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:** Mar 30, 2012 **Last Updated Date:** May 14, 2012

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 and Reproductive Health, Perinatal and Reproductive Health : Newborn
De.5 **Cross Cutting Areas** (*Check all the areas that apply)*: Prevention, Prevention : Immunization

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

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

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

2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

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

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

Unvaccinated infants transferred for care to another hospital/birthing facility before 1 month of age should be counted and reported for hepatitis B vaccine coverage by the facility assuming care for, or discharging the infant.

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

2a. 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 Actual/Planned Use *(Check all the planned 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-

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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

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September 21, 2010

Public Health Evaluation Project

A Feasibility Study of Using Birth Dose Hepatitis B Vaccination Rates as a Quality Metric in Hospitals

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Acknowledgements
Hospitals that participated in the feasibility metric survey

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Table of Contents

List of Tables

List of Figures

1 Background

In May 2009, the National Quality Forum (NQF) published its recommended standards for perinatal care. The purpose of these standards is "to improve the quality of maternal-child care – through accountability and public reporting – by standardizing quality measurement in all relevant care settings."[1] These standards include the administration of hepatitis B vaccine to all newborns before discharge from the hospital (i.e., NQF Measure ID#0475). The NQF has granted time-limited endorsement of this quality metric for which the Centers for Disease Control and Prevention (CDC) is the intellectual property owner.

Part of the NQF initiative for establishing standards or quality measurement and for endorsing various quality measures is an evaluation process of proposed quality measures owned by various public health and medical entities. This process includes four major criteria:[2] (1) importance to measure and report; (2) scientific acceptability of the measurement properties; (3) usability; and (4) feasibility.

The objective of this study was to determine the feasibility of a hospital-based measure of hepatitis B vaccine administration for live newborns before hospital discharge. Results from the feasibility study are described in this report. The findings are organized based on the criteria outlined by the NQF for evaluating a field-tested, time-limited endorsed standard.[3] These criteria include:

1. Multi-site testing in a variety of settings;
2. Measurement of vaccination and/or excluded refusal rates, including number of cases, measure calculations, sample size, and definition of exclusions;
3. Analysis of excluded cases;
4. Challenges to measuring vaccination and refusal rates and planned changes that may facilitate ability to provide data;
5. Baseline performance data by each testing site;
6. Time burden to collect data for this metric;
7. Direct or indirect costs associated with data collection;
8. Demonstration of reliability and validity;
9. Types of data sources used for responses to the feasibility study; and
10. Stratification of hepatitis B vaccination rates by patient characteristics.

The CDC funded this feasibility study,[4] which was nested in a public health evaluation project conducted by the Texas Department of State Health Services (DSHS) from February 2009 through June 2010. The purpose of this evaluation project, *Public Health Evaluation Project – Assessing Hospital Policies and Practices of Hepatitis B, HIV,*

[1] National Quality Forum (NQF). National Voluntary Consensus Standards for Perinatal Care 2008: A Consensus Report. Washington, DC: NQF; 2009.
[2] National Quality Forum (NQF). Burstin H. Maximizing impact of quality measurement research on policies and programs. Academy Health Webinar, May 27, 2010.
[3] National Quality Forum (NQF). Time-Limited Endorsement Policy. 2007.
[4] The NQF feasibility study will be referred to as the feasibility study in this document.

Rubella, and Syphilis Screening and Vaccination among Texas Newborns in 2008,[5] was to assess policies and practices related to screening and vaccination for hepatitis B, human immunodeficiency virus (HIV), rubella, and syphilis through reviews of mother and infant medical charts at birthing hospitals in Texas. The feasibility study took advantage of hepatitis B vaccination rates determined from medical chart reviews to compare to birth dose coverage estimates in the feasibility study.

DSHS contracted with The Litaker Group to conduct the public health evaluation project and feasibility study. The Litaker Group is a management consulting firm specializing in health and medical preparedness, as well as research, evaluation, and public policy. The educational experience of staff members who worked on this project consists of doctoral degrees in health outcomes research and microbiology and master's degrees in public health, pharmacy administration, and microbiology. Vocational experience of staff members includes public health practice, research and evaluation, public policy, and health and medical preparedness.

[5] Headley VL, Litaker JR, Chou, JY, Ramón M, Hasty K. Assessing Hospital Policies and Practices of Hepatitis B, HIV, Rubella, and Syphilis Screening and Vaccination among Texas Newborns in 2008. June 2010.

2 Methods

This feasibility study was conducted as part of a larger public health evaluation project to assess policies and practices related to the prevention of perinatal transmission of hepatitis B, HIV, syphilis, and rubella. Details of methods used to select the 119 hospitals and 25,706 medical records (12,670 maternal records and 13,036 neonate records) for review in the public health evaluation project are available in Section 5: Appendix: Methods for Public Health Evaluation Report. The methods described below are specific to the feasibility study.

2.1 Sample Selection

The sample of hospitals was selected from the cohort of hospitals in the larger public health evaluation project.[6] The hospitals for the evaluation project were selected based on the following criteria: (1) geographically located in each of the eight DSHS health service regions (See Section 8: Appendix: DSHS Health Service Regions); (2) having a significant number of births as defined by greater than 100 live births or 30 cesarean births in 2008;[7] (3) geographically located in areas of the state with a known high incidence of hepatitis B; and (4) identified by DSHS regional perinatal nurse coordinators to be included in the evaluation project.[8] A total of 119 hospitals participated in the DSHS public health evaluation project, and all were eligible for and invited to participate in the feasibility study.

Participants were identified from the larger public health evaluation project cohort of hospitals; however, those that chose to participate in this feasibility study self-selected themselves for participation. Hospitals were not provided an incentive to participate but were encouraged to do so in order to assist with evaluating the feasibility of using the NQF-endorsed hospital-based hepatitis B vaccination metric. Some hospitals indicated that did not participate voluntarily because of a lack of time and staff to devote to gathering information to respond to the survey. No other attempt was made to collect information on other reasons for nonparticipation in the study.

2.2 Survey Development

The Litaker Group created an assessment tool to support data gathering for this feasibility study. Both DSHS and the CDC provided invaluable comments on the assessment tool before the survey was released to the hospitals (See Section 7: Appendix: Survey Tool).

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[6] Headley VL, Litaker JR, Chou, JY, Ramón M, Hasty K. Assessing Hospital Policies and Practices of Hepatitis B, HIV, Rubella, and Syphilis Screening and Vaccination among Texas Newborns in 2008. June 2010.

[7] A significant number of births are those from hospitals identified in the DSHS Annual Hospital Survey with greater than 100 deliveries per year (2008) and the Texas Healthcare Information Collection with greater than 30 cesarean births per year (2007). A total of 225 Texas hospitals met these criteria.

[8] Headley VL, Litaker JR, Chou, JY, Ramón M, Hasty K. Assessing Hospital Policies and Practices of Hepatitis B, HIV, Rubella, and Syphilis Screening and Vaccination among Texas Newborns in 2008. June 2010.

2.3 Survey Administration

A cover letter and the assessment tool were sent via email to each of the 119 hospitals (See Section 6: Appendix: Cover Letter). The survey was completed at the sole discretion of the respondent, although reminder notifications were provided via e-mail and telephone calls over a five-week period until 50 total hospitals agreed to participate. Participating hospitals could submit results by fax, mail, or online. Responses to the feasibility survey were received from hospitals between March and April 2010. Data collection ceased and data analysis commenced when the minimum number of participating facilities was obtained. The minimum number of participating hospitals was determined in accordance with the NQF field-testing criterion that states that the adequacy of the sample size for "multi-site testing in a variety of settings" is 50-100 entities.[9] The sample size of 50 hospitals represented an overall annual birth cohort of over 100,000 births.

2.4 Data Collection

Data requested for this survey were for calendar year 2008.[10] If the designated person for a hospital could not provide data for the calendar year 2008, that person was asked to identify and provide data for an alternate time period so that the hospital would not be excluded from the study sample.

Key data elements in the survey included:

- Number of neonates vaccinated in calendar year 2008 or alternate time period;
- Number of guardian refusals for the same time period for which the hospitals provided the number of vaccinated neonates;
- Source information for all data provided (e.g., pharmacy records, medical records, etc.);
- Time and resources to collect this data; and
- Changes to be made by hospitals for enhancing their ability to collect the data (e.g., anticipated use of electronic medical records).

2.5 Data Analyses

Survey responses were compiled and analyzed in Microsoft® Excel® 2007. A designated Litaker Group staff member with experience in research and evaluation was responsible for all data cleaning, manipulation, and analysis in this study.

Calculations included sums, proportions, averages, medians, minimum and maximum values. Only descriptive analyses were conducted with data collected for this study because of the small sample size and participant self-selection basis. No inferential analyses were attempted. Therefore, the power of the sample size was not determined.

[9] National Quality Forum (NQF). Time-Limited Endorsement Policy. 2007.
[10] Calendar year 2008 was chosen as the data collection period for the public health evaluation project because the project began in March 2009; therefore calendar year 2008 data were the most recent data available for review.

Normally, inferential analyses such as regressions require 15 to 20 cases for each variable to be included, for a power of 0.80 and an alpha level of 0.05.[11]

Analyses of the data included consideration to NQF-specified criteria for a feasibility study (See Section 1: Background). Four of the 10 criteria in particular are discussed below (i.e., multi-site testing in a variety of settings, analysis of vaccination and refusal rates, analysis of excluded cases, and demonstration of reliability and validity). Findings for all 10 criteria are discussed in Section 3: Results.

2.5.1 Multi-site testing in a variety of settings

Representation of hospitals that participated versus those that did not was determined based on comparisons of ownership type (i.e., for profit, not for profit, or public),[12] geographical area designation (i.e., urban or rural[13]), DSHS-designated health service region,[14] birth cohort, and number of licensed beds (See Section 3.1 and Table 3.1). Testing of the hepatitis B vaccination metric in various settings was not within the scope of this feasibility study.

2.5.2 Vaccination and refusal rates

The NQF hepatitis B vaccination metric (ID#0475)[15] is defined as follows:

$$\frac{\text{Number of newborns received hepatitis B vaccine prior to discharge from the hospital}}{\text{Number of live newborns discharged from the hospital minus those with guardian/parental refusals}}$$

Participants of this study were asked to estimate vaccination and refusal rates with survey items 3, 3a, 3b, 8, 8a, and 8b (See Section 7: Appendix: Survey Tool and Section 3.2: Ability to Measure Vaccination or Refusal Rates). The participants were asked to determine the number of neonates born in the calendar year 2008 who were vaccinated with hepatitis B prior to discharge in that calendar year, during any 12-month period, and/or other specified time period. Similarly, participants were asked how many newborns were not administered hepatitis B vaccine prior to discharge because of parental or guardian refusals. The number of live births in 2008 collected from the public health evaluation project was used as the denominator to calculate vaccination rates in this study. Hospitals that responded to the NQF survey provided the number of live

[11] Cohen J and Cohen P. Applied Multiple Regression / Correlation Analysis for the Behavioral Sciences – 2nd Edition. Hillsdale, New Jersey: Lawrence Erlbaum Associates Publishers. 1983.
[12] Ownership type was defined according to information provided for each facility in the DSHS Annual Hospital Survey (2008): ownership by corporation, partnership or private entity ("For profit"); ownership by Church or other not-for-profit corporation ("Not for profit"); or ownership by governmental agency ("Public"). Source: DSHS 2008 Annual Survey. http://www.dshs.state.tx.us/chs/hosp/Forms/AHS08.pdf. Accessed August 16, 2010.
[13] Urban hospitals were those located in metropolitan statistical areas, and rural hospitals were defined as those hospitals located in non-metropolitan cities, as defined in the annual survey. Source: DSHS 2008 Annual Survey. http://www.dshs.state.tx.us/chs/hosp/Forms/AHS08.pdf. Accessed August 16, 2010.
[14] Texas has been divided into 11 regions served by eight DSHS regional offices (See Appendix 8: Health Service Regions Map). Representation of hospitals in this feasibility study differed among the eight health service regions (Table 3.1). Therefore, this variable is included in this report to show the potential effect of variation among health service regions on the measure of hospital-based hepatitis B vaccination.
[15] National Quality Forum (NQF). National Voluntary Consensus Standards for Perinatal Care 2008: A Consensus Report. Washington, DC: NQF; 2009.

births for any alternate period data if they did not have data for 2008. The vaccination rates reported in this survey were compared to estimates from medical chart reviews of the public health evaluation project (See Section 2.5.4: Demonstration of Reliability and Validity).[16]

2.5.3 Analysis of excluded cases

The only exclusion criterion specified by NQF for the hepatitis B vaccination metric was parental or guardian refusal rate. This rate was used to calculate adjusted vaccination rates See Section 2.5.2: Vaccination and Refusal Rates and Section 3.2: Ability to Measure Vaccination or Refusal Rates).

2.5.4 Demonstration of reliability and validity

Reliability and validity of using the hospital-based hepatitis B vaccination metric were examined through the following methods (Note: the public health evaluation project is also discussed to show comparability of the two different data sources):

- **Reproducibility of data:** The NQF study was conducted as part of the larger public health evaluation project so that results from the feasibility survey could be compared to results from the public health evaluation project. In addition, **s**urvey responses for the feasibility survey were requested for calendar year 2008 so that comparisons could be made to data collected for the public health evaluation project. Data abstracted from medical chart review for the public health evaluation project were used to measure concurrent validity.

- **Inter-rater and inter-respondent variability:** Data abstraction for the public health evaluation project was conducted using a data abstraction tool with data validation and training of Litaker Group staff members who conducted the chart reviews.[17] Inter-respondent variability for the feasibility study was controlled by the design of survey questions and use of checkbox responses wherever possible.

[17] For hospitals that participated in the public health evaluation project, medical charts were selected using interval sampling based on the size of annual birth cohort for the entire calendar year of 2008. The number of medical charts to be reviewed was determined based on a 75% vaccination rate (±8%) with a 95% confidence level.

3 Results

3.1 Demographic Information on Respondent Hospitals

In the public health evaluation study, the number of paired charts reviewed ranged from 75 to 124 per hospital, with an average of 109 paired charts. Of the 119 eligible hospitals, 50 (42.0%) participated in this NQF feasibility study.

The distribution of the responding hospitals based on DSHS health service region (HSR) designation,[18] geographical area location, and ownership type is presented in Table 3.1. Range and median of licensed bed size and birth cohorts (total live births) are also presented in Table 3.1. Overall, both the larger number of hospitals that participated in the public health evaluation project and the subset of hospitals that responded to the feasibility survey were comparable based on demographic measures. To a small degree, not-for-profit hospitals and hospitals located in rural areas were underrepresented in both studies, and urban hospitals were overrepresented. Hospitals located in the southernmost region of Texas (DSHS HSR 11) were also overrepresented in both study groups because of the high incidence of cases of hepatitis B and high cases of infants born to HBsAg-positive mothers.[19] Thus a request was made to sample more hospitals in this region.

[18] Given that Texas is a large state and there is a variation in representation among DSHS designated health service regions, this distribution is included in Table 3.1.

[19] Hospitals included in the public health evaluation project were selected based on a variety of factors including input from perinatal hepatitis B coordinators in the DSHS health service regions.

Table 3.1: Characteristics of hospitals that participated in the feasibility survey as compared to hospitals that participated in the public health evaluation project and hospitals statewide

	Feasibility Study Participants	Feasibility Study Non-Participants	Public Health Evaluation Participants	Hospitals with Significant Births** Statewide
Ownership type	**n (%)*** **	**n (%)*** **	**n (%)*** **	**n (%)*** **
For Profit	18 (36.0)	20 (29.0)	38 (31.9)	75 (33.3)
Not for Profit	25 (50.0)	37 (53.6)	62 (52.1)	98 (43.6)
Public	7 (14.0)	12 (17.4)	19 (16.0)	45 (20.0)
Geographic Area Designation				
Urban	40 (80.0)	63 (91.3)	103 (86.6)	160 (71.1)
Rural	10 (20.0)	6 (8.7)	16 (13.4)	65 (28.9)
DSHS HSR Designation				
1	2 (4.0)	4 (5.8)	2 (1.7)	14 (6.2)
2/3	8 (16.0)	24 (34.8)	16 (13.4)	58 (25.8)
4/5N	5 (10.0)	9 (13.0)	4 (3.4)	22 (9.8)
6/5S	9 (18.0)	27 (39.1)	18 (15.1)	45 (20.0)
7	7 (14.0)	14 (20.3)	7 (5.9)	26 (11.6)
8	5 (10.0)	15 (21.7)	10 (8.4)	25 (11.1)
9/10	4 (8.0)	9 (13.0)	5 (4.2)	16 (7.1)
11	10 (20.0)	17 (24.6)	7 (5.9)	19 (8.4)
Total number of hospitals	**50**	**69**	**119**	**225**
	Mean (Range); Median	**Mean (Range); Median**	**Mean (Range); Median**	**Mean (Range); Median**
Licensed Bed Size	336 (19 – 1,049); 275	360 (42 – 1082); 326	350 (19 – 1,082); 308	278 (17 – 1,763); 198
Birth Cohort*	2,263 (219 – 6,530); 2,012	2,589 (226-15,482); 2,337	2,452 (219 – 15,482); 2,179	1,800 (114 – 15,800); 1,166

* In the current study, "Birth Cohort" is defined as the total number of live births in 2008. Total birth cohort represented in feasibility study = 113,150, in public health evaluation project = 291,767, and statewide = 404,165. True birth cohort numbers are unavailable for the statewide hospital comparison group, as the data for these hospitals were derived from the 2008 DSHS Annual Hospital Survey. That instrument only collected the total number of deliveries, data for which are shown. Actual birth cohort numbers can be assumed to be higher due to multiple birth events. Assumed statewide birth cohort of 404,165 is based on a multiple birth event frequency of 1.03, as defined by the National Vital Statistics Reports, Volume 57, Number 7, January 7, 2009 (http://www.cdc.gov/nchs/data/nvsr/nvsr57) and Texas birth rates by race from the Summary of 2006 Vital Statistics (http://www.dshs.state.tx.us/chs/vstat/latest/data.shtm#birth).

** A significant number of births are those from hospitals identified in the DSHS Annual Hospital Survey with greater than 100 deliveries per year (2008) and the Texas Healthcare Information Collection with greater than 30 cesarean births per year (2007).

*** Column percents.

3.2 Ability to Measure Vaccination or Refusal Rates

Hospitals were asked whether they are able to measure:

1. The number of neonates who received hepatitis B vaccination prior to discharge (See Appendix: Survey Tool); and
2. The number of neonates whose mother/parents declined vaccination (guardian refusal) (See Appendix: Survey Tool).

Results are presented in Table 3.2. Two hospitals reported having the ability to measure the number of newborns vaccinated and guardian refusals of vaccinations, but declined to do so, citing time burden for data collection too great for response. An additional hospital provided the number of vaccinated newborns, but declined to provide the number of guardian refusals of vaccination, citing excessive time burden to provide this information.

Table 3.2: Number and percent of participating hospitals that were able to measure the number of neonates administered hepatitis B vaccine prior to discharge and number of refusals

	Able to measure number of neonates vaccinated for hepatitis B prior to discharge	Able to measure the number of refusals for hepatitis B vaccination prior to discharge
	n (%)*	n (%)*
Able[a]	2 (4)	3 (6)
No	12 (24)	31 (62)
Yes (CY 2008 numbers)	32 (64)	14 (28)
Yes (Other time period[b])	4 (10)	2 (4)
Yes (Total)[c]	36 (72)	16 (32)

a. But declined to provide information
b. Other time periods provided: three provided numbers for vaccinations in CY 2009 and one provided a number for fiscal year (beginning September 2008); one provided a number for guardian refusals in CY2009, and one provided a number for its fiscal year
c. Total number of hospitals that participated =50
CY = Calendar Year
* % = number / 50

3.3 Calculated Hepatitis B Vaccination Rate

The performance level for NQF measure #0475 is defined as vaccination of all newborns prior to discharge, with newborns whose guardian refused vaccination excluded from metric calculations.[20] Less than a quarter of the hospitals that could and would provide birth dose information (22%, n=8 of 36) achieved the metric-defined performance level (i.e., birth dose vaccination at 100%), when guardian refusals were not taken into account. When guardian refusal rates were considered (i.e., excluded from calculations), 63% of the hospitals surveyed that could provide the information (n=10 of 16) met metric-defined performance level (See Table 3.3 for individual hospital vaccination rates before and after exclusions).

[20] National Quality Forum (NQF). National Voluntary Consensus Standards for Perinatal Care 2008: A Consensus Report. Washington, DC: NQF; 2009.

Table 3.3: Vaccination rate and adjusted for refusal vaccination rate based on reported data from participating hospitals

Hospital ID	Ability to Calculate Refusal Rate*	Vaccination Rate (%)	Vaccination Rate Adjusted for Refusals (%)
1	No	73	-
2	No	75	-
3	No	100	-
4	No	19	-
5	No	70	-
6	No	97	-
7	No	88	-
8	No	93	-
9	No	83	-
10	No	69	-
11	No	101	-
12	No	99	-
13	No	97	-
14	No	72	-
15	No	94	-
16	No	98	-
17	No	96	-
18	No	91	-
19	No	94	-
20	Declined	100	-
21	Yes	98	98
22	Yes	100	100
23	Yes	8	8
24	Yes	75	100
25	Yes	100	100
26	Yes	95	96
27	Yes	100	100
28	Yes	81	100
29	Yes	95	99
30	Yes	94	95
31	Yes	95	100
32	Yes	90	100
33	Yes	84	93
34	Yes	107	107
35	Yes	100	100
36	Yes	96	101*

n = 36 hospitals reported being able to calculate vaccination rate, n=16 hospitals reported being able to provide guardian refusal rate in addition to vaccination rate
Yes=Ability of hospital to measure this metric; No=Inability of hospital to measure this metric; Declined=Ability to measure, but hospital declined to provide the number for this metric;
Vaccination Rate=Number of reported vaccinations / number of live births in CY 2008 or alternate time period
Adjusted Vaccination Rate=Number of reported vaccinations / number of live births in CY 2008 or alternate time period minus number of refusals.
*Some rates were >100% due to artifacts in using data collected from different sources.

3.4 Challenges in Determining Vaccination and Refusal Rates

Respondent hospitals reported having faced challenges in determining the number of neonates vaccinated with hepatitis B vaccine (n=18, 36%) or refusals for hepatitis B vaccination prior to discharge (n=35, 70%). Some hospitals cited no challenges in determining either number (n=14, 28%). Seventeen hospitals (34%) cited having challenges determining both the number of neonates vaccinated and number of vaccinations refused.

3.4.1 Number of newborns vaccinated

Two thirds of all respondent hospitals (n=32 of 50) were able to provide data for newborns vaccinated with hepatitis B in 2008 (Table 3.4). Nearly all respondents who could provide data for the number of newborns vaccinated in 2008 did not cite challenges for obtaining the number of vaccinated (n=31/32, 97%). One hospital that provided data for a time period other than calendar year 2008 did not cite any challenges. Three hospitals that provided data for an alternate time period cited challenges to providing 2008 data. These hospitals cited information management (n=2, e.g., lack of data field in electronic medical record (EMR) or lack of appropriate EMR query), time burden (n=1, e.g., for reviewing paper records), and record accessibility (n=2, e.g., lack of immediate access to medical records because of off-site storage or separate departments) as challenges. The 14 hospitals that could not provide any data cited information management, time burden, and lack of or limited record accessibility as challenges. In Table 3.4, the hospitals could cite more than one challenge or could decline to cite any challenges. Therefore, the number of hospitals citing each challenge may be greater than the total column numbers.

Table 3.4: The types of challenges reported by respondent hospitals in the inability to determine rates for hepatitis B immunization

Challenge Cited to Providing CY2008 Vaccination Information	Provided 2008 Data	Provided Alternate Time Period Data	Could Not Provide Any Data
	n (%)*	n (%)*	n (%)*
Information management	1 (3)	2 (50)	9 (64)
Time burden	0 (0)	1 (25)	10 (71)
Record accessibility	0 (0)	2 (50)	1 (7)
None	31 (97)	1 (25)	0 (0)

n = Number of hospitals to cite challenge. Hospitals could cite more than one challenge, or could decline to cite any.
*Total number of hospitals = 50
* Column percents

3.4.2 Number of newborns with guardian refusals

Nearly 30% of all respondent hospitals provided data for newborns whose guardians or parents refused hepatitis B vaccination in 2008 (n=14) (Table 3.5). None of the hospitals cited any challenges. Two hospitals provided data for an alternate period, with one hospital citing record accessibility as a challenge. Hospitals that could not provide any data cited information management, time burden, and record accessibility as challenges.

In Table 3.5, the hospitals could cite more than one challenge or could decline to cite any challenges. Therefore, the number of hospitals citing each challenge may be greater than the total column numbers.

Table 3.5: The types of challenges reported by respondent hospitals in the inability to determine guardian refusal rates for hepatitis B immunization

Challenge Cited to Providing CY2008 Guardian Refusal Information	Provided 2008 Data	Provided Alternate Time Period Data	Could Not Provide Data
	n (%)*	n (%)*	n (%)*
Information management	0 (0)	0 (0)	34 (100)
Time burden	0 (0)	0 (0)	4 (12)
Record accessibility	0 (0)	1 (50)	5 (15)
None	14 (100)	1 (50)	0 (0)

n = Number of hospitals to cite challenge. Hospitals could cite more than one challenge, or could decline to cite any.
*Total number of hospitals = 50
* Column percents

Hospitals cited a variety of challenges in providing vaccination and guardian refusal information. Tables 3.6 and 3.7 provide descriptive analyses of hospital ability to provide this information by ownership type and geographical area designation.

Table 3.6: Distribution of hospitals by ability to provide hepatitis B vaccination data by business ownership, geographical setting, and hospital size metrics

	Provided 2008 Data	Provided Alternate Time Period Data	Could Not Provide Any Data
Ownership Type	n (%)*	n (%)*	n (%)*
For Profit	10 (31)	2 (50)	6 (43)
Not for Profit	16 (50)	2 (50)	7 (50)
Public	6 (19)	0 (0)	1 (7)
Geographical Area Designation			
Urban	23 (72)	4 (100)	13 (93)
Rural	9 (28)	0 (0)	1 (7)
Total number of hospitals	**32**	**4**	**14**
	Mean (Range)	Mean (Range)	Mean (Range)
Licensed Bed Size	335 (19 – 1,049)	273 (178 – 320)	356 (100 – 936)
Birth Cohort**	1,943 (219 – 4,907)	3,289 (738 – 6,530)	2,702 (757 – 5,433)

* Column percents
**Birth Cohort: total annual live births in provided data. Total Birth cohort in those hospitals providing 2008 data= 62,173; those providing alternate time period data =13,156, those not able to provide data = 37,821.

Table 3.7: Distribution of hospitals by ability to provide hepatitis B vaccination guardian refusal data by business ownership, geographical setting, and hospital size metrics

	Provided 2008 Data	Provided Alternate Time Period Data	Could Not Provide Any Data
Ownership Type	**n (%)***	**n (%)***	**n (%)***
For Profit	4 (29%)	1 (50%)	13 (38%)
Not for Profit	8 (57%)	1 (50%)	16 (47%)
Public	2 (14%)	0 (0%)	5 (15%)
Geographical Area Designation			
Urban	9 (64%)	2 (100%)	29 (85%)
Rural	5 (36%)	0 (0%)	5 (15%)
Total number of hospitals	**14**	**2**	**34**
	Mean (Range)	**Mean (Range)**	**Mean (Range)**
Licensed Bed Size	266 (49 – 660)	296 (280 – 312)	366 (19 – 1,049)
Birth Cohort**	1,460 (219 – 4,907)	4,595 (2,659 – 6,530)	2,456 (287 – 5,433)

* Column percents

**Birth Cohort: total annual live births in provided data. Total birth cohort in those hospitals providing 2008 vaccine refusal data= 20,444; those providing alternate time period data =9,189, those not able to provide data = 83,517

3.5 Planned Changes That May Facilitate Ability to Provide Data

Hospitals were asked to provide information about upcoming changes in infrastructure or processes that would enable them to provide data on the number of hepatitis B vaccinations to neonates before discharge (See Table 3.8). There was a larger number of hospitals that could provide vaccination rates than hospital that could not that reported anticipating changes (i.e., adopt the use of electronic medical records, upgrade to electronic medical records or develop non-EMR based reports or databases). These reported anticipated changes would allow the hospitals to continue or begin providing hepatitis B vaccination data. There was also a larger number of hospitals that provided data than those that could not that reported not anticipating any changes.

Table 3.8: Number of hospitals that listed anticipated changes for facilitating data reporting

Anticipated Change	Hospitals Not Providing Rates (n)	Hospitals Providing Rates (n)	Total n (%)*
Adoption of electronic medical record	1	7	8 (16)
Upgrade of current electronic medical record	4	9	13 (26)
Development of non-EMR based reports or databases	1	2	3 (6)
None identified	8	18	26 (52)

Total number of hospitals = 50
* % = Number / 50

3.6 Time Burden to Collect Data for this Metric

Participating hospitals were asked to estimate the time burden for collecting data (See Table 3.9). Hospitals that used paper records reported a mean time of data collection of 10.1 hours compared to 3.7 hours for hospitals with an entirely electronic medical record system. For three hospitals that accessed records in a mixed format of both electronic and paper, the mean time to collect data was 3.1 hours.

Table 3.9: Time in hours to determine number of neonates vaccinated with hepatitis B prior to discharge by retrieval method

Retrieval Method	n	Mean (Hours)	Median (Hours)	Minimum (Hours)	Maximum (Hours)
Paper record	15	10.1	1.0	0.2	72.0
Electronic medical record	12	3.7	1.0	0.2	30.0
Mixed paper and electronic records	3	3.1	1.0	0.2	8.0
Electronic archive of paper record	1	--	--	1.0	1.0
No information provided on retrieval method	3	3.0	4.0	1.0	4.0
Total	**34**	**6.3**	**1.0**	**0.2**	**72.0**

n = Number of hospitals

3.7 Direct or Indirect Costs Associated with Data Collection

A subset of respondents provided data on the direct and indirect costs associated with data collection. Table 3.10 provides a summary of estimated cost burden, and Table 3.11 provides a summary of cost by method of data retrieval.

Table 3.10: Direct and indirect costs to determine number of neonates vaccinated with hepatitis B prior to discharge

Cost	n	Mean	Median	Minimum	Maximum
Direct cost to determine vaccination rate	6	$ 65.00	$ 25.00	$ 0.00	$ 240.00
Indirect cost to determine vaccination rate	11	$ 303.30	$ 100.00	$ 0.00	$ 1,650.00
Direct cost to determine refusal rate	5	$ 594.00	$ 10.00	$ 0.00	$ 2,000.00
Indirect cost to determine refusal rate	6	$ 136.33	$ 26.50	$ 0.00	$ 725.00

Direct cost=Actual cost to retrieve records
Indirect cost= Cost of resource hours to retrieve records
n =Number of hospitals, n = 13 (The hospitals that could provide one or both the direct and indirect cost so the total number of hospitals providing any data = 13)
Note: One respondent noted a cost of greater than $50,000 as a direct cost for data retrieval. Presumably, this was a cost for the full-time equivalent employee salary to provide this information. This data point was considered an outlier and was not included in the data analysis.

Table 3.11: Total cost to determine number of neonates vaccinated with hepatitis B prior to discharge by retrieval method

Retrieval Method	n	Mean	Median	Minimum	Maximum
Paper record	6	$ 336.83	$ 117.50	$ 56.00	$ 1,450.00
Electronic medical record	5	$ 970.00	$ 1,160.00	$ 0.00	$ 2,000.00
Mixed paper and electronic records	0	--	--	--	--
Electronic archive of paper record	0	--	--	--	--
No information provided on retrieval method	2	$ 170.00	$ 240.00	$ 100.00	$ 240.00
Total	**13**	**$ 554.69**	**$ 135.00**	**$ -**	**$ 2,000.00**

n=Number of hospitals

3.8 Validity of Data Provided by Respondents

The validity of data collected was determined by comparing rates of vaccination reported by hospitals through the feasibility survey (n=36/50) and rates of vaccination calculated from the same hospitals by reviewing a sample of medical records in the larger public health evaluation study. Validity of data collected by the feasibility study as compared to data collected by the public health evaluation study is summarized in Tables 3.12 and 3.13 and Figures 3.1 and 3.2. Most rates as determined by the hospitals (Table 3.12, Columns C and F) fell within ±10% of rates determined by the medical chart review in the public health evaluation study (Columns D and G).

Table 3.12: Comparison of data collected by the feasibility study and data collected by the public health evaluation study

		Unadjusted Vaccination Rate			Adjusted Vaccination Rate to Account for Refusal		
(A) FS Ability to Calculate Vaccination Rate	(B) FS Ability to Calculate Refusal Rate	(C) FS	(D) PHE	(E) Difference between FS and PHE	(F) FS	(G) PHE	(H) Difference between FS and PHE
1. Yes	No	73%	70%	2%	-	77%	-
2. Yes	No	75%	76%	-1%	-	77%	-
3. Yes	No	100%	99%	1%	-	100%	-
4. Yes	No	19%	89%	-70%	-	92%	-
5. Yes	No	70%	93%	-23%	-	100%	-
6. Yes	No	97%	98%	-2%	-	99%	-
7. Yes	No	88%	91%	-3%	-	91%	-
8. Yes	No	93%	97%	-5%	-	98%	-
9. Yes	No	83%	56%	27%	-	58%	-
10. Yes	No	69%	70%	-1%	-	70%	-
11. Yes	No	101%	98%	3%	-	98%	-
12. Yes	No	99%	99%	-1%	-	100%	-
13. Yes	No	97%	73%	24%	-	90%	-
14. Yes	No	72%	72%	0%	-	72%	-
15. Yes	No	94%	99%	-5%	-	100%	-
16. Yes	No	98%	97%	1%	-	97%	-
17. Yes	No	96%	100%	-4%	-	100%	-
18. Yes	No	91%	96%	-5%	-	97%	-
19. Yes	No	94%	96%	-2%	-	96%	-
20. Yes	Declined	100%	94%	6%	-	97%	-
21. Yes	Yes	84%	89%	-5%	93%	98%	-5%
22. Yes	Yes	100%	100%	-2%	100%	100%	-2%
23. Yes	Yes	98%	100%	-2%	98%	100%	-2%
24. Yes	Yes	8%	100%	-92%	8%	100%	-92%
25. Yes	Yes	75%	94%	-19%	100%	97%	3%
26. Yes	Yes	100%	99%	1%	100%	99%	1%
27. Yes	Yes	95%	97%	-3%	96%	98%	-2%
28. Yes	Yes	100%	99%	1%	100%	99%	%
29. Yes	Yes	81%	80%	1%	100%	80%	20%
30. Yes	Yes	95%	91%	4%	99%	93%	6%
31. Yes	Yes	94%	94%	0%	95%	95%	-1%
32. Yes	Yes	95%	96%	-1%	100%	97%	3%
33. Yes	Yes	90%	98%	-8%	100%	98%	2%
34. Yes	Yes	107%	99%	8%	107%	99%	8%
35. Yes	Yes	101%	99%	2%	101%	99%	2%
36. Yes	Yes	96%	95%	2%	101%	97%	4%

n=36 Hospitals; Yes=Ability of hospital to measure this metric; No=Inability of hospital to measure this metric; Declined=Hospital was able but declined to provide this metric; Vaccination Rate=Number of reported vaccinations / number of live births in CY 2008 or alternate time period; Adjusted Vaccination Rate= Number of reported vaccinations / number of live births in CY 2008 or alternate time period minus number of refusals. Some rates were >100% due to artifacts in using data collected from different sources. All rates and differences rounded to the nearest whole number.

* Note: In Column (G) (Lines 1-20) refusal rates were identified during the medical chart review in accordance with the protocol established for the DSHS public health evaluation study. There were no corresponding data reported from the feasibility study for comparison.

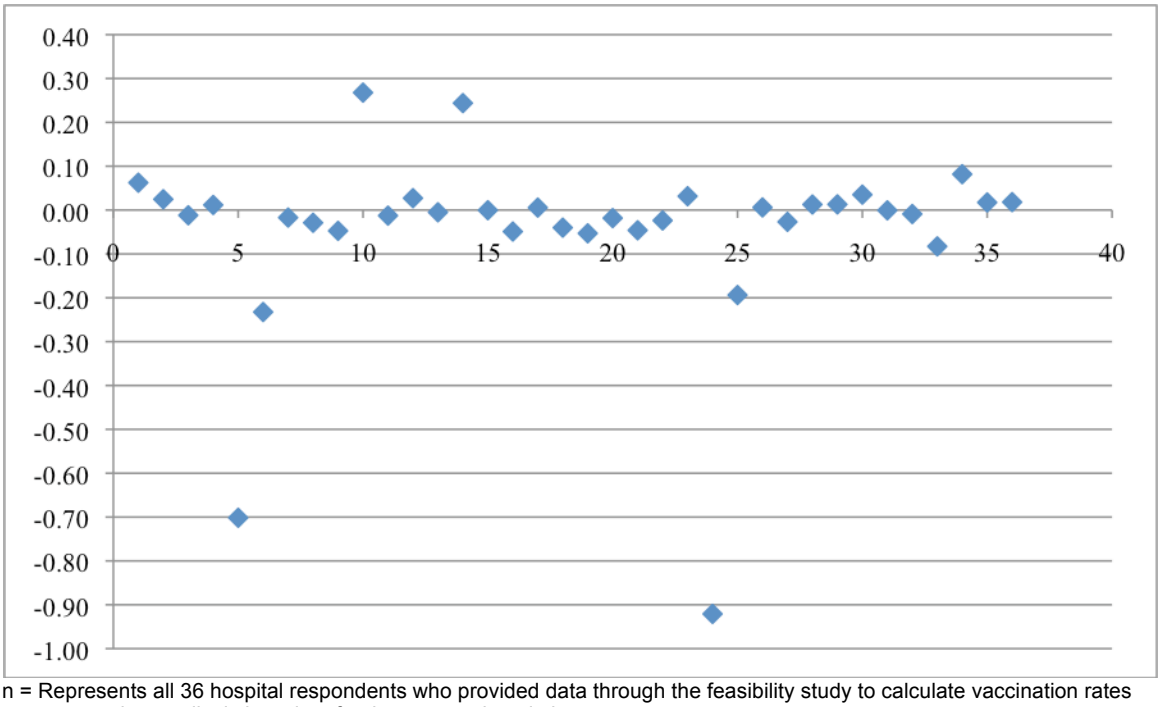
FS=Feasibility Study; PHE=Public Health Evaluation

Table 3.13: Vaccination rate variations

Rate Difference	n	Mean	Median	Standard Deviation
Vaccination rate	36	-5.0%	-1.0%	21.0%
Adjusted vaccination rate	16	-3.0%	2.0%	24.0%

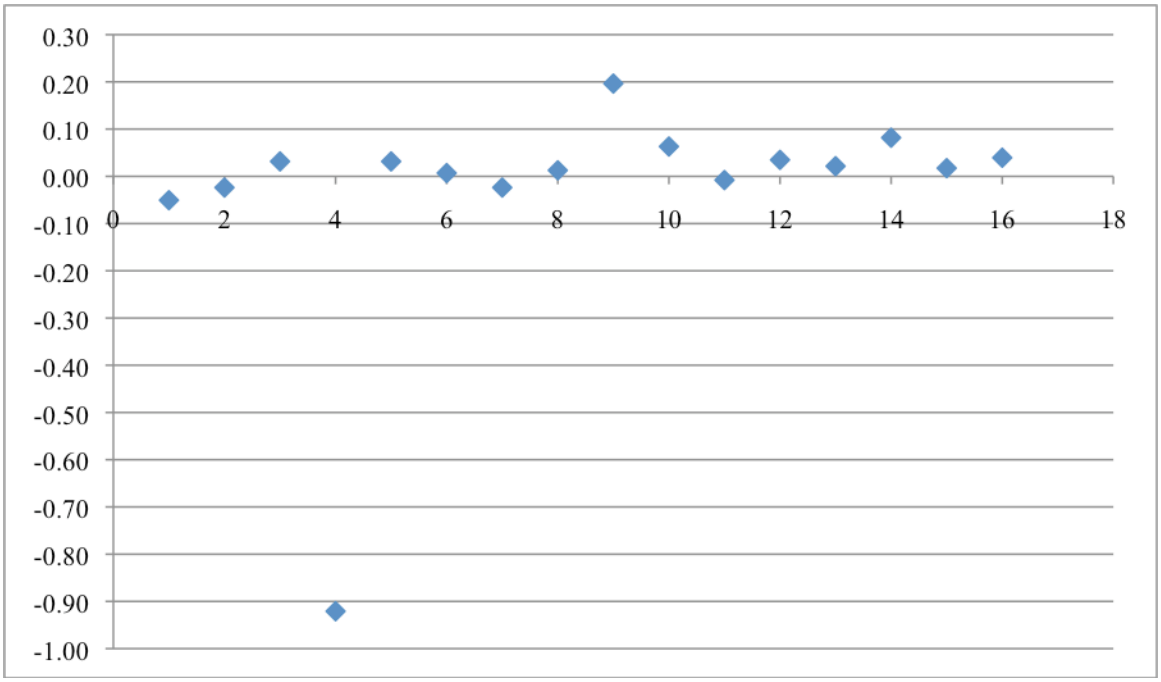
n=Number of hospitals; Adjusted vaccination rate=Number vaccinated divided by (total birth cohort minus refusals)

Figure 3.1: Difference between respondent-based feasibility assessment and on-site medical chart review in public health evaluation study for non-adjusted vaccination rates



n = Represents all 36 hospital respondents who provided data through the feasibility study to calculate vaccination rates as compared to medical chart data for these same hospitals
Note: Hospitals that are outliers in the graph either reported no challenges for accurate vaccination reporting, did not track refusals, or cited time burden for review of paper records as a challenge.

Figure 3.2: Difference between respondent-based feasibility assessment and on-site medical chart review in public health evaluation study for adjusted vaccination rates



n = Represents the 16 hospital respondents who provided refusal data through the feasibility study to calculate vaccination rates as compared to medical chart data for these same hospitals
Note: Hospitals that are outliers in the graph either reported no challenges for accurate vaccination reporting, did not track refusals, or cited time burden for review of paper records as a challenge.

3.9 Data Sources for Responses to the Feasibility Study

The types of data sources used to determine the numbers of neonates vaccinated varied by facility (Tables 3.14 and 3.15). Some used single sources (Table 3.14) while others indicated that they used up to four different data sources (Table 3.15). Hospitals with outlier rate determinations used the same types of sources as other hospitals that had more accurate determinations. Factors accounting for the outliers cannot be determined from the data collected and are not known.

Table 3.14: Single data source use for determination of hepatitis B vaccination rates with and without adjustment for guardian refusals, by variation from medical chart-based rate for accuracy estimation

Single Data Source	Vaccination Rate Accuracy			Adjusted Vaccination Rate Accuracy		
	+/-0.10	>+0.10	<-0.10	+/-0.10	>+0.10	<-0.10
Pharmacy (n)	6		1			
MAR (n)	1		1			1
Claims (n)	1					
Clinical Database (n)	3	2		1		
Vaccine Consent (n)				1		
Delivery Logs (n)	4			3	1	
Unspecified EMR (n)	2			1		
State Registry (n)	2			1		
n with Single Source	**23**			**9**		

MAR = Medication administration record; EMR = Electronic medical record; n = Number of hospitals

Table 3.15: Multiple data source use for determination of hepatitis B vaccination rates with and without adjustment for guardian refusals, by variation from medical chart-based rate for accuracy estimation

Multiple Data Source	Vaccination Rate Accuracy			Adjusted Vaccination Rate Accuracy		
	+/-0.10	>+0.10	<-0.10	+/-0.10	>+0.10	<-0.10
Pharmacy + Delivery Log (n)	1			1		
Pharmacy + State Registry (n)			1			1
Pharmacy + Vaccine Consent + Nurses Notes (n)	1					
Pharmacy + MAR (n)	2					
Pharmacy + MAR + Vaccine Consent (n)	1					
MAR + Vaccine Consent (n)	1					
MAR + Vaccine Consent + Delivery Log (n)	1					
MAR + Vaccine Consent + Nurses Notes + Delivery Log (n)	2					
MAR+ Delivery Log (n)				1		
Pharmacy + Delivery Log (n)				1		
MAR + Pharmacy + Nurses Notes (n)				1		
Vaccine Consent + Nurses Notes (n)				1		
MAR + Vaccine Consent + Nurses Notes (n)				1		
n with Multiple Sources	**10**			**7**		

MAR = Medication administration record; EMR = Electronic medical record; n = Number of hospitals

3.10 Effects of Patient Characteristics on Outcome Measure Calculations

Individual patient information was not collected in this feasibility study, and no risk adjustment or stratification of data by patient characteristic was made. However, the data collected during the medical chart review of the public health evaluation study were reviewed for possible patient-related factors that might influence the outcome of hepatitis B vaccination before discharge. The results are presented in the following tables:

- Table 3.16 shows adjusted vaccination rates (guardian refusals removed from the denominator of newborns discharged from the hospital) by race/ethnicity of the mother.
- Table 3.17 shows the adjusted vaccination rates by gestational age of the neonate.
- Table 3.18 shows the adjusted vaccination rates by neonatal birth weight.
- All of the proportions shown in Tables 3.16 – 3.18 are for all 119 participating hospitals in the perinatal hepatitis B public health evaluation study, and the rate proportions are calculated based on the sum of the statistical weights (total charts reviewed divided by the total birth cohort of the hospital).

Table 3.16: Medical chart based on adjusted neonatal hepatitis B vaccination rate by race/ethnicity of mother

Mother's Race/Ethnicity	Adjusted Vaccination Rate (Statistical Weight)	n	Total n
African American	93%	1,379	1,488
American Indian/Alaskan	75%	14	16
Asian	92%	259	282
Hawaiian/Pacific Islander	85%	20	24
Hispanic	95%	5,128	5,425
Multiracial	98%	10	11
No data entered	99%	44	45
Not recorded	95%	155	160
Other	93%	336	357
Unknown	94%	217	232
White	90%	4,189	4,642
Total	**93%**	**11,751**	**12,682**

n = Number of neonates

Table 3.17: Medical chart based on adjusted neonatal hepatitis B vaccination rate by gestational age of neonate

Gestational Age (Weeks)	Adjusted Vaccination Rate (Statistical Weight)	n	Total n
20	34%	1	2
21	0%	-	2
22	0%	-	1
23	22%	1	6
24	84%	7	10
25	55%	9	16
26	73%	6	11
27	92%	9	13
28	79%	16	26
29	85%	21	29
30	90%	23	30
31	78%	31	43
32	86%	61	74
33	93%	89	100
34	89%	183	210
35	92%	298	329
36	91%	578	628
37	93%	1,348	1,433
38	92%	2,864	3,098
39	94%	3,304	3,546
40	94%	1,900	2,042
41	95%	440	464
42	98%	47	48
43	100%	4	4
45	100%	1	1
Total	**93%**	**11,241**	**12,166**

n = Number of neonates

Table 3.18: Medical chart based on adjusted neonatal hepatitis B vaccination rate by birth weight (grams) of neonate

Birth Weight	Adjusted Vaccination Rate (Statistical Weight)	n	Total n
0-500	75%	18	25
500-1,000	64%	31	61
1,000-1,500	84%	86	114
1,500-2,000	87%	177	217
2,000-2,500	92%	669	737
2,500-3,000	94%	2,593	2,751
3,000-3,500	93%	4,837	5,170
3,500-4,000	93%	2,698	2,920
4,000-4,500	95%	571	608
4,500-5,000	93%	59	66
5,000-5,500	92%	10	11
5,500-6,000	100%	1	1
6,500-7,000	100%	1	1
Total	**93%**	**11,751**	**12,682**

n = Number of neonates

3.11 Summary of Key Findings

This feasibility study demonstrated the following:

- Data were derived from 50 hospitals that are representative of labor and delivery hospitals in Texas.
- The reproducibility of the NQF hepatitis B vaccination measure was demonstrated by vaccination rates calculated based on hospital reported rates and vaccination rates from medical chart reviews for the public health evaluation study.
- The sample size of 50 hospitals represented an overall annual birth cohort of over 100,000 births. Information was provided on vaccination rates from an annual birth cohort representing over 62,000 births. Information on exclusions due to guardian refusals was provided from an annual birth cohort of over 30,000 births. Hospitals that could not or did not provide any information on vaccination and/or refusal rates represented the remaining portion of the study cohort.
- When guardian refusals were excluded from analysis – as allowed under the definition for this metric, the level of universal vaccination rate increased from 5 of 16 (31%) to 10 of 16 (63%) for hospitals capable of responding to both variables in this metric.
- Respondent hospitals cited information management practices as a challenge for obtaining data to calculate the hepatitis B vaccination metric, including data for guardian refusal rates.
- Variation was observed in baseline performance of the measure across hospitals, with the calculated measure ranging from 8-100%. Sixty-three percent of providers who could provide information for the complete calculation of the measure met the standard of 100% vaccination.
- Estimations of time and cost burden for determining the hepatitis B vaccination measure varied widely among hospitals. Time burdens were highest for facilities that did not use an electronic medical record system.
- Analysis of data for the hospital-based measure compared to estimates derived from medical chart review showed a variance of ±10% for most of the hospitals (30/36). Most hospitals obtained their information from multiple data sources, with the most common source being pharmacy records.
- The measure was not risk adjusted, either in the hospital-based calculations or in the medical chart-based calculations, for any patient characteristic. Vaccination rates as measured in the public health evaluation study showed some variation by both gestational age and birth weight, with pre-term, newborns weighing less than 2000 grams having lower vaccination rates as compared to term, normal weight babies.

3.12 Limitations

The results from this study should be interpreted in consideration of the following limitations. One limitation is responder bias (i.e., those who could favorably measure vaccination rates chose to respond whereas those without the capacity to self-measure vaccination rates chose not to participate). When encouraged to participate by e-mail reminder, several hospitals responded that they had declined participation initially because they could not measure vaccine administration rates. They were encouraged to complete the survey so that their inability to measure vaccination rates and the challenges they faced could be captured. There are no documented open-ended responses collected from non-participating hospitals. Reasons for why other hospitals did not participate or respond are unknown. No adjustments were made to the data from this study for non-response.

Calculations included sums, proportions, averages, medians, minimum and maximum values. Only descriptive analyses were conducted for this study because of the small sample size and participant self-selection basis. No inferential analyses were attempted; therefore, the power of the sample size was not determined. Normally, inferential analyses such as regressions require 15 to 20 cases for each variable to be included, for a power of 0.80 and an alpha level of 0.05.[21]

The hospitals that participated in this survey were all participants in the hepatitis B public health evaluation study in Texas. The limitations of hospital representation in that study are therefore also pertinent to this study. The hospitals in the public health evaluation study represented a fairly balanced statewide sampling of all hospitals in Texas with significant labor and delivery services, but they were not a random selection of hospitals.

Further, Texas might not be fully representative of the United States. Hepatitis B birth dose coverage in Texas based on the National Immunization Survey for children born in 2005-2007 was 67% whereas statewide estimates of birth dose coverage varied from 19% to 78%.[22] Thus, variability within hospitals and the ability to self-measure vaccination rates across the nation might be greater than represented in this feasibility study.

[21] Cohen J and Cohen P. Applied Multiple Regression / Correlation Analysis for the Behavioral Sciences – 2nd Edition. Hillsdale, New Jersey: Lawrence Erlbaum Associates Publishers. 1983.
[22] National, state, and local area vaccination coverage among children aged 19-35 months - United States, 2008. MMWR 2009;58(33):921-6

4 Conclusions

For the majority of hospitals responding to this feasibility study, the measurement of the rate of hepatitis B vaccine administration was a feasible endeavor. Only a few hospitals were able to measure guardian refusal rates. For hospitals where refusals occur at significant rates, the inability to measure refusals will impact whether a given hospital has an accurate measure of first birth dose administration rates for hepatitis B.

Given the current trend of increased implementation of electronic medical records in health care systems, the ability of hospitals to measure numbers of live newborns who received hepatitis B vaccination prior to discharge may improve over time. Increasing awareness of hepatitis B vaccination as a quality metric for hospitals will allow thoughtful implementation of appropriate data fields and queries for relevant information, such as for documentation of guardian refusals.

5 Appendix: Methods for Public Health Evaluation Project

The following sections describe the method selection process for the public health evaluation project entitled *Public Health Evaluation Project – Assessing Hospital Policies and Practices of Hepatitis B, HIV, Rubella, and Syphilis Screening and Vaccination among Texas Newborns in 2008*.[23] It is included in this report to provide the context in which the feasibility study was conducted.

Three types of data were collected for the public health evaluation project: (1) policies and practices data related to prevention of perinatal transmission of hepatitis B, HIV, and rubella; (2) maternal and neonate hospitalization data from medical records; and (3) National Quality Forum (NQF) indicator data. Policy and practices data and medical record data were collected from the 119 participating hospitals. NQF data were collected from a subset of these 119 hospitals (n=50). Hospital selection criteria and medical record selection criteria are described in Sections 5.1 and 5.2, respectively.

5.1 Hospital Selection

5.1.1 Selection Criteria for the Policies and Practices Survey and the Medical Record Review

A total of 119 hospitals were selected to participate in this survey. Selection criteria included hospitals: (1) located in each of the eight DSHS regions; (2) with more than 100 live births or 30 cesarean births;[24] (3) located in areas of the state with a high incidence of hepatitis B; and (4) identified by DSHS regional perinatal nurse coordinators.

5.1.2 Selection Criteria for the National Quality Forum (NQF) Survey

All 119 hospitals that participated in the policies and practices survey and the medical record review were eligible to participate in a follow-up survey to assess hospital practices with regard to an endorsed NQF metric (See Section 7: Appendix: Survey Tool). Of the 119 eligible hospitals, 50 (42.0%) participated in the NQF assessment.

[23] Headley VL, Litaker JR, Chou, JY, Ramón M, Hasty K. Assessing Hospital Policies and Practices of Hepatitis B, HIV, Rubella, and Syphilis Screening and Vaccination among Texas Newborns in 2008. June 2010.

[24] A significant number of births are from those hospitals identified in the DSHS Annual Hospital Survey with greater than 100 deliveries per year (2008) and the Texas Healthcare Information Collection with greater than 30 cesarean births per year (2007).

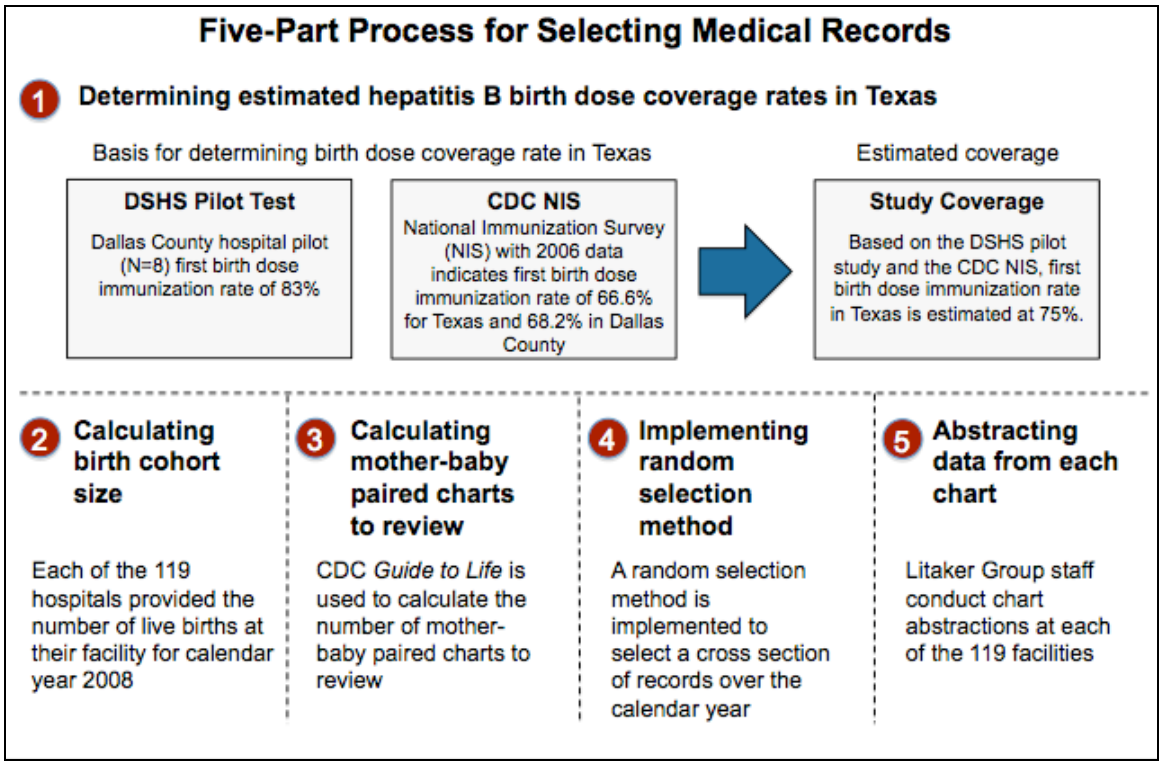
5.2 Medical Record Selection

Medical record selection was a five-part process (See Figure 5.1). It included:

1. Determining the estimated hepatitis B birth dose coverage rate in Texas;
2. Determining the birth cohort size at each hospital;
3. Calculating the number of mother-baby paired charts to review based on (1) and (2);
4. Implementing a random selection method to identify which specific medical records to review; and
5. Abstracting data from each chart.

Each step is described below.

Figure 5.1: The five-part process for selecting medical records for data abstraction



5.2.1.1 Determining the Estimated Hepatitis B Birth Dose Coverage Rate in Texas

For the purposes of this study, the expected hepatitis B birth dose coverage rate is estimated at 75% based on findings from the CDC National Immunization Survey (2006 data) and from a DSHS pilot study of eight hospitals in Dallas County in 2008. The National Immunization Survey reported statewide hepatitis B birth dose coverage of 66.6% and coverage in Dallas County of 68.2%. The DSHS pilot study in Dallas County reported birth dose immunization of hepatitis B at 83%.

5.2.1.2 Calculating Birth Cohort Size

Participating hospitals reported the number of live births in calendar year 2008 as part of the response to the policies and practices survey.

5.2.1.3 Calculating Mother-Baby Paired Charts to Review

Calculating the number of mother-baby paired charts to review at each hospital was based on two variables: (1) the expected hepatitis B vaccine birth dose coverage rate; and (2) the number of 2008 live births at a particular hospital. Data for these two variables are discussed in Sections 5.2.1.1 and 5.2.1.2, respectively.

Data for these two variables were applied to Table 5.1 to determine the number of mother-baby chart pairs to review. As an example, if a hospital reported between 1,500 and 2,000 live births and the expected birth dose coverage rate is 75%, 107 mother-baby paired medical records were reviewed to meet methodological standards established by the CDC. In instances where the actual reported number of live births fell between two birth cohort sizes in Table 5.1 rounding to the closest birth cohort size occurred to determine the number of charts to review.

Table 5.1: The CDC methodology used to calculate mother-baby pair sample sizes for medical record review based on hospital birth cohort size and expected maternal screening or birth-dose coverage

Expected Maternal HBsAg Screening or Hepatitis B Vaccine Birth-Dose Coverage*										
Birth Cohort Size	95%	90%	85%	80%	**75%**	70%	65%	60%	55%	50%
100	22	35	43	49	**53**	56	58	59	60	60
200	25	43	55	65	**72**	77	81	84	85	86
300	26	46	61	73	**82**	89	94	97	99	100
450	27	48	65	79	**90**	98	105	109	112	113
600	27	50	68	83	**95**	104	111	116	119	120
800	28	51	70	86	**99**	109	117	122	125	126
1,000	28	51	71	88	**101**	112	120	126	129	130
1,500	28	52	73	90	**105**	116	125	131	135	136
2,000	**28**	**53**	**74**	**92**	**107**	119	128	134	138	140
3,000	28	53	75	93	108	121	131	137	142	143
5,000	28	53	75	94	110	123	133	140	144	146
10,000	28	54	76	95	111	124	135	142	146	148
20,000	28	54	76	96	112	125	136	143	147	149
40,000	28	54	76	96	112	126	136	144	148	150
50,000	28	54	76	96	112	126	136	144	148	150
70,000	29	54	76	96	112	126	136	144	148	150
80,000	29	54	76	96	112	126	136	144	148	150
100,000	29	54	76	96	112	126	136	144	148	150
150,000	29	54	76	96	112	126	136	144	148	150
300,000	29	54	77	96	113	126	136	144	148	150
* Using confidence interval of +/– 8%										

Source: CDC Guide to Life, Managing a Perinatal Hepatitis B Prevention Program-Chapter 2: Establishing Program Goals and Evaluating Your program, Page 9; HBsAg: Hepatitis B surface antigen.

5.2.1.4 Implementing an Interval Selection Method

An interval sampling method was used to identify and request specific medical records from each hospital. This method was on the CDC protocol and allowed records to represent the entire calendar year. Hospitals were instructed to retrieve records in a specific sequence to ensure record representation of the entire 2008 population. The medical record or health information department at each hospital was responsible for collecting these records based on instructions provided by The Litaker Group. The interval sampling method for each hospital was calculated as follows.

(Number of Live Births in 2008) / (Number of Records to Review) = Sampling Interval for Medical Record Pull

For example, if a hospital had 2,000 live births and 100 records were requested for review, the interval sampling method would be 20. This means that starting with the first birth record in January 2008, the hospital would pull each twentieth record thereafter until 100 records were pulled. To mitigate incomplete or unavailable medical records, each hospital was to pull an additional three records beyond the sample number determined by CDC protocol. If fewer than the required number of records was retrieved by the end of December 2008, hospitals were requested to pull the necessary number of records to complete the total number requested. The total number of mother-baby paired medical records reviewed at each hospital ranged from a low of 96 to a high of 116, with an average of 106 record pairs reviewed at each hospital. A total of 12,670 maternal records and 13,036 baby records were reviewed. Neonate records outnumbered maternal records because of some multiple birth events, in which case hospitals were asked to retrieve records for all live births associated with the birth event.

5.3 Data Collection Tools

Three data collection tools were created for this public health evaluation project. Each is described separately below.

1. Perinatal Hepatitis B Hospital Policies and Practices Survey
2. Perinatal Hepatitis B Chart Audit Data Collection Tool
3. National Quality Forum Measure Assessment Tool

5.3.1 Policies and Practices Data Collection Tool

5.3.1.1 Background

The Perinatal Hepatitis B Hospital Polices and Practices Survey was developed to obtain specific information from each participating hospital related to hospital demographics, written polices, preprinted orders, and other questions as applicable to hepatitis B, HIV, and rubella.[25]

5.3.1.2 Data Collection

The hospital administrator or other designee was identified as the initial contact person to receive this survey. The name and address of each hospital administrator was verified by calling each of the 119 facilities. The survey was administered to each hospital between April and May 2009, except for one facility that completed the survey in November 2009. Data collected for this survey were for calendar year 2008. Hospitals could submit their responses by mail, fax, or online.

5.3.1.3 How Data Were Used

Data from the policies and practices surveys were used to identify associations between specific hospital activities (e.g., prenatal screening for maternal hepatitis B surface antigen (HBsAg), birth dose administration of hepatitis B vaccine to a newborn, administration of hepatitis B immunoglobulin (HBIG) when indicated, and practices and policies in place to guide these activities). The number of live births in the 2008 metric was used to determine the number of medical records to review for each hospital (See Section 5.2).

5.3.2 Chart Audit Data Collection Tool

5.3.2.1 Background

The Perinatal Hepatitis B Chart Audit Data Collection Tool was used to collect data at each hospital. Site visits were conducted from April 2009 to February 2010. No personally identifiable data elements were collected, obtained, or recorded by The Litaker Group. This tool was created based on input from DSHS program staff, a previous data collection instrument, and potential analyses to be conducted. Data were entered into a

[25] Headley VL, Litaker JR, Chou, JY, Ramón M, Hasty K. Assessing Hospital Policies and Practices of Hepatitis B, HIV, Rubella, and Syphilis Screening and Vaccination among Texas Newborns in 2008. June 2010.

Microsoft Access database designed specifically for this tool. Key features of this database included internal validation to prevent errors from occurring.

5.3.2.2 Data Collection

Data collection was completed by one of eight Litaker Group staff members on site at each hospital for four to five days, except for one hospital that allowed for remote access to electronic health records. Table 5.2 outlines activities associated with data abstraction at each hospital.

Table 5.2: Summary of data abstraction activities at each hospital

Activity	Action
1. Litaker Group (LG) advises hospital of records to make available	• LG staff advised hospitals in advance of site visit to pull specified number of records using internal sampling method
2. LG schedules appointments	• LG staff scheduled appointments at each facility to begin on a Monday morning at 9:00am, unless otherwise requested by the hospital.
3. LG conducts kick-off meeting	• Along with a representative of the local health department, a LG staff member conducted a kick-off meeting to discuss the project, the process for data collection, and project outcomes, unless the hospital requested not to have a kick-off meeting or if the health department representative was not available.
4. Hospital staff introduces medical record system	• Hospital staff members instructed LG staff on how to review and abstract data from either paper or electronic records.
5. Hospital staff provides listing of pulled records	• Hospital staff provided LG staff member a paper list of all pulled records. • LG staff made notes on this document and left it with the project contact when data collection was complete. • Any medical record with a positive screen for hepatitis B surface antigen, HIV, or syphilis was noted by an asterisk on this list for follow-up (See Activity 8; Table 5.2) by the local health department. • Project contact was asked to keep this list on file.
6. LG staff conducts data review and abstraction	• LG staff reviewed thoroughly each medical record based on protocol and abstracted data into the MS Access database.
7. LG staff aggregates into master file	• LG project manager aggregated data into a master file on an ongoing basis.
8. Local health department staff follows up with hospitals post-visit[26]	• LG staff contacted local health department to follow up on cases of positive screens for hepatitis B surface antigen, HIV, or syphilis.

[26] Litaker Group protocol stated that LG staff would collect no identifiable personal health information on any patient or medical record reviewed. In order to notify local health departments of positive screens for hepatitis B surface antigen, HIV and syphilis, LG staff would note any positive cases on the list of records provided by each hospital with a generic symbol, such as an asterisk, that would not be defined on the list nor indicate to an uninformed observer of the list the nature of the notation. This list would then be returned to the hospital at the end of the medical review. LG staff would make a note that a particular hospital had a "positive" case for follow-up. The LG would contact the local health department and note a "positive" case and provide the contact name and number of the hospital representative to conduct follow-up.

5.3.2.3 How Data Were Used

Data from the medical chart abstraction were used in conjunction with data from the policies and practices survey to conduct statistical analyses.

5.3.3 National Quality Forum Measure Assessment Tool

5.3.3.1 Background

The National Quality Forum has endorsed a quality metric to assess hepatitis B birth dose immunization at the hospital level. The Centers for Disease Control and Prevention is the intellectual property owner of this metric. As part of the hepatitis B public health evaluation project, The Litaker Group also collected data to assist the CDC and NQF with evaluating this metric. A NQF assessment tool was created and used to collect feasibility data. Section 5.1.2 outlines the selection criteria for hospitals to participate in this assessment.

5.3.3.2 Data Collection

The hospital contact person identified through the Policies and Practices Survey or through data collection activities was the designated contact person to complete the NQF survey. The survey was administered to each hospital between April and May 2010. Data collected for this survey were for calendar year 2008. If measurements could not be made for this time period, hospitals were asked to identify and provide data for an alternate time period. Guardian refusal rate was also requested, as this piece of data is allowed as an exclusion criterion by the NQF metric in establishing the rate of birth dose coverage.

5.3.3.3 How Data Were Used

Data from the NQF measure assessment tool were used to identify the types of data related to birth dose coverage for hepatitis B that could be collected by a hospital and the feasibility of collecting this data. Information was also compared to data collected in the policies and practices survey and the medical record review.

5.4 Data Analyses

Two types of data were used in analyses for this project: (1) raw data counts and (2) weighted data counts. Data collected from the hospital policies and practice surveys were analyzed based on the raw count with the hospital as the unit of analysis. Data collected from the medical record review were analyzed using weighted maternal and neonatal data. The number of medical records obtained at each hospital varied based on the birth cohort size of that particular hospital (See Section 5.2: Medical Record Selection) and ranged from 96 – 116 chart pairs per hospital. Applying a statistical weight to maternal and neonatal data based on the chart sample variation allowed for comparison between hospital and data aggregation. All analyses were conducted using Microsoft® Office Excel® 2007 with confidence intervals calculated using OpenEpi, Version 2.

6 Appendix: NQF Survey Cover Letter

See attached PDF.

7 Appendix: Survey Tool

Background Information

1. Please provide the following details for the primary contact person and your hospital

Name of primary contact for completion of this survey _____

Title / position of primary contact _____

Phone number of primary contact _____

Fax number of primary contact _____

Email address of primary contact _____

Name of Hospital _____

Address of Hospital _____

City of Hospital _____

Zip-Code of Hospital _____

County Hospital Located In _____

2. Do you have the capability to assess the number of neonates who receive hepatitis B vaccine prior to discharge?

☐ Yes (Please continue to question 3) ☐ No (go to question 4)

3. How many neonates born in your facility in calendar year 2008 received hepatitis B vaccine prior discharge?

☐ Enter number here _____ ☐ Unable to determine the number (go to question 3a)

Select the source of this data (check all that apply):

☐ Medication Administration Record ☐ Claims Data ☐ Pharmacy Record

☐ Vaccine Consent Statement ☐ Clinical Database ☐ Nurses Notes

☐ Other Data or Record Source (please describe)

_____

Select method of retrieving this information (check all that apply and go to question 5)

☐ Digital EMR (HIMS) ☐ PDF / Scanned EMR ☐ Paper-Based Records

3a. How many neonates born in your facility, for any 12-month period, received hepatitis B vaccine prior discharge? (If you answered Question 3 proceed to Question 5)

☐ Enter number vaccinated here _____ ☐ Unable to determine the number (go to question 3b)

Define the 12-month period here _____

Define the number of live births during this time period _____

Select the source of this data (check all that apply):

☐ Medication Administration Record ☐ Claims Data ☐ Pharmacy Record

☐ Vaccine Consent Statement ☐ Clinical Database ☐ Nurses Notes

☐ Other Data or Record Source (please describe)

_____

Select method of retrieving this information (check all that apply and go to question 4)

☐ Digital EMR (HIMS) ☐ PDF / Scanned EMR ☐ Paper-Based Records

3b. How many neonates were born in your facility, for any other specified period of time, received hepatitis B vaccine prior to discharge? (If you answered Question 3 or 3a proceed to Question 4 or 5 as directed in that question)

☐ Enter number vaccinated here _____ ☐ Unable to determine the number (go to question 4)

Define the time period here _____

Define the number of live births during this time period _____

Select the source of this data (check all that apply):

☐ Medication Administration Record ☐ Claims Data ☐ Pharmacy Record

☐ Vaccine Consent Statement ☐ Clinical Database ☐ Nurses Notes

☐ Other Data or Record Source (please describe)

_____

Select method of retrieving this information (check all that apply and go to question 4)

☐ Digital EMR (HIMS) ☐ PDF / Scanned EMR ☐ Paper-Based Records

4. If you are unable to provide information on the number of neonates vaccinated before discharge from your facility, why not (please answer for each time frame in which you are not able to provide this information)?

	Time burden for reviewing records is too great	**Immunization data not part of accessible medical record**	**Records off site**	**Cannot query for immunization data**	**Other (please describe below)**
For the CY 2008	☐	☐	☐	☐	_____
For an alternate 12-month period	☐	☐	☐	☐	_____
For a period other than 12 months	☐	☐	☐	☐	_____

5. What other data sources did you consider to determine the number of neonates who received the hepatitis B vaccine prior to discharge?

☐ **None**

☐ **Other (indicate data sources):** _____

☐ Unable to determine vaccination number for any defined time period

6. How many hours did it take to determine the number of neonates who received the hepatitis B vaccine prior to discharge, once you decided on the source of data and method?

☐ Number of hours _____

☐ Unable to determine vaccination number for any defined time period

7. Do you have the capability to assess the number of neonates who do not receive vaccination prior to hospital discharge due to parent or guardian refusal?

☐ Yes (Please continue to question 8) ☐ No (go to question 9)

8. How many neonates born in your facility, in calendar year 2008, did not receive the hepatitis B vaccine prior discharge due to parent or guardian refusal?

☐ Enter number refused here _____ ☐ Unable to determine the number refused for this time period (go to question 8a)

Select the source of this data (check all that apply):

☐ Medication Administration Record ☐ Claims Data ☐ Pharmacy Record

☐ Vaccine Consent Statement ☐ Clinical Database ☐ Nurses Notes

☐ Other Data or Record Source (please describe)

_____

Select method of retrieving this information (check all that apply and go to question 10)

☐ Digital EMR (HIMS) ☐ PDF / Scanned EMR ☐ Paper-Based Records

8a. How many neonates born in your facility, for any 12-month period, did not receive the hepatitis B vaccine prior discharge due to parent or guardian refusal? (If you answered Question 8 proceed to Question 10)

☐ Enter number refused here _____ ☐ Unable to determine the number refused for this time period (go to question 8b)

Define the 12-month period here _____

Define the number of births during this time period _____

Select the source of this data (check all that apply):

☐ Medication Administration Record ☐ Claims Data ☐ Pharmacy Record

☐ Vaccine Consent Statement ☐ Clinical Database ☐ Nurses Notes

☐ Other Data or Record Source (please describe)

_____

Select method of retrieving this information (check all that apply and go to question 9)

☐ Digital EMR (HIMS) ☐ PDF / Scanned EMR ☐ Paper-Based Records

8b. How many neonates born in your facility for any other specified period of time did not receive the hepatitis B vaccine prior discharge due to parent or guardian refusal? (If you answered Question 8 or

8a proceed to Question 9 or 10 as directed in that question)

☐ Enter number refused here _____ ☐ Unable to determine the number refused for any time period (go to question 9)

Define the time period here _____

Define the number of births during this time period _____

Select the source of this data (check all that apply and go to question 4):

☐ Medication Administration Record ☐ Claims Data ☐ Pharmacy Record

☐ Vaccine Consent Statement ☐ Clinical Database ☐ Nurses Notes

☐ Other Data or Record Source (please describe)

_____

Select method of retrieving this information (check all that apply and go to question 9)

☐ Digital EMR (HIMS) ☐ PDF / Scanned EMR ☐ Paper-Based Records

9. If you are unable to provide information on the number of neonates who are not vaccinated before discharge from your facility due to parent or guardian refusal, why not (please answer for each time frame in which you are not able to provide this information)?

	Records are not accessible	**Do not track consent refusals in paper record**	**Do not track consent refusals in EMR**	**No standardized data field in the EMR**	**Other (please describe below)**
For the CY 2008	☐	☐	☐	☐	_____
For a 12-month period	☐	☐	☐	☐	_____
For another period	☐	☐	☐	☐	_____

10. Can you provide an estimated cost, either direct (actual cost of record retrieval, if any) and/or indirect (cost for resource hours used to retrieve records) associated with determining the number of neonates who received the hepatitis B vaccine prior to discharge?

	Direct Cost	Indirect Cost	Unable to Determine

☐ Vaccination with hepatitis B prior to discharge	$ _____	$ _____	☐
☐ No vaccination due to parent or guardian refusal	$ _____	$ _____	☐

11. Are there any anticipated or planned changes in the next 3 years regarding health information management at your facility that would allow you to provide or make it easier to provide the following information?

The number of neonates born at your facility who receive the hepatitis B vaccine before discharge	☐ Yes	☐ No
The number of consent refusals by parents or guardians who do not allow their newborn to vaccinated for hepatitis B	☐ Yes	☐ No

If either above checked “Yes”, please briefly describe anticipated change(s):

_____

8 Appendix: DSHS Health Service Regions Map

Figure 8.1: Map of Texas Department of State Health services health service region boundaries