

# Prevention of Perinatal Transmission of Hepatitis B Virus: Assessment Among Wisconsin Maternity Hospitals

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## ABSTRACT

**Purpose:** To evaluate the completeness of identification of pregnant women testing positive for hepatitis B surface antigen (HBsAg) and birth dose hepatitis B vaccine administration, and the extent of appropriate prophylaxis of infants born to women with and without maternal HBsAg status documented in the infant medical record.

**Methods:** We conducted medical record reviews of 3058 maternal and infant pairs at 58 Wisconsin maternity hospitals that cumulatively delivered 90% of Wisconsin's 2010 birth cohort.

**Results:** A documented HBsAg test result for the current pregnancy was included in 2928 (95.7%) of maternal records, and in 2676 (87.5%) infant records. Four infants (15%) were born to HBsAg-positive women; all 4 infants received appropriate prophylaxis: hepatitis B immunoglobulin (HBIG) and a dose of hepatitis B vaccine within 12 hours of birth. However, among 382 infants without a documented maternal HBsAg test result in the infant medical record, only 135 (35%) received appropriate prophylaxis: a dose of hepatitis B vaccine within 12 hours of birth or a dose of hepatitis B vaccine and HBIG within 12 hours of birth for infants weighing <2000 g. Among all infants, 81.6% received hepatitis B vaccine prior to hospital discharge.

**Conclusions:** Hospitals must ensure that infants without a documented maternal HBsAg test result receive appropriate prophylaxis to prevent hepatitis B vaccine infection. All infants, regardless of maternal HBsAg test result, should receive a dose of hepatitis B vaccine before hospital discharge to serve as a "safety net" to prevent infection among infants born to HBsAg-positive women who are not identified prenatally. A written hospital policy for universal hepatitis B vaccine birth dose administration should be developed to reinforce admission orders.

## INTRODUCTION

Hepatitis B virus (HBV) is a major cause of acute and chronic hepatitis, cirrhosis, and primary hepatocellular carcinoma. In the United States, an estimated 1.4 million people have chronic HBV

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infection, which is the underlying cause of 2000 to 4000 deaths annually.<sup>1</sup> Prevalence of HBV infection varies among subpopulations in Wisconsin, and is high among immigrants and refugees from highly endemic regions. In 2013, 46% (162/354) of Wisconsin residents with newly reported HBV infection were Asian or Pacific Islander. This subpopulation represents 5% of the US population and 2.3% of the Wisconsin population,<sup>2</sup> but more than 50% of US residents living with chronic HBV infections.<sup>1</sup>

One common mode of HBV transmission is from mother to infant during birth or infancy; 70% to 90% of infants born to women who test positive for hepatitis B surface antigen (HBsAg) will become infected with HBV if they do not receive timely prophylaxis with hepatitis B immunoglobulin (HBIG) and hepatitis B vaccine.<sup>3</sup> Among HBV-infected infants, approximately 90% will become chronically infected; about

25% of those chronically infected will die prematurely from cirrhosis or hepatocellular carcinoma.<sup>3</sup> Because perinatal infection and potential sequelae can be prevented through screening and identification of HBV-infected pregnant women and by provision of prophylaxis to infants born to these women, the Advisory Committee on Immunization Practices (ACIP) recommends universal screening of pregnant women for HBV infection and administration of a dose of hepatitis B vaccine to all newborns before hospital discharge (birth dose).<sup>4,5</sup>

Nationally, about 95% of pregnant women are tested for HBsAg. A positive result indicates HBV infection, and a high percentage of infants born to HBsAg-positive women complete postexposure prophylaxis. In 2013, local health departments in Wisconsin reported 161 births to HBsAg-positive women. Nearly all of these infants (99%; 160/161) received appropriate prophylaxis at birth. However, gaps remain in the identifi-

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CME available. See page 80 for more information.

cation and subsequent case management of HBsAg-positive pregnant women and their infants.<sup>6</sup> One important gap involves errors in documenting maternal HBsAg test results. Compared to infants born to women with appropriately documented HBsAg test results, infants born to women with unknown or discrepant HBsAg test results are less likely to receive HBIG or a birth dose of hepatitis B vaccine.<sup>6</sup>

To address this gap, a comprehensive medical record review was conducted among Wisconsin hospitals to evaluate completeness of the following: identification of HBsAg-positive pregnant women before delivery, hepatitis B vaccine birth dose administration, use of admission orders for birth dose administration and appropriate prophylaxis of infants born to HBsAg-positive women or infants born to women without maternal HBsAg status documented in the infant medical record.

## METHODS

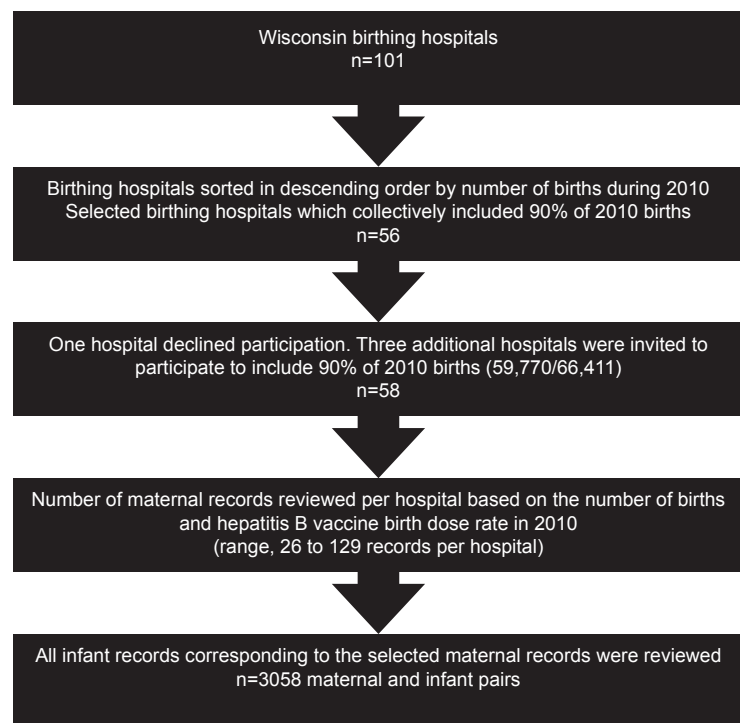
Medical record reviews were conducted at hospitals that cumulatively delivered 90% of the Wisconsin birth cohort during the year 2010. Maternal and infant hospital medical records were reviewed for the presence of any maternal HBsAg test result (including the test date), administration of hepatitis B vaccine and HBIG within 12 hours of birth to infants born to HBsAg-positive women, administration of hepatitis B vaccine within 12 hours of birth to infants born to women without maternal HBsAg status documented in the infant medical record, administration of a dose of hepatitis B vaccine to all infants prior to hospital discharge, birth weight, insurance status, type of attending provider, and patient demographic data.

This study was a required cooperative agreement objective for all funded state Perinatal Hepatitis B Prevention Programs administered by the Centers for Disease Control and Prevention (CDC). This public health study was exempt from institutional review board review.

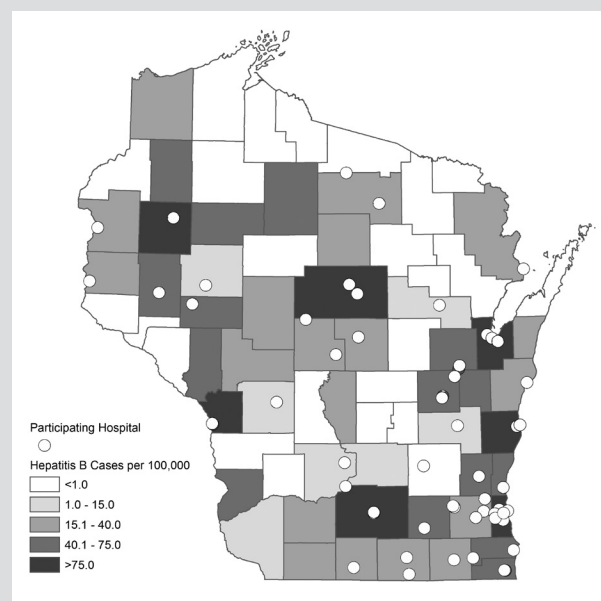
## Sampling Methods

We used the number of births in 2010 (by hospital) obtained from the Wisconsin Department of Public Health (DPH) office of health informatics<sup>7</sup> to select the Wisconsin hospitals that accounted for 90% (59,770/66,411) of births in 2010. The 101 Wisconsin hospitals were sorted by the number of live births in 2010, and those with the highest volume were selected in order from greatest to least until the selection cumulatively represented

**Figure 1.** Selection of Wisconsin Hospitals to Receive Site Visits, and Number of Medical Records Reviewed at Each Hospital

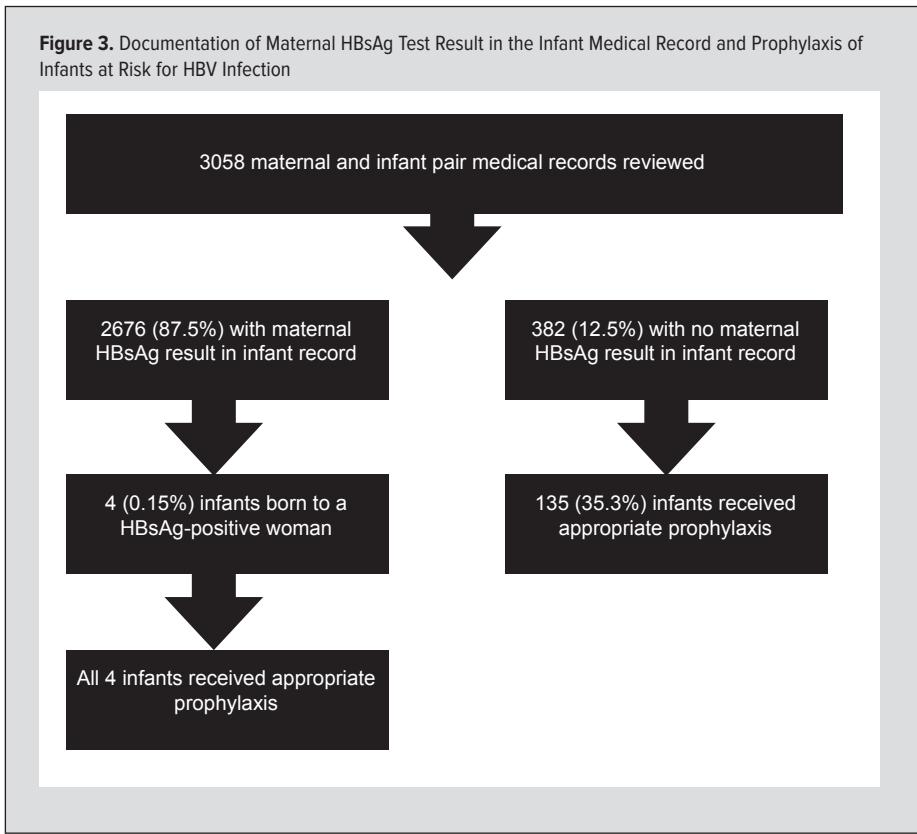


**Figure 2.** Geographic Distribution of Hospitals Visited and Mean Annual Incidence of HBV Infection per 100,000 Women Aged 15-44 During 2001-2010, by County



90% of the 2010 birth cohort. The number of paired (maternal and infant) medical records to review at each hospital was generated using the number of live births in 2010 at each hospital,

**Figure 3.** Documentation of Maternal HBsAg Test Result in the Infant Medical Record and Prophylaxis of Infants at Risk for HBV Infection



the number of infants who received a dose of hepatitis B vaccine before hospital discharge (by hospital) from a 2010 survey of Wisconsin maternity hospitals (unpublished), and a table of sample sizes (provided by the CDC) for hospital medical record reviews to assess maternal HBsAg screening or hepatitis B vaccine birth dose.<sup>8</sup> The number of records selected for review at each hospital was more heavily weighted on the hospital birth dose coverage rather than the number of live births at each hospital. For a given birth cohort size, the greater the expected birth dose coverage the smaller the number of records needed.

#### Site Visits and Data Abstraction

A letter was sent to each of the selected hospitals to arrange for the site visit. Each hospital was provided with instructions regarding proper selection of the paired (maternal and infant) medical records. This included listing all 2010 births in alphabetical order according to birth mother's last name, pulling every fifth record until the requested number of records was reached, and then pulling the corresponding infant medical records. If a selected woman gave birth to multiple infants (ie, twins), we reviewed the medical record for each infant born to her. Site visits were conducted during 2011-2013. Medical record abstraction forms were either completed while on site (41 hospitals) or through review of hospital-specific data that was sent electronically (17 hospitals). Site visits were conducted at hospitals that sent data electronically after analyzing and summarizing their hospital specific data.

#### Analysis

Descriptive analyses and pair-wise comparisons using the chi-square test for significance were conducted using SAS 9.2 (SAS Institute, Inc, Cary, North Carolina).

#### RESULTS

Initially, 56 hospitals were selected. After 1 hospital declined to participate, 3 additional hospitals were selected for a total of 58 hospitals (Figure 1). Among these, the total number of live births during 2010 was 59,957 and the range in number of births per participating hospital was 291 to 3702 (median 725) births. The number of paired records reviewed ranged from 26 to 129 per hospital (Figure 1). Among the 43 nonselected hospitals (including the one not participating), the total number of live births during 2010 was 6454 births, and the range in number of births per hospital was 8 to 885 (median 136) births. Hospitals selected were largely representative of Wisconsin counties known to have

a significant HBV-infected population (Figure 2).

Site visits were conducted at 58 of the 101 Wisconsin hospitals and medical records for 4.6% (3058/66,411) of the 2010 Wisconsin birth cohort were reviewed (Figure 1). Among the 3058 maternal and infant pairs, 3024 (98.9%) represented singleton births and 34 (1.1%) represented 17 twin births. Among 3058 maternal and infant pair records reviewed, 2928 (95.7%) had a documented HBsAg test result in the maternal record for the current pregnancy and 2676 (87.5%) had a documented maternal HBsAg test result in the infant record (Figure 3).

Among 2676 infants born to women with a documented HBsAg test result in the infant record, 4 (0.15%) were born to an HBsAg-positive woman, each at a different hospital. All 4 of these infants received prophylaxis that was appropriate for this situation: HBIG and a dose of hepatitis B vaccine within 12 hours of birth. There were 382 infants with absence of a maternal HBsAg test result in the infant medical record, although 339 (89%) of the corresponding 382 maternal records included documentation of the maternal HBsAg test result. Among these 382 infants, only 135 (35.3%) received prophylaxis that was appropriate for this situation: a dose of hepatitis B vaccine within 12 hours of birth or a dose of hepatitis B vaccine and HBIG within 12 hours of birth for infants weighing <2000 g. Four hospitals accounted for 295 (77.2%) of 382 infants with the absence of a maternal HBsAg test result in the infant medical record.

Extrapolation of these data to the population from which our

sample was derived (90% of the 2010 birth cohort) results in estimates of 78 infants born to HBsAg-positive women, and 7466 infants born to women whose HBsAg test results or test status were not included in the infant medical records. Among the latter group, an estimated 4853 infants would not have received appropriate prophylaxis.

Among 3046 infants with birth dose information available (not available in 12 infant records), 2486 (81.6%) received a birth dose of hepatitis B vaccine prior to hospital discharge. Among 560 infants who did not receive a birth dose, 276 (49.3%) had a documented guardian refusal in the medical record and 284 did not have a documented guardian refusal. Thus, among 2770 infants without documented guardian refusals, 2486 (89.7%) received a birth dose. Infants born to mothers with private health insurance were significantly less likely to receive a birth dose compared to infants born to mothers with Medicaid coverage ( $P < .0001$ ) (Table). There were no significant differences in birth dose receipt rate by maternal race or type of attending provider (obstetrician or family physician) (Table).

Based on data from the 58 site visits involving 2414 infants who received a birth dose and had information regarding whether it was administered following an admission order in the medical record, 2239 infants (92.8%) received the birth dose following an admission order in the medical record.

During medical record abstraction, 5 maternal and infant pairs were detected with discordant HBsAg test results wherein the maternal record included a positive HBsAg test result and the infant record included a negative test result or the result was missing. Each of these HBsAg test results was abstracted from a clinician-transcribed result rather than the original laboratory report, which is the current recommendation. Further investigation revealed that laboratory reports for each of these women included a negative HBsAg test result.

## DISCUSSION

This evaluation of practices to prevent perinatal HBV transmission was conducted among Wisconsin maternity hospitals representing 90% of the 2010 Wisconsin birth cohort. While these hospitals provided appropriate prophylaxis to all infants born to known HBsAg-positive women, our evaluation detected issues of concern with opportunities for substantial improvement, particularly regarding the provision of prophylaxis to infants born to women without maternal HBsAg status documented in the infant medical record.

We found that documentation of prenatal HBsAg test results was more complete among maternal records than infant records. Providers should routinely test each pregnant woman for HBsAg early during each pregnancy and document the result by placing a copy of the original laboratory report in the woman's medical record and her infant's medical record, upon birth. It is impor-

**Table.** Factors Associated With Infant Hepatitis B Vaccination at Birth

Characteristic	n <sup>a</sup>	No. With Birth Dose (%)	p <sup>b</sup>
<b>Attending Provider</b>			
Obstetrician	2331	1920 (82.4)	.145
Family physician	440	349 (79.3)	
Other/unknown	218	167 (76.6)	
<b>Maternal Insurance Status</b>			
Private	1951	1534 (78.6)	< .0001
Medicaid	946	830 (87.7)	
Other/unknown	126	102 (81.0)	
<b>Mother's Race</b>			
White	2426	1964 (81.0)	.126
Non-white <sup>c</sup>	364	212 (85.1)	
Other/unknown	249	303 (83.2)	

a The total number varies, by characteristic, as a result of missing information.

b Value does not include other/unknown category.

c Includes African American, Asian, American Indian or Alaska Native, and Native Hawaiian or other Pacific Islander race categories.

tant to document the maternal HBsAg test result in the infant medical record to alert the child's pediatrician or family physician of the need for timely prophylaxis against HBV infection when it is indicated.

Our results demonstrated that all 4 infants born to HBsAg-positive women received timely and appropriate prophylaxis, but this success is difficult to extrapolate broadly because the sample of HBsAg-positive women was small. Notably, among the nearly 13% of infants who were born to women whose maternal HBsAg status was not documented in the infant medical record, only 35% received appropriate prophylaxis, which has been reported previously.<sup>6,9</sup> Because the likelihood of developing a chronic HBV infection is inversely related to age at the time of infection, HBV infected infants are at particularly high risk of chronic HBV infection. Hospitals must ensure that appropriate prophylaxis is received by infants who are born to HBsAg-positive women or to women whose maternal HBsAg status is not documented in the infant medical record.

During our medical record abstraction, we detected 5 maternal and infant pairs with discordant HBsAg test results. These test results were abstracted from a clinician-transcribed result rather than the original laboratory report. Although investigation revealed that laboratory reports for each of these women contained a negative HBsAg test result, this highlights the need to verify the maternal HBsAg test result with the original laboratory report because transcription error does occur and has been well documented.<sup>6,10</sup>

The percentage of infants who received a dose of hepatitis B vaccine before hospital discharge was relatively high and is on track to meet or exceed the Healthy People 2020 target of 85%.<sup>11</sup> Administering a birth dose to all infants before hospital discharge serves as a "safety net" to prevent perinatal infection among infants born to HBsAg-positive women who were not identi-

fied as a result of errors in maternal HBsAg testing or failures in reporting of test results.<sup>12</sup> In our study, 49% of the infants who did not receive a dose of hepatitis B vaccine before hospital discharge did not receive a dose because of a guardian refusal. Luthy et al found that parents who exempted their children from 1 vaccine most commonly exempted the hepatitis series (hepatitis A and B), and that parents associated HBV infection with sexual transmission and therefore did not perceive the need for their child to be vaccinated.<sup>13</sup> Parents who are hesitant about or who refuse the birth dose of hepatitis B vaccine for their infant should be asked additional questions to elicit their specific vaccination concern so it may be addressed by hospital labor and delivery staff. Hospitals should ensure that each infant receives a dose of hepatitis B vaccine prior to hospital discharge and educate parents regarding the importance of on-schedule immunization. In addition, it is important that infants born to HBsAg-positive women obtain postvaccination serologic testing after completing the vaccine series to confirm vaccine-induced immunity to HBV.

We noted that among the birth doses administered to infants in our study, the vast majority were administered as a result of hospital admission orders. Although the number of hospitals with written policy to routinely administer a dose of hepatitis B vaccine to all infants before hospital discharge was not assessed during this study, results of a separate survey of Wisconsin maternity hospitals during 2011 demonstrated that 60% (56/94) had a written policy and 89% (87/98) used admission orders to routinely administer hepatitis B vaccine to all infants before hospital discharge. Madlon-Kay noted the strongest predictor of vaccine administration was having a written hospital policy for universal hepatitis B vaccine administration to newborns before hospital discharge.<sup>14</sup> Our data, and data from other studies, strongly support the use of a written hospital policy that includes obtaining consent on admission for the hepatitis B vaccine birth dose.<sup>6</sup> Therefore, we recommend a written hospital policy for universal hepatitis B vaccine birth dose administration to reinforce admission orders.

Our study has some limitations. First, although the majority of data abstractions were conducted by DPH staff, the remainder were abstracted by trained hospital personnel. This may have resulted in some inconsistencies in abstraction. Second, medical records reviewed within each hospital were not selected randomly. While we believe this was unlikely to have generated selection bias, it is feasible. Third, our study included hospitals which collectively accounted for 90% of the 2010 birth cohort; however, 43 hospitals were not included. Hospitals in each of the Wisconsin counties known to have a sizeable HBV-infected population were included in our study; most of the 43 hospitals not included are located in rural areas and had smaller numbers of births.

In Wisconsin, recommendations for testing pregnant women during each pregnancy are generally being followed, and results are being documented in the maternal medical record (and to a lesser extent in the infant medical record). Additionally, infants born to HBsAg-positive women received appropriate prophylaxis. However, among infants without a maternal HBsAg result included in their infant medical record, an alarmingly low percentage received appropriate prophylaxis. Hospitals should not underestimate the importance of documenting the maternal HBsAg result in the infant record. The percentage of infants who received a birth dose of hepatitis B vaccine was relatively high; however, there is an opportunity for improvement. In February 2013, the National Quality Forum endorsed a measure specific to the vaccination of newborn infants with hepatitis B vaccine before hospital discharge.<sup>15</sup> The use of a National Quality Forum measure marks progress toward improving the hepatitis B birth dose vaccination rate, although other aspects of perinatal hepatitis B prevention will need considerable attention before elimination of perinatal HBV transmission will be a reasonable prospect.

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