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Assessment of State Perinatal Hepatitis B Prevention Laws

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Abstract

Introduction—Identifying pregnant women with hepatitis B virus (HBV) infection for post-exposure prophylaxis of their infants is critical to preventing mother-to-child transmission of HBV infection. HBV infection in infancy results in premature death from chronic liver disease or cancer in 25% of affected infants. Universal screening of pregnant women for HBV infection is the standard of care, and in many states is supported by laws for screening and reporting these infections to public health. No recent assessment of state screening and reporting laws for HBV infection has been published.

Methods—In 2014, the authors analyzed laws current through December 31, 2013 from U.S. jurisdictions (50 states and the District of Columbia) related to HBV infection and hepatitis B surface antigen screening and reporting requirements generally and for pregnant women specifically.

Results—All states require reporting of cases of HBV infection. Twenty-six states require pregnant women to be screened. Thirty-three states require public health reporting of HBV infections in pregnant women, but only 12 states require reporting pregnancy status of women with HBV infection.

Conclusions—This assessment revealed significant variability in laws related to screening and reporting of HBV infection among pregnant women in the U.S. Implementing comprehensive HBV infection screening and reporting laws for pregnant women may facilitate identifying HBV-infected pregnant women and preventing HBV infection in their infants.

Introduction

Screening pregnant women for hepatitis B virus (HBV) infection is the standard of care in the U.S. because mother-to-child transmission (MTCT) of HBV infection is considered

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preventable.[1–4] HBV infection progresses to chronic HBV infection in 90% of infants and results in premature death from liver failure or liver cancer in approximately 25%.[1,2] When post-exposure prophylaxis (PEP) for HBV-exposed infants is initiated within 12 hours of birth, it prevents 95% of HBV infections via MTCT.[1] Improved identification of pregnant women with HBV infection allows public health authorities to assist medical providers ensure high rates of PEP administration for these infants. Screening and reporting laws have the potential to increase identification of pregnant women with HBV infection, particularly through laboratory reporting.[5]

To prevent MTCT of HBV infection, PEP initiated within 12 hours of birth begins with administration of HBV immunoglobulin and the first dose of the HBV vaccination series. PEP is considered complete after post-vaccination serologic testing of the infants at age 9–12 months. The results of testing determine whether the infants have vaccine protection, immunity, or chronic HBV infection.[2,6]

Since 1988, the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (CDC) has recommended screening all pregnant women for HBV infection at the first prenatal visit of each pregnancy.[7] Screening identifies HBV-infected pregnant women whose infants are at risk for MTCT of HBV infection; identifying at-risk infants prior to their birth and notifying birth hospitals helps ensure that these infants receive appropriate PEP at birth.[2] Hepatitis B surface antigen (HBsAg) is the serologic marker recommended for determining HBV infection in pregnant women (Table 1).[2] Additional testing is recommended for HBsAg-positive individuals. This testing usually includes hepatitis B e antigen (HBeAg), hepatitis B viral load (HBV DNA), and liver enzymes to assess liver disease activity and the need for considering antiviral treatment.[8–11]

In 1990, the Perinatal Hepatitis B Prevention Program (PHBPP) was created within CDC-funded public health immunization programs to accelerate elimination of MTCT of HBV infection.[12] CDC is authorized under Section 317 of the Public Health Service Act of 1963 to award funds for PHBPP activities in 64 immunization programs, including the 50 states and the District of Columbia (DC). PHBPP coordinators seek to identify all pregnant women with HBV infection in their jurisdiction and to assist pregnant women and their providers (both public and private) to ensure optimal PEP for HBV-exposed infants. HBV-infected pregnant women are not evenly distributed throughout the U.S. For example, in 2013, five states (California, Texas, New Jersey, Florida, and Georgia) identified 3,907 (42%) births to HBsAg-positive women identified by PHBPPs in the 50 states and DC (CDC, unpublished data, 2014).

Historically, HBV infection has been reportable to state public health departments, including PHBPPs throughout the U.S.[5] Although public health requirements for reporting specific serologic markers of HBV infection vary, results of positive tests for HBsAg are commonly required. The federal Clinical Laboratory Improvement Amendment requires that providers ordering laboratory tests include information on patient sex and age or birth date, but does not require information on pregnancy status.[13] The lack of an indicator of pregnancy status in HBV case reports is a barrier for PHBPP coordinators attempting to identify HBsAg-positive pregnant women from among all received reports, increasing the chance that HBV-

infected pregnant women will be missed. PHBPPs seek notification of possible pregnant HBV cases from various sources, including required notifiable disease reporting by laboratories, physicians, and hospitals.[14] Some states document maternal HBsAg status on the birth certificate or document administration of PEP at birth in the state's immunization information system, also known as an immunization registry (N. Fenlon, CDC, personal communication, 2016).[14,15]

This analysis examined state laws to determine whether requirements exist that could help public health programs identify HBV-infected pregnant women, and achieve the Health and Human Services Viral Hepatitis Action Plan (2014) goal of eliminating perinatal HBV transmission.

Methods

This study was based on methods used in a 2006 assessment of state laws pertaining to vaccination of healthcare workers and patients.[16] For this assessment, researchers again evaluated laws of the 50 states and DC, but limited the scope to those pertaining to HBV infection. The study was conducted by CDC's Public Health Law Program. Researchers examined the following two questions: Does the jurisdiction require screening of pregnant women specifically for HBV infection or HBsAg? Does the jurisdiction require reporting of HBV infection or HBsAg in pregnant women?

The current assessment also examined two additional questions to give a more complete picture of how HBV infection in pregnant women is reported: Does the jurisdiction require general reporting of HBV infection? Does the jurisdiction require reporting the pregnancy status of women who have HBV infection or who test positive for HBsAg?

Researchers used WestlawNext, a subscription-only, online legal research service (www.westlaw.com), to systematically identify all statutes and regulations pertaining to screening and reporting of HBV infection and HBsAg of the population generally, and of pregnant women specifically. Researchers first searched the statutory code and administrative regulations of each state, as well as municipal regulations from DC, using the search term *hepatitis B* (n=51 jurisdictions). Laws pertaining to reporting HBV or HBsAg-positive infections and to screening pregnant women were reviewed. Specific characteristics were analyzed and coded and then entered into a database. Analysis was performed on laws through December 31, 2013. Researchers analyzed statutes and regulations by jurisdiction and determined screening and reporting requirements using generally accepted rules and conventions of statutory interpretation.[17]

Screening laws were analyzed for the timing of the screening, the parties responsible for screening, and requirements for screening high-risk pregnant women.[2] Reporting laws were analyzed to determine what types of HBV laboratory markers must be reported, parties responsible for reporting, and when cases of HBV infection must be reported to public health authorities. Using t-tests, researchers looked for an effect of state screening and reporting laws on the mean proportion of infants born to HBsAg-positive women in 2013. The identified number of infants was taken from PHBPP program data, and the expected

number of infants was based on CDC models.[12] Because this study did not involve human subjects, no human subjects review was conducted.

Results

Twenty-six states require pregnant women to be screened for HBV infection or HBsAg (Table 2). Nineteen states require pregnant women to be screened at the initial prenatal visit or shortly thereafter. For example, Kansas law states that women must be screened "within 14 days after diagnosis of pregnancy"[18]; Pennsylvania provides that screening must occur "at the time of the first examination (including the initial visit when a pregnancy test is positive) or within 15 days thereafter"[19]; and Washington requires screening "during the first trimester of pregnancy."[20] Two of these states, Arkansas and Florida, require all pregnant women to be screened during the third trimester, in addition to the initial screening.

Ten states require pregnant women to be screened at admission for delivery if there is no record of HBV test results during the pregnancy. Arkansas, for example, requires screening pregnant women "if not attended prenatally, at the time of delivery."[21] New Jersey law highlights the availability of the test results, requiring "[a] ll pregnant women admitted to the hospital with unknown or undocumented hepatitis B surface antigen (HBsAg) assay results shall be immediately screened for the hepatitis B virus using the HBsAg test or other standardized hepatitis B tests."[22] Alaska's provision applies only to birth centers and requires that "[i]f a client requests the services of the birth center late in pregnancy and has no evidence of ongoing prenatal care, the birth center shall ensure that (1) the risk assessment … includes necessary laboratory testing," including screening for hepatitis.[23] Texas requires pregnant women to be screened at admission for delivery in addition to the initial screening, regardless of known or suspected risk factors.[24] In addition to requiring screening at admission for delivery if there is no record of test results, New York has a second screening law (with an indeterminate timing requirement), namely, when the "healthcare provider attending a pregnant woman takes a blood sample to be tested for syphilis or at another time when blood is drawn during prenatal care."[25]

Nineteen of the jurisdictions requiring prenatal screening assign the prenatal care practitioner the responsibility for ensuring pregnant women are screened. Some states' laws enumerate the medical professionals who are required to screen for HBV infection. For example, Missouri requires, "[e]very licensed physician, midwife, registered nurse, and all persons who may undertake, in a professional way, the obstetrical and gynecological care of a pregnant woman" to screen for HBV.[26] Other states designate the party responsible for screening using a more general term that may or may not be defined elsewhere in statute. For example, Hawaii law simply states that "[t]he attending practitioner" must conduct the screening.[27] Four states (Alaska, Colorado, Minnesota, New Hampshire) require midwives to screen for HBV infection during pregnancy but do not indicate a requirement for other obstetric providers.

Six states require additional testing during the third trimester or upon admission for delivery for women considered at high risk for acquiring HBV infection during pregnancy. States differ as to how they define women at high risk for HBV. For example, Florida defines high-

risk women as those who appear at delivery or within 30 days postpartum with no record of prenatal care, no record of testing, or no record of testing after 27 weeks gestation.[28] Illinois defines high-risk women as those with a recent history of a sexually transmitted disease, injection drug use, or other possible risk factors for HBV infection.[29]

All jurisdictions examined require reporting of cases of HBV infection (Table 3). Thirty-two states and DC require reporting HBV infections and HBsAg in pregnant women. Twelve states require reporting the pregnancy status of women with HBV infection or who test positive for HBsAg; no state laws explicitly prohibit the capture or recording of pregnancy status of women who are screened. Seven states require reporting positive HBeAg or HBV DNA test results in pregnant women.

Healthcare providers are named the responsible party for reporting HBV infection cases in 49 jurisdictions (all except North Carolina and DC). Laboratories are required to report HBV infection cases in 49 jurisdictions (all except Missouri and DC). Hospitals or other healthcare facilities are required to report HBV infection cases in 33 states. DC's municipal regulation states that HBV infection, "shall be reported in writing within forty-eight (48) hours of diagnosis or the appearance of suspicious symptoms," but does not specify which parties must report cases of HBV infection.[30]

Twenty-seven states require reporting within 1 day of diagnosis or positive laboratory test result. Twenty-nine states require reporting within 2–7 days of diagnosis, and two states (Arizona and Washington) require reporting within 30 days of diagnosis. These categories of timing requirements for reporting are not mutually exclusive; some states have different time interval reporting requirements for different reporting entities or different methods of diagnosis (e.g., laboratory test versus clinical diagnosis). Nine states have different time interval requirements for different diagnoses: for example, Indiana requires HBV infection cases to be reported within 72 hours, but HBV infection in pregnant women or in perinatally exposed infants must be reported immediately.[31] By contrast, Maine mandates that acute cases of HBV be reported immediately, whereas all other cases must be reported within 48 hours of diagnosis.[32] Five states do not have specific timing requirements for reporting of HBV infection (Table 3).

In an analysis of 2013 data for infants born to HBsAg-positive women, there was no statistically significant difference in the mean proportion of identified-to-expected number of infants in states with or without screening laws. Similarly, there was no statistically significant difference in the mean proportion of identified-to-expected number of infants in states with or without reporting laws.

Discussion

Because PEP is an effective means to prevent MTCT of HBV infection and significantly decrease long-term morbidity and mortality resulting from chronic HBV infection, it is important that every pregnant woman with HBV infection be identified so her infant can receive PEP. For this reason, states have developed explicit requirements for screening and reporting rather than simply relying on adherence to standard of care. Although it is

unknown what proportion of reporting is attributable to the presence of a law versus a provider's desire to benefit public health, laws likely have an effect. An evaluation of the New York State PHBPP cited state laws requiring universal testing and reporting of pregnant women with HBV infection as the primary factor leading to a 96% case ascertainment rate and 92% of infants born to reported mothers receiving PEP within 48 hours of birth.[15]

This assessment revealed significant variability in laws related to screening and reporting of HBV infection among pregnant women in U.S. public health jurisdictions. Only 26 of 51 jurisdictions require that providers screen for HBV infection among pregnant women, despite the significant health risks to infants born to infected mothers. Because of the important individual and public health consequences of HBV infection, all jurisdictions require reporting of HBV infection (including HBsAg-positive pregnant women). However, researchers found that only 12 of 51 jurisdictions require reporting of pregnancy status for HBV-infected women.

Failing to identify HBsAg-positive pregnant women increases the risk that the brief "window" of opportunity to initiate prevention of MTCT of HBV infection will be missed. Identification of HBV-infected pregnant women among all reported HBV-infected women is labor intensive for PHBPPs, and may require review and follow-up of thousands of reports of positive HBV test results. When identified and case managed by PHBPPs, the rates of chronic HBV infection among exposed infants who received post-vaccination testing was as low as 0.5% (CDC, unpublished data, 2014). Rates of MTCT can be as high as 90% among infants who miss timely PEP.[2] In contrast with previous studies, this analysis did not demonstrate an effect of state screening or reporting laws on identification of infants born to HBV-infected women.[15] This may be due to differential compliance with existing laws or uncertainties in the data used to calculate the expected number of infants born to infected women.[12]

National advisory committees recommend that people with chronic HBV infection, including pregnant women, receive counseling and medical evaluation for care and treatment.[2,10] Evaluation generally includes HBV-specific tests, such as the presence of HBeAg or the HBV DNA level.[10] In this review, 33 states require reporting of positive markers for HBV, but only seven states have statutes specifically requiring reporting of positive HBeAg or HBV DNA results. Only one of these states (Arizona) requires both reporting of pregnancy status and HBeAg or HBV DNA. Laws that require reporting of HBeAg positivity or DNA results in addition to pregnancy status may assist city and state PHBPPs to educate providers on options for achieving successful prevention of MTCT of HBV infection.[33–36] CDC and the American College of Obstetricians and Gynecologists offer an algorithm indicating prenatal HBeAg or HBV DNA testing should be included in the initial evaluation of HBsAg-positive women.[10] If these tests meet certain criteria defined by the algorithm, the women should have a prenatal consultation with a provider skilled in the management of chronic HBV.

Limitations

First, this assessment was restricted to statutes and regulations in U.S. state jurisdictions and DC; relevant laws may also exist in counties or municipalities. Second, researchers did not

comprehensively review case law, professional licensing board opinions or rules, and other enforcement guidance, such as opinions from attorneys general, that could affect HBV screening and reporting. Therefore, the analysis might not fully reflect reporting or screening requirements in a jurisdiction. Third, the analysis did not examine how the law was applied in practice. Compliance might vary from jurisdiction to jurisdiction—or even within a jurisdiction—depending on whether public health authorities have sufficient resources to educate and enforce screening and reporting laws. It might vary with practitioners' awareness and understanding of a law, whether they perceive it is enforced, and whether they believe the benefits of noncompliance outweigh any penalties. Finally, the results of this analysis provide a snapshot at the end of 2013, and some laws might have changed since then.

Conclusions

Screening and reporting requirements are an important tool for early identification of HBV infection in pregnant women and, consequently, an important tool in the prevention and identification of HBV infection in their infants. As new laws are considered to reduce MTCT of HBV infection, several provisions to increase the effectiveness of screening and reporting could be considered. Requiring all pregnant women to be screened for HBsAg at either the initial prenatal visit or at admission for delivery if there is no record of test results, and reporting pregnancy status in HBsAg-positive women, could increase the number of women identified for prenatal intervention. Requiring reporting of positive test results within 1 day could increase the number of women identified in time for intervention. Finally, screening laws that are inclusive of all types of obstetric care providers (e.g., including unlicensed midwives) can help to ensure universal screening for HBV infection among pregnant women. Ultimately, implementation of comprehensive HBV infection screening and reporting laws for pregnant women could accelerate efforts by public health and medical professionals to reduce chronic HBV infection and fatal liver disease in the U.S.

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T. Murphy conceived the study. L. Culp and T. Murphy contributed to the study design. L. Culp and L. Caucci collected and analyzed the legal data. All authors participated in the interpretation of the data, and the drafting and revision of the manuscript.

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20. WAC 246-680-010. See also Arkansas “at or near the initiation of care” (Code Ark. R. 007.13.4-400); California “as early as possible during prenatal care” (Cal. Health & Safety Code §125085); Tennessee “at the time of first examination and visit or within ten (10) days after the first examination” (T.C.A. §68-5-602); Utah “at an early prenatal care visit” (UT ADC R386-702); Virginia “within 15 days after beginning such attendance” (12 VAC 5-90-130).
21. Ark. Code Ann. § 20-16-507. See also Tennessee,“[i]f the first visit is at the time of delivery, or after delivery, the standard serological test … shall be performed at that time” (Tenn. Code Ann. § 68-5-602).
22. N.J. Admin. Code § 8:43G-19.2. See also New York mandating if “a woman who has not been tested for HBsAg during pregnancy is admitted for delivery or if a woman’s HBsAg test result is not at the time of admission for delivery, the healthcare facility shall: (1) submit immediately a

satisfactory blood specimen from such a woman to a clinical laboratory that will test it for HBsAg" (10 N.Y. Comp. Codes R. & Regs. 69-3.3).

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Table 1

Laboratory Markers of HBV Infection

Marker name	Abbreviation	Description
Hepatitis B virus	HBV	Virus causing hepatitis B infection
Hepatitis B surface antigen	HBsAg	Protein present on the surface of hepatitis B virus; the principal marker of acute and chronic HBV infection
Hepatitis B e antigen	HBeAg	Protein present during active replication of hepatitis B virus; indicates an increased risk of transmitting HBV
Hepatitis B viral DNA	HBV DNA	Indicates active HBV infection
Antibody to hepatitis B core antigen (IgG and IgM)	Anti-HBc, total	Indicates acute, chronic, or resolved HBV infection; often persists for life

IgG, immunoglobulin G; IgM, immunoglobulin M.

Table 2

Legal Provisions for HBV Infection Screening for Pregnant Women

Legal provision	Jurisdictions, *n*	Jurisdictions
Screening		
Require pregnant women be screened for HBV infection or HBsAg	26	AK, AR, CA, CO, DC, FL, HI, IL, KS, KY, MI, MN, MO, MT, NV, NH, NJ, NY, NC, OR, PA, TN, TX, UT, VA, WA
Screening: timing		
Require screening at the initial prenatal visit or shortly thereafter	19	AK, AR, CA, CO, DC, FL, IL, KS, MI, MO, MT, NH, OR, PA, TN, TX, UT, VA, WA
Require screening at admission for delivery if there is no record of test results	10	AK, AR, CA, DC, MI, MO, NJ, NY, TN, UT
Require screening during the third trimester in addition to the initial screening for all women	2	AR, FL
Require screening at admission to delivery in addition to the initial screening for all women	1	TX
Screening: responsible party		
Require the attending practitioner to ensure the woman is screened	19	AR, CA, DC, FL, HI, KS, KY, MI, MO, MT, NV, NJ, NY, OR, PA, TN, TX, UT, VA
Only require midwives to ensure the woman is screened	4	AK, CO, MN, NH
Party responsible for screening not specified	3	IL, NC,WA
Screening: high-risk women		
Require additional testing during the third trimester or upon admission for delivery for women who are considered high risk	6	FL, IL, TN, UT, VA, WA

HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus.

Table 3

Legal Provisions for HBV Infection Reporting

Characteristics	Legal provision	Jurisdictions, *n*	Jurisdictions
Reporting	Require general reporting of hepatitis B	51	All (50 states + DC)
	Require reporting of HBV infection or HBsAg in pregnant women	33	AZ, AR, CA, CT, DC, FL, GA, HI, IL, IN, KS, KY, LA, ME, MI, MN, MS, MO, MT, NV, NH, NJ, NY, NC, OH, OK, RI, TN, TX, UT, VT, WA, WV
	Require reporting of pregnancy status in women who have HBV infection or who test positive for HBsA	12	AK, AZ, FL, IA, KS, MD, MN, NE, TX, UT, VA, WY
Reporting: what must be reported	Case or suspected case of HBV infection	51	All (50 states + DC)
	Positive laboratory markers for hepatitis B	33	AK, AZ, AR, CA, CO, CT, DC, FL, HI, ID, IL, KY, LA, MI, MN, MS, MO, NE, NH, NJ, NY, NC, OK, OR, PA, RI, SC, TN, UT, VT, VA, WA, WV
	HBeAg or HBV DNA results	7	AL, AZ, CO, IN, OK, VT, WA
Reporting: responsible party	Providers (all types)	49	All except D.C. and NC[a]
	Laboratories	49	All except D.C. and MO
	Other—hospital and healthcare facility administrators	33	AL, CA, CO, CT, DE, FL, GA, ID, IN, KS, KY, ME, MD, MN, MO, MT, NE, NV, NJ, NY, ND, OK, OR, PA, RI, SC, SD, TX, UT, VA, WA, WI, WY
	No responsible party specified	1	DC
Reporting: timing	≤1 day (includes immediate, ≤24 hours, or next business day)	27	AR, CA, CT, FL, ID, IN, KY, LA, ME, MD, MA, MI, MN, NJ, NM, NY, NC, ND, OH, OK, OR, PA, TX, VT, WA, WV, WY
	2–7 days (includes 48 hours, 72 hours, within 3 days, within 5 days, or within 7 days)	29	AL, AK, CO, CT, DE, DC, ID, IL, IN, IA, KS, LA, ME, MS, MO, MT, NE, NH, NJ, NC, OH, PA, SD, TN, TX, UT, VA, WA, WI
	>7 days (includes within 30 calendar days)	2	AZ, WA
	Different time intervals for different hepatitis B diagnoses (e.g., perinatal, pregnancy, acute, or chronic)	9	IL, IN, LA, ME, NC, OH, OK, TX, WA
	Not specified	5	GA, HI, NV, RI, SC

[a]North Carolina requires only laboratories to report cases of hepatitis B, not providers.

HBeAg, bepatitis B e antigen; HBsAg, bepatitis B surface antigen; HBV, hepatitis B virus.