Early Recognition and Treatment of Severe Sepsis and Septic Shock
The AHA/HRET HEN would like to acknowledge our partner, Cynosure Health, for their work in developing the Severe Sepsis & Sepsis Shock Change Package.
SEVERE SEPSIS & SEPTIC SHOCK CHANGE PACKAGE

OVERVIEW

Background
Severe sepsis and septic shock strike millions of people around the world each year – with a mortality rate of 20-50% – and, unfortunately, are increasing in incidence. Appropriate therapy, administered promptly after severe sepsis develops, results in significantly improved patient outcomes. Evidence-based interventions presented in these Surviving Sepsis Campaign Bundles have been shown to decrease mortality in at-risk populations by 50%.

Suggested AIM
• Decrease patient mortality associated with severe sepsis and septic shock by 25% within 18 months.

Potential Measures

Outcome: Reduce mortality rate for patients admitted with severe sepsis and septic shock per 1,000 discharges. (OPT-HEN-SEPSIS-1)

Process:
1. Compliance with Severe Sepsis Screening Measures: performed by Emergency Department triage. (OPT-HEN-SEPSIS-4)
2. Compliance with Severe Sepsis Screening performed on ALL potentially infected, seriously ill hospitalized patients. (OPT-HEN-SEPSIS-5)
3. Compliance with the 3-Hour Resuscitation Bundle. (Individual or all bundle elements) (OPT-HEN-SEPSIS-2)
4. Compliance with the 6-Hour Bundle. (Individual or all bundle elements) (OPT-HEN-SEPSIS-3)

KEY ELEMENTS

IDEAS TO TEST

Reliable Early Identification and Recognition of Patients with Severe Sepsis and Septic Shock
• Educate ALL disciplines about the significance of severe sepsis and septic shock and the lives that may be saved with the implementation of the bundles.
• Adopt a published sepsis screen and screen ALL adult patients when they are triaged in the ED.
• Implement sepsis screening on all potentially infected, seriously ill hospitalized patients every shift; begin a trial in one department on one shift.
• Create an environment that allows for prompt escalation of notification to and facilitation of action by care providers. Consider an “Alert” process for the hospital setting.

3-hour Resuscitation Bundle Implementation for Patients with Severe Sepsis
• Measure lactate levels.
• Develop an agreement with the laboratory department to provide either Point of Care Test (POCT) lactate levels or serum lactate results in less than 1 hour. Invest in the equipment necessary to achieve this goal.
• Create a protocol, standing order or/an order set to allow for blood cultures and a lactate level to be drawn at the same time.
• Obtain blood cultures prior to the administration of antibiotics.
• Administer broad-spectrum antibiotics within an hour of recognition of sepsis.
• Engage Pharmacy and Infectious Disease Specialists in advance to collaborate on the antibiotics to be recommended when sepsis is recognized.
• Administer 30mL/kg crystalloid for hypotension or lactate levels > 4mmol/L.
• Create protocols for fluid resuscitation to promote rapid fluid administration.
• Provide visual cues for the timing of necessary interventions starting at “Time Zero.”
• Prompt performance of necessary imaging studies to confirm potential sources of infection.

6-Hour Bundle Implementation for Patients with Septic Shock
• Administer vaspressors if hypotension is refractory to fluid resuscitation.
• Measure Central Venous Pressure (CVP) & Central Venous Oxygenation Saturation with target goals for therapy to be a CVP of 8-12 mmHg and an Scvo2 of 70% or greater.
• Re-measure lactate if the initial lactate value was elevated.
• Develop an order set that ensures the re-measurement of the serum lactate within 6 hours.

Making Changes
• These interventions are in the Surviving Sepsis Campaign, Society of Critical Care Medicine and Institute of Healthcare Improvement guidelines. National meetings, webinars, monthly coaching calls, change packages and other tools will augment state association activities.

Key Resources
• 2012 International Guidelines for Management of Severe Sepsis and Septic Shock
• Severe Sepsis and Septic Shock Practice Alerts Retrieved at: http://www.aacn.org/wd/practice/content/practicealerts.pcms
**SEVERE SEPSIS & SEPTIC SHOCK DRIVER DIAGRAM**

**AIM:** AIM: Reduce mortality of patients admitted with severe sepsis and septic shock by 25% in 18 months.

<table>
<thead>
<tr>
<th>PRIMARY DRIVERS</th>
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<th>CHANGE IDEAS</th>
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<td>Reliable Early Identification and Recognition of Patients with Severe Sepsis and Septic Shock</td>
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<td>• Adopt sepsis screening on all potentially infected, seriously ill hospitalized patients.</td>
<td>• Adopt and trial a sepsis screening tool to be utilized in triage by the ED Nurse/admitting clerk, and/or ED tech. Obtain approval of the tool and buy-in for its use from ED physicians.</td>
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<td>• Create an environment that allows for prompt escalation of notification of and facilitation of action by care providers.</td>
<td>• Trial a standard screening tool as an adopted package. Modify the tool based on the trial and retest to assess the effectiveness of the modifications.</td>
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**PRIMARY DRIVERS**

Reliable Early Identification and Recognition of Patients with Severe Sepsis and Septic Shock

- Adopt the Severe Sepsis Screen and screen ALL adult patients when they are triaged in the ED.
- Adopt sepsis screening on all potentially infected, seriously ill hospitalized patients.
- Create an environment that allows for prompt escalation of notification of and facilitation of action by care providers.

**SECONDARY DRIVERS**

- Develop a process in which all patients for whom the Rapid Response Team is called have a severe sepsis screen by the team.
- Develop a process for an “Alert” or standardized escalation system to appropriate levels of Physicians and Specialists to improve coordination of care and promote effective action by the care team.
- Develop clear roles and expectations for all members of the health care team with established and pre-approved protocols and policy.
- Implement standardized communication with SBAR and hand-off tools.
- Implement a process for continuous performance feedback for physicians and staff.
**SEVERE SEPSIS & SEPTIC SHOCK DRIVER DIAGRAM**

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| **3-hour Resuscitation Bundle Implementation for Patients with Severe Sepsis** | • Measure lactate level.  
• Obtain blood cultures prior to the administration of antibiotics.  
• Administer broad spectrum antibiotics.  
• Administer 30mL/kg crystalloid for hypotension or lactate levels > 4mmol/L.  
• Promptly perform appropriate imaging studies to confirm potential sources of infection. | • Implement the use of visual cues to identify a patient with severe sepsis or septic shock, e.g. a clock with 3-hour targets highlighted, or a colored blanket on the patient’s bed.  
• Develop an agreement with the laboratory department to process either POCT lactate levels or serum lactate results in less than 1 hour. Invest in the equipment necessary to achieve this function.  
• Develop a protocol for immediate physician notification if lactate values are >4mmol/L, or if other critical lab values are noted.  
• Develop order sets that bundle lactate and blood culture draws, and supports automatic action from frontline staff.  
• Develop a process that ensures staff is available to rapidly draw blood cultures prior to antibiotic administration, ideally within the first hour of care.  
• Involve the Pharmacy in antibiotic decision-making, supply, and delivery, with clear roles in the “Alert” process.  
• Engage Infectious Disease Specialists in the pre-selection of antibiotics to be used in this setting.  
• Place broad-spectrum antibiotics in the Emergency Department medication delivery system.  
• Develop order sets and protocols for the administration of antibiotics.  
• Develop and deliver training for the appropriate staff in the placement of large bore IVs, or inter-osseous or central lines.  
• Develop order sets and or protocols for the rapid administration of fluids when indicated.  
• Provide visual cues for the timing of interventions for this bundle beyond “Time Zero.”  
• Promptly order and perform imaging studies, as appropriate, to confirm sources of infection.  
• Develop a hand-off tool to standardize communications and hand-offs between departments and disciplines. |
**SEVERE SEPSIS & SEPTIC SHOCK DRIVER DIAGRAM**

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| **6-Hour Bundle Implementation for Patients with Septic Shock** | • Administer vasopressors.  
• Measure CVP and Central Venous Oxygenation Saturation.  
• Re-measure lactate if the initial lactate value was elevated. | • Administer vasopressors to treat hypotension refractory to fluid resuscitation (Norepinephrine is the recommended first choice.)  
• Measure CVP & Central Venous Oxygenation Saturation in the presence of persistent hypotension OR initial lactate levels > 4mmol/L.  
• Monitor CVP and Scvo2 to reach target goals for therapy of CVP 8-12 mmHg and an Scvo2 of 70% or greater, as well as urine output > 0.5mL/kg per hour.  
• Initiate Inotropic Therapy for appropriate patients, i.e. those with evidence of tissue hypoxia despite adequate perfusion (MAP).  
• Develop a protocol and order set that ensures the re-measurement of lactate levels within 6 hours.  
• Develop protocols and order sets for all bundle elements, and include documentation requirements.  
• Use visual cues such as a clock to identify bundle elements in process and the time intervals for their institution.  
• Implement source-control measures as soon as possible following successful resuscitation.  
• Provide ongoing education regarding CVP and central venous saturation for ALL RNs in the ED and ICU.  
• Provide ultrasound-guided central line placement training for all ED and ICU physicians if needed.  
• Implement a process for continuous performance feedback for physicians and staff.  
• Implement “Smart Pump” technology, and enhance the availability of helpful technology in the ED and Critical Care units. |
| **Provision of Other Supportive Therapies** | • Blood Products Administration.  
• Mechanical Ventilation in Sepsis-Induced ARDS.  
• Sedation, Analgesia, and Neuromuscular Blockade in Sepsis.  
• Glucose Control.  
• Renal Replacement Therapy.  
• Deep Vein Thrombosis Prophylaxis.  
• Stress Ulcer Prophylaxis.  
• Nutrition.  
• Setting Goals of Care. | • Develop a blood products administration decision-tree and order set.  
• Using the ARDS-Net standards, develop a mechanical ventilation protocol in conjunction with respiratory therapists and pulmonary specialists.  
• Develop and provide ongoing education regarding additional therapies that support the care of patients with severe sepsis and septic shock.  
• Implement a post-resuscitation care conference within 72 hours after ICU admission to present and discuss goals of care with patients and families.  
• Implement a process for continuous performance feedback for providers and staff. |
The 6-Hour Septic Shock bundle includes the following elements which should be completed within 6 hours of the time of patient presentation:

1. Application of vasopressors (for hypotension that does not respond to initial fluid resuscitation with maintenance of a Mean Arterial Pressure (MAP) ≥65 mm Hg).

2. If arterial hypotension persists despite volume resuscitation (Septic Shock) or if the Initial lactate level is ≥4 mmol/L (36 mg/dL), implement
   b. Measurement the Central Venous Oxygen Saturation (ScvO2).

3. If the initial lactate level was elevated, periodic re-measurement of lactate levels is indicated. (within 6 hours of the initial result).

These bundles have been approved by the National Quality Forum (NQF) as the first scientifically sound, valid, and reliable elements for the care of the severely septic patient. The intent of these bundles is to promote the performance of all of the indicated tasks within the first 6 hours after the identification of severe sepsis – 100 percent of the time. Targets for intervention and resuscitation are a CVP ≥8mmHg, a ScvO2 of ≥70%, and normalization of lactate levels.

In addition to the initial bundles, other Supportive Therapies have been recommended, including:

- Blood Product Administration,
- Mechanical Ventilation of Sepsis-Induced ARDS,
- Sedation, Analgesia, and Neuromuscular Blockade in Sepsis,
- Glucose Control,
- Renal Replacement Therapy,
- Deep Vein Thrombosis Prophylaxis,
- Stress Ulcer Prophylaxis,
- Nutrition,
- Setting Goals of Care.

The full document can be retrieved at: http://www.ihi.org/resources/Pages/Tools/SevereSepsisBundles.aspx
The bundles have been written to include as few instructions as possible, allowing for tailoring of protocols, guidelines, care paths, equipment, and procedures at the local level. The tailoring process promotes collaboration among multiple departments and brings about necessary adaptations via multi-disciplinary creativity and problem solving. Consider these bundles as initial steps toward standardized care and the creation of lasting positive changes in the practice environment and the care delivered.

- Assemble the experts in the facility, i.e. the front-line clinicians from multiple disciplines who will be affected by the sepsis protocol. Include physicians and nurses from the emergency department, intensive care units, and medical-surgical floors, as well as pharmacists, respiratory therapists, laboratory supervisors, and quality assurance personnel.
- Using the Severe Sepsis Bundles as well as local knowledge and expertise, design a protocol which includes all the bundle steps that will be acceptable for the organization's stakeholders.
- Implement the protocol.
- Utilize feedback from physicians and staff to improve and revise the protocol, and continue iterative testing as long as is necessary to maximize protocol function.

**SUGGESTED AIM**

The first step towards improving care of patients with severe sepsis and septic shock is to make a strong commitment to achieving a solid goal or aim in this arena.

An AIM statement for the severe sepsis change package could be:

- Decrease the mortality associated with severe sepsis and septic shock by 25% in 18 months.

The new related measures recommended for organizations that have implemented the “Original Sepsis Management Bundle” are:

- Improve the reliability of the bundle element implementation to a level of 95%.
- Improve compliance with the bundles to a level of 100%.

Both of these measures would support the goal of mortality reduction.

**RELIABLE EARLY IDENTIFICATION AND RECOGNITION OF PATIENTS WITH SEVERE SEPSIS AND SEPTIC SHOCK**

Adoption of an accurate screening tool for severe sepsis will help to launch a systematic approach to the identification and treatment of this population.

**Suggested Process Measures**

- Compliance with Severe Sepsis Screening performed on all patients by the Emergency Department's (ED) triage nurse.
- Compliance with Severe Sepsis Screening performed on ALL potentially infected, seriously ill patients hospitalized.
- Improvement in the percentage of patients identified with severe sepsis or septic shock within 2 hours of triage in the ED.
- Improvement in the percentage of patients who have severe sepsis that are identified/diagnosed in the medical/surgical units.

**Secondary Driver: Implement a Severe Sepsis Screening Tool during triage in the Emergency Department.**

In order to identify patients early and reliably, a severe sepsis screen should be completed on all adult patients when they are triaged in the ED, resulting in a systematic approach to the identification and treatment of patients at risk.

**Change Ideas:**

- Educate ALL disciplines about the significance of severe sepsis and septic shock and the lives that may be saved with the implementation of the bundles.
- Use of actual patient stories is a valuable tool to utilize to demonstrate the significant impact sepsis, severe sepsis and septic shock can have on patients and families for all levels of care providers from leadership to the bedside staff.
- Develop a common vocabulary and definitions for Systemic Inflammatory Response Syndrome (SIRS), sepsis, severe sepsis, and septic shock for the staff to understand and employ.
- With the approval and support of the ED physicians, adopt and trial a sepsis screening tool to be utilized in triage by the ED Nurse/admitting clerk or ED tech.
- Do not reinvent the wheel; instead, trial a standard screening tool from a package. Modify the tool and retest its functionality as needed.
- Use visual cues to identify patients who are POSITIVE for severe sepsis.
- Develop a reliable process for escalation of notification to and involvement by physicians and/or specialists.
Secondary Driver: Adopt Sepsis Screening on ALL potentially infected, seriously ill hospitalized patients.
Lack of recognition of potential sepsis is a major obstacle to sepsis bundle implementation. To increase early identification, the new recommendations include routine screening of potentially infected, seriously ill patients.²,³

Change Ideas:
• Educate staff from ALL disciplines about the significance of Severe Sepsis and Septic Shock and the lives that may be saved with the implementation of the bundles.
• Implement a severe sepsis screening tool on the inpatient units that are likely to have patients at risk for sepsis. (e.g. Medicine, Oncology, Surgery, and Telemetry).
• Allow RNs to trial the tool in one department on one shift. Modify the tool as needed and re-test.
• Use visual cues to identify patients who are POSITIVE for severe sepsis.
• Consider integration of the sepsis screen into the EMR. Program prompts for its use into the EMR, e.g. pop-up reminders for RNs to screen if appropriate patient criteria are met.
• Consider a positive result on the severe sepsis screen a trigger to call the Rapid Response Team in the inpatient setting and, potentially, in the ED setting.
• Develop a process in which all patients for whom the Rapid Response Team is called have a severe sepsis screen performed by the team.
  — Rapid Response Team members may include an ICU RN and Respiratory Therapist, and, in some settings, a hospitalist or an intensivist.
• Develop a reliable process for escalation of notifications to physicians and/or specialists.

Secondary Driver: Create an environment that facilitates prompt escalation of notification to providers and promotes timely interventions and action by providers for at-risk patients.
To minimize variability in the execution of the bundle guidelines, develop standard processes for communicating with and notifying providers, and for facilitating their timely interventions.

Change Ideas:
• Develop a process for triggering a standard “Alert” to improve coordination of care and action from the care team.
• Develop clear roles and expectations for all members of the health care team and document these roles and expectations in the developed protocols and policy.
• Identify “Time Zero” as the time of triage in the ED, and establish that the “clock has started” by using visual cues in the environment and in the EMR.
• Standardize communication by using Situation, Background, Assessment, Recommendation (SBAR) and hand-off tools.
• Implement a process for continuous performance feedback to physicians and staff.

Additional recommendations include:
• Screen all patients for SIRS or sepsis criteria promptly when they present to ED triage.
• All patients screened as positive should have standing order sets implemented as per protocol by the ED triage nurse. These sets may include the ordering of appropriate laboratory tests to assist with definitive diagnosis.
• Any patient meeting sepsis criteria should have resuscitation efforts begun as medically appropriate, e.g. insertion of large bore IV, administration of fluids, etc.
• Protocols should be prepared and vetted in advance to prevent the need for “waiting for the specialist” before intervention.
• Attending physicians should be allowed to identify when deviation from a protocol is medically appropriate, and document the justifications.

3-hour Resuscitation Bundle Implementation for Patients with Severe Sepsis
This bundle is designed to allow teams to follow the timing sequence and achieve the goals of each element. Create protocols which ensure that all elements of the bundle are incorporated.⁴

Suggested Process Measures
• Auditing of turn-around time for lactate results, with the goal of decreasing that time interval.
• Auditing compliance with the 3-Hour Resuscitation Bundle. (Individual items or all items.)
• Determining the percentage of patients who received broad-spectrum antibiotics within an hour of recognition of severe sepsis.
**Secondary Driver: Measure Lactate.**
The measurement of lactate can identify tissue hypo-perfusion in patients who are not yet hypotensive but who are at risk for septic shock. All patients with elevated lactate levels >4mmol/L should enter the 6-hour septic shock bundle. To effectively monitor and treat severely septic patients, lactate levels must be processed with a rapid turn-around time (i.e. within minutes).

**Change Ideas:**
- Develop an agreement with the laboratory department to process either Point of Care Testing (POCT) lactate levels or serum lactate level results in less than 1 hour. Invest in the equipment necessary to perform these functions.
- Develop order sets that bundle lactate levels and blood cultures.
- Develop a protocol for immediate notification of the attending physician for lactate levels >4mmol/L. (i.e. the critical lab value for lactate).

**Secondary Driver: Obtain Blood Cultures Prior to the Administration of Antibiotics.**
The incidence of sepsis and bacteremia in critically ill patients has been increasing in the past two decades. The best approach to identify the organism that is causing severe sepsis in an individual patient is to collect blood cultures prior to antibiotic administration. Two or more blood cultures per patient are recommended, with at least one sample drawn percutaneously.

**Change Ideas:**
- Develop order sets that bundle serum lactate level and blood culture orders.
- Develop a process that ensures staff is immediately available to draw blood cultures prior to antibiotic administration, i.e. within the first hour of care.

**Secondary Driver: Administer Broad-Spectrum Antibiotics.**
As soon as severe sepsis has been identified, antibiotics must be started to treat the underlying infection. Treatment should be completed within the first hour after diagnosis. A standing protocol may be developed in advance by the Sepsis committee in conjunction with the Infectious Disease specialist(s) to reduce the need for ID consultation at the bedside that might delay therapy. The ID specialist will consider the antibiotic susceptibility of the most likely pathogens in the hospital and local community and may determine the most effective broad-spectrum antibiotics to administer. However, the attending physician, as medically appropriate, may wish to call on the ID specialist acutely to evaluate an individual case and make specific recommendations for treatment. The protocol-recommended antibiotics should be available in the Emergency Department and the Critical Care units to allow for prompt administration.

**Change Ideas:**
- Involve the Pharmacy in the recommendations for, and the supply, delivery and administration of antibiotics, by assigning them clear roles in the "Alert" process.
- Engage the Infectious Disease Specialist in advance to consult on the pre-selection of antibiotics to be used for treatment if sepsis is suspected or diagnosed. Develop options for acute ID consultation for patients with sepsis if needed.
- Develop protocols and order sets for the prescription and administration of the selected antibiotics and provide guidelines for handling deviations when necessary.
- Place the recommended broad-spectrum antibiotics in the Emergency Department medication delivery system so that they will be easily and rapidly accessible.

**Secondary Driver: Administer 30mL/kg crystalloid for hypotension or for lactate levels > 4mmol/L.**
Patients with severe sepsis and septic shock may experience ineffective arterial circulation due to vasodilation associated with infection and/or impaired cardiac output. Patients who are hypotensive or have a lactate level greater than 4 mmol/L (36 mg/dL) will require intravenous fluids to expand their circulating volume and to restore the blood pressure necessary for effective cardiovascular and other organ system perfusion. Fluid resuscitation should begin as early as possible and be administered in the form of a fluid challenge or bolus instead of as an increase in the standard IV infusion rate. The quantitative targets for successful resuscitation provided in the Bundle guidelines are the achievement of a CVP of ≥8 mm Hg, an ScvO2 of ≥70 percent, and the normalization of lactate levels. If central venous monitoring is not available for the patient, alternate targets could be a MAP > 65mmHg and a HR <110 beats/minute without evidence of pulmonary edema.
Change Ideas:
- Develop a protocol and order sets for placement of a large bore IV, an inter-osseous needle, or a central line to provide an effective access route for fluid infusions in patients with sepsis. Train the appropriate staff as necessary to enhance placement skills.
- Develop protocols and order sets for rapid fluid administration in sepsis.
- Use visual cues to signal the establishment of "Time Zero" and to support appropriate timing of the interventions recommended in the protocols.
- Develop a hand-off tool to standardize communications among various departments and disciplines. Standardized communications promote continuity in resuscitations if patients are moved between departments.

Secondary Driver: Prompt performance of imaging studies to confirm potential source of infection.
Identifying the source of infection is an essential step in the management of sepsis and can inform the development of strategies that may mitigate destructive inflammatory and mediator responses. Once an infection source is identified, the appropriate interventions can and should be implemented quickly.13

Change Ideas:
- By developing advance agreements and multi-disciplinary protocols, ensure resources are available for timely imaging studies to confirm sources of infection. (e.g. Transportation, CT scan, etc.)

Suggested Process Measures
- Audit compliance with the 6-Hour Bundle. (Individual or all bundle elements.)
- Determine the percentage of patients with lactate levels > 4mmol/L that received the 6-Hour Bundle elements within 6 hours of “time zero.”
- Audit compliance with the monitoring of CVP and Scvo2 in the Critical Care units.

Secondary Driver: Administer vasopressors to reverse hypotension refractory to fluid resuscitation.
Before using a vasopressor in a patient with septic shock, ensure that adequate fluid resuscitation has been performed. If a fluid challenge fails to restore an adequate arterial pressure and effective organ perfusion, therapy with vasopressor agents should be started to promote the achievement of a MAP of 65 or greater. Norepinephrine is frequently chosen as a vasopressor. For the safe use of vasopressors, central venous access is essential, and arterial blood pressure should be closely monitored.14

Change Ideas:
- Develop protocols and order sets to cover all bundle elements and include documentation requirements.
- Use visual cues to indicate that a patient has been diagnosed with severe sepsis or septic shock, e.g. a clock with 6-hour targets highlighted or a colored blanket on the patient’s bed.
- Invest in “Smart Pump” technology and ensure its availability in the ED and Critical Care units.
- Implement a process for continuous performance feedback to physicians and staff.

Secondary Driver: Maintain adequate CVP and central venous saturation.
In patients with septic shock, it is critical to maintain adequate central venous pressure (CVP) and to maximize central venous saturation (Scvo2). CVP is maintained with fluid infusions. Scvo2 is enhanced by providing blood products/transfusions if the patient’s hematocrit is < 30%, and then by administering inotropic medications such as Dobutamine. If an Scvo2 of 70% is not achieved, consider mechanical ventilation.15,16

6-HOUR BUNDLE IMPLEMENTATION FOR PATIENTS WITH SEPTIC SHOCK
This portion of the Severe Sepsis Guidelines applies to patients who remain hypotensive despite fluid resuscitation efforts or demonstrate a lactate level of > 4mmol/L. If the lactate level is > 4mmol/L, implementation of these elements should begin immediately.
The following items are no longer recommended in this setting: Intravenous Immunoglobulin, Selenium, and Bicarbonate Therapy.\(^\text{18}\)

**Suggested Process Measures**

- Compliance with recommended supportive measures if they are implemented.
- The percentage of patients who receive supportive therapies if appropriate.

**Secondary Driver: Blood Product Administration; Mechanical Ventilation of Sepsis-Induced ARDS; Sedation, Analgesia, and Neuromuscular Blockade in Sepsis; Glucose Control; Renal Replacement Therapy; Deep Vein Thrombosis Prophylaxis; Stress Ulcer Prophylaxis; Nutrition; and Setting Goals of Care.**

Unlike the items in the previous bundles, these therapies have specific clinical indications and are not generalized to the entire population. The teams caring for patients with septic shock, e.g. in the Critical Care Unit, should be responsible for developing the decision-making algorithms and protocols that recommend the consideration or inclusion of supportive interventions. Patient outcomes should be monitored and audited to assess effectiveness of these algorithms and protocols and the need for revision of processes or additional training.

**Change Ideas:**

- Develop a decision-tree and order set for the administration of blood products.
- Collaborate with the respiratory therapist and pulmonary specialist to develop a mechanical ventilation protocol that incorporates the ARDS-Net standards.
- Develop and provide initial and ongoing education about these additional therapies that support the care of patients with severe sepsis and septic shock.
- Schedule a post-resuscitation care conference to discuss the goals of care with patients and families. (No later than 72 hours after a patient is admitted to the ICU.)
- Implement a process for performance feedback to physicians and staff.

**PROVISION FOR OTHER SUPPORTIVE THERAPIES**

The Surviving Sepsis Campaign guidelines provide recommendations for additional therapies that support the care of severely septic patients and patients with septic shock. The therapy recommendations include the following:

- Blood Product Administration,
- Mechanical Ventilation of Sepsis-Induced ARDS,
- Sedation, Analgesia, and Neuromuscular Blockade in Sepsis,
- Glucose Control,
- Renal Replacement Therapy,
- Deep Vein Thrombosis Prophylaxis,
- Stress Ulcer Prophylaxis, Nutrition,
- Setting Goals of Care.
Potential Barriers

- Initiatives that involve multiple disciplines and departments may promote the tendency of staff to define tasks as “ours” and “theirs.”
  — To promote effective collaboration, enlist key stakeholders such as physicians, bedside nurses, pharmacists, laboratory personnel specialists, and respiratory therapists, patient and families (where capable) on improvement teams to work together in the development of protocols, workflows, peer education programs, and performance review.
- Recognize that many physicians may perceive these guidelines as a change in their practice, especially if order sets or standard protocols are implemented. Some physicians may view order sets and protocols as “cookbook” medicine.\textsuperscript{19,20}
  — Educating the hesitant physicians about the proven value of standard order sets in reducing errors can mitigate resistance and promote adoption of changes. Presenting the options for patient customization and MD “opt-out” can promote acceptance.
  — Enlist several physician-champions to serve as “ambassadors” and mentors to their peers and provide information and reassurance about the changes. Invite representatives from administration, nursing, respiratory therapy, and pharmacology to join physicians and other leaders on the Sepsis committee to promote multi-disciplinary buy-in. Broad participation by relevant stakeholders will provide early momentum and drive implementation efforts forward.
- Recognize that, for many physicians, the introduction or evolution of technology will demand changes in their practice. The use of alerts, stops, and decision-support tools may be new, and may invoke feelings of loss of control and of “being told how to practice medicine.”
  — To help engage physicians in the use of technology, recruit one or two early-adopting physician champions to serve as role-models for the change.

Enlist administrative leaders and sponsors to help remove or mitigate barriers

- Each institution committed to quality improvement should involve senior leaders in establishing the specific aims in order to ensure that these aims are aligned with the organization’s strategic goals. When senior leaders approve the aims, they should also make a commitment to give the implementation team the support needed for successful aim achievement. An executive sponsor can remove and/or mitigate financial and other resource barriers, as well as communicate to employees and the community a vision of the “big picture” benefits of these changes for the organization and its clients.
- Executive leadership can also provide solutions to problems that may arise during implementation.
- Respected physician-leaders are crucial for the successful implementation of these changes in practice. By serving as role models to trial new processes in their own practices or units, physician-leaders can encourage and motivate their peers to consider and adopt necessary and beneficial changes.
- Senior leadership from all departments (e.g. Nursing, Pharmacy) assisting with Bundle development and implementation can also advocate for the successful adoption and implementation of new ideas and change processes which result in continuous quality improvement.

This change in practice may also be a change in culture for your organization.

- To achieve the organization’s improvement goals, everyone involved with the care of severe sepsis patients must be included in the development and implementation of the elements in this bundle. The processes, protocols, and order sets must be carefully scripted and standardized; tested, reviewed, and revised; and, to promote staff awareness and commitment, communicated to all employees by the senior leadership. Successful bundle implementation must be a team effort that crosses disciplines and departments, and requires leadership support as well as buy-in from all stakeholders involved with the care of these patients.
Successful change is created through three different levels of participation:

1. An active work-team responsible for daily planning, documentation, communication, education, monitoring, and evaluation of the change activities.

The work-team must be multidisciplinary, with representation from all departments involved in the change processes – doctors, nurses, pharmacists, respiratory therapists and other staff with roles in the specific change process, such as clerks and technicians. Team members should be knowledgeable about the specific aim for mortality reduction in sepsis, the current local work processes, the associated literature, and any environmental issues that will be affected by these changes.

2. The leadership group or individual, who helps remove barriers, provides resources, monitors overall progress, and gives suggestions from an institutional perspective.

The work-team needs someone with authority in the organization to overcome the barriers that arise and someone who can allocate the resources the team needs to achieve its goal. This leadership needs to understand both the benefits of the proposed changes for various parts of the system and the potential unintended consequences such a change might instigate.

3. Providers, including all stakeholders who are involved in providing care to these patients.

Effective communication procedures are necessary to keep providers and other stakeholders informed and to offer a mechanism to receive provider input and feedback. To promote change buy-in and facilitate implementation, providers must be confident that their input is valued and respected, and will influence the process.21

Tips on the use of the Model for Improvement

• Implement the Severe Sepsis Bundle one element at a time:
  • Step One: Plan
    — Begin by promoting early detection and recognition of severe sepsis and septic shock via screening.
    — If you are already screening for severe sepsis in the emergency department, begin screening inpatients at risk in a medical or surgical unit.
    — Don’t reinvent the wheel; adopt and revise a proven screening tool.
  • Step Two: Do —
    — Enlist a receptive, early-adopter physician on your improvement committee to trial these changes with his/her next few patients in the Emergency Department or in the inpatient unit.
    — Ask a receptive nurse and/or ED tech on your Sepsis committee to trial the screening tool as well.
    — Test “small”: Coordinate with the physician champion to trial the screening tool on one patient, with one nurse, and/or one ED technician.
  • Step Three: Study —
    — Debrief as soon as possible after the test with those participating, asking:
      — What happened?
      — What went well?
      — What didn’t go well?
      — What do we need to revise for next time?
  • Step Four: Act —
    — Do not wait for the next committee meeting to make necessary changes. Revise the protocols and re-test the revisions with the same physician, the same nurse, and/or the same ED technician.
  • Step Five: Feedback
    — Monitor quality improvement by collection and analysis of data from sepsis screening and bundle compliance in the care of patients with severe sepsis and septic shock
    — Use variance/risk reports and coded data to identify “missed” sepsis cases and opportunities for improvement.
    — Timely feedback with for all members of the sepsis team care promotes immediate change and understanding.
APPENDIX I — SUGGESTED ICU SEVERE SEPSIS SCREENING TOOL

ICU Severe Sepsis Screening Tool
Severe Sepsis = Infection + SIRS + Organ Dysfunction

**Directions:** The screening tool is for use in identifying patients with severe sepsis. Screen each patient upon admission, once per shift and PRN with change in condition.

<table>
<thead>
<tr>
<th>Date:</th>
<th>Time:</th>
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</table>

**I. SIRS-Systemic Inflammatory Response Syndrome (two or more of the following):**
- Temperature greater than or equal to 101°F or less than or equal to 96.8°F
- Heart Rate greater than 90 beats/minute
- Respiratory Rate greater than 20 breaths per minute
- WBC greater than or equal to 12,000/mm3 or less than or equal to 4,000/mm3 or greater than 0.5 K/uL bands
- Blood glucose greater than 140 mg/dL in non-diabetic patient
- Negative screen for severe sepsis (Please initial)
- If check two of the above, move to II

**II. Infection (one or more of the following):**
- Suspected or documented infection
- Antibiotic Therapy (not prophylaxis)
- If check none of above - Negative screen for severe sepsis (Please initial) – answer Infection question NO in I-View
- If check one of the above – answer Infection question YES in I-View, call physician for serum lactate acid order and move to III

**III. Organ Dysfunction (change from baseline):**
(One or more of the following within 3 days of new infection)
- Respiratory: SaO2 less than 90% OR increasing O2 requirements
- Cardiovascular: SBP less than 90mm Hg OR 40mm Hg less than baseline OR MAP less than 65mm Hg
- Renal: urine output less than 0.5 ml/kg/hr; creatinine increase of greater than 0.5mg/dl from baseline
- CNS: altered consciousness (unrelated to primary neuro pathology)
- Glasgow Coma Score less than or equal to 12
- Hematologic: platelets less than 100,000; INR greater than 1.5
- Hepatic: Serum total bilirubin greater than or equal to 4mg/dl
- Metabolic: Serum lactate acid greater than or equal to 2mEq/L

**Negative screen for severe sepsis (Please initial)**
If check one in section III or a severe sepsis alert fires, patient has screened positive for severe sepsis,
1. Call rapid response team
2. Call physician, physician assistant or nurse practitioner and implement urgent measures protocol.
3. Initiate or ensure IV access (2 large bore IV’s if no central access)
4. Obtain a venous blood gas (peripheral draw), serum lactate acid, CBC (if it has been greater than 12 hrs since last test), two sets of blood cultures (if greater than 24 hours since last test)
5. If patient is hypotensive: Give crystallloid (NS) fluid bolus ~30ml/kg over one hour or as fast as possible until hypotension resolved, unless known EF is less than 35% or active treatment for heart failure.

**SEPSIS INDUCED HYPOPERFUSION?**
(Clinical picture of severe sepsis plus one or both of the following criteria)

- 1. hypotension AFTER initial fluid bolus (30 ml/kg)
- 2. Lactate greater than or equal to 4 mEq/L with any BP

**NO**
- For Lactate 2-2.9
- Initiate General Care Severe Sepsis Bundle on back and complete interventions

**YES**
- Activate CODE SEPSIS
- Initiate transfer to MICU
- Meanwhile, continue crystalloid resuscitation of 250-1000ml boluses if hypotensive after the initial bolus – per physician order

**For Lactate 3-3.9 or Initial hypotension that responded to the 30 ml/kg fluid bolus, initiate transfer to MICU**
- Initiate Intermediate Care Severe Sepsis Bundle on back and complete interventions

**For Lactate 3-3.9 or Initial hypotension that responded to the 30 ml/kg fluid bolus, initiate transfer to MICU**
- Initiate Intermediate Care Severe Sepsis Bundle on back and complete interventions

RN Signature, Initial Date & Time:

---

NEW FORM — ICU PATIENT — ISVT 6/15/15

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APPENDIX I — SUGGESTED ICU SEVERE SEPSIS SCREENING TOOL (CONTINUED)
APPENDIX II — SEPSIS LANGUAGE

SEPSIS STEPS

SIRS
T: >100.4°F
< 96.8°F
RR: >20
HR: >90
WBC: >12,000
< 4,000
>10% bands
PCO2 < 32 mmHg

SEPSIS
2 SIRS
+ Confirmed or suspected infection

SEVERE SEPSIS
Sepsis + Signs of End Organ Damage
Hypotension (SBP < 90)
Lactate > 4 mmol

SEPTIC SHOCK
Severe Sepsis with persistent:
Hypotension
Signs of End Organ Damage
Lactate > 4 mmol
APPENDIX III — SAMPLE SEPSIS SCREENING TOOL

Evaluation for Severe Sepsis Screening Tool

Instructions: Use this optional tool to screen patients for severe sepsis in the emergency department, on the medical/surgical floors, or in the ICU.

1. Is the patient’s history suggestive of a new infection?
   - [ ] Pneumonia, empyema
   - [ ] Urinary tract infection
   - [ ] Acute abdominal infection
   - [ ] Meningitis
   - [ ] Skin/soft tissue infection
   - [ ] Bone/joint infection
   - [ ] Wound infection
   - [ ] Blood stream catheter infection
   - [ ] Endocarditis
   - [X] No
   - [ ] Implantable device infection
   - [ ] Other infection

2. Are any two of the following signs & symptoms of infection both present and new to the patient? Note: laboratory values may have been obtained for inpatients but may not be available for outpatients.
   - [ ] Hyperthermia > 38.3 °C (101.0 °F)
   - [ ] Hypothermia < 36 °C (96.8°F)
   - [ ] Tachypnea > 20 bpm
   - [ ] Leukocytosis (WBC count >12,000 μL⁻¹)
   - [ ] Leukopenia (WBC count < 4000 μL⁻¹)
   - [ ] Hyperglycemia (plasma glucose >140 mg/dL) or 7.7 mmol/L in the absence of diabetes

   If the answer is yes, to both questions 1 and 2, suspicion of infection is present:
   - [X] Yes
   - [X] No

3. Are any of the following organ dysfunction criteria present at a site remote from the site of the infection that are NOT considered to be chronic conditions? Note: in the case of bilateral pulmonary infiltrates the remote site stipulation is waived.
   - [ ] SBP < 90 mmHg or MAP <65 mmHg
   - [ ] SBP decrease > 40 mm Hg from baseline
   - [ ] Creatinine > 2.0 mg/dL (176.8 mmol/L) or urine output < 0.5 ml/kg/hour for 2 hours
   - [ ] Bilirubin > 2 mg/dL (34.2 mmol/L)
   - [ ] Platelet count < 100,000 μL
   - [ ] Lactate > 2 mmol/L (16.0 mg/dL)
   - [ ] Coagulopathy (INR > 1.5 or aPTT >60 secs)
   - [ ] Acute lung injury with PaO2/FiO2 <250 in the absence of pneumonia as infection source
   - [ ] Acute lung injury with PaO2/FiO2 <200 in the presence of pneumonia as infection source

   If suspicion of infection is present AND organ dysfunction is present, the patient meets the criteria for SEVERE SEPSIS and should be entered into the severe sepsis protocol.

Date: ____/____/____ (circle: dd/mm/yy or mm/dd/yy)

Time: ____: ____ (24 hr. clock)

Version 7.2.13
APPENDIX IV — EMR SEPSIS SCREEN

Sepsis Screen Notes

1) 2 or more new SIRS Criteria met?
   - Yes: [ ]
   - No: [ ]
   - **No data filed**
   - Row Information:
     - SIRS Criteria definition:
       - Temp over 100.4 F (38 C) or under 96.8 F (36 C).
       - Resp Rate over 20.
       - Pulse over 90 bpm.
       - Change in mental status:
       - Blood glucose greater than 120.
       - WBC greater than 12000 or less than 4000 or Bands (immature neutrophils) greater than 10%.

2) Actual/Potential source(s) of infection identified?
   - Yes, confirmed source identified [ ]
   - Pending more information [ ]
   - Potential infection suspected, source not ide ...
   - **No data filed**
   - Row Information:
     - Medical History for Endocarditis, Immunosuppression, Chronic Infection, Indwelling Devices, etc.
     - Positive culture results.

3) 1 or more new signs of severe sepsis
   - Yes: [ ]
   - No: [ ]
   - Awaiting more data [ ]
   - **No data filed**
   - Row Information:
     - SBP less than 90 mmHg or 40 mmHg below baseline or MAP less than 65 mmHg
     - Vaspressor Support to maintain adequate blood pressure
     - Respiratory Indicators: new or increased O2 requirements to maintain SpO2 greater than 90% or PaO2/FIO2 ratio less than 300
     - Low Urine Output less than 0.5 ml/khour for greater than 2 hours or Creatinine greater than 2.0 mg/dL
     - Lactate greater than 4.0 mmol/L
     - Platelet Count less than 100000 or Coagulopathy: INR greater than 1.5 or aPTT greater than 60 secs
     - Elevated Total Bilirubin greater than 2 mmol/L

If yes to any 1 of the above 3 questions, action taken:
   - Called/Notify physician [ ]
   - Called Rapid Response Team [ ]
   - Physician already aware [ ]
   - **No data filed**

Sepsis Screen Notes: If positive screen found or suspected, notify treating MD immediately; request Lactate Level, Baseline Labs, Blood Cultures, IV Fluids, Antibiotics, Central Line Placement, CVP, Monitoring, etc.

Additional Note [ ]

**No data filed**
APPENDIX VI — SEPSIS CLOCK

What Time Is It?

EGDT Time

Definition of Time Zero:
* The result time of lactate ≥4
* 1 hr after initial episode of SBP = 90 mm Hg
* The time central line placed
  for Very High Risk patient
  (intermediate lactate and
  elevated BUN, see chart below)

RN and MD Reassessment

RN remember to do the following:
* Repeat lactate (as ordered)
* Update MD on pt meeting and
  maintaining hemodynamic targets
  (MAP ≥65, CVP ≥8 and ScvO2 ≥70%)

Hemodynamic Targets

Time Zero

Central Line Placed

Antibiotics

Return clock to the charge nurse when EGDT is completed.

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Severe Sepsis/Septic Shock Top Ten Checklist

<table>
<thead>
<tr>
<th>TOP TEN EVIDENCE BASED INTERVENTIONS</th>
<th>IN PLACE</th>
<th>NOT DONE</th>
<th>WILL ADOPT</th>
<th>NOTES (RESPONSIBLE AND BY WHEN?)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adopt a Sepsis Screening tool/system in the ED and/or in one inpatient department.</td>
<td>☐</td>
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</tr>
<tr>
<td>Screen every adult patient during triage in the ED and/or once a shift in one identified inpatient department.</td>
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<tr>
<td>Develop an &quot;Alert&quot; mechanism to provide for prompt escalation and action from care providers with defined roles and responsibilities.</td>
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<td>Develop standard order set or protocol linking blood cultures and lactate lab draws (blood culture = lactate level).</td>
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<tr>
<td>Develop a process to have lactate results within 45min. Make a lactate of &gt; 4mmol/L a CRITICAL result for prompt notification.</td>
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<tr>
<td>Place broad-spectrum antibiotics in the ED medication delivery system to allow for antibiotic administration within 1 hour (collaborate with Pharmacy and Infectious Disease Specialist for appropriate selection).</td>
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<td>&quot;Protocolize&quot; fluid administration for sepsis patients to achieve goal of 30mL/kg crystalloid for rapid resuscitation.</td>
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<tr>
<td>Develop an order-set or protocol for 3-hour resuscitation bundle and the 6-hour septic shock bundle that uses an &quot;opt-out&quot; process instead of an &quot;opt-in&quot; for all bundle elements with the explicit end goals of therapy.</td>
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<tr>
<td>Ensure resources available for prompt performance of necessary imaging studies to confirm potential source of infection and intervene within 12 hours.</td>
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<td>Utilize a &quot;TIME ZERO&quot; method that also displays visual cues for the health care team for timing of interventions for the sepsis bundle (identification time).</td>
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<td></td>
</tr>
</tbody>
</table>
REFERENCES


12. Retrieved at: http://www.survivingsepsis.org/SiteCollectionDocuments/Bundle-3-Hour-Step4-Fluids.pdf


15. Retrieved at: http://www.survivingsepsis.org/SiteCollectionDocuments/Bundle-6Hour-Step2a-CVP.pdf


