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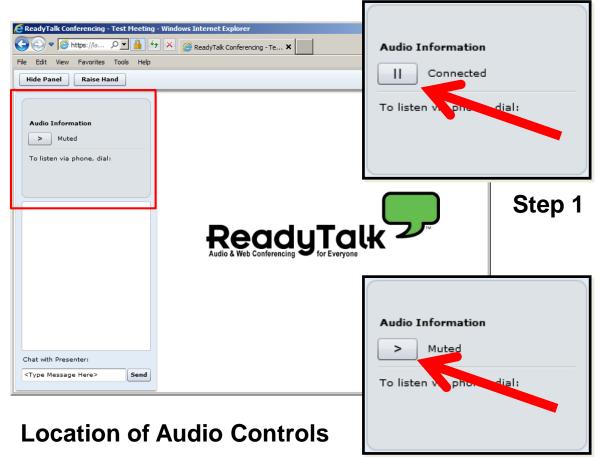
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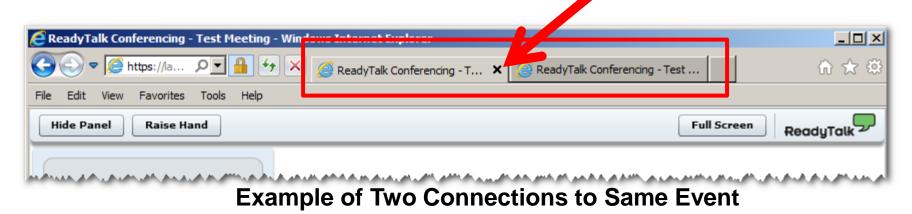
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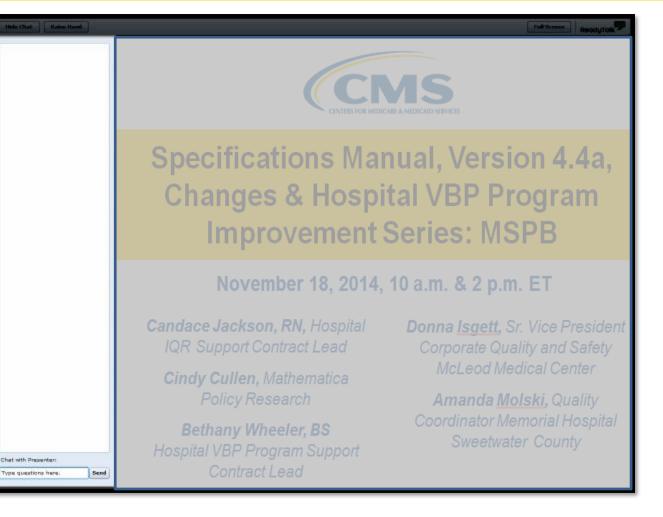
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The Clinician Perspective on Sepsis Care: Early Management Bundle for Severe Sepsis/Septic Shock

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November 16, 2016

Objectives

At the end of the presentation participants will be able to:

- Describe the basis, rationale, and content of the Early Management Bundle, Severe Sepsis/Septic Shock measure
- Explain the importance of the collection of the Sepsis Bundle
- Recognize the updates that have been made to SEP-1 since its introduction
- Recognize common critiques of SEP-1 and offer responses
- Explore baseline analysis of the breakdown of overall SEP-1 cases and bundles.

Acronyms

APN	Advanced Practice Nurse
CVC	Central Venous Catheter
CVP	Central Venous Pressure
CMS	Centers for Medicare & Medicaid Services
DX	
ED	Diagnosis Emorgonov Deportment
	Emergency Department
EDM	Esophageal Doppler Monitoring
EGDT	Early Goal Directed Therapy
IVC US	Inferior Vena Cava Ultrasound
MAP	Mean Arterial Pressure
NQF	National Quality Forum
NNT	Number Needed to Treat
PA	Physician Assistant
PB	Protocol-Based
SBP	Systolic Blood Pressure
Scv02	Central Venous Oxygen Saturation
SI	Stroke Index
TTE	trans-thoracic echocardiogram
TEE	trans-esophageal echocardiogram
VAD	Ventricular Assist Device

Disclaimer

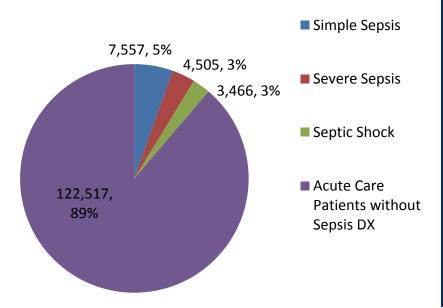
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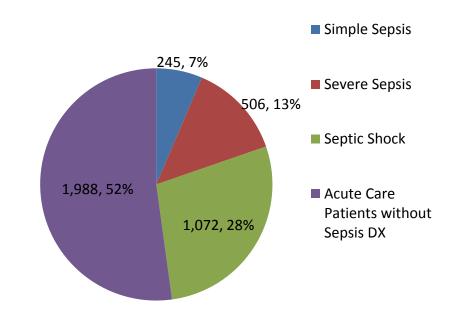
All presenters have indicated no conflicts of interest.

Sepsis is the #1 Cause of Inpatient Deaths

2014 Acute Care Discharges 11% of Patients Have Sepsis DX



2014 Acute Care Deaths 48% of Patients Have Sepsis DX



SEP-1

To be completed within **three hours** of time of presentation*:

- 1. Measure lactate level
- 2. Obtain blood cultures prior to administration of antibiotics
- 3. Administer broad spectrum antibiotics
- Administer 30ml/kg crystalloid for hypotension or lactate ≥ 4mmol/L

 ^{* &}quot;Time of presentation" is defined as the time of earliest chart annotation consistent with all elements of severe sepsis or septic shock ascertained through chart review.

SEP-1

To be completed within **six hours** of time of presentation*:

- Administer vasopressors (for hypotension that does not respond to initial fluid resuscitation) to maintain a mean arterial pressure (MAP) ≥ 65mmHg
- In the event of persistent hypotension after initial fluid administration (MAP < 65 mm Hg) or if initial lactate was ≥ 4 mmol/L, re-assess volume status and tissue perfusion and document findings according to Table 1
- 3. Re-measure lactate if initial lactate elevated

^{* &}quot;Time of presentation" is defined as the time of earliest chart annotation consistent with all elements of severe sepsis or septic shock ascertained through chart review.

SEP-1: TABLE 1

Document reassessment of volume status and tissue perfusion with **either**:

 Repeat focused exam (after initial fluid resuscitation) by licensed independent practitioner, including vital signs, cardiopulmonary, capillary refill, pulse and skin findings

[or]

- Two of the following:
 - Measure CVP
 - Measure ScvO2
 - Bedside cardiovascular ultrasound
 - Dynamic assessment of fluid responsiveness with passive leg raise or fluid challenge

SEP-1: Time Zero

- Will always be when the chart annotation suggests signs and symptoms are all present
- May be from nursing charts, lab flow sheets, physician documentation, anything with a time stamp
- Will equal triage time, if all signs and symptoms are present at triage

SEP-1: Completing The Bundles

Required Action	Severe	Sepsis	Septic	Shock
	Three Hour Bundle	Six Hour Bundle	Three Hour Bundle	Six Hour Bundle
Initial Lactate Collection	Yes		Must be completed	
Blood Culture Collection	Yes		within three hours of	
Initial Antibiotic Started	Yes	S	Severe Sepsis Presenta	tion
Repeat Lactate Collection (if Initial Lactate greater than 2)	Y	es	· · · · · · · · · · · · · · · · · · ·	hin six hours of Severe esentation
30mL/kg Crystalloid Fluids Started	N/A	N/A	Yes	Must be completed within three hours of Septic Shock
Vasopressor Given (if decreasing BP persists)	N/A	N/A	Must be completed within six hours of	Yes
Repeat Volume Status/ Tissue Perfusion Assessment	N/A	N/A	Septic Shock	Yes

SEP-1: Two Clocks (1 of 3)

A patient developed severe sepsis at 3
 p.m. but did not become hypotensive and fail to respond to fluids until 5 p.m.

Does the **shock clock** start at **5 p.m.**?

 If so, does the six hour window to complete the physical exam requirement begin at 5
 p.m. with the shock clock or at 3
 p.m. when severe sepsis was first noted?

SEP-1: Two Clocks (2 of 3)

- The severe sepsis clock would start with the presentation of severe sepsis at **3 p.m.**
- The **septic shock clock** would start with presentation of septic shock at **5 p.m.**
- The presentation of severe sepsis at **3 p.m.** will trigger the following counters with the start time being **3 p.m.**
 - The Sepsis Three Hour Counter would require the following be completed by 6 p.m.
 - o Initial lactate level measurement
 - o Antibiotic administration
 - Blood cultures prior to antibiotics
 - Sepsis Six Hour Counter would require the repeat lactate if initial lactate is >2

SEP-1: Two Clocks (3 of 3)

The presentation of **septic shock** at **5 p.m.** will trigger the following counters with the start time being at **5 p.m.**

- The **Shock Three Hour Counter** would require the resuscitation with 30 mL/kg of crystalloid fluids be started by **8 p.m.**
- The Shock Six Hour Counter would require the following be completed by 11 p.m., ONLY if hypotension persists
 - Vasopressor administration
 - Repeating the volume status and tissue perfusion assessment

Updates to SEP-1

- Received stakeholder feedback since
 October 1, 2015
- Based revisions on feedback effective July 1, 2016 (v5.1)
- Based additional revisions (v5.2) on feedback effective January 1, 2017

Summary of SEP-1 v5.1 Updates

Data Element(s)	Brief Summary of Changes
Administrative Contraindication to Care, Severe Sepsis AND Administrative Contraindication to Care, Septic Shock;	 Renamed original Administrative Contraindication to Care to account for severe sepsis. NEW data element to account for septic shock. Administrative contraindication time frame is prior to or within 3 hours following severe sepsis presentation, and prior to or within 6 hours following septic shock presentation.
Broad Spectrum or Other Antibiotic Administration Selection	 Clarified guidance for antibiotics use within 3 hours following presentation of severe sepsis if causative organism and susceptibility known.
Cardiopulmonary Evaluation Performed	 Must be performed and documented by a Physician/APN/PA.

Summary of SEP-1 v5.1 Updates (2 of 3)

Data Element	Brief Summary of Changes
Capillary Refill Examination Performed, Passive Leg Raise Exam Performed, Peripheral Pulse Evaluation Performed, and Skin Examination Performed	 Focused exam and reassessment data elements do not need to be performed by a physician/APN/PA but still must be documented by physician/APN/PA.
Crystalloid Fluid Administration	 Terms "bolus" and "wide open" acceptable if equivalent to 30 mL/kg, IV route. PlasmaLyte and Normosol acceptable. Single or multiple orders. If stopped before 30 mL/kg is completely infused select value "2 (No)."
Initial Hypotension and Documentation of Septic Shock	• NEW data elements Initial Hypotension and Documentation of Septic Shock to close algorithm loophole.

Summary of SEP-1 v5.1 Updates

(3 of 3)

Data Element	Brief Summary of Changes
Directive for Comfort Care or Palliative Care, Severe Sepsis an Directive for Comfort Care or Palliative Care, Septic Shock	 Clarified that physician/APN/PA documentation of comfort measure or palliative care is acceptable. Added palliative care to data element name and guidance.
Vasopressor Administration	 Clarified the time frame for intravenous vasopressor administration.
Vital Signs Review Performed	 Clarified that actual values are no longer required for this data element.

Summary of SEP-1 v5.2a Updates, effective 01/01/2017 (1 of 3)

Data Element	Brief Summary of Changes
Blood Culture Collection Acceptable Delay	• NEW data element. Takes into consideration cases where it is acceptable for blood cultures to be drawn after antibiotic administration.
Capillary Refill Examination Performed, Cardiopulmonary Evaluation Performed, Peripheral Pulse Evaluation Performed, Skin Examination Performed, and Vital Signs Review Performed	 Physician/APN/PA attestation to reviewing or performing is now acceptable as option to original specification requirements.

Severe Sepsis Present, Septic Shock Present Subsequent Physician/APN/PA documentation acceptable to override earlier clinical criteria or Physician/APN/PA documentation, if within 6 hours

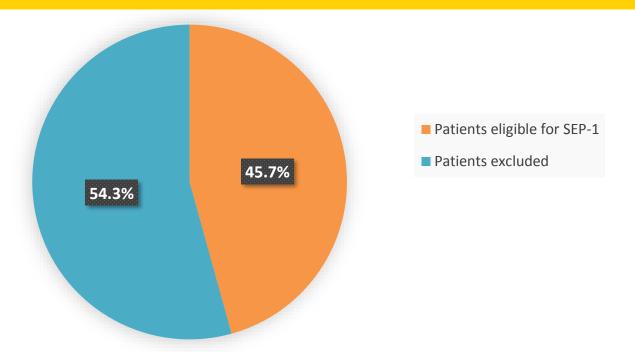
Summary of SEP-1 v5.2a Updates, effective 01/01/2017 (2 of 3)

Data Element	Brief Summary of Changes
Severe Sepsis Present	 Disregard initial documentation of infection if within 6 hours there is physician/APN/PA documentation the infection is not present. Do not use SIRS criteria if Physician/APN/PA documents is normal, due to chronic condition, condition not infection, or medication.
Broad Spectrum, Crystalloid Fluid, Persistent Hypotension, Severe Sepsis Present, and Vasopressor Administration	 Documentation in pre-hospital records considered part of the medical record is acceptable.
Administrative Contraindication to Care, Severe Sepsis and Administrative Contraindication to Care, Septic Shock	 Nursing documentation is acceptable.

Summary of SEP-1 v5.2a Updates, effective 01/01/2017 (3 of 3)

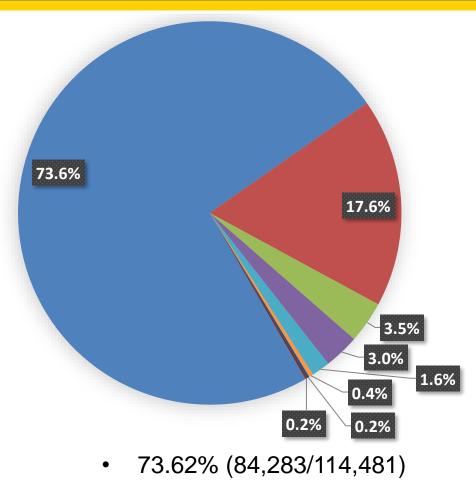
Data Element	Brief Summary of Changes
Broad Spectrum or Other Antibiotic Administration Selection	 If the causative organism is identified as <i>C.</i> difficile, susceptibility testing is not required. Acceptable if patient is receiving oral vancomycin with or without oral or IV metronidazole (Flagyl).
Initial Hypotension, Septic Shock Present, and Persistent Hypotension	• Do not use SBP < 90 mmHg, or MAP < 65 mmHg if Physician/APN/PA documentation indicating is normal, due to chronic condition, condition not an infection, or medication.
Crystalloid Fluid Administration	If a patient has a ventricular assist device (VAD), they are excluded from the measure. Crystalloid fluid volumes (ordered) up to 10% lower than the target 30 mL/kg volume are acceptable.

SEP-1 Initial Patient Population: 210,997 patients



- Quarter Four FY 2015 (Oct 1, 2015 Dec 31, 2015) discharges, >99% of hospitals successfully submitted SEP-1 data
- 210,997 patients in the initial patient population
- (96,516 / 210,997) met criteria to be included in the measure (Eligibles)
- (114,481 / 210,997) did not meet criteria to be included in the measure (Exclusions)

Breakdown of SEP-1 Exclusion Population:



• 17.62% (20,176/114,481)

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

Initial Population Breakdown by Bundle and Total Eligible Cases

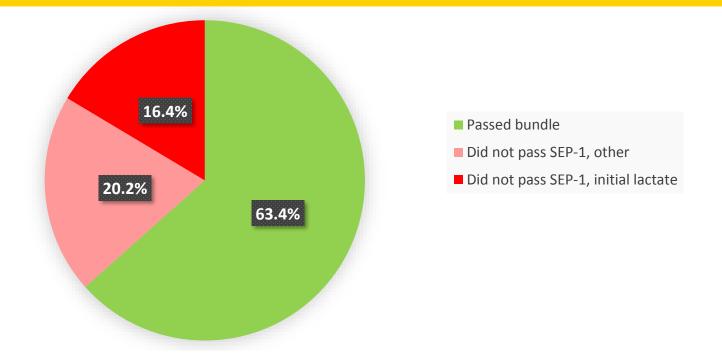
Bundle	Population
INITIAL PATIENTS	210,997
Initial Severe Sepsis three Hour	100,996
Initial Severe Sepsis six Hour	52,844
Initial Septic Shock three Hour Bundle	24,669
Initial Septic Shock six Hour Bundle (Vasopressors)	5,127
Initial Septic Shock six Hour Bundle (Repeat Volume Status and Tissue Perfusion Assessment)	8,567
	blank.
Total Eligible Cases*	96,516

*Total Eligible Cases are patients in the initial patient population 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.

SEP-1: Completing The Bundles

Required Action	Severe	Sepsis	Septic	Shock
	Three Hour Bundle	Six Hour Bundle	Three Hour Bundle	Six Hour Bundle
Initial Lactate Collection	Yes		Must be completed	
Blood Culture Collection	Yes		within three hours of	
Initial Antibiotic Started	Yes	Se	evere Sepsis Presenta	tion
Repeat Lactate Collection (if Initial Lactate is greater than two)	Y	es		I within six hours of s presentation
30mL/kg Crystalloid Fluids Started	N/A	N/A	Yes	Must be completed within three hours of Septic Shock
Vasopressor Given (if decreasing BP persists)	N/A	N/A	Must be completed within six hours of	Yes
Repeat Volume Status/ Tissue Perfusion Assessment	N/A	N/A	Septic Shock	Yes

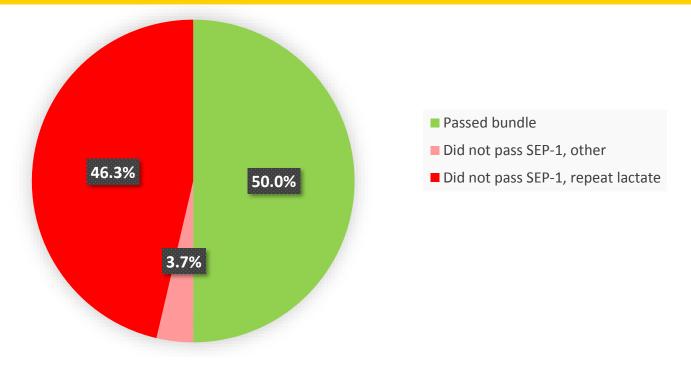
Breakdown by SEP-1 Bundles: Initial Severe Sepsis Three Hour Bundle



- (64,033/100,966*) passed the bundle
- (36,963/100,966*) did not pass bundle
 - (16,589/100,966*) did not pass initial lactate level collection data element
 - (20,374/100,966*) did not pass other data elements

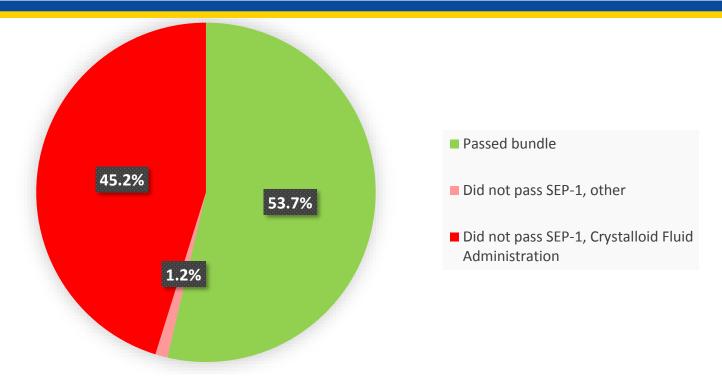
^{*}patients who are only eligible for Severe Sepsis three hour bundle

Breakdown by SEP-1 Bundles: Initial Severe Sepsis Six Hour Bundle



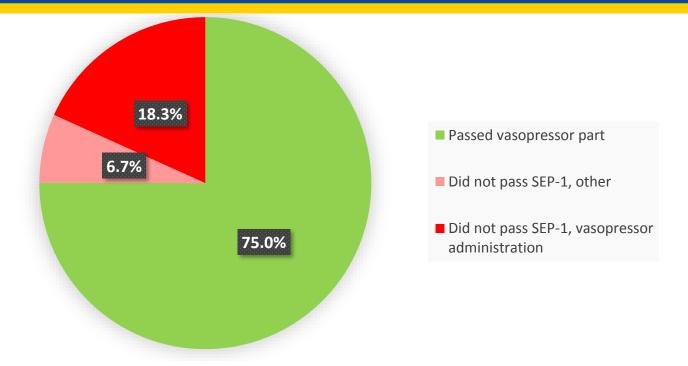
- (26,426/52,844) passed the bundle
- (26,418/52,844) did not pass bundle
 - (24,487/52,844) did not pass repeat lactate level collection data element
 - (1,931/52,844) did not pass other data elements

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



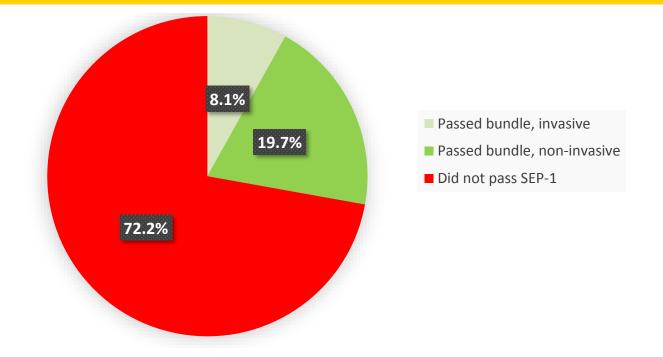
- (13,235/24,669) passed the bundle
- (11,434/24,669) did not pass bundle
 - (11,146/24,669) did not pass Crystalloid Fluid Administration data element
 - (288/ 24,669) did not pass other data elements within Septic Shock three hour bundle

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



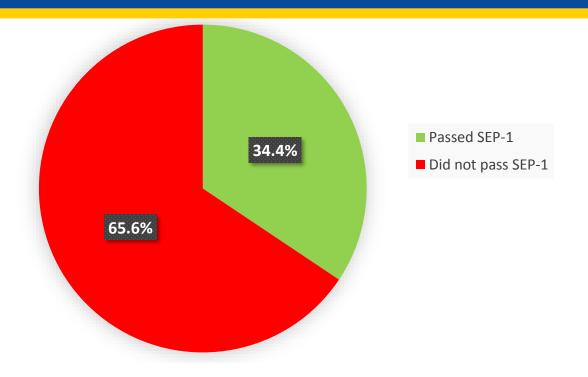
- (3,847/5,127) passed the bundle
- (1,280/ 5,127) did not pass bundle
 - (936/ 5,127) did not pass vasopressor administration data element
 - (344/ 5,127) did not pass other data elements within the vasopressor portion

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



- (2,384/ 8,567) passed the bundle
 - (694/ 8,567) passed invasive status and assessment
 - (1690/ 8,567) passed non-invasive focused exam
- (6,183/ 8,567) did not pass repeat status and assessment bundle

Breakdown of SEP-1 Combined Bundles for Eligible Population:



- 33,189/96,516 passed all steps of the measure
- 63,327/96,516 did not pass all steps of the measure

Appendix: Exclusions Details

Exclusion Criteria	Number of Cases	Percent of Total Exclusions	Bundle
Did not meet severe sepsis clinical criteria or have documentation that severe sepsis was present or suspected	84,283	73.62%	Pre Severe Sepsis Three Hour and Six Hour Bundle Exclusions
Received as transfers from another hospital	20,176	17.62%	Pre Severe Sepsis Three Hour and Six Hour Bundle Exclusions
Received an antibiotic within 24 hours prior to severe sepsis presentation and received a dose of the same antibiotic more than 24 hours prior to presentation	4,031	3.52%	Severe Sepsis Three Hour
Had a directive for comfort care prior to or within three hours of severe sepsis presentation	3,394	2.96%	Pre Severe Sepsis Three Hour and Six Hour Bundle Exclusions
Had documentation in the medical record indicating refusal of blood draws, IV fluid administration, or IV antibiotic administration during hospitalization	1,782	1.56%	Pre Severe Sepsis Three Hour and Six Hour Bundle Exclusions
Had a directive for comfort care prior to or within six hours of septic shock presentation	416	0.36%	Pre Septic Shock Tree Hour and Six Hour Bundle Exclusions
Expired within six hours following Septic Shock Presentation	218	0.19%	Pre Septic Shock Three Hour and Six Hour Bundle Exclusions
Expired within three hours following Severe Sepsis Presentation	181	0.16%	Pre Severe Sepsis Three Hour and Six Hour Bundle Exclusions
Total Cases Excluded	114,481		
44/40/0040			05

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)

Continuing Education Approval

- This program has been approved for 1.0 continuing education (CE) unit for the following professional boards:
 - Florida Board of Clinical Social Work, Marriage and Family Therapy and Mental Health Counseling
 - Florida Board of Nursing Home Administrators
 - Florida Council of Dietetics
 - Florida Board of Pharmacy
 - Board of Registered Nursing (Provider #16578)
 - It is your responsibility to submit this form to your accrediting body for credit.

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2. If you have questions or concerns, please feel free to	o leave your name and phone number or email address and we will contact you.
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QUESTIONS?