The Utility of a Quality Improvement Bundle in Bridging the Gap between Research and Standard Care in the Management of Severe Sepsis and Septic Shock in the Emergency Department

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Abstract

The research in the management of severe sepsis and septic shock has resulted in a number of therapeutic strategies with significant survival benefits. These results also emphasize the primary importance of early hemodynamic resuscitation, or early goal-directed therapy (EGDT), and place the emergency physician in the center of the multidisciplinary team caring for patients with this disease. However, in a busy emergency department, the translation of research into clinical practice is far from ideal. While the benefits are significant, the successful implementation of EGDT is filled with challenges and obstacles. In this article, we will discuss the steps taken at our institution to create, implement, measure, and improve on a six-hour severe sepsis and septic shock treatment bundle incorporating EGDT in the emergency department setting, resulting in significant mortality benefit.

Keywords: severe sepsis, septic shock, early goal-directed therapy, implementation, bundle

Integrating the best available evidence from research into clinical practice is a challenge all medical practitioners face. Although early treatment of severe sepsis and septic shock (severe sepsis/septic shock) has been shown to have a significant impact on mortality, significant barriers are encountered when transitioning research findings into sustainable improvements in clinical care. This is especially true when the best practices are more time- and labor-intensive than usual practices. Recent studies determining compliance with the recommended treatments for severe sepsis/septic shock have shown great variability.

The Surviving Sepsis Campaign promotes evidence-based guidelines in the treatment of patients with severe sepsis/septic shock. From these guidelines, the Institute for Healthcare Improvement recommended the development of sepsis “bundles” for initial resuscitation (six hours) and management (24 hours) as performance improvement tools. These bundles have been endorsed by multiple medical societies and, when implemented as a whole, provide better outcomes than when performed individually. Crucial to the six-hour resuscitation bundle is the early administration of antibiotics and completion of early goal-directed therapy (EGDT) in the emergency department (ED), which was shown to be associated with a 16% absolute decrease in mortality. EGDT includes an algorithmic approach targeting specific hemodynamic end points to optimize the cardiovascular system. The algorithm provides stepwise incorporation of interventions, including fluid resuscitation, vasoactive agents, packed red blood cell transfusion, inotropic support, and mechanical ventilation. In this article, we review the challenges and strategies of implementing the research evidence in a sustainable early severe sepsis/septic shock management program incorporating EGDT.
BARRIERS TO IMPLEMENTATION

Several hurdles have prevented the adoption of EGDT over the five years since it was first reported. These include perceived lack of time and staffing, unfamiliarity of staff with the definitions of severe sepsis/septic shock, the need for specialized equipment and protocols, and lack of collaboration among medical specialties.

Lack of sufficient time and staffing is often listed as a reason for noncompliance with EGDT. A persistently hypotensive, septic patient will require multiple procedures (e.g., central line placement, intubation), continuous assessment of resuscitation efforts, review of laboratory and radiographic studies, and management of vasopressors and mechanical ventilation. This may require the physician’s continued attention throughout the initial resuscitation period of six or more hours. Hemodynamic monitoring and multiple medication orders entail a great deal of manpower at all levels of staffing. Nursing care alone usually requires a minimum of two nurses in the initial phases of EGDT delivery.

Next, many clinicians are discouraged by the special equipment and resources required because these are often complicated by the need for prior administrative approval, increased expenditures, and incorporation of additional inventory and procedures in systems already filled to capacity. The protocol is intensive; physicians, nurses, and even administrators need to undergo initial education about the process and continually attend in-services. This requires additional investment of time and effort and, of course, funding.

Another barrier is lack of collaboration among medical specialties. Optimal severe sepsis/septic shock management requires a continuum of early recognition, early intervention, rational selection of novel therapies, and continual assessment for supportive therapies. This continuum requires teamwork among multiple specialties and levels of provider. In contrast, the ED, the medical ward, the operating arena, and the intensive care unit (ICU) are often islands of expertise, making it more difficult to establish coherent hospital-wide protocols.

A more important barrier is acceptance of new therapies by the treating physicians themselves. Physicians often practice by clinical gestalt, along with many years of individual experiences, believing that not every patient fits into a particular treatment guideline. Furthermore, in the era of evidence-based practice, a natural inclination for well-intentioned physicians is to wait for more evidence when faced with new, untried therapeutic advances. For example, a study that examined why physicians did not follow guidelines for preventing ventilator-associated pneumonia found that the most common barrier to adherence was physician disagreement with the available evidence.

Despite these barriers, we have seen severe sepsis/septic shock programs successfully implemented with improved patient outcomes. At our own hospital, we performed a prospective, observational cohort study of 330 patients that spanned a two-year implementation period of a six-hour severe sepsis/septic shock bundle in the ED. Compliance to the entire bundle rose from a baseline of zero to 51.2% by the end of the study period. Overall, we saw 21% mortality in the bundle compliant group versus 40% in the noncompliant group.

IMPLEMENTING A SEVERE SEPSIS/SEPTIC SHOCK BUNDLE

Often, physicians apply evidence-based medicine into their individual clinical practice because they have reviewed the most recent literature, attended symposia, or followed the recommendation of an expert. However, without a system-wide standardized process of accountability, optimal care will remain haphazard and inconsistent. In this section, we describe the process we underwent to create, implement, measure performance of, and improve on compliance to a six-hour severe sepsis/septic shock bundle in the ED as standard care.

Creation of a Severe Sepsis/Septic Shock Bundle for the ED Setting

While there was some concern in our physician group that the outcome benefits from EGDT resulted only from a single-center study, the majority agreed that we should improve our practice in the management of severe sepsis/septic shock. Thus, we decided to implement EGDT via a bundling approach in quality improvement (QI), similar to the recommendations by the Institute for Healthcare Improvement. A physician champion was then assigned the task of designing the bundle and the QI process (Figure 1). This champion had special academic/research and clinical interest in severe sepsis as a disease and also was given the responsibility for bundle implementation by the ED chairman and medical director. Ten hours per month of effort was allocated for this champion.

The bundle and its components were derived from best practice advances in the early management of severe sepsis and septic shock. We followed the recommendation from the Institute for Healthcare Improvement regarding bundle design. The content of the bundle had to adhere to the following rules: 1) the components or interventions are generally accepted clinical recommendation from the Institute for Healthcare Improvement; 2) all components need to be completed in the same time and space, that is, the ED setting; 3) the completion of each component can be determined by a “yes” or “no” on chart review; and 4) the completion of the entire bundle can be determined by a “yes” or “no.” We identified five components to comprise the bundle (Table 1).

We also believed in the notion that local acceptance of any QI process is crucial to successful implementation. Thus, a survey questionnaire regarding the validity (evidence-based) and feasibility (practicality) of the bundle was given to the emergency physicians in our group. A score of 1–3 (not acceptable), 4–6 (uncertain), or 7–9 (acceptable) was assigned by each physician to rate the validity and feasibility of each bundle component: 1) initiate central venous pressure/central venous oxygen saturation (CVP/ScvO2) monitoring within two hours, 2) give broad-spectrum antibiotics within four hours, 3) complete EGDT at six hours, 4) give corticosteroid if on vasopressor or if adrenal insufficiency was suspected, and 5) monitor for lactate clearance. We surveyed 23 emergency physicians. The mean validity score for each
component was 7.5, 8.6, 8.0, 7.3, and 7.4, respectively, and the mean feasibility score was 6.7, 8.5, 6.4, 7.3, and 5.9, respectively. From this survey, we observed that our physicians believed the bundle was acceptable with respect to validity and evidence-based. However, there was some uncertainty with respect to feasibility in placing a central line for monitoring within two hours, completing EGDT at six hours, and the ability to achieve lactate clearance. Despite these uncertainties, we agreed to move forward with the implementation. With this brief survey, we also aimed to bridge the gap between research and clinical practice by following the four stages from evidence to action as advocated by Pathman et al.30: awareness, agreement, adoption, and adherence. We believe that clinicians can be easily aware of new evidence, but agreement (or acceptance of our bundle) is a crucial step in moving toward adoption and further adherence to the evidence in clinical practice. However, we did not study further the barriers or transfer rate through each of these stages of evidence uptake.

Bundle Implementation and QI Process

A two-year implementation program was started in October 2003, including three-month quartiles that included three initial phases—baseline, education, and operational—followed by five QI phases.

The baseline phase included data gathering on the current level of care applying a standardized one-page checklist.31 This checklist was utilized to gather bundle compliance data. Equipment for CVP and ScvO2 monitoring were also acquired during this phase. A proposal illustrating the potential benefits of EGDT was submitted to hospital administration to purchase two ScvO2 monitoring devices for use in the ED. ScvO2 catheters were also acquired as disposable products in addition to our currently available triple-lumen central venous catheters. The proposal was immediately approved.

The education phase consisted of physician, nurse, and residency staff training on the implementation of the bundle, such as sepsis definitions and recognition, hemodynamic monitoring utilizing CVP and ScvO2, and completing the EGDT protocol. Bundle initiation criteria and timely completion of the bundle components were emphasized. The physician champion and nurse educator provided conference lectures, bedside teaching, and in-services to physicians and nurses during this phase. Most important to training was hemodynamic monitoring. The physicians attended in-services on the necessity for timely central line insertion via the subclavian vein approach or an ultrasound-guided internal jugular vein approach. The nurses attended in-services on initial calibration for CVP and ScvO2 monitoring after the central line was inserted by the physicians. With respect to disease recognition, we emphasized the utility of lactate level, in addition to refractory hypotension to fluids, as an indicator of illness severity. We found that physicians were more willing to accept hypotension than lactate level as a criterion to initiate the bundle, and this was another important barrier to address in our education efforts. Our bedside in-services and conference lectures emphasized lactate level as a prognosticator of poor outcome. Physicians and nurses were increasingly adopting the use of lactate level monitoring in the early recognition of high-risk patients, especially when we were observing more and more patients who presented with normal vital signs and elevated lactate levels but later

Figure 1. Implementation of a severe sepsis/septic shock bundle including early goal-directed therapy (EGDT) as a quality improvement process in the emergency department. CVP = central venous pressure, ScvO2 = central venous oxygen saturation.
required vaspressors and mechanical ventilation and sometimes died.

The operational phase began the bundle implementation in the ED setting. This phase was considered a trial period without accountability by the physicians and nurses. Physicians and nurses utilized a sepsis toolkit31 and pocket cards as daily reminders of the processes involved in bundle delivery. The toolkit included a brief outline of sepsis definitions and management in the ED, protocol delivery flowcharts, approved physician sepsis order set, bedside checklist, ScvO2 user’s guide, bundle quality measurement tool, and quality indicators. This toolkit has evolved to include a 24-hour sepsis bundle and management tools for ICU-admitted patients and was a collaborative effort with our ICU and quality resource management colleagues.

The QI phase consisted of five quartiles (QI 1 to QI 5). This was the most difficult phase in bundle implementation, as we set out to target >80% compliance. We initially utilized concurrent measurement of bundle compliance. Physicians were instructed to complete the bundle checklist at the bedside as they were evaluating and treating patients. This method of immediate feedback proved not useful because emergency physicians were constantly multitasking, handling tens of patients, not just one. We were able to achieve high compliance in those patients who received the checklist; however, the number of patients being given this level of concurrent compliance measurement was very minimal. We then instructed the nurses, rather than the physicians, to complete the bundle checklist concurrent to patient care. We provided a minimal incentive in the form of a gift certificate for each completed checklist submitted by a nurse. However, with a nurse-to-patient ratio up to 1:4, our nurses also found it difficult to sustain this level of QI.

Finally, we found that physician and nursing retrospective feedback at the end of each QI quartile was most successful at increasing compliance. The physicians and nurses received regular reminders and updates on bundle delivery in the ED. They were held accountable to providing the best care for severe sepsis/septic shock patients within two hours of patient arrival and adhering to the bundle components. For bundle compliance measurement, the physician champion performed monthly review of patient medical charts via a two-level screening.

Level 1 screening included the department of medical records providing the physician champion with a monthly list of patients meeting the following criteria: 1) admission to the hospital from the ED and 2) sepsis-related International Classification of Diseases, Ninth Revision (ICD-9) diagnoses. These ICD-9 diagnostic codes included the following: 038.0–038.9 septicemia, 790.7 bacteremia, 117.9 disseminated fungal infection, 995.91 systemic inflammatory response syndrome due to infectious process without organ dysfunction, 995.92 systemic inflammatory response syndrome due to infectious process with organ dysfunction, 785.52 septic shock.

Level 2 screening consisted of review of medical charts obtained from level 1 screening. Patients meeting criteria for initiation of the bundle were included in the bundle compliance measurement process. For patients whom the treating physicians determined would not benefit from bundle delivery (including central line placement) after discussion with the patients or their families, such as those patients with terminal illness or do-not-attempt-resuscitation status, the physicians were instructed to place a chart notation of their decision. For these patients, the physicians would not be accountable for bundle compliance during the chart review process. A trained data abstractor completed a bundle checklist for each patient selected from level 2 screening. The physician champion then verified the compliance checklist for correctness. Completeness of documentation was crucial in obtaining the compliance data. Thus, if a patient had optimal bundle delivery, but CVP was not documented at six hours, the physician had failed in completing the bundle.

The physician champion provided interval summary reports of bundle compliance to the physicians and nurse
managers as feedback during our bimonthly ED QI meetings. These meetings included discussions and reviews of QI topics on all levels of patient care in the ED. Thus, our sepsis bundle implementation effort was one among other ongoing QI projects. The summary reports included the number of patients with severe sepsis who met indications for the bundle, treatments given in the ED, percentage compliance, and outcome. Individual cases were discussed in a peer-review forum, allowing for two-way discussions between the physician champion and the treating physicians. Areas of improvement were then discussed at the departmental level. A reminder letter from the ED medical director was sent to physicians who did not complete the bundle in patients for whom there were indications. This letter from our medical director was a mechanism for positive reinforcement on the importance of bundle compliance, rather than a punitive action against an individual physician. Our physician group perceived this method of feedback as beneficial for the purpose of improved patient care.

Patient Management

All emergency physicians and nurses were responsible for delivery of the bundle. Intensive care consultation was obtained for ICU admission; however, the intensivists were not involved in the delivery of the bundle in the ED before admission. This model of implementation mirrored the original EGDT study as being completed solely in the ED setting.

Once a patient met bundle initiation criteria (time 0), hemodynamic monitoring was initiated with placement of a central venous catheter. After radiographic verification of catheter placement, the ED nurse performed calibration for CVP and ScvO2 monitoring within two hours of time 0. Broad-spectrum antibiotics were administered; however, we also encouraged the physicians to select the antibiotics that were appropriate for the source(s) of infection. Hemodynamic optimization following the EGDT protocol was achieved utilizing fluid resuscitation, red blood cell transfusion, vasopressors, and inotropes at the treating physician’s discretion. Mechanical ventilation was initiated if necessary. Corticosteroids were administered if the patient became vasopressor-dependent or if adrenal insufficiency was suspected. A repeat lactate level was obtained to assess for lactate clearance. A previous study demonstrated that lactate clearance of 10% after six hours of ED management was associated with significant decreased mortality. For practical reasons, we utilized venous lactate and allowed a 12-hour window period for the physician to reorder a second lactate level to determine clearance. The first abnormal lactate level would provide the inclusion criteria for bundle initiation. After bundle completion, the patient would be admitted to the ICU and the intensivists would obtain the second lactate level as part of the admission orders. With a mean (±SD) ED length of stay of 8.5 (±4.4) hours for all patients during the bundle implementation period, the second lactate level obtained by our intensivists would approximate 9–12 hours after the first measurement.

Achieving Bundle Compliance

Over two years of implementation, we examined 330 patients in our QI process and observed an increase in overall bundle compliance from zero at baseline to 51.2% during the last quartile. With respect to compliance to the individual bundle components during the last quartile of implementation, 82.9% of patients meeting bundle initiation criteria received CVP/ScvO2 monitoring within two hours and 90.2% of patients received antibiotics within four hours, with mean time to antibiotics of 1.5 hours. EGDT was completed at six hours in 53.7% of patients, and this completion appeared to be the determining factor in overall bundle completion. Over the two-year period, we observed a statistically significant 19% absolute decreased mortality (20.8% vs. 39.5%) in patients who had the bundle completed compared with those patients who did not have the bundle completed but may have had some components completed. A multivariate analysis including the five bundle components as independent variables showed that completing EGDT at six hours was the only component associated with a significantly decreased odds ratio for mortality (odds ratio, 0.36; 95% confidence interval = 0.17 to 0.79; Figure 2).

While our level of complete bundle compliance may seem low compared with nonsepsis quality initiatives targeting >90% compliance, our results are similar or higher compared with other efforts examining compliance to the sepsis bundles. Preliminary data from various studies showed that compliance to the six-hour bundle in a QI program was achievable in only 6%–41% of patients. With other therapies for severe sepsis, lung

![Figure 2. Odds ratio for in-hospital mortality relative to completion of each bundle component and overall completion of the bundle in the emergency department over a two-year period. In a univariate analysis of the bundle components, there was a significantly decreased odds ratio for mortality in patients who received antibiotics by four hours, completed early goal-directed therapy (EGDT) at six hours, and had lactate clearance. A multivariate analysis including the five bundle components as independent variables showed that completing EGDT at six hours was the only component associated with significant decreased odds ratio for mortality (odds ratio, 0.36; 95% confidence interval = 0.17 to 0.79). Patients with the bundle completed had a mortality rate of 20.8% compared with a mortality rate of 39.5% in those patients who did not have the bundle completed but may have had some components completed. CVP = central venous pressure, ScvO2 = central venous oxygen saturation. Adapted from Nguyen HB, Corbett SW, Steele R, et al. Implementation of a bundle of quality indicators for the early management of severe sepsis and septic shock is associated with decreased mortality. Crit Care Med. 2007; 35:1105–12. 27]
protective strategies have been achieved in only 39% of
patients. Tight glucose control was achieved 19% of the
time with routine insulin protocols. The administration
of recombinant human activated protein C ranged
from 4% to 33% of patients in other studies examining the
effectiveness of a sepsis protocol.

Implementing a six-hour severe sepsis/septic shock
treatment bundle in the ED setting is not as simple as a
physician ordering a new drug therapy. Our bundle in-
cluded a physician placing a central venous catheter, a
nurse calibrating for CVP/ScvO2 monitoring, the phy-
sician confirming placement with a chest x-ray, and the
nurse documenting CVP and ScvO2 values by two hours.
The physician and nurse team administer early and
sometimes multiple antibiotics. EGDT then requires
that the patient receives optimal fluid resuscitation,
vasopressor(s), inotrope(s), transfusion, and mechanical
ventilation to achieve a CVP >8 mm Hg, mean arterial
pressure >65 mm Hg, and ScvO2 >70% by six hours.
Furthermore, managing a patient with severe sepsis/septic
shock in this manner must be concurrent to treatments
given to the many other patients in the ED. Our bundle
was performed without any sepsis team or ICU involve-
ment but by all emergency physicians and nurses as stan-
dard care. Thus, a goal for future investigations should
include understanding and overcoming the difficulties
in achieving a much higher compliance threshold for se-
vere sepsis management in the ED setting. Questions that
we raised during our efforts were as follows: what are
the factors influencing physician and nurse acceptance
and adherence to our bundle, how much time is needed
to achieve a compliance level >90%, and what are the
process issues that we need to overcome?

Resource Utilization for Bundle Implementation
The bundle was implemented as an ED-centered QI
program and was delivered by emergency physicians,
residents, and nurses as standard care. Before imple-
mentation, we obtained administrative approval to pur-
chase two systems for continuous ScvO2 monitoring
(Vigileo; Edwards Lifesciences, Irvine, CA). No other
start-up cost was incurred.

For patient care, a typical patient with severe sepsis/
septic shock required the attending physician at the bed-
side for the crucial components of the bundle such as
central venous catheterization and intubation (if needed).
A resident physician then provided the remainder of care
under supervision of the attending physician, such as
fluid resuscitation, transfusion, and vasopressor man-
agement. Two nurses were involved in the patient care
for approximately one to two hours. One nurse initiated
CVP/ScvO2 monitoring, while the second nurse adminis-
tered fluids, antibiotics, and vasopressor medications.
The remainder of the bundle would then be completed
by the physician and one nurse. This level of intensive
care was very similar to care provided for patients in
cardiac arrest or traumatic shock, and we required no
additional staffing resources for bundle delivery. Our
critically ill patients often have an ED length of stay
longer than six hours, sometimes more than 24 hours,
awaiting ICU bed availability. For EDs with similar over-
crowding and long lengths of stay, early and optimal
management for these patients becomes paramount.

With respect to the QI process, a data abstractor was
dedicated one day per week to review patient charts
and obtain bundle compliance data. This data abstractor
was an existing resource in our department and was
trained by the physician champion to measure bundle
compliance. The physician champion dedicated ten hours
per month to review the compliance data and compile
summary reports for feedback to the ED QI committee.
The champion also served as the departmental sepsis
consultant to the emergency physicians and nurses, trou-
bleshooting any issue that may arise with respect to bun-
dle implementation. This consultant role was part of
the academic effort for the physician champion.

THE KEY TO FUTURE SUCCESS
A key feature of our implementation and the success of
any severe sepsis QI program is the designation of a
physician champion to serve as the program leader.
Without such a champion, the implementation barriers
will quickly overwhelm the program and bring it to a pre-
mature halt. We also implicitly incorporated the “plan,
do, study, and act” (PDSA) cycles of QI in our imple-
mentation of the bundle. The PDSA cycle is shorthand
for testing a change—by planning it, trying it, observing
the results, and acting on what is learned. Actively using a
system such as this helps accelerate performance im-
provement.

In “planning,” we received departmental leadership
support, identified and obtained local physician accep-
tance of the bundle components, educated physicians
and nurses on the process of bundle delivery, and devel-
oped a compliance measurement method. The physician
champion achieved initial buy-in from the participating
physicians by involving them in the selection of goals
deemed both valid and feasible in the ED setting. Com-
mittees of multiple expertise and patient care levels de-
veloped and approved the program, ensuring that all
providers through the continuum of care agreed with
the steps in the process.

In “doing,” we collected baseline data, performed a
trial period (operational phase) of bundle delivery, and
then implemented the bundle in phases of QI. A trial
period was important for staff familiarization with the
new tools, equipment, and expectations. A sepsis toolkit
served as an educational reminder and further stream-
lined care. The staff must understand why expectations
are being changed, especially with the necessity for
CVP and ScvO2 monitoring. Experienced physicians
must accept new protocols and technologies, while those
still in training need the sepsis concepts reinforced
frequently. It was crucial that the physician champion
develop a systematic educational program so that all
parties involved were able to perform their essential
roles during protocol delivery.

In “studying,” we analyzed and summarized the data
regularly, provided feedback to physicians and nurses,
and determined the ongoing barriers to bundle compli-
ance. The critical component of the program was the re-
view and feedback process. Tremendous efforts were
made at the front end of the program to gain system-
wide approval; therefore, the physician champion
needed some way to ensure that sufficient individual
progress was being made. Of the several methods attempted, retrospective chart review using the departmental QI process proved most practical and effective in our ED. This process showed us where improvement was needed. It provided a forcing function for teamwork and culture change among physicians and nurses to provide optimal care for patients with severe sepsis awaiting ICU bed availability.

Finally, in “acting,” we made sincere efforts as a physician and nursing group to improve our percentage compliance. Incentives that targeted specific behavior changes were initiated and then the process reevaluated. Additional education and in-service, along with individual feedback, were also crucial in increasing the bundle compliance. With this approach, we overcame some of the barriers in bundle implementation. We continually ask ourselves about potential changes to affect improvement. We then modified our individual behaviors toward achieving the goals with expectations to restart the cycle at “planning” again.

CONCLUSIONS

The management of severe sepsis/septic shock no longer simply includes antibiotics and fluids. Evidence for successful hemodynamic optimization and specific medications and treatments in the ED results in improved patient outcomes and requires a system-wide change in practice to overcome the many barriers. Multiple medical centers have been able to overcome these obstacles and have shown decreased patient mortality after implementation of a severe sepsis/septic shock management program. The key features are to have a physician champion, departmental consensus on the content of the protocol, physician and staff education, bedside protocol reminders, and a QI process. With continual performance feedback, these measures are associated with a significant decrease in mortality for patients who present to the ED with severe sepsis/septic shock.

The authors thank the emergency physicians, nurses, students, staff, medical records personnel, and our administrative leadership for their contribution in the effort to provide the best care to a patient population that often goes unrecognized in an overcrowded environment in which we all work.

References