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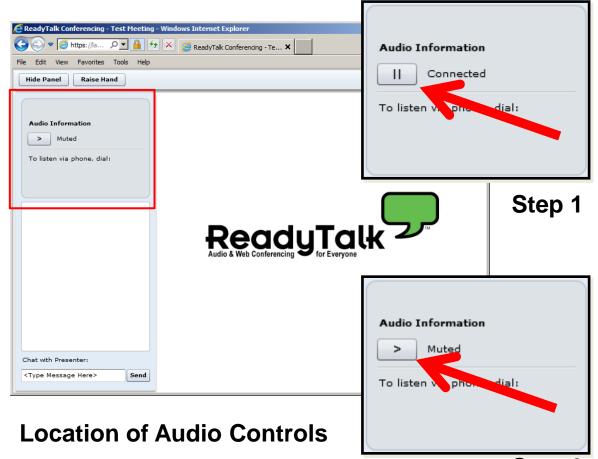
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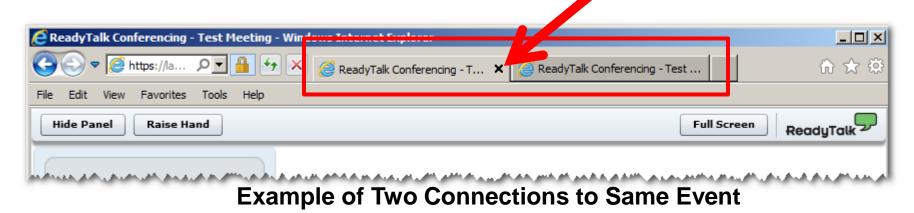
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Specifications Manual, Version 4.4a, Changes & Hospital VBP Program Improvement Series: MSPB

November 18, 2014, 10 a.m. & 2 p.m. ET

Candace Jackson, RN, Hospital IQR Support Contract Lead

> **Cindy Cullen,** Mathematica Policy Research

Bethany Wheeler, BS Hospital VBP Program Support Contract Lead **Donna Isgett,** Sr. Vice President Corporate Quality and Safety McLeod Medical Center

Amanda Molski, Quality Coordinator Memorial Hospital Sweetwater County



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

Sean Robert Townsend, MD

Vice President of Quality and Safety at California Pacific Medical Center

Lemeneh Tefera, MD, MSc

Medical Officer at Centers for Medicare & Medicaid Services (CMS)

September 10, 2015

Purpose

- Provide physicians, medical directors, clinicians, nurses, clinical documentation teams, and pharmacists with insights that will help them better understand the *Early Management Bundle, Severe Sepsis/Septic Shock* measure
- Discuss the importance of data collection

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

Acronyms

- CVC Central Venous Catheter
- CVP Central Venous Pressure
- **CMS** Centers for Medicare & Medicaid Services
- DX Diagnosis
- ED Emergency Department
- **EGDT** Early Goal Directed Therapy
- MAP Mean Arterial Pressure
- NQF National Quality Forum
- NNT Number Needed to Treat
- **PB** Protocol-Based
- **SBP** Systolic Blood Pressure
- Scv02 Central Venous Oxygen Saturation
- SI Stroke Index



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

SEP-1: First National Core Measure on Sepsis Care

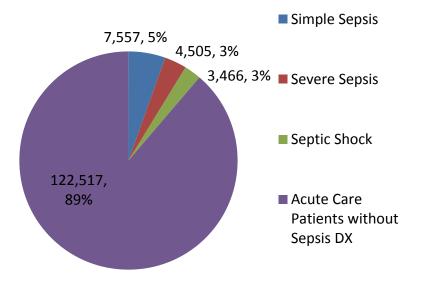
Surviving Sepsis ··· Campaign

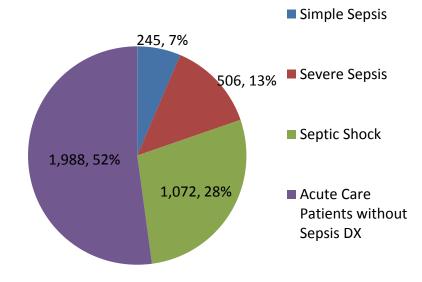
This presenter has nothing to disclose.

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





Old NQF Bundle: Sepsis 0500

To be completed within <u>three hours</u> 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
- * "Time of presentation" is defined as the time of triage in the ED or, if presenting from another care venue, from the earliest chart annotation consistent with all elements severe sepsis or septic shock ascertained through chart review.

Old NQF Bundle: Sepsis 0500 cont.

To be completed within <u>six hours</u> of time of presentation:

- Apply vasopressors (for hypotension that does not respond to initial fluid resuscitation to maintain a mean arterial pressure (MAP) ≥65mmHg)
- In the event of persistent arterial hypotension despite volume resuscitation (septic shock) or initial lactate ≥4 mmol/L (36mg/dl)
 - a. Measure central venous pressure (CVP)*
 - b. Measure central venous oxygen saturation (ScvO2)*
- 3. Re-measure lactate*

^{*} Targets for quantitative resuscitation included in the guidelines are CVP of ≥8 mm Hg, ScvO2 of ≥70% and lactate normalization

Quantitative Resuscitation

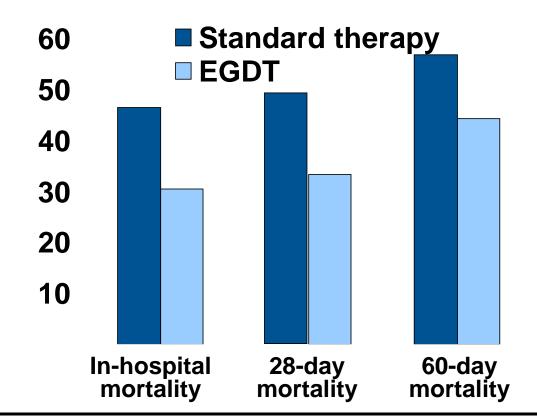
Review: Quantitative Resuscitation Strategy for Sepsis Comparison: 01 Quantitative Resuscitation vs. Standard Care Outcome: 01 Mortality

Study or sub-category	Treatment n/N	Control n/N	OR (random) 95% Cl	OR (random) 95% Cl	Quality
01 Early					
Lin 2006	58/108	83/116	_ _	0.46 [0.27, 0.80]	А
Rivers 2001	38/130	59/133	_ _	0.52 [0.31, 0.86]	А
Alia 1999	23/31	21/32		1.51 [0.51, 4.46]	А
Yu 1998	15/58	15/29 -		0.33 [0.13, 0.83]	С
Yu 1993	4/30	6/22		0.41 [0.10, 1.68]	в
Tuchschmidt 1992	13/26	18/25 -		0.39 [0.12, 1.24]	С
Subtotal (95% CI)	383	357	•	0.50 [0.37, 0.69]	
Total events: 151 (Treatr	ment), 202 (Control)		•		
Test for heterogeneity: C Test for overall effect: Z).40), l² = 2.4%			
02 Late					
Xiao-Zhi 2006	4/16	7/17 —		0.48 [0.11, 2.11]	В
Gattinoni 1995	84/124	37/57		1.14 [0.59, 2.20]	A
Hayes 1994	17/24	12/23		2.23 [0.67, 7.40]	В
Subtotal (95% CI)	164	97		1.16 [0.60, 2.22]	
Total events: 105 (Treatr Test for heterogeneity: C Test for overall effect: Z	chi ² = 2.51, df = 2 (P = 0	0.29), I ² = 20.3%			
Total (95% CI)	547	454	•	0.64 [0.43, 0.96]	
Total events: 256 (Treatr Test for heterogeneity: C Test for overall effect: Z	chi² = 14.59, df = 8 (P =	0.07), l ² = 45.2%			
		0.1	0.2 0.5 1 2 5	10	
		F	re treatment Equare contro	1	

Favors treatment Favors control

Early Goal Directed Therapy

NNT to prevent one event (death) = 6-8



Adapted from Table 3, page 1374, with permission from 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

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

ProCESS, ARISE, ProMISE, AND Usual CARE

The New England Journal of Medicine

ORIGINAL ARTICLE

A Randomized Trial of Protocol-Based Care for Early Septic Shock

The ProCESS Investigators*

The New England Journal of Medicine

ORIGINAL ARTICLE

Goal-Directed Resuscitation for Patients with Early Septic Shock

The ARISE Investigators and the ANZICS Clinical Trials Group*

ABSTRACT

ProCESS Randomized Groups

	PROTOCOL-BASED EGDT (n 439)	PROTOCOL-BASED STANDARD TX (n 446)	USUAL CARE (n 456)
TEAM	Trained MD, RN, Prompts Non-adherence 11.9% (+ ScvO2<70)	Same as EGDT Non-adherence 4.4%	No prompts Trained for PB?
CENTRAL LINES	Continuous ScvO2	Only if inadequate peripheral access "no" CVP, ScvO2 < 6 hr	No instruction
GOALS	EGDT	SBP, SI, Perfusion and fluid status per clinician	Not specified
PRIMARY OUTCOME 60 Day Mortality	21.0%	18.2%	18.9%

ARISE Results

Table 2. Study Outcomes.					
Variable	EGDT (N=793)	Usual Care (N=798)	Relative Risk (95% CI)	Risk Difference (95% CI)*	P Value
				percentage points	
Primary outcome: death by day 90 — no./total no. (%)	147/792 (18.6)	150/796 (18.8)	0.98 (0.80 to 1.21)	-0.3 (-4.1 to 3.6)	0.90
Secondary outcomes					
Median duration of stay (IQR)†					
Emergency department — hr	1.4 (0.5–2.7)	2.0 (1.0-3.8)			<0.001
ICU — days	2.8 (1.4-5.1)	2.8 (1.5-5.7)			0.81
Hospital — days	8.2 (4.9-16.7)	8.5 (4.9-16.5)			0.89
Use and duration of organ support‡					
Invasive mechanical ventilation — no./total no. (%)	238/793 (30.0)	251/798 (31.5)	0.95 (0.82 to 1.11)	-1.4 (-6.0 to 3.1)	0.52
Median duration of invasive mechanical ventilation (IQR) — hr	62.2 (23.5–181.8)	65.5 (23.0–157.9)			0.28
Vasopressor support — no./total no. (%)	605/793 (76.3)	525/798 (65.8)	1.16 (1.09 to 1.24)	10.5 (6.1 to 14.9)	< 0.001
Median duration of vasopressor support (IQR) — hr	29.4 (12.9-61.0)	34.2 (14.0-67.0)			0.24
Renal-replacement therapy — no./total no. (%)	106/793 (13.4)	108/798 (13.5)	0.99 (0.77 to 1.27)	-0.2 (-3.5 to 3.2)	0.94
Median duration of renal-replacement therapy (IQR) — hr§	57.8 (25.3–175.0)	85.9 (29.3–182.9)			0.40
Tertiary outcomes — no./total no. (%)					
Death by day 28	117/792 (14.8)	127/797 (15.9)	0.93 (0.73 to 1.17)	-1.2 (-4.7 to 2.4)	0.53
Death by the time of discharge from ICU	79/725 (10.9)	85/661 (12.9)	0.85 (0.64 to 1.13)	-2.0 (-5.4 to 1.5)	0.28
Death by the time of discharge from hospital¶	115/793 (14.5)	125/797 (15.7)	0.92 (0.73 to 1.17)	-1.2 (-4.7 to 2.3)	0.53

Differences Between Treatment and Control Groups in the ProCESS, ARISE, and ProMISE Trials

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

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

Conclusions

- Required monitoring of CVP and ScvO2 via a CVC as part of early resuscitation does not confer survival benefit in all patients with septic shock who have received timely antibiotics and fluid resuscitation compared with controls.
- Requiring measurement of CVP and ScvO2 in all patients with lactate >4 mmol/L and/or persistent hypotension after initial fluid challenge and timely antibiotics is not supported by available evidence.

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

NEW BUNDLES AND CMS "CORE MEASURES" TO BEGIN OCTOBER 2015

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
- * "Time of presentation" is defined as the time of earliest chart annotation consistent with all elements severe sepsis or septic shock ascertained through chart review.

SEP-1

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

- Apply 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

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: Two Clocks

- Severe Sepsis: Three hour and six hour Counters
- Septic Shock: **Three** hour and **six** hour Counters

Clinical example follows

SEP-1: Two Clocks cont.

• 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, then 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 cont.

- The **severe sepsis clock** would start with the presentation of severe sepsis (**3 p.m.**).
- The **septic shock clock** would start with presentation of septic shock (**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
 - o Blood cultures prior to antibiotics
 - Sepsis Six Hour Counter would require the following be completed by 9 p.m.:
 - Repeat lactate if initial lactate is >2

SEP-1: Two Clocks cont.

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

Definition: Measure CVP

Criteria for Data Abstraction

- Expected response: "Yes" or "No" ("Yes" meaning CVP was checked)
- Requirements:
 - CVC placed in superior vena cava

or

Right heart (Swan-Ganz) catheter placement

in either case

Measurement occurs within six hours of the presentation of septic shock

- Clinically necessary or definitional, but documentation not required
- Goal CVP is 8–12mm Hg

Definition: Measure ScvO2 (or SvO2 for Pulmonary Artery Catheter)

Criteria for Data Abstraction

- Expected response: "Yes" or "No" ("Yes" meaning ScvO2 was measured and documented)
- Requirements:
 - CVC placed in superior vena cava (Scv02)

or

Right heart (Swan-Ganz) catheter placement (Sv02)

in either case

Measurement occurs within six hours of the presentation of septic shock

- Clinically necessary or definitional, but documentation not required
- If right heart (Swan-Ganz) catheter is placed, the value of SvO2 (mixed venous oxygen saturation is appropriate)
- Definitional: Goal ScvO2 is >70%
- Definitional: Goal SvO2 is >65%

Definition:

Bedside Cardiovascular Ultrasound

Criteria for Data Abstraction

- Expected response: "Yes or "No" ("Yes" meaning an appropriate ultrasound was done)
- Requirement: Ultrasound occurs within six hours of the presentation of septic shock
- Appropriate exams to qualify for a "Yes" include:
 - TTE (trans-thoracic echocardiogram)
 - TEE (trans-esophageal echocardiogram)
 - IVC US (Inferior Vena Cava ultrasound)
 - Esophageal Doppler monitoring

- Clinically necessary or definitional, but documentation not required
- Definitional: caval index: IVC expiratory diameter IVC inspiratory diameter, divided by IVC expiratory diameter × 100 = caval index (%)
- Definitional: the caval index is written as a percentage, where a number close to 100% is indicative of almost complete collapse (and therefore volume depletion), while a number close to 0% suggests minimal collapse (i.e., likely volume overload)
- Informational: correlations between IVC size and CVP

Inferior Vena Cava Size (cm)	Respiratory Change	Central Venous Pressure (cm H ₂ O)
<1.5	Total collapse	0–05
1.5 – 2.5	> 50% collapse	6–10
1.5 – 2.5	< 50% collapse	11–15
>2.5	< 50% collapse	16–20
>2.5	No change	>20

Definition: Passive Leg Raise

Criteria for Data Abstraction

- Expected response: "Yes" or "No" ("Yes" meaning a passive leg raise is documented or administration of a fluid challenge is documented)
- Requirements:
 - Passive leg raise or fluid challenge occurs within six hours of the presentation of septic shock
 - No documentation of lower extremity amputation in the case of passive leg raise
 - Presence of a passive leg raise test typically documented as "PASSIVE LEG RAISE (PLR):" with findings "positive," "negative," "fluid responsive," "not fluid responsive," or other language

- Clinically necessary or definitional, but documentation not required
 - Patient is seated at 45 degrees head up semi-recumbent position
 - Patient's upper body is lowered to horizontal and legs passively raised to 45 degrees up
 - Maximal effect occurs at 30–90 seconds
 - Definitional: a 10% increase in stroke volume as documented on a cardiac output monitor reflects a
 positive test and a 9% increase in stroke volume has 86% sensitivity and 90% specificity
- Definitional: a 10% increase in pulse pressure as documented via an arterial line has a 79% sensitivity and 85% specificity

Definition: Repeat Physical Exam

Criteria for Data Abstraction

- Expected response: "Yes" or "No" ("Yes" meaning a complete exam is recorded)
- Requirements: clinical exam components within six hours of the presentation of septic shock and **must include each of the following**:
 - Vital signs (including temperature, heart rate, blood pressure, respiratory rate: all four must be present)
 - Presence of a cardiopulmonary exam, typically documented as "HEART" <u>and</u> "LUNGS"
 - <u>Documentation examples:</u> HEART- "RRR," "Irregular," "S1, S2, S3, S4", "murmur;" or other LUNG -"clear," "crackles," "diminished," "dull," or other language
 - Presence of peripheral pulses examination typically "PULSES:" with findings
 - o <u>Documentation examples:</u> "1+," or "2+," or "absent," or other language
 - Presence of documentation of capillary refill
 - <u>Documentation examples:</u> "brisk," "< 2 seconds," "> 2 seconds," or other language
 - Presence of a skin examination
 - o <u>Documentation examples:</u> "mottled," "not mottled," "knee caps clear/mottled," or other language.

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- This program has been approved for 1.0 continuing education (CE) unit for the following professional boards:
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