on the type of information we're able to use. Dr. Romano reviewed the use of SIRS criteria, suspected infection, and organ dysfunction to define sepsis.

a. **TEP Input (SIRS criteria):**

i. Ms. Seckel noted that the SEP-1 bundle uses a temperature threshold of 38.3 degrees Celsius

1. Dr. Romano said that we can adopt the clarification of 38.3.

ii. Dr. Klompas asked for confirmation that the intent is for the electronic quality measure to use the SIRS criteria as the foundational point for finding sepsis cases.

1. Dr. Romano confirmed, in combination with the organ dysfunction criteria and suspected infection criteria.

iii. Dr. Klompas asked why we are not using the Sepsis-3 definition.

1. Dr. Romano explained that this approach was developed based on guidance from CMS to align as closely as possible with the SEP-1 bundle denominator definition, while taking into

consideration the limitations of that measure and the need to rely on electronic information.

iv. Dr. Klompas noted concerns about the sensitivity and specificity of the SIRS criteria, challenges implementing the criteria, and their susceptibility to variation in the quality of the data and cautioned that we may encounter complexity and challenges by using the SIRS criteria. Dr. Klompas also noted that a quantitative analysis looking at the performance of the SEP-1 versus Sepsis-3 definitions would be useful.

    1. Dr. Romano said that the non-specificity doesn't matter since we will also be requiring criteria for suspected infection as well as criteria for organ dysfunction.

    2. Dr. Sandrock agreed with Dr. Romano and said that incorporating infection criteria and organ dysfunction criteria with the SIRS criteria will hopefully allow us to find the right balance between the SEP-1 bundle, which allows for early intervention, and the fidelity of that Sepsis-3 definition.

v. Dr. Cosgrove asked whether a patient who only met one of the SIRS criteria would be included.

    1. Dr. Romano clarified that two SIRS criteria would need to be met in order to be included.

vi. Dr. Barbash asked for clarification as to whether organ dysfunction and suspected infection are required for cohort entry and meeting SIRS criteria.

    1. Dr. Romano confirmed that these are all "and" statements, and that all three (organ dysfunction, suspected infection, and SIRS) are required.

vii. Dr. Barbash expressed support for Dr. Klompas' suggestion for a quantitative analysis to explore the marginal benefit of using the SEP-1 definition for case acquisition versus the marginal cost of pulling these data (SIRS criteria) and analyzing them.

    1. Dr. Romano stated that the marginal cost would be near zero as the measure will use structured fields from the EHR; there may be some additional analytic costs related to additional data elements incorporated into the SAS logic, but those costs would be minimal.

viii. Dr. Classen asked whether satisfying at least two SIRS criteria could occur anytime within the first 48 hours or whether they would need to have a time overlap (e.g., within 30 minutes of each other). Dr. Classen thought it would be problematic if the criteria could occur anytime within the first 48 hours. He would prefer to see some temporal proximity built into the measure, and Ms. Seckel concurred.

ix. Dr. Schmidt noted that meeting two simultaneous criteria is quite common and that a prior large, multi-institution study found that about half of ward patients (excluding ICU patients) met SIRS criteria at some point during their hospital stay.

b. **TEP Input (suspected infection):**

i. Dr. Burden asked whether we could use more inclusive language when discussing the suspected infection criteria (e.g., using 'provider' instead of 'physician' to encompass different types of advanced practice providers [APP]).

1. Dr. Yealy suggested retaining the language as-is, since APPs work with physicians in these acute care settings.

ii. Dr. Kadri asked whether we had considered including the act of ordering a culture in measure logic (along with starting antibiotics). He said that the threshold for starting antibiotics in patients is low and those patients may not represent suspected infection with sepsis. One approach to avoid false positives is to limit to patients who received a blood culture due to concern for systemic infection.

1. Dr. Romano said that this is an option and asked Dr. Kadri to confirm that his suggestion is to modify the second criterion within suspected infection to include both obtaining a culture of an ordinarily sterile site and initiating antibiotics.

2. Dr. Cosgrove expressed support for Dr. Kadri's suggestion.

iii. Dr. Yealy commented that culture results are not practical. He clarified that he was referring to potential contamination, and that the results are often not reported in a timely manner. He also noted that 40% of culture results are negative in suspected sepsis, with or without an underlying bacterial pathogen.

iv. Dr. Cosgrove asked for additional clarification about the coding approach and how we avoid capturing people who don't actually have an infection and missing those who do.

    1. Dr. Romano explained that the suspected infection criteria is written with "or" logic, linking the first and second statements (and as individuals in the chat pointed out, that makes the third statement redundant). Using "or" logic is designed for greater sensitivity but may introduce more false positives, but requiring satisfaction of both statements may cause more false negatives.

v. Dr. Barbash asked for confirmation that "physician-documented" is based on selection of an ICD-10-CM code and not based on review of unstructured data in the EHR.

    1. Dr. Romano confirmed that this is based on the professional coders review of the physician documentation.

vi. Dr. Barbash asked what types of cases we believe are being captured only under the first statement (physician documentation) but not the second (physician behavior).

    1. Dr. Cosgrove expressed concern that we would be capturing cases that were not actually patients with sepsis if they never had a blood culture or any antibiotics.

    2. Dr. Kadri said that much of this would depend on the set of codes being used to select for infection and we need to ensure that our selection of codes is limited to infections that could lead to sepsis.

    3. Dr. Romano agreed with Dr. Kadri and shared that the IMPAQ team has completed prior work reviewing, identifying and removing codes for superficial infections and nonbacterial infections.

vii. Ms. Seckel asked how we are using the R65.2 codes from ICD-10-CM.

    1. Dr. Romano explained that if we are using "or" logic, then we would limit the first statement to diagnosis codes that actually indicate sepsis (including R65.2-). If we adopt "and" logic instead, then we would propose a broader set of ICD-10-CM diagnosis codes that would include other bacterial infections.

viii. Ms. Bartel commented that frequently antibiotics are given before blood cultures are done when patients present to the ED.

1. Drs. Romano and Yealy agreed, as there may be a lot known about a patient and the type of infection they're likely to have and thus there may be a desire to start antibiotics quickly.

2. Dr. Cosgrove said that you cannot do that and pass SEP-1 criteria, so most places have adapted to obtaining blood cultures or documenting why you couldn't obtain a culture.

3. Dr. Romano noted that the SEP-1 bundle relies heavily on manual review of physician and nursing documentation but that isn't possible within our framework. He expressed a concern that relying strictly on ordering blood cultures and then initiating antibiotics and continuing them for 3 days may be too narrow – some patients may have looked septic but responded so well that antibiotics were discontinued earlier.

4. Ms. Seckel supported the idea of a time window for initiation of antibiotics up to 24 hours prior to or 3 hours after presentation with suspected sepsis.

ix. Dr. Kadri expressed concern about using "and" logic between the two statements and relying on the sensitivity of each infection diagnosis code. He noted scenarios where patients may not be coded for certain infections but clearly have sepsis and they would be missed by the first statement, even if it's a broad list of diagnosis codes.

x. Dr. Schmidt shared that patients being treated for septic shock but not coded as such isn't a significant problem at his institution but noted that other institutions may have a very different approach to diagnosis codes.

xi. Dr. Cosgrove said that the second statement encourages stewardship and would encourage hospitals to discontinue antibiotics that weren't indicated by day 3 or 4.

c. **TEP Input (organ dysfunction):**

i. Dr. Yealy suggested, and Dr. Kadri agreed, that we replace the "and/or" in the criteria with "or" to create a minimum threshold.

ii. Dr. Cosgrove asked whether we could be confident that the information on organ dysfunction extracted from the electronic record is related to the episode of sepsis or whether we risk capturing organ dysfunction that was unrelated to sepsis, particularly in complex patients.

    1. Dr. Romano said that we can construct strict criteria within the measure logic to address this and provided an example from other measure development work involving AKI.

iii. Dr. Yealy asked about the use of noninvasive ventilation and for clarification as to why we are suggesting GCS <12 and not <15.

    1. Dr. Sandrock said that we've limited it to mechanical ventilation because there are some challenges with noninvasive ventilation in patients with other comorbidities, such as obstructive lung disease. Dr. Sandrock clarified we used GCS <12 as it was the benchmark used in other recent studies.

    2. Dr. Yealy asked whether we could consider "new" noninvasive ventilation or "new" GCS <15. Dr. Sandrock thought Dr. Yealy's suggestions were reasonable.

    3. Ms. Seckel noted that documenting GCS on every patient is not the standard of care in every ED.

    4. Dr. Romano noted that there is some variability in the GCS benchmarks used in the SOFA criteria and the Henry group, so we can consider tweaking the GCS criteria to 13 or 14.

    5. Dr. Romano also noted that the GCS criterion was not included in the original ASE definition so it might improve the sensitivity and reduce false negatives.

iv. Dr. Schmidt suggested that the renal dysfunction (U/O <0.5 ml/kg/hr) criterion be present for a minimum amount of time.

v. Dr. Schmidt also suggested that we consider the pulse oximetric saturation Spo2/Fio2 (SF) ratio as an alternative to blood gas analysis.

vi. Dr. Townsend shared a paper by Rhee et al published in JAMA which included a table with the test performance for all of these EHR definitions versus explicit and implicit diagnosis codes.

5. **Exclusions and Transfers:** Dr. Monika Ray summarized the proposed denominator exclusions and the key issues we are seeking TEP input on – how should the proposed measure address (1) subsequent inpatient episodes of sepsis within the 30-day window from presentation for a prior inpatient episode of sepsis, (2) patients discharged alive (without transfer) within a certain number of hours of presentation or who die en route to another hospital, and (3) transferred patients.

    a. **TEP Input (subsequent inpatient episodes):**

        i. Dr. Cosgrove asked whether the team had completed analyses exploring the impact of using a 90-day or 6-month "clean window" between sepsis episodes.

            1. Dr. Romano said that we haven't completed such analyses but explained that one could infer the impact from the data presented, which reflects a three-year period for Medicare enrollees.

        ii. Ms. Posa asked whether multiple sepsis episodes per admission could be counted.

            1. Dr. Romano said that since we are focusing on community-acquired sepsis, we would only count the first episode of sepsis.

        iii. Ms. Bartel commented that many patients have repeated episodes of sepsis during a one-year period.

            1. Dr. Romano agreed, and said that is why our team is skeptical of using Yale/s approach of randomly selecting one sepsis episode per year and would prefer to use a defined time window. No TEP members expressed disagreement.

    b. **TEP Input (discharges within X hours of presentation):**

        i. Dr. Yealy said that patients who die en route during transfer shouldn't be counted against the receiving facility and isn't sure they should count against the transferring facility either.

        ii. Dr. Romano asked for TEP input on the 6-hour minimum time window used by the SEP-1 bundle for death attribution.

            1. Dr. Barbash was open to considering a longer time window, as death within 6 hours of presentation with sepsis may not necessarily modifiable.

2. Dr. Yealy agreed with Dr. Barbash and said that while the 6-hour window was well-suited to a process measure (SEP-1), he did not think it transfers well to an outcome assessment. He suggested that 24 hours would make more sense to him.

3. Dr. Classen, Dr. Barbash, Ms. Seckel, Dr. Posa and Ms. Bartel agreed with Dr. Yealy's suggestion (that discharges alive to non-acute care within 24 hours of presentation – or "less than two midnights" if exact times are not available – should be excluded).

c. **TEP Input (transfers):**

i. Dr. Yealy and Ms. Seckel recommended aligning with SEP-1 on this issue (i.e., option 4). They expressed discomfort with blaming the second hospital when the first hospital did not do early process intervention.

ii. Dr. Panzer agreed with Dr. Yealy and said that excluding any hospitalization that follows transfer from another facility's ED or inpatient care (option 4) was much cleaner given the variable practices of EDs on whether and how they formally admit patients.

iii. Dr. Burden raised concerns about transferring hospitals being dinged for the next hospital's care and acknowledged that this is a tricky issue.

1. Dr. Romano agreed and noted that the advantage of requiring a 24-hour period at the index hospital is that it probably allows enough time for the transferring hospital to figure out what is happening and make the appropriate decisions.

iv. Dr. Townsend said that focus of most research (though observational) is on the effectiveness of therapies and interventions delivered within the first 6 hours and suggested that mortality should be attributed to the index hospital if the patient stayed there at least 6 hours.

1. Dr. Barbash reiterated the importance of this question.

2. Dr. Romano restated Dr. Townsend's suggestion to confirm that if the patient stays between 6-24 hours at the first facility, the suggestion is to not count them if they went home or to a skilled nursing facility (SNF), but if they died or were transferred to another hospital, then the outcome should be attributed to the first hospital.

3. Dr. Barbash noted in agreement that these are very different patient populations – those being sent home vs those who are so sick with sepsis that they're being sent to another facility – and we know that the quality of care and adherence to early treatment is worse in patients who are transferred early in their care, since the transfer process induces treatment delays.

v. Dr. Burden expressed concerns about the index hospital being judged by a 30-day mortality rate for a patient when they were only responsible for a fraction of the care.

1. Dr. Barbash agreed with the concern about being held accountable for downstream outcomes, but most of the downstream treatment is general hospital care and this is intended to be a measure of sepsis care, and the focus of sepsis intervention is early treatment.

2. Dr. Yealy and Dr. Townsend agreed with Dr. Barbash.

SUMMARY OF TEP PREFERENCE POLLING RESULTS

The TEP members were asked to indicate their preference on five questions. The results of the preference polling are as follows:

Exhibit 2: TEP Preference Polling Results

Preference Polling Question	TEP Preference Polling Results
Do you agree with our recommendation to utilize a 30-day mortality time window from presentation to the index hospital?	Yes – 100% (9 votes) No – 0% (0 votes) Abstain – 0% (0 votes)
Do you agree with our recommendation to focus on community-acquired sepsis, and defer hospital-acquired sepsis to a separate measure?	Yes – 100% (10 votes) No – 0% (0 votes) Abstain – 0% (0 votes)

Preference Polling Question	TEP Preference Polling Results
Do you agree with our recommendation to define sepsis criteria for a hybrid measure, using both structured fields from the EHR and ICD-10-CM diagnoses?	Yes – 83% (10 votes) No – 8%* (1 vote) Abstain – 8% (1 vote)
Do you agree with our recommendation to exclude the following sepsis episodes? • Age <18 or >115 • Uncertainty regarding patient sex or date of death • Discharge against medical advice, or alive (without transfer) within X hours of presentation • Hospice enrollment • Discontinuous Medicare FFS Part A and B enrollment, as dictated by risk-adjustment approach • Prior inpatient episode of reported sepsis within 30-day window	Yes – 100% (9 votes) No – 0% (0 votes) Abstain – 0% (0 votes)
Do you agree with our recommendation to adapt the Yale/CMS approach for attribution of mortality among transferred patients to the first hospital in a transfer sequence?	Yes – 100% (10 votes) No – 0% (0 votes) Abstain – 0% (0 votes)

**Note: This "no" vote was due to disagreement about using SIRS criteria at all in the denominator definition, due to their poor specificity.*

CONCLUSIONS AND NEXT STEPS

Following the TEP meeting, the MIDS Patient Safety team produced the meeting summary notes. IMPAQ plans to collect availability for the third TEP meeting in the coming weeks, aiming for August 2021 to hold the next TEP meeting. During the third TEP meeting, IMPAQ plans to focus on resolving remaining questions related to denominator specification, and particularly the potential variables for risk adjustment.

Appendix A: TEP Composition List

Name, Credentials, and Professional Role	Organizational Affiliation, City, State	Conflict of Interest Disclosure
Ian Barbash, MD, MS Physician Researcher	University of Pittsburgh; UPMC Health System Pittsburgh, PA	AHRQ Grant
Rosie Bartel, MA Patient Advisor & Advocate	PFA network Chilton, WI	None
Marisha Burden, MD, FACP, SFHM Division Head of Hospital Medicine, Academic Hospitalist	Society of Hospital Medicine; University of Colorado School of Medicine Denver, CO	None
David Classen, MD, MS Professor of Medicine and Infectious Diseases	University of Utah School of Medicine, VA SLC, Pascal Metrics Salt Lake City, UT	None
Steven Coffee, Lt Col, USAF, MA Patient & Family Caregiver	MedStar Georgetown University Hospital Patient and Family Advisory Council for Quality and Safety Woodbridge, VA	None
Sara Cosgrove, MD, MS Professor, Department of Medicine, Division of Infectious Diseases	The Society for Healthcare Epidemiology of America Baltimore, MD	None
Michael Klompas, MD, MPH, FIDSA, FSHEA Infectious Disease Specialist, Hospital Epidemiologist, Professor of Population Medicine	Brigham & Women's (ID), Harvard Boston, MA	CDC project on sepsis definitions
Tiffany Osborn, MD, MPH, FCCM, FACEP, FAAEM Director: Barnes-Jewish Hospital Sepsis Quality Improvement; Physician Champion: BJC System Sepsis Quality Improvement	Barnes-Jewish Children's Hospital System St. Louis, MO	BJH Foundation Grant; Advisory Board for Inflammatix, Becker Medical, and Viven Health
Robert Panzer, MD Chief Quality Officer, U of R Medical Center & Strong Memorial Hospital, Associate VP for Patient Care Quality and Safety	University of Rochester Medical Center Rochester, NY	None

Name, Credentials, and Professional Role	Organizational Affiliation, City, State	Conflict of Interest Disclosure
Patricia Posa, RN, BSN, MSA, CCRN-K, FAAN Quality and Patient Safety Program Manager	Michigan Medicine; University of Michigan Ann Arbor, MI	None
Jean Proehl, RN, MN, CEN, CPEN, TCRN, FAEN, FAAN Emergency Clinical Nurse Specialist	Emergency Nurses Association Cornish, NH	None
Gregory Schmidt, MD, FCCP Professor, Associate CMO, Associate Chief Quality Officer	University of Iowa Hospitals Iowa City, IA	Author for UpToDate
Maureen Seckel, RN, APRN, MSN, ACNS-BC, CCNS, CCRN, FCNS, FCCM Clinical Nurse Specialist Critical Care and Sepsis Coordinator	Christiana Care Newark, DE	None
Sean Townsend, MD Vice President Quality and Safety, CMS Measure Steward for SEP-1	California Pacific Medical Center - Sutter San Francisco, CA	Sep-1 Measure Steward
Donald Yealy, MD Professor and Chair of Emergency Medicine	University of Pittsburgh; UPMC Pittsburgh, PA	NHLBI grant
SameerKadri, MD, MS, FIDSA Head, Clinical Epidemiology Section; Associate Professor of M (Adjunct), USUHS ***Non- Voting Member***	Critical Care Medicine Department, NIH Clinical Center Bethesda, MD	None
Cristin Mount, MD, FACP, COL, USA Deputy Commander Medical Services ***Non- Voting Member***	Madigan Army Medical Center Tacoma, WA	None
Runa Gokhale, MD, MPH Medical Officer, Division of Healthcare Quality Promotion ***Federal Observing Member***	Centers for Disease Control and Prevention Atlanta, GA	None
Anthony Fiore, MD, MPH Chief of the Epidemiology Research and Innovations Branch, Division of Healthcare Quality Promotion ***Federal Observing Member***	Centers for Disease Control and Prevention Atlanta, GA	None

Appendix B: Project Staff

IMPAQ Team	
Name	**Role**
Kendall Hall, MD, MS	Project Director
Anna Michie, MHS, PMP	Project Manager
Mia Nievera, MSN, RN	eCQM Lead
Stacie Schilling, MPH	NQF Lead
Bo Feng, PhD	NQF SME
Michelle Lefebvre	eCQM SME
Katie Magoulick	eCQM SME
Hannah Klein, PMP	TEP Lead
Leah Dillard	TEP Meeting Coordination & Support
Kennell Team	
Name	**Role**
Allison Russo, DrPH, MPH	Information Gathering Lead
Christina Superina, MPP	Project Manager
Sarah Irie	Team Member
Courtney Colahan	Team Member
UC Davis Team	
Name	**Role**
Patrick Romano, MD, MPH	PSI Measure Development Lead
Christian Sandrock, MD, MPH	Clinical SME
Jacqueline Stocking, PhD, MSN, RN	Clinical SME
Garth Utter, MD, MSc	Clinical SME
Daniel Tancredi, PhD	Statistical SME
Guibo Xing, PhD	Measure Testing Lead
Monika Ray, PhD	Computer Science SME
Meghan Weyrich, MPH	Project Manager