

April 4, 2013

NQF Board of Directors
National Quality Forum
1030 15th Street, NW
Suite 800
Washington, D.C. 20005

To the Steering Committee:

The American College of Chest Physicians (ACCP), American Association of Critical-Care Nurses (AACN), Greater New York Hospital Association (GNYHA), Midwest Critical Care Collaborative (MWCCC), National Association for Medical Direction of Respiratory Care (NAMDR), Society for Academic Emergency Medicine (SAEM), and Society of Hospital Medicine (SHM) would like to appeal the National Quality Forum's (NQF) recent decision to endorse the maintenance of *Severe Sepsis and Septic Shock: Management Bundle*. The organizations listed represent pulmonary, critical care, hospital medicine, and emergency medicine clinicians from across the United States. The ACCP would specifically like to apologize for not commenting earlier on this composite measure; however we believe that the Severe Sepsis and Septic Shock measure, as specified, creates concern about scientific acceptability, usability and feasibility.

We strongly support the development and implementation of performance measures targeting severe sepsis and septic shock. In fact, as part of an NQF request to identify gaps in performance measures in critical care, the ACCP worked with its partner professional societies to propose specific performance measures in the management of severe sepsis and septic shock (see enclosure). Furthermore, we suggested performance measures very similar to the first four components of the proposed bundle (measurement of serum lactate, blood cultures, administration of broad spectrum antibiotics and administration of intravenous crystalloids for volume resuscitation). Indeed, we continue to support these target elements for performance improvement. Moreover, we would further suggest emphasizing the rapid administration of appropriate antibiotics as suggested by the recent Surviving Sepsis Guidelines¹, ideally within 1 hour of recognition of septic shock (1B recommendation) or severe sepsis (1C recommendation)²⁻⁴. Including time to appropriate antibiotics would be a reasonable addition to the proposed measures.

On the other hand, we are concerned that the specification within the Severe Sepsis and Septic Shock bundle that resuscitation must be guided by a central venous catheter would have unintended deleterious effects, even while recognizing that this element is included in the current Surviving Sepsis Guidelines. Central venous catheter guided fluid management has not been shown to be superior (or even equivalent) to resuscitation guided by other measures, including other invasive or non-invasive assessments of volume status and perfusion. Despite the fact that the measure developer responded that "when the central venous pressure component is utilized as part of the bundle, there is a decrease in mortality", identical CVP targets were used in both arms of that clinical trial⁵. Additionally, the current measure does not target a specific value for CVP or central venous oxygen saturation— only that it be measured. We suggest that the available data does not support the scientific acceptability criteria for the

measure to be specified as it is. In the analysis of the Surviving Sepsis Campaign efforts, neither the CVP nor the CVO2 target was independently associated with improved survival⁶.

Along similar lines, the Greater New York Hospital Association (GNYHA)/United Hospital Fund (UHF) adopted recommendations along the same lines that the ACCP is proposing. The GNYHA/UHF was not prescriptive in the resuscitation strategy employed. This 55 hospital collaborative found that the use of a noninvasive strategy (without central venous catheterization) became more common over time even while mortality continued to improve. This experience provides a basis for the New York state regulations regarding sepsis care as introduced by Governor Cuomo.

We point to other illustrations of continued equipoise surrounding this issue based upon the conduct of the ARISE study (Clinical Trials #NCT00975793) in Australia and the PROCESS study (Clinical Trials #NCT00510835) in the United States. These multi-center studies are scheduled to complete in 2013 and should provide greater clarity regarding the need for invasive monitoring.

Therefore, we respectfully suggest that central venous catheter guided fluid resuscitation not be specified, or that it be replaced with wording such as, “the resuscitation is objectively monitored using a method such as lactate clearance, ScvO2 monitoring or CVP monitoring”.

Beyond the mandated use of central venous catheter guidance for volume resuscitation, the ACCP has additional concerns regarding the usability of the measure as written. For example, the specifications allow for identification of patients retrospectively via ICD-9 codes included in the discharge record. The measure developer suggests in his responses to the submitted comments (comment 6a of the response to the ACEP) that if ICD-9 codes were used retrospectively, data abstractors “would determine if severe sepsis was present in the ED and if so, time zero would be defined as triage time.” It is not clear, however, that these measure only apply to severe sepsis and septic shock patients presenting in the Emergency Department as specified. If the measure includes patients who develop severe sepsis or septic shock as an inpatient subsequent to admission, as well as patients transferred to a facility already septic, use of ED triage time as “time zero” will likely result in inaccurate assessments of performance based upon the facility’s rates of nosocomial sepsis and hospital-to-hospital referral patterns. Furthermore, there is no mitigation for patients presenting with severe sepsis and septic shock at one Emergency Department and transferred to another. The receiving Emergency Department will be held accountable for care provided elsewhere currently.

Beyond this issue of usability, retrospective identification of discharges with sepsis may create an unreasonable burden of data collection. As the Steering Committee is aware, ICD-9 codes may be included in the discharge record even when the diagnosis is ultimately not present. The specified ICD-9 codes include uncomplicated sepsis, not a population targeted for intervention by the measure. The measure developer describes approximately 750,000 admissions for severe sepsis and septic shock. A recent estimate from the CDC suggests over 1.6 million admissions involving sepsis per year and the measure developer described 2 millions ED visits per year for sepsis. This means that the data will have to be abstracted from more than twice as many charts as they are ultimately targets for intervention.

We reiterate our desire to have well-specified performance measures for use as tools to improve care for severe sepsis and septic shock patients. We suggest the following

modifications to create more scientifically acceptable, usable and feasible set of measures. We also feel these changes will be more easily implemented allowing benefit for a greater number of patients. Such modifications would in no way prohibit facilities from exceeding or supplementing these practices.

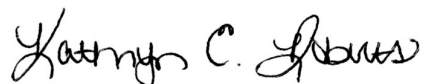
1. The *Severe Sepsis and Septic Shock: Management Bundle* measures should be limited to patients presenting to the reporting Emergency Department. Those transferred from other hospitals and those developing sepsis after admission should be excluded. This mirrors the performance measures developed around community-acquired pneumonia.
2. For patients with severe sepsis, the bundle elements should be simplified to include:
 - a. Blood cultures before antibiotics (with an exception for culturing resulting in delays in antibiotics administration, as consistent with current guidelines¹)
 - b. Measurement of serum lactate level
 - c. Administration of broad spectrum antibiotics
 - d. We would also define “time zero” as the time when blood is first drawn in the ED for patients with severe sepsis. Since severe sepsis is most often defined by laboratory abnormalities, this would tie the time-based metrics to the timing of an assessment for such organ failures.
3. For patients with septic shock, we suggest the severe sepsis bundle plus the following:
 - a. Administer 30 ml/kg crystalloid intravenous fluids
 - b. Median time to antibiotics
 - c. We suggest “time zero” as the time when blood was first drawn or when hypotension occurred, whichever comes earlier.
4. We suggest that CVP and central venous oxygen saturation and re-measuring lactate either:
 - a. Be removed from the current bundle or
 - b. Be provided as examples, with other invasive and noninvasive modalities (e.g., bioimpedance, serial ultrasonographic assessments, response to fluid challenge, etc.) qualifying as acceptable alternative approaches when part of a protocol to guide resuscitation.

We look forward to your response and hope to be able to endorse and promote revised measures. We again apologize for the late comments.

Sincerely,



Darcy Marciniuk, MD, FCCP
President, American College of Chest Physicians



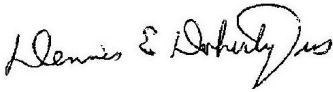
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Reference List

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- (2) Daniels R, Nutbeam T, McNamara G et al. The sepsis six and the severe sepsis resuscitation bundle: a prospective observational cohort study. Emerg Med J 2011; 28(6):507-512.
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- (4) Sebat F, Musthafa AA, Johnson D et al. Effect of a rapid response system for patients in shock on time to treatment and mortality during 5 years. Crit Care Med 2007; 35(11):2568-2575.
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