NATIONAL QUALITY FORUM

Measure Submission and Evaluation Worksheet 5.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the submitting standards web page.

NQF #: 0400 **NQF Project:** Infectious Disease Project
(for Endorsement Maintenance Review) **Original Endorsement Date:** Jul 31, 2008 **Most Recent Endorsement Date:** Jul 31, 2008 **Last Updated Date:** Jan 08, 2013
BRIEF MEASURE INFORMATION
De.1 **Measure Title:** Paired Measure: Hepatitis C: Hepatitis B Vaccination (paired with 0399)
Co.1.1 **Measure Steward:** AMA-convened Physician Consortium for Performance Improvement
De.2 **Brief Description of Measure:** 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
2a1.1 **Numerator Statement:** Patients who have received at least one injection of Hepatitis B vaccine, or who have documented immunity to Hepatitis B
2a1.4 **Denominator Statement:** All patients aged 18 years and older with a diagnosis of hepatitis C
2a1.8 **Denominator 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
1.1 **Measure Type:** Process 2a1. 25-26 **Data Source:** Claims, Electronic Health Data, Electronic Health Records, Other, Registry Data 2a1.33 **Level of Analysis:** Clinician : Group/Practice, Clinician : Individual 1.2-1.4 **Is this measure paired with another measure?** Yes 2099:Paired Measure 0399 and 0400 De.3 **If included in a composite, please identify the composite measure** (*title and NQF number if endorsed*)**:**

STAFF NOTES (*issues or questions regarding any criteria*)
Comments on Conditions for Consideration:
Is the measure untested? Yes○ No○ If untested, explain how it meets criteria for consideration for time-limited endorsement:
1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (*check De.5*)**:** **5. Similar/related endorsed or submitted measures** (*check 5.1*)**:** **Other Criteria:**

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

Staff Reviewer Name(s):

1. IMPACT, OPPORTUITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT

Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See guidance on evidence.

Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. **(evaluation criteria)**

1a. High Impact: **H● M● L● I ●**
(*The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.*)

De.4 Subject/Topic Areas *(Check all the areas that apply)*: Infectious Diseases (ID), Liver : Viral Hepatitis
De.5 Non-Condition Specific (*Check all the areas that apply)*: Immunization

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, A leading cause of morbidity/mortality, Patient/societal consequences of poor quality

1a.2 If "Other," please describe:

1a.3 Summary of Evidence of High Impact *(Provide epidemiologic or resource use data)*:
The hepatitis C virus (HCV) is a major public health problem and a leading cause of chronic liver disease.(1) An estimated 180 million people are infected worldwide.(2) In the United States, the prevalence of HCV infection between the years 1999 and 2002 was 1.6%, equating to about 4.1 million persons positive for antibody to hepatitis C (anti-HCV), 80% of whom are estimated to be viremic.(3) Hepatitis C is the principal cause of death from liver disease and the leading indication for liver transplantation in the U.S.(4) Some calculations suggest that mortality related to HCV infection (death from liver failure or hepatocellular carcinoma) will continue to increase over the next two decades.(5)

1a.4 Citations for Evidence of High Impact cited in 1a.3: (1) Williams R. Global challenges in liver disease. HEPATOLOGY 2006;44: 521-526.

(2) www.who.int/immunization/topics/hepatitis_c/en/.

(3) Armstrong GL, Wasley A, Simard EP, McQuillan GM, Kuhnert WL, Alter MJ. The prevalence of hepatitis C virus infection in the United States, 1999 through 2002. Ann Intern Med 2006;144:705-714.

(4) Kim WR. The burden of hepatitis C in the United States. HEPATOLOGY 2002;36(Suppl):S30-S34.

(5) Deuffic-Burban S, Poynard T, Sulkowski MS, Wong JB. Estimating the future health burden of chronic hepatitis C and human immunodeficiency virus infections in the United States. J Viral Hepat 2007;14:107-115.

1b. Opportunity for Improvement: **H● M● L● I ●**
(*There is a demonstrated performance gap - variability or overall less than optimal performance*)

1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this measure:
Assure that hepatitis B vaccination is received except for cases of documented medical reasons. This vaccination decreases the potential for a patient acquiring hepatitis B which would contribute to further liver damage.

1b.2 Summary of Data Demonstrating Performance Gap *(Variation or overall less than optimal*

performance across providers): **[*For Maintenance* –** *Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.***]**
CMS Physician Quality Reporting Initiative:

This measure was used in the 2008, 2009 and 2010 CMS Physician Quality Reporting Initiative/System. There is a gap in care as shown by this data; 88.78% is the aggregate performance rate in the total patient population and 80.93% is the mean performance rate of TIN/NPI's.

10th percentile: 0.00%
25th percentile: 75.00%
50th percentile: 100.00%
75th percentile: 100.00%
90th percentile: 100.00%

1b.3 Citations for Data on Performance Gap: [*For Maintenance* – *Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included***]**
Confidential CMS PQRI 2010 Performance Information by Measure. Jan 2010-February 2011 TAP file

1b.4 Summary of Data on Disparities by Population Group: [*For Maintenance* –*Descriptive statistics for performance results for this measure by population group***]**
Although the continued prevalence of HCV is problematic in communities across America, inequalities in disease prevalence, treatment, and outcomes make it a particularly important minority health issue.(1) First, there are disparities in the prevalence of HCV infection, with African Americans being twice as likely to have ever been infected with HCV, and having a higher prevalence of chronic HCV infection compared with non-Hispanic white Americans.(2) Additionally, there are significant disparities in access to HCV care for racial and ethnic minorities.(3) Finally, African American and Hispanic patients with HCV infection, even once properly diagnosed, have less desirable treatment outcomes compared to white patients.(4) These trends are indicative of a growing healthcare crisis with regards to HCV that threatens minority communities for decades to come.(1)

1b.5 Citations for Data on Disparities Cited in 1b.4: [*For Maintenance* – *Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included***]**
1) Bryant Cameron Webb. The "Secret" epidemic: Disparities in Hepatitis C Incidence, Treatment, and Outcomes. Prepared for the Joint Center for Political and Economic Studies. October 2010.

(2) Alter MJ, Kruszon-Moran D, Nainan OV, et al. The prevalence of hepatitis C virus infection in the United States, 1988 through 1994. New England Journal of Medicine. 1999:341(8): 556-562.

(3) Trooskin SB, Navarro VJ, Winn RJ, et al. Hepatitis C risk assessment, testing and referral for treatment in urban primary care: Role of race and ethnicity. World J Gastro 2007:13:1074.

(4) Conjeevaram HS, Fried MW, Jeffers LJ, et al. Virahep-C study group. Peginterferon and ribavirin treatment in African American and Caucasian American patients with hepatitis C genotype 1. Gastroenterology. 2006 Aug; 131(2):470-7.

1c. Evidence (*Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.*)
Is the measure focus a health outcome? Yes○ No○ If not a health outcome, rate the body of evidence.

Quantity: H○ M○ L○ I ○ Quality: H○ M○ L○ I ○ Consistency: H○ M○ L○ I ○

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

Quantity	Quality	Consistency	Does the measure pass subcriterion1c?
M-H	**M-H**	**M-H**	**Yes✪**
L	**M-H**	**M**	**Yes✪** IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise **No✪**
M-H	**L**	**M-H**	**Yes✪** IF potential benefits to patients clearly outweigh potential harms: otherwise **No✪**
L-M-H	**L-M-H**	**L**	**No ✪**

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service	**Does the measure pass subcriterion1c?** **Yes✪** IF rationale supports relationship

1c.1 Structure-Process-Outcome Relationship *(Briefly state the measure focus, e.g., health outcome, intermediate clinical outcome, process, structure; then identify the appropriate links, e.g., structure-process-health outcome; process- health outcome; intermediate clinical outcome-health outcome)*:
Assure that hepatitis B vaccination is received except for cases of documented medical reasons. This vaccination decreases the potential for a patient acquiring hepatitis B which would contribute to further liver damage.

1c.2-3 Type of Evidence *(Check all that apply)*:
Clinical Practice Guideline

1c.4 Directness of Evidence to the Specified Measure *(State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population)*:
Although no specific recommendation has been advanced for vaccination against hepatitis B, the evidence that persons co-infected with hepatitis B and C have a worse prognosis than those with HCV infection alone suggests that hepatitis B vaccination should be offered to persons who are at risk for exposure to hepatitis B if they lack preexisting antibody to hepatitis B. (AASLD 2009)

1c.5 Quantity of Studies in the Body of Evidence *(Total number of studies, not articles)*: The guideline developer did not state the quantity of studies used.

1c.6 Quality of Body of Evidence (*Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events*): While the quality of the body of evidence is not addressed, the guideline developer stated: These recommendations provide a data-supported approach to establishing guidelines. They are based on the following: (1) a formal review and analysis of the recently published world literature on the topic (Medline search up to September 2008); (2) the American College of Physicians' Manual for Assessing Health Practices and Designing Practice Guidelines; (3) guideline policies, including the American Association for the Study of Liver Diseases' (AASLD) Policy on the Development and Use of Practice Guidelines and the American Gastroenterological Association's Policy Statement on the Use of Medical Practice Guidelines; and (4) the experience of the authors in regard to hepatitis C. (AASLD 2009)

In addition, Class IIa, Level C recommendations reflect Class 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.

1c.7 Consistency of Results across Studies *(Summarize the consistency of the magnitude and direction*

of the effect): The consistency of results across studies was not addressed by the guideline.

1c.8 Net Benefit *(Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms)***:**
The benefit over harms across studies was not addressed by the guideline.

1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? No

1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: n/a

1c.11 System Used for Grading the Body of Evidence: Other

1c.12 If other, identify and describe the grading scale with definitions: n/a

1c.13 Grade Assigned to the Body of Evidence: n/a

1c.14 Summary of Controversy/Contradictory Evidence: A summary of controversy/contradictory evidence was not provided.

1c.15 Citations for Evidence other than Guidelines*(Guidelines addressed below)*:
n/a

1c.16 Quote verbatim, <u>the specific guideline recommendation</u> *(Including guideline # and/or page #)***:**
All persons with chronic HCV infection who lack antibodies to hepatitis A and B should be offered vaccination against these two viral infections. (Class IIa, Level C) (AASLD 2009-Recommendation 63)

1c.17 Clinical Practice Guideline Citation: Marc G. Ghany, Doris B. Strader, David L. Thomas, and Leonard B. Seeff. American Association for the Study of Liver Diseases' (AASLD) Practice Guidelines: Diagnosis, Management, and Treatment of Hepatitis C: An Update. Hepatology, April 2009: 1335-1374.

1c.18 National Guideline Clearinghouse or other URL: http://guideline.gov/content.aspx?id=14708

1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? Yes

1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: The Practice Guidelines Committee of the AASLD. Potential conflict of interest: Drs. Marc Ghany, Leonard Seeff, and Doris Strader have no financial relationships to declare. Dr. David Thomas was on the Advisory Board of Merck, Sharpe and Dohme at the time of writing but has since resigned from this position.

1c.21 System Used for Grading the Strength of Guideline Recommendation: Other

1c.22 If other, identify and describe the grading scale with definitions: Classification Description
Class I Conditions for which there is evidence and/or general agreement that a given diagnostic evaluation procedure or treatment is beneficial, useful, and effective.
Class II Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a diagnostic evaluation, procedure or treatment.
Class IIa Weight of evidence/opinion is in favor of usefulness/efficacy.
Class IIb Usefulness/efficacy is less well established by evidence/opinion.
Class III Conditions for which there is evidence and/or general agreement that a diagnostic evaluation, procedure/treatment is not useful/effective and in some cases may be harmful.

Level of Evidence Description

Level A	Data derived from multiple randomized clinical trials or meta-analyses.
Level B	Data derived from a single randomized trial, or nonrandomized studies.
Level C	Only consensus opinion of experts, case studies, or standard-of-care.

NOTE: To more fully characterize the quality of evidence supporting recommendations, the Practice Guidelines Committee of the AASLD requires a Class (reflecting benefit versus risk) and Level (assessing strength or certainty) of Evidence to be assigned and reported with each recommendation (Table 1, adapted from the American College of Cardiology and the American Heart association Practice Guidelines).

1c.23 Grade Assigned to the Recommendation: Class IIa, Level C

1c.24 Rationale for Using this Guideline Over Others: It is the PCPI policy to use guidelines, which are evidence-based, applicable to physicians and other health-care providers, and developed by a national specialty organization or government agency. In addition, the PCPI has now expanded what is acceptable as the evidence base for measures to include documented quality improvement (QI) initiatives or implementation projects that have demonstrated improvement in quality of care.

Based on the NQF descriptions for rating the evidence, what was the developer's assessment of the quantity, quality, and consistency of the body of evidence?
1c.25 Quantity: Moderate **1c.26** Quality: Moderate**1c.27** Consistency**:** Moderate
1c.28 Attach evidence submission form**:**
1c.29 Attach appendix for supplemental materials**:**

Was the threshold criterion, *Importance to Measure and Report*, met?
(*1a & 1b must be rated moderate or high and 1c yes*) Yes○ No○
Provide rationale based on specific subcriteria:

For a new measure if the Committee votes NO, then STOP.
For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.

2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. **(evaluation criteria)**
Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See guidance on measure testing.

S.1 Measure Web Page *(In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained*). Do you have a web page where current detailed specifications for this measure can be obtained? Yes

S.2 If yes, provide web page URL: www.physicianconsortium.org

2a. RELIABILITY. Precise Specifications and Reliability Testing: H○ M○ L○ I ○

2a1. Precise Measure Specifications. (*The measure specifications precise and unambiguous.*)

2a1.1 Numerator Statement *(Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome)***:**

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

2a1.2 Numerator Time Window *(The time period in which the target process, condition, event, or outcome is eligible for inclusion)*:
Once during the measurement period

2a1.3 Numerator Details *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, codes with descriptors, and/or specific data collection items/responses*:
Definition: *Received includes documentation that a patient received at least one injection of hepatitis B vaccine from another provider

EHR Specifications:
eMeasure developed – see attached

Claims Specifications:

CPT Category II code (in development): 4149F – Hepatitis B vaccine injection administered or previously received

OR
CPT Category II code: 3216F - Patient had documented immunity to Hepatitis B

2a1.4 Denominator Statement *(Brief, narrative description of the target population being measured)*:
All patients aged 18 years and older with a diagnosis of hepatitis C

2a1.5 Target Population Category *(Check all the populations for which the measure is specified and tested if any)*: Adult/Elderly Care

2a1.6 Denominator Time Window *(The time period in which cases are eligible for inclusion)*:
12 conseuctive months

2a1.7 Denominator Details (*All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
EHR Specifications:
eMeasure developed – see attached

Claims Specifications:
ICD-9-CM diagnosis codes: 070.51, 070.54, 070.70

AND

CPT Codes: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, 99245

2a1.8 Denominator Exclusions *(Brief narrative description of exclusions from the target population)*:
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

2a1.9 Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
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 B 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

Claims Specifications:
4149F-1P: Documentation of medical reason(s) not administering at least one injection of hepatitis B vaccine

4149F-2P: Documentation of patient reason(s) for not administering at least one injection of hepatitis B vaccine

2a1.10 Stratification Details/Variables *(All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses)*:
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.

2a1.11 Risk Adjustment Type *(Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13)*: No risk adjustment or risk stratification **2a1.12 If "Other," please describe:**

2a1.13 Statistical Risk Model and Variables *(Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in 2b4.)*:
None

2a1.14-16 Detailed Risk Model Available at Web page URL (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:

2a1.17-18. Type of Score: Rate/proportion

2a1.19 Interpretation of Score *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)*:

Better quality = Higher score

2a1.20 Calculation Algorithm/Measure Logic*(Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.)***:**
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) 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 (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 e-measure which was emailed to NQF staff.

2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:

2a1.24 Sampling (Survey) Methodology. If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate)**:**
Not applicable. The measure does not require sampling or a survey.

2a1.25 Data Source *(Check all the sources for which the measure is specified and tested*). If other, please describe**:**
Claims, Electronic Health Data, Electronic Health Records, Other, Registry Data

2a1.26 Data Source/Data Collection Instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.*)**:** Not Applicable

2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment:

2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment:

2a1.33 Level of Analysis (*Check the levels of analysis for which the measure is specified and tested)*:
Clinician : Group/Practice, Clinician : Individual

2a1.34-35 Care Setting *(Check all the settings for which the measure is specified and tested)*:
Other:Hospital Outpatient Clinic, Outpatient Services

2a2. Reliability Testing. (*Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability*.)

2a2.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
Refer to the validity section for a description of the data sample for our EHR testing project.

2a2.2 Analytic Method *(Describe method of reliability testing & rationale)*:
Refer to the validity section for a description of the analytic methods for our EHR testing project.

2a2.3 Testing Results *(Reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
Refer to the validity section for a description of the testing results for our EHR testing project.

2b. VALIDITY. Validity, Testing, including all Threats to Validity: H○ M○ L○ I ○

2b1.1 Describe how the measure specifications *(measure focus, target population, and exclusions)* **are consistent with the evidence cited in support of the measure focus (***criterion 1c)* **and identify any differences from the evidence:**
The measure specifications are consistent with the evidence from the guideline.

2b2. Validity Testing. (*Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.)*

2b2.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
EHR Measure Validity
The measure performance was calculated from data collected using two different methods of collection:
- Automated EHR report
- Visual inspection of the medical record by professional data abstractors to capture the data elements to manually construct the performance

The data source was electronic health records in the ambulatory care setting.
The data sample came from 2 sites representing a community health center and a large independent specialty practice, both in the midwest region
The sample consisted of 1144 patient encounters.
Visual inspection of the medical record was performed in 2010.

Face Validity
An expert panel was used to assess face validity of the measure. This panel consists of 22 members, with representation from the following specialties: infectious diseases, gastroenterology, methodology, hepatology, family medicine, OB/GYN, internal medicine, nursing, health plan representation and patient advocacy.

Oluwatoyin Adeyemi, MD (infectious diseases) Cook County Hospital, Rush University Medical Center, Chicago, IL
Maureen L. Borkowski, RN, BSN Information Specialist, American Liver Foundation, Cedar Grove, NJ
Joel V. Brill, MD (gastroenterology) American Gastroenterological Association, Phoenix, AZ
Betty Jo Edwards, MD (OB/GYN) Texas Medical Arts Tower, Houston, TX

Debra Esser, MD, MMM (family medicine) Omaha, NE
Gregory T. Everson, MD (gastroenterology) University of Colorado Denver, Section of Hepatology, Aurora, CO
Troy Fiesinger, MD, FAAFP (family medicine) Memorial Family Medicine Residency, Physicians at Sugar Creek, Sugar Land, TX
Michael W. Fried, MD (gastroenterology, hepatology) Professor of Medicine, Director, UNC Liver Center, University of North Carolina @ Chapel Hill, Chapel Hill, NC
Stephen A. Harrison, MD (gastroenterology) Assistant Professor, Division of Gastroenterology, Brooke Army Medical Center, Fort Sam Houston, TX
Ira Jacobson, MD (gastroenterology, hepatology) Chief, Division of GI & Hepatology, Weill Medical College of Cornell, New York, NY
Catherine MacLean, MD, PhD (health plan representative) Medical Director, Programs for Clinical Excellence WellPoint, Inc., Westlake Village, CA
Lynn McElroy American Liver Foundation, Cedar Grove, NJ
Paola Ricci, MD (gastroenterology) VA Medical Center-Gastroenterology, Minneapolis, MN
Sam J. W. Romeo, MD, MBA (family medicine) General Partner, Tower Health & Wellness Center, LP, Turlock, CA
John F. Schneider, MD, PhD (internal medicine) Past President, Illinois State Medical Society, Flossmoor, IL
Leonard B. Seeff, MD (hepatology) Food and Drug Administration, Silver Spring, MD
Kenneth E. Sherman, MD, PhD (hepatology, gastroenterology) Director, Division of Digestive Disease, University of Cincinnati School of Medicine, Cincinnati, OH
Alan D. Tice, MD, FACP (infectious diseases) Infections Limited Hawaii, Honolulu, HI
Monte Troutman, DO, FACOI (gastroenterology) Chairman, Department of Medicine, Chief, Division of Gastroenterology, University of North Texas Health Science Center/ Texas College of Osteopathic Medicine, Fort Worth, TX
John Ward, MD (internal medicine) Director, Division of Viral Hepatitis, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (proposed), Centers for Disease Control and Prevention, Atlanta, GA
Josie R. Williams, MD, MMM (gastroenterology/methodology) Director, Rural & Community Health Institute: QPSI, Asst. Professor of Internal & Family Medicine, Texas A&M University System, College Station, TX
John B. Wong, MD (gastroenterology, hepatology) Tufts New England Medical Center, Clinical Decision Making, Boston, MA

2b2.2 Analytic Method *(Describe method of validity testing and rationale; if face validity, describe systematic assessment)*:
EHR Measure Validity
Data from a performance report for the measure automatically-generated from the EHR (designed to collect the necessary data elements to identify eligible cases and calculate the performance score) were compared to data elements found and scores calculated manually on visual inspection of the medical record by trained abstractors.

Data analysis included:
• Percent agreement at the denominator, numerator
• Kappa statistic to ensure that agreement rates are not a phenomenon of chance

Face Validity
Face validity of the measure score as an indicator of quality was systematically assessed as follows.
After the measure was fully specified, the expert panel (workgroup membership) was asked to rate their agreement with the following statement:
The scores obtained from the measure as specified will provide an accurate reflection of quality and can be used to distinguish good and poor quality.
Scale 1-5, where 1= Strongly Disagree; 3=Neither Agree nor Disagree; 5= Strongly Agree

2b2.3 Testing Results *(Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment)*:
EHR Measure Validity
This measure demonstrates moderate agreement when comparing EHR automated report to visual inspection of the medical record.

Reliability: N, Kappa (95% CI)
Overall: 123, 0.48 (0.083- 0.535)

Face Validity
The results of the expert panel rating of the validity statement were as follows: N = 13; Mean rating = 4.85 and 100.00% of respondents either agree or strongly agree that this measure can accurately distinguish good and poor quality

The results of the expert panel rating of the validity statement were as follows:
Frequency Distribution of Ratings
1 - 0 (Strongly Disagree)
2 - 0
3 - 0 (Neither Disagree nor Agree)
4 - 2
5 - 11 (Strongly Agree)

POTENTIAL THREATS TO VALIDITY. (*All potential threats to validity were appropriately tested with adequate results.*)

2b3. Measure Exclusions. (*Exclusions were supported by the clinical evidence in 1c or appropriately tested with results demonstrating the need to specify them.*)

2b3.1 Data/Sample for analysis of exclusions *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
EHR Measure Validity
The measure performance was calculated from data collected using two different methods of collection:
- Automated EHR report
- Visual inspection of the medical record by professional data abstractors to capture the data elements to manually construct the performance

The data source was electronic health records in the ambulatory care setting.
The data sample came from 2 sites representing a community health center and a large independent specialty practice, both in the midwest region
The sample consisted of 1144 patient encounters.
Visual inspection of the medical record was performed in 2010.

2b3.2 Analytic Method (*Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference)*:
EHR Measure Validity
- An automated report of performance was created.
- Manual abstractors reviewed each patient who did not meet the measure according to the automated report.
- Exceptions were documented even for performance measures that did not allow for exceptions in the specifications in an attempt to see whether some measures should include denominator exceptions to more accurately reflect quality.

2b3.3 Results *(Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity*

analyses):
EHR Measure Validity
The automated report was unable to capture exceptions for this measure, as there was no discrete field for allowable exception. The percentage of false negatives due to exception (the 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 3/14 or 21.4%. This represents a change in measure performance from 56.3% to 60.9% with an exception rate of 7.5%.

2b4. Risk Adjustment Strategy. (*For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.*)

2b4.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)***:**
This measure is not risk adjusted.

2b4.2 Analytic Method (*Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables)***:**
This measure is not risk adjusted.

2b4.3 Testing Results *(Statistical risk model: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. Risk stratification: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata)***:**
This measure is not risk adjusted.

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: As a process measure, no risk adjustment is necessary.

2b5. Identification of Meaningful Differences in Performance. (*The performance measure scores were appropriately analyzed and discriminated meaningful differences in quality.*)

2b5.1 Data/Sample *(Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)***:**
CMS Physician Quality Reporting Initiative:
2,450 cases were reported on for the 2010 program, the most recent year for which data is available.

The following information is for the 2008 program, the only year for which such data is available.
Clinical Condition and Measure: Hepatitis C: Hepatitis B Vaccination in Patients with HCV
Eligible Professionals: 67,332
Professionals Reporting >=1 Valid QDC: 226
% Professionals Reporting >=1 Valid QDC: 0.34%
# Professionals Satisfactorily Reporting: 108
% Professionals Satisfactorily Reporting: 47.79%

2b5.2 Analytic Method *(Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance)***:**
CMS Physician Quality Reporting Initiative:
The inter-quartile range (IQR) was calculated to determine the variability of performance on the measure.

2b5.3 Results *(Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*:
Scores on this measure: N =1,123; 88.78% is the aggregate perormance rate in the total patient population.

10th percentile: 0.00%
25th percentile: 75.00%
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 25.00, and indicates that 50% of physicians have performance on this measure ranging from 75.00% and 100.00%. A quarter of reporting physicians have performance of 75.00% or less.

Source: Confidential CMS PQRI 2010 Performance Information by Measure. TAP file.

2b6. Comparability of Multiple Data Sources/Methods. (*If specified for more than one data source, the various approaches result in comparable scores.*)

2b6.1 Data/Sample *(Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)***:**
Please refer to the EHR Measure Validity section of this form.

2b6.2 Analytic Method *(Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure)***:**
Please refer to the EHR Measure Validity section of this form.

2b6.3 Testing Results *(Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted)***:**
Please refer to the EHR Measure Validity section of this form.

2c. Disparities in Care: H○ M○ L○ I ○ NA○ (*If applicable, the measure specifications allow identification of disparities.*)

2c.1 If measure is stratified for disparities, provide stratified results *(Scores by stratified categories/cohorts)***:** 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.

2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:
The PCPI advocates that performance measure data should, where possible, be stratified by race, ethnicity, and primary language to assess disparities and initiate subsequent quality improvement activities addressing identified disparities, consistent with recent national efforts to standardize the collection of race and ethnicity data. A 2008 NQF report endorsed 45 practices including stratification by the aforementioned variables.(1) A 2009 IOM report "recommends collection of the existing Office of Management and Budget (OMB) race and Hispanic ethnicity categories as well as more fine-grained categories of ethnicity(referred to as granular ethnicity and based on one's ancestry) and language need (a rating of spoken English language proficiency of less than very well and one's preferred language for health-related encounters)."(2)

References:
(1)National Quality Forum Issue Brief (No.10). Closing the Disparities Gap in Healthcare Quality with Performance Measurement and Public Reporting. Washington, DC: NQF, August 2008.

(2)Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. March 2010. AHRQ Publication No. 10-0058-EF. Agency for Healthcare Research and Quality, Rockville, MD. Available at:
http://www.ahrq.gov/research/iomracereport. Accessed May 25, 2010.

2.1-2.3 Supplemental Testing Methodology Information:

Steering Committee: Overall, was the criterion, *Scientific Acceptability of Measure Properties*, met? (*Reliability and Validity must be rated moderate or high*) Yes✪ No✪
Provide rationale based on specific subcriteria:

If the Committee votes No, STOP

3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. **(evaluation criteria)**

C.1 Intended Actual/Planned Use *(Check all the planned uses for which the measure is intended)***:** Public Reporting, Quality Improvement (Internal to the specific organization)

3.1 Current Use *(Check all that apply; for any that are checked, provide the specific program information in the following questions)*: Public Reporting, Quality Improvement (Internal to the specific organization)

3a. Usefulness for Public Reporting: H✪ M✪ L✪ I ✪
(*The measure is meaningful, understandable and useful for public reporting.*)

3a.1. Use in Public Reporting - disclosure of performance results to the public at large *(If used in a public reporting program, provide name of program(s), locations, Web page URL(s)).* If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: **[*For Maintenance* –** *If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.***]**
This measure is currently in use in PQRS and has been since 2008. It´s also been proposed for inclusion in CMS´s EHR Incentive Program: Meaningful Use Stage 2.

The PCPI believes that the reporting of participation information is a beneficial first step on a trajectory toward the public reporting of performance results, which is appropriate since the measure has been tested and the reliability of the performance data has been validated. Continued NQF endorsement will facilitate our ongoing progress toward this public reporting objective.

3a.2.Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results**:** The PCPI believes that the reporting of participation information is a beneficial first step on a trajectory toward the public reporting of performance results, which is appropriate since the measure has been tested and the reliability of the performance data has been validated. Continued NQF endorsement will facilitate our ongoing progress toward this public reporting objective.

3.2 Use for other Accountability Functions (payment, certification, accreditation). If used in a public accountability program, provide name of program(s), locations, Web page URL(s)**:** This measure may be used in a Maintenance of Certification program.

3b. Usefulness for Quality Improvement: H✪ M✪ L✪ I ✪
(*The measure is meaningful, understandable and useful for quality improvement.*)

3b.1. Use in QI. If used in quality improvement program, provide name of program(s), locations, Web page

URL(s):
[*For Maintenance* – *If not used for QI, indicate the reasons and describe progress toward using performance results for improvement*].
All PCPI measures are suitable for use in quality improvement initiatives and are made freely available on the PCPI website and through the implementation efforts of medical specialty societies and other PCPI members. The PCPI strongly encourages the use of its measures in QI initiatives and seeks to provide information on such initiatives to PCPI members.

3b.2. Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated *(e.g., QI initiative),* describe the data, method and results:
The PCPI believes that the use of PCPI measures in quality improvement initiatives is a beneficial way to gather scientific data with which to improve physician performance. This is appropriate since the measure has been tested and the reliability of the performance data has been validated. NQF endorsement will facilitate our ongoing progress toward this quality improvement objective.

Overall, to what extent was the criterion, *Usability*, met? H○ M○ L○ I ○
Provide rationale based on specific subcriteria:

4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. **(evaluation criteria)**

4a. Data Generated as a Byproduct of Care Processes: H○ M○ L○ I ○

4a.1-2 How are the data elements needed to compute measure scores generated? *(Check all that apply).*
Data used in the measure are**:**
generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition

4b. Electronic Sources: H○ M○ L○ I ○

4b.1 Are the data elements needed for the measure as specified available electronically *(Elements that are needed to compute measure scores are in defined, computer-readable fields)***:** ALL data elements in electronic health records (EHRs)

4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources:

4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: H○ M○ L○ I ○

4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results:
We are not aware of any unintended consequences related to this measurement.

4d. Data Collection Strategy/Implementation: H○ M○ L○ I ○

A.2 Please check if either of the following apply (*regarding proprietary measures*)**:**
4d.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues *(e.g., fees for use of proprietary measures)***:**
This measure was found to be reliable and feasible for implementation.

Overall, to what extent was the criterion, *Feasibility*, met? H○ M○ L○ I ○
Provide rationale based on specific subcriteria:

OVERALL SUITABILITY FOR ENDORSEMENT

Does the measure meet all the NQF criteria for endorsement? Yes○ No○
Rationale:

If the Committee votes No, STOP.
If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.

5. COMPARISON TO RELATED AND COMPETING MEASURES

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

5.1 **If there are related measures *(either same measure focus or target population)* or competing measures *(both the same measure focus and same target population*), list the NQF # and title of all related and/or competing measures:**
0412 : HIV/AIDS: Hepatitis B Vaccination

5a. Harmonization

5a.1 **If this measure has EITHER the same measure focus OR the same target population as NQF-endorsed measure(s): Are the measure specifications completely harmonized?** Yes

5a.2 **If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:**

5b. Competing Measure(s)

5b.1 **If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s):**
Describe why this measure is superior to competing measures *(e.g., a more valid or efficient way to measure quality)***; OR provide a rationale for the additive value of endorsing an additional measure.** *(Provide analyses when possible)***:**
No competing measure.

CONTACT INFORMATION

Co.1 **Measure Steward (Intellectual Property Owner):** American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI), 515 N. State St., Chicago, Illinois, 60654

Co.2 **Point of Contact:** Mark S., Antman, DDS, MBA, Director, Measure Development Operations Performance Improvement, mark.antman@ama-assn.org, 312-464-5056-

Co.3 **Measure Developer if different from Measure Steward:** American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI), 515 N. State St., Chicago, Illinois, 60654

Co.4 **Point of Contact:** Mark S., Antman, DDS, MBA, Director, Measure Development Operations Performance Improvement, mark.antman@ama-assn.org, 312-464-5056-

Co.5 Submitter: Katherine, Ast, MSW, LCSW, katherine.ast@ama-assn.org, 312-464-4920-, American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI)

Co.6 Additional organizations that sponsored/participated in measure development:
American Association for the Study of Liver Diseases, American Gastroenterological Association Institute

Co.7 Public Contact: Mark S., Antman, DDS, MBA, Director, Measure Development Operations Performance Improvement, mark.antman@ama-assn.org, 312-464-5056-, American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI)

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development
Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.
Co-Chairs:
John B. Wong, MD (gastroenterology, hepatology, methodology)
John W. Ward, MD (internal medicine)

Work Group Members:
Joel V. Brill, MD (gastroenterology)
Roger Chou, MD (internal medicine, guideline experience)
Richard H. Davis, Jr., PA-C (physician assistant)
Yngve Falck-Ytter, MD, AGAF (gastroenterology/liver/hepatologist)
Troy Fiesinger, MD, FAAFP (family medicine)
Marc G. Ghany, MD, MHSc (guideline experience/hepatology)
Arthur Yu-shin Kim, MD (HIV and HCV co-infection)
Barbara H. McGovern, MD (HIV and HCV co-infection)
Daniel B. Raymond (consumer/patient advocacy group)
Paola Ricci, MD (hepatology/gastroenterology)
Saverio Sava, MD (CHC representative/hepatologist)
Lynn Gardiner Seim, MSN, RN (patient advocacy)
Jessica A. Shepherd, MD, MBA (OB/GYN)
Margaret C. Shuhart, MD, MS (hepatology/gastroenterology)
Amy Hirsch Shumaker, PharmD, BCPS (pharmacy, hepatology, infectious disease)
Chris Taylor (patient advocacy/public health)
Glenn Treisman, MD, PhD (HIV and HCV psychiatrist)
Weifeng Weng, PhD (health services researcher/ABIM PIM development)
John Yao, MD, MPH, MBA, MPA, FACP (health plan representative)

PCPI measures are developed through cross-specialty, multi-disciplinary work groups. All medical specialties and other health care professional disciplines participating in patient care for the clinical condition or topic under study are invited to participate as equal contributors to the measure development process. In addition, the PCPI strives to include on its work groups individuals representing the perspectives of patients, consumers, private health plans, and employers. This broad-based approach to measure development ensures buy-in on the measures from all stakeholders and minimizes bias toward any individual specialty or stakeholder group. All work groups have at least two co-chairs who have relevant clinical and/or measure development expertise and who are responsible for ensuring that consensus is achieved and that all perspectives are voiced.

Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for adapting the original measure and any work with the original measure steward: n/a

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.3 Year the measure was first released: 2006
Ad.4 Month and Year of most recent revision: 06, 2012
Ad.5 What is your frequency for review/update of this measure? See Ad.9.
Ad.6 When is the next scheduled review/update for this measure? 06, 2012

Ad.7 Copyright statement: Physician Performance Measures (Measures) and related data specifications have been developed by the American Medical Association (AMA)-convened Physician Consortium for Performance Improvement® (PCPI™).

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Ad.8 Disclaimers:

Ad.9 Additional Information/Comments: Coding/Specifications updates occur annually. The PCPI has a formal measurement review process that stipulates regular (usually on a three-year cycle, when feasible) review of the measures. The process can also be activated if there is a major change in scientific evidence, results from testing or other issues are noted that materially affect the integrity of the measure.

Date of Submission (*MM/DD/YY*)**:** 07/02/2012