

April 19, 2013

NQF Board of Directors  
National Quality Forum  
1030 15<sup>th</sup> Street NW  
Suite 800  
Washington, DC 20005

Dear Directors:

I understand that one appeal with seven co-signatories was received during the appeal period for Infectious Diseases #0500, Severe Sepsis and Septic Shock: Early Management Bundle (#0500). I appreciate the opportunity to address the concerns of the appellants on behalf of the Society of Critical Care Medicine (SCCM), a co-founder of the Surviving Sepsis Campaign (SSC) with support from the measure developers. Support also comes from several important, noteworthy cosignatories listed in this communication. Some of the endorsers represent large hospital systems that are already implementing these measures to benefit the patients and families they serve. Together we endeavor to represent the overwhelming coalition of interests assembled during the Consensus Measures Development Process.

As you know, the Consensus Measures Development Process is designed to call for input and carefully consider the interests of stakeholder groups from across the healthcare industry. To that end, we wish to begin by noting that in member voting the measure has secured the support of:

- 100% of the Consumer Measure Council
- 100% of the Health Plan Measure Council
- 82% of the Health Professional Measure Council
- 100% of the Purchaser Measure Council
- 100% of the QMRI Measure Council
- 100% of the Supplier/Industry Measure Council
- 29% of the Providers Measure Council

The measure had an overall Member Council approval rating of 87%. This consensus is more than sufficient grounds to continue to endorse the measure despite the concerns raised by the appellants. Clarifying the value of the measure to this group, however, would be beneficial to develop further consensus.

We think this letter will explain why the appellants' suggestions cannot be adopted at this time. We believe that the appellants' unfamiliarity with the Consensus Measures Development Process

has led them to prematurely request consideration of strategies that cannot be simply inserted into the process now. We will address those issues here and defer to Dr. Rivers and Dr. Townsend to address the specific scientific arguments presented in the appeal in a separate letter.

- 1. The appellants misunderstand the Consensus Measures Development Process and recommend a suite of ideas that could not simply be adopted by the Board without proper review for scientific acceptability, usability, feasibility, reliability, and validity – a standard the therapies they recommend could not meet in any case because they have never been tested in performance improvement.**

The appellants seek to appeal the measure asserting, in part, that a host of new strategies to monitor volume status exists and that they are being tested now in clinical trials such as ARISE, PROMISE, and PROCESS.

While the outcomes of these trials are unknown, the Consensus Measures Development Process has demonstrated that: 1) a performance gap exists now as regards sepsis therapies; 2) a scientific basis for the therapies in #0500 exists; 3) when tested in performance improvement trials, the measure itself can be applied reliably; 4) when tested in performance improvement trials, the measure itself can be applied with validity; and 5) in 210 hospitals of all types and sizes across the country, the measure is usable and feasible.

The trials underway could show a benefit to the modalities the appellants prefer in severe sepsis and septic shock. However, the time course to publish mature clinical science from these trials in the literature is not short. Once the trials conclude—which they have not—the primary data must be analyzed, papers must be written for submission to journals, peer review must be completed, revisions to manuscripts will be required. This process may take 1-2 years from the conclusion of the ongoing trials. Even after publication, left wholly unconsidered by the appellants is that the clinical science will then need to be incorporated into new measures for testing, followed by a prolonged period of performance improvement and, if the resulting data show the metric is sound, it may then be ready to be brought before NQF.

The burden for measure development is high. The hypothetical new measure must demonstrate that it is: 1) reliable in performance; 2) valid as a measure; 3) usable and feasible in hospitals. Four years were needed to generate the data that the SSC relies on in advancing #0500. The appellants must expect years of meticulous data collection, analyses, and efforts to publish those results as a precursor to establishing a new valid and reliable performance measure. To wit, #0500 itself was nearly rejected before the SSC was able to bring data on the reliability and validity of the measure to bear.

Therefore, the appellants' request that alterations be made in the start time ("time zero") of the measure, that some items simply be deleted or, in the alternative, changed to read that "the resuscitation is objectively monitored using a method such as lactate clearance, ScvO<sub>2</sub> monitoring or CVP monitoring," cannot be done. These suggestions speak to an

entirely different measure from #0500 that would require its own supporting data to enter the Consensus Measures Development Process.

An estimate of up to 5 years to develop such a performance metric is not unreasonable. Case in point: one of the therapies that the appellants wish to see available, “lactate clearance,” was first published in 2010 after a randomized control trial established its efficacy.<sup>1</sup> However, 3 years later no data exist on using this therapy as a performance metric, and it therefore cannot demonstrate the requirements that the Consensus Measures Development Process demands.

Were the appellants to be successful in overturning #0500, the demonstrated performance gap would continue and the proven adverse impact on patients would continue unchecked.

**2. The present measure allows for innovation, testing, and development of new strategies, but preserves a basic public health function that any competing strategy cannot fulfill.**

While any competing measure is far off in terms of fulfilling the requirements for the Consensus Measures Development Process, the present measure represents no adverse impact on the appellants and represents a floor of measurement, not a ceiling.

As endorsed by the Board, #0500 does not restrict providers from trial of therapies they may consider to be better. Providers are free to use any other method of volume assessment in addition to the placement of a central venous catheter. The placement of the catheter itself in these severely ill patients should not be controversial: nearly all patients with the underlying condition, sepsis-induced hypoperfusion (hypotension, lactate > 4 mmol/dL), will need to have a central venous catheter placed early in their therapy, either due to the likely need to administer vasopressors or to provide multiple simultaneous therapies. When placed, the catheter is almost always positioned in the superior vena cava to prevent further infection in these already-infected patients. For example, in the trial the appellants cite regarding use of the novel therapy “lactate clearance,” all patients received central venous catheters. Thus, assessing central venous pressure (CVP) is but one more variable for providers’ consideration.

While the appellants are concerned that there are no targets specified for CVP or central venous oxygen assessment (ScvO<sub>2</sub>), this permits the provider to interpret the data alongside any other information gathered. The provider may still assess, via minimally invasive or non-invasive technique, other estimates of volume status. We encourage this strategy. In the meantime, patients should not be deprived proven therapies embodied in #0500.

---

<sup>1</sup> Jones AE, Shapiro NI, Trzeciak S, et al. Lactate clearance vs central venous oxygen saturation as goals of early sepsis therapy: a randomized clinical trial. *JAMA*. 2010;24;303(8):739-746.

Considering #0500 as a basic public health safeguard is essential and its approach is utilitarian. The developer has been successful in demonstrating that a large number of hospitals can apply this measure. Every hospital in the country, at least in principle, has the capacity to secure central venous access.<sup>2</sup>

It is equally important to consider that the other volume assessment modalities entertained by the appellants (“bioimpedence, serial ultrasonographic assessments”) meet no such standard. Only some large community hospitals or academic medical centers will have the equipment available. Even those hospitals have not demonstrated the operational capacity to deploy the therapies within the first hours of care. The appellants cannot show the Board that the 5000 hospitals across the country have such equipment ready to use. On the other hand, every hospital in the country at least has a central line kit in supply.

Therefore, a successful appeal would remove the floor standard set by #500 as a public health safeguard and replace it with either nothing or wholly uncertain care.

### **3. The Consensus Measures Development Process is designed to handle complexity in measure development and ensure a proper result.**

Once a measure is developed, a “measure steward” is identified. That steward must submit yearly reports on the measure. In this instance, the SSC and its representatives have served this role.

The steward may initiate an “ad hoc review” *at anytime* in the event that credible evidence emerges that challenges the measure or requires an update of the measure. In addition, *any party* (including the appellants) can also request an ad hoc review at any time to have new evidence considered under the standards of the Consensus Development Measures Process. Beyond those safeguards, the measure will be comprehensively reviewed every 3 years and competing measures will be evaluated for readiness for deployment under NQF’s Consensus Measures Development Process Measure Maintenance Program.

Given the long gap (years) between the emergence of the clinical trials establishing the value of the newer modalities and conducting clinical performance initiatives that will provide the foundation for a new valid and reliable measure, these standard windows for review are entirely appropriate to address any needed revisions in the current measure.

---

<sup>2</sup> For those critical access hospitals that may be unable to comply due to a lack of available skilled providers, third party payers (such as CMS) typically exclude critical access facilities from financial penalty for value-based purchasing metrics.

The SSC is a trusted steward and reviewer of available evidence as the only guidelines that rank the quality of the evidence in the literature were advanced by the SSC. Those guidelines have always been developed with the inclusion of most of the appellants. The SSC will gladly work with these groups again in the event that the literature changes and requires an update of this measure. This spirit of cooperation among the societies has been critical to bringing the present measure forward as a mature measure with sufficient data to justify its deployment.

**4. The appeal does not meet NQF threshold standards for consideration because the appellants have not demonstrated a direct and material adverse impact on their interests as required by the appeal rules.**

The appellants have not shown a direct and material adverse impact to adoption of the measure. The letter states only that the appellants have concerns that the use of a central venous catheter would have “unintended deleterious effects,” but these deleterious effects are never specified. The letter contends that central venous catheter-guided fluid management, and CVP in particular, have not been demonstrated to be superior to other methods, that targets are not specified, and that there is allegedly equipoise on the question of optimal volume assessment and fluid management. None of these concerns demonstrates a “direct and material harm” to the appellants. At best, these concerns suggest the therapies in #0500 are “not superior” to other therapies. Again, the measure is a floor, not a ceiling. Thus, there is no adverse impact to the appellants under the NQF rules for appeals.<sup>3</sup>

**5. Several of the appellants have already endorsed the measure *exactly* as specified as a bundle in their endorsement of the 2012 Surviving Sepsis Campaign Guidelines in February of this year.**

We respect the rights of the appellants to appeal for modification of the measure. We suspect that they do not understand that a successful appeal will result in non-adoption of any measure, not in modifications along the lines they suggest.

The appellants write that they “strongly support the development of performance measures targeting severe sepsis and septic shock” and several are co-sponsors of the 2012 Surviving Sepsis Campaign Guidelines. Co-sponsorship means that their organization has endorsed the evidence-based rankings in the guidelines. The guidelines

---

<sup>3</sup> In addition, the appellants represent provider organizations. The measure is a hospital-level measure. The NQF standard of direct adverse impact is therefore not present inasmuch as any theoretical (not actual) harm would be indirectly related to the provider and directly related to the hospital.

paper specifically includes the composite measure elements specified in #0500 **verbatim**.<sup>4</sup>

To conclude, the appellants seek modification rather than appeal; however, the appellants have not (and cannot at this time) show sufficient data to accept their proposed modifications through the Consensus Measures Development Process.

**6. The issues raised by the appellants have been raised already during the proper proceedings in the Consensus Measures Development Process and rejected.**

The appellants join the Consensus Measures Development Process late with regard to their concerns; however, this does not mean that each of the issues raised in their letter has not already been addressed. Specifically, the Infectious Diseases Steering Committee **twice** voted on the scientific acceptability of the evidence and twice approved the measure. Issues about central venous pressure monitoring were duly considered. Even after approval in the Infectious Diseases Steering Committee, the Greater New York Hospital Association (GNYHA) raised these scientific issues again at the level of the Consensus Standards Approval Committee. The issues they raised, which substantially mirror those that the appellants now raise, were turned aside because the evidence basis exists to support the measure the Board has endorsed.<sup>5</sup>

Continuing to raise the issue is not productive for a measure that has been scientifically validated and that remains statistically reliable and valid.

Finally, abandoning #0500 through a successful appeal would have measurable consequences. The SSC data demonstrate when more than 200 hospitals engage in this composite measure, a 7% absolute risk reduction (ARR) in mortality is achieved.<sup>6</sup> Conservative estimates suggest there are 750,000 cases of severe sepsis or shock annually, with an average mortality rate of 29% and resulting in 217,500 deaths annually.<sup>7</sup> The 7% ARR as shown by the SSC would therefore save 15,225 lives each year if all hospitals were accountable to this metric. Stated differently, #0500 stands to save 1,269 lives per month if this measure becomes a national standard.

---

<sup>4</sup> Dellinger RP, Levy MM, Rhodes A, et al. Surviving Sepsis Campaign: International guidelines for management of severe sepsis and septic shock: 2012. *Crit Care Med.* 2013;41:580-637.

<sup>5</sup> Please see Dr. Rivers' and Dr. Townsend's peer review of the available unpublished GNYHA data in their separate letter of reply.

<sup>6</sup> Levy MM, Dellinger RP, Townsend SR, et al. The Surviving Sepsis Campaign: results of an international guideline-based performance improvement program targeting severe sepsis. *Crit Care Med.* 2010;38(2):367-374.

<sup>7</sup> Angus DC, Linde-Zwirble WT, Lidicker J, et al. Epidemiology of severe sepsis in the United States: analysis of incidence, outcome, and associated costs of care. *Crit Care Med.* 2001;29(7):1303-1310.

In conclusion, for the reasons set out above, SCCM, the measure developers, the cosignatories on this letter, and leadership from the Surviving Sepsis Campaign continue to support #0500. We believe the Member Councils support the measure for the same reasons. This basic public health measure stands to advance care for thousands of patients who develop severe sepsis each year and provides a floor of standards for their care while not prohibiting other efforts.

Thank you for your continued consideration.

Sincerely,



Carol L. Thompson, PhD, ACNP, CCRN, FCCM  
President, Society of Critical Care Medicine  
Professor, Critical Care Nursing  
University of Tennessee Health Science Center  
Memphis, Tennessee


Cosignatories



Adrienne Kirby, PhD, FACHE  
President and Chief Executive Officer  
Cooper University Hospital  
Camden, New Jersey



Jean-Daniel Chiche  
President, European Society of Intensive Care Medicine (Co-founder organization  
Surviving Sepsis Campaign)  
Reanimation Medicale – Hospital Cochin  
Paris, France



Michelle B. Schreiber, MD  
 Associate Chief Quality Officer  
 Senior Vice President Clinical Transformation and Clinical Information Technology Integration  
 Henry Ford Health System  
 Detroit, Michigan



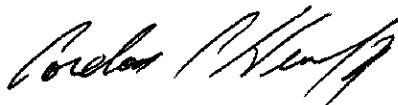
David A. Relman, MD  
 President  
 Infectious Diseases Society of America  
 Arlington, Virginia



Jed Weissberg, MD  
 SVP, Hospitals, Quality and Care Delivery Excellence  
 Kaiser Foundation Health Plans and Hospitals  
 Kaiser Permanente  
 Oakland, California



Martin E. Doerfler, MD  
 SVP, Clinical Strategy and Development  
 Center for Learning and Innovation  
 North Shore LIJ Health System  
 New Hyde Park, New York



Gordon C. Hunt, MD, MBA  
 Senior Vice President/Chief Medical Officer  
 Sutter Health  
 Sacramento, California