



**Stony Brook Medicine
Severe Sepsis/Septic Shock
Recognition and Treatment Protocols**

Subject: Severe Sepsis/Septic Shock	Published Date: August 9, 2013
Scope: Hospital Wide	Original Creation Date: August 9, 2013

Protocol:

The institution of evidence-based early recognition and invasive/non-invasive treatment guidelines for severe sepsis and septic shock through active surveillance screening, via both electronic and staff observation tools, regarding patients presenting on admission through our Emergency Department and those developing nosocomial infections or suspected infections within our inpatient units at Stony Brook University Medical Center. Treatment guidelines follow those recommended by the Surviving Sepsis Campaign, a workgroup of the Society for Critical Care Medicine and the European Society of Intensive Care Medicine and are updated accordingly. Pediatric protocols are also consistent with American College of Critical Care Medicine guidelines. Stony Brook University Hospital is a level 3 tertiary care hospital. All patients are treated on-site as we provide the highest level of care.

Definitions:

Surviving Sepsis Campaign: An international collaborative recommending resuscitation and management care bundles for the recognition and treatment of severe sepsis/septic shock. Recommendations were first published as in *Critical Care Medicine*, Mar 2004.

SIRS (Systemic inflammatory response syndrome): The clinical syndrome that results from a deregulated inflammatory response or to a noninfectious insult.

Sepsis: SIRS that is secondary to infection that has been diagnosed clinically. Positive cultures add to the validity but are not required for the diagnosis.

Severe Sepsis: Sepsis plus at least one sign of hypoperfusion or organ dysfunction (see below), that is new, and not explained by other known etiology of organ dysfunction.

Septic Shock: Severe sepsis associated with refractory hypotension (BP<90/60) despite adequate fluid resuscitation and/or a serum lactate level ≥ 4.0 mmol/L.

Rapid Response Team: A team of qualified clinicians that respond to a perceived change in, or deterioration of, the condition of patients by bringing critical care expertise to the bedside.

Presentation Time: Initial time of recognition of severe sepsis (SIRS and organ dysfunction). Emergency Department presentation is judged to be a patient's triage time unless clinically evidenced otherwise. All other presentations rely on a time at which signs, symptoms, and laboratory findings are first consistent with the above definitions of severe sepsis/septic shock.

Practice Protocols:

I. Recognition

A. Criteria

Adult

Adult screening criteria and protocols are applied to patients housed in our adult units.

Sepsis is defined as at least two of the following signs and symptoms (SIRS) that are both present and new to the patient and suspicion of new infection:

- Hyperthermia >38.3°C or Hypothermia <36°C
- Tachycardia >90 bpm
- Leukocytosis (>12,000 μL^{-1}) or Leukopenia (<4,000 μL^{-1}) or >10% bands.
- Acutely Altered Mental Status
- Tachypnea >20 bpm
- Hyperglycemia (>120 mg/dl) in the absence of diabetes

Severe sepsis includes SIRS and at least one of the following signs of hypoperfusion or organ dysfunction that is new and not explained by other known etiology of organ dysfunction:

- Hypotension (<90/60 or MAP <65)
- Areas of mottled skin or capillary refill ≥ 3 seconds
- Disseminated intravascular coagulation (DIC)
- Acute renal failure or urine output <0.5 ml/kg/hr for at least 2 hours
- Cardiac dysfunction
- Lactate >2
- Creatinine >2.0 mg/dl
- Platelet count <100,000
- Hepatic dysfunction as evidenced by Bilirubin >2 or INR >1.5
- Acute lung injury or ARDS

New septic shock is defined as severe sepsis associated with refractory hypotension (BP<90/60) despite adequate fluid resuscitation and/or a serum lactate level ≥ 4.0 mmol/L.

Pediatric

Pediatric screening criteria and protocols are applied to patients housed in our pediatric units, and patients ≤ 18 years old in our emergency department.

Pediatric age-specific SIRS criteria

Age Group	Heart Rates, Beats/Min ^{b,c}			Leukocyte Count	
	Tachycardia	Bradycardia	Respiratory Rate	Leukocytes X 10 ³ /mm ^{3b,c}	Hypotension, mm Hg
0 days to 1 wk	>180	<100	>60	>34	<59
1 wk to 1 mo	>180	<100	>50	>19.5 OR <5	<75
1 mo to	>180	<90	>35	>17.5 OR <5	<75

	Heart Rates, Beats/Min ^{b,c}		Leukocyte Count		
<2 yrs					
2-5 yrs	>140	Not applicable	>30	>15.5 OR <6	<75
6-12 yrs	>130	Not applicable	>20	>13.5 OR <4.5	<83
>12 yrs	>110	Not applicable	>20	>11 OR <4.5	<90

Severe sepsis includes SIRS and at least one of the following signs of hypoperfusion or organ dysfunction that is new and not explained by other known etiology of organ dysfunction:

- Hypotension < 5th percentile for age or systolic BP < 2 SD below normal age for age
- Need for vasoactive drug to maintain BP in normal range (dopamine >5 µg/kg/min or dobutamine, epinephrine at any dose)
- Two of the following:
 - Unexplained metabolic acidosis: base deficit > 5.0 mEq/L
 - Increased arterial lactate > times upper limit of normal
 - Oliguric: urine output <0.5 mL/kg/hr
 - Prolonged capillary refill: > 5 secs
 - Core to peripheral temperature gap > 3°C
- PAO₂/FIO₂ <300 in absence of cyanotic heart disease or preexisting lung disease
- PaCO₂ >65 torr or 20 mm Hg over baseline PaCO₂
- Proven need for >50% FIO₂ to maintain saturation ≥ 92%
- Need for nonelective invasive or noninvasive mechanical ventilation
- Glasgow Coma Score ≤11 (75)
- Acute change in mental status with a decrease in Glasgow Coma Score ≥3 points from abnormal baseline
- Platelet count < 80,000/mm³ or a decline of 50% in platelet count from highest value recorded over the past 3 days (for chronic hematology/oncology patients)
- International normalized ratio >2
- Serum creatinine ≥ 2 times upper limit of normal for age or 2-fold increase in baseline creatinine
- Total bilirubin ≥4 mg/dL (not applicable for newborn)
- ALT 2 times upper limit of normal for age

B. Screening Process

1. In the Emergency Department:

- a. Triage nurse assesses all patients for possible severe sepsis.
- b. If the patient exhibits SIRS criteria, and the triage RN suspects the patient may have severe sepsis, a check mark is placed in the EMR next to the field possible severe sepsis.

- c. Patients suspected of having severe sepsis are deemed level two and are evaluated by the physician for severe sepsis.

2. In the inpatient Units:

- a. Manual process: Patients are screened for severe sepsis upon admission and daily thereafter using our paper screening tool. Patients meeting severe sepsis criteria are faxed to the Quality Department for chart review.
- b. Automatic process: SBUH is in the process of deploying an automatic Sepsis Alert in the patient's electronic medical record based on recent patient vital signs, querying the record for signs of SIRS. Nursing and physician clinical judgment, determinations and pending treatment plan are documented within the alert.
 - 1. Electronic sepsis alert incorporates a perpetual 4 hour review of a patient's vital signs for abnormal or significant changes.
 - 2. An electronic sepsis screening tool is fired to the bedside nurse when the patient meets SIRS criteria.
 - 3. Upon answering and completion of the alert, the electronic review will desist for an 8 hour period.
 - 4. Our ICR and ICU alerts qualify SIRS criteria using a 20% increase in RR and HR from the last charted value, increasing specificity while ensuring sensitivity for a more critical population than the Medicine/Surgical units.
- c. The Rapid Response Team, operating throughout the hospital, includes an evaluation for severe sepsis with each response.

2. Treatment

A. Resuscitation

3-hour bundle - The below actions are to be taken within the first 6 hours of resuscitation upon initial recognition for adults and within 60 minutes upon initial recognition for pediatric patients.

- 1. Serum lactate measured within 3 hours of presentation.
- 2. Blood Cultures obtained prior to antibiotic administration to determine all potential site and source of infection.
- 3. Early and appropriate broad-spectrum antibiotic administration
Timely re-evaluation of antibiotic therapy based on causative agent and susceptibilities is recommended.
- 4. Initial fluid administration of 30 ml/kg crystalloid or colloid equivalent for hypotension or lactate >4 mmol/L (adults only). Initial fluid administration of 20 ml/kg crystalloid in children.

6- hour bundle - The actions below are to be taken within the first 6 hours of resuscitation upon initial recognition for adults and within 60 minutes upon initial recognition for pediatric patients. Treatment will follow one of two tracks, invasive or non-invasive, based on the

criticality and initial response to hemodynamic measures. The recommended bundle elements include:

1. Vasopressor therapy for persistent hypotension (MAP <65 in adults) despite initial fluid administration.
2. Re-measure lactate if the initial value was elevated.

Criteria for Invasive versus Noninvasive Protocol:

1. Invasive

a. A central venous catheter capable of hemodynamic measuring is inserted in a severely septic/septic shock patient in the first 6 hours after presentation if one or more of the below conditions are met*:

1. Patient exhibits persistent hypotension despite fluid resuscitation
2. Patient requires vasopressor therapy for hypotension
3. Inability to obtain adequate peripheral access in patient for fluid resuscitation, blood products, or medications.

*For massive fluid resuscitation consider cordis

2. Non-invasive

a. Contraindications to the above criteria include:

1. Patient is at risk for bleeding
2. Patient is too unstable/code imminent
3. Patient has a high risk of developing pneumothorax
4. Insertion of line would not change the course of treatment
5. Patient refuses to give consent
6. Vascular access is not possible (e.g., bilateral clots)

b. The trending of lactate levels to gauge fluid response is used with critical value alerts for lactates resulting >4 mmol/L and suggested serial trending within 2 hours of this critical result.

1. Lactate levels >4mmol/L in our ED require a Medical ICU consult.
2. Serial lactate trending goal to achieve a 10% decrease from an initial lactate value within 6 hours of presentation if the patient is to be transferred to a medical/surgical (non- critical care) unit.

B. Exclusion Criteria

1. Patients for whom the interventions in the protocol are clinically contraindicated.
2. Patients with advance directives in place at the time of care which preclude any of the protocol interventions.
3. Patients for whom the patient or surrogate decision maker declined or is unwilling to consent to such interventions.
4. Patients enrolled in IRB approved clinical trials for which trial interventions are inconsistent with established protocols.
5. Protocols for children exclude newborns and infants in the NICU.

3. Education

- A. Nursing Staff – Severe sepsis recognition and treatment training is incorporated into new employee orientation and annual recertification requirements.
- B. Resident, Licensed Independent Practitioner and Attending Staff – Severe sepsis recognition and treatment training: Residents are required to receive the training annually. LIPs and Attendings are required to receive the training prior to their reappointment. **Exceptions to this educational requirement include Pathologists, Speech Pathologists, Audiologists and Psychologists.**
- C. Pharmacy, Respiratory, and Laboratory Staff - Severe sepsis recognition and treatment training is incorporated into new employee orientation and annual recertification requirements.

4. Use of Technology

- a. Identification of Severe Sepsis - SBUH is in the process of deploying an automatic Sepsis Alert in the patient's electronic medical record based on recent patient vitals, querying the record for signs of SIRS. Nursing and physician clinical judgment, determinations and pending treatment plan is documented within the alert.
 - i. Electronic sepsis alert incorporates a perpetual 4 hour review of a patient's vital signs for abnormal or significantly changes.
 - ii. An electronic sepsis screening tool is fired to the bedside nurse when the patient meets SIRS criteria.
 - iii. Upon answering and completion of the alert, the electronic review will desist for an 8 hour period.
 - iv. Our ICR and ICU alerts qualify SIRS criteria using a 20% increase in RR and HR from the last charted value, increasing specificity while ensuring sensitivity for a more critical population than the Med/Surg units.
- b. Treatment - Sepsis electronic order sets exist for our Emergency Dept, Pediatric and Med/Surg units, and our ICUs and are electronically suggested for all patients meeting the suspicion criteria. All bundle elements are included in these plans including suggested vitals and labs, interventions and infusions, and antibiotic regimen based on suspected source of infection.
- c. Data Collection - Electronic reports containing patients coded for severe sepsis (ICD-9 Code 995.92) and septic shock (ICD-9 Code 785.52) are generated at least monthly. Data captured in discrete fields are to be automatically generated. Data not available in discrete fields are to be extracted manually.

References:

Dellinger, R. Phillip et al, *Surviving Sepsis Campaign: International Guidelines for Management of Severe Sepsis and Septic Shock: 2012*. Critical Care Medicine, Feb.2013, Vol.41, No2.

Goldstein, Brahm et al, *International pediatric sepsis consensus conference: Definitions for sepsis and organ dysfunction in pediatrics*. Pediatric Critical Care Medicine, 2005, Vol.6, No.1.