



TO: Infectious Disease Steering Committee

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SU: Infectious Disease Endorsement Maintenance: Post-Comment Call to Discuss Member and Public Comments on Addendum- Measure 0500: *Severe sepsis and septic shock: Management bundle* and to Reconsider Measure 0393: *Testing for chronic hepatitis C – Confirmation of hepatitis C viremia*

DA: November 29, 2012

The Infectious Disease Steering Committee will meet via conference call on Wednesday, December 5. The purpose of this call is to:

- Review and discuss comments received during the Member and Public Comment period for measure **0500 Severe sepsis and septic shock: Management bundle**. The Committee will provide input on responses to comments and determine whether reconsideration of the measure or other course of action is warranted.
- Reconsideration of measure **0393: Testing for chronic hepatitis C – Confirmation of hepatitis C viremia**. The Committee will discuss and evaluate the measure against NQF's criteria and make a final recommendation for endorsement.

Steering Committee Action:

1. Review this briefing memo, which includes comment themes and action items.
2. Review the individual comments received during the public and member comment period for measure 0500 and proposed responses. (See Appendix A). Committee members should be prepared to provide feedback and input on proposed comment responses.
3. Review the revised submission form for measure 0393 and be prepared to discuss how well the measure meets NQF's endorsement criteria.

Conference Call: *Wednesday, December 5, 2012*

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

Dial-in Number: 1-888-799-5160

Confirmation Code: 70119817

Event Title: Infectious Disease SC – Post-Comment Call (Sepsis Measure)

Webinar: Register at <http://nqf.commpartners.com/se/Rd/Mt.aspx?157701>

All Committee and speaker phone lines will be open. Please place your phone on mute when not speaking. Please do not place your phone on hold during the call.

Attachments

- Agenda with dial-information
- Table of submitted comments (excel spreadsheet)
- Letter from American College of Emergency Physicians (ACEP): their comments are also in the comment table)
- Appendix A: Measure developer responses to submitted comments
- Revised measure submission form for measure 0393: *Testing for chronic hepatitis C – Confirmation of hepatitis C viremia*

Public and Member Comments for measure 0500: *Severe sepsis and septic shock: Management bundle*

NQF received 11 comments on the addendum report from 7 public and NQF members. The comments generally split into three organizations that support the measure and four organizations that raise concerns with the reliability, validity and feasibility of the measure. The measure developer was asked to respond to the comments.

Please refer to the comment table (excel spreadsheet) to view all of the comments received. This comment table contains the commenter's name, as well as the complete comment. Please refer to Appendix A to view the measure developer's response to the submitted comments.

Major Themes

The two major themes were:

1. General support for the measure
2. Concerns with the reliability, validity and feasibility of the measure

Theme 1: General support for the measure

Description: Three NQF members submitted comments in support of the measure noting that the developer had responded to questions from the Steering Committee. One commenter stated that “[the] steering committee questioned whether the sepsis quality measure addressing a bundle should be endorsed versus specific validated elements of the bundle. The SS Campaign noted that by making the bundles standard practice, there is elimination of piecemeal or chaotically applied standards for sepsis care that exist in many clinical environments today.” One supportive comment suggested that implementation may difficult with claims data.

Theme 2: Concerns with the reliability, validity and feasibility for the measure

Description: Three NQF members submitted similar comments identifying the following concerns about the measure:

- Lack of evidence for the central venous pressure (CVP) measure component

A commenter noted that “While we recognize that the SSC recommends central venous pressure monitoring (an unreliable and seldom followed parameter), both it and measuring central venous oxygen saturation are only supported by one single center clinical trial (as such limited evidence supports its use).”

ACEP states that “ACEP has serious concerns surrounding the lack of evidence for measuring CVP as a surrogate for intravascular volume. “ “the measure developers have now cited five additional studies in which multivariate logistic regression demonstrated no independent effect on mortality in patients who achieve CVP targets versus patients who do not. (Castellanos-Ortega 2010, Nguyen 2007, Jeon 2012, Levy 2010, Cannon 2010).”

A commenter suggested that “There may be the unintended consequence of increasing the use of central lines in situation where they may actually not be needed and potentially causing harm by their placement (bleeding pneumothorax, pain) or causing infections. By including this single item in the composite measure may encourage the over utilization of central line placement specifically not to fail the measure rather than taking care of the patients best interests.”

- Lack of evidence for blood culture prior to antibiotics element.

A commenter stated that “The whole point is that the patients receive broad spectrum antibiotics not that they are timed prior to antibiotic administration. The theoretical concern about sensitivities should not trump actual administration of those antibiotics. If not eliminated than perhaps altering the wording to simply state; “obtaining appropriate cultures” which would allow simplicity and more flexibility in the actual abstraction process. Having to identify the time of antibiotic administration along with the time of collection of cultures adds significantly to the burden and complexity of the abstraction process. Theoretically this may seem important but does the act of obtain blood cultures or any culture prior to the administration of antibiotics actually have any effect on outcomes?”

- Reliability of triage being time zero for ED patients and the impact of ED length of stay.

A commenter states that “Often time’s patient present to the ED with normal vital signs then decompensate and meet criteria of sepsis. Including the initial time of presentation

as the start time may not reflect patient's condition adequately. This ambiguity of utilizing different criteria of time of presentation based on location, calls into question the measure reliability."

Another commenter suggests that "Many ED patients will present with uncomplicated pneumonia, urinary tract infection, or cellulitis only to meet the criteria for severe sepsis/septic shock hours later. If the measure calls for early goal directed therapy within three hours of triage, but the patient does not meet criteria for severe sepsis or septic shock until four hours later, then even if all required interventions are completed within an hour, the hospital will fail on this measure as currently specified. That type of measurement does not differentiate hospitals based on the quality of care provided, but rather on the ED length of stay. If used for accountability as specified, this measure could cause the unintended consequence of penalizing large volume and safety net hospitals."

Another commenter argued that "Time-based measures that potentially start the clock ticking prior to patients meeting the defining criteria of the syndrome in question have to be recognized as invalid. The developers responded that ED patients with infections are "somewhere on the natural trajectory of becoming septic regardless of point of presentation." Statements such as this encourage overly aggressive treatment for patients who do not initially meet criteria for severe sepsis/septic shock due to provider concern of being deemed retrospectively "non-compliant" should the patients' condition subsequently change. The developers state "if the patient who becomes hypotensive or has a high lactate does so in the ED, the reason for the presentation to the ED is severe sepsis or shock." While this is true in cases where criteria are met at triage, it's absolutely not the case for those who only do so hours later. Patients present with chief complaints (which are often non-specific), not diagnoses."

- Feasibility of abstracting the composite measure.

A commenter noted that "This new composite is far too complex for implementation as a potential accountability measure. Furthermore, all of the data elements and time stamps required to calculate this measure are not readily available discrete fields from existing electronic sources making it a significant burden on hospitals to sort and collect this data."

A public comment noted the lack of targets for CVP and ScvO2

ACTION ITEM: After review and discussion of the comments on the sepsis measure, does the Committee wish to change their evaluation of any of the criteria or overall recommendation for endorsement?

Reconsideration of measure 0393: Testing for chronic hepatitis C – Confirmation of hepatitis C viremia

On the November 9 conference call, the Committee determined that the comments submitted requesting reconsideration of this measure had merit. The developers agreed to update the submission form and the Committee decided to reconsider the measure.

ACTION ITEM: The Committee will discuss and evaluate the measure against the NQF endorsement criteria on this conference call.