Memo

Background

This report reflects the review of measures in the Infectious Disease project. NQF has endorsed a number of consensus standards to evaluate the quality of care for topic areas related to infectious disease over the past decade. As quality measurement has matured, better data systems have become available, electronic health records are closer to widespread adoption, and the demand for meaningful performance measures has prompted development of more sophisticated measures of healthcare processes and outcomes for infectious disease conditions. An evaluation of the NQF endorsed infectious disease measures and consideration of new measures will ensure the currency of NQF's portfolio of voluntary consensus standards. This measurement cycle focused on measures for HIV/AIDS and Sepsis.

The 16-person Infectious Disease Standing Committee reviewed nine measures and all nine measures were recommended for endorsement.

Recommended for endorsement:
- 2082: HIV Viral Load Suppression (Health Resources and Services Administration - HIV/AIDS Bureau)
- 3210: HIV Viral Load Suppression – Legacy eMeasure (Health Resources and Services Administration - HIV/AIDS Bureau)
- 2079: HIV Medical Visit Frequency (Health Resources and Services Administration - HIV/AIDS Bureau)
- 3209: HIV Medical Visit Frequency – Legacy eMeasure (Health Resources and Services Administration - HIV/AIDS Bureau)
- 2080: Gap in HIV Medical Visit (Health Resources and Services Administration - HIV/AIDS Bureau)
- 2083: Prescription of HIV Antiretroviral Therapy (Health Resources and Services Administration - HIV/AIDS Bureau)
- 3211: Prescription of HIV Antiretroviral Therapy – Legacy eMeasure (Health Resources and Services Administration - HIV/AIDS Bureau)
- 3215: Adult Inpatient Risk Adjusted Sepsis Mortality (New York State Department of Health, Office of Quality and Patient Safety)

- 0500: Severe Sepsis and Septic Shock: Management Bundle (Henry Ford Hospital)

NQF Member and Public Commenting

NQF Members and the public are encouraged to provide comments via the online commenting tool on the draft report as a whole, or on the specific measures evaluated by the Infectious Disease Standing Committee.

Please note that commenting concludes on May 15, 2017 by 6:00 pm ET – no exceptions.

NQF-Endorsed Measures for Infectious Disease

DRAFT REPORT FOR COMMENT

April 14, 2017

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

NATIONAL QUALITY FORUM

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

2

Contents

NATIONAL QUALITY FORUM

3

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

Infectious Disease

DRAFT REPORT

Executive Summary

Many infectious diseases have been controlled or eradicated through the use of vaccines and advanced medicine, infectious disease continues to cause widespread morbidity and mortality, and rising health care costs. However, infectious disease persist, from viruses and bacteria that cause respiratory illnesses to sexually transmitted infections (STI) and more.

The Infectious Disease portfolio currently has nine endorsed measures for infectious disease addressing sepsis and septic shock, HIV/AIDS, and respiratory conditions. Appendix B details the full portfolio of infectious disease measures.

For this project, the Standing Committee evaluated four newly-submitted measures and five measures undergoing maintenance review against NQF's standard evaluation criteria. All nine measures were recommended for endorsement. The nine measures recommended by the Standing Committee are:

- 2082: HIV Viral Load Suppression (Health Resources and Services Administration - HIV/AIDS Bureau)
- 3210: HIV Viral Load Suppression – Legacy eMeasure (Health Resources and Services Administration - HIV/AIDS Bureau)
- 2079: HIV Medical Visit Frequency (Health Resources and Services Administration - HIV/AIDS Bureau)
- 3209: HIV Medical Visit Frequency – Legacy eMeasure (Health Resources and Services Administration - HIV/AIDS Bureau)
- 2080: Gap in HIV Medical Visit (Health Resources and Services Administration - HIV/AIDS Bureau)
- 2083: Prescription of HIV Antiretroviral Therapy (Health Resources and Services Administration - HIV/AIDS Bureau)
- 3211: Prescription of HIV Antiretroviral Therapy – Legacy eMeasure (Health Resources and Services Administration - HIV/AIDS Bureau)
- 0500: Severe Sepsis and Septic Shock: Management Bundle (Henry Ford Hospital)
- 3215: Adult Inpatient Risk Adjusted Sepsis Mortality (New York State Department of Health, Office of Quality and Patient Safety)

Brief summaries of the measures currently under review are included in the body of the report; detailed summaries of the Committee's discussion and ratings of the criteria for each measure are in Appendix A.

Introduction

Many infectious diseases have been controlled or eradicated through the use of vaccines and advanced medicine, infectious disease continues to cause widespread morbidity and mortality, and rising health care costs. However, infectious disease persist, from viruses and bacteria that cause respiratory illnesses to sexually transmitted infections (STI) and more. Specifically:

- Infectious diseases account for 3.9 million hospital visits per year and are a leading cause of death in the United States[1];
- Each year, the nation spends more than $120 and $5 billion to treat infectious diseases and antibiotic resistant bacteria, respectively[2];
- Septicemia is the most expensive condition treated in US hospitals at $20.3 billion in 2011.[3]

Effective quality measures are critically important to improve national efforts to advance treatment of infectious disease and improve patient safety and healthcare outcomes. Providing resources, such as patient education and intervention programs along with continued scientific research for existing and emerging diseases, will reduce mortality and healthcare costs.

NQF has endorsed a number of consensus standards to evaluate the quality of care for topic areas related to infectious disease over the past decade. As quality measurement has matured, better data systems have become available, electronic health records are closer to widespread adoption, and the demand for meaningful performance measures has prompted development of more sophisticated measures of healthcare processes and outcomes for infectious disease conditions. An evaluation of the NQF endorsed infectious disease measures and consideration of new measures will ensure the currency of NQF's portfolio of voluntary consensus standards. This measurement cycle focused on measures for HIV/AIDS and Sepsis.

HIV/AIDS

HIV (human immunodeficiency virus) is an infectious disease that attacks the immune system; if left untreated, HIV will progress to AIDS.[4] Fortunately, advances in care and treatment have shown that people living with HIV (PLWH) who are stable on antiretroviral medication are more likely to achieve viral suppression and are therefore less likely to transmit the virus to others.[5] Quality measures that allow for the monitoring of client engagement and retention in care, and the assessment of health outcomes such as viral load, are needed to reduce the incidence and prevalence of HIV infection and related morbidity and mortality.

Sepsis and Septic Shock

Sepsis is a complication caused by the body's responses to infection.[6] According to the Centers for Disease Control and Prevention (CDC), sepsis can occur to anyone, at any time, from any type of infection, and can affect any part of the body.[7] Clinicians have identified three stages of sepsis based on the severity of the infection and the body's responses[8]:

- Sepsis: the infection reaches the bloodstream and causes inflammation in the body.

- Severe sepsis: the infection is severe enough to affect the organs, such as the heart, brain, and kidneys.
- Septic shock: a significant drop in blood pressure that can lead to respiratory or heart failure, stroke, failure of other organs, and death.

Every year, severe sepsis strikes more than a million Americans.[9] Experts estimate that between 28 and 50 percent of patients with sepsis die—far more than the number of U.S. deaths from prostate cancer, breast cancer and AIDS combined.[10] The number of sepsis cases per year is likely rising due to a combination of factors, including increased awareness and tracking of the condition, an aging population, the increased longevity of people with chronic diseases, the spread of antibiotic-resistant organisms, an upsurge in invasive procedures and broader use of immunosuppressive and chemotherapeutic agents.[11]

The Agency for Healthcare Research and Quality (AHRQ) lists sepsis as the most expensive condition treated in U.S. hospitals, costing more than $20 billion in 2011.[12] Readmission due to sepsis is two to three times more likely—and two or three times more costly—than readmission resulting from many other conditions, including heart failure, pneumonia and chronic obstructive pulmonary disease.[13]

Trends and Performance

Approximately 1.2 million people are living with HIV in the United States today; about 87 percent of them are aware that they are infected.[14] In 2015, the Centers for Disease Control and Prevention (CDC) released an analysis showing that HIV diagnoses fell by 19 percent over the past decade.[15] This decline was driven by a decrease in HIV diagnoses among heterosexuals, people who inject drugs, and African American women and heterosexual men.[16] The CDC also reported that, thanks to sustained testing efforts, the proportion of Americans with HIV who know their status has reached an all-time high of 87 percent.[17] The implementation of the Affordable Care Act (ACA) continued to increase access to critical HIV testing, prevention, and care services nationwide.[18]

Recent scientific advances to stop HIV include improved testing techniques, early treatment with antiretroviral medications, and pre-exposure prophylaxis. Unfortunately, these advances are not reaching many people in need. According to the CDC, surveillance data show 57 percent of people diagnosed with HIV are receiving care for their infection, and only 55 percent have their virus suppressed through treatment.[19] The CDC also reports that there are substantial gaps between Southern states and the rest of the country on death rates among people with diagnosed HIV and knowledge of HIV – positive status.[20]

In addition to geographic disparities, progress has been uneven among racial, ethnic, gay, and bisexual men. The CDC's analysis found that HIV diagnoses dropped 18 percent among white men who have sex with men (MSM) between 2005 and 2014, but increased 24 percent among Latino MSM.[21] Black MSM HIV diagnoses have remained about the same since 2010 though initially increased 22 percent.[22]

The CDC compared national estimates of sepsis-related mortality based on death certificates with previously published sepsis mortality estimates generated using administrative claims data. Using death certificate data for the period 1999–2014, the CDC found that a total of 2,470,666 decedents (6 percent

of all deaths) had sepsis listed among the causes of death (sepsis-related deaths); for 22 percent of these decedents, sepsis was listed as the underlying cause of death.[23] The Centers for Medicare & Medicaid Services (CMS) recently implemented the severe sepsis and septic shock bundle (SEP-1) as part of its Inpatient Quality Reporting (IQR) program but results are not currently publicly reported.

NQF Portfolio of Performance Measures for Infectious Disease Conditions

The Infectious Disease Standing Committee (see Appendix D) oversees NQF's portfolio of Infectious Disease measures that includes measures for HIV/AIDS, Sepsis and Septic Shock (see Appendix B). This portfolio contains nine measures: seven process measures, one outcome measure, and one composite measure (see table below).

Table 1. NQF Infectious Disease Portfolio of Measures

	Process	Outcome/Resource Use	Composite
HIV/AIDS	5	1	0
Sepsis and Septic Shock	0	0	1
Respiratory	2	0	0
Total	7	1	1

Additional measures related to Infectious Disease are assigned to other projects. These include various screening measures for sexually transmitted infections and Hepatitis C (Perinatal and Health and Well-being projects), vaccination measures (Perinatal and Health and Well-being projects), respiratory measures (Pulmonary project), facility acquired infection measures (Patient Safety project) and perioperative antibiotic measures (Surgery).

National Quality Strategy

NQF-endorsed measures for Infectious Disease care support the National Quality Strategy (NQS). NQS serves as the overarching framework for guiding and aligning public and private efforts across all levels (local, State, and national) to improve the quality of healthcare in the U.S. The NQS establishes the "triple aim" of better care, affordable care, and healthy people/communities, focusing on six priorities to achieve those aims: *Safety, Person and Family Centered Care, Communication and Care Coordination, Effective Prevention and Treatment of Illness, Best Practices for Healthy Living, and Affordable Care.*

Quality measures for HIV/AIDS and sepsis care align with several of the NQS priorities, including:

- **Effective Prevention and Treatment.** Vaccinations against the flu or pneumonia help prevent infections that can lead to sepsis. In addition to prevention, early treatment of sepsis decreases morbidity and mortality.
- **Care Affordability.** The implementation of the Affordable Care Act (ACA) increased access to critical HIV testing, prevention, and care services nationwide.

NATIONAL QUALITY FORUM

8

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

Use of Measures in the Portfolio

Endorsement of measures by NQF is valued not only because the evaluation process itself is both rigorous and transparent, but also because evaluations are conducted by multi-stakeholder committees comprised of clinicians and other experts from the full range of healthcare providers, employers, health plans, public agencies, community coalitions, and patients—many of whom use measures on a daily basis to ensure better care. Moreover, NQF-endorsed measures undergo routine "maintenance" (i.e., re-evaluation) to ensure that they are still the best-available measures and reflect the current science. Importantly, federal law requires that preference be given to NQF-endorsed® measures for use in federal public reporting and performance-based payment programs. NQF measures also are used by a variety of stakeholders in the private sector, including hospitals, health plans, and communities.

The measures in the infectious disease portfolio are in use in at least one federal program. The HIV/AIDS measures are included in CMS' Physician Quality Reporting System (PQRS) and HRSA's Ryan White & Global HIV/AIDS Programs. The sepsis measure is included in the CMS Hospital Inpatient Quality Reporting (IQR) program. See Appendix C for details of federal program use for the measures in the portfolio.

Improving NQF's Infectious Disease Portfolio

During their discussions, the Committee identified additional areas where measure development is needed, including:

- Measures that underscore the value of infectious disease (ID) consultation, which studies have shown to improve outcomes. For example, the rate of ID consults in those with Staphylococcus aureus bacteremia, cryptococcal infection and HIV patients on ART.
- HPV screening in females with HIV.

The Committee reviewed the measurement gaps previously identified in 2012. Since that time, many of the previously identified gaps have been filled by new measures in various NQF projects. Specifically, 10 outcome measures related to infectious disease are now endorsed, measures that evaluate improvement in device associated infections in the hospital setting (two measures), measures that include follow up for screening tests (one measure), screening for STI's including HPV (three measures), and antimicrobial stewardship measures (one measure). Please see Appendix B for more details.

Infectious Disease Measure Evaluation

On March 14, 2017, the Infectious Disease Standing Committee evaluated four new measures and five measures undergoing maintenance review against NQF's standard evaluation criteria. To facilitate the evaluation, the committee and candidate standards were divided into two workgroups for preliminary review of the measures against the evaluation sub-criteria prior to consideration by the entire Standing Committee.

Table 2. Infectious Disease Measure Evaluation Summary

	Maintenance	New	Total

	Maintenance	New	Total
Measures under consideration	5	4	9
Measures recommended for endorsement	5	4	9
Reasons for not recommending	Importance – 0 Scientific Acceptability – 0 Overall – 0 Competing Measure – 0	Importance – 0 Scientific Acceptability – 0 Overall – 0 Competing Measure – 0	

Comments Received Prior to Committee Evaluation

NQF solicits comments on endorsed measures on an ongoing basis through the Quality Positioning System (QPS). In addition, NQF solicits comments prior to the evaluation of the measures via an online tool located on the project webpage. For this evaluation cycle, the pre-evaluation comment period was open from February 9 – February 23, 2017. A total of six pre-evaluation comments were received (Appendix G).

All submitted comments were provided to the Committee prior to its initial deliberations during the workgroups calls.

Overarching Issues

During the Standing Committee's discussion of the measures, several overarching issues emerged that were factored into the Committee's ratings and recommendations for multiple measures and are not repeated in detail with each individual measure.

Unintended Consequences

The Committee expressed concerns with the potential unintended consequences associated with diagnosing and treating sepsis. The combination of symptoms associated with sepsis may be associated with other diagnoses such as pneumonia or myocardial infarction (MI). The Committee noted that patients may receive antibiotics prior to a conclusive diagnosis of sepsis – this is similar to the unintended consequences that occurred with the overuse of antibiotics in the emergency room for pneumonia. Patients may experience hypotension due to an acute MI rather than sepsis, yet, receive IV fluids in an effort to meet the data elements associated with the sepsis bundle.

Balancing Measures

The Committee discussed the need for balancing measures to avoid unintended consequences as described above. The Committee suggested the following balancing measures for sepsis:

- Overuse of broad spectrum antibiotics
- Patients with heart failure and/or a MI who were overloaded with IV fluids
- Incidence of c. difficile secondary to overuse of antibiotics

NQF-endorsed measures related to antimicrobial use and c. difficile include #2720: National Healthcare Safety Network (NHSN) Antimicrobial Use Measure and #1717: National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-Onset Clostridium Difficile Infection (CDI). There are no NQF endorsed measures related to fluid overload in patients with heart failure and/or MI.

Refining the NQF Measure Evaluation Process

In an effort to respond to evolving stakeholder needs, NQF constantly works to improve the consensus development process (CDP). In 2014, NQF transitioned to the use of standing committees for ongoing maintenance of endorsed measures and in 2015, NQF updated its Maintenance of NQF Endorsement policy to emphasize what has been learned about previously endorsed measures. Changes to the Maintenance of Endorsement policy is described below.

Maintenance of NQF Endorsement

To streamline and improve the periodic evaluation of currently-endorsed measures, NQF has updated the way it re-evaluates measures for maintenance of endorsement. This change took effect beginning October 1, 2015. NQF's endorsement criteria have not changed, and all measures continue to be evaluated using the same criteria. However, under the new approach, there is a shift in emphasis for evaluation of currently-endorsed measures:

- **Evidence**: If the developer attests that the evidence for a measure has not changed since its previous endorsement evaluation, there is a decreased emphasis on evidence, meaning that the Committee may accept the prior evaluation of this criterion without further discussion or need for a vote. This applies only to measures that previously passed the evidence criterion without an exception. If a measure was granted an evidence exception, the evidence for that measure must be revisited.
- **Opportunity for Improvement (Gap)**: For re-evaluation of endorsed measures, there is increased emphasis on current performance and opportunity for improvement. Endorsed measures that are "topped out" with little opportunity for further improvement are eligible for Inactive Endorsement with Reserve Status.
- **Reliability:**
  - Specifications: There is no change in the evaluation of the current specifications.
  - Testing: If the developer has not presented additional testing information, the Committee may accept the prior evaluation of the testing results without further discussion or need for a vote.
- **Validity:** There is less emphasis on this criterion if the developer has not presented additional testing information, and the Committee may accept the prior evaluation of this sub criterion without further discussion and vote. However, the Committee still considers whether the specifications are consistent with the evidence. In addition, for outcome measures, the Committee discusses questions required for the SDS Trial even if no change in testing is presented.
- **Feasibility:** The emphasis on this criterion is the same for both new and previously-endorsed measures, as feasibility issues might have arisen for endorsed measures that have been implemented.

- **Usability and Use**: For re-evaluation of endorsed measures, there is increased emphasis on the use of the measure, especially use for accountability purposes. There also is an increased emphasis on improvement in results over time and on unexpected findings, both positive and negative.

The New Endorsement and Appeals Process

In August 2016, NQF implemented changes to its ratification and appeals process that were initiated and approved by its Board of Directors. Following public comment and voting by the NQF membership, the Consensus Standards Approval Committee (CSAC) will make the final measure endorsement decision, without ratification by another body. Additionally, the Board requested NQF to establish a five-member Appeals Board that will be responsible for adjudicating all submitted appeals regarding measure endorsement decisions. These changes apply to NQF measure endorsement projects with in-person meetings scheduled after August 2016.

The newly, constituted Appeals Board, composed of NQF Board members and former CSAC and/or committee members, will adjudicate appeals to measure endorsement decisions without a review by the CSAC. The decision of the Appeals Board will be final.

All submitted appeals will be published on the NQF website. Staff will compile the appeals for review by the Appeals Board, which will evaluate the concern(s) raised and determine if the appeal should warrant overturning the endorsement decision. Decisions on an appeal of endorsement will be publicly available on NQF's website.

Throughout the process, project staff will serve as liaisons between the CSAC, the Appeals Board, the committee, developers/stewards, and the appellant(s) to ensure the communication, cooperation, and appropriate coordination to complete the project efficiently.

NATIONAL QUALITY FORUM
NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

12

Summary of Measure Evaluation

The following brief summaries of the measure evaluation highlight the major issues that were considered by the Committee. Details of the Committee's discussion and ratings of the criteria for each measure are in included in Appendix A.

HIV/AIDS

2082 HIV Viral Load Suppression (Health Resources and Services Administration - HIV/AIDS Bureau): Recommended

Description: Percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year; **Measure Type**: Outcome; **Level of Analysis**: Facility; **Setting of Care**: Clinician Office/Clinic; **Data Source**: Laboratory, Paper Records

The main goal of antiretroviral therapy for people living with HIV (PLWH) is to inhibit HIV replication, which in turn reduces PLWH's risk of HIV-associated morbidity and mortality. This maintenance measure was last endorsed in 2012 and calculates the percentage of clients with a viral load of <200 copies/mL at the last viral load test. The Committee agreed that an opportunity for improvement in performance continues to exist. The developer provided updated reliability testing and explained that they did not update the validity testing because they intend to replace this paper-based measure with #3210, the electronically specified version of this measure. The Committee agreed the measure met the reliability and validity criteria.

3210 HIV Viral Load Suppression – *Legacy eMeasure* (Health Resources and Services Administration - HIV/AIDS Bureau): Recommended

Description: Percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year; **Measure Type**: Outcome; **Level of Analysis**: Facility; **Setting of Care**: Clinician Office/Clinic; **Data Source**: Electronic Health Record (Only), Other

This "legacy" eMeasure is the electronically specified version of #2082, currently used in federal programs. The Committee discussed #2082 first, and because the information provided for evidence and opportunity for improvement is identical for the two measures, the Committee agreed to apply the voting results for these criteria to #3210. The developer tested the measure with the Bonnie tool using synthetic test cases. Testing results showed that the test cases passed the measure as expected which demonstrates the measure logic performs as constructed. The Committee agreed the measure met the minimum criteria for reliability and validity required for legacy eMeasures at this time.

2079 HIV Medical Visit Frequency (Health Resources and Services Administration - HIV/AIDS Bureau): Recommended

Description: Percentage of patients, regardless of age, with a diagnosis of HIV who had at least one medical visit in each 6-month period of the 24-month measurement period with a minimum of 60 days between medical visits.; **Measure Type**: Process; **Level of Analysis**: Facility; **Setting of Care**: Clinician Office/Clinic; **Data Source**: Paper Records

Poor retention in care is associated with delayed or failed receipt of antiretroviral (ART) therapy, delayed time to viral suppression, and other behaviors or adverse clinical events such as low adherence to ART therapy and increased sexual risk transmission behaviors. This maintenance measure last endorsed in 2012 calculates the percentage of patients with HIV who had at least one medical visit in each 6-month period of a 24-month measurement period with a minimum of 60 days between medical visits. The Committee questioned the 6-month time interval and minimum 60-day interval between visits because the evidence provided does not include a specific time interval. The Committee did not agree that the evidence supported the measure focus; however, the Committee agreed retention in care was important and voted to pass the measure on evidence with an exception. The Committee agreed that an opportunity for improvement in performance continues to exist. The developer provided updated reliability testing and explained that they did not update the validity testing because they intend to replace this paper-based measure with #3209, the electronically specified version of this measure. The Committee agreed the measure met the reliability and validity criteria.

3209 HIV Medical Visit Frequency – *Legacy eMeasure* (Health Resources and Services Administration - HIV/AIDS Bureau): Recommended

Description: Percentage of patients, regardless of age, with a diagnosis of HIV who had at least one medical visit in each 6-month period within 24 months with a minimum of 60 days between medical visits. A medical visit is any visit in an outpatient/ambulatory care setting with a nurse practitioner, physician, and/or a physician assistant who provides comprehensive HIV care; **Measure Type**: Process; **Level of Analysis**: Facility; **Setting of Care**: Clinician Office/Clinic; **Data Source**: Electronic Health Record (Only)

This "legacy' eMeasure is the electronically specified version of #2079, currently used in federal programs. The Committee discussed #2079 first, and because the information provided for evidence and opportunity for improvement is identical for the two measures, the Committee agreed to apply the voting results for these criteria to #2079.   The developer tested the measure with the Bonnie tool using synthetic test cases. Testing results showed that the test cases passed the measure as expected which demonstrates the measure logic performs as constructed. The Committee agreed the measure met the minimum criteria for reliability and validity required for legacy eMeasures at this time.

2080 Gaps in HIV Medical Visits (Health Resources and Services Administration - HIV/AIDS Bureau): Recommended

Description: Percentage of patients, regardless of age, with a diagnosis of HIV who did not have a medical visit in the last 6 months of the measurement year; **Measure Type**: Process; **Level of Analysis**: Clinician: Group/Practice, Facility; **Setting of Care**: Clinician Office/Clinic; **Data Source**: Other, Paper Records

Retention in care plays a critical role in assisting people living with HIV in their pursuit of achieving viral control and reducing new infections. This maintenance measure last endorsed in 2012 calculates the percentage of HIV patients who did not have a medical visit in the last 6 months of the measurement year (at least one visit every six months). The Committee noted that guidelines have changed and now recommend viral load assessment every six months but durably suppressed patients can be seen less

frequently. The Committee agreed that the evidence provided was insufficient; however, they agreed retention in care is important and voted to pass the measure on evidence with an exception. Notably, the Committee agreed that the measure could be used to help providers prioritize clients who have not been in care. The Committee agreed an opportunity for improvement continues to exist and noted disparities in care among age, gender, and racial/ethnic groups. The developer provided updated reliability testing and explained that they did not update the validity testing because they intend to replace this paper-based measure with the electronically specified version of this measure currently under development. The Committee agreed the measure met the reliability and validity criteria.

2083 Prescription of HIV Antiretroviral Therapy (Health Resources and Services Administration - HIV/AIDS Bureau): Recommended

Description: Percentage of patients, regardless of age, with a diagnosis of HIV prescribed antiretroviral therapy for the treatment of HIV infection during the measurement year; **Measure Type**: Process; **Level of Analysis**: Facility; **Setting of Care**: Clinician Office/Clinic; **Data Source**: Other, Paper Records, Pharmacy

Antiretroviral therapy (ART) delays the progression of HIV and current treatment guidelines recommend ART for all people living with HIV (PLWH). This maintenance measure last endorsed in 2012 calculates the percentage of HIV patients with a prescription for ART. . The Committee debated the evidence noting that the guideline recommends that PLWH be on ART although the focus of the measure is whether the provider prescribed ART. Ultimately, the Committee agreed the evidence provided was sufficient and accepted the previous Committee's vote on this criterion. The Committee agreed an opportunity for improvement continues to exist and noted disparities in care among age, gender, and racial/ethnic groups. The developer provided updated reliability testing and explained that they did not update the validity testing because they intend to replace this paper-based measure with #3211, the electronically specified version of this measure. The Committee agreed the measure met the reliability and validity criteria.

3211 Prescription of HIV Antiretroviral Therapy – *Legacy eMeasure* (Health Resources and Services Administration - HIV/AIDS Bureau): Recommended

Description: Percentage of patients, regardless of age, with a diagnosis of HIV prescribed antiretroviral therapy for the treatment of HIV infection during the measurement year; **Measure Type**: Process; **Level of Analysis**: Facility; **Setting of Care**: Clinician Office/Clinic; **Data Source**: Electronic Health Record (Only)

This "legacy' eMeasure is the electronically specified version of #2083, currently used in federal programs. The Committee discussed #2083 first, and because the information provided for evidence and opportunity for improvement is identical for the two measures, the Committee agreed to apply the voting results for these criteria to #2083. The developer tested the measure with the Bonnie tool using synthetic test cases. Testing results showed that the test cases passed the measure as expected which demonstrates the measure logic performs as constructed. The Committee agreed the measure met the minimum criteria for reliability and validity required for legacy eMeasures at this time.

NATIONAL QUALITY FORUM

15

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

Sepsis and Septic Shock

3215 Adult Inpatient Risk Adjusted Sepsis Mortality (New York State Department of Health): Recommended

Description: Annual risk adjusted inpatient mortality rate for adult patients (aged 18 and over) admitted to acute care hospitals with diagnosis of severe sepsis or septic shock. The measure includes patients in acute care hospital settings over one year timeframe who had, either on admission, or during their hospital stay, a clinical diagnosis of severe sepsis (now referred to as ´sepsis´) or septic shock using criteria described in the International Sepsis Definitions (Sepsis-2); **Measure Type**: Outcome; **Level of Analysis**: Facility; **Setting of Care**: Hospital: Acute Care Facility; **Data Source**: Claims (Other), EHRs Hybrid, Laboratory, Management Data, Non-Medical Data, Paper Records, Pharmacy, Registry

Hospitals that use early sepsis detection approaches coupled with rapid delivery of basic resuscitation interventions are able to influence mortality rates and improve patient outcomes. This newly-submitted facility-level measure estimates the probability of mortality for patients admitted to acute care hospitals with severe sepsis or septic shock. The Committee agreed that the performance rates that ranged from 1.0% to 95.0% in 2015 demonstrated a variation in hospital performance. The Committee did not express any concerns with the reliability and validity of the measure. The Committee discussed the amount of manual chart abstraction required to collect the necessary data for this measure but concluded it was feasible.

0500 Severe Sepsis and Septic Shock Management Bundle (Henry Ford Hospital): Recommended

Description: This measure focuses on adults 18 years and older with a diagnosis of severe sepsis or septic shock. Consistent with Surviving Sepsis Campaign guidelines, the measure contains several elements, including measurement of lactate, obtaining blood cultures, administering broad-spectrum antibiotics, fluid resuscitation, vasopressor administration, reassessment of volume status and tissue perfusion, and repeat lactate measurement. As reflected in the data elements and their definitions, these elements should be performed in the early management of severe sepsis and septic shock; **Measure Type**: Composite; **Level of Analysis**: Facility; **Setting of Care**: Hospital; **Data Source**: Imaging-Diagnostic, Laboratory, Other, Paper Records, Pharmacy

Patients diagnosed with severe sepsis or septic shock who receive all the elements of care, including measurement of lactate levels (initial and repeat), blood cultures, broad spectrum antibiotics, fluid resuscitation, vasopressor administration and volume status and tissue perfusion reassessment have shown a decrease in mortality. This facility-level, all-or-none, composite measure, originally endorsed in 2012, and most recently in 2014, assesses the percentage of patients that received all of the applicable elements of care for severe sepsis or septic shock. The Committee agreed that despite the performance increase from 34.4 percent in Q4 2015 to 44.0 percent in Q2 2016, a performance gap exists. The Standing Committee thoroughly discussed the reliability and validity of the measure and concluded the testing and specifications met both criteria. Due to several concerns voiced related to unintended consequences, the Committee did not reach consensus on the Usability and Use criterion. However, the Committee supported the measure overall and recommended it for endorsement.

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NATIONAL QUALITY FORUM   18

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

Appendix A: Details of Measure Evaluation

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

Measures Recommended

2082 HIV Viral Load Suppression
Submission	Specifications
Description: Percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year. A medical visit is any visit in an outpatient/ambulatory care setting with a nurse practitioner, physician, and/or a physician assistant who provides comprehensive HIV care.
Numerator Statement: Number of patients in the denominator with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year
Denominator Statement: Number of patients, regardless of age, with a diagnosis of HIV with at least one medical visit in the measurement year
Exclusions: There are no patient exclusions.
Adjustment/Stratification: No risk adjustment or risk stratification
Level of Analysis: Facility
Setting of Care: Clinician Office/Clinic
Type of Measure: Outcome
Data Source: Laboratory, Paper Records
Measure Steward: Health Resources and Services Administration - HIV/AIDS Bureau
STANDING COMMITTEE MEETING [03/14/2017]   **1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>**   (1a. Evidence, 1b. Performance Gap)   1a. Evidence: **Y-16; N-0**; 1b. Performance Gap: **H-10**; **M-3**; **L-0**; **I-0;**   Rationale: - For the 2013 endorsement evaluation, the developer noted that viral suppression is a main goal of HIV treatment and an indicator of treatment success and reduction of potential HIV transmission. The developer also provided multiple guidelines for the administration of antiretroviral therapy and viral load monitoring intervals for adults, adolescents and pregnant women.   - For the current maintenance of endorsement evaluation, the Committee agreed with the developer that antiretroviral therapy and viral suppression reduce morbidity and mortality associated with HIV. The developer also submitted updated guidelines for the administration of antiretroviral therapy and viral load monitoring intervals for people living with HIV (PLWH).   - A Committee member pointed out CDC data that showed viral suppression rates were overestimated by 20% when looking at the last viral load test in a measurement period. Specifically, the analysis showed that not all patients that were suppressed at the end of the year were suppressed *throughout* the year. The developer clarified that this measure is not intended to be a durable suppression measure.   - The Committee reviewed 2010-2014 performance gap data from the Ryan White HIV/AIDS Program Services Report, with 65% viral load suppression among the 10th percentile of providers, and 94% among the 90th percentile.   - Overall, the Committee agreed that the measure met this criterion.
2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>   (2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)   2a. Reliability: **H-12; M-4; L-0; I-0** 2b. Validity: **Accepted prior evaluation**   Rationale:

NATIONAL QUALITY FORUM

19

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

2082 HIV Viral Load Suppression

- For the 2013 endorsement evaluation, the developer conducted a signal-to-noise analysis using nine of 18 HIV Research Network (HIVRN) sites and 11,134 patients in 2010. The clinic-specific reliability ranged from 0.93 to 0.99 with a between clinic variance of 0.0066.
- For the current evaluation, the developer provided updated reliability testing using the beta binomial method to assess the signal-to-noise-ratio in over 800 clinics participating in the RSR database; median reliability ranged from 0.95 to 0.98 indicating high reliability.
- A Committee member noted that since reliability ranged from 0.29 to 0.98 that some clinics may not be performing well on the measure. The developer stated that lower signal-to-noise ratios generally came from clinics with small patient populations (i.e., <25 patients).
- A Committee member questioned why the measure is specified at less than 200 copies/mL. The developer cited HHS guidelines, which indicate that although tests can quantify a viral load down to individual copies of the virus, it is generally accepted that 200 is the threshold for viral load suppression.
- Another Committee member asked the developer to define "comprehensive HIV care." The developer noted that HIV care is in various models, but ultimately they define comprehensive care as being provided by someone who is addressing the patient's HIV care (i.e., assessing whether the client is on antiretroviral medications and that viral load testing has been performed).
- One Committee member asked how the measure accounts for providers who could game the measure by choosing not to see or to create an unfavorable environment for non-adherent patients. The developer noted that it would be difficult to capture that information at the individual provider level since providers do not have a lot of control over the patients they see. The developer also noted that there is a measure (#2079) that assesses whether patients come back to the same clinic.
- In discussing what constitutes a medical visit, the Committee questioned whether non-face to face visits are included in the measure. The developer clarified that face-to-face, video visits, or another type of visit that is documented by the provider as a medical visit. If a patient comes in for lab work, to meet with an ancillary staff member or to pick up paperwork, the visit is not counted as a medical visit. The measure does not address whether visits are billable. The developer also clarified that patients are counted in the denominator if they came in for at least one visit.
- The Committee noted that the developer used a technical group and Ryan White grant recipients to test the face validity of the measure. A Committee member questioned whether the same group of people established the measure and assessed face validity. The developer clarified that these were the same group of people.
- A Committee member expressed concern that although the measure is not risk adjusted, since people living with HIV (PLWH) are a marginalized population, that the measure could be used in MIPS, a pay for performance program. The Committee member expressed concern that a provider could be penalized based on poor performance on this measure if they provided medical care to populations who are non-adherent to medical care (e.g., people experiencing homelessness, active substance users).
- The developer stated that existing methods for risk adjustment do not apply to this measure because it is currently not used in a payment program. However, the eMeasure version of this measure was submitted for consideration in the Centers for Medicare & Medicaid Services (CMS) Merit-based Incentive Payment System (CMS MIPS); therefore, the developer will work with CMS to develop appropriate methods for risk adjustment of the eMeasure.
- The Committee emphasized that there are concerns among PLWH that as measurement of HIV care is increasingly implemented, that providers will make an unfavorable environment for PLWH.
- The Committee questioned how the measure accounts for patients who have access to the care but choose not to receive it. The developer clarified that the intent of the measure is not to achieve 100%, nor is it a measure of the patient's compliance or ability to participate in care. The measure is intended to assess the clinic's ability to support a client in reaching viral load suppression.
- Upon a vote, the Committee agreed the measure met the reliability criteria.
- For the 2013 endorsement evaluation, face validity was established through a technical work group established for the development of the measures. This measure was found to be important, usable, and feasible by the technical work group overseeing the development of this measure and several others.

2082 HIV Viral Load Suppression

- For the current evaluation, the developer did not provide updated validity testing because they intend to replace this paper-based measure with #3210, the electronically specified version of this measure. The Committee agreed that the previous validity testing results were sufficient and accepted the prior evaluation without further discussion and vote.

3. Feasibility: H-14; M-1; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- All data elements for this measure are generated during routine provision of care and are in defined fields in the electronic health record. Without further discussion, the Committee agreed the measure met this criterion.

4. Usability and Use: H-15; M-0; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The measure is publicly reported and used by accountability programs including MIPS and PQRS. The measure has shown improvement in viral load suppression and no potential harms were identified in measure implementation. Without further discussion, the Committee agreed the measure met this criterion.

5. Related and Competing Measures

- This measure is related to the following:
  - 0407 HIV/AIDS: HIV RNA Control After Six Months of Potent Antiretroviral Therapy
  - 0405 HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis
  - 0409 HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis
  - 2079 HIV Medical Visit Frequency
  - 2080 Gap in HIV Medical Visits
  - 2083 Prescription of HIV Antiretroviral Therapy
  - 3211 Prescription of HIV Antiretroviral Therapy
  - 3210 HIV Viral Suppression
  - 3209 HIV Medical Visit Frequency

Per the developer, this measure is harmonized with all measures except for #0405 and #0409; there are plans to harmonize with #0405 and #0409.

Standing Committee Recommendation for Endorsement: **Y-16; N-0**

6. Public and Member Comment

-

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

NATIONAL QUALITY FORUM 21

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

3210 HIV Viral Load Suppression

Description: Percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.

Numerator Statement: Patients with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year. The outcome being measured is HIV viral suppression.

Denominator Statement: Patients, regardless of age, diagnosed with HIV during the first 3 months of the measurement year or prior to the measurement year who had at least one medical visit in the measurement year. The target population for this measure is all people living with HIV.

Exclusions: There are no patient exclusions.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Clinician Office/Clinic

Type of Measure: Outcome,

Data Source: Electronic Health Record (Only), Other

Measure Steward: Health Resources and Services Administration - HIV/AIDS Bureau

STANDING COMMITTEE MEETING [03/14/2017]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Applied the vote from #2082**; 1b. Performance Gap: **Applied the vote from #2082**

<u>Rationale</u>:

- The Committee acknowledged that this measure shares the same evidence as #2082. Because it is a legacy eMeasure, there are no performance data. The Committee agreed to apply the vote from #2082 to this criterion.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

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

2a. Reliability: H-0; **M-15; L-1; I-0** 2b. Validity: **H-0; M-16; L-0; I-0**

<u>Rationale</u>:

- This measure was tested using 34 synthetic cases with the Bonnie tool. Results showed 100% coverage and all 34 cases passed the measure as expected, demonstrating that the measure logic works as constructed. All test cases with missing data performed according to the HQMF standard as expected. Testing also included specific ways to search for patients that might fall at the edge of the measure specifications.
- Without further discussion, the Committee agreed the measure met these criteria.

3. Feasibility: H-12; M-4; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

<u>Rationale</u>:

- Feasibility testing showed that the measure is feasible but the Committee questioned why the variable "Encounter Performed: Face-to-Face Interaction" and "Patient Characteristic Payer" scored a 2 out of 3 on the feasibility scorecard. The developer clarified that "Face-to-Face Interaction" scored lower because the value set is defined in SNOMED whereas the other encounter value sets are defined in CPT. The developer further clarified that the variable "Patient Characteristic Payer" is a supplemental data element required to be submitted for measures in federal programs but is not used in the measure logic.
- The Committee asked the developer to explain why they expect feasibility to improve from 98.89% to 99.44%. The developer clarified that the addition of the SNOMED codes will increase the feasibility.
- Overall, the Committee agreed the measure met this criterion.

3210 HIV Viral Load Suppression

4. Usability and Use: H-8; M-8; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The Committee noted that the measure was reviewed by NQF's Measure Application Partnership (MAP) for consideration in CMS' MIPS program. MAP recommended support of this measure for rulemaking with the condition that the Infectious Disease Standing Committee review the performance data to ensure a gap in care continues to exist.
- The developer clarified that this measure is intended to be used in an accountability program. Without further discussion, the Committee agreed the measure met this criterion.

5. Related and Competing Measures

- This measure is related to the following:
  - 0407 HIV/AIDS: HIV RNA Control After Six Months of Potent Antiretroviral Therapy
  - 0405 HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis
  - 0409 HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis
  - 2079 HIV Medical Visit Frequency
  - 2080 Gap in HIV Medical Visits
  - 2083 Prescription of HIV Antiretroviral Therapy
  - 3211 Prescription of HIV Antiretroviral Therapy
  - 3210 HIV Viral Suppression
  - 3209 HIV Medical Visit Frequency
- Per the developer, this measure is harmonized with all measures except for #0405 and #0409; there are plans to harmonize with #0405 and #0409.

Standing Committee Recommendation for Endorsement: **Y-16; N-0**

6. Public and Member Comment

-

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

2079 HIV Medical Visit Frequency

Description: Percentage of patients, regardless of age, with a diagnosis of HIV who had at least one medical visit in each 6-month period of the 24-month measurement period with a minimum of 60 days between medical visits. A medical visit is any visit in an outpatient/ambulatory care setting with a nurse practitioner, physician, and/or a physician assistant who provides comprehensive HIV care.

Numerator Statement: Number of patients in the denominator who had at least one medical visit in each 6-month period of the 24-month measurement period with a minimum of 60 days between first medical visit in the prior 6-month period and the last medical visit in the subsequent 6-month period. (Measurement period is a consecutive 24-month period of time.)

Denominator Statement: Number of patients, regardless of age, with a diagnosis of HIV with at least one medical visit in the first 6 months of the 24-month measurement period.

Exclusions: Patients who died at any time during the 24-month measurement period.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Clinician Office/Clinic

Type of Measure: Process

Data Source: Paper Records

Measure Steward: Health Resources and Services Administration - HIV/AIDS Bureau

STANDING COMMITTEE MEETING [03/14/2017]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-0; M-2; L-1; I-13**; Evidence with Exception: **Y-14; N-2**; 1b. Performance Gap: **H-13; M-3; L-0; I-0**

Rationale:

- This measure calculates the percent of clients retained in care over a 24-month time period. Patients are counted in the numerator if they have had at least one medical visit at least 60 days apart in each 6 months of the measurement period.
- The Committee acknowledged the developer submitted updated evidence for the systematic monitoring of retention in care they could include visit adherence, gaps in care, and number of visits during a specified visit. A Committee member questioned whether there was evidence to support the 6-month interval and the 60-days between medical visits, especially when the guidelines state that clinically stable clients can be seen less frequently.
- The developer stated that the 6-month time period was selected as a 'middle ground' based on DHHS guidelines that outline the frequency of labs performed and medical visits. The 60-day period between medical visits was selected so as to not count patients, who for instance, have medical visits on consecutive days.
- Another Committee member expressed concern for programs receiving Ryan White program funds who must report this measure. The committee member noted that some programs may be forced to see stable clients more frequently just to meet the measure's requirements.
- The Committee then debated that the measure should focus on frequency of viral load testing for stable clients who only need to see a provider for lab work. They also questioned how the measure accounts for not penalizing providers who have durably suppressed clients. Some Committee members supported that the measure focus was acceptable since retention in care has been associated with improved clinical outcomes. A Committee member commented that medical visit frequency is more controlled by the health system than by the individual provider.
- The developer further clarified that they do not expect to reach 100% adherence on this measure and the measure is applicable broadly across all types of providers caring for any patient living with HIV.
- The Committee was conflicted as to whether the measure should be used for public health rather than quality improvement purposes.

NATIONAL QUALITY FORUM

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

24

2079 HIV Medical Visit Frequency

- Upon a vote, the Committee did not pass the measure on the Evidence criterion but agreed to vote on whether the measure warranted an exception to the evidence. The Committee discussed the importance of the measure on outcomes for people living with HIV but did not have evidence that explicitly stated that the measure as specified would lead to those outcomes. After a full discussion, the Committee opted to invoke the exception to the evidence criterion and agreed that medical visit frequency needed to be assessed since patients cannot be treated if they have not been seen by a provider. Ultimately, a majority of the Committee agreed that providers should be held accountable for this measure in the absence of empiric evidence and passed the measure on this criterion.
- The Committee noted that medical visit frequency had increased from 67% to 73%, with disparities – similar to those seen in #2082 – among race/ethnic, gender, and age groups.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>
(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
2a. Reliability: **H-13; M-2; L-0; I-0** 2b. Validity: **Accepted previous Evaluation**
<u>Rationale</u>:

- The Committee reviewed testing data from the RSR (covering 11 sites and more than 17,000 patients) that showed a median reliability of 0.97; upon a vote, the Committee agreed the measure met this criterion.
- Committee members questioned whether the measure is stratified to determine the model of care the patient receives (i.e., care from a primary care provider or an infectious disease provider). The developer clarified that the measure is not stratified by the type of provider.
- As was discussed for #2082, the developer clarified that tele-visits or other advanced methods count as a medical visit; the measure does not specify how the visit is delivered or whether the visit is billable.
- In response to the Committee's question as to why validity testing was not updated, the developer responded they used their resources for the testing and development of the eMeasures. The Committee then noted the performance data demonstrated the measure was able to identify differences in performance among providers. The Committee chose to accept the previous evaluation on this criterion.

3. Feasibility: H-13; M-1; L-0; I-0
(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)
<u>Rationale</u>:

- The Committee agreed that the measure was feasible with all data elements collected and generated as part of routine delivery of care. Without further discussion, the Committee agreed the measure met this criterion.

4. Usability and Use: H-11; M-4; L-0; I-0
(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)
<u>Rationale</u>:

- The measure is currently in use in CMS' Physician Quality Report System (PQRS), Value Based Payment Modifier (VBPM), and MIPS programs. Without further discussion, the Committee agreed the measure met this criterion.

5. Related and Competing Measures

- This measure is related to the following:
  - 2080 Gap in HIV Medical Visits
  - 2082 HIV Viral Suppression
  - 2083 Prescription of HIV Antiretroviral Therapy
  - 3211 Prescription of HIV Antiretroviral Therapy
  - 3210 HIV Viral Suppression

2079 HIV Medical Visit Frequency

o   3209 HIV Medical Visit Frequency
       o   0405 HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis
       o   0409 HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis
 	
• Per the developer, the measure is harmonized with the first six measures listed above. For these six measures the target population is the same (i.e., people living with HIV), however the measure focus is different (gaps in visit, prescription of ARV therapy, and viral load suppression).
 	
• NQF #0405 and #0409 have been deferred for maintenance of endorsement. There are no additional steps the developer must take since the measure focus is different (HIV patients receiving PCP prophylaxis and those screened for STDs).

Standing Committee Recommendation for Endorsement: **Y-15; N-0**
6. Public and Member Comment   •
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

3209 HIV Medical Visit Frequency

Description: Percentage of patients, regardless of age, with a diagnosis of HIV who had at least one medical visit in each 6-month period within 24 months with a minimum of 60 days between medical visits. A medical visit is any visit in an outpatient/ambulatory care setting with a nurse practitioner, physician, and/or a physician assistant who provides comprehensive HIV care.

Numerator Statement: Patients who had at least one medical visit in each 6-month of a consecutive 24 month period with a minimum of 60 days between first medical visit in the prior 6-month period and the last medical visit in the subsequent 6-month period.

Denominator Statement: Patients, regardless of age, diagnosed with HIV during the first 3 months of the year preceding the measurement period or prior to the measurement period with at least one medical visit in the first 6 months of the year preceding the measurement period. The target population for this measure is all people living with HIV.

Exclusions: Patients who died at any time during the measurement period or the 12 months preceding the measurement period.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Clinician Office/Clinic

Type of Measure: Process

Data Source: Electronic Health Record (Only)

Measure Steward: Health Resources and Services Administration - HIV/AIDS Bureau

STANDING COMMITTEE MEETING [03/14/2017]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Applied the vote from #2079**; 1b. Performance Gap: **Applied the vote from #2079**

<u>Rationale</u>:

- The Committee acknowledged that this measure shares the same evidence as #2079. Because it is a legacy eMeasure, there is no performance data. The Committee agreed to apply the vote from #2079 to this criterion.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

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

2a. Reliability: **H-0**; **M-10**; **L-5**; **I-0** 2b. Validity: **H-0**; **M-14**; **L-1**; **I-0**

<u>Rationale</u>:

- This measure was tested using 64 synthetic cases with the Bonnie tool. Results showed 100% coverage and all 64 cases passed the measure as expected, demonstrating that the measure logic works as constructed. Testing also included specific ways to search for patients that might fall at the edge of the measure specifications.
- The Committee noted that the measure excludes patients who die during the measurement period. Another Committee member stated that the measure should exclude patients who are incarcerated during the measurement period since providers could be penalized on this measure if they provide care to specific populations that experience incarceration. The developer clarified that there is no standardized variable for incarceration in electronic health records.
- Without further discussion, the Committee agreed this measure met this criterion.

3. Feasibility: H-9; M-6; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

<u>Rationale</u>:

- Feasibility testing showed that the measure is feasible at 98.21% and will increase to 98.81%.

3209 HIV Medical Visit Frequency

- The Committee questioned why the variable "Encounter Performed: Face-to-Face Interaction" and "Patient Characteristic Payer" scored a 2 out of 3 on the feasibility scorecard. The developer clarified in the discussion of #3210 that "Face-to-Face Interaction" scored lower because the value set is defined in SNOMED whereas the other encounter value sets are defined in CPT. The "Patient Characteristic Payer" variable is a supplemental data element required to be submitted for measures in federal programs but is not used in the measure logic.
- Overall, the Committee agreed the measure met this criterion.

4. Usability and Use: H-7; M-8; L-0; I-1

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The Committee noted that the measure is not publically reported. The measure is planned to be used in MIPS. Without further discussion, the Committee agreed the measure met this criterion.

5. Related and Competing Measures

- This measure is related to the following:
  - 2080 Gap in HIV Medical Visits
  - 2082 HIV Viral Suppression
  - 2083 Prescription of HIV Antiretroviral Therapy
  - 3211 Prescription of HIV Antiretroviral Therapy
  - 3210 HIV Viral Suppression
  - 3209 HIV Medical Visit Frequency
  - 0405 HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis
  - 0409 HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis
- Per the developer, the measure is harmonized with the first six measures listed above. For these six measures the target population is the same (i.e., people living with HIV), however the measure focus is different (gaps in visit, prescription of ARV therapy, and viral load suppression).
- NQF #0405 and #0409 have been deferred for maintenance of endorsement. There are no additional steps the developer must take since the measure focus is different (HIV patients receiving PCP prophylaxis and those screened for STDs).

Standing Committee Recommendation for Endorsement: **Y-16; N-0**

6. Public and Member Comment

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7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

NATIONAL QUALITY FORUM   28

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

2080 Gap in HIV Medical Visits

Description: Percentage of patients, regardless of age, with a diagnosis of HIV who did not have a medical visit in the last 6 months of the measurement year. A medical visit is any visit in an outpatient/ambulatory care setting with a nurse practitioner, physician, and/or a physician assistant who provides comprehensive HIV care.

Numerator Statement: Number of patients in the denominator who did not have a medical visit in the last 6 months of the measurement year (Measurement year is a consecutive 12-month period of time).

Denominator Statement: Number of patients, regardless of age, with a diagnosis of HIV who had at least one medical visit in the first 6 months of the measurement year. (The measurement year can be any consecutive 12-month period.)

Exclusions: Patients who died at any time during the measurement year.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Clinician : Group/Practice, Facility

Setting of Care: Clinician Office/Clinic

Type of Measure: Process

Data Source: Other, Paper Records

Measure Steward: Health Resources and Services Administration-HIV/AIDS Bureau

STANDING COMMITTEE MEETING [03/14/2017]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-0**; **M-2**; **L-0**; **I-11** 1b. Performance Gap: **H-3**; **M-10**; **L-0**; **I-0;** Evidence Exception: **Y-12; N-1**

<u>Rationale</u>:

- The Committee questioned the value of the measure over the related measure, #2079. The developer clarified that this measure looks at a shorter time period and that some users pair this measure with the longer term retention measure (#2079).
- A Committee member acknowledged the importance of retention in care, but did not believe there was evidence related to two medical visits and health outcomes. The Committee asked the developer to clarify the definition of a medical visit. The developer noted they do not specify the mode of the visit (face-to-face vs. tele-health) but that tele-health visits are not ruled out.
- In response to the Committee's question as to how a gap in medical care is defined, the developer stated that if a patient has a medical visit in the first six months of the measurement period but not within the second six months then the client would have experienced a gap in care. Based on this definition, their data indicates that 21% of patients had a gap in medical visits. Better performance for this measure is indicated by a lower rate e.
- A Committee member noted that the guidelines have changed to say that viral load should be assessed every six months but that durably suppressed clients can be seen less frequently.
- The Committee agreed that the evidence provided was insufficient; however, they agreed retention in care is important and voted to pass the measure on evidence with an exception. Notably, the Committee agreed that the measure could be used to help providers prioritize clients who have not been in care.
- The Committee noted that the performance gap had increased from 2010 to 2014 (i.e., more people are not getting regular care). Without further discussion, the Committee agreed the measure met this criterion.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

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

2a. Reliability: **Accepted prior evaluation** 2b. Validity: **Accepted prior evaluation**

<u>Rationale</u>:

- The Committee reviewed the testing data from over 800 participants in the Ryan White HIV/AIDS

2080 Gap in HIV Medical Visits

Program (RWHAP) that showed a median reliability of 0.973; without further discussion agreed to accept the prior evaluation of this measure.

- In discussion of measure validity, the Committee noted that new testing was provided but that face validity was completed. They also noted the exclusion for patients who died (<1%) had minimal impact on the overall score.
- The developer clarified they are field-testing an electronic version of this measure. Without further discussion, the Committee agreed to accept the prior evaluation of this measure.

3. Feasibility: H-10; M-3; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The Committee acknowledged that data are generated or collected by and used by health care professionals during the provision of care. All data elements are in defined fields in electronic health records. There are no fees, licenses, or other requirements to use this measure.
- A Committee member commented that the measure is calculated in the inverse and it could be confusing to those who use the measure.

4. Usability and Use: H-10; M-3; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The Committee asked the developer to explain the measure selection process for recipients of RWHAP grant funds. The developer clarified that RWHAP does not specify which measures recipients must use.
- The Committee discussed that the measure is the most useful to determine how to schedule patients, with Committee members anecdotally sharing they find the measure valuable.
- A Committee member questioned how the measure is implemented in paper records. Other Committee members responded that smaller providers with paper records have to manually count the measure and that larger centers with paper records may find the manual implementation of the measure to be difficult.

5. Related and Competing Measures

- This measure is related to the following:
  - 2079 HIV Medical Visit Frequency
  - 2082 HIV Viral Suppression
  - 2083 Prescription of HIV Antiretroviral Therapy
  - 3211 Prescription of HIV Antiretroviral Therapy
  - 3210 HIV Viral Suppression
  - 3209 HIV Medical Visit Frequency
  - 0405 HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis
  - 0409 HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis
- Per the developer, the measure is harmonized with the first six measures listed above. For these six measures the target population is the same (i.e., people living with HIV), however the measure focus is different (medical visit frequency, prescription of ARV therapy, and viral load suppression).
- NQF #0405 and #0409 have been deferred for maintenance of endorsement. There are no additional steps the developer must take since the measure focus is different (HIV patients receiving PCP prophylaxis and those screened for STDs).

Standing Committee Recommendation for Endorsement: **Y-13**; **N-0**

6. Public and Member Comment

-

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

2080 Gap in HIV Medical Visits
8. Board of Directors Vote: Y-X; N-X
9. Appeals

NATIONAL QUALITY FORUM

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

2083 Prescription of HIV Antiretroviral Therapy

Submission | Specifications

Description: Percentage of patients, regardless of age, with a diagnosis of HIV prescribed antiretroviral therapy for the treatment of HIV infection during the measurement year. A medical visit is any visit in an outpatient/ambulatory care setting with a nurse practitioner, physician, and/or a physician assistant who provides comprehensive HIV care.

Numerator Statement: Number of patients from the denominator prescribed HIV antiretroviral therapy during the measurement year.

Denominator Statement: Number of patients, regardless of age, with a diagnosis of HIV with at least one medical visit in the measurement year.

Exclusions: There are no patient exclusions.

Adjustment/Stratification:

Level of Analysis: Facility

Setting of Care: Clinician Office/Clinic

Type of Measure: Process

Data Source: Other, Paper Records, Pharmacy

Measure Steward: Health Resources and Services Administration - HIV/AIDS Bureau

STANDING COMMITTEE MEETING [03/14/2017]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Accepted previous evaluation**; 1b. Performance Gap: **H-12**; **M-0**; **L-0**; **I-0**;

Rationale:

- A Committee member noted that the evidence base for this measure addresses viral suppression but not the prescription of antiretroviral (ARV) therapy, which is the measure's focus. The Committee member pointed out that they should consider whether the mere *prescription* of antiretroviral therapy rather than the *receipt* of the therapy by the patient is adequate evidence.
- The developer noted that there is not a way to measure whether patients are picking up their medications from the pharmacy and that this measure is used in tandem with #2082.
- The Committee acknowledged that the measure is based on a strong recommendation for ARV (i.e., that the patient is taking the medication) but noted there is a difference between writing a prescription (i.e., the focus of this measure) and a patient actually receiving the medication. The Committee stated that although the measure is valuable, there does not seem to be a link between *prescribing* ARV and viral suppression.
- Ultimately, the Committee decided not to re-vote on the evidence and accepted the previous evaluation.
- From 2010 to 2014, measure performance improved from 68.4% to 77.6%, with a median score of 90% in 2014. The Committee reviewed data that showed disparities among age, gender, and racial/ethnic groups. Overall, the Committee agreed the measure met this criterion.

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

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

2a. Reliability: **Accepted prior evaluation** 2b. Validity: **Accepted prior evaluation**

Rationale:

- The Committee reviewed testing data from the Ryan White HIV/AIDS Program Services Report (RSR) (covering 2000 RWHAP recipients) showing reliability at 0.99 and found the testing method appropriate; without further discussion the Committee accepted the previous evaluation on this criterion.
- The Committee noted that the measure is abstracted from paper and electronic records and questioned why the measure does not exclude patient death. The developer sited that some providers

2083 Prescription of HIV Antiretroviral Therapy

are starting to use electronic health records and noted that death was not an exclusion for this measure because HIV mortality is extremely low and the increased burden of data collection and analysis does not add value to the measure.

- The Committee accepted the previous evaluation for reliability and validity.

3. Feasibility: H-11; M-1; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The Committed note the data elements are in electronic records, are in use and are readily available. Without further discussion, the Committee agreed the measure met this criterion.

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

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale

- The Committee acknowledges that the measure is in use and is publically reported in PQRS and MIPS. The Department of Health and Human Services selected this measure as a core HIV indicator. The Committee then agreed that the measure met this criterion.

5. Related and Competing Measures

- This measure is related to the following:
  - o 2079 HIV Medical Visit Frequency
  - o 2080 Gap in HIV Medical Visits
  - o 2082 HIV Viral Suppression
  - o 3211 Prescription of HIV Antiretroviral Therapy
  - o 3210 HIV Viral Suppression
  - o 3209 HIV Medical Visit Frequency
  - o 0405 HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis
  - o 0409 HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis
- Per the developer, the measure is harmonized with the first six measures listed above. For these six measures the target population is the same (i.e., people living with HIV), however the measure focus is different (gaps in visits, medical visit frequency, and viral load suppression).
- NQF #0405 and #0409 have been deferred for maintenance of endorsement. There are no additional steps the developer must take since the measure focus is different (HIV patients receiving PCP prophylaxis and those screened for STDs).

Standing Committee Recommendation for Endorsement: **Y-12**; **N-0**

6. Public and Member Comment

-

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

NATIONAL QUALITY FORUM   33

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

3211 Prescription of HIV Antiretroviral Therapy

Submission | Specifications

Description: Percentage of patients, regardless of age, with a diagnosis of HIV prescribed antiretroviral therapy for the treatment of HIV infection during the measurement year. A medical visit is any visit in an outpatient/ambulatory care setting with a nurse practitioner, physician, and/or a physician assistant who provides comprehensive HIV care.

Numerator Statement: Number of patients from the denominator prescribed HIV antiretroviral therapy during the measurement year.

Denominator Statement: Number of patients, regardless of age, with a diagnosis of HIV with at least one medical visit in the measurement year.

Exclusions: There are no patient exclusions.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Clinician Office/Clinic

Type of Measure: Process

Data Source: Electronic Health Record (Only)

Measure Steward: Health Resources and Services Administration - HIV/AIDS Bureau

STANDING COMMITTEE MEETING [03/14/2017]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Applied the vote from #2083**; 1b. Performance Gap: **Applied the vote from #2083**

Rationale:

- The Committee acknowledged that this measure shares the same evidence as #2083. Because it is a legacy eMeasure, there is no performance data. The Committee agreed to apply the vote from #2083 to this criterion.

2. Scientific Acceptability of Measure Properties: <u>The measure does meet the Scientific Acceptability criteria</u>

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

2a. Reliability: **H-0; M-12; L-0; I-0** 2b. Validity: **H-0; M-12; L-0; I-0**

Rationale:

- This measure was tested using 34 synthetic cases with the Bonnie tool. Results showed 100% coverage and all 34 cases passed the measure as expected, demonstrating that the measure logic works as constructed. Testing also included specific ways to search for patients that might fall at the edge of the measure specifications.
- The Committee agreed that the measure specifications are consistent with the evidence and noted that a panel of experts looked at each synthetic cases and assigned an outcome which then correlated with the results of the Bonnie testing, which demonstrates that the measure logic works.

3. Feasibility: H-9; M-3; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The Committed acknowledge measure feasibility at 98.33% and noted that data elements are in electronic records, are in use and are readily available. The Committee agreed the measure met this criterion.

4. Usability and Use: H-7; M-5; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

NATIONAL QUALITY FORUM

34

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

3211 Prescription of HIV Antiretroviral Therapy

Rationale

- The Committee acknowledges that the measure usability is similar to #2083 and without further discussion agreed the measure met this criterion.

5. Related and Competing Measures

- This measure is related to the following:
  - 2079 HIV Medical Visit Frequency
  - 2080 Gap in HIV Medical Visits
  - 2082 HIV Viral Suppression
  - 3210 HIV Viral Suppression
  - 3209 HIV Medical Visit Frequency
  - 0405 HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis
  - 0409 HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis
- Per the developer, the measure is harmonized with the first six measures listed above. For these six measures the target population is the same (i.e., people living with HIV), however the measure focus is different (gaps in visits, medical visit frequency, and viral load suppression).
- NQF #0405 and #0409 have been deferred for maintenance of endorsement. There are no additional steps the developer must take since the measure focus is different (HIV patients receiving PCP prophylaxis and those screened for STDs).

Standing Committee Recommendation for Endorsement: **Y-12**; **N-0**

6. Public and Member Comment

-

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

3215 Adult Inpatient Risk Adjusted Sepsis Mortality

Submission **| Specifications**

Description: Annual risk adjusted inpatient mortality rate for adult patients (aged 18 and over) admitted to acute care hospitals with diagnosis of severe sepsis or septic shock. The measure includes patients in acute care hospital settings over one year timeframe who had, either on admission, or during their hospital stay, a clinical diagnosis of severe sepsis (now referred to as 'sepsis') or septic shock using criteria described in the International Sepsis Definitions (Sepsis-2)

Hospitals were required to submit a protocol for early identification and treatment of severe sepsis or septic shock. Subsequent to protocol submission, hospitals were required to submit 100% of their patient cases to a data collection portal using a standardized data dictionary (see relevant sections for details). Numerous data elements including patient demographics and comorbidities among other patient care details were reported. A random sample of the data submissions were validated for accuracy. The full adult data for discharges within calendar year 2015 was used to generate statewide and hospital-specific risk adjusted mortality rates for the calendar year.

Numerator Statement: Outcome is risk adjusted inpatient mortality rate for adult patients (18 and over) admitted to an acute care hospital with a diagnosis of severe sepsis or septic shock or who develop severe sepsis or septic shock during their hospital stay.

Denominator Statement: All adult patient discharges (18 and over) in a calendar year with a diagnosis of severe sepsis or septic shock on admission or at any time during their hospital stay. This may include multiple admissions of the same patient during the measurement year. Denominator includes all cases identified using any means (administrative, registry, electronic health records, billing data, etc.), either prospectively, retrospectively, or both, that meet the International consensus definition (Sepsis- 2) of severe sepsis or septic shock.

Exclusions: Patients with advanced directives in place prior to episode of sepsis which specifically restrict any hospital specific sepsis protocol interventions or who decline (or their proxy declines) treatment for sepsis. Patients who have been transferred from one acute care hospital to another are excluded.

Adjustment/Stratification: Multivariate logistic regression model

Level of Analysis: Facility

Setting of Care: Hospital : Acute Care Facility

Type of Measure: Outcome

Data Source: Claims (Other), EHRs Hybrid, Laboratory, Management Data, Non-Medical Data, Paper Records, Pharmacy, Registry

Measure Steward: New York State Department of Health, Office of Quality and Patient Safety

STEERING COMMITTEE MEETING [03/14/2017]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Y-16**; **N-0**; 1b. Performance Gap: **H-12**; **M-3**; **L-0**; **I-1**

Rationale:

- Mortality is an important outcome for patients with sepsis and according to the developer, mortality rates are high and show significant variability across acute care hospitals unrelated to patient factors.
- The developer suggested that hospitals are able to influence mortality rates using early sepsis detection approaches coupled with rapid delivery of basic resuscitation interventions including the use of adequate intravenous fluids, antibiotics, blood pressure support medications and dynamic clinical monitoring for response.
- The Committee agreed that the developer clearly identified how healthcare facilities and providers influence sepsis mortality outcomes.
- The developer provided the risk-adjusted probability of inpatient sepsis mortality rates from 179 hospitals and 43,204 patients in New York State from January 1, 2015 – December 31, 2015 for this newly developed measure. The mean performance rate in Q1 2015 was 30.4%, 28.9% in Q2 2015,

NATIONAL QUALITY FORUM   36

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

3215 Adult Inpatient Risk Adjusted Sepsis Mortality

28.8% in Q3 2015 and 28.4% in Q5 2015. The performance rates in 2015 ranged from a minimum of 1.0% (Q1-Q4) to a maximum of 95.0% (Q4). The developer also provided the probability of inpatient sepsis mortality rates by population group, which included race/ethnicity, gender, age and insurance/payer. White, non-Hispanics had a rate of 28.2%; Black, non-Hispanics had a rate of 31.5%; and Hispanics had a rate of 26.3%. Rates based on gender were similar with 28.4% for females and 29.8% for males. Patients 70 to 80+ years old had rates from 31.0% to 33.9%. The probability of inpatient sepsis mortality also varied based on insurance/payer. Patients with Medicare had a rate of 30.6%; Medicaid patients had a rate of 26.2%; Private pay and/or HMO patients had a rate of 27.1%; self-pay patients had the highest probability of inpatient sepsis morality, 34.3%.

- The Committee recognized the variability in coding practices related to sepsis and the potential impact on the denominator of this measure. After a lengthy discussion, the Committee agreed that the data presented by the developer demonstrated significant variation and an opportunity for improvement in inpatient sepsis mortality across hospitals.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

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

2a. Reliability: **H-2**; **M-8**; **L-0**; **I-6** 2b. Validity: **H-4**; **M-8**; **L-1**; **I-3**

<u>Rationale</u>:

- The developer conducted data element validity testing, which counted for data element reliability testing as well.
- The dataset included hospitals in New York State that were required to develop and implement early recognition and treatment protocols for sepsis. As part of this statewide initiative, hospitals were required to submit quarterly clinical data to the New York State Department of Health to be evaluated for protocol use, adherence to time interventions and patient outcomes, including mortality.
  - The dataset included 179 hospitals with 43,204 patients diagnosed with severe sepsis and septic shock from January 1, 2015 to December 31, 2015.
  - The dataset used to develop the logistic regression model included:
    - Development sample: 38,884 (90%) patients; 179 hospitals
    - Validation sample: 4,319 (10%) patients; 160 hospitals
- The developer validated the accuracy of the data submission from the hospitals against manual chart abstraction by external auditors (Audit Results), which is considered the gold standard. The developer calculated the percent agreement between the hospital submissions to the chart-abstracted data. Percent agreement from the audit results ranged from 89.9% to 99.1% for the following data elements:
  - Site of infection: 98.9%
  - Lower Respiratory Infection: 98.8%
  - Mechanical Ventilation: 97.8%
  - Age (Date of Birth): 99.2%
  - Thrombocytopenia: 97.7%
  - Septic Shock: 98.4%
  - Serum Lactate (Lactate Level): 93.9%
  - Metastatic Cancer: 97.1%
  - Lymphoma, Leukemia, Multiple Myeloma: 99.1%
  - Square Root of Comorbidity Count (Range of Comorbidities): 89.9% - 99.1%
- The developer noted that the data elements race, ethnicity, payer and admission source were not manually audited but were aligned to state administrative datasets to ensure accuracy.
- The developer did not provide sensitivity, specificity, positive predictive value (PPV) and negative predictive values (NPV) in addition to percent agreement.
- The developer clarified that if a case was initially coded as severe sepsis or septic shock but the manual review found that the case did not meet the clinical definition of severe sepsis or septic shock, the hospital was able to exclude the case.
- A Committee member asked if the developer had compared patients that present to the emergency department (ED) with sepsis vs. patients that develop sepsis while hospitalized. The developer replied

NATIONAL QUALITY FORUM   37

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

that they intend to continue researching the differences in outcomes for patients that present to the ED with sepsis vs. patients that acquire sepsis in the hospital.

- The Committee did not express any other concerns with the reliability of the measure and agreed it met the reliability criterion.
- Empirical validity testing of the measure score was assessed by comparing the performance of the risk-adjusted model in the development sample to the validation sample.
    - The developer used the Hosmer-Lemeshow goodness of fit test to assess the observed and expected mortality rates in the development and validation samples.
        - The development dataset was split into group sizes of 10, 100, 500 and 1,000. The p-values were 0.568, 0.972, 0.735, and 0.735, respectively.
        - The validation dataset was split into group sizes of 10, 50, 100 and 150. The p-values were 0.651, 0.977, 0.985, and 0.974, respectively.
- The performance of the risk-adjustment model was similar in the development and validation datasets. The areas under the receiver operating characteristic (ROC) curve (or c-statistic) were **0.770** and **0.773**, respectively. A c-statistic is a model of discrimination statistic. A c-statistic of 0.77 means that 77.0% of all possible pairs of patients – one who died and one who lived – the model correctly assigned a higher probability to those who died. The similar c-statistics indicates good model discrimination.
- A Committee member questioned whether a c-statistic of 0.7 was sufficient. NQF staff responded that although NQF staff does not have specific statistical thresholds, generally, a c-statistic of at least 0.70 is considered acceptable.
- Exclusions include patients with advanced directives in place prior to episode of sepsis which specifically restrict any hospital specific sepsis protocol interventions or who decline (or their proxy declines) treatment for sepsis and patients who have been transferred from one acute care hospital to another. The developer maintained that keeping patients in the dataset that had an advanced directive or declined intervention would bias the results towards higher hospital mortality.
- In the pre-evaluation comments, one of the Committee members questioned why excluding patients with multiple admissions is appropriate because this would artificially increase the mortality rate; however, patients with multiple admissions are not excluded from the denominator. The denominator details state that multiple admissions of the same patient during the measurement year are included.
- This measure is risk-adjusted using a multivariable logistic regression model with 16 variables to estimate the probability of mortality for patients admitted to acute care hospitals with severe sepsis or septic shock. The model was built using the development dataset and starting with all possible covariates in the model. Using an iterative procedure, variables were removed from the model, one by one, if the p-values were not significant at 0.05 level until a parsimonious model was reached.
    - Variables removed during the development procedure were added back into the reduced model if the p-values were significant at the 0.05 level and if model calibration (Hosmer-Lemeshow goodness of fit) was improved through their inclusion.
    - The scale of the three continuous variables (patient age, first serum lactate, and the count of the number of comorbidities) remaining in the model was assessed. Using the method of fractional polynomials patient age was included in the model as a linear term, number of comorbidities was transformed by taking the square root, and first serum lactate was entered into the model as a quadratic expression (linear and a squared term).
    - Model calibration was further improved by adding the following interactions to the model: lower respiratory infection (LRI) by MV severity, patient age by the square root of the number of comorbidities, and first serum lactate by the square root of the number of comorbidities.
    - Age, gender, payer, race and ethnicity were initially included in the model. Gender was the only variable included in the model since its odds ratio and corresponding p-value was 1.0003 and 0.992, respectively. All of the other demographic variables had p-values < 0.001 for at least one of the levels of a specific demographic.
- The developer stated that the intent of this risk model is to estimate the *probability* of mortality due to sepsis not *predict* mortality rates due to sepsis. By estimating the probability, the developer continued, the expected number of events (sepsis mortality) for each hospital is calculated. Variables

3215 Adult Inpatient Risk Adjusted Sepsis Mortality

must be clinically and statistically significant to be included in the risk model. The Committee recognized that the developer deliberately excluded hospital characteristics from the variables in the risk model because organizational variables do modify the probability of mortality for patients.

- One of the Committee members stated that they would like to see a statistical analysis, such as a funnel plot, demonstrating outliers (i.e., # of hospitals, hospital size and statistical threshold). A funnel plot is helpful in illustrating real variation among hospitals vs. noise.
- Ultimately, the Committee agreed the measure met the validity criterion.

3. Feasibility: H-1; M-11; L-3; I-1

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The developer noted that some data elements are in defined fields in electronic sources, and that some demographic variables can be extracted electronically and used in a standard format. Other variables are collected manually by hospitals though some hospitals have created electronic data capture avenues.
- During the workgroup call, the Committee discussed the amount of manual chart abstraction that would be required to collect the data for this measure. The Committee acknowledged the challenges related to the feasibility of this measure but agreed that it was not impossible.

4. Usability and Use: H-2; M-10; L-1; I-3

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- This measure is in use in New York State. New York State requires the Department of Health to collect and report data regarding the performance of hospitals for patients with sepsis including risk adjusted mortality rates for individual hospitals.
- The Committee agreed that hospitals in other states could use this measure to track sepsis mortality outcomes.

5. Related and Competing Measures

- This measure is related to:
  - #0500: Severe Sepsis and Septic Shock: Management Bundle
- The developer stated the measure specifications are harmonized to the extent possible.

Standing Committee Recommendation for Endorsement: **Y-11; N-5**

6. Public and Member Comment

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7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

0500 Severe Sepsis and Septic Shock: Management Bundle

Submission **| Specifications**

Description: This measure focuses on adults 18 years and older with a diagnosis of severe sepsis or septic shock. Consistent with Surviving Sepsis Campaign guidelines, the measure contains several elements, including measurement of lactate, obtaining blood cultures, administering broad spectrum antibiotics, fluid resuscitation, vasopressor administration, reassessment of volume status and tissue perfusion, and repeat lactate measurement. As reflected in the data elements and their definitions, these elements should be performed in the early management of severe sepsis and septic shock.

Numerator Statement: The number of patients in the denominator who received ALL of the following components (if applicable) for the early management of severe sepsis and septic shock: initial lactate levels, blood cultures, antibiotics, fluid resuscitation, repeat lactate level, vasopressors, and volume status and tissue perfusion reassessment.

- Within 3 hours of presentation of severe sepsis:
    - o Measure initial lactate level
    - o Draw blood cultures prior to antibiotics
    - o Administer broad spectrum or other antibiotics
- Within 6 hours of presentation of severe sepsis:
    - o Repeat lactate level (if initial lactate > 2 mmol/L)
- Within 3 hours of presentation of septic shock:
    - o Administer 30 ml/kg crystalloid for hypotension or lactate ≥ 4 mmol/L
- Within 6 hours of presentation of septic shock:
    - o Apply vasopressors (for hypotension that does not respond to initial fluid resuscitation) to maintain a mean arterial pressure (MAP) ≥ 65 mm Hg
    - o Reassess volume status and tissue perfusion in the event of persistent hypotension (MAP <65 mm Hg) after initial fluid administration or initial lactate level ≥ 4 mmol/L
        - ▪ The clinician is no longer required to state the method of reassessment used (e.g. physical exam, bedside cardiovascular ultrasound, passive leg raising, CVP, ScV02 assessment). The clinician can attest that volume and perfusion reassessment has occurred, even without reference to the method used. This will meet the measure's volume and perfusion reassessment requirement. A provider may also opt to state their chosen method, but this is not required.

Denominator Statement: Inpatients age 18 and over with an ICD-10-CM Principal or Other Diagnosis Code of Sepsis, Severe Sepsis, or Septic Shock.

Exclusions: The following patients are excluded from the denominator:

- Severe sepsis is not present
- Patients Transferred in from another acute care facility
- Patients receiving IV antibiotics for more than 24 hours prior to presentation of severe sepsis.
- Patients with a Directive for Comfort Care or Palliative Care within 3 hours of presentation of severe sepsis
- Patients with an Administrative Contraindication to Care within 6 hours of presentation of severe sepsis
- Patients with an Administrative Contraindication to Care within 6 hours of presentation of septic shock
- Patients with a Directive for Comfort Care or Palliative Care within 6 hours of presentation of septic shock
- Patients with septic shock who are discharged within 6 hours of presentation
- Patients with severe sepsis who are discharged within 6 hours of presentation
- Patients with a Length of Stay >120 days
- Patients included in a Clinical Trial

0500 Severe Sepsis and Septic Shock: Management Bundle

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Hospital

Type of Measure: Composite

Data Source: Imaging-Diagnostic, Laboratory, Other, Paper Records, Pharmacy

Measure Steward: Henry Ford Hospital

STEERING COMMITTEE MEETING [03/14/2017]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-4**; **M-9**; **L-0**; **I-2**; 1b. Performance Gap: **H-14**; **M-0**; **L-1**; **I-0;** 1c. Composite – Quality Construct and Rationale: **H-5; M-7; L-1; I-2**

<u>Rationale</u>:

- For the 2012 endorsement-maintenance evaluation, the developer provided the 2008 Surviving Sepsis Campaign guidelines with recommendations for initial resuscitation, measuring lactate, obtaining appropriate blood cultures, antibiotic therapy, fluid therapy, vasopressors and monitoring central venous pressure (CVP) and central venous oxygen saturation (ScvO$_2$).
- In 2012, concerns were raised about the level of evidence supporting invasive monitoring of CVP and ScvO2. The Infectious Disease Steering Committee acknowledged these concerns yet determined that the current evidence at the time was sufficient to warrant endorsement of the full bundle, and the measure was approved as specified. NQF received an appeal and the Consensus Standards Approval Committee (CSAC) upheld the measure's endorsement with the condition that NQF commit to an immediate re-evaluation of the measure upon release of new evidence from several ongoing studies including the Protocolized Care for Early Septic Shock (ProCESS) trial.
- In 2014, the Patient Safety Standing Committee conducted an *ad hoc* review based on a request from the American College of Emergency Physicians (ACEP). The *ad hoc* review focused on the evidence supporting CVP and ScvO2 and the new data from the ProCESS trial. See [NQF-Endorsed Measures for Patient Safety (January 30, 2015)](#) for complete summary.
  - The ProCESS trial demonstrated no difference in mortality outcomes when using an invasive approach to monitoring CVP and ScvO2 compared to usual care or protocolized care without invasive monitoring. The Committee noted that the new results from the ProCESS trial suggested that a mandate to measure CVP and ScvO2 with an invasive line might not be necessary in all patients with severe sepsis and septic shock.
  - Experts in support of maintaining these elements in the measure argued additional trials (ARISE and PROMISE) were underway; however, these trials were smaller than the ProCESS trial and not performed in the U.S. In addition, these experts argued that the protocolized care and requirement for CVP and ScvO2 monitoring was particularly helpful in community hospitals, which were not included in the ProCESS trial.
  - After extensive discussions and negotiations the measure developers, ProCESS trial investigators and specialty societies (including the Society of Critical Care Medicine (SCCM) and the American College of Emergency Physicians (ACEP)) reached a compromise for an evidence-based replacement element – optional measurement of CVP and ScvO2, along with reassessment by other means (re-assess volume status and tissue perfusion after initial resuscitation and document findings).
- For the current maintenance of endorsement evaluation, the developer provided the following updated evidence to support the changes to the measure since the last submission:
  - The developer provided a synthesis of the literature for the following updated components, which are based on the [Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock: 2016.](#) *[Note: Grading of recommendations for the components below are taken from the Sepsis and Septic Shock 2016 Guidelines]*

NATIONAL QUALITY FORUM

41

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

0500 Severe Sepsis and Septic Shock: Management Bundle

> - Measure lactate level; Repeat lactate if initial lactate is elevated *[weak recommendation, low quality of evidence1]*
> - Obtain cultures prior to antibiotics *[Best practice statement]*
> - Administer broad spectrum antibiotics *[strong recommendation, moderate quality of evidence]*
> - Administer 30 ml/kg crystalloid for hypotension or lactate ≥ 4 mmol/L *[strong recommendation, low quality of evidence]*
> - Apply vasopressors (for hypotension that does not respond to initial fluid resuscitation to maintain a mean arterial pressure ≥ 65 mmHg) *[strong recommendation, moderate quality of evidence]*
> - Reassess volume status and tissue perfusion *[Best practice statement]*. The developer provided a synthesis of the literature for some common practices used when reassessing volume status and tissue perfusion in the event of persistent hypotension (MAP <65 mm Hg) after initial fluid administration or initial lactate level ≥ 4 mmol/L. ***[Note: Clinician is no longer required to document the method used; attestation is sufficient]***

- One of the Committee members questioned the use of lactic levels to diagnose sepsis because other conditions can elevate lactate levels. The developer responded that measuring lactate levels alone does not diagnose sepsis. However, in the presence of a suspected infection, elevated lactate levels are useful in determining illness severity.
- The Committee pointed out the varying level of evidence for the different components but agreed that overall, the updated evidence is consistent with the 2016 Guidelines for Management of Sepsis and Septic Shock.
- The developer provided the following composite performance rates from CMS' Hospital Inpatient Quality Reporting (IQR) program from October 2015 to June 2016:

	Oct-Dec 2015	Jan-Mar 2016	Apr-Jun 2016
# of hospitals	3,134	3,182	3,193
# of eligible cases	96,516	104,166	101,599
Overall performance rate	34.4	39.5	44.0
10th percentile	5.0	7.7	12.5
25th percentile	17.9	21.6	25.8
Median	31.0	36.1	41.7
75th percentile	45.8	51.3	57.1
90th percentile	60.0	66.7	71.4
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
Average	32.6	37.1	41.9
Standard Deviation	21.1	21.9	22.9

- The developer also provided the following component rates categorized by 3 and 6 hour elements:

Population Description	Cases	Bundle %
Initial Population Number of Sepsis Cases	325,809	--

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1 Per guideline authors, 'low' grade assigned to quality of evidence (5 RCTs) because 1) all studies were judged to be at high risk of bias due to lack of clarity of the intervention, therefore, we downgraded the quality of evidence by one level for risk of bias; 2) We downgraded the quality of evidence by one level for imprecision, the CI contained small benefit that was lower than the decision threshold; and 3) We assumed a mortality rate for patients with septic shock to be 40%.

0500 Severe Sepsis and Septic Shock: Management Bundle

Total Number of Excluded Sepsis Cases	*166,520*	*--*
Total Number of Eligible Sepsis Cases	**159,289**	**--**
Total Number of Passed Sepsis Cases	*64,051*	*--*
Total Number of Failed Sepsis Cases	*95,238*	*--*
Severe Sepsis 3 Hour Bundle Eligible Cases	**167,114**	**--**
Severe Sepsis 3 Hour Bundle Passes	*110,078*	*65.9%*
Severe Sepsis 3 Hour Bundle Failures	*54,618*	*32.7%*
Initial Lactate Level Failures	26,503	48.5%
Broad Spectrum or Other Antibiotic Administration Failures	20,951	38.4%
Blood Culture Collection Failures	18,772	34.4%
Severe Sepsis 6 Hour Bundle Eligible Cases	**90,385**	**--**
Severe Sepsis 6 Hour Bundle Passes	*53,475*	*59.2%*
Severe Sepsis 6 Hour Bundle Failures	*36,910*	*40.8%*
Repeat Lactate Level Failures	36,910	
Septic Shock 3 Hour Bundle Eligible Cases	**40,989**	**--**
Septic Shock 3 Hour Bundle Passes	*22,359*	*54.5%*
Septic Shock 3 Hour Bundle Failures	*18,630*	*45.5%*
Crystalloid Fluid Administration Failures	18,630	
Vasopressor Shock 6 Hour Bundle Eligible Cases	**8,177**	**--**
Vasopressor Shock 6 Hour Bundle Passes	*6,157*	*75.3%*
Vasopressor Shock 6 Hour Bundle Failures	*2,020*	*24.7%*
Vasopressor Administration Failures	2,020	
Focus Exam Shock 6 Hour Bundle Eligible Cases	**14,630**	**--**
Focus Exam Shock 6 Hour Bundle Passes	*3,801*	*26.0%*
Focus Exam Shock 6 Hour Bundle Failures	*9,935*	*67.9%*
Hemodynamic Choices Shock 6 Hour Bundle Eligible Cases	**10,829**	**--**
Hemodynamic Choices Shock 6 Hour Bundle Passes	*894*	*8.3%*
Hemodynamic Choices Shock 6 Hour Bundle Failures	*9,935*	*91.7%*

- The developer noted that the 'repeat volume' and 'perfusion assessment' data is broken down into 'focused exam' and 'hemodynamic choice' – data elements that are no longer required. No performance data is yet available on the new attestation strategy.
- The developer also provided the following composite performance rates by ethnicity, gender and Medicare/non-Medicare:

	Oct-Dec 2015	Jan-Mar 2016	Apr-Jun 2016
Hispanic	34.53	39.8	44.23
Non-Hispanic	32.64	36.35	40.82
Females	33.82	39.22	43.28

NATIONAL QUALITY FORUM   43

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

0500 Severe Sepsis and Septic Shock: Management Bundle

Males	34.93	39.86	44.63
Medicare	34.9	40.07	44.57
Non-Medicare	33.32	38.47	42.76
Black	30.64	35.93	40.29
White	34.95	40.08	44.58
Other	34.95	40.01	43.82

- The performance rates for different age categories were similar (~34.0).
- The Committee agreed that the developer presented abundant data demonstrating a performance gap and opportunity for improvement in severe sepsis and septic shock care.
- Another Committee member commented that in addition to a performance gap in care, there is still a lack of implementation of this measure in the clinical setting.
- This all-or-none composite measure requires patients with severe sepsis or septic shock to meet all of the eligible components in the composite: lactate collection, delivery of broad-spectrum antibiotics, obtaining blood cultures, delivering resuscitation fluids, applying vasopressors as needed, reassessing volume and perfusion status and repeating lactate values. All components are equally weighted. The developer noted that the composite ensures a strategy aimed at reducing mortality. The components could not stand alone unless certain preceding conditions have been met. In addition, the components are aggregated in three and 6-hour elements for severe sepsis and septic shock.
- A Committee member suggested that the data elements should be weighted differently based on the level of evidence for each. The Committee member also questioned the two different time periods. The developer responded that severe sepsis and septic shock are two different diagnoses that qualify for this measure. Therefore, the measure is constructed so that there are dependencies, both in time and condition, based on the diagnosis of severe sepsis or septic shock. The severity of the patient's condition determines whether they qualify to receive all of the components in the composite measure and when.
- The Committee agreed, that overall, the quality construct and rational for the composite was clearly stated and logical*.*

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

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

2a. Reliability: **H-7**; **M-7**; **L-0**; **I-1** 2b. Validity: **H-0**; **M-11**; **L-1**; **I-3**

<u>Rationale</u>:

- For the 2012 endorsement evaluation, the developer conducted a signal-to-noise analysis of the individual bundle elements and overall bundle reliability and composite measure reliability by site for 165 hospitals and 15,022 patients from January 2005 – March 2008.
- Effective 2013, NQF determined that reliability of the individual component measures was not sufficient; reliability must be demonstrated for the composite measure score.
- For the current evaluation, the developer provided updated reliability testing at the composite score level using a random sample of SEP-1 chart-abstracted data submitted to CMS as part of the Hospital Inpatient Quality Reporting (IQR) program. The sample included 302,281 cases in the denominator (after exclusions) and 119,048 cases in the numerator from 3,134 to 3,193 hospitals (depending on the quarter) from October 2015 to June 2016.
- The developer used a beta-binomial model to assess the signal-to-noise ratio. A reliability of 0.0 implies that all the variability in a measure is attributable to measurement error. A reliability of 1.00 implies that all the variability is attributable to real differences in performance. The higher the reliability score, the greater is the confidence with which one can distinguish the performance of one provider from another. This is an appropriate test for measure score reliability. A reliability of 0.70 is generally considered a minimum threshold for reliability.
  - The median reliability score was calculated including all facilities and facilities with a minimum of 10 eligible cases (more than 86% of reporting facilities).
  - The developer provided the overall reliability score for the composite measure for each quarter:
    - October 2015 – December 2015: 0.92 (CI 0.41 – 1.00)

- o January 2016 – March 2016: 0.93 (CI 0.47 – 1.00)
- o April 2016 – June 2016: 0.93 (CI 0.42 – 1.00)
- In the pre-evaluation comments, the Committee expressed some concerns that the self-reported clinician attestation for the data element 'volume and perfusion reassessment' may lead to more subjectivity but lauded the developers in their efforts to reduce documentation and chart abstraction burden.
- During the in-person meeting, the Committee did not voice any additional concerns related to reliability and agreed the reliability testing results were sufficient.
- For the 2012 endorsement evaluation, the developer assessed the validity of the measure score by testing the hypothesis that those with higher scores on the composite performance measure should have a lower score on a risk-adjusted mortality measure. The developer reported that hospital mortality was reduced by 10% for patients that were compliant with the composite measure.
- For the current evaluation, the developer provided updated validity testing at the composite score level. The developer performed a Chi-Square Test of Association and Equal Proportions between two categorical variables: Measure Outcome (Failed or Passed) and Mortality Result (Died or Survived). The Chi-Square Test of Association and Equal Proportions demonstrated a p-value of <.0001, a risk ratio of 1.3856, a lower 95% confidence limit of 1.3616 and an upper 95% confidence limit of 1.4101. A risk ratio higher than 1.0 with a significant p-value, would indicate that there is a higher risk of dying when a case fails the measure compared to when a case passes the measure.
    - o The risk ratio can be expressed as an actual ratio and it can be said with 95% confidence, cases that fail the measure have 1.36 to 1.41 times the risk of dying compared to cases that pass the measure; or
    - o The risk ratio can also be used as a percentage and be said that with 95% confidence, cases that fail the measure have a 36% to 41% increase in risk of dying compared to cases that pass the measure.
- The developer provided sepsis rate comparisons analyses, which demonstrated a negative association between pass rates and mortality rates from October 2015 to June 2016.
- The developer also included an analysis of pass rates and mortality rates by percentiles and a two-proportions z-test. The z-test determines if there is a statistically significant difference in mortality rates between percentiles. These methods are appropriate for empirically assessing the validity of the composite measure score. The results of the sepsis mortality analysis demonstrated that 30.4% of the total number of 'Failed Sepsis Cases' died (at discharge and up to 30 days after discharge) compared to 21.9% of the total number of 'Passed Sepsis Cases'. The two-proportion z-test demonstrated that four of the percentile comparisons have a statistically significant difference between mortality rates at a significance level of 0.05. Three additional percentile comparisons are fairly close to a statistically significant difference between mortality rates at a significance level of 0.10.
- The developer also provided the mortality rate for patients who received all applicable elements of care for the composite measure (passed sepsis cases) and those who did not (failed sepsis cases) for each quarter – the mortality rate for those who received all applicable elements was on average 8.5% lower compared to patients who did not receive all applicable elements of care.

Description	Severe Sepsis and Septic Shock Mortality Rate		
	2015 Q4	2016 Q1	2016 Q2
Did not Meet Guidelines for SEP-1	29.6%	31.8%	29.7%
Met Guidelines for SEP-1	21.3%	23.0%	21.4%
Absolute Reduction Rate	8.3%	8.8%	8.3%
Relative Reduction Rate	28.04%	27.7%	27.9%
	Potential Preventable Deaths		
	2,783	2,864	2,411

NATIONAL QUALITY FORUM

45

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

0500 Severe Sepsis and Septic Shock: Management Bundle

- The Committee discussed the results of the patient-level data element validity testing conducted by CMS. Several Committee members were concerned because out of the 55 data elements tested for validity, 15 data elements (27.27%) had a percent agreement higher than 90%. The remaining 40 data elements (72.73%) had a percent agreement lower than 90%. The developer stated that there have been numerous education and outreach efforts and updates to the measure with the intent of clarifying guidance and decreasing abstractor complexities in an effort to improve successive validation testing. NQF staff noted that this method is not appropriate for composite measures. NQF composite performance measure evaluation guidance (2013) states that validity testing is directed toward the inferences that can be made about accountable entities on the basis of their performance measure scores. For the purposes of endorsing composite performance measures, validity testing of the constructed composite performance measure score is more important than validity testing of the component measures. Even if the individual component measures are valid, the aggregation and weighting rules for constructing the composite could result in a score that is not a true reflection of quality (p. 12-13).
- The developer stated that the number of exclusions was not significant enough to unfairly distort measure performance results and potentially negatively affect the reliability of the measure because the vast majority of the exclusions were cases where severe sepsis was not present (72.34%) and should not be analyzed.
- The developer provided the table included in performance gap to demonstrate the contribution of each component to the composite score.
- The Committee agreed that the measure met the validity criterion.

3. Feasibility: H-1; M-9; L-5; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- Data elements are abstracted from a record by someone other than the person obtaining the original information (e.g. chart abstraction); some data elements are in defined fields in electronic sources.
- The developer noted that the measure is complex and requires data abstractors to "comb through documentation and interpret" clinician documentation; however, the most recent updates to the measure should lessen documentation and abstractor burden. The developer also stated that the measure has gone through three updates to lessen abstractor burden and address issues related to data availability, missing data, and frequency of data collection.
- The developer also stated that preliminary efforts to convert this measure to an electronic measure within the HQMF/QDM framework were not feasible. Currently, there are no plans to respecify this measure into an eMeasure.
- There are no fees or licenses required to use this measure.
- In the pre-evaluation comments and during the in-person meeting, the Committee noted that the feasibility of this measure was a significant concern. In the pre-evaluation comments one of the Committee members acknowledged that although clinicians routinely document the required data elements for this measure, it is complex and likely results in significant time and costs associated with data collection and reporting. During the in-person meeting, the developer clarified that it is the clinician's responsibility to document appropriate care, therefore, decreasing the burden on the abstractors.
- The developer and CMS representatives reiterated that they regularly receive feedback from hospitals and their abstractors and are currently monitoring the most recent changes to the specifications and implementation guide.
- The Committee concluded that the feasibility of this measure is challenging but it meets the criteria.

4. Usability and Use: H-2; M-6; L-6; I-0 Consensus was not reached on the Usability and Use criteria

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

NATIONAL QUALITY FORUM

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

46

0500 Severe Sepsis and Septic Shock: Management Bundle
Rationale: • The measure is currently used in CMS' Hospital Inpatient Quality Reporting (IQR) Program for acute care hospitals nation-wide. Across the three quarters of available data, between 3,134 and 3,193 providers submitted data, which represents more than 95% of eligible providers nationwide. • The measure is not currently publicly reported, but will be added to the Hospital Compare website at a date to be determined. Due to the complexity of the measure specifications, CMS desires to review and analyze the data prior to making it publicly available. There were also several updates to the specifications based on stakeholder feedback, and CMS wants to assure stability of the specifications before public reporting. • The Committee discussed the unintended consequences associated with diagnosing and treating sepsis. Because sepsis is a combination of symptoms rather than a disease, the Committee noted, patients often receive antibiotics prior to a conclusive diagnosis of sepsis – this is similar to the unintended consequences that occurred with the overuse of antibiotics in the emergency room in an effort to meet the now retired pneumonia measure. • At the end of the discussion, the Committee did not reach consensus on the usability and use of the measure during the in-person meeting.
5. Related and Competing Measures • This measure is related to: o 3215: Adult Sepsis Mortality Outcome Measure (New York State Department of Health)
Standing Committee Recommendation for Endorsement: **Y-10**; **N-4**
6. Public and Member Comment •
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

Measures Withdrawn from Consideration

Seven measures previously endorsed by NQF have not been re-submitted for maintenance of endorsement. Endorsement for these measures will be removed.

Measure	Reason for withdrawal
0393: Hepatitis C: Confirmation of Hepatitis C Viremia	In order to align the change in endorsement status with CMS's transition from the Physician Quality Reporting System (PQRS) to the Quality Payment Program (QPP).
0395: Paired Measure: Hepatitis C Ribonucleic Acid (RNA) Testing Before Initiating Treatment (paired with 0396)	In order to align the change in endorsement status with CMS's transition from the Physician Quality Reporting System (PQRS) to the Quality Payment Program (QPP).
0396: Paired Measure: Hepatitis C Virus (HCV) Genotype Testing Prior to Treatment (paired with 0395)	In order to align the change in endorsement status with CMS's transition from the Physician Quality Reporting System (PQRS) to the Quality Payment Program (QPP).
0398: Hepatitis C: Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Testing Between 4-12 Weeks after Initiation of Treatment	In order to align the change in endorsement status with CMS's transition from the Physician Quality Reporting System (PQRS) to the Quality Payment Program (QPP).
0399: Paired Measure: Hepatitis C: Hepatitis A Vaccination (paired with 0400)	In order to align the change in endorsement status with CMS's transition from the Physician Quality Reporting System (PQRS) to the Quality Payment Program (QPP).
0404: HIV/AIDS: CD4 Cell Count or Percentage Performed	Developer is no longer able to support measure. Retired by Developer.
0408: HIV/AIDS: Tuberculosis (TB) Screening	Developer is no longer able to support measure. Retired by Developer.

Appendix B: NQF Infectious Disease Portfolio and Related Measures

Denotes the measure is within the Infectious Disease portfolio

HIV/AIDS

2079: HIV Medical Visit Frequency*

2080: Gap in HIV Medical Visits*

2083: Prescription of HIV Antiretroviral Therapy*

0405: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis*

2082: HIV Viral Load Suppression*

3086: Population Level HIV Viral Load Suppression

Sexually Transmitted Infections

0409: Sexually Transmitted Diseases – Screening for Chlamydia, Gonorrhea, and Syphilis*

0033: Chlamydia Screening in Women

Hepatitis

3059: One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk – trial use

3060: Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users – trial use

3061: Appropriate Screening Follow-up for Patients Identified with Hepatitis C Virus (HCV) Infection – trial use

Vaccinations – Hepatitis B

0475: Hepatitis B Vaccine Coverage Among All Live Newborn Infants Prior to Hospital or Birthing Facility Discharge

Vaccinations – Childhood Immunizations

0038: Childhood Immunization Status (CIS)

1407: Immunizations for Adolescents

Vaccinations – HPV

1959: Human Papillomavirus Vaccine for Female Adolescents (HPV)

Vaccinations – Influenza

0039: Flu Vaccinations for Adults Ages 18 and Older

0041: Preventive Care and Screening: Influenza Immunization

0431: Influenza Vaccination Coverage Among Healthcare Personnel

NATIONAL QUALITY FORUM

49

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

0680: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (short stay)

0681: Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine (long stay)

1659: Influenza Immunization

0226: Influenza Immunization in the ESRD Population (Facility Level)

Vaccinations – Pneumococcal

0043: Pneumococcal Vaccination Status for Older Adults (PNU)

Sepsis

0500: Severe Sepsis and Septic Shock: Management Bundle*

3215: Adult Inpatient Risk Adjusted Sepsis Mortality*

Antimicrobial Use

2720: National Healthcare Safety Network (NHSN) Antimicrobial Use Measure

ENT

0654: Acute Otitis Externa: Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use (ENT)

Respiratory

0058: Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis (AAB)*

0069: Appropriate Treatment for Children with Upper Respiratory Infection (URI)*

0147: Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients

0096: Community-Acquired Bacterial Pneumonia (CAP): Empiric Antibiotic

2414: Pediatric Lower Respiratory Infection Readmission Measure

Facility-Acquired Infections

1716: National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure

1717: National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure

0138: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure

0139: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure

0684: Percent of Residents with a Urinary Tract Infection (Long-Stay)

3025: Ambulatory Breast Procedure Surgical Site Infection (SSI) Outcome Measure

Perioperative Antibiotics – Selection

0268: Perioperative Care: Selection of Prophylactic Antibiotic: First OR Second Generation Cephalosporin

0528: Prophylactic Antibiotic Selection for Surgical Patients

0126: Selection of Antibiotic Prophylaxis for Cardiac Surgery Patients

Perioperative Antibiotics – *Timing*

0269: Timing of Prophylactic Antibiotics – Administering Physician

0527: Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision

Perioperative Antibiotics – Discontinuation

0271: Perioperative Care: Discontinuation of Prophylactic Parenteral Antibiotics (Non-Cardiac Procedures)

0529: Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time

0128: Duration of Antibiotic Prophylaxis for Cardiac Surgery Patients

Perinatal

1746: Intrapartum Antibiotic Prophylaxis for Group B Streptococcus (GBS)

0472: Appropriate Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision – Cesarean Section

0304: Late sepsis or meningitis in Very Low Birth Weight (VLBW) neonates (risk-adjusted)

NATIONAL QUALITY FORUM

51

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

Appendix C: Infectious Disease Portfolio—Use in Federal Programs

NQF #	Title	Federal Programs: Finalized as of 2016 - 2017
0500	Severe Sepsis and Septic Shock: Management Bundle	Centers for Medicare & Medicaid Services Hospital Inpatient Quality Reporting Program
2079	HIV Medical Visit Frequency	Centers for Medicare & Medicaid Services Physician Quality Reporting System
2082	HIV Viral Load Suppression	Centers for Medicare & Medicaid Services Physician Quality Reporting System, Medicaid Adult Core Set
2083	Prescription of HIV Antiretroviral Therapy	Centers for Medicare & Medicaid Services Physician Quality Reporting System

Appendix D: Project Standing Committee and NQF Staff

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Appendix E: Measure Specifications

	2079 HIV Medical visit frequency
Steward	Health Resources and Services Administration - HIV/AIDS Bureau
Description	Percentage of patients, regardless of age, with a diagnosis of HIV who had at least one medical visit in each 6-month period of the 24-month measurement period with a minimum of 60 days between medical visits. A medical visit is any visit in an outpatient/ambulatory care setting with a nurse practitioner, physician, and/or a physician assistant who provides comprehensive HIV care.
Type	Process
Data Source	Paper Records
Level	Facility
Setting	Clinic/Clinician office
Numerator Statement	Number of patients in the denominator who had at least one medical visit in each 6-month period of the 24-month measurement period with a minimum of 60 days between first medical visit in the prior 6-month period and the last medical visit in the subsequent 6-month period. (Measurement period is a consecutive 24-month period of time.)
Numerator Details	To be included in the numerator, patients must have had at least one medical visit in each 6-month period of the 24-month measurement period with a minimum of 60 days between first medical visit in the prior 6-month period and the last medical visit in the subsequent 6-month period.
Denominator Statement	Number of patients, regardless of age, with a diagnosis of HIV with at least one medical visit in the first 6 months of the 24-month measurement period.
Denominator Details	To be included in the denominator, patients must meet all of the following conditions/events: 1. Patients of any age during the measurement period 2. Patients without a date of death during the 24-month measurement period 3. Patients diagnosed with HIV during the first 3 months of the 24-month measurement period or prior to the measurement period 4. Patients who had at least one medical visit in the first 6 months of the 24-month measurement period
Exclusions	Patients who died at any time during the 24-month measurement period.
Exclusion details	This measure has one exclusions – patient death during the measurement period. Due to constraints, the developer was not able to test the impact of the exclusion on this measure. It is important to note that patient mortality has reduced dramatically over the years primarily in relation to the development and dissemination of HIV antiretroviral therapy. Thus, we do not anticipate a significant number of patients that would be excluded from the measure.
Risk Adjustment	No risk adjustment
Stratification	No stratification
Type Score	Rate/proportion, Better quality = Higher score
Algorithm	1. Identify the individuals who satisfy all specific criteria for inclusion in the denominator: 1.) diagnosed with HIV during the first 3 months of the 24-month measurement period or prior to the 24-month measurement period; 2.) did not have a date of death during the 24-month measurement period; and 3.) had at least one medical visit in the first 6 months of the 24-month measurement period. The individuals who met these three criteria are the denominator population. 2. Identify the individuals from the denominator population who meet the criterion for inclusion in the numerator: must have had at least one medical visit in each 6-month period

	2079 HIV Medical visit frequency
	of the 24-month measurement period with a minimum of 60 days between first medical visit in the prior 6-month period and the last medical visit in the subsequent 6-month period.
	3. Calculate the rate by dividing the numerator population by the denominator population and multiply by 100.
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	2080 Gaps in HIV medical visits
Steward	Health Resources and Services Administration-HIV/AIDS Bureau
Description	Percentage of patients, regardless of age, with a diagnosis of HIV who did not have a medical visit in the last 6 months of the measurement year
Type	Process
Data Source	Other, Paper Records
Level	Clinician : Group/Practice, Facility
Setting	Clinician Office/Clinic
Numerator Statement	Number of patients in the denominator who did not have a medical visit in the last 6 months of the measurement year (Measurement year is a consecutive 12-month period of time).
Numerator Details	To be included in the numerator, patients must not have had a medical visit in the last 6 months of the measurement year.
Denominator Statement	Number of patients, regardless of age, with a diagnosis of HIV who had at least one medical visit in the first 6 months of the measurement year. (The measurement year can be any consecutive 12-month period.)
Denominator Details	To be included in the denominator, patients must meet all of the following conditions/events:
	1. Patients of any age during the measurement year
	2. Patients without a date of death during the measurement year
	3. Patients diagnosed with HIV during the first 3 months of the measurement year or prior to the measurement year
	4. Patients who had at least one medical visit in the first 6 months of the measurement year
Exclusions	Patients who died at any time during the measurement year.
Exclusion details	Patients with a date of death during the measurement year.
Risk Adjustment	No risk adjustment
Stratification	No risk stratification
Type Score	Rate/Proportion, Better quality = Lower score
Algorithm	1. Identify the individuals who satisfy all specific criteria for inclusion in the denominator:
	1.) had a HIV diagnosis prior to the measurement year or during the first three months of the measurement year; 2.) did not have a date of death during the measurement year; and 3.) had at least one medical visit in the first 6 months of the measurement year. The individuals who met these three criteria are the denominator population.
	2. Identify the individuals from the denominator population who meet the criterion for inclusion in the numerator: did not have a medical visit in the last 6 months of the

NATIONAL QUALITY FORUM

56

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

	2080 Gaps in HIV medical visits
	measurement year. 3. Calculate the percentage by dividing the numerator population by the denominator population and multiply by 100.
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	3209 HIV Medical visit frequency
Steward	Health Resources and Services Administration - HIV/AIDS Bureau
Description	Percentage of patients, regardless of age, with a diagnosis of HIV who had at least one medical visit in each 6-month period within 24 months with a minimum of 60 days between medical visits. A medical visit is any visit in an outpatient/ambulatory care setting with a nurse practitioner, physician, and/or a physician assistant who provides comprehensive HIV care.
Type	Process
Data Source	Electronic Health Record
Level	Facility
Setting	Clinician Office/Clinic
Numerator Statement	Patients who had at least one medical visit in each 6-month of a consecutive consecutive 24 month period with a minimum of 60 days between first medical visit in the prior 6-month period and the last medical visit in the subsequent 6-month period.
Numerator Details	HIV medical visits are represented by a QDM variable that is comprised of the below seven different encounter type QDM elements: • Encounter, Performed: Face-to-Face Interaction using Face-to-Face Interaction Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1048) • Encounter, Performed: Office Visit using Office Visit Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1001) • Encounter, Performed: Outpatient Consultation using Outpatient Consultation Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1008) • Encounter, Performed: Preventive Care - Established Office Visit, 0 to 17 using Preventive Care - Established Office Visit, 0 to 17 Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1024) • Encounter, Performed: Preventive Care Services - Established Office Visit, 18 and Up using Preventive Care Services - Established Office Visit, 18 and Up Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1025) • Encounter, Performed: Preventive Care Services-Initial Office Visit, 18 and Up using Preventive Care Services-Initial Office Visit, 18 and Up Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1023) • Encounter, Performed: Preventive Care- Initial Office Visit, 0 to 17 using Preventive Care- Initial Office Visit, 0 to 17 Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1022)
Denominator Statement	Patients, regardless of age, diagnosed with HIV during the first 3 months of the year preceding the measurement period or prior to the measurement period with at least one medical visit in the first 6 months of the year preceding the measurement period.
Denominator	The patient's HIV diagnosis is represented by the QDM element "Diagnosis: HIV" using "HIV

NATIONAL QUALITY FORUM   57

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

	3209 HIV Medical visit frequency
Details	Grouping Value Set (2.16.840.1.113883.3.464.1003.120.12.1003)". The patient's medical visits are represented by the following QDM elements:
	• Encounter, Performed: Face-to-Face Interaction using Face-to-Face Interaction Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1048)
	• Encounter, Performed: Office Visit using Office Visit Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1001)
	• Encounter, Performed: Outpatient Consultation using Outpatient Consultation Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1008)
	• Encounter, Performed: Preventive Care - Established Office Visit, 0 to 17 using Preventive Care - Established Office Visit, 0 to 17 Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1024)
	• Encounter, Performed: Preventive Care Services - Established Office Visit, 18 and Up using Preventive Care Services - Established Office Visit, 18 and Up Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1025)
	• Encounter, Performed: Preventive Care Services-Initial Office Visit, 18 and Up using Preventive Care Services-Initial Office Visit, 18 and Up Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1023)
	• Encounter, Performed: Preventive Care- Initial Office Visit, 0 to 17 using Preventive Care- Initial Office Visit, 0 to 17 Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1022)
	The target population is identified by selecting patients based on their diagnosis with HIV.
Exclusions	Patients who died at any time during the measurement period or the 12 months preceding the measurement period.
Exclusion details	This measure has one exclusion – patient death during the measurement period. The developer reports that the exclusion was tested similarly to other criteria using synthetic patients in Bonnie. When the exclusion element was present, the patients were correctly excluded from the measure. In the absence of the exclusion element, cases were not excluded from the measure.
Risk Adjustment	No risk adjustment
Stratification	No risk stratification
Type Score	Rate/proportion
Algorithm	1. Identify the individuals who satisfy all specific criteria for inclusion in the denominator: 1.) diagnosed with HIV during the first 3 months of the 24-month measurement period or prior to the 24-month measurement period; 2.) did not have a date of death during the 24-month measurement period; and 3.) had at least one medical visit in the first 6 months of the 24-month measurement period. The individuals who met these three criteria are the denominator population.
	2. Identify the individuals from the denominator population who meet the criterion for inclusion in the numerator: must have had at least one medical visit in each 6-month period of the 24-month measurement period with a minimum of 60 days between first medical visit in the prior 6-month period and the last medical visit in the subsequent 6-month period.
	3. Calculate the rate by dividing the numerator population by the denominator population and multiply by 100.
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NATIONAL QUALITY FORUM

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

	2082 HIV Viral load suppression
Steward	Health Resources and Services Administration - HIV/AIDS Bureau
Description	Percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year A medical visit is any visit in an outpatient/ambulatory care setting with a nurse practitioner, physician, and/or a physician assistant who provides comprehensive HIV care.
Type	Outcome
Data Source	Laboratory, Paper records
Level	Facility
Setting	Clinician Office/Clinic
Numerator Statement	Number of patients in the denominator with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year
Numerator Details	To be included in the numerator, patients had a HIV viral load less than 200 copies/mL at the last HIV viral load test during the measurement year
Denominator Statement	Number of patients, regardless of age, with a diagnosis of HIV with at least one medical visit in the measurement year
Denominator Details	To be included in the denominator, patients must meet all of the following conditions/events: 1. Patients of any age during the measurement year 2. Patients diagnosed with HIV during the first 3 months of the measurement year or prior to the measurement year 3. Patients who had at least one medical visit during the measurement year
Exclusions	No patient exclusions
Exclusion details	N/A
Risk Adjustment	No risk adjustment
Stratification	No risk stratification
Type Score	Rate/proportion, Better quality = Higher score
Algorithm	1. Identify the individuals who satisfy all specific criteria for inclusion in the denominator: 1.) diagnosed with a HIV during the first 3 months of the measurement year or prior to the measurement year; and 2.) had at least one medical visit during the measurement year. The individuals who met these criteria are the denominator population. 2. Identify the individuals from the denominator population who meet the criterion for inclusion in the numerator: had a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year. 3. Calculate the percentage by dividing the numerator population by the denominator population and multiply by 100.
Copyright / Disclaimer	N/A

|	**3210 HIV Viral load suppression**
Steward	Health Resources and Services Administration - HIV/AIDS Bureau
Description	Percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.
Type	Outcome
Data Source	Electronic Health Record, Other
Level	Facility
Setting	Clinician Office/Clinic
Numerator Statement	Patients with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year. The outcome being measured is HIV viral suppression.
Numerator Details	The viral load suppression laboratory test is represented by the QDM element "Laboratory Test, Performed: HIV Viral Load" using "HIV Viral Load Grouping Value Set (2.16.840.1.113883.3.464.1003.120.12.1002)". The result of the laboratory test is modeled as an attribute of the Viral Load Suppression QDM element and represented as a numerical result associated with copies/mL as the reporting unit.
Denominator Statement	Patients, regardless of age, diagnosed with HIV during the first 3 months of the measurement year or prior to the measurement year who had at least one medical visit in the measurement year. The target population for this measure is all people living with HIV.
Denominator Details	The patient's HIV diagnosis is represented by the QDM element "Diagnosis: HIV" using "HIV Grouping Value Set (2.16.840.1.113883.3.464.1003.120.12.1003)". The patient's medical visits are represented by the following QDM elements: • "Encounter, Performed: Face-to-Face Interaction" using "Face-to-Face Interaction Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1048)" • "Encounter, Performed: Office Visit" using "Office Visit Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1001)" • "Encounter, Performed: Outpatient Consultation" using "Outpatient Consultation Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1008)" • "Encounter, Performed: Preventive Care - Established Office Visit, 0 to 17" using "Preventive Care - Established Office Visit, 0 to 17 Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1024)" • "Encounter, Performed: Preventive Care Services - Established Office Visit, 18 and Up" using "Preventive Care Services - Established Office Visit, 18 and Up Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1025)" • "Encounter, Performed: Preventive Care Services-Initial Office Visit, 18 and Up" using "Preventive Care Services-Initial Office Visit, 18 and Up Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1023)" • "Encounter, Performed: Preventive Care- Initial Office Visit, 0 to 17" using "Preventive Care- Initial Office Visit, 0 to 17 Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1022)"
Exclusions	No patient exclusions
Exclusion details	Not applicable
Risk Adjustment	No risk adjustment
Stratification	No risk stratification
Type Score	Rate/proportion, Better quality = Higher score
Algorithm	1. Identify patients who meet the initial population criteria as defined by eCQM logic;

NATIONAL QUALITY FORUM   61

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

	3210 HIV Viral load suppression
	2. Identify and count subset of the initial population that meet denominator criteria as defined by eCQM logic;
	3. Identify and count subset of patients in the denominator that meet numerator criteria as defined by eCQM logic.
	4. Calculate the performance measure rate: by dividing the number of patients in the numerator population by the number of patients in the denominator population.
	Note: the eCQM logic criteria for each population is defined in a computable format in the eCQM specifications provided as an attachment to this submission.
Copyright / Disclaimer	Not applicable

NATIONAL QUALITY FORUM

62

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

	2083 Prescription of HIV Antiretroviral Therapy
Steward	Health Resources and Services Administration - HIV/AIDS Bureau
Description	Percentage of patients, regardless of age, with a diagnosis of HIV prescribed antiretroviral therapy for the treatment of HIV infection during the measurement year. A medical visit is any visit in an outpatient/ambulatory care setting with a nurse practitioner, physician, and/or a physician assistant who provides comprehensive HIV care.
Type	Process
Data Source	Paper records, Pharmacy, other
Level	Facility
Setting	Clinician Office/Clinic
Numerator Statement	Number of patients from the denominator prescribed HIV antiretroviral therapy during the measurement year.
Numerator Details	To be included in the numerator, patients were prescribed HIV antiretroviral therapy during the measurement year. HIV antiretroviral therapy at least one HIV antiretroviral medication.
Denominator Statement	Number of patients, regardless of age, with a diagnosis of HIV with at least one medical visit in the measurement year
Denominator Details	To be included in the denominator, patients must meet all of the following conditions/events: 1. Patients of any age during the measurement year 2. Patients diagnosed with HIV during the first 3 months of the measurement year or prior to the measurement year 3. Patients who had at least one medical visit during the measurement year
Exclusions	No patient exclusions
Exclusion details	Not applicable
Risk Adjustment	No risk adjustment
Stratification	No risk stratification
Type Score	Rate/proportion, Better quality = Higher score
Algorithm	1. Identify the individuals who satisfy all specific criteria for inclusion in the denominator: 1.) diagnosed with HIV during the first 3 months of the measurement year or prior to the measurement year; and 2.) had at least one medical visit during the measurement year. The individuals who met these criteria are the denominator population. 2. Identify the individuals from the denominator population who meet the criterion for inclusion in the numerator: prescribed HIV antiretroviral therapy during the measurement year. 3. Calculate the percentage by dividing the numerator population by the denominator population and multiply by 100.
Copyright / Disclaimer	Not applicable

	3211 Prescription of HIV Antiretroviral Therapy
Steward	Health Resources and Services Administration - HIV/AIDS Bureau
Description	Percentage of patients, regardless of age, with a diagnosis of HIV prescribed antiretroviral therapy for the treatment of HIV infection during the measurement year. A medical visit is any visit in an outpatient/ambulatory care setting with a nurse practitioner, physician, and/or a physician assistant who provides comprehensive HIV care.
Type	Process
Data Source	Electronic Health Record
Level	Facility
Setting	Clinician Office/Clinic
Numerator Statement	Number of patients from the denominator prescribed HIV antiretroviral therapy during the measurement year.
Numerator Details	The antiretroviral therapy medication order is represented by the QDM element "Medication, Order: FDA Approved HIV Antiretroviral Therapy" using "HIV Antiretroviral Therapy RXNORM Value Set (2.16.840.1.113762.1.4.1032.1)." In order to be included in the numerator, the "Medication, Order: FDA Approved HIV Antiretroviral Therapy" element must start during the measurement period.
Denominator Statement	Number of patients, regardless of age, with a diagnosis of HIV with at least one medical visit in the measurement year
Denominator Details	The patient's HIV diagnosis is represented by the QDM element "Diagnosis: HIV" using "HIV Grouping Value Set (2.16.840.1.113883.3.464.1003.120.12.1003)". The patient's medical visits are represented by the following QDM elements: • "Diagnosis: HIV 1" using "HIV 1 Grouping Value Set (2.16.840.1.113883.3.464.1003.120.12.1004)" • "Encounter, Performed: Face-to-Face Interaction" using "Face-to-Face Interaction Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1048)" • "Encounter, Performed: Office Visit" using "Office Visit Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1001)" • "Encounter, Performed: Outpatient Consultation" using "Outpatient Consultation Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1008)" • "Encounter, Performed: Preventive Care - Established Office Visit, 0 to 17" using "Preventive Care - Established Office Visit, 0 to 17 Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1024)" • "Encounter, Performed: Preventive Care Services - Established Office Visit, 18 and Up" using "Preventive Care Services - Established Office Visit, 18 and Up Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1025)" • "Encounter, Performed: Preventive Care Services-Initial Office Visit, 18 and Up" using "Preventive Care Services-Initial Office Visit, 18 and Up Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1023)" • "Encounter, Performed: Preventive Care- Initial Office Visit, 0 to 17" using "Preventive Care- Initial Office Visit, 0 to 17 Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1022)"
Exclusions	No patient exclusions
Exclusion details	Not applicable
Risk Adjustment	No risk adjustment
Stratification	No risk stratification

NATIONAL QUALITY FORUM

64

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

	3211 Prescription of HIV Antiretroviral Therapy
Type Score	Rate/proportion, Better quality = Higher score
Algorithm	1. Identify the individuals who satisfy all specific criteria for inclusion in the denominator: 1.) diagnosed with HIV during the first 3 months of the measurement year or prior to the measurement year; and 2.) had at least one medical visit during the measurement year. The individuals who met these criteria are the denominator population.
	2. Identify the individuals from the denominator population who meet the criterion for inclusion in the numerator: prescribed HIV antiretroviral therapy during the measurement year.
	3. Calculate the percentage by dividing the numerator population by the denominator population and multiply by 100.
Copyright / Disclaimer	Not applicable

	0500 Severe Sepsis and Septic Shock Management Bundle
Steward	Henry Ford Hospital
Description	This measure focuses on adults 18 years and older with a diagnosis of severe sepsis or septic shock. Consistent with Surviving Sepsis Campaign guidelines, the measure contains several elements, including measurement of lactate, obtaining blood cultures, administering broad spectrum antibiotics, fluid resuscitation, vasopressor administration, reassessment of volume status and tissue perfusion, and repeat lactate measurement. As reflected in the data elements and their definitions, these elements should be performed in the early management of severe sepsis and septic shock.
Type	Composite
Data Source	Imaging-Diagnostic, Laboratory, Other, Paper Records, Pharmacy
Level	Facility
Setting	Hospital
Numerator Statement	• The number of patients in the denominator who received ALL of the following components (if applicable) for the early management of severe sepsis and septic shock: initial lactate levels, blood cultures, antibiotics, fluid resuscitation, repeat lactate level, vasopressors, and volume status and tissue perfusion reassessment. Within 3 hours of presentation of severe sepsis: - Measure initial lactate level - Draw blood cultures prior to antibiotics - Administer broad spectrum or other antibiotics • Within 6 hours of presentation of severe sepsis: - Repeat lactate level (if initial lactate > 2 mmol/L) • Within 3 hours of presentation of septic shock: - Administer 30 ml/kg crystalloid for hypotension or lactate ≥ 4 mmol/L • Within 6 hours of presentation of septic shock: - Apply vasopressors (for hypotension that does not respond to initial fluid resuscitation) to maintain a mean arterial pressure (MAP) ≥ 65 mm Hg - Reasses volume status and tissue perfusion in the event of persistent hypotension (MAP <65 mm Hg) after initial fluid administration or initial lactate level ≥ 4 mmol/L - The clinician is no longer required to state the method of reassessment used (e.g. physical exam, bedside cardiovascular ultrasound, passive leg raising, CVP, ScV02 assessment). The clinician can attest that volume and perfusion reassessment has occurred, even without reference to the method used. This will meet the measure's volume and perfusion reassessment requirement. A provider may also opt to state their chosen method, but this is not required.
Numerator Details	In addition to the previous information (above) about assessing the numerator population, the following also are part of the numerator details. • Within 3 hours of presentation of severe sepsis: o Measure initial lactate level o Draw blood cultures prior to antibiotics

	0500 Severe Sepsis and Septic Shock Management Bundle
	o Administer broad spectrum or other antibiotics • Within 6 hours of presentation of severe sepsis: o Repeat lactate level (if initial lactate > 2 mmol/L) • Within 3 hours of presentation of septic shock: o Administer 30 ml/kg crystalloid for hypotension or lactate ≥ 4 mmol/L • Within 6 hours of presentation of septic shock: o Apply vasopressors (for hypotension that does not respond to initial fluid resuscitation) to maintain a mean arterial pressure (MAP) ≥ 65 mm Hg o Reasses volume status and tissue perfusion in the event of persistent hypotension (MAP <65 mm Hg) after initial fluid administration or initial lactate level ≥ 4 mmol/L ⬚ The clinician is no longer required to state the method of reassessment used (e.g. physical exam, bedside cardiovascular ultrasound, passive leg raising, CVP, ScV02 assessment). The clinician can attest that volume and perfusion reassessment has occurred, even without reference to the method used. This will meet the measure's volume and perfusion reassessment requirement. A provider may also opt to state their chosen method, but this is not required. The full definitions of each of these data elements and additional information are included in the data dictionary, attached to the submission
Denominator Statement	Inpatients age 18 and over with an ICD-10-CM Principal or Other Diagnosis Code of Sepsis, Severe Sepsis, or Septic Shock.
Denominator Details	Discharges age 18 and over with an ICD-10-CM Principal or Other Diagnosis Code of Sepsis, Severe Sepsis, or Septic Shock as defined in the table below: ICD-10-CM Code Code Description A021 Salmonella sepsis A227 Anthrax sepsis A267 Erysipelothrix sepsis A327 Listerial sepsis A400 Sepsis due to streptococcus, group A A401 Sepsis due to streptococcus, group B A403 Sepsis due to Streptococcus pneumoniae A408 Other streptococcal sepsis A409 Streptococcal sepsis, unspecified A4101 Sepsis due to Methicillin susceptible Staphylococcus aureus A4102 Sepsis due to Methicillin resistant Staphylococcus aureus A411 Sepsis due to other specified staphylococcus A412 Sepsis due to unspecified staphylococcus A413 Sepsis due to Hemophilus influenzae A414 Sepsis due to anaerobes A4150 Gram-negative sepsis, unspecified A4151 Sepsis due to Escherichia coli [E. coli] A4152 Sepsis due to Pseudomonas A4153 Sepsis due to Serratia A4159 Other Gram-negative sepsis

NATIONAL QUALITY FORUM

67

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

	0500 Severe Sepsis and Septic Shock Management Bundle
	A4181 Sepsis due to Enterococcus
	A4189 Other specified sepsis
	A419 Sepsis, unspecified organism
	A427 Actinomycotic sepsis
	A5486 Gonococcal sepsis
	B377 Candidal sepsis
	R6520 Severe sepsis without septic shock
	R6521 Severe sepsis with septic shock
	Data elements required to calculate the denominator (in alphabetical order):
	• Administrative Contraindication to Care, Septic Shock
	• Administrative Contraindication to Care, Severe Sepsis
	• Admission Date
	• Birthdate
	• Directive for Comfort Care or Palliative Care, Septic Shock
	• Directive for Comfort Care or Palliative Care, Severe Sepsis
	• Discharge Date
	• Discharge Disposition
	• Discharge Time
	• Transfer From Another Hospital or ASC
	The full definitions of each of these data elements and additional information are included in the data dictionary, attached to the submission
Exclusions	The following patients are excluded from the denominator:
	• Severe sepsis is not present
	• Patients Transferred in from another acute care facility
	• Patients receiving IV antibiotics for more than 24 hours prior to presentation of severe sepsis.
	• Patients with a Directive for Comfort Care or Palliative Care within 3 hours of presentation of severe sepsis
	• Patients with an Administrative Contraindication to Care within 6 hours of presentation of severe sepsis
	• Patients with an Administrative Contraindication to Care within 6 hours of presentation of septic shock
	• Patients with a Directive for Comfort Care or Palliative Care within 6 hours of presentation of septic shock
	• Patients with septic shock who are discharged within 6 hours of presentation
	• Patients with severe sepsis who are discharged within 6 hours of presentation
	• Patients with a Length of Stay >120 days
	• Patients included in a Clinical Trial
Exclusion details	To determine the length of stay, the admission date and discharge date are entered. If the result of the calculation subtracting the admission date from the discharge date is greater than 120 days, the patient is excluded from the measure. Data Elements required to determine denominator exclusions (in alphabetical order):

NATIONAL QUALITY FORUM

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

68

	0500 Severe Sepsis and Septic Shock Management Bundle
	Administrative Contraindication to Care, Septic Shock
	Administrative Contraindication to Care, Severe Sepsis
	Admission Date
	Birthdate
	Clinical Trial
	Directive for Comfort Care or Palliative Care, Septic Shock
	Directive for Comfort Care or Palliative Care, Severe Sepsis
	Discharge Date
	Discharge Disposition
	Discharge Time
	Transfer from Another Hospital or ASC
	The full definitions of each of these data elements and additional information are included in the data dictionary, attached to the submission.
Risk Adjustment	No risk adjustment
Stratification	No risk stratification
Type Score	Rate/proportion, Better quality = Higher score
Algorithm	The detailed measure algorithm for SEP-1 is available in the data dictionary attached to the submission, along with a diagram.

Algorithm (continued):

1. Find the patients who meet the initial population (ie, the general group of patients that a set of performance measures is designed to address).
2. From the patients within the initial population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria) Note: in some cases the initial population and denominator are identical. Remove any patients that meet the denominator exclusion criteria.
3. The following actions are required within 3 hours of presentation of severe sepsis:
   a. Measure initial lactate level
   b. Draw blood cultures prior to antibiotics
   c. Administer broad spectrum or other antibiotics
4. The following actions are required within 6 hours of presentation of severe sepsis:
   a. Repeat lactate level (if initial lactate > 2 mmol/L)
5. The following actions are required within 3 hours of presentation of septic shock:
   a. Administer 30 ml/kg crystalloid for hypotension or lactate $\geq$ 4 mmol/L
6. The following actions are required within 6 hours of presentation of septic shock:
   a. Apply vasopressors (for hypotension that does not respond to initial fluid resuscitation) to maintain a mean arterial pressure (MAP) $\geq$ 65 mm Hg
   b. Reasses volume status and tissue perfusion in the event of persistent hypotension (MAP <65 mm Hg) after initial fluid administration or initial lactate level $\geq$ 4 mmol/L

Note: The clinician is no longer required to state the method of reassessment used (e.g. physical exam, bedside cardiovascular ultrasound, passive leg raising, CVP, ScV02 assessment). The clinician can attest that volume and perfusion reassessment has occurred, even without reference to the method used. This will meet the measure's volume and perfusion reassessment requirement. A provider may also opt to state their chosen method,

NATIONAL QUALITY FORUM

69

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

	0500 Severe Sepsis and Septic Shock Management Bundle
	but this is not required. 7. All of the above numerator components (as applicable) must be in compliance, otherwise the case is calculated as a 'failed' sepsis case.
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NATIONAL QUALITY FORUM

70

NQF REVIEW DRAFT—Comments due by May 15, 2017 by 6:00 PM ET.

	3215 Adult Inpatient Risk Adjusted Sepsis Mortality
Steward	New York State Department of Health, Office of Quality and Patient Safety
Description	Annual risk adjusted inpatient mortality rate for adult patients (aged 18 and over) admitted to acute care hospitals with diagnosis of severe sepsis or septic shock. The measure includes patients in acute care hospital settings over one year timeframe who had, either on admission, or during their hospital stay, a clinical diagnosis of severe sepsis (now referred to as ´sepsis´) or septic shock using criteria described in the International Sepsis Definitions (Sepsis-2)
Type	Outcome
Data Source	Claims (Other), EHRs Hybrid, Laboratory, Management Data, Non-Medical Data, Paper Records, Pharmacy, Registry
Level	Facility
Setting	Hospital
Numerator Statement	Outcome is risk adjusted inpatient mortality rate for adult patients (18 and over) admitted to an acute care hospital with a diagnosis of severe sepsis or septic shock or who develop severe sepsis or septic shock during their hospital stay.
Numerator Details	Inpatient mortality is noted on data submission from hospital. Clinical variables needed for risk adjustment including demographics, co-morbidities, severity, and potential exclusions are reported by hospital as described in the data dictionary.
Denominator Statement	All adult patient discharges (18 and over) in a calendar year with a diagnosis of severe sepsis or septic shock on admission or at any time during their hospital stay. This may include multiple admissions of the same patient during the measurement year. Denominator includes all cases identified using any means (administrative, registry, electronic health records, billing data, etc.), either prospectively, retrospectively, or both, that meet the International consensus definition (Sepsis- 2) of severe sepsis or septic shock.
Denominator Details	All adult patients meeting International consensus definition (Sepsis-2) for Severe Sepsis/Septic shock identified through combination of any relevant hospital clinical and/or administrative databases, prospectively or retrospectively.
Exclusions	Patients with advanced directives in place prior to episode of sepsis which specifically restrict any hospital specific sepsis protocol interventions or who decline (or their proxy declines) treatment for sepsis. Patients who have been transferred from one acute care hospital to another are excluded.
Exclusion details	Patients who have any of the following characteristics, reported on data variables fully described in the data dictionary, are excluded from the calculation of risk adjusted mortality rates for a specific hospital:

NATIONAL QUALITY FORUM

NQF REVIEW DRAFT—Comments due by Month DD, YYYY by 6:00 PM ET.

71

	3215 Adult Inpatient Risk Adjusted Sepsis Mortality
	1. Advanced Directives in place prior to diagnosis of severe sepsis or septic shock that specifically preclude active treatment according to that hospital´s protocol for severe sepsis and septic shock.
	2. Patient or patient proxy refusal of treatment for severe sepsis or septic shock according to that hospital´s protocol for severe sepsis and septic shock. 3. Patients who were transferred between acute care hospitals.
Risk Adjustment	Statistical risk model
Stratification	Not applicable
Type Score	Rate/proportion, Better quality= Lower score
Algorithm	The study objective was to develop a logistic regression model to estimate the probability of hospital mortality among septic patients entering 179 New York State hospitals over the period of January 1, 2015 through December 31, 2015. The a priori analysis plan eliminated any patient with an advanced directive or who declined interventions. When a patient was discharged from a hospital as "transfer to acute care", only the patient's data from the receiving hospital was used in the dataset. If a patient was in the dataset multiple times for sepsis, only the final admission was used. This preserved the outcome of interest (mortality) and observation independence in the data file for developing logistic regression models. This resulted in a database total of 43,204 septic patients. The a priori analysis used only patient demographics, comorbidities, and admission characteristics to estimate the probability of hospital mortality. Specifically treatment variables were not used in the model. **Septic patients** All subjects entered into the model met the admitting hospital's criteria for severe sepsis or septic shock. Severe sepsis was defined as a suspected or confirmed infection, at least two systemic manifestations of infection and one or more acute organ dysfunctions. Septic shock was defined as severe sepsis where at least one organ dysfunction with sustained hypotension after a fluid challenge. For this paper, the term sepsis or septic represents the dataset population of severe sepsis and septic shock patients. Mortality is defined as in-hospitals deaths. **Statistical Methods** Logistic regression developed a model to estimate the probability of mortality for patients with severe sepsis or septic shock during their hospital stay. A list of the possible predictor variables and definitions are given in Table 1. Maximum likelihood was used to estimate model coefficients and associated standard errors. The hierarchical nature of the data supports random-effects logistic regression use since patients are nested within the 179

NATIONAL QUALITY FORUM

72

NQF REVIEW DRAFT—Comments due by Month DD, YYYY by 6:00 PM ET.

3215 Adult Inpatient Risk Adjusted Sepsis Mortality

hospitals. However, the 179 random-effect coefficients would have made the resulting model specific only to those 179 New York hospitals and would not be generalizable to patients outside these specific hospitals. A random sample of 10% (N = 4,319) of the observations were set aside and the logistic regression model was developed on the remaining 90% (38,884 observations). The final model was validated on the 10% of observations that were set aside. Patient comorbidities were generated using the list shown in supplemental Table S1. We generated a variable called mechanical ventilation (MV) severity that indicated a severity of illness relating to mechanical ventilation. This dichotomous variable was defined when a patient was admitted to the hospital already mechanically ventilated or requiring mechanical ventilation within 6 hours post admission. Initial serum lactate was not measured in 2,528 (5.9%) patients and was imputed using single imputation. Specifically, truncated linear regression was used during the imputation procedure where the lower limit of left truncation was set at a serum lactate level 0.1 mmol/L (1st percentile) and the upper limit of the right truncation was set at 30.0 mmol/L (99th percentile). A list of predictor variables is shown in supplemental Table S2.

A multivariable logistic regression model was built using the developmental dataset and starting with all possible covariates in the model. Using an iterative procedure, variables were removed from the model, one by one, if their p-values were not significant at 0.05 level until a parsimonious model was reached. Variables removed during the development procedure were added back into the model if their p-values were significant at the 0.05 level and if model calibration (Hosmer-Lemeshow goodness of fit) was improved through their inclusion. We then assessed the scale of the 3 continuous variables (patient age, first serum lactate, and the count of the number of comorbidities) remaining in the model. Specifically, we were interested in determining whether these variables had a linear relationship with mortality. Using the method of fractional polynomials patient age was included in the model as a linear term, the number of comorbidities was transformed by taking the square root of the number of comorbidities, and first serum lactate was entered into the model as a quadratic expression (linear and a squared term). Model calibration was further improved by adding the following interactions to the model: lower respiratory infection (LRI) and MV severity, patient age and the square root of the number of comorbidities, and first serum lactate and the square root of the number of comorbidities.

Model calibration was assessed using the Hosmer-Lemeshow goodness of fit on both the developmental and the validation datasets. Group sizes of 10, 100, 500, and 1,000 were chosen for the large, developmental, dataset while group sizes of 10, 50, 100, and 150 were chosen for the smaller validation dataset. Model discrimination was assessed using the area under the receiver operating characteristic (ROC) curve for both the developmental and

NATIONAL QUALITY FORUM

73

NQF REVIEW DRAFT—Comments due by Month DD, YYYY by 6:00 PM ET.

	3215 Adult Inpatient Risk Adjusted Sepsis Mortality
	validation datasets.
	The estimated probability of mortality was generated using the model coefficients and the specific patient attributes. If the patient attribute is defined by a categorical variable, then the possible values are either a 0 or 1. If the attribute is defined by a continuous variable, then the specific value is used such as the patient's age. Interaction values are generated by multiplying the values of each of the two individual variables defined by the interaction. The product of the coefficient and the patient's value for all of the variables in the model are generated. Next the logic is defined as the sum of the above products. Finally, the probability of mortality for a specific patient is generated using the follow equation:
	Probability of mortality= $\exp(\text{logit})/(1+\exp(\text{logit}))$
Copyright / Disclaimer	Not applicable

NATIONAL QUALITY FORUM   74

NQF REVIEW DRAFT—Comments due by Month DD, YYYY by 6:00 PM ET.

Appendix F: Related and Competing Measures

Comparison of NQF #2079, #2080, #2082, and #2083

	2079 HIV Medical Visit Frequency	2080 Gaps in Medical Visits	2082 HIV Viral Load Suppression	2083 Prescription of HIV Antiretroviral Therapy
Steward	Health Resources and Services Administration - HIV/AIDS Bureau	Health Resources and Services Administration-HIV/AIDS Bureau	Health Resources and Services Administration - HIV/AIDS Bureau	Health Resources and Services Administration - HIV/AIDS Bureau
Description	Percentage of patients, regardless of age, with a diagnosis of HIV who had at least one medical visit in each 6-month period of the 24-month measurement period with a minimum of 60 days between medical visits. A medical visit is any visit in an outpatient/ambulatory care setting with a nurse practitioner, physician, and/or a physician assistant who provides comprehensive HIV care.	Percentage of patients, regardless of age, with a diagnosis of HIV who did not have a medical visit in the last 6 months of the measurement year	Percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year A medical visit is any visit in an outpatient/ambulatory care setting with a nurse practitioner, physician, and/or a physician assistant who provides comprehensive HIV care.	Percentage of patients, regardless of age, with a diagnosis of HIV prescribed antiretroviral therapy for the treatment of HIV infection during the measurement year. A medical visit is any visit in an outpatient/ambulatory care setting with a nurse practitioner, physician, and/or a physician assistant who provides comprehensive HIV care.
Type	Process	Process	Outcome	Process
Data Source	Paper Records	Other, Paper Records	Laboratory, Paper records	Paper records, Pharmacy, other
Level	Facility	Clinician : Group/Practice, Facility	Facility	Facility
Setting	Clinic/Clinician office	Clinician Office/Clinic	Clinician Office/Clinic	Clinician Office/Clinic
Numerator Statement	Number of patients in the denominator who had at least one medical visit in each 6-month period of the 24-month measurement period with a minimum of 60 days between first medical visit in the prior 6-month period and the last	Number of patients in the denominator who did not have a medical visit in the last 6 months of the measurement year (Measurement year is a consecutive 12-month period of time).	Number of patients in the denominator with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year	Number of patients from the denominator prescribed HIV antiretroviral therapy during the measurement year.

NATIONAL QUALITY FORUM

75

NQF REVIEW DRAFT—Comments due by Month DD, YYYY by 6:00 PM ET.

	2079 HIV Medical Visit Frequency	2080 Gaps in Medical Visits	2082 HIV Viral Load Suppression	2083 Prescription of HIV Antiretroviral Therapy
	medical visit in the subsequent 6-month period. (Measurement period is a consecutive 24-month period of time.)			
Numerator Details	To be included in the numerator, patients must have had at least one medical visit in each 6-month period of the 24-month measurement period with a minimum of 60 days between first medical visit in the prior 6-month period and the last medical visit in the subsequent 6-month period.	To be included in the numerator, patients must not have had a medical visit in the last 6 months of the measurement year.	To be included in the numerator, patients had a HIV viral load less than 200 copies/mL at the last HIV viral load test during the measurement year	To be included in the numerator, patients were prescribed HIV antiretroviral therapy during the measurement year. HIV antiretroviral therapy at least one HIV antiretroviral medication.
Denominator Statement	Number of patients, regardless of age, with a diagnosis of HIV with at least one medical visit in the first 6 months of the 24-month measurement period.	Number of patients, regardless of age, with a diagnosis of HIV who had at least one medical visit in the first 6 months of the measurement year. (The measurement year can be any consecutive 12-month period.)	Number of patients, regardless of age, with a diagnosis of HIV with at least one medical visit in the measurement year	Number of patients, regardless of age, with a diagnosis of HIV with at least one medical visit in the measurement year
Denominator Details	To be included in the denominator, patients must meet all of the following conditions/events: 1. Patients of any age during the measurement period 2. Patients without a date of death during the 24-month measurement period 3. Patients diagnosed with HIV during the first 3 months of the 24-month	To be included in the denominator, patients must meet all of the following conditions/events: 1. Patients of any age during the measurement year 2. Patients without a date of death during the measurement year 3. Patients diagnosed with HIV during the first 3 months of the measurement year or prior to the measurement year	To be included in the denominator, patients must meet all of the following conditions/events: 1. Patients of any age during the measurement year 2. Patients diagnosed with HIV during the first 3 months of the measurement year or prior to the measurement year 3. Patients who had at least one medical visit during the measurement year	To be included in the denominator, patients must meet all of the following conditions/events: 1. Patients of any age during the measurement year 2. Patients diagnosed with HIV during the first 3 months of the measurement year or prior to the measurement year 3. Patients who had at least one medical visit during the measurement year

NATIONAL QUALITY FORUM

76

NQF REVIEW DRAFT—Comments due by Month DD, YYYY by 6:00 PM ET.

	2079 HIV Medical Visit Frequency	2080 Gaps in Medical Visits	2082 HIV Viral Load Suppression	2083 Prescription of HIV Antiretroviral Therapy
	measurement period or prior to the measurement period 4. Patients who had at least one medical visit in the first 6 months of the 24-month measurement period	4. Patients who had at least one medical visit in the first 6 months of the measurement year		
Exclusions	Patients who died at any time during the 24-month measurement period.	Patients who died at any time during the measurement year.	No patient exclusions	No patient exclusions
Exclusion Details	This measure has one exclusions – patient death during the measurement period. Due to constraints, the developer was not able to test the impact of the exclusion on this measure. It is important to note that patient mortality has reduced dramatically over the years primarily in relation to the development and dissemination of HIV antiretroviral therapy. Thus, we do not anticipate a significant number of patients that would be excluded from the measure.	Patients with a date of death during the measurement year.	Not Applicable	Not applicable
Risk Adjustment	No risk adjustment	No risk adjustment	No risk adjustment	No risk adjustment
Stratification	No stratification	No risk stratification	No risk stratification	No risk stratification
Type Score	Rate/proportion, Better quality = Higher score	Rate/Proportion, Better quality = Lower score	Rate/proportion, Better quality = Higher score	Rate/proportion, Better quality = Higher score
Algorithm	1. Identify the individuals who satisfy all specific criteria for inclusion in the denominator:	1. Identify the individuals who satisfy all specific criteria for inclusion in the denominator:	1. Identify the individuals who satisfy all specific criteria for inclusion in the denominator: 1.)	1. Identify the individuals who satisfy all specific criteria for inclusion in the denominator: 1.)

NATIONAL QUALITY FORUM

77

NQF REVIEW DRAFT—Comments due by Month DD, YYYY by 6:00 PM ET.

	2079 HIV Medical Visit Frequency	2080 Gaps in Medical Visits	2082 HIV Viral Load Suppression	2083 Prescription of HIV Antiretroviral Therapy
	1.) diagnosed with HIV during the first 3 months of the 24-month measurement period or prior to the 24-month measurement period; 2.) did not have a date of death during the 24-month measurement period; and 3.) had at least one medical visit in the first 6 months of the 24-month measurement period. The individuals who met these three criteria are the denominator population. 2. Identify the individuals from the denominator population who meet the criterion for inclusion in the numerator: must have had at least one medical visit in each 6-month period of the 24-month measurement period with a minimum of 60 days between first medical visit in the prior 6-month period and the last medical visit in the subsequent 6-month period. 3. Calculate the rate by dividing the numerator population by the denominator population and multiply by 100.	1.) had a HIV diagnosis prior to the measurement year or during the first three months of the measurement year; 2.) did not have a date of death during the measurement year; and 3.) had at least one medical visit in the first 6 months of the measurement year. The individuals who met these three criteria are the denominator population. 2. Identify the individuals from the denominator population who meet the criterion for inclusion in the numerator: did not have a medical visit in the last 6 months of the measurement year. 3. Calculate the percentage by dividing the numerator population by the denominator population and multiply by 100.	diagnosed with a HIV during the first 3 months of the measurement year or prior to the measurement year; and 2.) had at least one medical visit during the measurement year. The individuals who met these criteria are the denominator population. 2. Identify the individuals from the denominator population who meet the criterion for inclusion in the numerator: had a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year. 3. Calculate the percentage by dividing the numerator population by the denominator population and multiply by 100.	diagnosed with HIV during the first 3 months of the measurement year or prior to the measurement year; and 2.) had at least one medical visit during the measurement year. The individuals who met these criteria are the denominator population. 2. Identify the individuals from the denominator population who meet the criterion for inclusion in the numerator: prescribed HIV antiretroviral therapy during the measurement year. 3. Calculate the percentage by dividing the numerator population by the denominator population and multiply by 100.
Submission items	5.1a. Identified measures 0403 : HIV/AIDS: Medical Visit 0405: HIV/AIDS: Pneumocystis	5.1a Identified Measures: 0405: HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis	5.1a Identified Measures: 0407: HIV/AIDS: HIV RNA Control After Six Months of Potent	5.1a Identified Measures: 0405: HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP)

2079 HIV Medical Visit Frequency	2080 Gaps in Medical Visits	2082 HIV Viral Load Suppression	2083 Prescription of HIV Antiretroviral Therapy
Jiroveci Pneumonia (PCP) Prophylaxis	0409: HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis	Antiretroviral Therapy	Prophylaxis
0409: HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis	2079: HIV Medical Visit Frequency	0405: HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis	0409: HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis
2080: Gap in HIV Medical Visits	2080: HIV Viral Suppression	0409: HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis	2079: HIV Medical Visit Frequency
2082: HIV viral suppression	2083: Prescription of HIV Antiretroviral Therapy	2079: HIV Medical Visit Frequency	2080: Gap in HIV Medical Visits
2083: Prescription of HIV Antiretroviral Therapy	5a.1 Are specs completely harmonized? Yes	2080: Gap in HIV Medical Visits	2082: HIV Viral Suppression
3211: Prescription of HIV Antiretroviral Therapy	5b. Competing Measures: This measure does not have a competing measure.	2083: Prescription of HIV Antiretroviral Therapy	3211: Prescription of HIV Antiretroviral Therapy
3210: HIV viral suppression		3211: Prescription of HIV Antiretroviral Therapy	3210: HIV viral suppression
3010: HIV Medical Visit Frequency		3210: HIV Viral Suppression	3010: HIV Medical Visit Frequency
5a. Are the measure specifications harmonized to the extent possible?		3010: HIV Medical Visit Frequency	3211: Prescription of HIV Antiretroviral Therapy
Yes		5a.1 Are specs completely harmonized? No	5a.1 Are specs completely harmonized? Yes
5b. Competing Measures: This measure does not have a competing measure.		5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.	5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.
		Harmonized with all measures except 405 and 409. Plans to harmonize with 405 and 409.	Harmonized with all measures except 405 and 409. Plans to harmonize with 405 and 409.

NATIONAL QUALITY FORUM

79

NQF REVIEW DRAFT—Comments due by Month DD, YYYY by 6:00 PM ET.

	3209 HIV Medical Visit Frequency eMeasure	3210 HIV Viral Load Suppression eMeasure	3211 Prescription of HIV Antiretroviral Therapy eMeasure
Steward	Health Resources and Services Administration - HIV/AIDS Bureau	Health Resources and Services Administration - HIV/AIDS Bureau	Health Resources and Services Administration - HIV/AIDS Bureau
Description	Percentage of patients, regardless of age, with a diagnosis of HIV who had at least one medical visit in each 6-month period within 24 months with a minimum of 60 days between medical visits. A medical visit is any visit in an outpatient/ambulatory care setting with a nurse practitioner, physician, and/or a physician assistant who provides comprehensive HIV care.	Percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Percentage of patients, regardless of age, with a diagnosis of HIV prescribed antiretroviral therapy for the treatment of HIV infection during the measurement year. A medical visit is any visit in an outpatient/ambulatory care setting with a nurse practitioner, physician, and/or a physician assistant who provides comprehensive HIV care.
Type	Process	Outcome	Process
Data Source	Electronic Health Record	Electronic Health Record, Other	Electronic Health Record
Level	Facility	Facility	Facility
Setting	Clinician Office/Clinic	Clinician Office/Clinic	Clinician Office/Clinic
Numerator Statement	Patients who had at least one medical visit in each 6-month of a consecutive consecutive 24 month period with a minimum of 60 days between first medical visit in the prior 6-month period and the last medical visit in the subsequent 6-month period.	Patients with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year. The outcome being measured is HIV viral suppression.	Number of patients from the denominator prescribed HIV antiretroviral therapy during the measurement year.
Numerator Details	HIV medical visits are represented by a QDM variable that is comprised of the below seven different encounter type QDM elements: • Encounter, Performed: Face-to-Face Interaction using Face-to-Face Interaction Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1048) • Encounter, Performed: Office Visit using Office Visit Grouping Value Set	The viral load suppression laboratory test is represented by the QDM element "Laboratory Test, Performed: HIV Viral Load" using "HIV Viral Load Grouping Value Set (2.16.840.1.113883.3.464.1003.120.12.1002)". The result of the laboratory test is modeled as an attribute of the Viral Load Suppression QDM element and represented as a numerical result associated with copies/mL as the reporting unit.	The antiretroviral therapy medication order is represented by the QDM element "Medication, Order: FDA Approved HIV Antiretroviral Therapy" using "HIV Antiretroviral Therapy RXNORM Value Set (2.16.840.1.113762.1.4.1032.1)." In order to be included in the numerator, the "Medication, Order: FDA Approved HIV Antiretroviral Therapy" element must start during the measurement period.

	3209 HIV Medical Visit Frequency eMeasure	3210 HIV Viral Load Suppression eMeasure	3211 Prescription of HIV Antiretroviral Therapy eMeasure
	(2.16.840.1.113883.3.464.1003.101.12.1001) • Encounter, Performed: Outpatient Consultation using Outpatient Consultation Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1008) • Encounter, Performed: Preventive Care - Established Office Visit, 0 to 17 using Preventive Care - Established Office Visit, 0 to 17 Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1024) • Encounter, Performed: Preventive Care Services - Established Office Visit, 18 and Up using Preventive Care Services - Established Office Visit, 18 and Up Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1025) • Encounter, Performed: Preventive Care Services-Initial Office Visit, 18 and Up using Preventive Care Services-Initial Office Visit, 18 and Up Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1023) • Encounter, Performed: Preventive Care- Initial Office Visit, 0 to 17 using Preventive Care- Initial Office Visit, 0 to 17 Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1022)		
Denominator	Patients, regardless of age, diagnosed	Patients, regardless of age, diagnosed with HIV	Number of patients, regardless of age, with a

NATIONAL QUALITY FORUM

81

NQF REVIEW DRAFT—Comments due by Month DD, YYYY by 6:00 PM ET.

	3209 HIV Medical Visit Frequency eMeasure	3210 HIV Viral Load Suppression eMeasure	3211 Prescription of HIV Antiretroviral Therapy eMeasure
Statement	with HIV during the first 3 months of the year preceding the measurement period or prior to the measurement period with at least one medical visit in the first 6 months of the year preceding the measurement period.	during the first 3 months of the measurement year or prior to the measurement year who had at least one medical visit in the measurement year. The target population for this measure is all people living with HIV.	diagnosis of HIV with at least one medical visit in the measurement year
Denominator Details	The patient's HIV diagnosis is represented by the QDM element "Diagnosis: HIV" using "HIV Grouping Value Set (2.16.840.1.113883.3.464.1003.120.12.1003)". The patient's medical visits are represented by the following QDM elements: • Encounter, Performed: Face-to-Face Interaction using Face-to-Face Interaction Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1048) • Encounter, Performed: Office Visit using Office Visit Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1001) • Encounter, Performed: Outpatient Consultation using Outpatient Consultation Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1008) • Encounter, Performed: Preventive Care - Established Office Visit, 0 to 17 using Preventive Care - Established Office Visit, 0 to 17 Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1024)	The patient's HIV diagnosis is represented by the QDM element "Diagnosis: HIV" using "HIV Grouping Value Set (2.16.840.1.113883.3.464.1003.120.12.1003)". The patient's medical visits are represented by the following QDM elements: • "Encounter, Performed: Face-to-Face Interaction" using "Face-to-Face Interaction Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1048)" • "Encounter, Performed: Office Visit" using "Office Visit Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1001)" • "Encounter, Performed: Outpatient Consultation" using "Outpatient Consultation Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1008)" • "Encounter, Performed: Preventive Care - Established Office Visit, 0 to 17" using "Preventive Care - Established Office Visit, 0 to 17 Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1024)" • "Encounter, Performed: Preventive Care Services - Established Office Visit, 18 and Up" using "Preventive Care Services - Established Office Visit, 18 and Up Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1025)" • "Encounter, Performed: Preventive	The patient's HIV diagnosis is represented by the QDM element "Diagnosis: HIV" using "HIV Grouping Value Set (2.16.840.1.113883.3.464.1003.120.12.1003)". The patient's medical visits are represented by the following QDM elements: • "Diagnosis: HIV 1" using "HIV 1 Grouping Value Set (2.16.840.1.113883.3.464.1003.120.12.1004)" • "Encounter, Performed: Face-to-Face Interaction" using "Face-to-Face Interaction Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1048)" • "Encounter, Performed: Office Visit" using "Office Visit Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1001)" • "Encounter, Performed: Outpatient Consultation" using "Outpatient Consultation Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1008)" • "Encounter, Performed: Preventive Care - Established Office Visit, 0 to 17" using "Preventive Care - Established Office Visit, 0

NATIONAL QUALITY FORUM

82

NQF REVIEW DRAFT—Comments due by Month DD, YYYY by 6:00 PM ET.

	3209 HIV Medical Visit Frequency eMeasure	3210 HIV Viral Load Suppression eMeasure	3211 Prescription of HIV Antiretroviral Therapy eMeasure
	• Encounter, Performed: Preventive Care Services - Established Office Visit, 18 and Up using Preventive Care Services - Established Office Visit, 18 and Up Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1 025) • Encounter, Performed: Preventive Care Services-Initial Office Visit, 18 and Up using Preventive Care Services-Initial Office Visit, 18 and Up Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1 023) • Encounter, Performed: Preventive Care- Initial Office Visit, 0 to 17 using Preventive Care- Initial Office Visit, 0 to 17 Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1 022) The target population is identified by selecting patients based on their diagnosis with HIV.	Care Services-Initial Office Visit, 18 and Up" using "Preventive Care Services-Initial Office Visit, 18 and Up Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1023)" • "Encounter, Performed: Preventive Care- Initial Office Visit, 0 to 17" using "Preventive Care- Initial Office Visit, 0 to 17 Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1022)"	to 17 Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1024)" • "Encounter, Performed: Preventive Care Services - Established Office Visit, 18 and Up" using "Preventive Care Services - Established Office Visit, 18 and Up Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1025)" • "Encounter, Performed: Preventive Care Services-Initial Office Visit, 18 and Up" using "Preventive Care Services-Initial Office Visit, 18 and Up Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1023)" • "Encounter, Performed: Preventive Care- Initial Office Visit, 0 to 17" using "Preventive Care- Initial Office Visit, 0 to 17 Grouping Value Set (2.16.840.1.113883.3.464.1003.101.12.1022)"
Exclusions	Patients who died at any time during the measurement period or the 12 months preceding the measurement period.	No patient exclusions	No patient exclusions
Exclusion Details	This measure has one exclusion – patient death during the measurement period. The developer reports that the exclusion was tested similarly to other criteria using synthetic patients in Bonnie. When the exclusion element was present, the patients were correctly excluded from the measure. In the absence of the	Not applicable	Not applicable

NATIONAL QUALITY FORUM

83

NQF REVIEW DRAFT—Comments due by Month DD, YYYY by 6:00 PM ET.

	3209 HIV Medical Visit Frequency eMeasure	3210 HIV Viral Load Suppression eMeasure	3211 Prescription of HIV Antiretroviral Therapy eMeasure
	exclusion element, cases were not excluded from the measure.		
Risk Adjustment	No risk adjustment	No risk adjustment	No risk adjustment
Stratification	No risk stratification	No risk stratification	No risk stratification
Type Score	Rate/proportion, Better quality = Higher score	Rate/proportion, Better quality = Higher score	Rate/proportion, Better quality = Higher score
Algorithm	1. Identify the individuals who satisfy all specific criteria for inclusion in the denominator: 1.) diagnosed with HIV during the first 3 months of the 24-month measurement period or prior to the 24-month measurement period; 2.) did not have a date of death during the 24-month measurement period; and 3.) had at least one medical visit in the first 6 months of the 24-month measurement period. The individuals who met these three criteria are the denominator population. 2. Identify the individuals from the denominator population who meet the criterion for inclusion in the numerator: must have had at least one medical visit in each 6-month period of the 24-month measurement period with a minimum of 60 days between first medical visit in the prior 6-month period and the last medical visit in the subsequent 6-month period. 3. Calculate the rate by dividing the numerator population by the denominator population and multiply by 100.	1. Identify patients who meet the initial population criteria as defined by eCQM logic; 2. Identify and count subset of the initial population that meet denominator criteria as defined by eCQM logic; 3. Identify and count subset of patients in the denominator that meet numerator criteria as defined by eCQM logic. 4. Calculate the performance measure rate: by dividing the number of patients in the numerator population by the number of patients in the denominator population. Note: the eCQM logic criteria for each population is defined in a computable format in the eCQM specifications provided as an attachment to this submission.	1. Identify the individuals who satisfy all specific criteria for inclusion in the denominator: 1.) diagnosed with HIV during the first 3 months of the measurement year or prior to the measurement year; and 2.) had at least one medical visit during the measurement year. The individuals who met these criteria are the denominator population. 2. Identify the individuals from the denominator population who meet the criterion for inclusion in the numerator: prescribed HIV antiretroviral therapy during the measurement year. 3. Calculate the percentage by dividing the numerator population by the denominator population and multiply by 100.

NATIONAL QUALITY FORUM

84

NQF REVIEW DRAFT—Comments due by Month DD, YYYY by 6:00 PM ET.

	3209 HIV Medical Visit Frequency eMeasure	3210 HIV Viral Load Suppression eMeasure	3211 Prescription of HIV Antiretroviral Therapy eMeasure
Submission items	5.1a Identified Measures: 0403: HIV/AIDS: Medical Visit 0405: HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis 0409: HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis 2080: Gap in HIV Medical Visits 2082: HIV viral suppression 2083: Prescription of HIV Antiretroviral Therapy 3211: Prescription of HIV Antiretroviral Therapy 3210: HIV viral suppression 3010: HIV Medical Visit Frequency 5a.1 Are specs completely harmonized? Yes 5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden. Harmonized with all measures except 405 and 409. Plans to harmonize with 405 and 409.	5.1a Identified Measures: 0405: HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis 0409: HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis 2079: HIV Medical Visit Frequency 2080: Gap in HIV Medical Visits 2082: HIV Viral Suppression 2083: Prescription of HIV Antiretroviral Therapy 3211: Prescription of HIV Antiretroviral Therapy 3010: HIV Medical Visit Frequency 5a.1 Are specs completely harmonized? No 5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden. Harmonization exists with all measures except 405 and 409. Plan to harmonize with 405 and 409.	5.1a Identified Measures: 0405: HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis 0409: HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis 2079: HIV Medical Visit Frequency 2080: Gap in HIV Medical Visits 2082: HIV Viral Suppression 3210: HIV Viral Suppression 3010: HIV Medical Visit Frequency 5a.1 Are specs completely harmonized? Yes 5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden. This measure does not have a competing measure.

NATIONAL QUALITY FORUM

85

NQF REVIEW DRAFT—Comments due by Month DD, YYYY by 6:00 PM ET.

	0500 Severe Sepsis and Septic Shock Management Bundle	3215 Adult Inpatient Risk Adjusted Sepsis Mortality
Steward	Henry Ford Hospital	New York State Department of Health, Office of Quality and Patient Safety
Description	This measure focuses on adults 18 years and older with a diagnosis of severe sepsis or septic shock. Consistent with Surviving Sepsis Campaign guidelines, the measure contains several elements, including measurement of lactate, obtaining blood cultures, administering broad spectrum antibiotics, fluid resuscitation, vasopressor administration, reassessment of volume status and tissue perfusion, and repeat lactate measurement. As reflected in the data elements and their definitions, these elements should be performed in the early management of severe sepsis and septic shock.	Annual risk adjusted inpatient mortality rate for adult patients (aged 18 and over) admitted to acute care hospitals with diagnosis of severe sepsis or septic shock. The measure includes patients in acute care hospital settings over one year timeframe who had, either on admission, or during their hospital stay, a clinical diagnosis of severe sepsis (now referred to as ´sepsis´) or septic shock using criteria described in the International Sepsis Definitions (Sepsis-2)
Type	Composite	Outcome
Data Source	Imaging-Diagnostic, Laboratory, Other, Paper Records, Pharmacy	Claims (Other), EHRs Hybrid, Laboratory, Management Data, Non-Medical Data, Paper Records, Pharmacy, Registry
Level	Facility	Facility
Setting	Hospital	Hospital
Numerator Statement	• The number of patients in the denominator who received ALL of the following components (if applicable) for the early management of severe sepsis and septic shock: initial lactate levels, blood cultures, antibiotics, fluid resuscitation, repeat lactate level, vasopressors, and volume status and tissue perfusion reassessment. Within 3 hours of presentation of severe sepsis: o Measure initial lactate level o Draw blood cultures prior to antibiotics o Administer broad spectrum or other antibiotics • Within 6 hours of presentation of severe sepsis: o Repeat lactate level (if initial lactate > 2 mmol/L) • Within 3 hours of presentation of septic shock: o Administer 30 ml/kg crystalloid for hypotension or lactate ≥ 4 mmol/L • Within 6 hours of presentation of septic shock:	Outcome is risk adjusted inpatient mortality rate for adult patients (18 and over) admitted to an acute care hospital with a diagnosis of severe sepsis or septic shock or who develop severe sepsis or septic shock during their hospital stay.

NATIONAL QUALITY FORUM

NQF REVIEW DRAFT—Comments due by Month DD, YYYY by 6:00 PM ET.

86

	0500 Severe Sepsis and Septic Shock Management Bundle	3215 Adult Inpatient Risk Adjusted Sepsis Mortality
	o Apply vasopressors (for hypotension that does not respond to initial fluid resuscitation) to maintain a mean arterial pressure (MAP) ≥ 65 mm Hg o Reasses volume status and tissue perfusion in the event of persistent hypotension (MAP <65 mm Hg) after initial fluid administration or initial lactate level ≥ 4 mmol/L ⬜ The clinician is no longer required to state the method of reassessment used (e.g. physical exam, bedside cardiovascular ultrasound, passive leg raising, CVP, ScV02 assessment). The clinician can attest that volume and perfusion reassessment has occurred, even without reference to the method used. This will meet the measure's volume and perfusion reassessment requirement. A provider may also opt to state their chosen method, but this is not required.	
Numerator Details	In addition to the previous information (above) about assessing the numerator population, the following also are part of the numerator details. • Within 3 hours of presentation of severe sepsis: o Measure initial lactate level o Draw blood cultures prior to antibiotics o Administer broad spectrum or other antibiotics • Within 6 hours of presentation of severe sepsis: o Repeat lactate level (if initial lactate > 2 mmol/L) • Within 3 hours of presentation of septic shock: o Administer 30 ml/kg crystalloid for hypotension or lactate ≥ 4 mmol/L • Within 6 hours of presentation of septic shock: o Apply vasopressors (for hypotension that does not respond to initial fluid resuscitation) to maintain a mean arterial pressure (MAP) ≥ 65 mm Hg o Reasses volume status and tissue perfusion in the event of persistent hypotension (MAP <65 mm Hg) after initial fluid administration or initial lactate level ≥ 4 mmol/L	Inpatient mortality is noted on data submission from hospital. Clinical variables needed for risk adjustment including demographics, co-morbidities, severity, and potential exclusions are reported by hospital as described in the data dictionary.

NATIONAL QUALITY FORUM

NQF REVIEW DRAFT—Comments due by Month DD, YYYY by 6:00 PM ET.

87

	0500 Severe Sepsis and Septic Shock Management Bundle	3215 Adult Inpatient Risk Adjusted Sepsis Mortality
	☐ The clinician is no longer required to state the method of reassessment used (e.g. physical exam, bedside cardiovascular ultrasound, passive leg raising, CVP, ScV02 assessment). The clinician can attest that volume and perfusion reassessment has occurred, even without reference to the method used. This will meet the measure's volume and perfusion reassessment requirement. A provider may also opt to state their chosen method, but this is not required. The full definitions of each of these data elements and additional information are included in the data dictionary, attached to the submission	
Denominator Statement	Inpatients age 18 and over with an ICD-10-CM Principal or Other Diagnosis Code of Sepsis, Severe Sepsis, or Septic Shock.	All adult patient discharges (18 and over) in a calendar year with a diagnosis of severe sepsis or septic shock on admission or at any time during their hospital stay. This may include multiple admissions of the same patient during the measurement year. Denominator includes all cases identified using any means (administrative, registry, electronic health records, billing data, etc.), either prospectively, retrospectively, or both, that meet the International consensus definition (Sepsis- 2) of severe sepsis or septic shock.
Denominator Details	Discharges age 18 and over with an ICD-10-CM Principal or Other Diagnosis Code of Sepsis, Severe Sepsis, or Septic Shock as defined in the table below: ICD-10-CM Code Code Description A021 Salmonella sepsis A227 Anthrax sepsis A267 Erysipelothrix sepsis A327 Listerial sepsis A400 Sepsis due to streptococcus, group A A401 Sepsis due to streptococcus, group B A403 Sepsis due to Streptococcus pneumoniae A408 Other streptococcal sepsis A409 Streptococcal sepsis, unspecified	All adult patients meeting International consensus definition (Sepsis-2) for Severe Sepsis/Septic shock identified through combination of any relevant hospital clinical and/or administrative databases, prospectively or retrospectively.

NATIONAL QUALITY FORUM
NQF REVIEW DRAFT—Comments due by Month DD, YYYY by 6:00 PM ET.

88

0500 Severe Sepsis and Septic Shock Management Bundle	3215 Adult Inpatient Risk Adjusted Sepsis Mortality
A4101 Sepsis due to Methicillin susceptible Staphylococcus aureus A4102 Sepsis due to Methicillin resistant Staphylococcus aureus A411 Sepsis due to other specified staphylococcus A412 Sepsis due to unspecified staphylococcus A413 Sepsis due to Hemophilus influenzae A414 Sepsis due to anaerobes A4150 Gram-negative sepsis, unspecified A4151 Sepsis due to Escherichia coli [E. coli] A4152 Sepsis due to Pseudomonas A4153 Sepsis due to Serratia A4159 Other Gram-negative sepsis A4181 Sepsis due to Enterococcus A4189 Other specified sepsis A419 Sepsis, unspecified organism A427 Actinomycotic sepsis A5486 Gonococcal sepsis B377 Candidal sepsis R6520 Severe sepsis without septic shock R6521 Severe sepsis with septic shock Data elements required to calculate the denominator (in alphabetical order): • Administrative Contraindication to Care, Septic Shock • Administrative Contraindication to Care, Severe Sepsis • Admission Date • Birthdate • Directive for Comfort Care or Palliative Care, Septic Shock • Directive for Comfort Care or Palliative Care, Severe Sepsis	

NATIONAL QUALITY FORUM

NQF REVIEW DRAFT—Comments due by Month DD, YYYY by 6:00 PM ET.

89

	0500 Severe Sepsis and Septic Shock Management Bundle	3215 Adult Inpatient Risk Adjusted Sepsis Mortality
	• Discharge Date • Discharge Disposition • Discharge Time • Transfer From Another Hospital or ASC The full definitions of each of these data elements and additional information are included in the data dictionary, attached to the submission	
Exclusions	The following patients are excluded from the denominator: • Severe sepsis is not present • Patients Transferred in from another acute care facility • Patients receiving IV antibiotics for more than 24 hours prior to presentation of severe sepsis. • Patients with a Directive for Comfort Care or Palliative Care within 3 hours of presentation of severe sepsis • Patients with an Administrative Contraindication to Care within 6 hours of presentation of severe sepsis • Patients with an Administrative Contraindication to Care within 6 hours of presentation of septic shock • Patients with a Directive for Comfort Care or Palliative Care within 6 hours of presentation of septic shock • Patients with septic shock who are discharged within 6 hours of presentation • Patients with severe sepsis who are discharged within 6 hours of presentation • Patients with a Length of Stay >120 days • Patients included in a Clinical Trial	Patients with advanced directives in place prior to episode of sepsis which specifically restrict any hospital specific sepsis protocol interventions or who decline (or their proxy declines) treatment for sepsis. Patients who have been transferred from one acute care hospital to another are excluded.
Exclusion Details	To determine the length of stay, the admission date and discharge date are entered. If the result of the calculation subtracting the admission date from the discharge date is greater than 120 days, the patient is excluded from the measure.	Patients who have any of the following characteristics, reported on data variables fully described in the data dictionary, are excluded from the calculation of risk adjusted mortality rates for a specific hospital: 1. Advanced Directives in place prior to diagnosis of severe sepsis or

NATIONAL QUALITY FORUM   90

NQF REVIEW DRAFT—Comments due by Month DD, YYYY by 6:00 PM ET.

	0500 Severe Sepsis and Septic Shock Management Bundle	3215 Adult Inpatient Risk Adjusted Sepsis Mortality
	Data Elements required to determine denominator exclusions (in alphabetical order): Administrative Contraindication to Care, Septic Shock Administrative Contraindication to Care, Severe Sepsis Admission Date Birthdate Clinical Trial Directive for Comfort Care or Palliative Care, Septic Shock Directive for Comfort Care or Palliative Care, Severe Sepsis Discharge Date Discharge Disposition Discharge Time Transfer from Another Hospital or ASC The full definitions of each of these data elements and additional information are included in the data dictionary, attached to the submission.	septic shock that specifically preclude active treatment according to that hospital´s protocol for severe sepsis and septic shock. 2. Patient or patient proxy refusal of treatment for severe sepsis or septic shock according to that hospital´s protocol for severe sepsis and septic shock. 3. Patients who were transferred between acute care hospitals.
Risk Adjustment	No risk adjustment	Statistical risk model
Stratification	No risk stratification	Not applicable
Type Score	Rate/proportion, Better quality = Higher score	Rate/proportion, Better quality=Lower score
Algorithm	The detailed measure algorithm for SEP-1 is available in the data dictionary attached to the submission, along with a diagram. 1. Find the patients who meet the initial population (ie, the general group of patients that a set of performance measures is designed to address). 2. From the patients within the initial population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria) Note: in some cases the initial population and denominator are identical. Remove any patients that meet the denominator	The study objective was to develop a logistic regression model to estimate the probability of hospital mortality among septic patients entering 179 New York State hospitals over the period of January 1, 2015 through December 31, 2015. The a priori analysis plan eliminated any patient with an advanced directive or who declined interventions. When a patient was discharged from a hospital as "transfer to acute care", only the patient's data from the receiving hospital was used in the dataset. If a patient was in the dataset multiple times for sepsis, only the final admission was used. This preserved the outcome of interest (mortality) and observation independence in the data file for developing logistic regression models. This resulted in a database total of 43,204 septic patients. The a priori analysis used only patient demographics, comorbidities,

NATIONAL QUALITY FORUM

NQF REVIEW DRAFT—Comments due by Month DD, YYYY by 6:00 PM ET.

91

0500 Severe Sepsis and Septic Shock Management Bundle	3215 Adult Inpatient Risk Adjusted Sepsis Mortality
exclusion criteria. 3. The following actions are required within 3 hours of presentation of severe sepsis: a. Measure initial lactate level b. Draw blood cultures prior to antibiotics c. Administer broad spectrum or other antibiotics 4. The following actions are required within 6 hours of presentation of severe sepsis: a. Repeat lactate level (if initial lactate > 2 mmol/L) 5. The following actions are required within 3 hours of presentation of septic shock: a. Administer 30 ml/kg crystalloid for hypotension or lactate ≥ 4 mmol/L 6. The following actions are required within 6 hours of presentation of septic shock: a. Apply vasopressors (for hypotension that does not respond to initial fluid resuscitation) to maintain a mean arterial pressure (MAP) ≥ 65 mm Hg b. Reasses volume status and tissue perfusion in the event of persistent hypotension (MAP <65 mm Hg) after initial fluid administration or initial lactate level ≥ 4 mmol/L Note: The clinician is no longer required to state the method of reassessment used (e.g. physical exam, bedside cardiovascular ultrasound, passive leg raising, CVP, ScV02 assessment). The clinician can attest that volume and perfusion reassessment has occurred, even without reference to the method used. This will meet the measure's volume and perfusion reassessment requirement. A provider may also opt to state their chosen method, but this is not required. 7. All of the above numerator components (as applicable) must be in compliance, otherwise the case is calculated as a 'failed' sepsis case.	and admission characteristics to estimate the probability of hospital mortality. Specifically treatment variables were not used in the model. Septic patients All subjects entered into the model met the admitting hospital's criteria for severe sepsis or septic shock. Severe sepsis was defined as a suspected or confirmed infection, at least two systemic manifestations of infection and one or more acute organ dysfunctions. Septic shock was defined as severe sepsis where at least one organ dysfunction with sustained hypotension after a fluid challenge. For this paper, the term sepsis or septic represents the dataset population of severe sepsis and septic shock patients. Mortality is defined as in-hospitals deaths. Statistical Methods Logistic regression developed a model to estimate the probability of mortality for patients with severe sepsis or septic shock during their hospital stay. A list of the possible predictor variables and definitions are given in Table 1. Maximum likelihood was used to estimate model coefficients and associated standard errors. The hierarchical nature of the data supports random-effects logistic regression use since patients are nested within the 179 hospitals. However, the 179 random-effect coefficients would have made the resulting model specific only to those 179 New York hospitals and would not be generalizable to patients outside these specific hospitals. A random sample of 10% (N = 4,319) of the observations were set aside and the logistic regression model was developed on the remaining 90% (38,884 observations). The final model was validated on the 10% of observations that were set aside. Patient comorbidities were generated using the list shown in supplemental Table S1. We generated a variable called mechanical ventilation (MV) severity that indicated a severity of illness relating to mechanical ventilation. This dichotomous variable was defined when a patient was admitted to the hospital already mechanically ventilated or requiring mechanical ventilation within 6 hours post

NATIONAL QUALITY FORUM

NQF REVIEW DRAFT—Comments due by Month DD, YYYY by 6:00 PM ET.

92

0500 Severe Sepsis and Septic Shock Management Bundle	3215 Adult Inpatient Risk Adjusted Sepsis Mortality
	admission. Initial serum lactate was not measured in 2,528 (5.9%) patients and was imputed using single imputation. Specifically, truncated linear regression was used during the imputation procedure where the lower limit of left truncation was set at a serum lactate level 0.1 mmol/L (1st percentile) and the upper limit of the right truncation was set at 30.0 mmol/L (99th percentile). A list of predictor variables is shown in supplemental Table S2.
	A multivariable logistic regression model was built using the developmental dataset and starting with all possible covariates in the model. Using an iterative procedure, variables were removed from the model, one by one, if their p-values were not significant at 0.05 level until a parsimonious model was reached. Variables removed during the development procedure were added back into the model if their p-values were significant at the 0.05 level and if model calibration (Hosmer-Lemeshow goodness of fit) was improved through their inclusion. We then assessed the scale of the 3 continuous variables (patient age, first serum lactate, and the count of the number of comorbidities) remaining in the model. Specifically, we were interested in determining whether these variables had a linear relationship with mortality. Using the method of fractional polynomials patient age was included in the model as a linear term, the number of comorbidities was transformed by taking the square root of the number of comorbidities, and first serum lactate was entered into the model as a quadratic expression (linear and a squared term). Model calibration was further improved by adding the following interactions to the model: lower respiratory infection (LRI) and MV severity, patient age and the square root of the number of comorbidities, and first serum lactate and the square root of the number of comorbidities.
	Model calibration was assessed using the Hosmer-Lemeshow goodness of fit on both the developmental and the validation datasets. Group sizes of 10, 100, 500, and 1,000 were chosen for the large, developmental, dataset while group sizes of 10, 50, 100, and 150 were chosen for the smaller validation dataset. Model discrimination was assessed using the area under the receiver operating characteristic (ROC) curve for both the developmental and

NATIONAL QUALITY FORUM

93

NQF REVIEW DRAFT—Comments due by Month DD, YYYY by 6:00 PM ET.

	0500 Severe Sepsis and Septic Shock Management Bundle	3215 Adult Inpatient Risk Adjusted Sepsis Mortality
		validation datasets.
		The estimated probability of mortality was generated using the model coefficients and the specific patient attributes. If the patient attribute is defined by a categorical variable, then the possible values are either a 0 or 1. If the attribute is defined by a continuous variable, then the specific value is used such as the patient's age. Interaction values are generated by multiplying the values of each of the two individual variables defined by the interaction. The product of the coefficient and the patient's value for all of the variables in the model are generated. Next the logit is defined as the sum of the above products. Finally, the probability of mortality for a specific patient is generated using the follow equation:
		Probability of mortality= $\exp(logit)/(1+\exp(logit))$
Submission items	5.1a Are there related measures or competing measures: No	5.1a Identified Measures:
		0500: Severe Sepsis and Septic Shock: Management Bundle
		5a.1 Are specs completely harmonized? Yes

NATIONAL QUALITY FORUM

NQF REVIEW DRAFT—Comments due by Month DD, YYYY by 6:00 PM ET.

94

Appendix G: Pre-Evaluation Comments

Comments received as of February 23, 2017

Topic	Commenter	Comment
0500 Severe Sepsis and Septic Shock	Submitted by American Medical Association	The American Medical Association (AMA) appreciates the opportunity to comment prior to the NQF Infectious Disease Standing Committee's review. We strongly support the modifications that the developer made to the measure, #500, Severe Sepsis and Septic Shock: Management Bundle. Specifically, the additional requirement requiring documentation by a clinician to confirm severe sepsis addresses our concern that the previous denominator was too broadly defined and could have unintended negative consequences by including patients inappropriately. We also appreciate the additional enhancements made to the measure to capture individual patient circumstances, including capturing appropriate delays in obtaining blood cultures prior to antibiotic administration and the additional data elements to better identify those patients for whom crystalloid fluid administration is suitable. We would request one clarification in the measure specifications regarding one of the exclusions. Specifically, the denominator exclusions in S.8 include the following element, Patient included in clinical trial; yet, S.3.2, where changes to the measure are outlined, states that this exclusion has been removed. It would be helpful to have the developer clarify this discrepancy prior to releasing the measure for public and member comment. We look forward to monitoring the discussion of the measure and the opportunity to comment during the review and endorsement process.
0500 Severe Sepsis and Septic Shock	Submitted by Federation of American Hospitals	The Federation of American Hospitals ("FAH") appreciates the opportunity to comment prior to the NQF Infectious Disease Standing Committee's review. FAH believes that effective and timely treatment of severe sepsis and septic shock in patients is vital and we support the intent of the measure. FAH appreciates the modification to the measure to allow for administration of targeted antibiotics when the causative organism and susceptibility are known. FAH encourages the developer to continue to monitor the measure to ensure that this additional flexibility addresses the ongoing efforts of effective antibiotic stewardship and minimizing the potential for overuse. The FAH also asks for clarification of one of the

Topic	Commenter	Comment
		measure specifications. Specifically, the denominator exclusions in S.8 include the following element, "Patient included in clinical trial"; yet, S.3.2, where changes to the measure are outlined, states that this exclusion has been removed. The FAH strongly encourages the developer to clarify this discrepancy prior to releasing the measure for public and member comment.
		The FAH remains extremely concerned that the sepsis measure continues to be overly complex and burdensome to collect, and, therefore, hampers the ability of hospitals to appropriately evaluate their performance on this measure since many of the data elements required for this measure can be captured only through chart abstraction. This complexity is evidenced by the validity testing results where forty data elements achieved less than 90% percent agreement between the data abstracted by hospitals and data abstracted by independent medical abstractors. FAH believes that the validity results demonstrate the inherent problems with implementing a measure with more than 140 data elements. In addition, even though hospitals collected the data for the measure since the last quarter of 2015 and the Centers for Medicare & Medicaid Services (CMS) now has a full year of data, CMS has not yet publicly reported results due to concerns with data quality. The FAH asks that the committee consider these findings during the measure evaluation. While the FAH understands there are limitations to what can be collected in electronic health records currently, we strongly urge the developer to revise the measure to enable electronic data capture. Developing an eMeasure in this area would further ensure that the relevant information is available for use at the point of care and facilitate communication with providers at the next level of care. Continuing to maintain and endorse a measure that requires manual abstraction with this many elements should not be viewed as a long-term solution given the current environment of promoting electronic data capture.
3209 HIV Medical Visit Frequency eMeasure	Submitted by New York State Department of Health AIDS Institute	Please review my comment on NQF#2079 related to the rigidity of frequency measures and their inability to apply to all people with HIV given established practice and clinical guidelines.
2079 HIV Medical Visit Frequency	Submitted by New York State	Representing the HIV Quality of Care Advisory Committee and Consumer Advisory Committee of the NY State

NATIONAL QUALITY FORUM

96

NQF REVIEW DRAFT—Comments due by Month DD, YYYY by 6:00 PM ET.

Topic	Commenter	Comment
	Department of Health AIDS Institute	Department of Health AIDS institute we would advise that this measure be dropped based on the variation of expected frequency of visits for patients based on their viral load suppression status. Frequency measures suggest that a rigid spacing of intervals of visits can be universally applied which is no longer the global standard of care - even in resource limlited settings where differentiated care models are promoted by WHO and the Global Fund. The measure is not as useful at clinic level for improvement as missed visit measures, based on extensive research led by Mugavero among others.
2080 Gap in HIV Medical Visits	Submitted by New York State Department of Health AIDS Institute	Gaps in care should be focused on minimum standards applying to all patients as absence of a clinical visit within a 12 month period.
Comments on Standards not recommended	Submitted by New York State Department of Health AIDS Institute	In the proposed measures list, measures for CD4 monitoring and PCP prophylaxis still appear. The former is not a useful measure given the role of VL monitoring and suppression and the inability to see change easily over time. Although PCP prophyalxis is obviously of critical importance the number of eligible patients for intervention has diminished dramatically to make it of limited value as a quality measure.