Sepsis change bundles: Converting guidelines into meaningful change in behavior and clinical outcome

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The incidence of severe sepsis (sepsis with organ dysfunction) is increasing (1). Several recently published studies have demonstrated decreased mortality and morbidity as a result of interventions and therapeutics applied to patients with sepsis (2–5). These new data, resulting from rigorously performed, randomized, controlled trials, combined with previous data for beneficial interventions not specific to sepsis management (6–10), such as deep vein thrombosis and stress ulcer prophylaxis, lend significant weight to the belief that critical care clinicians can now, if they use these effective interventions, significantly reduce mortality in patients with severe sepsis and septic shock.

When patients with myocardial infarction receive evidence-based interventions, mortality is reduced. Up to now, there has been no attempt to reproduce such an approach in severe sepsis. The Surviving Sepsis Campaign hopes to change that. The campaign, initiated in 2002, is comprised of three phases.

The first phase was the introduction of the campaign at several major international critical care medicine conferences, beginning with the ESICM meeting in Barcelona in 2002, and followed by the Society of Critical Care Medicine meeting in 2003. The overall goal of the campaign is to increase clinician and public awareness of the incidence of sepsis, severe sepsis, and septic shock, to develop guidelines for the management of severe sepsis, and to foster a change in the standard of care in sepsis management that will result in a reduction in mortality.

Phase 2 of the campaign consisted of an international consensus committee representing 11 international organizations with interest and expertise in sepsis with the purpose of creating evidence-based guidelines for the management of severe sepsis and septic shock. The executive summary of these guidelines were recently published in both Critical Care Medicine and Intensive Care Medicine (11, 12). This supplement represents the complete work of the consensus committee.

It takes on average 17 yrs from discovery of effective therapies to their routine use. The transfer of research from the bench to the bedside is a long, tortuous process—one that is not driven by anything very clear and seems to be based more on fad and coincidence than on a keen, evidence-based evaluation of the literature. What motivates clinicians to change? There are several obvious factors, including quality of the evidence, magnitude of the treatment effect, precision of the treatment effect, risk/benefit ratio, and cost/benefit analysis. In addition, there are intangible factors that drive the rate at which clinicians adapt research into new standards of care. These include physiological rationale for a new intervention, peer pressure, and how easy it is to use or apply a new intervention. Changing clinicians’ behaviors in response to published data has long been a glaring failure in medicine. We would like to believe that with the dawn of the information age, this lag time between the publication of rigorous data and incorporation into routine practice at the bedside would finally be reduced. In general, the guidelines to be used must be aware of them, agree with their recommendations, and have the ability to use them (13). The Surviving Sepsis Campaign (SSC) is working on all three of these. One of the primary goals of the SSC is to establish a model that will facilitate translation of high-quality research into bedside clinical practice.

Phase 3 of the campaign aims to operationalize the executive summary recommendations into a set of practical yet valid performance measure. In collaboration with the Institute of Healthcare Improvement (IHI), a set of user-friendly tools have been created to allow clinicians to incorporate these new recommendations into bedside care. These tools include educational programs designed to increase awareness and agreement with the recommendations, checklists or bundles to help ensure patients receive the intervention, and performance measures designed to provide feedback regarding how often patients receive the evidence. In addition, the SSC, the Institute of Healthcare Improvement (IHI), and the Volunteer Hospitals Association (VHA) have developed a set of quality indicators to precisely evaluate a hospital’s performance with respect to sepsis care. Together these measures will allow hospitals to have an objective assessment of the quality of sepsis care being rendered at their institution and teach interested hospitals and teams how to improve to meet the standard of care outlined in the guidelines.

A set of core changes extracted from the SSC guidelines have been incorporated into a package of key elements or goals that when introduced into clinical practice have a high likelihood of reducing mortality due to severe sepsis. The package is referred to as the sepsis bundle. The aim of the sepsis bundle is two-fold: first, to eliminate the piecemeal application of guidelines that characterizes the majority of clinical environments today, and second, to make it easier for clinicians to bring the guidelines into practice.

A bundle is a selected set of interventions or processes of care distilled from evidence-based practice guidelines that when implemented as a group provide a more robust picture of the quality of care provided. Individual hospitals can and should codify the bundle elements into customized clinical protocols that function best in their institutions. However, to provide standard of care therapies to patients, no one bundle element can be ignored. The
criteria used for choosing the specific Guideline recommendations to be included in the sepsis bundle were as follows: a) the evidence suggests that the use of the intervention is associated with decreased mortality; and b) the recommendation could be converted into data elements that can be precisely defined, with clearly identified failure modes, and that could be measured by retrospective chart audit (or potentially in real time using a checklist). In addition, the number of goals included was judged to be feasible with proper motivation and organization. The implementation of the bundles is aimed at tracking change in practice and reporting how often these evidence-based interventions are used. Engendering evidence-based change through motivational strategies while monitoring and sharing the impact with healthcare practitioners is the key to improving outcome in severe sepsis.

The SSC’s concerted strategy to help hospitals improve their care of septic patients is hosted at the IHI Web-site. This Web-site provides a hospital or unit (ICU or ED) all the information and tools necessary to transform the management of sepsis at their institution so as to conform with the Guidelines. Linking to this site either through http://www_survivingsepsis.org or http://www.ihi.org/IHI/Topics/CriticalCare/Sepsis/

brings interested parties to a dynamic resource that: a) allows hospitals, intensive care units, or emergency departments to learn how to change clinical processes in their hospitals; b) facilitates the implementation of a core set of changes encompassed in the sepsis bundles; and c) provides to measure the results of those changes and the way to improvement. Monitoring and sharing the results of these efforts to improve with fellow healthcare practitioners and institutions is the key to improving the care of septic patients and reducing mortality due to severe sepsis.

It is important to measure the results of changes to know that they actually represent improvements. There is a need to measure not only the outcome—a reduction in mortality due to severe sepsis—but also the success of the implementation of the individual evidence-based changes along the path to improvement, so-called process measures. Both process and outcomes measures are essential because it is important to assess the result of changes to know that they actually represent improvements.

The quality indicators that have been developed, based on the exhaustive review of the sepsis literature, are valid and feasible measures. The necessary data collection is also accomplished using the preconfigured data collection tool and can be recovered simultaneously from the same sample of charts as above. The quality indicators will also serve to provide insight into the improvement process itself and allow for refinement of goals as the SSC moves forward. The establishment of robust indicators of quality with respect to sepsis care will ground the effort to create a global standard of care for sepsis management.

The Surviving Sepsis Campaign, in partnership with the IHI and VHA, represents an important step for international critical care societies. Recognizing the long history of delay in incorporating research into bedside care, these organizations are commit-
ted to working together to facilitate bench-to-bedside transfer of recent research. Thus, the campaign represents an ongoing commitment to excellence in patient care. The Surviving Sepsis Campaign has established a target of a 25% reduction in mortality worldwide from sepsis over the next 5 yrs. If the Surviving Sepsis Campaign is able to bring the guidelines into routine use, it is possible to achieve this goal. For the campaign to be successful, it will require more than good will from the international critical care community. It will require a further commitment from bedside clinicians to appraise new research rapidly and to adopt interventions proven to be effective. The evidence for best sepsis management is a dynamic process and as additional studies are done and the results published, there will be a need for an update of the guidelines and the sepsis bundles. The next guidelines revision is planned for late 2005 or early 2006. This process will be greatly facilitated by the use of sepsis bundles (Fig. 1).

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REFERENCES