

SEPSIS MORTALITY REDUCTION

Cynosure Health CHANGE PACKAGE



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ABOUT CYNOSURE

Cynosure Health is a nonprofit organization that works with diverse stakeholders to accelerate spread, implementation, and sustainable improvement in healthcare quality. Although our work spans multiple sectors in topics such as collaborative learning and care management, we specialize in working with hospitals, clinicians, health systems, and community-based coalitions on federal and statewide initiatives, regional collaboratives, and local partnerships. For over two decades, the Cynosure team has played a key role in developing and spreading proven strategies to improve outcomes, and we are committed to fostering innovative solutions to health care's toughest challenges.

ABOUT THIS CHANGE PACKAGE

Change Packages developed by our team of experts are tools to translate evidence into action, to help health care improvement teams make patient care safer and improve outcomes. In this Change Package, you will find best practices and ideas to test from other high performing health organizations. It was developed with contributions from subject matter experts, literature review, and sharing from health care organizations that have successfully implemented the identified practices. This change package helps to translate the evidence into a menu of strategies, change concepts and specific actionable items that any hospital can implement based on need or for purposes of improving patient quality of life and care.

Cynosure Health Change Packages are organized around a topic-specific Driver Diagram. Driver Diagrams are utilized to identify, organize, and prioritize improvement activities. Each primary driver for improvement in this Change Package has accompanying ideas to test for hospitals seeking to improve outcomes.



PART 1: DEFINITION AND SCOPE

Current definition of harm topic: 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.¹

While Sepsis-3 definitions no longer recognize systemic inflammatory response syndrome (SIRS) criteria (sepsis is pro- and anti-inflammatory), the Surviving Sepsis Campaign and the Society of Critical Care Medicine suggest that in the presence of infection or suspected infection the SIRS criteria 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 change package. Additionally, sepsis syndrome and septicemia considered antiquated concepts.^{2,3}

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
- And receive prompt treatment when infection is suspected, including blood cultures and tailored antibiotics, and undergo further investigation for infection-related organ dysfunction.⁴

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 with systolic BP less than 90mmHg, signs of end-organ dysfunction, or lactate levels greater than 4mmol/L.

A new diagnostic tool accompanies Sepsis-3 definitions:

- **quickSOFA, or qSOFA (sequential [sepsis induced] organ failure assessment)** — consists of three simple parameters that clinicians can assess 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.^{5,6}

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.

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.⁷ The intent of these

bundles are 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.⁸

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

The “Hour 1 bundle” was released in 2018 and then rereleased in January of 2019 by the SSC with essential interventions from the 3 & 6 hour bundle elements:

1. Measure lactate level. Remeasure lactate if initial lactate elevated ($> 2\text{mmol/L}$).
2. Obtain blood cultures before administering antibiotics.
3. Administer broad-spectrum antibiotics.
4. Rapidly administer 30 mL/kg crystalloid for hypotension or lactate $\geq 4\text{ mmol/L}$.
5. Apply vasopressors if hypotensive during or after fluid resuscitation to maintain a mean arterial pressure $\geq 65\text{ mm Hg}$.

These elements encourage clinicians to act as quickly as possible to obtain blood cultures, administer broad spectrum antibiotics, initiate appropriate fluid resuscitation, measure lactate and begin vasopressors as indicated. *These interventions would ideally ALL BEGIN in the **first hour** from sepsis recognition but may not necessarily be completed in the first hour.*

Implementing the “Hour 1 Bundle” can be a catalyst to move your sepsis program to its ideal state.

COVID-19 has prompted a release of care guidelines for critical care patients from the Surviving Sepsis Campaign. These recommendations and the literature supporting the guidelines are dynamic. Here is the [link](#) for the latest information.

The Sepsis Change Package 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 ARISE⁹, ProMISe¹⁰ and ProCESS¹¹ 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 among optional methods to assess volume and dynamic fluid assessments are preferred (passive leg raise or echocardiogram). 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.¹²

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 13.¹³ 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 1 million patients each year in the United States.¹⁴ 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.¹⁵ Sepsis is not only expensive and prevalent; patients diagnosed with sepsis are estimated to have a mortality rate of 28 percent to 50 percent.¹⁶ 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.¹⁷ Tools and resources from the Sepsis Alliance are referenced throughout this change package.

PART 2: MEASUREMENT

A key component to making patient care safer in your hospital is to track your progress toward improvement. 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.

NATIONALLY RECOGNIZED MEASURES: PROCESS AND OUTCOME

Evaluation Measures

- 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: HOW TO IMPROVE

INVESTIGATE YOUR PROBLEM AND IMPLEMENT BEST PRACTICES

Driver Diagrams

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.

Suggested bundles and toolkits

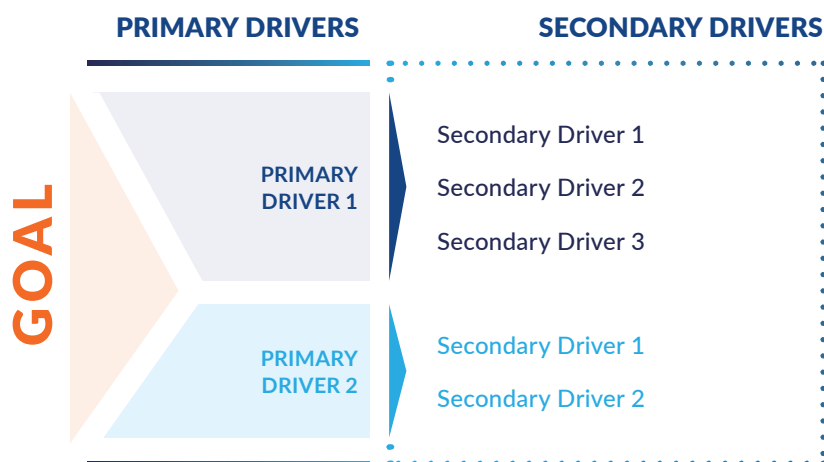
[Surviving Sepsis Campaign](#)

[Surviving Sepsis – three-hour and six-hour bundles](#)

[Surviving Sepsis Guidelines](#)

[IHI Information on Sepsis](#)

For key tools and resources related to preventing and reducing sepsis mortality, visit this [link](#).



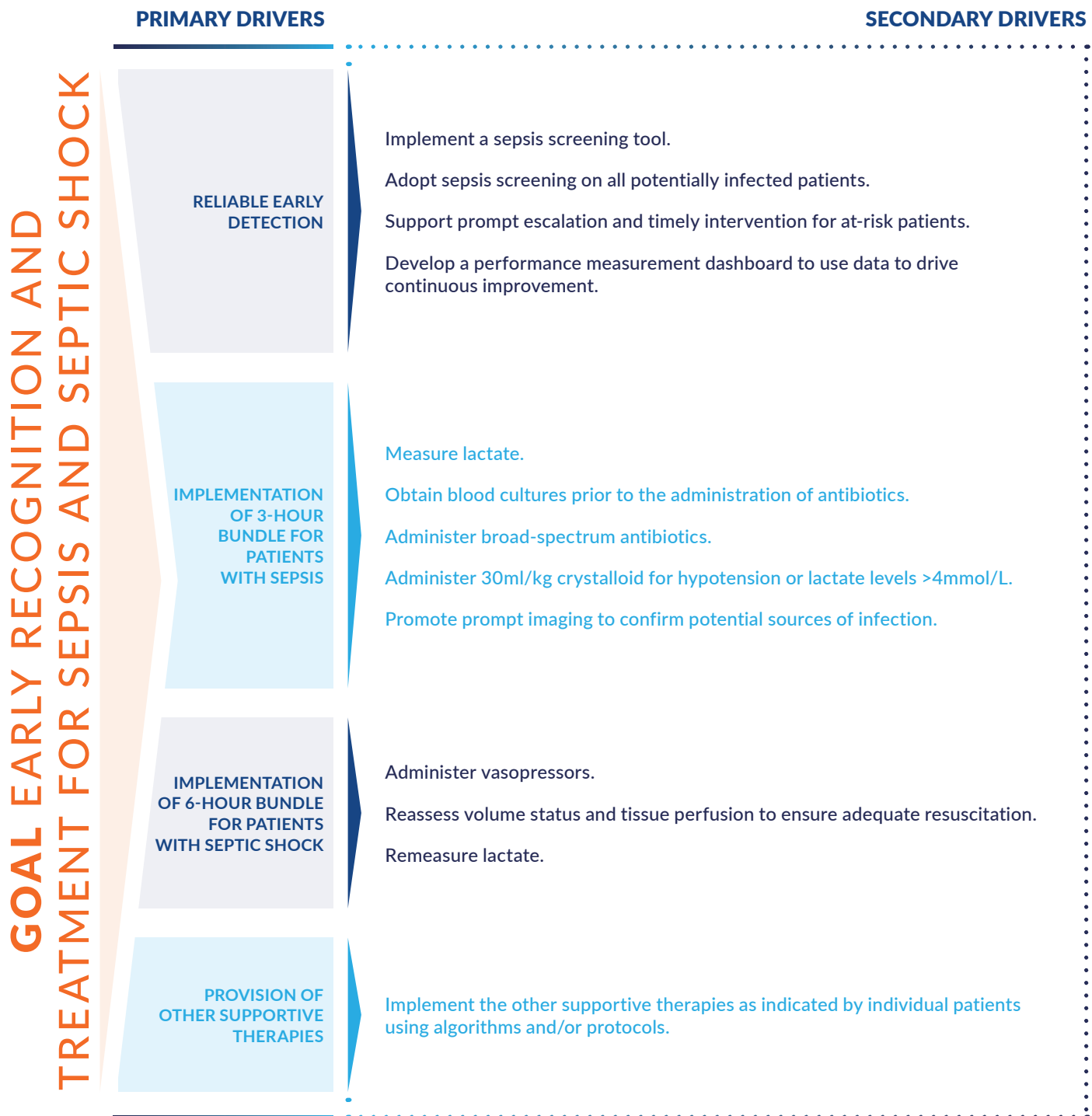
AIM: A clearly articulated goal or objective describing the desired outcome. It should be specific, measurable and time-bound.

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



Driver 1 RELIABLE EARLY DETECTION

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

SECONDARY DRIVERS IN THIS SECTION

1. **Implement a sepsis screening tool.**
2. **Adopt sepsis screening on all potentially infected patients.**
3. **Support prompt escalation and timely intervention for at-risk patients.**
4. **Develop a performance measurement dashboard to use data to drive continuous improvement.**

1. Implement a sepsis screening tool.

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 V**.
- Develop a reliable process for escalation of notification to and involvement by physicians and/or specialists.

2. Adopt sepsis screening on all potentially infected inpatients.

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.¹⁸

Change Ideas

Review medical records of readmitted patients for reason(s) and aggregate findings to prioritize efforts.

- 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.
- 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.
- 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.
- Use visual cues to identify patients who are positive for sepsis. See **Appendix V**.
- 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.

3. Support prompt escalation and timely intervention for at-risk patients.

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 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 V**.
- Implement a process for continuous performance feedback to physicians and staff.
- Standardize communication by using Situation, Background, Assessment and Recommendation (SBAR) and hand-off tools.
- 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.

Driver 2 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.¹⁹

SECONDARY DRIVERS IN THIS SECTION

1. Measure lactate.
2. Obtain blood cultures prior to the administration of antibiotics.
3. Administer broad-spectrum antibiotics.
4. Administer 30ml/kg crystalloid for hypotension or lactate levels >4mmol/L.
5. Promote prompt imaging to confirm potential sources of infection.

1. 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 (e.g., within minutes).²⁰

Change Ideas

- 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).
- 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.

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

3. 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.^{24,25,26}

Change Ideas

- Ensure pharmacy involvement in recommendations, supply, delivery and administration of antibiotics.
- 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.

4. Administer 30ml/kg crystalloid for hypotension or lactate levels >4mmol/L.

Patients with septic shock may experience ineffective arterial circulation due to vasodilation 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 using dynamic evaluation of successful fluid resuscitation such a passive leg raise or SVC filling with echocardiogram and the normalization of lactate levels.

Alternate targets could be a MAP >65mmHg and a HR <110 beats/minute without evidence of pulmonary edema.²⁷

Change Ideas

- 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.
- 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.

5. 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.²⁸

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

- Track 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
- Track 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.

Driver 3 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.

SECONDARY DRIVERS IN THIS SECTION

1. **Administer vasopressors.**
2. **Reassess volume status and tissue perfusion to ensure adequate resuscitation.**
3. **Remeasure lactate.**

1. 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.²⁹

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 V**.
- 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.

2. 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.³⁰

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 all nurses and physicians in the ED and the ICU.

- 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.
- Invest in monitoring equipment.
- 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.

3. 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.³¹

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 ≥ 4 mmol/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.

Driver 4 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.³²

SECONDARY DRIVERS IN THIS SECTION

1. Implement the other supportive therapies as indicated by individual patients using algorithms and/or protocols.

1. Implement the other supportive therapies as indicated by 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.
- Implement a process for performance feedback to physicians and staff.
- 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).

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.

COMMON CHALLENGES TO IMPROVEMENT

CHALLENGE 1

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.

CHALLENGE 2

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.” ^{33,34}

- 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.

SOLUTIONS

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 (e.g., nursing, pharmacy) assisting with bundle development and implementation can also advocate for the successful adoption and implementation of new ideas and change processes 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.

CONCLUSION & 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


- 1. Collect and analyze sepsis mortality data.
- 2. Gather a program planning team, including organizational leaders, physician champions, sepsis advisors and multidisciplinary members from the ED, ICU and med/surg, to develop a strategy for implementing improvement ideas.
- 3. Adopt a sepsis screening tool or system in the ED and/or in one inpatient department.
- 4. Screen every adult patient during initial evaluation in the ED and/or once a shift in one identified inpatient department.
- 5. Develop an alert mechanism to provide for prompt escalation and action from care providers with defined roles and responsibilities.
- 6. Develop a standard order set or protocol linking blood cultures and lactate lab draws (blood culture = lactate level) and ensure lactate results are available within 45 minutes. Consider a lactate of > 4mmol/L, a CRITICAL result to prompt notification.
- 7. Place broad-spectrum antibiotics in the ED medication delivery system to allow for antibiotic administration within 1 hour (collaborate with pharmacy and infectious disease for appropriate selection).
- 8. 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.
- 9. Develop a process for rapid fluid infusion of isotonic solution 30ml/kg for patients with septic shock for timely resuscitation.
- 10. Utilize a “time zero” method that also displays visual cues for the health care team for timing of interventions for the sepsis.

APPENDIX II: SUGGESTED ICU SEPSIS SCREENING TOOL

Associated Hospital/Organization: Saint 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>



SAINT
JOSEPH
MERCY
HEALTH SYSTEM

32011-021 R 1/16 (M)

St. Joseph Mercy Ann Arbor
St. Joseph Mercy Livingston

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.

	DATE:	TIME:			
I. SIRS-Systemic Inflammatory Response Syndrome (two or more of the following) current values:					
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 ³ or less than or equal to 4,000/mm ³ or greater than 0.5 K/uL bands (in last 24 hours)					
Negative screen for severe sepsis (Please initial)					
If check two of the above, move to II					
II. Infection (one or more of following):					
Suspected or documented infection					
Antibiotic Therapy (not prophylaxis)					
If check none of above – Negative screen for severe sepsis (Please initial) – answer infection question NO in I-View					
If check one of the above – answer infection question YES in I-View, obtain serum lactic acid per protocol and move to III					
III. Organ Dysfunction (change from baseline) (one or more of the following in an organ system distant from the infection)					
Respiratory: SaO ₂ less than 90% OR increasing O ₂ 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 2mEq/L					
Negative screen for severe sepsis (Please initial)					
If check one in section III or a severe sepsis alert fires, patient has screened positive for severe sepsis					
1. Call rapid response team					
2. Call physician, physician assistant or nurse practitioner and implement urgent measures protocol.					
3. Initiate or ensure IV access (2 large bore IV's if no central access)					
4. Obtain a venous blood gas (peripheral draw), serum 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.					

SEPSIS INDUCED HYPOPERFUSION?
(Clinical picture of severe sepsis plus one or both of the following criteria)
1. Hypotension AFTER initial fluid bolus (30 ml/kg)
OR
2. Require vasopressor
OR
3. Initial lactic acid greater than or equal to 4 mEq/L with any BP

NO

For lactic acid 2-2.9

Initiate **General Care Severe Sepsis Bundle** on back and complete interventions

YES

Activate **CODE SEPSIS**

Initiate transfer to ICU


Meanwhile, continue crystalloid resuscitation of 250-1000ml boluses if hypotensive after the initial bolus – per physician order

Initiate the **Septic Shock Clinical Pathway** on back and complete interventions

NO

For lactic acid 3-3.9 or initial hypotension that responded to the 30 ml/kg fluid bolus, initiate transfer to IMC

Initiate **Intermediate Care Severe Sepsis Bundle** on back and complete interventions.



* A A 1 5 4 6 *

RN Signature, Initial 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 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?

- | | | |
|---|--|---|
| <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 the following signs & symptoms of infection both present and new to the patient? Note: laboratory values may have been obtained for inpatients but may not be available for outpatients.

- | | | |
|--|--|---|
| <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 μ L ⁻¹) | |
| <input type="checkbox"/> Altered mental status | <input type="checkbox"/> Leukopenia (WBC count < 4000 μ L ⁻¹) | |
| <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 μ 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.

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

Sepsis Screen Notes

1) 2 or more new
SIRS Criteria met?

Yes

No

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?

Yes, confirmed source identified

Pending more information

Potential infection suspected, source not ide ...

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

Yes

No

Awaiting more data

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:

Called/Notified Physician

Called Rapid Response Team

Physician already aware

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 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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