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 #: 0479 NQF Project: Perinatal and Reproductive Health Project
(for Endorsement Maintenance Review) Original Endorsement Date: Oct 24, 2008 Most Recent Endorsement Date: Oct 24, 2008
BRIEF MEASURE INFORMATION
De.1 Measure Title: Birth dose of hepatitis B vaccine and hepatitis B immune globulin for newborns of hepatitis B surface antigen (HBsAg) positive mothers
Co.1.1 Measure Steward: California Department of Public Health
De.2 Brief Description of Measure: Percentage of infants born to hepatitis B surface antigen (HBsAg)-positive mothers who receive a birth dose of hepatitis B virus (HBV) vaccine and hepatitis B immune globulin (HBIG)
2a1.1 Numerator Statement: Number of infants born to HBsAg positive mothers who receive a birth dose of HBV vaccine and HBIG upon delivery
2a1.4 Denominator Statement: Number of infants born to mothers who tested positive for HBsAg during prenatal screening or upon admission to the hospital for delivery
2a1.8 Denominator Exclusions: Pregnancies of HBsAg positive mothers which result in any one of the following: stillbirths, voluntary abortions, miscarriages
1.1 Measure Type: Process 2a1. 25-26 Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Pharmacy, Electronic Clinical Data : Registry, Paper Records 2a1.33 Level of Analysis: Facility 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)*: Cancer : Liver, Infectious Diseases : Hepatitis, Perinatal, Prevention, Prevention : Immunization
De.5 Cross Cutting Areas (*Check all the areas that apply)*: Disparities, Population Health

1a.1 Demonstrated High Impact Aspect of Healthcare: Severity of illness

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

1a.3 Summary of Evidence of High Impact *(Provide epidemiologic or resource use data)*:
Because viral hepatitis is a hidden epidemic with significant public health consequences, the Department of Health and Human Services released "Combating the Silent Epidemic of Viral Hepatitis," an action plan for the prevention, care and treatment of viral hepatitis in May 2011. Among the goals of this action plan is to eliminate perinatal transmission of hepatitis B which is possible when infants born to HBsAg positive mother are not appropriately prophylaxed as defined by the administration of HBV vaccine and HBIG within 12 hours of birth.

1a.4 Citations for Evidence of High Impact cited in 1a.3: The DHHS report can be found at the following URL: http://www.hhs.gov/ash/initiatives/hepatitis/actionplan_viralhepatitis2011.pdf

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:
This measure ensures that all infants born to hepatitis B surface antigen positive women will receive a birth dose of the hepatitis B vaccine and the hepatitis B immune globulin as recommended by the Advisory Committee on Immunization Practices. Administration of these prophylaxis within 12 hours of birth is effective against hepatitis B transmission and infection.

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.*]
The California Department of Public Health (CDPH) Perinatal Hepatitis B Prevention Program officially reported to the Centers for Disease Control (CDC) that in 2009, 2138 infants were born to HBsAg positive mothers. Out of 2138 infants, 2077 (97.1%) received the first dose of the hepatitis B vaccine and the hepatitis B immune globulin within 24 hours of birth. (Note, although this is not a 12 hour time frame as stated in the measure, this data is from the official report CDPH has sent to the CDC and is thus preferred to include in this measure compared to an unofficial data measure.) Although a high percentage, there is still room for improvement to prevent perinatal hepatitis B at birth as well as to identify HBsAg positive women who are pregnant.

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*]
Data collected by the California Department of Public Health Perinatal Hepatitis B Prevention Program

1b.4 Summary of Data on Disparities by Population Group: [*For Maintenance –Descriptive statistics for performance results for this measure by population group*]
Although there is population disparities for hepatitis B infection, this specific measure does not vary by population group.

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*]
N/A. This measure does not vary by population.

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)*:
Administering birth dose of the hepatitis B vaccine and HBIG to all newborns of HBsAg positive women is a highly effective method to prevent transmission of hepatitis B. The health outcome for this measure is prevention of hepatitis B transmission and infection from mother to infant (i.e., vertical transmission).

1c.2-3 Type of Evidence *(Check all that apply)*:
Clinical Practice Guideline, Selected individual studies (rather than entire body of evidence)

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)*:
There are no differences in the measure focus, measure target population, and evidence. This measure is based on clinical guidelines and studies that indicate evidence of preventing vertical transmission of hepatitis B.

1c.5 Quantity of Studies in the Body of Evidence *(Total number of studies, not articles)*: There are numerous articles that indicate how administering prophylaxis of HBV vaccine and HBIG to infants born to HBsAg-positive women prevents HBV transmission from mother to infant (i.e., vertical transmission).

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*): Published studies have been of varying study designs and have focused on various population groups. Studies have ranged from retrospective medical record reviews to prospective studies that monitor the sero-conversions of infants after prophylaxis. Moreover, various states and countries have performed studies regarding the effectiveness of this measure or even the rate of this measure.

1c.7 Consistency of Results across Studies *(Summarize the consistency of the magnitude and direction of the effect):* Published studies have been of varying study designs and have focused on various population groups. However, the study conclusions have been consistent in the message that prophylaxis (i.e., HBV vaccine and HBIG) of infants upon birth will prevent hepatitis B transmission from the infected mother to the infant.

1c.8 Net Benefit *(Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms)*:
The administrations of HBIG and HBV vaccine at birth are safe. Therefore, the net benefit is the prevention of hepatitis B transmission from mother to infant.

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

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

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

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

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

1c.14 Summary of Controversy/Contradictory Evidence: No areas of controversy

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

1c.16 Quote verbatim, the specific guideline recommendation *(Including guideline # and/or page #)*:
"Administration of a birth dose of hepatitis B vaccine is required for effective postexposure immunoprophylaxis to prevent perinatal HBV infection. Although infants who require postexposure immunoprophylaxis should be identified by maternal HBsAg testing, administering a birth dose to infants even without HBIG serves as a ´safety net´ to prevent perinatal infection among infants born to HBsAg-positive mothers who are not identified because of errors in maternal HBsAg testing or failures in reporting of test results. The birth dose also provides early protection to infants at risk for infection after the perinatal period. Administration of a birth dose has been associated with higher rates of on-time completion of the hepatitis B vaccine series" (p.8). "Both passive-active postexposure prophylaxis (PEP) with HBIG and hepatitis B vaccine and active PEP with hepatitis B vaccine alone have been demonstrated to be highly effective at preventing transmission after exposure to HBV. HBIG alone has also been demonstrated to be effective in preventing HBV transmission, but with the availability of hepatitis B vaccine, HBIG typically is used as an adjunct to vaccination. The major determinant of the effectiveness of PEP is early administration of the initial dose of vaccine. The effectiveness of PEP diminishes the longer it is initiated after exposure" (p.10). "PEP with hepatitis B vaccine and HBIG administered 12-24 hours after birth, followed by completion of a 3-dose vaccine series, has been demonstrated to be 85-95% effective in preventing acute and chronic HBV infection in infants born to women who are positive for both HBsAg and HBeAg...Infants born to HBsAg-positive/HBeAg-negative mothers who receive passive-active PEP with HBIG and hepatitis B vaccine should have the same high degree of preotection as infants born to women who are HBsAg-positive/HBeAg-positive" (p.11).

1c.17 Clinical Practice Guideline Citation: Reference: Centers for Disease Control and Prevention (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 I: immunization of infants, children, and adolescents. MMWR 2005;54(No. RR-16):1-32.

1c.18 National Guideline Clearinghouse or other URL: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5416a1.htm

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

1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: 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: The Advisory Committee on Immunization Practices (ACIP) consists of 15 experts in fields associated with immunization who have been selected by the Secretary of the US Department of Health and

Human Services to provide advice and guidance to the Secretary, the Assistant Secretary for Health, and the Centers for Disease Control and Prevention (CDC) on the control of vaccine-preventable diseases. The ACIP is the only entity in the federal government that develops written recommendations for the routine administration of vaccines to children and adults in the civilian population. The overall goals of the ACIP are to provide advice that will lead to a reduction in the incidence of vaccine-preventable diseases in the US, and an increase in the safe use of vaccines and related biological products. The ACIP has reviewed all of the available scientific, clinical, and policy-based evidence in the area of testing and immunization against HBV, and has made its recommendation in accordance with the balance of this collective evidence. The ACIP does not make unsupported or precipitous recommendations. Therefore, this guideline is strongly supported by ample evidence and is designed to benefit the overall public health of the entire US population.

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: High1c.27 Consistency: High

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

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

2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

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

S.1 Measure Web Page *(In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained*). Do you have a web page where current detailed specifications for this measure can be obtained? No

S.2 If yes, provide web page URL:

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

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

2a1.1 Numerator Statement *(Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome)*:
Number of infants born to HBsAg positive mothers who receive a birth dose of HBV vaccine and HBIG upon delivery

2a1.2 Numerator Time Window *(The time period in which the target process, condition, event, or outcome is eligible for inclusion)*:
Within 12 hours of birth

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*:
HBsAg = hepatitis B surface antigen, HBV = hepatitis B virus, HBIG = hepatitis B immune globulin, Numerator includes infants (live births) born to a woman who was confirmed to be hepatitis B surface antigen positive from blood specimen results during prenatal screening or upon admission to the hospital for delivery

2a1.4 Denominator Statement *(Brief, narrative description of the target population being measured)*:
Number of infants born to mothers who tested positive for HBsAg during prenatal screening or upon admission to the hospital for delivery

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)*:
No denominator time window. All infants born to HBsAg positive mothers are eligible for inclusion.

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)*:
HBsAg = hepatitis B surface antigen, Denominator includes infants (live births) born to a woman who was confirmed to be hepatitis B surface antigen positive from blood specimen results during prenatal screening or upon admission to the hospital for delivery

2a1.8 Denominator Exclusions *(Brief narrative description of exclusions from the target population)*:
Pregnancies of HBsAg positive mothers which result in any one of the following: stillbirths, voluntary abortions, miscarriages

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)*:
HBsAg = hepatitis B surface antigen

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)*:
Given a large enough population, this measure does not require stratification for calculation. Stratification is only applicable when calculating estimates for specific populations. At minimum, the facility where HBIG and HBV vaccine was administered to the infant would be a variable for stratification. ´Facility´ is an appropriate stratification variable due to the policies specific to the facility (e.g., birth hospital) which would have specific policies and/or standing orders to the administration of the HBIG and HBV vaccine.

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.)*:

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.)*:
Identify total HBsAg positive pregnant women at during prenatal screening or upon admission to the hospital for delivery whose pregnancy resulted in a live birth (Denominator). Exclude pregnancies that resulted in stillbirths, voluntary abortions, and miscarriages. Identify number of live births to HBsAg positive pregnant women who have received the HBV vaccine and HBIG (Numerator). Divide this number by the total HBsAg positive women who delivered a live birth.

2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:
Attachment
Calculation Algorithm Measure Logic Diagram for Measure 0479.pptx

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

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

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.*): Pregnancy and HBsAg status of woman is obtained from medical records and/or laboratory reports. Administration of HBV vaccine birth dose and HBIG is obtained from medical records, pharmacy data, and/or medication administration records.

2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment: URL
http://www.cdph.ca.gov/programs/immunize/Documents/PHPPCOORDINATORHANDBOOK22309.pdf

2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment:
URL
http://www.cdph.ca.gov/programs/immunize/Documents/PHPPCOORDINATORHANDBOOK22309.pdf

2a1.33 Level of Analysis (*Check the levels of analysis for which the measure is specified and tested)*: Facility

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

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

2a2.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
The data sample constitutes the approximate past twenty years of the California Department of Public Health Perinatal Hepatitis B Program which has consistently been managing the reporting of HBsAg positive pregnant women and their respective infants.

2a2.2 Analytic Method *(Describe method of reliability testing & rationale)*:
Testing for hepatitis B surface antigen (HBsAg) is reliable due to its high specificity and sensitivity. HBsAg testing is actually the gold standard in determining whether the woman is infected with hepatitis B. Therefore, measures and guidelines for prevention of hepatitis B vertical transmission utilize HBsAg as the factor for implementing preventive efforts to the exposed infant. Moreover, HBsAg testing is always confirmed before being reported thus ensuring reliability of the test results itself. Moreover, a copy of the laboratory report is recommended to be included in the report to the hospital, clinician, and/or local/state perinatal hepatitis B program thus ensuring reliability of the actual report of an infected pregnant woman. Additionally, because hepatitis B vaccine and immune globulin are considered medication, administration is recorded in the hospital/clinic medical record notes, summaries, forms, and/or medication administration record. Thus, this ensures reliability for the infant being prophylaxed.

2a2.3 Testing Results *(Reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
Per perinatal guidelines, every woman who is pregnant is tested for hepatitis B surface antigen as part of the prenatal care panel. This amounts to a minimum of 500,000 women annually tested in California. At least 3,000 HBsAg positive pregnant women and their respective infants are reported to the local perinatal hepatitis B programs.

2b. VALIDITY. Validity, Testing, <u>including all Threats to Validity</u>: 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:
Increase in the measure will result in the measure focus. There are no differences from the evidence. Increasing the percentage of prophylaxed infants will increase the prevention of vertical hepatitis B transmission.

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)*:
In 2008, the California Department of Public Health Perinatal Hepatitis B undertook a study to determine the rate of hepatitis B infection in pregnant women who gave birth in 2006 and the prophylaxis rate of their respective infants. Thirty-five hospitals were randomly selected which reported at least one birth in 2006. Within each hospital, at least 10% of the 2006 birth cohort of each hospital were randomly selected. The maternal and infant delivery charts were reviewed. Only live births were included. This resulted in 1688 mothers reviewed for HBsAg status and 1699 infants reviewed for administration of HBIG and/or hepatitis B vaccine.

2b2.2 Analytic Method *(Describe method of validity testing and rationale; if face validity, describe systematic assessment)*:
For each mother, the hepatitis B surface antigen status was reviewed in the medical records (e.g., history and physical summary), perinatal records, and/or any laboratory report included in the delivery charts. For each infant, the prophylaxis of HBV vaccine and/or HBIG was reviewed in the medical record notes and medication administration 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)*:
Out of 121 mothers determined to be HBsAg positive at the time of their 2006 pregnancy, 114 (95.7%) received prophylaxis within 12 hours of birth. If compared to the report submitted to the Centers for Disease Control and Prevention (CDC) which utilized a time period of prophylaxis within 1 calendar day of birth, 118 (97.5%) infants of the HBsAg-positive mothers received prophylaxis. This is comparable to the 98.7% of all infants born in 2009 to HBsAg positive mothers that was officially reported to the CDC. Additionally, only approximately 25% of the HBsAg positive mothers and all of the mothers had a laboratory report included in the delivery chart that indicated confirmation of HBsAg testing results; per the recommendation of ACIP.

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

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

2b3.1 Data/Sample for analysis of exclusions *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
N/A

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

2b3.3 Results *(Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses):*
Measure exclusions are limited to stillbirths. Vaccines and HBIG will not be administered in these cases.

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)*:
Measure not risk adjusted.

2b4.2 Analytic Method (*Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables)*:
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: This measure is not risk adjusted because according to recommended guidelines by the Advisory Committee on Immunization Practices and the Centers for Disease Control and Prevention, birth does of the hepatitis B vaccine and the hepatitis B immune globulin for newborns to hepatitis B surface antigen positive mothers should be the standard for care.

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)*:
There are no identified meaningful differences in performance as this is a recommended guidelines for clinical practice.

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)*:
N/A- multiple data sources not used.

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)*: This measure is not specifically stratified for disparities.

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

2.1-2.3 Supplemental Testing Methodology Information:

Steering Committee: Overall, was the criterion, *Scientific Acceptability of Measure Properties*, met?
(*Reliability and Validity must be rated moderate or high*) Yes☐ No☐

Provide rationale based on specific subcriteria:
If the Committee votes No, STOP

3. USABILITY

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

C.1 Intended Purpose/ Use *(Check all the purposes and/or uses for which the measure is intended)*: Public Health/Disease Surveillance, Public Reporting

3.1 Current Use *(Check all that apply; for any that are checked, provide the specific program information in the following questions)*: Public Reporting, Public Health/ Disease Surveillance

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.*]
The results in this measure are reported to the Centers for Disease Control and Prevention through the California Department of Public Health Perinatal Hepatitis B Prevention Program (PHPP). The results are used to ensure proper care of newborns to hepatitis B surface antigen positive mothers as well as CDC´s measure of how effective the PHPP.

Webpage: http://www.cdc.gov/hepatitis/Partners/PeriHepBCoord.htm

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: Birth is a crucial time for the prevention of chronic hepatitis B. This simple measure performance results show whether we are doing our part in the prevention process. Maximum prevention efforts, including this measure, will yield a high percentage of newborns to hepatitis B surface antigen positive mothers who receive a birth dose of hepatitis B virus vaccine and hepatitis B immune globulin. Because these 2 shots are so effective in prevention at birth, if this percentage was 100%, vertical transmission of hepatitis B could be eliminated.

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): N/A

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*].
N/A

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:
N/A

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

4. FEASIBILITY

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

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

4a.1-2 How are the data elements needed to compute measure scores generated? *(Check all that apply).*
Data used in the measure are:
generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition,
Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

4b. Electronic Sources: H☐ M☐ L☐ 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: Data for this measure is mainly collected from birth hospitals which have varying types of health information systems. Thus, some data for this measure may still be abstracted from paper.

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:
The susceptibility is minimal since we are looking for pregnancy status, hepatitis B surface antigen (HBsAg) status for mother, pregnancy outcome (i.e., live birth), and whether or not the newborn received the first dose of the hepatitis B vaccine and the hepatitis B immune globulin within 12 hours of birth. These are all items regularly and commonly documented in the medical records for the mother and infant.

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)*:
The data collection strategy is straightforward and easy to implement. Pregnancy status of mother, pregnancy outcome, hepatitis B surface antigen status of mother and receipt of hepatitis B vaccine and hepatitis B immune globulin for newborn at birth are all points of data that exist in medical records and are easily extracted or collected.

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): California Department of Public Health, Immunization Branch, 850 Marina Bay Parkway, Building P, 2nd floor, Richmond, California, 94804

Co.2 Point of Contact: Catheryn, Salibay, MPH, Catheryn.Salibay@cdph.ca.gov, 510-620-3846-

Co.3 Measure Developer if different from Measure Steward: Asian Liver Center at Stanford University, 490 S. California Avenue, Suite 300, Palo Alto, California, 94306-1988

Co.4 Point of Contact: Samuel, So, samso@stanford.edu, 650-566-8818-

Co.5 Submitter: Chrissy, Cheung, ccheung1@stanford.edu, 650-566-8818-, Asian Liver Center at Stanford University

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

Co.7 Public Contact: Samuel, So, samso@stanford.edu, 650-566-8818-, Asian Liver Center at Stanford University

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.

No work group or panel used

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

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.3 Year the measure was first released: 2008

Ad.4 Month and Year of most recent revision: 11, 2010

Ad.5 What is your frequency for review/update of this measure?

Ad.6 When is the next scheduled review/update for this measure? 11, 2012

Ad.7 Copyright statement:

Ad.8 Disclaimers:

Ad.9 Additional Information/Comments:
Date of Submission (*MM/DD/YY*): 10/17/2011