Randomization and Clinical Decision Support: An EHR-based Severe Sepsis Alert

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Sepsis is costly

<table>
<thead>
<tr>
<th>Rank</th>
<th>CCS principal diagnosis category and name</th>
<th>Aggregate hospital costs, U.S. $, in millions</th>
<th>National costs, %</th>
<th>Number of hospital discharges, in thousands</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Septicemia (except in labor)</td>
<td>20,298</td>
<td>5.2</td>
<td>1,094</td>
</tr>
<tr>
<td>2</td>
<td>Osteoarthritis</td>
<td>14,810</td>
<td>3.8</td>
<td>964</td>
</tr>
<tr>
<td>3</td>
<td>Complication of device, implant or graft</td>
<td>12,881</td>
<td>3.3</td>
<td>699</td>
</tr>
<tr>
<td>4</td>
<td>Liveborn</td>
<td>12,390</td>
<td>3.2</td>
<td>3,818</td>
</tr>
<tr>
<td>5</td>
<td>Acute myocardial infarction</td>
<td>11,504</td>
<td>3.0</td>
<td>612</td>
</tr>
<tr>
<td>6</td>
<td>Spondylosis, intervertebral disc disorders, other back problems</td>
<td>11,218</td>
<td>2.9</td>
<td>667</td>
</tr>
<tr>
<td>7</td>
<td>Pneumonia (except that caused by tuberculosis and sexually transmitted diseases)</td>
<td>10,570</td>
<td>2.7</td>
<td>1,114</td>
</tr>
<tr>
<td>8</td>
<td>Congestive heart failure, nonhypertensive</td>
<td>10,535</td>
<td>2.7</td>
<td>970</td>
</tr>
<tr>
<td>9</td>
<td>Coronary atherosclerosis</td>
<td>10,400</td>
<td>2.7</td>
<td>605</td>
</tr>
<tr>
<td>10</td>
<td>Respiratory failure, insufficiency, arrest (adult)</td>
<td>8,749</td>
<td>2.3</td>
<td>404</td>
</tr>
</tbody>
</table>
We know what to do (kind of)

Late recognition
Our approach

- SIRS
- Concern for infection
- Organ dysfunction

Alert criteria met

Alert to crisis RN & MD

Evaluate for sepsis

Sepsis bundle

• Pager text message
• Document sepsis or not

- Lactate
- Blood cultures
- Antibiotics
- IVF
Quality Improvement and Confounding

Please Do Something, Anything!
Quality Improvement vs. Research?

[Notice of Determination of Human Subject Research]

- Exempt from IRB as QI initiative
- 1:1 encounter-level randomization
- Performance metric endpoints: antibiotics, IVF, lactate, blood cultures
- Expected randomization period of 7 months to see 10% difference

**THIS PROJECT DOES NOT REQUIRE SUBMISSION TO THE STANFORD IRB, BECAUSE:**

- This project does not meet the Federal definition of research [DHHS 45 CFR 46.102(d)] or clinical investigation [FDA 21 CFR 50.3(c), 56.102(c)]. See Is My Project “Research”? [AID-H8].
Results at 6 months

- 1138 encounters randomized
- 2 of 4 process metrics statistical improvement
An Argument for Randomization