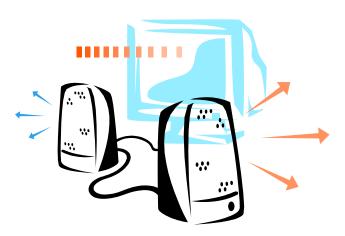
Early Management Bundle, Severe Sepsis/Septic Shock

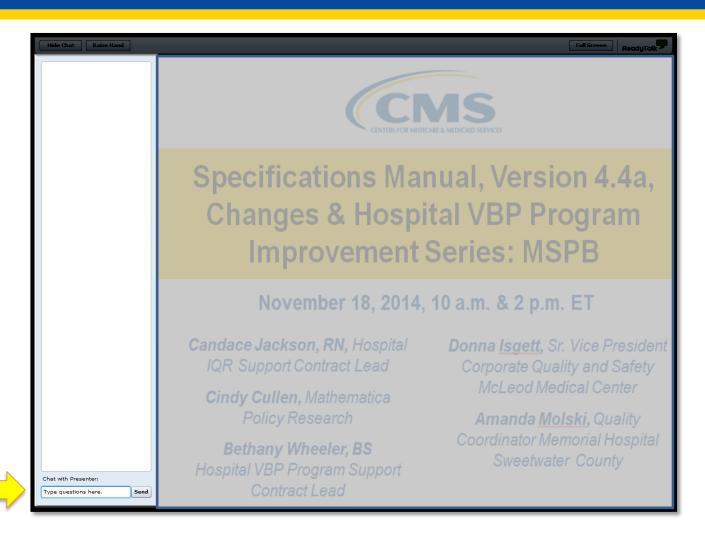
- Audio for this event is available via INTERNET STREAMING.
- No telephone line is required.

 Computer speakers or headphones are necessary to listen to streaming audio.



Submitting Questions

Type questions in the "Chat with Presenter" section, located in the bottom-left corner of your screen.





Early Management Bundle, Severe Sepsis/Septic Shock

Laura Elise Evans, MD, MSc
Associate Professor at New York University (NYU) School of Medicine

Mary F. Therriault, MS, R.N.

Senior Director, Quality Research and Initiatives at Healthcare Association of New York State (HANYS)

Sean Robert Townsend, MD

Vice President of Quality and Safety at California Pacific Medical Center

Purpose

- Provide participants the basis, rationale, and content of the Early Management Bundle, Severe Sepsis/Septic Shock measure
- Explain the importance of data collection
- Detail improvements that have been seen since the collection of data

6/22/2015 4

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 improvements that have been identified since collection of the Sepsis Bundle measure.

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New York State Experience with Severe Sepsis/Septic Shock

Mary Therriault, R.N. M.S. Senior Director, Quality and Research Initiatives Laura Evans, M.D., M.Sc. NYU School of Medicine



New York State (NYS) Sepsis Regulations

- Evidence-based protocol
 - Adult and pediatrics
 - Emergency Department (ED) and Inpatient units
- Hospitals are required to report
 - adherence to protocol elements
 - risk-adjusted sepsis mortality



Incidence of Severe Sepsis and Septic Shock

Nationally

- Sepsis is the leading cause of death in U.S. hospitals
- Strikes 750,000
 Americans each year
- Mortality rate of 28%–50%
- Same number of deaths caused annually by heart attacks

National Institute of General Medical Services

New York

 NYS predicted that sepsis regulations could save the lives of 5,000–8,000 New Yorkers per year.



NYS Regulations

- Definitions of severe sepsis and septic shock
- Adoption of evidence-based protocols for early identification and treatment of adults and children with severe sepsis and septic shock
- Initial and periodic training for staff addressing recognition of sepsis and protocols
- Protocols submitted by September 3, 2013
- Protocols implemented by December 31, 2013
- Collection and submission of protocol adherence data
- Department of Health (DOH) to develop risk-adjusted severe sepsis and septic shock mortality rates in consultation with appropriate national, hospital and expert stakeholders



NYSDOH Sepsis Advisory Committee

- Comprised of state clinical leaders, hospital associations
- Consultation with national experts
- Key issues:
 - Protocol requirements
 - Data collection requirements
 - Risk adjusted mortality methodology
 - Public reporting



DOH Sepsis Data Dictionary

- 100+ elements
 - Process adherence
 - Patient outcomes
 - Enable risk adjustment
- Undergone many revisions
- Posted at https://ny.sepsis.ipro.org

DATA DICTIONARY FOR SEVERE SEPSIS OR SEPTIC SHOCK

Version 1.43

April 9, 2015



Process Adherence Measures

- National Quality Forum (NQF) #0500 Severe
 Sepsis (Adult) detailed in NYS Guidance Document
- Regulations apply to children, but do not reference a specific measure or protocol for the pediatric population
- Patients in the ED, Intensive Care Unit (ICU), and patient units



Outcome Measure

- Risk Adjusted Severe Sepsis/ Septic Shock Mortality Rate
 - No clear national methodology
 - NYS working with the New York State Cardiac Services to develop model



Case Identification

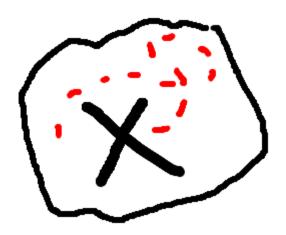
- Retrospective
 - Used coding to identify patients who have been discharged and go back to collect data
- Prospective
 - Identify patients in as close to "real time" as possible



Retrospective Case Identification: Identifying Patients by Coding

Pros:

- Easy
- Less time consuming to find patients
- No change to existing work flow



Cons:

- Potential for misclassification
- Potential for bias
 - More likely to capture more severe cases
- Difficult to use coded cases for performance improvement
 - Time lag for feedback



Prospective Case Identification: Identifying Patients by Screening

Pros:

- Less likely to have misclassification
- More complete population of cases
- "Real time" feedback to providers to guide Quality Improvement (QI) efforts

Cons:

- Time consuming
- Potentially need to change existing work flow to facilitate identification





Documentation

- Strategies for determining Time Zero
 - Code Sepsis called in ED and Critical Care unit
 - Electronic Health Record (EHR) protocol first time stamp is Severe Sepsis Protocol began
 - Paper order sheet time noted when Severe Sepsis protocol began
 - Rapid Response Teams identify Severe Sepsis on patient units



Documentation

- Documentation in the medical record that shows patient meets the definition of severe sepsis and/or septic shock
 - Present on Admission
 - Positive Systematic Inflammatory Response
 Syndrome (SIRS), infection, organ failure not present
 - Health Information Management (HIM) coding issues
- Quality reviewing all coded severe sepsis or septic shock



Process Adherence: Challenges

- 3 Hour Bundle
 - Administration of fluids
 - Documentation
 - AntibioticStewardship
 - Transfer patients
 - Role of Emergency Medical Services (EMS)

- 6 Hour bundle
 - International discussion of evidence-based treatment



HANYS' Response



Staff Time

- Input to NYS Department of Health
- HANYS' Sepsis Advisory Committee
- Technical and clinical assistance
- Identifying national expert speakers and facilitating education programs
- Data collection worksheet creation and updating
- Resource Guide creation and updating
- Website creation and updating
- Regular communication to members



HANYS' Sepsis Advisory Committee

- Regular meetings
 - Inform HANYS' advocacy
 - Provide input to DOH Sepsis Advisory Committee
 - Identify resource needs
 - Discuss implementation issues
 - Share best practices



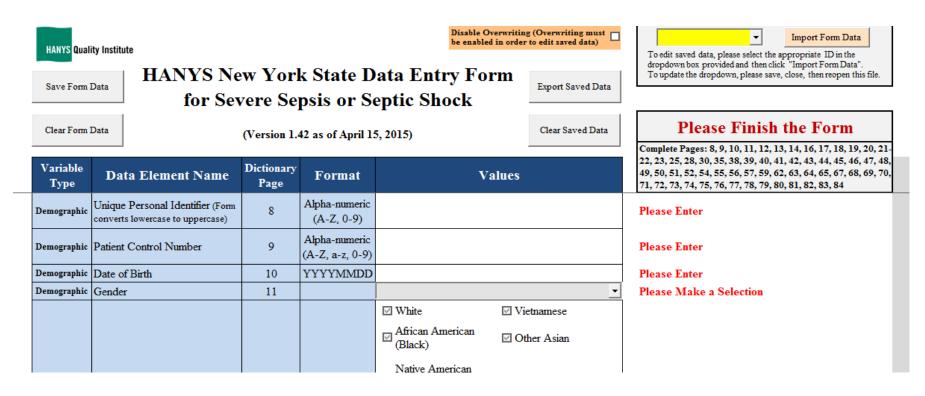
Partnership with National Organizations

- Surviving Sepsis Campaign
- Health Research and Educational Trust (HRET)



HANYS' Data Collection Tool

Severe Sepsis Septic Shock Excel worksheet (correct flat CSV file for upload to IPRO)





Education and Resources

- Development of Hospital Sepsis Care Resource Guide
- Webinars beginning in 2012
- Sepsis Comprehensive Unit-Based Safety Program (CUSP) Series funded by HRET
- Office Hours with the Surviving Sepsis Campaign (SSC) and NYSDOH





Next Steps and Outstanding Issues



Data Reporting

- Beginning in June 2015
 - Audits of NYS claims data
 - Medical chart reviews
 - Hospitals responding to DOH-generated
 Data Integrity Reports



HANYS' Advocacy

- Alignment with CMS, where possible
- Risk-adjusted mortality and morbidity





Questions?





Surviving Sepsis · · Campaign •

SEP-1: First National Core Measure on Sepsis Care

Sean R. Townsend, MD

VP Quality & Safety, California Pacific Med. Ctr.

Clinical Assistant Professor

University of California, San Francisco

This presenter has nothing to disclose.

Sepsis is the #1 Cause of Inpatient Deaths

2014 Acute Care Discharges 11% of Pts Have Sepsis DX

Simple Sepsis

7,557,5%

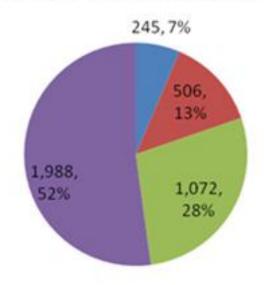
4,505,3%

122,517,89%



■ Severe Sepsis

2014 Acute Care Deaths 48% of Pts have Sepsis DX



6/22/2015

without Sepsis DX

Old NQF 0500

TO BE COMPLETED WITHIN 3 HOURS OF TIME OF PRESENTATION †:

- 1. Measure lactate level
- 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 0500

TO BE COMPLETED WITHIN 6 HOURS OF TIME OF PRESENTATION:

- 5. 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):
 - Measure central venous pressure (CVP)*
 - Measure central venous oxygen saturation (ScvO2)*

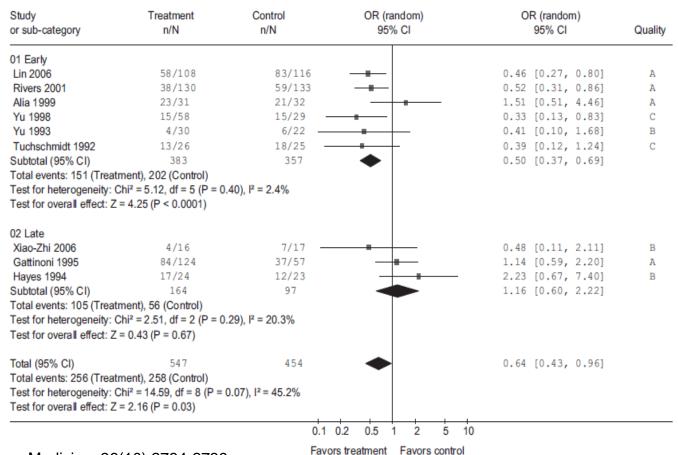
7. Re-measure lactate*

^{*} 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

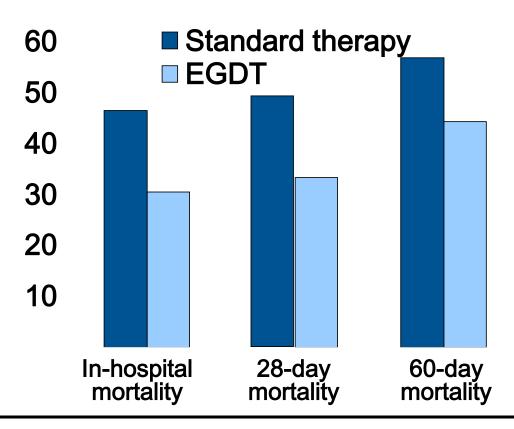
Outcome: 01 Mortality



Critical Care Medicine. 36(10):2734-2739

Early Goal Directed Therapy (EGDT)





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

ProCESS, ARISE, ProMISE, and Usual Care

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?	
TRAINING	CCI – SPI – Co - others	Same	Same	
CENTRAL LINES	Continuous ScvO2	Only if inadequate peripheral access No instruction "no" CVP, ScvO2 < 6 hr		
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

	EGDT	Usual Care	Relative Risk	Risk Difference	
Variable	(N=793)	(N=798)	(95% CI)	(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

Conclusions

- Required monitoring of CVP and ScvO2 via a central venous catheter (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.

New Bundles & CMS "Core Measures" to Begin October 2015

SEP-1

TO BE COMPLETED WITHIN 3 HOURS OF TIME OF PRESENTATION † :

- Measure lactate level
- 2. Obtain blood cultures prior to administration of antibiotics
- 3. Administer broad spectrum antibiotics
- 4. 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 6 HOURS OF TIME OF PRESENTATION:

- 5. Apply vasopressors (for hypotension that does not respond to initial fluid resuscitation) to maintain a mean arterial pressure (MAP)
 ≥65mmHg
- 6. 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.
- 7. 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 charting, lab flow sheets, physician documentation, anything with a time stamp
- Will = triage time if all signs and symptoms are present at triage

- Severe Sepsis: Three Hour and six Hour Counters
- Septic Shock: Three Hour and Six Hour Counters
- Clinical Example follows

- A patient developed severe sepsis <u>at 3 p.m</u>. but did not become hypotensive and fail to respond to fluids until <u>5 p.m.</u> Does the "shock clock" start <u>at 5 p.m</u>.?
- If so, then does the six hour window to complete the physical exam requirement begin at <u>5</u>
 <u>p.m.</u> with the shock clock or <u>at 3 p.m.</u> when severe sepsis was first noted?

- The severe sepsis clock would start with the presentation of severe sepsis (3 p.m.) and the septic shock clock would start with presentation of septic shock (5 p.m.).
- The presentation of severe sepsis <u>at 3 p.m.</u> will trigger the following counters with the start time being <u>3 p.m.</u>:
 - "Sepsis Three Hour Counter" would require the following be completed by 6 p.m.:
 - Initial lactate level measurement
 - Antibiotic Administration
 - 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

- The presentation of Septic Shock <u>at 5 p.m.</u> will trigger the following counters with the start time being <u>at 5 p.m.</u>.:
 - "Shock Three Hour Counter" would require the following be completed by <u>8 p.m.</u>:
 - Resuscitation with 30 mL/kg of crystalloid fluids
 - "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/no (yes meaning CVP was checked)
- Requirements:
 - CVC placed in superior vena cava; OR
 - Right heart (Swan-Ganz) catheter placement
 - Measurement occurs within six hours of the presentation of septic shock

Physician Reference

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

Definition: Measure Scv02 (or SvO2 for pulmonary artery catheter)

Criteria for Data Abstraction

- Expected response: yes/no ("yes" meaning ScvO2 was measured and documented)
- Requirements:
 - CVC placed in superior vena cava (Scv02); OR
 - Right heart catheter (Swan-Ganz) Catheter placement (Sv02)
 - Measurement occurs within six hours of the presentation of septic shock

Physician Reference

- 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/no ("yes" meaning an appropriate ultrasound was done)
- Requirements 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

Physician Reference

- Clinically Necessary or definitional, but documentation not required
- Definitional: Caval index: IVC expiratory diameter IVC inspiratory diameter, divided by IVC expiratory diameter x 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/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

Physician Reference

- 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/no ("yes" meaning a complete exam is recorded)
- Requirements: Clinical exam components within 6 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)

<u>and</u>

- Presence of a cardiopulmonary exam: typically documented as "HEART:" and "LUNGS:"
- <u>Documentation examples:</u> HEART- "RRR," "Irregular," "S1, S2, S3, S4", "murmur;" or other LUNG "clear," "crackles," "diminished,"" dull," or other language

<u>and</u>

- Presence of peripheral pulses examination typically "PULSES:" with findings
- <u>Documentation examples:</u> "1+," or "2+," or "absent," or other language

<u>and</u>

- Presence of documentation of capillary refill
- <u>Documentation examples:</u> "brisk," "< 2 seconds," "> 2 seconds," or other language

<u>and</u>

- Presence of a skin examination
- <u>Documentation examples:</u> "mottled," "not mottled," "knee caps clear/mottled," or other language

Thank You! Questions?

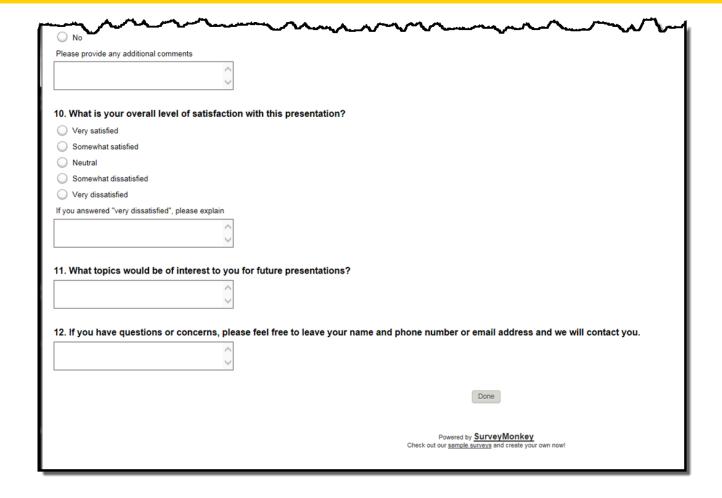
Continuing Education Approval

- This program has been approved for 1.0 continuing education (CE) unit given by CE Provider #50-747 for the following professional boards:
 - Florida Board of Nursing
 - 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
- Professionals licensed in other states will receive a Certificate of Completion to submit to their licensing boards.

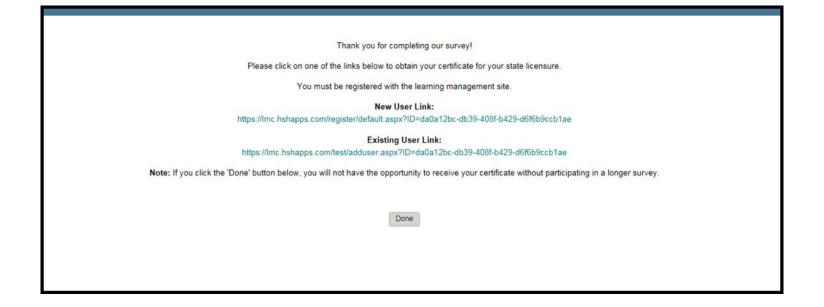
CE Credit Process

- Complete the ReadyTalk® survey you will receive by email within the next 48 hours or the one that will pop up after the webinar.
- The survey will ask you to log in or register to access your personal account in the Learning Management Center.
 - A one-time registration process is required.

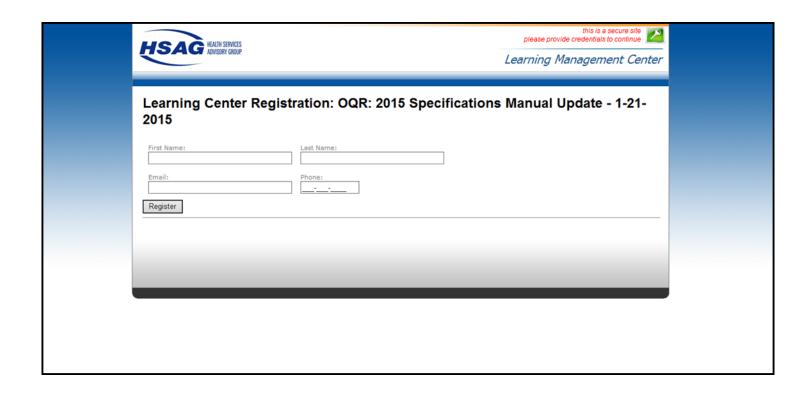
CE Credit Process: Survey



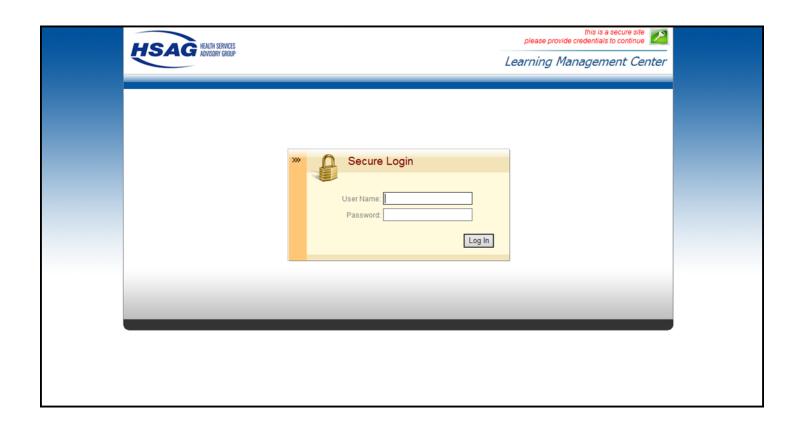
CE Credit Process



CE Credit Process: New User



CE Credit Process: Existing User



QUESTIONS?

This material was prepared by the Inpatient Value, Incentives, and Quality Reporting Outreach and Education Support Contractor, under contract with the Centers for Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. HHSM-500-2013-13007I, FL-IQR-Ch8-06172015-02