Actionable Patient Safety Solution (APSS) #9:
EARLY DETECTION & TREATMENT OF SEPSIS

Executive Summary Checklist

☐ Commitment from hospital governance and senior administrative leadership to support early detection and appropriate management of sepsis in their healthcare system.

☐ Develop a team approach to implement a protocol for early sepsis identification and treatment.

☐ Create a sepsis dashboard for your organization’s leadership.

☐ Implement a Sepsis Rapid Response Team or incorporate early detection of sepsis into your existing medical emergency teams (e.g. rapid response teams).

☐ Formalize processes to screen patients for signs of sepsis throughout the entire institution.

☐ Implement an effective monitoring system to accomplish continuous monitoring and early detection, based on acute changes to patient data.

☐ Select an EHR or leverage the existing EHR to serve as a data collection tool and repository for predicting risk of sepsis for patients. A system that provides a data collection tool and allows for continuous analysis and surveillance will be most beneficial.

☐ Implementation of automated electronic screening and documentation of process of care based on existing data (SIRS criteria, MEWS or any other warning system being used).

☐ Design a workflow specific to level of alert
  ● qSOFA or SIRS met – assess for infection
    ○ SIRS: temperature >38.3°C or <36°C, heart rate >90 beats/min, respiratory rate >20 breaths/min, white blood cell count >12,000 μL (or 12 K/μL) or <4000 μL (or 4 K/μL)
    ○ qSOFA: altered mental status, elevated respiratory rate, decreased blood pressure
  ● If patient has sepsis – increase monitoring or assessment for presence of severe sepsis
    ○ Signs of organ dysfunction/tissue hypoperfusion: systolic blood pressure <90 mmHg or decrease >40 mmHg from baseline, mean arterial pressure <70 mmHg, skin changes (mottling) or prolonged capillary-refill time, or lactate >2 mmol/L
    ○ Acutely altered mental status
    ○ Pulmonary infiltrates with increasing oxygen requirements to maintain SpO2 >90%
    ○ Decrease in urine output or acutely increased creatinine
    ○ Bilirubin >2 mg/dL
    ○ Platelet count <100,000/μL (or 100 K/μL) or coagulopathy

☐ Implement a process for continuous monitoring of electronic systems and protocols
  ● Compliance, efficacy and outcome measures

☐ Implement case reviews for outliers

☐ Treatment/Interventions
  ● For severe sepsis implement workflow for rapid assessment and intervention at the bedside and initiate severe sepsis bundle (3 hour elements)
• For septic shock implement workflow checklist for rapid assessment, intervention and need for higher level of care and initiate septic shock bundle (6 hour elements)
The Performance Gap

Sepsis is a growing threat worldwide. The U.S. Centers for Disease Control and Prevention have reported that sepsis cases have increased in the U.S. from 621,000 in the year 2000 up to 1,141,000 in 2008.¹ According to the World Sepsis Day Newsletter, “Preventing infections and fighting Sepsis to save 800,000 lives each year.”² At least 10 to 15% of sepsis deaths are avoidable by: vaccination, hygienic measures, early detection, and prompt treatment measures. Hospitals and healthcare institutions need to do all that is practicable to eliminate hospital-acquired infections.²

Sepsis is the most common cause of death in U.S. hospitals and nearly 15% of all sepsis deaths are preventable. Severe sepsis is estimated to affect 750,000 people annually in the U.S. and the infection has a 28.6 percent mortality rate. It kills more people than stroke and pneumonia.³ Nationally, mortality rates for sepsis cases entering the hospital through the emergency department range from 20 percent to more than 50 percent.³ Sepsis is a clinical syndrome with a continuum of increasingly severe manifestations. While a unified definition of sepsis remains in evolution, the term refers to the body’s response to an infection that has moved beyond localized tissue to become systemic inflammatory response syndrome (SIRS). In SIRS, signs and symptoms result from systemic activation of the immune response to an infection or an injury (such as trauma or acute pancreatitis). SIRS manifestations include tachycardia, tachypnea or hyperventilation, body-temperature changes, and leukocytosis or leukopenia.³ Unless identified and treated early, sepsis can progress to severe sepsis, which is defined by the presence of end organ dysfunction or tissue hypo-perfusion. Septic shock, at the far end of the sepsis continuum, is defined by persistent hypotension even after fluid resuscitation.

Early detection of sepsis, with the timely administration of appropriate fluids and antibiotics, appear to be the single most important factors in reducing morbidity and mortality from sepsis. It has become increasingly apparent that there is a long delay in both the recognition of sepsis and the initiation of appropriate therapy in many patients. This translates into an increased incidence of progressive organ failure and a higher mortality. Healthcare providers, therefore, need to have a high index of suspicion for the presence of sepsis and must begin appropriate interventions quickly. Early treatment of sepsis, severe sepsis, or septic shock with quantitative fluid resuscitation has been shown to improve patient outcomes in multiple studies,⁴⁵ as has early treatment with antibiotics;⁶⁷⁸ however, to attain the greatest benefit from these therapies, sepsis must be identified as early as possible in its course. Multiple instruments have been developed to screen for sepsis.

The Evaluation for Severe Sepsis Screening Tool, developed by the Surviving Sepsis Campaign and the Institute for Healthcare Improvement, consists of several components: ⁹

- A suspected or confirmed infection: checklist of common sites of infection
- Signs/symptoms of SIRS: temperature >38.3°C or <36°C, heart rate >90 beats/min, respiratory rate >20 breaths/min, acutely altered mental status, white blood cell count >12,000 μL (or 12 K/μL) or <4000 μL (or 4 K/μL)
- Signs of organ dysfunction/tissue hypoperfusion: systolic blood pressure <90 mmHg or decrease >40 mmHg from baseline, mean arterial pressure <70 mmHg, pulmonary infiltrates with increasing oxygen requirements to maintain SpO2 >90%, creatinine >2.0 mg/dL, bilirubin >2 mg/dL, platelet count <100,000/μL (or 100 K/μL), coagulopathy, or lactate >2 mmol/L
- Decrease in urine output and skin changes (mottling) or prolonged capillary-refill time.

A team approach is essential to developing a protocol for sepsis identification and treatment in the patient care unit/department/hospital. Early intervention in sepsis has been found to improve patient outcomes and mortality rates, but relies on completion of screening for rapid identification and communication of the results to the team members who can initiate appropriate treatments. It is the care delivered by the multidisciplinary team that is effective in improving patient outcomes.

**Leadership Plan**

The plan should include fundamentals of change outlined in the National Quality Forum safe practices, including awareness, accountability, ability, and action. ⁷

- Identify: Hospital governance and senior administrative leadership must commit to become aware of their current performance regarding early detection and early appropriate management in their own healthcare system.
  - A questionnaire has been developed so that leadership can gauge their level of readiness for a Sepsis Early Detection & Treatment Program (Appendix A).
- Plan: Hospital governance, senior administrative leadership, and clinical/safety leadership must close their own performance gap by implementing a comprehensive approach to addressing the performance gap (Strategy to Evaluation).
- Timeline set: A goal date should be set to implement the plan to address the gap with measurable quality indicators - “Some is not a number. Soon is not a time.”
- Resources allocated: Specific budget allocations for the plan should be evaluated by governance boards and senior administrative leaders.
- Systems leadership and engagement: Clinical/safety leadership should endorse the plan and drive implementation across all providers and systems.
- An effective sepsis program should include the training of prehospital personnel and the development of prehospital care protocols.

**Practice Plan**

**Screening/Surveillance:**

- Formally assess opportunities to identify sepsis and to improve outcomes for those patients that acquire and are at risk for sepsis. Implement strategies that will identify an early sepsis warning.
- Implement systematic protocols for early identification and time-sensitive evidence-based treatment of sepsis.
- Implement an effective monitoring system to accomplish continuous monitoring and notification based upon acute changes of the following data (1); ¹
  - qSOFA score
  - Fever (> 38.3°C);

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○ Hypothermia (temperature < 36°C);
○ Heart rate > 90/min or 1 or more than two standard deviations above the normal value for age;
○ Tachypnea (RR > 20)
○ Altered mental status;
○ Hyperglycemia (plasma glucose > 140 mg/dL or 7.7 mmol/L) in the absence of diabetes;
○ Leukocytosis (WBC count > 12,000 μL−1);
○ Leukopenia (WBC count < 4000 μL−1);
○ Normal WBC count with greater than 10% immature forms;
○ Plasma C-reactive protein more than two standard deviations above the normal value;
○ Plasma procalcitonin more than two standard deviations above the normal value;
○ Hypotension (SBP < 90 mm Hg, MAP < 70 mmHg, or an SBP decrease > 40 mmHg in adults or less than two standard deviations below normal for age);
○ Hypoxemia (Pao2 < 60 mmHg or Sp02 < 90%)
○ Acute oliguria (urine output < 0.5 mL/kg/hr. for at least 2 hrs. despite adequate fluid resuscitation);
○ Creatinine increase > 0.5 mg/dL. or 44.2 μmol/L;
○ Coagulation abnormalities (INR > 1.5 or aPTT > 60 sec);
○ Thrombocytopenia (platelet count < 100,000 μL−1);
○ Hyperbilirubinemia (plasma total bilirubin > 4 mg/dL or 70 μmol/L);
○ Hyperlactatemia (> 2 mmol/L);
○ Prolonged capillary refill time or mottling.
○ EtCO2 (< 25mmHg)

● Distribute the above “sepsis detection checklist” to all hospital care areas.
● Adhere to the Surviving Sepsis Campaign practices as noted by the Society of Critical Care Medicine.9
● Formalize a process to screen patients for signs of sepsis throughout the entire institution.
● Formalize workflows for clinicians to adhere to after a patient sepsis alert has been noted.
● Implement a sepsis response team or incorporate early detection of sepsis into existing medical emergency teams (e.g. rapid response teams)
  ○ Identify the opportunities for implementation of a sepsis response team and protocol for initiating a sepsis response call for patients who have been identified as potentially septic.
● Implement standardized protocols for patient/family engagement/communication:
  ○ Coordinate with family or caregiver to reduce sepsis risk factors and identify clinical indicators at first sign;
  ○ Disclose all sepsis related events;
  ○ Provide an explanation as to why/how the sepsis occurred;
  ○ Explain how the effects of sepsis will be minimized; and
  ○ Discuss/state steps that the caregiver or organization will take to prevent recurrences of sepsis.

Treatment/Intervention:
● For severe sepsis implement workflow for rapid assessment and intervention at the bedside and initiate severe sepsis bundle (3 hour elements)
  ○ Measure lactate level and base deficit
  ○ Obtain blood cultures prior to administration of antibiotics
  ○ Administer broad spectrum antibiotics
  ○ Administer 30 mL/kg Crystalloid for hypotension or lactate ≥4 mmol/L
  ○ Remeasure lactate if initial lactate was elevated
● For septic shock implement workflow checklist for rapid assessment, intervention and need for higher level of care and initiate septic shock bundle (6 hour elements)
  ○ Apply vasopressors (for hypotension that does not respond to initial fluid resuscitation to maintain a mean arterial pressure (MAP) ≥65 mm Hg)
  ○ In the event of persistent hypotension despite volume resuscitation (Septic Shock) or initial lactate ≥4 mmol/L (36 mg/dL):
    ■ Measure central venous pressure (CVP)
    ■ Measure central venous oxygen saturation (ScvO2)
    ■ Measure PVI (Pleth Variability Index)
○ Remeasure lactate if initial lactate was elevated

Technology Plan

Suggested technologies are limited to those proven to show benefit or are the only known technologies with a particular capability. Other technology options may exist or emerge after the publication of this APSS, please send information on any additional technologies, along with appropriate evidence, to info@patientsafetymovement.org.

● Electronic Health Record (EHR)
  ○ Web-based/EHR predictive algorithms that elicit specific data such as but not limited to vital signs (BP, Temp, HR, RR, and SpO2) lab values, nurses notes, and event reports.
  ○ EHR serves as a data collection tool and repository for predicting risk of sepsis for patients. A system that provides a data collection tool that allows for continuous analysis and surveillance could be most beneficial.
  ○ System must be able to identify SIRS criteria and offer clinical decision support (CDS) to healthcare professionals (such as EPIC system developed collaboratively with UCSF or Cerner implementation at Intermountain Healthcare).

● Continuous pulse oximetry:
  ○ Adhesive pulse oximetry sensor connected with pulse oximetry technology proven to accurately measure through motion and low perfusion to avoid false alarms and detect true physiologic events, with added importance in care areas without minimal direct surveillance of patients (Masimo SET® pulse oximetry, in a standalone bedside device or integrated in one of over 100 multi-parameter bedside monitors).
  ○ Remote monitoring and notification system
  ○ Remote monitoring with direct clinician alert capability compatible with pulse oximetry technology compatible with recommended pulse oximetry technology (Masimo Patient Safety Net™, or comparable multi-parameter monitoring system)
  ○ Direct clinician alert through dedicated paging systems or hospital notification system.

● Network
  ○ Medical-grade wireless network suitable to permit reliable, continuous remote monitoring and documentation during ambulation and/or transport.
  ■ Alternatively, a wired network can be used which allows surveillance of patients while they are in bed but not while they are ambulating.

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Patient Engagement

Current strategies to reduce loss of life from sepsis focus on data collection and analysis to establish life-saving protocols. This logical starting point must evolve quickly to seek innovative ways to engage patients and families as safety partners.

Health care advocates have long supported patient education and engagement as a means to reduce the incidence of all medical events, including sepsis. A significant struggle is the public’s lack of awareness of the existence and the prevalence of sepsis, which hinders their ability to recognize and report early signs of the disease.

The public desperately needs resources to provide information and support to help them assist in efforts to screen, prevent, recognize, diagnose and to pursue evidence-based intervention and treatment. Those afflicted and their loved ones need assistance in coping during the immediate recovery period and in knowing what to expect during the oftentimes protracted post-sepsis healing process.

A foundation of information is needed in conjunction with public awareness campaigns. Helping the public develop basic skills and confidence and providing them with appropriate support both during and after a sepsis diagnosis is the key to reducing the injuries and deaths from sepsis. To achieve these goals, public involvement in the initial strategic efforts must be an integral part of developing sepsis protocols.

Sepsis Resources for the Public:

- Resources for those diagnosed with sepsis: [http://www.sepsis.org/resources/diagnosed_with_sepsis/](http://www.sepsis.org/resources/diagnosed_with_sepsis/)
- If a loved one has sepsis: [http://www.sepsis.org/resources/how_to_help/](http://www.sepsis.org/resources/how_to_help/)
- Life after sepsis [http://www.sepsis.org/life_after_sepsis/](http://www.sepsis.org/life_after_sepsis/)
- Faces of Sepsis video from Sepsis Alliance [http://www.sepsis.org/resources/](http://www.sepsis.org/resources/)
- Patient Safety Movement Sepsis video [https://vimeo.com/115035782](https://vimeo.com/115035782)
- Sepsis resources from the CDC [http://www.cdc.gov/sepsis/basic/](http://www.cdc.gov/sepsis/basic/)
Metrics

Topic:

Sepsis Mortality Rate
Rate of mortality for severe sepsis and/or septic shock patients per 1000 patients with severe sepsis and/or septic shock.

Outcome Measure Formula:
Numerator: Number of inpatient mortalities for patients with severe sepsis and/or septic shock
Denominator: Total number of patients with severe sepsis and/or septic shock diagnosis codes that are admitted to the intensive care unit from the emergency department or from an acute floor setting.

*Rate is typically displayed as Mortalities/1000 Patients

Metric Recommendations:

Direct Impact:
All patients with severe sepsis and/or septic shock

Lives Spared Harm:

\[ \text{Lives} = (\text{Mortality Rate}_{\text{baseline}} - \text{Mortality Rate}_{\text{measurement}}) \times \text{Patients}_{\text{baseline}} \]

*Patients_{baseline}: the total number of patients that are counted with the diagnosis of severe sepsis and/or septic shock.

Notes:
Patients with severe sepsis and/or septic shock are determined by the following ICD9 diagnosis codes:
995.92 (Severe Sepsis)
785.52 (Septic Shock)
Additionally, patients must be admitted to the intensive care unit from the emergency department or from an acute floor setting. If feasible, manual review of diagnosis codes is desirable due to the complex nature of sepsis.

If manual review is feasible, consideration may be given to include an ICD9 diagnosis code: 995.91 (Sepsis) with an additional diagnosis for acute organ failure.

Data Collection:
Data may be pulled from electronic billing data with the above diagnosis codes. Additionally, data may be collected exclusively through manual chart review, or a hybrid method of chart review and electronic billing data.

Limitations:
Sepsis mortality rates are derived by healthcare organizations differently. We recommend risk adjusting the outcome measure, in this case mortality, and consider exclusion criteria such as: DNR status, comfort care as goal of care established.

Settings:
Intensive care units, emergency department, and acute floor settings

Mortality (will be calculated by the Patient Safety Movement Foundation):
The PSMF, when available, will use the mortality rates associated with Hospital Acquired Conditions targeted in
the Partnership for Patient’s grant funded Hospital Engagement Networks (HEN). The program targeted 10 hospital acquired conditions to reduce medical harm and costs of care. “At the outset of the PIP initiative, HHS agencies contributed their expertise to developing a measurement strategy by which to track national progress in patient safety—both in general and specifically related to the preventable HACs being addressed by the PIP. In conjunction with CMS’s overall leadership of the PIP, AHRQ has helped coordinate development and use of the national measurement strategy. The results using this national measurement strategy have been referred to as the “AHRQ National Scorecard,” which provides summary data on the national HAC rate.\textsuperscript{13}

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\textbf{Conflicts of Interest Disclosure:}
*This Workgroup member has reported a financial interest in an organization that provides a medical product or technology recommended in the Technology Plan for this APSS.

Appendix A: Questionnaire

Sepsis Early Detection and Treatment Program Questionnaire

Organization query
1. Demographics: hospital bed count; type: community, academic; Electronic Health Record vendor
   a. Does your hospital have a defined sepsis program? Y/N
   b. Is there dedicated staff to lead the sepsis program? Y/N
   c. What department is the program housed within? Quality, Nursing, Central hospital administration, others?
2. Are there dedicated resources for a Sepsis Program/Sepsis as quality measure?
   a. Does your hospital have a defined sepsis program? Y/N
   b. Is there dedicated staff to lead the sepsis program? Y/N
   c. What department is the program housed within? Quality, Nursing, Central hospital administration, others?
3. Is there ongoing formal sepsis education offered for
   a. Nurses
   b. Physicians, NPs/PAs
   c. Allied health team members (Pharmacists, Rehab Therapists, Respiratory Therapists, et al)

Sepsis Screening/Surveillance
1. Does your hospital have a standardized surveillance or routine screening process for early detection of sepsis, severe sepsis, and/or septic shock? Y/N/NA
   a. Locations that have standardized surveillance: ED, Urgent care, Acute care, transitional care, ICU, other
   b. Is there automated continuous surveillance of data in electronic health record? Y/N
      i. Who receives alerts? –RN, MD, Pharmacy, Rapid response clinicians others, all
      ii. What action does the alert prompt/activate? Notification instructions, bringing clinicians to see patient, orders for care diagnostics or interventions other
   c. Is there intermittent routine screening by clinicians/nurses using a standardized process e.g. sepsis checklist, section of assessment flow-sheet, etc?
      i. What is the frequency of intermittent screening? Every 8 hrs, 12 hrs, 24 hrs, and/or PRN change in patient condition
      ii. What action does the intermittent screening result prompt/activate? Notification instructions, bringing clinicians to see patient, orders for care diagnostics or interventions, other
2. Does your Emergency Department have an active surveillance or routine screening process for early detection of sepsis, severe sepsis, septic shock? Y/N/NA
   a. If yes, is it electronic-based? Y/N
3. Does your Urgent Care Department have an active surveillance or routine screening process for early detection of sepsis, severe sepsis, septic shock? Y/N/NA
   a. If yes, is it electronic-based? Y/N

Sepsis management
1. Does your hospital have a standardized sepsis care bundle as part of a protocol, policy, order set? Y/N/NA
   a. If yes, see below:
      i. Which of the following are included in your sepsis care bundle?
         1. Obtain lactate level
         2. Obtain blood cultures/other cultures (urine, CSF, wound, etc) before antimicrobial agent administration
         3. Administer broad-spectrum antimicrobial agents within 1 hour of time of presentation (for inpatients) or within 3 hours of time of presentation (for ED patients)
         4. Administer IV fluid challenge for hypotension or lactate $\geq 4 \text{ mmol/L}$
5. Administer vasopressor medications to maintain MAP ≥ 65 mmHg after IV fluid challenge and within 6 hours of time of presentation

6. Obtain a follow up lactate level if initial lactate was elevated (>2), to evaluate resuscitation interventions (Target is normalization of lactate level)

7. If persistent hypotension, after 1-hour from completion of the 30 mL/kg IV fluid challenge resuscitation or lactate ≥ 4 mmol/L, measure CVP and/or Scv02 levels (Target is CVP 8-12 mmHg, Scv02 of ≥70% -these targets are being debated based on recent trial results – ARISE, PROCESS, PROMISE)

Measurement – What are the metrics used? What are the measurement procedures (manual, automated reports, etc)? Where is measurement data reported to?

1. Screening compliance, screening tool accuracy (sensitivity/specificity)
2. Sepsis care/management bundle compliance
   a. CMS National Hospital Inpatient Quality Measure
   b. Reporting based on hospital discharges October 2015
3. Outcomes
   a. Sepsis-associated mortality (hospital)

Patient/Family Engagement

1. Are materials or resources (website, classes, pamphlets, videos, etc) available for patients and families regarding:
   a. Sepsis – what it is, risks, prevention, early detection, management, possible trajectory (ICU, post-ICU), outcomes – post-hospital resources
      i. How you, as the patient or family member, can participate in prevention and early detection
   b. The hospital’s sepsis program – what, when, who, etc? e.g. screening, code sepsis, etc
   c. For hospitals without a sepsis program – Do you have a rapid response team or a Condition H program?
   d. Is your rapid response or Condition H also patient-activated?
   e. How are patients and families alerted and oriented to the rapid response system?
   f. Which provider or department is the contact point if the patient or family suspects infection or sepsis after discharge?