Failure mode effects and criticality analysis: innovative risk assessment to identify critical areas for improvement in emergency department sepsis resuscitation

Abstract

Background: Sepsis is an increasing problem in the practice of emergency medicine as the prevalence is increasing and optimal care to reduce mortality requires significant resources and time. Evidence-based septic shock resuscitation strategies exist, and rely on appropriate recognition and diagnosis, but variation in adherence to the recommendations and therefore outcomes remains. Our objective was to perform a multi-institutional prospective risk-assessment, using failure mode effects and criticality analysis (FMECA), to identify high-risk failures in ED sepsis resuscitation.

Methods: We conducted a FMECA, which prospectively identifies critical areas for improvement in systems and processes of care, across three diverse hospitals. A multidisciplinary group of participants described the process of emergency department (ED) sepsis resuscitation to then create a comprehensive map and table listing all process steps and identified process failures. High-risk failures in sepsis resuscitation from each of the institutions were compiled to identify common high-risk failures.

Results: Common high-risk failures included limited availability of equipment to place the central venous catheter and conduct invasive monitoring, and cognitive overload leading to errors in decision-making. Additionally, we identified great variability in care processes across institutions.

Discussion: Several common high-risk failures in sepsis care exist: a disparity in resources available across hospitals, a lack of adherence to the invasive components of care, and cognitive barriers that affect expert clinicians’ decision-making capabilities. Future work may concentrate on dissemination of non-invasive alternatives and overcoming cognitive barriers in diagnosis and knowledge translation.

Keywords: cognition; health services research; risk assessment; sepsis.

Introduction

Sepsis, defined as an overwhelming body infection, is a complex disease that includes a range of clinical conditions. Sepsis begins with an infection and the body’s systemic response to that infection (in the form of vital sign abnormalities, the systemic inflammatory response syndrome, SIRS) and may progress quickly to severe sepsis, sepsis with evidence of organ dysfunction, and septic shock, severe sepsis with evidence of sepsis-induced hypotension [1]. Sepsis affects more than 750,000 people in the United States (US) each year [1, 2], carrying a 50%–60% mortality rate when progressing to septic shock. Optimal care for severe sepsis requires significant resources from
the healthcare system as a whole, including prolonged intensive care unit stays with complex treatments including mechanical ventilation, hemodynamic management with vasopressors and invasive monitoring, and possibly hemodialysis [3]. Costs for severe sepsis have increased faster than any other cause for hospitalization, with an annual estimated cost of $54 billion [4]. The majority of patients with sepsis are identified and initially resuscitated in the emergency department (ED), making the ED the ideal place for interventions to improve care and reduce patient mortality [2, 5–7].

Sepsis is one of the most challenging, complex, and time-sensitive disease states that clinicians will encounter. Similar to other critical diagnoses such as acute myocardial infarction and stroke, the speed and appropriateness with which a clinical team is able to deliver care can influence outcomes. But sepsis presents unique challenges because it presents as a continuum of signs and symptoms and, therefore, is a healthcare quality and patient safety challenge to treating clinicians who must recognize sepsis at its multiple stages, share their impressions, and decide to act.

Evidence-based septic shock resuscitation strategies exist, predominantly in the form of the sepsis resuscitation bundle (Bundle) initiated in 2004 by the Institute for Healthcare Improvement and the Surviving Sepsis Campaign, which has been shown to reduce mortality by over 25% if applied within the first six hours of presentation [3, 8–11]. The Bundle is based on an “early-goal-directed care” strategy that was originally published in 2001, and was combined with other evidence-based strategies, including adequate fluids resuscitation and early antibiotic delivery. The intention is that physicians perform all Bundle tasks 100% of the time in patients with severe sepsis or septic shock [9, 10]. Adherence to the Bundle requires appropriate recognition and diagnosis as the disease progresses from sepsis to severe sepsis to septic shock. The original Bundle was produced nearly 10 years ago. Although the Bundle is evidence-based and widely disseminated, variation in adherence to the recommendations still remain, and this parallels variation in clinical outcomes for severely septic patients [12, 13]. While some improvement in compliance has been shown with traditional education, alerts, the formation of collaboratives, and sepsis response teams, compliance across the nation remains low. Documented rates of Bundle compliance remain as low as 50%, despite intervention [13–18].

To date, we are unaware of a published report documenting the processes and systems of care that contribute to the persistently low Bundle compliance rates in the ED. The objective of this investigation was to perform a multi-institutional prospective risk-assessment, using failure mode effects and criticality analysis (FMECA), to identify high-risk critical barriers to 100% Bundle compliance in ED severe sepsis and septic shock (sepsis) resuscitation.

Materials and methods

Study design

We conducted a qualitative analysis, based on techniques of grounded theory (i.e., there is no preconceived hypotheses, but rather a continual comparative analysis of the data leads to the generation of theories and results) [19], of severe sepsis and septic shock resuscitation in the ED setting. Specifically, we employed a specialized qualitative risk assessment approach: failure mode effects and criticality analysis (FMECA), which prospectively identifies barriers and critical areas for improvement in systems and processes [20, 21]. It is a tool initially described by the aviation and nuclear power industries to determine the magnitude of adverse consequences and events as well as the likelihood of the occurrence of these events [14, 15]. Traditionally, FMECA has been used in the investigation of a binary operational event (i.e., widget works vs. widget does not work), but has been increasingly applied to complex healthcare process such as intravenous drug administration, blood transfusion, sterilization of surgical instruments, and acute ST-elevation myocardial infarction “door-to-balloon” time in the ED [22–33]. This approach provides benefits over traditional qualitative methodologies, such as those employing focus groups and surveys, in that we are able to prospectively: (1) identify all action steps in a process of care; (2) investigate potential failures at each process action step; (3) evaluate the frequency and potential severity of harm of each failure to assign a criticality value; and (4) assess how each failure may affect overall system performance [34, 35]. However, this analysis uses a novel extension of the FMECA approach to evaluate a process that focuses more on cognitive processes as opposed to institutional processes. For example, we sought to examine how clinicians decide that a patient is in septic shock and the resultant treatment decisions as opposed to examining how a medication is administered, instruments are sterilized, or the process of critical laboratory value notification [23, 25, 32]. Institutional Review Board approval was obtained at each of the study institutions’ affiliated IRBs.

Study setting and population

FMECAs were conducted at three hospitals with diverse institutional characteristics. The first site is an urban academic teaching hospital with 876 inpatient beds. The ED consists of 54 beds and has an annual census of over 85,000 ED visits with approximately 6000 intensive care unit admissions annually. Critically ill patients are seen in the main ED, which is staffed by two to four emergency medicine (EM) attending physicians, four to six EM and rotating resident physicians per EM attending, and 14 to 27 nurses. The second site, a tertiary care referral hospital, is a 616-bed academic tertiary care...
The research team took field notes at each session. All sessions were audio-recorded and two members of the study team documented the process by at least two members of the study team using sticky notes. To ensure accurate representation of the process as described by the participants, all sessions were audio-recorded and two members of the research team took field notes at each session.

In the first session at each site, the facilitator began the discussion with a hypothetical patient presenting to the ED with critical signs indicative of severe sepsis which progresses to septic shock and concluded with completion of the Bundle or transfer out of the ED. The surviving sepsis bundle was reviewed and provided to the clinicians and managers, patient safety officers, laboratory staff, and hospital pharmacists, which helped ensure that a comprehensive description of all process steps was elicited. Each session lasted approximately 90 min; all meetings were scheduled up to four weeks in advance of all process steps was elicited. Each session lasted approximately 90 min; all meetings were scheduled up to four weeks in advance to accommodate department schedules. Participants received modest remuneration in the form of a gift card for each session attended. Verbal consent was obtained from all participants prior to the start of all meetings.

Study protocol

We adapted the FMECA process from that described previously by Khare et al. in the process of evaluating an institution’s door-to-balloon process of care for patients presenting to the ED with STElevation myocardial infarction [28]. For each participating site, the boundaries of the FMECA were set to the sepsis resuscitation bundle [9] and the discussion was limited to the care of patients with sepsis who proceed to be diagnosed with severe sepsis and septic shock in the ED from arrival in patient room to disposition from the ED. Triage processes were excluded from the discussion. The FMECA sessions were facilitated by study investigators and the process documented by at least two members of the study team using sticky notes. To ensure accurate representation of the process as described by the participants, all sessions were audio-recorded and two members of the research team took field notes at each session.

In the first session at each site, the facilitator began the discussion with a hypothetical patient presenting to the ED with critical signs indicative of severe sepsis which progresses to septic shock and concluded with completion of the Bundle or transfer out of the ED. The surviving sepsis bundle was reviewed and provided to the participants [9]. Participants were then asked to further describe the process by which they care for patients with severe sepsis or septic shock. The study team then translated the described processes into formal Process Maps (Microsoft Visio 2010; Microsoft Corporation, Redmond, WA, USA). Process Maps lay out, step-by-step all steps and decision points in a process (see Supplemental Data, Appendix 1, which accompanies the article at http://www.degruyter.com/view/j/dx.2014.1.issue-2/issue-files/dx.2014.1.issue-2.xml). Prior to the second session, FMECA participants were asked to review their respective Process Map and offer any revisions. The final Process Map for each site was then translated into a Risk Assessment Chart: an Excel document listing all steps and decision points in the ED Sepsis Resuscitation process (Microsoft Excel 2011; Microsoft Corporation, Redmond, WA, USA).

During the second session, FMECA participants (1) systematically reviewed each process step and identified potential failures and their causes; (2) ranked the frequency of each identified potential failure (range: F1 [low] to F4 [high]); (3) outlined the consequences of each potential failure (range: C0 [none] to C4 [certain]); and (4) discussed institutional safeguards already in place. Following the two FMECA sessions, researchers met with individual participants as needed to fill in any gaps in the Process Map or Risk Assessment Chart. Results were used to develop a finalized Risk Assessment Chart, which included all identified potential failure points (see Supplemental Data, Appendices 1 and 2 for Process Maps and Risk Assessment Chart).

Key outcome measures

The key outcome measures of this study were the identification of common high-risk critical failures to 100% Bundle compliance across the three institutions. Secondary outcomes included the identification of the causes of each of these high-risk critical failures across the three institutions.

Data analysis

To then identify the most critical systematic and process vulnerabilities (high-risk critical failures), the research team used an established method from the US Department of Energy, adapted for healthcare, which categorizes each failure’s frequency and consequence scores into different “Risk Bins” [36, 37]. Identified failure points were given a criticality score of high, medium, or low based on the frequency and consequence of the failure. Process steps were identified as high risk if the step was either missed frequently or the consequence was severe if missed. High-risk steps in Bundle compliance from each of the three institutions were then compiled to identify common high-risk steps and causes of compliance failures across the three institutions.

Results

The results of this multi-institutional FMECA study of ED sepsis resuscitation revealed several common high-risk failure steps across all the three participating sites (Figure 1). Six out of the eight identified high-risk failure steps are central to clinician recognition, reassessment, and the decision to proceed with the Bundle. Across all participating sites, many of the identified failure causes...
were related to cognitive barriers or errors in decision-making (Table 1). As shown in Table 1, clinicians’ cited reasons for not pursuing treatment of severe sepsis and septic shock were the same as for the decision not to place a central venous catheter. In particular, physicians discussed that they often do not choose to implement the Bundle because they overanalyze the patient’s vital signs, become convinced that they are not in septic shock (e.g., “The patient does not have persistent hypotension to indicate septic shock, their blood pressure always runs low”) and therefore do not initiate aggressive care. Across all sites, physicians cited a lack of consistent, immediate availability of equipment necessary to place the central venous catheter. The rural center reported that they did not have access to invasive monitoring techniques, central venous pressure (CVP) monitoring, or central venous oxygen saturation (ScVO₂) lab testing and therefore were unable to complete the Bundle. Physicians also mentioned distractors including other critical patients and high patient volumes as barriers to reassessing the septic patient, leading to delays in their identification and intervention. There were multiple other high-risk failure steps at each individual institution, and many present at two of the three institutions, that are not shown in Figure 1 or Table 1. These steps include physician orders (laboratories and IV fluids), additional reassessment steps early in the sepsis process (i.e., during initial IV fluid administration), the pharmacy process (including physician ordering and pharmacy verification and delivery of antibiotics), and nurse administration of vasopressors (data not shown).

### Discussion

The results of this multidisciplinary, multi-institutional prospective risk assessment identified several common high-risk failures and causes of sub-optimal Bundle compliance across the three institutions. Barriers to clinical guideline adherence, such as the Bundle, have been previously described through a framework of knowledge (familiarity, awareness, cognitive biases/dilemmas), attitudes (disagreements about outcomes, efficacy, or lack of motivation/inertia of prior practice), and behaviors (external barriers, environmental factors) [38]. Our findings indicate barriers to successful Bundle compliance fall into each of these categories: including limited availability of equipment to place the central venous catheter and conduct invasive monitoring, and cognitive overload and biases leading to errors in decision-making by clinicians. Additionally, we identified great variability in process of care across the hospitals. It is important to note that the goal of this work was not to quantify Bundle compliance at various institutions, but rather to identify common risks for sub-optimal Bundle compliance.

A number of previous studies have examined implementation of sepsis protocols and several have examined factors related to compliance with these protocols. These studies all document low compliance rates with the Bundle across institutions [13, 14, 16, 39–41]. Similar to previous studies, we demonstrate failures associated with placing the central venous catheter, and obtaining and meeting goals of care through CVP and ScVO₂, through issues in the demands of nursing care and availability of equipment, highlighting behavioral barriers [13, 39, 42]. Our results also highlight the decision to pursue severe sepsis and septic shock treatment as a high-risk step, highlighting knowledge and attitude barriers, as other studies have. In addition, other studies report failure to consider sepsis and initiate the Bundle at all, but this was not considered in our study given that the process was bound to patients with sepsis who proceed to have severe sepsis or septic shock and clinicians were told to consider sepsis at the start of the process [14, 39].

The FMECA results highlight institutional variations in care processes and resource availability across the three sites. For example, clinicians at the rural site endorse that they only rarely place a central venous catheter in the ED, a step in the Bundle that is necessary to deliver life-saving vasopressor medication [3]. In this instance, a patient with severe sepsis and septic shock is usually transferred to an outside hospital for critical management and there is a common belief that the patient will receive the necessary aggressive management at the receiving institution (i.e., central venous catheter placement and vasopressor medications) and therefore does not immediately require the placement of a central venous catheter at the rural site. But, the transfer process often takes several hours and places the patient out of the Bundle-prescribed six-hour.

#### Common high-risk steps across participating sites:

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>ED RN gives 2 L of IV fluid</td>
</tr>
<tr>
<td>2.</td>
<td>ED team decision to pursue severe sepsis/septic shock treatment</td>
</tr>
<tr>
<td>3.</td>
<td>ED MD decision to place a central venous catheter</td>
</tr>
<tr>
<td>4.</td>
<td>ED MD reassessment of patient and decision to give more fluids or initiate vasopressors to treat shock</td>
</tr>
<tr>
<td>5.</td>
<td>ED MD orders vasopressors</td>
</tr>
<tr>
<td>6.</td>
<td>ED MD decision to order CVP monitoring</td>
</tr>
<tr>
<td>7.</td>
<td>ED MD and RN reassessment of patient with CVP, BP, repeat lactate</td>
</tr>
<tr>
<td>8.</td>
<td>ED MD decision to order ScVO₂, and treats the patient based on the result</td>
</tr>
</tbody>
</table>

**Figure 1** Common high-risk steps across participating sites.
Table 1 Causes of common high-risk process step failures present at all three institutions.

<table>
<thead>
<tr>
<th>High-risk process step failures</th>
<th>High-risk process step failure causes</th>
<th>Tertiary Care Referral Hospital</th>
<th>Rural Hospital</th>
<th>Cognitive barriers</th>
</tr>
</thead>
</table>
| ED RN does not give patient 2L of IVF | - RN not aware of Bundle.  
- RN has competing interests.  
- Poor communication. | - RN not aware of Bundle.  
- RN has competing interests.  
- Poor communication. | - RN not aware of Bundle.  
- RN has competing interests.  
- Poor communication. | |
| ED team does not decide to pursue severe sepsis treatment | - Patient does not appear that ill.  
- The MD is hesitant to “pull the trigger” and increase resource consumption.  
- MD hesitant to go “overboard”.  
- MDs are focused elsewhere in the ED and wants patient to be managed in ICU. | - Patient does not appear that ill.  
- MD prefers more conservative treatment.  
- The MD is hesitant to “pull the trigger” and increase resource consumption.  
- MD hesitant to go “overboard.”  
- MDs attention focused elsewhere, wants patient to be managed in ICU. | - Patient does not appear that ill.  
- MD has competing interests given that it is a single coverage department.  
- MD is hesitant to place central venous catheter.  
- Most patients do not receive central venous catheter in the ED. | ✓ ✓ |
| ED MDs do not decide to place central venous catheter | - MD does not believe in CVP monitoring and it is not prioritized  
- Lack of communication.  
- CVP not charted or communicated. | Process Step Usually Omitted: CVP Monitoring performed in ICU | - CVP monitoring equipment not available. | |
| ED MD does not order CVP monitoring | - Lack of reassessment.  
- ED MD hesitant to order: patient’s blood pressure “runs low.”  
- Difficulty interpreting CVP.  
- ED MD busy with other patient care. | - Lack of reassessment.  
- ED MD hesitant to order: patient’s blood pressure “runs low.”  
- Does not want to pursue aggressive treatment.  
- Believe that vasopressors will be initiated in the ICU. | - Central venous catheter not placed.  
- Lack of reassessment.  
- ED MD hesitant to order: patient’s blood pressure “runs low.”  
- RN and MD distracted by other tasks.  
- RN unclear on how to administer vasopressors. | ✓ |
| ED MDs do not decide to initiate vasopressors for septic shock (and therefore does not order them) | - Difficulty interpreting CVP. False sense of security for patient’s stability.  
- Busy with other patients. Lack of communication.  
- Competing patient priorities.  
- Patient away from ED for testing. | - CVP Frequently Omitted.  
- False sense of security for patient’s stability.  
- Busy with other patients. Lack of communication.  
- Competing patient priorities.  
- Patient away from ED for testing. | - CVP monitoring not available.  
- False sense of security for patient’s stability.  
- RN busy with other tasks.  
- Lack of communication.  
- Lack of RN experience.  
- Patient away from ED unmonitored. | ✓ |
| ED MD and RN do not reassess and record patient CVP/BP, or order repeat lactate (non-invasive management) | - Difficulty interpreting CVP. False sense of security for patient’s stability.  
- Busy with other patients. Lack of communication.  
- Competing patient priorities.  
- Patient away from ED for testing. | - CVP Frequently Omitted.  
- False sense of security for patient’s stability.  
- Busy with other patients. Lack of communication.  
- Competing patient priorities.  
- Patient away from ED for testing. | - CVP monitoring not available.  
- False sense of security for patient’s stability.  
- RN busy with other tasks.  
- Lack of communication.  
- Lack of RN experience.  
- Patient away from ED unmonitored. | ✓ |
| ED MD does not order ScVO₂ | - ScVO₂ not prioritized. Limited time (patient being transferred to ICU).  
- Hesitancy to engage additional resources. | Process Step Usually Omitted: Ordering ScVO₂ | - ScVO₂ testing not available. | |
| | | | | |
window [3]. Additionally, if the patient is admitted to the rural hospital ICU, there is often not an intensivist on-site to place the central venous catheter to adhere to Bundle compliance, making central venous catheter placement in the ED even more important. In further exploring the issue of invasive treatment and monitoring as a part of the Bundle, the FMECA not only identified limited availability of invasive monitoring equipment at rural hospitals but also minimal trust in CVP monitoring, hesitancy to engage additional resources, and hesitancy to order the ScVO₂ across all institutions. These findings touch upon knowledge, attitudinal, and behavioral barriers [38].

Given that all hospitals do not have the ability to meet 100% Bundle compliance, especially regarding the invasive CVP and ScVO₂ monitoring components, and that the literature has questioned the value of CVP monitoring [43, 44], research in implementing non-invasive alternatives for diagnosis in early goal directed therapy is certainly warranted, and three multi-national trials are on-going [45]. Non-invasive alternatives to measure CVP and ScVO₂ were introduced in the latest 2012 Surviving Sepsis Campaign Guidelines [3] (e.g., the use of ultrasound assessment of inferior vena cava collapse correlates with CVP [46] and clearance of serum lactate by 10% over two hours) [47], however, the basic tenants of the Bundle remain the same: early antibiotics and hemodynamic optimization (still with an invasive central venous catheter if necessary) [48]. Given these new advances in the management of severe sepsis and septic shock resuscitation, it can be argued that the same outcomes of the Bundle could be achieved without achieving CVP and ScVO₂ goals in particular, if non-invasive goals are used and the other Bundle elements are still met.

The majority of identified high-risk failure causes were related to knowledge and attitudes or cognitive barriers that clinicians experience in caring for patients with sepsis, severe sepsis, and septic shock that impede them from pursuing aggressive, invasive care. These cognitive barriers have been described as failed heuristics, biases, or cognitive dispositions to respond, that clinicians use to form judgments and make decisions and can often lead to medical errors [49]. The clinical environment, especially the ED, is primed for cognitive impairment as there are many barriers to effectively translating the knowledge of the Bundle into practice: time pressure and constraints, scattered information across multiple providers, shift changes, a chaotic working environment, and clinician bias (e.g., anchor bias, reliance on past experiential knowledge) [50–53]. Furthermore, since humans do not always accurately perceive and interpret information from their environment, we must rely on biases and other cognitive mechanisms to prioritize and filter information [51]. For example, FMECA participants cited that despite vital signs and laboratory values indicative of septic shock, they may not diagnose the patient with septic shock if the patient initially appeared well (Table 1). As a result, the sepsis Bundle is not initiated. This is an example of the cognitive error of “anchoring”: the tendency to lock onto features in a patient’s initial presentation and not alter this perception despite evidence to the contrary [49]. This example demonstrates issues with expert cognition: expert clinicians are required to work quickly and balance many different inputs and demands and therefore do not always have the time to fully and logically consider all options. They rely on experiential knowledge or the representative heuristic (i.e., ‘the patient doesn’t look sick, therefore he/she must not be in shock’) [49]. In the case of sepsis, operating under this experiential knowledge may result in the clinician’s failure to initiate the Bundle, despite evidential vital signs, because they do not appear ‘that ill’.

While this study focused on the diagnosis and care of patients with sepsis who proceed to be diagnosed with severe sepsis and septic shock in the ED from arrival in patient room to disposition from the ED, and excluded initial diagnostic steps made through the triage process, we anticipate that similar high-risk failures would be found, specifically focusing on cognitive barriers, biases, and barriers to reassessment. Upon arrival to the ED, triage nurses must act with limited knowledge and only have access to chief complaint, initial vital signs, and the physical appearance of the patient to make the initial diagnosis of “too sick to wait” or “well enough to wait”. The triage nurse is likely to rely more heavily on past experience and be more vulnerable to cognitive biases. Furthermore, as EDs become more crowded, and patients are required to wait longer for transfer back to an ED care space, reassessment for change in clinical condition becomes more important, and more difficult, leading clinicians in the waiting room to anchor on initial presentation more.

Future interventions to improve sepsis care across the country should be performed both on the individual hospital level to improve equipment availability and on the national level to increase research on non-invasive alternatives to invasive Bundle monitoring and disseminate this knowledge. Future educational and operational interventions might also incorporate an understanding of expert clinician cognition – its capabilities and its limitations – in an effort to guide clinicians’ decision making. Cognitive debiasing strategies can be useful to improve knowledge retention and sustain Bundle compliance [49], but are often very complex to employ [54].
One alternative is to use simulation, perhaps counterintuitively, to distort reality in order to better guide the cognitive system through educational interventions. Another alternative is to deploy robust decision support systems to guide clinicians by indicating the critical nature of multiple data points that exist with a patient’s record [55].

Limitations

There are limitations inherent to the FMECA approach. Although we selected institutions that may be representative of the spectrum of hospitals across the US, the identified high-risk barriers and causes may be institution-specific and others may experience alternate barriers and causes. Further, the methodology relies on convenience sampling and cannot involve all clinicians involved in each institution’s ED sepsis resuscitation process. It is possible that if additional clinicians participated in the FMECA sessions that other process steps, barriers, and causes would have been revealed. It is also possible that participants may have inaccurately gauged the frequency and consequences of the identified potential failures. Additionally, this study begins with the assumption that clinicians recognize the possibility of sepsis in this case and then have knowledge of and use the Bundle (as we presented participants with the surviving sepsis bundle prior to the FMECA). Clinicians were also told that the patient would proceed to develop severe sepsis and then septic shock. It is possible that additional failures exist surrounding recognition of sepsis at all in clinical practice and in basic knowledge of the Bundle. To mitigate this limitation, we did ask clinicians to consider all process steps and possible failures in the diagnosis and treatment of severe sepsis and then septic shock, including knowledge of the Bundle components. An additional limitation relates to the methodology’s development of individual consequence scores and subsequent criticality rating (i.e., risk binning). Common issues include participants being over-optimistic and tending to underestimate the potential consequences since the failure is perceived as considerably frequent and no severe consequences have actually occurred; or being over-pessimistic, wherein although the participants have never experienced the failure, they cannot exclude that the failure will ever occur [20, 28, 56]. Furthermore, the frequency and consequence scores could be perceived differently by various participants and when one participant might rate a failure as low frequency, another could rate it as common. We attempted to mitigate this failure by coming to a group consensus regarding the majority of discussed failures.

Conclusions

This multidisciplinary, multi-institutional prospective risk assessment revealed several common high-risk failures to successful implementation of the sepsis resuscitation bundle: a disparity in resources available across hospitals, a lack of adherence to the invasive components of the Bundle, and cognitive barriers that affect expert clinicians’ decision-making capabilities as they proceed through the steps of the Bundle. Future work may concentrate on dissemination of non-invasive alternatives to the invasive Bundle protocol and overcoming cognitive barriers in diagnosis and knowledge translation of the evidence-based Bundle.

Conflict of interest statement

Authors’ conflict of interest disclosure: The authors stated that there are no conflicts of interest regarding the publication of this article. Research funding played no role in the study design; in the collection, analysis, and interpretation of data; in the writing of the report; or in the decision to submit the report for publication.

Research funding: Dr. Powell was supported by grant F-32 HS 020766-01 from AHRQ and the Emergency Medicine Foundation. Dr. Khare was supported by grant K08HS019005–01 from AHRQ.

Employment or leadership: None declared.

Honorarium: None declared.

Received February 7, 2014; accepted March 24, 2014; previously published online April 12, 2014

References


