Sepsis – Best Practice in Acute Care Management

Gil Allen MD, FCCM
Professor of Medicine
UVM Larner College of Medicine
Chief of Critical Care
UVM Medical Center
Yearly Incidence of Sepsis

![Graph showing the yearly incidence of sepsis from 1979 to 2000 for men and women, with error bars indicating the standard error.]


**Figure 1.** Population-Adjusted Incidence of Sepsis, According to Sex, 1979–2000. Points represent the annual incidence rate, and I bars the standard error.
Mortality (%) according to age

What’s in the distinction?

SIRS $\rightarrow$ Sepsis $\rightarrow$ Severe Sepsis $\rightarrow$ Septic Shock

Sick (7% mortality) $\rightarrow$ Sicker (16%) $\rightarrow$ Sickest (20-46%)

Rangel-Fauusto MS, et al. *JAMA* 1995; 273: 117-123
Why is this Important?

- Sepsis is **life threatening**
- Early intervention **saves lives**
- Early intervention requires early recognition
- …it’s also now a core measure

http://lumibyte.eu/medical/sepsis-diagnosis/
## Mortality – Comparison

<table>
<thead>
<tr>
<th>Cause of Death</th>
<th>Mortality</th>
<th>Other</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>STEMI</td>
<td>2.5-10%</td>
<td>30 Day</td>
<td>UpToDate; Feb 16, 2017 Am J Med 2011;124:4 0-7</td>
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<tr>
<td>STEMI with PCI</td>
<td>4%</td>
<td>In 2 hours</td>
<td>Open Heart 2016;3: doi: 10.1136/openhrt-2016-000405</td>
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<tr>
<td>NSTEMI</td>
<td>2-3%</td>
<td>30 Day</td>
<td>N Engl J Med 2001;344:1879</td>
</tr>
<tr>
<td>CVA</td>
<td>16-23%</td>
<td>30 Day</td>
<td>Neurol Clin 2008;26 871-95</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Lancet Neurol 2003 2:43-53</td>
</tr>
<tr>
<td>Septic Shock</td>
<td>46%</td>
<td></td>
<td>JAMA. 1995;273:117</td>
</tr>
</tbody>
</table>
Sepsis Inpatients (volume – d/c diagnosis)

Sepsis Admissions By Service

- FY 2015
- FY 2016
- FY 2017
- FY 2018

Medicine, Surgery, Pediatrics
Sepsis Deaths Inpatient (discharge diagnosis)

Sepsis Mortality Rate (%) by Service

- FY 2015
- FY 2016
- FY 2017
- FY 2018

- Medicine
- Surgery
- Pediatrics
A Brief History of Protocols
Early Goal Directed Therapy

The New England Journal of Medicine

EARLY GOAL-DIRECTED THERAPY IN THE TREATMENT OF SEvere SEPSIS AND SEPTIC SHOCK

EMANUEL RIVERS, M.D., M.P.H., BRYANT NGUYEN, M.D., SUZANNE HAVSTAD, M.A., JULIE RESSLER, B.S., ALEXANDRIA MUZZIN, B.S., BERNHARD KNOBlich, M.D., EDWARD PETERSON, Ph.D., AND MICHAEL TOMLANovich, M.D., FOR THE EARLY GOAL-DIRECTED THERAPY COLLABORATIVE GROUP*

- 6 hours early goal directed therapy vs standard therapy
- Central line, IV fluids, vasopressors
- CVP monitoring, goal Hgb 10, goal ScvO₂ 70%

SIRS criteria and systolic blood pressure ≤ 90 mm Hg or lactate ≥ 4 mmol/liter

Assessment and consent

Standard therapy in emergency department (n=133)

Randomization (n=263)

Early goal-directed therapy (n=130)

Vital signs, laboratory data, cardiac monitoring, pulse oximetry, urinary catheterization, arterial and central venous catheterization

CVP ≥ 8–12 mm Hg

MAP ≥ 65 mm Hg

Urine output ≥ 0.5 ml/kg/hr

Standard care

Hospital admission

Continuously monitoring and early goal-directed therapy for ≥ 6 hr

CVP ≥ 8–12 mm Hg

MAP ≥ 65 mm Hg

Urine output ≥ 0.5 ml/kg/hr

ScvO₂ ≥ 70%

SaO₂ ≥ 93%

Hematocrit ≥ 30%

Cardiac index

VO₂

Vital signs and laboratory data obtained every 12 hr for 72 hr

Did not complete 6 hr (n=14)

Follow-up

Did not complete 6 hr (n=13)
In hospital mortality

- Early Goal-Directed Therapy: 30.5%
- Standard Therapy: 46.5%

No way to know which of the bundled interventions led to the benefit
Resuscitation Goals being set
- Expedited ICU admission
- CVP 8-12 mmHg
- MAP $\geq$ 65 mmHg
- UOP $\geq$ 0.5 ml/kg/hour
- Blood cultures
- Antibiotics
- Source Identification and control


SURVIVING SEPSIS CAMPAIGN BUNDLES

TO BE COMPLETED WITHIN 3 HOURS:
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

TO BE COMPLETED WITHIN 6 HOURS:
5) Apply vasopressors (for hypotension that does not respond to initial fluid resuscitation) to maintain a mean arterial pressure (MAP) ≥ 65 mm Hg
6) In the event of persistent arterial hypotension despite volume resuscitation (septic shock) or initial lactate ≥4 mmol/L (36 mg/dL):
   - Measure central venous pressure (CVP)*
   - Measure central venous oxygen saturation (Scvo₂)*
7) Remeasure lactate if initial lactate was elevated*

*Targets for quantitative resuscitation included in the guidelines are CVP of ≥8 mm Hg, Scvo₂ of ≥70%, and normalization of lactate.
2013:

- SCCM Surviving Sepsis Guidelines released Feb 2013
- First Sepsis Taskforce meeting March 2013
  - Guidelines reviewed and consensus achieved
- First draft of Combined ICU-ED Early Goal Directed Therapy protocol composed in June 2013
- Green and Red Sepsis Alerts announced
- PRISM UPGRADE
Protocols at UVMMC

Severe Sepsis
Early Goal-Directed Therapy for Short Term Use

**Medication Considerations**
- Broad Spectrum Antibiotic Goal: Within 1hr of Identification of severe sepsis
- Prohibited: Use of any Heta-Starch (HES) Containing Solutions

**Respiratory Considerations**
- Caution: in sepsis avoid use of Etomidate for intubation
- Lung Protective Strategy: VT 6mL/kg Ideal Body Weight or less (See ALI protocol)
- Plateau Pressure Goal: < 30 cm H₂O (with “auto-flow” turned off)

**Fluid Volume Goals**
- CVP: 8-12mmHg
- PVC Diameter: > 18% change post bolus (intubated)
- > 50% w/ “sniff test” (non-intubated)
- Urea: 0.5 mg/kg/hr
- SW / PVO: < 13% (non-intubate & non-aflb)

**Crystalloid Bolus**
- Normosol-R: 30 mL/kg Lactated Ringers or
- Not met

**Repete with Crystalloid Boluses**
- Evaluate after each liter for goal attainment.
- If unable to meet fluid volume goals after multiple liters consider colloid.
  (May alternate between Normosol-R and LR; avoid hyperchloremia and AKI)
- Not met

**Map Goal**
- MAP: > 65mmHg
- Not met

**Oxygen Delivery (DO₂) Goals**
- Svo₂: ≥ 70%
- Lactate: ≤ 2
- O₂Sat: ≥ 90%
- Not met

**Norepinephrine**
- 5-30 mcg/min

**Vasopressin**
- Start At: 0.03 units/min

**Abbreviations**
- CVP: Central Venous Pressure
- DO₂: Oxygen Delivery
- FBS: Finger Stick Blood Sugar
- IN: Inferior Vena Cava
- PWV: Pulse Pressure Variation
- SvO₂: Mixed Venous Oxygen Saturation
- SWV: Stroke Volume Variation
- VT: Tidal Volume
- Hgb: Hemoglobin

*Policy Release Date: November 1, 2013*
*Policy Review Date: November 1, 2015*
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 30ml/kg crystalloid for hypotension or lactate ≥4mmol/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 of severe sepsis or septic shock ascertained through chart review.

TO BE COMPLETED WITHIN 6 HOURS OF TIME OF PRESENTATION:

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 hypotension after initial fluid administration (MAP < 65 mm Hg) or if initial lactate was ≥4 mmol/L, re-assess volume status and tissue perfusion and document findings according to Table 1.
7. Re-measure lactate if initial lactate elevated.
Lactate
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Sepsis Steering Committee (current)

- **Critical Care** (Gil Allen, Ryan Clouser)
- **Surgery** (Lyle Gerety)
- **Emergency Dept.** (Michael Sheeser)
- **Hospitalists** (Maria Burnett)
- **Medicine Resident** (Elena Kozakawich)
- **Infectious Disease** (Lindsay Smith)
- **Nursing** (Mary David, Deb Hebert, Janice Ploof)
- **Pharmacy** (Jeff Endicott)
- **Jeffords** (Pam Stevens, Melissa Holman, Johanna Sheehey-Jones, Lauren Church, Merry Mashtare)
Making it Happen

“Divide and Conquer.”

Charter Phase I
- Total Sepsis Mortality
  - Sepsis POA
    - Emergency Department (UED)
  - Sepsis Non-POA
    - Inpatients

Charter Phase II
Sepsis Alert and Protocol

- **GREEN** Sepsis: Activated by RN
  - Suspected infection AND
  - SBP < 90 or MAP < 70
  OR
  - Two or more of following
    - Temp > 38.3º or < 36ºC
    - Heart Rate > 90 bpm
    - Respiratory Rate > 20 breaths/minute
    - WBC > 12,000 or < 4,000 per μl; Bands > 10%
    - PaCO₂ < 35
Sepsis Protocol and Alert

- **RED** Sepsis: Activated by MD
  - Lactate level > 4
  - OR
  - Hypotensive despite 2 liters IV fluid
- Sepsis alert page to PPS and MICU
  - Ensure adequate IV Access
  - Indwelling urinary catheter with urometer
  - Broad spectrum antibiotics
  - Source Identification and control
Sepsis Alert and Protocol

Choose if alert is falsely triggered by other conditions: ex. pain

Not indicated is a provider decision; potentially more comfort care then sepsis alert.

Choose if care and sepsis pathway already initiated! Way to go!

To defer or not to defer? Need more information—defer, but remember to communicate to rest of pt. care team.

Green Sepsis Alert
# Sepsis Order Set

## Order Sets
- **Manage User Order Sets**
- **ICU Sepsis Orders**

### General
- **Vital Signs**
  - CVP Monitoring
    - Routine, EVERY 6 HOURS First occurrence Today at 1000 for 12 hours
    - Goal: 6-10 cm H2O non-intubated; 10-12 cm H2O intubated After 8 hours consider bedside echo or Pulse Pressure Variation Monitoring

### Laboratory
- **Chemistry Basic**
  - Lactic Acid
    - Routine, EVERY 4 HOURS First occurrence Today at 1000 Last occurrence Today at 1800 for 3 occurrences
- **Blood Gases, Venous**
  - STAT, ONE TIME, Starting 6/11/14, Repeat in 2 hours if Svo2<70%

### Point of Care
- **POCT Glucose NOW**
- **POCT Glucose - Recheck**
  - Routine, ONE TIME First occurrence Today at 1000
  - in 2 hours if greater than 150 call HQ to start insulin drip.
- **POCT Blood Gas, G3 I-STAT**
  - Routine, ONE TIME, Starting 6/11/14, Arterial Blood Gas

### General
- **Respiratory**
  - Assist Control Ventilation (Mechanical Ventilation)
    - Routine, CONTINUOUS starting Today at 1000 Until Specified
    - Autoflow: No
    - Non-Invasive: No
    - Protocols: ARO/SALI, Weaning Protocol
    - FiO2 to maintain sats > 90%

### Labs
- **Microbiology Orders**
  - Blood Culture X2 Panel
  - Bacterial Culture/Smear, Respiratory
  - ONE TIME
  - Bacterial Culture, Urine
  - ONE TIME
2014:
- Red sepsis alert in ED (via PAS) goes live
  - MICU team to assess patient at bedside for expedited admit
- PRISM build begins (BPA - alerts/physician order sets)
- CMS hinting about Sepsis Core Measures

2015:
- ED green sepsis alert/nursing order panel in PRISM
- CMS announces Core Measures
- Core measure audits and analyst involvement
- Inpatient algorithm drafted and nursing pilot planned
CMS Core Measures 2015

SEP-1 Bundle as of 2/1/2017

- New organ dysfunction present:
  - Lactate > 2 mmol/L
  - Acute respiratory failure; need for new invasive or noninvasive vent
  - Creatinine >3.0 (or hourly urine measured & output <0.5 mL/kg/hour for 2 consecutive hours)
  - Total bilirubin >2 mg/dL
  - Platelet < 100k
  - INR >1.5 or aPTT >50 sec
  - Hypotension

- Hypotension present:
  - SBP < 90 mmHg
  - MAP < 65 mmHg
  - SBP decrease > 40 with MD/NPPA saying so

- Initial lactate >4.0 mmol/L

- Deep vein thrombosis

3 hrs

1. Initial lactate
2. Blood cultures 1st
3. Antibiotics (broad spectrum)
4. IVF 30 ml/kg
5. Repeat Lactate
6. Vasopressors
7. Repeat Volume Assessment

- A focused exam including:
  - Vital signs, AND
  - Cardiopulmonary exam, AND
  - Capillary refill evaluation, AND
  - Peripheral pulse evaluation, AND
  - Skin examination

- Any two of the following four
  - Central venous pressure measurement
  - Central venous oxygen measurement
  - Bedside cardiovascular ultrasound
  - Passive leg raise or fluid challenge

Screen for severe sepsis, labs including:

Either

William Baker, MD
Corrections, contact me wbaker@bu.edu
EMDocBaker
Any questions?

CMS mandates for treating severe sepsis
Core Measure Audits

Key source of Failure:
1. Second Lactate
2. Complete 30 cc/kg
3. Re-eval with 6 hours
Green and Red Alerts

Green Sepsis BPA Accepted or Treated Pts - Red Sepsis Alert Pts - Sepsis POA Admitted to MICU - Sepsis POA Admitted To Any Unit By Week

- Pts W/ BPA "Accepted" Or "Treated"
- Red Sepsis Alert Pts
- Sepsis POA Admits (MICU)
- Sepsis POA Admits (Any Unit)
- Linear (Pts W/ BPA "Accepted" Or "Treated")
- Linear (Sepsis POA Admits (MICU))
Green and Red Alerts
2016:

- Added Lactate as a critical value to policy
  - notify clinician if value > 2
- Created “rapidsepsiseval” note
- Added 30 cc/kg IV crystalloid to ED quickset
- Updated order set antibiotics (compliant with CMS rules)
Lactic Acid as a Critical Lab

- A lactic acid level ≥ 2 will now be considered a critical lab.
- Nursing should follow policy for how to document and report a critical value.
- If lactic acid ≥ 2, the level should be redrawn in 4 hours.
Rapid Sepsis Eval

Brief Critical Care Bedside Sepsis Assessment

Suspected Infection: [Suspected Infection:304113241]

Suspected Source of Infection: [Sepsis Infection Source:304113242]

BP 110/76 mmHg | Pulse 99 | Temp(Src) 36.5 °C (97.7 °F) (Axillary) | Resp 20 | Wt 42 kg (92 lb 9.5 oz)

Exam:
Lungs: {Exam; lung:16931::"clear to auscultation bilaterally"}
Heart: {Exam; heart:5510::"regular rate and rhythm, S1, S2 normal, no murmur, click, rub or gallop"}
Pulses: {Peripheral Pulse Exam:304113252}
Skin: {Skin Assessment:304113253}
Capillary refill: {Capillary Refill:304113248}

OR

Two or more of the following:

CVP: *** mmHg
CvO2 saturation: *** %
Bedside Cardiovascular Ultrasound: {Ultrasound, Bedside Results:304113249}
Passive Leg Raise: {Leg Raise, Passive:304113250}
Fluid Challenge: {Fluid Challenge:304113251}
# Sepsis PRISM Data (FY2017)

<table>
<thead>
<tr>
<th>PRISM Location</th>
<th>Times Fired/Utilized</th>
</tr>
</thead>
<tbody>
<tr>
<td>ED Sepsis Alert</td>
<td>24,500</td>
</tr>
<tr>
<td>ED Green Order Panel</td>
<td>592</td>
</tr>
<tr>
<td>ED Sepsis Order Set</td>
<td>52</td>
</tr>
<tr>
<td>IP Sepsis Alert</td>
<td>86,260</td>
</tr>
<tr>
<td>IP Sepsis Order Panel</td>
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</tr>
</tbody>
</table>
Updates Continued

2016:

• Completed Education (eLearn) for pilot (SB3, SB4)
• Inpatient Green Sepsis alert (BPA and MD notification) piloted
• Physician education ongoing: (ED, ICU, med/surgery residents)
• Created inpatient Green Sepsis order panel for Hospitalists
• Begin supporting CVMC with sepsis initiative
Inpatient Alerts

Inpatient Sepsis Core Measure Algorithm
Jeffords Institute for Quality

Process Steps

1. Green Alert (BPA) issues
   - Is there suspicion of sepsis? (YES)
   - Call MD
   - MD to bedside
   - Is there suspicion of sepsis? (YES)
   - Order:
     - Lactate
     - Blood cultures
     - CBC
   - Consider:
     - Fluids
     - Antibiotics

2. Does the patient have lactated Ringer's? (NO)
   - Call CAT's #111
   - Does the patient need to go to ICU? (NO)
   - Call ICU for expected transfer and/or consultation

Explanation of Process Step

- **Green Alert**: triggered by:
  - SBP <90
  - Temp ≥ 38.8° or < 36.5°C (oral)
  - WBC > 12,000/mm³ or < 4,000/mm³, or >10% bands
  - Heart Rate > 90 bpm
  - Respiratory Rate > 20 breaths per minute
  - PaO2 < 85

- **3 Hour Bundle**:
  - Initiate lactate
  - Blood cultures
  - CBC
  - Fluids
  - Antibiotics

- **Severe Sepsis**:
  - Lactate ≥ 4.0
  - Acute CI ≥ 2.0
  - RI ≥ 2.0
  - Procalcitonin > 0.5
  - Respiratory Rate > 20 breaths per minute
  - Hypertension

- **Use ICU Sepsis order set**
  - Check for expected transfer and/or consultation

41
Green Sepsis Alert

Inpatient Green Sepsis Alert

THIS PATIENT MEETS CRITERIA FOR AN INPATIENT GREEN SEPSIS ALERT

Please select an item and follow the below instructions.

- **Defer**: Defer to primary nurse - no action required.
- **No Suspicion**: No suspicion for new or worsening infection - no action required.
- **High Suspicion or Uncertain**: High suspicion/Uncertain of Sepsis - CALL MD IMMEDIATELY

Acknowledge reason: [Blank]

[Defer] [No Suspicion] [High Suspicion or Uncertain]
Average Number Of Silent Sepsis BPA Firings Per Patient Per Day
14 Day Period - By Nursing Unit

- Baird 3 Surgery: 15
- Baird 4 Gen Medicine: 17
- Baird 6 Surgery: 17
- Baird 7 Maternity: 15
- Mcclure 3 SICU: 64
- Mcclure 4 MICU: 58
- Mcclure 5 Telemetry: 24
- Mcclure 6 Neurology: 14
- Mcclure 7 Birthing CTR: 50
- Shep 3N CT Surgery: 22
- Shep 3S Psychiatry: 6
- Shep 4N Hem/onc: 17
- Shep 6 Psych: 5

avg number of silent sepsis bpa fires per pt per day
This is what the Sepsis Green Order Panel Looks like…

- **Lactic Acid**
  - **STAT, ONE TIME** First occurrence Today at 1700
  - Lactic Acid should be repeated within 4 hours if result $\geq 2$.

- **Bacterial Culture, Blood**
  - **STAT, ONE TIME**, Starting 1/13/16

- **Bacterial Culture, Blood**
  - **STAT, ONE TIME**, Starting 1/13/16

- **Hemogram**
  - **STAT, ONE TIME**, Starting 1/13/16

- **Urinalysis with Reflex Microscopic**
  - **STAT, ONE TIME**, Starting 1/13/16

- **PORTABLE CHEST 1 VIEW**
  - Routine
2017:

- Completed nursing education and go-live for inpatient BPA on all med-surg units
- Added core measure components (lactate, fluids) to ED Quicklist to facilitate provider compliance
- Physician case review of core measure failures
- Key Driver analysis of current state
- Met with leaders/physicians at VT Department of Health to discuss organizational work and barriers to success
- Ad hoc project team designed nursing handoff checklist
Data Review
35% per FY of sepsis admissions are transfers

Top 10 sending organizations:

<table>
<thead>
<tr>
<th>NORTHWESTERN MEDICAL CENTER</th>
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<tbody>
<tr>
<td>CENTRAL VERMONT MEDICAL CTR</td>
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<tr>
<td>PORTER MEDICAL CENTER</td>
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<tr>
<td>STARR FARM NURSING CENTER</td>
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<tr>
<td>CANTON-POTSDAM HOSPITAL</td>
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<tr>
<td>CHAMPLAIN VALLEY PHYSICIANS</td>
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<td>RUTLAND REGIONAL MEDICAL CENTER</td>
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<tr>
<td>ALICE HYDE HOSPITAL</td>
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<td>MASSENA MEMORIAL HOSP</td>
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<td>BIRCHWOOD TERRACE HEALTHCARE</td>
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### Sepsis Admissions from OSH/SNF (top ten)

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<td><strong>MASSENA MEMORIAL HOSP</strong></td>
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<td><strong>BURLINGTON HEALTH &amp; REHAB</strong></td>
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</table>
Core Measure Compliance 2015 to 2018

- Continued work by steering committee to address core measure failures
Core Measure Compliance 2018

Sepsis Core Measure Rate Based

P Chart
Summary
+
Target
+3 sigma

Feb 15, 2019 11:50:42
Core Measure Compliance

The graph displays the Sepsis Core Measure Rate Based P Chart, showing the compliance rate over time from November 2015 to March 2019. The graph includes target lines at +3 sigma with a deviation from 29.7%.
Time in ED – Red Alert vs Green only

Green Alert Only

Red Alert
% Drop in Lactate – Red Alert vs Green only

Green Alert Only

Red Alert
Antibiotic and Fluid Administration

Sepsis Care - ED Arrival To First Antibiotic Administration Interval

Sepsis Care - ED Arrival To First Fluids Administration Interval
Sepsis Mortality – Vizient

Sepsis Mortality Index

OE RATIO

Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec Jan Feb '18 '18 '18 '18 '18 '18 '18 '18 '19 '19 '19 '19

1.39 Worst Quartile
1.2 Median
1 Best Quartile
0.83 Target Best Decile

No Data

Obs.
Future Directions

- Communication
- Hand-offs
- Simplify workflow in EMR
- Reach out to outlying hospitals and affiliates
Nursing Handoff Tool (pilot)

- ICU education and ED education
- Start date 1/15/18
- Look for improvement in Jan/Feb discharges
- Goal – to capture transfers to ICU where EPIC drops orders (between units)
Virtual White Board for tracking

[Image of ED Track Board (UCSF Emergency Department) - Last Refresh Time: 4/21/2014 12:37:26 PM]

Courtesy of Christopher Fee, MD, Assoc. Professor, UCSF
New Developments

The NEW ENGLAND JOURNAL of MEDICINE

A Randomized Trial of Protocol-Based Care for Early Septic Shock

The ProCESS Investigators*

1341 patients in 31 US Emergency Departments
  – Of 12,707 screened (6841 excluded, 2492 eligible but excluded)

Randomly assigned to one of 3 groups
  – Protocol based EGDT (Rivers trial)
  – Protocol based “Standard Therapy” (IVF/pressors & MAP goal)
  – “Usual Care”

IV fluids within 1st 6 hours

- Protocol-based EGDT: 2.8 liters
- Protocol-based standard therapy: 3.3 liters
- Usual Care: 2.3 liters
- $P < 0.001$
A Randomized Trial of Protocol-Based Care for Early Septic Shock

The ProCESS Investigators*

- Protocol-based EGDT: 54.9%
- Protocol-based standard therapy: 52.2%
- Usual Care: 44.1%
- P=0.003

ProCESS Investigators *New Engl J of Med* 2014; 370: 1683-93
• Protocol-based EGDT: 97.5%
• Protocol-based standard Therapy: 97.1%
• Usual Care: 97.9%
• P=0.003
Antibiotics at time of Randomization

A Randomized Trial of Protocol-Based Care for Early Septic Shock

The ProCESS Investigators*

- Protocol-based EGDT: 75.6%
- Protocol-based standard Therapy: 76.9%
- Usual Care: 76.1%
- P=0.003
A Randomized Trial of Protocol-Based Care for Early Septic Shock

The ProCESS Investigators

A Cumulative In-Hospital Mortality to 60 Days

B Cumulative Mortality to 1 Yr

No. at Risk
Protocol-based EGDT 439 373 356 348 347 347 347
Protocol-based standard therapy 446 389 376 368 366 366 365
Usual care 456 396 376 371 371 371 370

No. at Risk
Protocol-based EGDT 439 289 217 194 175 156 145
Protocol-based standard therapy 446 308 212 196 179 158 142
Usual care 456 285 211 199 181 164 139

Protocol-based EGDT  Protocol-based standard therapy  Usual care

Trial of Early, Goal-Directed Resuscitation for Septic Shock

Paul R. Mouncey, M.Sc., Tiffany M. Osborn, M.D., G. Sarah Power, M.Sc., David A. Harrison, Ph.D., M. Zia Sadique, Ph.D., Richard D. Grieve, Ph.D., Rahi Jahan, B.A., Sheila E. Harvey, Ph.D., Derek Bell, M.D., Julian F. Bion, M.D., Timothy J. Coats, M.D., Mervyn Singer, M.D., J. Duncan Young, D.M., and Kathryn M. Rowan, Ph.D., for the ProMISE Trial Investigators*

Goal-Directed Resuscitation for Patients with Early Septic Shock

The ARISE Investigators and the ANZICS Clinical Trials Group*
NYSDOH database: April 1, 2014 to June 30, 2016
  – After 2013 NY Rules and Regulations 405.2 and 405.4
• Required to identify 111,816 cases in 185 NY hospitals identified
• Protocols tailored by 49,331 cases at 149 hospitals included
  – Each hospital
  – Include 3 hour bundle and 6 hour bundles
• 82.5% completed 3 hour bundle within 3 hours
• Completion rates higher among smaller non-teaching EDs

Time to Treatment and Mortality during Mandated Emergency Care for Sepsis

- Median time to antibiotics 1.3 hours (IQR 0.65 to 2.35)
- Median time to fluid bolus 2.56 hours (IQR 1.33 to 4.20)
- Longer time to completion ~ higher risk in-hospital death
  - OR 1.04 per hour, (95%CI 1.02 to 1.05, p<0.001)
- Longer time to antibiotics ~ higher risk in-hospital death
  - OR 1.04 per hour, (95% CI 1.03 to 1.06, p< 0.001)
- Longer time to IV fluids – not significant
  - OR 1.01 per hour, (95% CI 0.99 to 1.021, p=0.21)

**A 3-Hr Bundle**

- **In-Hospital Mortality (%)**
  - Crude
  - Risk adjusted

**B Administration of Antibiotics**

- **In-Hospital Mortality (%)**
  - Crude
  - Risk adjusted

**C Initial Bolus of Intravenous Fluids**

- **In-Hospital Mortality (%)**
  - Crude
  - Risk adjusted

Time to Treatment and Mortality during Mandated Emergency Care for Sepsis
Limitations

• No comparison group
  – No historical controls from NY prior to legislation
  – No control group from states without legislated mandates

• Study tells us….
  – Earlier antibiotics save lives
  – Earlier attention (bundle completion) saves lives
  – We already knew this

• Study does not tell us….
  – State legislated mandates dictate earlier detection and attention
  – …better bundle compliance
  – …or better outcomes
Currently enrolled in Vizient Collaborative
None of the 63 centers participating are using these “up to date” definitions
All are using SIRS-based definition driving current SEP-1 CMS audits

Lactate Clearance vs Central Venous Oxygen Saturation as Goals of Early Sepsis Therapy
A Randomized Clinical Trial

Early Lactate-Guided Therapy in Intensive Care Unit Patients
A Multicenter, Open-Label, Randomized Controlled Trial

Tim C. Jansen¹, Jasper van Bommel¹, F. Jeanette Schoonderbeek³, Steven J. Sleeswijk Visser¹, Johan M. van der Klooster⁵, Alex P. Lima¹, Sten P. Willemsen², and Jan Bakker¹, for the LACTATE study group

Infectious Diseases Society of America (IDSA) POSITION STATEMENT: Why IDSA Did Not Endorse the Surviving Sepsis Campaign Guidelines

IDSA Sepsis Task Force
Antibiotic Stewardship

[Diagram showing the decline in defined daily doses (DDD) of antibiotics from 2010 to 2015.]
Antibiotic Stewardship
Other Organizations/Best Practice

- Early warning system
  - EPIC Sepsis detection systems
  - PeraTrend

- Physician order sets
  - Contain bundle/core measure compliant actions

- Sepsis Coordinator
  - Real time coordination of patient care/sepsis bundle
  - Supporting early identification and compliant documentation