2016 Sepsis Update: Pearls, Pitfalls, and Core Measure Quicksand

Jack Perkins, MD FACEP, FAAEM, FACP
Assistant Professor of Emergency and Internal Medicine
Virginia Tech Carilion School of Medicine
Why Do We Need a Core Measure for Sepsis?
Objectives

- Arise, ProMISE, ProCESS
- Key points in sepsis management
- The new CMS sepsis core measure
- Our hospital’s “sepsis alert process”
Cost of Sepsis Care to U.S. Healthcare System

- Most expensive condition to treat in the United States since 2008
- 2011 Hospital costs: > $20 billion
- 1997 Hospital costs: $4.4 billion

This data likely underestimates cost
Rivers and EGDT for Severe Sepsis and Septic Shock

- 263: “EGDT” vs. Standard
- Enrollment: ≥ 2 SIRS plus either
  1) Lactate ≥ 4 mmol/liter
  2) SBP < 90 after 20-30ml/kg bolus
- Mortality 30.5% EGDT
- Mortality 46.5% Standard
ProCESS 2014

- All groups ~ 2200 ml bolus before enrollment
- Antibiotics within ~ 100 minutes for all
- Eligibility: ≥ 2 SIRS + either
  1) Refractory hypotension (after bolus)
     - SBP < 90 mmHg or vasopressors
  OR
  2) Lactate ≥ 4.0 mmol/liter
ARISE 2014

- Similar enrollment criteria to ProCESS
- Eligibility: $\geq 2$ SIRS + either
  1) Refractory hypotension (after bolus)
     - SBP < 90 mmHg or MAP < 65 mmHg
     OR
  2) Lactate $\geq 4.0$ mmol/liter
ARISE and ProCESS Big Picture

1) All patients received aggressive IVF before enrollment (2000-2500 ml)

2) Most patients received antibiotics within 100 minutes
Key Statement from ARISE

“The results of our trial show that EGDT, as compared with *usual* resuscitation practice, did not decrease mortality among patients presenting to the emergency department with early septic shock.”
Where do We Stand in 2016?

What “fundamentals” of sepsis care remain if a protocol is not necessary?
Key Point #1 – Timing of Antibiotics

- Mortality ↑ every hour that antibiotics are not given within the 1st six hours of evaluation!

- Kumar et al. Crit Care Med 2006
- Gaieski et al. Crit Care Med 2010
Key Point #2 – Choose the Antibiotic Wisely

- Inappropriate antibiotics for septic shock
  ⇒ 5-fold reduction in survival

- Kumar et al. *Chest* 2009
Key Point #3 – Early and Aggressive Fluid Resuscitation

- Early fluid resuscitation improves mortality
- Lee et al. *Crit Care Med* 2012
- ARISE, ProMISE, ProCESS
Key Point #3.5 – Fluid Resuscitation Caveats

- Goal is minimum 30ml/kg bolus except...
- Caution in patients w/ CHF or ESRD
- Consider smaller bolus and reassess volume status
- May need early transition to vasopressors
Key Point #4 - Severe Sepsis is Subtle

Evidence of organ dysfunction (attributed to sepsis)

- Sepsis induced hypotension
- Elevation of serum lactate above lab upper limit normal
- Urine output <0.5ml/kg/hr
- Acute lung injury \( \frac{\text{PaO}}{\text{FiO}_2} <250 \) in the absence of pneumonia or <200 in the presence of pneumonia.
- Creatinine >2.0 mg/dL
- Bilirubin >2 mg/dL
- Platelet count <100,000 µL
- International normalized ratio (INR) >1.5
Flashing Back to 2012

Surviving Sepsis Campaign
International Guidelines for Management of Severe Sepsis and Septic Shock: 2012

Critical Care Medicine
2013 Feb;41(2):580-637
Flashing Back to 2012

- “Protocolized” treatment in 1st six hours
- CVP 8-12 mmHg
- MAP $\geq$ 65 mmHg
- Urine output $\geq$ 0.5 ml/kg/hour
- ScvO$_2$ $\geq$ 70%
- Lactate normalization
Key Point #5 – Resuscitation Goals 2016

- “Protocolized” treatment in 1st six hours
- CVP 8-12 mmHg
- MAP ≥ 65 mmHg
- Urine output ≥ 0.5 ml/kg/hour
- ScvO₂ ≥ 70%
- Lactate normalization
Key Point #5 – Resuscitation Goals 2016

- MAP $\geq$ 65 mmHg
- Urine output $\geq$ 0.5 ml/kg/hour
- Lactate normalization
In Steps the Government

- Can we have a national standard?
  - Three main concepts
    1) Early antibiotics
    2) Aggressive IVF
    3) Meaningful resuscitation endpoints
What is a “Core Measure”?

- CMS (Center for Medicare and Medicaid Services) and JC partnered in 2001

- Original measures: PNA, CHF, ACS, pregnancy
What is a “Core Measure”? 

- Designed to hold hospitals accountable for “standards of care”
- Many measures come from the National Quality Foundation (NQF)
The Stick

- Financial penalties for failing to meet core measures
- Hospitals scrambled to meet measures
Good Idea…

- Core measure mandating ASA for ACS
- Evidence-based and non-controversial
- Reasonable expectation for hospitals of all sizes
Bad Idea...

- CAP core measure
CAP Core Measure

- Patients need antibiotics within 4 hours of registration if CAP suspected
- Ummm….what could go wrong?
Introducing the Azithro Pez Dispenser in Triage!
CAP Core Measure

- They also need blood cultures before antibiotics…

- What are the chances of a false positive?

- How does a “true” positive change management?
The Sepsis Core Measure

- Most difficult disease to diagnose
- Wide spectrum of disease
- Definitions have undergone change
- Don’t even have accurate estimates of disease incidence
Introducing the CMS Sepsis Core Measure
Core Measure Basics

- Went “live” 10/1/15
- But only in “data collecting phase”
- Penalties begin 10/1/16
- Unclear how much money is at stake
Which Patients Qualify?

- ED patients and inpatients
- Severe sepsis and septic shock
- Clock starts when severe sepsis/shock is recognized
- That last one could be a problem
Severe Sepsis/Shock Specifics

Within 3 Hours Complete:

- Lactate measurement
- Broad spectrum abx administered
- Blood cultures prior to abx
- 30ml/kg crystalloid (for SBP <90 or decrease by >40mmHg from baseline, or MAP <65, or lactate >/= 4)
Septic Shock Specifics

Within 6 Hours Complete:

- Repeat volume status and tissue perfusion assessment
- Hmmm…this could be an issue
Option One

Document All of the Following

- Vital signs
- Cardiopulmonary exam
- Cap refill
- Peripheral pulse evaluation
- Skin examination (e.g. mottling, cool)
Option Two

Document Two of the Four

- CVP
- ScvO2
- Bedside CV Ultrasound
- Passive leg raise or fluid challenge
Last Few Items

Within Six Hours

- Repeat lactate if elevated initially

- Initiate vasopressors if hypotensive after fluid administration
Some of the Issues...

- Not clear when “time zero” starts
- Only Normal Saline and LR count as fluids
- CVP is like reintroducing the Iron Lung
- How long do you “wait” for cultures?
- Their definition of severe sepsis is problematic to be kind
Core Measure Severe Sepsis

- Evidence of organ dysfunction (attributed to sepsis)
  - Sepsis induced hypotension
  - Elevation of serum lactate above lab upper limit normal
  - Urine output <0.5ml/kg/hr
  - Acute lung injury PaO/FiO₂ <250 in the absence of pneumonia or <200 in the presence of pneumonia.
  - Creatinine >2.0 mg/dL
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Reason for Optimism

- Evidence of organ dysfunction (attributed to sepsis)
  - Sepsis induced hypotension
  - Elevation of serum lactate above lab upper limit normal
  - Urine output <0.5ml/kg/hr
  - Acute lung injury PaO/FiO₂ <250 in the absence of pneumonia or <200 in the presence of pneumonia.
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Why Does This Make Sense?

Severe Sepsis
Severe Sepsis Mortality

Vincent J, Crit Care Med; 2006
Severe Sepsis

- Tough to identify
- NINE different qualifiers
- Mortality rises with each qualifier
- Classic patient “waiting to crump”
Our Hospital Solution
CRMH 2014

- 140-200+ patients with sepsis per month

- 40-60% severe sepsis/septic shock
  - Approximately 65% from ED
  - Almost 30% mortality
Mortality 2014

- Jun-Oct ED CRMH Sev. Sepsis w. Shock
- Jun-Oct ED CRMH Septic Shock
- ARISE Trial EGDT group
- ARISE Trial Usual Care Group
- Process Trial EGDT
- Process Trial Standard
- Process Trial Usual
# Arrival (Hours) to 1ST Antibiotic for Severe Sepsis Patients 2014

**Hours**

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<th>Month</th>
<th>Average of time to abx (hrs)</th>
<th>Average of ABX Goal 1 hrs</th>
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<td>May 2014</td>
<td>4.95</td>
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<td>June 2014</td>
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Jun-Oct ED CRMH Sev. Sepsis w. Shock, 6.4

ARISE Trial
EGDT group, 1.4

ARISE Trial Usual Care Group, 2

ED LOS median

CRMH vs. ARISE trial- ED LOS
CRMH vs ProCESS Average Hospital LOS

- Jun-Oct ED CRMH Septic Shock: 15.88
- Process Trial EGDT: 11.1
- Process Trial Standard: 12.3
- Process Trial Standard: 11.3
Summary of Problems at CRMH

• Mortality exceeds national average
• Time to 1st antibiotics excessive
• ED LOS too long
• Hospital LOS above national average
• Cost excessive (i.e. significant potential cost savings)
Sepsis Alert Process
Go Live date: 3/1/15

Key Features of new sepsis alert

1) POD RN 1:1 with sepsis alert patient
2) Inpatient team will see patient in < 60 min
3) Transfer center to prioritize beds
4) All fluids for sepsis alert now “Normosol”
5) Everything required for 1st three hours in orderset (EPIC)
When to Trigger Sepsis Alert

• All septic shock patients

• Lactate $\geq$ 4.0 mmol/L + sepsis

• Severe sepsis + three qualifiers

• Provider discretion if none of above
Automatic ICU Admission

1) Septic shock

2) Mechanical ventilation

3) Lactate $\geq 4.0$ mmol/L

4) Severe sepsis + $\geq$ three qualifiers
Our Hospital Data
Control Group

- 249 patients
- Severe sepsis or septic shock present on admission before 3/1/15
- MEDS score to compare severity of illness
Variables Analyzed

- Time to initial antibiotic
- ED length of stay
- Hospital length of stay
- Death in hospital
- Death at 30 days (all cause)
Study Group

• All “Sepsis Alerts” since 3/1/15 (218 patients)

• Limitation: \(\sim 80\%\) of “Sepsis Alerts” truly had sepsis as final etiology of illness
Control Group
- MEDS: 10.9
- Time to 1st ABX: 2.76 hours
- ED LOS: 8.23 hours
- Hospital LOS: 9.91 days
- In hospital mortality: 21.3%
- 30 day mortality: 25.3%

Study Group (Alerts)
- MEDS 11.01
- Time to 1st ABX: 1.59 hours
- ED LOS: 5.75 hours
- Hospital LOS: 7.91 days
- In hospital mortality: 18.9%
- 30 day mortality: 20.0%
Estimated Cost Savings

• Roughly $500,000 averaged over 12 months

• Mostly due to decreased ICU days
Core Measure Summary

- Core measure “goal” is admirable
- Numerous flaws to iron out
- Core measure or not: each hospital has to evaluate and optimize care to improve patient-centered outcomes
Sepsis Key Points Summary

- Early, broad-spectrum antibiotics
- Early and aggressive IVF
- Meaningful resuscitation end points
- Do not underestimate severe sepsis
Questions or the Slides?

Jackperkins37@gmail.com