NATIONAL QUALITY FORUM

Memo

TO: NQF Members

FR: NQF Staff

RE: Voting Draft Report: *National Voluntary Consensus Standards: Infectious Disease Endorsement Maintenance 2012, Addendum Report*

DA: December 19, 2012

Background

This memo describes two remaining measure recommendations from the Infectious Disease Endorsement Maintenance project:

Following the Public and Member Comment period of the draft report, National Voluntary Consensus Standards: Infectious Disease Endorsement Maintenance 2012,the Committee decided to reconsider measure ***393: Testing for chronic hepatitis C – Confirmation of hepatitis C viremia*** due to the comments received and additional evidence and data that were recently released to support the measure focus. The final evaluation and recommendation are included in this addendum report.

In the draft report, National Voluntary Consensus Standards: Infectious Disease Endorsement Maintenance 2012, a final recommendation had not been made on measure ***0500: Severe sepsis and septic shock: Management bundle*** to allow the Committee to review additional information on the measure's reliability testing provided after the in-person meeting.

Comments and Revised Voting Report

NQF received 11 comments from 7 member and public organizations on measure ***0500: Severe sepsis and septic shock: Management bundle:***

Consumers – 0	Professional – 3
Purchasers – 0	Health Plans – 1
Providers – 1	QMRI – 0
Supplier and Industry – 1	Public & Community Health – 0
Public – 1	

A table of complete comments submitted during the comment period, with the responses to each comment and the actions taken by the Steering Committee, is posted to the project page on the NQF website, along with the measure submission forms.

The Steering Committee reviewed and responded to all comments received. Revisions to the draft report and the accompanying measure specifications are identified as red-lined changes. (Note: Typographical errors and grammatical changes have not been red-lined, to assist in reading.)

Comments and their Disposition

Major Themes

Three major themes were identified in the comments for both the sepsis and hepatitis C measures:

1. General support for the sepsis measure (NQF #0500)
2. Concerns with the reliability, validity and feasibility of the sepsis measure
3. Disagreement with the hepatitis C measure not being recommended

Theme 1 - General Support for the Sepsis Measure

0500: Severe sepsis and septic shock: Management bundle

Description: Three NQF members submitted comments in support of the measure noting that the developer had responded to questions from the Steering Committee. One commenter stated that "[the] steering committee questioned whether the sepsis quality measure addressing a bundle should be endorsed versus specific validated elements of the bundle. The SS Campaign noted that by making the bundles standard practice, there is elimination of piecemeal or chaotically applied standards for sepsis care that exist in many clinical environments today." One supportive comment suggested that implementation may difficult with claims data.

Theme 2 – Concerns with the Reliability, Validity and Feasibility of the Sepsis Measure

0500: Severe sepsis and septic shock: Management bundle

Description: Three NQF members submitted similar comments identifying the following concerns about the measure:

Lack of evidence for the central venous pressure (CVP) measure component

A commenter noted that "While we recognize that the SSC recommends central venous pressure monitoring (an unreliable and seldom followed parameter), both it and measuring

central venous oxygen saturation are only supported by one single center clinical trial (as such limited evidence supports its use)."

ACEP states that "ACEP has serious concerns surrounding the lack of evidence for measuring CVP as a surrogate for intravascular volume. " "The measure developers have now cited five additional studies in which multivariate logistic regression demonstrated no independent effect on mortality in patients who achieve CVP targets versus patients who do not. (Castellanos-Ortega 2010, Nguyen 2007, Jeon 2012, Levy 2010, Cannon 2010)."

A commenter suggested that "There may be the unintended consequence of increasing the use of central lines in situation where they may actually not be needed and potentially causing harm by their placement (bleeding pneumothorax, pain) or causing infections. By including this single item in the composite measure may encourage the over utilization of central line placement specifically not to fail the measure rather than taking care of the patients best interests."

> **Action Taken:** The developer indicated that when the central venous pressure (CVP) component is utilized as part of the bundle, there is a decrease in mortality. Some members of the Committee did agree that there may be limited evidence for CVP use; however, the Committee concluded that use of the bundle as specified with CVP demonstrated reduction in mortality.

Lack of evidence for blood culture prior to antibiotics element

A commenter stated that "The whole point is that the patients receive broad spectrum antibiotics not that they are timed prior to antibiotic administration. The theoretical concern about sensitivities should not trump actual administration of those antibiotics. If not eliminated than perhaps altering the wording to simply state; "obtaining appropriate cultures" which would allow simplicity and more flexibility in the actual abstraction process. Having to identify the time of antibiotic administration along with the time of collection of cultures adds significantly to the burden and complexity of the abstraction process. Theoretically this may seem important but does the act of obtain blood cultures or any culture prior to the administration of antibiotics actually have any effect on outcomes?"

> **Action Taken:** The Committee concluded that blood cultures remain important for adjusting antibiotic coverage in patients with severe sepsis and reduced response to treatment and that the bundle of care processes are related to patient outcomes. The Committee determined that the measure met the evidence criteria (Y-12; N-0; I-2).

Reliability of triage being time zero for ED patients and the impact of ED length of stay

A commenter states that "Often time's patient present to the ED with normal vital signs then decompensate and meet criteria of sepsis. Including the initial time of presentation as the start

time may not reflect patient's condition adequately. This ambiguity of utilizing different criteria of time of presentation based on location, calls into question the measure reliability."

Another commenter suggests that "Many ED patients will present with uncomplicated pneumonia, urinary tract infection, or cellulitis only to meet the criteria for severe sepsis/septic shock hours later. If the measure calls for early goal directed therapy within three hours of triage, but the patient does not meet criteria for severe sepsis or septic shock until four hours later, then even if all required interventions are completed within an hour, the hospital will fail on this measure as currently specified. That type of measurement does not differentiate hospitals based on the quality of care provided, but rather on the ED length of stay. If used for accountability as specified, this measure could cause the unintended consequence of penalizing large volume and safety net hospitals."

Another commenter argued that "Time-based measures that potentially start the clock ticking prior to patients meeting the defining criteria of the syndrome in question have to be recognized as invalid. The developers responded that ED patients with infections are "somewhere on the natural trajectory of becoming septic regardless of point of presentation." Statements such as this encourage overly aggressive treatment for patients who do not initially meet criteria for severe sepsis/septic shock due to provider concern of being deemed retrospectively "non-compliant" should the patients' condition subsequently change. The developers state "if the patient who becomes hypotensive or has a high lactate does so in the ED, the reason for the presentation to the ED is severe sepsis or shock." While this is true in cases where criteria are met at triage, it's absolutely not the case for those who only do so hours later. Patients present with chief complaints (which are often non-specific), not diagnoses."

> **Action Taken:** There was significant discussion on the post-comment call regarding the reliability of triage being time zero for Emergency Department (ED) patients and the impact of the ED length-of-stay. Some Committee members did agree that certain elements of the measure may be related to hospital situations (beds, changing clinical status) that are out of the control of the provider. The Committee reconsidered their evaluation of reliability and determined it meets the reliability criteria at moderate to high.

Feasibility of abstracting the composite measure

A commenter noted that "This new composite is far too complex for implementation as a potential accountability measure. Furthermore, all of the data elements and time stamps

required to calculate this measure are not readily available discrete fields from existing electronic sources making it a significant burden on hospitals to sort and collect this data."

Action Taken: Committee members discussed the data collection burden for the input of multiple data points and the timestamps. Some members were less concern due to the large number of hospitals who are currently collecting the data for the measure. The Committee reconsidered their evaluation of this criterion and rated feasibility as moderate.

FINAL ACTION: After review of the comments, the Committee agreed to re-evaluate the measure criteria and recommendation for endorsement. The Committee again determined that the measure meets NQF's criteria and recommended the measure for endorsement (Y-11; N-3).

Theme 3 – Disagreement with the Hepatitis C Measure not being Recommended

0393: Testing for chronic hepatitis C – Confirmation of hepatitis C viremia

Description: The commenter requested reconsideration of this measure and noted that a few Steering Committee members discussed the indirect evidence linking the process to the outcome. Additional information provided by the developer included a meta-analysis of 31 studies that found a consistent overall estimate of 15 to 20 percent of people who become infected with acute Hepatitis C will clear the virus. The absence of confirmatory viral testing may then leave these 15 to 20 percent of patients with the mistaken belief that they have chronic Hepatitis C, subjecting these patients to unnecessary anxiety and other harms. The remaining viral positive patients could benefit from the additional counseling for their own and for transmission risk, as mentioned by SC members, namely avoiding alcohol, getting vaccinated, and providing counseling regarding transmission and remaining engaged in care. Thus, this test is critically important in differentiating whether or not people have resolved infection or are currently infected with HCV, regardless of whether antiviral treatment is contemplated.

Action Taken: The Committee agreed that the comments had merit and reconsidered the measure on the December 5 call. The Committee decided to recommend the measure for continued endorsement due to documentation of HCV viremia will be essential for any patient found to have a positive antibody test.

NQF Member Voting

Information for electronic voting has been sent to NQF Member organization primary contacts. Accompanying comments must be submitted via the online voting tool.

Please note that voting concludes on January 3, 2013 at 6:00 pm ET – no exceptions.

National Voluntary Consensus Standards: Infectious Disease Endorsement Maintenance 2012

ADDENDUM DRAFT TECHNICAL REPORT FOR VOTING

December 19, 2012

NATIONAL QUALITY FORUM

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National Voluntary Consensus Standards: Infectious Disease Endorsement Maintenance 2012

ADDENDUM DRAFT TECHNICAL REPORT

Introduction

In the draft report, National Voluntary Consensus Standards: Infectious Disease Endorsement Maintenance 2012, measure 0500: *Severe sepsis and septic shock: Management bundle* was pending final recommendation from the Steering Committee to allow the Committee to review additional information on the measure's reliability testing that was not available for review at the time of the in-person meeting. The Committee reviewed the additional information provided by the developer via email to complete its evaluation following the in-person meeting. On December 5, the Steering Committee met via conference call to review and discuss the submitted comments received during the Public and Member Comment period of the addendum report. Due to the number of comments surrounding the concerns of reliability, validity and feasibility of the sepsis measure, the Committee agreed to re-vote on whether measure 0500 met the NQF criteria for endorsement. Following the re-vote, measure 0500 was recommended by the Committee for NQF endorsement.

Following the Public and Member Comment period of the draft report, the Committee decided to reconsider measure 393: *Testing for chronic hepatitis C – Confirmation of hepatitis C viremia* due to the comments received and additional evidence and data was recently released to support the measure focus. The final evaluation and recommendation are also included in this addendum report.

Measure Evaluation Summary

Measures Recommended

NOTE: The measure submission forms can be accessed by clicking on the NQF measure number in the tables below.

Measures Recommended

Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable; Y=Yes; N=No

0500 Severe sepsis and septic shock: Management bundle

Status: Maintenance, Original Endorsement: Oct 24, 2008

Description: This measure will focus on patients aged 18 years and older who present with symptoms of severe sepsis or septic shock. These patients will be eligible for the 3 hour (severe sepsis) and/or 6 hour (septic shock) early management bundle.

Numerator Statement: If:

A. measure lactate level

B. obtain blood cultures prior to antibiotics

C. administer broad spectrum antibiotics

D. administer 30 ml/kg crystalloid for hypotension or lactate >=4 mmol/L

E. apply vasopressors (for hypotension that does not respond to initial fluid resuscitation to maintain a mean areterial pressure >= 65)

F. In the event of persistent arterial hypotension despite volume resuscitation (septic shock) or initial lactate >=4 mmol/L (36 mg/dl) measure central venous pressure and central venous oxygen saturation

G. remeasure lactate if initial lactate is elevated

represent processes of care:

Numerator statement: Patients from the denominator who received all the following: A, B, and C within 3 hours of time of presentation† AND IF septic shock is present (as either defined as hypotension* or lactate >=4 mmol/L) who also received D and E and F and G within 6 hours of time of presentation.

† "time of presentation" is defined as the time of triage in the Emergency Department 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.

* "hypotension" is defined as systolic blood pressure (SBP) <90 mm Hg or mean arterial pressure (MAP) <70 mm Hg or a SBP decrease >40 mm Hg or <2 SD below normal for age or known baseline.

Denominator Statement: Number of patients presenting with severe sepsis or septic shock.

Exclusions: A) Patients with advanced directives for comfort care are excluded.

B) Clinical conditions that preclude total measure completion should be excluded (e.g. mortality within the first 6 hours of presentation as defined above in 2a1.1).

C) Patients for whom a central line is clinically contraindicated (e.g. coagulopathy that cannot be corrected, inadequate internal jugular or subclavian central venous access due to repeated cannulations).

D) Patients for whom a central line was attempted but could not be successfully inserted.

E) Patient or surrogate decision maker declined or is unwilling to consent to such therapies or central line placement.

Adjustment/Stratification: No risk adjustment or risk stratification None Henry Ford Hospital (HFH) encourages the results of this measure to be stratified by race, ethnicity, gender, and primary language, illness severity and have included these variables as recommended data elements to be collected.

Level of Analysis: Facility, Integrated Delivery System

Type of Measure: Composite

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Paper Medical Records, Electronic Clinical Data : Registry

Measure Steward: Henry Ford Hospital **Other organizations:** Henry Ford Hospital System(HFHS)

California Pacific Medical Center/Sutter Health (CPMC)

Society of Critical Care Medicine (SCCM)

Infectious Diseases Society of America (IDSA)

0500 Severe sepsis and septic shock: Management bundle

Institute for Healthcare Improvement (IHI)
Surviving Sepsis Campaign (SSC)
Ohio State University (OSU)

STEERING COMMITTEE MEETING [08/28/2012]

Importance to Measure and Report: The measure met the Importance criteria

(1a. High Impact: 1b. Performance Gap, 1c. Evidence)

1a. Impact: **H-19; M-1; L-0; I-0**; 1b. Performance Gap: **H-7; M-12; L-1; I-0** 1c. Evidence: **Y-11; N-5; I-4**

Rationale:

- There are greater than 750,000 estimated cases of severe sepsis a year in the United States. Additionally, there are an estimated 400,000 ICU admissions for sepsis, approximately 200,000 deaths a year, and at an estimated cost of $17 billion a year.
- More than 50 publications have reported improved survival with use of the bundle in the past decade with the vast majority of the studies being observational. Some Committee members noted the lack of randomized controlled trials and they were informed that there are three randomized controlled trials currently ongoing in the U.S., UK and Australia.
- Committee members noted that there is some controversy in the field about the need for all of the bundle elements, specifically measuring central venous pressure (CVP). However, only about 15 percent of patients end up needing a CVP line because of the care algorithm in the bundle.
- Meta-analyses have shown survival benefit. National and international guidelines have been created for the management of severe sepsis and septic shock based on the data. The recommendations in the guidelines mirror the bundle in this measure.
- The developer pointed to the recent GENESIS trial published in the *Journal of Intensive Care Medicine* of 6000 patients in 11 hospitals throughout the U.S.; hospitals ranging from 100 to 1,000 patients found that meeting the bundle in a prospective, observational cohort resulted in mortality reduction of 14 percent.

2. Scientific Acceptability of Measure Properties: The measure met the Scientific Acceptability criteria

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

Initial review: 2a. Reliability: **H-1; M-7; L-5; I-7** 2b. Validity**: NA**

Rationale:

- Committee members asked how the measure clearly distinguishes patients with severe sepsis versus those with septic shock.
  - Developer response: The key difference is hypotension refractory to fluid administration that requires a vasopressor or a persistent lactate level greater than 4 is septic shock as specified.
- After several questions regarding the specifications, NQF staff realized that an attachment containing the data collection tool submitted by the developer had not been provided to the Committee. NQF staff provided the document to the Committee after the meeting.
- Committee members questioned whether the inter-rater reliability study of 498 patients in one institution would apply to other institutions. The developer responded that the measure is being used in a variety of health care systems such as Kaiser, Loma Linda University, University of Kansas and Intermountain Health in Utah.

NOTE: During the meeting, the Committee decided there was insufficient information included in the submission to determine whether the measure met the reliability criteria. Because the Committee had not been given all of the submitted information and the developer indicated additional data on reliability testing could be provided, the Committee agreed to revisit this measure. Additional information was provided to address the questions on reliability.

0500 Severe sepsis and septic shock: Management bundle

After Review of all Submitted Information and Additional Information Addressing Reliability via Email:

2a. Reliability: **H-5; M-11; L-1; I-0** 2b. Validity: **H-1; M-14; L-2; I-0**

Rationale:

- The term 'broad spectrum antibiotics' is not defined. This could potentially be problematic for a data abstractor to precisely, accurately and reproducibly identify antimicrobials that will satisfy the measure. A Committee member noted that the term 'broad spectrum antibiotics' was not used in the reliability testing results, instead, the term 'timely antibiotics' was used, which seemed to be more specific to measure
    - Developer response: The surviving sepsis campaign defined "broad spectrum antibiotics" as those with both Gram positive and Gram negative bacterial coverage. The rationale for antibiotic selection is further discussed in the 2004 and 2008 sepsis guidelines publications. Credit for timely antibiotics was assigned in the data set used for the analyses only if both species were covered.
- The ICD-9 diagnostic codes to identify the denominator were thought to be appropriate.
- The measure was tested both at the data element and measure score levels for reliability. For validity the measure was only tested at the measure score level.
- In review of the validity testing, a Committee member noted that measuring central venous pressure (CVP) and central venous oxygen saturation (ScvO2) were not a part of the validity testing.
- Committee members noted that the validity testing indicated that after adjusting for baseline characteristics, only administration of broad spectrum antibiotics and obtaining blood cultures before their initiation were associated with lower hospital mortality.
- The question of whether the sepsis bundle as a whole should be incorporated versus specific validated elements of the bundle (e.g., antibiotic selection and timing) was discussed. Though a few members supported individual measure, the majority support the bundle.
- The question of how the specifications indicate accountability was raised. A member commented that time zero is triage for time limited Emergency Department (ED) therapies. If a patient presents to the ED triage and does not qualify as severe sepsis or septic shock but develops it later, would the hospital and/or physician be held accountable? Another accountability example was if a patient presents to the ED with pneumonia without severe sepsis or septic shock, and 4 hours later the patient becomes hypotensive, would the ED physicians and/or hospital be held accountable for not providing care over a timeline that had elapsed once the patient developed symptoms? Although unit and ICU time zero is based upon when the patient is diagnosed, in the ED it is time of triage which may or may not be the time at which the patient developed symptoms. The Committee member questioned how it would be reconciled.
    - Developer response: The patient is somewhere on the natural trajectory of becoming septic regardless of the point of presentation. If the patient who becomes hypotensive or has a high lactate does so in the ED, the reason for presentation to the ED is severe sepsis or shock. Likewise, the patient who presents with septic physiology on the floor and becomes hypotensive there after an initial admit for something else need to have time to start the clock. In both instances, we are relying on the presence of key features of severe sepsis or shock to make the attribution. Specifying triage time in the ED is not only reasonable since that is most likely what occasioned their visit to the ED, but also provides a standard time. The evidence in the literature also is consistent with picking triage time on this basis. There is less certainty with the floor patient, but again, a proper review yields the time that all the key features were first present. Thus, while there may be some admitted variability between the wards and the ED time of presentation in terms of precision, both are accurate for purposes of measurement.

The data in the reliability and validity sections of the NQF submission accept this loss of precision in favor of accuracy. The evidence and data cited demonstrate a high degree of reliability at the level of a performance measure even with this known variability. Thus, we do not need to view it as a threat to reliability. According to the RAND paper, these very high scores on the signal-to-noise reliability indicator actually mean that meaningful comparisons can be drawn in performance using this metric "as is" even with some known variability.

3. Usability: H-1; M-15; L-1; I-0

(*Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)*

Rationale:

- This measure is currently in wide use for public reporting and quality improvement by Kaiser Permanente, Surviving Sepsis Campaign, Catholic Healthcare West, Intermountain Healthcare and Sutter Healthcare.
- Highmark has been using the measure in its pay for performance program for the past two years. They initially had some data collection issues been those were soon resolved.
- The University of Kansas is currently using the measure in their EHR with real-time notifications.

4. Feasibility: H-1; M-10; L-6; I-0

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

- The measure requires chart review and manual abstraction.
- The measure still has elements that may not be captured completely by EHR. The amount of data that needs to be collected may be overwhelming for facilities trying to work on improving outcomes for sepsis. Some of the individual elements may be helpful for internal monitoring within the institution to evaluate improvement over time.

5. Related and Competing Measures

- No related or competing measures noted.

Steering Committee Recommendation for Endorsement: Y-13; N-4

6. Public and Member Comment

General Support for the Measure

- Three NQF members submitted comments in support of the measure noting that the developer had responded to questions from the Steering Committee. One commenter stated that "[the] steering committee questioned whether the sepsis quality measure addressing a bundle should be endorsed versus specific validated elements of the bundle. The SS Campaign noted that by making the bundles standard practice, there is elimination of piecemeal or chaotically applied standards for sepsis care that exist in many clinical environments today." One supportive comment suggested that implementation may difficult with claims data.

Lack of Evidence for the Central Venous Pressure (CVP) Measure Component

- A commenter noted that "While we recognize that the SSC recommends central venous pressure monitoring (an unreliable and seldom followed parameter), both it and measuring central venous oxygen saturation are only supported by one single center clinical trial (as such limited evidence supports its use)."
- ACEP states that "ACEP has serious concerns surrounding the lack of evidence for measuring CVP as a

surrogate for intravascular volume. " "The measure developers have now cited five additional studies in which multivariate logistic regression demonstrated no independent effect on mortality in patients who achieve CVP targets versus patients who do not. (Castellanos-Ortega 2010, Nguyen 2007, Jeon 2012, Levy 2010, Cannon 2010)."

- A commenter suggested that "There may be the unintended consequence of increasing the use of central lines in situation where they may actually not be needed and potentially causing harm by their placement (bleeding pneumothorax, pain) or causing infections. By including this single item in the composite measure may encourage the over utilization of central line placement specifically not to fail the measure rather than taking care of the patients best interests."

Committee Response: The developer indicated that when the central venous pressure (CVP) component is utilized as part of the bundle, there is a decrease in mortality. Some members of the Committee did agree that there may be limited evidence for CVP use; however, the Committee concluded that use of the bundle as specified with CVP demonstrated reduction in mortality.

Lack of Evidence for Blood Culture prior to Antibiotics Element

- A commenter stated that "The whole point is that the patients receive broad spectrum antibiotics not that they are timed prior to antibiotic administration. The theoretical concern about sensitivities should not trump actual administration of those antibiotics. If not eliminated than perhaps altering the wording to simply state; "obtaining appropriate cultures" which would allow simplicity and more flexibility in the actual abstraction process. Having to identify the time of antibiotic administration along with the time of collection of cultures adds significantly to the burden and complexity of the abstraction process. Theoretically this may seem important but does the act of obtain blood cultures or any culture prior to the administration of antibiotics actually have any effect on outcomes?"
- A commenter states that "Often time's patient present to the ED with normal vital signs then decompensate and meet criteria of sepsis. Including the initial time of presentation as the start time may not reflect patient's condition adequately. This ambiguity of utilizing different criteria of time of presentation based on location, calls into question the measure reliability."

Committee Response: The Committee concluded that blood cultures remain important for adjusting antibiotic coverage in patients with severe sepsis and reduced response to treatment and that the bundle of care processes are related to patient outcomes. The Committee determined that the measure met the evidence criteria (Y-12; N-0; I-2).

Reliability of Triage being Time Zero for ED Patients and the Impact of ED Length of Stay

- Another commenter suggests that "Many ED patients will present with uncomplicated pneumonia, urinary tract infection, or cellulitis only to meet the criteria for severe sepsis/septic shock hours later. If the measure calls for early goal directed therapy within three hours of triage, but the patient does not meet criteria for severe sepsis or septic shock until four hours later, then even if all required interventions are completed within an hour, the hospital will fail on this measure as currently specified. That type of measurement does not differentiate hospitals based on the quality of care provided, but rather on the ED length of stay. If used for accountability as specified, this measure could cause the unintended consequence of penalizing large volume and safety net hospitals."
- Another commenter argued that "Time-based measures that potentially start the clock ticking prior to patients meeting the defining criteria of the syndrome in question have to be recognized as invalid. The developers responded that ED patients with infections are "somewhere on the natural trajectory of becoming septic regardless of point of presentation." Statements such as this encourage overly aggressive treatment for patients who do not initially meet criteria for severe sepsis/septic shock due to provider concern of being deemed retrospectively "non-compliant" should the patients' condition subsequently change. The developers state "if the patient who becomes hypotensive or has a high lactate does so in

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the ED, the reason for the presentation to the ED is severe sepsis or shock." While this is true in cases where criteria are met at triage, it's absolutely not the case for those who only do so hours later. Patients present with chief complaints (which are often non-specific), not diagnoses."

Committee Response: There was significant discussion on the post-comment call regarding the reliability of triage being time zero for Emergency Department (ED) patients and the impact of the ED length-of-stay. Some Committee members did agree that certain elements of the measure may be related to hospital situations (beds, changing clinical status) that are out of the control of the provider. The Committee reconsidered their evaluation of reliability and determined it meets the reliability criteria at moderate to high.

Feasibility of Abstracting the Composite Measure

- A commenter noted that "This new composite is far too complex for implementation as a potential accountability measure. Furthermore, all of the data elements and time stamps required to calculate this measure are not readily available discrete fields from existing electronic sources making it a significant burden on hospitals to sort and collect this data."

Committee Response: Committee members discussed the data collection burden for the input of multiple data points and the timestamps. Some members were less concern due to the large number of hospitals who are currently collecting the data for the measure. The Committee reconsidered their evaluation of this criterion and rated feasibility as moderate.

Re-vote following Public and Member Comment

Following the Public and Member Comment period of the addendum report, the Committee decided to re-vote on whether the measure met the NQF criteria for endorsement.

Importance to Measure and Report: The measure met the Importance criteria

(1a. High Impact: 1b. Performance Gap, 1c. Evidence)

1a. Impact: **H-13; M-1; L-0; I-0**; 1b. Performance Gap: **H-5; M-9; L-0; I-0** 1c. Evidence: **Y-12; N-0; I-2**

2. Scientific Acceptability of Measure Properties: The measure met the Scientific Acceptability criteria

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

2a. Reliability: **H-1; M-11; L-2; I-0 2b.** Validity: **H-0; M-14; L-0; I-0**

3. Usability: H-0; M-12; L-1; I-1

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

4. Feasibility: H-0; M-8; L-5; I-1

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Steering Committee Recommendation for Endorsement: Y-11; N-3

0393 Hepatitis C: Testing for chronic hepatitis C – Confirmation of hepatitis C viremia

Status: Maintenance, Original Endorsement: Jul 31, 2008

Description: Percentage of patients aged 18 years and older with a diagnosis of hepatitis C seen for an initial

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evaluation who had HCV RNA testing ordered or previously performed

Numerator Statement: Patients for whom HCV RNA testing was ordered or previously performed

Denominator Statement: All patients aged 18 years and older with a diagnosis of hepatitis C seen for initial evaluation

Exclusions: Documentation of medical reason(s) for not ordering or performing HCV RNA testing

Documentation of patient reason(s) for not ordering or performing HCV RNA testing

Adjustment/Stratification: No risk adjustment or risk stratification None We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.

Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Registry

Measure Steward: American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI) **Other organizations:** American Association for the Study of Liver Diseases, American Gastroenterological Association Institute

STEERING COMMITTEE MEETING [08/28/2012]

Importance to Measure and Report: The measure does not meet the Importance criteria

(1a. High Impact: 1b. Performance Gap, 1c. Evidence)

1a. Impact: **H-16; M-4; L-0; I-0**; 1b. Performance Gap: **NA** 1c. Evidence: **Y-3; N-8; I-9**

Rationale:

- Hepatitis C affects a large portion of the baby boomer population. Recently CDC recommended that all adults born from 1945 to 1965 receive hepatitis C screening. More patients with chronic HCV will be identified.
- More people died in 2007 from hepatitis C than HIV.
- Hepatitis C is a highly prevalent condition with a large health impact. However, there was no evidence provided that this test is not being done.
- The Committee noted that there is little to no disparities data available for hepatitis C for the individual performance measures, though minorities are over-represented in the population of patients with HCV
- Studies on long term benefit or treatment, which results from the test, are all observational except one, and do not look at long term benefits/harms.
- A body of evidence does exist, but weakly addressed in the measure submission. The measure defaults to AASLD guidelines that were based on data and rated IB and 1A. Consistency was not addressed. Additional information provided by PCPI included a meta-analysis of 31 studies and all are consistent with an overall estimate of 15 to 20 percent of people who become infected with hepatitis C who clear the virus. Thus, this test is important in differentiating whether or not people have resolved infection or chronic infection.
- Committee members asked about the evidence that it is important to know whether the patient is viremic if they are not candidates for treatment. Others noted that it is important to other aspects of care such as avoiding alcohol, vaccination, counseling regarding transmission and remaining engaged in care.
- The Committee discussed the need for evidence for a standard assessment measure. NQF staff advised the Committee that CSAC has discouraged assessment measures that are essentially a standard of care.
- Some Committee members concluded that the question regarding the timing of the testing and whether or not the initial time is appropriate and beneficial to patient outcomes, particularly in view of measure 0584: *Hepatitis C: Viral load test* which is testing before therapy.
- The Committee elected not to make an exception for the evidence criteria.

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6. Public and Member Comment

- CDC does not support (encourage recommendation). CDC has recommended prompt RNA confirmation of Hepatitis C without regard to the intent to provide antiviral treatment (Recommendations for Prevention and Control of Hep C Virus (HCV) Infection and HCV-Related Chronic Disease MMWR October 16, 1998 / 47(RR19);1-3 9; Recommendations for the Identification of Chronic Hep C Virus Infection Among Persons Born During 1945–1965 August 17, 2012 / 61(RR04);1-18). CDC does not agree that such testing is performed so regularly that it can be regarded as "standard of care". We recognize that data in the NQF report demonstrate substantial adherence to the recommendation: "CMS Physician Quality Reporting Initiative: Scores on this measure: 95.86% is the aggregate performance rate in the total patient population (N = 1,610) and 95.84% is the mean performance rate of TIN/NPI's

  10th percentile: 87.50%

  25th percentile: 100.00%

  50th percentile: 100.00%

  75th percentile: 100.00%

  90th percentile: 100.00%

  The inter-quartile range (IQR) provides a measure of the dispersion of performance. The IQR is 0.00 and indicates that at least 50% or more of physicians have performance on this measure at 100.00%. The bottom 10% of physicians are performing at or below 87.50%. Source: Confidential CMS PQRI 2009 Performance Information by Measure. TAP file." However, such data may not be representative at all. There are other reports that indicate there is substantial performance gap: Of 20,285 reports of HCV infection received by CDC from state/local surveillance programs in 2006-2007, a total of 10,834 (47.6%) reports had no positive result for HCV RNA. Klevens RM, Miller J, Iqbal K, Thomas A, et al. The Evolving Epidemiology of Hepatitis A in the United States: Incidence and Molecular Epidemiology from Population-Based Surveillance. Arch Intern Med. 2010;170(20):1811-1818. CDC recently reviewed electronic health records of >1,652,055 adult patients seen from January 2006 through December 2010 at 4 integrated healthcare systems in Detroit, Michigan; Danville, Pennsylvania; Portland, Oregon; and Honolulu, Hawaii were collected and analyzed. Of 9086 patients with a positive HCV antibody test, 3428 (37.7%) had no documented follow-up HCV RNA testing in the electronic database." MoormanAC, Gordon SC, Rupp et al. Baseline Characteristics and Mortality Among People in Care for Chronic Viral Hepatitis: The Chronic Hepatitis Cohort Study. Clin Infect Dis.2012 Oct 19. [Epub ahead of print]. A poster presentation from the 2012 IDSA meeting demonstrated a decline in the documentation of HCV viremia from 73% to 63%: "Quality of Hepatitis C care at an urban tertiary medical center" IDSA San Diego Oct 17-21 2012; Sabrina A. Assoumou MD, Wei Huang MA, Benjamin P. Linas, MD MPH.
- The majority of SC members determined that the requirement for evidence was not met. However, a few SC members recognized the importance of the measure and discussed the indirect evidence linking the process to the outcome. Additional information provided by the Work Group included a meta-analysis of 31 studies that found a consistent overall estimate of 15 to 20 percent of people who become infected with acute Hepatitis C will clear the virus. The absence of confirmatory viral testing may then leave these 15 to 20 percent of patients with the mistaken belief that they have chronic Hepatitis C, subjecting these patients to unnecessary anxiety and other harms. The remaining viral positive patients could benefit from the additional counseling for their own and for transmission risk, as mentioned by SC members, namely avoiding alcohol, getting vaccinated, and providing counseling regarding transmission and remaining engaged in care. Thus, this test is critically important in differentiating whether or not people have resolved infection or are currently infected with HCV, regardless of whether antiviral treatment is contemplated. The SC was also concerned that little evidence was provided to demonstrate opportunity for improvement and that, like most assessment measures, it represents the "Standard of Care" and does not warrant a performance measure. However, additional evidence provided by the CDC, Boston Medical

Center and the Cleveland VA Medical Center below shows that a substantial performance gap remains, illustrating that in practice, confirmatory testing after initial HCV antibody testing is NOT being done often enough to constitute "Standard of Care." Of 20,285 reports of HCV infection received by CDC from state/local surveillance programs in 2006-2007, a total of 10,834 (47.6%) reports had no positive result for HCV RNA.1 CDC recently reviewed electronic health records of >1,652,055 adult patients seen from January 2006 through December 2010 at 4 integrated healthcare systems in Detroit, Michigan; Danville, Pennsylvania; Portland, Oregon; and Honolulu, Hawaii. Of 9,086 patients with a positive HCV antibody test, 3,428 (37.7%) had no documented follow-up HCV RNA testing in the electronic database.2 A study conducted at Boston Medical Center of CMS-defined HCV quality indicators, comparing data from 2005-2007 to 2008-2011, revealed a decline in the confirmation of HCV viremia from 73% to 63%.3 Members of the Department of Medicine at Louis Stokes Cleveland Department of Veterans Affairs Medical Center in Cleveland, OH found similar rates of testing in their study and included additional information in their conclusions related to implications. They looked at ~400 people who lacked HCV nucleic acid amplification technology (NAT) testing to characterize behaviors in response to patients who have a positive HCV antibody (ab) test but lack viral confirmatory testing. Below are their findings: 1. 31% of patients with a positive HCV ab test, never had that result acknowledged by a medical provider (HCV ordering or other provider), resulting in missed opportunities for follow-up liver care and Hepatitis C treatment.4 2. In 251 instances, the positive HCV ab test was acknowledged by the ordering provider, and despite the lack of viral NAT, these providers took actions that indicated they believed patients had chronic Hepatitis C.4 These actions included addition of the ICD-9 diagnosis for chronic Hepatitis C to the patient's problem list, ordering serial liver function tests, ordering HAV/HBV vaccinations, etc. Interestingly, very few providers ordered confirmatory NAT in response to the positive HCV ab. 3. In the cases where HCV was entered into the patient's problem list in the EMR, this unconfirmed diagnosis was "perpetuated" by future medical providers that the patient saw in 85% of instances.4 While this data is not randomized, nor does it contain a control group, it highlights some of the misconceptions about HCV diagnosis amongst general medical providers and mental health providers that may order HCV ab tests as part of their practices. Unconfirmed diagnoses of HCV can lead to stigmatization, receipt of unnecessary medical interventions, and avoidance of important medical interventions (e.g., statin use). This may be even more impactful as the CDC's birth cohort screening recommendations trigger more screening. Based on all available evidence, our Hepatitis C Expert Work Group agrees that this measure is of great value. Ultimately, by not recommending Measure #0393, there will be no NQF-endorsed measure to promote use in national measurement programs. We hope that these explanatory comments better clarify the importance of confirming Hepatitis C viremia after initial testing for the HCV antibody to confirm a diagnosis of HCV infection. We respectfully request that the SC reconsider recommending this valuable measure to improve the quality of care provided to patients with Hepatitis C. References: 1 Speers S, Klevens RM, Vonderwahl C, Bryant T, Daniloff E, Capizzi J, Poissant T, Roome A. Electronic matching of HIV/AIDS and hepatitis C surveillance registries in three states. Public Health Rep. 2011 May-Jun;126(3):344-8. 2 Moorman AC, Gordon SC, Rupp et al. Baseline Characteristics and Mortality Among People in Care for Chronic Viral Hepatitis: The Chronic Hepatitis Cohort Study. Clin Infect Dis. 2012 Oct 19. [Epub ahead of print]. 3 Sabrina A. Assoumou MD, Wei Huang MA, Benjamin P. Linas, MD MPH. [Poor] Quality of Hepatitis C care at an urban tertiary medical center. Study conducted at Boston Medical Center. Outcomes: Centers for Medicare & Medicaid (CMS)-defined HCV quality indicators introduced in 2008: HCV RNA testing, Genotype testing, Hep A & Hep B vaccinations. Poster presentation from the Infectious Diseases Society of America (IDSA) meeting, 2012. 4 Yang Liu, BA, Renee H. Lawrence, PhD, Brook Watts, MD, Yngve Falck-Ytter, MD, Amy Hirsch, PharmD. Understanding the Care Gap and Missed Opportunities for Hepatitis C Confirmatory Viral testing. Poster presentation from the Society of General Interal Medicine (SGIM) meeting, 2012.

Committee Response: The Committee agreed that the comments had merit. The purpose of viral load testing is to identify those individuals who need to be linked to a provider who is able to provide counseling for their hepatitis

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C and potential treatment and to differentiate from the individuals who have resolved the infection. Avoiding inappropriate intervention in 15-20 percent of patients that spontaneously resolve the Hepatitis C infection is important. The Committee agreed to reconsider the measure. The measure developer is encouraged to update the measure submission with all relevant information for the Committee to consider. The Committee will evaluate the measure on the December 5 conference call. The final recommendation will be included in the addendum to the main report and has been removed from this current report.

Re-vote following Public and Member Comment

Following the Public and Member Comment period of the draft report, the Committee decided to reconsider the measure.

Importance to Measure and Report: The measure met the Importance criteria

(1a. High Impact: 1b. Performance Gap, 1c. Evidence)

1a. Impact: **H-5; M-8; L-0; I-0**; 1b. Performance Gap: **H-7; M-6; L-0; I-0;** 1c. Evidence: **Y-13; N-0; I-0**

Rationale:

- CDC received 20,285 reports of HCV infection from state and local surveillance programs in 2006-2007, 47 percent of those reports had no positive result for HCV RNA.
- A study conducted at Boston Medical Center showed a decline in the confirmation of HCV viremia from 73 percent (2005-2007) to 63 percent (2008-2011).

2. Scientific Acceptability of Measure Properties: The measure met the Scientific Acceptability criteria

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

2a. Reliability: **H-4; M-9; L-0; I-0** 2b. Validity**: H-3; M-10; L-0; I-0**

Rationale:

- The measure was only tested in EHRs.
- The kappa for the measure result comparing the automated results from the EHR and the visual inspection of the record was 0.948.
- The measure was assessed using face validity (an expert panel of 22 members) with a mean rating of 4.92 out of 5.

3. Usability: H-4; M-9; L-0; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

Rationale:

- This measure has been in used in PQRS since 2008 though not publicly reported.

4. Feasibility: H-6; M-7; L-0; I-0

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

- This measure is specified for use in EHRs.

5. Related and Competing Measures

- No related or competing measures noted.

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Steering Committee Recommendation for Endorsement: Y-13; N-0

Appendix A: Measure Specifications

	0500 Severe sepsis and septic shock: Management bundle
Status	Maintenance, Original Endorsement: Oct 24, 2008, Most Recent Endorsement: Oct 24, 2008 Time-limited
Steward	Henry Ford Hospital Other organizations: Henry Ford Hospital System(HFHS) California Pacific Medical Center/Sutter Health (CPMC) Society of Critical Care Medicine (SCCM) Infectious Diseases Society of America (IDSA) Institute for Healthcare Improvement (IHI) Surviving Sepsis Campaign (SSC) Ohio State University (OSU)
Description	This measure will focus on patients aged 18 years and older who present with symptoms of severe sepsis or septic shock. These patients will be eligible for the 3 hour (severe sepsis) and/or 6 hour (septic shock) early management bundle.
Type	Composite
Data Source	Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Paper Medical Records, Electronic Clinical Data : Registry Surviving Sepsis Campaign Electronic Database: http://www.survivingsepsis.org/manual_database/Pages/default.aspx Paper Tools: http://www.survivingsepsis.org/About_the_Campaign/Documents/monthlymeasurementworksheet.pdf http://www.survivingsepsis.org/About_the_Campaign/Documents/individualchartmeasurementtool.pdf URL http://www.survivingsepsis.org/manual_database/Pages/default.aspx URL http://www.survivingsepsis.org/About_the_Campaign/Documents/le_field_descriptions_and_coding_information.pdf
Level	Facility, Integrated Delivery System
Setting	Hospital/Acute Care Facility
Numerator Statement	If: A. measure lactate level B. obtain blood cultures prior to antibiotics C. administer broad spectrum antibiotics D. administer 30 ml/kg crystalloid for hypotension or lactate >=4 mmol/L E. apply vasopressors (for hypotension that does not respond to initial fluid resuscitation to maintain a mean areterial pressure >= 65)

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	F. In the event of persistent arterial hypotension despite volume resuscitation (septic shock) or initial lactate >=4 mmol/L (36 mg/dl) measure central venous pressure and central venous oxygen saturation G. remeasure lactate if initial lactate is elevated represent processes of care: Numerator statement: Patients from the denominator who received all the following: A, B, and C within 3 hours of time of presentation† AND IF septic shock is present (as either defined as hypotension* or lactate >=4 mmol/L) who also received D and E and F and G within 6 hours of time of presentation. † "time of presentation" is defined as the time of triage in the Emergency Department 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. * "hypotension" is defined as systolic blood pressure (SBP) <90 mm Hg or mean arterial pressure (MAP) <70 mm Hg or a SBP decrease >40 mm Hg or <2 SD below normal for age or known baseline.
Numerator Details	Time Window: Bundle elements should be *completed* in the times outlined in the numerator statement, however patients are *eligible* for inclusion in the numerator if diagnosed with severe sepsis or septic shock at anytime during their hospitalization. Following the scheme outlined in 2a1.1 "A" requires a response of "yes" to the question: "Was a lactate level obtained within 3 hours of time of presentation?" "B" requires a response of "yes" to the question: "Were blood cultures obtained prior to antibiotic administration and within 3 hours of time of presentation?" "C" requires a response of "yes" to the question: "Were broad spectrum antibiotics administered within 3 hours of the time of presentation?" "Septic Shock" requires a response of "yes" to the question: "Was either hypotension (defined as SBP < 90 or MAP < 65 or decrease in SBP 30 mmHg from baseline) OR lactate >=4 mmol/L present in the first 6 hour of the time of presentation?" "D" requires a response of "yes" or "not applicable" to the question: "Were 30ml/kg of crystalloid administered for hypotension or lactate >= 4 mmol/L within 6 hours of the time of presentation?" "E" requires a response of "yes" or "not applicable" to the question: "Were vasopressors applied within 6 hours of the time of presentation for hypotension that did not respond to initial fluid resuscitation to maintain a mean arterial pressure >= 65 mmHg?" "F" requires a response of "yes" or "not applicable" to the question: "Were central venous pressure (CVP) and central venous oxygen saturation (ScVO2) measured within 6 hours of presentation in the event of hypotension despite volume resuscitation or initial lactate >= 4 mmol/L (36 mg/dl)?" "G" requires a response of "yes" or "not applicable" to the question: "Was serum lactate re-measured if initially elevated within 6 hours of presentation."
Denominator Statement	Number of patients presenting with severe sepsis or septic shock.
Denominator Details	Time Window: Patients are eligible for inclusion in the denominator for each episode of severe sepsis or septic shock during a hospitalization from emergency room presentation though discharge. The collection period for each increment of data reporting is monthly.

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	The denominator may be derived by a) prospective real-time screening of all patients presenting for care to the facility, or b) retrospective screening through chart review of all patients presenting to the medical facility, or c) both methods. In each case the clinical diagnostic criteria for severe sepsis or septic shock as outlined below are applied to the population initially identified. The clinical criteria that must be applied in either instance do not vary whether prospective or retrospective data collection is employed. SEVERE SEPSIS: Severe sepsis is defined as a suspected source of clinical infection, 2 or more manifestations of systemic infection (SIRS criteria) and the presence of sepsis-induced organ dysfunction. SIRS criteria include: Temperature >38.3 C or <36.0 C, Heart rate >90 beats per minute, Respiration > 20 breaths/min, White blood cell count >12,000 or <4000/mm3, or >10% bandemia. Organ dysfunction variables include: (SBP)<90 mm Hg or mean arterial pressure <70 mm Hg or a SBP decrease >40 mm Hg or <2 SD below normal for age or known baseline, Creatinine > 2.0 mg/dl (176.8 mmol/L) or Urine Output < 0.5 ml/kg/hour for > 2 hours, Bilirubin > 2 mg/dl (34.2 mmol/L), Platelet count < 100,000, Coagulopathy (INR >1.5 or aPTT >60 secs), Lactate > 2 mmol/L (18.0 mg/dl). SEPTIC SHOCK: Septic shock requires the presence of severe sepsis as above AND as sepsis-induced hypoperfusion persisting despite adequate fluid resuscitation OR lactate > 4 mmol/L. Sepsis induced tissue hypoperfusion is present with (SBP)<90 mm Hg or mean arterial pressure <70 mm Hg or a SBP decrease >40 mm Hg or <2 SD below normal for age or known baseline. If clinical coding documentation is used to derive the denominator in a retrospective collection effort, the codes that should be applied include: ICD9 DX: a) 0031: SALMONELLA SEPTICEMIA b) 0362: MENINGOCOCCEMIA c) 0380: STREPTOCOCCAL SEPTICEMIA d) 03810: STAPH SEPTICEMIA NOS e) 03811: MSSA SEPTICEMIA f) 03812: MRSA SEPTICEMIA g) 03819: STAPH SEPTICEMIA NEC h) 0382: PNEUMOCOCCAL SEPTICEMIA i) 0383: ANAEROBIC SEPTICEMIA j) 03840: GRAM-NEG SEPTICEMIA NOS k) 03841: H. INFLUENZAE SEPTICEMIA l) 03842: E. COLI SEPTICEMIA m) 03843: PSEUDOMONAS SEPTICEMIA n) 03844: SERRATIA SEPTICEMIA o) 03849: GRAM-NEG SEPTICEMIA NEC p) 0388: SEPTICEMIA NEC q) 0389: SEPTICEMIA NOS r) 78552: SEPTIC SHOCK s) 99591: SEPSIS t) 99592: SEVERE SEPSIS

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Exclusions	A) Patients with advanced directives for comfort care are excluded. B) Clinical conditions that preclude total measure completion should be excluded (e.g. mortality within the first 6 hours of presentation as defined above in 2a1.1). C) Patients for whom a central line is clinically contraindicated (e.g. coagulopathy that cannot be corrected, inadequate internal jugular or subclavian central venous access due to repeated cannulations). D) Patients for whom a central line was attempted but could not be successfully inserted. E) Patient or surrogate decision maker declined or is unwilling to consent to such therapies or central line placement.
Exclusion Details	The exclusion details described in 2a1.8 must be ascertained by chart review. No specific definitions are required to discover this information from standard chart annotation.
Risk Adjustment	No risk adjustment or risk stratification None
Stratification	Henry Ford Hospital (HFH) encourages the results of this measure to be stratified by race, ethnicity, gender, and primary language, illness severity and have included these variables as recommended data elements to be collected.
Type Score	Non-weighted score/composite/scale better quality = higher score
Algorithm	The data calculations may be performed in one of two ways. The Surviving Sepsis Campaign Database available at SurvivingSepsis.org automatically performs all calculations if data is entered into the required fields. However, hospitals are not restricted to use of the database to perform the required calculations. Two paper tools described below capture the logic. The two tools, URLs provided in 2a1.26.1, ("Individual Chart Measurement Tool" [ICMT], and "Monthly Measurement Worksheet" [MMW]) govern the calculation of the elements of the "all or nothing" composite measure. The tools, in fact, exceed the information required for calculation of the composite measure extending care to variables beyond the scope of this submission (e.g. care patterns for the first 24 hours of care such as the application of steroids or glucose control; calculation of individual component measures not requested for endorsement at this time). They are provided as a clear, yet highly detailed, statement of the logic. To simplify matters, the algorithm will be described in plain language here: 1. Find the patients who meet the initial patient population (ie, the general group of patients that the performance measure is designed to address). This is accomplished as described in 2a1.7 either through prospective, retrospective or both forms of data screening. Codes and criteria are specified in 2a1.7. 2. From the patients within the initial patient population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria). All exclusions identified by chart review in 2a1.8 will not, by definition, qualify for the denominator. Note: in some cases the initial patient population and denominator are identical. 3. From the patients within the denominator less those excluded, find the patients who qualify for the Numerator (ie, the group of patients in the denominator for whom a process or outcome of care occurs). The individual component elements of the composite indicator (eg, lactate collected, blood cultures obtained, etc.) will be found on each instance of the ICMT (one per patient chart reviewed). Each month, all ICMT's will be gathered and tabulated to generate the composite numerator using the MMW. In this way the MMW consolidates all information gathered in each ICMT to create the composite numerator. For more detail, the steps are

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	identified below: a. The logic on the ICMT captures all necessary data to be abstracted from a single chart to inform the numerator. b. The "time of presentation" is captured as defined in 2a1.1 in question 3 of the ICMT. c. Collection of lactate is determined and timed in question 4 of the ICMT. d. Administration of broad spectrum antibiotics and timing are captured in question 5 of the ICMT. e. Collection of blood cultures and timing is captured in question 6 of the ICMT. f. Next, required determinations to inform the conditional elements in the composite measure are made. Specifically, since component elements "D, E, F, G" defined in 2a1.1 above are dependent on the presence of septic shock, the shock state is documented in question 7 of the ICMT. i. If the patient has shock documentation of the administration of fluids is captured in question 7c of the ICMT. ii. If the patient has shock documentation of the application of vasopressors is captured in question 7e of the ICMT. iii. If the patient has shock documentation of the assessment of CVP and timing is captured in question 8 of the ICMT. iv. If the patient has shock documention of the assessment of ScVO2 and timing is captured in question 9 of the ICMT. g. If shock is not present, credit is assigned for the dependent elements "D, E, F, G" and documented on line 16 of the ICMT. h. The tally of affirmative responses (or where credit has been assigned) to the individual component measures on a per chart basis is recorded by placing a mark in the designated boxes in line 16 of the ICMT. i. Note: questions 10-15 on the ICMT do not apply to the composite measure under submission here. j. Once monthly the MMW will be employed to tabulate all of the line 16 scores on the ICMT to generate the composite numerator for the month. i. While the MMW is designed to report out the component measures as individual quality indicators, this is not required for the composite measure under consideration. Thus, questions 1 to 12 on the MMW are not necessary in this instance. ii. Question 13 on the MMW generates the monthly "all or nothing" numerator by requiring that ALL boxes on line 16 of each ICMT be marked complete. iii. If a single box on line 16 of the ICMT is not completed, then the "all or nothing" criterion is not met and the individual chart is not included in the numerator. This represents a quality failure. iv. Questions 14 and 15 also do not apply to the composite measure under consideration here. 4. Although the exclusion cases are removed from the denominator population for the performance calculation, the number of patients with valid exclusions should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI. URL http://www.survivingsepsis.org/About_the_Campaign/Documents/individualchartmeasurementtool.pdf AND http://www.survivingsepsis.org/About_the_Campaign/Documents/monthlymeasurementworksheet.pdf

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Copyright/ Disclaimer	Performance measures and related data specifications developed by the Henry Ford Hospital in collaboration with representatives from emergency medicine, critical care medicine (SCCM), and infectious diseases (IDSA). These performance measures are not clinical guidelines and do not establish a standard of medical care, and have not been tested for all potential applications. Neither the Henry Ford Hospital nor its affiliates or ageents shall be responsible for any use of the measures.

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Status	Maintenance, Original Endorsement: Jul 31, 2008, Most Recent Endorsement: Jul 13, 2008
Steward	American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI) Other organizations: American Association for the Study of Liver Diseases, American Gastroenterological Association Institute
Description	Percentage of patients aged 18 years and older with a diagnosis of hepatitis C seen for an initial evaluation who had HCV RNA testing ordered or previously performed
Type	Process
Data Source	Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Registry Not Applicable Attachment AMA-PCPI_0393_Confirmation_HepC_Viremia_7.11.12.pdf
Level	Clinician : Group/Practice, Clinician : Individual, Clinician : Team
Setting	Ambulatory Care : Clinician Office/Clinic, Other, Ambulatory Care : Urgent Care Hospital Outpatient Clinic
Numerator Statement	Patients for whom HCV RNA testing was ordered or previously performed
Numerator Details	Time Window: Once, at time of diagnosis EHR Specifications: eSpecifications attached
Denominator Statement	All patients aged 18 years and older with a diagnosis of hepatitis C seen for initial evaluation
Denominator Details	Time Window: 12 consecutive months EHR Specifications: eSpecifications attached
Exclusions	Documentation of medical reason(s) for not ordering or performing HCV RNA testing

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Exclusion Details	The PCPI exception methodology uses three categories of reasons for which a patient may be removed from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are sometimes provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For this measure, exceptions may include medical reason(s) and patient reason(s) for not ordering or performing HCV RNA testing. Where examples of exceptions are included in the measure language, value sets for these examples are developed and included in the eSpecifications. Although this methodology does not require the external reporting of more detailed exception data, the PCPI recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The PCPI also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement. Additional details by data source are as follows: EHR Specifications: eSpecifications attached
Risk Adjustment	No risk adjustment or risk stratification None
Stratification	We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.
Type Score	Rate/proportion better quality = higher score
Algorithm	To calculate performance rates: 1) Find the patients who meet the initial patient population (ie, the general group of patients that a set of performance measures is designed to address). 2) From the patients within the initial patient population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial patient population and denominator are identical. 3) From the patients within the denominator, find the patients who qualify for the Numerator (ie, the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator 4) From the patients who did not meet the numerator criteria, determine if the physician has documented that the patient meets any criteria for denominator when exceptions have been specified [for this measure: medical reason(s) patient reason(s)]. If the patient meets any exception criteria, they should be removed from the denominator for performance calculation. -- Although the exception cases are removed from the denominator population for the performance calculation, the exception rate (ie, percentage with valid exceptions) should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI. If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure. Calculation algorithm is included in data dictionary/code table attachment 2a1.30.

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