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Sepsis Wave II

CMS SEP-1 measure—Early Insights and Experience

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Disclaimer

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Presenters

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CMS Sepsis Measure (SEP-1)

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

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Centers for Medicare and Medicaid Services

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

Disclaimer

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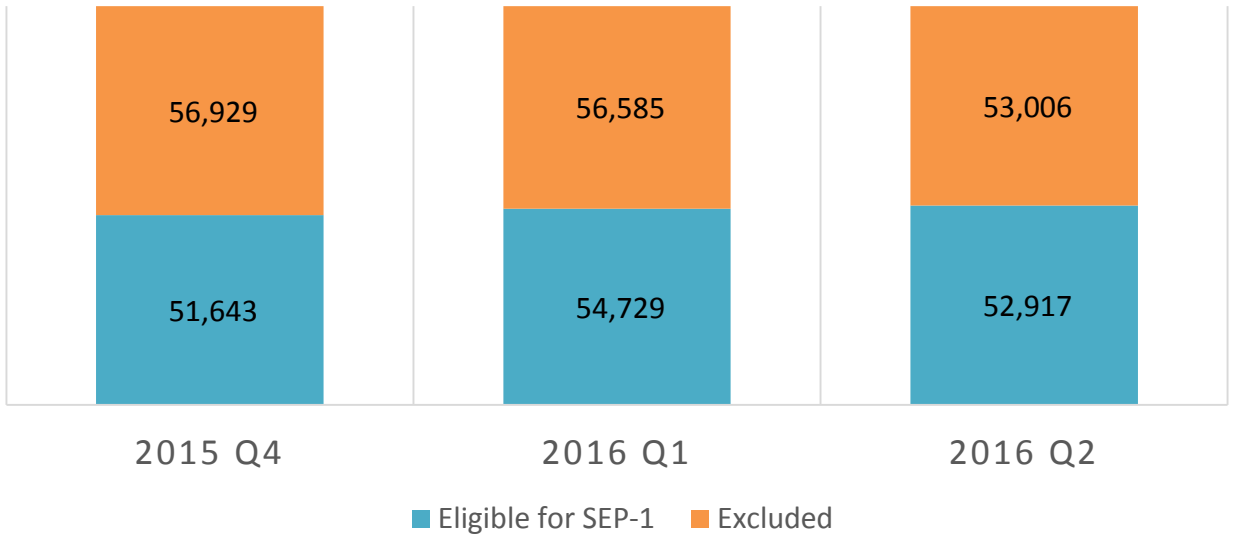
SEP-1: Completing The Bundles

<table>
<tr><th rowspan="2">Required Action</th><th colspan="2">Severe Sepsis</th><th colspan="2">Septic Shock</th></tr>
<tr><th>Three Hour Bundle</th><th>Six Hour Bundle</th><th>Three Hour Bundle</th><th>Six Hour Bundle</th></tr>
<tr><td>Initial Lactate Collection</td><td>Yes</td><td colspan="3" rowspan="3">Must be completed
within three hours of
Severe Sepsis Presentation</td></tr>
<tr><td>Blood Culture Collection</td><td>Yes</td></tr>
<tr><td>Initial Antibiotic Started</td><td>Yes</td></tr>
<tr><td>Repeat Lactate Collection
(if Initial Lactate is greater than two)</td><td colspan="2">Yes</td><td colspan="2">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>N/A</td><td>Yes</td><td>Must be completed within three hours of Hypotension</td></tr>
<tr><td>Vasopressor Given
(if decreased BP persists)</td><td>N/A</td><td>N/A</td><td rowspan="2">Must be completed within six hours of Septic Shock</td><td>Yes</td></tr>
<tr><td>Repeat Volume Status/ Tissue Perfusion Assessment</td><td>N/A</td><td>N/A</td><td>Yes</td></tr>
</table>

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
Based on Hospital's Initial Patient Population Size for the Sepsis Measure

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

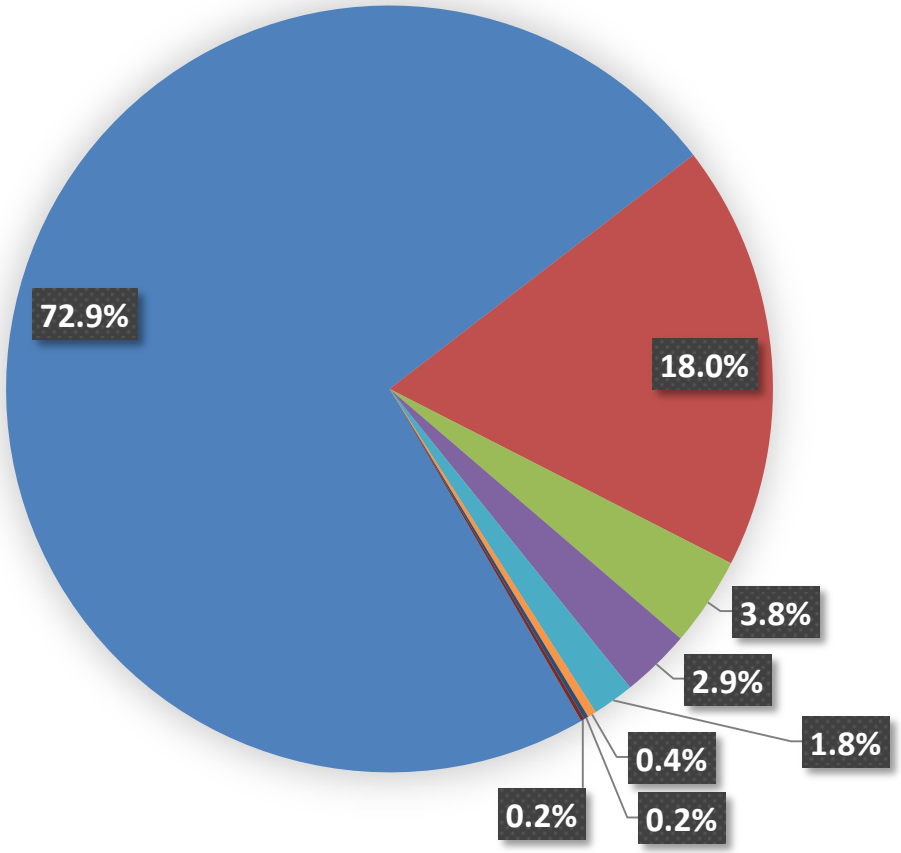
Monthly Sampling

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

Monthly Sample Size
Based on Hospital's Initial Patient Population Size for the Sepsis Measure

Average Monthly Initial Patient Population Size *"N"*	Minimum Required Sample Size *"n"*
≥ 101	20
51 - 100	20% of Initial Patient Population size
10 - 50	10
< 10	No sampling; 100% Initial Patient Population required

Breakdown of SEP-1 Exclusion Population:



- Did not meet Severe Sepsis Criteria
- Transfers
- Antibiotic Exclusion
- Comfort Care prior to or within three hours of Severe Sepsis Presentation
- Administrative Contraindication to Care
- Comfort Care prior to or within six hours of Septic Shock
- Expired within six hours of Septic Shock
- Expired within three hours of Severe Sepsis

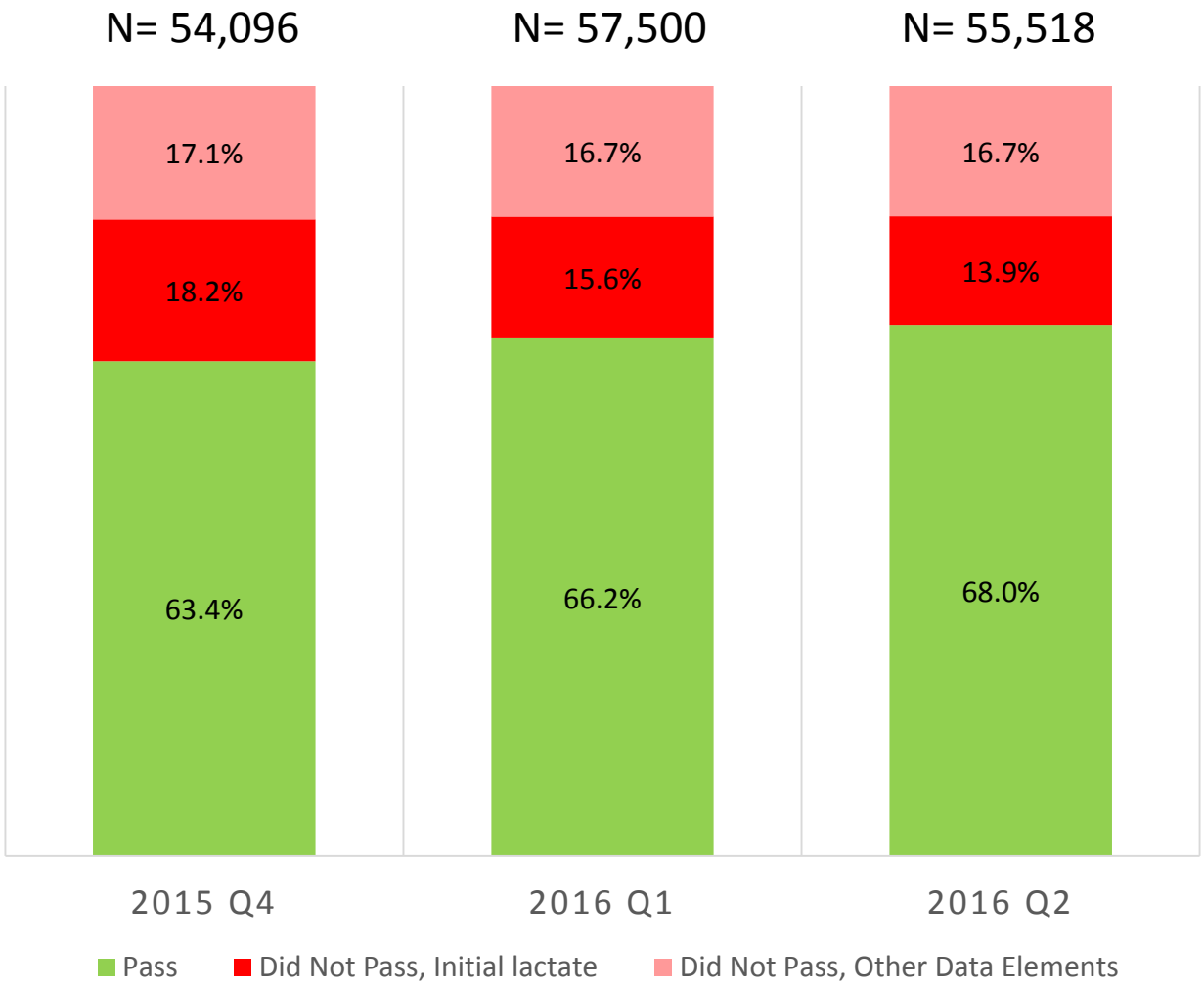
Note: Cumulative data from October 2015 – March 2016
(166,520 total exclusions for cases with identified Medicare Payment source)

Initial Population Breakdown by Bundle and Total Eligible Cases

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

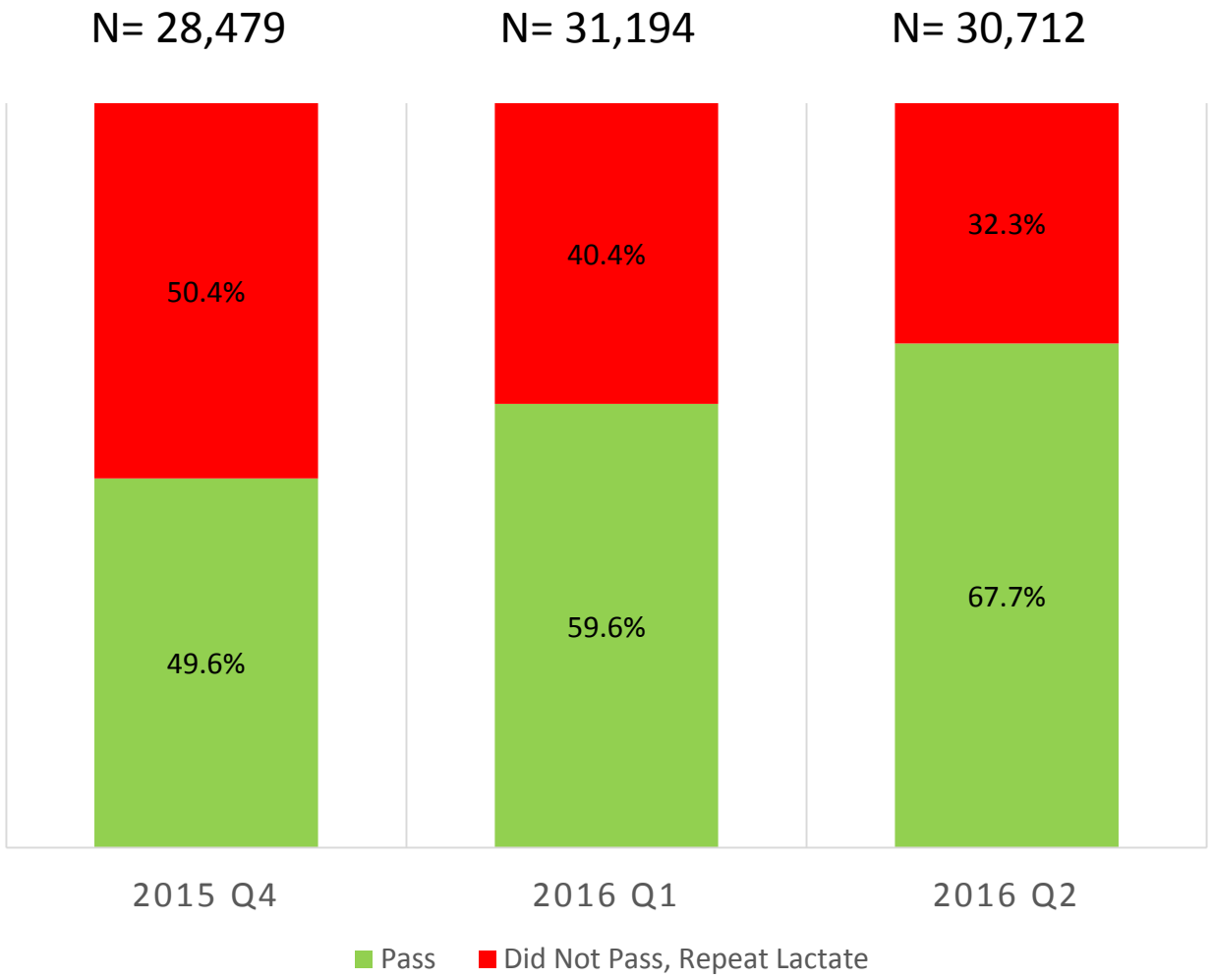
*Total Eligible Cases are patients in the initial patient population with identified Medicare payment source that did not meet any exclusion criteria. Only cases that either passed or failed the measure are included. Exclusion criteria occurs throughout the measure algorithm.

Breakdown by SEP-1 Bundles:
Severe Sepsis Three Hour Bundle

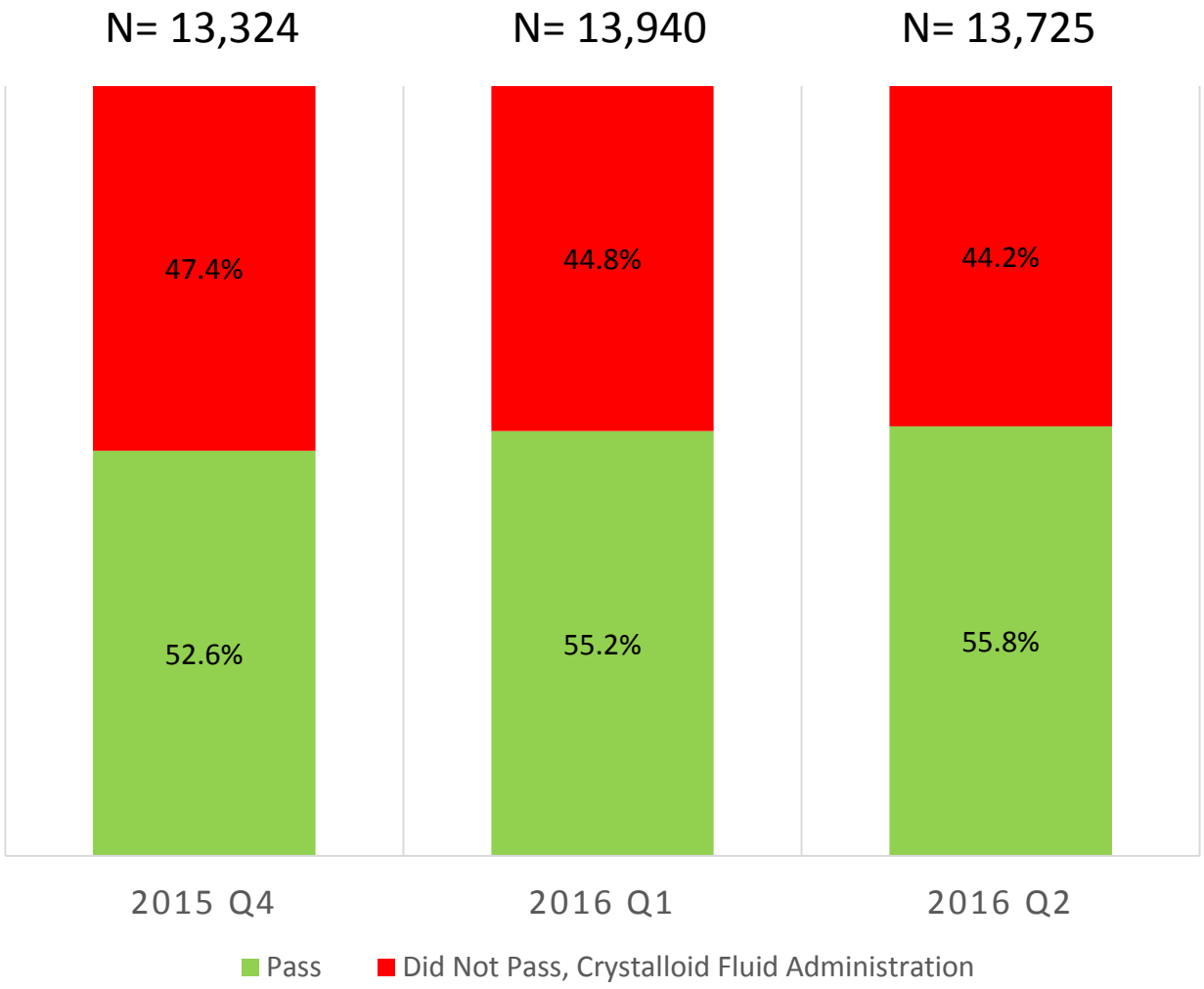


Breakdown by SEP-1 Bundles:

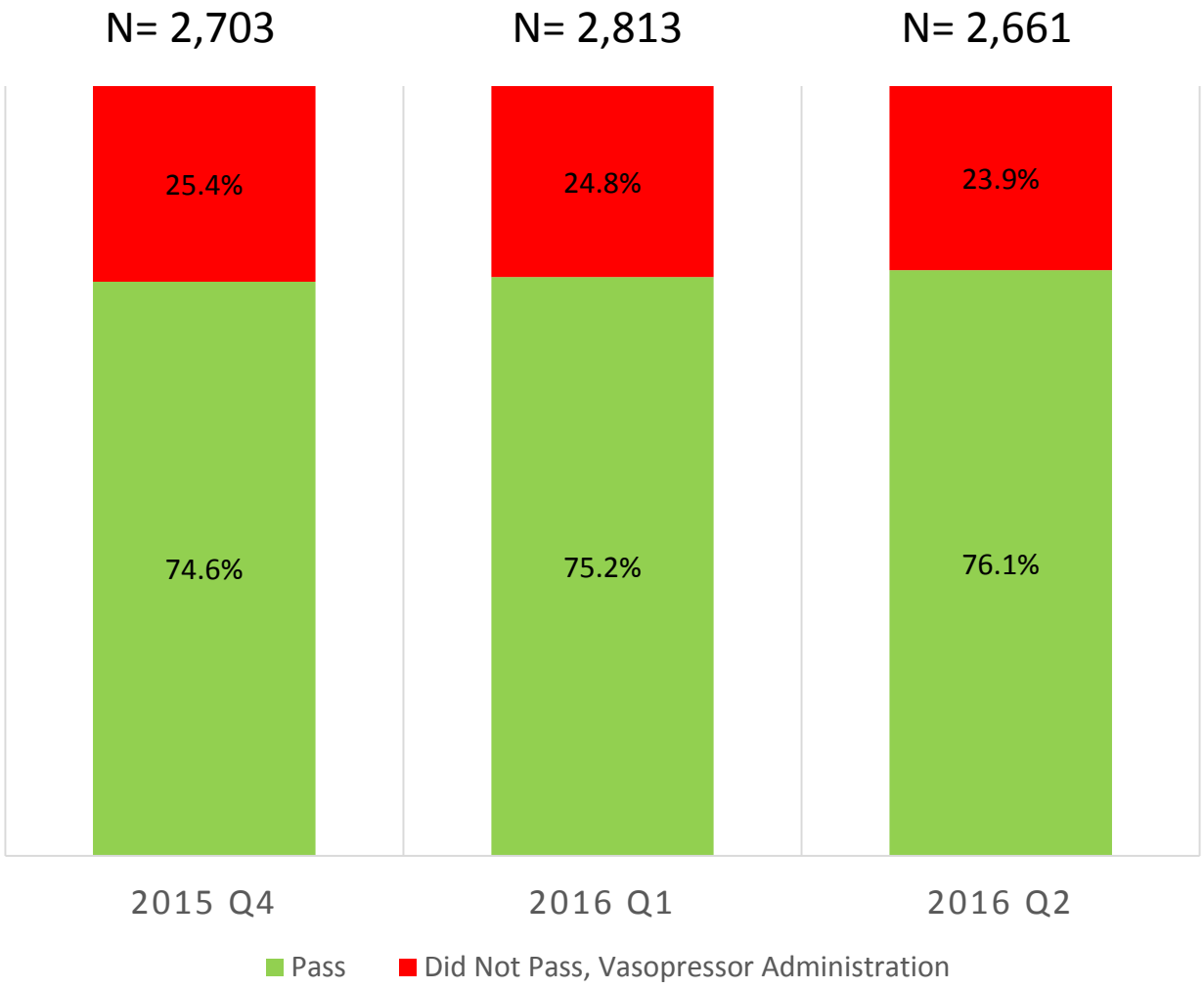
Severe Sepsis Six Hour Bundle



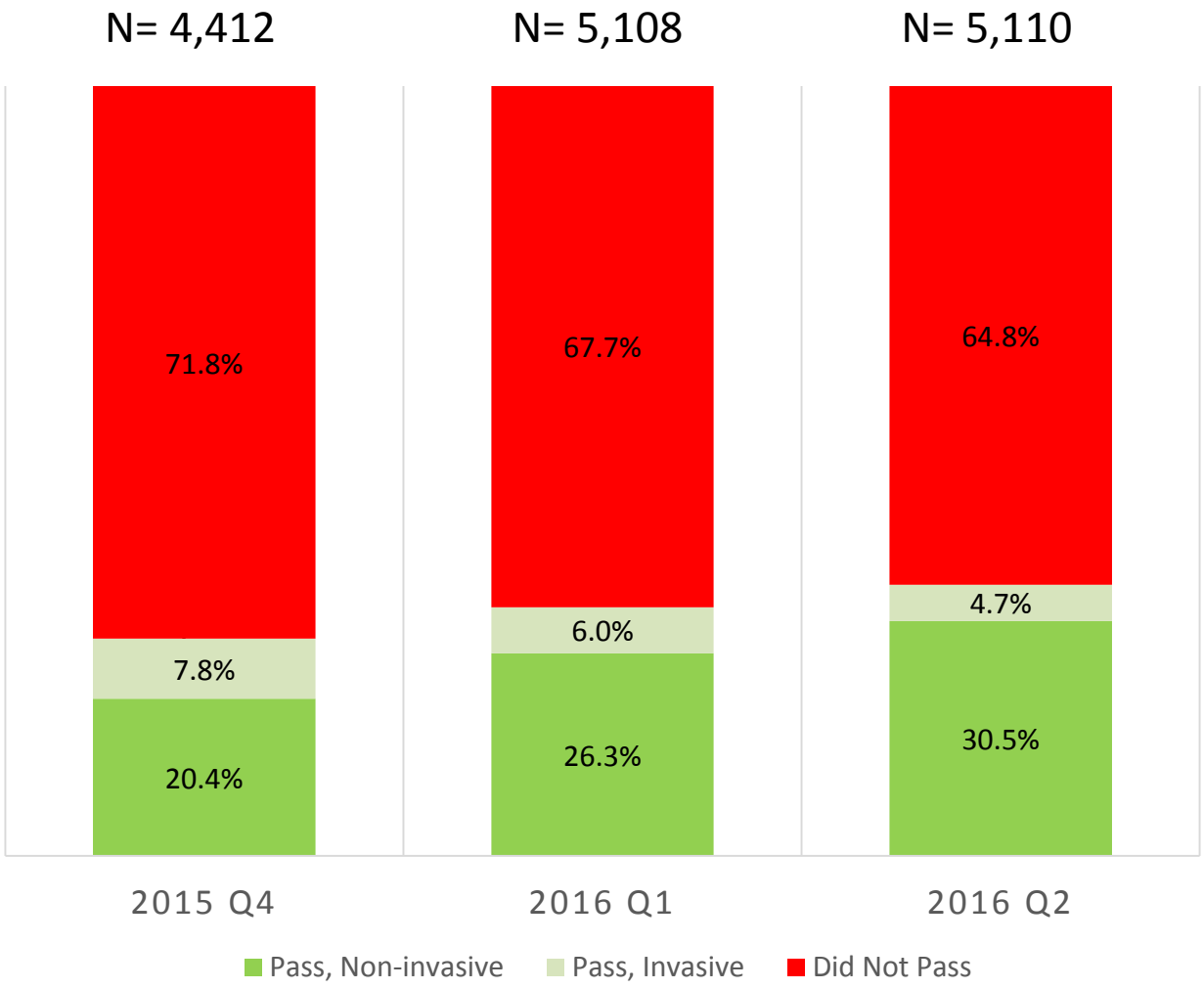
Breakdown by SEP-1 Bundles:
Septic Shock Three Hour Bundle



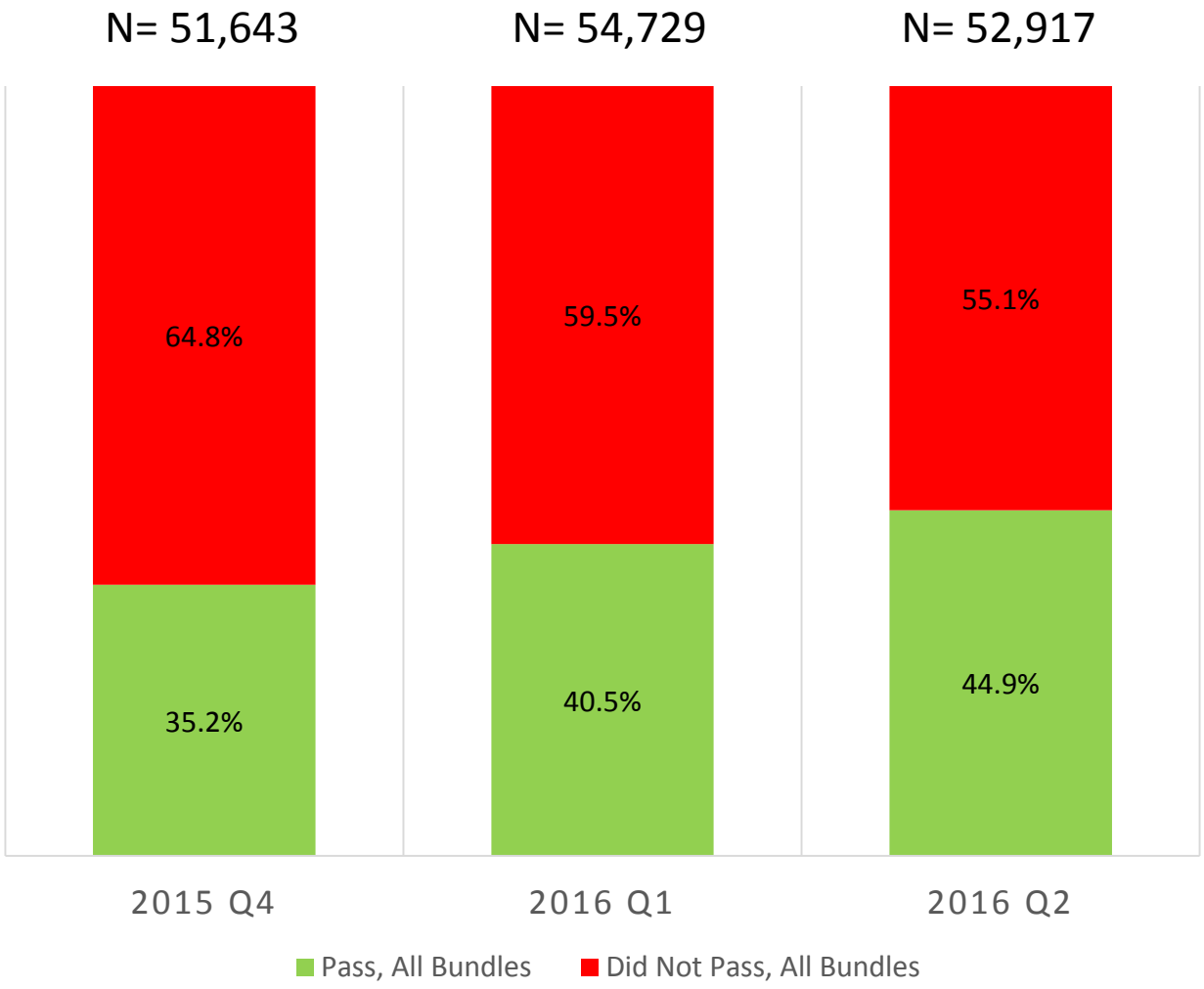
Breakdown by SEP-1 Bundles:
Shock Six Hour Bundle – Vasopressors



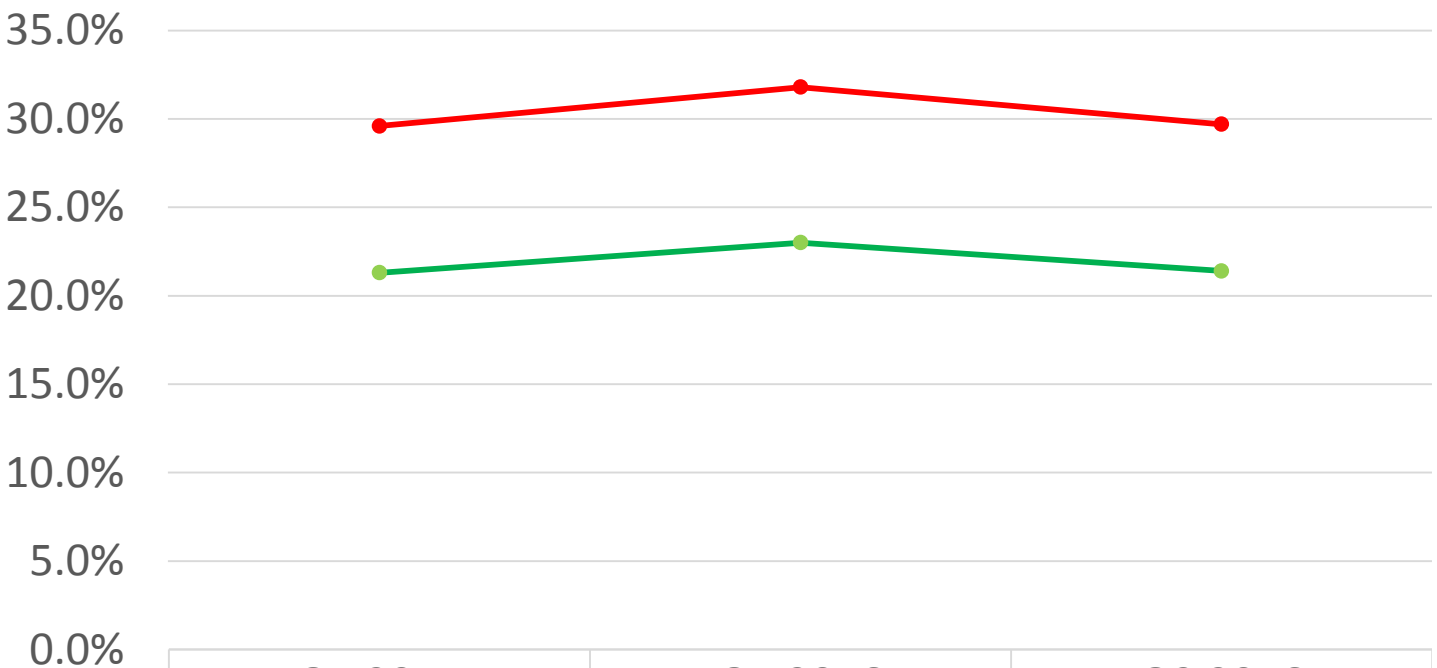
Breakdown by SEP-1 Bundles:
Septic Shock Six Hour Bundle – Assessment



Breakdown of SEP-1:
Combined Bundles for Eligible Population

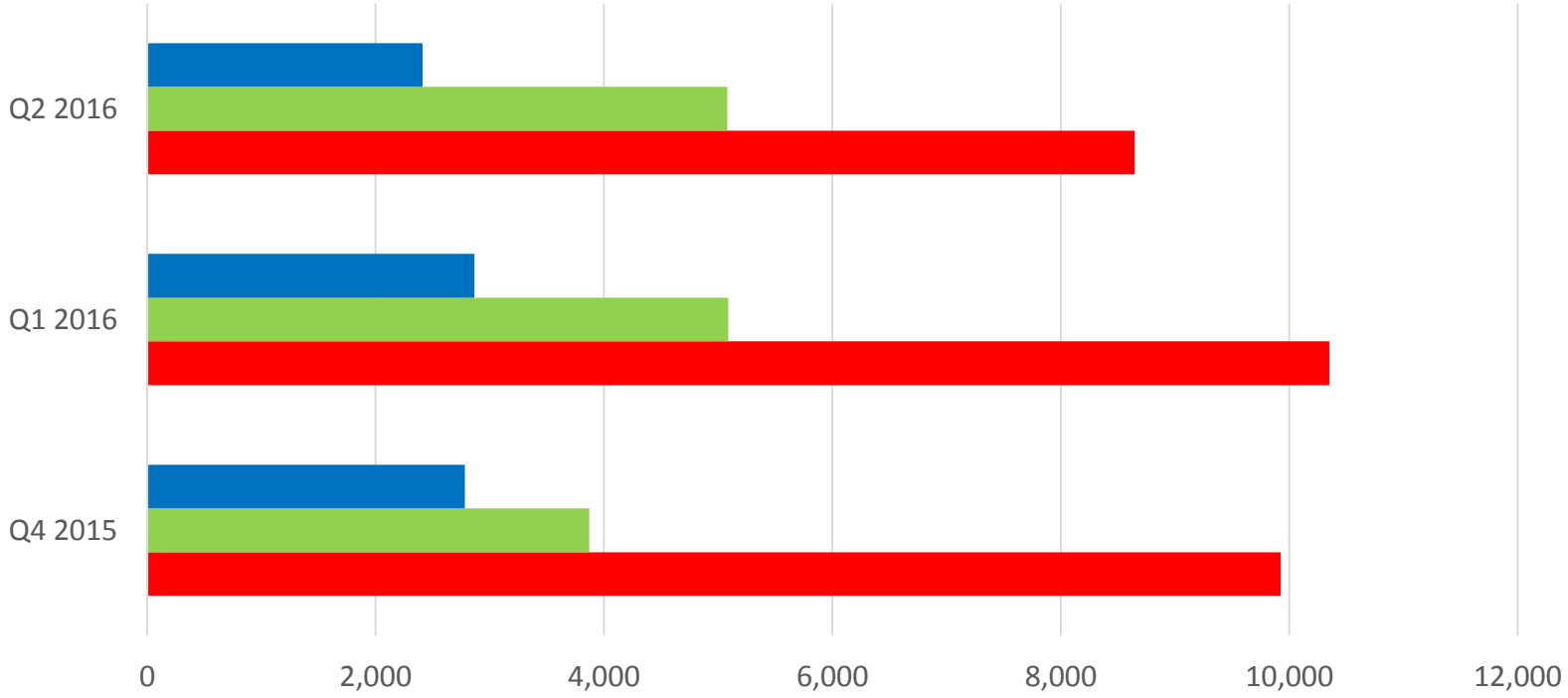


SEP-1 Mortality Rate Trend for Eligible Population:



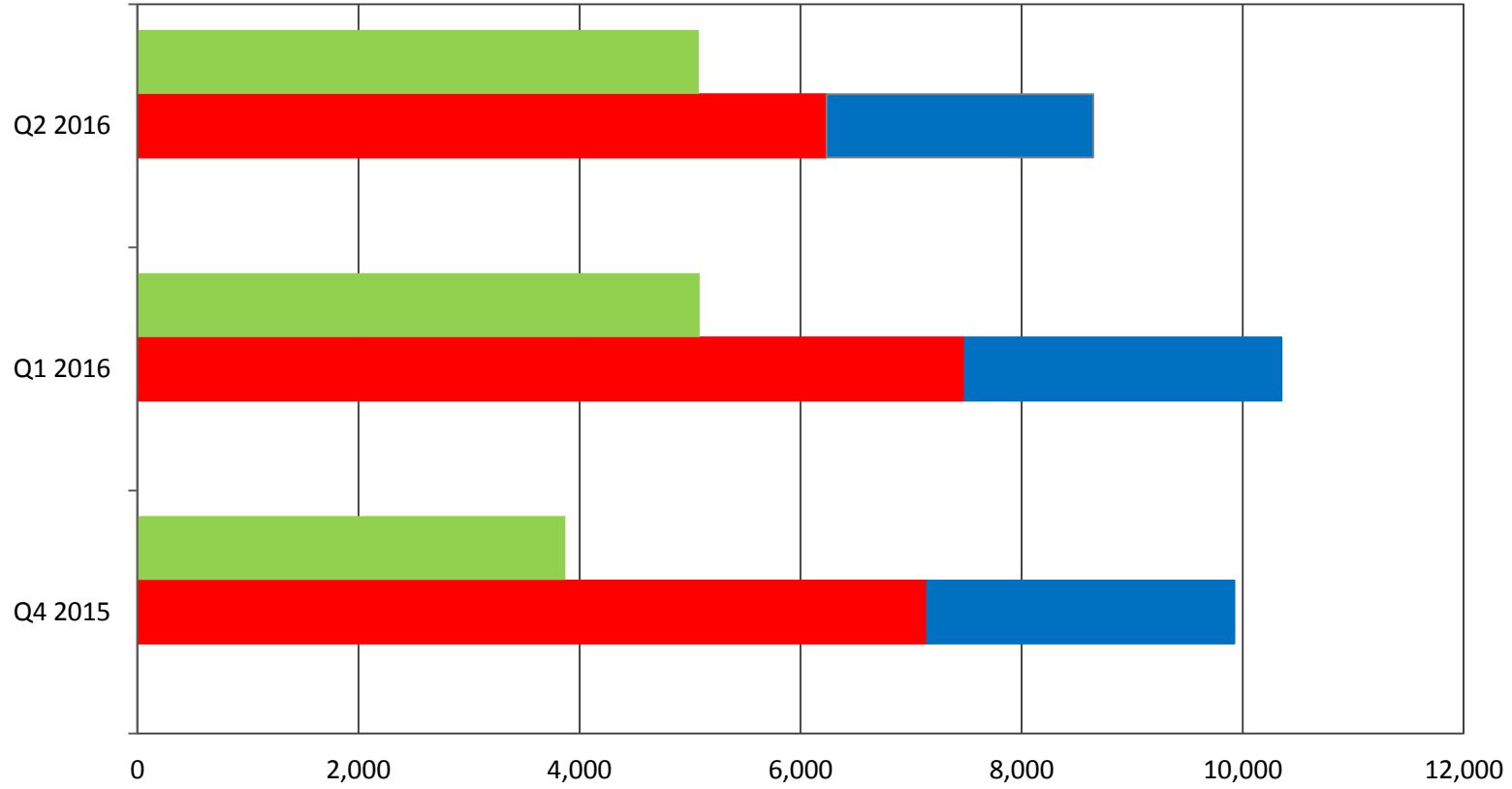
	Q4 2015	Q1 2016	Q2 2016
Delta	8.5%	8.8%	8.3%
Passed	21.3%	23.0%	21.4%
Did Not Pass	29.6%	31.8%	29.7%

Overall Absolute Deaths vs Potential Preventable Deaths by Quarter



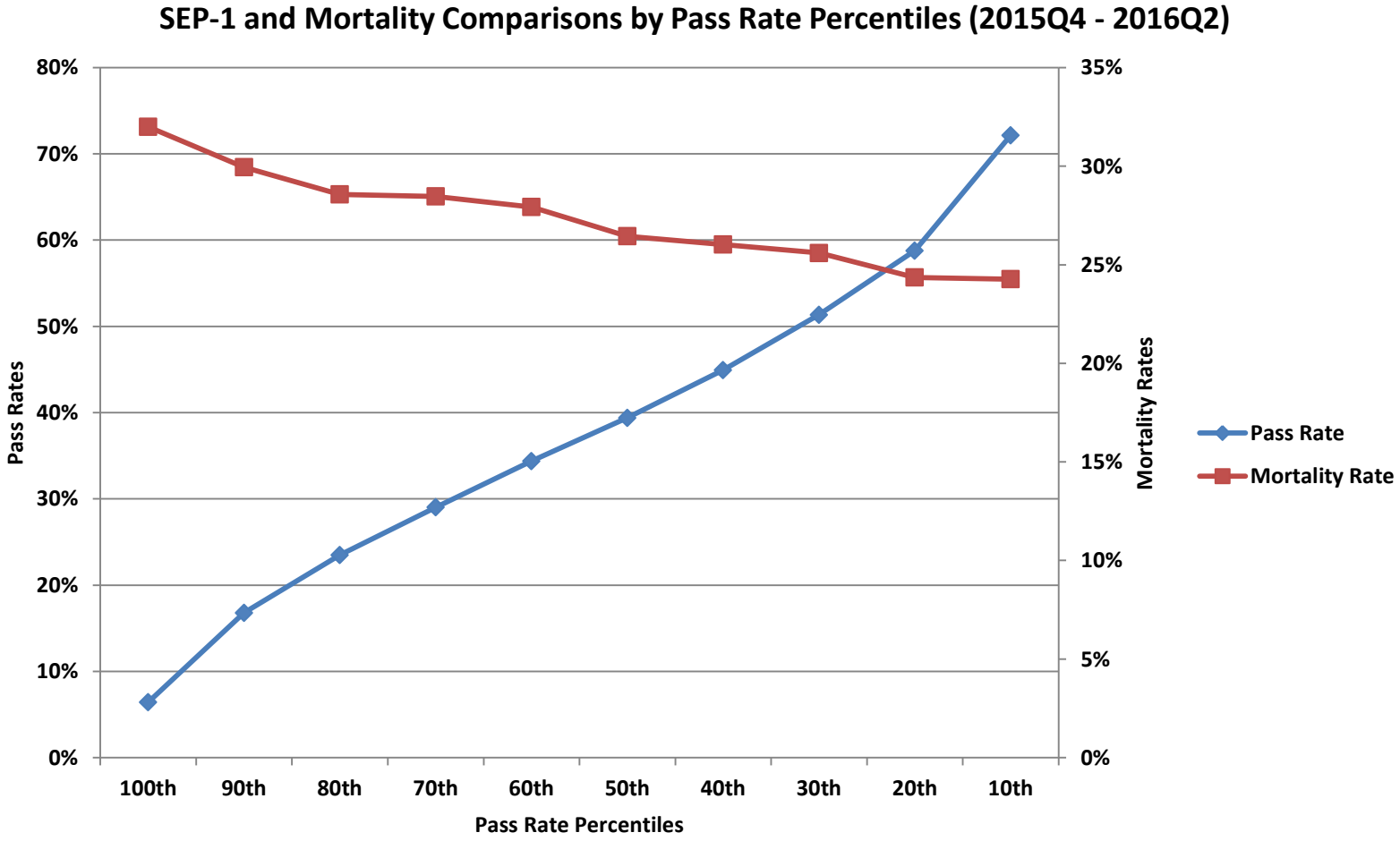
	Q4 2015	Q1 2016	Q2 2016
Preventable deaths	2,783	2,864	2,411
Passed	3,872	5,088	5,079
Did not Pass	9,926	10,351	8,647

Overall Absolute Deaths for Patients Meeting Measure vs Not Meeting Measure and Potentially Preventable Deaths by Quarter



	Q4 2015	Q1 2016	Q2 2016
Did not pass deaths	7,143	7,487	6,236
Did not pass deaths - preventable	2,783	2,864	2,411
Met measure deaths	3,872	5,088	5,079

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:

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Center for Program Integrity

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Appendix:

Differences between treatment and control groups in the ProCESS, ARISE, and ProMISE Trials:

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

ProCESS Investigators, Yealy DM, Kellum JA, Juang DT, et al. A randomized trial of protocol-based care for early septic shock. N Engl J Med 2014; 370(18):1683-1693.
The ARISE Investigators and the ANZICS Clinical Trials Group. Goal-directed resuscitation for patients with early septic shock. N Engl J Med 2014; 371:1496-1506.
Mouncey PR, Osborn TM, Power GS, et al for the ProMISe trial investigators. Trial of early, goal-directed resuscitation for septic shock. N Engl J Med 2015: DOI: 10.1056/NEJMoa1500896.
Rivers E, Nguyen B, Havstad S, et al. Early goal-directed therapy in the treatment of severe sepsis and septic shock. N Engl J Med 2001;345:1368-1377

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

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- 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

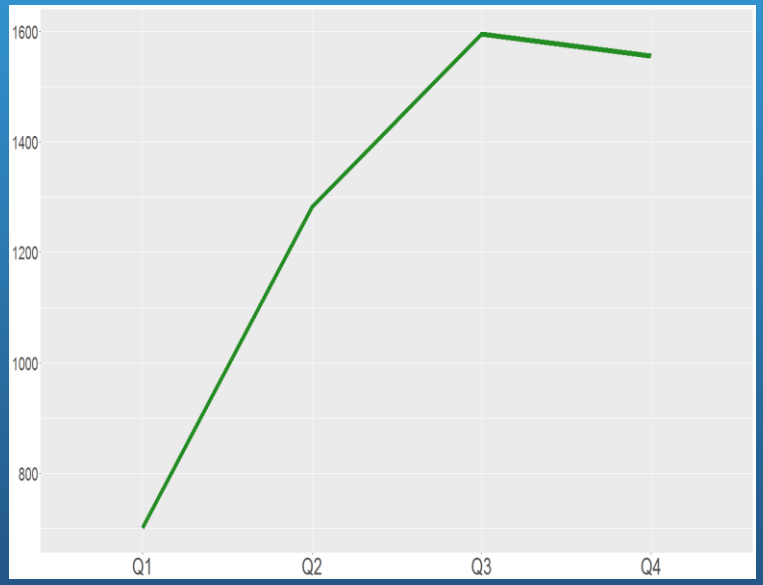
- A total of 50 EDs, which care for an estimated 2 million patients annually, participated - **5133 patients**

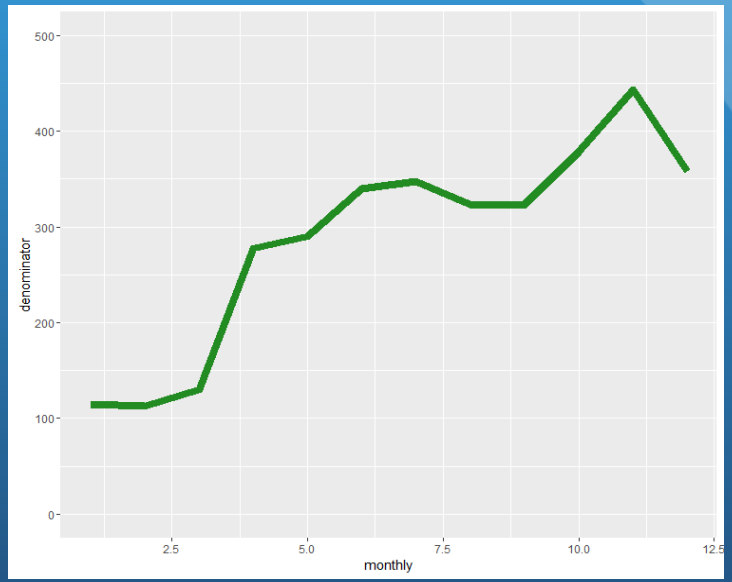
  - 74% were community, non-teaching sites
  - 26% were affiliated with academic centers
  - 80% of EDs were non-MSA status, located in regions with relatively low population density

  - 32 EDs submitted data monthly and 18 submitted quarterly

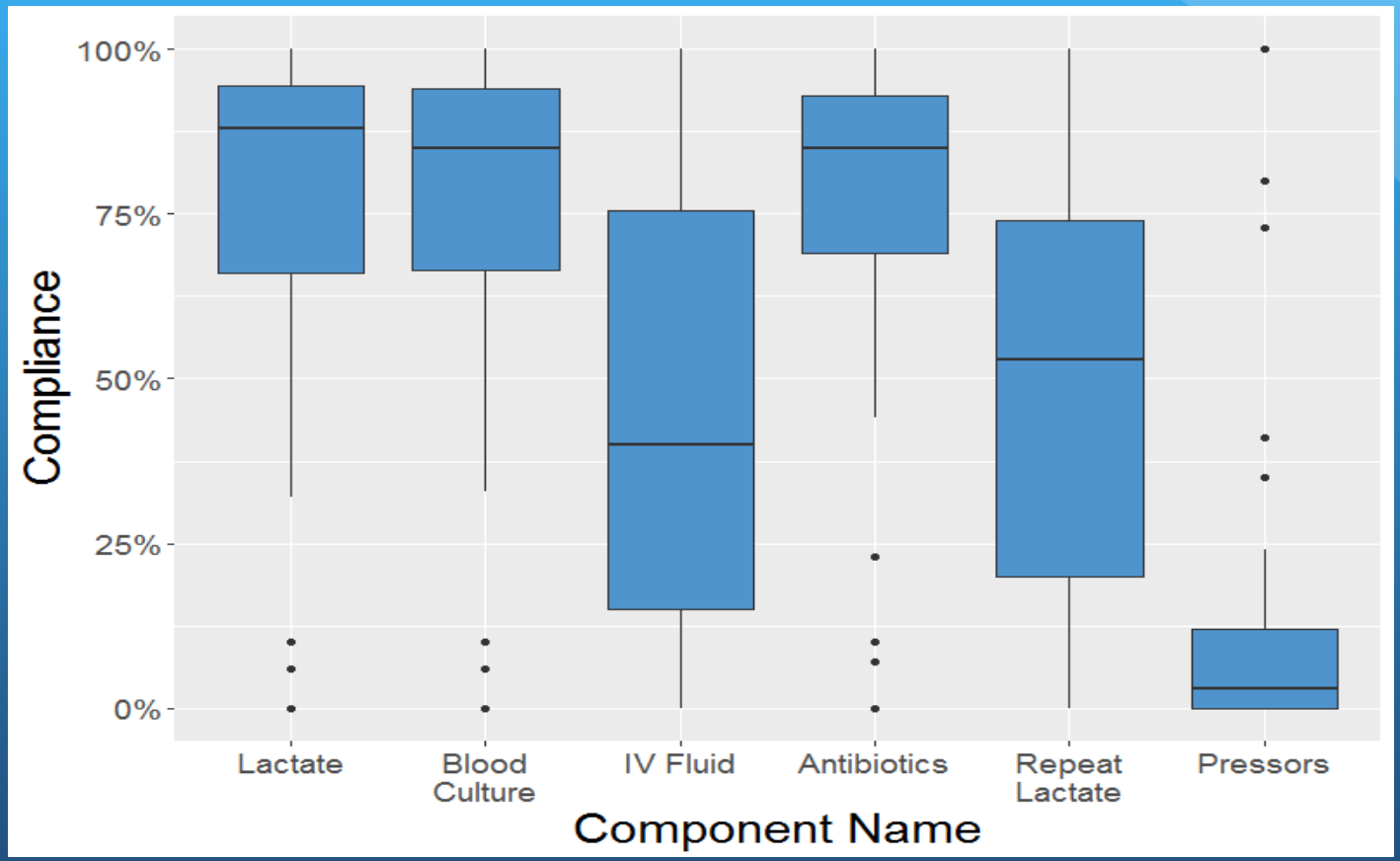
Results

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





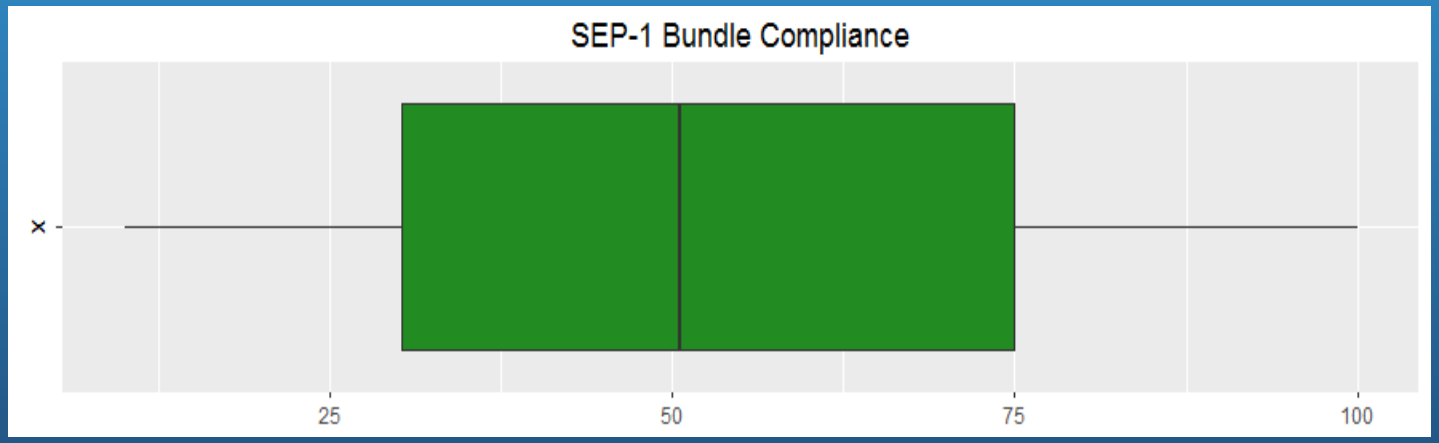
Component Compliance



- Problems with skip logic likely affected Pressor results

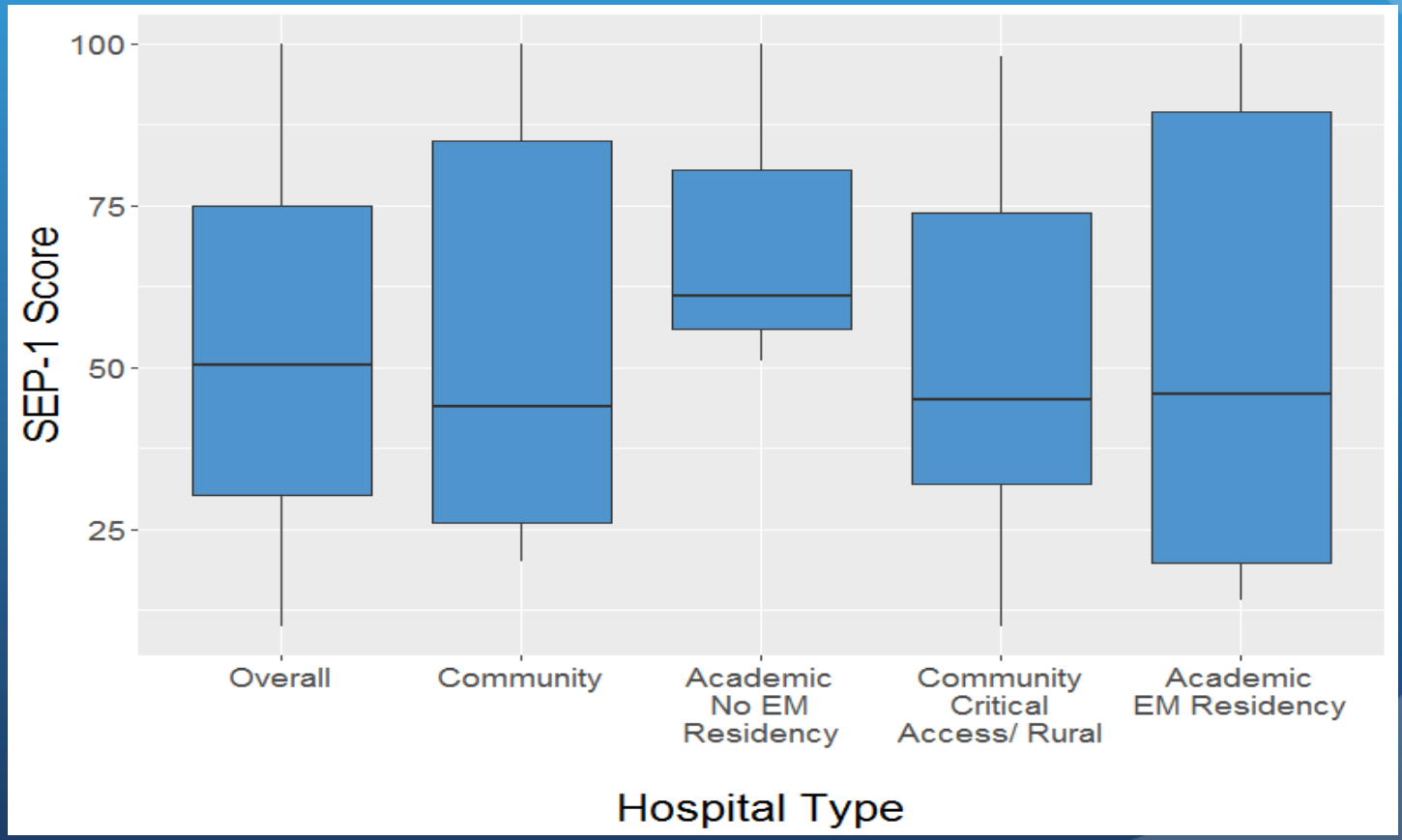
Bundle Compliance

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



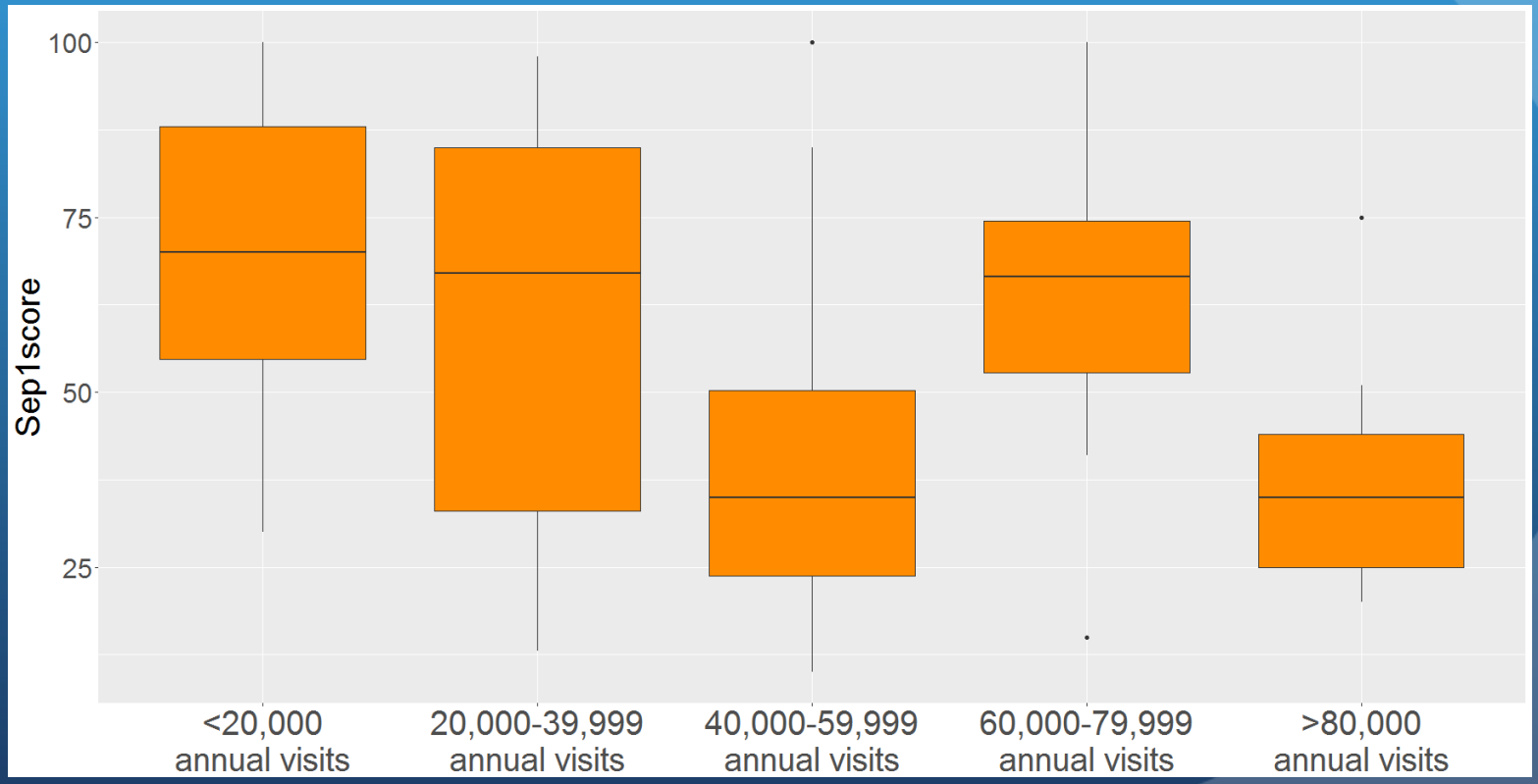
Bundle Compliance

- Broad variation across all ED types



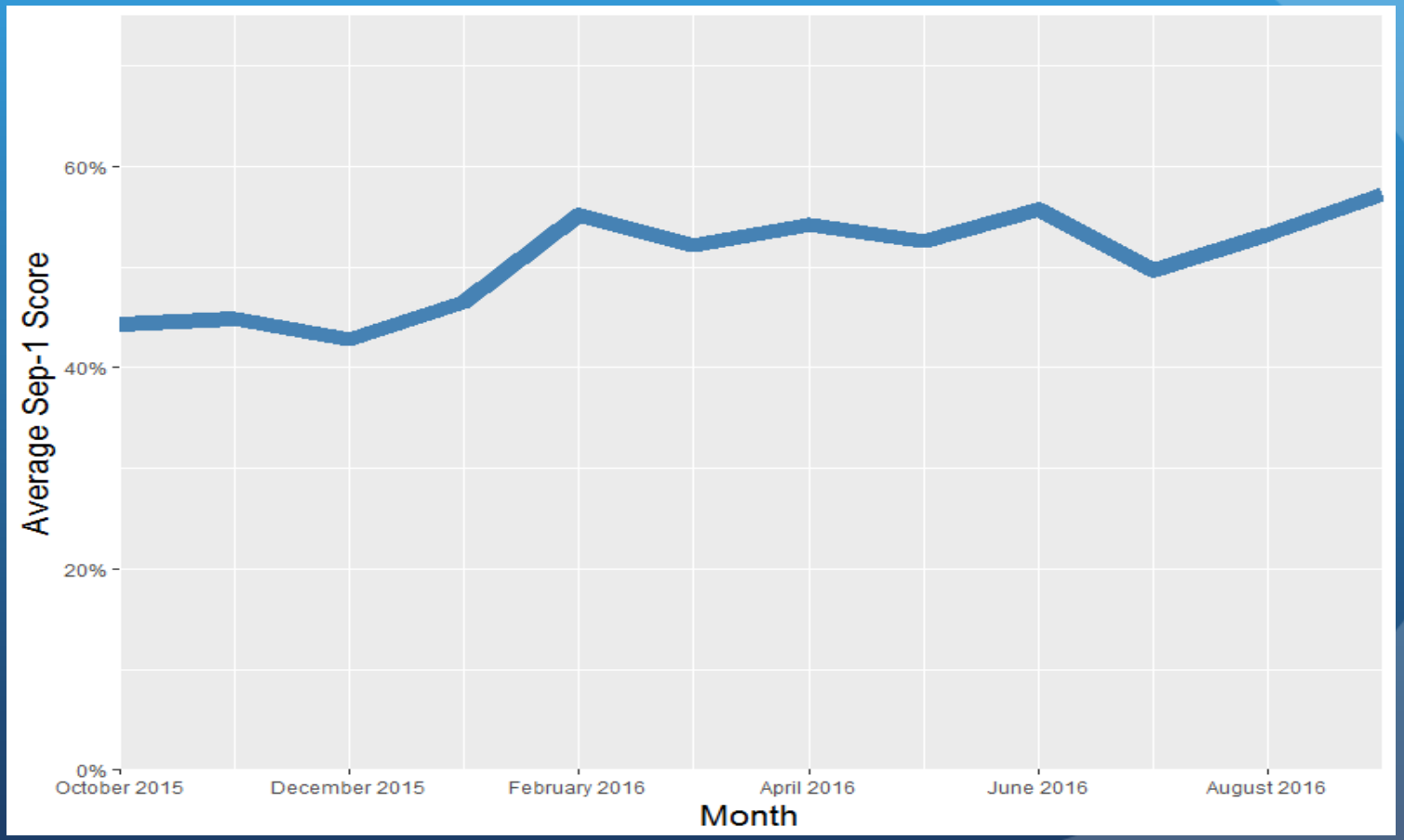
Bundle Compliance

- 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

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

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

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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

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