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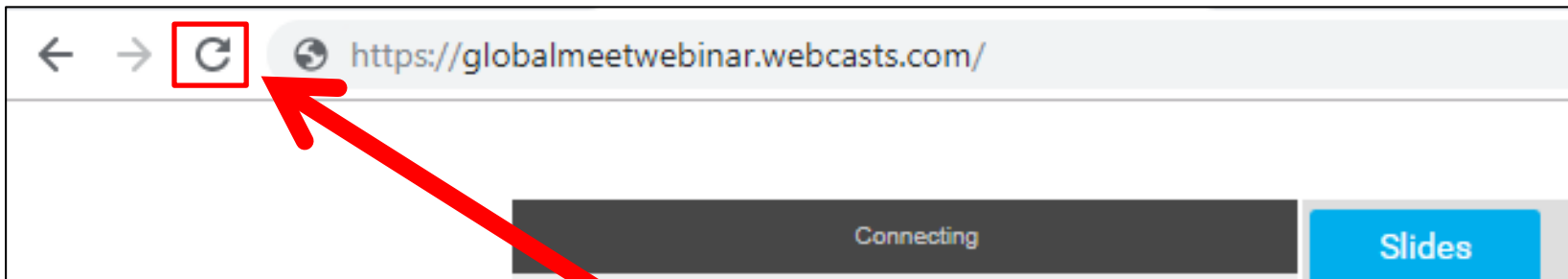
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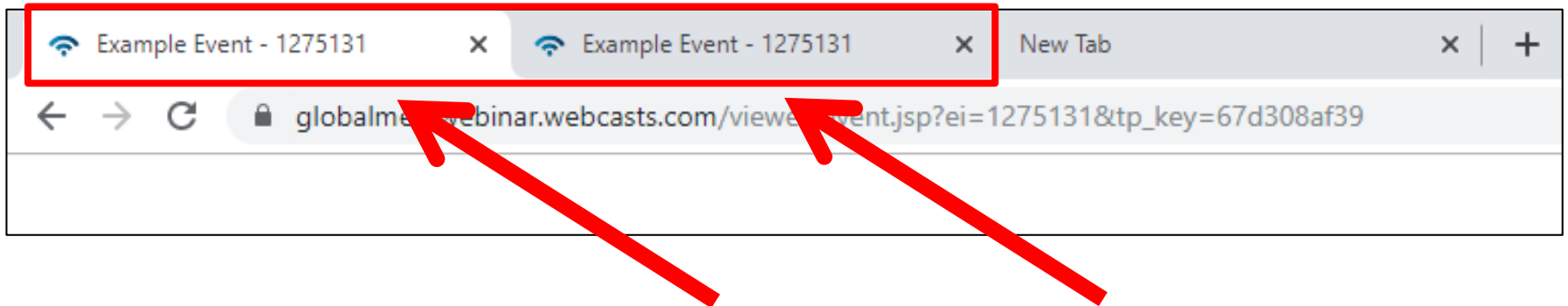
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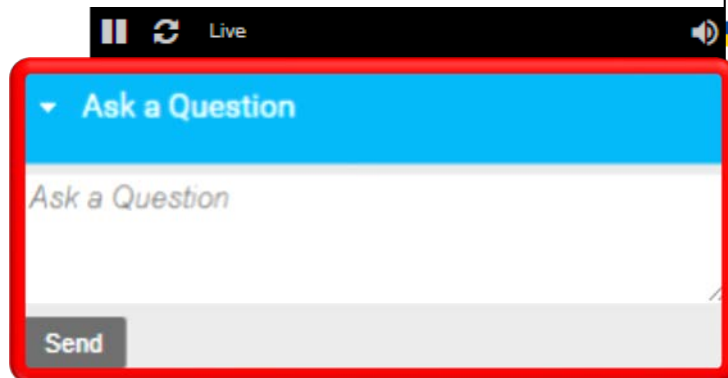
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Today's Presentation



Fluids, Lactate, and Champions:

An Emergency and Preventive Medicine Physician's Perspective on Sepsis and the SEP-1 Core Measure

October 7, 2020

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- 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.

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 CMS's views.

Acronyms and Abbreviations

ABG	arterial blood gas	EGDT	early goal-directed therapy	LOS	length of stay
ACCP-SCCM	American College of Chest Physicians/Society of Critical Care Medicine	ESRD	end stage renal disease	MAP	mean arterial pressure
BiPap	bilevel positive airway pressure	FAQ	frequently asked questions	mL	milliliters
BP	blood pressure	FP	false positive	mmHg	millimeters of mercury
C	Celsius	h	hour	mmol	millimole
cc	cubic centimeters	HR	heart rate	NA	not applicable
CHF	congestive heart failure	hr	hour	PR	public relations
CMS	Centers for Medicare & Medicaid Services	ICU	intensive care unit	QI	quality improvement
COVID-19	Coronavirus disease 2019	IV	intravenous	SEP	sepsis
CV	cardiovascular	IVF	intravenous fluid	SOFA	Sequential Organ Failure Assessment
CXR	chest x-ray	kg	kilogram	U/O	urine output
ED	emergency department	L	liter	VBG	venous blood gas

Purpose

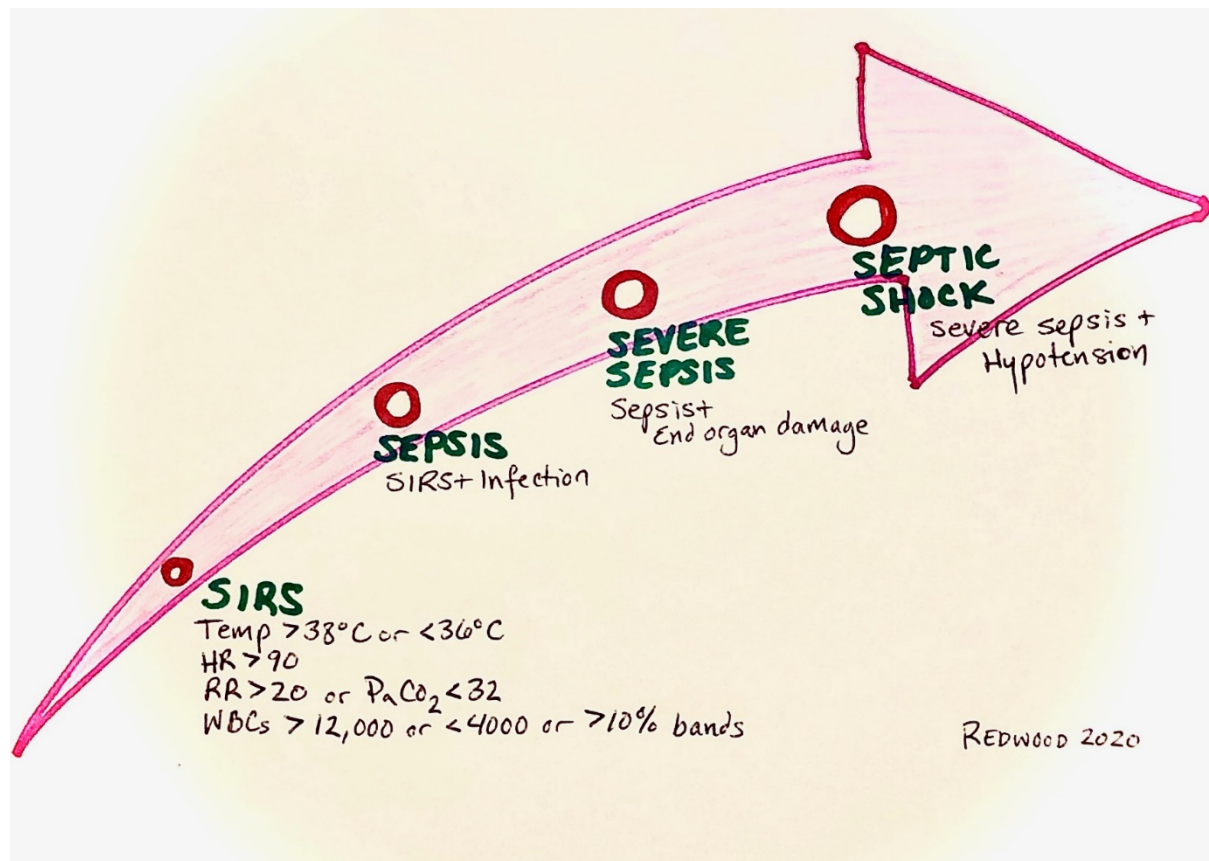
The purpose of this event is to provide a physician's perspective on the SEP-1 measure as it relates to population health and sepsis care in the emergency department.

Objectives

Participants will be able to:

- Discuss various sepsis definitions.
- Identify key benefits of the 30 mL/kg fluid bolus in severe sepsis and septic shock.
- Identify the utility of serum lactate in screening for septic shock and guiding resuscitation efforts.
- Identify strategies for engaging a physician champion in sepsis quality improvement efforts.

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.

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)



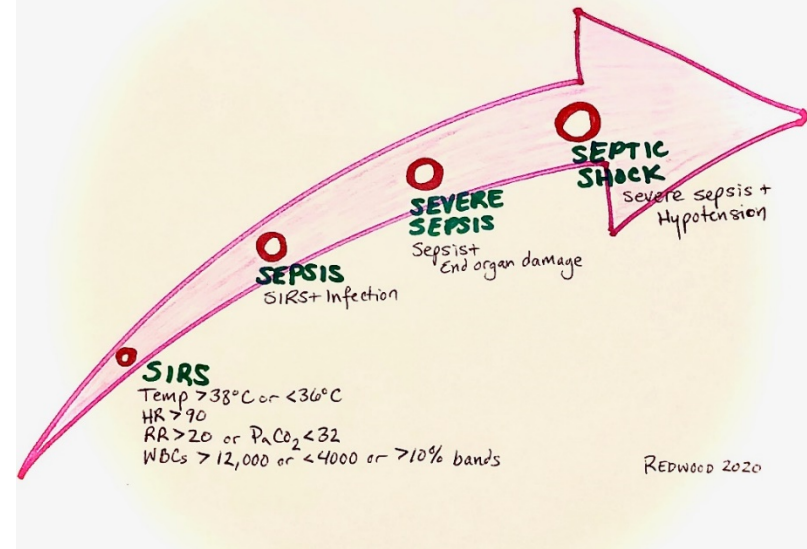
Sepsis Definitions: Old and New

	Established Definitions	Sepsis-3 Definitions	Surviving Sepsis Campaign Guidelines
Sepsis	Presumed/known infection + ≥ 2 systemic inflammatory response syndrome criteria	≥ 2 Sequential Organ Failure Assessment (SOFA) criteria (present or increased) Includes hypotension + normal lactate (shock)	Sepsis = severe sepsis
Severe Sepsis	Sepsis + end organ dysfunction, Lactate > 2	Not a category	"Sepsis" = established severe sepsis definition
Septic Shock	Sepsis + refractory hypotension (+/- lactate)	Vasopressors and lactate > 2 mmol/L	Sepsis + refractory hypotension (+/- lactate)
Mortality ratio = Observed mortality ----- expected mortality	Sepsis = low acuity Observed mortality low ----- Expected mortality low	Sepsis = higher acuity Observed mortality higher ----- Expected mortality low	NA

Sharp, B. "CMS SEP-1/Sepsis Updates." Presentation at Wisconsin American College of Emergency Physicians Spring Symposium, Milwaukee, WI, April. 3 2019.

What's in a Name?

There are multiple sepsis definitions discussed in clinical literature. SEP-1 is based off the 1991 Consensus Conference definition and this definition is useful for clinical practice.



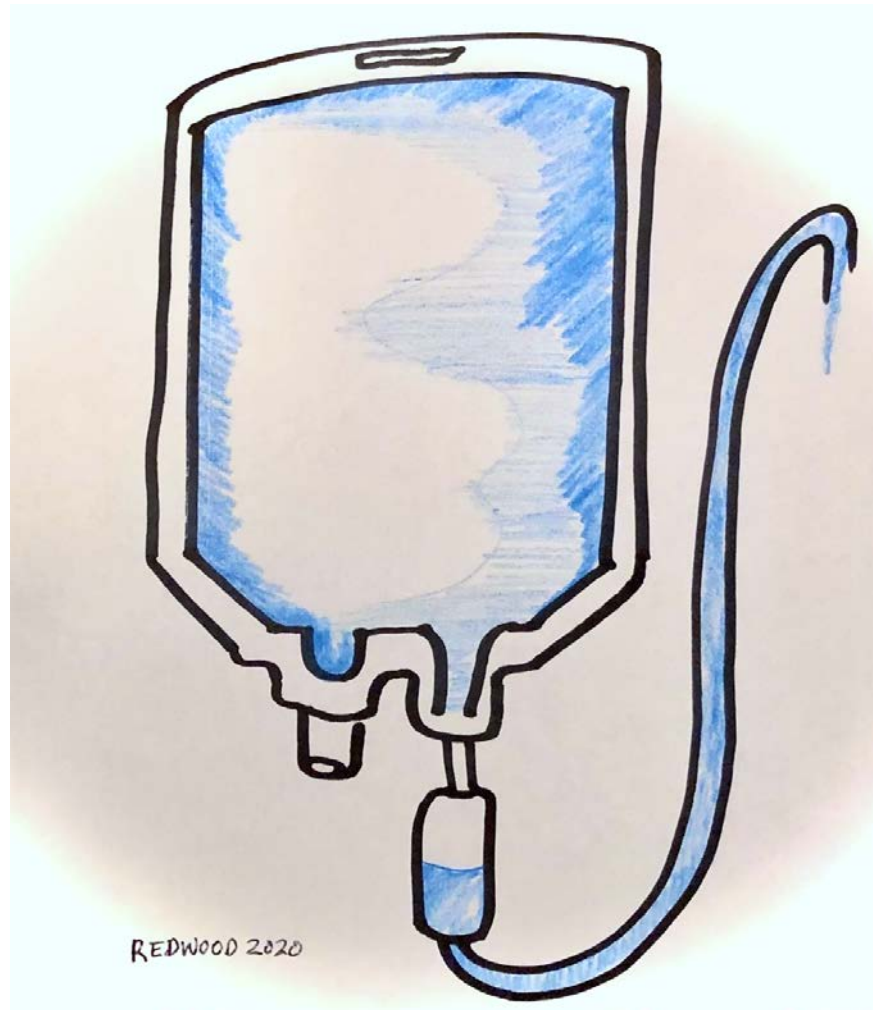
My definitions based on clinical research and experience:

- Really sick (sepsis with lactate ≥ 4 = **30% mortality**)
- Ready to crump (sepsis with low BP = **36.7% mortality**)
- Transfer please! (low BP + lactate ≥ 4 = **46.1% mortality**)

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.

Shapiro, NI, M.D. Howell, D. Talmor, L.A. Nathanson, A. Lisbon, R.E. Wolfe, and J.W. Weiss. "Serum lactate as a predictor of mortality in emergency department patients with infection." *Annals of Emergency Medicine*, vol. 45, no. 5, 2005, pp. 524-528.

Fluids



Early Goal Directed Therapy Controversy and Rebuttal

- Promise, Process, & Arise Trials. 2015.
 - EGDT is not superior to usual care for ED patients with septic shock but is associated with increased utilization of ICU resources.
- Rebuttals
 - Saleh et al 2018.
 - Analysis of data from the three trials showed a lower risk of serious adverse events in the EGDT group compared to usual care.
 - Jaehne et al 2018.
 - “Hydrophobia is unwarranted in early sepsis care. Recent EGDT septic shock trials used similar amounts resuscitation fluids in the acute phase when compared to the original EGDT trial. This was associated all time lows in mortality.”
 - Ding et al. 2018 (Meta-analysis, 16 Studies, 6000 patients)
 - EGDT reduces mortality in adult patients with severe sepsis and septic shock. Lactate guided therapy may result in an even greater mortality benefit than EGDT.

Saleh, A.S. "Is early goal-directed therapy associated with a higher risk of adverse events?" *Journal of Intensive Care*, vol 6., no.1, 2018, pp. 1-4.

Jaehne, A. K., and E.P. Rivers. "Early liberal fluid therapy for sepsis patients is not harmful: Hydrophobia is unwarranted but drink responsibly." *Critical Care Medicine*, vol. 44, no. 12, 2016, pp. 2263.

Ding, X., "Early goal-directed and lactate-guided therapy in adult patients with severe sepsis and septic shock: a meta-analysis of randomized controlled trials." *Journal of Translational Medicine*, vol 16, no. 1. 2018, pp. 331.

“30 by 3” in CHF

- Leisman et al. 2016
 - Early initiation of IV fluids improves survival in severe sepsis or septic shock.
 - IV fluids within 30 minutes had a mortality of 13.3% compared to 18% in patients receiving IVF later
- Rourke et al. 2019 (1114 septic patients, 229 with CHF)
 - Decreased mortality in 30 by 3 cohort, no significant increase in iatrogenic pulmonary edema. Longer LOS if 30 by 3 not given.
 - Physicians reluctant to give 30 by 3 because of “CHF” label on chart (not because of exam, CXR findings, or last ejection fraction)
- Duttuluri et al. 2016 (1010 septic patients, 333 with CHF)
 - In patients with pre-existing CHF presenting with severe sepsis and septic shock and hypotension, inadequate fluid resuscitation (<30 mL/kg) increases in-hospital mortality and intubation rates.

Leisman, D, "Association of fluid resuscitation initiation within 30 minutes of severe sepsis and septic shock recognition with reduced mortality and length of stay." *Annals of Emergency Medicine*. vol 68, no.3, 2016, pp. 298-311.

Rourke, "Fluid resuscitation in septic patients with comorbid congestive heart failure." *Proceedings in Wisconsin American College of Emergency Physicians*, Spring Symposium, 2019.

Duttuluri, M. "Fluid resuscitation dilemma in patients with congestive heart failure presenting with severe sepsis/septic shock." *Critical Care: Circulatory Hemodynamics, Shock, Cardiovascular Disease, and Fluid Management*, *American Thoracic Society*, 2016.

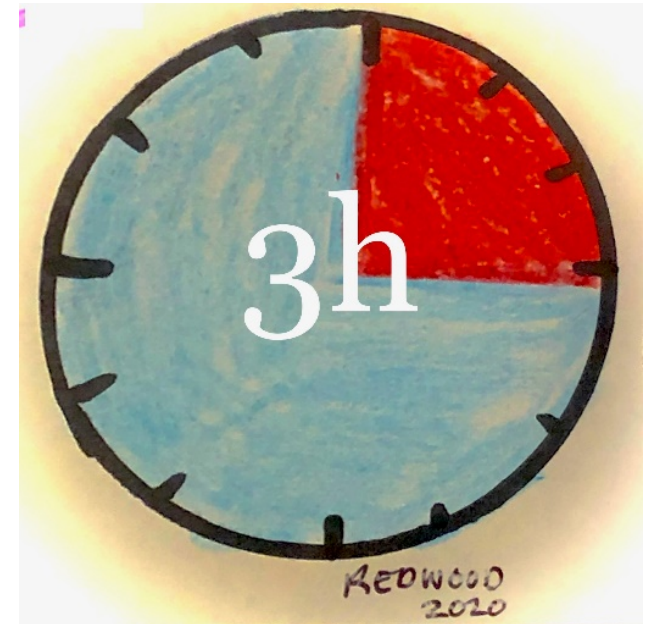
“30 by 3” Despite Comorbidities in Sepsis

- Your patient may well need more than 30 mL/kg; use defined endpoints to guide further fluid resuscitation.
 - U/O >0.5 cc/kg/hr, MAP >65, Normalization of lactate.
- In CHF/ESRD, prioritize fluid resuscitation over respiratory status.
 - Iatrogenic fluid overload is uncommon in severe sepsis (even in CHF/ESRD).
 - Re-assess, re-assess, re-assess.
 - You’re probably not saving an intubation in the ED; these patients often get crash intubations on the floor or get tubed in the ICU.
- Play The Worst-Case Scenario Game.
 - Iatrogenic pulmonary edema or respiratory distress.
 - Patient may need BiPAP, emergent dialysis or intubation.
 - This is a NET GOOD compared to CV collapse and death from septic shock.

Jaehne, A. K., and E. P. Rivers. "Early liberal fluid therapy for sepsis patients is not harmful: Hydrophobia is unwarranted but drink responsibly." *Critical Care Medicine*, vol. 44, no.12, 2016, pp. 2263.

Who should not get the 30 by 3?

- In general, very few exceptions
 - Patients who are not truly septic (false positives)
 - Patients with clinical pulmonary edema (even in this situation, a fluid challenge may be appropriate)
 - COVID-19 patients who are not clearly dehydrated
 - Comfort care patients
 - Patient refusal after shared decision making
- Not exceptions
 - CHF patients with sepsis
 - ESRD patients with sepsis
 - Morbidly obese patients with sepsis



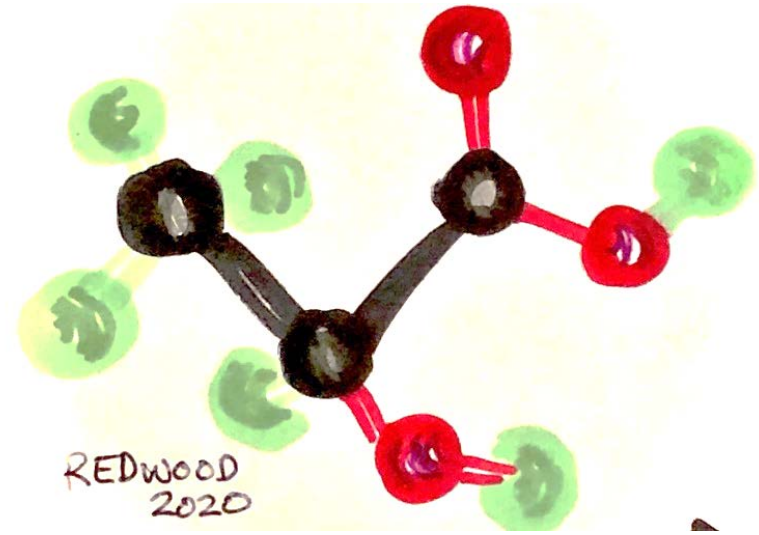
Jaehne, A. K., and E. P. Rivers. "Early liberal fluid therapy for sepsis patients is not harmful: Hydrophobia is unwarranted but drink responsibly." *Critical Care Medicine*, vol 44, pp. 12, 2016, pp. 2263.

Lactate



Highlight on Serum Lactate: Definition and FAQs

- Lactate corresponds with adrenergic state and cytokine storm (not tissue hypoxia as previously believed).
- Do I need an arterial lactate? No, excellent correlation between ABG & VBG.
- Are tourniquet samples ok? Yes.
- Un-iced sample ok? Yes, for 15 minutes.
- Acceptable turn-around time? <1-minute test, 30-minute result in ED is reasonable
- Is lactate expensive? No, \$39.53.
- Note: These recommendations come from clinical research and experience and are not necessarily specified in the SEP-1 measure specifications.



Shapiro, NI, M.D. Howell, D. Talmor, L.A. Nathanson, A. Lisbon, R.E. Wolfe, and J.W. Weiss. "Serum lactate as a predictor of mortality in emergency department patients with infection." *Annals of Emergency Medicine*, vol. 45, no. 5, 2005, pp. 524-528.

Younger, J.G., J.L. Falk, and S.G. Rothrock. "Relationship between arterial and peripheral venous lactate levels." *Academic Emergency Medicine*. vol. 3, no. 7. 1996, pp. 730-744.

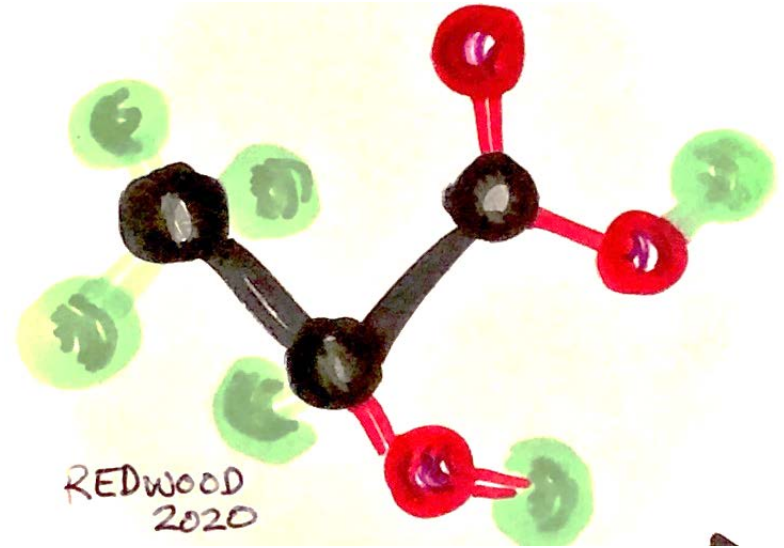
Lavery, R.F., D.H. Livingston, B.J. Tortella, J.T. Sambol, B.M. Slomovitz, and J.H. Siegel. "The utility of venous lactate to triage injured patients in the trauma center." *Journal of the American College of Surgery*, vol 190, no. 6, 2000, pp. 656-64.

Jones, A.E., M.M. Leonard, J. Hernandez-Nino, and J.A. Kline. "Determination of the effect of in vitro time, temperature, and tourniquet use on whole blood venous point-of-care lactate concentrations." *Academic Emergency Medicine*, vol. 14, no. 7, 2007, pp. 587-591.

Ward, M.J., W.H. Self, A. Singer, D. Lazar, and J.M. Pines. "Cost-effectiveness analysis of early point-of-care lactate testing in the emergency department." *Journal of Critical Care*. vol. 36, 2016, pp. 69-75.

Highlight on Serum Lactate: Two Main Lactate Critiques

- It's a non-specific test with a broad differential diagnosis. Why are we relying so heavily on this?
- Why are we using 2.0 as a lactate cut-off; it's only meaningful after 4.0?



Andersen, L.W., Mackenhauer, J., Roberts, J.C., Berg, K.M., Cocchi, M.N., and Donnino, M.W. "Etiology and therapeutic approach to elevated lactate levels." *Mayo Clinic Proceedings*, vol. 88, no. 10, 2013, pp. 1127-1140.

#1 Lactate Critique

- Question #1: It's a non-specific test with a broad differential diagnosis. Why are we relying so heavily on this?
- Answer: The lactate is a screening test designed to cast a wide net. False positives are expected.
- Recall: Lactate is an independent predictor of in-hospital mortality. Even if your patient is not septic, lactate levels STILL predict mortality. (Is that not useful?)

Shapiro, NI, M.D. Howell, D. Talmor, L.A. Nathanson, A. Lisbon, R.E. Wolfe, and J.W. Weiss. "Serum lactate as a predictor of mortality in emergency department patients with infection." *Annals of Emergency Medicine*, vol. 45, no. 5, 2005, pp. 524-528.

Lactic Acidosis

Differential Diagnosis

Type A: Adrenergic State

- **Shock** Most Common Cause
- Post-cardiac arrest
- Regional tissue ischemia
- Anaerobic muscle activity

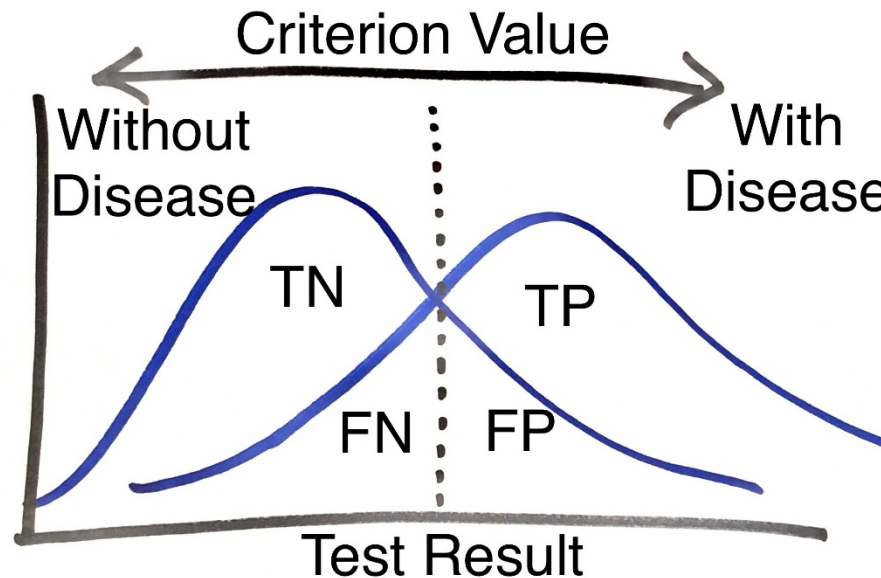
Type B: Not Adrenergic State

- Toxins (Cocaine and toxic alcohols)
- Pharmacological agents (i.e. metformin)
- Thiamine deficiency
- Malignancy
- Liver failure
- Mitochondrial disease
- Diabetic ketoacidosis

Andersen, L.W., Mackenhauer, J., Roberts, J.C., Berg, K.M., Cocchi, M.N., and Donnino, M.W. "Etiology and therapeutic approach to elevated lactate levels." *Mayo Clinic Proceedings*, vol. 88, no. 10, 2013, pp. 1127-1140.

#2 Lactate Critique

- Question #2: Why are we using 2.0 as a lactate cut-off?
It's only meaningful after 4.0.
- Answer: Err on the side of conservative cut-offs and let the epidemiology experts adjust it as we gather more meta-data on our outcomes.



Andersen, L.W., Mackenhauer, J., Roberts, J.C., Berg, K.M., Cocchi, M.N., and Donnino, M.W. "Etiology and therapeutic approach to elevated lactate levels." *Mayo Clinic Proceedings*, vol. 88, no. 10, 2013, pp. 1127-1140.

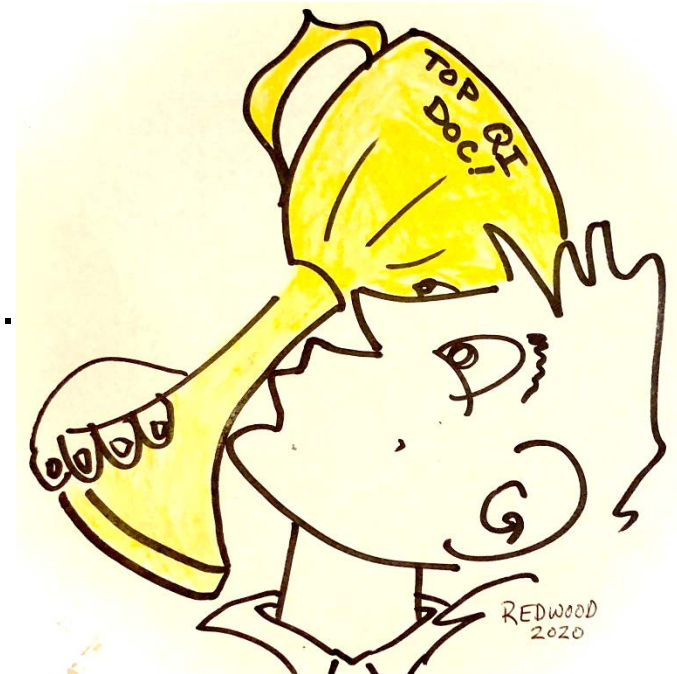
Champions



Physician Engagement:

Role of the SEP-1 Physician Champion

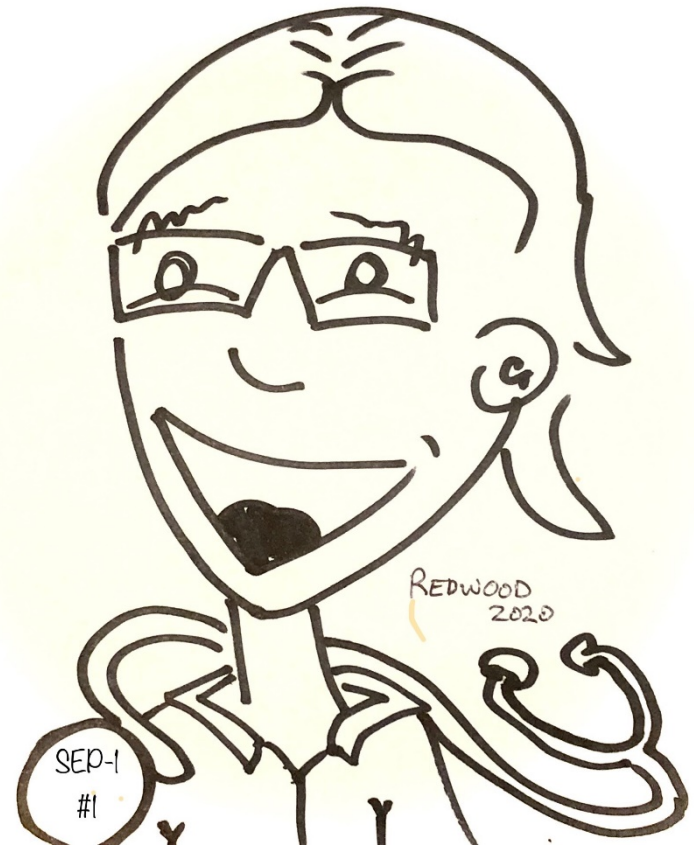
- Be available for special tasks (often one-time responsibilities) that will help move the project forward.
- Be an ambassador for the QI team.
- Provide real-time feedback on QI projects.
- Be willing to be the first physician to trial the changes.
- Help guide expectations/accountability when building ongoing measures into the medical staff structure.



Physician Engagement:

Key Traits of the SEP-1 Physician Champion

- **Must Have:** Believer in the SEP-1 core measure and consistent presence in your hospital
- **Bonus:**
 - Personal commitment
 - Professional credibility
 - Active participation in a quality improvement team
 - Skills in quality improvement (or desire to develop them)
 - An effective relationship with other groups (ex: administration, nursing) in the hospital



Physician Engagement:

How to Retain or Lose a Physician Champion

- Retention: The Right “Ask”
 - Ask for clinical expertise; don’t expect a volunteer QI professional.
 - Be strategic in their involvement.
 - Do they need to be present for every meeting?
Best to engage when it involves changing practice.
 - Respect their time.
 - Offload them of clerical, organizational, or mundane tasks whenever possible.
 - Use non-meeting meetings.
- Buh-Bye: The Wrong “Ask”
 - Pushing for interventions that are overly burdensome to clinical work-flow.
 - Putting them in an adversarial position with their peers or medical director.
 - Asking them to abandon their physician voice (i.e. anecdotes/PR talk).

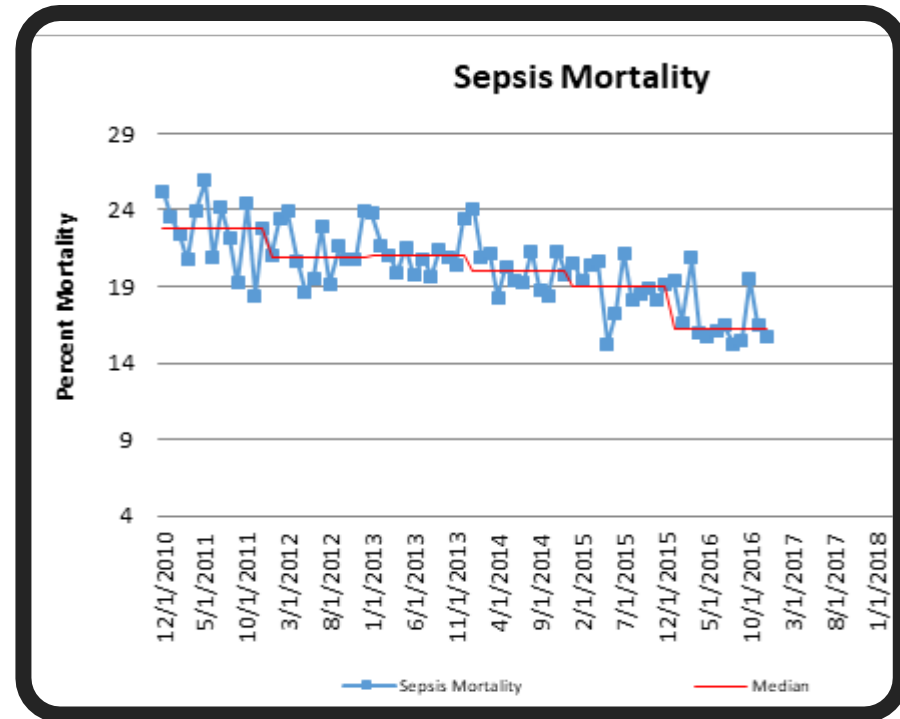
Summary Points

- Fluids
 - “30 by 3” is safe and should be administered in severe sepsis and septic shock despite co-morbidities.
 - CHF on the chart \neq 0% ejection fraction. Most septic CHF patients can tolerate the 30 by 3.
 - Iatrogenic fluid overload in ED sepsis resuscitation is rare and highly avoidable with frequent reassessment.
- Lactate
 - Lactate is a screening test for shock and an independent predictor of in-hospital mortality.
 - False positives are expected, easily dealt with, and have little effect on clinical care.
- Physician Engagement
 - Find a believer and a stable presence.
 - Their main role is promoting education and behavior change; make the rest easy.

The Wisconsin Experience

Road Map to Success

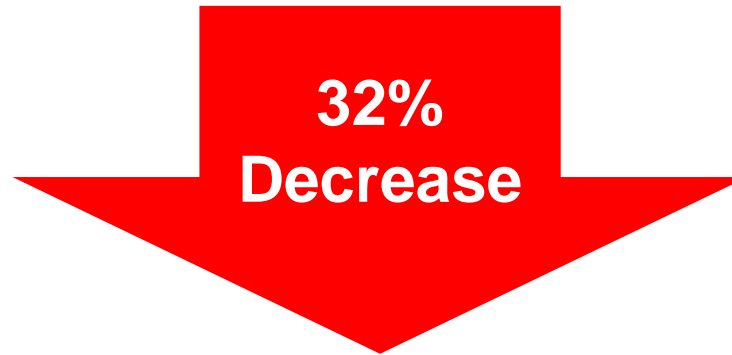
- Create and activate an interdisciplinary team (include ED and ICU)
- Establish process for routine screening in all patient areas with a standardized screening tool
- Design automated alerts for severe sepsis/septic shock
- Standardize care protocols for patients who screen positive
- Keep the conversation going (i.e. showcase your results—good or bad—on a “scoreboard” in a clinical, but public area)
- Keep your compass at true north and never give up!



Wisconsin Hospital Sepsis Outcomes

Wisconsin Hospital Sepsis Mortality Rate*

2010
25.2%



2018
17.1%

*Wisconsin Hospital Association

Resources

- For questions, please contact Dr. Bobby Redwood at:
rredwood@cooleydickinson.org

Fluids, Lactate, and Champions: An Emergency and Preventative Medicine Physician's Perspective on Sepsis and the SEP-1 Core Measure

Questions

Continuing Education (CE) Approval

This program has been approved for [CE 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
 - Board of Nursing Home Administrators
 - Board of Dietetics and Nutrition Practice Council
 - Board of Pharmacy

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

Fluids, Lactate, and Champions: An Emergency and Preventative Medicine Physician's Perspective on Sepsis and the SEP-1 Core Measure

Thank you

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