

# Severe Sepsis and Septic Shock

2016 UPDATE

## Change Package

*SEPSIS MORTALITY REDUCTION*



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### How to Use this Change Package

This change package is intended for hospitals participating in the Hospital Engagement Network (HEN) 2.0 project led by the Centers for Medicare & Medicaid Services (CMS) and the Partnership for Patients (PFP); it is meant to be a tool to help you make patient care safer and improve care transitions. This change package is a summary of themes from the successful practices of high performing health organizations across the country. It was developed through clinical practice sharing, organization site visits and subject matter expert contributions. This change package includes a menu of strategies, change concepts and specific actionable items that any hospital can choose to implement based on need and to begin testing for purposes of improving patient quality of life and care. This change package is intended to be complementary to literature reviews and other evidence-based tools and resources.

## PART 1: ADVERSE EVENT AREA (AEA) DEFINITION AND SCOPE

**Current Definition:** Sepsis care has evolved in the last five years, as has the vocabulary used to define its stages.<sup>1</sup> Systemic inflammatory response syndrome, a serious condition that can lead to organ dysfunction and failure, stems from non- infectious as well as infectious causes. Signs and symptoms of SIRS include:

- temperature of <36 degrees Celsius or >38 degrees Celsius,
- heart rate >90/minute,
- respiratory rate >20/minute,
- PaCO<sub>2</sub> 32mmHg and
- white blood cell count <4,000 or >12,000 per microliter and/or >10% bands.

If a patient exhibits two or more of the SIRS criteria, and has a known or suspected infection, he or she is diagnosed with sepsis. Sepsis that results in end organ dysfunction, hypotension less than 90mmHg, and/or lactate levels greater than 4mmol/L is defined as severe sepsis. The final stage is septic shock, which is defined as severe sepsis with persistent hypotension, signs of end-organ damage, or lactate levels greater than 4mmol/L.

The risk of mortality and urgency for immediate action when treating all stages of sepsis drove the development of sepsis care bundles, which are approved by the National Quality Forum as the first scientifically sound, valid and reliable elements for the care of the septic patient.<sup>2</sup> The intent of these bundles is to promote the performance of all of the indicated tasks within the first three to six hours after the identification of septic symptoms—100 percent of the time. Severe sepsis patients should have the “severe sepsis 3-hour resuscitation bundle” completed within three hours of patient presentation. Septic shock patients should have the ‘six-hour septic shock bundle’ completed within six hours of patient presentation. The clock begins once the patient meets SIRS criteria. For patients who present to the Emergency Department, this means “zero” hour is at presentation to triage. For inpatients, the “zero” hour is when the patient’s vital signs first meet SIRS criteria, regardless of when it was recognized and treated.<sup>3</sup>

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.

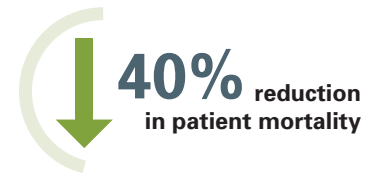
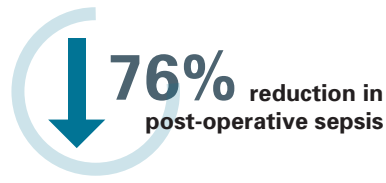
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### Magnitude of the Problem

Sepsis is diagnosed in over one million patients each year in the United States.<sup>4</sup> Furthermore, septicemia treatment resulted in an estimated \$20.3 billion or 5.2 percent of the total cost for all hospitalizations and was the most expensive condition treated in the year 2011.<sup>5</sup> Not only is sepsis expensive and prevalent, patients diagnosed with sepsis are estimated to have a mortality rate of 28 to 50 percent.<sup>6</sup> The Sepsis Alliance supports World Sepsis Day in September to bring attention to what sepsis is, what it does and how we can make a difference and save lives.<sup>7</sup>

## HEN 1.0 Progress

From 2011 – 2014, the AHA/HRET HEN reduced post-operative sepsis by 76 percent.



## HEN 2.0 Reduction Goals

Reduce patient mortality related to severe sepsis and septic shock by 40 percent by September 23, 2016.

**Since the last Sepsis Change Package published by HRET, the science has evolved, and there are key changes:**

1. Early goal-directed therapy for volume replacement via formal algorithms has been shown by the ARISE<sup>8</sup>, ProMISe<sup>9</sup> and ProCESS<sup>10</sup> studies to not offer a clinical advantage.
2. The Surviving Sepsis Campaign has changed the 6-hour bundle, updating the assessment of volume status. The 6-hour bundle no longer requires the use of central venous pressure lines or ScvO<sub>2</sub> if early recognition of sepsis and timely antibiotic administration has occurred. Instead these two modalities are one of the optional methods to assess volume. No changes have been made to the 3-hour bundle.
3. New information suggests that hypotonic fluids, when used for resuscitation and maintenance volume therapy, place the acutely ill patient at significant risk for hyponatremia. Isotonic fluid should be used. Data is insufficient to recommend balanced versus unbalanced isotonic solutions.<sup>11</sup>

Additionally, in 2014 the Centers for Medicare & Medicaid Services added a requirement for hospitals to report post-operative sepsis as a Hospital Acquired Condition. The measure used comes from the Agency for Healthcare Research and Quality Patient Safety Indicator 13.<sup>12</sup> The definition of this measure is postoperative sepsis cases (secondary diagnosis) per 1,000 elective surgical discharges for patients ages 18 years and older. CMS recently added the first National Core Measure for Sepsis beginning October 2015 measuring compliance with the 3-hour and 6-hour bundle interventions to reduce sepsis mortality.

## PART 2: MEASUREMENT

A key component to making patient care safer in your hospital is to track your progress toward improvement. This section outlines the nationally recognized process and outcome measures that you will be collecting and submitting data on for the AHA/HRET HEN 2.0. Collecting these monthly data points at your hospital will guide your quality improvement efforts as part of the Plan-Do-Study-Act (PDSA) process. Tracking your data in this manner will provide valuable information you need to study your data across time, and determine the effect your improvement strategies are having in your hospital at reducing patient harm. Furthermore, collecting these standardized metrics will allow the AHA/HRET HEN to aggregate, analyze and report its progress toward reaching the project's 40/20 goals across all AEAs by September 2016.

### Nationally Recognized Measures: Process and Outcome

Please download and reference the encyclopedia of measures (EOM) on the HRET HEN website for additional measure specifications and for any updates after publication at: <http://www.hret-hen.org/audience/data-informatics-teams/EOM.pdf>

## HEN 2.0 EVALUATION MEASURE

Postoperative Sepsis Rate (ARHQ PSI 13)

Sepsis Mortality Rate (NQF 0351 and ARHQ PSI 04)

## PROCESS MEASURES

Percentage of identified sepsis patients that receive all elements of the three-hour bundle

Percentage of identified sepsis patients that receive all elements of the six-hour bundle

# PART 3: APPROACHING YOUR AEA

## Suggested Bundles and Toolkits

- Surviving Sepsis Campaign, retrieved from: <http://www.survivingsepsis.org/Pages/default.aspx>
- Surviving Sepsis 3-hour and 6-hour bundles, retrieved from: <http://www.survivingsepsis.org/Bundles/Pages/default.aspx>
- Surviving Sepsis Guidelines, retrieved from: <http://www.survivingsepsis.org/Guidelines/Pages/default.aspx>
- IHI information on Sepsis, retrieved from: <http://www.ihl.org/topics/Sepsis/Pages/default.aspx>
- For key tools and resources related to preventing and reducing sepsis mortality, visit [www.hret-hen.org](http://www.hret-hen.org).

## Investigate Your Problem and Implement Best Practices

A driver diagram visually demonstrates the causal relationship between change ideas, secondary drivers, primary drivers and your overall aim. A description of each of these components is outlined in the table below. This change package is organized by reviewing the components of the driver diagram to (1) help you and your care team identify potential change ideas to implement at your facility and (2) to show how this quality improvement tool can be used by your team to tackle new process problems.

Aim	Primary Driver	Secondary Driver	Change Idea
		Secondary Driver	Change Idea
	Primary Driver	Secondary Driver	Change Idea

**AIM:** A clearly articulated goal or objective describing the desired outcome. It should be specific, measurable and time-bound.

**PRIMARY DRIVER:** System components or factors which contribute directly to achieving the aim.

**SECONDARY DRIVER:** Action, interventions or lower-level components necessary to achieve the primary driver.

**CHANGE IDEAS:** Specific change ideas which will support/achieve the secondary driver.

## Drivers in This Change Package

Early Recognition and Treatment for Severe Sepsis and Septic Shock	Reliable Early Detection	Implement a Severe Sepsis Screening Tool	Change Idea
		Adopt Sepsis Screening on All Potentially Infected Patients	Change Idea
		Support Prompt Escalation and Timely Intervention for At-Risk patients	Change Idea
	Implementation of 3-hour Bundle for Patients with Severe Sepsis	Measure Lactate	Change Idea
		Obtain Blood Cultures Prior to the Administration of Antibiotics	Change Idea
		Administer Broad-Spectrum Antibiotics	Change Idea
		Administer 30mL/kg Crystalloid for Hypotension or Lactate Levels >4mmol/L	Change Idea
		Promote Prompt Imaging to Confirm Potential Sources of Infection	Change Idea
	Implementation of 6-hour Bundle for Patients with Septic Shock	Administer Vasopressors	Change Idea
		Re-Assess Volume Status and Tissue Perfusion to Ensure Adequate Resuscitation	Change Idea
		Re-Measure Lactate	Change Idea
	Provision of Other Supportive Therapies	Implement the Other Supportive Therapies as Indicated by Individual Patients Using Algorithms and/or Protocols	Change Idea

## Driver Diagram Table

### OVERALL AIMS: EARLY RECOGNITION AND TREATMENT FOR SEVERE SEPSIS AND SEPTIC SHOCK

#### Primary Driver > Reliable early detection

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

#### Secondary Driver > Implement a severe sepsis screening tool

In order to identify patients early and reliably, a severe sepsis screen should be completed on all adult patients upon initial evaluation in the emergency department (ED), resulting in a systematic approach to the identification and treatment of patients at-risk.

## Change Ideas

- + Educate all inpatient and emergency department physicians, nurses and other practitioners 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 demonstrate the significant impact severe sepsis and septic shock can have on patients and families for all levels of care providers from leadership to the bedside staff.
- + Utilize the standard vocabulary and definitions for SIRS, sepsis, severe sepsis and septic shock for the staff to understand and employ treatment based on definition.
- + With the approval and support of physicians, adopt and trial a sepsis screening tool to be utilized in triage by the ED nurse and/or ED tech.
- + Do not reinvent the wheel; instead, trial a standard screening tool from one of the suggested bundles or toolkits above. Modify the tool and retest its functionality as needed.
- + Use visual cues to identify patients who are positive for severe sepsis. See Appendix VI.
- + 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 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 all potentially infected, seriously ill patients.<sup>13</sup>

## 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 nurses 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. See Appendix VI
- + Consider integration of the sepsis screen into the electronic medical record (EMR). Program prompts for its use into the EMR, for example, pop-up reminders for nurses 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 (RRT) in the inpatient setting and, potentially, in the ED setting.
- + Develop a process in which all patients for whom the RRT is called have a severe sepsis screen performed by the team.
  - > RRT members may include an ICU nurse and respiratory therapist and, in some settings, a hospitalist or a critical care specialist.

### Secondary Driver > Support prompt escalation and timely intervention 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 reliable process for escalation of notifications to physicians and/or specialists.
- + 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 earliest chart annotation consistent with all elements of severe sepsis or septic shock ascertained through chart review.
- + Establish that the clock has started by using visual cues in the environment and in the EMR. See Appendix VI.
- + Standardize communication by using Situation, Background, Assessment and Recommendation (SBAR) and hand-off tools.
- + Implement a process for continuous performance feedback to physicians and staff.
- + Consider standing orders for all patients screened as positive to eliminate delay in care as per protocol by the ED 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, (i.e., insertion of large bore IV, administration of fluids).
- + Attending physicians should be allowed to identify when deviation from standard treatment is medically appropriate and document the justifications.



## Suggested Process Measures for Your Test of Change

- + Number of ED staff compliant with severe sepsis screening on all ED patients
- + Number of severe sepsis screenings performed on all potentially infected, seriously ill patients hospitalized
- + Percentage of patients identified with severe sepsis or septic shock within two hours of admission to the ED
- + Percentage of patients who have severe sepsis that are identified/diagnosed in the medical/surgical units

## Hardwire the Process

Standard screening for sepsis in the emergency department during the initial patient evaluation for all adult patients for early recognition of this disease spectrum is a strategy to be hardwired. Screening for sepsis at regular intervals in the inpatient departments also needs to become part of the workflow for early recognition and treatment to decrease mortality.

## Primary Driver > Implementation of 3-hour bundle 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 order sets that ensure all elements of the bundle are incorporated.<sup>14</sup>

### 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 greater than 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 (e.g., within minutes).<sup>15</sup>

### Change Ideas

- + Develop an agreement with the laboratory department to process either point of care testing of lactate levels or serum lactate level results in less than one hour. Invest in the equipment necessary to perform these functions.
- + Develop order sets that bundle lactate levels and blood cultures.
- + Develop a standard protocol for immediate notification of the attending physician for lactate levels greater than 4mmol/L (e.g., 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.<sup>16,17</sup> 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 percutaneous draw.<sup>18</sup>

### 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, ideally 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 (ID) 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 ED and the critical care units to allow for prompt administration.<sup>19,20,21</sup>

## Change Ideas

- + Involve the pharmacy in the recommendations for, and the supply, delivery and administration of antibiotics. Assign the pharmacy clear roles in the alert process.
- + Engage the ID 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 ED and critical care units medication delivery system so that they will be easily and rapidly accessible.

## Secondary Driver > Administer 30mL/kg crystalloid for hypotension or 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 greater than 8 mmHg, an ScvO<sub>2</sub> of >70 percent or an alternate evaluation of successful fluid resuscitation, 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.<sup>22</sup>

## 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 sepsis resuscitations if patients are moved between departments.

## Secondary Driver > Promote prompt imaging to confirm potential sources 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.<sup>23</sup>

## Change Ideas

- + Develop advanced agreements and multi-disciplinary protocols to ensure resources are available for timely imaging studies to confirm sources of infection.

## Suggested Process Measures for Your Test of Change

- + Tracking turnaround time for lactate results to decrease time
- + Percentage of compliance with the 3-hour resuscitation bundle (individual items or all items)
- + Percentage of patients who received broad-spectrum antibiotics within an hour of recognition of severe sepsis
- + Tracking turnaround time of imaging studies needed to determine source of infection to decrease time

## Hardwire the Process

A positive sepsis screen requires a hardwired process for protocols, order sets and standard interventions. These need to include blood culture and lactate lab draws, broad-spectrum antibiotics administration, and fluids to begin early treatment of the patient with sepsis and to determine the severity of the disease spectrum.

## Primary Driver > Implementation of 6-hour bundle 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 greater than or equal to 4mmol/L. If the lactate level is greater than or equal to 4mmol/L, implementation of these elements should begin immediately.

### Secondary Driver > Administer vasopressors

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 mean arterial pressure (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 pressures should be closely monitored.<sup>24</sup>

### 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 six-hour targets highlighted or a colored blanket on the patient's bed. See Appendix VI
- + 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 > Re-assess volume status and tissue perfusion to ensure adequate resuscitation

In patients with septic shock, it is critical to maintain adequate volume status and tissue perfusion. Re-assessment of volume can be done by:

1. Repeating focused exam (after initial fluid resuscitation) by licensed independent practitioner including vital signs, cardiopulmonary, capillary refill, pulse and skin findings. Document these findings in the medical record.
2. Measuring CVP (mean value of 8-12mmHg), measuring ScvO<sub>2</sub> (a value of 70 percent), conducting a bedside cardiovascular ultrasound, dynamically assessing fluid responsiveness with passive leg raise or fluid challenge.<sup>25</sup>

Adequate volume status and perfusion is maintained with fluid infusions, vasopressors, inotropic infusion and consideration of mechanical ventilation.

### Change Ideas

- + Provide initial and ongoing education regarding volume re-assessment strategies for all nurses and physicians in the ED and the ICU.
- + Invest in monitoring equipment.
- + Ensure smart pump technology is available in the ED and critical care units.
- + Develop order sets and protocols for all bundle elements that include documentation requirements.
- + Provide ultrasound guided central line placement education for all ED and ICU physicians as needed.
- + Develop monitoring guidelines for CVP and ScvO<sub>2</sub> if this is the method of reassessment utilized. Achieve and maintain therapeutic target goals of: a CVP 8-12 mmHg and a ScvO<sub>2</sub> of 70 percent or greater, as well as urine output >0.5mL/kg/hr.

### Secondary Driver > Re-measure lactate

Mortality rate is high in septic patients with both hypotension and lactate levels  $\geq 4$  mmol/L, and is also increased in severe sepsis patients with lactate levels  $\geq 4$  mmol/L alone. If a ScvO<sub>2</sub> value is not available, lactate normalization may be used in patients with severe sepsis-induced tissue hypoperfusion as an end point for therapy and as a prognostic indicator.<sup>26</sup>

### Change Ideas

- + Develop a protocol and order set that requires the re-measurement of lactate levels within 6 hours of initial therapy in patients with septic shock.

### Suggested Process Measures for Your Test of Change

- + Percentage of compliance with the 6-hour bundle (individual or all bundle elements) in different settings (e.g., ICU, ED, other units)
- + Percentage of patients with lactate levels greater than or equal to 4mmol/L that received the 6-hour bundle elements within 6 hours of time zero
- + Percentage of compliance with re-assessment of volume status documentation

## Hardwire the Process

Implementation of care for patients with septic shock requires a hardwired process for escalation of care upon immediate identification of shock. Order sets and protocols allow for timely treatment and need to have built in triggers to ensure accurate monitoring and evaluation.

## Primary Driver > 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 other supportive 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

The following items are no longer recommended in this setting: intravenous immunoglobulin, selenium, and bicarbonate therapy.<sup>27</sup>

## Secondary Driver > Implement the other supportive therapies as indicated by the individual patients using algorithms and/or protocols

Unlike the items in the previous bundles, the other supportive therapies listed above have specific clinical indications and are not generalized to the entire population. The teams caring for patients with septic shock 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 in patients with a sepsis diagnosis.
- + 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.

### Suggested Process Measures for Your Test of Change

- + Percent of high-risk patients receiving a review of medications by a pharmacist
- + Percent of falls with medications attributed to the cause of the fall

## Hardwire the Process

Monitoring adherence to algorithms developed to provide supportive treatments to patients who have septic shock will hardwire this strategy to ensure reliable appropriate care for these severely ill patients.

## PDSA IN ACTION | TIPS ON HOW TO USE THE MODEL FOR IMPROVEMENT

There are many potentially effective interventions to reduce the risks of sepsis. Improvement teams should begin their efforts by asking: “What is the greatest need at our facility? Where can we have the greatest impact?” Do not wait for EHR or the lab panel to arrive to implement prevention strategies. Do small tests of change using the resources available and then upgrade the processes, equipment and technology over time.

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### Implement Small Tests of Change

Implement the severe sepsis bundle

#### PLAN

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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.

#### DO

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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 technician 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.

#### STUDY

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Ask the physician and/or nurse the following questions:

- What happened?
- What went well?
- What didn't go well?
- What do we need to revise for next time?

#### ACT

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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. 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. Providing timely feedback for all members of the sepsis team care promotes immediate change and understanding.

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## Identify potential barriers

- Initiatives that involve multiple disciplines and departments may promote the staff to define tasks as “ours” and “theirs.”
  - > To enhance effective collaboration, enlist key stakeholders such as physicians, bedside nurses, pharmacists, laboratory personnel specialists, respiratory therapists, patients and families (where able) 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 as cookbook medicine.<sup>28,29</sup>
  - > Educate the hesitant physicians about the proven value of standard order sets to reduce errors in order to mitigate resistance and promote adoption of changes. Present the options for patient customization and provider opt-out to promote acceptance.
  - > Enlist several physician champions to serve as ambassadors and mentors to their peers and provide information and reassurance about the changes.
  - > 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.

## Enlist administrative leadership as sponsors to help remove or mitigate barriers

- Each institution committed to quality improvement should involve senior leaders in establishing the specific aims 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 (i.e., 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.

## Change not only the practice, but also the culture

- 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.

## PART 4: CONCLUSION & YOUR NEXT STEPS

Sepsis, severe sepsis and septic shock continue to be the leading cause of mortality in hospital settings and it is time to mitigate their effect. Understand your organization's data, identify gaps in your current sepsis management and begin to test improvement. Identify your champions and ensure leadership support for this initiative. Early identification through reliable screening processes in both the emergency department and the inpatient setting are the first step for better outcomes. Change the culture throughout the organization to recognize sepsis as an emergency and mobilize resources. Ensure that clear standard definitions for sepsis, severe sepsis and septic shock are utilized, as these definitions drive appropriate treatment. Create an environment with automatic order sets and bundled interventions to allow for efficient coordination of care and eliminate delays in treatment. Leverage technology to provide alerts and best practice prompts when patient condition warrants intervention. These strategies will foster sepsis mortality reduction in your organization.

## PART 5: APPENDICES

### APPENDIX I: SEPSIS MORTALITY REDUCTION TOP TEN CHECKLIST

**Associated Hospital/Organization:** AHA/HRET HEN 2.0

**Purpose of Tool:** A checklist to review current or initiate new sepsis mortality reduction interventions in your facility

**Reference:** [www.hret-hen.org](http://www.hret-hen.org)

#### 2015 Sepsis Mortality Reduction Top Ten Checklists

Process Change	In Place	Not Done	Will Adopt	Notes (Responsible And By When?)
Collect and analyze sepsis mortality data.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Gather a program planning team and inclusive of organizational leaders, physician champions, sepsis advisors and multidisciplinary members from the, ED, ICU and med/surg to develop a strategy for implementation of improvement ideas.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Adopt a sepsis screening tool or system in the ED and/or in one inpatient department	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Screen every adult patient during initial evaluation in the ED and/or once a shift in one identified inpatient department.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Develop an alert mechanism to provide for prompt escalation and action from care providers with defined roles and responsibilities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Develop standard order set or protocol linking blood cultures and lactate lab draws (blood culture = lactate level) and ensure lactate results are available within 45 min. Consider a lactate of > 4mmol/L a CRITICAL result to prompt notification.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Develop an order-set or protocol for 3-hour resuscitation bundle and the 6-hour septic shock bundle that uses an “opt-out” process instead of an “opt-in” for all bundle elements with the explicit end goals of therapy and assessment of volume status.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Develop a process for rapid fluid infusion of isotonic solution 30ml/kg for patients with septic shock for timely resuscitation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Utilize a “TIME ZERO” method that also displays visual cues for the health care team for timing of interventions for the sepsis.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



# APPENDIX II: SUGGESTED ICU SEVERE SEPSIS SCREENING TOOL

**Associated Hospital/Organization:** St Joseph Mercy Health System

**Purpose of Tool:** An example of a severe sepsis screening tool for patients in the ICU and suggested interventions.

**Reference:** <http://www.survivingsepsis.org/SiteCollectionDocuments/Protocols-Sepsis-Screening-StJoseph.pdf>



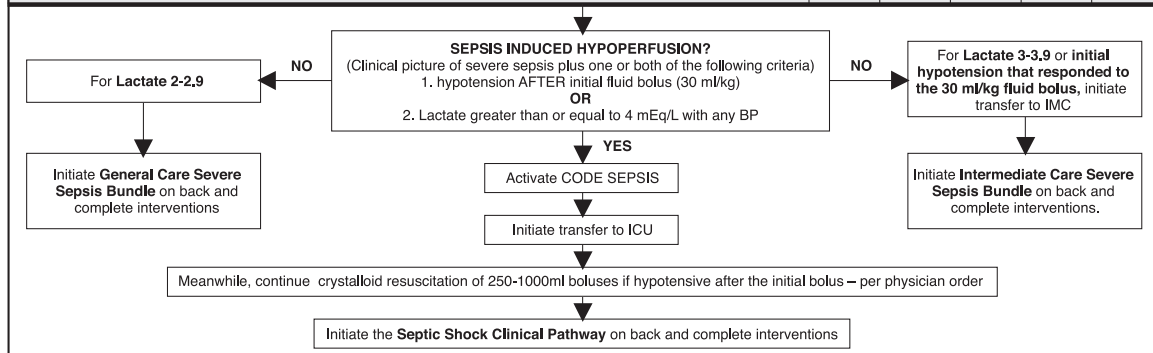
ST. JOSEPH MERCY ANN ARBOR  
ST. JOSEPH MERCY LIVINGSTON  
ST. JOSEPH MERCY SALINE

## 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.

	<b>DATE:</b>				
	<b>TIME:</b>				
<b>I. SIRS-Systemic Inflammatory Response Syndrome (two or more of the following):</b>					
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/mm <sup>3</sup> or less than or equal to 4,000/mm <sup>3</sup> 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)					
<b>if check two of the above, move to II</b>					
<b>II. Infection (one or more of following):</b>					
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 lactic acid order and move to III					
<b>III. Organ Dysfunction (change from baseline) (one or more of the following within 3 days of new infection)</b>					
Respiratory: SaO <sub>2</sub> less than 90% OR increasing O <sub>2</sub> requirements					
Cardiovascular: SBP less than 90mmHg OR 40mmHg less than baseline OR MAP less than 65mmHg					
Renal: urine output less than 0.5ml/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 lactic acid greater than or equal to 2mEq/L					
<b>Negative screen for severe sepsis (Please initial)</b>					
<b>If check one in section III or a severe sepsis alert fires, patient has screened positive for severe sepsis</b>					
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 lactic 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 set)					
5. If patient is hypotensive: Give crystalloid (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.					



\* A A 0 0 0 0 \*

**RN Signature, Initial Date & Time:**


NEW FORM – ICU PATIENT – DRAFT R 9/12 (MJD)

APPENDIX II: SUGGESTED ICU SEVERE SEPSIS SCREENING TOOL, CONTINUED.

**General Care Severe Sepsis Bundle**

For patients with 2 or more SIRS + known/suspected infection + initial lactic acid 2-2.9 w/o additional organ dysfunction

- Blood cultures x 2
- Antibiotics w/in 1 hr of screening positive for sepsis. Ensure antibiotic is ordered STAT (call Rx and notify of STAT order)
- Vital signs: every 1 hr x4, then every 4 hr x 2, then once per shift
- Lactic acid every 4 hr x 24 hr
- I & O every 2 hr (if no void w/in 4 hr, bladder scan- if greater than 200 mL perform intermittent straight cath), call MD if less than 0.5 mL/kg/hr
- Maintain/monitor for:
  - SBP greater than 90 mmHg
  - Urine output greater than 0.5 mL/kg/hr
  - Decrease in lactic acid x 3 results or normalization x2 within 12 hours
- \*\*If unable to maintain these parameters or if pt has additional organ dysfunction, call MD for possible transfer to IMC/ICU**
- Continue sepsis screen every shift and prn change in patient condition
- Complete 0 to 1 hour interventions, below

**Intermediate Care Severe Sepsis Bundle**

For patients with 2 or more SIRS + known/suspected infection + initial lactic acid 3-3.9 or had hypotension that responded to fluid bolus

- Blood cultures x 2
- Antibiotics w/in 1 hr of screening positive for sepsis. Ensure antibiotic is ordered STAT (call Rx and notify of STAT order)
- Vital signs: every 30 min x 4, then every 1hr x 2, then every 2hr x 4; then every 4 hr
- Lactic acid every 4 hr x 24 hr
- I & O every 2 hr (if no void w/in 4 hr, bladder scan- if greater than 200 mL perform intermittent straight cath), call MD if less than 0.5 mL/kg/hr
- Continue to administer fluid boluses per physician order to achieve/maintain the following goals:
  - SBP greater than 90 mmHg
  - Urine output greater than 0.5 mL/kg/hr
  - Decrease in lactic acid x 3 results or normalization x2 within 12 hours
- \*\*If unable to achieve these parameters or if pt has increase in lactic acid of 0.5 or more, increase in O2 requirements, mental status change, or additional organ dysfunction, call MD for possible transfer to ICU**
- Complete 0 to 1 hour interventions, below

Date/Time: \_\_\_\_\_ to \_\_\_\_\_

\_\_\_\_\_ If hypotensive, volume resuscitate: initial 30 mL/kg as fast as possible, then additional boluses as needed per order

\_\_\_\_\_ Time 30 mL/kg fluid bolus infused

\_\_\_\_\_ Broad spectrum antibiotic-start after obtaining blood culture

\_\_\_\_\_ Time antibiotic hung

\_\_\_\_\_ Initial Labs: serum lactate, additional labs as ordered by physician

Yes No Serum lactic acid drawn

Yes No Blood Cultures x 2

\_\_\_\_\_ Time 1: \_\_\_\_\_ Time 2: \_\_\_\_\_

\_\_\_\_\_ Other cultures:

\_\_\_\_\_ Establish IV access (2 large bore IVs)

Signature: \_\_\_\_\_ Date/Time: \_\_\_\_\_

Date/Time: \_\_\_\_\_ to \_\_\_\_\_

\_\_\_\_\_ If hypotensive, volume resuscitate: initial 30 mL/kg as fast as possible, then additional boluses as needed per order

\_\_\_\_\_ Time 30 mL/kg fluid bolus infused

\_\_\_\_\_ Broad spectrum antibiotic-start after obtaining blood culture

\_\_\_\_\_ Time antibiotic hung

\_\_\_\_\_ Initial Labs: serum lactate, additional labs as ordered by physician

Yes No Serum lactic acid drawn

Yes No Blood Cultures x 2

\_\_\_\_\_ Time 1: \_\_\_\_\_ Time 2: \_\_\_\_\_

\_\_\_\_\_ Other cultures:

\_\_\_\_\_ Establish IV access (2 large bore IVs)

Signature: \_\_\_\_\_ Date/Time: \_\_\_\_\_

# APPENDIX III: SAMPLE SEPSIS SCREENING TOOL

**Associated Hospital/Organization:** Surviving Sepsis Campaign

**Purpose of Tool:** A general sepsis screening tool to be used or modified to begin sepsis screening in the emergency department, ICU or the medical/surgical departments.

**Reference:** <http://www.survivingsepsis.org/SiteCollectionDocuments/ScreeningTool.pdf>

\*Chart record – use patient label. Do not remove from chart\*

## 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?**

- |   |  |   |
|---|--|---|
| <input type="checkbox"/> Pneumonia, empyema         | <input type="checkbox"/> Bone/joint infection            | <input type="checkbox"/> Implantable device infection |
| <input type="checkbox"/> Urinary tract infection    | <input type="checkbox"/> Wound infection                 | <input type="checkbox"/> Other infection _____        |
| <input type="checkbox"/> Acute abdominal infection  | <input type="checkbox"/> Blood stream catheter infection |   |
| <input type="checkbox"/> Meningitis                 | <input type="checkbox"/> Endocarditis                    |   |
| <input type="checkbox"/> Skin/soft tissue infection |  |   |

\_\_\_ Yes \_\_\_ No

**2. Are any two of 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.**

- |  |  |   |
|--|--|---|
| <input type="checkbox"/> Hyperthermia > 38.3 °C (101.0 °F) | <input type="checkbox"/> Tachypnea > 20 bpm                                      | <input type="checkbox"/> Hyperglycemia (plasma glucose >140 mg/dL or 7.7 mmol/L in the absence of diabetes) |
| <input type="checkbox"/> Hypothermia < 36 °C (96.8°F)      | <input type="checkbox"/> Leukocytosis (WBC count >12,000 $\mu$ L <sup>-1</sup> ) |   |
| <input type="checkbox"/> Altered mental status             | <input type="checkbox"/> Leukopenia (WBC count < 4000 $\mu$ L <sup>-1</sup> )    |   |
| <input type="checkbox"/> Tachycardia > 90 bpm              |  |   |

\_\_\_ Yes \_\_\_ No

**If the answer is yes, to both questions 1 and 2, suspicion of infection is present:**

- ✓ Obtain: **lactic acid, blood cultures**, CBC with differential, basic chemistry labs, bilirubin.
- ✓ At the physician's discretion obtain: UA, chest x-ray, amylase, lipase, ABG, CRP, CT scan.

**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  $\mu$ L
- Lactate > 2 mmol/L (18.0 mg/dl)
- Coagulopathy (INR >1.5 or aPTT >60 secs)
- Acute lung injury with PaO<sub>2</sub>/FiO<sub>2</sub> <250 in the absence of pneumonia as infection source
- Acute lung injury with PaO<sub>2</sub>/FiO<sub>2</sub> <200 in the presence of pneumonia as infection source

\_\_\_ Yes \_\_\_ No

**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

**Associated Hospital/Organization:** Sutter Hospitals

**Purpose of Tool:** An example of how to leverage technology using the electronic medical record to document sepsis screening

**Reference:** Mills Peninsula Hospital System in Burlingame, CA



### Sepsis Screen Notes

1) 2 or more new SIRS Criteria met?    

Last Filed Value:  
\*\*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?     

Last Filed Value:  
\*\*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     

Last Filed Value:  
\*\*No data filed\*\*



Row Information:

- SBP less than 90 mmHg or 40 mmHg below baseline or MAP less than 65 mmHg
- Vasopressor 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/kg/hour 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

4) Yes to any 1 of the above 3 questions, action taken:     

Last Filed Value:  
\*\*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   

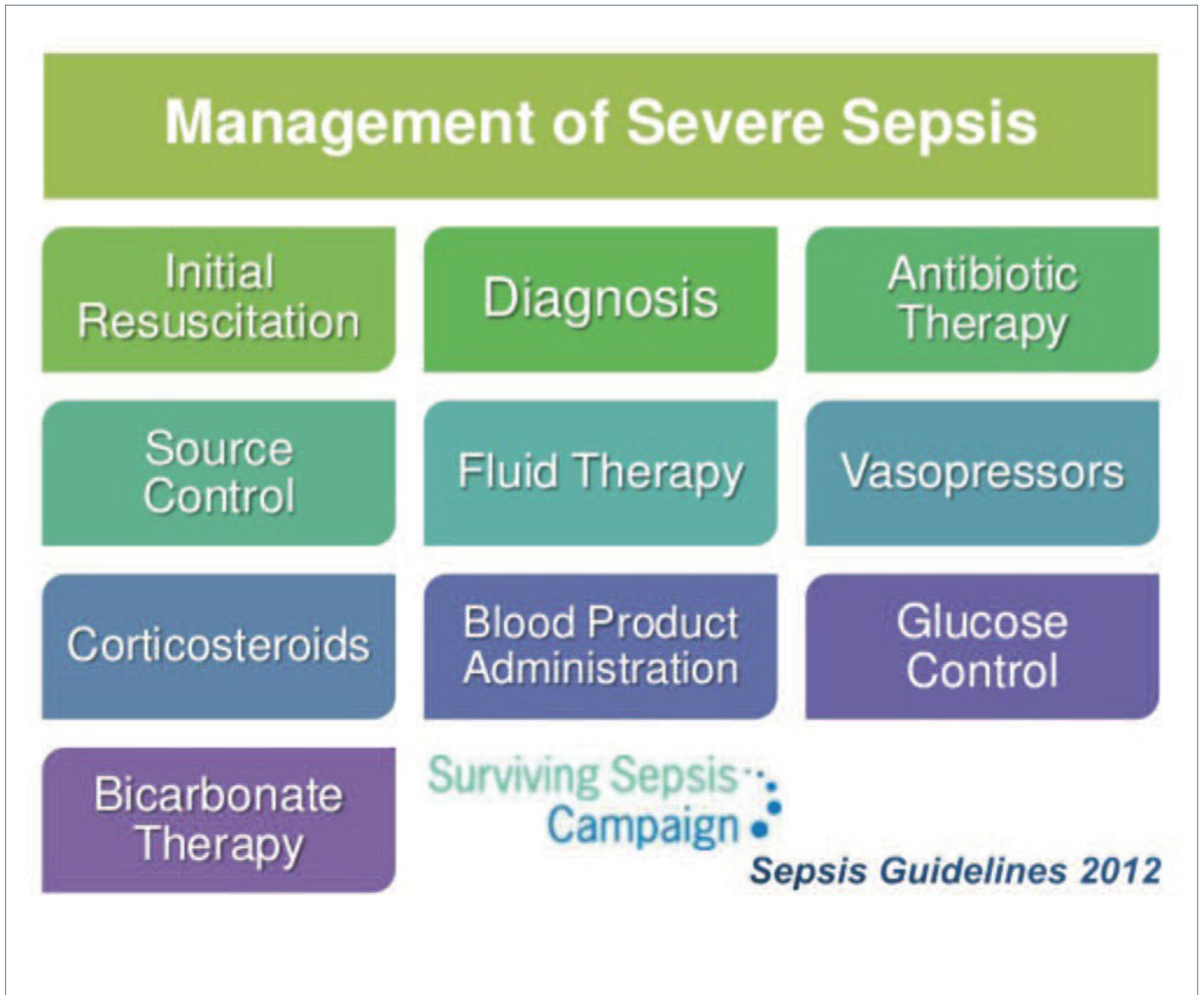
Last Filed Value:  
\*\*No data filed\*\*

## APPENDIX V: SEPSIS WALL POSTER

**Associated Hospital/Organization:** Surviving Sepsis Campaign

**Purpose of Tool:** A visual reminder of the tools for treatment of sepsis, severe sepsis and septic shock

**Reference:** Surviving Sepsis Campaign - <http://www.survivingsepsis.org>



# APPENDIX VI: SEPSIS CLOCK

**Associated Hospital/Organization:** Kaiser Permanente

**Purpose of Tool:** Visual reminder for the timing of the various bundle interventions, place near patient to allow all team members visual cues

**Reference:** Kaiser Foundation Hospital in Santa Clara, CA



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