

SEPSIS AND SEPTIC SHOCK CHANGE PACKAGE

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# How to Use This Change Package

This change package is intended for hospitals participating in the Hospital Innovation and Improvement Network (HIIN) 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. Hospitals may use it to begin testing for purposes of improving patients' 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: New sepsis definitions and early warning signs were released at the Society of Critical Care Medicine's 45th Critical Care Congress and published in the February 2016 issue of JAMA. Leading sepsis experts reached a consensus and put forth new recommendations for definitions and diagnosis. The new "Sepsis-3" definitions are:

- > Sepsis is life-threatening organ dysfunction due to a dysregulated host response to infection.
- > Septic shock is a subset of sepsis in which particularly profound circulatory, cellular and metabolic abnormalities substantially increase mortality.<sup>1</sup>

While Sepsis-3 definitions no longer recognize systemic inflammatory response syndrome (SIRS) criteria (sepsis is pro- and anti-inflammatory), the Surviving Sepsis Campaign suggests that in the presence of infection or suspected infection the SIRS criteria (see below) are symptoms of infection and should be used in the screening of patients for early sepsis identification. Absent from the new definitions is the term "severe sepsis" — a significant change from previous definitions. Sepsis has a mortality rate of 10 percent or higher, making the condition already severe. Accordingly, you will note that the term "severe sepsis" has been removed from this updated change package. Additionally, sepsis syndrome and septicemia are considered antiquated concepts.<sup>2,3</sup>

These new definitions do not change the primary focus of early sepsis identification and initiation of timely treatment in the management of this vulnerable population. Therefore, patients should be:

- > Screened for infections or possible infection
- > Assessed by Systemic Inflammatory Response Syndrome (SIRS) criteria. This remains acceptable, provided an infection is suspected, and helps identify patients with sepsis.
  - temperature of <36 degrees Celsius or >38 degrees Celsius
  - heart rate >90/minute
  - respiratory rate >20/minute
  - PaCO2 32mmHg
  - white blood cell count <4,000 or >12,000 per microliter and/or >10% bands.
- > Treated promptly when infection is suspected, including blood cultures and tailored antibiotics, and undergo further investigation for infection-related organ dysfunction.<sup>4</sup>

If a patient exhibits two or more of the SIRS criteria and/or has a known or suspected infection, he or she is diagnosed with sepsis. Sepsis that results in end-organ dysfunction, including lactate levels greater than 2mmol/L, is considered sepsis with organ dysfunction (previously referred to as severe sepsis). The final stage is septic shock, which is defined as sepsis with persistent hypotension less than 90mmHg, signs of end-organ dysfunction, or lactate levels greater than 4mmol/L.

# **New Diagnostic Tools**

A new diagnostic tool accompanies Sepsis-3 definitions:

- > quickSOFA, or qSOFA (sequential [sepsis induced] organ failure assessment) consists of three simple tests that clinicians can conduct at the bedside to identify patients at risk for sepsis:
  - · an alteration in mental status
  - a decrease in systolic blood pressure of less than 100 mm Hg
  - a respiration rate greater than 22 breaths/min
- > Data indicates that patients with two or more of these conditions are at a significantly greater risk of having a prolonged ICU stay (three or more days) or to die in the hospital.<sup>5,6</sup>

**Please Note:** *qSOFA does not define sepsis.* These studies contain only retrospective data. However, the presence of two qSOFA criteria is correlated with both increased mortality and ICU stays of more than three days in non-ICU patients. Recent literature concluded the qSOFA tool had poor sensitivity and moderate specificity for short-term mortality when used with sepsis patients, and that SIRS criteria had sensitivity superior to that of qSOFA, supporting the use of SIRS for screening of patients and as a prompt for treatment initiation.

The risk of mortality and the 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. 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. Sepsis patients should have the "3-hour resuscitation bundle" completed within three hours of patient presentation. Septic shock patients should have the "6-hour septic shock bundle" completed within six hours of patient presentation. The clock begins once the patient meets sepsis diagnosis or screens positive for sepsis. 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 and indicate the presence or suspicion of infection, regardless of when it was recognized and treated.

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 standarding care and create lasting positive changes in practice environment and the care delivery.

This revised Sepsis Change Package published by HRET acknowledges the evolution of science and the following key revisions:

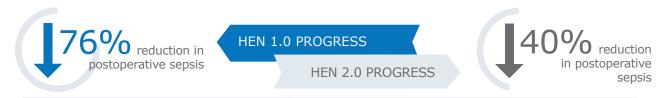
- 1. Early goal-directed therapy for volume replacement via formal algorithms has been shown by the ARISE<sup>9</sup>, ProMISe<sup>10</sup> and ProCESS<sup>11</sup> studies to not offer a clinical advantage.
- 2. The Surviving Sepsis Campaign has changed the 6-hour bundle, updating the assessment of volume status. The 6-hour bundle no longer requires the use of central venous pressure lines or ScvO2 if early recognition of sepsis and timely antibiotic administration have occurred. Instead, these two modalities are the among 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>12</sup>
- 4. Ongoing controversy in the literature continues as the science evolves regarding many elements of the treatment bundles: lactates, fluid resuscitation for patients with septic shock (hypotension or lactate greater than or equal to 4mmol/L) and the 3 hour bundle from SSC and the SEP-1 measures from CMS are unchanged. Consensus continues though that the focus must remain on early recognition, treatment and antibiotics without delay.
- 5. Updates released by Society of Critical Care Medicine and the Surviving Sepsis Campaign recommend an important change for 2018: combining the 3 and 6 hour sepsis treatment bundles into a single "hour 1 bundle", striving for immediate resuscitation and management. The "hour 1 bundle" prioritizes the following interventions:
  - Measure lactate level. Re-measure if initial lactate is>2 mmol/L
  - Obtain blood cultures prior to administration of antibiotics
  - Rapidly administer 30 ml/kg crystalloid for hypotension or lactate≥4 mmol/L
  - Apply vasopressors if patient is hypotensive during or after fluid resuscitation to maintain MAP ≥65 mm Hq

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>13</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.

# Magnitude of the Problem

Sepsis is diagnosed in over one million patients each year in the United States.<sup>14</sup> In 2011, sepsis treatment resulted in an estimated \$20.3 billion in health care costs, 5.2 percent of the total cost for all hospitalizations, and was the most expensive condition treated.<sup>15</sup> Sepsis is not only expensive and prevalent; patients diagnosed with sepsis are estimated to have a mortality rate of 28 percent to 50 percent.<sup>16</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>17</sup> Tools and resources from the Sepsis Alliance are referenced throughout this change package.

- > HEN 1.0 Progress
  - From 2011 2014, the AHA/HRET HEN reduced post operative sepsis by 76 percent.
- > HEN 2.0 Progress
  - Reduced patient mortality related to severe sepsis and septic shock by 40 percent by September 23, 2016.
- > HIIN Progress
  - Reduce patient mortality related to sepsis and septic shock by 20 percent by September 28, 2018.



HIIN GOAL 20% reduction in patient mortality and post-op sepsis

# 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. 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 20/12 goals across all adverse event areas.

# **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-hiin.org/data/hiin\_eom\_core\_eval\_and\_add\_req\_topics.pdf

- > HIIN Evaluation Measure
  - Postoperative Sepsis Rate (ARHQ PSI- 13)
  - Hospital-Onset Sepsis Mortality Rate
  - Overall Sepsis Mortality Rate
- > Process Measures
  - · Percentage of identified sepsis patients that receive all elements of the 3-hour bundle
  - Percentage of identified sepsis patients that receive all elements of the 6-hour bundle

# PART 3: APPROACHING YOUR AEA

- > Suggested Bundles and Toolkits

http://www.survivingsepsis.org/Pages/default.aspx

- Surviving Sepsis three-hour and six-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.ihi.org/topics/Sepsis/Pages/default.aspx

 For key tools and resources related to preventing and reducing sepsis mortality, visit: http://www.hret-hiin.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 your care team identify potential change ideas to implement at your facility and (2) show how this quality improvement tool can be used by your team to tackle new process problems.

AIA	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 that 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 or achieve the secondary driver.

# **Drivers in This Change Package**

EARLY RECOGNITION AND TREATMENT FOR SEPSIS AND SEPTIC SHOCK		IMPLEMENT A SEPSIS SCREENING TOOL	Change Idea
	RELIABLE EARLY DETECTION	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 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
		REASSESS VOLUME STATUS AND TISSUE PERFUSION TO ENSURE ADEQUATE RESUSCITATION	Change Idea
		REMEASURE 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

# **OVERALL AIMS**

# EARLY RECOGNITION AND TREATMENT FOR SEPSIS AND SEPTIC SHOCK

# Primary Driver:

# RELIABLE EARLY DETECTION

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



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

### **Change Ideas**

- > Educate all ED physicians, nurses and other practitioners about the significance of 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 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, sepsis with organ dysfunction and septic shock so the staff understands and employ treatment based on definition
- > With the approval and support of physicians, adopt and test a sepsis screening tool to be utilized in triage by the ED nurse and/or ED tech.
- > Do not reinvent the wheel; instead, test a standard screening tool from one of the suggested bundles or toolkits on page six. Modify the tool and retest its functionality as needed.
- > Use visual cues to identify patients who are positive for sepsis. See Appendix VI.
- > Develop a reliable process for escalation of notification to and involvement by physicians and/or specialists.

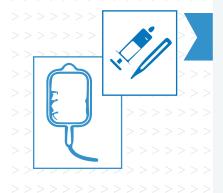
# Secondary Driver > ADOPT SEPSIS SCREENING ON ALL POTENTIALLY INFECTED PATIENTS

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>18</sup>

## **Change Ideas**

- > Educate staff from all disciplines in the inpatient setting about the significance of sepsis and septic shock and the lives that may be saved with the implementation of the bundles.
- > Implement a 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 test the tool in one department on one shift. Modify the tool as needed and retest.
- > Use visual cues to identify patients who are positive for sepsis. See Appendix VI.
- > Consider integration of the 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 sepsis screen a trigger to call the rapid response team (RRT) in the inpatient setting and, potentially, in the ED setting.





- > Develop a sepsis screening process by for the RRT team so all patients for whom the team is called are screened.
  - 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

In order to identify patients early and reliably, a 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**

- > 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. Consider adopting "code sepsis," text paging or phone triggers to gather all members of 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 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 sepsis screening on all ED patients
- Number of sepsis screenings performed on all potentially infected, seriously ill patients hospitalized
- Percentage of patients identified with sepsis or septic shock within two hours of admission to the ED
- Percentage of patients who have sepsis that are identified/diagnosed in the medical/ surgical units

### **Hardwire the Process**

Build standard screening for sepsis into the workflow of the emergency department, inpatient care and RRT evaluation processes for all adult patients. This allows for early recognition of this disease spectrum and hardwiring of this strategy. Screening for sepsis at regular intervals in the inpatient departments using the EMR should also become part of the workflow for early recognition and treatment to decrease mortality.

# Primary Driver:

# IMPLEMENTATION OF 3-HOUR BUNDLE FOR PATIENTS WITH 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>19</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 septic patients, lactate levels must be processed with a rapid turnaround time (i.e., within minutes).<sup>20</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 (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.  $^{21,22}$  The best approach to identify the organism that is causing 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.  $^{23}$ 

## **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 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 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>24,25,26</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 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 ScvO2 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.  $^{27}$ 

### **Change Ideas**

- > Develop a protocol and order sets for placement of a large bore IV, an interosseous 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>28</sup>

# **Change Ideas**

> Develop advanced agreements and multidisciplinary 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 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 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>29</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 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 >** REASSESS 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. Reassessment 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 ScvO2 (a value of 70 percent), conducting a bedside cardiovascular ultrasound and dynamically assessing fluid responsiveness with passive leg raise or fluid challenge.<sup>30</sup>

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

# **Change Ideas**

- > Provide initial and ongoing education regarding volume reassessment 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 ScvO2 if this is the method of reassessment utilized. Achieve and maintain therapeutic target goals of a CVP 8-12 mmHg and a ScvO2 of 70 percent or greater, as well as urine output >0.5mL/kg/hr.

# **Secondary Driver > REMEASURE LACTATE**

Mortality rate is high in septic patients with both hypotension and lactate levels >=4 mmol/L, and is also increased in sepsis patients with lactate levels >=4 mmol/L alone. If a ScvO2 value is not available, lactate normalization may be used in patients with sepsis-induced tissue hypoperfusion as an end point for therapy and as a prognostic indicator.<sup>31</sup>

# **Change Ideas**

> Develop a protocol and order set that requires the remeasurement 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 >= to 4mmol/L that received the six-hour bundle elements within six hours of time zero
- Percentage of compliance with reassessment 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
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>32</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 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 the effectiveness of these algorithms and protocols and the need for revising processes or providing 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 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**

- Percentage of patients who receive mechanical ventilation utilizing the ARDS-net standards
- Number of patients and families who participate in post resuscitation care conference to develop goals of care

### **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 EMR 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.

# **IMPLEMENT SMALL TESTS OF CHANGE**

# Implement the Sepsis Bundle

# **PLAN**

Begin by promoting early detection and recognition of sepsis and septic shock via screening. If you are already screening for sepsis in the emergency department, begin screening at-risk inpatients in a medical or surgical unit. Don't reinvent the wheel; adopt and revise a proven screening tool.

# DO

Enlist a receptive, early-adopter physician on your improvement committee to test 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 test the screening tool as well. Test small; coordinate with the physician champion to test the screening tool on one patient, with one nurse, and/or one ED technician.

# STUDY

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**

Do not wait for the next committee meeting to make necessary changes. Revise the protocols and retest 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 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.

# **Identify Potential Barriers**

- > Initiatives that involve multiple disciplines and departments may prompt 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 reviews.
- > 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>33,34</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 test 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 that 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 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 AND ACTION PLANNING

Sepsis and septic shock continue to be the leading cause of mortality in hospital settings and it is time to mitigate their effects. 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 is 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 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.

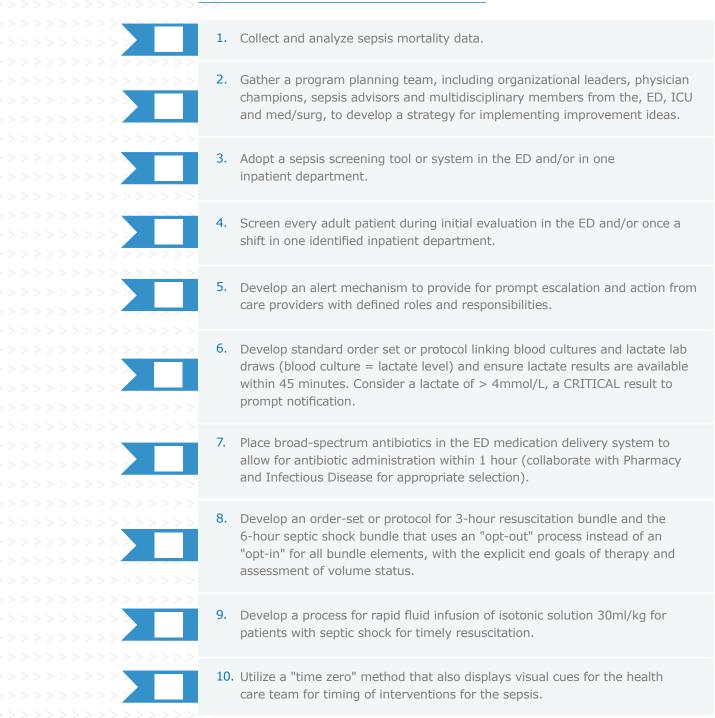
# PART 5: APPENDICES

# APPENDIX I: SEPSIS MORTALITY REDUCTION TOP TEN CHECKLIST

**Associated Hospital/Organization: HRET HIIN** 

Reference: www.hret-hiin.org

# 2017 Sepsis Mortality Reduction Top Ten Checklist

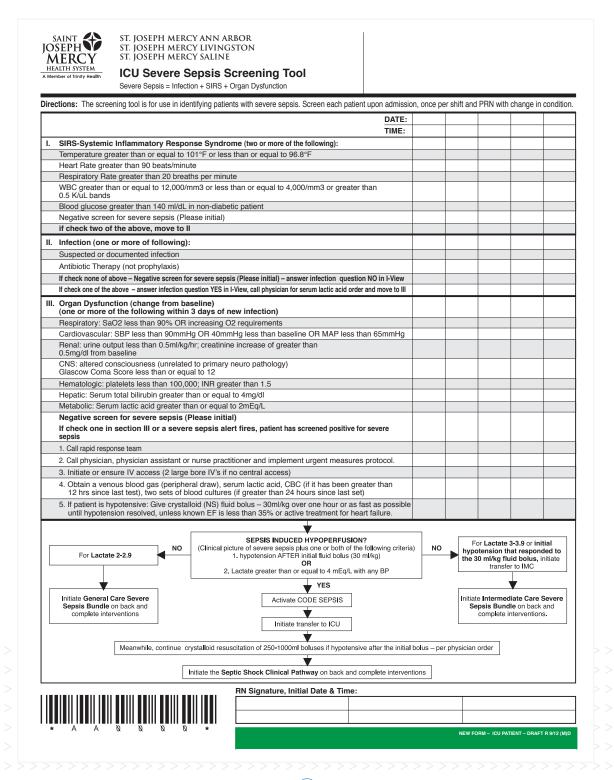


# APPENDIX II: SUGGESTED ICU SEPSIS SCREENING TOOL

Associated Hospital/Organization: St Joseph Mercy Health System

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

Reference: http://www.survivingsepsis.org/SiteCollectionDocuments/Protocols-Sepsis-Screening-StJoseph.



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# SEPTIC SHOCK CLINICAL PATHWAY

ICU admission Date:

Room #

invasive lines and tubes Was there an organism lactic acid is greater than or equal to 4mEq/L organism sensitive to Re-evaluate need for antibiotics based on decrease from baseline after 30ml/kg fluid the initial antibiotic? for broad spectrum Confirm Infectious Septic Shock (Time Zero) defined as: bolus, or requires vasopressors or initial Nutrition Therapy Progress Mobility Re-assess need If YES, was the culture reports. SBP less than 90mmHg or 40mmHg Vancomvcin if 24-72 Hours Discontinue appropriate identified? Yes No Yes No Date ٥ Are the static or plateau vasopressor at greater Patient on mechanical of ideal body weight in inspiratory pressures less than 30cmH2O in Consider Vasopressin In patients with acute lung injury Is tidal volume 6ml/kg for refractory septic Septic Shock Bundle PaO2 / FiO2 ratio first 24 hours? first 24 hours? 6-24 Hours than 6 hours Yes No Is patient on ventilator shock Yes No Yes No Yes No Yes No ☐ Floor ☐ ICU Admission ☐ During ICU Stay Date ᅙ Time CVP placed (record first CVP reading prior to x-ray confirmation) compartment syndrome (fluid resuscitation SCVO<sub>2</sub> greater than 70%: mixed venous greater than or equal to 65% Optimized stroke volume Repeat lactic acid every 4-6 hours Assess for risk factors for abdominal CVP 8-12 mmHg on vent 12-15 mmHg MAP greater than or equal to 65 mmHg Septic Shock Bundle Resuscitation Goals Record the **FIRST TIME** the following is achieved: greater than 5 Lin 24 hours or less) CVP placed If no, why? 1-6 Hours (optional) Attending physician at time of diagnosis: ED Yes No Yes No Time Time Time Date Time ž or normalization x2 within 12 hours

• Begin next column (Septic Shock Bundle)
if additional organ dysfunction occurs 8/
or patient remains/becomes hypotensive
after initial 30 mil/g fluid bolus □ ED is Yes If YES to lactic acid & additional organ dysfunction, please continue to next column (Septic Shock Bundle) equal to 65 mmHg

Maintain U/O of 0.5 m/kg/hour

Consider arterial line insertion

Monitor Stroke Volume & Stroke
Volume Variation to guide fluid If NO to additional organ dysfunction, □ Ensure decrease in lactic acid x3 Yes No Is lactic acid greater or equal to 4 mEq/L? Is patient hypotensive after initial fluid bolus? · Decision to move to comfort care in first 24 hours after diagnosis If YES to either, continue to next column (Septic Shock Bundle) Maintain MAP greater than or of additional organ dysfunction besides elevated lactic acid? Did patient require vasopressor(s)? Patient was identified as having severe sepsis or septic shock: Time: Yes No Is there evidence **Decision Grid** please continue below: resuscitation dysfunction, Septic Shock\* diagnosis (Time Zero): Date: res No Yes No Patient transferred from (unit or hospital): Discharge status: Alive Expired Serum lactic acid drawn Was a new antibiotic initiated for this episode of septic shock? Initial Labs: serum lactic acid, additional labs as ordered by physician Guide to Antimicrobial Therapy) Please complete the following: Volume resuscitate: initial as fast as possible then additional boluses as needed per order Time initial fluid bolus completed to resolve Antibiotic-start after obtain blood culture (see Infonet under Pharmac Time antibiotic hung Establish IV access Blood Cultures X 2 30ml/kg over 1 hour or **Broad Spectrum** Other Cultures: Source Control ICU discharge: Date: 0-1 Hours hypotension 2 Signature, Date & Time Yes No Yes No Physician Date Nurse Time Nurse

# 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 department.

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? Pneumonia, empyema ■ Bone/joint infection ☐ Implantable device Urinary tract infection Wound infection infection ☐ Other infection П Acute abdominal infection ■ Blood stream catheter Meningitis infection Skin/soft tissue infection □ Endocarditis \_\_ 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. ☐ Hyperthermia > 38.3 °C ☐ Tachypnea > 20 bpm ☐ Hyperglycemia (plasma (101.0 °F) ☐ Leukocytosis (WBC count glucose >140 mg/dL) or Hypothermia < 36 °C 7.7 mmol/L in the absence  $>12,000 \mu L-1)$ Leukopenia (WBC count < (96.8°F) of diabetes Altered mental status 4000  $\mu$ L-1) 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 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 \_ 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.

\_ (24 hr. clock)

Date: \_\_\_\_/\_\_\_ (circle: dd/mm/yy or mm/dd/yy)

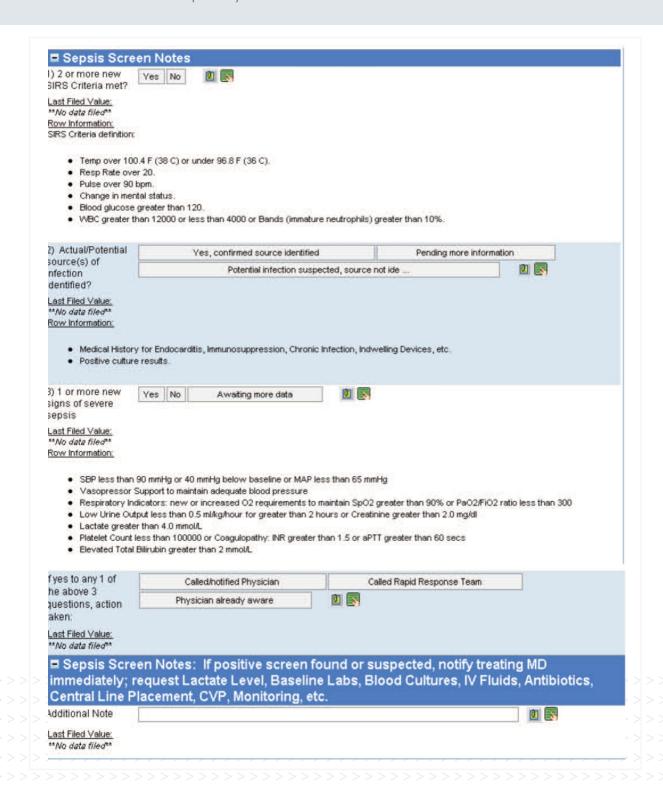
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# **APPENDIX IV: EMR SEPSIS SCREEN**

**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

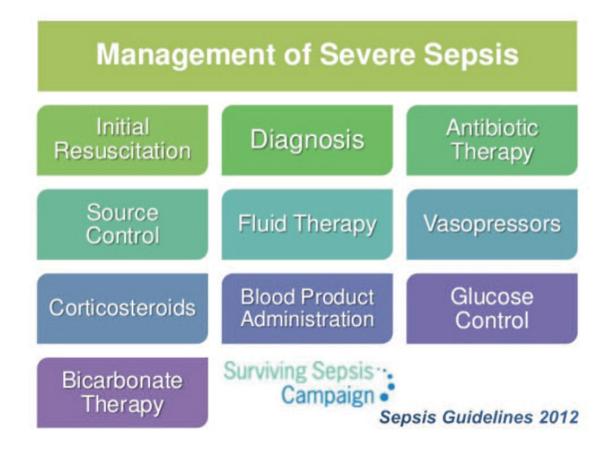


# **APPENDIX V: SEPSIS WALL POSTER**

Associated Hospital/Organization: Surviving Sepsis Campaign

Purpose of Tool: A visual reminder of the tools for treatment of sepsis and septic shock.

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

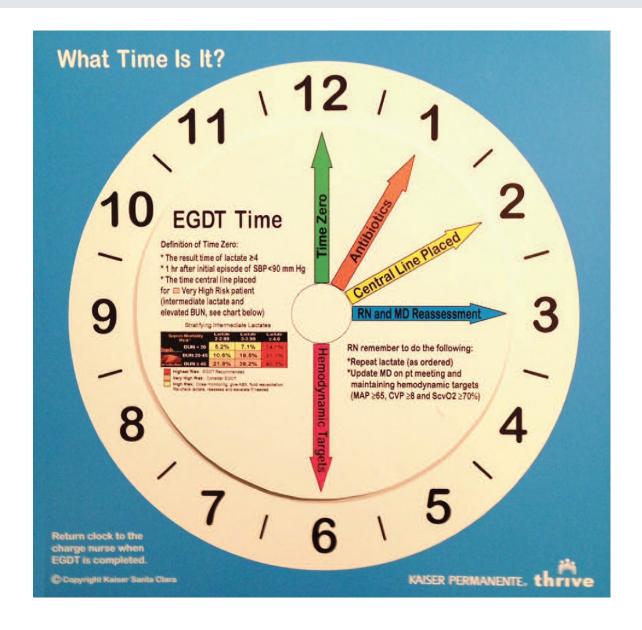


# **APPENDIX VI: SEPSIS CLOCK**

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 SCH



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