Northern Westchester Hospital
Medical Affairs

Subject: Sepsis Protocol

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PURPOSE: To provide the most effective evidence-based care to admitted/observed patients and patients presenting to the Emergency Department with signs and symptoms that may be related to severe sepsis or septic shock

DEFINITIONS:

- Sepsis – the probable or documented presence of infection together with systemic manifestations of infection (systemic inflammatory response syndrome)
  - Systemic inflammatory response syndrome in adults includes elevation of temperature (>100.4°F), abnormally low temperature (<96.8°F), elevated heart rate (>90/min), elevated respiratory rate (>20/min or $PaCO_2$<32mmHg) and abnormal leukocyte count (WBC <4,000, >12,000, or ≥ 10% bands)
  - Systemic inflammatory response syndrome in children includes elevation of temperature (>101.3°F), hypothermia (<96.8°F), or age-specific abnormalities in heart rate, respiratory rate, systolic blood pressure, and leukocyte count (as indicated in Pediatric SIRS Criteria Table below)

- Severe Sepsis - Adults – sepsis plus sepsis-induced organ dysfunction or hypoperfusion, as evidenced by any one of the following:
  - Sepsis-induced hypotension – systolic blood pressure (SBP) < 90 mmHg or mean arterial pressure (MAP) < 70 mmHg or a SBP decrease > 40 mmHg or less than two standard deviations below normal for age in the absence of other causes of hypotension
  - Organ dysfunction, which may include acute oliguria (urine output < 0.5mL/kg/hour for 2 or more hours), acute kidney injury (serum creatinine > 2.0 or at least a 50% increase from patient's baseline), elevated serum lactate (≥ 2.2), coagulopathy (Platelet count<100,000 or INR>1.5), serum bilirubin > 2, PaO_2/FIO_2 ratio < 300, or increasing oxygen demand to maintain O_2 saturation > 90%.

- Severe Sepsis – Pediatrics – sepsis plus one of the following:
  - Cardiovascular organ dysfunction
  - Acute respiratory distress syndrome (ARDS)
  - Two or more organ dysfunctions:
    - Hypotension
    - Prolonged capillary refill
    - Metabolic acidosis or elevated lactate
    - Need for >59% FiO_2 to maintain oxygen saturation > 92%
    - Glasgow coma score ≤ 11 or acute change in mental status
    - Platelet count < 80,000 or DIC
    - Oliguria or serum creatinine > 2 times upper limit of normal for age
    - Total bilirubin ≥ 4 mg/dl or ALT > 2 times upper limit for age

- Septic Shock – sepsis-induced hypotension persisting despite adequate fluid resuscitation

- Pediatric Population – six age groups are identified for age-specific vital signs.

PEDIATRIC SIRS CRITERIA TABLE					
AGE GROUP		**Heart Rate (beats/min)**	**Respiratory Rate (breaths/min)**	**SBP (mmHg)**	**Leukocyte Count ($x10^3$)**
Newborn	0 - 1 week	>180 or <100	>50	<59	>34.0
Neonate	1 wk to 1 month	>180 or <100	>40	<79	>19.5 or <5.0
Infant	1 month to 1 y	>180 or <90	>34	<75	>17.5 or <5.0
Toddler	1-5 y	>140	>22	<74	>15.5 or <6.0
School age	5-12 y	>130	>18	<83	>13.5 or <4.5
Adolescent	12-18 y	>110	>14	<90	>11.0 or <4.5

POLICY:

EARLY IDENTIFICATION

Potentially infected seriously ill patients will be routinely screened for severe sepsis to allow earlier implementation of therapy

1. Nursing Assessments performed periodically on admitted/observed adult patients and at triage of adult and pediatric patients presenting to the Emergency Department will allow for the early identification of possible severe sepsis or septic shock

2. For adult patients, any two (2) or more of the following, along with known or suspected infection, will be identified as possible sepsis:
   - Temperature >100.4°F or <96.8°F
   - Heart rate > 90 beats per minute
   - Respiratory rate > 20 breaths per minute
   - WBC>12,000, WBC<4,000, or bands>10%

3. For adult patients, any two (2) or more of the following, along with known or suspected infection, AND with a systolic blood pressure < 90mmHg or a mean arterial pressure < 60mmHg, will be identified as possible severe sepsis:
   - Temperature >100.4°F or <96.8°F
   - Heart rate > 90 beats per minute
   - Respiratory rate > 20 breaths per minute
   - WBC>12,000, WBC<4,000, or bands>10%

- Based on vital sign abnormalities, the electronic medical record will alert the nurse entering the vital signs about possible sepsis or severe sepsis, unless he/she has documented that the patient is already being treated for sepsis

- If at ED triage of adult or pediatric patients, an RN identifies possible sepsis, the RN will notify the ED physician

- If at ED triage of adult or pediatric patients, an RN identifies possible severe sepsis, the RN will active **Code Green**

- If on assessment of admitted/observed adult patients (age ≥ 18), an RN identifies possible sepsis, the RN will notify the patient's attending (covering) physician

- If on assessment of admitted/observed adult patients (age ≥ 18), an RN identifies possible severe sepsis, the RN will activate **RRT-Code Green**

4. For admitted/observed Pediatric patients (age < 18) who are seriously ill with any of the following signs, the Pediatric Nurse Manager or Charge Nurse will use Vocera and the paging system to notify the Pediatric Hospitalist or ED Physician, Administrative Supervisor, Respiratory Therapist, and IV team of the concern:

   Fever or hypothermia
   Tachycardia or bradycardia
   Tachypnea, bradypnea, or apnea
   Hypotension
   Decreased peripheral pulses compared with central pulses
   Mottled or cool extremities
   >3 second capillary refill time
   Dry mucus membranes, sunken eyes, decreased urine output
   Altered mental status (irritability, anxiety, confusion, lethargy, somnolence)

TREATMENT

INITIAL RESUSCIATION OF PEDIATRIC PATIENTS: (within 6 hours)

1. Physicians will follow one of the relevant evidence-based (ZYNX) order set protocols for the initial management of pediatric patients with possible severe sepsis or septic shock:

   - ED: Peds Sepsis (1m-18y)
     - Includes measuring serum lactate, obtaining blood cultures prior to administration of antibiotics, and when clinically or age-appropriate, obtaining cerebral spinal fluid by lumbar puncture
     - Includes guidelines for administration of a crystalloid fluid bolus of 20 ml/kg and continued IV fluids

- Includes guidelines for an initial dose of broad spectrum antibiotic therapy within 1 hour of recognition of severe sepsis or septic shock
- Includes initiation of dopamine to maintain SBP $\geq$ 90, in those patients who fail to respond to initial fluid resuscitation (septic shock)

2. After initial stabilization of blood pressure, as defined below, all pediatric patients with severe sepsis or septic shock will be transferred to the Pediatric Critical Care Unit of a tertiary care Children's Hospital.

Age Range	Target Systolic Blood Pressure
< 1 month	60 mmHg
1 month – 10 years	70 mmHg plus 2x age in years
10 years or older	90 mmHg

INITIAL RESUSCITATION OF ADULT PATIENTS: (within 6 hours)

1. Physicians will follow one of the relevant evidence-based (ZYNX) order set protocols for the initial management of adult patients with possible severe sepsis or septic shock:

- ED: Sepsis Code Green
  - Includes measuring serum lactate level and obtaining blood cultures prior to administration of antibiotics
  - Includes guidelines for administration of a crystalloid fluid challenge within 3 hours of recognition for hypotension or lactate $\geq$ 4 mmol/L
  - Includes guidelines for empiric broad spectrum antibiotics based on presumed source or pathogen, whenever possible to be administered within one (1) hour of recognition of severe sepsis or septic shock

- RRT Sepsis Code Green (for patients outside the ED, being treated for primary reasons other than sepsis)
  - Includes measuring serum lactate level and obtaining blood cultures prior to administration of antibiotics
  - Includes guidelines for administration of a crystalloid fluid challenge within 3 hours of recognition for hypotension or lactate $\geq$ 4 mmol/L with resuscitation targets
  - Includes guidelines for empiric broad spectrum antibiotics based on presumed source or pathogen, whenever possible to be administered within one (1) hour of recognition of severe sepsis or septic shock

- Sepsis: Admit ICU
  - Includes measuring serum lactate level at baseline and 6 hours later, obtaining blood cultures prior to administration of antibiotics
  - Includes guidelines for administration of a crystalloid fluid challenge within 3 hours of recognition for hypotension or lactate $\geq$ 4 mmol/L with resuscitation targets

- Includes guidelines for empiric broad spectrum antibiotics based on presumed source or pathogen, whenever possible to be administered within one (1) hour of recognition of severe sepsis or septic shock
- Includes guidelines for vasopressor therapy to maintain SBP ≥ 90, beginning with norepinephrine, in those patients who fail to respond to initial fluid resuscitation (septic shock)
- Includes consideration of albumin therapy in those who require substantial amounts of crystalloids
- Includes guidelines for VTE prophylaxis and stress ulcer prophylaxis to prevent upper GI bleeding
- Includes recommendation for oral or enteral feedings, if tolerated, rather than complete fasting or only IV glucose within the first 48 hours
- Includes guidelines for the appropriate use of insulin infusion (to maintain glucose < 180 mg/dl) and systemic corticosteroids in specific settings
- Includes a reminder to have a discussion with patient and/or family or surrogate decision maker as soon as practical regarding goals of treatment and likely outcomes

2. A non-invasive protocol will be followed; a central venous catheter need not be placed initially and may not be required in those who achieve and maintain an adequate response to a fluid challenge. The timing of central venous catheter insertion will be determined by the attending physician, and used at a minimum in those who do not maintain a response to fluid therapy and require vasopressors.

   - In adult patients without a central venous catheter, resuscitation targets will be SBP ≥ 90 mmHg (mean arterial pressure≥65 mmHg), urine output ≥ 0.5 mL/kg/hr, and normalization of serum lactate level in those with elevated serum lactate. All of the following must be documented on repeat physical exam regarding adequacy of resuscitation:
     - Complete set of vital signs (temperature, heart rate, blood pressure, and respiratory rate)
     - Heart and lung exam
     - Examination of peripheral pulses
     - Examination of capillary refill
     - Skin examination

   - In adult patients with a central venous catheter, resuscitation success will be determined by the above measures as well as a central venous pressure (CVP) 8-12 mmHg and central venous oxygen saturation of 70% or greater.

CONTINUED CARE OF ADULT PATIENTS

1. Empiric broad-spectrum antibiotics will be de-escalated to the most appropriate single therapy as soon as the susceptibility profile is known and ideally within the first 3-5 days of therapy.

2. Duration of antimicrobial therapy will be 7-10 days, but may be longer in those who have a delayed response to treatment, an undrainable source of infection, Staphylococcus aureus bacteremia, a fungal or viral cause of infection, or an immunologic deficiency.

3. Appropriate imaging studies will be performed in attempt to determine or confirm a potential source of infection.

4. Appropriate interventions will be undertaken for source control within 12 hours of diagnosis when possible, which may include percutaneous or surgical drainage of an abscess, surgical removal of necrotic or non-viable tissue, and removal of potentially infected medical devices. The plan for such interventions will involve prompt consultation with interventional radiology and or surgical specialists.

5. Hemoglobin target will be 7-9 g/dl in the absence of tissue hypoperfusion, coronary artery disease, or acute hemorrhage.

6. Respiratory care and ventilator management will be under the direction of the critical care pulmonologist, with consideration of low tidal volume, use of PEEP, and conservative fluids for ARDS and use of head of bed elevation (30-45°) when not contraindicated and protocols for weaning and sedation.

7. The care team will address goals of care, including treatment plans and end-of-life planning, as appropriate, within 72 hours of admission to the critical care unit.

EXCLUSIONS

The following patients are excluded from this sepsis protocol:

1. Patients for whom described interventions are clinically contraindicated
2. Patients with advanced directive in place and documented at the time of care which preclude any protocol interventions
3. Patients who decline or whose surrogate decision makers decline on their behalf any protocol interventions
4. Newborns, neonates, and infants who are in the Neonatal Intensive Care Unit (NICU)

TRAINING AND EDUCATION

1. The Quality Management Department will be responsible for oversight of the training and ongoing education of nursing staff regarding recognition and management of severe sepsis and septic shock. Such education will be part of the orientation of incoming nurses and minimally on an annual basis.
2. The Quality Management Department will be responsible for oversight of the training and ongoing education of pharmacy, laboratory, and imaging staff to facilitate their role

as part of the patient care team in managing patients with severe sepsis or septic shock. Such education will be part of the orientation of incoming staff and minimally on an annual basis.

3. The Chief Medical Officer, Chief of Emergency Medicine, and Medical Director of the Critical Care Unit will provide ongoing education to all physicians involved in the care of patients with severe sepsis and septic shock through periodic on-line education programs and education sessions at department and committee meetings.
4. All physicians and clinical staff have continuous access from any hospital computer to UP TO DATE to provide current information from published medical literature.
5. The Chief Medical Officer and Chief Medical Information Officer will ensure that computer-based order set protocols related to diagnosis and management of sepsis, severe sepsis, and septic shock are kept current using the ZYNX software product.

PERFORMANCE MEASURES

1. The following process measures will be collected on a quarterly basis for all patients with a diagnosis of "severe sepsis without septic shock" (R65.20), "severe sepsis with septic shock" (R65.21), or "postprocedural septic shock, initial encounter" (T81.12XA):

    - Evidence-based (ZYNX) order set protocol used (goal = 100%)
    - Serum lactate measured at baseline (goal = 100%)
    - Serum lactate measured 6 hours after initial (goal = 100%) (exclude if initial lactate not elevated $\geq$ 2.2 mmol/L or 18 mg/dl)
    - Time from presentation (triage in ED or assessment for admitted/observed patients) to serum lactate specimen taken (goal < 1 hour)
    - Time from serum lactate specimen taken to serum lactate result reported (goal < 2 hours)
    - Fluid bolus (30 ml/kg adults; 20 ml/kg pediatrics) administered if hypotension or lactate $\geq$ 4 mmol/L (goal = 100%)
    - Time from presentation to fluid bolus resuscitation (goal < 3 hours)
    - Time from presentation to first broad spectrum antibiotic administered (goal < 1 hour)
    - Blood cultures drawn prior to antibiotic administration (goal = 100%)
    - Broad spectrum IV antibiotics administered (goal = 100%)
    - Of those with hypotension:
        - % in which fluid resuscitation able to maintain SBP > 90
        - % in which vasopressors were required to maintain SBP > 90
    - Discharge disposition: home, SNF, mortality (stratified by diagnosis of severe sepsis and septic shock)

2. All performance measures will be stratified into the following populations:
    - Adults (age 18 and older) Emergency Department
    - Pediatrics (age < 18) Emergency Department
    - Adults Admitted/Observed
    - Pediatrics Admitted/Observed

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References:

Dellinger, RP et al. Surviving Sepsis Campaign: International Guidelines for Management of Severe Sepsis and Septic Shock: 2012. *Crit Care Med* 2013; 41:580-637

"Surviving Sepsis Campaign: Updated Bundles in Response to New Evidence," http://www.survivingsepsis.org/SiteCollectionDocuments/SSC.Bundle.pdf (October 5, 2015)

New York State Health Code 405.4(a)(4) Sepsis Regulations: Guidance Document, June, 2013

Approvals:

Chief Medical Officer 08/13, 11/15
Chief Nursing Officer 08/13
VP, Quality Management 08/13
Medical Director, Emergency Medicine 08/13
Medical Director, Critical Care Unit 08/13
Patient Care Director, Emergency Department 08/13
Patient Care Director, Medicine-Surgery 08/13
Patient Care Manager, Critical Care Unit 08/13
Medical Board 09/13