Sepsis: A Medical Emergency

April 24, 2017

Jim O’Brien, MD, MS
System Vice President, Quality and Patient Safety
OhioHealth
Disclosures: 2010 – February 2017

- **Non-industry grant monies:**
  - NIH Clinical Research Loan Repayment Program ($152,781, 10/03-6/05, 7/06-6/10)
  - NIA 1R01AG035117 ($200,722, 3/11 – 6/12)
  - NHLBI 1U01HL102547 ($250,182, 7/11 – 6/12)
  - NPSF ($100,000, 7/11 – 6/12)

- **Industry grant monies:**
  - PI for calfactant (Pneuma, $0, 9/08 – 6/12)

- **Committee membership**
  - NQF Measures Committee – Pulmonary & Critical care (2016 – current)

- **Consultant/Speakers’ Bureau:**
  - Board of Directors, Sepsis Alliance
  - Executive Board, Global Sepsis Alliance, World Sepsis Day

- **Honoraria to Sepsis Alliance (Travel/ accommodations may have been provided), various lectures, seminars, educational materials, advisory boards**
  - Consultant, Tenax, 2015 - current
  - Consultant, GenEndeavor LLC, 2015 – current
  - Consultant, Quorum Therapeutics, 2016 - current
Disclosures: 2010 – February 2017

I think sepsis is a medical emergency.

I think better sepsis care has a robust ROI.

I think the next challenge in sepsis care will be return to function.

I think we will eventually get our act together – it is just a question of how much we will spend and how many will die before then.

Pulmonary & Critical care (2016 – current)

Consultant: Quorum Therapeutics, 2016 – current
Objectives

• To understand the outcomes from sepsis when treated as a medical emergency
• To understand the core components of high-value sepsis care, including appropriate antibiotics and intravenous fluids
• To explore the unintended consequences of sepsis care, including antibiotic-resistance and fluid overload
• To explore methods for raising suspicion of sepsis in a variety of clinical settings
Framing the problem
What is Sepsis?

- Sepsis = SIRS + Infection
- Severe Sepsis = Sepsis + Organ Failure
- Septic Shock = Sepsis + Hypoperfusion (low blood pressure)
- Mortality increases with more organ failure
What is Sepsis?

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- Severe Sepsis = Sepsis + Organ Failure
- Sepsis = Sepsis + Organ Failure
- Septic Shock = Sepsis + Hypoperfusion (low blood pressure)
- Mortality increases with more organ failure
The Third International Consensus Definition for Sepsis and Septic Shock (Sepsis-3)
Singer et al. *JAMA* 2016; 315(8): 801-810

- **Sepsis** = a life-threatening organ dysfunction caused by a dysregulated host response to infection
  - *Used to be SEVERE SEPSIS*
- Organ dysfunction can be identified by an acute change in SOFA score ≥2 (mortality risk ~10%)
- **Septic shock** = a subset of sepsis in which underlying circulatory and cellular/metabolic abnormalities are profound enough to substantially increase mortality
  - Blood pressure and Lactate
Sepsis Is Common And Becoming More Common

- 6th most common principal reason for hospitalization
- 1 in 23 patients affected
- 7.9% annual growth

Sepsis Is Common And Becoming More Common

One in 185 Americans will be hospitalized this year with sepsis.

Patients hospitalized for septicemia or sepsis were more than eight times as likely to die during their hospitalization.

Table. Hospitalizations for septicemia or sepsis compared with hospitalizations for other diagnoses, by discharge disposition, 2008

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Septicemia or sepsis</th>
<th>Other diagnoses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disposition</td>
<td>Percent</td>
<td>Percent</td>
</tr>
<tr>
<td>Routine(^1)</td>
<td>39</td>
<td>79</td>
</tr>
<tr>
<td>Transfer to other short-term care facility(^1)</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Transfer to long-term care institution(^1)</td>
<td>30</td>
<td>10</td>
</tr>
<tr>
<td>Died during the hospitalization(^1)</td>
<td>17</td>
<td>2</td>
</tr>
<tr>
<td>Other or not stated</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>Total</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

\(^1\)Difference is statistically significant at the 0.05 level.

Sepsis contributes to 1 in every 2 to 3 deaths in hospitals. Majority had sepsis on presentation to the hospital.

Liu et al. JAMA May 18, 2014.
258,000 deaths a year in the US

27 Deaths* every ~55 min

*2010-2014 US air traffic deaths

2974 Deaths every ~4.2 days
258,000 deaths a year in the US

Deaths from
Breast cancer
Lung Cancer
+Prostate Cancer
TOTAL < Deaths from Sepsis
Late mortality after sepsis: propensity matched cohort study
Prescott et al. BMJ. 2016;353: i2375

- Sepsis matched to:
  - Not currently in hospital
  - Admitted with non-sepsis infection – infection but no organ dysfunction
  - Admitted with sterile inflammation – trauma, fracture, burn, pancreatitis, etc
- Examined late mortality (31d to 2y)
- Infection was most common reason for terminal admission for ALL groups

22.1% increase in late mortality
10.4% increase in late mortality
16.2% increase in late mortality
<table>
<thead>
<tr>
<th>Sepsis is the most costly in-patient hospital condition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sepsis annual hospital costs (2013)</strong></td>
</tr>
<tr>
<td>$23.6 Billion</td>
</tr>
<tr>
<td><strong>Sepsis average cost per hospital stay</strong></td>
</tr>
<tr>
<td><em>Double the average cost per stay across all other conditions</em></td>
</tr>
<tr>
<td>$18,400</td>
</tr>
<tr>
<td><strong>Sepsis average annual cost growth</strong></td>
</tr>
<tr>
<td><em>Annual growth 3x the growth rate of overall hospital costs</em></td>
</tr>
<tr>
<td>11.5%</td>
</tr>
<tr>
<td><strong>Annual costs of readmission after sepsis</strong></td>
</tr>
<tr>
<td><em>Ranks in top 10 readmission for all payers</em></td>
</tr>
<tr>
<td>$4.0 Billion</td>
</tr>
</tbody>
</table>

*Torio et al, National Inpatient Hospital Costs HCUP Statistical Brief #204
**Pfuntner et al, Costs for Hospital Stays in the United States, 2013 HCUP Statistical Brief #168
***Hines et al, HCUP Statistical Brief #172, April 2014
Survivorship Issues after Sepsis

- **20,000 new cases of cognitive dysfunction per year** among survivors of sepsis (Iwashyna JAMA 2010;304(16):1787-94)
- **74% with functional disabilities** after 3 years (Iwashyna J Am Ger Soc 2012; 60:1070-7)
- ~60% with symptoms of depression and/or anxiety and/or PTSD (Rosendahl Crit Care Med 2013; 41)
- **Brain atrophy and low-frequency on EEG** 6-24 months after discharge (Semmier J Neurol Neurosurg Psych 2013; 84: 62-9)
- **Wives** of sepsis survivors four times more likely to experience depressive symptoms (Davydow Crti Care Med 2012; 40: 2335-41)
- One-quarter of relatives of survivors with anxiety and one-half with PTSD symptoms at six months post ICU (Jones Intens Care Med 2004; 30: 456-60)
Sepsis as a medical emergency
Antibiotics – No time to waste

- Every hour in delay of appropriate atbx = 7.6% lower survival
- Median time to appropriate atbx = 6h

Shock to Effective Antibiotic Time and Mortality in Septic Shock*

Adapted from Kumar et al.  *Crit Care Med* 2006; 34: 1589-96.

<table>
<thead>
<tr>
<th>Time (h)</th>
<th>%Mortality</th>
<th>% of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-2h</td>
<td>26.7</td>
<td>26.8</td>
</tr>
<tr>
<td>&gt;2-3h</td>
<td>36.1</td>
<td>9.0</td>
</tr>
<tr>
<td>&gt;3-4h</td>
<td>36.6</td>
<td>7.8</td>
</tr>
<tr>
<td>&gt;4-6h</td>
<td>46.8</td>
<td>12.8</td>
</tr>
<tr>
<td>&gt;6-12h</td>
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<td>18.8</td>
</tr>
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<td>&gt;12h</td>
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*Assuming 130,000 septic shock cases per year
### Shock to Effective Antibiotic Time and Mortality in Septic Shock*

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*Assuming 130,000 septic shock cases per year
Door to Balloon Time and Mortality in STEMI*

<table>
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<tr>
<th>Percentage of patients</th>
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<tr>
<td>0-2h</td>
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<td>5.2</td>
<td>23.5</td>
</tr>
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<td>21.1</td>
</tr>
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<td>6.7</td>
<td>21.6</td>
</tr>
<tr>
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<td>17.3</td>
</tr>
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<td>&gt;12h</td>
<td>5.5</td>
<td>8.5</td>
</tr>
</tbody>
</table>

*Assuming 400,000 STEMIs per year

Door to Balloon Time and Mortality in STEMI*

Percent of patients

% Mortality

0-2h | >2-3h | >3-4h | >4-6h | >6-12h | >12h

4.9 | 5.2  | 6.5  | 6.7   | 6.9   | 5.5

% of patients

8  | 23.5 | 21.1 | 21.6  | 17.3  | 8.5

*Assuming 400,000 STEMIs per year

Adapted from Cannon et al. JAMA 2000; 283: 2941-7.
Door to Balloon Time and Mortality in STEMI*

By getting door-to-balloon times of <2h for ALL STEMI patients, we would save **4775 lives per year**. (13 people a day)

Shock to Effective Antibiotic Time and Mortality in Septic Shock*

*Assuming 130,000 septic shock cases per year

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<th>% of Patients</th>
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<td>83.1</td>
<td>24.9</td>
</tr>
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</table>

Adapted from Kumar et al. Crit Care Med 2006; 34: 1589-96.
By getting shock-to-antibiotic times of <2h for ALL septic shock patients, we would save **32,360 lives per year**.

(89 people a day)

(3.7 people an hour)

(3.5 times the effect of STEMI intervention)

Adapted from Kumar et al. *Crit Care Med* 2006; 34: 1589-96.
The First 12 Hours Matter Even More

For first 12 hours, 1% mortality per 5 minute delay

Funk and Kumar, *Crit Care Clinics* 2011; 53-76.
Multicenter Implementation of a Severe Sepsis and Septic Shock Treatment Bundle

• QI project in 11 hospitals in Utah and Idaho
• ED patients with severe sepsis or septic shock
• January 2004 – December 2010

• Screened 15,109 patients
• 4379 with severe sepsis or septic shock
  – 29.2% of patients screened
  – 2 of every 7 patients

Multicenter Implementation of a Severe Sepsis and Septic Shock Treatment Bundle

**All patients get:**
- Serum lactate within 3h of ED admission
- Blood cx prior to antibiotics within 3h of ED admission
- Broad-spectrum atbx within 3h of ED admission
- Mean glucose ≤180 12-24 h after ED admission

**Eligible patients get:**
- If sbp≤90, MAP≤65, or lactate ≥4, at least 20 ml/kg PBW crystalloid
- If low bp continues after fluids, use vasopressors
- If low bp or high lactate, CVP and ScvO2 measured regularly and goals of CVP≥8 and ScvO2≥70%
- If CVP ≥8 and ScvO2≤70%, inotropes or PRCs
- If on higher dose vasopressors, give steroids
- If on vent, tidal volume 6ml/kg PBW

Absolute bundle compliance increase of 68.5%

Absolute mortality reduction of 12.5%

If care remained as provided in 2004 (vs 2008-10), these hospitals would:

- consume 1416 more hospital days a year
- consume 266 more ICU days a year
- kill 99 patients a year
<table>
<thead>
<tr>
<th></th>
<th>2004</th>
<th>2008-10</th>
<th>“Relative waste reduction”</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Eligible for later bundle elements</strong>*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluid resuscitation</td>
<td>75%</td>
<td>71%</td>
<td>5%</td>
</tr>
<tr>
<td>Vasopressors</td>
<td>63%</td>
<td>35%</td>
<td>44%</td>
</tr>
<tr>
<td>CVP and ScvO2 monitoring</td>
<td>64%</td>
<td>29%</td>
<td>55%</td>
</tr>
<tr>
<td>Inotropes and RBC transfusions</td>
<td>59%</td>
<td>13%</td>
<td>78%</td>
</tr>
<tr>
<td>Glucocorticoids</td>
<td>63%</td>
<td>21%</td>
<td>67%</td>
</tr>
<tr>
<td>Lung protective ventilation</td>
<td>43%</td>
<td>14%</td>
<td>67%</td>
</tr>
</tbody>
</table>

*By diagnosing severe sepsis and providing atbx, blood cultures and lactate measurement at very high rates.
Unintended consequences
Superbug resistant to all available antibiotics killed elderly northern Nevada woman

This illustration released by the Centers for Disease Control and Prevention shows a group of carbapenem-resistant Enterobacteriaceae bacteria. The image was based on scanning electron micrographic imagery. (Melissa Browne/Centers for Disease Control and Prevention via AP)

By PASHATA USIFZY
LAS VEGAS REVIEW-JOURNAL

A Northern Nevada woman died last year from a bacterial infection resistant to all 26 antibiotics available in the U.S., highlighting the growing public health threat posed by so-called “superbugs.”

The woman, an unidentified Washoe County resident in her 70s who had traveled to India, died in July 2016. She had been hospitalized for an infection caused by carbapenem-resistant Enterobacteriaceae, a group of bacteria that have become untreatable with antibiotics.
Where to start

- 70% of total medically important antibiotic sales by volumes are in food animal production
  - FDA policy implemented in Jan 2017 – addition of antibiotics to feed or water requires oversight of a veterinarian
- Antibiotic stewardship programs - <40% of US hospitals have full program
- 13% of outpt visits result in an antibiotic prescription – 30% (47million) are unnecessary

www.pewtrusts.org
Multicenter Implementation of a Treatment Bundle for Patients with Sepsis and Intermediate Lactate Levels


- QI project in 21 community hospitals, Mar 11- Feb 14, n=18,122
- Sepsis POA with lactate 2-4, without shock
- Antibiotics, intravenous fluids (30ml/kg OR 2L), repeat lactate
- Already robust process for checking lactate (974% increase in # annual tests) and antibiotic administration (>95% within 3h of arrival)
- Evaluated interaction with pre-existing diagnosis of heart failure and/or chronic kidney disease
Multicenter Implementation of a Treatment Bundle for Patients with Sepsis and Intermediate Lactate Levels


- Bundle compliance increased from 32.2% to 44.9%
- Driven by increases in lactate goal (10% reduction) and fluid goal
- Risk adjusted 30d mortality 16% lower
Multicenter Implementation of a Treatment Bundle for Patients with Sepsis and Intermediate Lactate Levels


Table 4. Hospital Mortality in Heart Failure and Chronic Kidney Disease Subgroups

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All patients</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital</td>
<td>8.8</td>
<td>9.3</td>
<td>7.9</td>
<td>0.02</td>
</tr>
<tr>
<td>30 d</td>
<td>13.7</td>
<td>14.1</td>
<td>12.6</td>
<td>0.03</td>
</tr>
<tr>
<td><strong>History of heart failure</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital</td>
<td>13.0</td>
<td>14.8</td>
<td>11.6</td>
<td>0.03</td>
</tr>
<tr>
<td>30 d</td>
<td>18.8</td>
<td>20.7</td>
<td>17.8</td>
<td>0.13</td>
</tr>
<tr>
<td><strong>History of kidney disease</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital</td>
<td>9.7</td>
<td>11.5</td>
<td>7.5</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>30 d</td>
<td>15.9</td>
<td>17.7</td>
<td>13.3</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td><strong>Heart failure or kidney disease</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital</td>
<td>10.7</td>
<td>12.5</td>
<td>8.7</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>30 d</td>
<td>16.8</td>
<td>18.3</td>
<td>14.5</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td><strong>No heart failure or kidney disease</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital</td>
<td>7.4</td>
<td>6.5</td>
<td>7.2</td>
<td>0.40</td>
</tr>
<tr>
<td>30 d</td>
<td>11.3</td>
<td>10.5</td>
<td>10.8</td>
<td>0.60</td>
</tr>
</tbody>
</table>

No increase in LOS, ICU admission
Finding needles in piles of needles
Effect of a rapid response system for patients in shock on time to treatment and mortality during 5 years

Sebat et al. CHEST 2007; 35: 2568-2575

HYPOTENSION (low BP) OR Normal BP with 3 of following:
Mental status change, cool extremities, RR≥20, Low urine output, Elevated lactate, Fever

Fluid Bolus (over 10-15 min)
1000mL if ED
250mL if ward

Reassess for Presence of Criteria

ACTIVATE TEAM
Effect of a rapid response system for patients in shock on time to treatment and mortality during 5 years

Sebat et al  
CHEST 2007; 35: 2568-2575

HYPOTENSION (low BP)
OR
Normal BP with 3 of following:
Mental status change, cool extremities, RR≥20, Low urine output, Elevated lactate, Fever

43% of patients with septic shock
(46% “hypovolemic”)

ACTIVATE TEAM
Effect of a rapid response system for patients in shock on time to treatment and mortality during 5 years


Unadjusted Mortality

Mortality Observed / Expected Mortality APACHE III

Median Time to 3 Most Rapid Interventions p<0.001

40.0%

NNT = 4

11.8%

Minutes

O/E
Effect of a rapid response system for patients in shock on time to treatment and mortality during 5 years


Among septic shock patients, mortality decreased from 50% to 10%
NNT = 2.5
Evaluating the impact of a computerized surveillance algorithm and decision support system on sepsis mortality
Manaktala and Claypool J Am Med Inform Assoc 2016

• Real-time electronic sepsis surveillance performed in 2 medical units
• Nurses received alerts on mobile and desktop computers on a secured network
• Alerts included: informational prompts, diagnostic alerts, advice alerts, reminder alerts
Evaluating the impact of a computerized surveillance algorithm and decision support system on sepsis mortality
Manaktala and Claypool *J Am Med Inform Assoc* 2016

Table 4: Test Characteristics for the Electronic Diagnosis of Sepsis vs. Gold-Standard Comprehensive Chart Review

<table>
<thead>
<tr>
<th>Statistic</th>
<th>Result (95% CIs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>True positives</td>
<td>118</td>
</tr>
<tr>
<td>False negatives</td>
<td>6</td>
</tr>
<tr>
<td>False positives</td>
<td>117</td>
</tr>
<tr>
<td>True negatives</td>
<td>530</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>95.16 (89.77-98.20)</td>
</tr>
<tr>
<td>Specificity</td>
<td>81.92 (78.73-84.8)</td>
</tr>
<tr>
<td>Positive likelihood ratio</td>
<td>5.26 (4.45-6.23)</td>
</tr>
<tr>
<td>Negative likelihood ratio</td>
<td>0.06 (0.03-0.13)</td>
</tr>
<tr>
<td>Sepsis prevalence&lt;sup&gt;a&lt;/sup&gt;</td>
<td>16.08 (13.56, 18.87)</td>
</tr>
<tr>
<td>Positive predictive value&lt;sup&gt;a&lt;/sup&gt;</td>
<td>50.21 (43.64, 56.78)</td>
</tr>
<tr>
<td>Negative predictive value&lt;sup&gt;a&lt;/sup&gt;</td>
<td>98.88 (97.58, 99.59)</td>
</tr>
</tbody>
</table>

- Sepsis-related mortality dropped from 90 to 42 deaths per 1000 sepsis cases
- Patients screened using the sepsis CDS system had 2.1 times lower risk of death compared to pre-implementation period
- Readmissions after sepsis dropped from 19.1% to 13.2%
In summary

• Sepsis is a time-sensitive disease = medical emergency
• Getting the basics right as soon as possible improves outcomes AND simplifies care
• We still have much to learn about sepsis and its care – but there is much we can offer patients today
• There may be unintended consequences to ideal sepsis care – but some of these consequences are also due to less than ideal care
• There are more and more tools available to identify sepsis patients – but none is the standard
"I believe that this nation should commit itself to achieving the goal, before this decade is out, of landing a man on the Moon and returning him safely to the Earth."

–President John F. Kennedy, 5/25/1961
“We choose to go to the moon in this decade and do the other things, not because they are easy, but because they are hard, because that goal will serve to organize and measure the best of our energies and skills, because the challenge is one we are willing to accept, one we are unwilling to postpone, and one which we intend to win.”

—President John F. Kennedy, 9/12/1962
BELIEVE IN WE™ OhioHealth

A FAITH-BASED, NOT-FOR-PROFIT HEALTHCARE SYSTEM

RIVERSIDE METHODIST HOSPITAL + GRANT MEDICAL CENTER + DOCTORS HOSPITAL
GRADY MEMORIAL HOSPITAL + DUBLIN METHODIST HOSPITAL + DOCTORS HOSPITAL—NELSONVILLE
HARDIN MEMORIAL HOSPITAL + MARION GENERAL HOSPITAL + REHABILITATION HOSPITAL + O’BLENESS HOSPITAL
MEDCENTRAL MANSFIELD HOSPITAL + MEDCENTRAL SHELBY HOSPITAL + WESTERVILLE MEDICAL CAMPUS
HEALTH AND SURGERY CENTERS + PRIMARY AND SPECIALTY CARE + URGENT CARE + WELLNESS
HOSPICE + HOME CARE + 28,000 PHYSICIANS, ASSOCIATES & VOLUNTEERS