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 <u>submitting standards web page</u>.

NQF #: 0412 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: Jul 13, 2012

BRIEF MEASURE INFORMATION

De.1 Measure Title: HIV/AIDS: Hepatitis B Vaccination

Co.1.1 Measure Steward: National Committee for Quality Assurance

De.2 Brief Description of Measure: 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

2a1.1 Numerator Statement: Patients who have received at least one injection of hepatitis B vaccination, or who have documented immunity

2a1.4 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 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)

2a1.8 Denominator Exclusions: None.

1.1 Measure Type: Process

2a1. 25-26 Data Source: Administrative claims, Electronic Clinical Data

2a1.33 Level of Analysis: Clinician : Group/Practice, Clinician : Individual

1.2-1.4 Is this measure paired with another measure? No

De.3 If included in a composite, please identify the composite measure (*title and NQF number if endorsed*): N/A

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 <u>endorsed</u> or submitted measures (*check 5.1*):
Other Criteria:

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 <u>guidance on evidence</u>.

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, Infectious Diseases : Hepatitis, Infectious Diseases : Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS), Infectious Diseases : Immunization De.5 Cross Cutting Areas (Check all the areas that apply): Prevention : Immunization

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

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

1a.3 Summary of Evidence of High Impact (Provide epidemiologic or resource use data):

Approximately 1.2 million people in the U.S. age 13 and older are estimated to be living with HIV and as many as 20 percent of them are undiagnosed. (CDC, 2012) Despite strong efforts that have prevented significant increases in new cases of HIV/AIDS since 2006, an average of 50,000 people are newly infected each year, (CDC, Aug 2011) and although the number of deaths due to HIV/AIDS infection declined 7 percent from 2006-2009, (CDC, Feb 2011) it is still one of the top leading causes of death for black males and females and Hispanic/Latina females in the 35–44 age group. (CDC, 2012) These steady incidence rates and declining mortality rates mean more people than ever are living with HIV/AIDS; ensuring they receive recommended, high-quality care supports prevention efforts and significantly affects their ability to lead healthier lives. Preventing HIV and its related illness and death is a significant national health policy objective and 18 of the U.S. Healthy People 2020 goals are related to HIV prevention and treatment. (USDHHS, 2012)

Of the 40 million people worldwide estimated to have HIV, 2 to 4 million of them also have the Hepatitis B virus (HBV). (Alter, 2005) Up to 90% of HIV-infected persons have at least one serum marker of previous exposure to HBV, and approximately 10% have evidence of chronic HBV. (Rodriguez-Mendez, et al., 2000) Chronic HBV might lead to mild, moderate, or severe hepatitis with eventual development of cirrhosis and portal hypertension, and people with chronic HBV are at an increased risk for liver-related mortality and morbidity. (Collin, et al., 1999; Thio, et al., 2002) Immunosuppressed individuals are more likely to have primary HB infections that become chronic. To prevent transmission of HBV and disease progression and mortality in HIV patients, all children and adolescents under age 19 and those HIV-infected patients with no evidence of previous exposure to HBV should be vaccinated with HBV vac¬cine. (CDC, April 2009; CDC, Sep 2009) In addition, routine provision of HBV vaccine at major HIV counseling and testing sites has been found to be a highly effective and cost-effective approach to preventing HBV among high-risk adults. (Kim, et al., 2006)

1a.4 Citations for Evidence of High Impact cited in 1a.3: Alter MJ. Epidemiology of viral hepatitis and HIV co-infection. J Hepatol. 2006;44(1 Suppl):S6-9. Epub 2005 Nov 21.

Centers for Disease Control and Prevention (CDC). HIV in the United States: At a Glance. National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Division of HIV/AIDS Prevention. Last Updated March 12, 2012. Accessed May 14, 2012. http://www.cdc.gov/hiv/resources/factsheets/us.htm

Centers for Disease Control and Prevention (CDC). Estimates of New HIV Infections in the United States, 2006–2009. CDC Fact Sheet, August 2011. Accessed May 14, 2012. http://www.cdc.gov/nchhstp/newsroom/HIVIncidenceResources.html

Centers for Disease Control and Prevention (CDC). HIV Surveillance Report, 2009; vol. 21. Published February 2011. Accessed May 14, 2012. http://www.cdc.gov/hiv/surveillance/resources/reports/2009report/

Centers for Disease Control and Prevention (CDC), the National Institutes of Health, and the HIV Medicine Association of the

Infectious Diseases Society of America. Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents. Morbidity and Mortality Weekly Report, vol. 58, April 10, 2009.

Centers for Disease Control and Prevention (CDC), NIH, IDSA, Pediatric Infectious Diseases Society, American Academy of Pediatrics. Guidelines for the Prevention and Treatment of Opportunistic Infections Among HIV-Exposed and HIV-Infected Children. Morbidity and Mortality Weekly Report, vol. 58, September 4, 2009.

Colin JF, Cazals-Hatem D, Loriot MA, et al. Influence of human immunodeficiency virus infection on chronic hepatitis B in homosexual men. Hepatology 1999;29:1306–10.

Kim SY, Billah K, Lieu TA, Weinstein MC. Cost effectiveness of hepatitis B vaccination at HIV counseling and testing sites. Am J Prev Med. 2006 Jun;30(6):498-506.

Rodriguez-Mendez ML, Gonzalez-Quintela A, Aguilera A, Barrio E. Prevalence, patterns, and course of past hepatitis B virus infection in intravenous drug users with HIV-1 infection. Am J Gastroenterol 2000;95:1316–22.

Thio CL, Seaberg EC, Skolasky R, Jr., et al. HIV-1, hepatitis B virus, and risk of liver-related mortality in the Multicenter Cohort Study (MACS). Lancet 2002;360:1921–6.

USDHHS. Healthy People 2020 Topics and Objectives Index. Last updated May 1, 2012. http://www.healthypeople.gov/2020/topicsobjectives2020/default.aspx.

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: Preventing, identifying, and managing individuals co-infected with HIV-1 and HBV, especially those with low CD4 nadir counts, can prevent them from having an increased risk for liver-related mortality. (Thio, et al., 2002) It can also prevent transmission of HBV to others. (CDC, April 2009; CDC, Sep 2009)

Thio CL, Seaberg EC, Skolasky R, Jr., et al. HIV-1, hepatitis B virus, and risk of liver-related mortality in the Multicenter Cohort Study (MACS). Lancet 2002;360:1921–6.

Centers for Disease Control and Prevention (CDC), the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents. Morbidity and Mortality Weekly Report, vol. 58, April 10, 2009.

Centers for Disease Control and Prevention (CDC), NIH, IDSA, Pediatric Infectious Diseases Society, American Academy of Pediatrics. Guidelines for the Prevention and Treatment of Opportunistic Infections Among HIV-Exposed and HIV-Infected Children. Morbidity and Mortality Weekly Report, vol. 58, September 4, 2009.

1b.2 Summary of Data Demonstrating Performance Gap (Variation or overall less than optimal performance across providers): [For <u>Maintenance</u> – Descriptive statistics for performance results <u>for this measure</u> - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.]

Although this measure is not yet publicly reported, there is data to indicate there is a gap in performance with room for improvement. The Centers for Disease Control and Prevention (CDC) analyzed data from the 2010 National Health Interview Survey (NHIS), and found that among adults aged 19-49 years at high risk for infection, 42.0% had received at least three doses of the hepatitis B vaccine. Testing positive for HIV was one risk factor for hepatitis B. The hepatitis B vaccination rate was highest for non-Hispanic whites (44.5%), followed by non-Hispanic blacks (41.6%), non-Hispanic Asians (40.2%), and was lowest for Hispanics (33.8%).

1b.3 Citations for Data on Performance Gap: [For <u>Maintenance</u> – 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]

Centers for Disease Control and Prevention. Adult Vaccination Coverage — United States, 2010. Morbidity and Mortality Weekly Report. February 3, 2012 / 61(04);66-72.

1b.4 Summary of Data on Disparities by Population Group: [*For <u>Maintenance</u> – Descriptive statistics for performance results <u>for this measure</u> by population group]*

The measure is not stratified by patient groups or cohorts that could potentially be affected by disparities in care. NCQA has participated with IOM and others in attempting to include information on disparities in measure data collection. However, at the present time, this data is not coded in a standard manner, and is incompletely captured. There are no consistent standards for what entity (physician, group, plan, and employer) should capture and report this data. While "requiring" reporting of the data could push the field forward, it has been our position that doing so would create substantial burden without generating meaningful results. We believe that the measure specifications should NOT require this unless absolutely necessary since the data needed to determine disparities cannot be ascertained from the currently available sources.

1b.5 Citations for Data on Disparities Cited in 1b.4: [For <u>Maintenance</u> – 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]

N/A

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
 Consistency:
 H
 M
 L
 I
 I

Quantity	Quality	Consistency	Does the measure pass subcriterion1c?	
M-H	M-H	M-H	Yes	
L	M-H	М	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		s relationship to at least tervention, 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):

This is a process measure.

Provide hepatitis B vaccination to patients with HIV/AIDS >> Protect against transmission of hepatitis B >> Protect against liverrelated illness >> Reduce morbidity and mortality

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):

Clinical practice guidelines released by the Centers for Disease Control and Prevention (CDC) recommend that HIV-infected patients who do not have evidence of previous exposure to HBV should be vaccinated with hepatitis B vac¬cine (A-II). Guidelines for the primary care of patients with HIV/AIDS from the HIV Medicine Association (HIVMA) recommend that HIV-infected patients be screened for evidence of HBV infection upon initiation of care by detection of hepatitis B surface antigen (HBsAg), antibody to HBsAg, and antibody to hepatitis B total core antigen (A-III), and those who are susceptible to infection should be vaccinated against HBV (B-II).

Pediatric guidelines from the CDC recommend all infants born to HBV-infected women, including HIV co-infected women, should receive hepatitis B vaccine and hepatitis B immune globulin (HBIG) within 12 hours after birth, a second dose of hepatitis B vaccine at age 1–2 months, and a third dose at age 6 months (A-I).

1c.5 Quantity of Studies in the Body of Evidence (*Total number of studies, not articles*): A total of 23 studies were cited in the CDC guidelines for adult and adolescent patients. Three were randomized control trials of at least 210 patients, five were controlled clinical trials of 303 patients, three were uncontrolled clinical trials of 245 patients, two were cohort studies of 324 patients, and five were observational studies of 6,151 patients. Information on four of the cited studies could not be determined and one citation was another set of guidelines. The CDC pediatric guidelines cited two cohort studies of 110 patients and also the CDC's Advisory Committee on Immunization Practices vaccination recommendations. The HIVMA guidelines cited six other sets of guidelines and one uncontrolled clinical trial of 69 patients.

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): The evidence behind the hepatitis B vaccination recommendations for adults with HIV/AIDS is moderate and includes at least one well-designed clinical trial without randomization, from cohort or case-controlled analytic studies (preferably from more than one center), or from multiple time-series studies, or dramatic results from uncontrolled experiments. The evidence behind hepatitis B vaccination for infants born to HBV-infected women, including HIV co-infected women, is strong and is based on at least 1 properly designed randomized, controlled trial.

1c.7 Consistency of Results across Studies (Summarize the consistency of the magnitude and direction of the effect): The evidence cited in the CDC and HIVMA guidelines is consistent in showing the benefits of providing hepatitis B vaccination for people with HIV/AIDS.

1c.8 Net Benefit (Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms):

CDC Prevention and Treatment of Opportunistic Infections in HIV-infected Adults and Adolescents Clinical Practice Guidelines: The panel determined there was a positive net benefit for prevention of viral infections in HIV-infected adults and adolescents.

CDC Prevention and Treatment of Opportunistic Infections in HIV-Exposed and –Infected Children Clinical Practice Guidelines: The panel determined there was a positive net benefit for prevention of viral infections in HIV-exposed and infected children.

HIVMA Guidelines: The HIVMA determined there was a positive net benefit for prevention of viral infections in patients with HIV.

1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? Yes

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

These guidelines were developed by a panel of specialists from the United States government and academic institutions. For each infection covered in the guidelines, a small group of specialists with content-matter expertise reviewed the literature for new information since the guidelines were last pub¬lished; they then proposed revised recommendations at a meeting held at NIH in June 2007. After those presentations and a discussion, the revised guidelines were further reviewed by the co-editors; by the Office of AIDS Research, NIH; by specialists at CDC; and by HIVMA of IDSA before final approval and publication. CDC and its planners and content specialists disclosed they had no finan¬cial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters, with the exception of Constance Benson and King K. Holmes. Dr. Benson disclosed being on the Advisory Board for Merck, GlaxoSmithKline, and Boehringer Ingelheim; being a grant recipient for Gilead; and being a Data Safety Monitoring Board (DSMB) member for Achillion and JJR Australia. Her spouse also was a consultant for Merck, Gilead, Achillion, Monogram, and Vertex. Dr. Holmes disclosed being a DSMB member of Merck, receiving an honorarium at the 2005 Infectious Diseases Society of America Conference, and serving on the Mycology Research

Laboratories scientific advisory board. However, their presentations did not include any discussion of the unlabeled use of a product or a product under investigational use.

CDC Pediatrics Guidelines:

The guidelines were developed by a panel of specialists in pediatric HIV infection and infectious diseases (the Pediatric Opportunistic Infections Working Group) from the U.S. government and academic institutions. For each OI, a pediatric specialist with content-matter expertise reviewed the literature for new information since the last guidelines were published; they then proposed revised recommendations at a meeting at the National Institutes of Health (NIH) in June 2007. After these presentations and discussions, the guidelines underwent further revision, with review and approval by the Working Group, and final endorsement by NIH, CDC, the HIV Medicine Association (HIVMA) of the Infectious Diseases Society of America (IDSA), the Pediatric Infectious Disease Society (PIDS), and the American Academy of Pediatrics (AAP). CDC and its planners and content specialists disclosed they had no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters, with the exception of Kenneth Dominguez, who serves on Advisory Board for Committee on Pediatric AIDS (COPD) –Academy of Pediatrics and Kendel International, Inc. antiretroviral Pregnancy Registry and Peter Havens serves on the Advisory board for Abbott Laboratories, Grant Co. Investigator for Gilead, Merck, and Bristrol-Myers Squibb as well as a Grant Recipient for BI, GlaxoSmithKline, Pfizer, Tibotec and Orthobiotech.

HIVMA Guidelines:

A panel of experts composed of specialists in internal medicine, pediatrics, infectious diseases, obstetrics, and gynecology prepared the 2009 update to these guidelines. All members of the panel participated in the preparation and review of the draft guidelines and feedback from external peer reviewers was obtained. These guidelines were reviewed and cleared by the CDC and the IDSA Standards and Practice Guidelines Committee. All members of the Expert Panel complied with the IDSA policy on conflicts of interest, which requires disclosure of any financial or other interest that might be construed as constituting an actual, potential, or apparent conflict. Members of the Expert Panel were provided with the IDSA's conflict of interest disclosure statement and asked to identify ties to companies developing products that might be affected by promulgation of the guidelines. Information was requested regarding employment, consultancies, stock ownership, honoraria, research funding, expert testimony, and membership on company advisory committees. The Panel made decisions on a case-by-case basis as to whether an individual's role should be limited as a result of a conflict. No limiting conflicts were identified.

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

1c.12 If other, identify and describe the grading scale with definitions: CDC Guidelines:

Rating Strength of recommendation: A: Both strong evidence for efficacy and substantial clinical benefit support recommendation for use. Should always be offered; B: Moderate evidence for efficacy—or strong evidence for efficacy but only limited clinical benefit—supports recommendation for use. Should generally be offered; C: Evidence for efficacy is insufficient to support a recommendation for or against use. Or evidence for efficacy might not outweigh adverse conse¬quences (e.g. drug toxicity, drug interactions) or cost of the treatment or alternative approaches. Optional; D: Moderate evidence for lack of efficacy or for adverse outcome supports a recommendation against use. Should generally not be offered; E: Good evidence for lack of efficacy or for adverse outcome supports a recommendation against use. Should never be offered. Rating Quality of the evidence supporting the recommendation: I: Evidence from at least one properly-designed randomized, controlled trial; II: Evidence from at least one well-designed clinical trial without randomization, from cohort or case-controlled analytic studies (preferably from more than one center), or from multiple time-series studies, or dramatic results from uncontrolled experiments; III: Evidence from opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert committees.

HIVMA Guidelines:

Strength of recommendation- Grade A: Good evidence to support a recommendation for use Grade B: Moderate evidence to support a recommendation; Quality of evidence- Level I: Evidence from at least 1 properly designed randomized, controlled trial; Level II: Evidence from at least 1 well-designed clinical trial, without randomization; from cohort or case-controlled analytic studies (preferably from 11 center); from multiple time series; or from dramatic results of uncontrolled experiments Level III: Evidence from opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

1c.13 Grade Assigned to the Body of Evidence: A-I to B-II

1c.14 Summary of Controversy/Contradictory Evidence: Clinical practice guidelines from the Advisory Committee on Immunization Practices (ACIP) recommend the entire hepatitis B series (at least three doses). The dose schedule for this vaccine, for individuals who were not vaccinated as children or were improperly vaccinated, states that the third dose of the vaccine must be administered at least 8 weeks after the second dose and should follow the first dose by at least 16 weeks. The minimum interval between the first and second doses is 4 weeks. Therefore, the minimum amount of time within which an individual may be vaccinated is 4 months. (Mast, 2005) Since patients may drop out of a provider's care within that four month interval, NCQA has decided to measure whether providers are initiating appropriate care by measuring whether at least one dose has been given to individuals who do not have established, documented immunity.

Mast EF, Margolis HS, Fiore AE, Brink EW, Goldstein ST, Wang SA, et al. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States. Recommendations of the Advisory Committee on Immunization Practices (ACIP) Part I: Immunization of infants, children, and adolescents. MMWR. 2005 Dec 23. 54:(RR16);1-23.

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 #): [Strength of recommendation and quality of evidence are in parentheses, following each recommendation]

HIVMA Guidelines (Aberg, 2009):

HIV-infected patients should be screened for evidence of HBV infection upon initiation of care by detection of hepatitis B surface antigen (HBsAg), antibody to HBsAg, and antibody to hepatitis B total core antigen (A-III), and those who are susceptible to infection should be vaccinated against HBV (B-II). HBV vaccination should be administered to those persons who have a positive hepatitis B total core antigen antibody result with negative HBsAg and anti-HBsAg antibody results and who do not have detectable HBV DNA.

CDC Adults & Adolescents Guidelines (CDC, April 2009):

HIV-infected patients who do not have evidence of previous exposure to HBV should be vaccinated with hepatitis B vac¬cine (A-II). On the basis of these data, early vaccination is recommended in HIV-infected patients before the CD4+ count declines to <350 cells/ μ L (A-II). However, vaccination should not be deferred for those with negative or indeterminate serolo¬gies while awaiting a rise in CD4+ count to >350 cells/ μ L. Because some HIV-infected patients with CD4+ counts <200 cells/ μ L do respond to vaccination, vaccination should be performed as previously recommended (A-II), with testing for anti-HBs 1 month after completion of the series (B-III).

CDC Pediatrics Guidelines (CDC, Sept. 2009):

All infants born to HBV-infected women, including HIV coinfected women, should receive hepatitis B vaccine and hepatitis B immune globulin (HBIG) within 12 hours after birth, a second dose of hepatitis B vaccine at age 1–2 months, and a third dose at age 6 months (A-I). The three-dose series of hepatitis B vaccine also is recommended for all children and adolescents aged <19 years who were not previously vaccinated.

1c.17 Clinical Practice Guideline Citation: 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.

Centers for Disease Control and Prevention (CDC), the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents. Morbidity and Mortality Weekly Report, vol. 58, April 10, 2009. Available at: http://www.aidsinfo.nih.gov/contentfiles/Adult_OI.pdf . Accessed May 25, 2012.

Centers for Disease Control and Prevention (CDC), NIH, IDSA, Pediatric Infectious Diseases Society, American Academy of Pediatrics. Guidelines for the Prevention and Treatment of Opportunistic Infections Among HIV-Exposed and HIV-Infected Children. Morbidity and Mortality Weekly Report, vol. 58, September 4, 2009. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr58e0826a1.htm . Accessed May 25, 2012.

1c.18 National Guideline Clearinghouse or other URL:

http://www.uphs.upenn.edu/bugdrug/antibiotic_manual/idsahivprimarycare2009.pdf. Accessed May 25; http://www.aidsinfo.nih.gov/contentfiles/Adult_OI.pdf; http://www.cdc.gov/mmwr/preview/mmwrhtml/rr58e0826a1.htm

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: HIVMA Guidelines; expert consensus with evidence review/ CDC Adult/Adolescent Guidelines; expert consensus with evidence review/ CDC Pediatrics Guidelines; expert consensus with evidence review

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

1c.22 If other, identify and describe the grading scale with definitions: HIVMA Guidelines:

Strength of recommendation- Grade A: Good evidence to support a recommendation for use Grade B: Moderate evidence to support a recommendation; Quality of evidence- Level I: Evidence from at least 1 properly designed randomized, controlled trial; Level II: Evidence from at least 1 well-designed clinical trial, without randomization; from cohort or case-controlled analytic studies (preferably from 11 center); from multiple time series; or from dramatic results of uncontrolled experiments Level III: Evidence from opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

CDC Guidelines:

Rating Strength of recommendation: A: Both strong evidence for efficacy and substantial clinical benefit support recommendation for use. Should always be offered; B: Moderate evidence for efficacy—or strong evidence for efficacy but only limited clinical benefit—supports recommendation for use. Should generally be offered; C: Evidence for efficacy is insufficient to support a recommendation for or against use. Or evidence for efficacy might not outweigh adverse conse¬quences (e.g. drug toxicity, drug interactions) or cost of the treatment or alternative approaches. Optional; D: Moderate evidence for lack of efficacy or for adverse outcome supports a recommendation against use. Should generally not be offered; E: Good evidence for lack of efficacy or for adverse outcome supports a recommendation against use. Should never be offered. Rating Quality of the evidence supporting the recommendation: I: Evidence from at least one properly-designed randomized, controlled trial; II: Evidence from at least one well-designed clinical trial without randomization, from cohort or case-controlled analytic studies (preferably from more than one center), or from multiple time-series studies, or dramatic results from uncontrolled experiments; III: Evidence from opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert committees.

1c.23 Grade Assigned to the Recommendation: A-I to A-III

1c.24 Rationale for Using this Guideline Over Others: It is NCQA policy to use guidelines that are evidence-based, applicable to physicians and other healthcare providers, and developed by a national specialty organization or government agency.

NCQA and PCPI convened an expert panel of diverse stakeholders to review the guidelines and evidence for this measure. The panel determined the measure was scientifically sound using the full body of evidence and guidelines for this measure concept.

Based on the NQF descriptions for rating the evidence, what was the <u>developer's assessment</u> of the quantity, quality, and consistency of the body of evidence?

1c.25 Quantity: High 1c.26 Quality: Moderate1c.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, <u>as specified</u>, 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 <u>guidance on measure testing</u>.

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 <u>this</u> measure can be obtained? Yes

S.2 If yes, provide web page URL: The NQF endorsed measure is available on AMA's website: http://www.ama-assn.org/apps/listserv/x-check/qmeasure.cgi?submit=PCPI

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

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 vaccination, or who have documented immunity

2a1.2 Numerator Time Window (*The time period in which the target process, condition, event, or outcome is eligible for inclusion*): 12-month 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: Patients who have received at least one injection of hepatitis B vaccination, or who have documented immunity

CPT® Procedure Code: 90723, 90740, 90744, 90746, 90747, 90748, or

HCPCS Code: G0010, or

CPT® Category II code: 4275F- Hepatitis B vaccine injection administered or previously received, or CPT® Category II code: 3216F- Patient has documented immunity to Hepatitis B, or CPT® Category II code: 4157F- Hepatitis B vaccine series previously received

2a1.4 **Denominator Statement** (*Brief, narrative description of the target population being measured*): 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 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)

2a1.5 Target Population Category (Check all the populations for which the measure is specified and tested if any): Adult/Elderly Care, Children's Health, Populations at Risk

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

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): 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 in between each visit

ICD-9-CM Diagnosis Code: 042, V08, and

CPT® E/M service code: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99381,99382, 99383, 99384, 99385, 99386, 99387, 99391, 99391, 99392, 99393, 99394, 99395, 99396, 99397, 99241,99242, 99243, 99244, 99245

Note: The denominators for the NCQA/AMA-PCPI HIV/AIDS measures have been harmonized, where appropriate.

2a1.8 **Denominator Exclusions** (Brief narrative description of exclusions from the target population): None.

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): N/A

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): N/A

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.): N/A

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.):

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 at least one hepatitis B vaccination, or documented immunity.

Step 4: Calculate the rate by dividing the total from Step 3 by the total from Step 2.

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

PCPI_Sample_Calculation_Algorithm-634770806772245948.pdf

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): This measure is not based on a sample or survey.

2a1.25 Data Source (Check all the sources for which the measure is specified and tested). If other, please describe: Administrative claims, Electronic Clinical 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.): N/A

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): Ambulatory Care : Clinician Office/Clinic

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):

Measure Validity

The measure performance was calculated from data collected using two different methods of collection:

-Automated electronic health record 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 four sites representing community health centers serving primarily low-income and uninsured patients with multiple, complex needs in the Midwest region.

The sample consisted of 1,630 patient encounters. Visual inspection of the medical records was performed in 2009.

2a2.2 Analytic Method (Describe method of reliability testing & rationale):

As referenced in the NQF Guidance on Measure Testing (2011), separate reliability testing of the data elements is not required if empirical validity testing of the data elements is conducted (e.g., if the validity of ICD-9 codes in administrative claims data as compared to clinical diagnoses in the medical record is demonstrated, then inter-coder or inter-abstractor reliability would not be required). Consequently, we are submitting validity testing results to demonstrate reliability for this measure.

Measure Validity

Data from a performance report for the measure automatically-generated from the electronic health record (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 and numerator.

2a2.3 Testing Results (*Reliability statistics, assessment of adequacy in the context of norms for the test conducted*): Measure Validity

Below are the results when comparing EHR automated report to visual inspection of the medical record.

Automated calculation of performance=29.6%

Manual calculation of performance=88%

Percentage Point Difference between Automated and Manual=59%

The difference between scores likely resulted from the lack of a standardized field for "documented immunity" in the electronic health record at the test sites. This data, however, was available from the paper medical record.

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 evidence is consistent with the focus and scope of this measure.

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):

Measure Validity

The measure performance was calculated from data collected using two different methods of collection:

-Automated electronic health record 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 four sites representing community health centers serving primarily low-income and uninsured patients with multiple, complex needs in the Midwest region. The sample consisted of 1,630 patient encounters. Visual inspection of the medical records was performed in 2009.

Face Validity

An expert panel was used to assess the face validity of this measure when it was re-evaluated in 2012. The full list of panel members is provided under the section Additional Information, Ad.1. Workgroup/Expert Panel Involved in Measure Development – 2012 (Measure Review) Panel.

2b2.2 Analytic Method (Describe method of validity testing and rationale; if face validity, describe systematic assessment): Measure Validity

Data from a performance report for the measure automatically-generated from the electronic health record (designed to collect the necessary data elements to identify eligible cases and calculate the performance score) were compared to data elements found

NQF #0412 HIV/AIDS: Hepatitis B Vaccination, Last Updated Date: Jul 13, 2012

and scores calculated manually on visual inspection of the medical record by trained abstractors.

Data analysis included percent agreement at the denominator and numerator.

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 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 or 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):

Measure Validity

Below are the results when comparing EHR automated report to visual inspection of the medical record.

Automated calculation of performance=29.6%

Manual calculation of performance=88%

Percentage Point Difference between Automated and Manual=59%

The difference between scores likely resulted from the lack of a standardized field for "documented immunity" in the electronic health record at the test sites. This data, however, was available from the paper medical record.

Face Validity

The results of the expert panel rating of the validity statement were as follows: N=8; Mean rating=3.25 and 62.5% 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 (Strongly Disagree)-2 members
- 2-1 member
- 3 (Neither Agree or Disagree)-0 members
- 4-3 members
- 5 (Strongly Agree)-2 members

Face validity results reflected a few workgroup members believed the measure should set a higher bar than at least one injection of Hepatitis B vaccine. However, due to the denominator being "at least two visits, at least 90 days apart," and vaccine schedule for Hepatitis B (minimum amount of time between the first dose and last dose is four months), NCQA believes that at least one injection of Hepatitis B vaccine is a good initiation of care measure.

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): N/A

2b3.2 Analytic Method (Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference):

N/A

2b3.3 Results (*Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses*): N/A

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): N/A

2b4.2 Analytic Method (Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables):

N/A

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. <u>Risk stratification</u>: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata): N/A

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: N/A

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):

Although this measure is not yet publicly reported, there is data to indicate there is a gap in performance with room for improvement from a CDC analysis of 2010 National Health Interview Survey data.

2b5.2 Analytic Method (Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance):

The Centers for Disease Control and Prevention (CDC) analyzed data from the 2010 National Health Interview Survey (NHIS). NHIS collects information about the health and health care of the noninstitutionalized, civilian population in the United States using nationally representative samples. Interviews are conducted in respondents' homes. Questions about receipt of recommended adult vaccinations are asked of a randomly selected adult within the household.

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*):

The CDC analysis found that among adults aged 19-49 years at high risk for infection, 42.0% had received at least three doses of the hepatitis B vaccine. Testing positive for HIV was one risk factor for hepatitis B. The hepatitis B vaccination rate was highest for non-Hispanic whites (44.5%), followed by non-Hispanic blacks (41.6%), non-Hispanic Asians (40.2%), and was lowest for Hispanics (33.8%).

Centers for Disease Control and Prevention. Adult Vaccination Coverage — United States, 2010. Morbidity and Mortality Weekly Report. February 3, 2012 / 61(04);66-72.

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):

This measure has not been compared across data sources.

2b6.2 Analytic Method (Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure): N/A

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*):

N/A

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*): The measure is not stratified by patient groups or cohorts that could potentially be affected by disparities in care. NCQA has participated with IOM and others in attempting to include information on disparities in measure data collection. However, at the present time, this data is not coded in a standard manner, and is incompletely captured. There are no consistent standards for what entity (physician, group, plan, and employer) should capture and report this data. While "requiring" reporting of the data could push the field forward, it has been our position that doing so would create substantial burden without generating meaningful results. We believe that the measure specifications should NOT require this unless absolutely necessary since the data needed to determine disparities cannot be ascertained from the currently available sources.

2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:

N/À

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 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)*). <u>If not publicly reported in a national or community program</u>, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: [*For <u>Maintenance</u> – 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.*]

While this measure is not currently used in national public reporting initiatives, NCQA will submit the NQF-endorsed measure to PQRS for consideration.

3a.2. Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. <u>If usefulness was demonstrated</u> (e.g., focus group, cognitive testing), describe the data, method, and results: While this

measure is not currently used in national public reporting initiatives, a similar measure is being used by the Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau (HAB) in its Core Clinical Performance Measure Module (PMM). This module is a reporting tool that allows providers to compare their performance regionally and nationally to other providers, and supports quality improvement.

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 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 <u>Maintenance</u> – If not used for QI, indicate the reasons and describe progress toward using performance results for improvement*].

The Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau (HAB) uses a similar measure in its Core Clinical Performance Measure Module (PMM). This module is a reporting tool that allows providers to compare their performance regionally and nationally to other providers, and supports quality improvement. Also, the measure specifications are made freely available on the PCPI website and through the implementation efforts of medical specialty societies.

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: A similar Hepatitis B vaccination measure is used by HAB's PMM, indicating that a measure with this focus is meaningful for quality

improvement for this patient population.

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, Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims), Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

4b. Electronic Sources: H M L

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 are in a combination of electronic sources

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

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): Proprietary measure

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):

As a result of our current review of the measures and our experience with the measures since 2008, we have learned and subsequently changed the NCQA/AMA-PCPI HIV/AIDS measures in the following ways.

• We have attempted to limit the number of exclusions/exceptions in these measures due to difficulties accurately capturing them in the health record.

• We have combined measures that address similar clinical areas (e.g., STD screening) into one measure to support feasibility and 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: 0400 : Paired Measure: Hepatitis C: Hepatitis B Vaccination (paired with 0399)

5a. Harmonization

5a.1 If this measure has EITHER the same measure focus OR the same target population as <u>NQF-endorsed measure(s)</u>: Are the measure specifications completely harmonized? No

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

The denominator of #400 is patients with Hepatitis C. The numerator for #0400 and #0412 are harmonized (both use at least one injection of hepatitis B vaccine).

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*): N/A

CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner): National Committee for Quality Assurance, 1100 13th Street NW, Suite 1000, Washington, District Of Columbia, 20005

Co.2 Point of Contact: Bob, Rehm, Assistant Vice President, Performance Measurement, Rehm@ncqa.org, 202-955-1728-

Co.3 Measure Developer if different from Measure Steward: National Committee for Quality Assurance, 1100 13th Street NW, Washington, District Of Columbia, 20005

Co.4 Point of Contact: Dawn, Alayon, MPH, CPH, alayon@ncqa.org, 202-955-3533-

Co.5 Submitter: Dawn, Alayon, MPH, CPH, Senior Health Care Analyst, alayon@ncqa.org, 202-955-3533-, National Committee for Quality Assurance

Co.6 Additional organizations that sponsored/participated in measure development:

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.

Co.7 Public Contact: Bob, Rehm, Assistant Vice President, Performance Measurement, Rehm@ncqa.org, 202-955-1728-, National Committee for Quality Assurance

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.

2007-2008 (Measure Development) Panel

The measure development panel helped guide development of this measure. Staff sought member feedback on all components of the measure (including denominator, numerator, exclusions). The panel met multiple times to achieve consensus on the measures and to address questions about the measure.

Workgroup members

Judith Aberg- Bellevue Hospital Center- New York University (co-chair) Michael Horberg- Santa Clara Medical Center (co-chair) Bruce Agins- New York State Department of Health AIDS Institute (NYSDOH) Steven Asch- RAND Health Communications Larry Bryant-Housingworks- Advocacy & Organizing Sophia Chang- California Healthcare Foundation Laura Cheever- Health Resources and Services Administration (HRSA) Antoine Douaihy- UPMC Mercy Arry Deiudonne- Center for Children- University Hospital Patricia Emmanuel- University of South Florida Marcy Fenton- LA County Department of Public Health Joel Gallant- Johns Hopkins University School of Medicine Joseph Gathe- Texas Medical Center Cyril Goshima- Hawaii AIDS Education and Training Center Andrew Hamilton- Alliance of Chicago Lisa Hischhorn- Harvard Medical School, JSI Research and Training Institute Jan King- Los Angeles County Department of Health Services W. Christopher Matthews- UC San Diego, Department of Medicine James L. Raper- University of Alabama at Birmingham Jennifer Read- National Institutes of Health (NIH) Kimberly Smith- Rush University Medical Center Alice Stek- University of Southern California Valerie Stone- Harvard Medical School, Massachusetts General Hospital Bob Tracy- Bob Tracy Consulting Paul Voldberding- VAMC

Rochelle Walensky- Massachusetts General Hospital Bruce Williams- University of New Mexico Health Sciences Center
Liaisons Brigid Krezek- American College of Obstetricians and Gynecologists Dan Green- Centers for Medicare & Medicaid Services (CDC) Deborah Willis-Fillinger- Health Resources and Services Administration (HRSA) Magda Barini-Garcia- Health Resources and Services Administration (HRSA) Lori DeLorenzo- Health Resources and Services Administration (HRSA) Christine Lubinski- Infectious Diseases Society of America/ HIV Medicine Association Jennifer Padberg- Infectious Diseases Society of America/ HIV Medicine Association
2012 (Measure Review) Panel The measure review panel reviewed the existing measure against current clinical practice guidelines to ensure it reflected current evidence.
Workgroup members Judith Aberg- New York University School of Medicine Bruce Agins- New York State Department of Health AIDS Institute (NYSDOH) Allison Agwu- Johns Hopkins Medical Institutions Marc Foca- Columbia University Rohan Hazra- National Institutes of Health (NIH) Lisa Hirschhorn- Harvard Medical School, JSI Research and Training Institute Gregory Lucas- Johns Hopkins University Michael Horberg- Mid-Atlantic Permanente Group, PC Vicki Peters- NYC Department of Health and Mental Hygiene Alice Stek- University of Southern California School of Medicine Bruce Williams- University of New Mexico Health Sciences Center
Liaisons Laura Cheever- Health Resources and Services Administration (HRSA) Anna Huang- Health Resources and Services Administration (HRSA) Marlene Matosky- Health Resources and Services Administration (HRSA) John Brooks- Centers for Disease Control and Prevention (CDC) Abigail Viall- Centers for Disease Control and Prevention (CDC) Pascale Wortley- Centers for Disease Control and Prevention (CDC)
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: 2008 Ad.4 Month and Year of most recent revision: 06, 2012

Ad.5 What is your frequency for review/update of this measure? Every three years, or sooner if clinical guidelines are updated. Ad.6 When is the next scheduled review/update for this measure?

Ad.7 Copyright statement: This Measure, while copyrighted, can be reproduced and distributed, without modification, for noncommercial purposed, e.g., use by health care providers in connection with their practices. Commercial use is defined as the sale, license, or distribution of the Measures for commercial gain, or incorporation of the Measures into a product or service that is sold, licensed or distributed for commercial gain. Commercial uses of the Measures require a license agreement between the user and American Medical Association, (on behalf of the Consortium) or NCQA. Neither the AMA, NCQA, Consortium nor its members shall be responsible for any use of the Measure.

© 2012 American Medical Association and National Committee for Quality Assurance. All Rights Reserved

Limited proprietary coding is contained in the Measure specifications for convenience. Users of the proprietary code sets should obtain all necessary licenses from the owners of these code sets. The AMA, the Consortium and its members disclaim all liability for use or accuracy of any Current Procedural Terminology (CPT®) or other coding contained in the specifications.

Ad.8 Disclaimers: These performance measures are not clinical guidelines and do not establish a standard of medical care, and have not been tested for all potential applications.

Ad.9 Additional Information/Comments: N/A

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

Sample PCPI Calculation Algorithm

Calculation for Performance

For performance purposes, a measure is calculated by creating a fraction with the following components: Numerator, Denominator, and Denominator Exclusions.

Numerator (A) Includes:

Number of patients meeting numerator criteria **Denominator (PD) Includes:** Number of patients meeting criteria for denominator inclusion

Denominator Exclusions (C) Include:

Number of patients with valid medical, patient or system exclusions (where applicable; will differ by measure)

Performance Calculation



If a measure does not allow for exclusion(s), it is calculated by creating a fraction with the following components: Numerator and Denominator.

Numerator (A) Includes:

Number of patients meeting numerator criteria Denominator (PD) Includes: Number of patients meeting criteria for denominator inclusion

A (# of patients meeting measure criteria)

PD (# of patients in denominator)

It is also possible to calculate the percentage of patients excluded overall, or excluded by medical, patient, or system reason where applicable:

Overall Exclusion Calculation

C (# of patients with any valid exclusion)	
PD (# patients in denominator)	

OR

Exclusion Calculation by Type

C1 (# patients with medical reason)	C ₂ (# patients with patient reason)	C ₃ (# patients with system reason)
PD (# patients in denominator)	PD (# patients in denominator)	PD (# patients in denominator)