Gaps in Hospital Policies and Practices to Prevent Perinatal Transmission of Hepatitis B Virus

WHAT’S KNOWN ON THIS SUBJECT: In the United States, an estimated 1.4 million people have chronic HBV infection, causing 2000 to 4000 deaths annually. Newborn HepB administration is a key intervention to prevent perinatal HBV transmission and morbidity and mortality caused by chronic HBV infection.

WHAT THIS STUDY ADDS: This study examined how well national recommendations for perinatal HBV prevention advocated by the CDC and the ACIP are implemented by hospitals. It also reveals considerable gaps in hospital policies and practices that need to be addressed.

abstract

OBJECTIVE: The objective of this study was to examine hospital policies and practices to prevent perinatal transmission of hepatitis B virus (HBV) in the United States and to and identify gaps.

METHODS: In March 2006, a nationally representative sample of 242 delivery hospitals in the 50 states, District of Columbia, and Puerto Rico (with at least 100 annual births) were surveyed about hospital perinatal hepatitis B prevention policies and asked to review paired maternal–infant medical records for 25 consecutive live births. Main outcome measures were hospital policies related to the prevention of perinatal transmission of hepatitis B and the proportion of infants who received recommended care.

RESULTS: A total of 190 of 242 hospitals responded to the survey and completed medical record reviews for 4762 mothers and 4786 infants. The proportion of hospitals that reported each of the 6 policies examined ranged from 63.0% to 80.6%. Among infants who were born to the 18 hepatitis B surface antigen (HBsAg)-positive women with documented prenatal test results, 62.1% received both hepatitis B vaccine and hepatitis B immunoglobulin within 12 hours, but 13.7% were unvaccinated and 19.7% did not receive hepatitis B immunoglobulin before hospital discharge. Among infants who were born to the 320 Women with unknown HBsAg status, only 52.4% were vaccinated within 12 hours of birth and 20.1% were unvaccinated before discharge. Among infants who were born to HBsAg-negative mothers, 69.1% received the hepatitis B vaccine before hospital discharge. The strongest predictor of vaccine administration was having a written hospital policy for newborn hepatitis B vaccination.

CONCLUSIONS: These findings indicate that significant gaps persist in hospital policies and practices to prevent perinatal HBV transmission in the United States. Efforts to avoid medical errors through appropriate implementation and monitoring of hospital practices are needed to eliminate perinatal HBV transmission. Pediatrics 2010;125:704–711

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ABBREVIATIONS
HBV—hepatitis B virus
CDC—Centers for Disease Control and Prevention
HBsAg—hepatitis B surface antigen
PEP—postexposure prophylaxis
HepB—hepatitis B vaccine
HBIG—hepatitis B immunoglobulin
ACIP—Advisory Committee on Immunization Practices
AHA—American Hospital Association
CI—confidence interval
NIS—National Immunization Survey

All authors are responsible for the reported research. All authors participated in the concept and design, analysis and interpretation of data, and drafting or revising of the manuscript and have approved the manuscript as submitted.

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The findings and conclusions in this article are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

The assessment protocol was reviewed by the CDC National Center for Immunization and Respiratory Diseases Human Subjects Contact and determined to be a nonresearch assessment of public health practice.

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In the United States, an estimated 1.4 million people have chronic hepatitis B virus (HBV) infection, which is the underlying cause of 2000 to 4000 deaths annually.1 Two primary modes of HBV transmission occur during infancy: infected mother to newborn during delivery and infected household contact to infant. In contrast to adults with an ~5% risk for chronic HBV infection once infected, infants have an ~90% risk for developing chronic HBV infection and when chronically infected have a 25% risk for dying prematurely of cirrhosis or liver cancer. An estimated 24 000 HBV-infected US women give birth annually (Centers for Disease Control and Prevention [CDC], unpublished data, 2004). Prenatal screening of all pregnant women is recommended to identify hepatitis B surface antigen (HBsAg)-positive women before giving birth to ensure that their newborns can receive post-exposure prophylaxis (PEP).2 PEP includes the administration of hepatitis B vaccine (HepB) and hepatitis B immunoglobulin (HBIG) to newborns within 24 hours of birth and is 85% to 95% effective in preventing HBV transmission; HepB administration alone within the same time frame is 70% to 95% effective.3,4 Hepatitis B vaccination of newborns also provides preexposure protection to infants born to uninfected women when, if HBV exposure were to occur, the risk for developing chronic HBV infection is greatest. Newborn HepB administration is a key intervention to prevent perinatal HBV transmission and the subsequent morbidity and mortality that are caused by chronic HBV infection.5

Despite the availability of PEP, infants continue to become infected. Approximately 40 to 90 perinatal HBV infections are reported to the CDC annually,6 although the true number of annual perinatal HBV infections may be 10 to 20 times higher.7 Perinatal HBV infections may occur as a result of various health care errors, including prenatal testing and reporting, failure to test all women who are admitted to delivery hospitals without prenatal HBsAg test results, lapses in reporting and documentation of HBsAg test results in maternal and newborn medical records,3 and failure to administer timely PEP.

The delivery hospital is the critical point for implementing perinatal HBV prevention activities; it is the safety net for ensuring that HBV-infected women are identified at delivery and it is where time-sensitive PEP must be delivered to the newborn. Delivery hospitals also play an important role in reporting HBsAg-positive women to health departments to ensure that infants complete the HepB series, undergo postvaccination serologic testing, and, if infected, are referred for evaluation and care. In December 2005, the Advisory Committee on Immunization Practices (ACIP) published recommendations to address the remaining challenges in prevention of perinatal transmission of HBV.4 To assess hospital policies and practices pertaining to perinatal HBV prevention, we conducted a nationally representative assessment that included a survey of hospital policies and medical record reviews.

METHODS

Sample Selection

The target population included all delivery hospitals in the 50 states, District of Columbia, and Puerto Rico as identified in the 2003 American Hospital Association (AHA) annual survey. Fifty-two percent of all hospitals (n = 3102) were eligible for selection based on number of births (>100 annually), accounting for 99.5% of births reported by hospitals in the AHA survey. With simple random sampling, a sample size of 200 hospitals was needed to estimate the proportion of hospitals reporting a given policy with a 95% confidence interval (CI) ± 7 percentage points. We allocated the sample size across 51 strata (50 states plus 1 stratum containing Washington, DC, and Puerto Rico) proportional to the number of hospitals in each stratum. When the number of hospitals allocated to a given stratum was <2, the selection of 2 was forced to calculate variance estimation on the basis of the sample design. We sampled 254 hospitals to allow for an ~80% response rate. Hospitals were contacted to verify provision of delivery services and to identify a contact person for survey receipt. Twelve hospitals did not provide delivery services, leaving a final sample of 242.

Hospital Policy Survey

The hospital policy survey was sent in March 2006 to nursing supervisors or clinical nurse managers of the selected hospital nurseries. The survey ascertained whether written policies regarding the following aspects of perinatal HBV prevention existed: review of maternal HBsAg test results during admission to labor and delivery units, testing on admission for women without documented prenatal HBsAg test results, management of infants who were born to women of HBsAg-positive and unknown status, and HepB administration to all newborns before discharge. Additional characteristics such as geographic location (ie, rural or urban [outside or within a metropolitan statistical area]), hospital affiliation type (medical school/residency training programs) and hospital funding type (for profit/not for profit) were obtained from the AHA survey.

Medical Record Review

Each sampled hospital was asked to review paired maternal and infant medical records for 25 consecutive...
live births between October 2005 and March 2006. Maternal medical record data collected included demographics (age, race/ethnicity, health insurance type), attending provider type, documentation of results of HBsAg testing during pregnancy and on admission, and admission time/date. Data collected from the infant medical record included time/date of birth, birth weight, administration time/date of infant HepB and HBIG, and documentation of maternal HBsAg test result.

Data Collection
Hospital survey and medical record data were collected by the designated hospital contact, state or local health department staff, or, in the majority of cases, a combination of both. The majority of participating health department staff provided assistance by conducting follow-up telephone calls to ensure survey receipt and completion.

Data Analysis
We conducted the following descriptive analyses: (1) prevalence of policies regarding prevention of perinatal HBV transmission; (2) factors that were associated with prenatal testing; (3) prevalence of maternal HBV infection; (4) HepB and HBIG receipt within 12 hours of delivery for infants who were born to women with HBsAg-positive or unknown status, according to ACIP recommendations; and (5) maternal and facility characteristics associated with HepB receipt at birth. We also compared maternal HBsAg test results that were documented in the maternal medical record from prenatal and on-admission testing, as well as maternal results that were documented in the infant’s medical record.

Among mother–infant pairs with any mention of a positive maternal HBsAg test result, we defined 2 subsets. First, for estimation of the national prevalence of HBV infection, pregnant women were considered infected when they had documentation of a positive HBsAg test result prenatally or on admission and when there were no contradictory results in any records (eg, women who were HBsAg-positive prenatally but HBsAg-negative according to infant medical record were excluded). Second, for assessment of management of infants of HBsAg-positive mothers who were identified prenatally, data on all infants whose mothers had a documented HBsAg-positive prenatal test result were included.

Hospital survey data were weighted according to inverse probability of hospital selection and adjusted for nonresponse. For data analysis of mother–infant pairs, hospitals were identified as primary sampling units (95% CI: 90.4–94.3) of maternal medical record and variation little by demographic characteristic. HBsAg test results were documented by copy of the laboratory report in 12.8% (95% CI: 9.6–16.9) of maternal medical records reviewed; documentation in the re-

<table>
<thead>
<tr>
<th>TABLE 1 Prevalence of Hospital Policies That Pertain to Prevention of Perinatal Hepatitis B Transmission (n = 190)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy</td>
</tr>
<tr>
<td>Review prenatal HBsAg test on admission</td>
</tr>
<tr>
<td>Test pregnant women on admission if no documented HBsAg test result</td>
</tr>
<tr>
<td>Give HBIG to exposed infants within 12 h</td>
</tr>
<tr>
<td>Give hepatitis B vaccine to exposed infants within 12 h</td>
</tr>
<tr>
<td>Give HepB to infants of mothers of unknown status within 12 h</td>
</tr>
<tr>
<td>Universal hepatitis B vaccination of newborns before hospital discharge</td>
</tr>
</tbody>
</table>
mainly 79.8% of maternal records was through clinical notes. Of 318 women without a documented prenatal test result, 57.3% (95% CI: 46.9–67.1) were tested on admission; overall, 96.8% of women had documented HBsAg test results. Among women without prenatal test documentation, the proportion tested on admission varied widely across states, ranging from 0% to 100%, with a median of 25%.

**Prevalence of Maternal HBV Infection**

Twenty-one women had documentation of a positive HBsAg prenatal test (n = 18) or tested positive on admission (n = 3) for an overall weighted prevalence of 0.9% (95% CI: 0.5–1.8). This prevalence estimate is based on test results for 96.8% of the sample; 174 women had neither documentation of a prenatal HBsAg test result nor a test on admission.

**Management of Infants Who Were Born to Women With HBsAg-Positive and HBsAg-Unknown Status**

Of the 18 infants who were born to HBsAg-positive women with a documented positive HBsAg prenatal test, 13 (67.1% [95% CI: 35.3–88.4]) received HepB within 12 hours of birth and 11 (62.1% [95% CI: 31.8–85.2]) received both HBIG and HepB within 12 hours. Two infants (13.7% [95% CI: 0.4–51.1]) did not receive HepB, and 5 infants (19.7% [95% CI: 5.3–51.8]) did not receive HBIG before discharge.

Among 320 infants who were born to women without documented prenatal HBsAg test results, 150 (52.4% [95% CI: 38.5–64.9]) were vaccinated within 12 hours of birth and 67 (20.1% [95% CI: 11.0–33.8]) were not vaccinated before discharge. Only 4 (1.9% [95% CI: 0.4–8.5]) of 41 infants who weighed <2000 g and were born to women of unknown HBsAg status received HBIG (Table 3).

**Documentation of Maternal HBsAg Status and Discrepant Test Results**

Table 4 provides data for 27 women with a documented HBsAg positive test result from any source. In 15 cases, the maternal test results in the infant medical record were discrepant or missing.

**Universal Newborn HepB Vaccination**

Overall, 68.7% (95% CI: 59.4–76.6) of infants received HepB at birth. Most strongly associated with vaccine administration was having a written hospital policy for HepB administration at birth and hospital location in a state with a universal birth dose policy. Other significant factors included maternal insurance carrier (Medicaid), hospital affiliated with a medical residency program, and rural location (Table 5).

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**TABLE 2** Demographic Characteristics of Mothers Sampled and Proportion Screened During Pregnancy by Demographic Characteristic

<table>
<thead>
<tr>
<th>Maternal Characteristic</th>
<th>Sample</th>
<th>Documented Prenatal HBsAg Test Result</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Wt % (95% CI)</td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>2893</td>
<td>47.5 (41.2–53.9)</td>
</tr>
<tr>
<td>Black</td>
<td>600</td>
<td>15.2 (12.1–19.0)</td>
</tr>
<tr>
<td>Asian</td>
<td>129</td>
<td>4.1 (2.8–6.0)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>657</td>
<td>24.5 (17.8–32.6)</td>
</tr>
<tr>
<td>Other/unknown</td>
<td>483</td>
<td>8.7 (6.1–12.2)</td>
</tr>
<tr>
<td>Insurance status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Private</td>
<td>2504</td>
<td>52.4 (46.5–58.3)</td>
</tr>
<tr>
<td>Medicaid</td>
<td>2055</td>
<td>37.2 (32.4–42.3)</td>
</tr>
<tr>
<td>Other/unknown</td>
<td>403</td>
<td>10.3 (7.0–15.0)</td>
</tr>
<tr>
<td>Maternal age at time of infant birth, y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;18</td>
<td>179</td>
<td>3.7 (2.8–4.8)</td>
</tr>
<tr>
<td>18–25</td>
<td>2101</td>
<td>37.2 (34.3–40.5)</td>
</tr>
<tr>
<td>26–30</td>
<td>1243</td>
<td>27.2 (24.9–30.0)</td>
</tr>
<tr>
<td>&gt;30</td>
<td>1219</td>
<td>29.1 (26.2–33.5)</td>
</tr>
<tr>
<td>Hospital location</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rural</td>
<td>1816</td>
<td>10.4 (7.6–14.1)</td>
</tr>
<tr>
<td>Urban</td>
<td>2946</td>
<td>89.6 (85.9–92.4)</td>
</tr>
</tbody>
</table>

**TABLE 3** Management of Infants Who Were Born to HBsAg-Positive Mothers and Mothers With Unknown HBsAg Status

<table>
<thead>
<tr>
<th>Parameter</th>
<th>n</th>
<th>No Administration ≤12 h</th>
<th>Administration, Unknown Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (Wt %)</td>
<td>95% CI</td>
<td>n (Wt %)</td>
</tr>
<tr>
<td>HepB administration</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Born to HBsAg positive mothers</td>
<td>18</td>
<td>2 (13.7)</td>
<td>2.4–51.1</td>
</tr>
<tr>
<td>Mother unknown status</td>
<td>320</td>
<td>67 (20.1)</td>
<td>11.0–33.8</td>
</tr>
<tr>
<td>HBIG administration</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Born to HBsAg positive mothers</td>
<td>18</td>
<td>5 (19.7)</td>
<td>5.3–51.8</td>
</tr>
<tr>
<td>&lt;2000 g mother unknown status</td>
<td>41</td>
<td>37 (98.1)</td>
<td>91.5–99.8</td>
</tr>
</tbody>
</table>

a Infants whose mothers had a documented positive prenatal test, regardless of subsequent notations in the medical record (see Table 4).

b Infants who were born to mothers with no documentation of prenatal HBsAg test result.
TABLE 4 Documentation of Maternal HBsAg Status: Comparison of Prenatal Test Results, Results of Tests Performed on Admission to Labor and Delivery Unit, and Test Results as Documented in Infant’s Medical Record for 27 Mother–Infant Pairs With Any Mention of Positive Maternal HBsAg Test Results

<table>
<thead>
<tr>
<th>Prenatal HBsAg Test Result (Maternal Record)</th>
<th>HBsAg Test Result on Admission (Maternal Record)</th>
<th>Maternal HBsAg Status (Infant Record)</th>
<th>n</th>
<th>No. of Infants Who Received HepB</th>
<th>No. of Infants Who Received HBIG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive&lt;sup&gt;a,b&lt;/sup&gt; Not documented</td>
<td>Positive</td>
<td>Positive</td>
<td>12</td>
<td>10</td>
<td>2&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>Positive&lt;sup&gt;a,b&lt;/sup&gt; Not documented</td>
<td>Positive</td>
<td>Not documented</td>
<td>3</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Negative&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Positive</td>
<td>Not documented</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Negative</td>
<td>Positive</td>
<td>Negative</td>
<td>3</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Not documented</td>
<td>Positive</td>
<td>Not documented</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Positive&lt;sup&gt;a&lt;/sup&gt; Not documented</td>
<td>Negative</td>
<td>Positive</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Positive&lt;sup&gt;a&lt;/sup&gt; Not documented</td>
<td>Negative</td>
<td>Negative</td>
<td>2</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Not documented</td>
<td>Not documented</td>
<td>Positive</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

<sup>a</sup> Cases included in estimate of percentage of mothers infected.
<sup>b</sup> Cases included in Table 3, infants who were born to HBsAg-positive mothers.
<sup>c</sup> Includes 1 infant who received birth dose but for whom time of receipt was not documented.

DISCUSSION

We conducted a national survey of hospitals to determine policies for prevention of perinatal HBV transmission and conducted medical record reviews for almost 5000 mother–infant pairs. Our findings document gaps in prevention of perinatal HBV transmission that illustrate the importance of fully implementing the 2005 ACIP recommendations to prevent perinatal HBV transmission. Although prenatal HBsAg screening rates are high and consistent with past studies conducted in selected areas,<sup>10–12</sup> they could be improved among selected groups, including, black and Hispanic individuals and those who have Medicaid. Furthermore, substantial gaps exist for hospital policies aimed at preventing perinatal HBV transmission. In addition, gaps exist in hospital practices for testing women who are admitted with unknown status and managing infants who are born to mothers with an HBsAg-positive or unknown test result.

Policies that are specific to various aspects of prevention of perinatal HBV transmission were absent in up to one third of hospitals. Previous national data on policies examined in this survey are available only for screening of women who present with unknown status. Two studies conducted in 1993 estimated that 51% and 56% of hospitals had policies to perform HBsAg testing of women with unknown status, as compared with the 63% of hospitals in this survey.<sup>13,14</sup> Data from the medical record review showed that the presence of policies was not uniformly associated with the outcome targeted by the policy. Specifically, although administration of HepB to all newborns was significantly associated with having a hospital policy for newborn vaccination, no association was observed for administration of HepB to infants who were born to women of unknown HBsAg status, and a nonsignificant association was observed for testing pregnant women on admission without documentation of prenatal HBsAg test results. This lack of consistency reflects gaps in implemented policies and highlights the importance of monitoring clinical practices and assessing performance indicators through hospital-based quality assurance reviews.

With respect to screening practices, although screening prenatally has become the norm, this is not true for screening women who are admitted without documented prenatal HBsAg results. A small proportion of women are admitted without test results and are not tested on admission. Hospitals in 3 states had high testing rates for such women, including those in Texas, where testing of all women who present for delivery is mandated. Reasons for the high testing rates in the 2 other states are unclear.

Errors in the transcription of maternal HBsAg status have been well documented; as a result, the revised 2005 ACIP statement recommends that a copy of the original laboratory report indicating HBsAg status be included in both the maternal and infant medical records. Of the 27 mother–infant pairs in our sample with any documentation of a positive maternal HBsAg test result (Table 4), maternal results in the infant medical records were discrepant or missing for 15, demonstrating a medical documentation error rate of >50%. This is alarming, particularly when one considers that these errors were identified only among mother–infant pairs with any documentation of
a positive maternal HBsAg test result and thus may represent only more readily identified errors. It is possible that additional HBsAg documentation errors could be discovered among mother–infant pairs without any documentation of a positive HBsAg test result where positive test results were consistently documented as negative or omitted altogether; however, uncovering these types of errors is more labor-intensive. As expected, a minority (16%) of hospitals documented maternal HBsAg status by placing a copy of the original laboratory report in the medical record. Infants who were born to women with inconsistencies in documented HBsAg status were less likely to receive prophylaxis, which has been reported previously.10

The strongest predictor of newborn HepB receipt was having a written hospital policy for HepB administration at birth, highlighting the importance of such policies. Newborn HepB coverage was higher in this study (69%) than that reported in the 2007 National Immunization Survey (NIS) where 53.2% of newborns were vaccinated by the third day of life.16 Infants who were included in the 2007 NIS were born January 2004 through June 2006, and infants who were included in this study were born January 2005 through December 2006. A potential reason for the difference between these 2 estimates is that this study included data that were collected directly from infant hospital medical records, whereas in the NIS, vaccination coverage was obtained from outpatient pediatric provider medical records. The latter might not always have records of hospital-administered HepB. Random error and systematic biases in either survey may also contribute to the differences.

The estimated HBsAg-positive prevalence among pregnant women in this assessment was 0.9% (95% CI: 0.5–1.8) compared with 0.4% (95% CI: 0.2–0.8) in the 1993 study13; however, this difference is not statistically significant. Given differences in the proportion of mothers with known HBsAg status between the 2 assessments and discrepancies in HBsAg test result documentation discussed, ascertainment of true infection rate from a medical record review is challenging.

There is a growing need for implementation of perinatal HBV prevention practices by delivery hospitals given that the number of births to foreign-born women is increasing. In 2004, 24% of all US births were to foreign-born women compared with 18% in 1993.17 In addition, immigra-
tion from countries with high endemicity has increased.1,18

There are certain limitations to these findings. First, personnel who conducted data collection varied, with the majority of medical record abstractions conducted by health department staff and the remainder by hospital personnel. Second, although the overall response rate was high, 2 large states, California and Texas, had low hospital participation rates, which could affect the representativeness of the data. Third, this study was not designed to follow infants who were born to HBsAg-positive mothers to determine perinatal HBV infection rate.

CONCLUSIONS

Given the existence of highly effective PEP, perinatal HBV transmission can be almost entirely prevented, but gaps in the delivery hospital prevention policies and practices persist. Universal newborn HepB vaccination, together with timely administration of appropriate prophylaxis in delivery hospitals. Although use of National Quality Forum performance measures is a promising step toward closing the persistent hospital gaps for perinatal HBV prevention in the United States, considerable work remains.

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