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 #: 0475 **NQF Project:** Perinatal and Reproductive Health Project

(for Endorsement Maintenance Review)
Original Endorsement Date: Oct 24, 2008 **Most Recent Endorsement Date:** Oct 24, 2008

BRIEF MEASURE INFORMATION

De.1 **Measure Title:** Hepatitis B Vaccine Coverage Among All Live Newborn Infants Prior to Hospital or Birthing Facility Discharge

Co.1.1 **Measure Steward:** Centers for Disease Control and Prevention

De.2 **Brief Description of Measure:** Percent of live newborn infants that receive hepatitis B vaccination before discharge at each single hospital/birthing facility during given time period (one year).

2a1.1 **Numerator Statement:** The number of live newborn infants administered hepatitis B vaccine prior to discharge from the hospital/birthing facility ("birth dose" of hepatitis B vaccine).

2a1.4 **Denominator Statement:** The number of live newborn infants born at the hospital/birthing facility during the reporting window (one calendar year)

2a1.8 **Denominator Exclusions:** a. Determine number of live newborn infants born at the hospital/birthing facility whose parent/guardian refused hepatitis B birth dose and exclude from the denominator. ICD-10 code for this information will include the following(link: http://www.icd10data.com/ICD10CM/Codes/Z00-Z99/Z20-Z28/Z28-/#Z28):
i. Z28.03 Immunization not carried out because of immune compromised state of patient
ii. Z28.04 Immunization not carried out because of patient allergy to vaccine or component
iii. Z28.1 Immunization not carried out because of patient decision for reasons of belief or group pressure
iv. Z28.20 Immunization not carried out because of patient decision for unspecified reason
v. Z28.21 Immunization not carried out because of patient refusal
vi. Z28.29 Immunization not carried out because of patient decision for other reason
vii. Z28.82 Immunization not carried out because of caregiver refusal

1.1 **Measure Type:** Process
2a1. 25-26 **Data Source:** Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Pharmacy, Electronic Clinical Data : Registry
2a1.33 **Level of Analysis:** Clinician : Group/Practice, Clinician : Individual, Facility, Health Plan

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 endorsed 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 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 : Hepatitis, Perinatal, Prevention, Prevention : Immunization

De.5 **Cross Cutting Areas** (*Check all the areas that apply)*: Population Health

1a.1 **Demonstrated High Impact Aspect of Healthcare:** Affects large numbers, A leading cause of morbidity/mortality, Frequently performed procedure, 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)*:

a. Hepatitis B virus (HBV) causes acute infection and chronic infections.

b. HBV transmission rates vary with infectivity of the pregnant mother. Women with high infectivity (high viral loads) transmit to ~ 90% of their infants; women with lower viral loads may transmit to 5-20% of their infants. In the United States, pregnant women are screened for chronic HBV infection, but not for infectivity. Thus, without intervention, transmission occurs in about 40% of pregnancies of women with chronic hepatitis B infection.

c. Most morbidity and mortality associated with perinatal HBV infection occurs among infants who develop chronic HBV infection. Approximately 90% of infants with perinatal HBV infection will develop chronic infection and about 25% of these infants will have premature death from complications of the chronic infection (i.e., cirrhosis, liver failure, and hepatocellular carcinoma). Without intervention, additional morbidity and mortality accrues from severe acute hepatitis B among infants whose mothers have lower viral load of HBV, but still transmit the infection. These infants, although far less common, suffer fulminant acute hepatitis B with very high mortality rates.

i. In 2008, an estimated 25,000 infants were born to HBV-infected mothers.

ii. Without vaccination (and hepatitis B immune globulin), 6000- 9000 of these infants would become chronically infected with HBV and ~2550 would be expected to die of chronic liver disease

iii. With delayed vaccination, additional uninfected infants will become infected after birth through exposure to household contacts with chronic hepatitis B.

iv. Because the majority of chronically infected infants and children are asymptomatic, children with chronic infection will be identified only if tested for hepatitis B surface antigen (HBsAg). Routine HBsAg testing of infants and children is not done in the United States unless the infant is known to be born of a HBsAg-positive pregnant woman. Children and adults might be tested when they develop endstage liver disease.

d. The primary goal of hepatitis B immunization starting at birth is to prevent chronic HBV infection when the risk is highest (at birth - 5 years of age):

Age at Acute infection	Risk of Symptomatic HBV Infection	Risk of Chronic HBV Inf
< 1 year	< 1%	90%
1-5 years	5-15%	25-50%
>5 years	20-50%	6-10%

e. There are 2 common modes of HBV transmission during infancy and early childhood: 1) transmission from an infected mother to her infant usually during delivery (perinatal), and 2) transmission from an infected (usually asymptomatic) household contact ("horizontal"). Both modes of transmission can be prevented by vaccination of infants starting at birth.

f. Vaccine efficacy in preventing mother to infant HBV transmission:

i. Without post-exposure prophylaxis (PEP), ~90% of infants of HBV-infected mothers will develop chronic HBV infection.

ii. PEP includes hepatitis B vaccine + hepatitis B immune globulin (HBIG) which is 85-95% effective in preventing mother to infant HBV transmission when administered within 12-24 hrs of birth followed by completion of a hepatitis B immunization series[i]. Current ACIP recommendations are for administration of hepatitis B vaccine and HBIG within 12 hours of birth when the mother is known to have chronic HBV infection.

iii. Hepatitis B vaccine alone (without HBIG) starting at birth prevents transmission in 70-95% of infants [ii-vii]. Hepatitis B vaccine alone starting in the first 24 hours after birth is used in many countries to prevent perinatal HBV transmission.

iv. The major determinant of the effectiveness of PEP is early administration of the initial dose of vaccine. Studies are limited on the maximum interval after exposure during which PEP is effective, but it is unlikely to exceed 7 days [viii-xi]. The ACIP recommendation states the first dose of hepatitis B vaccine should be given to all infants born to tested HBsAg-negative women before the infant is discharged from the birthing hospital or facility, which for most infants is before the 3rd day of life.

g. Prevention of HBV transmission from an infected household contact to an infant or child is a critical aspect of eliminating HBV transmission to vulnerable infants and children. Before perinatal hepatitis B prevention programs, studies showed that 61-66% of children with chronic HBV infection were born to uninfected mothers having acquired the infection from close contacts, usually from members of the household[xii, xiii] Hepatitis B vaccine birth dose with completion of the hepatitis B vaccine series will prevent these early childhood acquired infections.

h. Universal administration of a hepatitis B vaccine "birth dose" is the safety net that prevents chronic hepatitis B infection and life-long sequelae among infants born to HBsAg-positive pregnant women not identified due to lack of prenatal care, errors in testing, failure to report test results to public health, failure to administer timely post-exposure prophylaxis, and for infants exposed to hepatitis B virus from infected household contacts before protection through routine hepatitis B vaccination starting at a later age.

1a.4 Citations for Evidence of High Impact cited in 1a.3:

i. Andre FE, Zuckerman AJ. Review: protective efficacy of hepatitis B vaccines in neonates. J Med Virol 1994;44:144-51.
ii. Stevens CE, Neurath RA, Beasley RP, Szmuness W. HBeAg and anti-HBe detection by radioimmunoassay: correlation with vertical transmission of hepatitis B virus in Taiwan. J Med Virol 1979;3:237-41.
iii. Beasley RP, Hwang LY, Lee GC, et al. Prevention of perinatally transmitted hepatitis B virus infections with hepatitis B virus infections with hepatitis B immune globulin and hepatitis B vaccine. Lancet 1983;2(8359):1099-102.
iv. Lo KJ, Tsai YT, Lee SD, et al. Immunoprophylaxis of infection with hepatitis B virus in infants born to hepatitis B surface antigen-positive carrier mothers. J Infect Dis 1985;152:817-22.
v. Poovorawan Y, Sanpavat S, Pongpunlert W, et al. Comparison of a recombinant DNA hepatitis B vaccine alone or in combination with hepatitis B immune globulin for the prevention of perinatal acquisition of hepatitis B carriage. Vaccine 1990 (Suppl 8):S56-9.
vi. Assateerawatt A, Tanphaichitr VS, Suvatte V, In-ngarm L. Immunogenicity and protective efficacy of low dose recombinant DNA hepatitis B vaccine in normal and high-risk neonates. Asian Pac J Allergy Immunol 1991;9:89-93.
vii. Milne A, West DJ, Chinh DV, Moyes CD, Poerschke G. Field evaluation of the efficacy and immunogenicity of recombinant hepatitis B vaccine without HBIG in newborn Vietnamese infants. J Med Virol 2002;67:327-33.
viii. Krugman S, Overby LR, Mushahwar IK, Ling CM, Frosner GG, Deinhardt F. Viral hepatitis, type B: studies on natural history and prevention re-examined. N Engl J Med 1979;300:101-6.
ix. Grady GF. Viral hepatitis: passive prophylaxis with globulins---state of the art in 1978. In: Vyas GN, Cohen SN, Schmid R, eds. Viral hepatitis: a contemporary assessment of etiology, epidemiology, pathogenesis, and prevention. Philadelphia, PA: Franklin Institute Press, 1978:467-76.
x. Beasley RP, Stevens CE. Vertical transmission of HBV and interruption with globulin. In: Vyas GN, Cohen SN, Schmid R, eds. Viral hepatitis: a contemporary assessment of etiology, epidemiology, pathogenesis, and prevention. Philadelphia, PA: Franklin Institute Press; 1978:333-45.
xi. Marion SA, Tomm PM, Pi DW, Mathias RG. Long-term follow-up of hepatitis B vaccine in infants of carrier mothers. Am J Epidemiol 1994;140:734-46.
xii. Hurie MB, Mast EE, Davis JP. Horizontal transmission of hepatitis B virus infection to United States-born children of Hmong refugees. Pediatrics 1992;89:269-73.
xiii. Mahoney FJ, Lawrence M, Scott C, Le Q, Lambert S, Farley TA. Continuing risk for hepatitis B virus transmission among Southeast Asian infants in Louisiana. Pediatrics 1995;96:1113-6.

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:
Prevention of chronic hepatitis B cases and its morbidity and mortality will be strengthened through the safety net provided by administration of the birth dose of the hepatitis B vaccine to all infants before hospital discharge. The MEASURE highlights the critical importance of the birth dose of hepatitis B vaccine as a safety net for all infants. It provides an incentive to birthing hospitals/facilities to establish policies and address barriers to ensure hepatitis B birth dose for all infants born to consenting parents.

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.***]**
a. NQF MEASURE Feasibility Study: The Feasibility Study was conducted in 50 hospitals that were representative of labor and delivery hospitals in Texas. The annual birth cohort size at Study hospitals ranged from 219 to 6,530 and together represented more than 100,000 births. Hospitals were divided among urban and rural locations and included for-profit, not-for-profit and public facilities. Thirty-six of 50 hospitals representing more than 62,000 births calculated the measure. The hepatitis B birth dose vaccination rates not excluding parent/guardian refusals were: median 94.5%; minimum 8%; maximum 100%. [d]
b. Estimates from a variety of other sources demonstrate wide variation in performance across providers, and substantial room for improvement.
i. During July 1999-October 2002, a survey of public health departments reported >500 hospital medical errors in failures to administer immunoprophylaxis at birth: hepatitis B surface antigen (HBsAg) screening tests of mothers were incorrectly ordered, interpreted, transcribed, or communicated and routine birth dose was not part of hospital policy so that proper prophylaxis was not provided to infants [a]
ii. The 2010 National Immunization Survey reported weighted hepatitis B birth dose rates by state and jurisdiction using verified vaccination records for 0-3 days of life among infants born from January 2007-July 2009 (the latest available.) The survey reported a mean coverage of 64.1%± - 1.3; median 63.7% ± 7.1; minimum 21.4% ± 5.9; maximum 83.3% +/- 4.9. For 50 states and the District of Columbia, the calculated results for birth dose coverage were: median 66.7%; mean 65.7%; minimum 21.4%; maximum 83.3%. [b]
iii. A Public Health Evaluation Project (PHEP) at 119 Texas birthing hospitals examined by chart review during 2009-2010, the 0-3 day of life hepatitis B vaccination rates by birthing facility: mean 90.4%; median 95.5%; maximum 100%; minimum 21.2%. [c]
iv. A survey of a nationally representative sample birthing hospitals was conducted in 2005, with results of review of over 10,000 mother/infant charts. The study described major gaps in hospital policies and practices designed to prevent perinatal transmission of hepatitis B virus. Receipt of hepatitis B vaccine within 12 hours of birth as recommended by ACIP was confirmed in 67.1 % of infants born to HBsAg-positive pregnant women ; 13.7% of the infants born to HBsAg-positive women (infants at highest risk of HBV transmission) received no hepatitis B vaccine prior to hospital discharge. Overall, 69% of infants born to HBsAg-negative pregnant women received the birth dose prior to hospital discharge. The existence of a written policy was the strongest correlate of adherence to birth dose administration of newborn infants. [e]
v. The results of a hepatitis B birth dose "Best Practices" Survey were presented at the National Immunization Conference in 2011. The survey was conducted by the New York State Department of Health Perinatal Hepatitis B Prevention Program to identify common practices among hospitals with the highest birth dose coverage. Best practices that increased or were associated with high birth dose adherence included: early parental education prior to hospitalization, early consent before or upon hospital admission, staff education and "buy in", and state-funded vaccine for the birth dose at no cost to hospitals (a universal hepatitis B vaccine supply policy). [f]

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***]**
a. http://www.immunize.org/catg.d/p2128.pdf (Specific examples of medical errors resulting in HBV infection)
b. CDC. National and state vaccination coverage among children aged 19-35 months—United States, 2010. MMWR 2011; 60(34):1157-63.
c. Unpublished data from Texas Department of State Health Services, Public Health Evaluation Project (PHEP), 2010.
d. Feasibility Study report based on review of medical records (attached). See Report Appendix for summary of methods in Public Health Evaluation Project (PHEP).
e. Willis BC, Wortley P, Wang S, Jacques-Carroll L, Zhang F. Gaps in Hospital Policies and Practices to Prevent Perinatal Transmission of Hepatitis B Virus. Pediatrics.2010 125:704-711.(http://pediatrics.aappublications.org/content/125/4/704.full.html)
f. Pollock L. Hepatitis B Birth Dose Best Practices 2010 Survey. 2011 National Immunization Conference presentation (March 31,

2011). Website: http://cdc.confex.com/cdc/nic2011/webprogram/Paper25179.html

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

a. Among the cases of perinatal hepatitis B virus infections reported to CDC during 2002-2006 for whom race was provided (race was known for 58% of the cases), 68% were Asian/Pacific Islanders (note: annually in the United States, only 6% of live births are Asian/Pacific Islanders)[a].

b. A study that estimated the number of births in the United States to HBsAg-positive women, evaluated vital statistics data for 22 states that had information on country of birth of pregnant women. Results indicated that, foreign-born women from highly endemic countries for hepatitis B infection (despite being a minority of all women giving birth), US and Canadian-born non-Hispanic blacks, and Asian/Pacific Islanders represented the majority of all births to HBsAg-positive women. Of 2,359,912 births in the 22 states evaluated, approximately 16,500 births were estimated to be from HBV-infected women—80.6% of these were foreign-born women [b].

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*]

a. CDC, Division of Viral Hepatitis, Epidemiology and Surveillance Branch, surveillance data from the National Notifiable Disease Surveillance System.

b. Din E, Wasley A, Jacques-Carroll L, Sirotkin B, Wang S. Estimating the Number of Births to Hepatitis B Virus-infected Women in 22 States, 2006;Pediatr Infect Dis J 2011;30: 1-5.

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☐

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)*:

a. Measure Focus: Health outcome—prevention of chronic HBV infection

b. Appropriate Link: Process (birth dose)-Health outcome (prevention of chronic HBV infection)

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)*:

Cui F, Hadler SC, Wang F, Zheng H, Chen Y, et al. Factors Associated with Effectiveness of the First Dose of Hepatitis B Vaccine in China: 1992-2005. Vaccine. 2010 Aug 23; 28(37):5973-8.

i. 2006 Chinese national serological survey looking at factors associtated with effectiveness of the first dose of hepatitis B vaccine in China found

1. No effect of birth dose timing within 7 days of birth (but too few infants received the first dose between 1 and 7 days of life to evaluate effectiveness).
2. Children who received birth dose after 7 days had higher HBsAg prevalence than those who received the birth dose within 24 hours—difference was signficant for those that received birth dose after 181 days

1c.5 **Quantity of Studies in the Body of Evidence** *(Total number of studies, not articles)*: Cochrane Meta-Analysis of 29 Random Clinical Trials (RCTs) assessing the effects of hepatitis B vaccines and immunoglobulin for newborn infants of hepatitis B surface antigen positive mothers. The three outcomes of interest were 1) relative risk of hepatitis B occurrence 2) antibody levels to hepatitis B surface antigen and 3) adverse events.

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*): a. Lee C, Gong Y, Brok J, Boxall EH, Gluud C. Effect of hepatitis B immunisation in newborn infants of mothers positive for hepatitis B surface antigen: systematic review and meta-analysis. BMJ. 2006 Feb 11;332(7537):328-36)

i. Cochrane systematic review and meta-analysis of 29 randomized controlled trials (RCT) to assess the impact of vaccination (plasma derived vaccine or recombinant vaccine) with or without HBIG administered within the first month of life. Five of 29 studies were vaccine without HBIG and were identified as high quality and addressed the questions of interest; the extent of heterogeneity was measured by I2.

1. Hepatitis B vaccine (Recombinant vaccine vs. Plasma derived vaccine) vs. Placebo or No Intervention [No HBIG]
   a. Vaccination reduced the occurrence of hepatitis B, 95% CI, RR 0.28 (0.2 to 0.4).
   b. Subgroup analysis (retrospective) by vaccine schedules (0,1,and 6 months vs. 0,1,2, and 6 or 12 months) showed no significant difference
2. Recombinant vaccine vs. Plasma derived vaccine [No HBIG]
   a. Showed no significant difference in the occurrence of hepatitis B, 95% CI, RR 1.00 (0.70 to 1.42).
3. Conclusion
   a. Hepatitis B vaccine decreased the risk of hepatitis B infection among infants of mothers positive for hepatitis B surface antigen

1c.7 **Consistency of Results across Studies** *(Summarize the consistency of the magnitude and direction of the effect):* The Cochrane review found that there was no significant difference in the efficacy of the two vaccine formulations (plasma vaccine is no longer available), and that hepatitis B vaccination starting in the first 24 hours of birth is highly effective preventing perinatal transmission of hepatitis B infection.

1. Hepatitis B vaccine (Recombinant vaccine vs. Plasma derived vaccine) vs. Placebo or No Intervention [No HBIG]
   a. I2 = 54.2% (Heterogeneity was considerable)
2. Recombinant vaccine vs. Plasma derived vaccine [No HBIG]
   a. I2 = 0% (No heterogeneity was identified

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

a. Cochrane Meta-Analysis Review indicates that hepatitis B vaccination starting at birth prevents the occurrence of hepatitis B in the newborn infants of mothers positive for hepatitis B surface antigen.

b. Administering a universal birth dose to infants (even without HBIG) serves as an effective "safety net" to prevent HBV infection among infants born to HBsAg-positive mothers who are not identified due lack of screening pregnant women, errors in maternal HBsAg testing or failures in reporting or interpretation of tests results. The dose also provides early protection to infants at risk for infection transmitted during or after the perinatal period. The administration of hepatitis B vaccine without HBIG at birth prevents at least 70-95% of vertical HBV Infections (Mast E et al. MMWR 2005 54:(RR-16).

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:** World Health Organization Strategic Advisory Group of Experts (SAGE) Hepatitis B Workgroup has evaluated the strength of evidence for the following questions:

a. Should hepatitis B vaccine at birth be used for prevention of hepatitis B virus (HBV) infection in newborns?
i. Table can be found at the following website: http://www.who.int/immunization/sage/1_Grade_table_Hep_B.pdf
ii. Conclusions
1. Moderate quality evidence to support effectiveness of hepatitis B vaccine given within 24 hours of birth to prevent HBV infection
2. Low quality evidence to support effectiveness of hepatitis B vaccine given within 24 hours of birth to prevent incidence of hepatocelluar carcinoma (HCC) *Additional supportive evidence available since this analysis (Chang M-H, You S-L, Chen C-J et al. Decreased incidence of hepatocellular carcinoma in hepatitis B vaccinees: a 20 year follow-up study. J Natl Cancer Inst 2009;101:1348-55.)
3. Low quality evidence to support effectiveness of hepatitis B vaccine given within 24 hours of birth to prevent mortality from Hepatocellular Carcinoma (HCC)
b. Should hepatitis B vaccine within 7 days following birth be used for prevention of hepatitis B virus infection in infants?
i. http://www.who.int/immunization/sage/2_Grade_table_Hep_B.pdf
ii. Conlusions
1. Moderate quality evidence to support effectiveness of hepatitis B vaccine given within 7 days of birth to prevent HBV infection
2. Moderate quality evidence to support effectiveness of hepatitis B vaccine given within 7 days of birth to prevent chronic HBV infection.

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

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

1c.13 Grade Assigned to the Body of Evidence: Moderate

1c.14 Summary of Controversy/Contradictory Evidence: No contradictory evidence was found. Some pregnant women who have been screened for hepatitis B surface antigen (chronic hepatitis) and are reported to have a negative test, disagree with the national recommendation for universal hepatitis B vaccination at birth. Some of these women will refuse the birth dose of hepatitis B for their infants, assuming that their infant is not at risk of exposure to other children or adults who have asymptomatic chronic hepatitis B infection.

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

a. Should hepatitis B vaccine at birth be used for prevention of hepatitis B virus infection in newborns?
i. Hepatitis B virus infection: Ip et al. Lancet 1989;1(8635):406–10.
ii. Ip et al. Acta Paediatric Japanese 1989;31(6):654–8.
iii. Wong et al. Lancet 1984;1 (8383):921–6.
iv. Xu et al. The Journal of Infectious Diseases 1995;171(1):54–60.
v. Xu et al. Chinese Medical Journal 1985;98(9):623–6.
vi. Xu et al. Pediatrics 1985;76 (5):713–8.
vii. Liu LH. Zhonghua Liu Xing Bing Xue Za Zhi 1987;8 (6):325–8.
viii. Khukhlovich PA Zhurnal Mikrobiologii, Epidemiologii, Immunobiologii 1996; 2:55–9.
ix. Hepatocellular carcinoma incidence and mortality: Chang et al. NEJM. 1997 Jun 26;336(26):1855-9
b. Should hepatitis B vaccine within 7 days following birth be used for prevention of hepatitis B virus infection in infants?
i. Marion et al: Long-term follow-up of hepatitis B vaccine in infants of carrier mothers. Am J Epidemiol 1994;140:734-746

1c.16 Quote verbatim, <u>the specific guideline recommendation</u> *(Including guideline # and/or page #)*:

a. WHO-SAGE(2009)
i. Since perinatal or early postnatal transmission is an important cause of chronic infections globally, all infants should receive their first dose of hepatitis B vaccine as soon as possible (<24 hours) after birth even in low-endemicity countries.
ii. The primary hepatitis B immunization series conventionally consists of 3 doses of vaccine (1 mono-valent birth dose followed by 2 monovalent or combined vaccine doses at the time of DTP1 and DTP3 vaccine doses). However, 4 doses may be given for programmatic reasons (e.g. 1 monovalent birth-dose followed by 3 monovalent or combined vaccine doses with DTP vaccine doses), according to the schedules of national routine immunization programmes.
iii. Premature low birth weight (<2000g) may not respond well to vaccination at birth. However, by 1 month of chronological age,

premature infants, regardless of their initial weight or gestational age at birth, are likely to respond adequately. Therefore, doses given to infants <2000g should not be counted towards the primary series.
b. Advisory Committee on Immunization Practices (ACIP) (2005):
i. Infants born to mothers who are HBsAg-positive should receive hepatitis B vaccine and hepatitis B immune globulin (HBIG) <12 hours of birth.
ii. Infants born to mothers whose HBsAg status is unknown should receive hepatitis B vaccine <12 hours of birth. The mother should have blood drawn as soon as possible to determine her HBsAg status; if she is HBsAg positive, the infant should receive HBIG as soon as possible (no later than age 1 week).
iii. Full-term infants who are medically stable and weigh >2,000 g born to HBsAg-negative mothers should receive single-antigen hepatitis B vaccine before hospital discharge.
iv. Preterm infants weighing < 2000 g born to HBsAg-positive mothers should receive HBIG plus a single-antigen hepatitis B vaccine within 12 hours of birth. …. And 3 additional hepatitis B vaccine doses to complete the vaccine series.
v. Preterm infants weighing < 2000 g born to mothers whose HBsAg status is unknown should receive HBIG plus a single-antigen hepatitis B vaccine within 12 hours of birth… and 3 additional hepatitis B vaccine doses to complete the vaccine series.
vi. Preterm infants weighing <2,000 g born to HBsAg-negative mothers should receive the first dose of vaccine 1 month after birth or at hospital discharge.
c. AAP-ACOG Guidelines for Perinatal Care (2007):
i. Universal HBV immunization is recommended for all infants. Delivery hospitals should develop policies and procedures that ensure administration of a birth dose of the vaccine as part of routine care of all medically stable infants weighing at least 2,000 g at birth, unless there is a physician's order to defer immunization and the serologic status of the mother is in the infant's medical record…..

1c.17 Clinical Practice Guideline Citation: a. WHO: meeting of the Immunization Strategic Advisory Group of Experts, November 2008—Conclusions and Recommendations. Weekly Epidemiological Record (2009, 84: 405-420 . http://www.who.int/immunization/policy/immunization_tables/en/index.html
b. CDC: 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 1: Immunization of infants, children, and adolescents. MMWR 2005;54 (No. RR-16).
c. Guidelines for Perinatal Care, 6th edition. American Academy of Pediatrics Committee and the American College of Obstetrics and Gynecology. Perinatal Infections, pp 306-309. October 2007.

1c.18 National Guideline Clearinghouse or other URL:

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 United States Preventive Services Task Force (USPSTF)

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

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

1c.23 Grade Assigned to the Recommendation: A

1c.24 Rationale for Using this Guideline Over Others: ACIP recommendations are evidence-based guidelines that have undergone careful and exhaustive review prior to endorsement. ACIP recommendations are the basis for immunization practice and for vaccine purchase for children in the United States.

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: Moderate **1c.27** Consistency**:** High

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? No

S.2 **If yes, provide web page URL:**

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)*:
The number of live newborn infants administered hepatitis B vaccine prior to discharge from the hospital/birthing facility ("birth dose" of hepatitis B vaccine).

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

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*:
Per hospital/birthing facility, the number of live newborn infants, during a calendar year, who received a dose of hepatitis B vaccine prior to hospital/birthing facility discharge (or within 1 month of life, if the infant had an extended hospital stay). Acceptable data sources include: pharmacy records, vaccine consent forms, medication administration records, claims data, nurses notes, electronic medical records, or other available records.
a. Suggested ICD-9 code V05.3 converts to ICD-10 code z23 (type of immunization given will be identified by the procedure code—effective October 1, 2013. Procedure code for viral hepatitis unknown. Suggest the use of ICD-10 code z23.9955 described as "prophylactic administration of vaccine against other diseases" or ICD-10 code z23.9959 described as "other vaccination or inoculation"): http://www.icd10data.com/ICD10CM/Codes/Z00-Z99/Z20-Z28/Z23-/Z23
b. CPT administration codes: 90744 (hepatitis B vaccine) and 90471 (immunization administration code)

2a1.4 **Denominator Statement** *(Brief, narrative description of the target population being measured)*:
The number of live newborn infants born at the hospital/birthing facility during the reporting window (one calendar year)

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

2a1.6 **Denominator Time Window** *(The time period in which cases are eligible for inclusion)*:
One calendar year

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)*:
a. The number of live births at the hospital during one calendar year can be determined from a variety of sources, including the

paper or electronic patient records, claims data, nursery birth records, or other available records. ICD-10 codes can be used. Stillborn deliveries are not included in the definition of the MEASURE.
i. ICD-10 codes to be used (link: http://www.icd10data.com/ICD10CM/Codes/Z00-Z99/Z30-Z39/Z37-/#Z37 and http://www.icd10data.com/ICD10CM/Codes/Z00-Z99/Z30-Z39/Z38-/#Z38) :

1. Z37.0 Single live birth
2. Z37.2 Twins, both live born
3. Z37.3 Twins, one live born and one stillborn
4. Z37.50 Multiple births, unspecified, all live born
5. Z37.51 Triplets, all live born
6. Z37.52 Quadruplets, all live born
7. Z37.53 Quintuplets, all live born
8. Z37.54 Sextuplets, all live born
9. Z37.59 Other multiple births, all live born
10. Z37.60 Multiple births, unspecified, some live born
11. Z37.61 Triplets, some live born
12. Z37.62 Quadruplets, some live born
13. Z37.63 Quintuplets, some live born
14. Z37.64 Sextuplets, some live born
15. Z37.69 Other multiple births, some live born
16. Z38.00 Single live born infant, delivered vaginally
17. Z38.01 Single live born infant, delivered by cesarean
18. Z38.1 Single live born infant, born outside hospital
19. Z38.2 Single live born infant, unspecified as to place of birth
20. Z38.30 Twin live born infant, delivered vaginally
21. Z38.31 Twin live born infant, delivered by cesarean
22. Z38.4 Twin live born infant, born outside hospital
23. Z38.5 Twin live born infant, unspecified as to place of birth
24. Z38.61 Triplet live born infant, delivered vaginally
25. Z38.62 Triplet live born infant, delivered by cesarean
26. Z38.63 Quadruplet live born infant, delivered vaginally
27. Z38.64 Quadruplet live born infant, delivered by cesarean
28. Z38.65 Quintuplet live born infant, delivered vaginally
29. Z38.66 Quintuplet live born infant, delivered by cesarean
30. Z38.68 Other multiple live born infant, delivered vaginally
31. Z38.69 Other multiple live born infant, delivered by cesarean
32. Z38.7 Other multiple live born infant, born outside hospital
33. Z38.8 Other multiple live born infant, unspecified as to place of birth

The results of this measure will identify that the coverage excludes infants whose parent(s)/guardian(s) refused hepatitis B vaccine for their infant before hospital or facility discharge (or by 1 month of age if during a prolonged stay).

2a1.8 Denominator Exclusions *(Brief narrative description of exclusions from the target population)*:
a. Determine number of live newborn infants born at the hospital/birthing facility whose parent/guardian refused hepatitis B birth dose and exclude from the denominator. ICD-10 code for this information will include the following(link: http://www.icd10data.com/ICD10CM/Codes/Z00-Z99/Z20-Z28/Z28-/#Z28):
i. Z28.03 Immunization not carried out because of immune compromised state of patient
ii. Z28.04 Immunization not carried out because of patient allergy to vaccine or component
iii. Z28.1 Immunization not carried out because of patient decision for reasons of belief or group pressure
iv. Z28.20 Immunization not carried out because of patient decision for unspecified reason
v. Z28.21 Immunization not carried out because of patient refusal
vi. Z28.29 Immunization not carried out because of patient decision for other reason
vii. Z28.82 Immunization not carried out because of caregiver refusal

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)*:
Subtract from the number of infants discharged from the hospital/birthing facility, the number of infants born at the facility during one calendar year, whose parent/guardian refused administration of a birth dose of hepatitis B vaccine before discharge from the hospital/birthing facility. Information on exclusions might come from a variety of sources, including vaccine consent forms, clinical notes, and medication administration records. No billing codes exist for vaccine refusal; therefore ICD-10 codes in the Z28 series should be used to document vaccine refusal.

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.)*:
a. Determine the number of live newborn infants at each hospital/birthing facility during one calendar year
b. Determine the number of live newborn infants born at the same hospital/birthing facility during the same calendar year who received a dose of hepatitis B vaccine before hospital discharge (or by 1 month of age if not yet discharged)
c. Determine the number of parental/guardian refusals of hepatitis B birth dose
d. Divide the number of live newborn infants born at the same hospital/birthing facility during the same time period who received a dose of hepatitis B vaccine before hospital discharge(b), by the number of live newborns at the same hospital/birthing facility during the same time period (a) minus those who were not vaccinated because of parent/guardian refusal of hepatitis B birth dose (c).

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):
N/A, survey based on actual numbers.

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, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data :

Pharmacy, Electronic Clinical Data : Registry

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.*)**:** Data collected on uniform Survey tool (see attached report Appendix: Survey Tool, page 37-44)

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, Facility, Health Plan

2a1.34-35 Care Setting *(Check all the settings for which the measure is specified and tested)***:** Hospital/Acute Care Facility

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)***:**
The Feasibility Study was conducted in 50 hospitals that were representative of labor and delivery hospitals in Texas. The annual birth cohort size at Study hospitals ranged from 219 to 6,530 and together represented more than 100,000 births. Hospitals were divided among urban and rural locations and included for-profit, not-for-profit and public facilities. Thirty-six of 50 hospitals representing more than 62,000 births calculated the measure.

2a2.2 Analytic Method *(Describe method of reliability testing & rationale)***:**
Repeating the review within each facility to generate an additional calculation is not likely to be informative at this time. Reliability was evaluated by the level of concordance between the rates calculated by the facilities in the Feasibility Study when compared with the rates determined by medical chart review in the PHEP.

2a2.3 Testing Results *(Reliability statistics, assessment of adequacy in the context of norms for the test conducted)***:**
The baseline birth dose MEASURE as calculated by individual hospitals ranged from 8% - 100%. Analysis of these data compared with estimates from the chart reviews showed a variance of ± 10% for most hospitals that provided a result (30 of 36 hospitals). The difference between the hospital calculation of the MEASURE and the chart review estimate was substantially larger in the remaining 6 hospitals.

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 focus of the measure is prevention of chronic hepatitis B among infants. The target population in the random clinical trials (evidence) was known high risk infants (born to HBsAg-positive pregnant women). The target population of the measure differs in that no exclusions exist, all infants born to pregnant women, regardless of risk are recommended for vaccination.

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)***:**
The Feasibility Study was conducted in 50 hospitals that were representative of labor and delivery hospitals in Texas. The annual birth cohort size at Study hospitals ranged from 219 to 6,530 and together represented more than 100,000 births. Hospitals were divided among urban and rural locations and included for-profit, not-for-profit and public facilities. Thirty-six of 50 hospitals

representing more than 62,000 births calculated the measure. The validity portion of the birth dose measure was determined in a nested study of these 36 hospitals and a larger Study of 119 hospitals in Texas (PHEP).

2b2.2 Analytic Method *(Describe method of validity testing and rationale; if face validity, describe systematic assessment)*:
Validity of hospital-determined birth dose vaccination rate (the MEASURE) was determined by comparing the birth dose MEASURE result determined at each hospital with the birth dose rate estimated from review of a sample of infant birth charts at each hospital covering the same birth cohort. The minimum number of charts reviewed was determined from a table of sample sizes based on the expected hepatitis B birth dose coverage (range 50%-95%) and the hospital-specific size of the annual birth cohort (n = 100 - >20,000). The 2008 birth cohort size at each hospital was determined in a policy and practices survey in Texas. The estimated birth dose coverage rate was assumed to be 75% for all hospitals based on the Texas statewide coverage from the (2006) National Immunization Survey, and survey data from Dallas County, Texas. Charts were selected for review at each hospital using a sampling interval by date of birth depending on the total number of births annually (e.g., 1 chart for every 20 births). The number of infant charts reviewed per hospital ranged from 96-116 (average 106 records).

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)*:
The baseline birth dose MEASURE as calculated by individual hospitals ranged from 8% - 100%. Analysis of these data compared with estimates from the chart reviews showed a variance of ± 10% for most hospitals that provided a result (30 of 36 hospitals). The difference between the hospital calculation of the MEASURE and the chart review estimate was substantially larger in the remaining 6 hospitals.

a. The birth dose of hepatitis B vaccine contributes to quality of care by providing a safety-net for infants who would not receive post-exposure prophylaxis because their mother´s chronic hepatitis B infection is not determined or detected, is misinterpreted or incorrectly recorded, or who return to a household with risk of transmission from family members with chronic hepatitis B infection (often unknown). Infants have a 90% chance of chronic hepatitis B if infected. The first dose of hepatitis B vaccine provides the initial step for prevention of almost certain life-long chronic hepatitis B infection with ~25% risk of cirrhosis, liver failure, and liver cancer. This is the critical "window" for prevention since chronic hepatitis B infection is not "curable".

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)*:
A feasibility study (Feasibility Study) was conducted to evaluate adjusting the denominator to exclude infants whose parent/guardian refused the hepatitis B birth dose vaccination. ICD-9 codes (http://icd9cm.chrisendres.com/index.php?action=child&recordid=11296) used to determine parental/guardian refusal were V64.05—vaccination not carried out because of care giver/parental refusal (recorded in infant's medical chart) and/or V64.06—vaccination not carried out because of patient refusal (recorded in mother's medical chart). Thirty-eight percent of hospitals queried (representing >30,000 births) were able to make the adjustment for vaccine refusal at the time of the study (2010). The adjustment improved vaccination rates for some hospitals. About 50% of hospitals queried indicated they expected future improvements in electronic records that would facilitate or allow making this adjustment. However, currently, the adjustment relies on a variety of information sources and is not collected in a standardized manner. Some hospitals do not have the capacity to make this adjustment.

2b3.2 Analytic Method (*Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference)*:
Comparison of birth dose rate (MEASURE) including refusals and excluding refusals

2b3.3 Results *(Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses):*
The difference in birth dose coverage result was compared between the MEASURE including refusals and the MEASURE without refusals. In the Feasibility Study, 16 hospitals calculated this difference in birth dose rate: mean ± 4.0%; median +1%; range -8% to + 25%. In the Texas Public Health Evaluation Project (PHEP) for the same 16 hospitals based on chart reviews the differences were: mean ±1.0%; median 0%; range -3% to + 7%. Refusal rates for birth dose of hepatitis B vaccine was estimated in Texas 2009-2010: mean 2.9%; median 1.0%; minimum 0.0%; maximum 21.6%.

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. Risk stratification: 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)***:**
A feasibility study (Feasibility Study) was conducted to evaluate adjusting the denominator to exclude infants whose parent/guardian refused the hepatitis B birth dose vaccination. ICD-9 codes (http://icd9cm.chrisendres.com/index.php?action=child&recordid=11296) used to determine parental/guardian refusal were V64.05—vaccination not carried out because of care giver/parental refusal (recorded in infant's medical chart) and/or V64.06—vaccination not carried out because of patient refusal (recorded in mother's medical chart). Thirty-eight percent of hospitals queried (representing >30,000 births) were able to make the adjustment for vaccine refusal at the time of the study (2010). The adjustment improved vaccination rates for some hospitals. About 50% of hospitals queried indicated they expected future improvements in electronic records that would facilitate or allow making this adjustment. However, currently, the adjustment relies on a variety of information sources and is not collected in a standardized manner. Some hospitals do not have the capacity to make this adjustment.

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

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)*:
N/A

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)***:**
Until there is greater implementation of electronic medical records or their equivalent, all available data sources should be accepted in determining a birth dose coverage measure. It is likely that some facility to facility variation in the result will occur depending on the data sources, but the results should be relatively consistent within a facility as long as the methods remain the same. Data are not currently available to compare different sources (e.g., electronic, paper, combination) and it is not practical to make comparisons in the midst of the major transition to electronic medical record systems. Having an NQF measure in place will stimulate relevant programming of these electronic systems as they are put in place.

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 does not include stratification. The Feasibility Study results suggested the possibility of disparity by race/ethnicity group, and by very early gestational age/very low birth weight newborns (<2000 grams). The sample size for evaluating these factors in the Feasibility Study was too small to determine statistically significant differences. Future analysis could be useful as an adjunct to the quality MEASURE.

2c.2 **If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:**
Disparities in birth dose coverage for subgroups (e.g., low birth weight infants) could be analyzed in special studies once the methods for determining the MEASURE are functional at the hospital level.

2.1-2.3 **Supplemental Testing Methodology Information:**
Attachment
NQF Report_Final.pdf

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 Purpose/ Use** *(Check all the purposes and/or uses for which the measure is intended)*: Public Health/Disease Surveillance, 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)*: Not in use

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.***]**
Not currently being used in public reporting. The National Immunization Survey currently produces hepatitis B birth dose rate estimates at the state and national level. Obstetric and pediatric providers, hospital staff, public health National Hepatitis B Perinatal Program coordinators are acutely familiar with these results.

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**:** a. For the past 20 years, public health immunization programs have provided the leadership to establish, guide, provide services, and monitor activities to prevent perinatal transmission of hepatitis B infection in the United States. Some of these public health activities will be transitioned to the private sector. A quality measure will be increasingly important in monitoring prevention of perinatal hepatitis B in the US. A Healthy People 2020 goal addresses the reduction of perinatal hepatitis B transmission.
b. Because hepatitis B infection is largely asymptomatic until complications develop (accompanied by decreased life expectancy and productivity, and with ballooning healthcare costs), the universal hepatitis B birth dose will become an even more critical safety net. The purpose of this measure is to encourage administration of the birth dose of hepatitis B vaccine and to provide a safety-net for infants who would not receive post-exposure prophylaxis because their mother´s chronic hepatitis B infection is not determined or detected, is misinterpreted or incorrectly recorded, or who return to a household with risk of transmission from family members with chronic hepatitis B infection (often unknown). Infants have a 90% chance of chronic hepatitis B if infected. The first dose of hepatitis B vaccine provides the initial step for prevention of almost certain life-long chronic hepatitis B infection with ~25% risk of cirrhosis, liver failure, and liver cancer. This is the critical "window" for prevention since chronic hepatitis B infection is not "curable". A universal birth dose measure will be critical in measuring the quality of this important disease prevention activity.
c. The National Immunization Survey currently produces hepatitis B birth dose rate estimates at the state and national level. Obstetric and pediatric providers, hospital staff, public health National Hepatitis B Perinatal Program coordinators are acutely familiar with these results. However, data have not been available at the hospital level, with the exception of special studies, as was carried out by the Public Health Evaluation Project and Feasibility Studies in Texas. These studies are unlikely to be repeated given their cost and resource requirements.

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)**:** Could be used by Joint Commission or by CMS as a quality measure

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*].
Conducting surveys to obtain data similar to those of a MEASURE is a requirement of Perinatal Hepatitis B Prevention Programs as part of the process for monitoring outcomes. —Program staff conduct a chart review of a sample of births at each birthing hospital facility once per five year grant cycle to estimate hepatitis B birth dose coverage. This continuous chart review process can identify facilities that would benefit from improvement, but requires a level of resources that cannot be sustained. It also occurs too infrequently to be optimally effective. Identifying facilities with lagging coverage can focus facility and public health efforts and assist in breaking down barriers, thereby ensuring prevention of hepatitis B transmission. Most importantly, the MEASURE provides each facility feedback to gauge its success (or need for improvement), so that these can be addressed by the parties responsible for the outcomes.

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:
Monitor outcome of ACIP recommendation and focus effort in areas of need (facilities with poor performance or requiring assistance for addressing barriers).

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**:**

Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims)

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)***:** Some data elements are in 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:** Not all Hospital/Birthing facililties currently have the infrastructure for electronic sources therefore paper sources of administrative records, medical records, pharmacy, etc. must be used until such time as all hospital/birthing facilities have electronic source capababilities.

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:**
Hospitals have not had a requirement to report data on hepatitis B birth dose vaccination rates and/or guardian refusal of same. As a consequence, the Feasibility Study demonstrated a wide variety of hospital capacity for providing the data for this MEASURE. Some hospitals possessed the full capacity to produce the MEASURE via easily accessible electronic or paper records. Others required laborious review of paper records. Other hospitals did not capture all the required information for the complete calculation in either a paper or electronic form, or kept some data electronically and some in paper records. Despite these challenges, most hospitals were able to provide the MEASURE at a value within 10% of that determined by the sample of medical charts reviewed. A few hospitals provided a value that was considerably different. Inaccuracies in the calculations will be directly related to a given hospital´s information management practices for the data required. Although paper records will most likely require more time for review, this may not present an accuracy problem in hospitals with smaller delivery volumes that keep paper records and maintain them on site for easy access. Likewise, an electronic record management system will be accurate only so far as the data are required to be entered into the system, and the retrieval of the data is subsequently easy. ICD-9 and ICD-10 codes are available for both live births (V27.x) and hepatitis B vaccination (V05.3) (see section 2a1.7b above for ICD-10 codes). Guardian refusal of vaccination can be found in ICD-10 codes. The accuracy of the calculation excluding refusals will likely be adversely affected until hospitals develop effective information management of these data using these codes. An unintended consequence of reporting the MEASURE after removing parent/guardian refusals will be the loss of information about hospitals with an unusually high refusal rates. Conversely, a hospital with high rates of vaccination might be targeted with anti-vaccine advocacy pressure.

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)***:**
o The Feasibility Study was conducted in 50 hospitals that were representative of labor and delivery hospitals in Texas. The annual birth cohort size at Study hospitals ranged from 219 to 6,530 and together represented more than 100,000 births. Hospitals were divided among urban and rural locations and included for-profit, not-for-profit and public facilities. Thirty-six of 50 hospitals representing more than 62,000 births calculated the measure. No issue of patient confidentiality was encountered. Chart reviews were done under the public health authority of the Texas Department of State Health Services.
o Among 50 hospitals participating in the survey, overall 38 (76%) indicated they were able to provide data for the MEASURE; 2 of these hospitals eventually did not provide the data. However, only 19 (38%) of the hospitals indicated they had access to data to calculate the number of parent/guardian vaccination refusals (see 2d. justification of exclusions). The 2 most common reasons for not providing data were the time burden (71%) and information management (64%).
o The cost of providing the measure was based on responses from hospitals participating in the Feasibility Study. None had previous experience providing the MEASURE information, and thus, reflect a "start-up" cost. Additional cost information can be found in the attached Feasibility Study.
o To determine the direct cost associated with determining the number of neonates vaccinated with hepatitis B vaccine prior to discharge, 6 hospitals provided information: mean $65, median $ 25, minimum $0, maximum $240.
o To determine the indirect cost associated with determining the number of neonates vaccinated with hepatitis B vaccine prior to discharge, 11 hospitals provided information: mean $303, median $100, minimum $0, maximum $1650.

o To determine the direct cost associated with determining the parent/guardian vaccination refusal rate (done before implementation of ICD-10 coding), 5 hospitals provided information: mean $594, median $10, minimum $0, maximum $2000.

o To determine the indirect cost associated with determining the parent/guardian vaccination refusal rate, 6 hospitals provided information: mean $136, median $27, minimum $0, maximum $725.

o Costs varied considerably by retrieval method:
  o The highest cost was associated with retrieving information from an electronic medical record; 5 hospitals provided information: mean $970, median $1160, minimum $0, maximum $2000. Presumably some or most of this cost entailed initial programming which might not be necessary in subsequent years.
  o The lowest cost was associated with retrieving information from an unknown source; 2 hospitals provided information.

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:**

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?**

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)*:

CONTACT INFORMATION

Co.1 **Measure Steward (Intellectual Property Owner):** Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mail Stop- G37, Atlanta, Georgia, 30333

Co.2 **Point of Contact:** Trudy, V. Murphy, MD, Vaccine Research and Policy Team, Division of Viral Hepatitis, NCHHSTP/CDC, tkm4@cdc.gov, 404-639-8845-
Co.3 **Measure Developer if different from Measure Steward:** Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mail Stop- G37, Atlanta, Georgia, 30333 Co.4 **Point of Contact:** Tanja, Walker, MPH, Health Scientist, TYWalker@cdc.gov, 404-718-8532-
Co.5 **Submitter:** Trudy, V. Murphy, MD, Vaccine Research and Policy Team, Division of Viral Hepatitis, NCHHSTP/CDC, tkm4@cdc.gov, 404-639-8845-, Centers for Disease Control and Prevention
Co.6 **Additional organizations that sponsored/participated in measure development:**
Co.7 **Public Contact:** Trudy, V. Murphy, MD, Vaccine Research and Policy Team, Division of Viral Hepatitis, NCHHSTP/CDC, tkm4@cdc.gov, 404-639-8845-, Centers for Disease Control and Prevention

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.**
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:**
Measure Developer/Steward Updates and Ongoing Maintenance Ad.3 **Year the measure was first released:** 2007 Ad.4 **Month and Year of most recent revision:** 10, 2011 Ad.5 **What is your frequency for review/update of this measure?** Ad.6 **When is the next scheduled review/update for this measure?** 10, 2011
Ad.7 **Copyright statement:**
Ad.8 **Disclaimers:**
Ad.9 **Additional Information/Comments:**
Date of Submission (*MM/DD/YY*)**:** 10/17/2011