

Clinical Validation Guidelines

SEPSIS & SYSTEMIC INFLAMMATORY RESPONSE SYNDROME (SIRS)

Definition: a life-threatening dysregulated, systemic host response to an infection.

Diagnostic Criteria⁽¹⁻⁵⁾: To clinically validate the following diagnoses the listed criteria must be met AND the diagnosis must be documented by a physician in the medical records.

(R65.10 - R65.11) Systemic Inflammatory Response Syndrome (SIRS): (TWO or more of the following from Criteria #1- #4 + Criteria #5- #6 is needed to make the diagnosis)^(1,2):

- 1) WBC < 4 K or >12 K or Bands >10%
- 2) Temperature < 36°C (96.8°F) or >38°C (100.4°F)
- 3) Heart rate >90 bpm
- 4) Respiratory rate >20 breaths/min or PaCO₂ <32 mmHg
- 5) Non-infectious source is the underlying etiology (i.e. infection is ruled out)
- 6) Diagnostic criteria cannot be easily explained by another co-existing condition

(A41.9) Sepsis (ALL of the following Criteria #1 – Criteria #6 is needed to make the diagnosis):

- 1) Meets diagnostic criteria for SIRS (At least two of the four listed parameters with WBC or Temperature being at least one of the included parameters)
- 2) Diagnostic criteria cannot be easily explained by another co-existing condition
- 3) An infectious source is documented (suspected or confirmed)
- 4) **Additionally**, any patient with sepsis would be expected to exhibit some observable degree of distress (e.g. acute, mild, moderate distress) and/or general signs of illness (e.g. toxic or ill-appearing),² AND
- 5) Any patient with the diagnosis of sepsis would have a documented treatment approach such as initiation of a sepsis protocol in the ED, fluid resuscitation (at least 30 cc/kg over an hour), sending of pan cultures and relevant labs such as lactic acid, pro-calcitonin and CRP, the initiation of broad-spectrum antibiotic or consultation of an infectious diseases specialist.
- 6) Hospitalization period is not a short stay (LOS < 3 days)⁽⁵⁻⁷⁾

(R65.20) Severe Sepsis without Septic Shock (ALL of the following Criteria #1 – Criteria #8 is needed to make the diagnosis):

- 1) Meets diagnostic criteria for SIRS (Two or more of the listed parameters with WBC or Temperature being at least one of the included parameters)
- 2) Diagnostic criteria met cannot be easily explained by another co-existing condition
- 3) An infectious source is documented (suspected or confirmed)

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- 4) Presence of acute organ dysfunction where the organ dysfunction is clearly linked to sepsis⁽¹⁻²⁾, and includes ONE any of the following:
 - a. P/F ratio <300
 - b. Creatinine increase ≥ 0.5 mg/dL or urine output <0.5 m/kg/hr for at least 2 hours
 - c. Ileus (absent bowel sounds)
 - d. INR >1.5 or PTT >60 seconds
 - e. Platelets <100
 - f. Hyperbilirubemia (total bilirubin > 4 mg/dL)
 - g. Change in mental status (documented change in baseline GCS score (GCS <15) or baseline level of orientation (AAO < 3-4))
 - h. An acute increase of ≥ 2 points from baseline of the SOFA score (see Supplement C)^(1-2,8)
- 5) **Additionally**, any patient with severe sepsis would be expected to exhibit some observable degree of distress (e.g. acute, mild, moderate distress) and/or general signs of illness (e.g. toxic or ill-appearing), AND
- 6) Any patient with the diagnosis of sepsis would have a documented treatment approach such as initiation of a sepsis protocol in the ED, fluid resuscitation (at least 30 cc/kg over an hour), sending of pan cultures and relevant labs such as lactic acid, pro-calcitonin and CRP, the initiation of broad-spectrum antibiotic or consultation of an infectious diseases specialist.
- 7) Hospitalization period is not a short stay (LOS <3 days)

(R65.21) Severe Sepsis with Septic Shock (ALL of the following Criteria #1 – Criteria #8 is needed to make the diagnosis):

- 1) Meets diagnostic criteria for SIRS (Two or more of the listed parameters with WBC or Temperature being at least one of the included parameters)
- 2) Diagnostic criteria met cannot be easily explained by another co-existing condition
- 3) An infectious source is documented (suspected or confirmed)
- 4) Lactic acid >2.0 OR refractory hypotension (SBP <90 mmHg or MAP <65 or SBP decrease ≥ 40 mmHg and use of vasopressor therapy in the setting of adequate hydration (30 cc/kg of crystalloid over one hour)).
- 5) Presence of acute organ dysfunction where the organ dysfunction is clearly linked to sepsis⁽¹⁻²⁾, and includes ONE any of the following:
 - a. P/F ratio <300
 - b. Creatinine increase >0.5 mg/dL or urine output <0.5 m/kg/hr for at least 6 hours
 - c. Ileus (absent bowel sounds)
 - d. INR >1.5 or PTT >60 seconds
 - e. Platelets <100k

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- f. Hyperbilirubinemia (total bilirubin > 4 mg/dL)
 - g. Change in mental status (documented change in baseline GCS score (GCS <15) or baseline level of orientation (AAO < 3-4))
 - h. An acute increase of ≥ 2 points from baseline of the SOFA score (see Supplement C) ^(1-2,8)
- 6) **Additionally**, any patient with septic shock would be expected to exhibit some observable degree of distress (e.g. acute, mild, moderate distress) and/or general signs of illness (e.g. toxic or ill-appearing), AND
- 7) Any patient with the diagnosis of sepsis would have a documented treatment approach such as initiation of a sepsis protocol in the ED, fluid resuscitation (at least 30 cc/kg over an hour), sending of pan cultures and relevant labs such as lactic acid, pro-calcitonin and CRP, the initiation of broad-spectrum antibiotic or consultation of an infectious diseases specialist.
- 8) Hospitalization period is not a short stay (LOS < 3 days)

Common Causes of Sepsis and SIRS:

- SIRS: DKA, trauma, pancreatitis, burns, malignancies
- Sepsis: pneumonia, UTI

Clinical Indicators of Sepsis:

- Because tachypnea and tachycardia are so common in hospitalized patients for many reasons, they should not be used as the only criteria for diagnosing sepsis.¹
- Sepsis protocol initiated in ED
- Hyperglycemia > 140 mg/dL in the absence of diabetes
- Elevated C-reactive protein (> 2 ng/mL)
- Elevated pro-calcitonin (>10 mg/dL)
- Sepsis should not be documented without identification of the underlying infection. Provider can document a probable contributing infection.

Differential Diagnoses for Sepsis:

(No ICD-10 Code) SIRS due to an infection (“infectious SIRS”): is not a clinically validated diagnosis and must be clarified as sepsis. For example, a diagnosis of “SIRS due to pneumonia” will be coded as “pneumonia” unless sepsis is documented in the record.

(R78.71) Bacteremia: simply means a positive blood culture and is not synonymous (and therefore cannot be used interchangeably) with sepsis.

References:

- 1) Tang, C., Pinson, R. (2023). Sepsis-2, Sepsis-3, Shock and SIRS-Non-Infectious. CDI Pocket Guide (16th Edition), Pages 226-237.
- 2) Prescott, L., James, M. (2023). Sepsis and SIRS. ACDIS Pocket Guide: The Essential CDI Resource. Pages 450-464.
- 3) Singer M, Deutschman CS, Seymour CW, et al. The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). *JAMA*. 2016;315(8):801–810.
- 4) Evans, L., Rhodes, A., et al. Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock 2021. *Critical Care Medicine* 49(11):p e1063-e1143, November 2021.
- 5) Inpatient & Surgical Care >Optimal Recovery Guidelines>Infectious Diseases>Sepsis and Other Febrile Illness, without Focal Infection (M-160).
- 6) McCoy A, Das R. Reducing patient mortality, length of stay and readmissions through machine learning-based sepsis prediction in the emergency department, intensive care unit and hospital floor units. *BMJ Open Qual*. 2017 Oct 25;6(2).
- 7) Paoli CJ, Reynolds MA, Sinha M, Gitlin M, Crouser E. Epidemiology and Costs of Sepsis in the United States-An Analysis Based on Timing of Diagnosis and Severity Level. *Crit Care Med*. 2018 Dec;46(12):1889-1897.
- 8) Air Care Series. Sepsis Update. <https://www.tamingthesru.com/blog/air-care/sepsis-update>

SUPPLEMENTS:

(A): Systemic Inflammatory Response Syndrome (SIRS) Criteria⁸:

SIRS Criteria
<p>Temperature $>38^{\circ}\text{C}$ (100.4°F) or $<36^{\circ}\text{C}$ (96.8°F)</p> <p>Heart rate > 90</p> <p>Respiratory rate >20 or $\text{PaCO}_2 <32\text{ mm Hg}$</p> <p>WBC $>12,000/\text{mm}^3$ or $<4,000/\text{mm}^3$ or $>10\%$ bands</p>

(B) Sepsis Criteria⁸:

CMS Definitions	
Sepsis	≥ 2 SIRS criteria + known or suspected infection
Severe Sepsis	<p>Sepsis AND</p> <p>At least 1 sign of organ dysfunction:</p> <ul style="list-style-type: none"> Sepsis-induced hypotension <ul style="list-style-type: none"> SBP <90 MAP <65 \downarrow SBP >40 from normal baseline Cr >2.0 or urine output $<0.5\text{ mL/kg/hr}$ x2 hours Bilirubin $>2.0\text{ mg/dL}$ Platelet count $<100,000/\text{mm}^3$ INR >1.5 or PTT $>60\text{ sec}$ Lactate $>2\text{ mmol/L}$
Septic Shock	<p>Severe sepsis AND</p> <ul style="list-style-type: none"> Persistent hypotension after 30 mL/kg crystalloid Lactate $\geq 4\text{ mmol/L}$

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(C) Sequential (Sepsis-Related) Organ Failure Assessment (SOFA) Score⁸:

SOFA Criteria				
Points	1	2	3	4
RESPIRATION PaO ₂ /FiO ₂	<400	<300	<200	<100
COAGULATION Platelet Count	<150	<100	<50	<25
LIVER FUNCTION Bilirubin (mg/dL)	1.2 – 1.9	2.0 – 5.9	6.0 – 11.9	>12.0
CARDIOVASCULAR Hypotension	MAP <70	Dopamine ≤5 or dobutamine (any dose)	Dopamine >5 or epinephrine ≤0.1 or norepinephrine ≤0.1	Dopamine >15 or epinephrine >0.1 or norepinephrine >0.1
NEUROLOGIC GCS	13 – 14	10 – 12	6 – 9	<6
RENAL Creatinine/UOP	1.2 – 1.9	2.0 – 3.4	3.5 – 4.9 or UOP <500 mL/day	>5.0 or UOP <200 mL/day

(1) SOFA grades organ dysfunction on a scale of 0 to 4 depending on severity (0= no dysfunction). Organ dysfunction is determined by a two-point increase from baseline using six defined organ systems.

(2) The baseline SOFA score for any organ system is assumed to be 0 if the baseline is unknown and the patient has no known preexisting dysfunction in that organ system.¹