TO: Consensus Standards Approval Committee (CSAC)

FR: Reva Winkler, Senior Director
Alexis Morgan, Senior Project Manager

RE: An Amendment to the *National Voluntary Consensus Standards: Infectious Disease Endorsement Maintenance 2012, Addendum Report* Member Voting Results

DA: February 12, 2013

The CSAC will consider the Steering Committee's recommendations for two remaining measures within the Infectious Disease Endorsement Maintenance Project during its February 12th conference call. The complete voting draft addendum report and detailed measure information are available on the project webpage.

Member voting on the two recommended measures ended on February 6, 2013.

NQF MEMBER VOTING RESULTS

All of recommended measures were approved with 76% approval or higher. Representatives of 64 member organizations voted; no votes were received from the Public/Community Health Agency Council. Results for each measure are provided below. (Links are provided to the full measure summary evaluation tables.)

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

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	10	0	1	11	100%
Health Plan	6	0	0	6	100%
Health Professional	10	0	3	13	100%
Provider Organizations	9	4	4	17	69%
Public/Community Health Agency	0	0	0	0	0%
Purchaser	7	0	0	7	100%
QMRI	2	0	2	4	100%
Supplier/Industry	6	0	0	6	100%
All Councils	**50**	**4**	**10**	**64**	**93%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					96%

*equation: Yes/ (Total - Abstain)

Voting Comments:

- No voting comments were received.

Measure 0500 Severe sepsis and septic shock: Management bundle

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	10	0	1	11	100%
Health Plan	6	0	0	6	100%
Health Professional	9	2	2	13	82%
Provider Organizations	5	12	0	17	29%
Public/Community Health Agency	0	0	0	0	0%
Purchaser	7	0	0	7	100%
QMRI	4	0	0	4	100%
Supplier/Industry	4	0	2	6	100%
All Councils	**45**	**14**	**5**	**64**	**76%**
Percentage of councils approving (>50%)					86%
Average council percentage approval					87%

*equation: Yes/ (Total - Abstain)

Voting Comments:

- The Society of Critical Care Medicine and the Infectious Diseases Society of America: The letter of support is attached to this memo. (Attachment A)
- GNYHA: the letter addressed to Ms. Ann Monroe (Attachment B) and a response from the developer to GNYHA (Attachment C) are attached to this memo.
- American Hospital Association: While we think this is an important topic for measurement, and that this may turn out to be the right measurement, we do not see evidence that this measure has undergone a rigorous review to ensure its validity and reliability for comparative reporting or for use in pay for performance programs. It has only been used for internal quality improvement projects and collaboratives.
- AmeriHealth Mercy Family of Companies agrees with concerns raised in prior public comments that measurement of Central Venous Pressure does not meet evidence based medicine criteria. The argument that it is part of a protocol that has improved mortality does not mean that the measurement of CVP contributed to that improvement. Potentially the results could have been better without CVP if the catheters contributed to further infection. So would suggest that on future review the following be removed:
  6) 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 (CVP)
  - Measure central venous oxygen saturation (ScvO2)
- GNYHA voting comment (see page 3)
- Columbia University comment (see page 4)

GNYHA voting comment:
Since 2010, the GNYHA/UHF STOP Sepsis Collaborative has supported 57 hospitals in enhancing clinical systems to identify and treat patients with severe sepsis and septic shock. The Collaboratives diverse participants and inclusive approach across hospitals with varying resources and staffing produced important results which were not sufficiently considered in the development of measure 0500.

Many hospital emergency departments (EDs) lack the capacity to meet the aggressive therapeutic interventions associated with Early Goal Directed Therapy (EGDT) to which the NQF measure criteria map. Hospitals cite limited ED resources pointing to central venous pressure (CVP) measurement and lack of staff to insert and monitor central venous catheters as the reason.

Our Collaborative offered hospitals a choice of adhering to an invasive (EGDT) or a non-invasive protocol. The latter allows hospitals to use ultrasound assessment of responsiveness to intravascular volume administration as an alternative to CVP monitoring and to assess response to treatment using serial measurements of serum lactate measurement instead of mixed venous oxygen saturation (Sv02). Results including 10,000 severe sepsis and septic shock cases show the non-invasive approach being used in >80% of cases and achieving equivalent reductions in mortality as patients monitored with CVP. NQFs measure should encourage and allow all hospitals to optimally care for patients with sepsis rather than the small number of hospitals who are able to consistently deliver EGDT.

Prior to the Collaborative, most hospitals had no protocol-based approach to identification and treatment due to barriers adhering to EGDT. But when given training and evidence to support a non-invasive approach, hospitals quickly implemented these protocols in their EDs. A systematic application of the critical, best-validated components of treatment prompt, sufficient fluid resuscitation, timely, appropriate antibiotics and source control are all included in the non-invasive protocol and individually associated with reduced mortality. Further, evidence supports alternatives to invasive CVP and Sv02 monitoring.

This measure fails to consider evidence that alternative markers to CVP targets exist and are equally effective. Our Collaborative focuses on adapting and translating evidence-based therapies to make them feasible in busy EDs. Jones et al.(2010) successfully tested the hypothesis of non-inferiority between lactate clearance and Scv02 as goals of early sepsis resuscitation. This study's results, which assigned septic patients to one of two protocols, did not demonstrate significantly different in-hospital mortality.

If CVP properly assessed the adequacy of fluid resuscitation, then cost and harm associated with central line placement may be balanced by this benefit. However, Marik et al. 2008 meta-analysis demonstrated CVP to be a poor marker of fluid responsiveness. Currently, there are at least three large national and international trials evaluating CVP for sepsis resuscitation, indicating ongoing controversy with its use.

GNYHA urges NQF to consider the mounting evidence supporting alternatives to CVP measurement. There may be unintended consequences and harm associated with the use of a central line where it is not required. Including central line insertion as a component of the NQF measure may lead to inappropriate use and compromise patient care in order to meet each bundle element.

CVP or Scv02 measurement has not proven to be superior to non-invasive approaches, and is associated with risk of pneumothorax and catheter-associated bacteremia. Recently published data suggest newer

methods to assessing preload responsiveness such as bedside echocardiography, non-invasive cardiac output monitors, and measurement of inferior vena cava dimensions will be incorporated into clinical practice with improved predictive value.

Columbia University voting comment:
On behalf of the NewYork-Presbyterian Hospital, we are grateful for the opportunity to provide comments related to the proposed National Quality Forum (NQF) measure 0500, Severe Sepsis and Septic Shock: Management Bundle, focusing on patients aged 18 and older who present with symptoms of severe sepsis or septic shock. Although we support aims and goals of the Surviving Sepsis Campaign, we have concerns with the NQF measure 0500 as they are currently written.

Although the clinical evidence base supports the value of Early Goal Directed Therapy (EGDT), many hospitals find it difficult to adhere to EGDT processes. The most frequent reason has to do with limited emergency department resources to insert central venous catheters as well as measure and monitor central venous pressure (CVP).

NewYork-Presbyterian Hospital was one of the hospitals in the GNYHA/United Hospital Fund STOP Sepsis Collaborative.The Collaborative offered the 57 participating hospitals a non-invasive protocol as an alternative to the invasive EGDT approach. This non-invasive protocol provides the option of using ultrasound assessment of responsiveness to intravascular volume administration as an alternative to CVP monitoring. It also gives the option of assessing response to treatment using serial measurements of serum lactate measurement instead of mixed venous oxygen saturation. To date, the STOP Sepsis Collaborative found that the non-invasive approach was the choice selected by hospitals in over 80% of sepsis cases treated. Equivalent reductions in mortality were achieved compared with the sepsis cases monitored with CVP measurements.

There is strong and compelling literature to support an alternative to invasive CVP and mixed-venous oxygen saturation monitoring. Jones et al. (2010) successfully tested the hypothesis of non-inferiority between lactate clearance and central venous oxygen saturation as goals of early sepsis resuscitation. The results of this study, which assigned septic patients to one of two protocols an SCV02 group and a lactate clearance group did not demonstrate a significant difference in-hospital mortality.

Furthermore, CVP can be a poor marker of fluid responsiveness. Currently there are at least three large national and international trials evaluating the use of CVP for sepsis resuscitation demonstrating ongoing controversy and clinical equipoise with its use. Until the results of these large trials are known, the importance of CVP in sepsis resuscitation is currently unknown.

NewYork-Presbyterian Hospital urges NQF to reconsider the mounting evidence that supports alternatives to CVP measurement and consideration of these options before finalizing measure 0500. The use of central lines as an essential element in the composite measure may lead to inappropriate or unnecessary use of central lines, compromising patient care in an effort to meet each element of a bundle measure. Measurement of CVP or central venous oxygen saturation with a central venous catheter has not been demonstrated convincingly to be a superior approach to non-invasive approaches, and is inevitably associated with the risk of pneumothorax and catheter-associated bacteremia.

December 28, 2012

National Quality Forum
1030 15th Street NW, Ste. 800
Washington, DC 20005

Re: Member Comment, Measure 0500: Severe Sepsis and Septic Shock Management Bundle

The Society of Critical Care Medicine (SCCM) and the Infectious Diseases Society of America (IDSA), as members of the National Quality Forum (NQF), fully support adoption of Measure 0500. SCCM, a co-developer (with the Henry Ford Hospital System, and in cooperation the Institute for Healthcare Improvement and California Pacific Medical Center) of the measure set, strongly encourages endorsement by the NQF. The bundle provides a framework for performance improvement by delineating immediate clinical interventions that have been shown to reduce mortality even when compliance is modest. Further, adoption will close a measurement gap in direct alignment with the highest national priorities for patient-centered care that improves health outcomes and limits expenses.

There is a national imperative to improve the care delivered to septic patients in the United States. Sepsis is associated with mortality rates ranging between 16% and 49%. These rates are more than eight times higher than those observed in patients admitted to the hospital with other diagnoses. [1] From 2007 to 2009, more than 2,047,038 patients with a sepsis-related illness were admitted to medical facilities. [2] A recent report examining data compiled from 15,022 patients in 165 ICUs demonstrated that, over a two-year period, improved compliance with an earlier version of the measure set was associated with a decline in mortality from 37% to 30.4% – and this dramatic improvement in outcome did not reflect universal compliance. It logically follows that application of the bundle to a larger percentage of patients will result in an even greater decline in mortality. [3] Clearly, further extension of compliance with the measure set is an urgent national priority.

Thus, there is a pressing need to extend the use of the measures to patients in as many additional healthcare facilities as possible. The incidence of sepsis has increased 83% over the last decade, and two-thirds of the patients affected were older than 65 years. [4] As the population continues to age, the imperative becomes even more acute. Providing improved recognition of septic patients and urgent, reliable delivery of the right care, right now must be a universal priority for all patients within our healthcare system.

Measure 0500 exemplifies multidisciplinary care at its best. Early detection and treatment of patients with severe sepsis and septic shock and the universal implementation of the bundle requires the engagement of nurses, physicians, pharmacists, respiratory therapists – indeed, virtually all members of the healthcare team. Septic patients identified in both outpatient and inpatient settings can rapidly progress to develop multiple organ dysfunction. The consequences may be dire. In addition to the high mortality rate, patients who recover from sepsis-induced organ dysfunction may emerge with severe disabilities involving breathing, locomotion, and cognitive function. [5] The adoption of this measure set

by NQF assures improved recognition of this deadly medical emergency, provides much needed structure to facilitate activity, and delineates specific, potentially lifesaving interventions.

After more than six years of data collection and experience with performance improvement in hospitals across the globe, we know that these metrics can be implemented and that their use can save lives. The SSCM and IDSA are in full support of adoption of Measure 0500 and encourage NQF to vote in the affirmative for the sepsis management composite measures.

Sincerely,

David Relman, MD, FIDSA
President, IDSA

Clifford S. Deutschman, MS, MD, FCCM
President, SCCM

References

1. Elixhauser A, Friedman B, Stranges E. Septicemia in U.S. Hospitals, 2009. HCUP Statistical Brief #122, October 2011.
2. Reed K, McBratney S, Thompson D, Nicholas C. Healthgrades emergency medicine in American hospitals study. Health Grades. June, 2010 2011;The First Annual Report(1):1-28.
3. Levy MM, Dellinger RP, Townsend SR, et al. The Surviving Sepsis Campaign: results of an international guideline-based performance improvement program targeting severe sepsis. *Crit Care Med*. 2010;38(2):367-374.
4. Burt CW, McCaig LF, Rechtsteiner EA. Ambulatory medical care utilization estimates for 2005. *Adv Data*. Jun 29 2007(388):1-15
5. Iwashyna TJ, Ely EW, Smith DM, et al. Long-term impairment and functional disability among survivors of severe sepsis. *JAMA*. 2010;304:1787-1794.

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Greater New York Hospital Association
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Kenneth E. Raske, President

January
Eighteen
2013

Ann Monroe, M.A.
Chair, Consensus Standards Approval Committee
National Quality Forum
1030 15th Street N.W., Suite 800
Washington DC, 20005

Dear Ms. Monroe:

On behalf of the Greater New York Hospital Association (GNYHA), I appreciate the opportunity to provide comments related to the proposed National Quality Forum (NQF) measure 0500, *Severe Sepsis and Septic Shock*: *Management Bundle*, focusing on patients aged 18 and older who present with symptoms of severe sepsis or septic shock.

GNYHA is a not-for-profit trade association that represents nearly 250 hospitals and continuing care facilities, all of which are not-for-profit, charitable organizations or publicly sponsored institutions throughout New York State, New Jersey, Connecticut, and Rhode Island.

GNYHA and its members are committed to continually improving the quality and safety of care delivered at our hospitals. Over the past two years, the GNYHA/United Hospital Fund *STOP* Sepsis Collaborative supported 57 hospitals in enhancing their clinical systems to recognize early and effectively treat patients presenting with severe sepsis and septic shock. To participate in the Collaborative, hospitals implemented a severe sepsis protocol in their emergency departments and intensive care units and tracked their protocol adherence. Through this initiative, participating hospitals achieved significant results, including a 22% reduction in severe sepsis inpatient mortality rates from January 2011 to September 2012.

The Collaborative's diverse participants and inclusive approach allowed us to achieve important results across a large group of hospitals with varying resources and staffing complements. The following comments reflect this experience, which we believe was not sufficiently considered in the development of measure 0500. We urge NQF and the Infectious Disease Steering Committee to reconsider some elements of the measure based on real-world experience and results in hospitals with limited resources, as well as the developing scientific evidence to support these elements. Although we support the quality improvement principles of the Surviving Sepsis Campaign and its guidelines, we have concerns with the NQF measure 0500 as they are currently written, as follows:

Many hospital emergency departments do not have the capacity to meet the aggressive therapeutic interventions associated with Early Goal Directed Therapy (EGDT) to which the proposed NQF measure criteria map. While the evidence supports the value of EGDT, both national and local experience suggests that many hospitals do not adhere to EGDT processes and frequently cite limitations of emergency department resources—specifically pointing to measurement of central venous pressure (CVP) and lack of staff to insert and monitor central venous catheters—as the reason.

In 2010, the *STOP* Sepsis Collaborative offered the 57 participating hospitals a choice of adhering to either an invasive (EGDT process steps) protocol or a non-invasive protocol. The difference between the two approaches was that the non-invasive protocol allows hospitals the option of using ultrasound assessment of responsiveness to intravascular volume administration as an alternative to CVP monitoring, and gives the option of assessing response to treatment using serial measurements of serum lactate measurement instead of mixed venous oxygen saturation. Thus far, the *STOP* Sepsis Collaborative recorded the results of treatment of 10,000 cases of severe sepsis and septic shock, and the non-invasive approach was used in >80% of cases, achieving equivalent reductions in mortality with the group monitored with CVP measurements.

Perhaps a more important finding is that before participating in the Collaborative, the majority of the participating hospitals had no protocol-based approach to identifying and treating sepsis because they identified prohibitive barriers to adhering to EGDT procedures. Once provided with training and evidence to support a non-invasive approach, hospitals were quick to adopt these protocols and begin implementing them in their EDs. A systematic application of the most important and best-validated components of treatment—namely, prompt and sufficient fluid resuscitation, administration of appropriate antibiotics, and source control—are all included in the non-invasive protocol and are individually associated with reduced mortality. Further, there is strong and compelling literature to support an alternative to invasive CVP and mixed-venous oxygen saturation monitoring, as described further below.

GNYHA therefore urges NQF to adopt a measure that will encourage and allow for *all* hospitals to do the right thing for patients with severe sepsis and septic shock rather than the select and small number of hospitals who are able to consistently deliver EGDT.

NQF Measure 0500 fails to consider evidence in the literature indicating that alternative markers to CVP targets exist and are equally effective in monitoring patients' achieving resuscitation goals. The GNYHA/UHF *STOP* Sepsis Collaborative's primary focus was the adaptation and translation of evidence-based therapies to make them feasible in busy EDs. Alan Jones, et. al. (2010) successfully tested the hypothesis of non-inferiority between lactate clearance and central venous oxygen saturation as goals of early sepsis resuscitation. The results of this study, which assigned septic patients to one of two protocols—an $S_{CV}0_2$ group and a lactate clearance group—did not demonstrate significantly different in-hospital mortality.

If CVP was a good method of assessing the adequacy of fluid resuscitation, then cost and harm associated with central line placement may be balanced by this benefit. However, Marik et al.'s 2008 meta-analysis demonstrated CVP to be a poor marker of fluid responsiveness. Currently there are at least three large national and international trials evaluating the use of CVP for sepsis

resuscitation demonstrating ongoing controversy and clinical equipoise with its use. The importance of CVP in sepsis resuscitation cannot be quantified until the results of these large trials are known.

GNYHA urges NQF to reconsider the mounting evidence supporting alternatives to CVP measurement and give consideration to these options before finalizing measure 0500.

There may be unintended consequences and harms associated with the use of central lines in situations where they are not required. Including insertion of central lines as an essential element of the composite measure may lead to inappropriate or unnecessary use of central lines, compromising patient care in an effort to meet each element of a bundle measure. Measurement of CVP or central venous oxygen saturation with a central venous catheter has not been demonstrated convincingly to be a superior approach to non-invasive approaches, and is inevitably associated with the risk of pneumothorax and catheter-associated bacteremia. Based on more recently published data, it is likely that newer methods for assessing preload responsiveness such as bedside echocardiography, non-invasive cardiac output monitors, and measurement of inferior vena cava dimensions will be incorporated into clinical practice with improved predictive value.

GNYHA urges NQF to include alternative measures of assessing volume status and adequacy of resuscitation.

While the widespread and systematic adoption and use of severe sepsis and septic shock protocols holds tremendous potential for saving lives and improving morbidity, there is strong evidence to support alternative approaches to the management of severe sepsis and septic shock, and practical experience, including our own, in implementing these approaches with ready acceptance by clinicians and with impressive success. GNYHA looks forward to working with the measure developers, appropriate technical experts, and stakeholders to offer more practical options and to address the issues we have raised. Thank you in advance for the consideration of these comments and recommendations.

Please contact Zeynep Sumer (**zsumer@gnyha.org**) or Alissa D'Amelio (**adamelio@gnyha.org**) with questions about these comments.

Sincerely,

Kenneth E. Raske
President

cc: Gerry Shea, Interim President and Chief Executive Officer
Steven Brotman, M.D., J.D., Co-Chair, Infectious Disease Endorsement Maintenance Steering Committee
Edward Septimus, M.D., F.A.C.P., F.I.D.S.A., F.S.H.E.A., Co-Chair, Infectious Disease Endorsement Maintenance Steering Committee

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February 6, 2012

Kenneth E. Raske
President
Greater New York Hospital Association
555 W. 57th Street
New York, NY 10019

Dear Mr. Raske:

I am writing in my capacity as a member of the Executive Committee of the Surviving Sepsis Campaign (SSC). We are in receipt of your draft letter to Ms. Laura Miller, Interim President and Chief Executive Officer of The National Quality Forum (NQF), which was publicly forwarded to GNYHA hospitals regarding Sepsis Measure #0500 currently being considered by the NQF (attached).

I would like to sincerely congratulate the GNYHA and the STOP Sepsis Collaborative for the powerful work that you are doing. It is challenging to bring together so many hospitals and collect data on the care of severely septic patients. I applaud your commitment and innovation, and I can see the evident success of your effort.

I do have substantial concerns about the content of the letter you have drafted, both in terms of its representation of your results and the representation of the evidence it cites to support your position.

In particular, I am most concerned about the appropriateness of using non-published data to challenge the results of published data. As you know, the data from the Stop Sepsis Collaborative is not yet published. NQF sets a high bar for measure developers in proposing measures to be consistent with the evidence. The purpose of peer review is to ensure the integrity of the data in answering key questions. The key issues that sepsis quality improvement data must answer in peer review are: 1) how does one reassure themselves that the cited gains were not the result of identifying less ill patients as screening got better during the course of the collaborative – that would confound the claimed results irretrievably; and 2) how does one know that there was not an underlying secular trend towards declining mortality in the hospitals due to other interventions such as greater adherence to VAP bundles and CLABSI reductions – if so, there may be no actual gains attributable to the STOP collaborative.

To date, only the SSC data has answered these questions in peer review. We were able to do so statistically taking advantage if the staggered enrollment of patients over calendar time to show that mortality was not decreasing during the course of the intervention and through risk adjustment we demonstrated our patients were as severely ill at the beginning of the trial as afterwards.[1] This published data actually supports the intervention that you are most concerned about in your letter, the assessment of central venous pressure (CVP) and central venous oxygenation saturation (ScvO2), a.k.a early goal directed therapy (EGDT).

In the letter you state that your primary concern is that "…many hospitals do not adhere to EGDT processes and frequently cite the limitations of emergency department resources," but I am compelled to respectfully point out that the aim of improvement is not to just endorse strategies hospitals *already adhere to* as best practice. That would

[1] Levy MM, Dellinger RP, Townsend SR, The Surviving Sepsis Campaign: results of an international guideline-based performance improvement program targeting severe sepsis. Crit Care Med. 2010 Feb;38(2):367-74.

leave us with few avenues to improve. Moreover, the SSC data comes from more than 200 hospitals, the bulk of which were community facilities that improved their ability to comply with EGDT suggesting hospitals can exceed their current practice and improve.

Your draft letter implies that the community hospitals you represent cannot place central lines as required under Sepsis #0500. The published experience of the SSC would stand in against that notion. It may be the case that hospitals and physicians will not place central lines unless compelled by evidence based standards, but it seems less likely that they cannot place lines. Virtually all acute care facilities in the country have the ability to place central lines or PICC lines. This stands in distinction to the strategies that you are recommending in place of central access – the use of ultrasound and echocardiograms to assess volume status. It seems uncontestable that fewer clinicians are trained in the emergency department or in critical care to use ultrasound for volume assessment than to place central lines. Nevertheless, on your website you provide data (reproduced below) indicating that 65% of your hospitals are using the non-invasive technique:

8,556 patients with Severe Sepsis reportec through June 2012

Means of Resuscitation	#	%
Serum Lactate Drawn	7,145	84%
Central Line Inserted	2,752	32%

Protocol Use	#	%
Non-Invasive	5,583	65%
Invasive	2,342	27%
No Response	631	7%

:

When one further reviews just what this non-invasive technique is, the same slide set indicates that only 38% percent of these patients are receiving ultrasound assessment, but 47% are receiving “empiric fluid loading” without declaring what type of assessment they are actually receiving to determine if the fluid load is adequate:

8,556 patients with Severe Sepsis reported through June 2012

Means of Fluid Assessment	#	%
Empiric Fluid Loading	3,236	38%
Central Venous Pressure (CVP)	1,146	13%
IVC Ultrasound	147	2%
Other	301	4%
No Response	3,990	47%

Thus, only a third of the hospitals at best can use ultrasound as the STOP Sepsis Collaborative data suggest and 47% may or may not be assessing volume with any technique. Compared to the universal capability to place central access (a technique for which all emergency physicians or intensivists have at some point been trained), empiric fluid loading or ultrasound assessment would appear to be a challenging strategy to endorse based on the STOP Sepsis Collaborative data.

In your draft letter, I notice that you cite Allan Jones' 2010 paper in JAMA to support your approach of non-invasive monitoring. This paper sought to demonstrate that a strategy of clearing lactate by progressive fluid administration with a drop of 10% or more was equivalent to optimizing the central venous oxygenation (Scv02) in terms of mortality reduction. I wish to clarify that the Jones paper, does not support your conclusions that central venous access is unnecessary. In fact, every patient in the trial received central venous access and had the CVP optimized. The paper specifically notes in the intervention section, "[w]e randomly assigned patients to 1 of 2 resuscitation protocols. The ScvO2 group was resuscitated to normalize central venous pressure, mean arterial pressure, and ScvO2 of at least 70%; and the lactate clearance group was resuscitated to normalize central venous pressure, mean arterial pressure, and lactate clearance of at least 10%." Thus, the paper in fact supports central access.[2]

As the Infectious Disease Project Committee at NQF reviewing Sepsis #0500 has considered many times now, CVP may not be the most robust measure of volume status, but no other measure has ever been shown to be better, especially as part of a sepsis resuscitation protocol. We are left with the knowledge that when CVP is used as part of a larger protocol, mortality does decline in the peer reviewed literature.[3] Thus, the committee has twice voted in favor of the inclusion of CVP and ScvO2.

Lastly, I wish to point out as regards the unintended consequences of central line placement, the best evidence states that consequences that may be fatal occur less than <= 1% of the time (pneumothorax or hemothorax) with central line placement.[4] The 7% ARR in mortality with the SSC strategy shown in the Levy 2010 paper (cited above) would

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[2] It should also be noted that the evidence in the Jones paper has been ranked as inferior to the evidence supporting early goal directed therapy in the only evidence based guidelines published on the topic: Dellinger RP, Levy MM, Rhodes A et al. Surviving Sepsis Campaign: International Guidelines for Management of Severe Sepsis and Septic Shock: 2012. Crit Care Med. 2013 Feb;41(2):580-637.

[3] Please see the original NQF Sepsis #0500 submission section **1c.6. "Quantity of Studies in the Body of Evidence" for 55 citations confirming these findings.**

[4] Eisen LA, Narasimhan M, Berger JS, Mayo PH, Rosen MJ, Schneider RF, Mechanical complications of central venous catheters. J Intensive Care Med. 2006;21(1):40.

thus seem to overwhelm the risk of mortality due to line placement. Most of the time even pneumothorax or hemothorax, while severe complications, are not fatal conditions.

In conclusion, I believe the right thing for Stop Sepsis and GNYHA to do is to publish the information you are gathering and then present it as part of regular order in the Consensus Standards Development Process at the next review point. The NQF measure development process is designed to consider new evidence at staged intervals as it is available in the literature. I for one would be delighted to see published alternatives to our strategy to make it even stronger.

Please do not hesitate to contact me if you should have any questions or comments.

Best regards,

Sean R. Townsend, M.D.

CC: Ann Monroe, M.A., Chair Consensus Standards Approval Committee

Appendix D: Measure Evaluation Summary Tables

LEGEND: Y = Yes; N = No; H = High; M = Moderate; L = Low; I = Insufficient

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)

0500 Severe sepsis and septic shock: Management bundle

Infectious Diseases Society of America (IDSA)
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.

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.

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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 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.

0500 Severe sepsis and septic shock: Management bundle

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 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

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

(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.

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-

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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 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

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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

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• No related or competing measures noted.
Steering Committee Recommendation for Endorsement: Y-13; N-0