National Voluntary Consensus Standards: Infectious Disease Endorsement Maintenance 2012

TECHNICAL REPORT

June 2013

NATIONAL QUALITY FORUM

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National Voluntary Consensus Standards: Infectious Disease Endorsement Maintenance 2012

TECHNICAL REPORT

Introduction

While 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. Specifically:

- In 2008, hospital charges for infectious disease averaged $96 billion per year with an average 4.5 million hospital days per year.[1]
- An estimated 1.2 million Americans are living with HIV/AIDS, and nearly 642,000 Americans have died from AIDS since 1981.[2] Last year total federal spending on HIV/AIDS-related medical care, research, prevention, and other activities was $21.3 billion. For fiscal year 2013, President Obama has requested $22.4 billion to combat HIV in the U.S.[3]
- According to the Centers for Disease Control and Prevention (CDC), every year the healthcare system spends $17 billion on sexually transmitted infections.[4] It is estimated that in the U.S. there are roughly 19 million new infections every year.[5]

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. Appropriate use of antibiotics and antibiotic stewardship are critical factors in management of infectious disease. Antibiotic stewardship provides an opportunity to not only shorten an individual's length-of-stay in the hospital and improve patient outcomes, but also has the potential to reduce healthcare costs.[6] A University of Maryland study indicated that over 8 years, an antibiotic stewardship program saved $17 million.[7]

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.

Measure Evaluation

On August 28-29, 2012 the Infectious Disease Steering Committee evaluated 5 new measures and 29 measures undergoing maintenance review against NQF's standard evaluation criteria. To facilitate the evaluation, the Committee and candidate standards were divided into 4 workgroups for preliminary review of the measures against the evaluation sub-criteria prior to consideration by the entire Steering Committee. The Committee's discussion and ratings of the criteria are summarized in the evaluation tables beginning on page 8.

Infectious Disease Endorsement Maintenance 2012 Summary

	Maintenance	New	Total
Measures under Consideration	29	5	34
Measures Withdrawn from Consideration	7	0	7
Measures Endorsed	12	4	16
Measures Not Endorsed	10	1	11
Reasons for not Endorsing	Importance – 5 Scientific Acceptability – 4 Overall – 1	Importance-1	

Overarching Issues

During the Steering 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:

Disparities-sensitive Measures

HIV/AIDS and Hepatitis C affect certain groups disproportionately within the general population. According to the CDC, African Americans and gay and bisexual men account for a higher proportion of HIV infections at all stages of the disease—from new infections to deaths.[8] African Americans have a substantially higher rate of chronic Hepatitis C infection than do Caucasians and other ethnic groups. Within the African American community, chronic liver disease, often Hepatitis C-related, is a leading cause of death among people ages 45-64.[9]

While the measure submissions did not frequently include measure results stratified to assess disparities, seven measures were identified as disparities-sensitive (Appendix F), including four new measures for HIV/AIDS. This lack of data to assess the quality gap limited the ability of NQF's measure assessment protocol to identify disparities-sensitive measures, particularly for Hepatitis C in which there are known racial and ethnic disparities. In order to rectify this issue, the EHR specifications for the measures for HIV/AIDS and Hepatitis C now include key demographic data elements for gender, race, ethnicity, preferred language, payer and age that should allow for stratification over time.

Evidence guidance

Many measure submissions did not include sufficient information on the quantity, quantity and consistency of the evidence criteria as described by the NQF 2010 Evidence Task Force report. Many submissions refer to clinical guidelines without description of the underlying studies that support the guidelines. In July 2012, the Consensus Standards Approval Committee (CSAC) discussed the challenges of the information required for the evidence criterion identified by NQF staff and measure developers. The CSAC decided that despite the obvious challenges, there is no need to change the criteria and every effort should be made to assist the developers in providing the information needed by the Committee to evaluate the evidence criterion.

The information provided to the Committee for the Infectious Disease measures was quite variable in detail and responsiveness to the NQF criteria for the quantity, quality and consistency of the evidence.

To better understand the reasons for the Committee voting "NO" for the evidence criterion, two "NO" voting options were given:

- No, evidence does not meet guidance for quantity, quality, consistency (including no empirical evidence exists); or
- No, insufficient information submitted to rate quantity, quality, consistency of body of evidence.

If the Committee voted *No, evidence does not meet guidance for quantity, quality, consistency (including no empirical evidence exists)* they were given an opportunity to consider making an exception to the evidence criteria. If the Committee voted *No, insufficient information submitted to rate quantity, quality, consistency of body of evidence,* they were given an opportunity to re-vote on the criterion based on their own knowledge of the evidence as meeting NQF's criteria.

Electronic Health Record measure (eMeasure) testing

Many of the measures submitted for this project are generated from electronic health records (eMeasures). An eMeasure format review was performed by NQF's Health IT staff prior to Committee evaluation. The format review compares the eSpecifications to the numerator and denominator statements in the submission form and evaluates the data elements specified against the Quality Data Model (QDM), the value sets and the measure logic. Health IT staff noted that generally the eMeasures were in a human-readable output rather than Health Quality Measure Format (HQMF) which is a Health Level-7 (HL7) standard for eMeasures. Measure developers clarified several questions raised in the format review but no significant issues were identified.

The Committee had many questions regarding the testing expected for eMeasures. Most eMeasures were submitted with testing results as described in NQF's 2011 Testing Task Force report. For reliability, the only sub-criterion to consider was the measure specifications. The Committee asked how the exceptions were captured in electronic health records (EHRs). The developer responded that there are different value sets for exclusions for medical reasons and patient reasons and that to be able to automate this information requires a good EHR design and use of discrete fields and value sets, where applicable. The developer could not provide information on the number of EHR systems that include the fields for exceptions, but indicated that the Physicians Quality Reporting System (PQRS) program uses the exception categories so those EHR system reporting to PQRS would need to be able to capture these categories.

The validity testing presented for the eMeasures compared the automated result to the visual inspection of the EHR data. The testing results presented were usually limited to the percent agreement or a kappa score. Sometimes the validity results demonstrated substantial lack of agreement between the automated results calculated by the EHR and visual inspection of the record by professional data abstractors. Steering Committee members asked the measure developers how discordant testing results were handled. The developer responded that EHR automated reporting consistently under-reports unless modifications are made to enhance the data capture. After the initial testing, which is reported in the measure submissions, the test sites made modifications to work flow and data capture to improve the validity of the automated results. Committee members noted that testing in only 2-4 sites or a single EHR system may not be sufficient to evaluate reliability and validity of eMeasures for broader use.

Many of the original submissions for the eMeasures indicated other data sources for the measures; however, since testing was not performed using those data sources (e.g., CPT-II codes), the NQF endorsement applies only to eMeasure specifications. Some measures that were tested as eMeasures

were not submitted with eSpecifications. The developer provided the eSpecifications after the in-person meeting for review by the Committee.

Recommendations for Future Measure Development

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

- Outcome measures
- Antimicrobial stewardship
- HIV/AIDS
    - Testing for individuals 13-64 years of age
    - Colposcopy screening for women living with HIV who have abnormal PAP smear tests
    - Resistance testing for persons newly enrolled in HIV care with a viral load greater than 1000
    - HIV screening at first prenatal care visit for all pregnant women
    - Include stratification of disparity data
- Process and outcome measures to evaluate improvements in device associated infections in the hospital setting, particularly catheter-associated urinary tract infection
- Measures that include follow-up for screening tests
- Screening for sexually transmitted infections (STIs), including human papillomavirus (HPV)

Measure Evaluation Summary

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0500: Severe sepsis and septic shock: Management bundle 38
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0411: HIV/AIDS: Other infectious diseases - Hepatitis B screening 81
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0414: HIV/AIDS: Other infectious diseases - Hepatitis C 81
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Measures Endorsed

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

0058: Avoidance of antibiotic treatment in adults with acute bronchitis

Submission | **Specifications**

Status: Maintenance, Original Endorsement: Aug 10, 2009

Description: The percentage of adults 18–64 years of age with a diagnosis of acute bronchitis who were not dispensed an antibiotic prescription.

Numerator Statement: Patients who were dispensed antibiotic medication (see Table 1) on or three days after an outpatient or ED encounter for acute bronchitis (a higher rate is better). The measure is reported as an inverted rate (i.e. 1- numerator/denominator) to reflect the number of people that were not dispensed an antibiotic.

Denominator Statement: All patients 18 years as of January 1 of the year prior to the measurement year to 64 years as of December 31 of the measurement year with a claim/encounter for a diagnosis of acute bronchitis (refer to Table 2) and an outpatient or ED visit code (refer to Table 3) during the Intake Period (January 1–December 24 of the measurement year).

Exclusions: N/A

Adjustment/Stratification: No risk adjustment or risk stratification N/A

Level of Analysis: Health Plan, Integrated Delivery System

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Pharmacy

Measure Steward: National Committee for Quality Assurance

STEERING COMMITTEE MEETING [08/28/2012]

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

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

1a. Impact: **H-19; M-0; L-0; I-0**; 1b. Performance Gap: **H-16; M-2; L-0; I-0** 1c. Evidence: **Y-19; N-0; I-0;**

Rationale:

- Acute bronchitis is a very common diagnosis - it affects approximately 5 percent of U.S. adults annually and continues to rank among the top 10 conditions for which patients seek treatment in clinical settings.
- The use of antibiotics in these types of conditions is a significant harm in that it increases the selection of resistance for the common pathogens.
- The performance gap data indicates the percentage of patients who had acute bronchitis but were not prescribed an antibiotic is quite low (22-25 percent).
- The developer's data does not demonstrate much improvement over time. It is not clear how much effect this measure has had on improving appropriate antibiotic use for acute bronchitis.
- There is no data on disparities.
- An April 18, 2012 Cochrane systematic review of 15 trials of 2618 patients found limited evidence for marginal benefit of antimicrobials. The Cochrane review notes that "However, the magnitude of this benefit needs to be considered in the broader context of potential side effects, including medicalization for a self-limiting condition, increased resistance to respiratory pathogens and cost of antibiotic treatment[10].
- An *Up-To-Date* review of literature though July 2012 by T File noted "Update provides clearer evidence on the lack of effectiveness of antibiotics for acute bronchitis." "We recommend NOT treating patients with presumed acute bronchitis with empiric antibiotic therapy (Grade 1A)".

0058: Avoidance of antibiotic treatment in adults with acute bronchitis

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-15; L-1; I-1** 2b. Validity**: H-0; M-11; L-1; I-7**

<u>Rationale:</u>

- A signal to noise analysis of reliability for this measure was calculated using HEDIS health plan performance data for 2011. Reliability statistics at the level of the measure score are high.
- Committee members suggest that consistent classification of acute bronchitis and URI can be subjective and challenging.
- A recent review using data from a large, integrated health system examined trends in antibiotic use for acute bronchitis from 2006 to 2009 and observed an unintended consequence of this measure. While there was a significant reduction of patients treated with antibiotics for diagnosis code 466.0 (acute bronchitis) there was a significant increase in the use of diagnosis code 490 (bronchitis, not otherwise specified) associated with antibiotic use. As a result, the odds of an antibiotic prescription for codes 466 and 490 combined decreased only slightly and suggested the measure influenced a change in diagnosis coding as an unintended consequence which resulted in continuing antibiotic use[11].
    - The developer noted that auditors must sign off on the results that are submitted by the health plans, and they do look for shifts in measure rates, and would go back and look and see if there was a major shift in coding practices. The developers are also investigating different ways to look at the frequency of the codes used to identify certain conditions.
    - The developer also noted that the initial field testing in 2004 across four plans' different claims' diagnosis indicated using multiple claims to identify both the diagnosis and comorbidities between the two, that the use of code 466 was between 77 and 81 percent across different plans and the percentage of code 499 was an average of about 22 percent. The developer concluded the use of 466 was the appropriate code and the use of 490 was the inappropriate code. In light of the new evidence, the developers plan to retest the codes across different plans across the nation.
- Validity is a concern due to the potential shift in diagnosis because it reflects one billing code; a simple change to "bronchitis not specified" will miss the cases.
- When asked if the measure captures delayed prescriptions for patients with symptoms of bronchitis who were prescribed an antibiotic a week or so after having phone contact with their physician, the developer responded that they are not able to capture the phone encounter in claims data but may be able to do so in EHR. The EHR will be more flexible in the choices for dispensing medication.
- The developer reported that an EHR measure is in development; the feasibility testing has been completed but further testing for reliability and validity is pending. EHR testing for validity will provide another opportunity to look at validity of diagnosis and other threats to validity.

3. Usability: H-9; M-10; L-0; I-0

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

<u>Rationale</u>:

- This measure is used in public reporting for health plans through HEDIS - results are published through venues such as the annual State of Healthcare Quality report, Quality Compass and America's Best Health Plans.
- Committee members discussed the low rate of appropriate use of antibiotics (22 percent). Some members suggested that there is limited accountability and lack of appropriate incentives.

0058: Avoidance of antibiotic treatment in adults with acute bronchitis
4. Feasibility: H-8; M-10; L-1; I-0 *(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)* Rationale: • This is a health plan level measure based on administrative data and is widely used.   o The developer reported that the programming is done through certified software vendors' administrative claims algorithm that looks for these different comorbid conditions within a certain time frame from the initial encounter and diagnosis. • A Committee member indicated that this measure is used by Highmark BCBS for payment incentives and works very well from claims. • The developer indicated that an EHR version of this measure is in development.
5. Related and Competing Measures • No related or competing measures noted.
Steering Committee Recommendation for Endorsement: Y-19; N-0
Public and Member Comment (October 3, 2012-November 5, 2012) • This measure will incentivize appropriate antibiotic use in an area where antibiotics are used appropriately only 22 percent of the time. The measure is effectively being used in payment programs to the benefit of consumers, and can be used to assist purchaser decision-making because it is reportable at the plan level. Future iterations of the measure will be improved with e-specification and with the inclusion of additional, related diagnosis codes. • These measures are congruent with the Get Smart: Know When Antibiotics Work program efforts to reduce inappropriate antibiotic use for viral respiratory infections.
Consensus Standards Approval Committee (CSAC) Review (December 2012): Y-14; N-0; A-0 • Decision: Approved for continued endorsement
Board of Directors (January 4, 2013) • Decision: Ratified for continued endorsement

0069: Appropriate treatment for children with upper respiratory infection (URI)

Submission | **Specifications**

Status: Maintenance, Original Endorsement: Aug 10, 2009

Description: Percentage of children 3 months to 18 years of age with a diagnosis of URI who were not dispensed an antibiotic medication.

Numerator Statement: Patients who were dispensed antibiotic medication (Table 1) on or within 3 days after an outpatient or ED encounter for upper respiratory infection (URI) (a higher rate is better). The measure is reported as an inverted rate (i.e. 1- numerator/denominator) to reflect the number of children that were not dispensed an antibiotic.

Denominator Statement: All children age 3 months as of July 1 of the year prior to the measurement year to 18 years as of June 30 of the measurement year who had an ED or outpatient visit with only a diagnosis of nonspecific upper respiratory infection (URI) (Table 2) during the intake period (July 1st of the year prior to the measurement year to June 30th of the measurement year).

Exclusions: N/A

Adjustment/Stratification: No risk adjustment or risk stratification N/A

Level of Analysis: Health Plan, Integrated Delivery System

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Pharmacy

Measure Steward: National Committee for Quality Assurance

STEERING COMMITTEE MEETING [08/28/2012]

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

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

1a. Impact: **H-19; M-1; L-0; I-0**; 1b. Performance Gap: **H-3; M-15; L-2; I-0** 1c. Evidence: **Y-15; N-3; I-2**

Rationale:

- This is a common reason for ambulatory visits.
- There is better performance of this overuse measure compared to measure 0058: *Avoidance of antibiotic treatment in adults with acute bronchitis* because pediatricians are more selective in prescribing and there is a longer list of exclusions for this measure compared to 0058.
- Small improvement in performance rate - 84.49 percent in 2011 versus 83.61 percent in 2009 for Commercial and 87.18 percent in 2011 versus 85.49 percent in 2009 for Medicaid. A Committee member stated that even if the performance rate continues to improve this measure should not be retired due to the importance of the measure focus.
- No data on disparities was provided.
- There is a great deal of evidence for unnecessary antimicrobials in URIs and antibiotic resistance. There are more studies for adults than for children, but sufficient to meet NQF criteria.

0069: Appropriate treatment for children with upper respiratory infection (URI)

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-5; M-15; L-0; I-0** 2b. Validity**: H-2; M-14; L-2; I-2**

<u>Rationale:</u>

- This is a health plan level measure. The data is based on dispensed medications using pharmacy claims.
- A signal to noise analysis of reliability for this measure was calculated using HEDIS health plan performance data for 2011. Reliability statistics at the level of the measure score are high.
- Face validity tested by a panel of experts
- When asked if the measure captures delayed prescriptions for patients with symptoms of URI who were prescribed an antibiotic a week or so after having phone contact with their physician, the developer responded that they are not able to capture the encounter in claims data but may be able to do so in EHR. The EHR will be more flexible in the choice for dispensing medication. When the Committee asked about low cost drugs from discount pharmacies, the developer reported that these prescriptions are variably captured in the measure depending on whether the discount pharmacy shares the data.
- The developer noted that the time window was determined during the original field testing when it was found that three days was the appropriate time frame due to the other comorbid conditions and the appropriateness for the antibiotics in this population group
- A Committee member suggested testing this measure for the adult population and comparing it to the results for measure 0058 as another test of the validity of the measure. It was suggested that this analysis could answer the question of why the results of measures 0058 and 0069 are so different.

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

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

<u>Rationale</u>:

- This measure is used in public reporting for health plans through HEDIS - results are published through venues such as the annual State of Healthcare Quality report, Quality Compass and America's Best Health Plans.
- The EHR measure has been approved for Meaningful Use – the developer will submit the EHR measure for consideration of NQF endorsement when reliability and validity testing are completed.

4. Feasibility: H-4; M-14; L-2; I-0

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

<u>Rationale</u>:

- This is a health plan level measure that used administrative data and is widely used. Claims capture dispensed medication only.
- The developers indicate that an EHR version of this measure is in development. The EHR measure can look at prescribed as well as dispensed and will have additional options for future measures to determine the time frames between those prescribing and dispensing as they occur. A Committee member asked how delayed prescriptions work with ePrescribing. Others noted that some pharmacies put the ePrescription on file until the patient activates it though this does not seem to be a universal practice.

5. Related and Competing Measures

- No related or competing measures noted.

Steering Committee Recommendation for Endorsement: Y-19; **N-0**

0069: Appropriate treatment for children with upper respiratory infection (URI)

Public and Member Comment (October 3, 2012-November 5, 2012)

- These measures are congruent with the Get Smart: Know When Antibiotics Work program efforts to reduce inappropriate antibiotic use for viral respiratory infections.
- This measure reflects the current evidence that unnecessary antimicrobials in URIs breed antibiotic resistance (and that antibiotics are generally unnecessary for the treatment of URIs). This measure will incentivize delivery of appropriate care, thereby reducing waste, improving value, and reducing a contributing factor to the generation of antibiotic resistance. This measure is widely used in HEDIS reporting and the Electronic Health Records Meaningful Use program.

Consensus Standards Approval Committee (CSAC) Review (December 2012): Y-14; N-0; A-0

- Decision: Approved for continued endorsement

Board of Directors (January 4, 2013)

- Decision: Ratified for continued endorsement

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

Submission | **Specifications**

Status: Maintenance, Original Endorsement: Jul 31, 2008

Description: Percentage of patients aged 18 years and older with a diagnosis of hepatitis C seen for an initial evaluation who had HCV RNA testing ordered or previously performed

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

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

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

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

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

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

Type of Measure: Process

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

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

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

STEERING COMMITTEE MEETING [08/28/2012]

1. Importance to Measure and Report: <u>The measure does not meet the Importance criteria</u>

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

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

<u>Rationale</u>:

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

Public and Member Comment (October 3, 2012-November 5, 2012)

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

  10th percentile: 87.50%

  25th percentile: 100.00%

  50th percentile: 100.00%

  75th percentile: 100.00%

  90th percentile: 100.00%

  The inter-quartile range (IQR) provides a measure of the dispersion of performance. The IQR is 0.00 and indicates that at least 50% or more of physicians have performance on this measure at 100.00%. The bottom 10% of physicians are performing at or below 87.50%. Source: Confidential CMS PQRI 2009

Performance Information by Measure. TAP file." However, such data may not be representative at all. There are other reports that indicate there is substantial performance gap: Of 20,285 reports of HCV infection received by CDC from state/local surveillance programs in 2006-2007, a total of 10,834 (47.6%) reports had no positive result for HCV RNA. Klevens RM, Miller J, Iqbal K, Thomas A, et al. The Evolving Epidemiology of Hepatitis A in the United States: Incidence and Molecular Epidemiology from Population-Based Surveillance. Arch Intern Med. 2010;170(20):1811-1818. CDC recently reviewed electronic health records of >1,652,055 adult patients seen from January 2006 through December 2010 at 4 integrated healthcare systems in Detroit, Michigan; Danville, Pennsylvania; Portland, Oregon; and Honolulu, Hawaii were collected and analyzed. Of 9086 patients with a positive HCV antibody test, 3428 (37.7%) had no documented follow-up HCV RNA testing in the electronic database." MoormanAC, Gordon SC, Rupp et al. Baseline Characteristics and Mortality Among People in Care for Chronic Viral Hepatitis: The Chronic Hepatitis Cohort Study. Clin Infect Dis.2012 Oct 19. [Epub ahead of print]. A poster presentation from the 2012 IDSA meeting demonstrated a decline in the documentation of HCV viremia from 73% to 63%: "Quality of Hepatitis C care at an urban tertiary medical center" IDSA San Diego Oct 17-21 2012; Sabrina A. Assoumou MD, Wei Huang MA, Benjamin P. Linas, MD MPH.

- The majority of SC members determined that the requirement for evidence was not met. However, a few SC members supported the importance of the measure and discussed the indirect evidence linking the process to the outcome. Additional information provided by the measure developer Work Group included a meta-analysis of 31 studies that found a consistent overall estimate of 15 to 20 percent of people who become infected with acute Hepatitis C will clear the virus. The absence of confirmatory viral testing may then leave these 15 to 20 percent of patients with the mistaken belief that they have chronic Hepatitis C, subjecting these patients to unnecessary anxiety and other harms. The remaining viral positive patients could benefit from the additional counseling for their own and for transmission risk, as mentioned by SC members, namely avoiding alcohol, getting vaccinated, and providing counseling regarding transmission and remaining engaged in care. Thus, this test is critically important in differentiating whether or not people have resolved infection or are currently infected with HCV, regardless of whether antiviral treatment is contemplated. The SC was also concerned that little evidence was provided to demonstrate opportunity for improvement and that, like most assessment measures, it represents the "Standard of Care" and does not warrant a performance measure. However, additional evidence provided by the CDC, Boston Medical Center and the Cleveland VA Medical Center below shows that a substantial performance gap remains, illustrating that in practice, confirmatory testing after initial HCV antibody testing is NOT being done often enough to constitute "Standard of Care." Of 20,285 reports of HCV infection received by CDC from state/local surveillance programs in 2006-2007, a total of 10,834 (47.6%) reports had no positive result for HCV RNA.1 CDC recently reviewed electronic health records of >1,652,055 adult patients seen from January 2006 through December 2010 at 4 integrated healthcare systems in Detroit, Michigan; Danville, Pennsylvania; Portland, Oregon; and Honolulu, Hawaii. Of 9,086 patients with a positive HCV antibody test, 3,428 (37.7%) had no documented follow-up HCV RNA testing in the electronic database.2 A study conducted at Boston Medical Center of CMS-defined HCV quality indicators, comparing data from 2005-2007 to 2008-2011, revealed a decline in the confirmation of HCV viremia from 73% to 63%.3 Members of the Department of Medicine at Louis Stokes Cleveland Department of Veterans Affairs Medical Center in Cleveland, OH found similar rates of testing in their study and included additional information in their conclusions related to implications. They looked at ~400 people who lacked HCV nucleic acid amplification technology (NAT) testing to characterize behaviors in response to patients who have a positive HCV antibody (ab) test but lack viral confirmatory testing. Below are their findings: 1. 31% of patients with a positive HCV ab test, never had that result acknowledged by a medical provider (HCV ordering or other provider), resulting in missed opportunities for follow-up liver care and Hepatitis C treatment.4 2. In 251 instances, the positive HCV ab test was acknowledged by the ordering provider, and despite the lack of viral NAT, these providers took actions that indicated they believed patients had chronic Hepatitis C.4 These actions included addition of the ICD-9 diagnosis for chronic Hepatitis C to the patient's problem list, ordering serial liver function tests, ordering HAV/HBV vaccinations, etc.

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

Interestingly, very few providers ordered confirmatory NAT in response to the positive HCV ab. 3. In the cases where HCV was entered into the patient's problem list in the EMR, this unconfirmed diagnosis was "perpetuated" by future medical providers that the patient saw in 85% of instances.4 While this data is not randomized, nor does it contain a control group, it highlights some of the misconceptions about HCV diagnosis amongst general medical providers and mental health providers that may order HCV ab tests as part of their practices. Unconfirmed diagnoses of HCV can lead to stigmatization, receipt of unnecessary medical interventions, and avoidance of important medical interventions (e.g., statin use). This may be even more impactful as the CDC's birth cohort screening recommendations trigger more screening. Based on all available evidence, our Hepatitis C Expert Work Group agrees that this measure is of great value. Ultimately, by not recommending Measure #0393, there will be no NQF-endorsed measure to promote use in national measurement programs. We hope that these explanatory comments better clarify the importance of confirming Hepatitis C viremia after initial testing for the HCV antibody to confirm a diagnosis of HCV infection. We respectfully request that the SC reconsider recommending this valuable measure to improve the quality of care provided to patients with Hepatitis C. References: 1 Speers S, Klevens RM, Vonderwahl C, Bryant T, Daniloff E, Capizzi J, Poissant T, Roome A. Electronic matching of HIV/AIDS and hepatitis C surveillance registries in three states. Public Health Rep. 2011 May-Jun;126(3):344-8. 2 Moorman AC, Gordon SC, Rupp et al. Baseline Characteristics and Mortality Among People in Care for Chronic Viral Hepatitis: The Chronic Hepatitis Cohort Study. Clin Infect Dis. 2012 Oct 19. [Epub ahead of print]. 3 Sabrina A. Assoumou MD, Wei Huang MA, Benjamin P. Linas, MD MPH. [Poor] Quality of Hepatitis C care at an urban tertiary medical center. Study conducted at Boston Medical Center. Outcomes: Centers for Medicare & Medicaid (CMS)-defined HCV quality indicators introduced in 2008: HCV RNA testing, Genotype testing, Hep A & Hep B vaccinations. Poster presentation from the Infectious Diseases Society of America (IDSA) meeting, 2012. 4 Yang Liu, BA, Renee H. Lawrence, PhD, Brook Watts, MD, Yngve Falck-Ytter, MD, Amy Hirsch, PharmD. Understanding the Care Gap and Missed Opportunities for Hepatitis C Confirmatory Viral testing. Poster presentation from the Society of General Interal Medicine (SGIM) meeting, 2012.

Committee Response: The Committee agreed that the comments had merit. The purpose of viral load testing is to identify those individuals who need to be linked to a provider who is able to provide counseling for their hepatitis C and potential treatment and to differentiate from the individuals who have resolved the infection. Avoiding inappropriate intervention in 15-20 percent of patients that spontaneously resolve the Hepatitis C infection is important. The Committee agreed to reconsider the measure.

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

Reconsideration following Public and Member Comment

Following the Public and Member Comment period of the draft report, the Committee reconsidered the measure.

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

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

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

<u>Rationale</u>:

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

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

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

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

<u>Rationale</u>:

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

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

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

<u>Rationale</u>:

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

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

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

<u>Rationale</u>:

- This measure is specified for use in EHRs.

5. Related and Competing Measures

- No related or competing measures noted.

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

Consensus Standards Approval Committee (CSAC) Review (February 2013): Y-14; N-0; A-0

- Decision: Approved for continued endorsement

Board of Directors (March 4, 2013)

- Decision: Ratified for continued endorsement

0395: Paired Measure: Hepatitis C ribonucleic acid (RNA) testing before initiating treatment (paired with 0396)

Submission | **Specifications**

Status: Maintenance, Original Endorsement: Jul 31, 2008

Description: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom quantitative HCV RNA testing was performed within 6 months prior to initiation of antiviral treatment

Numerator Statement: Patients for whom quantitative HCV RNA testing was performed within 6 months prior to the initiation of antiviral treatment

Denominator Statement: All patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment

Exclusions: Documentation of medical reason(s) for not performing quantitative HCV RNA testing within 6 months prior to the initiation of treatment

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

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

Type of Measure: Process

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

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

STEERING COMMITTEE MEETING [08/28/2012]

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

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

1a. Impact: **H-9; M-10; L-0; I-0**; 1b. Performance Gap: **H-5; M-14; L-0; I-1** 1c. Evidence: **Y-13; N-2; I-5**

Rationale:

- Viral load testing prior to therapy is important to ensure that the patient hasn't cleared the virus as 15-20 percent of patient may, and to assess the magnitude of the viral load to monitor treatment.
- This clinician level measure was used in the 2008-2009 PQRS programs that reported a mean performance of 80 percent. The developer indicated that the 2010 results have dropped to 23.05 percent.
- Committee members questioned how representative the PQRS data relative to other national data:
  - The developer responded that the *Annals of Internal Medicine* paper by Kanwal[12] surprisingly stated that only about 60 percent of patients had a baseline viral load done within the prior six months.
  - Committee members questioned the drop in the performance results. The developer responded that in the PQRS program as more providers participate and report in later years, the providers are not doing as well. CMS does not audit the data in the PQRS program. The developer suggested that perhaps providers who originally signed up for PQRS did not continue to submit data because the incentive was not sufficient.
- The Committee noted that only the AASLD guideline was referenced for evidence. The developer provided additional information that 111 patients with biopsy-proven hepatitis C followed for more than five years, two patients spontaneously resolve their infections without any antiviral treatment. In 1667 patients with a history of injection drug use with hepatitis C infection assumed to be chronic, 90 out of 919 cleared the hepatitis C virus over 85 months.

0395: Paired Measure: Hepatitis C ribonucleic acid (RNA) testing before initiating treatment (paired with 0396)
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-1; M-17; L-1; I-1** 2b. Validity**: H-0; M-19; L-0; I-1** <u>Rationale:</u> • The measure was tested in EHRs. The kappa for the measure result comparing the automated results from the EHR and the visual inspection of the record was 0.47 (moderately reliability). • The Committee asked about the reliability of the CPT II codes. The developer confirmed that testing for reliability of the measure based on CPT II codes is not available. • Committee members asked how "newly initiated on therapy" status was determined outside of an EHR. The developer responded that the CPT II codes are used but they have not been tested for reliability. NQF staff advised the Committee that NQF only endorses measures on the data platforms on which they have been tested – so this measure can only be endorsed as an EHR measure. • The drop in performance from 80 percent to 20 percent in PQRS raised the question of the reliability and validity of the measure. The developer responded that the testing of the EHR measure did indicate reliability and validity.
3. Usability: H-12; M-8; L-0; I-0 (*Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)* <u>Rationale</u>: • The measure is easy to understand. • The measure has been in use in PQRS for several years though PQRS results are not publicly reported.
4. Feasibility: H-9; M-11; L-0; I-0 *(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)* <u>Rationale</u>: • This measure is available for EHRs.
5. Related and Competing Measures • No related or competing measures noted.
Steering Committee Recommendation for Endorsement: Y-19; **N-0**
Public and Member Comment (October 3, 2012-November 5, 2012) • CDC supports these recommendations
Consensus Standards Approval Committee (CSAC) Review (December 2012): Y-13; N-0; A-1 • Decision: Approved for continued endorsement
Board of Directors (January 4, 2013) • Decision: Ratified for continued endorsement

0396: Paired Measure: HCV genotype testing prior to treatment (paired with 0395)

Submission | **Specification**

Status: Maintenance, Original Endorsement: Jul 31, 2008

Description: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom HCV genotype testing was performed prior to initiation of antiviral treatment

Numerator Statement: Patients for whom HCV genotype testing was performed prior to initiation of antiviral treatment

Denominator Statement: All patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment

Exclusions: None

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

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

Type of Measure: Process

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

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

STEERING COMMITTEE MEETING [08/28/2012]

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

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

1a. Impact: **H-15; M-5; L-0; I-0**; 1b. Performance Gap: **H-3; M-16; L-1; I-0** 1c. Evidence: **Y-15; N-4; I-1**

Rationale:

- This is a very similar measure to 0395: *Hepatitis C ribonucleic acid (RNA) testing before initiating treatment* for genotype testing prior to therapy. Unlike viral RNA testing, there is no timeframe – the test needs to be done only once.
- Current therapy is determined by the genotype of the virus so this is an important pre-treatment test.
- The performance mean result from the 2008-2010 PQRS data is 80 percent.
- The use of genotype testing for treatment decisions seems well accepted, but not much documentation was presented.
- Some Committee members found it difficult to believe that treatment is being given without genotype testing since specific treatment is determined by the genotype.

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

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

2a. Reliability: **H-0; M-18; L-1; I-1** 2b. Validity**: H-1; M-19; L-0; I-0**

Rationale:

- This measure was only tested in EHRs similar to measure 0395.
- The results of reliability are similar to that of measure 0395. The kappa score is 0.56 (moderate agreement).

3. Usability: H-5; M-14; L-0; I-1

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

Rationale:

- The results are easy to understand and interpret.
- The measure has been used in the PQRS program since 2008.

0396: Paired Measure: HCV genotype testing prior to treatment (paired with 0395)
4. Feasibility: H-1; M-16; L-2; I-1 *(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)* Rationale: • Committee members noted some concern with the possibility of repeated testing when a patient is referred to a specialist for treatment as a potential unintended consequence.
5. Related and Competing Measures • No related or competing measures noted.
Steering Committee Recommendation for Endorsement: Y-19; N-0
Public and Member Comment (October 3, 2012-November 5, 2012) • CDC supports these recommendations
Consensus Standards Approval Committee (CSAC) Review (December 2012): Y-13; N-0; A-1 • Decision: Approved for continued endorsement
Board of Directors (January 4, 2013) • Decision: Ratified for continued endorsement

0398: Hepatitis C: HCV RNA testing at no greater than week 12 of treatment

Submission | **Specifications**

Status: Maintenance, Original Endorsement: Jul 31, 2008

Description: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom quantitative HCV RNA testing was performed at no greater than 12 weeks from initiation of antiviral treatment

Numerator Statement: Patients for whom quantitative HCV RNA testing was performed at no greater than 12 weeks from the initiation of antiviral treatment

Denominator Statement: All patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment

Exclusions: Documentation of medical reason(s) for not performing quantitative HCV RNA testing at no greater than 12 weeks from the initiation of antiviral treatment

Documentation of patient reason(s) for not performing quantitative HCV RNA testing at no greater than 12 weeks from the initiation of antiviral treatment

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

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

Type of Measure: Process

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

Measure Steward: American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI)

STEERING COMMITTEE MEETING [08/28/2012]

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

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

1a. Impact: **H-11; M-9; L-0; I-0**; 1b. Performance Gap: **H-3; M-15; L-1; I-0** 1c. Evidence: **Y-17; N-2; I-1**

Rationale:

- The Committee pointed out that the title says "at week 12 of treatment" and the description says "HCV RNA testing was performed at no greater than 12 weeks from initiation of antiviral treatment." The developer revised the title of the measure adding 'no greater than.'
- The impact of testing people for treatment results is extremely important because it will dictate the duration of therapy which has major impact on overall cost and success of therapy.
- The original submission only referred to AASLD guidelines that rated the testing recommendations as 1a, 2a and 2b. Additional information provided by the developer described a total of 14 studies in which the antiviral responses in the course of therapy at week 12 or prior to week 12 of therapy had a direct outcome on the subsequent duration of therapy. These studies included at least six meta-analyses and four randomized controlled trials, the most notable are three *New England Journal* reported trials (SPRINT-2, PROVE 2 and REALIZE trials).
- The virologic responses at week 12 are being used very heavily for "stopping rules" so people who are genotype 2 and 3 have viral loads that do not drop more than two logs are considered failures and are stopping therapy. These particular measurements early in therapy or particularly at week 12 have a big impact on the overall ability to stop therapy and reduce costs and toxicity to patients.
- The mean PQRS result is 91.6 percent and the aggregate performance is 89.9 percent, which is a small gap. The developer added that the Kanwal study[13] indicated performance at approximately 60 percent.

0398: Hepatitis C: HCV RNA testing at no greater than week 12 of treatment

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-1** 2b. Validity**: H-0; M-17; L-2; I-1**

<u>Rationale:</u>

- The measure is specified for a viral load within 12 weeks. This could be week 1, 4, 8 or any time up to week 12.
- In the workgroup discussion it was noted that genotype 1 patients require a viral load response at week four for a rapid virologic response. The developer indicated that the measure was meant to be inclusive which why they chose the 12 week parameter, not to be exclusive.
- This measure was tested in EHRs. The Committee raised the same issues with capturing exceptions as in measure 0397: *Antiviral treatment prescribed*.

3. Usability: H-3; M-16; L-0; I-1

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

<u>Rationale</u>:

- The measure is in use in PQRS but the results are not publicly reported.
- In response to a question from the Committee, NQF staff advised the Committee that NQF solicits implementation feedback at any time and specifically at the start of every endorsement maintenance project.

4. Feasibility: H-1; M-18; L-0; I-1

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

<u>Rationale</u>:

- This measure is similar to all other EHR based hepatitis C measures.

5. Related and Competing Measures

- No related or competing measures noted.

Steering Committee Recommendation for Endorsement: Y-19; **N-0**

Public and Member Comment (October 3, 2012-November 5, 2012)

- Consider revising the exclusionary criteria to account for "system" reasons (such as inability to schedule an appointment in the defined time frame for not performing the quantitative HCV RNA testing within the time frame). Further clarify of the language "no greater than 12 weeks" as it is unclear whether the time period is 84 days or 91 days.
    - *Developer Response:* We appreciate your comment and recommendation for this measure to add a "system" exception. For the exception reason to be justified for inclusion in the measure, there needs to be evidence that the reason occurs frequently enough. We don't believe that the example provided of "inability to schedule an appointment in the defined time frame" constitutes a justifiable reason that occurs often enough in clinical practice to be a system-level issue and therefore we would not support the recommendation of adding a "system" exception to this measure. If the patient is already receiving antiviral treatment (as defined by the denominator criteria), it seems plausible, then, and that the patient would be under the care of a clinician and therefore able to have HCV RNA testing within a 12 week time frame. To clarify the "no greater than 12 weeks" timeframe, the measure intent is that the test should occur at less than or equal to 84 days.
- CDC supports these recommendations

Consensus Standards Approval Committee (CSAC) Review (December 2012): Y-13; N-0; A-1

- Decision: Approved for continued endorsement

0398: Hepatitis C: HCV RNA testing at no greater than week 12 of treatment

Board of Directors (January 4, 2013)

- Decision: Ratified for continued endorsement

0399: Paired Measure: Hepatitis C: Hepatitis A vaccination (paired with 0400)

Submission | Specifications

Status: Maintenance, Original Endorsement: Jul 31, 2008

Description: Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who have received at least one injection of hepatitis A vaccine, or who have documented immunity to hepatitis A

Numerator Statement: Patients who have received at least one injection of hepatitis A vaccine, or who have documented immunity to Hepatitis A

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

Exclusions: Documentation of medical reason(s) for not receiving at least one injection of hepatitis A vaccine

Documentation of patient reason(s) for not receiving at least one injection of hepatitis A vaccine

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

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

Type of Measure: Process

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

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

0399: Paired Measure: Hepatitis C: Hepatitis A vaccination (paired with 0400)

STEERING COMMITTEE MEETING [08/28/2012]

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

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

1a. Impact: **H-5; M-10; L-1; I-4**; 1b. Performance Gap: **H-8; M-12; L-0; I-0** 1c. Evidence: **Y-7; N-6; I-7**

Exception to evidence: Y -16; N-4

<u>Rationale</u>:

- The measure submission indicates that 80 percent of the estimated 4.1 million persons positive for antibody to hepatitis C still have virus in the blood. Hepatitis C is the principal cause of death from liver disease and the leading indication for liver transplantation in the U.S.
- The measure submission discusses hepatitis C but not co-infection with Hepatitis A. There is no data on the rate of hepatitis A co-infection presented and no discussion of the extent of the problem of co-infection with hepatitis A for patients with hepatitis C.
    - The developer responded with results of a widely cited study[14] in the *New England Journal of Medicine* in which 17 cases of hepatitis A superimposed on hepatitis C with seven developing fulminant hepatic failure, six of whom died.
    - Committee members responded that the single study data does not represent complete data for the mortality of hepatitis A in patients with hepatitis C.
- 67.47 percent is the mean performance for the 244 clinicians reporting on 562 patients to CMS's PQRS program in 2010. The aggregate performance rate is 83.27 percent.
- Vaccination rates remain low in the US[15] and this measure may improve hepatitis A vaccination rates and reduce risk of further liver damage if exposed to hepatitis A.
- A Committee member asked about cost considerations. With more hepatitis C patients being identified due to the recent change in screening criteria, is there a cost benefit consideration with the increased use of vaccines? The developer noted that several cost-benefit studies in the U.S. suggest vaccination is cost effective.
- No disparities data were presented.
- A recent study shows gaps in vaccination in the VA population with chronic Hepatitis C infection. Although the incidence of superinfection with acute hepatitis B and hepatitis A were low, it was significantly lower in vaccinated patients[16].
- The developers present the evidence as based on the AASLD guideline that rates the recommendation and evidence as *Level IIa - Weight of evidence/opinion is in favor of usefulness/efficacy and Level C - Only consensus opinion of experts, case studies, or standard-of-care.*
- CDC recommends hepatitis A vaccination of all patients with chronic liver disease.
- Immunization rates for hepatitis A in children are rising and will reduce the population at risk in the future.
- The Committee approved an EXCEPTION to the evidence criteria because this measure aligns with immunization guidance from CDC and AASLD and vaccination is basic primary care for patients with hepatitis C.

0399: Paired Measure: Hepatitis C: Hepatitis A vaccination (paired with 0400)

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-1; M-16; L-2; I-1** 2b. Validity**: H-1; M-18; L-1; I-0**

<u>Rationale:</u>

- The measure specifies at least one dose of hepatitis A vaccine was given. The serologic response to one dose of hepatitis A vaccine (80 percent) is better than one dose of hepatitis B vaccine. Some Committee members indicated that a single injection is an adequate marker for receiving the entire series. Other members supported evaluating whether the entire series was given.
- The measure can be satisfied by either vaccination or testing for immunity.
- In the EHR testing, the comparison of results from automated calculation by the EHR and visual inspection of the medical record resulted in a kappa score of 0.48 (moderate agreement). The EHR did not capture allowable exclusions. The percentage of false negative results was 14.30 percent (3 out of 21 patients) for the measure. This represents a change in measure performance from 49.70 percent to 50.00 percent, with an exception rate of 0.80 percent.
- Committee members suggested that childhood immunization or immunization in the remote past may not be found in the medical records.
    - The developer stated that any information that was not in the electronic health record or in the patient's chart is considered not to be real information. If it is not documented, the provider doesn't know about it.
- When asked whether the 12 month time window could be confused with a need for annual vaccination, the developer responded that the patient must be seen within the 12-month time window but any vaccination that is relevant would count for the measure. SNOMED codes for EHRs allow specific documentation of immunity.

3. Usability: H-11; M-9; L-0; I-0

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

<u>Rationale</u>:

- This measure has been in use in the PQRS program since 2008 though results are not publicly reported.

4. Feasibility: H-7; M-13; L-0; I-0

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

<u>Rationale</u>:

- This measure is specified for use in EHRs.
- The measure is specified for only one injection to decrease the measurement burden.

5. Related and Competing Measures

- No related or competing measures noted.

Steering Committee Recommendation for Endorsement: Y-19; **N-1**

<u>Rationale</u>:

- The Committee approved an exception to the evidence criteria because this measure aligns with immunization guidance from CDC and AASLD and vaccination is basic primary care for patients with hepatitis C.

Public and Member Comment (October 3, 2012-November 5, 2012)

- CDC supports these recommendations

Consensus Standards Approval Committee (CSAC) Review (December 2012): Y-14; N-0; A-0

- Decision: Approved for continued endorsement

0399: Paired Measure: Hepatitis C: Hepatitis A vaccination (paired with 0400)

Board of Directors (January 4, 2013)

- Decision: Ratified for continued endorsement

0404: HIV/AIDS: CD4 cell count or percentage performed

Submission | Specifications

Status: Maintenance, Original Endorsement: Jul 31, 2008

Description: Percentage of patients aged six months and older with a diagnosis of HIV/AIDS, with at least two CD4 cell counts or percentages performed during the measurement year at least 3 months apart

Numerator Statement: Patients with at least two CD4 cell counts or percentages performed during the measurement year at least 3 months apart

Denominator Statement: All patients aged 6 months and older with a diagnosis of HIV/AIDS, who had at least two medical visits during the measurement year, with at least 90 days between each visit

Exclusions: None

Adjustment/Stratification: No risk adjustment or risk stratification N/A

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

Type of Measure: Process

Data Source: Electronic Clinical Data : Electronic Health Record

Measure Steward: National Committee for Quality Assurance **Other organizations:** Physician Performance Measures (Measures) and related data specifications have been developed by the American Medical Association (AMA) in collaboration with the Physician Consortium for Performance Improvement™ (the Consortium) and the National Committee

STEERING COMMITTEE MEETING [08/28/2012]

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

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

1a. Impact: **H-13; M-4; L-1; I-0** 1b. Performance Gap: **H-2; M-16; L-0; I-0** 1c. Evidence: **Y-15; N-3; I-0**

Rationale:

- This measure focuses on HIV patients six months and older with a CD4 cell count or percentage performed at least once every 6 months. CD4 cell count is a significant predictor of disease progression and survival.
- There are seven studies cited in the current DHHS guidelines. Five are cohort studies of 16,446 patients and two are control studies, case-controlled studies including 48 patients.
- In pediatrics, there are randomized controlled trials suggesting that monitoring frequency can lead to differential implementation of antiretroviral therapy. In this case, the evidence for children is actually higher than the adult population. The average performance rate in PQRS was 76.8 percent in 2009 and 83.9 percent in 2010.
- Committee members suggested that the apparently high percentage of testing overestimates the true activity. This measure requires two medical visits during the measurement year. One of the problems is that patients do not come back for a second visit; they are not counted in the measure.
- No information was provided on disparities. However, Committee members report that the CDC's Medical Monitoring Project [17] indicated that there were significant racial and ethnic disparities in HIV treatment.

0404: HIV/AIDS: CD4 cell count or percentage performed

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-11; L-4; I-4** 2b. Validity**: H-0; M-10; L-4; I-5**

<u>Rationale:</u>

- The measure was tested in EHRs. There was concern that the testing of this measure used a small sample of clinics in the same geographic area that all used the same EHR. Geographic variation of testing cities would have made the results more valid.
- There was significant difference between the automated versus manual calculation; noting there was confusion about the numerator criteria (i.e., which codes to use, timing of the CD count). The developer explained that when the measure was tested, they were using a CD4/CD8 ratio code that was included in the list of codes. The developer has since removed the CD8 ratio because it was not an appropriate CD4 test to perform. The developer also noted that the confusion regarding timing may be because the measure specifies 'within six months' whether that means within each six-month's period of the year or if it means every six months is not clear. The developer was open to making revisions to clarify the numerator criteria.
- The Committee was concerned with the numerator and the timing of the CD4 cell count. It was stated that a stable patient on therapy who has been undetectable for 15 years, could have a medical visit in January and in June and the measure will not be met because it has to be at least every 6 months. However, on the other hand, a patient could be seen in January and December and would meet the measure when in actuality they were only seen once a year.
- The Committee asked for the developer to adequately define the CD4 cell count timing of every 6 months.
- The developer confirmed that the measure is "test performed" not just "test ordered".
- Committee members noted that the most recent DHHS guidelines regarding stable patients on antiretroviral therapy who are suppressed on antiretroviral therapy states that CD4 may be monitored every 6 to 12 months unless there are changes in the patient's clinical status.

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

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

<u>Rationale</u>:

- The measure was used in CMS' PQRS program in 2009, 2010 and 2011. It will also be included in the 2012 program. In the future the measure may be used in a Maintenance of Certification program.

4. Feasibility: H-2; M-11; L-2; I-4

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

<u>Rationale</u>:

- All data elements are available electronically.

5. Related and Competing Measures

- No related or competing measures noted.

Steering Committee Recommendation for Endorsement: Y-11; **N-8**

0404: HIV/AIDS: CD4 cell count or percentage performed

Public and Member Comment (October 3, 2012-November 5, 2012)

- This is a strong indicator of disease impact and the values derived from this measure (the CD4 Count and/or percentage) are crucial in the management of HIV disease. This is a process measure and would recommend in the future that some component be included that would indicate and measure whether the patient received the results of the tests. Simply measuring that the test was performed does not indicate that the patient or the physician discussed the result. All HIV measures should include disparity data stratification. Disparities in HIV care do exist and this should be reflected in the measures so that the medical community and patients can address these disparities.
    - *Developer Response:* These suggestions will be considered in future reviews of the measure. Inclusion of data on disparities based on Institute of Medicine (IOM) recommendations will be considered in future review of these measures.
- This measure is effectively a proxy measure for patient retention (something that is better captured by measures specifically designed for this purpose such as #2079 and 2082). This measure captures provider-patient contact to a greater extent than it provides meaningful information on the effectiveness of Antiretroviral (ARV) therapy or the health of the patient. Rather than capturing patient CD4 levels over time, which would thus permit longitudinal tracking of the levels to assess whether improvement is occurring (i.e. outcomes), this measure accounts only for whether a count test was performed. And because it may not be possible for certain patients to return their CD4 count to healthy levels, measures of viral load suppression (such as #2082) have become more relevant indicators of outcomes than measures of CD4 levels.
    - *Developer Response:* We believe that this measure is complementary to #2079 and 2082. Monitoring CD4 cell count in HIV patients is one of the key factors in deciding whether to initiate antiretroviral therapy (ART) and prophylaxis for opportunistic infections, and it is the strongest predictor of subsequent disease progression and survival. (Mellors, et al., 1997; Egger, et al., 2002) Clinical guidelines recommend monitoring HIV patient CD4 count at entry to care, every 3 to 6 months following antiretroviral therapy (ART), and every 6 to 12 months in stable patients with suppressed viral load. (DHHS, 2012)

Committee Response: Committee members agreed that this measure complements the medical visit measures (2079 and 2080) and is not redundant. A patient may have a visit but not a lab test and the difference in results can point to a problem with getting lab tests performed. Conversely, lab results may be more readily available in electronic form compared to visit data. The Committee agreed that future measures should include review of the test results with the patient.

Consensus Standards Approval Committee (CSAC) Review (December 2012): Y-14; N-0; A-0

- Decision: Approved for continued endorsement

Board of Directors (January 4, 2013)

- Decision: Ratified for continued endorsement

0405: HIV/AIDS: Pneumocystis jiroveci pneumonia (PCP) prophylaxis

Submission | **Specifications**

Status: Maintenance, Original Endorsement: Jul 31, 2008

Description: Percentage of patients aged 6 weeks or older with a diagnosis of HIV/AIDS, who were prescribed Pneumocystis jiroveci pneumonia (PCP) prophylaxis

Numerator Statement: Numerator 1: Patients who were prescribed Pneumocystis jiroveci pneumonia (PCP) prophylaxis within 3 months of CD4 count below 200 cells/mm3

Numerator 2: Patients who were prescribed Pneumocystis jiroveci pneumonia (PCP) prophylaxis within 3 months of CD4 count below 500 cells/mm3 or a CD4 percentage below 15%

Numerator 3: Patients who were prescribed Pneumocystis jiroveci pneumonia (PCP) prophylaxis at the time of HIV diagnosis

Report a rate for each numerator (e.g., Numerator 1/Denominator 1, etc.) and a total rate (Total Numerator/Total Denominator)

Denominator Statement: Denominator 1. All patients aged 6 years and older with a diagnosis of HIV/AIDS and a CD4 count below 200 cells/mm3, who had at least two visits during the measurement year, with at least 90 days in between each visit; and,

Denominator 2. All patients aged 1 through 5 years of age with a diagnosis of HIV/AIDS and a CD4 count below 500 cells/mm3 or a CD4 percentage below 15%, who had at least two visits during the measurement year, with at least 90 days in between each visit; and,

Denominator 3. All patients aged 6 weeks through 12 months with a diagnosis of HIV, who had at least two visits during the measurement year, with at least 90 days in between each visit

Total denominator: The sum of the three denominators

Exclusions: Denominator 1 Exclusion: Patient did not receive PCP prophylaxis because there was a CD4 count above 200 cells/mm3 during the three months after a CD4 count below 200 cells/mm3

Denominator 2 Exclusion: Patient did not receive PCP prophylaxis because there was a CD4 count above 500 cells/mm3 or CD4 percentage above 15% during the three months after a CD4 count below 500 cells/mm3 or CD4 percentage below 15%

Adjustment/Stratification: No risk adjustment or risk stratification N/A

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

Type of Measure: Process

Data Source: Electronic Clinical Data : Electronic Health Record

Measure Steward: National Committee for Quality Assurance **Other organizations:** Physician Performance Measures (Measures) and related data specifications have been developed by the American Medical Association (AMA) in collaboration with the Physician Consortium for Performance Improvement™ (the Consortium) and the National Committee

0405: HIV/AIDS: Pneumocystis jiroveci pneumonia (PCP) prophylaxis

STEERING COMMITTEE MEETING [08/29/2012]

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

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

1a. Impact: **H-19; M-0; L-0; I-0**; 1b. Performance Gap: **H-14; M-4; L-0; I-1** 1c. Evidence: **Y-19; N-0; I-0**

Rationale:

- HIV is prevalent, late diagnosis is still common and CD4 cell counts below 200 continue to occur in the adult population. There are a substantial proportion of people in this country who still need prophylaxis for PCP.
- The different CD4 counts recommended for prophylaxis creates a complex measure with multiple numerators and denominators.
- PCP prophylaxis, when used in these risk groups, saves lives based on data from randomized controlled trials in both adults and children. The Committee determined that the impact is high and the data are of excellent quality.
- The performance data provided from PQRS shows that there is still a gap in performance (2009: 61.5 percent compliant and 2010: 75.8 percent compliant). Committee members were surprised at the gap in care from this data.
- A Committee member stated that although disparity data was not provided by the developer, disparities do exist amongst racial and ethnic backgrounds. Data from HRSA indicates there were disparities in the individuals who were prescribed PCP prophylaxis that was broken down by race and ethnicity with persons of color being less likely to be prescribed PCP.

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

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

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

Rationale:

- This measure has been included for Stage 2 of meaningful use; e-measure specifications are included.
- The developer reported that although this is a complex measure with three different denominators to account for the varying indications of PCP prophylaxis for different age populations, the testing of the e-measure among three different sites all found that the measure is feasible as specified despite the complexity of the measure because the measure does rely on discrete and fairly easy to capture data elements. The specifications for this measure include denominator exclusions which makes the measure more accurate by aligning with current guidelines.
- The EHR testing comprised 242 patient encounters in community health centers in the Midwest. The reliability and validity testing of the EHR measure was done at the level of the measure score.
- The face validity presented was from a very small group that was evenly split on face validity. The developer responded that the major concern was about the youngest age population and whether or not it's appropriate to look for the one-time prescription of PCP prophylaxis among the much younger age group. The evidence states that the younger age population should be on PCP prophylaxis for a longer amount of time.

3. Usability: H-10; M-9; L-0; I-0

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

Rationale:

- This measure is publicly reported through the CMS PQRS program and was accepted for Stage 2 meaningful use program.

0405: HIV/AIDS: Pneumocystis jiroveci pneumonia (PCP) prophylaxis
4. Feasibility: H-3; M-15; L-0; I-1 *(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)* Rationale: • This measure is specified for use in electronic health records. • Being a part of the meaningful use program will potentially provide IT resources to sites that are incorporating this measure into their EHR.
5. Related and Competing Measures • No related or competing measures noted.
Steering Committee Recommendation for Endorsement: Y-18; N-1
Public and Member Comment (October 3, 2012-November 5, 2012) • The committee recommended that Emergency Departments look closely at this measure for use with late testers or individuals not currently engaged in care. The use of PCP prophylaxis is also vital for persons who are either not ready or unwilling to begin an anti-retroviral regimen. o *Developer Response:* Your suggestions will be considered in future reviews of the measure. • This process measure has a close association with improved survival. This measure incentivizes the provision of a prophylaxis that has been shown to reduce mortality in both pediatric and adult populations. Randomized Control Trials clearly indicate that lives are saved by the use of PCP prophylaxis for HIV+ populations and for those with a CD4 count below 500 cells/mm3. This measure fills a measure gap and has already been accepted for use in MU2 and PQRS.
Consensus Standards Approval Committee (CSAC) Review (December 2012): Y-14; N-0; A-0 • Decision: Approved for continued endorsement
Board of Directors Vote (January 4, 2013) • Decision: Ratified for continued endorsement

0408: HIV/AIDS: Tuberculosis (TB) screening

Submission | **Specifications**

Status: Maintenance, Original Endorsement: Jul 31, 2008

Description: Percentage of patients aged 3 months and older with a diagnosis of HIV/AIDS, for whom there was documentation that a tuberculosis (TB) screening test was performed and results interpreted (for tuberculin skin tests) at least once since the diagnosis of HIV infection.

Numerator Statement: Patients for whom there was documentation that a tuberculosis (TB) screening test was performed and results interpreted (for tuberculin skin tests) at least once since the diagnosis of HIV infection.

NOTE: Results from the tuberculin skin test must be interpreted by a healthcare professional.

Denominator Statement: All patients aged 3 months and older with a diagnosis of HIV/AIDS, who had at least two visits during the measurement year, with at least 90 days in between each visit

Definition of "Medical Visit" - any visit with a health care professional who provides routine primary care for the patient with HIV/AIDS (may be but is not limited to a primary care clinician, ob/gyn, pediatrician, infectious diseases specialist)

Exclusions: Documentation of Medical Reason for not performing a tuberculosis (TB) screening test (e.g., patients with a history of positive PPD or treatment for TB)

Adjustment/Stratification: No risk adjustment or risk stratification N/A

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

Type of Measure: Process

Data Source: Electronic Clinical Data : Electronic Health Record

Measure Steward: National Committee for Quality Assurance **Other organizations:** Physician Performance Measures (Measures) and related data specifications have been developed by the American Medical Association (AMA) in collaboration with the Physician Consortium for Performance Improvement™ (the Consortium) and the National Committee

STEERING COMMITTEE MEETING [08/29/2012]

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

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

1a. Impact: **H-11; M-4; L-0; I-0**; 1b. Performance Gap: **H-8; M-7; L-0; I-0** 1c. Evidence: **Y-13; N-1; I-1;**

Rationale:

- HIV patients with latent TB have a much higher risk developing active tuberculosis. This is a particular problem for persons born outside the US.
- The measure requires either a tuberculin skin test or interferon gamma-releasing assays (IGRA). There is limited evidence available for which test is appropriate within this population. With low CD4 counts obviously the reliability of the tuberculin skin test is not very reliable.
- The evidence is based on one randomized controlled trial and three practice guidelines that are appropriately graded.
- The performance rate from HIVQUAL in 2009 was 68.7 percent. According to the Committee's personal experience, there is much room for improvement.

0408: HIV/AIDS: Tuberculosis (TB) screening

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-6; L-5; I-2** 2b. Validity**: H-1; M-7; L-7; I-0**

<u>Rationale:</u>

- The measure was tested in EHRs. Testing found that it is difficult to capture the data elements because of a lack of standardized fields for the test results/interpretation.
- There was a large gap between the manual and automated calculation. One Committee member suggested only allowing IGRA and not allow a PPD skin test which cannot be captured in the EHR.
- The measure as written specifies that the results are interpreted, but does not indicate by whom and how the results are documented. The interpretation of results, as written, could be done by any provider and the variability among provider perceptions of acceptable interpreters is too vast to have the numerator remain so unspecific.
- The numerator indicates screening at least once; the guideline cited by the developer, however, recommends annual screening for high risk populations.

3. Usability: H-0; M-10; L-4; I-1

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

<u>Rationale</u>:

- This measure is not currently used for public reporting.
- The measure specifications only require testing once since diagnosis. The Committee was concerned that there may be historical data that does not get captured in this measure.

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

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

<u>Rationale</u>:

- The Committee identified feasibility challenges, such as, appropriate interpretation of the test results and follow-up care.
- Data capture may be very labor intensive.
- The developer indicated that the measure suffers from a lack of standardized fields at the provider level for capturing the test result accurately which has led to a discordance of 20 percent in EHR testing.

5. Related and Competing Measures

- No related or competing measures noted.

Steering Committee Recommendation for Endorsement: Y-9; **N-6**

Public and Member Comment (October 3, 2012-November 5, 2012)

- TB screening of all persons with HIV is recommended with the assurance that the PPD was read by a medical professional and not patient self-report. Simply initiating the care is not enough, the screen must have a result and that result should be documented.
    - *Developer Response:* The numerator only includes patients for whom there was documentation that a tuberculosis (TB) screening test was performed and results interpreted (for tuberculin skin tests) at least once since the diagnosis of HIV infection. Results from the tuberculin skin test must be interpreted by a healthcare professional.

Consensus Standards Approval Committee (CSAC) Review (December 2012): Y-14; N-0; A-0

- Decision: Approved for continued endorsement

Board of Directors Vote (January 4, 2013)

- Decision: Ratified for continued endorsement

0409: HIV/AIDS: Sexually transmitted diseases – Screening for chlamydia, gonorrhea, and syphilis

Submission | **Specifications**

Status: Maintenance, Original Endorsement: Jul 31, 2008

Description: Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS, who have received chlamydia, gonorrhea, and syphilis screenings at least once since the diagnosis of HIV infection.

Numerator Statement: Patients who have received chlamydia, gonorrhea, and syphilis screenings at least once since the diagnosis of HIV infection.

Denominator Statement: All patients aged 3 months and older with a diagnosis of HIV/AIDS, who had at least two visits during the measurement year, with at least 90 days in between each visit.

Definition of "Medical Visit" - any visit with a health care professional who provides routine primary care for the patient with HIV/AIDS (may be but is not limited to a primary care clinician, ob/gyn, pediatrician, infectious diseases specialist)

Exclusions: None

Adjustment/Stratification: No risk adjustment or risk stratification N/A

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

Type of Measure: Process

Data Source: Electronic Clinical Data : Electronic Health Record

Measure Steward: National Committee for Quality Assurance **Other organizations:** Physician Performance Measures (Measures) and related data specifications have been developed by the American Medical Association (AMA) in collaboration with the Physician Consortium for Performance Improvement™ (the Consortium) and the National Committee

STEERING COMMITTEE MEETING [08/29/2012]

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

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

1a. Impact: **H-11; M-3; L-0; I-0**; 1b. Performance Gap: **H-7; M-8; L-0; I-0** 1c. Evidence: **Y-12; N-2; I-1**

Rationale:

- The measure when originally endorsed in 2008 was two measures; one measure for syphilis screening and one measure for gonorrhea and chlamydia screening.
- The evidence provided suggested that the HIV/AIDS population experiences a disproportionate disease burden compared to the general population. Control of sexually transmitted infections (STIs) is an important prevention measure.
- Evidence indicates that untreated specified STIs can increase HIV transmission.
- Data from PQRS indicated the chlamydia and gonorrhea performance rate was 32.4 percent and syphilis was 50.3 percent.
- Evidence was not provided on young patients with congenitally acquired HIV, who may or may not sexually active.

0409: HIV/AIDS: Sexually transmitted diseases – Screening for chlamydia, gonorrhea, and syphilis

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-4; I-1** 2b. Validity**: H-0; M-9; L-6; I-0**

<u>Rationale:</u>

- The Committee indicated the word 'screening' should be changed to 'serological testing'. Committee members indicated that providers could interpret the measure as screening for sexual activity and not perform the tests. The developer agreed to clarify the screening language to reflect that the measure is intended to capture a laboratory test.
- The Committee noted a significant difference between electronic health records versus manual calculation. The developer explained that at the particular site where the testing was performed, there was a problem in the EHR in which test data was not being captured in the correct standardized field. However, while the automated calculation was not correct, the information was available in the record. The developer has not tested this measure in other electronic medical records to see if the data could be more accurately captured
- The numerator time window is not aligned with the guideline, which would require an annual screening for those reporting sexual activity. The developer explained that their expert panel noted that might not be appropriate for all patients, particularly those that are not sexually active. In addition, the developer noted that identifying sexually active patients is difficult to do consistently, reliably or validly at present. The developer's expert panel was split over whether one test or annual testing should be measured. The developer is particularly wary of encouraging overuse of testing.
- Some Committee members agreed that determining who should get recurrent testing or annual testing is very difficult to operationalize and capture reliably and are willing to accept the measure that is a minimum standard as long as there's evidence that performance is low.
- The measure was assessed using face validity with a mean rating of 3.5 out of 5; the expert panel had concerns surrounding screening annually versus once following diagnosis.

3. Usability: H-2; M-12; L-1; I-0

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

<u>Rationale</u>:

- The measure is currently used in CMS' PQRS program.
- Use in PQRS shows a performance gap and continued use demonstrates usefulness.

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

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

<u>Rationale</u>:

- The measure results can be captured in EHRs.

5. Related and Competing Measures

- No related or competing measures noted.

Steering Committee Recommendation for Endorsement: Y-13; **N-2**

0409: HIV/AIDS: Sexually transmitted diseases – Screening for chlamydia, gonorrhea, and syphilis
Public and Member Comment (October 3, 2012-November 5, 2012) • In addition to the STIs in this bundle consideration also be given to screening for HPV. This measure should be an annual screen and not just a onetime event. Persons with HIV are sexual beings and as such will continue to engage in sexual activity which may put them at risk for G/C and Syphilis. The presence of STIs can lead to increased transmission of HIV and a onetime screening could potentially put others at risk of infection. o *Developer Response:* Your suggestions will be considered in future reviews of the measure. Your recommendation to require the screenings annually will be discussed with our expert panel. • The Committee indicated the word 'screening' should be changed to 'serological testing'- this will not be applicable all type of tests used to diagnose STDs. Agree with suggestion to clarify the screening language to reflect that the measure is intended to capture a laboratory test. The measure calls for screening at least once since the diagnosis of HIV infection. This is not consistent with CDC / IDSA recommendations ("Screening for STDs should be repeated periodically (i.e., at least annually) if the patient is sexually active or if earlier screening revealed STDs. Screening should be done more frequently (e.g., at 3–6-month intervals) for asymptomatic persons at higher risk"). MMWR Incorporating HIV Prevention into the Medical Care of Persons Living with HIV Recommendations and Reports July 18, 2003 / Vol. 52 / No. RR-12)), nor with forthcoming recommendations. o *Developer Response:* Your suggestions will be considered in future reviews of the measure. Your recommendation to require the screenings annually will be discussed with our expert panel. • While this measure does not capture screening results, the importance of capturing the incidence of these three prevalent STDs for the potentially immune-deficient HIV+ population is clear. This measure incentivizes serological screening for diseases that might otherwise remain undetected while causing harm to the individual and, potentially, to the population through increased risks of transmission Future iterations of this measure should go beyond documentation to capture the results of these tests and perhaps the pairing of this measure with a follow-up treatment measure. o *Developer Response:* Your suggestions will be considered in future reviews of the measure.
Consensus Standards Approval Committee (CSAC) Review (December 2012): Y-14; N-0; A-0 • Decision: Approved for continued endorsement
Board of Directors (January 4, 2013) • Decision: Ratified for continued endorsement

0500: Severe sepsis and septic shock: Management bundle

Submission | **Specifications**

Status: Maintenance, Original Endorsement: Oct 24, 2008

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

Numerator Statement: If:

A. measure lactate level

B. obtain blood cultures prior to antibiotics

C. administer broad spectrum antibiotics

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

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

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

G. remeasure lactate if initial lactate is elevated

represent processes of care:

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

† ”time of presentation” is defined as the time of triage in the Emergency Department or, if presenting from another care venue, from the earliest chart annotation consistent with all elements severe sepsis or septic shock ascertained through chart review.

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

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

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

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

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

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

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

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

Level of Analysis: Facility, Integrated Delivery System

Type of Measure: Composite

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

Measure Steward: Henry Ford Hospital

Other organizations: Henry Ford Hospital System(HFHS)

California Pacific Medical Center/Sutter Health (CPMC); Society of Critical Care Medicine (SCCM); Infectious Diseases Society of America (IDSA); Institute for Healthcare Improvement (IHI); Surviving Sepsis Campaign (SSC); Ohio State University (OSU)

0500: Severe sepsis and septic shock: Management bundle

STEERING COMMITTEE MEETING [08/28/2012]

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

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

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

Rationale:

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

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

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

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

Rationale:

- Committee members asked how the measure clearly distinguishes patients with severe sepsis versus those with septic shock.
  - Developer response: The key difference is hypotension refractory to fluid administration that requires a vasopressor or a persistent lactate level greater than 4 is septic shock as specified.
- Committee members questioned whether the inter-rater reliability study of 498 patients in one institution would apply to other institutions. The developer responded that the measure is being used in a variety of health care systems such as Kaiser, Loma Linda University, University of Kansas and Intermountain Health in Utah.
- The term 'broad spectrum antibiotics' is not defined. This could potentially be problematic for a data abstractor to precisely, accurately and reproducibly identify antimicrobials that will satisfy the measure. A Committee member noted that the term 'broad spectrum antibiotics' was not used in the reliability testing results, instead, the term 'timely antibiotics' was used, which seemed to be more specific to measure
  - Developer response: The surviving sepsis campaign defined "broad spectrum antibiotics" as those with both Gram positive and Gram negative bacterial coverage. The rationale for antibiotic selection is further discussed in the 2004 and 2008 sepsis guidelines publications. Credit for timely antibiotics was assigned in the data set used for the analyses only if both species were covered.
- The ICD-9 diagnostic codes to identify the denominator were thought to be appropriate.
- The measure was tested both at the data element and measure score levels for reliability. For validity the measure was only tested at the measure score level.
- In review of the validity testing, a Committee member noted that measuring central venous pressure (CVP) and central venous oxygen saturation (ScvO2) were not a part of the validity testing.

0500: Severe sepsis and septic shock: Management bundle

- Committee members noted that the validity testing indicated that after adjusting for baseline characteristics, only administration of broad spectrum antibiotics and obtaining blood cultures before their initiation were associated with lower hospital mortality.
- The question of whether the sepsis bundle as a whole should be incorporated versus specific validated elements of the bundle (e.g., antibiotic selection and timing) was discussed. Though a few members supported individual measure, the majority support the bundle.
- The question of how the specifications indicate accountability was raised. A member commented that time zero is triage for time limited Emergency Department (ED) therapies. If a patient presents to the ED triage and does not qualify as severe sepsis or septic shock but develops it later, would the hospital and/or physician be held accountable? Another accountability example was if a patient presents to the ED with pneumonia without severe sepsis or septic shock, and 4 hours later the patient becomes hypotensive, would the ED physicians and/or hospital be held accountable for not providing care over a timeline that had elapsed once the patient developed symptoms? Although unit and ICU time zero is based upon when the patient is diagnosed, in the ED it is time of triage which may or may not be the time at which the patient developed symptoms. The Committee member questioned how it would be reconciled.
    - Developer response: The patient is somewhere on the natural trajectory of becoming septic regardless of the point of presentation. If the patient who becomes hypotensive or has a high lactate does so in the ED, the reason for presentation to the ED is severe sepsis or shock. Likewise, the patient who presents with septic physiology on the floor and becomes hypotensive there after an initial admit for something else need to have time to start the clock. In both instances, we are relying on the presence of key features of severe sepsis or shock to make the attribution. Specifying triage time in the ED is not only reasonable since that is most likely what occasioned their visit to the ED, but also provides a standard time. The evidence in the literature also is consistent with picking triage time on this basis. There is less certainty with the floor patient, but again, a proper review yields the time that all the key features were first present. Thus, while there may be some admitted variability between the wards and the ED time of presentation in terms of precision, both are accurate for purposes of measurement.

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

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

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

Rationale:

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

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

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

Rationale:

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

5. Related and Competing Measures

- No related or competing measures noted.

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

Public and Member Comment (October 22, 2012-November 20, 2012)

General Support for the Measure

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

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

- A commenter noted that "While we recognize that the SSC recommends central venous pressure monitoring (an unreliable and seldom followed parameter), both it and measuring central venous oxygen saturation are only supported by one single center clinical trial (as such limited evidence supports its use)."
- ACEP states that "ACEP has serious concerns surrounding the lack of evidence for measuring CVP as a surrogate for intravascular volume. " "The measure developers have now cited five additional studies in which multivariate logistic regression demonstrated no independent effect on mortality in patients who achieve CVP targets versus patients who do not. (Castellanos-Ortega 2010, Nguyen 2007, Jeon 2012, Levy 2010, Cannon 2010)."
- A commenter suggested that "There may be the unintended consequence of increasing the use of central lines in situation where they may actually not be needed and potentially causing harm by their placement (bleeding pneumothorax, pain) or causing infections. By including this single item in the composite measure may encourage the over utilization of central line placement specifically not to fail the measure rather than taking care of the patients best interests."

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

Lack of Evidence for Blood Culture prior to Antibiotics Element

- A commenter stated that "The whole point is that the patients receive broad spectrum antibiotics not that they are timed prior to antibiotic administration. The theoretical concern about sensitivities should not trump actual administration of those antibiotics. If not eliminated than perhaps altering the wording to simply state; "obtaining appropriate cultures" which would allow simplicity and more flexibility in the actual abstraction process. Having to identify the time of antibiotic administration along with the time of collection of cultures adds significantly to the burden and complexity of the abstraction process.

Theoretically this may seem important but does the act of obtain blood cultures or any culture prior to the administration of antibiotics actually have any effect on outcomes?"

- A commenter states that "Often time's patient present to the ED with normal vital signs then decompensate and meet criteria of sepsis. Including the initial time of presentation as the start time may not reflect patient's condition adequately. This ambiguity of utilizing different criteria of time of presentation based on location, calls into question the measure reliability."

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

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

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

Committee Response: In response to the comment, the Committee again discussed the reliability of triage being time zero for Emergency Department (ED) patients and the impact of the ED length-of-stay. Some Committee members did agree that certain elements of the measure may be related to hospital situations (beds, changing clinical status) that are out of the control of the provider but indicated that the reliability presented was sufficient. The Committee reconsidered their evaluation of reliability and determined that it meets the reliability criteria at moderate to high (H-1; M-11; L-2; I-0).

Feasibility of Abstracting the Composite Measure

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

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

0500: Severe sepsis and septic shock: Management bundle

Re-vote following Public and Member Comment

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

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

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

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

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

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

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

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

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

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

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

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

Consensus Standards Approval Committee (CSAC) Review (February 2013): Y-14; N-0; A-0

- Decision: Approved for continued endorsement

Board of Directors (March 4, 2013)

- Decision: Ratified for continued endorsement

Appeals

One appeal was received on this measure:

- In summary, the appellants state "we are concerned that the specification within the Severe Sepsis and Septic Shock bundle that resuscitation must be guided by a central venous catheter (CVC) would have unintended deleterious effects, even while recognizing that this element is included in the current Surviving Sepsis Guidelines." The appellants note additional concerns with usability, specifically that patients are identified retrospectively by ICD-9 discharge diagnoses and the time identified as "time zero" for patients that develop sepsis while in the ED or hospital. The appellants note that there are ongoing trials in the United States and Australia that will be completed in 2013 and "should provide greater clarity regarding the need for invasive monitoring." The appellants made specific suggestions for revisions to the measure.
- **Developer Response:** Specifically, in response to the concern regarding the use of central venous pressure monitoring the developer responded "CVC placement and CVP have been part of management of the critically ill patient for almost 50 years. It has been recommended by the American College of Critical Care Medicine and the SCCM for the management of severe sepsis and septic shock since 1999. Recent studies have shown a significant association between the time to CVC placement and a decrease in organ failure and mortality particularly following publication of the initial Surviving Sepsis Campaign (SSC) guidelines. Further evidence indicates a mortality benefit with a minimum CVP target of 8 mm Hg and shows that a higher CVP target of 12 mm Hg may further lower mortality, particularly among those with an APACHE IV-predicted moderate risk of dying. When used in an algorithmic context as recommended in the measure, there is a significant reduction in 30-day mortality."
- The developer refers to the letter of support from multiple groups including the Society of Critical Care Medicine to respond to the issue of on-going trials that may provide new information in this area and states "These trials, regardless of the outcomes, will not yield new performance metrics ready for testing in the short term." The developer indicates that revisions to the measure as suggested would create a new measure that would need empiric testing for reliability and validity.

0500: Severe sepsis and septic shock: Management bundle

- Use of the sepsis bundle has been demonstrated to reduce mortality during the Surviving Sepsis Campaign and the bundle is aligned with the current sepsis management guidelines. As described in the evaluation and voting tables below, the issues raised by the appellants were discussed by the Steering Committee during their initial evaluation and in response to the comments submitted. The Committee considered the comments and developer's responses when making their recommendation for endorsement. Overall, the issues raised in the appeal have been considered during the Consensus Development Process. Though a cornerstone of the evidence evaluation process relates to the consistency of evidence, the Committee considered the evidence carefully and concluded that the evidence of mortality reduction associated with use of the sepsis bundle currently includes CVP monitoring as indicated. As new evidence emerges from ongoing clinical trials, NQF is committed to an immediate ad hoc re-evaluation of the measure.

Consensus Standards Approval Committee (CSAC) Review (May 2013):

- At their monthly call on May 14, the CSAC heard from the appellants, the Steering Committee Co-Chair and the measure developers regarding the issues raised in the appeal. The CSAC specifically discussed the following issues:
    - *Transfers:* The appellants noted that, as written, the measure doesn't account for patients that are transferred from another hospital. The developer agreed that patient transfers from outside facilities should be excluded from the measure. The developer confirmed that the Surviving Sepsis Campaign data used to test the reliability and validity of the measure set excluded transfers. The CSAC supported clarifying the specifications to include transfers as an exclusion from the measure.
    - *Defining Time-Zero:* The appellants questioned the definition of "time zero" -- i.e., the time the "clock" starts for the sepsis resuscitation bundle. The Committee Co-Chair noted that the Infectious Disease Steering Committee thoroughly discussed the definition and specification for time-zero. The developer noted that time zero is specifically defined as the time of triage for patients who arrived in the emergency department or the time of identification of sepsis for hospitalized patients. The appellants noted that the time zero for the 3 hour bundle was achievable. The developers noted that the time zero definition is identical for both the 3 hour and 6 hour bundles.
    - *Feasibility:* The appellants expressed concern that critical access hospitals would have difficulty complying with both the 3-hour and the 6-hour bundle. The developer noted that within Surviving Sepsis Campaign the 6-hour bundle data was collected from 210 hospitals on 30,000 patients. The measure is in current use by a variety of hospitals, health systems, and collaboratives as noted in the letters of support for the measure.
    - *Use of Central Venous Monitoring:* The appellants stated there are ongoing QI projects, including improvement projects by the Greater New York Hospital Association that are not aligned with the sepsis measure. The appellants stated that use of central venous pressure (CVP) in this process measure would cause unintended consequences including increased rates of CLABSI and iatrogenic complications. The developers pointed to a 2013 article by Walkey in the Journal of Critical Care Medicine that demonstrated increased used of CVP within 12 hours of admission over the past decade was associated with lower mortality. The Committee Co-Chair noted that CVP has been rigorously studied in peer-reviewed literature. The CSAC was made aware of ongoing trials that are investigating the effectiveness of non-invasive alternative therapies as alternatives to CVP. NQF is committed to performing an ad hoc review whenever new evidence emerges. The CSAC voted 13-1 to uphold endorsement of the measure with the clarification that hospital transfers are excluded.

Board of Directors (June 2013):

- The Board upheld the CSAC decision and voted unanimously to uphold endorsement of the measure with the clarification that hospital transfers are excluded.

2079: HIV medical visit frequency

Submission | **Specifications**

Status: New Submission

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 Not applicable Not applicable

Level of Analysis: Facility, Clinician : Group/Practice

Type of Measure: Process

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

Measure Steward: Health Resources and Services Administration - HIV/AIDS Bureau **Other organizations:** The Center For Disease Control and Prevention

STEERING COMMITTEE MEETING [08/29/2012]

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

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

1a. Impact: **H-13; M-5; L-1; I-0**; 1b. Performance Gap: **H-6; M-13; L-0; I-0** 1c. Evidence: **Y-14; N-4; I-1**

Rationale:

- This measure is looking at medical visits for HIV care in a 24-month period rather than a single year period. The measure is not specific to newly enrolled patients, but rather any patient currently receiving care.
- The intent of the measure is to examine not only adherence to the visit but also how frequently an individual made those visits over a 2-year period.
- The measure examines retention in care for HIV patients. Regular care provides opportunities for risk reduction counseling, monitoring of labs and initiation of treatment. The submission provides data that showed that each no-show clinic visit conveyed a 17 percent increased risk of delayed viral load suppression and CD4 counts were significantly greater amongst those with optimal retention.
- The evidence focused on two consistent, cohort studies and the DHHS guidelines for adults and adolescents with 14 studies examining the impact of treatment on reducing morbidity and mortality, 8 of studies focused on the impact of treatment on preventing transmission, 3 studies that supported the frequency of CD4 count monitoring and 9 studies supporting the frequency of viral load monitoring.
- There is significant room for improvement, as the data provided demonstrated that only 42.6 percent of patients met the HRSA criterion for retention to medical visits.
- The developer provided data on disparities which indicated that females, racial minorities and patient lacking private health insurance were significantly more likely to fail at establishing care.

2079: HIV medical visit frequency

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-13; L-2; I-1** 2b. Validity**: H-0; M-16; L-1; I-2**

<u>Rationale:</u>

- This measure encourages providers to examine what they can do to maximize retention, such as providing good customer satisfaction programs. Committee members agreed that if you are not in care, you will not do well.
- The Committee discussed the role of patient compliance and agreed that patient compliance is out of the clinic or the provider's control. Some Committee members noted that this measure provided an opportunity for the provider to reengage the patient.
- The developer does not expect this measure to have 100 percent performance; there is leeway to account for patients who do not make their medical visit.
- The developer indicated that they had considered exclusions for incarcerated patients but found difficulty in capturing this data.
- Face validity was used to establish validity of this measure; however threats to validity were not addressed.

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

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

<u>Rationale</u>:

- The intended use is for public health and disease surveillance, public reporting and quality improvement with benchmarking. The Committee agreed that a goal of 100 percent performance is unrealistic but improvement can be monitored.
- The developer intents to submit this measure for meaningful use and PQRS programs.

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

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

<u>Rationale</u>:

- All the data elements are contained within an electronic claims, appointment systems or EHRs.

5. Related and Competing Measures

- This measure directly relates to measure 2080: *Gaps in medical visit*. Measure 2079 looks at a two-year time period and measure 2080 looks at a one-year time period.
- Committee members concluded that the measures are complementary. Measure 2079 is assessing the clinic's persistency with care and excludes new patients who have not been treated in clinic for at least two years. Measure 2080 includes new patients who did not have a visit in the last six months. Measure 2080 has a shorter measurement period and includes more patients.

Steering Committee Recommendation for Endorsement: Y-18; **N-1**

Public and Member Comment (October 3, 2012-November 5, 2012)

- Revise the measure title to include the language "HIV/AIDS" to indicate this measure is applicable to patients with a diagnosis of HIV.
    - *Developer Response:* We would accept a title change to "HIV medical visit frequency."
- There is a high correlation between medical visit frequency and viral load suppression. This measure incentivizes provider practices to retain patients, which greatly assists with the provision of needed care to the patient. Should this measure be publically reported, it would benefit from stratification by race, gender, and type of insurance coverage in order to capture disparities. The two-year measurement period allows clinics to track their patient populations over time to create a better trajectory of care continuity. Using data from this measure, clinics are able to build a list of patients that, when juxtaposed

to the new patients captured in #2080, can reveal which patients have fallen into a gap in care. The measure's denominator population is inclusive.

- *Developer Response:* We anticipate that this is a disparities-sensitive measure and it could be used to highlight differences in access to care between subpopulations.

- Medical Visit Measures: Revisit measures #0403 and #2079, which cannot be viewed separately from a comparative and practical standpoint. Although NQF measure #0403 was not re-endorsed, from a practical standpoint it makes more sense than the variation of this metric (#2079) which was endorsed. The fact that measure #0403 is based on CPT II coding should not have ruled it out, because both the Veteran's Administration and Kaiser Permanente have demonstrated on a large scale that this measure can be captured electronically.[i],[ii] In addition, the 12-month medical visit frequency utilized in measure #0403 is consistent with the time period captured in all the other HIV metrics, whereas measure #2079 relies on a 24-month frequency. We question the rationale and practicality of using a 24-month timeframe, given that the patient population being measured may shift considerably within a 24-month window, and considering that the same 24-month outcome could be captured by looking at #0403 serially, over time. We also express concern about how measure #2079 could be reported as the denominator would be different every six months. Lastly, we would note that measure #2079 was tested only in HIV-specific clinical settings (Ryan White clinics) and may not be as applicable in other clinical settings. [i]Backus LI, Boothroyd DB, Phillips BR, Belperio PS, Halloran JP, Valdiserri RO, Mole LA, Arch Intern Med. National quality forum performance measures for HIV/AIDS care: the Department of Veterans Affairs' experience. 2010 Jul 26;170(14):1239-46. [ii]Horberg M, Hurley L, Towner W, Gambatese R, Klein D, Antoniskis D, Weinberg W, Kadlecik P, Remmers C, Dobrinich R, Quesenberry C, Silverberg M, Johnson M, "HIV Quality Performance Measures in a Large Integrated Healthcare System," AIDS, Patient Care, and STDs, 2011; 25(1): 21-28.
  - *Developer Response:* 1. Our understanding of what linkage to and retention in HIV medical care mean, and how they relate to morbidity and mortality outcomes, continues to evolve ,and thus so should our measurements. Studies have examined retention from multiple perspectives in order to understand its impact on patient health outcomes. Retention, as measured by #403, has a moderate impact on morbidity and mortality yet declines over time (1, 2). Long term retention in medical care among people living with HIV is associated with a significantly greater mean increase in baseline CD4 count (3). Additionally, mortality is higher among those with suboptimal retention (3). Examining retention over a greater period of time may thus be more meaningful with respect to how well it correlates with patient morbidity and mortality. Retention in care is crucial in maximizing the health outcomes of people living with HIV. As eloquently outlined by Mugavero, et al., there are several ways to measure retention and engagement with each having its own strengths and limitations (4). Facilities/Clinic may choose to utilize one or more measures depending on the facility/clinic characteristics, personnel administering the measure (clinician vs. administrator), and/or purpose of the measure (quality improvement, benchmarking, or monitoring). HIV care and treatment as well as performance measures are dynamic systems. As a result, it may be necessary to have more than one measure available for use. Additionally, we feel that serially measuring #403 over two time periods may result in additional work to compare the two sets of results and may not yield the same results as using #2079. Also, serially measuring #403 doesn't yield the same results as using #2079 since no one is ever required to be in care for 24 months to count as a success. For example, utilizing #403 for CY2010 and then again for CY2011 would not yield the same results as using #2079 which also spans 24 month retention. Measure #2079 follows the first 6 month patient cohort for the subsequent three 6 month periods. Measure #403 looks at a cohort of patients who had at least one visit in a 12 month period to see if they had two visits in the same period. Comparing the two measures, one could determine that measure 2079 assesses retention over a longer period of time. Also, we would like to clarify that the denominator doesn't shift every 6 months. Rather, it represents people who had a medical visit during one 6 month period and the measure then determines how many continue to be seen over the

subsequent 3 six-month periods. 2. When using #2079, it can report a "snapshot" of a cohort of patients with a medical visit from a 6 month period of time. (This is similar to using a denominator where the cohort is from a 12 month period.) This measure can be used to understand the retention of the patients retrospectively or monitor retention moving forward. HRSA has plans to promote this measure's inclusion in CMS's Meaningful Use program which would require its e-specification. 3. HRSA's HIV/AIDS Bureau currently has a HIV workforce study in the data collection phase. It is hypothesized that a significant portion clinical providers caring for people living with HIV in the U.S. receive Ryan White funding. Therefore, using a Ryan White clinic setting to test the measure is appropriate. The Ryan White provider community consists of a diverse cross-section of medical providers and locations. We believe the locations used for the scientific acceptability portion of the submission are representative of locations where people living with HIV receive medical care in the U.S. It is also important to note that the scientific acceptability (reliability and validity testing) is assessed to determine the reliability and validity of the measure score. Scientific acceptability is not dependent on the source of the data. The variables used in #2079 are the same variables used in #403. The variables, diagnosis date, medical visit dates, and date of death, are common within HIV medical care and also readily available in EHRs. 1. Please note: On July 24, 2012, Secretary Sebelius approved a package of seven common core measures for monitoring HHS-funded HIV prevention, treatment, and care services. The measures were generated following multiple consultations with a group of federal and non-federal stakeholders and are consistent both with the Institute of Medicine's recommendations for monitoring HIV services and measures deployed by the National Quality Forum (NQF) and the National Committee for Quality Assurance (NCQA). This measure, #2079 medical visit frequency, is one of the seven measures approved by Secretary Sebelius, supporting alignment of measures across HHS. 1. Marks G, Gardner L, Craw JA, Crepaz N. Entry and retention in medical care among HIV-diagnosed persons in the United States: a meta-analysis. AIDS 2010;24:2665–78. 2. Fleishman JA, Yehia BR, Moore RD, Korthuis PT, Gebo KA; for the HIV Research Network. Establishment, Retention, and Loss to Follow-Up in Outpatient HIV Care. J Acquir Immune Defic Syndr. 2012 Apr 23. [Epub ahead of print] 3. Tripathi A, Youmans E, Gibson JJ, Duffus WA. The impact of retention in early HIV medical care on viro-immunological parameters and survival: a statewide study. AIDS Res Hum Retroviruses. 2011; 27:751-8. 4. Mugavero MJ, Davila JA, Nevin CR, Giordano TP. From Access to Engagement: Measuring Retention in Outpatient HIV Clinical Care. AIDS Patient Care and STDs. October 2010, 24(10): 607-613

Committee Response: Committee members noted that consumers strongly support the 24-month timeframe as it provides a richer image of care provided to patients. The Committee maintained their original recommendation for measure 2079.

Consensus Standards Approval Committee (CSAC) Review (December 2012): Y-14; N-0; A-0

- Decision: Approved for NQF endorsement

Board of Directors Vote (January 4, 2013)

- Decision: Ratified for continued endorsement

2080: Gap in HIV medical visits

Submission | **Specifications**

Status: New Submission

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 Not applicable Not applicable

Level of Analysis: Facility, Clinician : Group/Practice

Type of Measure: Process

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

Measure Steward: Health Resources and Services Administration-HIV/AIDS Bureau **Other organizations:** The Centers For Disease Control

STEERING COMMITTEE MEETING [08/29/2012]

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

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

1a. Impact: **H-7; M-7; L-2; I-3**; 1b. Performance Gap: **H-6; M-12; L-0; I-0** 1c. Evidence: **Y-13; N-1; I-3**

Rationale:

- This measure examines the number of patients who did not have a visit in the last 6 months of the measurement year; the measure is looking at the absence of HIV care.
- The measure is not specific to newly enrolled patients, but rather any patient currently receiving care. The intent of this measure is to examine retention in care in programs that are managing HIV infected patients.
- The evidence is the same as for measure 2079 but looks at a different perspective of retention in care (i.e., the absence of HIV care).
- The measure is designed for clinicians, clinics or facilities providing HIV care though it can be used by other providers who do not necessarily specialize in HIV but who offer HIV services.
- Committee members noted that there are very consistent observational data and well-designed studies ranging from small to multi-center large studies showing that if patients are not retained in care they are less likely to be prescribed ART, less likely to adhere to ART, less likely to achieve viral suppression and survival time is shorter.
- The Committee discussed the relationship between better outcomes and increased retention and identified that the observational data provided by the developer did not assess causality. The Committee stated that in order to have more confidence in the data the developer should have controlled for confounding variables, and then proceeded to compare patient outcomes.
- The Committee discussed the notion of patients moving from provider to provider. However, data from Philadelphia showed that less than 3 percent of people with HIV/AIDS get seen by multiple providers in a 12-month period.
- Disparities were identified in this measure, especially amongst females and minorities.

2080: Gap in HIV medical visits

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-4; M-14; L-0; I-0** 2b. Validity**: H-2; M-14; L-0; I-2**

<u>Rationale:</u>

- Committee members were concerned whether or not the medical visit could be specified to identify who the medical visit was with, as the data would not support seeing another physician (such as an OB/GYN) in one 6 month period, and then the HIV specialist in the next 6 month period.
    - The developer clarified that the intent of the measure is to be used in a clinic or HIV care setting and most often the OB/GYN is not part of an HIV clinic.
- This measure assumes that the patient is being cared for by the same physician after 6 months.
- The Committee stated that the reliability testing of the measure score was high.
- Face validity using a technical work group of 20-25 members and a series of webinars with HIV providers across the U.S. was used to establish validity of this measure.

3. Usability: H-8; M-10; L-0; I-0

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

<u>Rationale</u>:

- The intended use is for public health and disease surveillance, public reporting and quality improvement with benchmarking.
- The developer intents to submit this measure for meaningful use and PQRS programs.

4. Feasibility: H-7; M-10; L-0; I-0

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

<u>Rationale</u>:

- All the data elements are contained within an electronic claims, appointment systems and EHRs.

5. Related and Competing Measures

- This measure directly relates to measure 2079: *Medical visit frequency*. Measure 2079 looks at a two-year time period and measure 2080 looks at a one-year time period.
- Committee members concluded that the measures are complementary. Measure 2079 is assessing the clinic's persistency with care and excludes new patients who have not been treated in clinic for at least two years. Measure 2080 includes new patients who did not have a visit in the last six months. Measure 2080 has a shorter measurement period and includes more patients.

Steering Committee Recommendation for Endorsement: Y-18; **N-0**

2080: Gap in HIV medical visits

Public and Member Comment (October 3, 2012-November 5, 2012)

- Revise the measure title to include the language "HIV/AIDS" to indicate this measure is applicable to patients with a diagnosis of HIV.
    - *Developer Response:* We would allow for the title to be changed to "Gap in HIV medical visits."
- This process measure that has a high correlation with health outcomes. Patients who are not retained in care are less likely to receive or adhere to appropriate therapies and therefore have shorter survival times. Measure 2080 compliments 2079 because of the difference in patient populations, time frames, and intent of the measures. Measures 2080 and 2079 should be paired so that they are reported together.
    - *Developer Response:* We would certainly support the use of #2079 medical visit frequency in tandem with #2080 gap in medical visits, but at this time, they are independent measures.
- While the intent of metric #2080 (Medical Visit Gap) is to capture retention in and continuity of care, this measure may not yield sufficiently helpful new information to justify the additional administrative burden it would entail.
    - *Developer Response:* We respectively disagree that this measure will not yield sufficient helpful new information. Performance measurement is just one aspect of quality of care. The other aspect is quality improvement. This measure dovetails well with quality improvement in that the patients identified in the numerator are those who are in most need of attention. As with other measures, the staff would need to perform additional work to identify those who are in need of follow-up. Finally, health systems may choose this measure based on their individual quality management and quality improvement needs. This measure may be used in tandem with NQF 2079 but this is not required.

Committee Response: After reviewing the comments, the Committee agreed the measure is important and provides usable information and reaffirmed their recommendation of the measure. The Committee did not recommend that the measures be paired. Committee members agreed that most implementers will use both measures without being formally paired.

Consensus Standards Approval Committee (CSAC) Review (December 2012): Y-14; N-0; A-0

- Decision: Approved for NQF endorsement

Board of Directors Vote (January 4, 2013)

- Decision: Ratified for continued endorsement

2082: HIV viral load suppression

Submission | **Specifications**

Status: New Submission

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 Not applicable Not applicable

Level of Analysis: Facility, Clinician : Group/Practice

Type of Measure: Outcome

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

Measure Steward: Health Resources and Services Administration - HIV/AIDS Bureau **Other organizations:** The Centers for Disease Control

STEERING COMMITTEE MEETING [08/29/2012]

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

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

1a. Impact: **H-18; M-1; L-0; I-0**; 1b. Performance Gap: **H-7; M-12; L-0; I-0** 1c. Evidence: **Y-18; N-1; I-0**

Rationale:

- There is a substantial relationship between viral load suppression and the reduction of morbidity, mortality and HIV transmission. Emerging evidence of earlier antiretroviral therapy indicates decreased HIV-associated complications.
- There is data to support the measure focus for the adolescent and adult populations; however, there are limited data for the pediatric population.
- While there is a movement towards treating all children with HIV, there are providers who do not treat asymptomatic high viral loads and high CD4 counts, in which this measure does not account for.
- The DHHS guidelines whose treatment recommendations are based on the analysis of six randomized controlled trials. One of those is a meta-analysis of nine randomized controlled trials. In addition, there were eight observational studies.
- The Committee asked why it is the last viral load and not any of the viral loads within that year. The developer responded that it's two fold. First, the last viral load is the most current information about the patient and second, it is very straightforward and easy to calculate.
- Data from the Medical Monitoring Project[18] showing 77 percent achieved viral load suppression at most recent test. Additional data from King County showed 65 percent achieved undetectable at the last test. Data from Kaiser Permanente showed that 94.5 percent achieved undetectable at the last viral load if they were known to be on ARV therapy with 69 percent achieving undetectable when looking at all HIV-infected populations in their data set.
- Disparities in race, sex and age were identified for viral load suppression.

2082: HIV viral load suppression

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-17; L-0; I-0** 2b. Validity**: H-1; M-17; L-0; I-0; Abstain-1**

<u>Rationale:</u>

- Reliability and validity were only assessed at the measure score level.
- The goal of treatment is an undetectable viral load, maximal suppression, which most assays now it's less than 50, less than 48, less than 20. However, blips in viral load that are thought to probably not be clinically relevant, at least immediately clinically relevant, are not uncommon. A treatment failure is when reproducible viral loads are over 200. The empiric data indicated that 200 is the appropriate cut off point. However, most experts would agree that's a reasonable standard and only a minor component of this measure.
- The Committee noted that the testing data for reliability was well-defined.
- Face validity was used as the method to test validity. [Note: Dr. Giordano was a member of the panel to assess validity of this measure. He recused himself from voting on validity.]

3. Usability: H-10; M-9; L-0; I-0

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

<u>Rationale</u>:

- The developer reports that this measure is currently in use as a national quality improvement project focusing on retention in medical care for individuals with HIV. Agencies with DHHS, Department of Veteran Affairs, HIV Medical Association and Kaiser Permanente commented on the importance of this measure.

4. Feasibility: H-8; M-11; L-0; I-0

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

<u>Rationale</u>:

- Though not yet specified for EHRs, all data elements are available in electronic health records.

5. Related and Competing Measures

- No related or competing measures noted.

Steering Committee Recommendation for Endorsement: Y-18; **N-1**

Public and Member Comment (October 3, 2012-November 5, 2012)

- This which is the sole outcome measure of this infectious disease endorsement measure set. There is a strong correlation between the reduction of viral loads and that of morbidity, mortality, and HIV transmission, which makes this measure beneficial not only to individual patients but to populations as well as transmission of the virus is reduced. Data for this measure should be stratified by race, ethnicity, gender, and age when it is publically reported so as to build a capacity to identify disparities in a nationally standardized, meaningful fashion. eSpecification of this measure should be developed for use with EHRs.
    - *Developer Response:* We appreciate the comment. We expect this is a disparities-sensitive measure and it can be used to highlight disparities in outcomes among HIV-infected patients.
- Reconsider, from a comparative and practical standpoint, the endorsed measure #2082 and the rejected measure #0407. Measure #2082 captures the percentage of ALL HIV-diagnosed patients that have achieved RNA control in a given 12 month period, whereas the rejected metric #0407 captures viral control within a six-month window from the start of treatment for patients on anti-retroviral therapy. Adoption of measure #2082 may penalize providers that have higher numbers of long-term non-progressors in their patient populations, and that the measure does not account for clinical judgment and patient choices not to begin ART for various reasons. Use of such a composite downstream outcome measure where all patients with an HIV diagnosis are presumed indicated to be on ART, suggests there

is no need for Measure #2083 (Prescription of Anti-Retroviral Therapy).

- *Developer Response:* As for no exclusion: A.) We do not expect performance to be at 100%. B.) This measure captures the entire population of people living with HIV within facilities or clinics that are engaged or accessing medical care. It does not apply any additional criteria such as needing to have a greater number of medical visits or be prescribed HIV antiretroviral therapy. This is important as a greater emphasis is placed on community HIV viral load and the body of evidence of "treatment as prevention" grows. C.) We have been working closely with CMS and ONC on the inclusion of HIV measures into Meaningful Use. From that experience, CMS and ONC are warning of the use of patient and provider exclusions. Adding exclusions to measures makes it more difficult, if not impossible, to e-specify the measure's use in an EHR. Long-term non-progressors make up a very small percentage of the HIV-infected population overall. In addition, long-term non-progressors generally have undetectable viral loads. As some of these patients could develop detectable viral loads over time, decisions would need to be made between patients and providers about when/if to begin ART. 2. We see value in having both a prescribed HIV antiretroviral therapy and viral load suppression measure. The #2083 "Prescribed HIV antiretroviral therapy" can be used to understand access to HIV medications, which is a key step on the road towards viral suppression. In addition, some patients, despite good adherence to ART, may never achieve viral load suppression due to their resistance profiles. Measuring ART use will help providers understand their viral load suppression data more fully. 3. Please note: On July 24, 2012, Secretary Sebelius approved a package of seven common core measures for monitoring HHS-funded HIV prevention, treatment, and care services. The measures were generated following multiple consultations with a group of federal and non-federal stakeholders and that are consistent both with the Institute of Medicine's recommendations for monitoring HIV services and measures deployed by the National Quality Forum (NQF) and the National Committee for Quality Assurance (NCQA). This measure, #2082 viral load suppression, is one of the seven measures approved by Secretary Sebelius, supporting alignment of HIV measures across HHS.

Committee Response: The Committee discussed that measure #407 does not capture patients that are not on anti-retroviral therapy; it is important to include all patients. There is benefit in knowing the percentage of all patients in the population being treated. The goal is for the measure results to be as high as possible but 100 percent compliance is not expected. The Committee indicated that measure 2082 provides the best view of the desired outcome and continued its recommendation for endorsement.

Consensus Standards Approval Committee (CSAC) Review (December 2012): Y-14; N-0; A-0

- Decision: Approved for NQF endorsement

Board of Directors (January 4, 2013)

- Decision: Ratified for continued endorsement

2083: Prescription of HIV antiretroviral therapy

Submission | **Specifications**

Status: New Submission

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 Not applicable

Level of Analysis: Population : Community, Population : County or City, Facility, Clinician : Group/Practice, Population : National, Population : Regional, Population : State

Type of Measure: Process

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

Measure Steward: Health Resources and Services Administration - HIV/AIDS Bureau **Other organizations:** The Centers for Disease Control

2083: Prescription of HIV antiretroviral therapy

STEERING COMMITTEE MEETING [08/29/2012]

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

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

1a. Impact: **H-18; M-1; L-0; I-0**; 1b. Performance Gap: **H-7; M-10; L-1; I-1** 1c. Evidence: **Y-14; N-3; I-1**

<u>Rationale</u>:

- Antiretroviral therapy delays the progression to AIDS and increases an individual's length of survival. It has also been shown to reduce transmission of HIV.
- The developer sees this measure not only being used within the HRSA programs, but also used at the Department of Health and Human Services (DHHS) level as well as in public reporting programs.
- Committee members noted that while it's not the current standard, there is growing evidence that children over the age of 5 who have higher CD4 counts should be treated. Most of the children in active treatment are adolescents. Many of these adolescents have trouble with adherence to medications that may have higher CD4 counts and are monitored due to concern of compliance.
- There were greater than five studies cited, including randomized clinical trials, Meta analyses and observational studies. Several of the observational studies were a collaboration of cohort studies.
- The Committee noted that the evidence for treatment is very clear for CD4 counts less than 500 but somewhat limited for individuals whose CD4 count is greater than 500. It was noted that the overall number of individuals with a CD4 count greater than 500 would be only 3 percent. However, an HIV-CAUSAL study suggested a morbidity benefit for individuals with CD4 counts above 500. The developer indicated that according to Jack Skarbinski's presentation on the Medical Monitoring Project (MMP) data from the 2012 Conference on Retroviruses and Opportunistic Infections (CROI), 66 percent of individuals with a CD4 count above 500 were prescribed antiretroviral therapy. In recent guidelines, both the International Antiviral Society USA guidelines and the HHS guidelines recommend treatment for all patients regardless of their CD4 count. The NA-ACCORD study[19] also suggested a survival benefit in people above 500.
- Committee members noted that in large jurisdictions including San Francisco and New York City, health officials are implementing a policy that all patients diagnosed with HIV regardless of CD4 counts should be treated.
- A Committee member stated that at the International AIDS Conference data was presented that showed a disparities gap in which African Americans had lower levels of suppressed HIV RNA levels and also had a low percentage in being on antiretroviral therapy.
    - The developer commented that in 2009 MMP data, a multivariate model of factors associated with prescription of ART found that young adults (18 to 29), non-Hispanic blacks, women who have sex with men and persons more recently diagnosed with HIV were less likely to be prescribed ART. The MMP only includes patients aged 18 years and over.

2083: Prescription of HIV antiretroviral therapy

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-17; L-0; I-0** 2b. Validity**: H-1; M-18; L-0; I-0**

<u>Rationale:</u>

- The data source is electronic medical records, electronic clinical data, pharmacy, and paper medical records.
- This measure does not provide exclusions for patients that refuse treatment or are not prescribed treatment for various reasons.
    - The developer responded that patient refusals are expected and the goal of the measure is not 100 percent performance. The developer noted that children less than 5 are approximately 0.1 percent of the population in the United States which is part of the reason the developer did not consider that particular age population as exclusion. A Committee member expressed a concern of the lack of exclusions, especially for patients depending on their clinical status and CD4 count who may be on the Ryan White ADAP waiting list for over a year before receiving antiretroviral therapy. The developer stated that they work closely with States to ensure that patients who are on the waiting list are on antiretroviral medication through the pharmacy assistance programs. However, the developer also noted that they do not expect 100 percent compliance; this measure was created to improve the quality of care and to bring awareness to low refusal rates and disparity issues amongst clinics.
- The developer used the HIV Research Network, a group of community and academic HIV provider sites to test the reliability of the measure. The range of the reliability scores was 0.93-0.99, with a median of 0.98.

3. Usability: H-7; M-12; L-0; I-0

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

<u>Rationale</u>:

- The developer will be submitting this measure for potential inclusion in the Stage 3 meaningful use program as well as PQRS.

4. Feasibility: H-2; M-17; L-0; I-0

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

<u>Rationale</u>:

- The list of ARVs has some potential for difficulties in data collection. The Committee preferred outlining the medications that should not be used together, rather than the approach of an abstractor trying to review regiments to see if they are consistent with the current guidelines. The developer stated that the definition of antiretroviral therapy is any regimen combination that is not "not recommended" should alleviate this concern.

5. Related and Competing Measures

- No related or competing measures noted.

Steering Committee Recommendation for Endorsement: Y-18; **N-1**

2083: Prescription of HIV antiretroviral therapy

Public and Member Comment (October 3, 2012-November 5, 2012)

- This measure should mirror the national guidelines which indicate that all persons with HIV regardless of CD4 count should be offered ART. This measure should include all persons with HIV with an exclusion for individuals who decline the care.
    - *Developer Response:* By not having any patient or provider exclusions, we do not expect performance to be at 100%. In addition, we believe it is important to capture all patients who are prescribed or not prescribed ART, in order to explore the myriad reasons why ART was not prescribed. We have been working closely with CMS and ONC on the inclusion of HIV measures into Meaningful Use. From that experience, CMS and ONC are warning of the use of patient and provider exclusions. Adding exclusions to measures makes it more difficult, if not impossible, to e-specify the measure's use in an EHR.
- This measure does not capture whether the ARV therapy was received by or had an effect on the patient. Though it is important to have measures that capture the effects of ARV therapy on HIV+ patients, this documentation measure falls short of meeting the needs of the affected population.
    - *Developer Response:* The intent of this measure is to assess the prescription of HIV antiretroviral therapy by medical providers. We see that this process measure that works in tandem with the viral load suppression measure (#2082). Ideally, medical care providers would use both measure in order to understand gaps in performance. We also see utility of this measure among support service and care coordination providers. Such providers can use this measure to focus adherence activities in order to support people living with HIV. Finally, "prescription" of HIV antiretroviral therapy is easily captured in an EHR. It would not be practical to measure "received" HIV antiretroviral therapy, because to truly measure this, one would have to observe patients swallowing pills. Please note: On July 24, 2012, Secretary Sebelius approved a package of seven common core measures for monitoring HHS-funded HIV prevention, treatment, and care services. The measures were generated following multiple consultations with a group of federal and non-federal stakeholders and that are consistent both with the Institute of Medicine's recommendations for monitoring HIV services and measures deployed by the National Quality Forum (NQF) and the National Committee for Quality Assurance (NCQA). This measure, #2084 prescription of HIV antiretroviral therapy, is one of the seven measures approved by Secretary Sebelius, supporting alignment of HIV measures across HHS.

Committee Response: The Committee preferred the specification of 2083 that defines HIV anti-retroviral therapy "*as any combination of HIV medications other than the regimens or components identified as not recommended at any time by the Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents from the Department of Health and Human Services*" rather than trying to define "potent ART" as specified in measure 406. The Committee agreed that the prescription of ART is an important process related to outcomes that will assist in understanding performance on the outcome measure (#2082).

Consensus Standards Approval Committee (CSAC) Review (December 2012): Y-14; N-0; A-0

- Decision: Approved for NQF endorsement

Board of Directors (January 4, 2013)

- Decision: Ratified for continued endorsement

Measures Not Endorsed

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

0298: Central line bundle compliance

Status: Maintenance, Original Endorsement: Nov 15, 2007

Description: Percentage of intensive care patients with central lines for whom all elements of the central line bundle are documented and in place.

The central line bundle elements include:

•Hand hygiene

•Maximal barrier precautions upon insertion

•Chlorhexidine skin antisepsis

•Optimal catheter site selection, with avoidance of the femoral vein for central venous access in patients 18 years and older

•Daily review of line necessity with prompt removal of unnecessary lines

Numerator Statement: Number of intensive care patients with central lines for whom all elements of the central line bundle are documented and in place.

The central line bundle elements include:

• Hand hygiene

• Maximal barrier precautions upon insertion

• Chlorhexidine skin antisepsis

• Optimal catheter site selection, with avoidance of the femoral vein for central venous access in patients 18 years and older

• Daily review of line necessity with prompt removal of unnecessary lines

Denominator Statement: Total number of intensive care patients with central lines on the day of sample.

Exclusions: Exclude patients less than 18 years of age at the date of ICU admission and patients outside the intensive care unit and patients whose lines were not placed in the intensive care unit

Adjustment/Stratification: No risk adjustment or risk stratification NA

Level of Analysis: Facility

Type of Measure: Composite

Data Source: Paper Medical Records

Measure Steward: Institute for Healthcare Improvement

0298: Central line bundle compliance

STEERING COMMITTEE MEETING [08/28/2012]

1. Importance to Measure and Report: <u>The measure does not meet the Importance criteria</u>

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

1a. Impact: **H-18; M-1; L-0; I-0**; 1b. Performance Gap: **H-2; M-5; L-5; I-7** 1c. Evidence: **Y-17; N-2; I-0**

<u>Rationale</u>:

- Studies have shown that implementation of the bundle has led to improved survival as well as cost benefits. Since this measure has been implemented, there has been drastic improvement in central line infections.
- The IDSA guidelines support bundling the steps to reduce the risk of infection.
- The developer did not provide any data on the performance rate of the bundle. However, the Committee indicated that in their experience compliance among hospitals is pretty high.
- A Committee member provided self-reporting data from more than 400 California hospitals where Central Line Insertion Practices (CLIP) measures were reported for the last 3 years. In 2011, the performance rate for adult-only ICUs was 96 percent and for pediatric ICUs the rate was 95 percent. Only 4 in California hospitals did not provide data.
- It was suggested that most CLABSIs occur outside the ICU and that in fact the maintenance of lines may be more critical than the insertion of those lines.
- There was concern that this is a documentation measure that does not necessarily reflect what is occurring at the bedside.
- There is currently a central line associated bloodstream infection (CLABSI) outcome measure, so there may not be a need for a process measure.
- Families can use the bundle checklist while monitoring their loved one's care.
- The Committee questioned whether there was a performance gap that would require documentation of the bundle; some indicated that this process has become a standard of care.
- According to the developer, two states, Rhode Island and Minnesota, use this measure currently and they utilize self-reported data from the individual hospitals.
- The developer added that the bundle is well-utilized and that it has become a very effective tool for Joint Commission review and overall process. The Joint Commission requires hospitals to document compliance with best practice.
- After the vast patient efforts of the last decade, the Committee wondered how many hospitals are not using the bundle or something similar.

Public and Member Comment

- Highmark strongly recommends approval of this measure. While it is clear that clinical quality measurement in general is best served through outcomes measurement, in this important HAI prevention measure - process may directly lead to the desired outcome of infection prevention. The process components within this measure establish a means of direct accountability and empower all caregivers to serve an active role in prevention and monitoring. We agree with the Steering Committee suggestion that expansion of this measure to a hospital-wide assessment tool would be of benefit. Highmark's P4P hospital program incorporates the monitoring of CLABSI. Our data demonstrates the following:

  2012 ICU = .700/1000 central line days

  2012 Non-ICU = .612/1000 central line days

  2011 ICU = .819/1000 central line days

  2011 Non-ICU = .713/1000 central line days

Committee Response: The Committee noted that the measure developer advised the Steering Committee that this measure has not been tested for reliability and validity. As a result the Committee agreed that the measure does not meet NQF criteria for endorsement.

0394: Hepatitis C: Counseling regarding use of contraception prior to antiviral treatment

Status: Maintenance, Original Endorsement: Jul 31, 2008

Description: Percentage of female patients aged 18 to 44 years and all men aged 18 years and older with a diagnosis chronic hepatitis C who are receiving antiviral treatment who were counseled regarding contraception prior to the initiation of antiviral treatment

Numerator Statement: Patients who were counseled regarding contraception prior to the initiation of treatment

Denominator Statement: All female patients aged 18 to 44 years and all male patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment

Exclusions: Documentation of medical reason(s) for not counseling patient regarding contraception

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

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

Type of Measure: Process

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

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

STEERING COMMITTEE MEETING [08/28/2012]

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

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

1a. Impact: **H-0; M-2; L-4; I-13**; 1b. Performance Gap: **NA** 1c. Evidence: **NA**

Rationale:

- Committee members indicated that this is a “check the box” measure.
- The Committee noted that many drugs are potential teratogens and questioned the need for a performance measure specific to this treatment.
- There is little data on the number of women who become pregnant while on treatment.
- The Committee questioned the impact of counseling on whether women or partners of men with hepatitis C get pregnant. No data was available to respond to the question.

Public and Member Comment

- No comments were received.

0397: Hepatitis C: Antiviral treatment prescribed

Status: Maintenance, Original Endorsement: Jul 31, 2008

Description: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who were prescribed at a minimum peginterferon and ribavirin therapy within the 12 month reporting period

Numerator Statement: Patients who were prescribed at a minimum peginterferon and ribavirin therapy within the 12 month reporting period

Denominator Statement: All patients aged 18 years and older with a diagnosis of chronic hepatitis C

Exclusions: Documentation of medical reason(s) why a patient was not prescribed at a minimum peginterferon and ribavirin therapy (e.g., patient was not a candidate for therapy, could not tolerate)

Documentation of patient reason(s) why a patient was not prescribed at a minimum peginterferon and ribavirin therapy (e.g., patient declined)

Documentation of system reason(s) why a patient was not prescribed at a minimum peginterferon and ribavirin therapy (e.g., patient has no insurance coverage, therapy not covered)

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

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

Type of Measure: Process

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

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

STEERING COMMITTEE MEETING [08/28/2012]

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

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

1a. Impact: **H-10; M-5; L-4; I-1**; 1b. Performance Gap: **H-7; M-12; L-1; I-0** 1c. Evidence: **Y-13; N-6; I-1**

<u>Rationale</u>:

- A number of studies have demonstrated the salutary effects of a sustained biologic response and liver-disease related outcomes including decompensation, death from liver failure, and hepatocellular carcinoma. There have been reductions as well in liver-related mortality of magnitudes ranging from 3.3 to 25-fold in one study and a meta-analysis suggesting a decrease in hepatocellular carcinoma of approximately two and a half-fold.
- Committee members discussed that a reasonable action for patients and providers is to wait before initiating therapy until newer and beneficial treatments are available (estimated 18-36 months) that might be more benign. The newer, oral regimens will likely move treatment into an infectious disease realm rather than waiting until it is a significant liver disease.
- Patient advocates in the community are advising patients to wait until the new regimens are available.
- The PQRS data indicates a mean performance of 68 percent.
- No information was provided on disparities. However, Committee members indicated that hepatitis C is more common in African Americans and do not have as high of a response rate to therapy compared to Caucasians. Inner city populations that are disproportionately weighted with ethnic minorities have exceptionally low treatment rates with peginterferon ribavirin.
- Due to all the reasons for not treating, Committee members estimated that only 20 percent of patients are currently receiving treatment.

0397: Hepatitis C: Antiviral treatment prescribed

2. Scientific Acceptability of Measure Properties: <u>The measure does not meet the Scientific Acceptability criteria</u>

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

2a. Reliability: **H-0; M-8; L-11; I-1** 2b. Validity**: NA**

<u>Rationale:</u>

- Committee members were not comfortable that the medical exceptions would include patients/providers that decided to wait before beginning therapy. The Committee suggested that more granularities are needed to identify exceptions based on intolerance, poor prior treatment response and a decision to wait for newer drugs.
- Some Committee members noted that the system exclusion may be an easy way to not be accountable for not prescribing therapy if the patient is poor or therapy is not covered by their insurance.
    - The developer responded that the data on exceptions is not lost but is tracked as well as the results.
- The Committee asked why the EHR testing demonstrated lower reliability that would be expected.
    - The developer responded that the test sites were asked to do the testing on their system as is. Based on the results they go back and make work flow changes because the test groups do continue to use these measures after testing. In repeat testing today the reliability would likely be higher because of changes made to the EHR to better capture data. The electronic health record automated reporting consistently under-reports performance unless changes are made to the EHR to be able to capture data more accurately.
- The Committee pointed out that there were a number of patients who appeared to fail the measure on automated calculation but were found to not meet the numerator and have a valid exception on the manual review was 46 percent.
- The Committee asked the developer how many EHR vendors include data fields for the exceptions. The developer could not answer the question.

0397: Hepatitis C: Antiviral treatment prescribed

Public and Member Comment

- The ID Draft Report for Comment notes that committee members discussed that a reasonable action for many patients and providers is to wait before initiating therapy until newer and beneficial treatments are available (estimated 18-36 months) that might be more benign. The newer, oral regimens will likely move treatment into an infectious disease realm rather than waiting until it is a significant liver disease. However, in the meantime, of all of the proposed measures, our Hepatitis C Expert Work Group believes that this is the one measure that would have the largest impact on outcomes. Currently, Hepatitis C is overall an undertreated disease. This is not fully reflected in the current performance measure because of the opportunity for numerous appropriate exclusions due to absolute or relative contraindications associated with recommended therapies. Current estimates are that only 20% of chronic Hepatitis C infected patients are eligible for currently recommended treatments. This measure is intended to encourage appropriate antiviral therapy for those with advanced fibrosis (because delayed treatment may expose them to risk for decompensation while waiting for Phase III studies and FDA approval) and would be a placeholder consistent with current guidelines to promote effective antiviral treatment with currently available agents for appropriate patients. In addition, antiviral therapy reduces the risk of hepatocellular carcinoma (HCC) in Hepatitis C-related fibrosis and cirrhosis.(5) The effect may be seen irrespective of the virological response, but is more pronounced among virological responders compared with non-responders.(5) 5 Kimer N, Dahl EK, Gluud LL, et al. Antiviral therapy for prevention of hepatocellular carcinoma in chronic hepatitis C: systematic review and meta-analysis of randomised controlled trials. BMJ Open 2012;2:e001313.doi:10.1136/bmjopen-2012-001313. The NQF committee members did not seem comfortable with the medical exceptions in the measure and were concerned that patients/providers may appropriately decide to wait before beginning therapy. The SC suggested that more granularities are needed to identify exceptions based on intolerance, poor prior treatment response, and a decision to wait for newer drugs. The Work Group would be more than happy to add increased specificity regarding an exception example for delaying treatment in favor of newer, better drugs. We'd like to emphasize that intolerance, poor prior treatment response, and desire to wait for new treatments would fall under medical or patient exceptions if stage of fibrosis is low or if it's the patient's choice. Furthermore, data on exceptions is not lost; rather, exception rates are captured and should be reported alongside of performance rates. In addition, we have performed extensive research and analysis on measure exception reliability in our Cardio-HIT project. In Cardio-HIT, over 90% of exceptions automatically reported were validated upon manual review of the medical record.(6) Finally, the SC recommended for endorsement Measure #2083 Prescription of HIV Antiretroviral Therapy, even though the list of ARVs has some potential for difficulties in data collection. The measure developer stated that they preferred outlining the medications that should not be used together, rather than using the approach of an abstractor trying to review regimens to see if they are consistent with the current guidelines. The developer stated that the definition of antiretroviral therapy is any regimen combination that does not fall into the "not recommended" category should alleviate this concern. Since this treatment measure for HIV, although difficult to specify and far from perfect, was recommended for endorsement by the same SC, our Work Group requests a reconsideration of our treatment measure for Hepatitis C. We'd also like to note that the PCPI has a process in place to update our measures once new evidence becomes available. Therefore, as soon as new treatments are approved and guidelines for Hepatitis C updated, we will be able to update our antiviral treatment measure accordingly. Ultimately, by not recommending Measure #0397, there will be no NQF-endorsed measure for antiviral treatment for patients with Hepatitis C to promote use in national measurement programs. We respectfully request that the SC reconsider recommending this measure to further emphasize the importance of tracking the treatment which should improve the outcomes of care provided to patients with Hepatitis C. 6 KmetikKS, O'Toole MF, Bossley H, et al. "Exceptions to Outpatient Quality Measures for Coronary Artery Disease in Electronic Health Records." Annals of Internal Medicine. February 2011: Volume 154 - Issue 4 - pp 227-234.

Committee Response: The Committee agreed that they had considered all the issues raised by the commenters during the in-person meeting and reaffirmed their prior evaluation and recommendation against the measure.

0400: Paired Measure: Hepatitis C: Hepatitis B vaccination (paired with 0399)

Status: Maintenance, Original Endorsement: Jul 31, 2008

Description: Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who have received at least one injection of hepatitis B vaccine, or who have documented immunity to hepatitis B

Numerator Statement: Patients who have received at least one injection of Hepatitis B vaccine, or who have documented immunity to Hepatitis B

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

Exclusions: Documentation of medical reason(s) for not receiving at least one injection of hepatitis B vaccine

Documentation of patient reason(s) for not receiving at least one injection of hepatitis B vaccine

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

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

Type of Measure: Process

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

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

STEERING COMMITTEE MEETING [08/28/2012]

1. Importance to Measure and Report: <u>The measure does not meet the Importance criteria</u>

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

1a. Impact: **H-4; M-7; L-6; I-3**; 1b. Performance Gap: **NA** 1c. Evidence: **Y-0; N-9; I-11**

Exception to Evidence: Y –10; N -10

<u>Rationale</u>:

- The submission does not describe the impact for co-infection with hepatitis C and hepatitis B. As noted for the hepatitis A measure, the VA population had lower superinfection with hepatitis B in vaccinated patients.
- The developers presented the evidence based on the AASLD guideline that rates the recommendation and evidence as *Level IIa - Weight of evidence/opinion is in favor of usefulness/efficacy* and *Level C - Only consensus opinion of experts, case studies, or standard-of-care.* The developer added that the evidence for potential harm is more substantial because there have been three systematic reviews, albeit not randomized controlled trials, that demonstrate much higher risk of hepatocellular carcinoma when co-infected with both hepatitis B and hepatitis C, above the additional effects of one on top of the other. A Committee member added that the higher risk applies only to 10 percent of hepatitis B patients that do not clear the infection and remain chronically infected.
- The measure specifies only one injection of the series of three injections because capturing the data for the full series is difficult. Evidence indicates that a single injection does not confer sufficient immunity to protect the patient. The third dose gives an amnestic booster response, which is important in terms of duration of potential protection.
- Some Committee members suggested that patients would want to see results for complete vaccination; a single injection is setting a very low bar.
- Unlike the recommendation for HIV patients, there is no recommendation for post-vaccination confirmation of immunity for hepatitis C patients.
- A majority of the Committee did not approve an exception for the evidence criteria for this measure because of the specification for only one injection.

0400: Paired Measure: Hepatitis C: Hepatitis B vaccination (paired with 0399)

Public and Member Comment

- The ID Draft Report reports that, as noted for the Hepatitis A measure, research has found a lower superinfection with Hepatitis B in vaccinated patients. The evidence for potential harm is more substantial because there have been three systematic reviews that demonstrate much higher risk of hepatocellular carcinoma when co-infected with both Hepatitis B and Hepatitis C, above the additional effects of one on top of the other. Our Hepatitis C Expert Work Group feels that Hepatitis B vaccination is even more important than Hepatitis A vaccination. Research shows that the vaccine is cost-effective in the general population. In 2010, CDC estimates approximately 35,000 persons were acutely infected with new cases of Hepatitis B; the age group with the highest incidence for acute Hepatitis is young middle-aged adults which also comprise the adult populations with the highest prevalence of HCV infection.(7) The measure specifies only one injection of the series of three because capturing the data for the full series is difficult and threatens measure feasibility. The measurement burden of 3 shots is high since significant time can pass between the 3 shots and patients may have switched providers or the injections may fall across calendar years. The ID Draft Report said that evidence indicates that a single injection does not confer sufficient immunity to protect the patient. Our CDC data agree and shows that 30%-55% of patients are protected after one vaccination, 75% of patients are protected after 2 shots, and the third shot is essentially the booster and can be administered at any time.(8) However, we disagree with the SC in that we believe that a 50% antibody reduction from just one shot is a sufficient improvement. Furthermore, it should be noted that the level of Hepatitis B antibody that is sufficient for protection or immunity remains unknown. Even though 50% of patients may not have detectable antibody levels, that may be due to the insensitivity of the assay and patients indeed may have adequate protection. Moreover, we are unaware of any data that demonstrate that physicians who give one Hepatitis B shot do not go on to complete the series. Unlike for HIV patients, there is no recommendation for post-vaccination confirmation of immunity for Hepatitis C patients. The "Exception to Evidence" vote at the SC meeting was tied: Y – 10, No – 10, giving compelling reasons for the SC to reconsider this measure. Ultimately, by not recommending Measure #0400, there will be no NQF-endorsed measure for Hepatitis B vaccination in patients with Hepatitis C to promote use in national measurement programs. We hope that these explanatory comments better clarify the value of our measure and we request that the SC reconsider recommending this measure.
  http://www.cdc.gov/hepatitis/Statistics/2010Surveillance/index.htm# 8 MMWR 2006 / 55(RR16);1-25
- CDC encourages the continued paired measurement of Hepatitis B vaccination AND Hepatitis A vaccination among those with Hepatitis C. Even 1 dose provides appreciative protection, although CDC agrees that documentation of full schedule immunization is (as the committee notes) very difficult at this time.

Committee Response: The Committee agreed that Hepatitis B vaccination is very important to the care of patients. However, they noted that a single dose (as specified in the measure) confers protection in only 30-50 percent of normal patients. Data was not available for the response rate for one dose for patients with Hepatitis C. The Committee emphasized that the benefit to patients is completion of the entire vaccination series, which should be the focus of the performance measure. The Committee acknowledged the feasibility concerns; however, they urged development of a measure of completion of the Hepatitis vaccination series for both Hepatitis C and HIV patients.

0401: Hepatitis C: Counseling regarding risk of alcohol consumption

Status: Maintenance, Original Endorsement: Jul 31, 2008

Description: Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who were counseled regarding the risks of alcohol consumption at least once within the 12 month reporting period

Numerator Statement: Patients who were counseled regarding the risks of alcohol consumption at least once within the 12 month reporting period.

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

Exclusions: None

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

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

Type of Measure: Process

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

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

STEERING COMMITTEE MEETING [08/28/2012]

1. Importance to Measure and Report: <u>The measure does not meet the Importance criteria</u>

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

1a. Impact: **H-1; M-5; L-6; I-6**; 1b. Performance Gap: **NA** 1c. Evidence: **NA**

<u>Rationale</u>:

- The submission discusses the evidence for the impact of alcohol consumption on patients with hepatitis C but not the impact of alcohol counseling.
    - The developer reported that regarding the evidence for the impact of counseling there are smaller studies within the hepatitis C infected patients of brief interventions. The larger body of data was obtained in two systematic reviews, one demonstrating modest effect and the other focused on quantifying the reduction of drinks per week. Based on 19 randomized controlled trials with 5600 patients, a brief alcohol intervention in a primary care setting indicated a reduction (between two to five drinks per week) in patients' consumption. Counseling was described as something the provider would do in the course of normal counseling with a patient; a brief interaction about the relative harms of alcohol. Most studies excluded heavy drinkers or dependent drinkers because it was anticipated that a brief intervention would have very little impact on their alcohol use.
- A Committee member inquired about the type of provider who performed the counseling – physician or other. The measure does not specify who performs the counseling.
- This was viewed as a "check the box" documentation measure.
- There was no information provided on sustained alcohol cessation after brief counseling.
- The notion of documentation does not verify that the patient was actually counseled. It may have been "okay, don't drink." There is no clear definition of what counseling means.

Public and Member Comment

- Such counseling is included in the recent CDC recommendations addressing Hepatitis C screening (Recommendations for the Identification of Chronic Hepatitis C Virus Infection Among Persons Born During 1945–1965 August 17, 2012 / 61(RR04);1-18).

Committee Response: After reviewing the comment the Committee agreed not to change their recommendation against the measure. NQF guidance indicates that patient education or counseling should be measured from the patient's point of view.

0403: HIV/AIDS: Medical visit

Status: Maintenance, Original Endorsement: Jul 31, 2008

Description: Percentage of patients, regardless of age, with a diagnosis of HIV/AIDS, with at least two medical visits during the measurement year, with a minimum of 90 and 180 days between each visit

Numerator Statement: Numerator 1: Patients with at least two medical visits during the measurement year, with a minimum 0f 90 days between each visit

Numerator 2: Patients with at least two medical visits during the measurement year, with a minimum of 180 days between each visit

Denominator Statement: All patients, regardless of age, with a diagnosis of HIV/AIDS

Exclusions: None.

Adjustment/Stratification: No risk adjustment or risk stratification N/A

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

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data

Measure Steward: National Committee for Quality Assurance **Other organizations:** Physician Performance Measures (Measures) and related data specifications have been developed by the American Medical Association (AMA) in collaboration with the Physician Consortium for Performance Improvement™ (the Consortium) and the National Committee

STEERING COMMITTEE MEETING [08/29/2012]

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

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

1a. Impact: **H-6; M-9; L-0; I-1**; 1b. Performance Gap: **H-0; M-13; L-1; I-2** 1c. Evidence: **Y-9; N-3; I-4**

<u>Rationale</u>:

- This measure aligns with the National HIV/AIDS strategy which defines continuous care as at least 2 visits at least 3 months apart. The visits do not have to be with the same provider and it is not required that the visit be for HIV care.
- The intent of this measure is to examine retention in care including visits to pediatricians or OB/GYN. The developer explained that future HIV care will be more integrated into primary care.
- Data is presented to suggest the importance of getting patients into care and keeping them in care but compelling data is not presented in the submission to suggest that the identified visit frequency or duration of follow-up of one year are optimal. It was noted that a longer timeframe might be more appropriate for patients with a chronic illness.
- Committee members suggested that the evidence is based on seeing a provider who is familiar with HIV care and having a certain volume of HIV patients make providers proficient in treating HIV.
- There was no evidence presented to allude that medical visits unrelated to HIV-related issues will benefit the patient.

0403: HIV/AIDS: Medical visit

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-1; M-11; L-1; I-3** 2b. Validity**: H-0; M-9; L-3; I-4**

<u>Rationale:</u>

- This measure has two numerators: two visits at least 90 days apart and two visits at least 180 days apart.
- The measure does not require the visit to be with the same physician. The Committee questioned how this measure looks at continuity of care if the same provider is not following up with the patient. The developer noted that it is unlikely a provider would have access to another patient's information unless the EHR system is integrated.
- The measure does not require that the visit to be for HIV-related care.
- The EHR automated versus manual calculation of performance was 91 percent and 95 percent respectively.
- Face validity was assessed by a panel of six experts with a mean rating of 4.67 out of 5; 100 percent of the expert panel either agreed or strongly agreed that the measure could accurately distinguish good and poor quality.

3. Usability: H-1; M-6; L-7; I-2

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

<u>Rationale</u>:

- The developer reported that this EHR measure is included in stage 2 of the Meaningful Use program, and has been adopted by the initial core set of healthcare quality measures from Medicaid-eligible adults.
- Some Committee members suggested that if there is no requirement that a medical visit be for HIV care, then the intent of this measure (how providers are attempting to retain people in care for HIV) may not meaningful and useful.

4. Feasibility: H-0; M-8; L-6; I-2

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

<u>Rationale</u>:

- All data elements are available electronically.

0403: HIV/AIDS: Medical visit

Public and Member Comment

- Meaningful Use: All measures that are endorsed should take into consideration metrics that have been accepted by other federal agencies, for example CMS's Medicare and Medicaid "meaningful use" incentive programs for adoption and utilization of electronic health records. We note that two of the HIV measures that were not selected for re-endorsement – #0403 (Medical Visit) and #0407 (Viral Control at 6 months potent ART) – are included among the three HIV measures newly approved in the final Stage II EHR "Meaningful Use" rule. It is unclear whether discontinuation of NQF endorsement of these measures will invalidate their use for CMS purposes.
    - **Committee Response:** The Committee discussed the comment and noted that the current use of measures was discussed under the usability criteria. For measure **403 Medical visit**, the Committee was concerned there is no requirement that a medical visit be for HIV care so this measure (how providers retain people in care for HIV) may not meaningful and useful. CMS would determine whether a measure in which NQF endorsement was removed would continue to be used in their programs.
- The Committee was asked to revisit measures 0403 and 2079. A commenter noted that although NQF measure 0403 was not re-endorsed, from a practical standpoint it makes more sense than the competing measure 2079 which was recommended. The 12-month medical visit frequency utilized in measure 0403 is consistent with the time period captured in all the other HIV metrics, whereas measure 2079 relies on a 24-month frequency. The comment questions the rationale and practicality of using a 24-month timeframe, given that the patient population being measured may shift considerably within a 24-month window, and considering that the same 24-month outcome could be captured by looking at measure 0403 serially, over time; how measure 2079 could be reported as the denominator would be different every six months; and measure 2079 was tested only in HIV-specific clinical settings (Ryan White clinics) and may not be as applicable in other clinical settings. (HIV Medicine Association)
    - **Committee Response:** Committee members noted that consumers strongly support the 24-month timeframe as it provides a richer image of care provided to patients. The Committee maintained their original recommendation for measure 2079.

Steering Committee Recommendation for Endorsement: Y-6; **N-10**

- There was no evidence presented to suggest that medical visits unrelated to HIV-related issues will benefit the patient. Some Committee members suggested that if there is no requirement that a medical visit be for HIV care, then the intent of this measure (how providers are attempting to retain people in care for HIV) may not meaningful and useful.

0406: HIV/AIDS: Adolescent and adult patients who are prescribed potent antiretroviral therapy

Status: Maintenance, Original Endorsement: Jul 31, 2008

Description: Percentage of patients with a diagnosis of HIV/AIDS, with at least two visits during the measurement year, with at least 90 days between each visit: aged 13 years and older who have a history of a CD4 count less than or equal to 500 cells/mm3; aged 13 years

Numerator Statement: Patients who were prescribed potent antiretroviral* therapy

*Potent antiretroviral therapy is described as any antiretroviral therapy that has demonstrated optimal efficacy and results in durable suppression of HIV as shown by prior clinical trials

Denominator Statement: A. All patients aged 13 years and older with a diagnosis of HIV/AIDS, with at least two medical visits during the measurement year, with at least 90 days between each visit, who have a history of a CD4 count less than or equal to 500 cells/mm3; and

B. All patients aged 13 years and older with a diagnosis of HIV/AIDS, with at least two medical visits during the measurement year, with at least 90 days between each visit, who have a history an AIDS-defining illness**, regardless of CD4 count; and

0406: HIV/AIDS: Adolescent and adult patients who are prescribed potent antiretroviral therapy

C. All patients with a diagnosis of HIV/AIDS, with at least two medical visits during the measurement year, with at least 90 days between each visit, who are pregnant, regardless of CD4 count or age.

**The most commonly used case definition for AIDS is the 1993 Revised Surveillance Case Definition from the CDC. It includes: Candidiasis of bronchi, trachea, or lungs; candidiasis, esophageal; cervical cancer, invasive; coccidiodomycosis, disseminated or extrapulmonary; cryptococcosis, extrapulmonary; crytosporidiosis, chronic intestinal (greater than 1 month's duration); cytomegalovirus disease (other than liver, spleen, or nodes); cytomegalovirus retinitis (with loss of vision); encephalopathy, HIV-related; herpes simplex: chronic ulcer(s) (greater than 1 month's duration); or bronchitis, pneumonitis, or esophagitis; histoplasmosis, disseminated or extrapulmonary; isosporiasis, chronic intestinal (greater than 1 month's duration); Kaposi's sarcoma; lymphoma, Burkitt's (or equivalent term); lymphoma, immunoblastic (or equivalent term); lymphoma, primary, of brain; mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary; mycobacterium tuberculosis, any site (pulmonary or extrapulmonary); mycobacterium, other species or unidentified species, disseminated or extrapulmonary; pneumocystis carinii pneumonia; pneumonia, recurrent; progressive multifocal leukoencephalopathy; salmonella septicemia, recurrent; toxoplasmosis of brain; wasting syndrome due to HIV. (Aberg, 2009; National Center for Infectious Diseases Division of HIV/AIDS)

Definition of "Medical Visit" - any visit with a health care professional who provides routine primary care for the patient with HIV/AIDS (may be but is not limited to a primary care clinician, ob/gyn, pediatrician, infectious diseases specialist)

Note: For potent antiretroviral therapy recommendations refer to current DHHS guidelines available at www.aids.gov

Aberg JA, Kaplan JE, Libman H, Emmanuel P, Anderson JR, Stone VE, Oleske JM, Currier JS, Gallant JE; HIV Medicine Association of the Infectious Diseases Society of America. Primary care guidelines for the management of persons infected with human immunodeficiency virus: 2009 update by the HIV medicine Association of the Infectious Diseases Society of America. Clin Infect Dis. 2009 Sep 1;49(5):651-81. Available at http://www.uphs.upenn.edu/bugdrug/antibiotic_manual/idsahivprimarycare2009.pdf. Accessed May 25, 2012.

National Center for Infectious Diseases Division of HIV/AIDS. 1993 Revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults. MMRW Recomm Rep. 1992;41(RR-17):1-19.

Exclusions: None

Adjustment/Stratification: No risk adjustment or risk stratification

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

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Pharmacy

Measure Steward: National Committee for Quality Assurance **Other organizations:** Physician Performance Measures (Measures) and related data specifications have been developed by the American Medical Association (AMA) in collaboration with the Physician Consortium for Performance Improvement™ (the Consortium) and the National Committee

0406: HIV/AIDS: Adolescent and adult patients who are prescribed potent antiretroviral therapy

STEERING COMMITTEE MEETING [08/28/2012]

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

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

1a. Impact: **H-14; M-5; L-0; I-0**; 1b. Performance Gap: **H-3; M-10; L-2; I-4** 1c. Evidence: **Y-17; N-2; I-0**

<u>Rationale</u>:

- This clinician-level measure applies to patients 13 years and older with a CD4 count less than or equal to 500 with at least two medical visits at least 60 days apart.
- The average performance rate in PQRS in 2009 was 90.3 percent and 97.2 percent in 2010. The Committee noted that the performance rate does not illustrate a large gap in care. However, if the two medical visit requirement was eliminated from the measure, there would be a performance gap. The developer stated that the performance rates were from PQRS which is a self-selecting reporting system in which only 60 providers in 2009 and 61 providers in 2010 participated and submitted their data.
- In 2009 and 2010, 202 facilities from HIVQUAL reported data for all a total of 9,153 patients. The facility means were 75.2 percent and 64.2 percent respectively.
- A Committee member referenced Irene Hall's data that suggests there is a gap because for all people living in this country who have HIV only about 21 percent have suppressed levels of HIV and about 30 percent or so are actually receiving antiretroviral therapy. An analysis was performed for people who were engaged in care and found that there was a gap among those engaged in care and those receiving antiretroviral therapy.
- According to the guidelines, if a patient is stable and on antiretroviral therapy, the patient will only need to be monitored every six months to a year; which would imply that this type of patient may not be included in this measure because of the two medical visits requirement.
- The developer's advisory panel stated strongly that they wanted to include denominator qualifications and not include all patients.
- No data was presented on disparities.

2. Scientific Acceptability of Measure Properties: <u>The measure does not meet the Scientific Acceptability criteria</u>

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

2a. Reliability: **H-1; M-13; L-3; I-2** 2b. Validity**: H-0; M-8; L-6; I-5**

<u>Rationale:</u>

- The specifications do not clearly define "potent" therapy. The developer responded that they refer providers who are reporting on this measure to the treatment guidelines in order to identify potent ART.
- The Committee questioned how potent antiretroviral therapy would be identified using an electronic health record. The developer stated that they may use HRSA's approach of any combination that is not recommended.
- The EHR testing results automated calculation of performance was 96.6 percent and manual calculation of performance was 100 percent with a 3 percent difference.
- To be included in the measure patients must meet all of the following conditions or 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; and 3) patients who had at least one medical visit during the measurement year. Committee members thought that if the measure is limited to people who have two medical visits the population would also be limited to people who are receiving a higher level of care. Thus, all patients with HIV would not be included in the measure.
- Many Committee members agreed that physicians should be held accountable for retaining people in care. It's a responsibility for clinicians to attempt to bring the patient back to care. The Committee noted that due diligence, such as calling patients or making home visits should occur.
- Committee members noted that it's extremely difficult to figure out which patients have a history of an AIDS defining condition because there aren't good ICD-9 codes for many of the conditions. The developer responded that the EHR can use SNOMED codes.
- It was also noted that it may be difficult to find a patient's old CD4 counts.

0406: HIV/AIDS: Adolescent and adult patients who are prescribed potent antiretroviral therapy

Public and Member Comment

- Prescription of ART Measures: Reconsider from a comparative and practical standpoint the endorsed measure #2083 and the rejected measure #0406. Based on our participation in the NCQA panel involved with updating the NCQA HIV metrics, NQF will have the same difficulty operationalizing measure #2083 that is occurring with attempts to update measure #0406 such that it comports with current clinical practice guidelines. We are concerned that the metric should capture and define prescription of not just any ART, but of "potent" ART, and that this definition should exclude ART combinations that are contraindicated.
    - *Developer Response: The commenter refers to their experience with #407 and its e-specification for CMS/ONC Meaningful Use Stage 2. Measure #406 was included in the in the proposed rule for the CMS/ONC Stage 2 of Meaningful Use. The e-specification contractor and the staff at the ONC were never able to determine a definition for "potent" ART. As a result, #406 was not included in the final rule for Stage 2 of Meaningful Use. #2083 does exclude ART regimens that are contraindicated, based on the HHS Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. 4. #2083 has the added value of highlighting all patients who are taking or not taking ART.The reasons for not taking ART may be diverse, and we expect that providers will be interested in exploring all reasons for not taking ART among their patients, including access to medications, provider choice, patient choice, and adverse reactions. Drawing from Meaningful Use Stage 2 process and from the Department of Health and Human Services (HHS) Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents, we felt that #2083 "Prescribed HIV antiretroviral therapy" is a scientifically sound measure. As with other measures HRSA submitted for endorsement, HRSA has plans to promote this measure's inclusion in CMS's Meaningful Use program which would require its e-specification. 5. Please note: On July 24, 2012, Secretary Sebelius approved a package of seven common core measures for monitoring HHS-funded HIV prevention, treatment, and care services. The measures were generated following multiple consultations with a group of federal and non-federal stakeholders and that are consistent both with the Institute of Medicine's recommendations for monitoring HIV services and measures deployed by the National Quality Forum (NQF) and the National Committee for Quality Assurance (NCQA). This measure, #2084 prescription of HIV antiretroviral therapy, is one of the seven measures approved by Secretary Sebelius, supporting alignment of HIV measures across HHS.*

Committee Response: The Committee preferred the specification of 2083 that defines HIV anti-retroviral therapy "*as any combination of HIV medications other than the regimens or components identified as not recommended at any time by the Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents from the Department of Health and Human Services*" rather than trying to define "potent ART" as specified in measure 406. The Committee agreed that the prescription of ART is an important process related to outcomes that will assist in understanding performance on the outcome measure (2082).

0407: HIV/AIDS: HIV RNA control after six months of potent antiretroviral therapy

Status: Maintenance, Original Endorsement: Jul 31, 2008

Description: Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS, who had at least two medical visits during the measurement year, with at least 90 days between each visit, who are receiving potent antiretroviral therapy*, who have a viral load <200 copies/mL after at least 6 months of potent antiretroviral therapy*

*Potent antiretroviral therapy is described as any antiretroviral therapy that has demonstrated optimal efficacy and results in durable suppression of HIV as shown by prior clinical trials

Numerator Statement: Patients with an HIV viral load <200 copies/mL

Denominator Statement: All patients aged 13 years or older with a diagnosis of HIV/AIDS, with at least two visits in the measurement year, with at least 90 days between each visit, who received potent antiretroviral therapy* for at least 6 months

Definition of "Medical Visit" - any visit with a health care professional who provides routine primary care for the patient with HIV/AIDS (may be but is not limited to a primary care clinician, ob/gyn, pediatrician, infectious diseases specialist)

*Potent antiretroviral therapy is described as any antiretroviral therapy that has demonstrated optimal efficacy and results in durable suppression of HIV as shown by prior clinical trials

Exclusions: None

Adjustment/Stratification: No risk adjustment or risk stratification N/A

Level of Analysis: Population : County or City, Clinician : Group/Practice, Clinician : Individual

Type of Measure: Outcome

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Pharmacy

Measure Steward: National Committee for Quality Assurance **Other organizations:** Physician Performance Measures (Measures) and related data specifications have been developed by the American Medical Association (AMA) in collaboration with the Physician Consortium for Performance Improvement™ (the Consortium) and the National Committee

STEERING COMMITTEE MEETING [08/29/2012]

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

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

1a. Impact: **H-17; M-1; L-0; I-0**; 1b. Performance Gap: **H-10; M-7; L-1; I-2** 1c. Evidence: **Y-17; N-1; I-0**

<u>Rationale</u>:

- To prevent disease advancement, all patients should have their RNA levels measured to monitor the effectiveness of antiretroviral therapy (ART).
- This measure builds off of measure 0406: *HIV/AIDS: Adolescent and adult patients who are prescribed potent antiretroviral therapy* to assess the viral load after 6 months of therapy. Control is defined as a viral load less than 200 copies per milliliter.
- HIV RNA plasma levels assess the efficacy of ART. RNA less than 50 is regarded as the optimal outcome although 200 copies is often used in clinical trials. For most individuals who are adherent to their ART and who do not have resistance viral suppression is generally achieved in 12 to 24 weeks although it could take longer in some patients.
- The DHHS guidelines rate achieving viral suppression as the goal of therapy as A1 level evidence. There were 10,000 patients summarized in the guidelines from 33 studies; there's a large evidence base to support viral suppression.
- The average PQRS performance rate in 2009 was 76.7 percent and 75.5 percent in 2010, which demonstrates room for improvement.
- The Committee discussed disparities in viral suppression for many demographic groups, such as gender and age and not only race/ethnicity.

0407: HIV/AIDS: HIV RNA control after six months of potent antiretroviral therapy

2. Scientific Acceptability of Measure Properties: <u>The measure does not meet the Scientific Acceptability criteria</u>

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

2a. Reliability: **H-0; M-8; L-7; I-4** 2b. Validity**: H-0; M-8; L-7; I-4**

<u>Rationale:</u>

- The Committee questioned how potent antiretroviral therapy would be identified using an electronic health record. The developer stated that they may use HRSA's approach of any combination that is not "not recommended."
- In the EHR testing, the difference between the manual result of 100 percent and the automated result of 96.6 percent with a 3 percent difference of measuring the indicator.
- Several Committee members were not convinced that 100 percent of the test population had viral suppression. The developer noted that since the measure was tested in 2009, updates have been made; the "or plan of care" component of the measure was removed.
- There was uncertainty regarding which viral load is used. A Committee member asked for clarification as to whether any viral load less than 200 in the measurement year is used or if the last viral load in the measurement year is used. The developer could not answer the question at the meeting but indicated that they would clarify later.

Public and Member Comment

- Meaningful Use: All measures that are endorsed should take into consideration metrics that have been accepted by other federal agencies, for example CMS's Medicare and Medicaid "meaningful use" incentive programs for adoption and utilization of electronic health records. We note that two of the HIV measures that were not selected for re-endorsement – #0403 (Medical Visit) and #0407 (Viral Control at 6 months potent ART) – are included among the three HIV measures newly approved in the final Stage II EHR "Meaningful Use" rule. It is unclear whether discontinuation of NQF endorsement of these measures will invalidate their use for CMS purposes.

Committee Response The Committee discussed the comment and noted that the current use of measures was discussed under the usability criteria. For measure **407 HIV/AIDS: HIV RNA control after six months of potent antiretroviral therapy** the Committee agreed that the measure did not meet the Scientific Acceptability criteria and so the Usability criteria was not addressed. CMS would determine whether a measure in which NQF endorsement was removed would continue to be used in their programs.

0412: HIV/AIDS: Hepatitis B vaccination

Status: Maintenance, Original Endorsement: Jul 31, 2008

Description: Percentage of patients aged six months and older with a diagnosis of HIV/AIDS, who have received at least one hepatitis B vaccination, or who have documented immunity

Numerator Statement: Patients who have received at least one injection of hepatitis B vaccination, or who have documented immunity

Denominator Statement: All patients aged six months and older with a diagnosis of HIV/AIDS, with at least two visits in the measurement year, with at least 90 days in between each visit

Definition of "Medical Visit" - any visit with a health care professional who provides rout

Exclusions: None.

Adjustment/Stratification: No risk adjustment or risk stratification N/A

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

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data

Measure Steward: National Committee for Quality Assurance **Other organizations:** Physician Performance Measures (Measures) and related data specifications have been developed by the American Medical Association (AMA) in collaboration with the Physician Consortium for Performance Improvement™ (the Consortium) and the National Committee

STEERING COMMITTEE MEETING [08/29/2012]

1. Importance to Measure and Report: <u>The measure does not meet the Importance criteria</u>

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

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

<u>Rationale</u>:

- Hepatitis B vaccination is recommended for all patients with HIV.
- Data was not provided to support the effectiveness of one of three injections to prevent hepatitis B.
- The Committee questioned why the developers are measuring the administration of only one vaccination.
    - The developer indicated that all three vaccines were not required to reduce measurement burden. The Committee stated that receiving one vaccine was not enough to confer immunity to hepatitis B. The Committee noted the same issues as with measure 0400: *Hepatitis C: Hepatitis B vaccination*.
- According to the measure submission, the denominator requirement of two visits at least 90 days apart drove the decision to measure only one dose due to the minimum amount of time required for the three-dose series where the first and the third dose must be given at least 16 weeks apart. Because of concerns that patients may drop out of care within 4 months it was decided to capture one dose to measure the start of the series.
- Some Committee members suggested that one injection is a surrogate for the likelihood of getting the entire series.
- No information was provided on disparities.
- The evidence for the benefit of the hepatitis B vaccination was based on receiving the entire series of three doses. One dose does not provide adequate immunity. There wasn't any direct data presented regarding the efficacy of one vaccine dose to prevent the outcome of hepatitis B.
- Vaccination in the remote past may not be captured in the medical record. Measures should account for past history of vaccination. Universal screening of younger children will enlarge the vaccinated population in the future. Committee members suggested creating a measure of the patient's hepatitis B surface antibody status.

0412: HIV/AIDS: Hepatitis B vaccination

Public and Member Comment

- Meaningful Use: All measures that are endorsed should take into consideration metrics that have been accepted by other federal agencies, for example CMS's Medicare and Medicaid "meaningful use" incentive programs for adoption and utilization of electronic health records. The Hepatitis B vaccination measure #0412 was dropped because it captures only a single vaccination rather than the indicated three-shot series of vaccinations. However, we note that a measure for the three shot Hepatitis B vaccine series was adopted by NCQA as part of a previous NCQA-managed consensus standards project, but that this metric was not moved forward for NQF endorsement.[i] [i]Horberg et al (CID, 15 September, 2010), measure #13, page 73

Committee Response: The Committee encourages developers to submit a measure that includes all three shots for complete vaccination. CMS would determine whether a measure in which NQF endorsement was removed would continue to be used in their programs.

0584: Hepatitis C: Viral load test

Status: Maintenance, Original Endorsement: Dec 04, 2009

Description: This measure identifies the percentage of patients with chronic Hepatitis C (HCV) who began HCV antiviral therapy during the measurement year and had HCV Viral Load testing 6 months prior to initiation of antiviral therapy.

Numerator Statement: Patients in the denominator who had an HCV Viral Load test 6 months prior to the initiation of antiviral therapy.

Denominator Statement: Our denominator is anyone with Hepatitis C diagnosed anytime in the past, based on historical claims on file, who have a new start of peginterferon in the last year, excluding people with documentation of a medical reason(s) for not performing quantitative HCV RNA testing within 6 months prior to initiation of treatment (CPT Category II code 3218F-1P).

Exclusions: Exclude anyone with a code which states the patient has a medical reason for not having the test done.

Adjustment/Stratification: No risk adjustment or risk stratification No stratification.

Level of Analysis: Health Plan

Type of Measure: Process

Data Source: Administrative claims

Measure Steward: Resolution Health, Inc.

0584: Hepatitis C: Viral load test

STEERING COMMITTEE MEETING [08/28/2012]

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

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

1a. Impact: **H-11; M-6; L-1; I-1**; 1b. Performance Gap: **H-4; M-14; L-2; I-0** 1c. Evidence: **Y-10; N-5; I-5**

<u>Rationale</u>:

- HCV has major disease burden in US. HCV RNA testing is important prior to starting therapy for multiple reasons: assessing virologic response during therapy, tailoring treatment to response, and shortening or terminating therapy if non-responsive.
- This measure looks at quantitative RNA viral measurement within 6 months of starting therapy. The evidence presented is based on the AASLD guidelines with a Class 1 recommendation, Level A evidence. A meta-analysis of 12 clinical trials showed the benefit of the HCV viral load test.
- Committee members noted that RNA testing is not enough; knowing the genotype of the virus is critical in planning treatment. The developer indicated they are looking at additional elements of pre-therapy testing to create a more comprehensive measure. Another Committee member noted that newer anti-viral treatments may not be specific to genotype, and in the future RNA testing may be all that is needed.
- Committee members questioned how the 6-month time window was determined. Viral loads can fluctuate; 6 months may be no better than 12 or 18 months. The developer noted that the 6 months' time window was a reflection of harmonization with measure 0395: *Hepatitis C ribonucleic acid (RNA) testing before initiating treatment* and seemed reasonable. Ultimately, the Committee and the developer clarified that the HCV RNA testing is done within 6 months prior to starting therapy.
- The developer reported that the compliance with this measure was roughly 68.8 to 84.8 percent. Committee members suggested that these results do not match their real world experience where insurers and third-party payers request the viral load as a pre-condition of authorization.

2. Scientific Acceptability of Measure Properties: <u>The measure does not meet the Scientific Acceptability criteria</u>

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

2a. Reliability: **H-1; M-5; L-4; I-10** 2b. Validity**: NA**

<u>Rationale:</u>

- This is a health plan level measure based on administrative claims.
- Committee members indicated that the cited performance gap did not match their own experience and raises question about the reliability and validity of the measure.
- The Committee questioned the information supplied by the developer for reliability. The developer agreed that there was no specific empiric testing for reliability.

Public and Member Comment

- No comments were received.

2081: Newly enrolled in medical care

Status: New Submission

Description: Percentage of patients, regardless of age, with a diagnosis of HIV who were newly enrolled and had a medical visit in each of the 4-month periods in the measurement year

Numerator Statement: Number of patients in the denominator who had at least one medical visit in each 4-month period 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 was newly enrolled with a medical provider and had at least one medical visit in the first 4 months of the measurement year. "Newly enrolled" patients are those who are: newly diagnosed with HIV and new to medical care; patient's new to medical care (previously diagnosed with HIV and never received HIV medical care); patients who transferred their medical care to your organization; or patients returning to medical care after a 2-year absence (patients re-engaged by the same organization).

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

Adjustment/Stratification: No risk adjustment or risk stratification Not applicable

Level of Analysis: Facility, Clinician : Group/Practice

Type of Measure: Process

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

Measure Steward: Health Resources and Services Administration - HIV/AIDS Bureau **Other organizations:** The Centers for Disease Control

STEERING COMMITTEE MEETING [08/29/2012]

1. Importance to Measure and Report: <u>The measure does not meet the Importance criteria</u>

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

1a. Impact: **H-14; M-3; L-2; I-0**; 1b. Performance Gap: **NA** 1c. Evidence: **Y-8; N-2; I-8**

<u>Rationale</u>:

- This measure is part of HRSA's suite of measures looking at retention in care, which is a significant issue within the context of HIV care, treatment and prevention.
- The Committed recognized that a measure does not define what actually occurs at the visit.
- There is lack of evidence to support the number of visits specified. The studies provided do not define what the optimal number of visits should be.
- The testing for this measure was performed using visits that were conducted by a physician, a nurse practitioner or a physician's assistant. The measure does not specify the visit must be with an HIV provider.
    - The developer explained that the purpose of this measure is not to look at HIV care specifically, but rather examine where those missed opportunities.
- The Committee questioned whether the evidence supports the need for many medical visits for individuals who do not necessarily have a gap in care but have recently transferred their care. If the patient has been retained in care over a 10-year period and transfers providers, the patients may not need the extra visits needed by a newly diagnosed patient.

2081: Newly enrolled in medical care

Public and Member Comment

- . Persons who are newly diagnosed face significant systemic and perceived barriers to remaining in care. This measure is different than the previous medical visit measures in that it supports a specific analysis of only persons newly enrolled into care. With increased testing efforts and the availability of home rapid testing, the system should be carefully measuring how these newly diagnosed individuals are adhering to medical visits. For persons who have previously fallen out of care, special attention may be needed to reengage them earlier to ensure successful re-linkage into care. The frequency and gap measure are good for entire patient populations but this measure stands alone in that it targets a special subpopulation of persons which need extra support that can be identified through the use of this measure.

Committee Response: The Committee indicated that newly enrolled patients can be evaluated as a subgroup of the other visit measures (measure 2080). There is no need for a separate measure.

Measures Withdrawn from consideration

7 measures previously endorsed by NQF have not been re-submitted or withdrawn from maintenance of endorsement. The following measures have had their endorsement removed:

Measure	Reason for retirement
0302: Ventilator bundle	Request for retirement by developer: Due to the lack of strong evidence to support the measure focus, the current national effort to define ventilator complications, and not intending for the measure to be used for public reporting.
0410: HIV/AIDS: Sexually transmitted diseases - Syphilis screening	This measure has been combined with measure 0409: *HIV/AIDS: Sexually transmitted disease-Chlamydia and gonorrhea screening*.
0411: HIV/AIDS: Other infectious diseases - Hepatitis B screening	Request for retirement by developer: The clinical practice guidelines for this measure focus give an AIII evidence grade (based on expert opinion). In addition, this is an intermediate process to hepatitis B vaccination.
0413: HIV/AIDS: Screening for high risk sexual behaviors	Request for retirement by developer: While it is important to screen for high risk sexual behavior among patients with HIV, the clinical practice guidelines do not provide a standardized approach to screening, making standardized measurement difficult. Since this measurement set uses claims and CPT Category II codes, the developer believed data gathered by the measures would be difficult to interpret.
0414: HIV/AIDS: Other infectious diseases - Hepatitis C	Request for retirement by developer: The clinical practice guidelines give this a BIII evidence grade (based on expert opinion). Hepatitis C screening is most important for patients with HIV who are sexually active. Since not all HIV patients are sexually active, the developer does not think this measure fits well into the primary care scope of this measurement set.
0415: HIV/AIDS: Screening for injection drug use	Request for retirement by developer: While it is important to screen for injection drug use among patients with HIV, the clinical practice guidelines do not provide a standardized approach to screening, making standardized measurement difficult. Since this measurement set uses claims and CPT Category II codes, the developer believed data gathered by the measures would be difficult to interpret.
0568: Appropriate follow-up for patients with HIV	Request for retirement by developer: Due to the large amount of resources required to participate in the maintenance process.

Endnotes

[1] Christensen KL, Holman RC, Steiner CA, et al. Infectious disease hospitalizations in the United States. *Clin Infect Dis*, 2009;49(7):1025-1035.

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Appendix A: Measure Specifications

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	0058 Avoidance of antibiotic treatment in adults with acute bronchitis
Status	Maintenance, Original Endorsement: Aug 10, 2009, Most Recent Endorsement: Aug 10, 2009 Time-limited
Steward	National Committee for Quality Assurance
Description	The percentage of adults 18–64 years of age with a diagnosis of acute bronchitis who were not dispensed an antibiotic prescription.
Type	Process
Data Source	Administrative claims, Electronic Clinical Data, Electronic Clinical Data: Pharmacy This measure is based on administrative claims collected in the course of providing care to health plan members. NCQA collects the Healthcare Effectiveness Data and Information Set (HEDIS) data for this measure directly from Health Management Organizations and Preferred Provider Organizations via the Interactive Data Submission System (IDSS) portal.
Level	Health Plan, Integrated Delivery System
Setting	Ambulatory Care : Clinician Office/Clinic, Ambulatory Care : Urgent Care
Numerator Statement	Patients who were dispensed antibiotic medication (see Table 1) on or three days after an outpatient or ED encounter for acute bronchitis (a higher rate is better). The measure is reported as an inverted rate (i.e. 1- numerator/denominator) to reflect the number of people that were not dispensed an antibiotic.

	0058 Avoidance of antibiotic treatment in adults with acute bronchitis
Numerator Details	Time Window: The measurement year (one calendar year) Table 1: Antibiotic Medications Aminoglycosides: Amikacin; Gentamicin; Kanamycin; Streptomycin; Tobramycin Aminopenicillins: Amoxicillin; Ampicillin Antipseudomonal penicillins: Piperacillin; Ticarcillin Beta-lactamase inhibitors: Amoxicillin-clavulanate; Ampicillin-sulbactam ; Piperacillin-tazobactam; Ticarcillin-clavulanate First-generation cephalosporins: Cefadroxil; Cefazolin ; Cephalexin Fourth-generation cephalosporins: Cefepime; Ketolides: Telithromycin; Lincomycin derivatives: Clindamycin; Lincomycin Macrolides: Azithromycin; Clarithromycin: Erythromycin; Erythromycin ethylsuccinate; Erythromycin lactobionate; Erythromycin stearate Miscellaneous antibiotics: Aztreonam; Chloramphenicol; Dalfopristin-quinupristin; Daptomycin; Erythromycin-sulfisoxazole; Linezolid; Metronidazole; Vancomycin Natural penicillins: Penicillin G benzathine-procaine; Penicillin G potassium; Penicillin G procaine; Penicillin G sodium; Penicillin V potassium; Penicillin G benzathine; Penicillinase resistant penicillin: Dicloxacilli; Nafcillin; Oxacillin; Quinolones: Ciprofloxacin; Gatifloxacin; Gemifloxacin; Levofloxacin; Lomefloxacin; Moxifloxacin; Norfloxacin; Ofloxacin; Sparfloxacin; Rifamycin derivatives: Rifampin Second generation cephalosporin: Cefaclor; Cefotetan; Cefoxitin; Cefprozil; Cefuroxime; Loracarbef; Sulfonamides: Sulfadiazine; Sulfisoxazole; Sulfamethoxazole-trimethoprim Tetracyclines: Doxycycline; Minocycline; Tetracycline Third generation cephalosporins: Cefdinir; Cefditoren; Cefixime; Cefotaxime; Cefpodoxime; Ceftazidime; Ceftibuten; Ceftriaxone Urinary anti-infectives: Fosfomycin; Nitrofurantoin; Nitrofurantoin macrocrystals-monohydrate; Trimethoprim; Nitrofurantoin macrocrystals
Denominator Statement	All patients 18 years as of January 1 of the year prior to the measurement year to 64 years as of December 31 of the measurement year with a claim/encounter for a diagnosis of acute bronchitis (refer to Table 2) and an outpatient or ED visit code (refer to Table 3) during the Intake Period (January 1–December 24 of the measurement year).
Denominator Details	Time Window: The measurement year (one calendar year) All patients 18 years as of January 1 of the year prior to the measurement year to 64 years as of December 31 of the measurement year with a claim/encounter for a diagnosis of acute bronchitis (refer to Table 2) and an outpatient or ED visit code (refer t
Exclusions	N/A
Exclusion details	N/A
Risk Adjustment	No risk adjustment or risk stratification N/A
Stratification	N/A
Type Score	Other The measure is reported as an inverted rate [1 – (numerator/denominator)], therefore a higher score represents the proportion of patients for whom antibiotics were not prescribed) better quality = higher score

	0058 Avoidance of antibiotic treatment in adults with acute bronchitis
Algorithm	Episode Date is defined as the date of service for any outpatient or ED visit (Table 3) during the Intake Period with any diagnosis of acute bronchitis (Table 2). Step 1 Determine the eligible population. To do so, identify all patients in the specified age range who had an outpatient or ED visit (Table 2) with a diagnosis of acute bronchitis (Table 3) during the Intake Period. Step 2 Determine all acute bronchitis Episode Dates during the intake period. For each patient identified in step 1, determine all outpatient or ED claims/encounters with a diagnosis of acute bronchitis. Step 3 Test for Negative Comorbid Condition History. Exclude Episode Dates when the patient had a claim/encounter with a diagnosis for a comorbid condition during the 12 months prior to or on the Episode Date (Table 4). Step 4 Test for Negative Medication History. Exclude Episode Dates where a new or refill prescription for an antibiotic medication (Table 1) was filled 30 days prior to the Episode Date or was active on the Episode Date. Step 5 Test for Negative Competing Diagnosis. Exclude Episode Dates where during the period 30 days prior to the Episode Date through 7 days after the Episode Date (inclusive) the patient had a claim/encounter with any competing diagnosis (Table 5). Step 6 Calculate continuous enrollment. The patient must be continuously enrolled with no more than one gap in coverage from 365 days (1 year) prior to the Episode Date through 7 days after the Episode Date. Step 7 Determine the number of patients in the eligible population who received a prescription for an antibiotic medication on or three days after the earliest episode start date Step 8 Calculate a rate (number of patients receiving an antibiotic) Step 9 Subtract the rate calculated in Step 8 from one to invert the measure result to represent appropriate treatment of adults with acute bronchitis (i.e. antibiotic not prescribed). The measure is reported as an inverted rate (i.e. 1- numerator/denominator) to reflect the number of people that were not dispensed an antibiotic.
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	0069 Appropriate treatment for children with upper respiratory infection (URI)
Status	Maintenance, Original Endorsement: Aug 10, 2009, Most Recent Endorsement: Aug 10, 2009 Time-limited
Steward	National Committee for Quality Assurance
Description	Percentage of children 3 months to 18 years of age with a diagnosis of URI who were not dispensed an antibiotic medication.
Type	Process

	0069 Appropriate treatment for children with upper respiratory infection (URI)
Data Source	Administrative claims, Electronic Clinical Data, Electronic Clinical Data: Pharmacy This measure is based on administrative claims collected in the course of providing care to health plan members. NCQA collects the Healthcare Effectiveness Data and Information Set (HEDIS) data for this measure directly from Health Management Organizations and Preferred Provider Organizations via the Interactive Data Submission System (IDSS) portal.URL http://www.ncqa.org/tabid/370/default.aspx
Level	Health Plan, Integrated Delivery System
Setting	Ambulatory Care : Clinician Office/Clinic, Ambulatory Care : Urgent Care
Numerator Statement	Patients who were dispensed antibiotic medication (Table 1) on or within 3 days after an outpatient or ED encounter for upper respiratory infection (URI) (a higher rate is better). The measure is reported as an inverted rate (i.e. 1- numerator/denominator) to reflect the number of children that were not dispensed an antibiotic.
Numerator Details	Time Window: The intake period, a 12 month beginning on July 1st of the year prior to the measurement year (a 12 month calendar year) and ending on June 30 of the measurement year. Table 1: Antibiotic Medications Aminopenicillins: Amoxicillin ; Ampicillin Beta-lactamase inhibitors: Amoxicillin-clavulanate First generation cephalosporins: Cefadroxil; Cefazolin; Cephalexin Folate antagonist: Trimethoprim Lincomycin derivatives: Clindamycin Macrolides: Azithromycin; Clarithromycin; Erythromycin; Erythromycin ethylsuccinate; Erythromycin lactobionate; Erythromycin stearate Miscellaneous antibiotics: Erythromycin-sulfisoxazole Natural penicillins: Penicillin G potassium; Penicillin G sodium: Penicillin V potassium Penicillinase-resistant penicillins: Dicloxacillin Quinolones: Ciprofloxacin; Gatifloxacin; Levofloxacin; Lomefloxacin; Moxifloxacin; Ofloxacin; Sparfloxacin Second generation cephalosporins: Cefaclor; Cefprozil; Cefuroxime; Loracarbef Sulfonamides: Sulfamethoxazole-trimethoprim; Sulfisoxazole Tetracyclines: Doxycycline; Minocycline; Tetracycline Third generation cephalosporins: Cefdinir; Cefixime; Cefpodoxime; Ceftibuten; Cefditoren; Ceftriaxone
Denominator Statement	All children age 3 months as of July 1 of the year prior to the measurement year to 18 years as of June 30 of the measurement year who had an ED or outpatient visit with only a diagnosis of nonspecific upper respiratory infection (URI) (Table 2) during the intake period (July 1st of the year prior to the measurement year to June 30th of the measurement year).
Denominator Details	Time Window: A 12 month period beginning on July 1st of the year prior to the measurement year (a 12 month calendar year) and ending on June 30 of the measurement year. All children age 3 months as of July 1 of the year prior to the measurement year to 18 years as of June 30 of the measurement year who had an ED or outpatient visit (see Table 3) with only a diagnosis of nonspecific upper respiratory infection (URI) (Table 2) during the intake period (July 1st of the year prior to the measurement year to June 30th of the measurement year). Patients must have (1) a negative medication history for antibiotics in the past 30 days and (2) a negative competing diagnosis for an acute condition in the past 30 days requiring antibiotics (see Table4).

	0069 Appropriate treatment for children with upper respiratory infection (URI)
Exclusions	N/A
Exclusion details	N/A
Risk Adjustment	No risk adjustment or risk stratification N/A
Stratification	N/A
Type Score	Other The measure is reported as an inverted rate [1 – (numerator/denominator)], therefore a higher score represents the proportion of patients for whom antibiotics were not prescribed) better quality = higher score
Algorithm	Episode Date is defined as the date of service for any outpatient or ED visit (Table 3) during the Intake Period with only a diagnosis of URI (Table 2). Step 1 Determine the eligible population. To do so, identify all patients who had an outpatient or ED visit (Table 3) with only a diagnosis of URI (Table 2) during the Intake Period. Exclude claims/encounters with more than one diagnosis. Step 2 Determine all URI Episode Dates during the intake period. For each patient identified in step 1, determine all outpatient or ED claims/encounters with a URI diagnosis. Step 3 Test for Negative Medication History. Exclude Episode Dates where a new or refill prescription for an antibiotic medication (Table 1) was filled 30 days prior to the Episode Date or was active on the Episode Date. Step 4 Test for Negative Competing Diagnosis. Exclude Episode Dates where the patient had a claim/encounter with a competing diagnosis (Table 4) on or three days after the Episode Date. Step 5 Calculate continuous enrollment. The patient must be continuously enrolled without a gap in coverage from 30 days prior to the Episode Date through 3 days after the Episode Date. Step 6 Determine the number of patients in the eligible population who were dispensed a prescription for an antibiotic medication on or three days after the earliest episode start date. Step 7 Calculate a rate (number of patients receiving an antibiotic/denominator) Step 8 Subtract the rate calculated in Step 7 from 1 to invert the measure result to represent appropriate treatment of children with URI (i.e. antibiotic not prescribed) The measure is reported as an inverted rate (i.e. 1- numerator/denominator) to reflect the number of children that were not dispensed an antibiotic.
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	0395 Paired Measure: Hepatitis C ribonucleic acid (RNA) testing before initiating treatment (paired with 0396)
Status	Maintenance, Original Endorsement: Jul 31, 2008, Most Recent Endorsement: Jul 31, 2008 Time-limited
Steward	American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI) Other organizations: American Association for the Study of Liver Diseases, American Gastroenterological Association Institute
Description	Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom quantitative HCV RNA testing was performed within 6 months prior to initiation of antiviral treatment
Type	Process
Data Source	Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Registry Not Applicable Attachment AMA-PCPI_0395_RNA_Testing_Before_Treatment_7.11.12.pdf
Level	Clinician : Group/Practice, Clinician : Individual, Clinician : Team
Setting	Ambulatory Care : Clinician Office/Clinic, Other, Ambulatory Care : Urgent Care Hospital Outpatient Clinic
Numerator Statement	Patients for whom quantitative HCV RNA testing was performed within 6 months prior to the initiation of antiviral treatment
Numerator Details	Time Window: Once within 6 months prior to initiation of antiviral treatment EHR Specifications: eSpecifications attached
Denominator Statement	All patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment
Denominator Details	Time Window: 12 consecutive months EHR Specifications: eSpecifications attached
Exclusions	Documentation of medical reason(s) for not performing quantitative HCV RNA testing within 6 months prior to the initiation of treatment
Exclusion details	The PCPI exception methodology uses three categories of reasons for which a patient may be removed from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For this measure, exceptions may include medical reason(s) for not performing quantitative HCV RNA testing within 6 months prior to the initiation of treatment. Where examples of exceptions are included in the measure language, value sets for these examples are developed and included in the eSpecifications. Although this methodology does not require the external reporting of more detailed exception data, the PCPI recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The PCPI also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement. Additional details by data source are as follows: EHR Specifications: eSpecifications attached

	0395 Paired Measure: Hepatitis C ribonucleic acid (RNA) testing before initiating treatment (paired with 0396)
Risk Adjustment	No risk adjustment or risk stratification None
Stratification	We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.
Type Score	Rate/proportion better quality = higher score
Algorithm	To calculate performance rates: 1) Find the patients who meet the initial patient population (i.e., the general group of patients that a set of performance measures is designed to address). 2) From the patients within the initial patient population criteria, find the patients who qualify for the denominator (i.e., the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial patient population and denominator are identical. 3) From the patients within the denominator, find the patients who qualify for the Numerator (i.e., the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator 4) From the patients who did not meet the numerator criteria, determine if the physician has documented that the patient meets any criteria for denominator when exceptions have been specified [for this measure: medical reason(s)]. If the patient meets any exception criteria, they should be removed from the denominator for performance calculation. --Although the exception cases are removed from the denominator population for the performance calculation, the exception rate (i.e., percentage with valid exceptions) should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI. If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure. Calculation algorithm is included in data dictionary/code table attachment 2a1.30.

	0395 Paired Measure: Hepatitis C ribonucleic acid (RNA) testing before initiating treatment (paired with 0396)
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	0396 Paired Measure: HCV genotype testing prior to treatment (paired with 0395)
Status	Maintenance, Original Endorsement: Jul 31, 2008, Most Recent Endorsement: Jul 31, 2008 Time-limited
Steward	American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI) Other organizations: American Association for the Study of Liver Diseases, American Gastroenterological Association Institute
Description	Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom HCV genotype testing was performed prior to initiation of antiviral treatment
Type	Process
Data Source	Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Registry Not Applicable Attachment AMA-PCPI_0396_Genotype_Test_Prior_to_Treatment_7.11.12.pdf
Level	Clinician : Group/Practice, Clinician : Individual, Clinician : Team
Setting	Ambulatory Care : Clinician Office/Clinic, Other, Ambulatory Care : Urgent Care Hospital Outpatient Clinic
Numerator Statement	Patients for whom HCV genotype testing was performed prior to initiation of antiviral treatment

	0396 Paired Measure: HCV genotype testing prior to treatment (paired with 0395)
Numerator Details	Time Window: Once prior to initiation of antiviral treatment EHR Specifications: eSpecifications attached
Denominator Statement	All patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment
Denominator Details	Time Window: 12 consecutive months EHR Specifications: eSpecifications attached
Exclusions	None
Exclusion details	Not applicable
Risk Adjustment	No risk adjustment or risk stratification None
Stratification	We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.
Type Score	Rate/proportion better quality = higher score
Algorithm	To calculate performance rates: 1) Find the patients who meet the initial patient population (i.e., the general group of patients that a set of performance measures is designed to address). 2) From the patients within the initial patient population criteria, find the patients who qualify for the denominator (i.e., the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial patient population and denominator are identical. 3) From the patients within the denominator, find the patients who qualify for the Numerator (i.e., the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator If the patient does not meet the numerator, this case represents a quality failure. Calculation algorithm is included in data dictionary/code table attachment (2a1.30).

	0396 Paired Measure: HCV genotype testing prior to treatment (paired with 0395)
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	0398 Hepatitis C: HCV RNA testing at no greater than week 12 of treatment
Status	Maintenance, Original Endorsement: Jul 31, 2008, Most Recent Endorsement: Jul 31, 2008 Time-limited
Steward	American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI)
Description	Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom quantitative HCV RNA testing was performed at no greater than 12 weeks from initiation of antiviral treatment
Type	Process
Data Source	Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Registry Not Applicable Attachment AMA-PCPI_0398_Testing_Week_12_7.11.12.pdf
Level	Clinician : Group/Practice, Clinician : Individual, Clinician : Team
Setting	Ambulatory Care : Clinician Office/Clinic, Other, Ambulatory Care : Urgent Care Hospital Outpatient Clinic
Numerator Statement	Patients for whom quantitative HCV RNA testing was performed at no greater than 12 weeks from the initiation of antiviral treatment

	0398 Hepatitis C: HCV RNA testing at no greater than week 12 of treatment
Numerator Details	Time Window: Once within 4-12 weeks after initiation of antiviral treatment Definition: 12 Weeks from Initiation – Patients for whom testing was performed between 4-12 weeks from the initiation of antiviral treatment will meet the numerator for this measure (depending upon the specific antiviral therapy used). EHR Specifications: eSpecifications attached
Denominator Statement	All patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment
Denominator Details	Time Window: 12 consecutive months EHR Specifications: eSpecifications attached
Exclusions	Documentation of medical reason(s) for not performing quantitative HCV RNA testing at no greater than 12 weeks from the initiation of antiviral treatment Documentation of patient reason(s) for not performing quantitative HCV RNA testing at no greater than 12 weeks from the initiation of antiviral treatment

	0399 Paired Measure: Hepatitis C: Hepatitis A vaccination (paired with 0400)
Status	Maintenance, Original Endorsement: Jul 31, 2008, Most Recent Endorsement: Jul 31, 2008 Time-limited
Steward	American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI) Other organizations: American Association for the Study of Liver Diseases, American Gastroenterological Association Institute
Description	Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who have received at least one injection of hepatitis A vaccine, or who have documented immunity to hepatitis A
Type	Process
Data Source	Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Registry Not Applicable
Level	Clinician : Group/Practice, Clinician : Individual, Clinician : Team
Setting	Ambulatory Care : Clinician Office/Clinic, Other, Ambulatory Care : Urgent Care Hospital Outpatient Clinic
Numerator Statement	Patients who have received at least one injection of hepatitis A vaccine, or who have documented immunity to Hepatitis A
Numerator Details	Time Window: Once during the measurement period Definition: *Received includes documentation that a patient received at least one injection of hepatitis A vaccine from another provider EHR Specifications: eMeasure developed – see attached
Denominator Statement	All patients aged 18 years and older with a diagnosis of hepatitis C

	0399 Paired Measure: Hepatitis C: Hepatitis A vaccination (paired with 0400)
Denominator Details	Time Window: 12 consecutive months EHR Specifications: eMeasure developed – see attached
Exclusions	Documentation of medical reason(s) for not receiving at least one injection of hepatitis A vaccine Documentation of patient reason(s) for not receiving at least one injection of hepatitis A vaccine
Exclusion Details	The PCPI exception methodology uses three categories of reasons for which a patient may be removed from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For this measure, exceptions may include medical reason(s) or patient reason(s) for not receiving at least one injection of hepatitis A vaccine. Where examples of exceptions are included in the measure language, value sets for these examples are developed and included in the eSpecifications. Although this methodology does not require the external reporting of more detailed exception data, the PCPI recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The PCPI also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement. Additional details by data source are as follows: EHR Specifications: eMeasure developed – see attached
Risk Adjustment	No risk adjustment or risk stratification None
Stratification	We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.
Type Score	Rate/proportion better quality = higher score

	0399 Paired Measure: Hepatitis C: Hepatitis A vaccination (paired with 0400)
Algorithm	To calculate performance rates: 1) Find the patients who meet the initial patient population (i.e., the general group of patients that a set of performance measures is designed to address). 2) From the patients within the initial patient population criteria, find the patients who qualify for the denominator (i.e., the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial patient population and denominator are identical. 3) From the patients within the denominator, find the patients who qualify for the Numerator (i.e., the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator 4) From the patients who did not meet the numerator criteria, determine if the physician has documented that the patient meets any criteria for denominator when exceptions have been specified [for this measure: medical reason(s) or patient reason(s)]. If the patient meets any exception criteria, they should be removed from the denominator for performance calculation. --Although the exception cases are removed from the denominator population for the performance calculation, the exception rate (i.e., percentage with valid exceptions) should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI. If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure. Calculation algorithm is included in e-measure which was emailed to NQF staff.
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	0393 Hepatitis C: Testing for chronic hepatitis C-Confirmation of hepatitis C viremia
Status	Maintenance, Original Endorsement: Jul 31, 2008, Most Recent Endorsement: Jul 13, 2008
Steward	American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI) Other organizations: American Association for the Study of Liver Diseases, American Gastroenterological Association Institute
Description	Percentage of patients aged 18 years and older with a diagnosis of hepatitis C seen for an initial evaluation who had HCV RNA testing ordered or previously performed
Type	Process
Data Source	Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Registry Not Applicable Attachment AMA-PCPI_0393_Confirmation_HepC_Viremia_7.11.12.pdf
Level	Clinician : Group/Practice, Clinician : Individual, Clinician : Team
Setting	Ambulatory Care : Clinician Office/Clinic, Other, Ambulatory Care : Urgent Care Hospital Outpatient Clinic
Numerator Statement	Patients for whom HCV RNA testing was ordered or previously performed
Numerator Details	Time Window: Once, at time of diagnosis EHR Specifications: eSpecifications attached
Denominator Statement	All patients aged 18 years and older with a diagnosis of hepatitis C seen for initial evaluation
Denominator Details	Time Window: 12 consecutive months EHR Specifications: eSpecifications attached
Exclusions	Documentation of medical reason(s) for not ordering or performing HCV RNA testing
Exclusion Details	The PCPI exception methodology uses three categories of reasons for which a patient may be removed from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are sometimes provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For this measure, exceptions may include medical reason(s) and patient reason(s) for not ordering or performing HCV RNA testing. Where examples of exceptions are included in the measure language, value sets for these examples are developed and included in the eSpecifications. Although this methodology does not require the external reporting of more detailed exception data, the PCPI recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The PCPI also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement. Additional details by data source are as follows: EHR Specifications: eSpecifications attached
Risk Adjustment	No risk adjustment or risk stratification None
Stratification	We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.
Type Score	Rate/proportion better quality = higher score

	0393 Hepatitis C: Testing for chronic hepatitis C-Confirmation of hepatitis C viremia
Algorithm	To calculate performance rates: 1) Find the patients who meet the initial patient population (ie, the general group of patients that a set of performance measures is designed to address). 2) From the patients within the initial patient population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial patient population and denominator are identical. 3) From the patients within the denominator, find the patients who qualify for the Numerator (ie, the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator 4) From the patients who did not meet the numerator criteria, determine if the physician has documented that the patient meets any criteria for denominator when exceptions have been specified [for this measure: medical reason(s) patient reason(s)]. If the patient meets any exception criteria, they should be removed from the denominator for performance calculation. -- Although the exception cases are removed from the denominator population for the performance calculation, the exception rate (ie, percentage with valid exceptions) should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI. If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure. Calculation algorithm is included in data dictionary/code table attachment 2a1.30.
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	0404 HIV/AIDS: CD4 Cell Count or Percentage Performed
Status	Maintenance, Original Endorsement: Jul 31, 2008, Most Recent Endorsement: Jul 31, 2008 Time-limited
Steward	National Committee for Quality Assurance Other organizations: Physician Performance Measures (Measures) and related data specifications have been developed by the American Medical Association (AMA) in collaboration with the Physician Consortium for Performance Improvement™ (the Consortium) and the National Committee for Quality Assurance (NCQA). The Health Resources and Services Administration (HRSA) and the Infectious Diseases Society of America also participated in the development of this measure.
Description	Percentage of patients aged six months and older with a diagnosis of HIV/AIDS, with at least two CD4 cell counts or percentages performed during the measurement year at least 3 months apart
Type	Process
Data Source	Electronic Clinical Data : Electronic Health Record N/A
Level	Clinician : Group/Practice, Clinician : Individual
Setting	Ambulatory Care : Clinician Office/Clinic
Numerator Statement	Patients with at least two CD4 cell counts or percentages performed during the measurement year at least 3 months apart
Numerator Details	Time Window: 12-month measurement period The medical record must include the date of the CD4 counts or percentages and the results or findings.
Denominator Statement	All patients aged 6 months and older with a diagnosis of HIV/AIDS, who had at least two medical visits during the measurement year, with at least 90 days between each visit
Denominator Details	Time Window: 12-month measurement year Definition of “Medical Visit” - any visit with a health care professional who provides routine primary care for the patient with HIV/AIDS (may be a primary care physician, ob/gyn, pediatrician or infectious diseases specialist)
Exclusions	None
Exclusion Details	N/A
Risk Adjustment	No risk adjustment or risk stratification N/A
Stratification	N/A
Type Score	Rate/proportion better quality = higher score
Algorithm	Measure Calculation For performance purposes, this measure is calculated by creating a fraction with the following components: Denominator, Numerator. Step 1: Determine the eligible population. The eligible population is all the patients, aged 6 months and older, with a diagnosis of HIV/AIDS. Step 2: Determine number of patients meeting the denominator criteria as specified in Section 2a1.7 above. Step 3: Determine the number of patients who meet the numerator criteria as specified in section 2a1.3 above. The numerator includes all patients in the denominator population who had a CD4 cell count or percentage performed at least once every 6 months. Step 4: Calculate the rate by dividing the total from Step 3 by the total from Step 2. Attachment PCPI_Sample_Calculation_Algorithm-634771031423103164.pdf

	0404 HIV/AIDS: CD4 Cell Count or Percentage Performed
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	0405 HIV/AIDS: Pneumocystis jiroveci pneumonia (PCP) prophylaxis
Status	Maintenance, Original Endorsement: Jul 31, 2008, Most Recent Endorsement: Jul 31, 2008 Time-limited
Steward	National Committee for Quality Assurance Other organizations: Physician Performance Measures (Measures) and related data specifications have been developed by the American Medical Association (AMA) in collaboration with the Physician Consortium for Performance Improvement™ (the Consortium) and the National Committee for Quality Assurance (NCQA). The Health Resources and Services Administration (HRSA) and the Infectious Diseases Society of America also participated in the development of this measure.
Description	Percentage of patients aged 6 weeks or older with a diagnosis of HIV/AIDS, who were prescribed Pneumocystis jiroveci pneumonia (PCP) prophylaxis
Type	Process
Data Source	Electronic Clinical Data : Electronic Health Record N/A
Level	Clinician : Group/Practice, Clinician : Individual
Setting	Ambulatory Care : Clinician Office/Clinic
Numerator Statement	Numerator 1: Patients who were prescribed Pneumocystis jiroveci pneumonia (PCP) prophylaxis within 3 months of CD4 count below 200 cells/mm3 Numerator 2: Patients who were prescribed Pneumocystis jiroveci pneumonia (PCP) prophylaxis within 3 months of CD4 count below 500 cells/mm3 or a CD4 percentage below 15% Numerator 3: Patients who were prescribed Pneumocystis jiroveci pneumonia (PCP) prophylaxis at the time of HIV diagnosis Report a rate for each numerator (e.g., Numerator 1/Denominator 1, etc.) and a total rate (Total Numerator/Total Denominator)
Numerator Details	Time Window: 12-month measurement period
Denominator Statement	Denominator 1. All patients aged 6 years and older with a diagnosis of HIV/AIDS and a CD4 count below 200 cells/mm3, who had at least two visits during the measurement year, with at least 90 days in between each visit; and, Denominator 2. All patients aged 1 through 5 years of age with a diagnosis of HIV/AIDS and a CD4 count below 500 cells/mm3 or a CD4 percentage below 15%, who had at least two visits during the measurement year, with at least 90 days in between each visit; and, Denominator 3. All patients aged 6 weeks through 12 months with a diagnosis of HIV, who had at least two visits during the measurement year, with at least 90 days in between each visit Total denominator: The sum of the three denominators
Denominator Details	Time Window: 12-month measurement period Definition of “Medical Visit” - any visit with a health care professional who provides routine primary care for the patient with HIV/AIDS (may be a primary care physician, ob/gyn, pediatrician or infectious diseases specialist)
Exclusions	Denominator 1 Exclusion: Patient did not receive PCP prophylaxis because there was a CD4 count above 200 cells/mm3 during the three months after a CD4 count below 200 cells/mm3 Denominator 2 Exclusion: Patient did not receive PCP prophylaxis because there was a CD4 count above 500 cells/mm3 or CD4 percentage above 15% during the three months after a CD4 count below 500 cells/mm3 or CD4 percentage below 15%
Exclusion Details	

	0405 HIV/AIDS: Pneumocystis jiroveci pneumonia (PCP) prophylaxis
Risk Adjustment	No risk adjustment or risk stratification N/A
Stratification	N/A
Type Score	Rate/proportion better quality = higher score
Algorithm	Measure Calculation For performance purposes, this measure is calculated by creating a fraction with the following components: Denominator, Numerator, Exclusions. Step 1: Determine the eligible population. The eligible population is all patients, aged 6 weeks and older, with a diagnosis of HIV/AIDS. Step 2: Determine number of patients meeting the denominator criteria as specified in Section 2a1.7 above. Step 3: Determine the number of patients who meet the numerator criteria as specified in Section 2a1.3 above. Step 4: Test for patients with valid exceptions from Step 3. Step 5: Calculate the rate by dividing the total from Step 4 by the total from Step 2. Attachment PCPI_Sample_Calculation_Algorithm-634770923023240700.pdf
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	0408 HIV/AIDS: Tuberculosis (TB) screening
Status	Maintenance, Original Endorsement: Jul 31, 2008, Most Recent Endorsement: Jul 31, 2008 Time-limited
Steward	National Committee for Quality Assurance Other organizations: Physician Performance Measures (Measures) and related data specifications have been developed by the American Medical Association (AMA) in collaboration with the Physician Consortium for Performance Improvement™ (the Consortium) and the National Committee for Quality Assurance (NCQA). The Health Resources and Services Administration (HRSA) and the Infectious Diseases Society of America also participated in the development of this measure.

	0408 HIV/AIDS: Tuberculosis (TB) screening
Description	Percentage of patients aged 3 months and older with a diagnosis of HIV/AIDS, for whom there was documentation that a tuberculosis (TB) screening test was performed and results interpreted (for tuberculin skin tests) at least once since the diagnosis of HI
Type	Process
Data Source	Electronic Clinical Data : Electronic Health Record N/A
Level	Clinician : Group/Practice, Clinician : Individual
Setting	Ambulatory Care : Clinician Office/Clinic
Numerator Statement	Patients for whom there was documentation that a tuberculosis (TB) screening test was performed and results interpreted (for tuberculin skin tests) at least once since the diagnosis of HIV infection. NOTE: Results from the tuberculin skin test must be interpreted by a healthcare professional.
Numerator Details	Time Window: Since diagnosis of HIV infection
Denominator Statement	All patients aged 3 months and older with a diagnosis of HIV/AIDS, who had at least two visits during the measurement year, with at least 90 days in between each visit
Denominator Details	Time Window: 12-month measurement period Definition of "Medical Visit" - any visit with a health care professional who provides routine primary care for the patient with HIV/AIDS (may be a primary care physician, ob/gyn, pediatrician or infectious diseases specialist)
Exclusions	Documentation of Medical Reason for not performing a tuberculosis (TB) screening test (e.g., patients with a history of positive PPD or treatment for TB)
Exclusion Details	
Risk Adjustment	No risk adjustment or risk stratification N/A
Stratification	N/A
Type Score	Rate/proportion better quality = higher score
Algorithm	Measure Calculation For performance purposes, this measure is calculated by creating a fraction with the following components: Denominator, Numerator, Exclusions. Step 1: Determine the eligible population. The eligible population is all patients, aged 3 months and older, with a diagnosis of HIV/AIDS. Step 2: Determine number of patients meeting the denominator criteria as specified in Section 2a1.7 above. Step 3: Determine the number of patients who meet the numerator criteria as specified in Section 2a1.3. The numerator includes all patients in the denominator population who had a TB screening test performed. Step 4: Test for patients with valid exclusions from Step 3. Step 5: Calculate the rate by dividing the total from Step 4 by the total from Step 2. Attachment PCPI_Sample_Calculation_Algorithm-634768432553834044.pdf

	0408 HIV/AIDS: Tuberculosis (TB) screening
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	0409 HIV/AIDS: Sexually transmitted diseases – Screening for chlamydia, gonorrhea, and syphilis
Status	Maintenance, Original Endorsement: Jul 31, 2008, Most Recent Endorsement: Jul 31, 2008 Time-limited
Steward	National Committee for Quality Assurance Other organizations: Physician Performance Measures (Measures) and related data specifications have been developed by the American Medical Association (AMA) in collaboration with the Physician Consortium for Performance Improvement™ (the Consortium) and the National Committee for Quality Assurance (NCQA). The Health Resources and Services Administration (HRSA) and the Infectious Diseases Society of America also participated in the development of this measure.
Description	Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS, who have received chlamydia, gonorrhea, and syphilis screenings at least once since the diagnosis of HIV infection
Type	Process
Data Source	Electronic Clinical Data : Electronic Health Record N/A
Level	Clinician : Group/Practice, Clinician : Individual
Setting	Ambulatory Care : Clinician Office/Clinic
Numerator Statement	Patients who have received chlamydia, gonorrhea, and syphilis screenings at least once since the diagnosis of HIV infection
Numerator Details	Time Window: Since diagnosis of HIV infection
Denominator Statement	All patients aged 13 years and older with a diagnosis of HIV/AIDS, who had at least two visits during the measurement year, with at least 90 days between visits

	0409 HIV/AIDS: Sexually transmitted diseases – Screening for chlamydia, gonorrhea, and syphilis
Denominator Details	Time Window: 12-month measurement period Definition of "Medical Visit" - any visit with a health care professional who provides routine primary care for the patient with HIV/AIDS (may be a primary care physician, ob/gyn, pediatrician or infectious diseases specialist)
Exclusions	None
Exclusion Details	N/A
Risk Adjustment	No risk adjustment or risk stratification N/A
Stratification	N/A
Type Score	Rate/proportion better quality = higher score
Algorithm	Measure Calculation For performance purposes, this measure is calculated by creating a fraction with the following components: Denominator, Numerator. Step 1: Determine the eligible population. The eligible population is all the patients, aged 13 years and older, with a diagnosis of HIV/AIDS. Step 2: Determine number of patients meeting the denominator criteria as specified in Section 2a1.7 above. Step 3: Determine the number of patients who meet the numerator criteria as specified in section 2a1.3 above. The numerator includes all patients in the denominator population who have received chlamydia, gonorrhea, and syphilis screenings at least once since the diagnosis of HIV/AIDS. Step 4: Calculate the rate by dividing the total from Step 3 by the total from Step 2. Attachment PCPI_Sample_Calculation_Algorithm.pdf
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	0500 Severe sepsis and septic shock: Management bundle
Status	Maintenance, Original Endorsement: Oct 24, 2008, Most Recent Endorsement: Oct 24, 2008 Time-limited
Steward	Henry Ford Hospital Other organizations: Henry Ford Hospital System(HFHS) California Pacific Medical Center/Sutter Health (CPMC) Society of Critical Care Medicine (SCCM) Infectious Diseases Society of America (IDSA) Institute for Healthcare Improvement (IHI) Surviving Sepsis Campaign (SSC) Ohio State University (OSU)
Description	This measure will focus on patients aged 18 years and older who present with symptoms of severe sepsis or septic shock. These patients will be eligible for the 3 hour (severe sepsis) and/or 6 hour (septic shock) early management bundle.
Type	Composite
Data Source	Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Paper Medical Records, Electronic Clinical Data : Registry Surviving Sepsis Campaign Electronic Database: http://www.survivingsepsis.org/manual_database/Pages/default.aspx Paper Tools: http://www.survivingsepsis.org/About_the_Campaign/Documents/monthlymeasurementworksheet.pdf http://www.survivingsepsis.org/About_the_Campaign/Documents/individualchartmeasurementtool.pdf URL http://www.survivingsepsis.org/manual_database/Pages/default.aspx URL http://www.survivingsepsis.org/About_the_Campaign/Documents/le_field_descriptions_and_coding_information.pdf
Level	Facility, Integrated Delivery System
Setting	Hospital/Acute Care Facility

	0500 Severe sepsis and septic shock: Management bundle
Numerator Statement	If: A. measure lactate level B. obtain blood cultures prior to antibiotics C. administer broad spectrum antibiotics D. administer 30 ml/kg crystalloid for hypotension or lactate >=4 mmol/L E. apply vasopressors (for hypotension that does not respond to initial fluid resuscitation to maintain a mean areterial pressure >= 65) F. In the event of persistent arterial hypotension despite volume resuscitation (septic shock) or initial lactate >=4 mmol/L (36 mg/dl) measure central venous pressure and central venous oxygen saturation G. remeasure lactate if initial lactate is elevated represent processes of care: Numerator statement: Patients from the denominator who received all the following: A, B, and C within 3 hours of time of presentation† AND IF septic shock is present (as either defined as hypotension* or lactate >=4 mmol/L) who also received D and E and F and G within 6 hours of time of presentation. † "time of presentation" is defined as the time of triage in the Emergency Department or, if presenting from another care venue, from the earliest chart annotation consistent with all elements severe sepsis or septic shock ascertained through chart review. * "hypotension" is defined as systolic blood pressure (SBP) <90 mm Hg or mean arterial pressure (MAP) <70 mm Hg or a SBP decrease >40 mm Hg or <2 SD below normal for age or known baseline.
Numerator Details	Time Window: Bundle elements should be *completed* in the times outlined in the numerator statement, however patients are *eligible* for inclusion in the numerator if diagnosed with severe sepsis or septic shock at anytime during their hospitalization. Following the scheme outlined in 2a1.1 "A" requires a response of "yes" to the question: "Was a lactate level obtained within 3 hours of time of presentation?" "B" requires a response of "yes" to the question: "Were blood cultures obtained prior to antibiotic administration and within 3 hours of time of presentation?" "C" requires a response of "yes" to the question: "Were broad spectrum antibiotics administered within 3 hours of the time of presentation?" "Septic Shock" requires a response of "yes" to the question: "Was either hypotension (defined as SBP < 90 or MAP < 65 or decrease in SBP 30 mmHg from baseline) OR lactate >=4 mmol/L present in the first 6 hour of the time of presentation?" "D" requires a response of "yes" or "not applicable" to the question: "Were 30ml/kg of crystalloid administered for hypotension or lactate >= 4 mmol/L within 6 hours of the time of presentation?" "E" requires a response of "yes" or "not applicable" to the question: "Were vasopressors applied within 6 hours of the time of presentation for hypotension that did not respond to initial fluid resuscitation to maintain a mean arterial pressure >= 65 mmHg?" "F" requires a response of "yes" or "not applicable" to the question: "Were central venous pressure (CVP) and central venous oxygen saturation (ScVO2) measured within 6 hours of presentation in the event of hypotension despite volume resuscitation or initial lactate >= 4 mmol/L (36 mg/dl)?" "G" requires a response of "yes" or "not applicable" to the question: "Was serum lactate re-measured if initially elevated within 6 hours of presentation."

	0500 Severe sepsis and septic shock: Management bundle
Denominator Statement	Number of patients presenting with severe sepsis or septic shock.
Denominator Details	Time Window: Patients are eligible for inclusion in the denominator for each episode of severe sepsis or septic shock during a hospitalization from emergency room presentation though discharge. The collection period for each increment of data reporting is monthly. The denominator may be derived by a) prospective real-time screening of all patients presenting for care to the facility, or b) retrospective screening through chart review of all patients presenting to the medical facility, or c) both methods. In each case the clinical diagnostic criteria for severe sepsis or septic shock as outlined below are applied to the population initially identified. The clinical criteria that must be applied in either instance do not vary whether prospective or retrospective data collection is employed. SEVERE SEPSIS: Severe sepsis is defined as a suspected source of clinical infection, 2 or more manifestations of systemic infection (SIRS criteria) and the presence of sepsis-induced organ dysfunction. SIRS criteria include: Temperature >38.3 C or <36.0 C, Heart rate >90 beats per minute, Respiration > 20 breaths/min, White blood cell count >12,000 or <4000/mm3, or >10% bandemia. Organ dysfunction variables include: (SBP)<90 mm Hg or mean arterial pressure <70 mm Hg or a SBP decrease >40 mm Hg or <2 SD below normal for age or known baseline, Creatinine > 2.0 mg/dl (176.8 mmol/L) or Urine Output < 0.5 ml/kg/hour for > 2 hours, Bilirubin > 2 mg/dl (34.2 mmol/L), Platelet count < 100,000, Coagulopathy (INR >1.5 or aPTT >60 secs), Lactate > 2 mmol/L (18.0 mg/dl). SEPTIC SHOCK: Septic shock requires the presence of severe sepsis as above AND as sepsis-induced hypoperfusion persisting despite adequate fluid resuscitation OR lactate > 4 mmol/L. Sepsis induced tissue hypoperfusion is present with (SBP)<90 mm Hg or mean arterial pressure <70 mm Hg or a SBP decrease >40 mm Hg or <2 SD below normal for age or known baseline. If clinical coding documentation is used to derive the denominator in a retrospective collection effort, the codes that should be applied include: ICD9 DX: a) 0031: SALMONELLA SEPTICEMIA b) 0362: MENINGOCOCCEMIA c) 0380: STREPTOCOCCAL SEPTICEMIA d) 03810: STAPH SEPTICEMIA NOS e) 03811: MSSA SEPTICEMIA f) 03812: MRSA SEPTICEMIA g) 03819: STAPH SEPTICEMIA NEC h) 0382: PNEUMOCOCCAL SEPTICEMIA i) 0383: ANAEROBIC SEPTICEMIA j) 03840: GRAM-NEG SEPTICEMIA NOS k) 03841: H. INFLUENZAE SEPTICEMIA l) 03842: E. COLI SEPTICEMIA m) 03843: PSEUDOMONAS SEPTICEMIA n) 03844: SERRATIA SEPTICEMIA o) 03849: GRAM-NEG SEPTICEMIA NEC p) 0388: SEPTICEMIA NEC

	0500 Severe sepsis and septic shock: Management bundle
	q) 0389: SEPTICEMIA NOS r) 78552: SEPTIC SHOCK s) 99591: SEPSIS t) 99592: SEVERE SEPSIS
Exclusions	A) Patients with advanced directives for comfort care are excluded. B) Clinical conditions that preclude total measure completion should be excluded (e.g. mortality within the first 6 hours of presentation as defined above in 2a1.1). C) Patients for whom a central line is clinically contraindicated (e.g. coagulopathy that cannot be corrected, inadequate internal jugular or subclavian central venous access due to repeated cannulations). D) Patients for whom a central line was attempted but could not be successfully inserted. E) Patient or surrogate decision maker declined or is unwilling to consent to such therapies or central line placement. F) Patients transferred to an acute care facility from another acute care facility.
Exclusion Details	The exclusion details described in 2a1.8 must be ascertained by chart review. No specific definitions are required to discover this information from standard chart annotation.
Risk Adjustment	No risk adjustment or risk stratification None
Stratification	Henry Ford Hospital (HFH) encourages the results of this measure to be stratified by race, ethnicity, gender, and primary language, illness severity and have included these variables as recommended data elements to be collected.
Type Score	Non-weighted score/composite/scale better quality = higher score
Algorithm	The data calculations may be performed in one of two ways. The Surviving Sepsis Campaign Database available at SurvivingSepsis.org automatically performs all calculations if data is entered into the required fields. However, hospitals are not restricted to use of the database to perform the required calculations. Two paper tools described below capture the logic. The two tools, URLs provided in 2a1.26.1, ("Individual Chart Measurement Tool" [ICMT], and "Monthly Measurement Worksheet" [MMW]) govern the calculation of the elements of the "all or nothing" composite measure. The tools, in fact, exceed the information required for calculation of the composite measure extending care to variables beyond the scope of this submission (e.g. care patterns for the first 24 hours of care such as the application of steroids or glucose control; calculation of individual component measures not requested for endorsement at this time). They are provided as a clear, yet highly detailed, statement of the logic. To simplify matters, the algorithm will be described in plain language here: 1. Find the patients who meet the initial patient population (ie, the general group of patients that the performance measure is designed to address). This is accomplished as described in 2a1.7 either through prospective, retrospective or both forms of data screening. Codes and criteria are specified in 2a1.7. 2. From the patients within the initial patient population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria). All exclusions identified by chart review in 2a1.8 will not, by definition, qualify for the denominator. Note: in some cases the initial patient population and denominator are identical. 3. From the patients within the denominator less those excluded, find the patients who qualify for the Numerator (ie, the group of patients in the denominator for whom a process or outcome of care occurs). The individual component elements of the composite indicator (eg,

lactate collected, blood cultures obtained, etc.) will be found on each instance of the ICMT (one per patient chart reviewed). Each month, all ICMT's will be gathered and tabulated to generate the composite numerator using the MMW. In this way the MMW consolidates all information gathered in each ICMT to create the composite numerator. For more detail, the steps are identified below:

a. The logic on the ICMT captures all necessary data to be abstracted from a single chart to inform the numerator.

b. The "time of presentation" is captured as defined in 2a1.1 in question 3 of the ICMT.

c. Collection of lactate is determined and timed in question 4 of the ICMT.

d. Administration of broad spectrum antibiotics and timing are captured in question 5 of the ICMT.

e. Collection of blood cultures and timing is captured in question 6 of the ICMT.

f. Next, required determinations to inform the conditional elements in the composite measure are made. Specifically, since component elements "D, E, F, G" defined in 2a1.1 above are dependent on the presence of septic shock, the shock state is documented in question 7 of the ICMT.

i. If the patient has shock documentation of the administration of fluids is captured in question 7c of the ICMT.

ii. If the patient has shock documentation of the application of vasopressors is captured in question 7e of the ICMT.

iii. If the patient has shock documentation of the assessment of CVP and timing is captured in question 8 of the ICMT.

iv. If the patient has shock documention of the assessment of ScVO2 and timing is captured in question 9 of the ICMT.

g. If shock is not present, credit is assigned for the dependent elements "D, E, F, G" and documented on line 16 of the ICMT.

h. The tally of affirmative responses (or where credit has been assigned) to the individual component measures on a per chart basis is recorded by placing a mark in the designated boxes in line 16 of the ICMT.

i. Note: questions 10-15 on the ICMT do not apply to the composite measure under submission here.

j. Once monthly the MMW will be employed to tabulate all of the line 16 scores on the ICMT to generate the composite numerator for the month.

i. While the MMW is designed to report out the component measures as individual quality indicators, this is not required for the composite measure under consideration. Thus, questions 1 to 12 on the MMW are not necessary in this instance.

ii. Question 13 on the MMW generates the monthly "all or nothing" numerator by requiring that ALL boxes on line 16 of each ICMT be marked complete.

iii. If a single box on line 16 of the ICMT is not completed, then the "all or nothing" criterion is not met and the individual chart is not included in the numerator. This represents a quality failure.

iv. Questions 14 and 15 also do not apply to the composite measure under consideration here.

4. Although the exclusion cases are removed from the denominator population for the performance calculation, the number of patients with valid exclusions should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI. URL http://www.survivingsepsis.org/About_the_Campaign/Documents/individualchartmeasurementtool.pdf AND

	0500 Severe sepsis and septic shock: Management bundle
	http://www.survivingsepsis.org/About_the_Campaign/Documents/monthlymeasurementworksheet.pdf
Copyright/ Disclaimer	Performance measures and related data specifications developed by the Henry Ford Hospital in collaboration with representatives from emergency medicine, critical care medicine (SCCM), and infectious diseases (IDSA). These performance measures are not clinical guidelines and do not establish a standard of medical care, and have not been tested for all potential applications. Neither the Henry Ford Hospital nor its affiliates or ageents shall be responsible for any use of the measures.

	2079 HIV medical visit frequency
Status	New Submission Time-limited
Steward	Health Resources and Services Administration - HIV/AIDS Bureau Other organizations: The Center For Disease Control and Prevention
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	Electronic Clinical Data: Electronic Health Record, Paper Medical Records Not applicable. Attachment Medical_visit_frequency_data_dictionary.pdf
Level	Facility, Clinician : Group/Practice
Setting	Ambulatory Care : 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 medical visit in the subsequent 6-month period. (Measurement period is a consecutive 24-month period of time.)
Numerator Details	Time Window: The numerator time window is a consecutive 24-month period of time. 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	Time Window: Patients are eligible for inclusion in the denominator if they had a medical visit in the first 6 months of the 24-month measurement period. 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 du
Exclusions	Patients who died at any time during the 24-month measurement period.
Exclusion Details	Patients with a date of death during the measurement period.

	2079 HIV medical visit frequency
Risk Adjustment	No risk adjustment or risk stratification Not applicable
Stratification	Not applicable
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 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. Attachment Medical_Visit_Frequency_Measure_Logic_6-20-12.pdf
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	2080 Gap in HIV medical visits
Status	New Submission Time-limited
Steward	Health Resources and Services Administration-HIV/AIDS Bureau Other organizations: The Centers For Disease Control
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.
Type	Process
Data Source	Electronic Clinical Data: Electronic Health Record, Paper Medical Records Not applicable. Attachment Gap_measure_data_dictionary-634781990173517766.pdf
Level	Facility, Clinician : Group/Practice
Setting	Ambulatory Care : 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	Time Window: The numerator time window is the last 6 months of the measurement year. (The measurement year can be any consecutive 12-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.
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.)

	2080 Gap in HIV medical visits
Denominator Details	Time Window: Patients are eligible for inclusion in the denominator if they had a medical visit in the first 6 months of 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 without a date of death during the measurement year 3. Patients diagnosed with HIV during the fir
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 or risk stratification Not applicable
Stratification	Not applicable
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 measurement year. 3. Calculate the percentage by dividing the numerator population by the denominator population and multiply by 100. Attachment Gap_Measure_Logic_6-20-12.pdf
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	2082 HIV viral load suppression
Status	New Submission Time-limited
Steward	Health Resources and Services Administration - HIV/AIDS Bureau Other organizations: The Centers for Disease Control
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	Electronic Clinical Data: Electronic Health Record, Electronic Clinical Data: Laboratory, Paper Medical Records Not applicable. Attachment Viral_load_measure_data_dictionary.pdf
Level	Facility, Clinician : Group/Practice
Setting	Ambulatory Care : 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

	2082 HIV viral load suppression
Numerator Details	Time Window: The numerator time window is the measurement year. The measurement year can be any consecutive 12-month period. 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	Time Window: The denominator time window is the measurement year. The measurement year can be any consecutive 12-month period. 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
Exclusions	There are no patient exclusions.
Exclusion Details	There are no patient exclusions.
Risk Adjustment	No risk adjustment or risk stratification Not applicable
Stratification	Not applicable
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. Attachment Viral_Load_Suppression_Measure_Logic_6-20-12.pdf
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	2083 Prescription of HIV antiretroviral therapy
Status	New Submission Time-limited
Steward	Health Resources and Services Administration - HIV/AIDS Bureau Other organizations: The Centers for Disease Control
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 Clinical Data: Electronic Health Record, Paper Medical Records, Electronic Clinical Data: Pharmacy Not applicable. Attachment ART_measure_data_dictionary.pdf

	2083 Prescription of HIV antiretroviral therapy
Level	Population : Community, Population : County or City, Facility, Clinician : Group/Practice, Population : National, Population : Regional, Population : State
Setting	Ambulatory Care : Clinician Office/Clinic
Numerator Statement	Number of patients from the denominator prescribed HIV antiretroviral therapy during the measurement year.
Numerator Details	Time Window: The numerator time window is a measurement year. A measurement year is a consecutive 12-month period. To be included in the numerator, patients were prescribed HIV antiretroviral therapy during the measurement year. HIV antiretroviral therapy is described as any combination of HIV medications other than the regimens or components identified as not recommended at any time by the Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. Available at http://www.aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf. Section accessed [6/2/2012] [G-3, G-4; Table 8] and Panel on Antiretroviral Therapy and Medical Management of HIV-Infected Children. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. August 11, 2011; pp. 1-268. Available at http://aidsinfo.nih.gov/ContentFiles/lvguidelines/PediatricGuidelines.pdf. Accessed (6/4/2012) [page 50, Table 9].
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	Time Window: The numerator time window is a measurement year. A measurement year is a consecutive 12-month period. 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
Exclusions	There are no patient exclusions.
Exclusion Details	There are no patient exclusions.
Risk Adjustment	No risk adjustment or risk stratification Not applicable
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. Attachment HIV_Antiretroviral_Therapy_Measure_Logic_6-20-12.pdf
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Appendix B: Project Steering Committee and NQF Staff

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Appendix C: Measures Endorsed in Infectious Disease Since July 2008

NQF Number	Title	Steward
1746	Intrapartum antibiotic prophylaxis for group B streptococcus (GBS)	Massachusetts General Hospital
0431	Influenza vaccination coverage among healthcare personnel	Centers for Disease Control and Prevention
0039	Flu shots for adults ages 50 and over	National Committee for Quality Assurance
0040	Flu shot for older adults	National Committee for Quality Assurance
0041	Influenza immunization	American Medical Association - Physician Consortium for Performance Improvement
0149	Influenza vaccination	Centers for Medicare & Medicaid Services
0522	Influenza immunization received for current flu season (Home Health)	Centers for Medicare & Medicaid Services
0226	Influenza immunization in the ESRD population (Facility Level)	Kidney Care Quality Alliance
0227	Influenza immunization	American Medical Association - Physician Consortium for Performance Improvement
1659	Influenza immunization	Centers for Medicare & Medicaid Services
0038	Childhood immunization status	National Committee for Quality Assurance
0680	Percent of residents or patients who were assessed and appropriately given the seasonal influenza vaccine (Short-Stay)	Centers for Medicare & Medicaid Services
0681	Percent of residents assessed and appropriately given the seasonal influenza vaccine (Long-Stay)	Centers for Medicare & Medicaid Services
0635	Chronic liver disease - Hepatitis A vaccination	ActiveHealth Management
0475	Hepatitis B vaccine coverage among all live newborn infants prior to hospital or birthing facility discharge	Centers for Disease Control and Prevention
0033	Chlamydia screening in women	National Committee for Quality Assurance
1395	Chlamydia screening and follow up	National Committee for Quality Assurance
0573	HIV screening: Members at high risk of HIV	IMS Health

NQF Number	Title	Steward
1959	Human papillomavirus vaccine for female adolescents	National Committee for Quality Assurance
0304	Late sepsis or meningitis in very low birth weight (VLBW) neonates (risk-adjusted)	Vermont Oxford Network
1716	National Healthcare Safety Network (NHSN) facility-wide inpatient hospital-onset methicillin-resistant staphylococcus aureus (MRSA) bacteremia outcome measure	Centers for Disease Control and Prevention
1717	National Healthcare Safety Network (NHSN) facility-wide inpatient hospital-onset clostridium difficile infection (CDI) outcome measure	Centers for Disease Control and Prevention

Appendix D: Related and Competing Measures

Comparison of NQF #2079 and NQF #2080

	2079 HIV medical visit frequency	2080 Gap in HIV medical visits
Steward	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 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	Process
Data Source	Electronic Clinical Data : Electronic Health Record, Paper Medical Records	Electronic Clinical Data : Electronic Health Record, Paper Medical Records
Level	Clinician: Group/Practice, Facility	Clinician: Group/Practice, Facility
Setting	Ambulatory Care : Clinician Office/Clinic	Ambulatory Care : 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 medical visit in the subsequent 6-month period. (Measurement period is a consecutive 24-month period of time.)	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	**Time Window:** The numerator time window is a consecutive 24-month period of time. 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.	**Time Window:** The numerator time window is a consecutive 24-month period of time. 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.	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.

	2079 HIV medical visit frequency	2080 Gap in HIV medical visits
Denominator Details	**Time Window:** Patients are eligible for inclusion in the denominator if they had a medical visit in the first 6 months of the 24-month measurement period. 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	**Time Window:** Patients are eligible for inclusion in the denominator if they had a medical visit in the first 6 months of the 24-month measurement period. 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.	Patients who died at any time during the 24-month measurement period.
Exclusion Details	Patients with a date of death during the measurement period.	Patients with a date of death during the measurement period.
Risk Adjustment	No risk adjustment or risk stratification	No risk adjustment or risk stratification
Stratification	Not applicable	Not applicable
Type Score	Rate/proportion better quality = higher score	Rate/proportion better quality = higher score

	2079 HIV medical visit frequency	2080 Gap in HIV medical visits
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. Attachment Medical_Visit_Frequency_Measure_Logic_6-20-12.pdf	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. Attachment Medical_Visit_Frequency_Measure_Logic_6-20-12.pdf
Submission items	**5.1 Identified measures:** 0403 : HIV/AIDS: Medical Visit **5a.1 Are specs completely harmonized?** No **5a.2 If not completely harmonized, identify difference, rationale, impact:** We have used the most current and available set of the National Committee on Quality Assurance (NCQA) measure when we set out to draft this measure. We will continue to work closely with the NCQA to continue to harmonize the measures for the care and treatment of people living with HIV. **5b.1 If competing, why superior or rationale for additive value:** The National Committee on Quality Assurance (NCQA) stewards a related measure NQF 403 medical visits. We have discussed the NQF 403 measure with the NCQA as well as the measures that we are submitting for endorsement. We have used the most current and	**5.1 Identified measures:** 0403 : HIV/AIDS: Medical Visit **5a.1 Are specs completely harmonized?** No **5a.2 If not completely harmonized, identify difference, rationale, impact:** We have used the most current and available set of the National Committee on Quality Assurance (NCQA) measure when we set out to draft this measure. We will continue to work closely with the NCQA to continue to harmonize the measures for the care and treatment of people living with HIV. **5b.1 If competing, why superior or rationale for additive value:** The National Committee on Quality Assurance (NCQA) stewards a related measure NQF 403 medical visits. We have discussed the NQF 403 measure with the NCQA as well as the measures that we are submitting for endorsement. We have used the most current and

	2079 HIV medical visit frequency	2080 Gap in HIV medical visits
	available set of NCQA measure when we set out to draft this measure. We will continue to work closely with the NCQA to continue to harmonize the measures for the care and treatment of people living with HIV. The body of literature regarding retention in HIV medical care has grown significantly in recent years. Studies have examined retention from multiple perspectives in order to understand its impact on patient health outcomes. Short term retention is moderate, but declines over time (1, 2). Retention in medical care among people living with HIV is associated with a significantly greater mean increase in baseline CD4 count (3). Also, the same study suggested that mortality was higher among those with suboptimal retention (3). Examining retention over a greater period of time may be important to patient morbidity and mortality. Retention in care is crucial in maximizing the health outcomes of people living with HIV. As eloquently outlined by Mugavero, et al., there are several ways to measure retention and engagement with each having its own strengths and limitations (4). Facilities/clinic may choose to utilize one or more measures depending on their characteristics, personnel administering the measure (clinician vs. administrator), and/or purpose of the measure (quality improvement, benchmarking, or monitoring). HIV care and treatment as well as performance measures are dynamic systems. As a result, it may be necessary to have more than one measure available for use. 1. Marks G, Gardner L, Craw JA, Crepaz N. Entry and retention in medical care among HIV-diagnosed persons in the United States: a meta-analysis. AIDS 2010; 24:2665–78. 2. Fleishman JA, Yehia BR, Moore RD, Korthuis PT, Gebo KA; for the HIV Research Network. Establishment, Retention, and Loss to Follow-Up in Outpatient HIV Care. J Acquir Immune Defic Syndr. 2012 Apr 23. [Epub ahead of print] 3. Tripathi A, Youmans E, Gibson JJ, Duffus WA. The impact of retention in early HIV medical care on viro-immunological parameters and survival: a statewide study. AIDS Res Hum Retroviruses. 2011; 27:751-8.	available set of NCQA measure when we set out to draft this measure. We will continue to work closely with the NCQA to continue to harmonize the measures for the care and treatment of people living with HIV. The body of literature regarding retention in HIV medical care has grown significantly in recent years. Studies have examined retention from multiple perspectives in order to understand its impact on patient health outcomes. Short term retention is moderate, but declines over time (1, 2). Retention in medical care among people living with HIV is associated with a significantly greater mean increase in baseline CD4 count (3). Also, the same study suggested that mortality was higher among those with suboptimal retention (3). Examining retention over a greater period of time may be important to patient morbidity and mortality. Retention in care is crucial in maximizing the health outcomes of people living with HIV. As eloquently outlined by Mugavero, et al., there are several ways to measure retention and engagement with each having its own strengths and limitations (4). Facilities/clinic may choose to utilize one or more measures depending on their characteristics, personnel administering the measure (clinician vs. administrator), and/or purpose of the measure (quality improvement, benchmarking, or monitoring). HIV care and treatment as well as performance measures are dynamic systems. As a result, it may be necessary to have more than one measure available for use. 1. Marks G, Gardner L, Craw JA, Crepaz N. Entry and retention in medical care among HIV-diagnosed persons in the United States: a meta-analysis. AIDS 2010;24:2665–78. 2. Fleishman JA, Yehia BR, Moore RD, Korthuis PT, Gebo KA; for the HIV Research Network. Establishment, Retention, and Loss to Follow-Up in Outpatient HIV Care. J Acquir Immune Defic Syndr. 2012 Apr 23. [Epub ahead of print] 3. Tripathi A, Youmans E, Gibson JJ, Duffus WA. The impact of retention in early HIV medical care on viro-immunological parameters and survival: a statewide study. AIDS Res Hum Retroviruses. 2011; 27:751-8.

	2079 HIV medical visit frequency	2080 Gap in HIV medical visits
	4. Mugavero MJ, Davila JA, Nevin CR, Giordano TP. From Access to Engagement: Measuring Retention in Outpatient HIV Clinical Care. AIDS Patient Care and STDs. October 2010, 24(10): 607-613.	4. Mugavero MJ, Davila JA, Nevin CR, Giordano TP. From Access to Engagement: Measuring Retention in Outpatient HIV Clinical Care. AIDS Patient Care and STDs. October 2010, 24(10): 607-613.

Appendix E: Implementation Comments

ID#	Council/ Public	Commenter	Implementation Comment	Measure Developer Response	Topic
2590	HPR	Mr. Andres Rodriguez, MBA/MSPH; Infectious Diseases Society of America	The Quality Improvement Task Force of the Infectious Disease Society of America (IDSA) continues to support Measure #0058, Avoidance of antibiotic treatment in adults with acute bronchitis and Measure #0069, Appropriate treatment for children with upper respiratory infection (URI). Studies have shown that acute bronchitis and URI are virtually always of viral etiology, yet clinicians continue to prescribe antibiotics inappropriately for those conditions. The measures include only those patients without claims/encounters for a diagnosis of a comorbid condition for the prior 12 months, and without competing diagnoses or new medications in the prior thirty days. We would, however, like to draw attention to the fact that classification of URIs can be a very subjective process. That is, one physician might opt for a diagnosis of acute bronchitis, while another chooses “common cold.” As a measure is used, there might be a shift in those subjective choices, either to avoid the evaluation or to choose a condition in which an antibiotic can at times be appropriate, such as acute sinusitis. It would be useful to consider a corollary to this measure that would look at all URI visits for the physician or practice during the evaluation time period to identify any shifts in coding of URIs. Although we submit our comments for consideration to improve the measure, we support endorsement of both measures for an additional 3 years.	Thank you for your support. We will bring your new measure suggestions to our measurement advisory panel for consideration.	0058: Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis

ID#	Council/ Public	Commenter	Implementation Comment	Measure Developer Response	Topic
2591	HPR	Mr. Andres Rodriguez, MBA/MSPH; Infectious Diseases Society of America	The Quality Improvement Task Force of the Infectious Disease Society of America (IDSA) continues to support Measure #0058, Avoidance of antibiotic treatment in adults with acute bronchitis and Measure #0069, Appropriate treatment for children with upper respiratory infection (URI). Studies have shown that acute bronchitis and URI are virtually always of viral etiology, yet clinicians continue to prescribe antibiotics inappropriately for those conditions. The measures include only those patients without claims/encounters for a diagnosis of a comorbid condition for the prior 12 months, and without competing diagnoses or new medications in the prior thirty days. We would, however, like to draw attention to the fact that classification of URIs can be a very subjective process. That is, one physician might opt for a diagnosis of acute bronchitis, while another chooses "common cold." As a measure is used, there might be a shift in those subjective choices, either to avoid the evaluation or to choose a condition in which an antibiotic can at times be appropriate, such as acute sinusitis. It would be useful to consider a corollary to this measure that would look at all URI visits for the physician or practice during the evaluation time period to identify any shifts in coding of URIs. Although we submit our comments for consideration to improve the measure, we support endorsement of both measures for an additional 3 years.	Thank you for your support. We will bring your new measure suggestions to our measurement advisory panel for consideration.	0069: Appropriate treatment for children with upper respiratory infection (URI)

ID#	Council/ Public	Commenter	Implementation Comment	Measure Developer Response	Topic
2592	HPR	Mr. Andres Rodriguez, MBA/MSPH; Infectious Diseases Society of America	The IDSA supports endorsement of measure #0298. We recognize the importance of bundling activities together to improve infection rates. If total compliance is not 100%, it would be useful to know if certain components are consistently omitted, and if so, infection rates associated with each type of omission could be determined. Hand hygiene, maximal barrier precautions upon central line insertion, and chlorhexidine skin antisepsis are essential and there should be no exceptions to compliance. Optimal catheter site selection is less conclusive. Some studies have not demonstrated higher infection rates with jugular as compared with subclavian insertion sites. There are noninfectious risks associated with subclavian placement that are less common with jugular sites. It is unclear that a requirement for documentation of the reason for not using the subclavian vein improves care. While it is important to complete daily review of necessity of the line, after years of this measure, it is prudent to evaluate if there is any impact- to see if hospitals with less than 100% compliance have higher BSI rates, or longer catheter-days. Grading 100% compliance and individual compliance would enrich the data. In addition, other measures require daily assessment of necessity, (foley urinary catheters). If bundled, it would be interesting to see if a dedicated discussion of all lines would result in earlier removal.	Thank you for your comments. The central line bundle was developed as an all/none measure, with the recommendation that hospitals assess compliance with individual bundle elements to identify opportunities for improving compliance. IHI has found that hospitals begin to demonstrate improvement in outcomes (central line-associated BSI) when they reliably provide all five components of the bundle. I also agree with your comments re: daily review of necessity of the lines and promoting a "dedicated discussion" of all lines, urinary catheter. Many hospitals have demonstrated success in removal of unnecessary central lines, urinary catheters by incorporating into overall review during daily rounding Diane Jacobsen MPH, CPHQ Director, Institute for Healthcare Improvement	0298: Central Line Bundle Compliance
2593	HPR	Mr. Andres Rodriguez, MBA/MSPH; Infectious Diseases Society of America	The IDSA supports endorsement of measure 0500. To be more consistent with the Surviving Sepsis Campaign guidelines, these items are referred to as part of a resuscitation rather than management bundle. We look forward to supporting future efforts to update this measure once updated guidelines are made public.	We would like to thank IDSA for their support of the measure, and look forward to collaborating with all stakeholders throughout the measure endorsement maintenance process.	0500: Severe sepsis and septic shock: Early management bundle

ID#	Council/ Public	Commenter	Implementation Comment	Measure Developer Response	Topic
2594	HPR	Mr. Andres Rodriguez, MBA/MSPH; Infectious Diseases Society of America	The IDSA supports the endorsement of measure #0393. Our members report that, in their experience, a minority of referring physicians (~25%) are performing this testing. As well, having the measure call for reflexing positive HCV Ab screens to additional HCV RNA tests could be more useful.	Thank you for your comment.	0393: Hepatitis C: Testing for Chronic Hepatitis C – Confirmation of Hepatitis C Viremia
2595	HPR	Mr. Andres Rodriguez, MBA/MSPH; Infectious Diseases Society of America	IDSA supports endorsement of measure #0394. Our physicians consider it to be the standard of care. They report the need for better standardization of information covered during counseling and standard documentation of methods of contraception (often 2).	Thank you for your comment.	0394: Hepatitis C: Counseling Regarding Use of Contraception Prior to Antiviral Treatment

ID#	Council/ Public	Commenter	Implementation Comment	Measure Developer Response	Topic
2596	HPR	Mr. Andres Rodriguez, MBA/MSPH; Infectious Diseases Society of America	IDSA does not support the endorsement of measure 0395 in the present form. Our physicians consider the standard of care to reflect updated treatment guidelines which are very specific concerning viral load measurements at various time points to determine continuation of therapy and/or length of response guided therapy (RGT) for GT1 patients on Protease Inhibitor therapy. In addition, measure 0395 appears to be similar to measure 0584, which suggests duplication/redundancy in measuring.	While updated treatment guidelines are specific regarding viral load measurements at various time points in order to determine continuation of therapy and/or length of response guided therapy, guidelines also support HCV RNA testing prior to initiation of treatment in order to identify the best course of treatment for the patient. According to NIH guidelines, determination of the HCV level provides important information on the likelihood of response to treatment in patients undergoing antiviral therapy. Our measure differs from measure 0584 in that it includes the 6 month time window, for HCV RNA level measurement. The time window was added to ensure that there is a recent HCV RNA level recorded to maximize the likelihood that treatment is appropriate for the patient's current viral load.	0395: Paired Measure: Hepatitis C Ribonucleic Acid (RNA) Testing Before Initiating Treatment (paired with 0396)
2597	HPR	Mr. Andres Rodriguez, MBA/MSPH; Infectious Diseases Society of America	IDSA support the endorsement of measure 0396 with modifications. This is standard of care and is typically required by health plans as part of the prior authorization process, indicating GT1a vs. GT1b. The 6 month timeframe is not appropriate. Once chronic infection is established, the genotype is unchanged. Therefore, a genotype obtained prior to 6 months before the start of treatment is acceptable; retesting is unnecessary and might represent overuse.	There is no 6 month time window associated with this measure. The measure description is as follows: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom HCV genotype testing was performed prior to initiation of antiviral treatment. The numerator time window is "once prior to initiation of antiviral treatment." The 6 month time window is associated with measure 0395 only.	0396: Paired Measure: HCV Genotype Testing Prior to Treatment (paired with 0395)

ID#	Council/ Public	Commenter	Implementation Comment	Measure Developer Response	Topic
2598	HPR	Mr. Andres Rodriguez, MBA/MSPH; Infectious Diseases Society of America	IDSA does not support the endorsement of measure #0397. Although all patients should be considered potential treatment candidates, the measure logic does not provide a feasible, usable way to identify denominator exclusions. The denominator exclusion data sources used in this measure are rarely submitted (e.g., CPT-II codes). Given this major limitation, this is a measure of resource use, not quality of care. Endorsement is not recommended. Also, the measure description does not address protease inhibitor use in the genotype 1 HCV infected person.	For clarification, this measure does not include exclusions, but includes medical, patient, and system exceptions. In the AMA-PCPI methodology, exclusions are absolute and apply to all patients and therefore are not part of clinical judgment within a measure. Exceptions are used to remove patients from the denominator of a performance measure when a patient does not receive a therapy or service AND that therapy or service would not be appropriate for the patient due to specific reasons. Exceptions are not absolute, and are based on clinical judgment, individual patient characteristics, or patient preferences. This measure was included in the PQRS program in 2008, 2009, and 2010 and we have not received feedback regarding difficulty in reporting the exceptions through the use of CPT II codes and modifiers. EHR specifications have also been submitted for electronic reporting of this measure. The updated evidence-based guideline from AASLD, published in 2011, describes treatment with protease inhibitors for genotype 1 patients, in addition to peginterferon and ribavirin therapy. As such, the measure language has been updated to capture this treatment. The measure description is written as follows: "Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who were prescribed at a minimum peginterferon and ribavirin therapy within the 12 month reporting period," with "at a minimum" intended to allow for the additional treatment recommended for genotype 1 patients.	0397: Hepatitis C: Antiviral Treatment Prescribed

ID#	Council/ Public	Commenter	Implementation Comment	Measure Developer Response	Topic
2599	HPR	Mr. Andres Rodriguez, MBA/MSPH; Infectious Diseases Society of America	IDSA supports the endorsement of measure #0398 with modification. RNA testing at 12 weeks is a reasonable measurement criterion for patients with genotype 2/ 3 infection. This measure should be modified to reflect management of patients with genotype 2/3 only. This measure does not address new RNA testing guidelines for genotype 1 patients on protease inhibitor treatment. A future measure should address this area.	The AMA-PCPI uses evidence-based guidelines to support the development of AMA PCPI measures. The updated evidence-based guideline from AASLD, published in 2011, indicates that treatment modifications may be necessary for genotype 1 patients at weeks 4, 8, or 12, based on HCV RNA levels and dependent upon the type of treatment the patient is receiving (including the use of protease inhibitors). Therefore, consistent with the guideline, the numerator language was updated to capture "Patients for whom quantitative HCV RNA testing was performed at no greater than 12 weeks from the initiation of antiviral treatment." The numerator definition is as follows: 12 Weeks from Initiation – Patients for whom testing was performed between 4-12 weeks from the initiation of antiviral treatment will meet the numerator for this measure (depending upon the specific antiviral therapy used).	0398: Hepatitis C: HCV RNA Testing at Week 12 of Treatment
2600	HPR	Mr. Andres Rodriguez, MBA/MSPH; Infectious Diseases Society of America	IDSA supports endorsement of measure #0399. The current measure identifies patients who received at least one injection of hepatitis A vaccine or have documented immunity to hepatitis A. This is clinically important. This measure would be improved if it identified completion of the hepatitis A vaccine or documented immunity. Our members note the challenge in meeting this measure related to insufficient insurance coverage or no insurance coverage often encountered with some Hep C Patients.	Thank you for your comment.	0399: Paired Measure: Hepatitis C: Hepatitis A Vaccination (paired with 0400)

ID#	Council/ Public	Commenter	Implementation Comment	Measure Developer Response	Topic
2601	HPR	Mr. Andres Rodriguez, MBA/MSPH; Infectious Diseases Society of America	IDSA supports endorsement of measure #0400. This is clinically important. This measure would be improved if it identified completion of the hepatitis B vaccine or documented immunity. Our members note the challenge in meeting this measure related to insufficient insurance coverage or no insurance coverage often encountered with some Hep C Patients.	Thank you for your comment.	0400: Paired Measure: Hepatitis C: Hepatitis B Vaccination (paired with 0399)
2602	HPR	Mr. Andres Rodriguez, MBA/MSPH; Infectious Diseases Society of America	IDSA supports endorsement of measure #0401. This is a critical measure, and when possible, counseling of patients should include spouse, significant other or partner to improve outcome.	Thank you for your comment.	0401: Hepatitis C: Counseling Regarding Risk of Alcohol Consumption
2603	HPR	Mr. Andres Rodriguez, MBA/MSPH; Infectious Diseases Society of America	IDSA supports endorsement of measure #0584. As noted earlier, this measure appears to be similar to measure #0395.	While measure 0395 relies exclusively upon CPT4 category II codes for recognizing quantification of viral load, we consider category I billing claims as well laboratory test results tagged with LOINC codes. Further, our definition of chronic HCV infection includes an additional four ICD-9-CM codes, accepting a history of hepatic coma (070.44), unspecified disease acuity (070.70, 070.71), and a declaration of being an HCV carrier (V0262). Other differences between the two measures have been harmonized.	0584: Hepatitis C: Viral Load Test

ID#	Council/ Public	Commenter	Implementation Comment	Measure Developer Response	Topic
2604	PRO	Ronald Walters, MD; University of Texas-MD Anderson Cancer Center	On behalf of The University of Texas MD Anderson Cancer Center, we appreciate the opportunity to provide feedback on this measure. Have you used this measure for any of the following purposes? 1. Quality improvement (internal to your specific organization) **Yes** 2. Quality improvement with benchmarking (external benchmarking to multiple organizations) **No** 3. Professional certification or recognition program **No** 4. Regulatory and accreditation programs **Yes – TJC NPSG.07.04.01** 5. Payment program **No** 6. Public reporting **No** 7. Other **N/A** • Have you encountered challenges while implementing this measure? 1. Problems with measure specifications **No** 2. Challenges in obtaining the necessary data **No** 3. Lack of harmonization with related measures (same measure focus or same target population) **No** 4. Difficulties interpreting or explaining the performance results **No** 5. Difficulties obtaining reliable and valid comparisons of performance We use an internal benchmark 6. Unintended consequences **No** • Do you have suggestions for how this measure could be improved? **No** Is there a better measure that should be considered in place of this measure? **No** • Should this measure receive endorsement for another three years? **Yes** Please provide rationale.	Thank you for your comments. The central line bundle was developed as an all/none measure, with the recommendation that hospitals assess compliance with individual bundle elements to achieve high reliability with the bundle. The focus of the central line bundle as a process (vs. outcome) measure was for internal improvement, as you reflect you have used the measure. Diane Jacobsen MPH, CPHQ Director, Institute for Healthcare Improvement	0298: Central Line Bundle Compliance

ID#	Council/ Public	Commenter	Implementation Comment	Measure Developer Response	Topic
2605	Public	Judith Aberg, MD, FIDSA; HIV Medicine Association	We understand that different time periods for medical visit intervals are under consideration by various measures development groups (60, 90 or 180 days). We note that the National HIV/AIDS Strategy (NHAS) performance metrics reflect a 90-day time period between medical visits. We strongly urge that whichever interval is chosen for this measure, it should be uniform across payers and health care platforms. We support continued NQF endorsement with uniformity of medical visit intervals across measures in which medical visit frequency is a factor.	NCQA has included HRSA, the CDC, and a representative from HIVQUAL in discussions about the time interval for the HIV/AIDS: Medical Visit measure. We have attempted to align with other HIV measurement programs.	0403: HIV/AIDS: Medical Visit
2606	Public	Judith Aberg, MD, FIDSA; HIV Medicine Association	We support continued NQF endorsement of this measure, but urge harmonization and alignment of the NQF-endorsed measure across and among federal agencies.	Thank you for your support.	0404: HIV/AIDS: CD4 Cell Count or Percentage Performed
2607	Public	Judith Aberg, MD, FIDSA; HIV Medicine Association	Change to percentage of patients (regardless of age) with CD4+ counts fewer than 200. We support continued NQF endorsement with this change.	We have convened an expert panel to provide us with guidance about aligning this measure with current guidelines.	0405: HIV/AIDS: Pneumocystis jiroveci pneumonia (PCP) Prophylaxis

ID#	Council/ Public	Commenter	Implementation Comment	Measure Developer Response	Topic
2608	Public	Judith Aberg, MD, FIDSA; HIV Medicine Association	In keeping with current clinical practice guidelines, we recommend deletion of qualifications to measure percentage of all patients prescribed antiretroviral therapy, such that the measure should read as follows: Percentage of patients with a diagnosis of HIV/AIDS with at least two visits during the measurement year, with at least 60 days – or whichever interval is selected for the medical visit measure -- between each visit who were prescribed potent antiretroviral therapy.	We convened an expert panel to provide us with guidance about aligning this measure with current guidelines. The expert panel did not support deleting qualifications from the denominator of this measure. Based on the current treatment guidelines and evidence, we will be measuring whether the following populations received potent ART: patients 13 and older with at least two visits, at least 90 days apart, who have a history of a CD4 count below or equal to 500 cells/mm3; patients 13 and older with at least two visits, at least 90 days apart, who have a history of an AIDS-defining illness; and patients, regardless of age, who are pregnant.	0406: HIV/AIDS: Adolescent and Adult Patients who are Prescribed Potent Antiretroviral Therapy
2609	Public	Judith Aberg, MD, FIDSA; HIV Medicine Association	We recommend that this measure be updated as follows: Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who had at least two medical visits during the measurement year, with at least 60 days – or whichever interval is selected for the medical visit measure -- between each visit, who are receiving potent antiretroviral therapy**, who have a viral load below limits of quantification* after at least 6 months of potent antiretroviral therapy. *Using laboratory cutoff level for reference laboratory used by that clinic. ** Potent antiretroviral therapy is described as any antiretroviral therapy that has demonstrated optimal efficacy and results in durable suppression of HIV as shown by prior clinical trials. Rationale: There are now sufficient medications to achieve viral control that this measure should strive to simply capture the percentage of patients in care and on ART who are virally suppressed. We support continued NQF endorsement of this measure, with the above update.	We agree with removing the plan of care component from this measure. After convening an expert panel to review this measure, we will submit the following measure to NQF: Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS, who had at least two medical visits during the measurement year, with at least 90 days between each visit, who are receiving potent antiretroviral therapy, who have a viral load <200 copies/mL after at least 6 months of potent antiretroviral therapy.	0407: HIV/AIDS: HIV RNA Control After Six Months of Potent Antiretroviral Therapy

ID#	Council/ Public	Commenter	Implementation Comment	Measure Developer Response	Topic
2610	Public	Judith Aberg, MD, FIDSA; HIV Medicine Association	We support continued NQF endorsement of this measure, as written. It is still clinically relevant.	Thank you for your support.	0408: HIV/AIDS: Tuberculosis (TB) Screening
2611	Public	Judith Aberg, MD, FIDSA; HIV Medicine Association	We understand that NCQA is considering merging measures #0409 and #0410 to measure Chlamydia, Gonorrhea and Syphilis. We support continued NQF endorsement of a measure along these lines, as it remains clinically relevant.	NCQA will be combining measures 0409 and 0410. Thank you for your support.	0409: HIV/AIDS: Sexually Transmitted Diseases – Screening for Chlamydia, Gonorrhea, and Syphilis
2612	Public	Judith Aberg, MD, FIDSA; HIV Medicine Association	We understand that NCQA is considering merging measures #0409 and #0410 to measure Chlamydia, Gonorrhea and Syphilis. We support continued NQF endorsement of a measure along these lines, as it remains clinically relevant.	NCQA will be combining measures 0409 and 0410. Thank you for your support.	0410: HIV/AIDS: Sexually Transmitted Diseases - Syphilis Screening
2613	Public	Judith Aberg, MD, FIDSA; HIV Medicine Association	We support continued NQF endorsement of this measure, as written, as it is still clinically relevant.	NCQA has decided not to submit this measure for re-endorsement, because we believe it is an intermediate process step before Hepatitis B vaccination, which is also being measured in measure #0412.	0411: HIV/AIDS: Other Infectious Diseases - Hepatitis B Screening
2614	Public	Judith Aberg, MD, FIDSA; HIV Medicine Association	We support continued NQF endorsement of this measure, as written, as it is still clinically relevant.	Thank you for your support.	0412: HIV/AIDS: Hepatitis B Vaccination

ID#	Council/ Public	Commenter	Implementation Comment	Measure Developer Response	Topic
2615	Public	Judith Aberg, MD, FIDSA; HIV Medicine Association	We understand that NCQA is considering combining measures 0413 and 0415. Also, we recommend that NQF carefully review the feasibility of this and other behavioral health measures, as performance of such screenings is not readily captured by most electronic health record (EHR) systems.	NCQA has decided not to submit this measure for re-endorsement, due to feasibility, reliability and validity concerns.	0413: HIV/AIDS: Screening for High Risk Sexual Behaviors
2616	Public	Judith Aberg, MD, FIDSA; HIV Medicine Association	We support continued NQF endorsement of this measure, as written, as it is still clinically relevant.	NCQA has decided not to submit this measure for re-endorsement, as we believe the evidence is not strong enough to support this measure.	0414: HIV/AIDS: Other Infectious Diseases - Hepatitis C
2617	Public	Judith Aberg, MD, FIDSA; HIV Medicine Association	We understand that NCQA is considering combining measures 0413 and 0415. Also, we recommend that NQF carefully review the feasibility of this and other behavioral health measures, as performance of such screenings is not readily captured by most electronic health record (EHR) systems without a manual chart review.	NCQA has decided not to submit this measure for re-endorsement, due to feasibility, reliability and validity concerns.	0415: HIV/AIDS: Screening for Injection Drug Use
2618	Public	Judith Aberg, MD, FIDSA; HIV Medicine Association	We recommend elimination of this measure, as it will conceptually be captured by measures 0403 and 0404.	NQF Staff Response: Health Benchmarks, Inc. has decided not to submit this measure for maintenance review due to the amount of resources required to participate in the NQF maintenance process.	0568: Appropriate follow-up for patients with HIV
2619	Public	Judith Aberg, MD, FIDSA; HIV Medicine Association	We recommend that NQF carefully review the feasibility of this and other behavioral health measures, as performance of such screenings is not readily captured by most electronic health record (EHR) systems without a manual chart review.	Based on the testing results, this measure was found to be feasible for implementation. We have provided testing data, which includes a comparison of E.H.R. automated reports to visual inspection of the medical record and had a kappa score of 0.54. This score shows that the measure is reliable and shows that the information can be accurately collected in both an electronic health record and a paper medical record.	0394: Hepatitis C: Counseling Regarding Use of Contraception Prior to Antiviral Treatment

ID#	Council/ Public	Commenter	Implementation Comment	Measure Developer Response	Topic
2620	Public	Judith Aberg, MD, FIDSA; HIV Medicine Association	We recommend that NQF carefully review the feasibility of this and other behavioral health measures, as performance of such screenings is not readily captured by most electronic health record (EHR) systems without a manual chart review.	Based on the testing results, this measure was found to be feasible for implementation. We have provided testing data, which includes a comparison of E.H.R. automated reports to visual inspection of the medical record and had a kappa score of 0.47. This score shows that the measure is reliable and shows that the information can be accurately collected in both an electronic health record and a paper medical record.	0401: Hepatitis C: Counseling Regarding Risk of Alcohol Consumption

ID#	Council/ Public	Commenter	Implementation Comment	Measure Developer Response	Topic
2621	PRO	Ronald Walters, MD; University of Texas-MD Anderson Cancer Center	On behalf of The University of Texas MD Anderson Cancer Center, we appreciate the opportunity to provide feedback on this measure. Have you used this measure for any of the following purposes? 1. Quality improvement (internal to your specific organization) **Yes** 2. Quality improvement with benchmarking (external benchmarking to multiple organizations) **No** 3. Professional certification or recognition program **No** 4. Regulatory and accreditation programs **No** 5. Payment program **No** 6. Public reporting **No** 7. Other **N/A** • Have you encountered challenges while implementing this measure? 1. Problems with measure specifications **No** 2. Challenges in obtaining the necessary data **No** 3. Lack of harmonization with related measures (same measure focus or same target population) **No** 4. Difficulties interpreting or explaining the performance results **No** 5. Difficulties obtaining reliable and valid comparisons of performance **We use an internal benchmark** 6. Unintended consequences **No** • Do you have suggestions for how this measure could be improved? **No** Is there a better measure that should be considered in place of this measure? **No** • Should this measure receive endorsement for another three years? **Yes** Please provide rationale.	Thank you for your comments. The ventilator bundle was developed as an all/none measure, with the recommendation that hospitals assess compliance with individual bundle elements to achieve high reliability with the bundle. The focus of the ventilator bundle is as a process (vs. outcome) measure was for internal improvement, as you reflect you have used the measure. IHI is not submitting this measure for consideration for public reporting. As process/composite measures, the measure wasn't designed or validated as a measure for public reporting. One key concern is that the measure would be self-reported (ongoing compliance with the bundle elements) and not verifiable without extensive and expensive auditing. Diane Jacobsen MPH, CPHQ Director, Institute for Healthcare Improvement	0302: Ventilator bundle

ID#	Council/ Public	Commenter	Implementation Comment	Measure Developer Response	Topic
2620	Public	Judith Aberg, MD, FIDSA; HIV Medicine Association	We support continued NQF endorsement of this measure, as written, as it is still clinically relevant.	The American Association for the Study of Liver Diseases rated the measure and the evidence supporting the measure Class I, Level A in 2009. This is based on the American College of Cardiology and American Heart Association Practice Guidelines.	0584: Hepatitis C: Viral Load Test

Appendix F: Assessment of Disparities Sensitive Measures

The Healthcare Disparities and Cultural Competency Steering Committee developed a protocol to systematically screen and tag NQF-endorsed measures as disparities sensitive, with the intent to identify measures that should be routinely stratified and reported by race/ethnicity and language. The disparities-sensitive screening protocol included a hierarchical approach and scoring system, with emphasis on prevalence of the condition among the minority population, the disparities quality gap (i.e., the greatest difference between % performance or other unit of measurement compared to the historically disadvantaged population), the impact of the condition, and whether a measure was mapped to an NQF-endorsed communication-sensitive practice for care coordination or cultural competency. Specific information about the protocol and process can be found in the NQF Commissioned Paper and the Disparities Assessment Draft Report.

Based on the assessment of the infectious disease measures considered by this Steering Committee, seven measures were identified as disparities-sensitive based on the criteria, in particular the threshold for the quality gap percentage of 14% or higher. The seven measures identified as disparities-sensitive measures include four measures that were newly submitted for this project, as well as three maintenance measures, which are all marked within the table.

NQF #	Measure Title	Prevalence[1]	Quality Gap[2]	Quality Gap Score	Impact[3]	1st Tier score
399	Paired Measure: Hepatitis C: Hepatitis A Vaccination (paired with 0400)	3	16.2%	4	1	8
2082	HIV viral load suppression	3	14.00%	4	1	8
2083	Prescription of HIV Antiretroviral Therapy	3	14.00%	4	1	8
2079	HIV medical visit frequency	3	14.90%	4	1	8
2080	Gap in HIV medical visits	3	14.90%	4	1	8
408	HIV/AIDS: Tuberculosis (TB) Screening	3	15%	4	0	7
409	HIV/AIDS: Sexually Transmitted Diseases – Screening for Chlamydia, Gonorrhea, and Syphilis	3	15.7%	4	1	8

[1] Prevalence: How prevalent is the condition among the minority population? Based on the conditions identified by the Office of Minority Health as large contributors of health disparities, the NQF portfolio was first reviewed for performance measures related to the following conditions: Cancer, Diabetes, Heart Disease (including Hypertension), HIV/AIDS, Immunizations, Infant Mortality, and Stroke, Tobacco use, Oral care. These measures were given 3 points. Measures that fell in cross-cutting areas (e.g., patient safety, care coordination, functional status, palliative care, pain management or *any* child health/pediatrics) also were scored 3 points. Measures that fell into the prioritized list of top 20 conditions for Medicare (amended to include substance abuse, obesity, and End Stage Renal Disease) were scored 2 points. All other measures scored 1 point.

[2] Quality Gap: How large is the gap in *quality of care* between the disadvantaged population and the group with the highest quality for that measure? The disparities quality gap indicated on the measure submission/evaluation form was reviewed and recorded. In some cases, information was not available and literature searches were performed by NQF staff to supplement where possible.

[3] Impact: The influence a condition or topic has financially, publically, and on the community at large. Performance measures addressing the National Quality Strategy priority areas or goals will be given a + 1 point each for EACH goal or concept.

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