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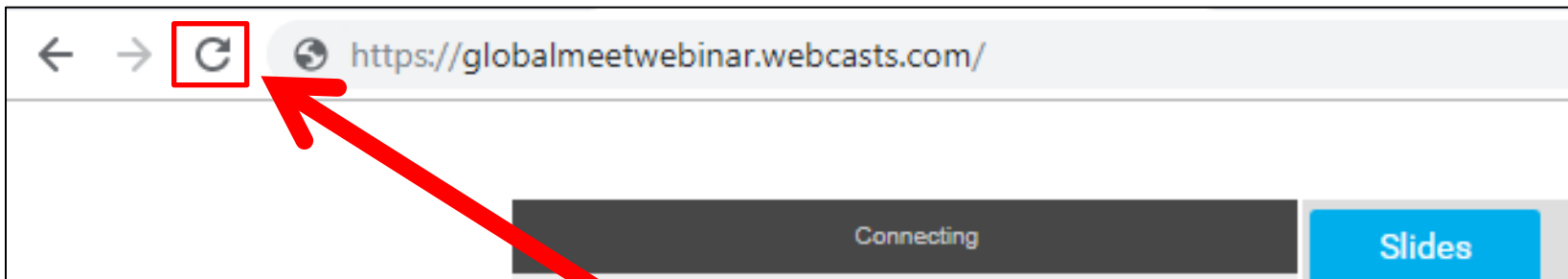
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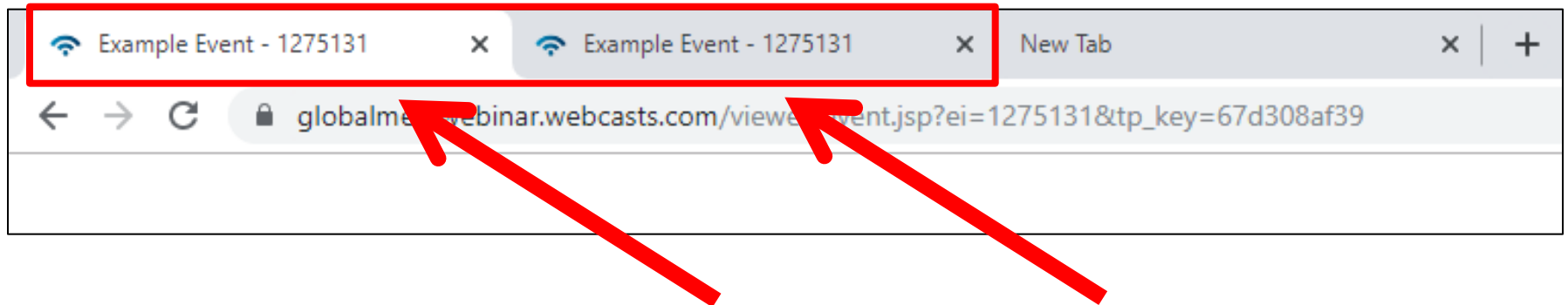
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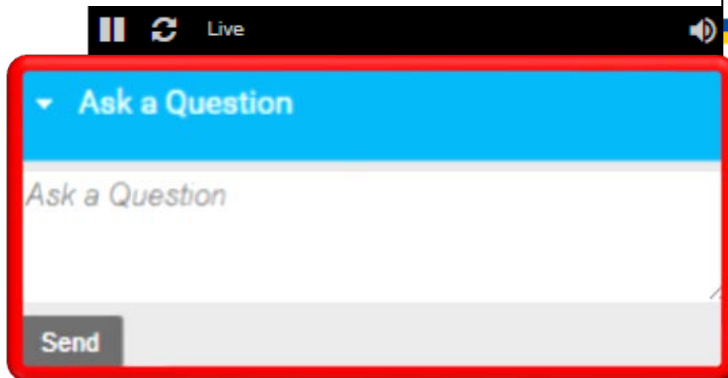
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Inpatient Value, Incentives, and Quality Reporting (VIQR) Outreach and Education Support Contractor



Today's Presentation



Hospital-Based Sepsis Care: The Evolving Definition of Sepsis and the Role of the ED Medical Director and Quality Team in Sepsis Care

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October 13, 2021

Purpose

This webinar will provide a physician's perspective on the evolution of the definition of sepsis and the SEP-1 measure as it relates to population health and sepsis care in the emergency department (ED).

Objectives

Participants will be able to:

- Understand and discuss various sepsis definitions.
- Discuss how the sepsis identification criteria used in the SEP-1 core measure can differ from how sepsis is identified in your facility.
- Understand and discuss the difference between a guideline and a measure.
- Discuss common organizational strategies for achieving success in the early identification and treatment of sepsis.
- Discuss the role of the emergency department medical director in sepsis quality improvement work.

Acronyms and Abbreviations

ACCP	American College of Chest Physicians	IOM	Institute of Medicine	PaO₂	partial pressure of oxygen
ASC	Ambulatory Surgery Center	IQR	Inpatient Quality Reporting	Q	quarter
C	Celsius	IV	intravenous	Q-SOFA	Quick Sepsis Organ Failure Assessment
CM	Clinical Modification	JAMA	Journal of the American Medical Association	RR	respiratory rate
CMS	Centers for Medicare & Medicaid Services	kg	kilogram	SCCM	Society of Critical Care Medicine
CQM	clinical quality measure	L	liter	SEP	sepsis
dL	deciliter	MAP	mean arterial pressure	SIRS	Systemic Inflammatory Response Syndrome
DRG	Diagnosis Related Group	mg	milligram	SOFA	Sepsis Organ Failure Assessment
ED	emergency department	mL	milliliter	T	temperature
F	Fahrenheit	mm	millimeter	UTD	Unable to Determine
HR	heart rate	mmHg	millimeters of mercury	v	version
ICD	International Classification of Diseases	mmol	millimole	VIQR	Value, Incentives, and Quality Reporting
ICU	intensive care unit	PaCO₂	partial pressure of carbon dioxide	WBC	white blood cell

Webinar Questions

- For questions regarding webinar content from the guest speaker, please contact Dr. Bobby Redwood at rredwood@cooleydickinson.org.
- For questions regarding content related to the Centers for Medicare & Medicaid Services (CMS) Hospital Inpatient Quality Reporting (IQR) Program SEP-1 measure and specification, please submit the question to the [QualityNet](https://cmsqualitysupport.servicenowservices.com/qnet_ga) Inpatient Questions and Answers Tool:
https://cmsqualitysupport.servicenowservices.com/qnet_ga

Disclaimer

This presentation includes evidence-based information for the clinical care of patients with sepsis and is not intended for use as abstraction guidance for SEP-1. The viewpoints shared in this presentation are those of presenter and do not necessarily represent the views of CMS.



Hospital-Based Sepsis Care:

The Evolving Definition of Sepsis and the Role of the ED Medical Director and Quality Team in Sepsis Care

October 11, 2021

Bobby Redwood MD, MPH, FACEP

- Emergency & Preventive Medicine Physician
- Chief of Emergency Medicine, Cooley Dickinson Hospital
- National Quality Improvement and Patient Safety Councilor, American College of Emergency Physicians
- Physician Improvement Advisor, Wisconsin Hospital Association (Wisconsin Hospital Association is a member of a CMS Hospital Improvement Innovation Network.)



Dr. Redwood has no real or apparent financial relationships to report.

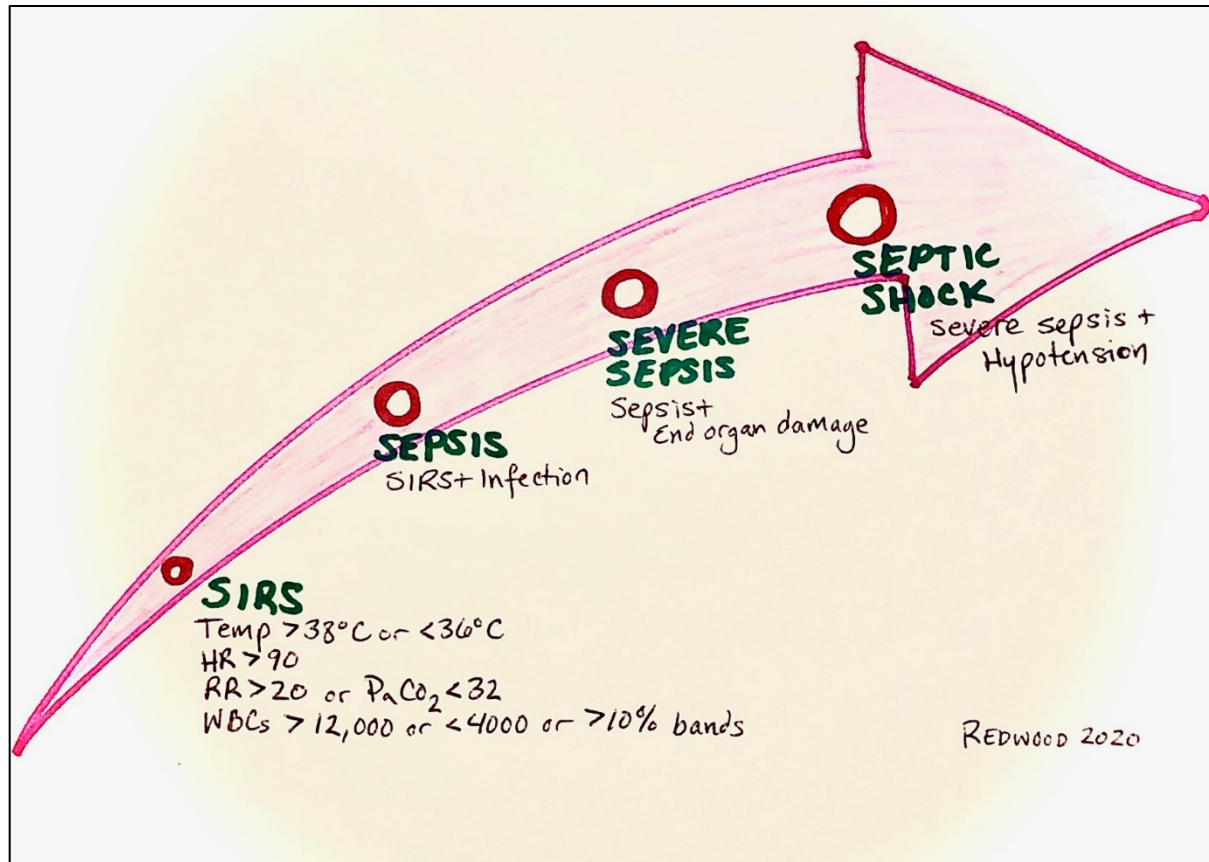
Sepsis Definitions

Objective:

Be able to understand and discuss various sepsis definitions.



1991 Consensus Conference Sepsis Definition



Bone, R.C., W.J. Sibbald, and C.L. Sprung. "The ACCP-SCCM Consensus Conference on Sepsis and Organ Failure." *Chest*, vol. 101, no. 6, 1992, pp. 1481-1483.

2016 Third Consensus Conference Sepsis Definition

- “Sepsis-3” redefined sepsis as “life-threatening organ dysfunction caused by a dysregulated host response to infection.”
- Key changes are below:
 - Severe sepsis category removed.
 - Organ dysfunction is quantified using the Sequential Organ Failure Assessment (SOFA) score.
 - Higher bar for “septic shock” designation:
Sepsis with vasopressor requirement to maintain
MAP > 65 and Lactate < 2mmol/L after fluid resuscitation

Singer M, Deutschman CS, Seymour CW, et al. The third international consensus definitions for sepsis and septic shock (Sepsis-3). JAMA. 2016;15:801-810.

2016 Third Consensus Conference Sepsis Definition (Continued)

SOFA Score Variables

- *Respiratory* (arterial oxygen pressure/fraction of inspired oxygen)
- *Cardiovascular* (mean arterial pressure or vasopressor requirements)
- *Liver* (bilirubin levels)
- *Renal* (creatinine levels)
- *Coagulation* (platelet levels)
- *Neurologic* (Glasgow Coma Scale score)

Singer M, Deutschman CS, Seymour CW, et al. The third international consensus definitions for sepsis and septic shock (Sepsis-3). JAMA. 2016;15:801-810.

Controversy #1: ED vs ICU

Which Sepsis Definition?

Emergency Department (ED)

- More patients/beds
- Less sick cohort
- Moderate-High resource care
- Many sepsis false positives
- Primary role of diagnosing, stabilizing and sorting patients
- Lab values not available on initial presentation

Intensive Care Unit (ICU)

- Fewer patients/beds
- More sick cohort
- Very high resource care
- Fewer sepsis false positives
- Primary role of continuing to stabilize and ultimately treating life threatening conditions
- Lab values available on initial presentation

Controversy #1: ED Solutions

- Systemic inflammatory response syndrome (SIRS)
 - Screening tool to identify patients who are high risk for sepsis/septic shock, not diagnostic tool
- SOFA
 - Scoring system for organ dysfunction and determination of resource needs, not diagnostic tool
- Solution
 - ED triage: Start with SIRS/1991 Consensus Conference Sepsis Definition
 - Intraservice: Broaden to 2016 Third Consensus Conference Sepsis Definition for probable admits

Controversy #2: SIRS vs Q-SOFA*

Which screens better?

Source
of
Infection

+

SIRS Variables

- Temperature
- Respiratory Rate
- Heart Rate
- White blood cell count

Q-SOFA Variables

- Respiratory rate
- Altered mental status
- Systolic blood pressure

*Q-SOFA = Quick Sequential Organ Failure Assessment

Controversy #2: SIRS vs Q-SOFA

Which screens better?

Jiang et al. 2018

Head-to-head comparison of qSOFA and SIRS criteria in predicting the mortality of infected patients in the emergency department: a meta-analysis.

SIRS	81% sensitive, 41% specific
Q-SOFA	42% sensitive, 88% specific “Q-SOFA appears to be a simple, rapid, and effective way to identify patients at high risk for death. However, it seems necessary to identify ways to improve its low sensitivity. Until then, it cannot completely replace the use of SIRS in the ED.”

Jiang J et al. Head-to-head comparison of qSOFA and SIRS criteria in predicting the mortality of infected patients in the emergency department: a meta-analysis. *Scand J Trauma Resusc Emerg Med.* 2018;26(1):56. 2018 Jul 11.

Controversy #2: ED Solutions

- Screen for sepsis in ED triage using SIRS criteria (more sensitive, casts a wide net).
- Patients who screen positive should be prioritized for prompt history and physical examination which may help to detect infection and organ dysfunction.
- Apply SEP-1 interventions for SIRS-positive patients with clinical concern for infection:
 - Blood cultures x2, Lactate x2, 30 mL/kg crystalloid fluid, and broad-spectrum antibiotics with attention to potential source of infection.
- Confounders exist (COVID, diabetic ketoacidosis, pulmonary embolism, etc.). Be prepared to reassess frequently and change course if clinically indicated. Anchoring on Sepsis too early is a pitfall.

Controversy #3:

Sepsis Definition Payor Denials

- 65-year-old male with pyelonephritis, WBC = 23000, T = 104°F HR = 120, Lactate = 5, Mean arterial pressure = 67
 - 2015: Sepsis (severe sepsis)
 - 2017: Not septic
- ICD-10-CM classification has not abandoned the 1991 Consensus Conference Sepsis Definition.
- Some payors have issued Diagnosis-Related Group (DRG) denials for sepsis, citing the Sepsis-3 definition was not met or a SOFA/Q-SOFA score is not documented.

Controversy #3: ED Solutions

- For patient care:
 - Don't get hung up on semantics.
 - SIRS/1991 Consensus Conference Sepsis Definition is still relevant: Think of it as “high risk for progression to sepsis.”
 - Treat per CMS SEP-1 core measure recommendations.
- For billing:
 - Sepsis-3 is or will become the standard, tightest charts may include the following:
 - “Dysregulated host response to infection”
 - Document infection + evidence of organ dysfunction
 - Hypotension, renal failure, encephalopathy, etc.
 - Include a SOFA score of 2 or more if applicable

Sepsis Definitions: A Summary

	First Consensus Definitions (1991)²¹	Second Consensus Definitions (2001)²²	Third Consensus Definitions (2016)²³
Infection	Pathology caused by invasion of normally sterile environment by pathogenic microorganisms	No change	Not defined
Sepsis	Inflammatory response from infection with the SIRS criteria proposed to define an inflammatory response	Suspected or confirmed infection with ≥ 2 SIRS criteria, as defined below: <ul style="list-style-type: none"> - Temperature of >38 °C or <36 °C - Heart rate >90 beats/min - Respiratory rate >20 breaths/min or $\text{PaO}_2 <32$ mm Hg - White blood cell count $>12,000$ or $<4,000$ cells/mm³ or $>10\%$ band neutrophils 	Organ dysfunction (defined by increase in SOFA score of ≥ 2) caused by dysregulated response to infection with a threat to survival
Severe sepsis	Sepsis associated with organ dysfunction	Sepsis with organ dysfunction, defined as any of the following: <ul style="list-style-type: none"> - Hypotension - Lactate 2 mmol/L or greater - International normalized ratio > 1.5 - Creatinine > 2.1 mg/dL or urine output < 0.5 mL/kg per hour - Platelet count $< 110,000$/L - Oxygen saturation $< 90\%$ 	Eliminated (now redundant with "sepsis")
Septic shock	Sepsis with concurrent hypotension despite adequate fluid resuscitation plus perfusion abnormalities, such as elevated lactate levels, low urine output, or altered mental status	Sepsis with concurrent hypotension despite adequate fluid resuscitation	Sepsis with vasopressors required to maintain MAP >65 mm Hg and lactate >2 mmol/L after fluid resuscitation

Yealy, Donald M., et al. "Early Care of Adults With Suspected Sepsis in the Emergency Department and Out-of-Hospital Environment: A Consensus-Based Task Force Report." *Annals of Emergency Medicine* (2021).

Hospital-Based Sepsis Care: The Evolving Definition of Sepsis and the Role of the ED Medical Director and Quality Team in Sepsis Care

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Behavioral Development and Inpatient and Outpatient
Measure Maintenance Support Contractor

The SEP-1 Core Measure

Objective:

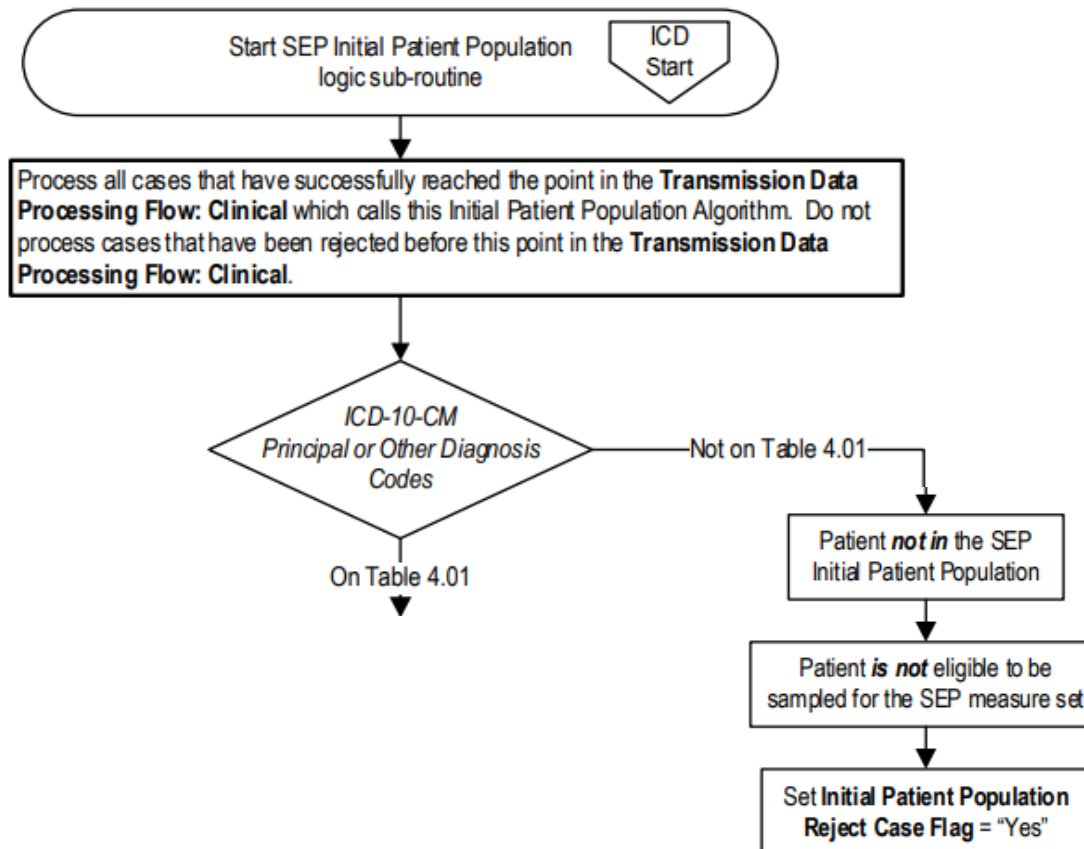
Discuss how the sepsis identification criteria used in the SEP-1 core measure can differ from how sepsis is identified in your facility.



Sepsis Initial Patient Population Algorithm v5.10

How do cases get into the measure?

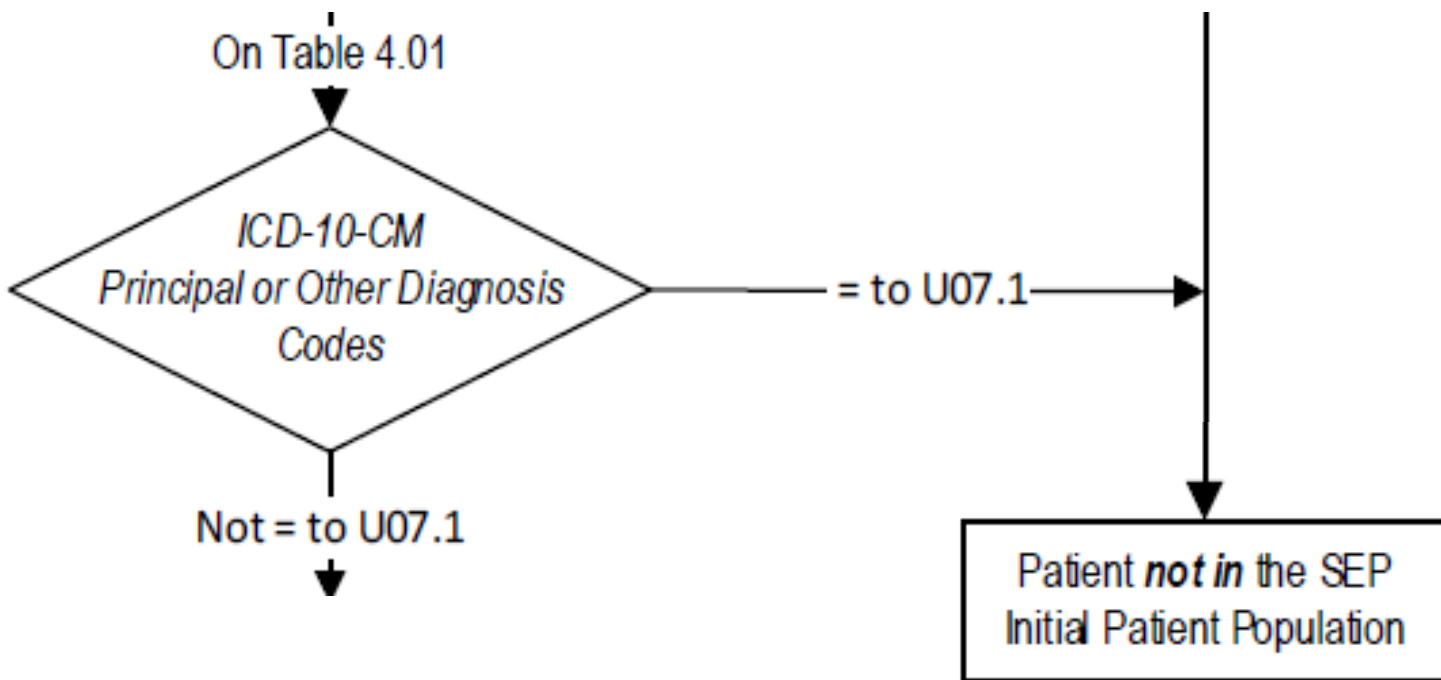
Sepsis Initial Patient Population Algorithm



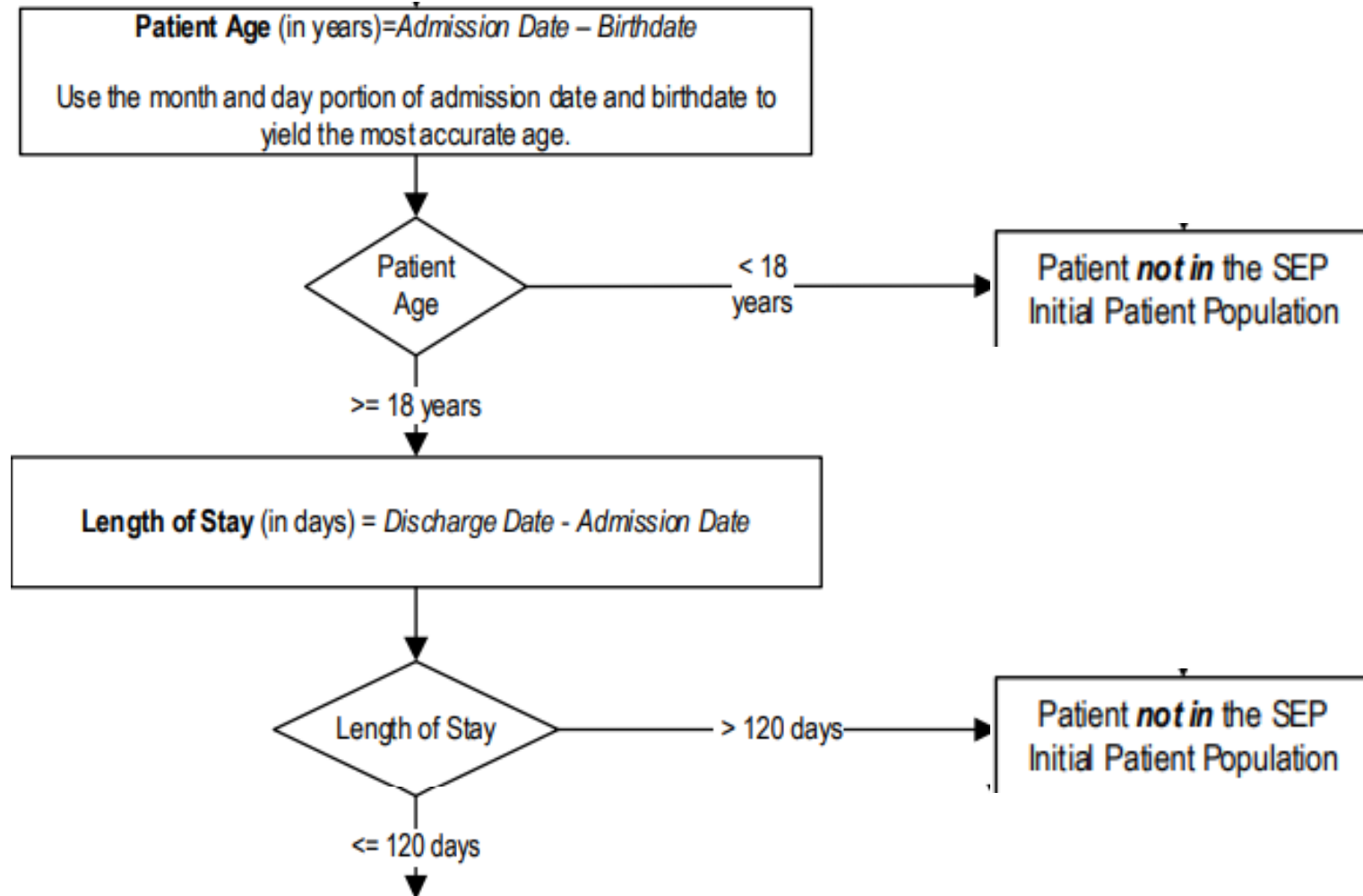
SEP-1 ICD-10 Codes Table 4.01: Severe Sepsis and Septic Shock

A021 Salmonella sepsis	A414 Sepsis due to anaerobes
A227 Anthrax sepsis	A4150 Gram-negative sepsis, unspecified
A267 Erysipelothrix sepsis	A4151 Sepsis due to Escherichia coli [E. coli]
A327 Listerial sepsis	A4152 Sepsis due to Pseudomonas
A400 Sepsis due to streptococcus, group A	A4153 Sepsis due to Serratia
A401 Sepsis due to streptococcus, group B	A4159 Other Gram-negative sepsis
A403 Sepsis due to Streptococcus pneumoniae	A4181 Sepsis due to Enterococcus
A408 Other streptococcal sepsis	A4189 Other specified sepsis
A409 Streptococcal sepsis, unspecified	A419 Sepsis, unspecified organism
A4101 Sepsis due to Methicillin susceptible Staphylococcus aureus	A427 Actinomycotic sepsis
A4102 Sepsis due to Methicillin resistant Staphylococcus aureus	A5486 Gonococcal sepsis
A411 Sepsis due to other specified staphylococcus	R6520 Severe sepsis without septic shock
A412 Sepsis due to unspecified staphylococcus	R6521 Severe sepsis with septic shock
A413 Sepsis due to Hemophilus influenzae	

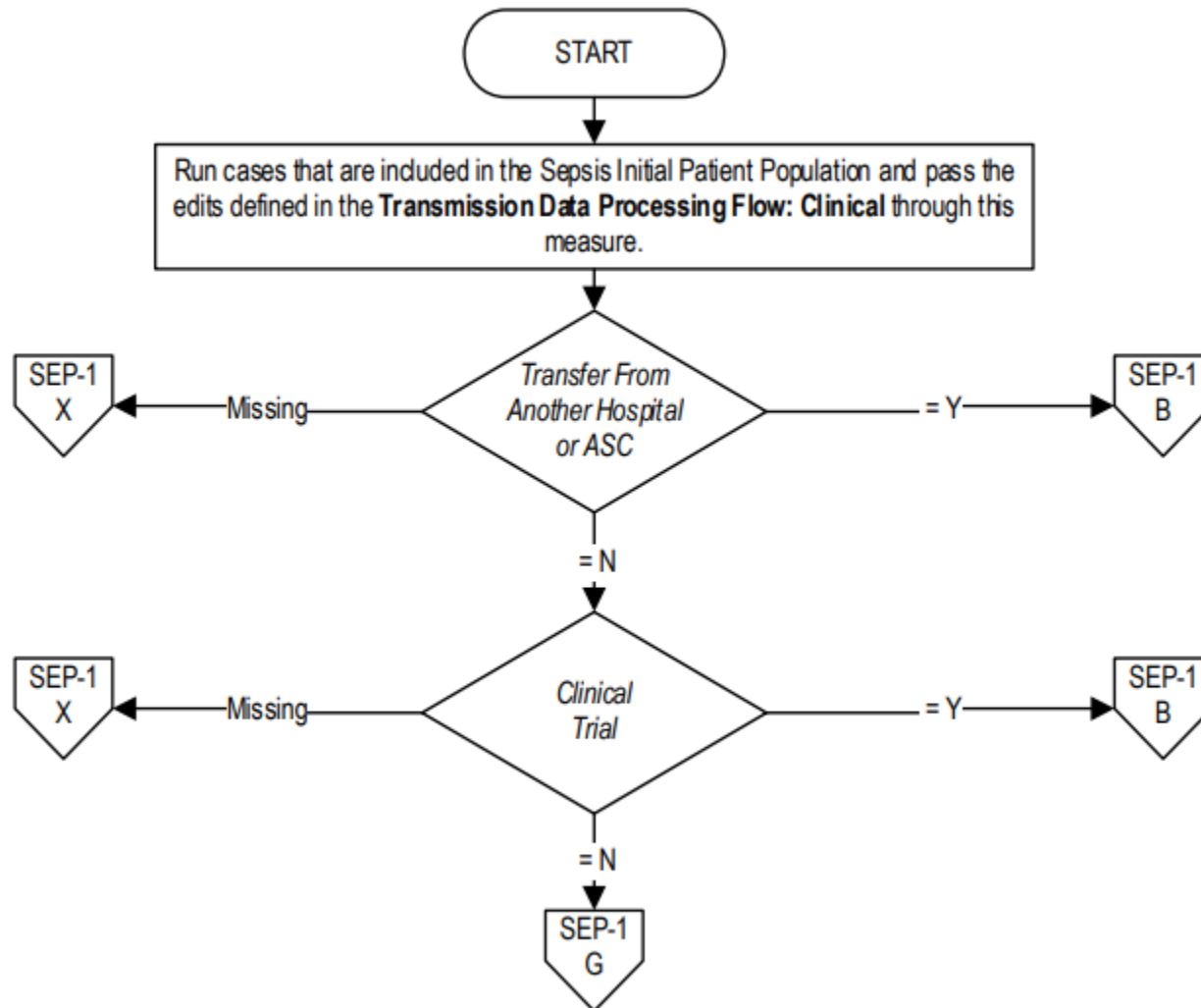
Sepsis Initial Patient Population Algorithm



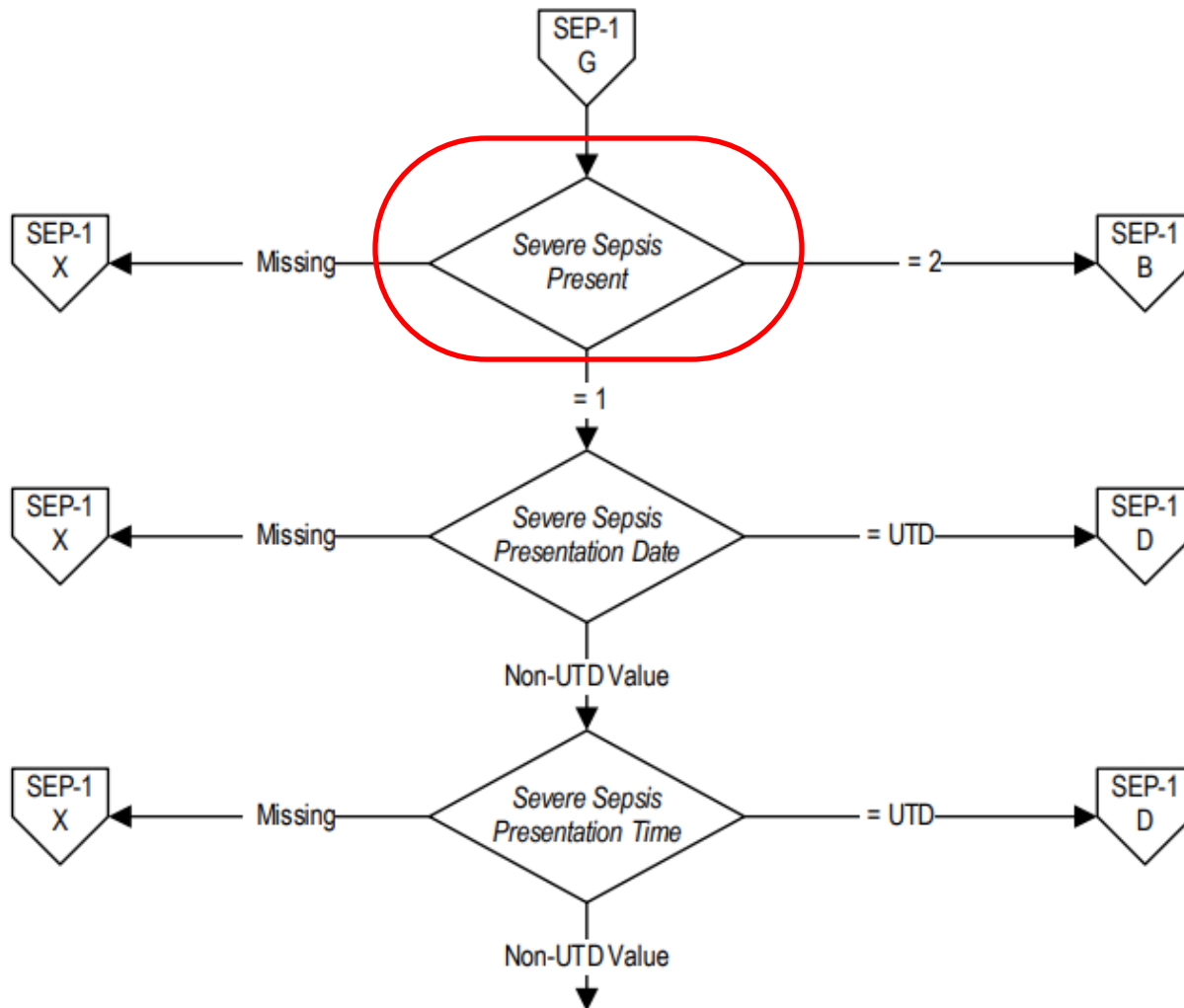
Sepsis Initial Patient Population Algorithm



SEP-1 Algorithm



SEP-1 Algorithm



Severe Sepsis Present v5.10

- **Clinical Criteria**

- a. Documentation of infection
- b. Two or more SIRS criteria
- c. One or more sign of organ dysfunction

- **Why SIRS?**

- Sensitivity vs. qSOFA
- Widely used
- Consistent with intent:
 - Early recognition
 - Early treatment

Temperature > 38.3 C or < 36.0 C (>100.9 F or <96.8 F)
Heart rate (pulse) > 90
Respiration > 20 per minute
White blood cell count > 12,000 or < 4,000 or > 10% bands

Guidelines and Quality Measures

Objective:

Be able to understand and discuss the difference between a guideline and a measure.



Guidelines and Quality Measures

Clinical practice guidelines:¹

“systematically developed statements to support practitioner and patient decisions about appropriate healthcare for specific clinical circumstances.”

Institute of Medicine (IOM) clinical practice guidelines:²

"statements that include recommendations, intended to optimize patient care, that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options"

1. CMS Measures Management System Blueprint (Blueprint v16.0) Glossary and Acronyms
<https://www.cms.gov/files/document/blueprint-glossary-and-acronyms.pdf>
2. Consensus report, Institute of Medicine. Clinical practice guidelines we can trust. March 23, 2011.
<http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx>

Guidelines and Quality Measures

Clinical quality measures (CQMs):

“mechanism used for assessing the degree to which a provider competently and safely delivers clinical services that are appropriate for the patient in an optimal time frame.”¹

“can be measures of processes, experiences and/or outcomes of patient care, observations or treatment that relate to one or more quality aims for health care such as effective, safe, efficient, patient-centered, equitable, and timely care.”²

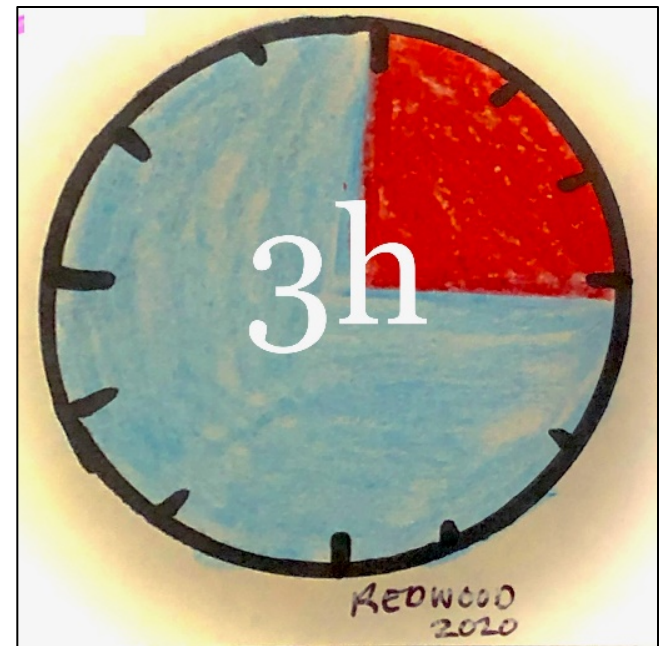
1. CMS Measures Management System Blueprint (Blueprint v16.0) Glossary and Acronyms
<https://www.cms.gov/files/document/blueprint-glossary-and-acronyms.pdf>
2. CMS EHR incentive program A Quick Guide to the Clinical Quality Measures
https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/downloads/guidetocqms_remediated_2011.pdf

What is SEP-1?

- **CQMs:**
 - Measures care using retrospective medical record review
 - Supports health care quality aims of effective, safe, and timely care
 - Doesn't dictate care
- Treatment at bedside should be based on guidelines and patient needs based on best clinical judgement of clinician.
- Based on: *Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock: 2016*

Critical Elements of the 3-Hour Bundles

- **Severe Sepsis 3-Hour Bundle:**
 - Measure lactate level.
 - Obtain blood cultures prior to administration of antibiotics.
 - Administer broad spectrum antibiotics.
- **Septic Shock 3-Hour Bundle:**
 - Start 30 mL/kg crystalloid for initial hypotension or lactate greater than or equal to 4 mmol/L.



Critical Elements of the 6-Hour Bundles

- **Severe Sepsis 6-Hour Bundle:**
 - Re-measure lactate if initial lactate elevated (initial lactate > 2 mmol/L).
- **Septic Shock 6-Hour Bundle:**
 - Apply vasopressors (for hypotension that does not respond to initial fluid resuscitation) to maintain a MAP greater than or equal to 65 mmHg.
 - Reassess fluid volume status and tissue perfusion (for persistent hypotension or initial lactate ≥ 4 mmol/L).



Hospital-Based Sepsis Care: The Evolving Definition of Sepsis and the Role of the ED Medical Director and Quality Team in Sepsis Care

Dr. Bobby Redwood, MD, MPH, FACEP
Chief of Emergency Medicine, Cooley Dickinson Hospital

Bringing Best Practices to the Bedside

Objective:

Discuss common organizational strategies for achieving success in the early identification and treatment of sepsis.

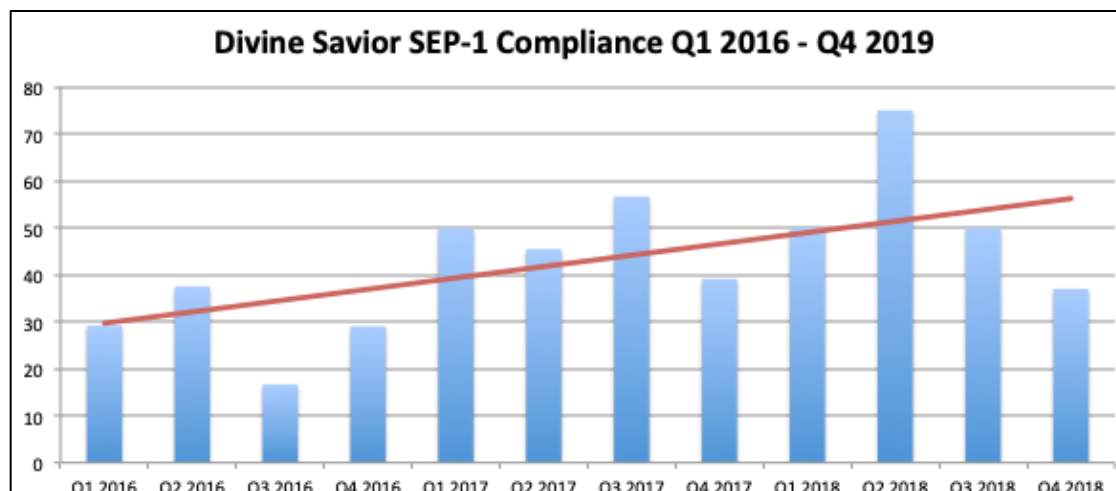


Roadmap to Success

- Create and activate an interdisciplinary team (include ED and ICU).
- Establish process for routine screening in all patient areas with a standardized screening tool.
- Design automated alerts for severe sepsis/septic shock.
- Standardize care protocols for patients who screen positive.
- Provide individual feedback for clinically significant “misses.”
- Plan interventions/Plan-Do-Study-Act projects if significant slip is identified.
- Keep the conversation going. (Showcase your results, good or bad, on a “scoreboard” in a clinical, but public area.)

Audit Overall Monthly Results and by SEP-1 Bundle Elements

Element	Percentage	Outcome
SIRS Screening	100%	✓
Blood Cultures	89%	✓
Initial Lactate	100%	✓
Repeat Lactate	75%	✓
30 mL/kg Bolus	38%	X
Broad spectrum Antibiotics	94%	✓
Vasopressors	100%	✓



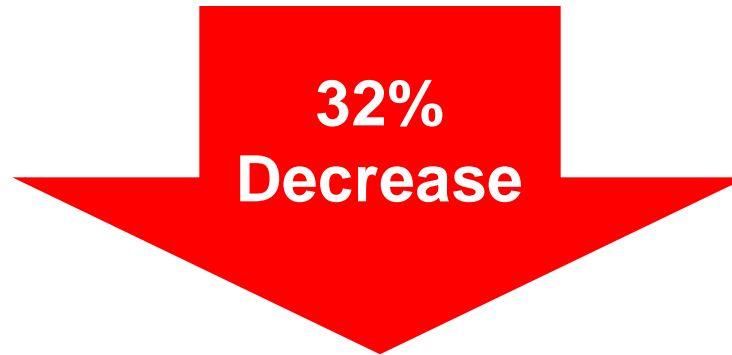
Plan-Do-Study-Act Examples

- Started looking at monthly instead of quarterly data
- Initiated Triage RN screening protocol
- Created blood cultures before antibiotics order **(Fail)**
- Created sepsis order set
- Repeat lactate didactics/meetings **(Fail)**
- Created reflex 2-hour lactate if initial lactate >2 order
- Made sepsis order set an RN-initiated protocol **(Fail)**
- Created suggested antibiotic resource and order set
- Posted ED Scoreboard in central location
- Created best practice alert pop-up if IV antibiotics are ordered without blood cultures

Wisconsin Hospital Sepsis Outcomes

Wisconsin Hospital Sepsis Mortality Rate*

2010
25.2%



2018
17.1%

*Wisconsin Hospital Association

Role of the ED Medical Director

Objective:

Discuss the role of the emergency department medical director in sepsis quality improvement work.



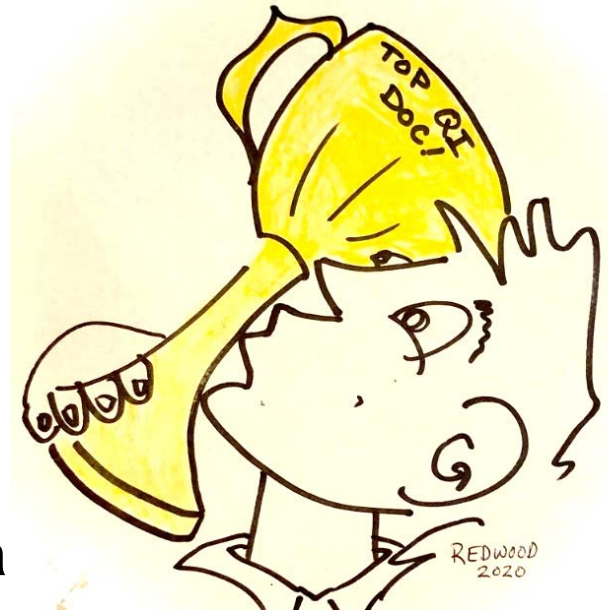
ED Medical Director as SEP-1 Educator

- Actively participate (or even chair) sepsis committee or Quality Improvement team
- Share monthly sepsis metrics.
- Solicit feedback from frontline ED staff as to how sepsis care is going (strengths, weaknesses, opportunities, threats).
- Keep current on medical literature related to sepsis and provide regular updates.
- Plan and participate in educational events like sepsis journal clubs, seminars, awareness campaigns or public relations videos.



ED Medical Director as SEP-1 Change Catalyst

- Form effective relationships within the hospital (administration, nursing, etc.).
- Meticulously review any change in sepsis policies or protocols.
- Be available for special tasks that will help move a sepsis Quality Improvement project forward.
- Be willing to be the first physician to trial a provide feedback for new sepsis workflows.
- Consider tracking and/or incentivizing quality sepsis care for the ED physician group:
 - Ongoing Professional Practice Evaluation
 - Incentive pay for SEP-1 performance
 - Recognize and reward top performers



Summary Points

- Definitions
 - 1991 Consensus Conference Sepsis Definition works well in ED.
 - 2016 Consensus Conference Sepsis Definition works well in ICU.
 - Q-SOFA lacks sensitivity compared to SIRS as a screening tool.
 - Clinicians will continue to straddle multiple definitions.
- Bringing Best Practices to the Bedside
 - Form a strong team, get organized, measure performance, celebrate success, and respond appropriately to slips.
- ED Medical Director
 - Cultivate a passion for sepsis care and use that passion to partner with your Quality Improvement team to educate others.
 - Use your position of influence and administrative tools to reward high performers and coach low performers.

Hospital-Based Sepsis Care: The Evolving Definition of Sepsis and the Role of the ED Medical Director and Quality Team in Sepsis Care

Question & Answer Session

Webinar Questions

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 - Board of Registered Nursing (Provider #16578)
- **Florida-only credit**
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