Sepsis Denials

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Sepsis-1

- From the first Sepsis Definition Conference in 1991
- Defined sepsis as systemic response syndrome (SIRS) due to infection
- SIRS defined as meeting more than 1 of 4 findings:
  - Body Temperature >38.0 ° C or <36.0 ° C
  - Heart Rate > 20 beats/min
  - Tachypnea >20 breaths/min or hyperventilation with $PaCO_2$ <32 mm Hg
  - WBC (WBC) count > 12,000 cells/mm^3
- Severe sepsis defined as sepsis associated with organ dysfunction
- Septic shock defined as sepsis with arterial hypotension despite adequate fluid resuscitation

Sepsis-2

- Research data showed a need to modify Sepsis-1 criteria to better reflect evolving knowledge of the pathophysiology of SIRS and severe sepsis
- A second International Sepsis Definition Conference was convened in 2001 with the results published in 2003
- The basic definitions for sepsis and severe sepsis remained in tact
- The criteria defining SIRS were greatly expanded (slide 6)
- Organ dysfunction variables for severe sepsis were more clearly defined
- Criteria for septic shock were specified under ***hemodynamic variables***

Sepsis-2

- As a diagnostic requirement, Sepsis-2 states “some” of the expanded criteria must be present
- Allows broad clinical flexibility in applying the criteria
- From Sepsis-2 comes the requirement for documentation supporting just how sick the patient appears (e.g. “This toxic appearing patient.” “This very ill-appearing patient.”)
- Sepsis-2 eliminated the requirement for positive blood cultures to confirm a diagnosis of sepsis
- If in the physician’s opinion, a criterion can be explained by a coexisting condition, then that criterion should not count!

Sepsis-2

- Since 2003 the Surviving Sepsis Campaign consistently reaffirms the 2001 criteria as the current standard with even further detail added
- Unfortunately many continue to use the criteria established for Sepsis-1 which lack precision
- The most recent Surviving Sepsis Campaign guidelines released in early 2017 began to accept at least some of the Sepsis-3 definitions and criteria
  - Eliminates severe sepsis as a category
  - Eliminates SIRS along with all other specific clinical parameters of end-organ dysfunction
  - Does ***not*** accept or recommend qSOFA as best practice

2001 Diagnostic Criteria for Sepsis

General variables	Fever (core temperature >38.3 °C)
	Hypothermia (core temperature <36.0 °C)
	Heart rate >90 beats/min
	Tachypnea (>20 breaths/ min)
	Altered mental status
	Significant edema or positive fluid balance (>20 mL/kg over 24 h)
	Hyperglycemia (plasma glucose level >120 mg/dL or >7.7 mmol/L) in the absence of diabetes
Inflammatory variables	Leukocytosis (WBC count >12,000 cells/mm^3)
	Leukopenia (WBC count <4,000 cells/mm^3)
	Normal WBC count with >10% immature forms ("bands")
	Plasma C-reactive protein level >2 SD above the normal value
	Plasma procalcitonin level >2 SD above the normal value

Hemodynamic variables	Arterial hypotension (SBP <90 mm Hg, MAP <70 mm Hg, or an SBP decrease >40 mm Hg in adults)
	SvO_2 >70%
	Cardiac index >3.5
Organ dysfunction variables	Arterial hypoxemia (PaO_2/FIO_2 <300)
	Acute oliguria (urine output <0.5 mL/kg of body weight per h for at least 2 h)
	Creatinine increase >0.5 mg/dL
	Coagulation abnormalities (INR >1.5 or aPTT >60 s)
	Ileus (absent bowel sounds)
	Thrombocytopenia (platelet count >100,000 cells/mm^3)
	Hyperbilirubinemia (plasma total bilirubin level >4 mg/dL)
Tissue perfusion variables	Hyperlactatemia (lactate level >1.0 mmol/L)
	Decreased capillary refill or mottling

Rules for Sepsis 2 Diagnostic Criteria

*If any of these criteria are, in the physician's judgment, "easily explained" by another coexisting condition (other than the infection), they should be excluded when deciding whether the patient has sepsis.

Based on reference 1. aPTT=activated partial thromboplastin time; INR=international normalized ratio; MAP=mean arterial blood pressure; SBP=systolic blood pressure; SD=standard deviation; SvO_2=mixed venous oxygen saturation; WBC=white blood cell.

Issues with Sepsis

- High mortality rate
- Difficult to diagnose
- Variable clinical presentations
- Few unifying pathological features
- Could be an appropriate host response
- SIRS presentation may be non-infective
- Increased WBC counts could be indicative of a non-infectious process
  - Medication-induced
  - Stress-induced
- Sepsis is dynamic!
  - Shifting clinical and laboratory manifestations
  - Not all criteria present at once
- Resource-intensive and costly making it highly audited!

Sepsis-3

- The Third International Consensus Definitions for Sepsis and Septic Shock published February 23, 2016
  - By a task force of the Society of Critical Care Medicine and the European Society of Intensive Care Medicine among others
- Defines sepsis as life-threatening organ dysfunction caused by a dysregulated host response to infection [suspected or confirmed]
  - The host is actually injuring its own tissues and organs
- Abandons the concept of sepsis as SIRS due to infection -- after 25 years!
- Sepsis-3 offers two standards for identifying organ dysfunction

SOFA: Defining Sepsis

- Sequential [sepsis-related] Organ Failure Assessment
  - Won out over the Logical Organ Dysfunction System (LODS)
  - SOFA considered easier to calculate
- Previously used to assess mortality in intensive care units
- SOFA grades the function of 6 organ systems on a scale of 0 to 4
  - Based on the degree of dysfunction
  - Uses objective measures (slide 13)
  - Assumed to be 0 for patients with no preexisting organ dysfunction

SOFA: Meeting the Requirement

- One-point increase in at least two organ systems
- Two-point increase or more in one organ system

SOFA: Six Organ Systems Used

1. Respiratory
2. Coagulation
3. Hepatic
4. Cardiovascular
5. Central Nervous System
6. Renal

SOFA: Scoring

Organ system	SOFA score				
	0	1	2	3	4
Respiratory, PO_2/FiO_2, mmHg (kPa)	≥400 (53.3)	<400 (53.3)	<300 (40)	<200 (26.7) with respiratory support	<100 (13.3) with respiratory
Coagulation, Platelets, $\times 10^3/mm^3$	≥150	<150	<100	<50	<20
Liver, Bilirubin, mg/dL	<1.2	1.2–1.9	2.0–5.9	6.0–11.9	>12.0
Cardiovascular	MAP ≥70 mmHg	MAP <70 mmHg	Dopamine <5 or dobutamine (any dose)[b]	Dopamine 5.1–15 or epinephrine ≤0.1 or norepinephrine ≤0.1[b]	Dopamine >15 or epinephrine >0.1 or norepinephrine >0.1[b]
Central nervous system, Glasgow Coma Scale	15	13–14	10–12	6–9	<6
Renal, Creatinine, mg/dL. Urine output, mL/d	<1.2	1.2–1.9	2.0–3.4	3.5–4.9 <500	>5.0 <200

qSOFA

- q = quick
- Derived from SOFA through multivariate logistic regression that showed good predictive value of these more easily attained variables
- Bedside clinical approach to identify patients with high risk for adverse outcomes
- Designed to be fast and easy for the healthcare environment
- Does not require laboratory tests
- Based on the presence of 2 or more of 3 criteria
  - Altered mentation
  - Respiratory rate ≥ 22 breaths/min
  - Systolic blood pressure ≤ 100 mm Hg
- A positive score would prompt clinicians to:
  - Look for organ dysfunction
  - Initiate or escalate therapy
  - Consider critical care
- Intended as a useful tool and not a substitute for SOFA criteria
- Not accepted by the Surviving Sepsis Campaign as of 2017

Sepsis-3: Severe Sepsis and Septic Shock

- Sepsis-3 considers the term severe sepsis to be redundant
- Sepsis without organ dysfunction does not exist
- Strict definition of septic shock:

> "Persisting hypotension requiring vasopressors to maintain mean arterial pressure (MAP) > 65 mmHG and a serum lactate level > 2 mmol/L (18 mg/dL) despite adequate volume resuscitation."

Issues with Using SIRS Criteria

- SIRS may reflect an ***appropriate*** host response to infection
- Infective and non-infective SIRS can co-exist
- Elevated WBC count could indicate stress and not infection
- Sepsis is dynamic and its manifestations can change without all criteria being present at once
- SIRS fails to promote an understanding of the underlying problem or disease process
- Hypotensive patients do not necessarily have shock
- Patients in shock may not be hypotensive

Issues with Using Sepsis-3

- Inconsistent with the ICD-10-CM Official Guidelines for Coding and Reporting (OCG)
  - Required under HIPAA
  - Distinguishes between sepsis with or without organ dysfunction
- Adherence to Sepsis-3 by not reporting any cases of sepsis without organ dysfunction would disrupt:
  - Coding
  - Reimbursement
  - Quality Analysis
  - Regulatory Oversight

Issues with Using Sepsis-3

- Additionally the Sepsis-3 consensus recommends
  - Reporting R65.20 as principal for severe sepsis
  - Reporting R65.21 as principal for septic shock

- I.d.1)(a) of the OCG states:

  - For a diagnosis of sepsis, assign the appropriate code for the underlying systemic infection. If the type of infection or causal organism is not further specified, assign code A41.9, Sepsis, unspecified organism.

Issues with Using Sepsis-3

- OCG continue with:

  A code from subcategory R65.2, Severe sepsis, should not be assigned unless severe sepsis or an ***associated*** acute organ dysfunction is documented.

- Following Sepsis-3 definitions will leave the expectations and practices for U.S. national coding and reporting requirements unmet
- The Sepsis-3 task force was comprised of 19 scientists
  - Consensus for future clinical research
- Debate in the U.S. over early enough recognition of sepsis
  - Limitations in the actual clinic setting

ACDIS Advisory Board

- Letter to the Sepsis-3 authors indicating conflicts with OCG and current CMS quality measures
- Position white paper stating:

> "While Sepsis-3 definitions set forth compelling evidence that cannot be dismissed, it remains to be seen how the clinical community will be able to operationalize or change its understanding of sepsis and septic shock."

- ACDIS cautioned against adopting the new guidelines into CDI programs

CMS' 2015 Core Measure for Treating Sepsis

- a.k.a Severe Sepsis/Septic Shock Early Management Bundle or SEP-1
- Comes from the National Quality Foundation's early-goal-directed therapy (EGDT)
- Not well received by the medical community
  - Would prefer ***sensitivity*** to ***specificity***
- Inconsistent with the definitions used in evidence-based studies since 2001
- Premature with no clear definitions for sepsis, severe sepsis or septic shock
- Reimbursement withheld if noncompliant with ***any*** portion of the measure which may be inappropriate for certain patients

CMS' 2015 Core Measure for Treating Sepsis

- Two main problems:
  - CMS definition-selected lactate values are below the threshold of widely accepted and studied lactate levels
  - Government-issued definitions for a disease that presents with a great deal of variability and where no gold standard definition exists
- Derived from the Surviving Sepsis Campaign and the National Quality Foundation definitions
  - CMS altered the lactate value
- Next slide just to indicate the various methodologies --

Table 4. Evolution of sepsis, severe sepsis and septic shock definitions with clinical criteria.

	1992 ACCP/SCCM Consensus statement	Levy	2012 SCCG	NQF	CMS	Sepsis-3	2016 SCCG
SIRS	Temperature > 38°C or < 36°C Heart rate > 90 bpm Respiratory rate > 20 or PaCO2 < 32 mm Hg White blood cell count > 12,000/cu mm, <4,000/cu mm or >10% bands	No change	No change	No change	No change	Eliminated and qSOFA introduced for purpose of risk stratification	No SIRS. No qSOFA.
Sepsis	Infection + 2 or more SIRS	No change	No change	No change	No change	Infection + 2 qSOFA criteria	Infection + end organ dysfunction. No clinical criteria offered.
Severe sepsis	Sepsis + end-organ dysfunction. No specific lactate level offered.	Sepsis + end- organ dysfunction. Lactate > 3*	Sepsis + end- organ dysfunction. Lactate > 4	No change	Sepsis + end- organ dysfunction. Lactate > 2	Eliminated	Eliminated
Septic shock	Sepsis + a SBP <90 mm Hg or a reduction of 40 mm Hg from baseline or evidence of low perfusion after adequate fluid bolus. No specific lactate level offered.	Same as 1992 with addition of MAP < 60 mm Hg despite adequate fluid bolus.	MAP threshold increased to < 70 mm Hg and fluid bolus defined as 30 mL/kg	No change	Initial lactate > 4 or SBP < 90 mm Hg after 30 mL/kg fluid bolus	SBP < 90 mm Hg AND lactate > 2 after adequate fluid resuscitation	Subset of sepsis with circulatory and cellular/ metabolic dysfunction associated with a higher risk of mortality. No clinical criteria offered.

MAP, mean arterial pressure, *SBP*, systolic blood pressure.
* all lactate levels in mmol/L values.

Clinical Validation

- Both a concept and a process
- Diagnoses documented in the medical record must be substantiated by clinical criteria generally accepted by the medical community
  - Authoritative professional guidelines
  - Consensus
  - Evidence-based sources
- In the absence of such sources –
  - Clinical diagnostic standards that most clinicians in a comparable specialty would reasonably agree are sufficient for establishing a particular diagnosis

Clinical Validation

- If the criteria are not met, but still the physician feels the diagnosis is valid, the physician must document a plausible alternative basis for the diagnosis that other clinicians would deem reasonable.
- Medicare requires that claims submitted for payment must not include codes for diagnoses that cannot be clinically validated.
- Payers and auditors apply clinical validation processes to professional and institutional claims to determine whether the submitted diagnoses are substantiated by widely accepted clinical criteria.

Clinical Validation

- Payers focus on diagnoses known for clinical validation deficiencies:
  - Sepsis
  - Acute respiratory failure
  - Pancreatitis
  - Severe malnutrition
  - Acute kidney injury
- Denials will often read “although well documented …”

Clinical Validation

- Clinicians need to keep current of authoritative standards and apply this in diagnosing patients
- Coders should not be held accountable for clinical validation
  - Well beyond their scope
  - But remain informed and involved
- If a clinician reasonably bases a diagnostic determination on something other than the widely recognized criteria, the rationale should be clearly stated I the record.

Clinical Validation

- The 2017 ICD-10-CM Official Guidelines for Coding and Reporting (OCG), § I.A.19, Code Assignment and Clinical Criteria:

  The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement the patient has a particular condition is sufficient. Code assignment is not abased on clinical criteria used b the provider to establish the diagnosis.

- Perplexing and problematic – creating a dilemma for many!
- Actually just clarifying that it is the clinicians responsibility to ensure the diagnoses documented in the medical record are clinically valid.

Clinical Validation

- Thus alleviating the coder from the responsibility for making such clinical distinctions
- Clinical validation remains a contractual, regulatory and statutory necessity!
- If clinicians do not consider the validity of diagnoses being reported, they will not be in compliance with CMS regulations and policies.
- This is where clinical documentation integrity and improvement comes into play!

Clinical Validation

- CDI reviews the medical record concurrently and is in a position to have any necessary conversations with clinicians to ensure every diagnosis being documented is clinically valid
- The medical record should then be good to go at the time of discharge
- Ensuring clinical validity will ensure a solid appeal of any denial

Denials Management for Sepsis

- Sepsis criteria used by hospitals may not have actually been intended for billing purposes
- Intended clinically to ensure better outcomes by casting a wide enough net to capture early sepsis
- Clinical parameters can and do change
- Consistent documentation of the patient's condition will always lead to appropriate coding, billing and reimbursement!

Denials Management for Sepsis

- The only ironclad/bulletproof defense for a sepsis denial is documentation showing a clear delineation of a non-systemic infection!
  - An H&P that adequately captures the severity of illness by the depiction of the patient's signs and symptoms
  - Explanation of the significance of any workup findings (risk for organ dysfunction)
  - Accounting of the patient's course of hospitalization (including response to treatment)
- When all of these depict a clinical picture of sepsis the record will withstand scrutiny!
- When documentation does not show anything beyond what is expected from a local infection, then it is not sepsis!

Denials Management for Sepsis

- With definitions in flux, now is the time for facilities to review their sepsis criteria standards, required documentation and coding practices to avoid lost reimbursement
- Payers and auditors are using the new sepsis criteria
- Facilities will also need to begin to move in that direction
- Trickle down to coding criteria and guidelines has been slow!
- Clinicians and coders still use the old SIRS criteria
- Coders code from physician documentation
- This gap opens the door for denials!
- Education!

Denials Management for Sepsis (HCCA)

Arguing for Sepsis Diagnosis Sepsis-3				
Vital Signs/Measurements	**Date(s)**	**Results**	**Reference Range of Values that are Representative of Sepsis**	**Page(s)**
Systolic Blood Pressure			< 100 mmHg	
Respiratory Rate			> 22/minute	
Sepsis: Mean Arterial Pressure (MAP)			< 70 mmHg	
Glasgow Coma Scale (GCS)			< 14	
Septic Shock: Mean Arterial Pressure (MAP)			Vasopressors needed to keep MAP ≥ 65	
Urine Output			< 500 mL/d	
Test	**Date(s)**	**Results**	**Reference Range of Values that are Representative of Sepsis**	**Page(s)**
PaO2/FiO2			< 400 mmHg	
Platelets			< 150	
Bilirubin			> 1.2 mg/dL	
Creatinine			> 1.2 mg/dL	
Lactate			> 2 mmol/L (<18 mg/dL)	

Denials Management for Sepsis (HCCA)

Arguing for Sepsis Diagnosis SIRS + Infection				
Vital Signs/Measurements	**Date(s)**	**Results**	**Reference Range of Values that are Representative of Sepsis**	**Page(s)**
Body Temperature			≥ 38°C (100.4°F) or ≤ 36°C (96.8°F)	
Heart Rate			≥ 90 beats/min	
Respiratory Rate			≥ 20 breaths/min (or PaCO2 ≤ 32 mmHg)	
Test	**Date(s)**	**Results**	**Reference Range of Values that are Representative of Sepsis**	**Page(s)**
ABG—PaCO2			≤ 32 mmHg	
WBC—Leukocytes			12,000 cells/μL or 4,000 cells/μL	
% Bands			> 10%	

Thank you! ☺