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ADVANCING EMERGENCY CARE

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Edward Septimus, MD, FACP, FIDSA, FSHEA
Co-Chairs, Infectious Disease Endorsement Maintenance Steering Committee
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Dear Drs. Brotman, Septimus and Winkler:

Thank you for the opportunity to provide member comment on the *Infectious Disease Endorsement Maintenance 2012: Draft Addendum Report*.[1] The American College of Emergency Physicians' (ACEP's) 30,000 members promote the highest quality of care for our patients with sepsis. With more than 500,000 septic patients per year coming through the Emergency Department (ED), our 30,000 members represent the front lines to save lives from this frequently fatal condition. ACEP has supported advancing the science and quality of sepsis care in our education, research and advocacy as demonstrated through our participation in the development and dissemination of the Surviving Sepsis Campaign guidelines and quality improvement initiatives for over a decade. Although ACEP supports the guidelines and the quality improvement efforts of the Surviving Sepsis Campaign, our members have significant concerns regarding the scientific acceptability, validity, and reliability of NQF Measure #0500: *Severe sepsis and septic shock management bundle* for use in any public reporting or accountability program as the proposed measure is currently specified in the measure submission and evaluation worksheet dated 10/08/2012.

Our three primary concerns, which were raised by my colleague Dr. David Seaberg in his letter of August 27, 2012, remain 1) the issues surrounding the reliability of triage being time zero, 2) the lack of evidence for the central venous pressure (CVP) measure component in the ED, and 3) the feasibility of abstracting the composite measure.

Reliability of Time Zero

ACEP believes that all of our septic patients deserve timely treatment, which is the hallmark of emergency care. In fact, mortality is significantly reduced for septic patients who present to the ED compared to those who are admitted directly to the ICU or the floors, because of the timely, high quality care treatment they receive.[2] However, with many EDs caring for patients being boarded for hours and days without an inpatient bed, we question the face validity of using triage time as time zero. 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. In general, high volume, urban, medical centers and safety net hospitals will fare worse than those with better access to inpatient beds, regardless of how well they perform guideline recommended interventions. By approving measure #0500, NQF is endorsing it for use in accountability programs (e.g. pay-for-performance). We have concerns that a measure so dependent on the length of

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stay of patients within the ED would unfairly penalize hospitals with prolonged ED length of stay (those with significant crowding and boarding) because of factors outside of their control. These factors include the patient population served (e.g. racial and insurance composition) and ED volume.[3,4] If used for accountability as specified, this measure could cause the unintended consequence of penalizing large volume and safety net hospitals.

The concept of a timed accountability measure, which uses a symptom-based assessment at triage as time zero, yet does not exclude all patients who develop symptoms subsequent to triage makes reliable measurement impossible. The measure developer response that patients presenting to the ED with signs of infection are "somewhere on the natural trajectory of becoming septic regardless of point of presentation" is unacceptable for an accountability measure. Furthermore the claim that this measure could be retrospectively reviewed based on ICD-9 hospital *discharge* codes, with triage as time zero is not an accurate measure of quality of care provided in the ED. Previous accountability measures attempting to measure the time to antibiotics for patients with pneumonia have already shown poor fidelity when using ICD-9 discharge codes, and demonstrated that a time-based metric only increased the unnecessary use of antibiotics in patients with respiratory symptoms ultimately not diagnosed with pneumonia.[5] Furthermore, application of the NQF's *Guidance for Measure Testing and Evaluating Scientific Acceptability of Measure Properties* would classify the reliability of this measure as "Low" when "one or more measure specifications are ambiguous with potential confusion in identifying who is included and excluded from the target population, or the event, condition, or outcome being measured; or how to compute the score."[6] None of the reliability data submitted addresses the core question of if the triage time is a reliable measure of when severe sepsis or septic shock starts.

Central Venous Pressure

ACEP has serious concerns surrounding the lack of evidence for measuring CVP as a surrogate for intravascular volume. NQF's *Composite Measure Evaluation Framework and National Voluntary Consensus Standards for Mortality and Safety – Composite Measures* clearly states in Table 1 that "the individual measures included in the composite or subcomposite must be either NQF endorsed; or assessed to have met the individual measure evaluation criteria as the first step in evaluating the composite measure."[7] Currently there are no NQF-endorsed measures that address central venous pressure in septic patients. Although the measure developer submitted a number of quality indicators as part of a 6-hour emergency department severe sepsis bundle in 2007, several of the component indicators including CVP were not included in the currently NQF endorsed measure #0500, because they did not meet the NQF criteria for scientific acceptability as component measures at that time. Please see NQF's 2009 report *National Voluntary Consensus Standards for Emergency Care* for more information.[8]

Since then 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.[9,10,11,12,13] The forest plots and tables for these studies described in the table below was included in the measure submission appendix which NQF staff provided to the Steering Committee after their evaluation of the evidence referred to on page 5 of the *Infectious Disease Endorsement Maintenance 2012: Draft Addendum Report*.[1]

Evidence for CVP Component Cited By Measure Developer in Appendices					
Reference	**Study Design**	**Description**	**N**	**Odds Ratio (Confidence Interval)**	**p-value**
Castellanos-Ortega 2010[9]	Quasi-experimental with an historical comparison group	Multivariate logistic regression of CVP ≥8mmHg achieved	384	OR= 0.86 (0.48-1.53)	0.604
Nguyen 2007[10]	Prospective observational cohort	In hospital mortality CVP/ScvO2 completed within 2 hrs	330	33.8% completed vs. 36.4% not completed	0.65
Jeon 2012[11]	Retrospective observational study	Achievement of CVP goal	366	OR=0.321 (0.089-1.162)	0.083
Levy 2010[12]	Before and after observational quality improvement study	Logistic regression of predictor variable (CVP ≥8mmHg)	15,022	Risk adjusted OR= 1.0 (0.89-1.12)	0.98
Cannon 2010[13]	Before-and-after observational quality improvement study	CVP ≥8mmHg	4,801	OR=1.17 (0.88-1.57)	0.28

Despite concerns raised by several Steering Committee members who noted CVP is one option of many potential surrogates for intravascular volume, they were not permitted to re-address their concerns regarding the validity of evidence when the appendix labeled "NQF Component Item Measure Analysis to Justify Inclusion in Composite" was provided at the end of the Steering Committee meeting. Measure developers also responded that only about 15 percent of patients end up needing a CVP when in compliance with the bundle, which is simply not true. In the Surviving Sepsis Campaign quality improvement study 7,854 of the 15,022 patients in that study were eligible for the CVP indicator,[11] and this number will vary from hospital to hospital based on case mix. NQF's *Composite Measure Evaluation Framework* clearly states that "all of the component measures must individually meet evaluation criteria," and this component does not meet the evidentiary threshold.[6]

In conclusion, we respectfully request that the Steering Committee give serious re-consideration of the NQF criteria for validity, reliability, and feasibility for the recently proposed measure 0500: *Severe Sepsis and Septic Shock: Management Bundle*. We urge the measure developers to work with the appropriate technical experts and stakeholders to address these questions.

ACEP looks forward to our continued collaboration with our NQF partners to provide the highest quality of care for our septic patients. Please do not hesitate to contact Jeremiah "Jay" Schuur, MD, MHS, FACEP, Chair, ACEP Quality and Performance Committee at jschuur@partners.org. Thank you for your continued leadership in defining and promoting high quality emergency care for infectious diseases.

Sincerely,

Andrew E. Sama, MD, FACEP
President

cc: David Seaberg, MD, CPE, FACEP, Immediate Past President & Chairman of the Board ACEP
Alex Rossenau, DO, CPE, FACEP, President-Elect, ACEP
Tiffany Osborn, MD, MPH, FACEP, ACEP Representative, NQF ID Steering Committee
Jeremiah Schuur, MD, MHS, FACEP, Chair, ACEP Quality & Performance Committee

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