Simplifying Sepsis: Saving Lives, Time, and Money

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Speakers

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Participants have no conflict of interest to disclose related to the work presented.
Who We Are

Session Objectives

- Define the three-hour bundle, identify its strengths and limitations, evaluate its clinical and financial impact

- Illustrate the subtle difference between compliance and improvement metrics in driving improved sepsis patient care

- Develop strategies for successful implementation and performance evaluation in various settings
**Session Themes**

1. The importance, adaptability, and repurposing of *data* to answer questions and solve problems

2. Don’t wait for the bell to ring – develop solutions that are *upstream* of the problem you are trying to fix

3. Engage and empower the people with the expertise

4. Develop a continually learning and evolving system

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**The Burden of Septic Disease**

- **Sepsis is Epidemic**

![Graph A: Incidence of severe sepsis by method over 6-year period](image1)

- **Sepsis is Deadly**

![Graph C: Total mortality of severe sepsis by method](image2)

**Sources:**

- Gaieski, D.J.; Edwards, J.; Kallan, M.J.; Carr, B.N. Critical Care Medicine. 41(5):1167-1174, May 2013. DOI: 10.1097/CCM.0b013e31827c09f8

The Burden of Septic Disease

There are a few things that we know work:

- Fast antimicrobial coverage
- Rapid IV Fluid Resuscitation
- Early diagnosis of hyperlactemia/monitoring for lactate clearance
- EARLY Intervention

Sources:
- Duration of hypotension before initiation of effective antimicrobial therapy is the critical determinant of survival in human septic shock. Kumar, Anand; Roberts, Daniel; Wood, Kenneth; Light, Bruce; Parrillo, Joseph; Sharma, Satendra; Suppes, Robert; Feinstein, Daniel; Zanotti, Sergio; Taiberg, Leo; Gurka, David; Kumar, Aseem; Cheang, Mary. Critical Care Medicine. 34(6):1589-1596, June 2006. DOI: 10.1097/01.CCM.0000217961.75225.E9
- Serum lactate is associated with mortality in severe sepsis independent of organ failure and shock. Mikkelsen, Mark; Miltiades, Andrea; Gaieski, David; Goyal, Munish; Fuchs, Barry; Shah, Chirag; Bellamy, Scarlett; Christie, Jason. Critical Care Medicine. 37(5):1670-1677, May 2009. DOI: 10.1097/CCM.0b013e31819fcf68

What's Being Done About It?

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What’s Being Done About It?

Seminal and Recent Literature Conflict:
- ARISE
- ProMISE

Our Approach

- Task Force
- Algorithm (Recognition)
- Bundle (Intervention)
- Process Improvement
- Data Collection
- Data Analysis
## Our Approach

**Task Force**

- Algorithm (Recognition)
- Bundle (Intervention)
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## A Case For Change

- **In 2008:**
  - 3,500 patients discharged with a Sepsis diagnosis across the System
  - Top APR-DRG by number of deaths across the System
  - Greatest single cause of in-hospital mortality in our health system

- Michael Dowling (NSLIJ CEO) identifies sepsis as our key opportunity for preventable mortality

- Considerable variation in care at all levels throughout the System
  - Evidence-based approaches to care exist that have been shown to improve outcomes

- 2009 System Sepsis Task Force Formed
Sepsis Task Force

- Let the people with the expertise drive the agenda
  - Our clinicians created our algorithm from what was reasonable in their world

- It’s never a one size fits all model
  - “What?” and “Why?” aren’t site specific but...
  - “Who?” and “How?” are
  - Sites take ownership of how to best utilize their resources

Our Approach

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NSLIJ Sepsis Algorithm

**Early Recognition Focus**

- Acknowledge sepsis as a continuum, and more than an ICU disease
  - Sepsis vs. Severe Sepsis and Septic Shock
  - Transposable and aggressive diagnostic triggers

- **Low Threshold for inclusion**
  - Lactate $\geq 2.2$ mmol/L (NSLIJ) vs. $\geq 4.0$ mmol/L (NQF/SSC guidelines)
  - Broad organ dysfunction criteria
  - Super-SIRS criteria

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**Sepsis – A Continuum**

- **SIRS**
- **Sepsis**
- **Severe Sepsis**
- **Septic Shock**

Clinical response arising from non-specific insult with $\geq 2$ of the following:

1. $T > 38^\circ C$ or $< 36^\circ C$
2. HR $> 90$ beats/min
3. RR $> 20$ min
4. WBC:
   - $> 12,000/mm^3$ or
   - $< 4,000/mm^3$ or
   - $> 10\%$ bands

**SIRS** with a presumed or confirmed infectious process

**Sepsis with organ failure**

**Refractory hypotension**

**Source:**
Adapted from *Chest* 1992;101:1644.
Relationship of SIRS, Sepsis, Infection

\( \text{BACTEREMIA} \quad \text{SIRS} \quad \text{PANCREATITIS} \quad \text{TRAUMA} \quad \text{BURNS} \quad \text{OTHER} \)

\( \text{FUNGEMIA} \quad \text{PARASITEMIA} \quad \text{VIREMIA} \quad \text{OTHER} \)

\( \text{INFECTION} \quad \text{SEVERE} \quad \text{SEPSIS} \quad \text{SEPSIS} \quad \text{SEPTIC} \quad \text{SHOCK} \)

\section*{Relationship of SIRS, Sepsis, Infection}

\section*{ARRIVAL AND EVALUATION

\section*{POSSIBLE SEPSIS

Two of the following:

- Temperature \( > 38.3 \) \( \degree C \) \((101 \degree F) \) or Recent Fever, or Clinical Suspicion of Infection
- SBP \( < 90 \) or MAP \( < 60 \)
- Pulse \( > 120 \) \( \text{bpm} \)
- Resp. Rate \( > 24 / \text{min} \)

\section*{SEPSIS

Yes

\section*{PATIENT WITH SUSPECTED SIGNIFICANT INFECTION (IE. POSSIBLE ADMISSION)

PLUS

T-0 = Lactate Order
CODE SEPSIS
T-0 = Triage Time
A
B
C

\section*{DISPOSITION

INTERVENTION

Sepsis Resuscitation Elements
(Unless clinically contraindicated)

- Lactate ordered and resulted \( \leq 90 \) min.
- BCx X 2 ordered and drawn before Abx.
- Abx \( \leq 3 \) hrs of arrival
- IV fluids \( \leq 6 \) hrs: \( 1 \text{L} \text{NS} \leq 2 \text{L} \text{over 2 hrs} \)
- Repeat lactate 4 h after initial draw
- Monitor, document VS \( \leq q 60 \) min.

\section*{DURING ED COURSE

Severe Sepsis Dx Criteria Met (Dx SS) if:

- Lactate \( > 2 \)
- Drop in SBP \( \leq 90 \)
- Severe Sepsis VS criteria met or
- New End Organ Dysfunction (SEE BOX)

\section*{CODE SEPSIS

YES

\section*{New End Organ Dysfunction

- \( \text{PaO}_2 / \text{FiO}_2 \) \( < 300 \)
- Increasing \( \text{O}_2 \) demand to maintain sat \( > 90\% \)
- Cr \( > 2.0 \) or \( > 50\% \) increase from known baseline
- UOP \( < 0.5 \text{ml/kg/hr for} > 2 \text{hrs} \)
- Bilirubin \( > 2.0 \text{mg/dl} \)
- Platelet Count \( < 100\text{K} \)
- INR \( > 1.5 \), PTT \( > 60 \text{sec} \)

Consultation, disposition, and transfer of care can occur at any point in the above care map.
Hand off communication is critical and must include discussion of incomplete and complete elements.
Our Approach

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  - Data Collection
  - Data Analysis

NSLIJ Basic 3-Hour Sepsis Bundle

**Early Intervention** Focus

- 4 simple intervention goals
  1. *Initiate* IV fluid resuscitation (30cc/kg) 0.9% NS within 30 minutes of algorithm inclusion (Severe Sepsis pathway)
  2. Draw lactate and have result available within 90 minutes of order time
  3. Draw blood cultures *prior* to starting antimicrobial therapy
  4. Administer broad-spectrum IV antibiotics within 180 minutes of algorithm inclusion (Stretch Goal 60 minutes in Severe Sepsis path)

- Interventions are cheap and transposable – and concordant with the scientific literature
Our Approach

- Task Force
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- Bundle (Intervention)

Process Improvement

- Data Collection
- Data Analysis

Sepsis Task Force: IHI/NSLIJ Collaboration

- Initiated by Michael Dowling, President & CEO of NSLIJ
- Takes advantage of the unique assets of each organization
  - Accelerating reduction in Sepsis Mortality
  - Strengthening the Infrastructure for Improvement of Large Systems
- Together we will learn for the North Shore-LIJ Health System and for the health care field
Process Improvement: Microsystems

It’s just like patient care:
- To improve a patient’s health status … You assess, diagnose, treat, and follow-up based on biomedical and care science
- To improve a microsystem’s “health” status … You assess, diagnose, treat, and follow-up based on improvement science and the science of clinical practice

PDSA Model for Improvement
- Improve patient care by applying the scientific method to clinical processes.
- Conduct test of change in a disciplined and rapid fashion
7 Year Performance: Mortality

Our Approach

- Task Force
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- Bundle (Intervention)
- Process Improvement

Data Collection

Data Analysis
Sepsis Data Collection

- Dedicated abstractor/abstraction team at all sites
- Data abstracted into centralized, internally managed quality improvement database.
- Standardized data collection form and data definitions
- Unstandardized collection procedures and processes
- Regular meetings to ensure uniformity and provide forum to address concerns and obstacles

Our Approach

Task Force
Algorithm (Recognition)
Bundle (Intervention)
Process Improvement
Data Collection

Data Analysis
**Sepsis Data Analysis**

- Performance analysis routinely presented at regular meetings at multiple levels:
  - Task Force Faculty vs. Data Abstractors vs. Front-line Staff
  - System wide vs. Site-specific vs. Department specific

- Non-punitive environment open to front-line feedback, and reflective of the effects of small scale implementations

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**Sepsis Data Analysis**

- Centralized analysis and dissemination with
  - Fall-out Review
  - Improvement Opportunity Identification
  - Solutions Testing

- Decentralized access to centralized data
  - Analytics and research team given autonomy to locally
    - Investigate problems and assess practices
    - Evaluate efficacy of new initiatives and implementations
  - Cross-subsidizes more resource constrained sites
What Does Data Driven Really Mean?

- Data points are selected based on:
  - Feasibility
  - Integrity
  - Value

What Does Data Driven Really Mean?

**Improvement measures** vs. **Compliance measures**
Improvement vs. Compliance: IV Fluids

- **30 Minute IV Fluid Initiation**
  - NQF and SSC guidelines call for *Completion* within 180 minutes
  - So does CMS and New York DOH for that matter…

- Data Integrity and Value drive the divergence here

- What can your data *really* tell you, and what *can’t* it tell you?

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**Improvement vs. Compliance Measures**
Improvement vs. Compliance: IV Fluids

- Literature to support IV fluid *initiation* time measure

![Graph showing hospital mortality comparison](image)

Predicted hospital mortality from fully adjusted models.

(A) Predicted hospital mortality from fully adjusted models for subjects with severe sepsis and prehospital hypotension (≤110 mmHg, hashed bars, N=554)


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Improvement vs. Compliance: IV Fluids

### Univariate Comparisons of IV Fluid bundle element compliance

<table>
<thead>
<tr>
<th></th>
<th>All Subjects</th>
<th>≤ 30 Minute Fluids</th>
<th>&gt; 30 Minutes</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>1,866</td>
<td>1,193</td>
<td>673</td>
<td></td>
</tr>
<tr>
<td>In-Hospital Mortality</td>
<td>282 (15.1%)</td>
<td>13.3% ± 1.9%</td>
<td>18.3% ± 3.0%</td>
<td>0.004</td>
</tr>
<tr>
<td>ICU Admission</td>
<td>528 (28.0%)</td>
<td>26.0% ± 2.5%</td>
<td>32.0% ± 4.0%</td>
<td>0.007</td>
</tr>
</tbody>
</table>

In adjusted logistic regression: patients who *didn’t* receive IV fluid resuscitation in ≤ 30 minutes had...

**75% increased mortality likelihood**

(OR: 1.53, p=0.004, CI, 1.15-2.04)

*(Hosmer and Lemeshow χ²=1.90, df=8, p=0.98)*

Source: All Severe Sepsis/Septic Shock cases over 13 months at Manhasset site in system database
Improvement vs. Compliance: IV Fluids

In Cox proportional hazards model, mortality censored: patients who did receive fluid resuscitation within 30 minutes had...

- **13.5% shorter LOS**
  (HR\(^1\): 0.865, p=0.008, CI\(_{0.05}\) 3.7%-22.3%)

![Product-Limit Survival Estimates](image)

<table>
<thead>
<tr>
<th>Outcome (\uparrow) Time</th>
<th>≤30 min.</th>
<th>31-60 min.</th>
<th>61-180 min.</th>
<th>180+ or no fluids</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOS (median)</td>
<td>6 days</td>
<td>7 days</td>
<td>7 days</td>
<td>8 days</td>
</tr>
<tr>
<td>ICU LOS [median]</td>
<td>3 days</td>
<td>4 days</td>
<td>4 days</td>
<td>5 days</td>
</tr>
<tr>
<td>Mortality Risk (mv log reg, OR, p value)</td>
<td>0.60 (p=0.006)</td>
<td>0.73 (p=0.242)</td>
<td>0.86 (p=0.563)</td>
<td>Reference group</td>
</tr>
<tr>
<td>LOS Risk* (Cox prop haz, HR, p value)</td>
<td>0.79 (p=0.002)</td>
<td>0.77 (p=0.016)</td>
<td>0.86 (p=0.164)</td>
<td>Reference group</td>
</tr>
<tr>
<td>(N) (total = 1,866)</td>
<td>1,193</td>
<td>177</td>
<td>177</td>
<td>319</td>
</tr>
</tbody>
</table>

Source: All Severe Sepsis/Septic Shock cases over 13 months at Manhasset site in system database
Improvement vs. Compliance: Lactate

- 90 minute Lactate order to result time
- Feasibility and Value drive the divergence here
- Diagnostic information that can drive clinical management
- What is the best we can do, 100% of the time?

The Right Data Has Environmental Effects

- Reflective, goal-driven data creates a positive top-down environment
- Focus on leadership’s interests
  - Mortality
  - ROI and financial benefit
  - Quality Measures: (read: CMS, P4P, bundled payment)
The **Right** Data Has Environmental Effects

- Meaningful, responsive data creates a positive ground-up environment
  - E.g., appropriate measures of compliance

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The Real Question

- Do we really know if this foundational bundle works?
### 3-hour Bundle: Clinical Outcomes

#### Results

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Bundle Comp.</th>
<th>Bundle Non-Comp.</th>
<th>Δ</th>
<th>95% CI Δ</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality*</td>
<td>101 (12.7%)</td>
<td>157 (17.0%)</td>
<td>5.3%</td>
<td>0.8-7.6%</td>
<td>0.014</td>
</tr>
<tr>
<td>ICU Admission</td>
<td>25.1%</td>
<td>30.9%</td>
<td>5.8%</td>
<td>(-)0.4-8.0%</td>
<td>0.076</td>
</tr>
<tr>
<td>Median LOS*</td>
<td>6 days</td>
<td>7 days</td>
<td>1 day</td>
<td>0-2 days</td>
<td>0.027</td>
</tr>
<tr>
<td>N (total = 1,697)</td>
<td>739</td>
<td>958</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Source: All Severe Sepsis/Septic Shock cases over Medicare FY 2014 at Manhasset site in system database

#### Multivariate Mortality Model

<table>
<thead>
<tr>
<th>Parameter</th>
<th>β</th>
<th>S.E.</th>
<th>Odds Ratio</th>
<th>95% CI</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bundle Compliance</td>
<td>0.41</td>
<td>0.14</td>
<td>1.64</td>
<td>1.14</td>
<td>1.98</td>
</tr>
</tbody>
</table>

Hosmer and Lemeshow: $\chi^2 = 6.24$, df = 8, $p = 0.621$

Area Under the Curve = 0.766
The Burden of Septic Disease

The Top Five Most Expensive Conditions Treated in U.S. Hospitals

3-hour Bundle: Financial Outcomes

Bundle compliant care was associated with a 17% ($3,000) reduction in total direct costs per patient encounter.

Compliance vs. Direct per Patient Costs

Northwell Health

p = 0.006
p = 0.012
p = 0.003

Total Direct Costs
Variable Costs
Fixed Costs
3-hour Bundle: Financial Outcomes

Receiving bundle compliant care was associated with a roughly 10% reduction in total direct costs.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>B</th>
<th>S.E.</th>
<th>95% CI</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>8.578</td>
<td>0.120</td>
<td>8.342 - 8.814</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Bundle Compliance</td>
<td>-0.090</td>
<td>0.035</td>
<td>-0.159 - 0.021</td>
<td>0.011</td>
</tr>
</tbody>
</table>

Scaling Up The Analysis

Across 8 hospitals: (4 community, 4 tertiary)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Bundle Comp.</th>
<th>Bundle Non-Comp.</th>
<th>Δ</th>
<th>95% CI</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality*</td>
<td>17.2%</td>
<td>22.1%</td>
<td>4.9%</td>
<td>3.6% - 6.1%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total Direct Costs</td>
<td>$16,147</td>
<td>$21,265</td>
<td>-$5,118</td>
<td>-$4,208 - -$6,028</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>N (total = 19,148)</td>
<td>5,358</td>
<td>13,790</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

- Number Needed to Treat: 20
  (CI: 16 - 28)

- Cost-Savings/Mortality Prevented
  $102,360
  (CI: $67,328 - $168,784)
Take Home Points

1. Develop solutions that are *upstream* of the problem you are trying to fix

Upstream Solutions

- We focused on *early* recognition and *early* intervention

- Our measures were about beating the guidelines, not meeting them

- Seek *improvement* measures, not *compliance* measures
Take Home Points

1. Don’t wait for the bell to ring – develop solutions that are *upstream* of the problem you are trying to fix

2. Engage and empower those with the expertise

---

3. Good systems continuously learn, evolve, and adapt

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“Insanity is doing the same thing over and over again and expecting different results.”

- Albert Einstein
Take Home Points

1. Develop solutions that are *upstream* of the problem you are trying to fix

2. Engage and empower those with the expertise

3. Good systems continuously learn, evolve, and adapt

4. Use your data to be flexible, responsive, and impactful.

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Take Home Points

1. Develop solutions that are *upstream* of the problem you are trying to fix

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Thank You

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"I'll pause for a moment so you can let this information sink in."