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Patient Safety, Spring 2021 Cycle: Public and Member Comments

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Measure-Specific Comments on Patient Safety Spring 2021 Submissions

NQF #0500, Comment #7759

Standing Committee Recommendation: Measure Recommended for Endorsement

Comment ID#: 7759

Commenter: Kevin Brennan, Coalition for Improving Sepsis and Antibiotic Practices; Submitted by Bruce Quinn

Council / Public: Public

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 9/7/21

Developer Response Required? Yes

Level of Support: Level of Support

Theme: target population

Comment

To Whom It May Concern:

We comment as the Coalition for Improving Sepsis and Antibiotic Practices (CISAP), which includes medical diagnostics companies Thermo Fisher Scientific, Roche Diagnostics, bioMérieux, Abbott, and Siemens. CISAP was formed several years ago to advance policy to improve sepsis care, promote antibiotic stewardship, and enhance patient health outcomes. We write to provide public comment on the National Quality Forum's (NQF) review of the Severe Sepsis and Septic Shock (SEP-1) quality metric.

Our member companies seek to advance knowledge among clinicians, policymakers, and payers of the benefits of using innovative, biomarker-assisted sepsis treatment and antibiotic use to improve critical public health outcomes. As stakeholders work to develop improved sepsis management measures -- including the Medicare SEP-1 quality metric -- CISAP encourages policymakers to consider evidence-based and biomarker-assisted sepsis management in both new and improved sepsis measures.

Sepsis is one of the most devastating and lethal health conditions, yet when recognized early, it is often treatable. Since 2015, Medicare has used a quality measure – SEP-1 – to rate hospitals with regard to their performance with potentially septic patients.

Sepsis always has an infectious cause – whether bacterial, viral, or fungal – but many patients with similar symptoms are not septic. SEP-1 requires that all patients meeting certain general symptom criteria be administered broad-spectrum antibiotics immediately and hospitals are penalized for not doing so. The Infectious Disease Society of America (IDSA) and other organizations have adopted policy positions that SEP-1 needs to be substantially reformed beyond the minor changes which have been made since 2015, such as not applying SEP-1 to patients on ventricular assist devices or to certain patients participating in clinical trials.

The Coalition takes the position that high-quality management and care pathways must be available to all patients who potentially have sepsis, regardless of emergency room or in-hospital settings. However,

an increasing body of peer-reviewed publications suggest that SEP-1 may not be the optimal way to do this. We need to use appropriate biomarker-based diagnostic tests to inform the management of sepsis, and we 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. The full range of knowledge and expertise in the healthcare community, along with the laboratory community, needs to be brought to bear on sepsis management. Now is the right time to encourage new thinking, through forums, town-halls, and other means, to ensure a national dialog on sepsis measures is both innovative and effective.

We thank the advisors and staff of the NQF for your continuing efforts to improve sepsis care and look forward to working with interested stakeholders in improving the diagnosis and treatment of individuals with sepsis.

Sincerely,

The Coalition for Improving Sepsis and Antibiotic Practices

Kevin Brennan

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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.

NQF Response

N/A

NQF Committee Response

NQF #0500, Comment #7771

Standing Committee Recommendation: Measure Recommended for Endorsement

Comment ID#: 7771

Commenter: Mary Hayden, Society for Healthcare Epidemiology of America; Submitted by Geeta Sood

Council / Public: Health Professional

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 9/9/21

Developer Response Required? Yes

Level of Support: Member Does not support

Theme: Lack of evidence, unintended consequences, target population

Comment

The Society for Healthcare Epidemiology of America (SHEA) appreciates the opportunity to provide comments on the proposed NQF 0500 sepsis metric. SHEA supports measurement and interventions that reduce harm to patients. We do not believe NQF 0500 meets this standard.

Performance metrics raise awareness of conditions that cause harm and incentivize hospitals to prioritize and add resources to prevent those harms. Poorly designed metrics may be ineffective in creating structural and process changes that reduce harm, may divert resources from evidence-based interventions known to work or worse, may cause more harm through unintended consequences.

The National Quality Forum's robust scientific endorsement process is an important mechanism to ensure that not only are important patient safety conditions being addressed, but that the specifications of the proposed metrics are effective, feasible, cost-effective, maximize safety, and minimize harm.

One million seven hundred thousand patients develop sepsis annually and sepsis accounts for 270,000 deaths in the United States annually. ^1Undoubtedly, sepsis is a serious and lethal public health risk.

We have reviewed the Infectious Disease Society of America comments and agree with the concerns raised regarding the 1) lack of good-quality evidence that using the SEP-1 sepsis bundle reduces mortality, and 2) lack of evidence that measuring lactate levels reduces mortality, 3) lack of specificity in the target population by conflating sepsis with septic shock, 4) unintended consequences of increased inappropriate antibiotic use, and 5) need for an objective time-zero definition in the SEP-1 metric that is more specific and simpler to abstract than the current definition based on systemic inflammatory response syndrome criteria, documentation of suspected infection, and organ dysfunction or refractory hypotension.

We would like to offer some additional comments to the well-described discussion by IDSA.

1. **Heterogeneity of the target population**
   Sepsis and septic shock are not clinical diagnoses per se but a constellation of symptoms. Just like it would be difficult to equate all patients with "fever", it is difficult to consider patients with fever and vital sign dysfunction as having the same underlying diagnosis. In many cases, this label may not reflect infection at all. Thirty – forty percent of patients coded as sepsis have a non-infectious cause for their sepsis symptoms [2,3].

2. **Unintended consequences – antibiotics and resources**
   In addition to the unintended consequences of unnecessary antibiotic administration, with consequential adverse effects (e.g. renal insufficiency, C. difficile infection, MDRO colonization and infection) noted in the IDSA statement, there is also the unintended consequence of diverting critical patient safety resources into data collection for this metric. The IDSA statement notes that chart abstraction is very time-consuming. There are several pages of data elements required for data collection for this metric. We would add that at present, hospitals employ FTEs whose sole responsibility is collection of data for the SEP-1 measure. The time and effort of those individuals would be better served by spearheading evidence-based initiatives known to improve sepsis care.
3. **Alternative measures**
   While we agree that sepsis is an important area of focus and that measures targeting this condition are valuable, we suggest that NQF and value-based purchasing programs evaluate alternative metrics to the SEP-1 metric that have demonstrated greater evidence of impact with greater specificity of the target population. A more precise target population would identify patients that are most likely benefit from these interventions and would reduce the unintended consequences from broad implementation.
   If the goal is to encourage rapid recognition of clinical deterioration events related to hospital-acquired infections, a more global measure such as hospital-onset bacteremia (HOB) or rate of admissions to the ICU >48 hours after hospitalization should be considered.
   Another alternative to the SEP-1 metric could be the ACEP-48 metric which focuses on sepsis in the emergency room. Ninety percent of cases of sepsis start outside of the hospital [1,2]. Thirty five percent were associated with previous hospitalization at an acute or long-term facility in the 30 days prior to index admission and 42% of cases occurred in the community with no healthcare exposure [3]. Ninety percent of cases of sepsis start outside of the hospital [1,2]. Thus interventions early in the hospital course are likely to be most impactful.
   Other researchers are also evaluating the CDC's hospital-onset Adult Sepsis Event metric that uses objective clinical criteria to identify sepsis, differentiates community and hospital-onset sepsis, and could be imbedded in the electronic medical record [4].

We appreciate the investment by NQF, other professional and community organizations and the public to improve the quality of care for patients with this highly prevalent and highly lethal condition, however we would like to ensure that metrics that are used to improve processes for sepsis care do improve clinical outcomes for patients without causing harm. While the SEP-1 metric targets an important condition, it does so without enough specificity for the patients that would benefit and without enough evidence of improvement in clinical outcomes.

We ask NQF to not endorse SEP-1 and to continue to evaluate other metrics that better impact sepsis outcomes.

Thank you,

Mary Hayden MD

President, Society for Healthcare Epidemiology of America

1. Sepsis: What is Sepsis. 8/17/2021. [1]https://www.cdc.gov/sepsis/what-is-sepsis.html (accessed 9/1/2021 2021).
2. Fay K, Sapiano MRP, Gokhale R, et al. Assessment of Health Care Exposures and Outcomes in Adult Patients With Sepsis and Septic Shock. JAMA Netw Open 2020; 3(7): e206004.
3. Novosad SA, Sapiano MR, Grigg C, et al. Vital Signs: Epidemiology of Sepsis: Prevalence of

Health Care Factors and Opportunities for Prevention. MMWR Morb Mortal Wkly Rep 2016; 65(33): 864-9.
4. Page B, Klompas M, Chan C, et al. Surveillance for Healthcare-Associated Infections: Hospital-Onset Adult Sepsis Events versus Current Reportable Conditions. Clin Infect Dis 2021.

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.

NQF Response

N/A

NQF Committee Response

NQF #0500, Comment #7770

Standing Committee Recommendation: Measure Recommended for Endorsement

Comment ID#: 7770

Commenter: Thomas Kim, Infectious Diseases Society of America; Submitted by Thomas Kim

Council / Public: Public

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 9/9/21

Developer Response Required? Yes

Level of Support: N/A

Theme: Lack of evidence, unintended consequences, target population

Comment

Patient Safety Post-Comment Web Meeting (Spring 2021 Cycle)

Comments on Severe Sepsis and Septic Shock: Early Management Bundle (SEP-1)

Submitted by the Infectious Diseases Society of America with endorsement from 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

September 9, 2021

NQF, CMS, and the SEP-1 measure stewards deserve due credit for creating SEP-1, which has helped raise awareness of sepsis and improved the standard of care for this deadly disease. However, data have emerged over the past 6 years that have identified problems that, if rectified, would significantly strengthen SEP-1 and reduce unintended measure consequences.

The Infectious Diseases Society of America is joined by the following five organizations in strongly urging that SEP-1 not be re-endorsed unless and until the bundle is revised: 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.

The goals for the major revisions we request are:

- Focus the bundle on the subset of patients most likely to benefit from rapid and aggressive interventions, i.e., those with septic shock, not those without shock
- Minimize antibiotic overuse and adverse effects by eliminating patients with sepsis without shock from the bundle, and redefining the goals for time to antibiotic delivery
- Eliminate bundle elements that do not contribute to improved patient outcomes, such as measuring serial lactates
- Streamline the reporting process to focus on clinical outcomes

- Make reporting electronic with data that is easily extractable from the electronic health record
- Get input and support for intended changes from all the professional organizations that are most affected by the measure

Below, we summarize our major concerns that were addressed in an IDSA position paper published in 2020 and endorsed by five major professional societies (Rhee 2021). For the purposes of this letter, "sepsis" and "severe sepsis" are used interchangeably hereafter and are distinguished from "septic shock."

1. Despite massive investments by US hospitals to implement, assess compliance with, and report data on the SEP-1 core measure, our analysis of published literature indicates that these SEP-1 activities have not improved outcomes for patients.

- Much of the evidence used to support the SEP-1 measure comes from before-after studies or studies of association that reported lower mortality rates in sepsis patients who received bundle compliant care versus those who did not. These studies are at high risk for confounding due to failure to adequately adjust for factors that influenced bundle compliance and outcomes leading to misleading claims of lower mortality (Rhee, 2021).
- More rigorous analyses using interrupted time series models and detailed clinical data for risk adjustment demonstrate that SEP-1 did lead to changes in the processes of care (50% increase in lactate checks, 10% increase in broad spectrum antibiotics, and a 30% increase in infusion of 30mL/kg fluids within 3 hours of culture orders) but no improvement in sepsis-associated mortality (Barbash, 2021). These data support the concern that SEP-1 forces clinicians and hospitals to focus on a low yield set of processes and interventions. These processes and interventions constrain practice but have not clearly led to better outcomes for patients.

2. SEP-1's requirement to immediately administer antibiotic therapy to all patients with possible sepsis risks increasing excessive and unwarranted antibiotic administration.

- The signs and symptoms of sepsis are non-specific and mimicked by many non-infectious conditions. At least one third of patients treated with antibiotics for possible sepsis turn out to have non-infectious conditions. A forced rush to treatment therefore exposes many patients to the risk of antibiotics without benefit. This in turn exacerbates the public health crisis of antibiotic resistance (Weinberger 2020, Klouwenberg 2015, Shappell 2021).

3. SEP-1 conflates the urgency of antibiotic administration for sepsis and septic shock.

- SEP-1 stipulates the same time-to-antibiotic goals for sepsis and septic shock, but the association between time-to-antibiotics and mortality is much stronger for septic shock than for sepsis.
- The perception that any delays in antibiotic therapy led to worse outcomes for patients with sepsis, regardless of severity-of-illness, contributes to inappropriate antibiotic prescribing and is the wrong message for providers Weinberger, 2020).

4. The current SEP-1 time-zero is complex, subjective, and not evidence based.

- The SEP-1 time zero definition requires documentation of suspected infection, SIRS criteria, and one of more than 8 potential organ dysfunction criteria within a limited time window. The complexity of the current time zero definition contributes to variability in abstraction and therein undermines the validity of the measure (Bauer, 2019)..

- The original early-goal directed therapy trial that served as the inspiration for SEP-1 focused on patients with septic shock, as defined by refractory hypotension or lactate levels ≥4 mmol/L (Rivers, 2001). The sepsis bundle has since been extrapolated to a much broader set of patients, but there are no high-quality studies demonstrating the benefit of immediate antibiotics in patients whose only signs of organ dysfunction are abnormal creatinine, bilirubin, coagulopathy, or mildly elevated lactate levels at the thresholds specified in the time zero definition.

5. Serial lactate measurements have not been shown to consistently improve clinical outcomes in patients with sepsis (Pepper, 2018).

- The lack of benefit of this bundle component is further supported by a recent randomized controlled trial of patients with septic shock that showed no difference in mortality between fluid resuscitation based on physical exam (capillary refill time) versus serial lactate measurements (Hernández, 2019).

Concrete suggestions to revise SEP-1 are as follows:

1. Sepsis without shock should be removed from SEP-1.

- Limiting SEP-1 to septic shock will focus the measure on the patients in whom the evidence best supports the potential benefit of immediate antibiotics.
- This will also reduce the risk of harm from unnecessary antibiotics (or unnecessarily broad antibiotics) by allowing clinicians more time and discretion in relatively stable patients to determine if infection is present versus one of the many conditions that can mimic infection.
- We note that this view is further emphasized in a separate statement by the American College of Emergency Medicine (Yealy, 2021).

2. SEP-1 should include a clear and reproducible definition of time-zero.

- The current SEP-1 time-zero definition is complex and subjective. SEP-1 should have an evidence-based time-zero that can be easily recorded from an electronic health record such as the time when vasopressors were initiated, sustained measures of hypotension, or the time of antibiotic order. This will increase reliability of time zero identification and reduce the burden of abstraction.

3. Serial lactate measurements should be removed from SEP-1.

- Requiring repeat lactate measurements in all patients with initial mildly elevated lactate levels is not evidence-based and a poor use of resources.

Over the long term, we believe that sepsis quality measurement should transition to an electronic measure focusing on outcomes rather than processes. We appreciate the opportunity to work with CMS and the IMPAQ group on developing an objective risk-adjusted electronic outcome measure that can help drive further innovations and improvements in sepsis care.

Until a validated outcome measure is established, however, we strongly recommend updating SEP-1 with the suggestions outlined above and believe that a decision by NQF against re-endorsing this measure will encourage the measure stewards to make these important updates to the measure. The impact of a CMS measure is substantially enhanced if stakeholders have confidence that the measure

truly improves outcomes, does not lead to unintended consequences, and has minimal reporting burden.

It should be noted that the American Medical Association has also issued formal comments (May 27, 2021) to NQF recommending removal of endorsement due to ongoing concerns over the lack of alignment with current evidence and the potential for negative unintended consequences such as incentivizing antibiotic overuse. **The fact that multiple professional societies are calling for change now suggests many well informed and thoughtful clinicians support the need for a substantial update of this high-stakes measure.**

Thank you for your consideration.

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.

NQF Response

N/A

NQF Committee Response

NQF #0500, Comment #7745

Standing Committee Recommendation: Measure Recommended for Endorsement

Comment ID#: 7745

Commenter: Submitted by Sean Townsend

Council / Public: Public

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 8/20/21

Developer Response Required? No

Level of Support: N/A

Theme: N/A

Comment

As SEP-1 measure stewards, Dr. Rivers and I are pleased to present published national performance data on SEP-1, which not fully availalble at the time of consideration by the Patient Safety Committee. Similar data was presented in the re-endorsement package, however these peer reviewed results confirm reductions in mortality with compliance with SEP-1 and decreased length of stay carefully adjusted for relevant confounding factors.

[1]https://pubmed.ncbi.nlm.nih.gov/34364867/

The citation is:

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.

References

1. https://nam02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fes.sonicurlprotection-sjl.com%2Fclick%3FPV%3D2%26MSGID%3D20210817013318050247 6%26URLID%3D3%26ESV%3D10.0.10.6443%26IV%3D8FAD7ECCEB35DA04D5C0773C7A03D93C%26TT%3D1629164002005%26ESN%3Dft2rjX0j0liH%252FiDv0cYdKIov%252BcdF96HuuvNrp8Q9480%253D%26KV%3D1536961729280%26B64_ENCODED_URL%3DaHR0cHM6Ly9wdWJtZWQubmNiaS5ubG0ubmloLmdvdi8zNDM2NDg2Ny8%26HK%3D3420766A6FDE7349EDCE1D28AFF59476E52FC98D5D3EDEFD1BC5559621F5CD8A&data=04%7C01%7Ctownsesr%40sutterhealth.org%7Cdab3f43063cb47a063be08d964011de3%7Caef453eadaa243e0be62818066e9ff63%7C0%7C0%7C637650779461839215%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0&sdata=ECA43BL%2BY0LibQepUS8VrESJ9OVcnk4Zo789%2BY8biuU%3D&reserved=0

Developer Response

N/A

NQF Response

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

NQF Committee Response

NQF #0500, Comment #7760

Standing Committee Recommendation: Measure Recommended for Endorsement

Comment ID#: 7760

Commenter: Submitted by Thomas Heymann

Council / Public: Consumer

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 9/8/21

Developer Response Required? No

Level of Support: N/A

Theme: N/A

Comment

We, the undersigned patient safety and advocacy organizations, on behalf of the many millions of patients, families, and survivors we represent, write to express strong support of and gratitude for the Patient Safety Standing Committee's re-endorsement of the continued measure of hospitals' compliance with the Severe Sepsis and Septic Shock Management Bundle (NQF # 0500, or SEP-1). We are grateful that the Standing Committee took what we believe to be a lifesaving step in re-endorsing this quality measure, and we urge the Consensus Standards Approval Committee (CSAC) and other decisionmakers within NQF to do the same.

Sepsis is the leading cause of death in U.S. hospitals[1][i] and claims over 270,000 American lives each year[2][ii]. Another 1.4 million American survive sepsis every year[3][iii], many of them with lingering costs and complications—including approximately 14,000 amputations[4][iv] annually.

SEP-1 focuses on timely recognition of sepsis and early intervention with life-saving therapies. Saving lives and limbs from sepsis is about time: 12% of septic emergency department patients develop shock within 48 hours of presentation[5][v] and each hour of delay until initial antimicrobials are administered is associated with an 8.0% increase in progression to septic shock[6][vi]. By emphasizing the screening of every patient in an effort to catch sepsis early, SEP-1 helps prevent the progression of sepsis to septic shock and ultimately saves lives. A new study of patient-level data reported to Medicare by 3,241 hospitals between 2015 and 2017 shows that SEP-1 compliance is associated with lower 30-day mortality[7][vii].

Moreover, studies have shown the association between performance metrics and patient outcomes[8][viii] and that decreased risk-adjusted sepsis mortality is associated with increased hospital-level compliance with mandated public reporting[9][ix]. The mandate that hospitals gather and report sepsis-relevant performance data is part of what makes SEP-1 a life-saving measure.

The effectiveness and widespread approval of the SEP-1 measure led to its incorporation into the CMS Hospital IQR program in 2015. Today, there are sepsis screening programs at every hospital in the U.S., which has brought every community hospital in America up to the level of an academic facility on diagnosing and treating this challenging syndrome.

We respectfully disagree with those who continue to urge removal of this measure. We understand that care is nuanced and that no single test can (yet) accurately or reliably establish a diagnosis of sepsis. In

fact, this lack of a precise test is exactly why we should maintain a measure meant to focus on improving the quality of care for the sepsis patient. Based on continued insights from analysis of the SEP-1 measure and associated outcomes, we support its continued improvement—there are, in fact, ongoing efforts to modify the measure in response to updated evidence and provider feedback. These include efforts to combat the growing threat of antimicrobial resistance and to encourage better multidisciplinary clinician engagement in the care of septic patients throughout their illness and recovery.

By re-endorsing the SEP-1 measure, the Patient Safety Standing Committee has taken a critical step toward assuring that focus is maintained on the number one cause of death in U.S. hospitals: sepsis. With modifications as appropriate, the SEP-1 measure will support the continued necessary education, screening, early recognition, and management of sepsis that improves care and saves lives in every community.

With this letter of support, our groups join with the many leaders in the field who strongly support the maintenance and continued development of the SEP-1 measure. We thank the Patient Safety Standing Committee for its lifesaving decision, and we urge the CSAC and other decisionmakers within NQF to follow suit.

Sincerely,

Tom Heymann

President & CEO, Sepsis Alliance

The Alliance for Aging Research

Americare CSS and Americare Inc

Home Care Association of New York State

The Leapfrog Group

MoMMA's Voices Coalition

NTM Info & Research

Peggy Lillis Foundation

Society to Improve Diagnosis in Medicine

[10][i] Liu V, et al. JAMA. 2014;312(1):90-92.
[11]http://jama.jamanetwork.com/article.aspx?articleid=1873131&resultClick=3

[12][ii] Rhee C, et al. JAMA. 2017;318(13):1241-1249.
[13]http://jamanetwork.com/journals/jama/fullarticle/2654187

14][iii] Rhee C, et al. JAMA. 2017;318(13):1241-1249.
[15]http://jamanetwork.com/journals/jama/fullarticle/2654187

[16][iv] Healthcare Cost and Utilization Project, Nationwide Inpatient Sample, 2012. Accessed April 6,2016

[17][v] Capp R, Horton CL, Takhar SS, Ginde AA, Peak DA, Zane R, Marill KA. Predictors of patients who

present to the emergency department with sepsis and progress to septic shock between 4 and 48 hours of emergency department arrival. Crit Care Med. 2015 May;43(5):983-8. doi: 10.1097/CCM.0000000000000861. PMID: 25668750.

[18][vi] Whiles BB, Deis AS, Simpson SQ. Increased Time to Initial Antimicrobial Administration Is Associated With Progression to Septic Shock in Severe Sepsis Patients. Crit Care Med. 2017 Apr;45(4):623-629. doi: 10.1097/CCM.0000000000002262. PMID: 28169944; PMCID: PMC5374449.

[19][vii] Townsend, Sean R., et al. "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, doi: 10.1016/j.chest.07.2167.

[20][viii] Levy MM, Rhodes A, Phillips GS, Townsend SR, Schorr CA, Beale R, Osborn T, Lemeshow S, Chiche JD, Artigas A, Dellinger RP. Surviving Sepsis Campaign: association between performance metrics and outcomes in a 7.5-year study. Crit Care Med. 2015 Jan;43(1):3-12. doi: 10.1097/CCM.0000000000000723. PMID: 25275252.

[21][ix] Levy MM, Gesten FC, Phillips GS, Terry KM, Seymour CW, Prescott HC, Friedrich M, Iwashyna TJ, Osborn T, Lemeshow S. Mortality Changes Associated with Mandated Public Reporting for Sepsis. The Results of the New York State Initiative. Am J Respir Crit Care Med. 2018 Dec 1;198(11):1406-1412. doi: 10.1164/rccm.201712-2545OC. PMID: 30189749; PMCID: PMC6290949.

Developer Response

N/A

NQF Response

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

NQF Committee Response

NQF #3621, Comment #7744

Standing Committee Recommendation: Measure Recommended for Endorsement

Comment ID#: 7744

Commenter: Rebecca Smith-Bindman, University of California, San Francisco; Submitted by Carly Stewart

Council / Public: Public

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 444208/12/21

Developer Response Required? Yes

Level of Support: N/A

Theme: N/A

Comment

I write in response to the NQF Patient Safety, Spring 2021 Cycle, draft CDP Report issued August 11, 2021.

The NQF standing committee has endorsed measure 3621, proposed by the American College of Radiology (ACR), titled “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.” There is ample need for quality measurement to inform clinicians and imaging facilities of how they can safely lower radiation doses in diagnostic CT while maintaining the quality of images needed for diagnosis. While measure 3621 has strengths, including encouraging radiologists to reduce the average doses for three common protocols, ultimately, measure 3621 is inadequate because it does not account for the strongest driver of excessive radiation dose, as I lay out below. I therefore remain against the endorsement of the proposed measure as it will not reduce the unintended harm of radiation in diagnostic imaging.

The evidence for measure 3621 highlights a critical patient safety imperative: extensive epidemiological and biological research suggests that exposure to radiation in the same range as that routinely delivered by CT increases a person's risk of developing cancer, and exposure to CT is estimated to cause over 2% of cancers diagnosed annually in the United States. Not only are CT radiation doses frequently much higher than needed for diagnosis, they are highly variable across imaging facilities for patients imaged for the same clinical indication. Yet, more so than patient or machine characteristics, the single most important predictor of radiation dose is the choice the radiologist makes as to what protocol to use for any given exam (e.g. a single-phase scan or double-phase scan). Protocols with more phases deliver proportionally more radiation, yet for most indications, there is no evidence suggesting the higher phase protocol provides better diagnostic utility. Also, in most high

radiation dose exams, the dose is frequently driven by multiple phases, not by upping technical parameters, such as the kilovoltage peak or milliampere-seconds. The fact that measure 3621 assesses only single-phase CT scans completely excludes most excessively dosed exams from scrutiny.

Measure 3621 will evaluate radiation doses used for three specific CT protocols: a single-phase head, single-phase chest, and single-phase abdomen. The measure will assess doses in these three groups against benchmarks only after the primary decision of protocol selection is made. In other words, the

measure does not consider the underlying clinical reason for imaging, nor assess whether the right protocol was selected. This limited assessment of dose within protocol groups ignores the primary factor determining dose, i.e. protocol selection, which is almost entirely at the discretion of the imaging physician. In effect, the measure will assess only the relatively smaller variation in technical parameters within single-phase head, chest, or abdomen protocols, but will leave unassessed the variation that occurs due to the choice of protocol.

Further, the denominator for measure 3621 is not stable. The ACR defines the target population for the measure 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." But since the measure does not account for underlying indication, it fails to identify those patients who required these exams, but who instead received much higher doses through unnecessary multi-phase exams. In the University of California, San Francisco International CT Dose Registry, which includes over 8 million CT scans from 162 hospitals and image facilities, these three CT exam types together make up 39% of exams overall across the registry. However, they account for 1% to 83% of exams across the different imaging facilities, suggesting 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.

Radiation doses must be assessed based on the intent and clinical question of the provider ordering the scan, not on the radiologist's subjective choice of protocol, which is too often driven more by preference than clinical need. The measurement of dose within the ACR's narrowly defined groups will only camouflage the large existing variation in practice and will not improve practice.

The University of California, San Francisco was contracted by CMS to develop a quality measure for CT, which was submitted to NQF for the Fall 2021 cycle review. This measure assesses radiation doses among adult patients who undergo diagnostic CT based on the diagnoses and clinical questions generated at the time of the test order, and therefore is not undermined by the concern raised in measure 3621.

Rebecca Smith-Bindman, MD

University of California, San Francisco

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.

NQF Response

N/A

NQF Committee Response

NQF #3501e, Comment #7763

Standing Committee Recommendation: Consensus Not Reached

Comment ID#: 7763

Commenter: Submitted by Anna Legreid Dopp

Council / Public: Health Professional

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 9/9/21

Developer Response Required? Yes

Level of Support: Member Does not support

Theme: N/A

Comment

September 7, 2021

National Quality Forum

1030 15th Street NW, Suite 800

Washington, DC 20005

Re: NQF #3501e Hospital Harm – Opioid-Related Adverse Events

ASHP is pleased to submit comments on the National Quality Forum (NQF) Patient Safety Spring 2021 Cycle Draft Report for Comment (hereinafter, the "Draft Report"). ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's more than 58,000 members include pharmacists, student pharmacists, and pharmacy technicians. For over 79 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

ASHP commends NQF for its commitment to patient safety and honors the contributions from the Patient Safety Standing Committee members. ASHP thanks NQF for the opportunity to comment on the medication-related measure in the proposed Draft Report, NQF 3501e Hospital Harm – Opioid-Related Adverse Events from Centers for Medicare & Medicaid Services. We support the Standing Committee's decision to delay consensus on NQF 3501e. Importantly this measure addresses an important medication safety gap related to opioid related overdose; however, it is important to carefully balance the public health impact of these measures with unintended consequences on patient care.

Our comments are designed to assist NQF in closing the gap between measuring and improving patient safety around medication use and opioid safety. There are a growing number of opioid-related process measures in the marketplace that are aimed at placing safeguards around prescribing practices. We recognize the value in having a suite of these type of measures, or a measure set, that enables a comprehensive and balanced evaluation of opioid prescribing for the purpose of minimizing opioid misuse and overdose.

NQF 3501e Hospital Harm – Opioid-Related Adverse Events

Overall, we understand how the committee was unable to reach consensus on this measure. In the past,

this measure was brought forth and not endorsed due to a lack of evidence and several comments discussing concerns about its applicability in real world settings. Some revisions made to NQF 3501e address past concerns such as expansion of the events considered beyond respiratory related to any opioid-related adverse outcome, removal of the exclusion of utilization of naloxone "within 2 hours of a procedure" (still only including events outside of the operating room), focus on naloxone alone and removal of doxapram/respiratory stimulants, and adjustments of the description/numerator/denominator utilized for the measure. While the NQF committee passed the measure in regards to evidence, consensus wasn't reached regarding the performance gap of the measure. This was due to discussions regarding the appropriateness of naloxone administration as an outcome, concerns about the disparity between states' event report rates (some with four-fold differences), and an overall low absolute rate reported from the measure's studies. Overall, we support the existence of a measure aimed at addressing opioid-related adverse events for the purpose of reducing hospital harm; however, we urge care in the development and endorsement of such a measure in meeting a performance gap while minimizing unintended consequences.

In summary, ASHP applauds the NQF Patient Safety Standing Committee for delaying its decision on NQF 3501e. We believe it is important to create measures related to hospital harm and related to the opioid epidemic; however feel more consideration is needed in NQF 3501e.

ASHP appreciates this opportunity to provide comments. Please contact me if you have any questions on ASHP's comments on the proposed draft report. I can be reached by telephone at 301-664-8889 or by email at [1]adopp@ashp.org.

Sincerely,

Anna Legreid Dopp, Pharm.D., CPHQ

Director, Clinical Guidelines and Quality Improvement

American Society of Health-System Pharmacists

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 to 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 qualityadjusted 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). Based on these results, which have been confirmed in the literature, and the precedent for endorsement of other harm measures at this frequency, we strongly believe that measure 3501e meets the NQF criteria for performance gap.

1. Herzig SJ, Rothberg MB, Cheung M, Ngo LH, Marcantonio ER. Opioid utilization and opioid- related adverse events in nonsurgical patients in US hospitals. J Hosp Med. 2014;9(2):73–81. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3976956/

NQF Response

N/A

NQF Committee Response

NQF #3501e, Comment #7751

Standing Committee Recommendation: Consensus Not Reached

Comment ID#: 7751

Commenter: Measure Developer, IMPAQ International; Submitted by Stacie Schilling

Council / Public: Public

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 444409/1/21

Developer Response Required? No

Level of Support: N/A

Theme: N/A

Comment

Opioids are often the foundation for acute pain control in the inpatient setting, but excessive administration of opioids can lead to serious adverse events, including over-sedation, respiratory depression and death. Opioid-related adverse events (ORAE) have both clinical and financial implications. Previous studies have shown that patients who experience ORAE have 55% longer lengths of hospital stay, 47% higher health care costs, 36% higher risk of 30-day readmission, and 3.4 times higher payments than those who do not suffer this adverse event (Kessler et al., 2013; Sahfi et al., 2018).

IMPAQ was tasked by CMS to develop the ORAE electronic clinical quality measure (eCQM) (NQF #3501e), using data solely from the electronic health record (EHR). This facility-level eCQM assesses the proportion of inpatient hospital encounters in which patients aged 18 or older are administered an opioid medication and are then administered an opioid antagonist (naloxone) within 12 hours, suggesting an ORAE. The eCQM excludes opioid antagonist (naloxone) administration occurring in the operating room setting, acknowledging that the use of opioid antagonist within the operating room setting may be part of the sedation plan.

The intent of the measure is not to reduce clinically appropriate use of naloxone, nor to reduce naloxone use to zero, but to identify hospitals that have particularly high rates of naloxone use, suggesting excessive dosing of opioids in the inpatient setting. Use of this measure will incentivize improved clinical practices, such as avoiding over-sedation and closely monitoring patients on opioids to prevent serious and potentially lethal adverse drug events.

As required by the evaluation rubrics set by the National Quality Forum (NQF), we assessed the measure's scientific properties by partnering with a large healthcare system and a quality measure reporting service provider with access to various hospitals, including rural and small hospitals. To evaluate measure feasibility, in particular, the extent to which critical data elements needed for measure implementation are readily available and electronically retrievable in the EHRs, we recruited 23 sites from our measure testing partners. These 23 sites cover major EHR systems in the mainstream market (Epic, Cerner, Meditech, and Allscripts). Testing results showed high feasibility of the measure's critical data elements.

To then quantify the measure performance rate, i.e., the rate of hospital-level ORAE, we selected six sites from the alpha testing participants to participate in measure implementation testing. These six sites vary along the following dimensions: EHR vendor (Meditech and Cerner), bed size (25-99 to 500+),

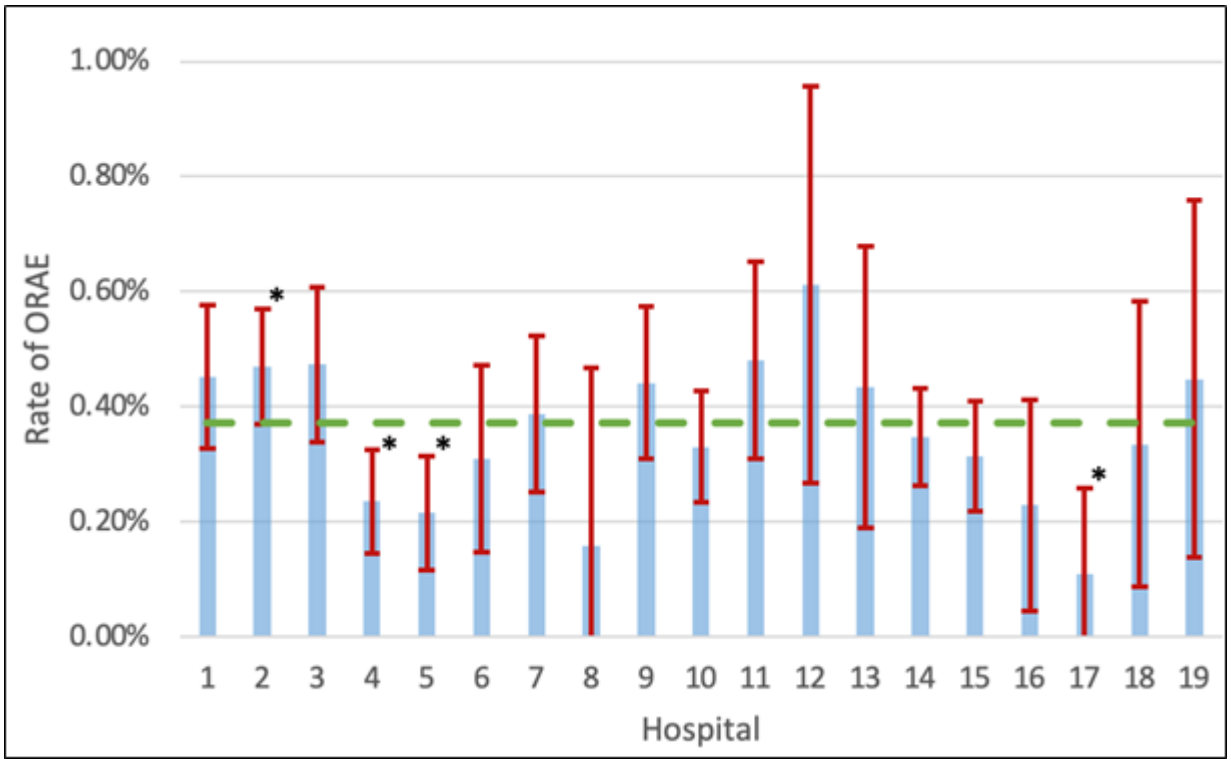
geographic location (Midwest and West), teaching and non-teaching status, as well as rural vs. urban. Using EHR data from calendar year (CY) 2019, measure implementation testing identified a total of 1,839, 2,089, 1,784, 11,273, 13,307, and 18,425 denominator encounters from each of the six sites, with the hospital-level harm rate ranging from 1.1 to 4.5 per 1,000 qualified inpatient encounters. The four-fold variation indicates ample room for quality improvement and a sufficient performance gap. Furthermore, while not an NQF requirement for new measures, we examined the measure performance rate in various subgroups of population to identify potential disparities. We found variability by age, sex, race, ethnicity, and payer source that may not be generalizable to the entire population but suggests a need to monitor these populations during measure implementation to gather evidence on possible performance gaps.

To better understand measure performance gaps, we worked with the large healthcare system (one of the two test partners) and collected frequency counts on the measure's numerators and denominators from 13 additional hospitals in CY 2019. These 13 hospitals vary in bed size, geographic location, teaching vs. non-teaching status, but all use Cerner. Table 1 shows the hospital-level performance rate by site and offers clear evidence that the measure performance gap exists. The rate of ORAE, with the addition of 13 sites, ranges from 1.1 to 6.1 per 1,000 qualified inpatient encounters. Given an overall system-wide rate of 0.37%, several hospitals' rates are significantly higher or lower than the system-wide rate (based on their 95% confidence intervals, shown in Figure 1). For example, Hospital 17's rate of 0.11% is significantly below the system-wide rate, and Hospital 2's rate of 0.47% is significantly above the system-wide rate.

Table 1. Measure Numerator and Denominator Counts and Measure Performance Rate; Data from CY 2019

Test Site	Numerator Ct.	Denominator Ct.	Measure Performance Rate
1	51	11,273	0.45%
2	84	17,903	0.47%
3	47	9,936	0.47%
4	26	11,029	0.24%
5	18	8,369	0.22%
6	14	4,523	0.31%
7	31	8,003	0.39%
8	1	632	0.16%
9	43	9,737	0.44%
10	44	13,307	0.33%
11	30	6,248	0.48%
12	12	1,961	0.61%
13	12	2,767	0.43%
14	64	18,425	0.35%
15	41	13,091	0.31%
16	6	2,615	0.23%
17	2	1,839	0.11%
18	7	2,089	0.34%
19	8	1,784	0.45%

Figure 1: Measure Performance Rate by Site; Data from CY 2019



Note: 95% confidence intervals are shown in capped red bars. Horizontal dashed line indicates system-wide average. * $p < 0.05$

Developer Response

N/A

NQF Response

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

NQF Committee Response

NQF #3501e, Comment #7774

Standing Committee Recommendation: Consensus Not Reached

Comment ID#: 7774

Commenter: Melissa Danforth, The Leapfrog Group; Submitted by Melissa Danforth

Council / Public: Public

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 9/9/21

Developer Response Required? No

Level of Support: Member supports

Theme: N/A

Comment

The Leapfrog Group and its members are aware of the debate regarding the performance gap for measure 3501e: Hospital Harm - Opioid-Related Adverse Events and welcomes the opportunity to submit comments.

Based on our review of the measure and the measure developer's detailed testing results regarding performance gap, we believe the measure unequivocally demonstrates clinically and statistically significant variation among hospitals that more than meets NQF's performance gap requirement. The stated intent of the measure is to identify hospitals with high rates of naloxone use, which might indicate excessive dosing of opioids in inpatients. The measure, as specified, accomplishes this intent. The measure developers have identified a hospital-level harm rate ranging from 1.1 to 4.5 per 1,000 inpatient encounters. This four-fold variation equates to 60,000 patients harmed annually - a very meaningful performance gap. Additionally, the measure developers 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.

We strongly support the endorsement of 3501e and strongly believe the performance gap demonstrated by the measure developers meets NQF's criteria.

Developer Response

N/A

NQF Response

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

NQF Committee Response

NQF #3501e, Comment #7749

Standing Committee Recommendation: Consensus Not Reached

Comment ID#: 7749

Commenter: Submitted by Steven Tremain

Council / Public: Public

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 444409/1/21

Developer Response Required? No

Level of Support: N/A

Theme: N/A

Comment

I am in support of this effort, although frankly I don't think it goes far enough. I would not exclude naloxone use in the operating theater, because the American Society of Anesthesiologists no longer supports the routine use of naloxone as a tool to assist patients in their emergence from anesthesia. Part of it may be because naloxone in some patients has a shorter half-life than certain opioids, even fentanyl.

Much of the variation we see in naloxone use in our hospitals is due to the outdated use of naloxone routinely by anesthesia at the end of surgeries.

In addition, I strongly encourage you to maintain the inclusion of procedural areas (i.e. gastroenterology labs, cardiovascular labs, interventional radiology labs) where too often throughput pressure encourages overuse of sedation followed by routine naloxone reversal. The patient safety risks are underappreciated while capacity is enhamced.

Overall, I strongly support this measure as a step in the right direction of responsible and safe opioid use.

Steven Tremain, MD FACPE

National ADE Advisor,

Convergence-Cynosure HQIC

Developer Response

N/A

NQF Response

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

NQF Committee Response

NQF #3389, Comment #7765

Standing Committee Recommendation: Measure Recommended for Endorsement

Comment ID#: 7765

Commenter: Lilian Ndehi, Humana Inc; Submitted by Lilian Ndehi

Council / Public: Public

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 9/9/21

Developer Response Required? No

Level of Support: N/A

Theme: N/A

Comment

September 9, 2021

National Quality Forum

1030 15th Street NW, Suite 800

Washington, DC 20005

Re: NQF #3389 Concurrent Use of Opioids and Benzodiazepines (COB)

Humana is pleased to submit comments on the National Quality Forum (NQF) measure #3389: Concurrent Use of Opioids and Benzodiazepines.

Opioid-related safety continues to be a major concern for both patients and their health plans. Recent data highlighting opioid utilization during the pandemic are especially troubling, with overdose rates spiking over the course of the last year, and studies suggesting more than a 25% increase in total overdose deaths, driven primarily by opioids. Opioid safety is as important and urgent now as ever, and it's critical that health plans have appropriate quality measures that address high-risk opioid prescribing associated with overdose at the population level.

One well established risk for overdose and other adverse events is concurrent use of opioids and benzodiazepines (COB). The 2016 Centers for Disease Control and Prevention Guidelines issued a class A recommendation that concurrent use of these medications should be avoided whenever possible, and the FDA issued a black box warning highlighting the danger of using these medications together. A broad body of evidence has continued to demonstrate the starkly higher overdose risk for patients receiving these drugs concurrently, while demonstrating that co-prescribing continues to occur at substantial levels [1,2].

The COB measure addresses a high priority area with identified performance gaps and is based on strong guideline recommendations and a broad body of clinical evidence. It is a feasible, actionable, and evidence-based measure that is improving patient safety in Humana's beneficiaries.

We remain concerned with both the high prevalence of concurrent opioids and benzodiazepines therapy, as well as instances of high MME accumulations and long durations. Humana continues to

support and implement programs that further educate our providers to evaluate risk versus benefit when prescribing the combination or continuing the therapies along with counselling the beneficiaries who concomitantly take opioids and benzodiazepines on their risks of harm along with possible alternative therapies.

Best Regards,

Lilian Ndehi, PharmD, MBA, BCPS

Associate Vice President, Clinical Pharmacy

Humana Inc.

References

1. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep. 2016;65. doi:10.15585/mmwr.rr6501e1er.

2. Hernandez I, He M, Brooks MM, Zhang Y. Exposure-Response Association Between Concurrent Opioid and Benzodiazepine Use and Risk of Opioid-Related Overdose in Medicare Part D Beneficiaries. JAMA Netw Open. 2018;1(2):e180919

Developer Response

N/A

NQF Response

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

NQF Committee Response

NQF #3389, Comment #7762

Standing Committee Recommendation: Measure Recommended for Endorsement

Comment ID#: 7762

Commenter: Submitted by Anna Legreid Dopp

Council / Public: Health Professional

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 9/9/21

Developer Response Required? No

Level of Support: Member Supports

Theme: N/A

Comment

September 9, 2021

National Quality Forum

1030 15th Street NW, Suite 800

Washington, DC 20005

Re: NQF #3389 Concurrent Use of Opioids and Benzodiazepines (COB)

Humana is pleased to submit comments on the National Quality Forum (NQF) measure #3389: Concurrent Use of Opioids and Benzodiazepines.

Opioid-related safety continues to be a major concern for both patients and their health plans. Recent data highlighting opioid utilization during the pandemic are especially troubling, with overdose rates spiking over the course of the last year, and studies suggesting more than a 25% increase in total overdose deaths, driven primarily by opioids. Opioid safety is as important and urgent now as ever, and it's critical that health plans have appropriate quality measures that address high-risk opioid prescribing associated with overdose at the population level.

One well established risk for overdose and other adverse events is concurrent use of opioids and benzodiazepines (COB). The 2016 Centers for Disease Control and Prevention Guidelines issued a class A recommendation that concurrent use of these medications should be avoided whenever possible, and the FDA issued a black box warning highlighting the danger of using these medications together. A broad body of evidence has continued to demonstrate the starkly higher overdose risk for patients receiving these drugs concurrently, while demonstrating that co-prescribing continues to occur at substantial levels [1,2].

The COB measure addresses a high priority area with identified performance gaps and is based on strong guideline recommendations and a broad body of clinical evidence. It is a feasible, actionable, and evidence-based measure that is improving patient safety in Humana's beneficiaries.

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when prescribing the combination or continuing the therapies along with counselling the beneficiaries who concomitantly take opioids and benzodiazepines on their risks of harm along with possible alternative therapies.

Best Regards,

Lilian Ndehi, PharmD, MBA, BCPS

Associate Vice President, Clinical Pharmacy

Humana Inc.

References

1. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep. 2016;65. doi:10.15585/mmwr.rr6501e1er.

2. Hernandez I, He M, Brooks MM, Zhang Y. Exposure-Response Association Between Concurrent Opioid and Benzodiazepine Use and Risk of Opioid-Related Overdose in Medicare Part D Beneficiaries. JAMA Netw Open. 2018;1(2):e180919

Developer Response

N/A

NQF Response

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

NQF Committee Response

NQF #3389, Comment #7773

Standing Committee Recommendation: Measure Recommended for Endorsement

Comment ID#: 7773

Commenter: Submitted by Elizabeth Bentley

Council / Public: Health Plan

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 9/9/21

Developer Response Required? No

Level of Support: N/A

Theme: N/A

Comment

The opioid epidemic continues to plague health care systems and society, with data from the past year suggesting a sharp increase in opioid-related adverse events during the pandemic. This context makes measures such as Concurrent Use of Opioids and Benzodiazepines (COB) critical, as health plans search for opportunities to mitigate the risk to patients at a population health level. There is a generous body of evidence to demonstrate that benzodiazepines, when used concomitantly with opioids, increase the risk of emergency department and/or hospital visits as well as both fatal and non-fatal overdose (see References). Both the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (Boxed Warning) caution against concurrent use of opioids and benzodiazepines due to the level of currently available evidence.

COB measures the percent of individuals 18 and older with concurrent use of opioids and benzodiazepines with at least 30 days of overlap during the measurement year. Individuals with cancer, sickle cell, or enrolled in hospice are excluded. The data available through the Medicare Part D Patient Safety Reports as well as data provided by Pharmacy Quality Alliance in the NQF Review Draft suggest variability in performance across health systems and opportunity for improvement.

In summary, COB addresses a gap in the performance measurement space related to safe use of opioids, and there is ample evidence to suggest opportunity for improvement along with a low risk of unintended consequences in the healthcare system. This evidence-based measure improves overall quality of care, particularly in its potential to reduce opioid-related adverse events.

Elizabeth Bentley, Kaiser Permanente, Clinical Pharmacy Services

References:

1. CDC. Overdose Deaths Accelerating during COVID-19. [1] https://www.cdc.gov/media/releases/2020/p1218-overdose-deaths-covid-19.html. December 17, 2020.

2. Dasgupta N, Funk MJ, Proescholdbell S, Hirsch A, Ribisl KM, Marshall S. Cohort Study of the Impact of High-Dose Opioid Analgesics on Overdose Mortality. Pain Med. 2016 Jan;17(1):85-98.

3. Garg RK, Fulton-Kehoe D, Franklin GM. Patterns of Opioid Use and Risk of Opioid Overdose Death Among Medicaid Patients. Med Care. 2017 Jul;55(7):661-668.

4. Hernandez I, He M, Brooks MM, Zhang Y. Exposure-Response Association Between Concurrent Opioid and Benzodiazepine Use and Risk of Opioid-Related Overdose in Medicare Part D Beneficiaries. JAMA Netw Open. 2018 Jun 1;1(2):e180919.

5. Park TW, Saitz R, Ganoczy D, Ilgen MA, Bohnert AS. Benzodiazepine prescribing patterns and deaths from drug overdose among US veterans receiving opioid analgesics: case-cohort study. BMJ. 2015 Jun 10;350:h2698.

6. Sun EC, Dixit A, Humphreys K, Darnall BD, Baker LC, Mackey S. Association between concurrent use of prescription opioids and benzodiazepines and overdose: retrospective analysis. BMJ. 2017 Mar 14;356:j760.

Developer Response

N/A

NQF Response

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

NQF Committee Response

NQF #3389, Comment #7775

Standing Committee Recommendation: Measure Recommended for Endorsement

Comment ID#: 7775

Commenter: Submitted by Sujith Ramachandran

Council / Public: Public

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 9/9/21

Developer Response Required? No

Level of Support: N/A

Theme: N/A

Comment

There has been a robust response to the opioid overdose crisis over the course of the past several years from governmental payers, private insurance agencies, quality developers and healthcare providers. This response has effectively reduced the number of opioid prescriptions back to levels similar to those in 2002, but the rates of death and overdose in the United States have not shown a parallel decrease. However, this change in prescribing practice has resulted in substitution and addition of opioid medications with other psychotropic medications such as benzodiazepines, which may lead to an even greater risk of adverse reactions. In addition, the increasing risk of mental health illnesses among patients with chronic pain have also led to an increase in co-prescribing of opioids with psychotropic substances such as benzodiazepines.

Among overdose deaths in the US today, a majority of cases involve multiple substances and not opioids alone. Given these changes, it is important for the quality measurement frameworks to adapt to the dynamic trends in opioid prescribing, and continue to strive toward high quality care among patients with pain. There is a large amount of evidence demonstrating the risks of interaction of opioids with benzodiazepines, as this is a synergistic interaction that can cause an increase in opioid plasma concentrations, potentiation of respiratory depressive effects, and risk of other adverse reactions.

Therefore, I believe this measure is a critical part of monitoring changes in opioid prescribing practices and evaluating safety among individuals receiving treatment for pain.

Developer Response

N/A

NQF Response

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

NQF Committee Response

NQF #3389, Comment #7761

Standing Committee Recommendation: Measure Recommended for Endorsement

Comment ID#: 7761

Commenter: Vikki Ahern, Magellan; Submitted by Kristina Arnoux

Council / Public: Public

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 9/9/21

Developer Response Required? No

Level of Support: N/A

Theme: N/A

Comment

September 9, 2021

Dana Gelb Safran

President and CEO

National Quality Forum

1099 14th Street NW

Suite 500

Washington, DC 20005

Attention: Patient Safety Portfolio Standing Committee

Re: Concurrent Use of Opioids and Benzodiazepines (NQF #3389)

Dear Dr. Safran:

Magellan Health, Inc. (Magellan) welcomes the opportunity to comment on NQF Measure #3389: Concurrent Use of Opioids and Benzodiazepines. Magellan supports the measure as proposed. The measure will help to reduce overdoses and other adverse events.

Magellan is a leader in managing the fastest growing, most complex areas of healthcare, including individuals with special healthcare needs, complete pharmacy benefits, and other specialty areas of healthcare. Through Magellan Rx Management, the full-service pharmacy benefit management division of Magellan, we specialize in solving complex pharmacy challenges for Medicare, Medicaid and other state programs, health plans and managed care organizations, and employers. We connect behavioral, physical, pharmacy, and social needs with high-impact, evidence-based clinical and community support programs to ensure the care and services provided to our members are individualized, coordinated, fully integrated, and cost effective.

Opioid misuse is a health crisis affecting communities all over the nation across a wide spectrum of social, racial and class boundaries. This is a situation deserving immediate and decisive action. At Magellan, we have an unyielding commitment to helping those impacted by the opioid crisis. As a

pioneer in offering integrated, comprehensive opioid risk and substance use management programs, we are uniquely positioned to bring together behavioral, medical and pharmaceutical programs to positively impact overall population health and cost.

Magellan is a national leader in serving individuals with OUD and other SUDs. Our experience includes a wide variety of activities, programs and tools for health plans, Medicare and Medicaid managed care organizations, employers, labor unions, state Medicaid programs, and military and government agencies designed to support long-term recovery and resiliency.

As a result, Magellan is familiar with the magnitude of the opioid crisis and has first-hand experience with its impact on individuals, families and communities. We have consistently taken a leadership role in promoting screening, assessment and evidence-based treatment for individuals with OUD and other SUDs.

Below, we are pleased to provide comments to NQF in support of the proposed NQF Measure #3389: Concurrent Use of Opioids and Benzodiazepines (COB).

Magellan's Comments

As the United States continues to grapple with the opioid epidemic, prescription opioids for pain management remain a major contributor to the crisis, with evidence suggesting that 21-29% of patients prescribed opioids for chronic pain will ultimately misuse them. The 2016 Centers for Disease Control and Prevention Guidelines issued a class A recommendation that concurrent use of these medications should be avoided whenever possible, and the FDA issued a black box warning highlighting the danger of using these medications together.

Subsequently, evidence continues to build and demonstrate the significant increase in overdose risk for patients receiving these drugs concurrently. Despite this clear data, co-prescribing continues to occur at considerable levels. The measure was developed in conjunction with a technical expert panel that provided input throughout the development process and unanimously found the measure to have face validity. This measure fills a recognized need and seeks to identify opportunities to reduce overdose deaths and adverse events. It is a feasible, actionable, and evidence-based measure that can improve patient safety.

Conclusion

Thank you for the opportunity to comment on NQF Measure #3389: Concurrent Use of Opioids and Benzodiazepines. We appreciate the Patient Safety Portfolio Standing Committee's leadership on these important issues. We look forward to engagement on these and other issues.

As NQF considers our comments, Magellan would be glad to answer questions. Please contact Brian Coyne, vice president of federal affairs, at (804) 548-0248 or bcoyne@magellanhealth.com; or, Kristina Arnoux, vice president of government affairs and public policy, at (401) 480-8034 or arnouxk@magellanhealth.com.

Thank you for the opportunity to share our perspective on this important issue.

Sincerely,

Vikki Ahern

SVP, Plan President, Medicare Part D

Magellan Rx Management

Developer Response

N/A

NQF Response

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

NQF Committee Response