SEPSIS MANAGEMENT - PROTOCOL VARIATION

“SO WHAT DO I DO NOW?”

Using Simulation as a Tool to Improve Performance and Outcomes
DISCLOSURE

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OUTLINE

• Compare and Contrast Sepsis Trials
  ▶ Trials
  ▶ Non-Invasive Strategies
  ▶ Commonalities
• Recognition is Key
  • Time Zero
  • Antibiotics
• Keys to a Successful Initiative
• Accelerating the Process - Using Simulation as Part of the Solution
• HASC Sepsis Training Results
• MSC Sepsis Quality Solution
THE TRIALS


Challengers

• **ProCESS** – published March 18, 2014 in NEJM
• **ARISE** - Estimated Study Completion Date: April 2015
  Estimated Primary Completion Date: July 2014
• **PRoMISE** – Estimated Completion Date – November 2014
SURVIVING SEPSIS CAMPAIGN GUIDELINES 3 HOUR BUNDLE

TO BE COMPLETED WITHIN 3 HOURS OF TIME OF PRESENTATION †:

1. Measure lactate level
2. Obtain blood cultures prior to administration of antibiotics
3. Administer broad spectrum antibiotics
4. Administer 30 mL/kg crystalloid for hypotension or lactate ≥4 mmol/L

† “time of presentation” is defined as the time of triage in the Emergency Department or, if presenting from another care venue, from the earliest chart annotation consistent with all elements severe sepsis or septic shock ascertained through chart review.
5. Apply vasopressors (for hypotension that does not respond to initial fluid resuscitation to maintain a mean arterial pressure (MAP) ≥ 65mmHg)

6. In the event of persistent arterial hypotension despite volume resuscitation (septic shock) or initial lactate ≥4 mmol/L (36mg/dl):
   - Measure central venous pressure (CVP)
   - Measure central venous oxygen saturation (ScvO2)

7. Remeasure lactate

8. Targets for quantitative resuscitation included in the guidelines are CVP of ≥8 mm Hg, ScvO2 of ≥70% and lactate normalization
**PROCESS³**

*Three Arms*

- **EGDT** – 439 patients
- **Protocolized Standard Therapy** – 446 patients
- **“Usual” care** - 456 patients
  - 31 hospitals participated

- Study sites had to use the measurement of serum lactate levels and had to adhere to the Surviving Sepsis Campaign guidelines for nonresuscitation aspects of care
  1. >75% received antibiotics prior to randomization
  2. All arms received > 2L NS prior to randomization

- Could not routinely use resuscitation protocols for septic shock
- Could not routinely use continuous Scvo2 catheters

**Results:** the 60 day all cause mortality was no different among the groups and ranged from 18% to 20%.
EGDT

- Dobutamine/PRBCs
- 93% central line placement
- Mortality 21%

Protocol-Based

- No dobutamine/PRBCs only if HGB < 7.5
- Fluids until MD thought patient was replete
- 57% central line placement
- Mortality rate 18.2%

"Usual Care"

- Bedside provider decided all aspects of care
- 58% central line placement
- Mortality rate 18.9%
Considerations:

- Patients were documented to have lower baseline lactate, were younger and less comorbidities, than in the Rivers trial.
- Usual care most likely heavily influenced by familiarity with EGDT
  - 70% of the hospitals in ProCESS had some form of "sepsis protocol"
  - The 18% mortality rate in the "usual care" arm of illustrates a dramatic change in the management and outcomes of patients with septic shock.
- Enrolled patients were recognized to be in septic shock
SURVIVING SEPSIS CAMPAIGN Responds to ProCESS Trial 28 March 2014

- ProCESS does not address the protocolized management of patients who are in severe sepsis without septic shock, a group of patients for whom early detection and treatment remain critical.

- Aggressive protocolized management of these patients has likely lowered severe sepsis and septic shock mortality since the inception of the SSC.
A National Quality Forum (NQF) patient-safety committee removed its earlier recommendation to use central-line catheterization in some sepsis patients on the heels due to the ProCESS findings that central lines did not improve patient outcomes.

10:44 AM - April 24, 2014
Jones 2010 – Lactate Clearance vs. ScvO2 Measurement

- Mortality was 23% in the ScvO2 group vs. 17% in the Lactate Clearance group (non significant difference)

Results
- EGDT protocol using serial measurement of serum lactate levels was not inferior to an EGDT protocol that used Scvo2 monitoring.
- In-hospital mortality and the use of intravenous fluids, blood transfusions, and dobutamine were similar to those seen in the ProCESS trial.
- Rivers’ study did appear to have sicker patients on average than Jones’ patients
The Australasian Resuscitation in Sepsis Evaluation (ARISE) study is an international, multicenter, randomized, controlled trial designed to evaluate the effectiveness of early goal-directed therapy compared with standard care for patients presenting to the emergency department with severe sepsis.

- Estimated Study Completion Date: April 2015
- Estimated Primary Completion Date: July 2014
- Final data collection date for primary outcome measure
• **Protocolised Management In Sepsis** - study to investigate whether early, goal-directed, protocolised resuscitation (targeting specific, measured hemodynamic goals) improve outcomes in emerging septic shock relative to usual resuscitation
  - **Duration:** April 2010 - November 2014
• Studies have correlated increased IVC collapse with low central venous pressures in septic patients\textsuperscript{7-9}
- Patients who were predicted to be fluid responsive (measured IVC collapse >50%) demonstrated statistically significant improvements in catheter-measured cardiac index, cardiac output and mean arterial pressure after fluid resuscitation. 10-11
The GNYHA/UHF STOP Sepsis Collaborative\textsuperscript{12}

- Alternative protocol of non-invasive options that uses ultrasonography to assess volume administration
- Measures serum lactate as a surrogate marker of tissue oxygenation

**Findings:**
- Hospitals that chose the non-invasive protocol over the invasive approach still achieved a comparable mortality benefit
STOP SEPSIS COLLABORATIVE’S SIMILARITIES TO PROCESS TRIAL

• Non-invasive and invasive severe sepsis protocols were applied only in patients with severe sepsis who came into the hospital through the ED and whose goals of care were curative

• All had severe sepsis or septic shock with hypotension despite being given 2L of fluids, or their serum lactate level was elevated at >4 mmol/L
The Surviving Sepsis Campaign leadership still recommends targeting

- CVP of 8-12 mm Hg,
- SCVO2 of 70% or SVO2 of 65%
- Lactate normalization

The Campaign recognizes some limitations with CVP and ScvO2 BUT maintain
- Low CVP and low ScvO2 are useful measurements to guide resuscitation
CAN WE REACH A CONSENSUS?

All studies agree:

• Early recognition is key

• Early treatment
  ❖ Time to antibiotics
  ❖ Time to tissue – (optimize tissue oxygenation) – fluids – lactate clearance

  1. *ProCESS* – lactate clearance emphasized
  2. *Jones* – lactate as efficient as ScvO2
  3. *SSC Guidelines* – 3 hr bundle – measure lactate/antibiotics/fluids

➢ No CVP or ScvO2 monitoring in 3 hr. bundle
THE MAIN PROBLEM - RECOGNITION
EARLY RECOGNITION

Time Zero

Needs to offer the best balance of:

- Reliability and reproducibility
- Optimizing the overall performance improvement effort as to:
  - Early diagnosis
  - Appropriate treatment of severe sepsis

Will lead to earlier and more frequent recognition → Increased total number patients with improved outcomes
Should time zero be onset of hypotension?

Such a time would:

- Falsely decrease the number of observed cases meeting severe sepsis criteria

- Diminish awareness of organ dysfunction other than hypotension
Early Recognition

Efforts to just treat **recognized sepsis** alone are incomplete

- A critical aspect of mortality reduction is pushing practitioners to identify sepsis earlier\(^{14}\)

- Earlier recognition accounts most likely accounts for much of the reduction in mortality and sharply increasing incidence\(^{15}\)
TIMELY ANTIBIOTICS

**Barriers to timely antibiotics:**

Delayed recognition of sepsis and septic shock

- Infection
- Hypotension
- Lack of protocol
- Logistical delays
TIMELY ANTIBIOTICS

Education of healthcare professionals

• Multidisciplinary approach
• Medical Emergency Teams

Update policies to minimize delays

• Administer antibiotics prior to transfer
• Order all initial IV antibiotics as stat
• Standardized treatment approach
  ❖ Symptom-based treatment pathway
  ❖ Sepsis protocols and order sets
TIMELY ANTIBIOTICS\textsuperscript{16}

- Each hour of delay in administration of antibiotics is associated with an average decrease in survival of 7.6%.

- By getting shock-to-antibiotic times of $< 2\text{h}$ for \textbf{ALL} septic shock patients, we would save \textbf{32,360 lives per year} (89 people a day) (3.7 people an hour)
Hospital Deaths in Patients With Sepsis From 2 Independent Cohorts
Vincent Liu, MD, MS1; Gabriel J. Escobar, MD1; John D. Greene, MA1; Jay Soule2; Alan Whippy, MD2; Derek C. Angus, MD, MPH3,4; Theodore J. Iwashyna, MD, PhD5

Kaiser Permanente Northern California (KPNC) and the Healthcare Cost and Utilization Project Nationwide Inpatient Sample (NIS).
- Sepsis contributed to 1 in every 2 to 3 deaths
- Most of these patients had sepsis at admission
- Patients with initially less severe sepsis made up the majority of sepsis deaths.
• Performance improvement efforts in the treatment of sepsis have primarily focused on standardizing care for the most severely ill patients

• Improvements in standardized care for patients with less severe sepsis could drive future reductions in hospital mortality.
REQUIREMENTS FOR A SUCCESSFUL INITIATIVE

1. **Formalize Identification** – Develop screening tools/alerts
   - Defined sepsis processes that coordinate the roles of the care team to deliver *timely treatment* for every patient, every time

2. **Accelerate Treatment** – Train and empower nurses to start bundles after identification in order to meet time goals

3. **Globalize Prevention** – Expand care efforts across health systems
   - Engage frontline clinicians to identify and address process breakdowns
   - Foster a *culture of accountability* for sepsis protocol adherence

Advisory Board Company – Crimson Continuum of Care and Physician Executive Council
REQUIREMENTS FOR A SUCCESSFUL INITIATIVE

Requires a System Approach
Optimal Sepsis Care Requires a Defined, Team Approach
• Sepsis failures rarely can be traced back to a single provider. The culprit is typically a system breakdown

Sepsis Program Rollout Should Start in the ED
• 83% of sepsis patients present to the ED

Requires a Continuous Learning Environment & Outcome Measurement

A Sepsis Initiative Should Ingrain Sustainable Behaviors • Accountability
REQUIREMENTS FOR A SUCCESSFUL INITIATIVE

Traditional Form of Staff Education
REQUIREMENTS FOR A SUCCESSFUL INITIATIVE

Benefits of Simulation

• Involves participants in clinically challenging situations
• Accelerates knowledge transfer\cite{19-21}
• Develops muscle memory
• No risk to a patient
• Improves functioning as a team
• Allows concentration on specific skills and knowledge
PRINCIPLES OF EFFECTIVE SIMULATION

• Assess needs first
• Must be carefully integrated with other educational events
• “Authenticity should have a high priority when programs for the assessment of professional competence are being designed.”
AGGREGATE HASC SEPSIS TRAINING SPRING 2014

KNOWLEDGE GAIN

Knowledge Check

Simulation Post-Test
HASC SEPSIS TRAINING RESULTS

- **197** healthcare professionals from 23 Southern California hospitals participated in the Sepsis Quality Initiative Program, May 5-9, 12 – May 16, and 19-23, 2014.

- **144** participants completed both of these assessments and are therefore included in the following aggregates. Individual assessment scores are available to each participant by logging onto the MSC website.

- Participants demonstrated a **31% increase** in knowledge from the knowledge check to the simulation post-test. Additionally, the standard deviation **decreased by 29%**.
• “We are in the process of developing our sepsis protocols. This training has been very helpful and giving an understanding of the treatment, causes of dealing with sepsis.” Hospital Director

• “This course will help us initiate the Code Sepsis protocol throughout the hospital. My recommendation will be mandatory 2 hour class on Sepsis and Septic Shock.” ICU RN
"Course is extremely well done. Simulation enforced the online learning. Everyone from critical care, Hospitalists and ED should take this program." ED MD

"The simulation provided more give and take information than just the online course. It also provided me with insight into the medical decision making that practitioners may use. In collecting data for our Sepsis sheet this has been very valuable." Educator
REFERENCES


5. www.Qualityforum.org


8. The role of echocardiography in hemodynamic monitoring John H. Boyd and Keith R. Walley


10. Emergency Department Bedside Ultrasonographic Measurement of the Caval Index for Noninvasive Determination of Low Central Venous Pressure Arun D. Nagdev, MD
REFERENCES


17. Vincent Liu, MD, MS; Gabriel J. Escobar, MD; John D. Greene, MA; Jay Soule; Alan Whippy, MD; Derek C. Angus, MD, MPH; Theodore J. Iwashyna, MD, PhD Hospital Deaths in Patients With Sepsis From 2 Independent Cohorts JAMA. Published online May 18, 2014. doi:10.1001/jama.2014.5804

18. Playbook for Elevating Septicemia Care Advisory Board Company – Crimson Continuum of Care and Physician Executive Council

