Mandated Emergency Care in Sepsis
Naeem Ali, September 15, 2017

Outline/Agenda

- Why is Sepsis a time sensitive disease?
- How did New York to the point of mandated clinical care?
- What happened with the “real-life” experiment?
- Is there anything on the “horizon” in Ohio?
Breaking the cycle

The challenge...

- 59 yo white female with back pain, normal blood pressure
- 68 yo hispanic male with acute confusion and cough
- 24 yo WF with myalgias and nausea
- 89 yo African American male with agitation and confusion
- 35 yo female with high fevers
- 54 yo male with post-op abdominal pain and nausea
- 18 yo Male with rash on his thigh
Antibiotics - Minutes Matter

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


The first 12 hours matters even more

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

Funk and Kumar, Crit Care Clinics 2011; 53-76
March 2012

Death of a Boy Prompts New Medical Efforts Nationwide

About New York
By TIM SANGER OCT. 16, 2012

Long before 12-year-old Rory Staunton set foot in a hospital in March, the paths to the catastrophe awaiting him had been heavily trod.

Told he had a minor bellyache, first by his pediatrician and then by a doctor in the emergency room at NYU Langone Medical Center, Rory was sent home with medicine to settle his stomach. Three days later, on April 1, he was dead from septic shock caused by an infection that had been present but not treated when he was seen by the doctors.
The story of Rory Staunton

March 28th, 2012: 1000 Rory Staunton, 12 yrs old, participates in Gym class and suffers scrape of the arm after a fall. Seen by School Nurse

March 29th, 2012: 2330 Rory awakens with a fever, stomach ache and nausea

March 30th, 2012: Rory presents to the ED, has labs drawn and receives IVFs

March 30th, 2012: 1800 Rory is seen with a fever and stomach ache in the Pediatricians office- referred to the ED for rehydration

March 31st, 2012: 0900 Rory awakens with worsened nausea and a fever to 103F

Staff believed the pt had a viral enteritis

There was a high prevalence of enteritis in the community

Labs were not reviewed until after DC

The family did not know what sepsis was

The practitioner had seen three enteritis cases that shift already

The ED was busy

Labs are not reviewed until the next day

Rory is sent home after IVF’s but before labs return

Moderate leukocytosis, significant left shift, low plts

March 31st, 2012: 0900 Rory awakens with worsened nausea and a fever to 103F

March 31st, 2012: 1200 Rory returns to the ED and is admitted to the ICU. Receives ABX

April 1st, 2012: 1800 Rory passes away in the ICU
January 2013

Governor Cuomo Announces New York State to Lead the Nation in Fighting Sepsis the #1 Killer in Hospitals and Make Major Improvements in Pediatric Care Through "Rory's Regulations"

Rory’s Regulations: Treatment

- Hospitals are required to adopt protocols that provide for:
  - The screening and early recognition of patients with sepsis, severe sepsis and septic shock;
  - A process to identify and document individuals appropriate for treatment through severe sepsis protocols; and
  - Guidelines for treatment including for early delivery of antibiotics.
Rory’s Regulations: Communication and Patient Engagement

• Ensure that all test results are reviewed upon completion by a physician, physician assistant or nurse practitioner;
• Ask the identity of a patient's primary care provider and forward all test results;
• Prohibit the discharge of a patient until test results that may reasonably be expected to yield "critical values" are completed and communicated;
• Communicate prior to discharge all categories of tests ordered, all critical value test results; and
• Carry out such communication in plain, understandable terms.

Pediatric rules include facilitating parent information and engagement and specifics for Pediatric care.

The New York State Experience 2016

• Documented Case fatality rate for the state went from 30.2% to 25.4% between 2013 to 2016
• The approach to demonstrate causality:
  – Use Departments of Health to require sepsis case reporting of pts and treatment/outcomes from treatment
  – When hospitals had experience with the protocol, (after April 2014) initiate a retrospective cohort study of statewide data
  – All Hospitals:
    • Had to systematically screen
    • For those screened positive (focus on the 3hr Resuscitation Bundle)
      • Culture
      • Resuscitate
      • Administer ABX
The New York State Experience

- The study:
  - Using Public Health Department CRFs
  - Reviewed 2014 through 2016 data from 185 Hospitals
    - Include
      - if >17 yo
      - Identified in ED
      - Severe Sepsis +/- Shock (Sepsis-2)
    - Exclude:
      - Records with sepsis treatment started prior to ED arrival
      - Identified with sepsis >6 hours after ED arrival
      - Took longer than 12 hours to complete the resuscitation bundle (intended for 3hrs)
      - DNR or other limitation of care orders
      - Pts treated at low volume hospitals <4 cases per month

Cumulative Probability of Completion of the 3-Hour Bundle, Administration of Broad-Spectrum Antibiotics, and Completion of the Initial Intravenous-Fluid Bolus after the Time That the Sepsis Protocol Was Initiated.

Primary outcome of the study:
- Mortality as a function of time to implementation of the resuscitation bundle…
Risk-Adjusted Odds Ratios of In-Hospital Death in the Primary Model and Prespecified Subgroups.

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>No. of Patients</th>
<th>Odds Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>49,331</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>25,689</td>
<td>1.04 (1.02–1.06)</td>
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<tr>
<td>Female</td>
<td>23,632</td>
<td>1.09 (1.02–1.18)</td>
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<tr>
<td>Vasopressor use</td>
<td></td>
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<tr>
<td>Yes</td>
<td>16,721</td>
<td>1.04 (1.01–1.07)</td>
</tr>
<tr>
<td>No</td>
<td>32,610</td>
<td>1.02 (1.00–1.04)</td>
</tr>
<tr>
<td>Admission source</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Home</td>
<td>33,464</td>
<td>1.04 (1.02–1.06)</td>
</tr>
<tr>
<td>Other</td>
<td>15,867</td>
<td>1.04 (1.02–1.06)</td>
</tr>
<tr>
<td>Cardiogenic shock</td>
<td>10,892</td>
<td>1.06 (1.04–1.08)</td>
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<tr>
<td>Ischemic heart failure</td>
<td>9,207</td>
<td>1.00 (1.00–1.00)</td>
</tr>
<tr>
<td>Chronic respiratory failure</td>
<td>5,798</td>
<td>1.06 (1.05–1.07)</td>
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<tr>
<td>Site of infection</td>
<td>19,639</td>
<td>1.03 (1.02–1.04)</td>
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<tr>
<td>Respiratory</td>
<td></td>
<td></td>
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<tr>
<td>Pulmonary</td>
<td>14,439</td>
<td>1.04 (1.02–1.06)</td>
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<tr>
<td>Other</td>
<td>15,955</td>
<td>1.04 (1.02–1.06)</td>
</tr>
<tr>
<td>Bloodstream</td>
<td>7,175</td>
<td>1.00 (0.98–1.01)</td>
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<tr>
<td>Gram-positive</td>
<td>6,435</td>
<td>1.00 (1.00–1.00)</td>
</tr>
<tr>
<td>Gram-negative</td>
<td>405</td>
<td>1.03 (1.01–1.04)</td>
</tr>
<tr>
<td>None</td>
<td>34,737</td>
<td>1.08 (1.06–1.10)</td>
</tr>
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• More rapid completion of a 3-hour bundle of sepsis care and rapid administration of antibiotics, but not rapid completion of an initial bolus of intravenous fluids, were associated with lower risk-adjusted in-hospital mortality.

What’s coming?

- States are following New York’s lead
  - New Jersey
  - Illinois
  - Pennsylvania
- Proof?
  - Reduced mortality temporally in NY
    - (But also dropped in states without regulations)
  - The study proved doing what you were supposed to improved outcomes
  - Legislation did accelerate adoption (side effects?)
- Now:
  - Failure to follow the standard of care = “malpractice”
- Future?:
  - Failure to follow standard of care = “institutional malfeasance”
Thank You

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