Sepsis Wave II

CMS SEP-1 measure—Early Insights and Experience
The project described is supported by Funding Opportunity Number CMS-1L1-15-002 from the U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services. The contents provided are solely the responsibility of the authors and do not necessarily represent the official views of HHS or any of its agencies.
Presenters

Dr. Lemeneh Tefera

Dr. Todd Slesinger
CMS Sepsis Measure (SEP-1)

Sepsis Measure Performance
Quarter 4 FY 2015
Quarter 1 FY 2016
Quarter 2 FY 2016

Lemeneh Tefera MD MSc
Centers for Medicare and Medicaid Services

Emergency Quality Network- Sepsis Series
American College of Emergency Physicians
March 22nd, 2017
Disclaimer

This presentation was current at the time it was published or uploaded onto the web. Medicare policy changes frequently so links to the source documents have been provided within the document for your reference.

This presentation was prepared as a service to the public and is not intended to grant rights or impose obligations. This presentation may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents.
# SEP-1: Completing The Bundles

<table>
<thead>
<tr>
<th>Required Action</th>
<th>Severe Sepsis</th>
<th>Septic Shock</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Three Hour Bundle</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial Lactate Collection</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Blood Culture Collection</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Initial Antibiotic Started</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Repeat Lactate Collection (if Initial Lactate is greater than two)</td>
<td>Yes</td>
<td>Must be completed within six hours of Severe Sepsis presentation</td>
</tr>
<tr>
<td>30mL/kg Crystalloid Fluids Started</td>
<td>N/A</td>
<td>Yes</td>
</tr>
<tr>
<td>Vasopressor Given (if decreased BP persists)</td>
<td>N/A</td>
<td>Yes</td>
</tr>
<tr>
<td>Repeat Volume Status/ Tissue Perfusion Assessment</td>
<td>N/A</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Six Hour Bundle</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial Lactate Collection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood Culture Collection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial Antibiotic Started</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Repeat Lactate Collection (if Initial Lactate is greater than two)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30mL/kg Crystalloid Fluids Started</td>
<td>N/A</td>
<td>Yes</td>
</tr>
<tr>
<td>Vasopressor Given (if decreased BP persists)</td>
<td>N/A</td>
<td>Yes</td>
</tr>
<tr>
<td>Repeat Volume Status/ Tissue Perfusion Assessment</td>
<td>N/A</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*Must be completed within three hours of Severe Sepsis Presentation*
SEP-1 Initial Patient Population

- **Quarter Four FY 2015** (Oct 1, 2015 – Dec 31, 2015) and **Quarter One FY 2016** (Jan 1, 2016 – Mar 31, 2016) discharges, >99% of hospitals successfully submitted SEP-1 data
- 325,809 total patients in the **initial patient population with Medicare Payment Source** over all three quarters
- (159,289 / 325,809) met criteria to be included in the measure (**Eligibles**)
- (166,520 / 325,809) did not meet criteria to be included in the measure (**Exclusions**)
### Description of Case Sampling:

#### Quarterly Sampling

Hospitals selecting sample cases for the sepsis measure must ensure that the population and quarterly sample size meets the following conditions:

**Quarterly Sample Size**

<table>
<thead>
<tr>
<th>Average Quarterly Initial Patient Population Size “N”</th>
<th>Minimum Required Sample Size “n”</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 301</td>
<td>60</td>
</tr>
<tr>
<td>151 - 300</td>
<td>20% of Initial Patient Population size</td>
</tr>
<tr>
<td>30 - 150</td>
<td>30</td>
</tr>
<tr>
<td>6 - 29</td>
<td>No sampling; 100% Initial Patient Population required</td>
</tr>
<tr>
<td>0 - 5</td>
<td>Submission of patient level data is encouraged but not required. If submission occurs, 1 – 5 cases of the Initial Patient Population may be submitted</td>
</tr>
</tbody>
</table>

#### Monthly Sampling

Hospitals selecting sample cases for the sepsis measure must ensure that the population and monthly sample size meets the following conditions:

**Monthly Sample Size**

<table>
<thead>
<tr>
<th>Average Monthly Initial Patient Population Size “N”</th>
<th>Minimum Required Sample Size “n”</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 101</td>
<td>20</td>
</tr>
<tr>
<td>51 - 100</td>
<td>20% of Initial Patient Population size</td>
</tr>
<tr>
<td>10 - 50</td>
<td>10</td>
</tr>
<tr>
<td>&lt; 10</td>
<td>No sampling; 100% Initial Patient Population required</td>
</tr>
</tbody>
</table>
Breakdown of SEP-1 Exclusion Population:

- Did not meet Severe Sepsis Criteria: 72.9%
- Transfers: 18.0%
- Antibiotic Exclusion: 3.8%
- Administrative Contraindication to Care: 2.9%
- Comfort Care prior to or within three hours of Severe Sepsis Presentation: 1.8%
- Comfort Care prior to or within six hours of Septic Shock: 0.4%
- Expired within six hours of Septic Shock: 0.2%
- Expired within three hours of Severe Sepsis: 0.2%

Note: Cumulative data from October 2015 – March 2016 (166,520 total exclusions for cases with identified Medicare Payment source)
**Initial Population Breakdown by Bundle and Total Eligible Cases**

<table>
<thead>
<tr>
<th>Bundle</th>
<th>Q4 2015</th>
<th>Q1 2016</th>
<th>Q2 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>INITIAL PATIENTS</td>
<td>108,572</td>
<td>111,314</td>
<td>105,923</td>
</tr>
<tr>
<td>Severe Sepsis Three Hour</td>
<td>54,096</td>
<td>57,500</td>
<td>55,518</td>
</tr>
<tr>
<td>Severe Sepsis Six Hour</td>
<td>28,479</td>
<td>31,194</td>
<td>30,712</td>
</tr>
<tr>
<td>Septic Shock Three Hour</td>
<td>13,324</td>
<td>13,940</td>
<td>13,725</td>
</tr>
<tr>
<td>Septic Shock Six Hour (Vasopressors)</td>
<td>2,703</td>
<td>2,813</td>
<td>2,661</td>
</tr>
<tr>
<td>Septic Shock Six Hour (Repeat Volume Status and Tissue Perfusion Assessment)</td>
<td>4,412</td>
<td>5,108</td>
<td>5,110</td>
</tr>
<tr>
<td>Total Eligible Cases*</td>
<td>51,643</td>
<td>54,729</td>
<td>52,917</td>
</tr>
</tbody>
</table>

*Total Eligible Cases are patients in the initial patient population with identified Medicare payment source that did not meet any exclusion criteria. Only cases that either passed or failed the measure are included. Exclusion criteria occurs throughout the measure algorithm.*
Breakdown by SEP-1 Bundles: Severe Sepsis Three Hour Bundle

- **2015 Q4**
  - N = 54,096
  - Pass: 63.4%
  - Did Not Pass, Initial lactate: 18.2%
  - Did Not Pass, Other Data Elements: 17.1%

- **2016 Q1**
  - N = 57,500
  - Pass: 66.2%
  - Did Not Pass, Initial lactate: 15.6%
  - Did Not Pass, Other Data Elements: 16.7%

- **2016 Q2**
  - N = 55,518
  - Pass: 68.0%
  - Did Not Pass, Initial lactate: 13.9%
  - Did Not Pass, Other Data Elements: 16.7%
Breakdown by SEP-1 Bundles: Severe Sepsis Six Hour Bundle

- **N= 28,479**
  - 50.4% Pass
  - 49.6% Did Not Pass, Repeat Lactate

- **N= 31,194**
  - 40.4% Pass
  - 59.6% Did Not Pass, Repeat Lactate

- **N= 30,712**
  - 32.3% Pass
  - 67.7% Did Not Pass, Repeat Lactate
Breakdown by SEP-1 Bundles: Septic Shock Three Hour Bundle

- **2015 Q4**: 47.4% Pass, 52.6% Did Not Pass
- **2016 Q1**: 44.8% Pass, 55.2% Did Not Pass
- **2016 Q2**: 44.2% Pass, 55.8% Did Not Pass
Breakdown by SEP-1 Bundles: Shock Six Hour Bundle – Vasopressors

- 2015 Q4: 74.6% Pass, 25.4% Did Not Pass
- 2016 Q1: 75.2% Pass, 24.8% Did Not Pass
- 2016 Q2: 76.1% Pass, 23.9% Did Not Pass
Breakdown by SEP-1 Bundles: Septic Shock Six Hour Bundle – Assessment

- 2015 Q4: 71.8% Pass, Non-invasive, 20.4% Pass, Invasive, 7.8% Did Not Pass
- 2016 Q1: 67.7% Pass, Non-invasive, 26.3% Pass, Invasive, 4.7% Did Not Pass
- 2016 Q2: 64.8% Pass, Non-invasive, 30.5% Pass, Invasive, 4.7% Did Not Pass
Breakdown of SEP-1: Combined Bundles for Eligible Population

- **2015 Q4**: N=51,643
  - Pass, All Bundles: 64.8%
  - Did Not Pass, All Bundles: 35.2%

- **2016 Q1**: N=54,729
  - Pass, All Bundles: 59.5%
  - Did Not Pass, All Bundles: 40.5%

- **2016 Q2**: N=52,917
  - Pass, All Bundles: 55.1%
  - Did Not Pass, All Bundles: 44.9%
SEP-1 Mortality Rate Trend for Eligible Population:

<table>
<thead>
<tr>
<th>Delta</th>
<th>Q4 2015</th>
<th>Q1 2016</th>
<th>Q2 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passed</td>
<td>21.3%</td>
<td>23.0%</td>
<td>21.4%</td>
</tr>
<tr>
<td>Did Not Pass</td>
<td>29.6%</td>
<td>31.8%</td>
<td>29.7%</td>
</tr>
</tbody>
</table>
Overall Absolute Deaths vs Potential Preventable Deaths by Quarter

Q4 2015
- Preventable deaths: 2,783
- Passed: 3,872
- Did not Pass: 9,926

Q1 2016
- Preventable deaths: 2,864
- Passed: 5,088
- Did not Pass: 10,351

Q2 2016
- Preventable deaths: 2,411
- Passed: 5,079
- Did not Pass: 8,647
### Overall Absolute Deaths for Patients Meeting Measure vs Not Meeting Measure and Potentially Preventable Deaths by Quarter

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Did not pass deaths</th>
<th>Did not pass deaths - preventable</th>
<th>Met measure deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q4 2015</td>
<td>7,143</td>
<td>2,783</td>
<td>3,872</td>
</tr>
<tr>
<td>Q1 2016</td>
<td>7,487</td>
<td>2,864</td>
<td>5,088</td>
</tr>
<tr>
<td>Q2 2016</td>
<td>6,236</td>
<td>2,411</td>
<td>5,079</td>
</tr>
</tbody>
</table>
SEP-1 and Mortality Comparisons by Pass Rate Percentiles (2015Q4 - 2016Q2)

Shows the overall SEP-1 Pass Rate compared to the overall Mortality Rate across each of the calculated hospital pass rate percentiles.
Takeaways

• SEP-1 measure refinement is an ongoing and iterative process
• The process involves engaging with multiple stakeholders
• Refinement is driven by these goals:
  ▪ Maximizing beneficiary sepsis care
  ▪ Minimizing clinician documentation burden
  ▪ Minimizing hospital abstraction burden
• Performance is poised for improvements in future analyses (ongoing quarter one 2016 and pending quarter two 2016)
• https://www.qualitynet.org/dcs/ContentServer?c=Page&pageName=QnetPublic%2FPage%2FQnetTier3&cid=1228772869636
Contact Information:

Lemeneh Tefera MD MSc
Center for Clinical Standards & Quality
Center for Program Integrity

Em: lemeneh.tefera@cms.hhs.gov
Twitter: @dr_tef
Appendix:
Differences between treatment and control groups in the ProCESS, ARISE, and ProMISE Trials:

<table>
<thead>
<tr>
<th>Clinical Trial</th>
<th>Cohort</th>
<th>Intravenous Fluids (milliliters)</th>
<th>Central Line Placement</th>
<th>Vasopressor Utilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>ProCESS</td>
<td>EGDT</td>
<td>2805 +/- 1957</td>
<td>411/439 (93.6%)</td>
<td>241/439 (54.9%)</td>
</tr>
<tr>
<td>May 2014</td>
<td>Usual Care</td>
<td>2279 +/- 1881</td>
<td>264/456 (57.9%)</td>
<td>201/456 (44.1%)</td>
</tr>
<tr>
<td></td>
<td>Δ</td>
<td>526ml</td>
<td>35.7%</td>
<td>10.8%</td>
</tr>
<tr>
<td>ARISE</td>
<td>EGDT</td>
<td>1964 +/- 1415</td>
<td>714/793 (90%)</td>
<td>528/793 (66.6%)</td>
</tr>
<tr>
<td>October 2014</td>
<td>Usual Care</td>
<td>1713 +/- 1401</td>
<td>494/798 (61.9%)</td>
<td>461/798 (57.8%)</td>
</tr>
<tr>
<td></td>
<td>Δ</td>
<td>251ml</td>
<td>28.1%</td>
<td>8.8%</td>
</tr>
<tr>
<td>ProMISE</td>
<td>EGDT</td>
<td>2000 (1150-3000)</td>
<td>575/624 (92%)</td>
<td>332/623 (53.3%)</td>
</tr>
<tr>
<td>May 2015</td>
<td>Usual Care</td>
<td>1784 (1075-2775)</td>
<td>318/625 (50.9%)</td>
<td>291/625 (46.6%)</td>
</tr>
<tr>
<td></td>
<td>Δ</td>
<td>216ml</td>
<td>41.1%</td>
<td>6.7%</td>
</tr>
</tbody>
</table>

Early Insights from the Emergency Quality Network SEP-1 Challenge

Todd L. Slesinger, MD, FACEP, FCCM, FCCP, FAAEM
Program Director and Academic Chair
Department of Emergency Medicine

Aventura Hospital and Medical Center
Disclosures

- ACEP Sepsis Expert panel – Vice Chair
- ACEP CMMI TCPI SAN – Sepsis Project Manager
Objectives

• Review the data of participants in our SEP-1 Challenge to gain early insights into spesis bundle performance

• Survey 8 Best Practices for Quality Improvement in Sepsis care

• Compare EQUAL Participants to national data
In October 2015, the American College of Emergency Physicians (ACEP) launched the Emergency Quality Network (E-QUAL) Sepsis Initiative as part of the CMS Transforming Clinical Practice Initiative with the explicit objective of improving the outcomes of ED patients with sepsis by enrolling EDs across the nation in a learning collaborative.
SEP-1 Benchmarking Challenge

- Survey of quality improvement data from hospital-based Emergency Departments participating in the EQUAL Sepsis Initiative

- Data collection and submission occurred over an 8-week period between October and December 2016, looking at data from the first year of the measure

- This quality improvement study was not considered human subjects research and exempt from IRB review
Participants

- Participation was permitted to any ED in the United States interested in sepsis quality improvement.

- A total of 81% of SEP-1 Benchmarking Challenge participants were enrolled in Wave I or Wave II of the EQUAL Sepsis Initiative.
Data Collection

- Data was collected using a standardized web-based data submission portal.
- Demographic characteristics collected from each ED included annual ED visit volume, hospital zip code, and hospital type.
- Each ED was classified as rural or urban based on zip code Metropolitan Statistical Area.
Data Collection

- Data elements collected included the total number of cases reviewed, total number excluded, and counts of severe sepsis and septic shock cases during the data collection period and the counts of cases in which sepsis bundle compliance was achieved.

- Consistent with CMS guidance for data collection, hospitals without sufficient sepsis case counts each month could abstract and submit data quarterly.

- Only SEP-1 numerator components specific to emergency care were collected (No Re-Assessment).
Outcomes

- The primary outcome for this study was SEP-1 bundle compliance defined as the proportion of all severe sepsis and septic shock cases receiving all required bundle elements.

- Secondary outcomes included conditional compliance on reported SEP-1 numerator components and ED implementation of sepsis quality improvement best practices.
Results

- A total of 50 EDs, which care for an estimated 2 million patients annually, participated - 5133 patients

- 74% were community, non-teaching sites
- 26% were affiliated with academic centers
- 80% of EDs were non-MSA status, located in regions with relatively low population density

- 32 EDs submitted data monthly and 18 submitted quarterly
Results

- There was increasing data availability over the duration of Wave 1:
Component Compliance

- Problems with skip logic likely affected Pressor results
Bundle Compliance

- Broad variation in performance in SEP-1 bundle compliance overall with average performance of 50.5% (range: 10%-100%)
Bundle Compliance

- Broad variation across all ED types
Bundle Compliance

- Broader variation and higher overall performance in lower-volume EDs
Bundle Compliance

- Average performance increased from 43.6% to 56.2% during 2016
Severe Sepsis Bundle

• **WITHIN 3 HOURS OF PRESENTATION**
  • Measure serum *Lactate* (80%)
  • Obtain *Blood Cultures* prior to antibiotics (78%)
  • Administer *Broad Spectrum Antibiotics* (79%)

• **WITHIN 6 HOURS OF PRESENTATION**
  • Repeat measurement of serum *Lactate* if initial is > 2.0 (51%)
Septic Shock Bundle

**WITHIN 3 HOURS OF PRESENTATION**
- Measure Serum Lactate
- Obtain Blood Cultures prior to antibiotics
- Administer broad spectrum antibiotics
- Resuscitation with 30mL/kg crystalloid fluids (46%)

**WITHIN 6 HOURS OF PRESENTATION**
- Repeat measurement of Serum Lactate if initial is > 2.0
- Repeat volume status and tissue perfusion assessment (NA)
- Vasopressor administration (12%)
Data Conclusions

- EQUAL participants performed a little better than preliminary national data - very similar trends
  - Our early data is very predictive of national results
  - Individual components performed similarly
    - Except for Vasopressor (data entry issue)
    - Fluids (30/kg) and Repeat Lactate have lowest performance

- National data appears to be pushed down from the Re-Assessment element
  - Not available in our sample
## Best Practices Survey

<table>
<thead>
<tr>
<th>Sepsis QI Best Practice</th>
<th>% ED Practices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic health record sepsis screen/ alert</td>
<td>71%</td>
</tr>
<tr>
<td>Sepsis metrics data dashboard</td>
<td>73%</td>
</tr>
<tr>
<td>Multi-disciplinary sepsis team</td>
<td>67%</td>
</tr>
<tr>
<td>Code sepsis protocol and alert (similar to STEMI)</td>
<td>38%</td>
</tr>
<tr>
<td>Dedicated sepsis or ED critical care team</td>
<td>14%</td>
</tr>
<tr>
<td>Nursing sepsis screen</td>
<td>92%</td>
</tr>
<tr>
<td>Reflex or automatic repeat lactate testing</td>
<td>67%</td>
</tr>
<tr>
<td>Use of point-of-care lactate testing in the ED</td>
<td>34%</td>
</tr>
</tbody>
</table>
Conclusions

• Sepsis is still a very important area of QI with high mortality rates
  • Bundle compliance has an association with mortality
  • Complex cases may affect this

• Data entry challenges / definitions clearly affect a large proportion of sites, despite a year of reporting
  • CMS Refinement is important

• Broad variation in performance and practices
  • Recommend increased use of Best Practices
**Questions?**

**Severe Sepsis Bundle**

- **WITHIN 3 HOURS**
  - Measure serum *Lactate*
  - Obtain *Blood Cultures* prior to antibiotics
  - Administer *Broad Spectrum Antibiotics*

- **WITHIN 6 HOURS**
  - Repeat measurement of serum *Lactate* if initial is > 2.0

**Septic Shock Bundle**

- **WITHIN 3 HOURS**
  - *Severe Sepsis Bundle* PLUS
  - Resuscitation with 30mL/kg crystalloid fluids

- **WITHIN 6 HOURS**
  - *Severe Sepsis Bundle* PLUS
  - Repeat volume status and tissue perfusion assessment
  - Vasopressor administration
What’s Next for Sepsis Wave II?

- Activity 2- Benchmarking Data
  Deadline has been extended to March 30th

- Register for the April Webinar
  www.acep.org/equal

- Questions? Contact the E-QUAL team at equal@acep.org