



Measure Information - Composite

This document contains the information submitted by measure developers/stewards, but is organized according to NQF's measure evaluation criteria and process. The item numbers refer to those in the submission form but may be in a slightly different order here. In general, the item numbers also reference the related criteria (e.g., item 1b.1 relates to subcriterion 1b).

Brief Measure Information

NQF #: 0500

De.2. Measure Title: Severe Sepsis and Septic Shock: Management Bundle

Co.1.1. Measure Steward: Henry Ford Hospital

De.3. Brief Description of Measure: 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.

1d.3. Developer Rationale: The purpose of Henry Ford Hospital's severe sepsis and septic shock early management bundle is to support the efficient, effective, and timely delivery of high quality sepsis care in support of the IOM's aims for improvement. This is consistent with the HHS National Quality Strategy's priorities directed at one of the leading causes of mortality. By providing timely patient-centered care, and making sepsis care more affordable through early intervention, reduced resource use and complication rates can result. The Severe Sepsis and Septic Shock Early Management Bundle provides a standard operating procedure for the early risk stratification and management of a patient with severe infection. Through applying this standard operating procedure a clinically and statistically significant decrease in organ failure, mortality, and the utilization of health care resources has been demonstrated for over ten years. The current measure project aimed to review and update the existing NQF #0500 Severe Sepsis and Septic Shock Management Bundle to ensure it reflects the latest guideline recommendations, address areas most in need of performance improvement, and incorporate results of worldwide data collection and quality improvement initiatives. Henry Ford Hospital consulted with leadership and representatives from critical care medicine (Society of Critical Care Medicine), infectious diseases (Infectious Diseases Society of America), and emergency physicians to review and update the Severe Sepsis and Septic Shock Early Management Bundle.

S.4. 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 hypotension after initial fluid administration (MAP < 65 mm Hg) or if initial lactate was = 4 mmol/L, re-assess volume status and tissue perfusion and document findings.*

* To meet the requirements, a focused exam[†] by a licensed independent practitioner (LIP) or any 2 other items are required:

- Measure CVP
- Measure ScvO₂
- Bedside cardiovascular ultrasound
- Dynamic assessment of fluid responsiveness with passive leg raise or fluid challenge
- Focused exam[†] including vital signs, cardiopulmonary, capillary refill, pulse and skin findings.

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.

S.7. Denominator Statement: Number of patients presenting with severe sepsis or septic shock.

S.10. Denominator 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.

F) Patients transferred to an acute care facility from another acute care facility.

De.1. Measure Type: Composite

S.23. Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Medical Records

S.26. Level of Analysis: Facility, Integrated Delivery System

IF Endorsement Maintenance – Original Endorsement Date: Jun 07, 2012 **Most Recent Endorsement Date:** Nov 10, 2014

1d.1. Composite Measure Construction:

Component Measures (if endorsed or submitted for endorsement):

1. Evidence, Performance Gap, Priority – Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. **Measures must be judged to meet all subcriteria to pass this criterion and be evaluated against the remaining criteria.**

1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form

[0500_Evidence_CompositeMSF1.0_Data.doc](#)

1b. Performance Gap

Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:

- considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or
- disparities in care across population groups.

1b.1. Briefly explain the rationale for this measure (e.g., the benefits or improvements in quality envisioned by use of this measure)

The benefits of the improvement in quality of care delivered to patients with severe sepsis and septic shock is improved mortality, decreased organ failure and decreases in the utilization of health care resources such as hospital length of stay, total costs of hospitalization, mechanical ventilation, hemodialysis and time spent in long term care facilities.

1b.2. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis. *(This is required for endorsement maintenance. Include mean, std dev, min, max, interquartile range, scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included). This information also will be used to address the subcriterion on improvement (4b.1) under Usability and Use.*

MEASURE LACTATE:

Measurement of lactate levels has been specifically associated with improved outcomes in sepsis, and an elevated lactate value identifies patients at higher risk for poor outcomes.(1,2) Up to 10% of in-hospital cardiac arrest in the US per year is secondary to sepsis (pneumonia). These patients are often misdiagnosed and sent to the medical floors only to suffer acute hemodynamic deterioration. These outcomes could be potentially avoided with lactate measurement upon admission providing risk stratification triggering alternative dispositions.

In the first quarter of a multicenter quality improvement program for sepsis care, only 61.0% of patients had lactate values measured consistent with guidelines.(3) In addition, prior studies have shown that care prompted by measurement of lactate levels in sepsis patients reduces resource utilization and cost.(4) This leads to lower likelihood of hospital-acquired conditions. This performance measure has been previously used as a core component of multicenter (5) and national quality improvement initiatives.(3) Formalizing it as a national performance measure will provide direct targets for intervention that are closely linked with improvements in mortality and cost.

BLOOD CULTURES:

In the first quarter of a multicenter quality improvement program for sepsis care, only 64.5% of patients had blood cultures collected.(3) Collecting blood cultures has been specifically associated with improved outcomes in sepsis, and pathogens identified by blood cultures allow for customized therapy. As a result, this is a recommendation of the current Surviving Sepsis Guidelines.(5) By obtaining blood cultures, antibiotic regimens can be customized to treat the specific infecting organism. This will result in less unneeded exposure to antibiotics, reducing complications associated with antibiotic use, including drug reactions, allergies and 5 adverse events, the development of drug-resistant organisms, and the occurrence of Clostridium difficile colitis. The performance measure for collecting blood cultures for suspected sepsis has been previously used as a core component of multicenter and national quality improvement initiatives.(3,5-6)

TIMELY ANTIBIOTICS:

In a multicenter observational study of antibiotics in septic shock, the median time to appropriate antibiotics was 6 h after shock.(7) In the first quarter of a multicenter quality improvement program for sepsis care, only 60.4% of patients received timely antibiotics.(3) Multiple studies have demonstrated that delays in administration of appropriate antibiotics in patients with sepsis and other severe infections are associated with longer lengths of stay, higher costs, and higher mortality.(6) In septic shock, a multicenter cohort study demonstrated that every hour in delay of appropriate antibiotics was associated with a 7.6% higher mortality. In a multicenter quality improvement project, the timely administration of broad-spectrum antibiotics was associated with significantly higher risk adjusted survival.(3) Based on a preponderance of data, the current recommendations in the international guidelines for the management of severe sepsis and septic shock includes the administration of broad-spectrum antibiotic therapy within 1 h of diagnosis of septic shock and severe sepsis.(5)

FLUID RESUSCITATION:

A common finding in patients with septic shock, manifested by low blood pressure and/or other signs of organ hypoperfusion, such as elevated serum lactate levels, is intravascular volume depletion. The degree of the intravascular volume deficit in sepsis varies, yet nearly all patients require initial volume resuscitation and many patients require continuing fluid resuscitation over the first 24 h. Early fluid resuscitation is associated with improved outcomes for patients with ALI due to septic shock.(8) International guidelines recommend that patients with suspected hypovolemia be initially treated with at least 1,000 mL of crystalloid over 30 min to determine clinical response.(5) In the first quarter of a multicenter quality improvement program for sepsis care, only 59.8% of patients received fluid resuscitation consistent with guidelines.(3) Timely fluid resuscitation avoids an error of omission in which indicated therapy is delayed or omitted. By improving outcomes, length of stay is reduced. This leads to lower likelihood of hospital-acquired conditions. This performance measure has been previously used as a core component of multicenter and national quality improvement initiatives.(3,9) Formalizing it as a national performance measure will provide direct targets for intervention that are closely linked with improvements in mortality and cost.

LACTATE CLEARANCE:

Elevated lactate levels prompt the consideration of specific care practices toward hemodynamic optimization guided by either central venous oxygen saturation (10) or lactate clearance.(11) International guidelines(5) recommend that patients with sepsis and

continued elevated lactate values have additional therapies until lactate levels are normalized. However, normal lactate levels can be seen in septic shock.

VASOPRESSORS, CVP, and ScvO₂:

Performance gaps in individual bundle elements can range from 79% (CI 69-89%) for vasopressors, to 27% (CI 18-36%) for CVP measurement, and as low as 15% (CI 7-23%) for ScvO₂ in some community emergency departments.(12) These numbers increase (50-75%) in larger hospital settings. CVP has been shown to have a significant association with mortality (20) and multiple studies and meta-analysis have shown a significant association with reaching an ScvO₂ of 70% and improved mortality.(20-26).

OVERALL BUNDLE COMPLIANCE:

Multicenter efforts to promote bundles of care for severe sepsis and septic shock was associated with improved guideline compliance and lower hospital mortality.(6) Even with compliance rates of less than 30%, absolute reductions in mortality of 4-6% has been noted.(3,6) Absolute reductions in mortality of over 20% has been seen with compliance rates of 52%.3 Coba et al has shown that when all bundle elements are completed and compared to patients who do not have bundle completion, the mortality difference is 14%.(27) Thus, there is a direct association between bundle compliance and improved mortality. Without a continuous quality initiative (CQI), even these compliance rates will not improve and will decrease over time.(6) Multiple studies have shown that standardized order sets, enhanced bedside monitor display, telemedicine and comprehensive CQI feedback is feasible, modifies clinician behavior and is associated with decreased hospital mortality.(14-19)

1b.3. If no or limited performance data on the measure as specified is reported in 1b2, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement.

1. Trzeciak S, Dellinger RP, Abate NL, Cowan RM, et al. Translating research to clinical practice: a 1-year experience with implementing early goal-directed therapy for septic shock in the emergency department. CHEST.2006 Feb; 129(2):225-32.
2. Drumheller B, Goyal M, Pines J et al. Elevated point-of-care lactate at triage is predictive of admission among sepsis patients presenting to the emergency department. Ann Emerg Med 2007; 50: S21–2.
3. Levy MM, Dellinger RP, et al.; Surviving Sepsis Campaign. 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
4. Otero R, Nguyen B, Huang D et al. Early Goal-Direct therapy in severe sepsis and septic shock revisited. CHEST 2006 Nov; 130(5):1579-95.
5. Dellinger RP, Levy MM, Carlet JM, Bion J, et al. Surviving Sepsis Campaign: international guidelines for management of severe sepsis and septic shock. Crit Care Med. 2008 Jan;36(1):296-327.
6. Ferrer R, Artigas A, et al. Improvement in Process of Care and Outcome After a Multicenter Severe Sepsis Education Program. JAMA 2008;299(19):2294-2303
7. Kumar A, Roberts D, Wood K, Light B, et al. Duration of Hypotension before Initiation of Effective Antimicrobial Therapy is the Critical Determinant of Survival in Human Septic Shock. Crit Care Med. 2006;34 (6):1589-96
8. Murphy C, Schramm G, Doherty J, et al. The Importance of Fluid Management in Acute Lung Injury Secondary to Septic Shock. CHEST . 2009 July; vol 136, no. 1;102-109
9. Suarez D, Ferrer R, Artigas A. et al. Cost-effectiveness of the Surviving Sepsis Campaign protocol for severe sepsis. Intensive Care Med. 2011 Mar;37(3):444-52
10. Rivers E, Nguyen B, Havstad S et al. Early goal-directed therapy in the treatment of severe sepsis and septic shock. N Engl J Med 2001; 345: 1368–77.
11. Jones AE, Shapiro NI, Trzeciak S et al. for the Emergency Medicine Shock Research Network (EMShockNet) Investigators. Lactate clearance vs central venous oxygen saturation as goals of early sepsis therapy. JAMA 2010; 303: 739–46.
12. O’Neill R, Morales J, and Jule M. Early goal directed therapy for severe sepsis and septic shock: which components of treatment are more difficult to implement in a community-based emergency department. Journal of Emergency Medicine 2011. 1-8.
13. Nguyen HB, Corbett SW, Clark RT, Cho T, Wittlake WA. Improving the Uniformity of Care with a Sepsis Bundle in the Emergency Department. Ann Emerg Med. 2005;46(3, Supplement 1):83-83.
14. Thiel SW, Asghar MF, Micek ST, Reichley RM, Doherty JA, Kollef MH. Hospital-wide impact of a standardized order set for the management of bacteremic severe sepsis. Crit Care Med. Mar 2009;37(3):819-824.
15. Micek ST, Roubinian N, Heuring T, et al. Before-after study of a standardized hospital order set for the management of septic shock. Crit Care Med. Nov 2006;34(11):2707-2713.
16. Winterbottom F, Seoane L, Sundell E, Niazi J, Nash T. Improving Sepsis Outcomes for Acutely Ill Adults Using Interdisciplinary Order Sets. Clin Nurse Spec. July/August 2011;25(4):180-185.
17. Schramm GE, Kashyap R, Mullon JJ, Gajic O, Afessa B. Septic shock: A multidisciplinary response team and weekly feedback to

- clinicians improve the process of care and mortality. Crit Care Med. Feb 2011;39(2):252-258.
18. Nguyen HB, Corbett SW, Steele R, et al. Implementation of a bundle of quality indicators for the early management of severe sepsis and septic shock is associated with decreased mortality. Crit Care Med. Apr 2007;35(4):1105-1112.
 19. Loyola S, Wilhelm J, Fornos J. An innovative approach to meeting early goal-directed therapy using telemedicine. Crit Care Nurs Q. Jul-Sep 2011;34(3):187-199.
 20. Varpula M, Tallgren M, Saukkonen K, Voipio-Pulkki LM, Pettila V. Hemodynamic variables related to outcome in septic shock. Intensive Care Med. Jun 23 2005;31:1066-1071.
 21. Pope JV, Jones AE, Gaieski DF, Arnold RC, Trzeciak S, Shapiro NI. Multicenter study of central venous oxygen saturation (ScvO₂) as a predictor of mortality in patients with sepsis. Ann Emerg Med. Jan 2010;55(1):40-46 e41.
 22. Castellanos-Ortega A, Suberviola B, Garcia-Astudillo LA, et al. Impact of the surviving sepsis campaign protocols on hospital length of stay and mortality in septic shock patients: Results of a 3-year follow-up quasi-experimental study. Crit Care Med. Feb 11 2010.
 23. Jeong SJ, Song YG, Kim CO, et al. Measurement of Plasma sTREM-1 in Patients with Severe Sepsis Receiving Early Goal-Directed Therapy and Evaluation of Its Usefulness. Shock. Mar 5 2012.
 24. Cannon CM, for the Multicenter Severe S, Septic Shock Collaborative G. The GENESIS Project (GENERALization of Early Sepsis InterventionS): A Multicenter Quality Improvement Collaborative. Acad Emerg Med. 2010;17(11):1258.
 25. Chamberlain DJ, Willis EM, Bersten AB. The severe sepsis bundles as processes of care: A meta-analysis. Aust Crit Care. Feb 14 2011.
 26. Grissom CK, Morris AH, Lanken PN, et al. Association of physical examination with pulmonary artery catheter parameters in acute lung injury. Crit Care Med. Oct 2009;37(10):2720-2726.
 27. Coba V, Whitmill M, Mooney R, et al. Resuscitation Bundle Compliance in Severe Sepsis and Septic Shock: Improves Survival, Is Better Late than Never. J Intensive Care Med. Jan 10 2011.

1b.4. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability. *(This is required for endorsement maintenance. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include.) This information also will be used to address the subcriterion on improvement (4b.1) under Usability and Use.*

Although it can affect anyone at any age, it is more common in infants, elderly, minorities and patients with chronic health conditions. Patients, particularly the elderly, who present with sepsis can have symptoms for over 24 before presenting to the hospital. Medicaid and Medicare beneficiaries also suffer disproportionately compared to those with private insurance or self-payers.[1-4] It is projected that over 50% of the U.S. population will be over 50 years of age by 2020.[5] This makes it imperative to examine quality initiatives that will not only improve care but also ameliorate the increasing pressure on Medicare Trust Fund which is projected to be insolvent by 2024. Because of diminished access to health care, minorities have a disproportionate greater use of the ED and are thus affected in greater numbers and of higher illness severity upon presentation.[6] These disparities can be partially ameliorated by focused interventions directed at these high risk patient populations.[7,8,9]

1b.5. If no or limited data on disparities from the measure as specified is reported in 1b4, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations.

1. National Healthcare Disparities Report 2011. Agency for Healthcare Research and Quality. March 2012: p. 146-147.
2. Wilper, A.P., et al., Waits to see an emergency department physician: U.S. trends and predictors, 1997-2004. Health Aff (Millwood), 2008. 27(2): p. w84-95.
3. Barnato, A.E., et al., Racial variation in the incidence, care, and outcomes of severe sepsis: analysis of population, patient, and hospital characteristics. Am J Respir Crit Care Med, 2008. 177(3): p. 279-84.
4. Rodriguez RM, Passanante M, Phelps MA, et al. Delayed emergency department presentation in critically ill patients. Crit Care Med. Dec 2001;29(12):2318-2321.
5. Angus DC, Linde-Zwirble WT, Lidicker J, Clermont G, Carcillo J, Pinsky MR. Epidemiology of severe sepsis in the United States: analysis of incidence, outcome, and associated costs of care. Crit Care Med. 2001;29(7):1303-1310.
6. Burt CW, McCaig LF, Rechtsteiner EA. Ambulatory medical care utilization estimates for 2005. Adv Data. Jun 29 2007(388):1-15.
7. Wilper AP, Woolhandler S, Lasser KE, et al. Waits to see an emergency department physician: U.S. trends and predictors, 1997-2004. Health Aff (Millwood). Mar-Apr 2008;27(2):w84-95.
8. Barnato AE, Alexander SL, Linde-Zwirble WT, Angus DC. Racial variation in the incidence, care, and outcomes of severe sepsis: analysis of population, patient, and hospital characteristics. Am J Respir Crit Care Med. Feb 1 2008;177(3):279-284.
9. El Solh AA, Akinnusi ME, Alsawalha LN, Pineda LA. Outcome of Septic Shock in Older Adults After Implementation of the Sepsis "Bundle". J Am Geriatr Soc. Nov 27 2007.

1c. High Priority (previously referred to as High Impact)

The measure addresses:

- a specific national health goal/priority identified by DHHS or the National Priorities Partnership convened by NQF; OR
- a demonstrated high-priority (high-impact) aspect of healthcare (e.g., affects large numbers of patients and/or has a substantial impact for a smaller population; leading cause of morbidity/mortality; high resource use (current and/or future); severity of illness; and severity of patient/societal consequences of poor quality).

1c.1. Demonstrated high priority aspect of healthcare

Affects large numbers, A leading cause of morbidity/mortality, Frequently performed procedure, High resource use, Patient/societal consequences of poor quality, Severity of illness

1c.2. If Other:

1c.3. Provide epidemiologic or resource use data that demonstrates the measure addresses a high priority aspect of healthcare.

List citations in 1c.4.

Sepsis, severe sepsis and septic shock can arise from a simple infection such as pneumonia, insect bite or urinary tract infection. Although it can affect anyone at any age, it is more common in infants, the elderly and patients with chronic health conditions such as diabetes and immunosuppressive disorders such as transplant patients. This condition is associated with a mortality rates of over 16-49%, which is over eight times higher than the rate for inpatient stays for other hospital admission.[1] Findings from the National Hospital Discharge Survey indicate that the number of hospital stays for septicemia more than doubled between 2000 and 2008, and patients with this conditions were more severely ill than patients hospitalized for other conditions.[3] Severe sepsis and septic shock is a frequent cause of re-hospitalizations, especially during the first year after the initial hospitalization.[4] From 1997 to 2008, costs related to septicemia grew at almost three times the rate of costs for overall hospital stays related to other conditions. The national bill for sepsis, pneumonia (sepsis caused by a lung infection) grew twice as fast as the overall growth in hospital charges—about a 180 percent increase from 1997 to 2005, accounting for over \$54 Billion per year. When combined with pneumonia, sepsis is the 3rd largest consumer of Medicare, 4th largest consumer of Medicaid and 5th largest consumer of private insurance financial resources and total hospital days. This figure is expected to increase as over 50% of the U.S. population will be over 60 years of age within the next 20 years. Thus, sepsis is also one of the top 5 most costly diseases treated in hospitals in the U.S.

Based on national discharge data reported by AHRQ (1), sepsis was the sixth most common principal reason for hospitalization in the United States in 2009, accounting for 836,000 hospital stays. There were an additional 829,500 stays with a secondary diagnosis of sepsis for a total of 1,665,400 inpatient stays and 258,000 deaths. From 1993 to 2009, sepsis-related hospital stays increased by 153%, with an average annual increase of 6%. Medicare was the predominant payer for sepsis-related hospital stays, covering 58.1% of patients. Sepsis cases and sepsis-related deaths are expected to continue to increase with the aging of the population.

Improvements in survival for acute myocardial infarctions or heart attacks (mortality 10%), trauma (mortality 5%), and stroke (mortality 15-20%) which are in the top 20 most expensive disease have been realized through early identification and implementation of time-sensitive therapies at the most proximal stage of disease presentation in the Emergency Department (ED). However, similar approaches to patients with severe sepsis and septic shock have been lacking. In a landmark study by Rivers et. al., it has been shown that an absolute and relative reduction in mortality from sepsis can be reduced 16 and 30%, respectively, when aggressive care is provided within 6 hours of hospital arrival. Furthermore, a recent study of a large national inpatient sample determined that patients admitted through the Emergency Department had a 17% lower likelihood of dying from sepsis than when directly admitted.[5]

From 2007 to 2009, over 2,047,038 patients were admitted with a sepsis-related illness.(6) For sepsis patients presenting to the hospital, 52.4% are diagnosed in the ED, 12.8% in the ICU and 34.8% on the hospital wards. The mortality is 27.6%, 41.3% and 46.8% for each of these respective locations.(7) Over 825,300 cases of sepsis present to Emergency Departments (ED) yearly and is the most common diagnosis resulting in hospital stays.(3) It is critically important that patients are diagnosed as soon as possible as mortality can almost 20% higher if a patient is sent the general floors instead of the ICU from the ED. It has also been shown that 12.8% of in-hospital cardiac arrests admitted from home have an admitting diagnosis of pneumonia.(8) This speaks to the fact that these patients are misdiagnosed and sent to the hospital wards to later deteriorate into cardiac arrest.

In contrast, other common diseases such as stroke, acute myocardial infarction and trauma have even lower mortalities because of standard operating procedures or quality measures for early diagnosis and management. Only in the last decade has there been a

similar approach to severe sepsis and septic shock which occurs just as frequent and is 5 times more deadly.(9)

The incidence of sepsis increased 83% over the last decade and two-thirds of the patients affected were over the age of 65 years.(10) It is projected that over 50% of the U.S. population will be over 50 years of age by 2020.(2, 12 These observations speak to the inordinate burden on Medicare and Medicaid resources both present and future that make this proposal highly relevant. Interventions to improve sepsis care would lead to significant reduction in morbidity, mortality, and health care resource consumption.(4, 13-20)

1c.4. Citations for data demonstrating high priority provided in 1a.3

1. Elixhauser, A., Friedman, B., and Stranges, E. Septicemia in U.S. Hospitals, 2009. HCUP Statistical Brief #122. October 2011
2. Wang, H.E., et al., National estimates of severe sepsis in United States emergency departments. Crit Care Med, 2007
3. Hall, M.J., Williams, S.N., DeFrances, C.J., Golosinskiy, A. Inpatient care for septicemia or sepsis: A challenge for patients and hospitals. NCHS data brief, no 62. Hyattsville, MD: National Center for Health Statistics. 2011
4. Lee H, Doig CJ, Ghali WA, Donaldson C, Johnson D, Manns B. Detailed cost analysis of care for survivors of severe sepsis. Crit Care Med. Apr 2004;32(4):981-985.
5. Powell, ES, Khare, RK, Courtney, DM, Feinglass, J. Lower mortality in sepsis patients admitted through the ED vs direct admission. Am J Emerg Med, 2011. 30(3): p. 432-439 .
6. 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.
7. Levy MM, Dellinger RP, Townsend SR, et al. The Surviving Sepsis Campaign: results of an international guideline-based performance improvement program targeting severe sepsis. Critical Care Medicine. Feb 2010;38(2):367-374.
8. Carr GE, Edelson DP, Yuen TC, et al. In-Hospital cardiac arrest among patients with coexisting pneumonia: a report from the american heart association's get with the guidelines - resuscitation program. Am. J. Respir. Crit. Care Med. May 1, 2011 2011;183(Meeting Abstracts):A6339.
9. Rivers E, Nguyen B, Havstad S, et al. Early goal-directed therapy in the treatment of severe sepsis and septic shock. N Engl J Med. Nov 8 2001;345(19):1368-1377.
10. Burt CW, McCaig LF, Rechtsteiner EA. Ambulatory medical care utilization estimates for 2005. Adv Data. Jun 29 2007(388):1-15.
11. Andrews R, Elixhauser A. The national hospital bill: growth trends and 2005 update on the most expensive conditions by payer. Healthcare Cost and Utilization Project. 2007;http://www.hcup-us.ahrq.gov/reports/statbriefs/sb42.pdf(Statistical Brief #42):1-13.
12. Angus DC, Linde-Zwirble WT, Lidicker J, Clermont G, Carcillo J, Pinsky MR. Epidemiology of severe sepsis in the United States: analysis of incidence, outcome, and associated costs of care. Crit Care Med. 2001;29(7):1303-1310.
13. Barnato AE, Alexander SL, Linde-Zwirble WT, Angus DC. Racial variation in the incidence, care, and outcomes of severe sepsis: analysis of population, patient, and hospital characteristics. Am J Respir Crit Care Med. Feb 1 2008;177(3):279-284.
14. http://www.hcup-us.ahrq.gov/reports/factsandfigures/2008/pdfs/FF_report_2008.pdf. HCUP Facts and Figures: Statistics on Hospital-Based Care in the United States. 2008.
15. Kumar G, Kumar N, Taneja A, et al. Nationwide trends of severe sepsis in the 21st century (2000-2007). Chest. Nov 2011;140(5):1223-1231.
16. Martin GS, Mannino DM, Eaton S, Moss M. The epidemiology of sepsis in the United States from 1979 through 2000. N Engl J Med. Apr 17 2003;348(16):1546-1554.
17. Thompson D, Nicholas C, M.S., T.C., May R, MD, et al. The Second Annual HealthGrades Emergency Medicine in American Hospitals Study April 2011. HealthGrades. 2010;2:1-32.
18. Reed K, May R. Healthgrades emergency medicine in american hospitals study. Health Grades. June, 2010 2010;The First Annual Report(1):1-28.
19. Rogers FB, Osler T, Lee JC, et al. In a mature trauma system, there is no difference in outcome (survival) between Level I and Level II trauma centers. J Trauma. Jun 2011;70(6):1354-1357.
20. Bennett KM, Vaslef S, Pappas TN, Scarborough JE. The volume-outcomes relationship for United States Level I trauma centers. J Surg Res. May 1 2011;167(1):19-23.

1c.5. If a PRO-PM (e.g. HRQoL/functional status, symptom/burden, experience with care, health-related behaviors), provide evidence that the target population values the measured PRO and finds it meaningful. (Describe how and from whom their input was obtained.)

1d. Composite Quality Construct and Rationale

1d.1. A composite performance measure is a combination of two or more component measures, each of which individually reflects quality of care, into a single performance measure with a single score.

For purposes of NQF measure submission, evaluation, and endorsement, the following will be considered composites:

- Measures with two or more individual performance measure scores combined into one score for an accountable entity.
- Measures with two or more individual component measures assessed separately for each patient and then aggregated into one score for an accountable entity:
 - all-or-none measures (e.g., all essential care processes received, or outcomes experienced, by each patient); or
 - any-or-none measures (e.g., any or none of a list of adverse outcomes experienced, or inappropriate or unnecessary care processes received, by each patient).

1d.1. Please identify the composite measure construction:

1d.2. Describe the quality construct, including:

- the overall area of quality
- included component measures and
- the relationship of the component measures to the overall composite and to each other.

Over the last 25 years, diseases such as stroke, acute myocardial infarction and trauma have resulted in lowered mortality rates through a continuous quality improvement (CQI) and standardized protocols for early intervention. The Surviving Sepsis Campaign (SSC), the GENeralized Early Sepsis Intervention Strategies (GENESIS) Project, and other sepsis quality initiatives are multifaceted continuous quality improvement (CQI) initiatives which includes: 1)early identification of high risk patients; 2)mobilization of resources for evidence based early interventions; 3)timely initiation of life-saving processes of care 4) a reduction of health care resource consumption and 5) reduced mortality, decreased organ failure, and reduced length of stay. Compliance with the bundle saves 1 in 6 patients who would otherwise die. The current mortality of severe sepsis and septic shock over 5 times higher than any of these aforementioned diseases. Only in the last decade has there been a similar approach to severe sepsis and septic shock.

1d.3. Describe the rationale for constructing a composite measure, including how the composite provides a distinctive or additive value over the component measures individually.

The purpose of Henry Ford Hospital's severe sepsis and septic shock early management bundle is to support the efficient, effective, and timely delivery of high quality sepsis care in support of the IOM's aims for improvement. This is consistent with the HHS National Quality Strategy's priorities directed at one of the leading causes of mortality. By providing timely patient-centered care, and making sepsis care more affordable through early intervention, reduced resource use and complication rates can result. The Severe Sepsis and Septic Shock Early Management Bundle provides a standard operating procedure for the early risk stratification and management of a patient with severe infection. Through applying this standard operating procedure a clinically and statistically significant decrease in organ failure, mortality, and the utilization of health care resources has been demonstrated for over ten years. The current measure project aimed to review and update the existing NQF #0500 Severe Sepsis and Septic Shock Management Bundle to ensure it reflects the latest guideline recommendations, address areas most in need of performance improvement, and incorporate results of worldwide data collection and quality improvement initiatives. Henry Ford Hospital consulted with leadership and representatives from critical care medicine (Society of Critical Care Medicine), infectious diseases (Infectious Diseases Society of America), and emergency physicians to review and update the Severe Sepsis and Septic Shock Early Management Bundle.

1d.4. Describe how the aggregation and weighting of the component measures are consistent with the stated quality construct and rationale.

The sepsis quality initiative is a multifaceted continuous quality improvement (CQI) initiative which includes: 1)early identification of high risk patients; 2)performance of the quality measures appropriate cultures, antibiotics and aggressive reversal of early hemodynamic abnormalities using available best practice; 3) assessment of compliance; 4) dedicated education and feedback to health care providers 5) quantification of health care resource consumption and 6)assessment of outcomes.

2. Reliability and Validity—Scientific Acceptability of Measure Properties

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. **Measures must be judged to meet the subcriteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.**

2a.1. Specifications The measure is well defined and precisely specified so it can be implemented consistently within and across

organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

De.5. Subject/Topic Area (check all the areas that apply):

Infectious Diseases, Infectious Diseases : Respiratory, Pulmonary/Critical Care, Pulmonary/Critical Care : Critical Care, Pulmonary/Critical Care : Pneumonia

De.6. Cross Cutting Areas (check all the areas that apply):

Disparities, Safety, Safety : Healthcare Associated Infections

S.1. Measure-specific Web Page (Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials. Do not enter a URL linking to a home page or to general information.)

S.2a. If this is an eMeasure, HQMF specifications must be attached. Attach the zipped output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications)

This is an eMeasure Attachment: Sepsis_0500.doc

S.2b. Data Dictionary, Code Table, or Value Sets (and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)

URL Attachment:

S.3. For endorsement maintenance, please briefly describe any changes to the measure specifications since last endorsement date and explain the reasons.

S.4. Numerator Statement (Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome)

IF an OUTCOME MEASURE, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm.

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 hypotension after initial fluid administration (MAP < 65 mm Hg) or if initial lactate was = 4 mmol/L, re-assess volume status and tissue perfusion and document findings.*

* To meet the requirements, a focused exam† by a licensed independent practitioner (LIP) or any 2 other items are required:

- Measure CVP
- Measure ScvO2
- Bedside cardiovascular ultrasound
- Dynamic assessment of fluid responsiveness with passive leg raise or fluid challenge
- Focused exam† including vital signs, cardiopulmonary, capillary refill, pulse and skin findings.

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.

S.5. Time Period for Data (What is the time period in which data will be aggregated for the measure, e.g., 12 mo, 3 years, look back to August for flu vaccination? Note if there are different time periods for the numerator and denominator.)

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.

S.6. Numerator Details (All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b) IF an OUTCOME MEASURE, describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm.

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: "Was a focused exam[†] or any 2 of other items below checked

- Measure CVP
- Measure ScvO₂
- Bedside cardiovascular ultrasound
- Dynamic assessment of fluid responsiveness with passive leg raise or fluid challenge
- Focused exam[†] including vital signs, cardiopulmonary, capillary refill, pulse and skin findings.

within hours 3 to 6 hours from 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."

S.7. Denominator Statement (Brief, narrative description of the target population being measured)

Number of patients presenting with severe sepsis or septic shock.

S.8. Target Population Category (Check all the populations for which the measure is specified and tested if any):

Senior Care

S.9. Denominator Details (All information required to identify and calculate the target population/denominator such as definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)

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 $<4000/mm^3$, 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

S.10. Denominator Exclusions (Brief narrative description of exclusions from the target population)

- 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.
- F) Patients transferred to an acute care facility from another acute care facility.

S.11. Denominator Exclusion Details (All information required to identify and calculate exclusions from the denominator such as definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)

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.

S.12. Stratification Details/Variables (All information required to stratify the measure results including the stratification variables, definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format with at S.2b)

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.

S.13. Risk Adjustment Type (Select type. Provide specifications for risk stratification in S.12 and for statistical model in S.14-15)

No risk adjustment or risk stratification

If other:

S.14. Identify the statistical risk model method and variables (Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development and testing should be addressed with measure testing under Scientific Acceptability)

None

S.15. Detailed risk model specifications (must be in attached data dictionary/code list Excel or csv file. Also indicate if available at measure-specific URL identified in S.1.)

Note: Risk model details (including coefficients, equations, codes with descriptors, definitions), should be provided on a separate worksheet in the suggested format in the Excel or csv file with data dictionary/code lists at S.2b.

S.15a. Detailed risk model specifications (if not provided in excel or csv file at S.2b)

S.16. Type of score:

Non-weighted score/composite/scale

If other:

S.17. Interpretation of Score (Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)

Better quality = Higher score

S.18. Calculation Algorithm/Measure Logic (Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.)

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 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 documentation 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.

S.19. Calculation Algorithm/Measure Logic Diagram URL or Attachment (You also may provide a diagram of the Calculation Algorithm/Measure Logic described above at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1) URL

S.20. Sampling (If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.)

IF a PRO-PM, identify whether (and how) proxy responses are allowed.

Not applicable. The measure does not require sampling or a survey. However, the minimum sample size recommended should be no less than 50 patients per facility.

S.21. Survey/Patient-reported data (If measure is based on a survey, provide instructions for conducting the survey and guidance on minimum response rate.)

IF a PRO-PM, specify calculation of response rates to be reported with performance measure results.

S.22. Missing data (specify how missing data are handled, e.g., imputation, delete case.)

Required for Composites and PRO-PMs.

S.23. Data Source (Check ONLY the sources for which the measure is SPECIFIED AND TESTED).

If other, please describe in S.24.

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

S.24. Data Source or Collection Instrument (Identify the specific data source/data collection instrument e.g. name of database, clinical registry, collection instrument, etc.)

IF a PRO-PM, identify the specific PROM(s); and standard methods, modes, and languages of administration.

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

S.25. Data Source or Collection Instrument (available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)

URL

S.26. Level of Analysis (Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED)

Facility, Integrated Delivery System

S.27. Care Setting (Check ONLY the settings for which the measure is SPECIFIED AND TESTED)

Hospital/Acute Care Facility

If other:

S.28. COMPOSITE Performance Measure - Additional Specifications (Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)

2a. Reliability – See attached Measure Testing Submission Form

2b. Validity – See attached Measure Testing Submission Form

[0500_MeasureTesting_CompositeMSF1.0_Data.zip](#)

3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3a. Byproduct of Care Processes

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).

3a.1. Data Elements Generated as Byproduct of Care Processes.

generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition, Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims), Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

If other:

3b. Electronic Sources

The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

3b.1. To what extent are the specified data elements available electronically in defined fields? (i.e., data elements that are needed to compute the performance measure score are in defined, computer-readable fields)

[Some data elements are in defined fields in electronic sources](#)

3b.2. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources.

[Specific formatting of text fields to allow automated capture should ensure future availability.](#)

3b.3. If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL.

Attachment:

3c. Data Collection Strategy

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing

demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

3c.1. Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

IF a PRO-PM, consider implications for both individuals providing PROM data (patients, service recipients, respondents) and those whose performance is being measured.

This measure was found to be reliable and feasible for implementation.

3c.2. Describe any fees, licensing, or other requirements to use any aspect of the measure as specified (e.g., value/code set, risk model, programming code, algorithm).

4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

4a. Accountability and Transparency

Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

4.1. Current and Planned Use

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement in addition to performance improvement.

Planned	Current Use (for current use provide URL)
Public Reporting	
Regulatory and Accreditation Programs	
Professional Certification or Recognition Program	
Quality Improvement with Benchmarking (external benchmarking to multiple organizations)	
Quality Improvement (Internal to the specific organization)	

4a.1. For each CURRENT use, checked above, provide:

- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included

4a.2. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons? (e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?)

4a.3. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement. (*Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.*)

4b. Improvement

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

4b.1. Progress on Improvement. (Not required for initial endorsement unless available.)

Performance results on this measure (current and over time) should be provided in 1b.2 and 1b.4. Discuss:

- Progress (trends in performance results, number and percentage of people receiving high-quality healthcare)
- Geographic area and number and percentage of accountable entities and patients included

4b.2. If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

4c. Unintended Consequences

The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

4c.1. Were any unintended negative consequences to individuals or populations identified during testing; OR has evidence of unintended negative consequences to individuals or populations been reported since implementation? If so, identify the negative unintended consequences and describe how benefits outweigh them or actions taken to mitigate them.

We are not aware of any unintended consequences related to this measurement.

5. Comparison to Related or Competing Measures

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

5. Relation to Other NQF-endorsed Measures

Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.

5.1a. List of related or competing measures (selected from NQF-endorsed measures)

5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.

5a. Harmonization

The measure specifications are harmonized with related measures;

OR

The differences in specifications are justified

5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed

<p>measure(s): Are the measure specifications completely harmonized?</p> <p>5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.</p>
<p>5b. Competing Measures The measure is superior to competing measures (e.g., is a more valid or efficient way to measure); OR Multiple measures are justified.</p> <p>5b.1. If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s): Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)</p>

<p>Appendix</p>
<p>A.1 Supplemental materials may be provided in an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed. Attachment:</p>
<p>Contact Information</p>
<p>Co.1 Measure Steward (Intellectual Property Owner): Henry Ford Hospital Co.2 Point of Contact: Emanuel, Rivers, erivers1@hfhs.org, 313-916-1801- Co.3 Measure Developer if different from Measure Steward: Henry Ford Hospital Co.4 Point of Contact: Emanuel, Rivers, erivers1@hfhs.org, 313-916-1801-</p>
<p>Additional Information</p>
<p>Ad.1 Workgroup/Expert Panel involved in measure development Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.</p> <ol style="list-style-type: none"> 1. Emmanuel Rivers, MD, MPH, FACEP, Emergency Medicine and Surgical Critical Care, Henry Ford Hospital, Institute of Medicine Fellow: measure developer, measure steward, review of current evidence, validity, reliability, usability, feasibility, and update of measure 2. William Conway, MD, Chief Medical Officer, Henry Ford Hospital, measure steward, review of current evidence, validity, reliability, usability, feasibility, and update of measure 3. Mitchell M Levy, MD, FCCM, Rhode Island Hospital, Society of Critical Care Medicine (SCCM) for the Surviving Sepsis Campaign (SSC): review of current evidence, validity, reliability, usability, feasibility, and update of measure 4. R. Phillip Dellinger, MD, FCCM, Cooper University Medical Center, Society of Critical Care Medicine (SCCM) for the Surviving Sepsis Campaign (SSC): review of current evidence and update of measure 5. Sean R. Townsend, MD, Institute for Healthcare Improvement (IHI), California Pacific Medical Center, San Francisco: review of current evidence, validity, reliability, usability, feasibility, and update of measure 6. Lawrence Martinelli, MD, Coventry Health Systems, Chair Quality Improvement Task Force, Infectious Diseases Society of America (IDSA): review of current evidence, validity, reliability, usability, feasibility, and update of measure 7. Gary Phillips, MAS, Biostatistician, Ohio State University Center for Biostatistics, for the Surviving Sepsis Campaign (SSC): statistical support for evaluation of current evidence, validity, and reliability.
<p>Measure Developer/Steward Updates and Ongoing Maintenance</p>

Ad.2 Year the measure was first released: 2008

Ad.3 Month and Year of most recent revision: 06, 2012

Ad.4 What is your frequency for review/update of this measure? Annually for minor changes, every three years detailed review of evidence and test results.

Ad.5 When is the next scheduled review/update for this measure? 06, 2013

Ad.6 Copyright statement: 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).

Ad.7 Disclaimers: 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 agents shall be responsible for any use of the measures.

Ad.8 Additional Information/Comments: