CVP nor ScvO₂ is a know all, be all. We also disagree with the comment that measurement of the CVP in the ED is “a close to an impossible task” because hospitals that have joined the SSC have achieved this goal repeatedly.

It is curious that Marik et al selected the Australian and New Zealand Intensive Care Society as an example of the difficulties with the international adoption of the SSC guidelines because this organization is a sponsor of the 2012 guidelines.  It is even more curious that even critics, cited and referenced by Marik et al, have conceded in their own meta-analysis that “sepsis care bundles were associated with consistent and significant increases in survival across eight studies.”

In conclusion, it is self-evident that care cannot be improved without understanding the deviation from known standards. Resisting standardization will simply perpetuate inefficient variation in care that has contributed to our unsustainable health-care economy. Partly for this reason and others, the United States ranks 37th among the world’s health-care systems for quality of care, including individual longevity, according to World Health Organization rankings.  Recently, Congress recognized the need for consistency and set a different course to correct economic and quality forces in American health care. There appears to be little strength left in the argument to preserve do-whatever-you-want care. We believe strongly that the time has come for reporting performance measures in severe sepsis and other serious critical illnesses.

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REFERENCES


Rebuttal From Dr Marik et al

Drs Dellinger and Townsend’s suggestion that bundles are always evolving is a key reason why bundles should not be universally mandated. Mechanisms invoked by bundles to produce benefits may also produce harm. Until the US Food and Drug Administration’s suspension, several years of organized advocacy accelerated diffusion of Xigris (Eli Lilly and Company) therapy in nonselected populations. Systematic promotion of evidence illustrates the power of bundles to magnify ineffective therapies. Strategies like the catheter-related bloodstream infection prevention bundle may work because of unique contextual factors at play at institutional, national, or specialty-specific levels. It is not clear that such checklist bundles can be transplanted without insight into the host culture.

Drs Dellinger and Townsend stress that bundles should be evidence based, yet we have shown that with few exceptions, the elements of the 6-h sepsis bundle and ventilator-associated pneumonia bundle are not based on credible scientific evidence. There is surprisingly few data to support the contention that outcomes are improved when ICU bundles are rigorously followed. Before-and-after trials investigating effects of bundle implementation have reported reductions in mortality, apparently justifying bundle validity and calling for widespread adoption. However, before-and-after trials should be viewed with skepticism because they are plagued by publication bias, patient selection bias, temporal bias, and the Hawthorne effect. Furthermore, such studies provide compelling data for the concept that bundling is seriously flawed and that several individual elements of bundles do not improve patient outcome (except for the timely use of antibiotics). For example, in the Edusepsis study conducted in Spain, only early, broad-spectrum antibiotic treatment was associated with improved outcomes. It is noteworthy that in this study, mortality fell from 44% to 39% (P = .04) despite the fact that compliance with the 6-h sepsis bundle was only 10%, suggesting that factors other than bundle compliance were responsible for improved outcome. In the prospective, two-phase cohort study by Westphal et al, patients with severe sepsis/septic shock were resuscitated in
accordance with the 6-h sepsis bundle. In the first phase of the study, patients were identified through usual clinical practice, whereas in the second phase, active surveillance for signs of sepsis risk was used. There were significant differences between phases I and II in the time required for the identification of severe sepsis/septic shock and in hospital mortality (61.7% vs 38.2%, \( P \leq .001 \)); however, compliance with the 6-h sepsis bundle did not differ (32% vs 25%). Similarly, Shiramizo et al\(^7\) noted a fall in mortality in patients with severe sepsis/septic shock from 41.4% to 16.2% between 2008 and 2009, despite a decline in compliance with the 6-h sepsis bundle. It is likely that earlier identification of sepsis and earlier administration of antibiotics are responsible for the mortality difference in all the before-and-after studies, with the other elements either having no beneficial effect or possibly being harmful. Many basic questions regarding the resuscitation of patients with sepsis remain unanswered: What type of fluid should be used (is saline the right fluid)? What BP should be targeted? How best to titrate fluids?

Dissemination of what does not work ought to match the marketing of treatments that work. In summary, we reiterate that the concept of bundling is scientifically unproven with no credible evidence that all-or-none bundle compliance improves patient outcomes. Physicians should not be mandated to provide care that may be potentially harmful.

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REFERENCES

1. Dellinger RP, Townsend SR. Point: are the best patient outcomes achieved when ICU bundles are rigorously adhered to? Yes. CHEST. 2013;144(2):372-374.