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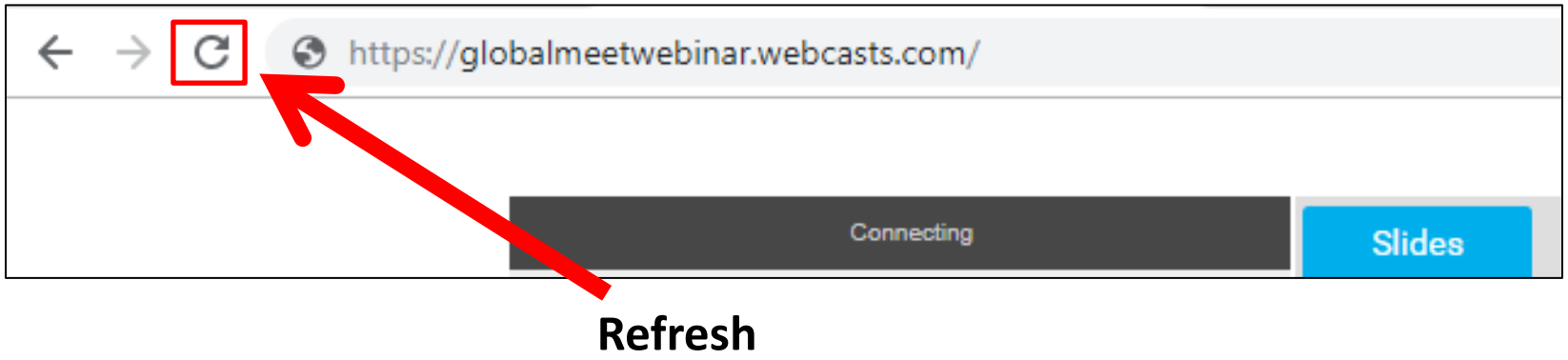

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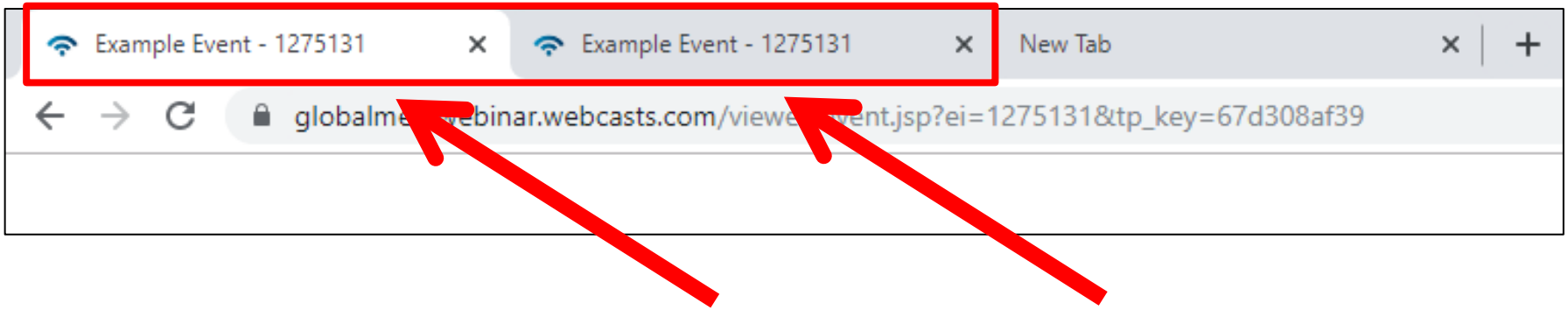

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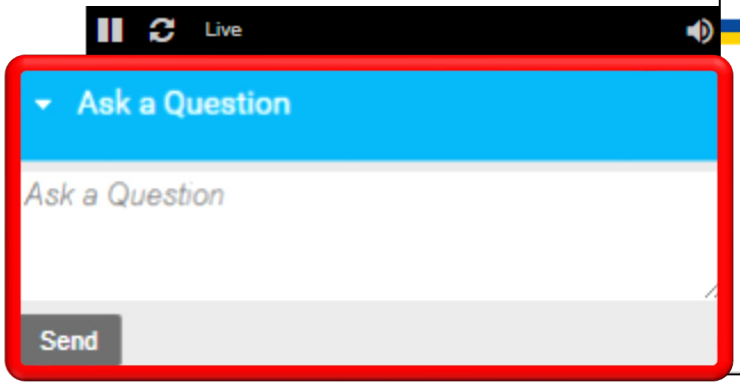

Inpatient Value, Incentives, and Quality Reporting (VIQR) Outreach and Education Support Contractor

Today's Presentation

SEP-1 and the 2021 Sepsis Guidelines Update: New Evidence, New Recommendations

Bobby Redwood, MD, MPH, FACEP
Physician Improvement Advisor, Wisconsin Hospital Association

Bob Dickerson, RRT, MSHSA
Senior Clinical Program Analyst
Behavioral Development and Inpatient and Outpatient
Measure Maintenance Support Contractor

November 16, 2022

Purpose

- To provide a summary of high-level updates in the Sepsis 2021 Guidelines
- To highlight how these updates may affect clinical care of the septic patient
- To highlight how these updates may affect hospital-level protocols and procedures relating to the SEP-1 core measure

Objectives

At the conclusion of the presentation, participants will be able to:

- Identify three or more key 2021 updates to sepsis guidelines.
- Identify one meaningful change in patient care in relation to the 2021 updates to sepsis guidelines.
- Identify one meaningful change in clinical documentation in relation to the 2021 updates to sepsis guidelines.

Acronyms and Abbreviations

APN	Advanced Practice Nurse	**ICU**	intensive care unit	**PEEP**	positive end-expiratory pressure
ARDS	acute respiratory distress syndrome	**IQR**	Inpatient Quality Reporting	**Q**	quarter
B	excluded	**IV**	intravenous	**qSOFA**	quick sepsis related organ failure assessment
C	Celsius	**kg**	kilogram	**SCCM**	Society for Critical Care Medicine
Cap	capillary	**L**	liter	**SEP**	sepsis
CHEST	American College of Chest Physicians	**MEWS**	Modified Early Warning Score	**SIRS**	systemic inflammatory response syndrome
CMS	Centers for Medicare & Medicaid Services	**mL**	milliliter	**SPO_2**	oxygen saturation
D	not met	**Mmol**	millimole	**SSC**	Surviving Sepsis Campaign
EHR	electronic health record	**MRSA**	Methicillin-resistant Staphylococcus aureus	**V**	version
F	Fahrenheit	**NEWS**	National Early Warning Score	**Vent**	ventilator
GRADE	Grading of Recommendations, Assessment, Development and Evaluation	**NQF**	National Quality Forum	**X**	rejected
ICD	International Classification of Diseases	**PA**	Physician Assistant		

Webinar Questions

- Send questions regarding the webinar content of guest speaker Dr. Bobby Redwood to rredwood@wha.org

- Send questions regarding the Centers for Medicare & Medicaid Services (CMS) Hospital Inpatient Quality Reporting (IQR) Program SEP-1 measure and specification to the QualityNet Inpatient Questions and Answers Tool: https://cmsqualitysupport.servicenowservices.com/qnet_qa

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SEP-1 and the 2021 Sepsis Guidelines Update:
New Evidence, New Recommendations

Bobby Redwood MD, MPH, FACEP

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

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

Key 2021 Updates to the Sepsis Guidelines

The Basics:

- The Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock 2021
- Fifth iteration of these guidelines
- Released in October 2021
- Includes 93 recommendations for the management of sepsis

Key 2021 Updates to the Sepsis Guidelines

Evidence-based recommendations related to the following:

- Screening and early treatment
- Initial resuscitation
- Management of infection/source control
- Hemodynamic monitoring
- Ventilation
- Long-term outcomes (new)
- Goals of care (new)

Evans L, Rhodes A, Alhazzani W, et.al. Surviving sepsis campaign: international guidelines for management of sepsis and septic shock 2021. Intensive Care Med. 2021 Nov;47(11):1181-1247. doi: 10.1007/s00134-021-06506-y. Epub 2021 Oct 2. PMID: 34599691; PMCID: PMC8486643.

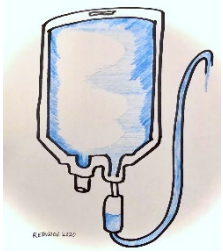
Key 2021 Updates to the Sepsis Guidelines

The Breakdown:

- Of the 93 statements:
  - 15 are strong recommendations (16%)
  - 54 are weak recommendations (58%)
  - 15 are best practice statements (16%)
  - 9 are statements declaring “no recommendation” (10%)
- This presentation will focus on strong recommendations, new recommendations, and best practices.

Evans L, Rhodes A, Alhazzani W, et.al. Surviving sepsis campaign: international guidelines for management of sepsis and septic shock 2021. Intensive Care Med. 2021 Nov;47(11):1181-1247. doi: 10.1007/s00134-021-06506-y. Epub 2021 Oct 2. PMID: 34599691; PMCID: PMC8486643.

Impact on Patient Care: *Fluid management*



- 30mL/kg crystalloid for initial hypotension or lactate greater than or equal to 4mmol/L is now suggested
- Due to the low quality of the evidence, the panel downgraded this from a strong to weak recommendation.
- Balanced crystalloid is *suggested* over normal saline.

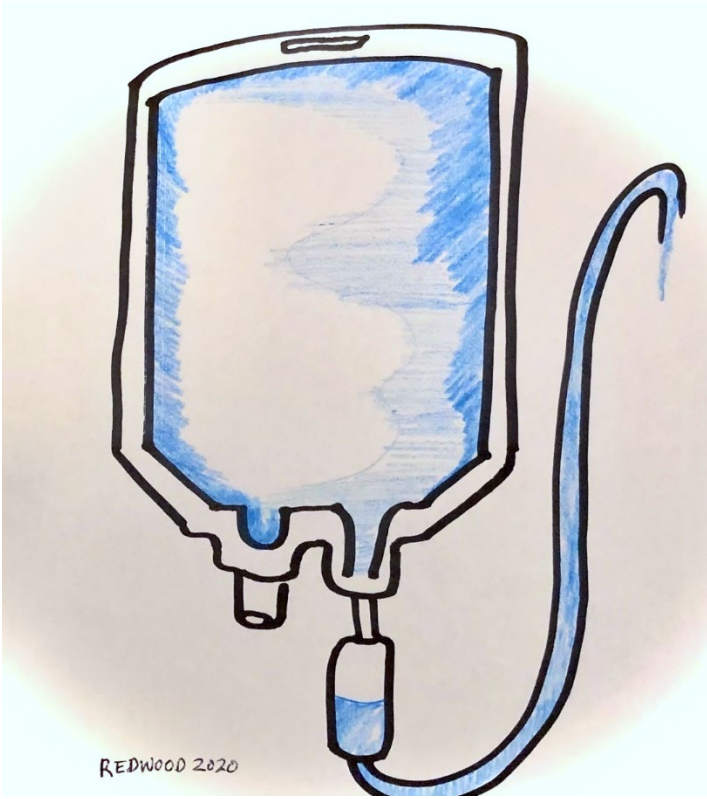
Evans L, Rhodes A, Alhazzani W, et.al. Surviving sepsis campaign: international guidelines for management of sepsis and septic shock 2021. Intensive Care Med. 2021 Nov;47(11):1181-1247. doi: 10.1007/s00134-021-06506-y. Epub 2021 Oct 2. PMID: 34599691; PMCID: PMC8486643.

Impact on Clinical Documentation

"or a lesser volume with a reason for the lesser volume specifically documented by the physician/APN/PA"*

Providers can now be compliant with the SEP-1 core measure when giving less than a 30 mL/kg crystalloid bolus.

- Reason must be clearly documented
- Fluid amount given must be clearly documented



* CMS Specifications Manual for National Hospital Inpatient Quality Measures Discharges from 01-01-2022 through 06-30-2022

Impact on Patient Care: *New, New, New*

Hemodynamic Measurement:

- *New suggestion*: Use capillary refill time to guide resuscitation, in addition to other assessments.
- *New suggestion:* Administer vasopressors via peripheral IV in medium to large vein for the first 6-hours to avoid delays related to central venous line placement.
- *New suggestion:* Administer IV corticosteroids for patients in septic shock on vasopressors.

Evans L, Rhodes A, Alhazzani W, et.al. Surviving sepsis campaign: international guidelines for management of sepsis and septic shock 2021. Intensive Care Med. 2021 Nov;47(11):1181-1247. doi: 10.1007/s00134-021-06506-y. Epub 2021 Oct 2. PMID: 34599691; PMCID: PMC8486643.

Impact on Patient Care:
Give the drugs… if you suspect the bugs

Antimicrobials:

- If “septic shock” or “high likelihood of sepsis,” give broad spectrum antibiotics within 1 hour.
- If low risk of infection, consider “time-limited” close monitoring, deferring antibiotics until an infectious diagnosis is clearer.
- Reserve MRSA coverage for those patients that are high risk for MRSA or have an established history (same for antifungals).

Evans L, Rhodes A, Alhazzani W, et.al. Surviving sepsis campaign: international guidelines for management of sepsis and septic shock 2021. Intensive Care Med. 2021 Nov;47(11):1181-1247. doi: 10.1007/s00134-021-06506-y. Epub 2021 Oct 2. PMID: 34599691; PMCID: PMC8486643.

SEP-1 and the 2021 Sepsis Guidelines Update:
New Evidence, New Recommendations

Bob Dickerson, RRT, MSHSA
Behavioral Health Measures Development and Inpatient and Outpatient Measure Maintenance Support Contractor

The SEP-1 Core Measure

Objective: Discuss the alignment of SEP-1 with the *Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock 2021*

SSC: International Guidelines 2021 Evidence Ratings

Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Certainty Ratings

Certainty	What it means
Very low	The true effect is probably markedly different from the estimated effect.
Low	The true effect might be markedly different from the estimated effect.
Moderate	The authors believe that the true effect is probably close to the estimated effect.
High	The authors have a lot of confidence that the true effect is similar to the estimated effect.

GRADE inherently has a degree of subjectivity and cannot be implemented mechanically. Two persons evaluating the same body of evidence might reasonably come to different conclusions about its certainty.
https://bestpractice.bmj.com/info/us/toolkit/learn-ebm/what-is-grade/

SSC: International Guidelines 2021 Recommendation Factors

Factors Determining Strong vs. Weak Recommendation

What should be considered	Recommendation Process
High or moderate evidence	**Strong:** higher quality evidence **Weak:** lower quality evidence
Certainty about benefits vs. harms and burdens	**Strong:** greater net benefits and desirable outcomes vs. potential harms, burden and undesirable outcomes **Weak:** smaller net benefits and lower certainty of benefit vs. potential harms, burden and undesirable outcomes
Certainty in, or similar, values	**Strong:** have more certainty or similarity in values and preferences **Weak:** lower certainty or similarity in values and preferences
Resource implications	**Strong:** lower cost of intervention compared to alternatives and other associated costs **Weak:** higher cost of intervention compared to alternatives and other associated costs

Rhodes A, Evans LE, Alhazzani W, et.al. Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock: 2016. Intensive Care Med. 2017 Mar;43(3):304-377. doi: 10.1007/s00134-017-4683-6. Epub 2017 Jan 18. PMID: 28101605.

SSC: International Guidelines for Management of Sepsis and Septic Shock 2021 Recommendation #2 *NEW*

2. We **recommend against** using qSOFA…as a single screening tool for sepsis or septic shock.

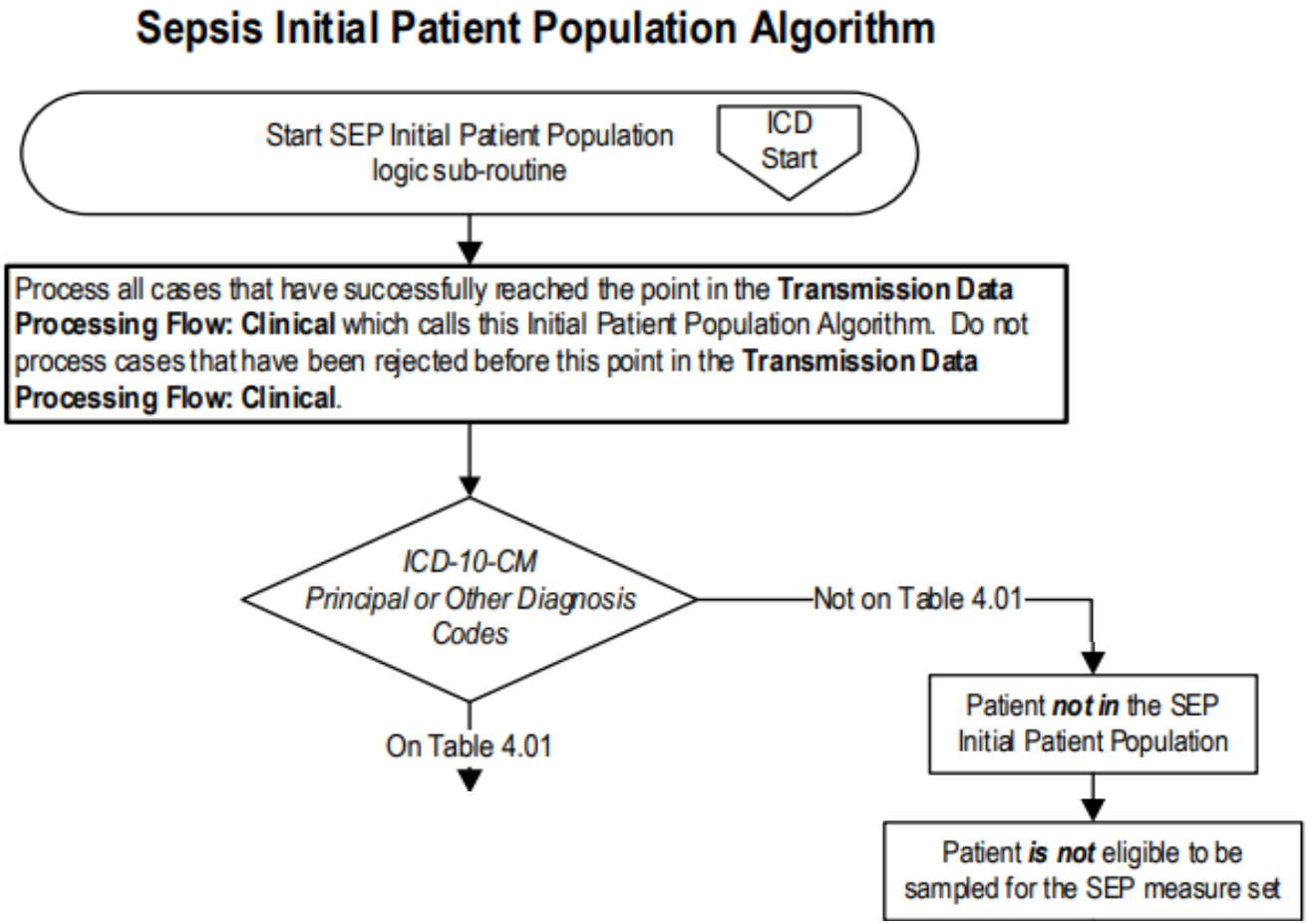
Strong recommendation, moderate-quality evidence

- qSOFA is more specific but less sensitive than having two of four SIRS criteria.
- Neither SIRS nor qSOFA are ideal screening tools; clinicians need to understand limitations of each.
- Because of poor sensitivity, the panel issued a strong recommendation against qSOFA as a single screening tool.

Evans L, Rhodes A, Alhazzani W, et.al. Surviving sepsis campaign: international guidelines for management of sepsis and septic shock 2021. Intensive Care Med. 2021 Nov;47(11):1181-1247. doi: 10.1007/s00134-021-06506-y. Epub 2021 Oct 2. PMID: 34599691; PMCID: PMC8486643.

Sepsis Initial Patient Population Algorithm v5.13

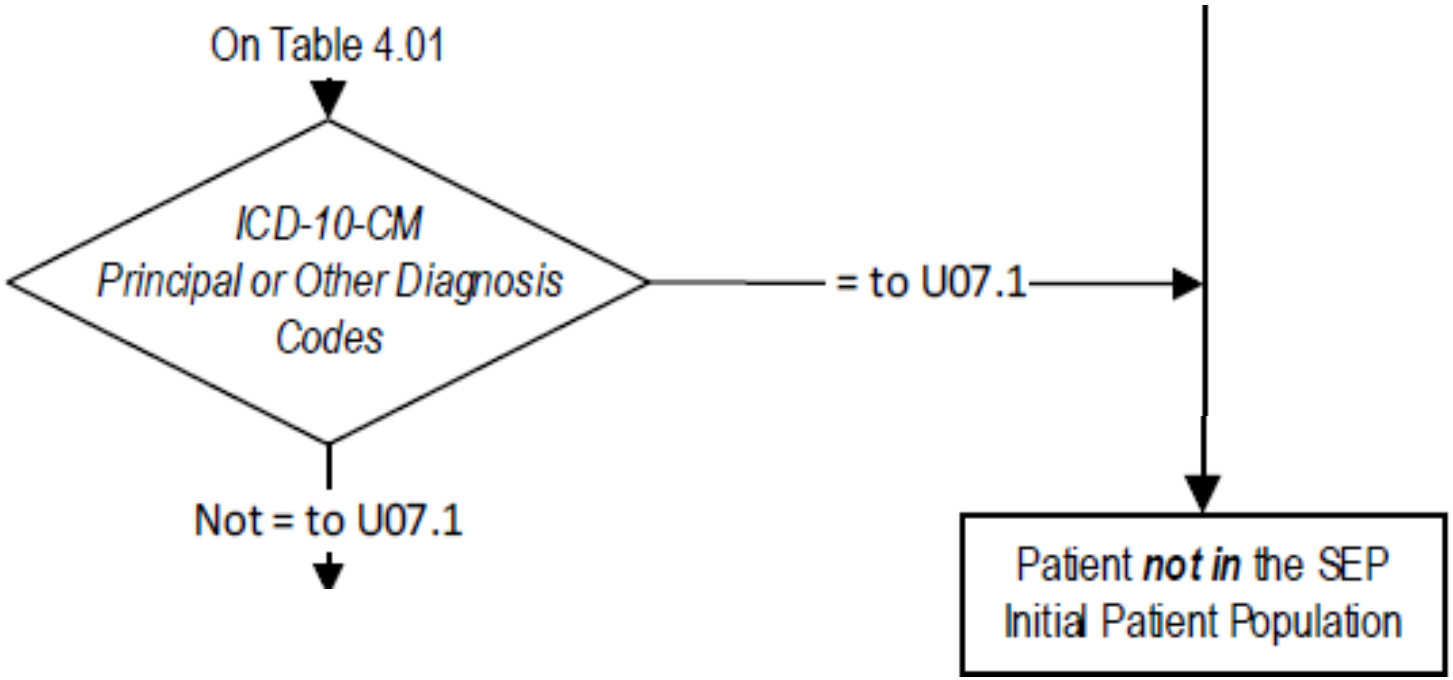
How do cases get into the measure?



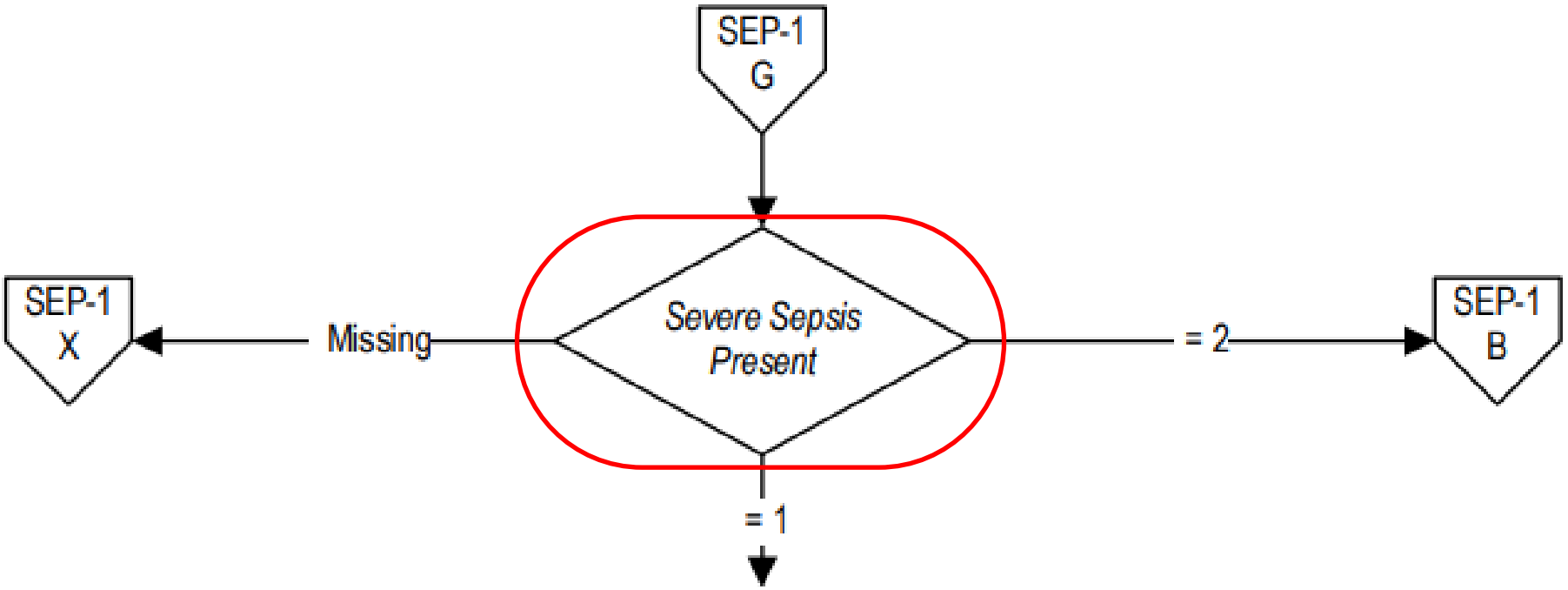
SEP-1 ICD-10 Codes Table 4.01: Severe Sepsis and Septic Shock

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



SEP-1 Algorithm



Severe Sepsis Present v5.13

- **SIRS 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

SSC: International Guidelines for Management of Sepsis and Septic Shock 2021 Recommendation #3 *No Change*

3. For adults suspected of having sepsis, we **suggest** measuring blood lactate.

Weak recommendation, low-quality evidence

- If sepsis is suspected, presence of elevated lactate levels significantly increases likelihood of a final diagnosis of sepsis.
- Lactate alone is not sensitive or specific enough to rule-in or rule-out a diagnosis of sepsis.
- This may not be readily available in resource-limited settings.
- Weak recommendation favors the use of lactate as an adjunctive test.

Evans L, Rhodes A, Alhazzani W, et.al. Surviving sepsis campaign: international guidelines for management of sepsis and septic shock 2021. Intensive Care Med. 2021 Nov;47(11):1181-1247. doi: 10.1007/s00134-021-06506-y. Epub 2021 Oct 2. PMID: 34599691; PMCID: PMC8486643.

SEP-1 Lactate

SEP-1 uses elevated lactate levels as a sign of organ dysfunction in combination with other criteria, sign of infection, and SIRS.

- There is a strong association between elevated lactate levels and mortality in patients with suspected infection or sepsis.
- Lactate is a required data element, is not used alone to determine presence of severe sepsis or septic shock.

SSC: International Guidelines for Management of Sepsis and Septic Shock 2021 Recommendation #5 *Downgraded*

5. For patients with sepsis induced hypoperfusion or septic shock, we **suggest** that at least 30 mL/kg of IV crystalloid fluid should be given within the first 3 hours of resuscitation.

Weak recommendation, low-quality evidence

- Timely, effective fluid resuscitation is critical to stabilize patients with sepsis-induced tissue hypoperfusion.
- No prospective studies compare different initial resuscitation crystalloid fluid volumes in sepsis or septic shock.
- Fluid administration should be guided by careful assessment of responsiveness to avoid over- and under-resuscitation.

Evans L, Rhodes A, Alhazzani W, et.al. Surviving sepsis campaign: international guidelines for management of sepsis and septic shock 2021. Intensive Care Med. 2021 Nov;47(11):1181-1247. doi: 10.1007/s00134-021-06506-y. Epub 2021 Oct 2. PMID: 34599691; PMCID: PMC8486643.

SEP-1 Crystalloid Fluid Administration Volume Updates (1)

- SEP-1 “default” crystalloid fluid volume is 30 mL/kg.
- Updates in v5.10* allowed for a lesser volume if documentation from a physician/APN/PA indicated that 30 mL/kg of crystalloid fluids would be detrimental or harmful for the patient and one of the following:
  - Portion of the volume was colloids, OR
  - advanced or end-stage heart failure, OR
  - advanced or end-stage chronic renal disease

* CMS Specifications Manual for National Hospital Inpatient Quality Measures Discharges from 07-01-2021 through 12-31-2021

SEP-1 Crystalloid Fluid Administration Volume Updates (2)

- In v5.11* crystalloid fluid volume options were further expanded to allow other reasons for a lesser volume, if specifically documented by the physician/APN/PA.
- SEP-1 “default” crystalloid fluid volume remains 30 mL/kg, if a lesser volume is not specified by the physician/APN/PA.

* CMS Specifications Manual for National Hospital Inpatient Quality Measures Discharges from 01-01-2022 through 06-30-2022

SSC: International Guidelines for Management of Sepsis and Septic Shock 2021 Recommendations #32, 33, and 34

32. For adults with sepsis or septic shock, we **recommend** using crystalloids as first-line fluid for resuscitation.

    Strong recommendation, moderate quality of evidence

33. For adults with sepsis or septic shock, we **suggest** using balanced crystalloids instead of normal saline for resuscitation.

    Weak recommendation, low quality of evidence

34. For adults with sepsis or septic shock, we **suggest** using albumin in patients who received large volumes of crystalloids over using crystalloids alone.

    Weak recommendation, moderate quality of evidence

Evans L, Rhodes A, Alhazzani W, et.al. Surviving sepsis campaign: international guidelines for management of sepsis and septic shock 2021. Intensive Care Med. 2021 Nov;47(11):1181-1247. doi: 10.1007/s00134-021-06506-y. Epub 2021 Oct 2. PMID: 34599691; PMCID: PMC8486643.

SEP-1 Crystalloid Fluids (1)

- In v5.0*, fluids initially limited to 0.9% Normal Saline or Lactated Ringers Solution.
- In v5.1**, Normosol and PlasmaLyte were added as acceptable fluids based on feedback from the field and emerging literature, demonstrating benefits of balanced crystalloids for some patients.

*CMS Specifications Manual for National Hospital Inpatient Quality Measures Discharges from 10-01-2015 through 06-30-2016

**CMS Specifications Manual for National Hospital Inpatient Quality Measures Discharges from 07-01-2016 through 12-31-2016

SEP-1 Crystalloid Fluids (2)

- In v5.3*, bullet points added:
  - Acceptable fluids are crystalloid or balanced crystalloid solutions.
  - Crystalloid fluid volumes to which the following electrolytes have been added may be counted toward the target ordered volume requirement: potassium, magnesium, calcium, lactate, acetate, or gluconate.
- In v5.10**, guidance allows for less than 30 mL/kg of crystalloid fluids if there is physician/APN/PA documentation that a portion of the crystalloid fluid volume was administered as colloids.

*CMS Specifications Manual for National Hospital Inpatient Quality Measures Discharges from 01-01-2018 through 06-30-2018

**CMS Specifications Manual for National Hospital Inpatient Quality Measures Discharges from 07-01-2021 through 12-31-2021

SSC: International Guidelines for Management of Sepsis and Septic Shock 2021 Recommendations #12 and 14

12. For adults with possible septic shock or a high likelihood for sepsis, we **recommend** administering antimicrobials immediately, ideally within 1 hour of recognition.

    Strong recommendation, low quality of evidence (septic shock)

    Strong recommendation, very low quality of evidence (sepsis without shock)

14. For adults with possible sepsis without shock, we **suggest** a time-limited course of rapid investigation and if concern for infection persists, the administration of antimicrobials within 3 hours from the time when sepsis was first recognized.

    Weak recommendation, very low quality of evidence.

Evans L, Rhodes A, Alhazzani W, et.al. Surviving sepsis campaign: international guidelines for management of sepsis and septic shock 2021. Intensive Care Med. 2021 Nov;47(11):1181-1247. doi: 10.1007/s00134-021-06506-y. Epub 2021 Oct 2. PMID: 34599691; PMCID: PMC8486643.

SSC: International Guidelines for Management of Sepsis and Septic Shock Antimicrobial Timing Recommendations History

- 2016 Guidelines**

  "…as soon as possible after recognition and within one hour for both sepsis and septic shock (strong recommendation, moderate quality of evidence; grade applies to both conditions)."

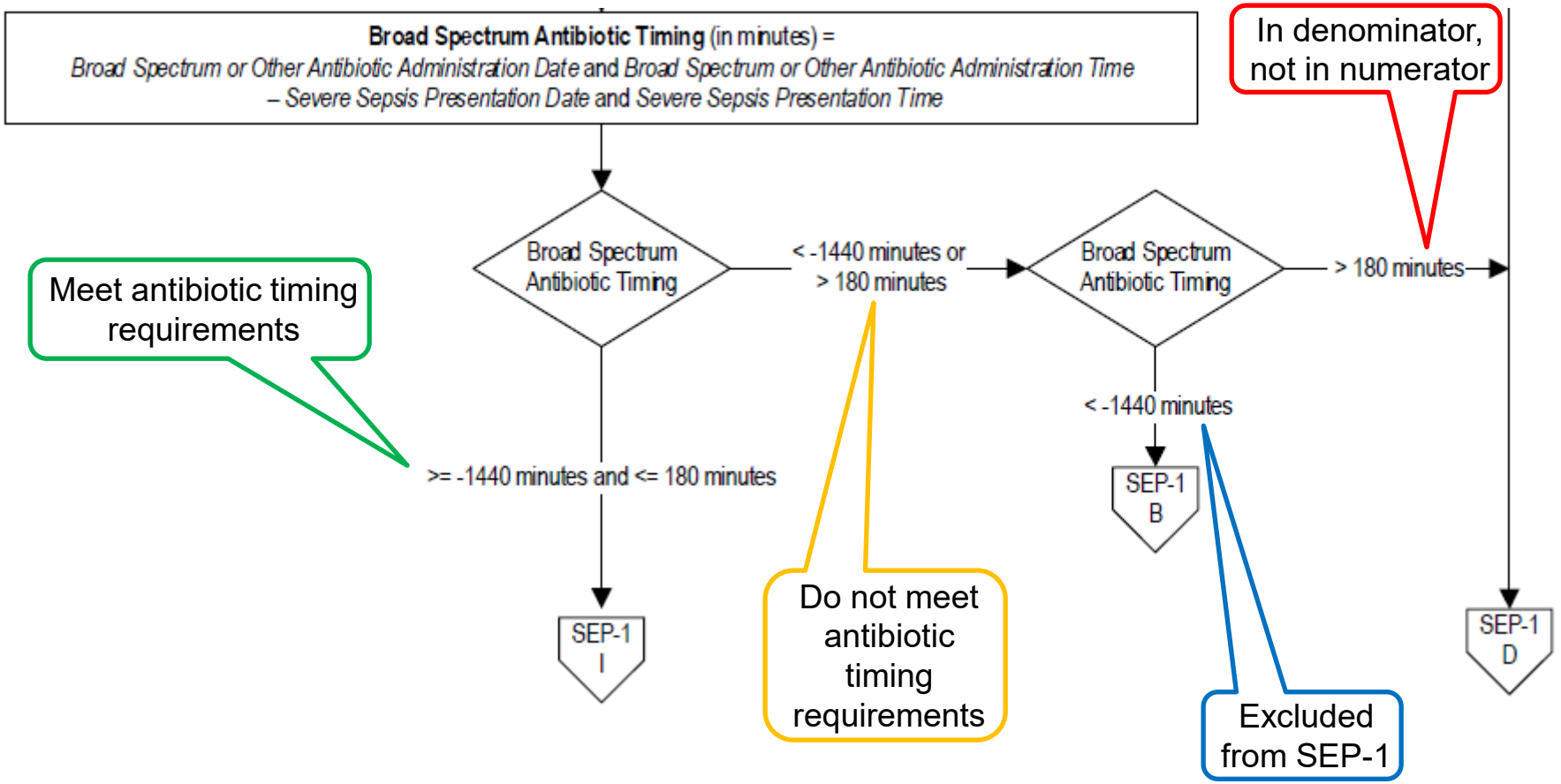
- 2012 Guidelines*

  "…within the first hour of recognition of septic shock (grade1B) and severe sepsis without septic shock (grade 1C)…"

*Rhodes, Evans, Alhazzani, et.al. Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock: 2016. Critical Care Medicine: March 2017 - Volume 45 - Issue 3 - p 486-552 doi: 10.1097/CCM.0000000000002255
https://journals.lww.com/ccmjournal/fulltext/2017/03000/surviving_sepsis_campaign__international.15.aspx

**Dellinger, Levy, Rhodes, et.al. Surviving Sepsis Campaign: International Guidelines for Management of Severe Sepsis and Septic Shock. Critical Care Medicine: February 2013 - Volume 41 - Issue 2 - p 580-637 doi: 10.1097/CCM.0b013e31827e83af
https://journals.lww.com/ccmjournal/fulltext/2013/02000/surviving_sepsis_campaign__international.24.aspx

SEP-1 Antimicrobial Timing



SEP-1 Antimicrobial Timing Considerations

- Operationalization challenges with vague or not clearly defined parameters
  - “as soon as possible”
  - “immediately”
  - “ideally within one hour”
- SEP-1 antimicrobial timing specific (within 24 hours prior to through three hours after identification of severe sepsis or septic shock) and considers:
  - Importance of early treatment
  - Operational workflow issues
  - An achievable timeframe

SEP-1 and the 2021 Sepsis Guidelines Update:
New Evidence, New Recommendations

Dr. Bobby Redwood, MD, MPH, FACEP
Physician Improvement Advisor, Wisconsin Hospital Association

Impact on Patient Care: *Ventilation Innovations*

Vent Settings:

- Recommend low tidal volume ventilation strategy for patients with sepsis-associated ARDS
- Recommend prone positioning in moderate-to-severe ARDS
- Recommend low tidal volume approach for all patients with sepsis-induced respiratory failure
- Suggest traditional recruitment maneuvers but recommend *against* an incremental PEEP strategy
- Jury is still out regarding use of liberal versus conservative oxygen targets (i.e., 88-92% versus > 96% SPO_2)

Evans L, Rhodes A, Alhazzani W, et.al. Surviving sepsis campaign: international guidelines for management of sepsis and septic shock 2021. Intensive Care Med. 2021 Nov;47(11):1181-1247. doi: 10.1007/s00134-021-06506-y. Epub 2021 Oct 2. PMID: 34599691; PMCID: PMC8486643.

Implications for Hospitals in Relation to SEP-1

- Guidelines recommend a standard operating system for the identification and treatment of sepsis (as opposed to a performance improvement model only).
  - Identification tools, standard order sets, etc.
- qSOFA is not recommended as a single screening tool for those at risk for sepsis.
  - The guidelines recommend multivariate instruments (i.e., SIRS).

Evans L, Rhodes A, Alhazzani W, et.al. Surviving sepsis campaign: international guidelines for management of sepsis and septic shock 2021. Intensive Care Med. 2021 Nov;47(11):1181-1247. doi: 10.1007/s00134-021-06506-y. Epub 2021 Oct 2. PMID: 34599691; PMCID: PMC8486643.

Implications for Hospital Systems of Care

Post discharge recovery and rehabilitation focus:

- Recommend
  - Screening for economic and social support
  - Involving patients and families in shared decision making around discharge planning
  - Medication reconciliation at both ICU and hospital discharge
  - Including information about sepsis and common impairment after sepsis in the discharge summary
  - Assessing for physical, cognitive, and emotional problems after hospital discharge

Evans L, Rhodes A, Alhazzani W, et.al. Surviving sepsis campaign: international guidelines for management of sepsis and septic shock 2021. Intensive Care Med. 2021 Nov;47(11):1181-1247. doi: 10.1007/s00134-021-06506-y. Epub 2021 Oct 2. PMID: 34599691; PMCID: PMC8486643.

Summary Points

- Key 2021 updates to the sepsis guidelines
- Potential impacts on patient care
  - **Fluids**: Crystalloids recommended, balanced instead of normal saline
  - **Hemodynamics**: Cap refill, peripheral pressors, corticosteroids if on pressors
  - **Antibiotics**: 1-hour if shock or likely sepsis, monitoring OK if unsure
  - **Vent**: Low tidal volumes, prone if ARDS, avoid incremental PEEP
- Potential impacts on clinical documentation
  - Fluid plan and rationale
- Implications for hospitals in relation to SEP-1
  - Hardwire sepsis care processes into policy, protocol, EHR-build, etc.
  - ICU transitional care program and attention to post-discharge care

Questions?

Question & Answer Session

Webinar Questions Follow-Up

- Send questions regarding the webinar content of guest speaker Dr. Bobby Redwood to rredwood@wha.org

- Send questions regarding the Centers for Medicare & Medicaid Services (CMS) Hospital Inpatient Quality Reporting (IQR) Program SEP-1 measure and specification to the QualityNet Inpatient Questions and Answers Tool: https://cmsqualitysupport.servicenowservices.com/qnet_qa

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This program has been approved for continuing education credit for the following boards:

- **National credit**
  - Board of Registered Nursing (Provider #16578)
- **Florida-only credit**
  - Board of Clinical Social Work, Marriage & Family Therapy and Mental Health Counseling
  - Board of Registered Nursing
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  - Board of Pharmacy

Note: To verify continuing education approval for any other state, license, or certification, please check with your licensing or certification board.

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