NATIONAL QUALITY FORUM
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Memo

October 13, 2021

To: Patient Safety Standing Committee

From: NQF staff

Re: Post-comment web meeting to discuss public comments received and NQF member expression of support

Introduction

The National Quality Forum (NQF) closed the public commenting period on the measures submitted for endorsement consideration to the Patient Safety Standing Committee. NQF received seven comments that require the Standing Committee's review and consideration during the Patient Safety post-comment meeting.

Purpose of the Call

The Patient Safety Standing Committee post-comment web meeting is scheduled for October 13, 2021 from 2:00pm – 5:00pm ET. The purpose of the post-comment call is to:

- Re-vote on one Consensus Not Reached (CNR) Measure
- Review and discuss comments received during the post-evaluation public and member comment period;
- Provide input on proposed responses to the post-evaluation comments;
- Review and discuss NQF members' expression of support of the measures under consideration; and
- Determine whether reconsideration of any measures or other courses of action are warranted.

Standing Committee Actions

1. Review this briefing memo and draft report.
2. Review and consider the full text of all comments received and the proposed responses to the post-evaluation comments (see comment table and additional documents included with the call materials).
3. Review the NQF members' expressions of support of the submitted measures.
4. Provide feedback and input on measures requiring additional Standing Committee discussion and voting as well as proposed post-evaluation comment responses.

Conference Call Information

Please use the following information to access the conference call line and webinar:

Meeting link: https://nqf.webex.com/nqf/j.php?MTID=ma544586bfa346d2eed3721b8d4754836
Meeting number: 2331 670 5125
Password: QMEvent
Join by phone: 1-844-621-3956

Background

The NQF Patient Safety Standing Committee, which consists of patient safety clinical leaders, patient representatives, and other thought leaders, carefully vets new and existing patient safety measures and makes recommendations for endorsement. A goal of patient safety measurement efforts over the last two decades has been to focus healthcare organizations on quality improvement to enhance care delivery and outcomes for patients. Medical errors and adverse events are major threats to patient safety in healthcare and are linked to over 100,000 preventable deaths per year in the United States.[1] Patient safety-related events occur across all settings, including hospitals and outpatient clinics as well as nursing homes, rehabilitation facilities, and others. These events include a variety of preventable outcomes, including healthcare-associated infections, falls, pressure ulcers, etc.

The NQF portfolio of patient safety measures span a variety of topical areas and includes outcomes, as well as important, measurable processes in healthcare that are associated with patient safety. Public accountability and quality improvement programs use many measures from the NQF portfolio. Nevertheless, significant gaps in patient safety persist. Over more than a decade, NQF's portfolio has expanded to address current and evolving public health issues, such as the opioid crisis.

The NQF Patient Safety Standing Committee oversees the NQF Patient Safety portfolio and assesses both new and existing performance measures for endorsement. During the spring 2021 cycle, the Standing Committee evaluated six measures against NQF's measure evaluation criteria. Measures focused on sepsis, pressure ulcers, falls, radiology, and medication use.

The Standing Committee recommended the following measures for endorsement:

- **#0500** Severe Sepsis and Septic Shock: Management Bundle (Henry Ford Hospital)
- **#3621** Composite Weighted Average for Computerized Tomography (CT) Exam Types: Overall Percent of CT exams for Which Dose Length Product Is at or Below the Size-Specific Diagnostic Reference Level (for CT Abdomen-Pelvis With Contrast/Single Phase Scan, CT Chest Without Contrast/Single (American College of Radiology [ACR])
- **#0679** Percent of High-Risk Residents With Pressure Ulcers (Long Stay) (Centers for Medicare & Medicaid Services)
- **#0674** Percent of Residents Experiencing One or More Falls With Major Injury (Long Stay) (Centers for Medicare & Medicaid Services)
- **#3389** Concurrent Use of Opioids and Benzodiazepines (COB) (Pharmacy Quality Alliance)

The Standing Committee did not reach consensus on the following measure:

- **#3501e** Hospital Harm – Opioid-Related Adverse Events (Centers for Medicare & Medicaid Services/IMPAQ International, LLC)

Comments Received

NQF accepts comments on measures undergoing review in various ways and at various times throughout the evaluation process. First, NQF solicits comments on endorsed measures on an ongoing

[1] Institute of Medicine. To Err Is Human: Building a Safer Health System. Washington, DC: The National Academies Press; 2000. https://www.nap.edu/catalog/9728/to-err-is-human-building-a-safer-health-system.

basis through the Quality Positioning System (QPS). Second, NQF solicits member and public comments during a 16-week comment period via an online tool on the project webpage.

Pre-evaluation Comments

NQF solicits comments prior to the evaluation of the measures via an online tool on the project webpage. For this evaluation cycle, the pre-evaluation comment period was open from April 29 to June 16, 2021 for the measures under review. The majority of the comments received focused on importance of evidence, potential for unintended consequences, and performance gap concerns. All of these pre-evaluation comments were provided to the Standing Committee prior to the measure evaluation meeting.

Post-evaluation Comments

The draft report was posted on the project webpage for public and NQF member comment on August 9 for 30 calendar days. The Standing Committee's recommendations will be reviewed by the Consensus Standards Approval Committee (CSAC) on November 30, 2021. The CSAC will determine whether or not to uphold the Standing Committee's recommendation for each measure submitted for endorsement consideration. All Standing Committee members are encouraged to attend the CSAC meeting to listen to the discussion. During this commenting period, NQF received 15 comments from six member organizations:

Member Council	# of Member Organizations Who Commented
Consumer	1
Health Plan	1
Health Professional	3
Purchaser	1

NQF staff have included all comments that were received (both pre- and post-evaluation) in the comment narrative posted to the Standing Committee SharePoint site. This comment narrative contains the commenter's name, comment, associated measure, topic (if applicable), and—for the post-evaluation comments—draft responses (including measure steward/developer responses) for the Standing Committee's consideration. Please review this narrative in advance of the meeting and consider the individual comments received and the proposed responses to each.

In order to facilitate discussion, the post-evaluation comments have been categorized into major topic areas or themes. Although all comments are subject to discussion, the intent is not to discuss each individual comment during the post-comment call. Instead, NQF staff will spend the majority of the time considering the themes discussed below and the set of comments as a whole. Please note that the organization of the comments into major topic areas is not an attempt to limit Standing Committee discussion. Additionally, please note measure stewards/developers were asked to respond where appropriate. Where possible, NQF staff has proposed draft responses for the Standing Committee to consider.

Measure-Specific Comments

#0500 Severe Sepsis and Septic Shock: Management Bundle

In a joint comment, the Infectious Diseases Society of America, the American College of Emergency Physicians, American Hospital Association, Pediatric Infectious Disease Society, Society for Healthcare Epidemiology of America, Society of Hospital Medicine, and Society of Infectious Disease Pharmacists, suggest changing the measure to minimize antibiotic overuse and adverse effects by removing sepsis without shock from the measure, removing serial lactate measurements from the measure, and including a clear and reproduceable time-zero definition to minimize variability in abstraction. The commenter also suggested using electronic health records for data collection rather than chart abstraction to facilitate the reporting process and focus it on clinical outcomes.

The comment raised concerns that recent published literature indicates that the SEP-1 activities (broad spectrum antibiotics and lactate checks) have not improved outcomes for patients. The concern was that SEP-1's requirement to immediately administer antibiotic therapy to all patients with possible sepsis leads to increased use of unneeded antibiotics and antibiotic resistance. In relation to sepsis versus septic shock, the commenter states that while timely administration of antibiotics can reduce mortality from septic shock, mortality is not similarly reduced in the case of sepsis. The commenter further notes that the measure requires complex documentation of suspected infection, SIRS criteria, and one of more than eight potential organ dysfunction criteria within a limited time window. The commenter states that due to the complexity of these requirements, there may be inconsistencies in abstraction and the measure may be applied to a wider patient population than necessary.

This comment additionally references and re-emphasizes comments submitted by the American Medical Association prior to Standing Committee evaluation over the measure's continued lack of alignment with the existing evidence base.

Measure Steward/Developer Response:

We genuinely appreciate the commentary submitted by the Infectious Diseases Society of America, the American College of Emergency Physicians, American Hospital Association, Pediatric Infectious Disease Society, Society for Healthcare Epidemiology of America, Society of Hospital Medicine, and Society of Infectious Disease Pharmacists. These remarks have been published elsewhere in a position paper by IDSA and their partner societies. This position paper was fully responded to by the CMS measure stewards. Please see: Townsend SR, Rivers EP, Duseja R. Centers for Medicare and Medicaid Services Measure Stewards' Assessment of the Infectious Diseases Society of America's Position Paper on SEP-1. *Clin Infect Dis.* 2021 Feb 16;72(4):553-555. doi: 10.1093/cid/ciaa458. PMID: 32374387.

We will summarize some of the most important fallacies and evidentiary deficiencies in the remarks above (and in the position paper) here for the sake of accessibility to the public.

In brief, the remarks above and the position paper assume that antibiotic resistance and other harms have been increasing after SEP-1 was launched. There is also an assumption that SEP-1 has directly caused increased antibiotic usage. These assumptions amount to rhetorical flourish because there is no credible evidence supporting the first assumption, and very low-quality evidence that the latter assumption is factual. Readers should not dismiss the significance of this absence of evidence: ungrounded arguments cannot drive policy-making considerations.

As to the first issue, IDSA and colleagues assume that resistant infections of all types have increased due to SEP-1's promotion of indiscriminate antibiotic usage across the United States since SEP-1 went into effect. In fact, as documented in two papers published by investigators from the Centers for Disease Control in the New England Journal of Medicine last year, most resistant infections of concern and rates of *Clostridium difficile* infections have decreased, including during the years since SEP-1 went into effect. Please see: Guh AY, Mu Y, Winston LG, et al. Trends in U.S. Burden of *Clostridioides difficile* Infection and Outcomes. *N Engl J Med*. 2020;382(14):1320-1330. Jernigan JA, Hatfield KM, Wolford H, et al. Multidrug-Resistant Bacterial Infections in U.S. Hospitalized Patients, 2012-2017. *N Engl J Med*. 2020;382(14):1309-1319.

As to the second issue, at the time of the publication of IDSA and colleagues' position paper, there were no published studies directly linking SEP-1 to increased antibiotic usage in the literature. The position paper referenced several low-quality studies with serious methodological flaws that were not studies of SEP-1 in an effort to indirectly establish this point. The table in the article by Townsend, Duseja and Rivers in *Clinical Infectious Diseases* cited above highlights the methodological flaws, confounding issues, and indirect nature of these studies.

Since that time, a single paper has been published in the literature that indicates that after SEP-1 was launched, *one hospital* experienced an increase in overly broad antibiotic therapy for urinary tract infections (no other infections had increased usage observed). That paper was a retrospective review, did not control for changing resistance patterns, did not account for patient characteristics or comorbidities beyond that the patients had sepsis and were similar in age and gender, and established no harm from the observed changes, among other serious deficiencies: Miller J, Hall B, Wilson K, Cobian J. Impact of SEP-1 on broad-spectrum combination antibiotic therapy in the emergency department. *Am J Emerg Med*. 2020 Dec;38(12):2570-2573. doi: 10.1016/j.ajem.2019.12.045. Epub 2020 Jan 7. PMID: 31932126.

IDSA and its society partners express concerns about the reliability of time zero in SEP-1, but they do not fairly represent the details of the only two studies in the literature to consider this question. The first study by Rhee et al. provided just one hour of training for non-professional abstractors, including bedside clinicians, and compared their results to professionally trained abstractors before assessing inter-rater reliability. Such an approach sets up an unfair comparison wherein poor agreement should be expected rather than a surprise. It should be noted that Medicare, through its Clinical Data Abstraction Center, audits hospital abstractors for clinical competency in abstraction of its measures including SEP-1 and does not permit hospitals that do not attain passing scores to submit data to Medicare. A second study by Bauer et al., which IDSA and colleagues cite here, found fair agreement among trained abstractors in the first few months after SEP-1 was first launched but attained *perfect reliability and concordance between abstractors* after improvement efforts. Bauer et al. conclude that, "[a]bstraction by a dedicated team for SEP-1 can reduce variability and improve efficiency."

Rhee C, Brown SR, Jones TM, et al. Variability in determining sepsis time zero and bundle compliance rates for the Centers for Medicare and Medicaid services SEP-1 measure. *Infect Control Hosp Epidemiol*. 2018;39(8):994-996.

Department of Health and Human Services [Internet]. Baltimore: CMS.gov, QualityNet [cited 2019 Nov 8]. Chart-Abstracted Data Validation [about 2 screens]. Available from: https://qualitynet.org/inpatient/data-management/chart-abstracted-data-validation.

Bauer SR, Gonet JA, Rosario RF, Griffiths LA, Kingery T, Reddy AJ. Inter-rater Agreement for Abstraction of the Early Management Bundle, Severe Sepsis/Septic Shock (SEP-1) Quality Measure in a Multi-Hospital Health System. *Jt Comm J Qual Patient Saf*. 2019;45(2):108-111.

IDSA and colleagues point to a recent time-series analysis by Barbash et al. that found changes in processes of care but no changes in mortality among sepsis patients after SEP-1's inception. Barbash et al. studied patients that do not meet published definitions of sepsis, specifically studying patients with an order for a blood, urine, respiratory or other culture who exhibited a change in SOFA score of ≥ 2 in the first 6 hours of care in the emergency department. This definition does not conform to sepsis-2, sepsis-3, or the CDC's Adult Sepsis Events definitions and appears to be novel.

Average in-hospital mortality was low in Barbash et al. at 4.5% in Q3 2015, before SEP-1, and 4% in Q4 2017, after SEP-1's inception, despite median ages compatible with a Medicare population (72 and 71 years, respectively).This low mortality population stands in contrast to the CMS measure stewards and colleagues' study of actual SEP-1 cases cited immediately above with average 30-day mortality at 26.7%. Studying all Medicare beneficiaries from 2012 to 2018, Buchman et al. found one-week mortality ranged from 16.4%–20.5% in severe sepsis and 41.1%–42.4% in septic shock (Buchman TG, Simpson SQ, Sciarretta KL, et al. Sepsis Among Medicare Beneficiaries: 1. The Burdens of Sepsis, 2012-2018. *Crit Care Med*. 2020;48(3):276-288).

The low mortality rates observed in Barbash et al. limit the generalizability of their findings and raise concerns that these patients may not have had sepsis by conventional definitions. In support of this belief, the mortality rate in Barbash et al. is similar to that of undifferentiated hospitalized patients (Shahian DM, Wolf RE, Iezzoni LI, Kirle L, Normand SL. Variability in the measurement of hospital-wide mortality rates [published correction appears in *N Engl J Med*. 2011 Apr 7;364(14):1382]. *N Engl J Med*. 2010;363(26):2530-2539).

The issues above as well as other concerns raised in IDSA and colleagues' remarks are substantively answered in the CMS measure stewards and colleagues' analysis of 333,770 verified SEP-1 patients from 3,241 U.S. hospitals. This study, carefully adjusted for possible confounding, found that compliance with SEP-1 is associated with substantial benefits including a reduction in 30-day mortality: 21.81% compliant care versus 27.48% non-compliant care, yielding an absolute risk reduction of 5.67% (95% confidence interval [CI]: 5.33–6.00; $P <$ 0.001). Townsend SR, Phillips GS, Duseja R, Tefera L, Cruikshank D, Dickerson R, Nguyen HB, Schorr CA, Levy MM, Dellinger RP, Conway WA, Browner WS, Rivers EP. Effects of Compliance with the Early Management Bundle (SEP-1) on Mortality Changes among Medicare Beneficiaries with Sepsis: A Propensity Score Matched Cohort Study. *Chest*. 2021 Aug 5:S0012-3692(21)03623-0. doi: 10.1016/j.chest.2021.07.2167. Epub ahead of print. PMID: 34364867.

In conclusion, the thrust of IDSA and colleagues' concerns results in their call for not requiring early antibiotic therapy for patients with severe sepsis and reserving these antibiotics for septic shock patients. We note that the study by Townsend, Phillips, Duseja et al. includes a super-majority of severe sepsis patients who appear to derive a notable benefit from early antibiotic therapy. We therefore believe IDSA and colleagues' request to not endorse SEP-1 is poorly grounded and insufficiently evidence-based.

Proposed Committee Response:

Thank you for your comment. The Standing Committee will review and consider this information in the upcoming meeting.

Action Item:

Review the comments received and determine whether to accept the proposed Standing Committee response.

The Society for Healthcare Epidemiology of America (SHEA) SHEA expressed support for measurement and interventions that reduce harm to patients but does not believe NQF 0500 meets that standard. The commenter noted that sepsis and septic shock are not clinical diagnoses and therefore a patient may exhibit symptoms that are not of septic origin. Concerns were raised that the target population for this measure requires additional specificity and suggests that sepsis without shock should be removed from the measure. The commenter also discussed potential unintended consequences of this measure, including increased inappropriate antibiotic use which can lead to adverse effects such as renal insufficiency, C. difficile infection, MDRO colonization and infection. Another unintended consequence outlined in this measure was the amount time-consuming chart abstraction and a high level of effort expended by hospital employees. Commenters note that in many hospitals, there are full time employees whose sole responsibility is collection of data for the SEP-1 measure rather than implementing evidence-based initiatives known to improve sepsis care. The commenter suggests use of a more global measure such as hospital-onset bacteremia (HOB), rate of admissions to the ICU >48 hours after hospitalization, or ACEP-48 metric as alternatives to this measure because they address a more global audience.

Measure Steward/Developer Response:

We appreciate the opportunity to address the concerns of The Society for Healthcare Epidemiology of America (SHEA) regarding SEP-1. We note that the balance of the remarks by SHEA are based upon the analysis and conclusions drawn in the Infectious Diseases Society of America (IDSA) position paper on SEP-1. We would politely request that SHEA and readers of these remarks kindly review our response to IDSA and colleagues elsewhere in these commentaries.

Please also see our formal published response to IDSA and their society partners in Clinical Infectious Diseases, and the recent publication by the CMS measure stewards regarding SEP-1 and mortality changes among Medicare beneficiaries, if they have not already been reviewed:

Townsend SR, Rivers EP, Duseja R. Centers for Medicare and Medicaid Services Measure Stewards' Assessment of the Infectious Diseases Society of America's Position Paper on SEP-1. Clin Infect Dis. 2021 Feb 16;72(4):553-555. doi: 10.1093/cid/ciaa458. PMID: 32374387.

Townsend SR, Phillips GS, Duseja R, Tefera L, Cruikshank D, Dickerson R, Nguyen HB, Schorr CA, Levy MM, Dellinger RP, Conway WA, Browner WS, Rivers EP. Effects of Compliance with the Early Management Bundle (SEP-1) on Mortality Changes among Medicare Beneficiaries with Sepsis: A Propensity Score Matched Cohort Study. Chest. 2021 Aug 5:S0012-3692(21)03623-0. doi: 10.1016/j.chest.2021.07.2167. Epub ahead of print. PMID: 34364867.

A position paper's conclusions are only valid if it firmly establishes the assumptions the paper's conclusions and suggestions rest upon. Here, the position paper falls short in establishing:

- that SEP-1 has increased antibiotic usage in the United States (the Centers for Disease Control reports that including years after SEP-1's inception, inpatient antibiotic usage has remained stable, see Baggs J, Kazakova S, Hatfield KM et al. 2891.Trends in Inpatient Antibiotic Use in US Hospitals, 2012–2017, Open Forum Infectious Diseases, Volume 6, Issue Supplement_2, October 2019, Page S79.);

- that the hypothesized increase in antibiotic usage due to SEP-1 has resulted in harm in the form of increasing antibiotic resistance and promoted increases in C. difficile infections (see well-done studies by investigators at the Centers for Disease Control finding the opposite during the years SEP-1 has been in effect including Guh AY, Mu Y, Winston LG, et al. Trends in U.S. Burden of Clostridioides difficile Infection and Outcomes. N Engl J Med. 2020;382(14):1320-1330, and Jernigan JA, Hatfield KM, Wolford H, et al. Multidrug-Resistant Bacterial Infections in U.S. Hospitalized Patients, 2012-2017. N Engl J Med. 2020;382(14):1309-1319.)

In short, it would be a rush to judgment to accept the IDSA position paper as having established the necessary assumptions with proper evidence to advance the claims they wish to make without consideration of these other publications which substantially refute these assumptions.

As regards other concerns raised by SHEA, we welcome the opportunity to describe our understanding of these matters:

1. **Heterogeneity of the target population**
   - SHEA notes that sepsis and septic shock are a constellation of symptoms that may not have the same underlying diagnosis and that coded patients with sepsis may not have infections.
   - While we appreciate the sense and meaning of the statement that sepsis is a constellation of symptoms, most conventional definitions of sepsis (sepsis-3) or severe sepsis (sepsis-2, the entity treated by SEP-1 along with septic shock) would run counter to this remark by going beyond symptoms and requiring documentation of a suspected infection and actual organ dysfunction.
   - SEP-1 carefully specifies criteria for making a diagnosis of sepsis and does not rely on coding to verify those criteria. While the population may be drawn from coded cases, clinicians at hospitals review each case for the presence of 1) physician documented suspicion of infection; 2) the presence of 2 or more systemic inflammatory response criteria; 3) specific quantifiable organ dysfunction. If any of these criteria are not met, the case is not included in the measure sample. Therefore, the comment that “forty percent of patients coded as sepsis have a non-infectious cause for their symptoms” would not apply to the SEP-1 population because SEP-1 does not rely on coding to establish the diagnosis of sepsis and because clinician documented suspicion of infection is required.
   - More generally, the concept that sepsis is a constellation of symptoms has not stopped substantial literature from developing about this entity or that it must be defined and treated somehow, since 270,000 patients die from this constellation of symptoms each year.
2. **Unintended consequences – antibiotics and resources**
   - SHEA is concerned about the unintended consequences of antibiotic administration, which we have addressed carefully in these commentaries elsewhere, and about diverting critical patient safety resources into data collection for SEP-1.
   - As regards the burdens of chart abstraction, we note SHEA is relying upon the characterization by IDSA regarding chart abstraction being overly burdensome. This characterization is unfortunately shorn from context.
   - Studying all Medicare beneficiaries from 2012 to 2018, Buchman et al. found one-week mortality ranged from 16.4%–20.5% in severe sepsis and 41.1%–42.4% in septic shock (Buchman TG, Simpson SQ, Sciarretta KL, et al.

Sepsis Among Medicare Beneficiaries: 1. The Burdens of Sepsis, 2012-2018. Crit Care Med. 2020;48(3):276-288). This study found Medicare's costs for sepsis admissions and skilled nursing care exceeded $41.5 billion annually. This highly lethal condition represents the single most costly healthcare condition in the United States. Given this estimate and the severity of the disease, the burden of SEP-1 abstraction is contextually appropriate.

- To quantify that burden realistically, SEP-1 permits hospitals to submit 20% of their cases each quarter (Department of Health and Human Services [Internet]. Baltimore: CMS.gov, QualityNet [cited 2020 May 28]. Hospital Inpatient Specifications Manuals; Version 5.8 - Specifications Manual for discharges 07/01/20 - 12/31/20 (Updated 04/2020) [about 2 screens]. Available from: https://www.qualitynet.org/inpatient/specifications-manuals).
- Abstractors spend 30–120 minutes abstracting each chart citing the same evidence IDSA references (which other studies suggest decreases with experience). In the unusual circumstance that a hospital accrued 300 sepsis cases per quarter, abstraction would require less than one-quarter full-time employee (assuming 300 cases in 3 months, 20% sample, 120 minutes of abstraction time per case, 40-hour work week).
- We would respectfully ask the question: is it a tenable position that hospitals should not dedicate a quarter of a full-time employee to measure sepsis improvement activities, the costliest healthcare condition in the United States, with a mortality rate that is equally as concerning?

3. **Alternative measures**
   - SHEA has suggested several alternative measures. We appreciate any advancements in the field and recognize that other measures may have value. We also recognize that the devil is in the detail of any measure once scrutiny is applied and there are published critiques of each of the measures SHEA has noted in the literature.
   - Under NQF rules, any of the alternative measures suggested by SHEA could be brought before NQF for evaluation if the developers so choose. We encourage innovation in the field and welcome the opportunity to evaluate new approaches.

Proposed Committee Response:

Thank you for your comment. The Standing Committee will review and consider this information in the upcoming meeting.

Action Item:

Review the comments received and determine whether to accept the proposed Standing Committee response.

The Coalition for Improving Sepsis and Antibiotic Practice (CISAP) notes that an increasing body of peer-reviewed publications suggest that SEP-1 may not be the optimal way to do this. Appropriate biomarker-based diagnostic tests should be used to inform the management of sepsis and should focus on measures that have been proven to impact outcomes in real-world healthcare settings, not only in the initial randomized clinical trials with elaborate educational procedures and other controls.

Measure Steward/Developer Response:
We appreciate CISAP's reference to the Infectious Disease Society of America (IDSA) Position Paper on SEP-1 and encourage readers to review our remarks on this document elsewhere in our replies to public commentary.

In summary, we support CISAP's call for better diagnostics for sepsis and bacterial infection and, as this early science matures, we look forward to the opportunity to incorporate such approaches to sepsis quality of care measures.

Proposed Committee Response:
Thank you for your comment. The Standing Committee will review and consider this information in the upcoming meeting.

Action Item:
Review the comments received and determine whether to accept the proposed Standing Committee response.

Sepsis Alliance was joined by eight other organizations in expressing strong support of this measure due to timely diagnosis and early treatment of sepsis. The commenter thanked the Standing Committee for re-endorsing the measure and cited studies that show an association between performance metrics and patient outcomes such as decreased risk-adjusted sepsis mortality and increased hospital-level compliance with mandated public reporting. The commenter also notes there are sepsis screening programs at every hospital in the U.S. and stated that they respectfully disagree with those who continue to urge removal of this measure, noting that sepsis care is nuanced and no single test is yet sufficient, which is why the SEP-1 measure is so crucial to focus on improving the quality of care for the sepsis patient. The commenter support SEP-1's continued improvement to update the measure in response to updated evidence and provider feedback while in use.

Measure Steward/Developer Response:
N/A

Proposed Committee Response:
Thank you for your comment. The Standing Committee will review and consider this information in the upcoming meeting.

Action Item:
Review the comments received and determine whether to accept the proposed Standing Committee response.

The measure developer provided a recently published paper on national performance data on SEP-1, which not fully available at the time of consideration by the Patient Safety Standing Committee. Similar data was presented in the re-endorsement package. The developer states that the peer reviewed results confirm reductions in mortality with compliance with SEP-1 and decreased length of stay carefully adjusted for relevant confounding factors. They cite the following study: Townsend SR, Phillips GS, Duseja R, Tefera L, Cruikshank D, Dickerson R, Nguyen HB, Schorr CA, Levy MM, Dellinger RP, Conway WA, Browner WS, Rivers EP. Effects of Compliance with the Early Management Bundle (SEP-1) on Mortality Changes among Medicare Beneficiaries with Sepsis: A Propensity Score Matched Cohort Study. Chest. 2021 Aug 5:S0012-3692(21)03623-0. doi: 10.1016/j.chest.2021.07.2167. Epub ahead of print. PMID: 34364867.

Measure Steward/Developer Response:
N/A

Proposed Committee Response:
Thank you for your comment. The Standing Committee will review and consider this information in the upcoming meeting.

Action Item:
Review the comments received and determine whether to accept the proposed Standing Committee response.

#3501e Hospital Harm – Opioid-Related Adverse Events

The American Society of Health-System Pharmacists (ASHP) raised concerns about balancing the public health impact of these measures with unintended consequences to patient care. Noting past concerns with measure 3501e, which was originally submitted for the fall 2019 cycle and underwent revisions, they believe that some but not all of these issues were addressed in the current submission. Issues addressed include expansion of the events to any opioid-related adverse outcome, removal of certain exclusions, and removal of doxapram and other respiratory stimulants from the measure.

However, the commenter felt that issues remain with the measure, especially as related to the performance gap. They question whether naloxone administration is an appropriate outcome and raised concerns about the disparity between states' event report rates and an overall low absolute rate reported from the measure's studies. Although the commenter recognizes the importance of opioid-related process measures to help curb the opioid epidemic, ASHP believes that potential unintended consequences could arise from measure implementation.

Measure Steward/Developer Response:
IMPAQ would like to thank the American Society of Health-System Pharmacists (ASHP) for their support of a measure that addresses an important medication safety gap related to opioid related overdose. Unfortunately, their comments do not appear to be relevant to the measure 3501e which was initially submitted to NQF for the Spring 2019 cycle and subsequently revised and resubmitted for the Spring 2021 cycle. Since IMPAQ acquired this measure under contract with CMS in 2019, there have been no exclusions for the use of naloxone within 2 hours of a procedure, nor did this measure address the use of doxapram or any other respiratory stimulant.

Based on feedback received from NQF during the 2019 Spring cycle, we made several substantive updates and re-tested the measure for the 2021 Spring cycle submission. Specifically, we:

- Updated the measure value sets to ensure that the most current codes for hospital administered opioids and naloxone are used and that the codes harmonize across other eCQMs in current CMS quality reporting programs;
- Limited the measure denominator to encounters where patients received at least one opioid during the hospitalization;
- Added a time constraint such that the opioid administration not only precedes the subsequent naloxone administration but also the time gap in between is no larger than 12 hours;
- Re-tested the refined measure for feasibility at 23 hospitals with four different EHR systems (Epic, Cerner, Meditech; and Allscripts); and
- Re-tested for the scientific acceptability of the measure's properties including reliability and validity at six implementation test sites.

- We would like to clarify that measure testing used de-identified EHR data from six hospitals with two different EHR systems (Cerner and Meditech). At no point did measure testing utilize state-based data.

We would also like to clarify that the NQF Standing Committee voted in favor of the appropriateness of naloxone as an opioid reversal agent typically used for severe opioid-related adverse events as they reached consensus in passing 3501e on the Evidence criterion. Empirically, we investigated the extent to which the measure as currently specified may suffer false positives and false negatives and found little evidence of the two. We refer the commenter to measure testing form of 3501e for details.

Lastly, we would like to remind the ASHP, the Patient Safety Standing Committee, and other readers of the substantial performance gap and variations in care which we identified. In addition to testing at six hospitals for reliability and validity, we collected frequency counts on the measure's numerators and denominators from 13 additional hospitals in CY 2019. The rate of ORAE, with the addition of 13 hospitals, ranges from 1.1 to 6.1 per 1,000 qualified inpatient encounters. Using the weighted average measure rate of 0.37%, we estimate that approximately 62,000 adult inpatients suffer ORAEs across the nation annually. While the absolute harm rate can appear small, these measures are of great value to the community both because there is so much room for quality improvement and because of the quality adjusted life years that could be gained. We also identified variability in performance by age, sex, race, ethnicity, and payer source, which following national implementation of the measure may uncover additional performance gaps among vulnerable populations. The literature also verifies that thousands of Americans experience severe adverse events related to hospital administered opioids each year (Herzig et al., 2014). Finally, we note that several NQF-endorsed "harm" measures are in the same frequency range as this eCQM (3501e).

Proposed Committee Response:

Thank you for your comment. The Standing Committee will review and consider this information in the upcoming meeting.

Action Item:

Review the comments received and determine whether to accept the proposed Standing Committee response.

#3621 Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

The University of California San Francisco (UCSF) commented on the measure and raised a specific concern about the measure's success in measuring excessive radiation dose. The commenter notes that the measure assesses only single-phase CT scans and excludes double-phase scans, and cited evidence that most excessively dosed exams are double-phase scans (i.e. more phases deliver proportionally more radiation). Whether to perform a single- or double-phase scan is determined by the radiologist's choice of protocol. The commenter also cites that there is no evidence suggesting the higher phase protocol provides better diagnostic utility. Because the measure focuses on single-phase head, single-phase chest, and single-phase abdomen scans, the commenter feels that the measure misses an important opportunity to measure variations in quality of care which are determined by radiologists' choice of protocol.

Additionally, UCSF raised a concern with the measure denominator's definition of the population to be measured. The measure population is defined as "all patients who require either a CT abdomen-pelvis

exam with contrast (single-phase scans), a CT chest exam without contrast (single-phase scans), and/or a CT head/brain (single-phase scans) exam." However, the commenter cited research that their own registry's numbers suggests that "the denominator for this measure does not reflect a patient population who require these exams, but rather reflects the varying decisions of radiologists to assign patients to different protocols." Again, they assert that because physician choice is not taken into account in calculating the measure, known variations in practice associated with differing quality of care will be missed by the measure.

Measure Steward/Developer Response:

The ACR appreciates the concerns raised by Dr. Smith-Bindman on the endorsement of our measure, NQF #3621.

We agree that protocol selection that is appropriate for a clinical indication is an important component of radiation dose management, along with radiation dose optimization. Our measure addresses optimization but not whether the exam performed was appropriate for the clinical indication or any of the other aspects of protocol selection.

We believe that the protocol selection issue needs to be addressed as a different quality action because the level of standardization and availability of national benchmarks on that is much less further along than dose optimization. Dose optimization results in a quality action for facilities to adjust their protocols and is a responsibility of the team as a whole – physicists, technologists, and physicians who oversee the team at the facility. Protocol selection addresses the appropriateness of the exam for the clinical indication and other factors such as patient time on the scanner and optimal radiation dose.

The measure UCSF and Dr. Smith-Bindman have submitted to NQF for the Fall 2021 cycle conflates appropriateness of protocol for the clinical indication and radiation dose optimization, and disregards applicability.

A facility's protocol selection process may result in more multi-phase studies than needed, resulting in increased radiation exposure. The most accurate way to address that is to measure both the appropriateness of an exam and the radiation dose output (dose indices per exam) and look at the two separately or together. However, the UCSF measure combines the effect of dose optimization and appropriateness; from that, a facility may not be able to determine if its performance could be improved by adjusting protocols or by focusing on appropriateness of the ordered exam, and therefore improvement may be limited.

There are challenges with the implementation of an indications-based measure. Indications for exams do not have standardized language that could be used to track them. Most health and IT systems have just enough ICD-10 coding for reimbursement, but not enough to characterize the patient's condition and the resulting rationale for performing an imaging exam. Electronic Health Records (EHRs) are notoriously incomplete with this type of information and interoperability issues exist with other software systems that might contain such information. In pursuit of an indication-based measure, how would correct characterization of exam appropriateness be determined? A validated method for determining classification of studies using high-dose vs routine protocols appropriate to the indication must be incorporated into such a measure. As benchmarks or guides to drive process improvement, indication-based benchmarks are ideal. We believe that the ACR measure is the first step in that process.

Furthermore, the claim that our measure amounts to as low as 1% exams is invalid. Head-Chest-Abdomen-Pelvis (HCAP) procedures account for nearly 75% of all CT exams, of which only 11% to 13% may be multiple-phase scans. [1]

The ACR will continue to work on a measure that looks at dose indices by indication, but that measure needs to be tested and gather consensus on groupings before it is usable for accountability.

1. National Council on Radiation Protection and Measurements (Ed.). (2019). Medical radiation exposure of patients in the United States: Recommendations of the National Council on Radiation Protection and Measurements. National Council on Radiation Protection and Measurements.

Proposed Committee Response:
Thank you for your comment. The Standing Committee will review and consider this information in the upcoming meeting.

Action Item:
Review the comments received and determine whether to accept the proposed Standing Committee response.

NQF Member Expression of Support

Throughout the 16-week continuous public commenting period, NQF members have the opportunity to express their support ('Support' or 'Do Not Support') for each measure to inform the Standing Committee's recommendations during the commenting period. This expression of support (or not) during the commenting period replaces the member voting opportunity that was previously held subsequent to Standing Committee deliberations. Six NQF members provided their expressions of support: See Appendix A.

Appendix A: NQF Member Expression of Support Results

Five NQF members provided their expressions of support/nonsupport. Three of six measures under consideration received support from NQF members. Results for each measure are provided below.

#0500: Severe Sepsis and Septic Shock: Management Bundle (Measure Steward/Developer)

Member Council	Support	Do Not Support	Total
Consumer	1	0	1
Health Professional	0	1	1

#3389: Concurrent Use of Opioids and Benzodiazepines (COB) (Measure Steward/Developer)

Member Council	Support	Do Not Support	Total
Health Plan	1	0	1
Health Professional	1	0	1

#3501e: Hospital Harm – Opioid-Related Adverse Events (Measure Steward/Developer)

Member Council	Support	Do Not Support	Total
Health Professional	1	0	1
Purchaser	1	0	1