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Postpartum laboratory follow-up in women with hepatitis B in Massachusetts from 2007–2012

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Abstract

Goals—To determine postpartum hepatitis B virus (HBV) laboratory testing rates and identify factors associated with a lack of follow-up testing in Massachusetts.

Background—Screening for HBV infection in pregnant women is standard of care. Guidelines recommend that patients with chronic HBV have ongoing care and laboratory testing, but little is known about postpartum maternal HBV care outcomes.

Study—We conducted a retrospective cohort study using MAVEN, an electronic public health surveillance system maintained by the Massachusetts Department of Public Health (MDPH). We identified women who tested hepatitis B surface antigen (HBsAg) positive during their first reported (index) pregnancy in Massachusetts 2007–2012 and measured HBV-related laboratory tests reported to MDPH during and after pregnancy.

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Conflicts of Interest: C.U. is an employee of Novartis Institute for Biomedical Research. Theremaining authors report no conflict of interest.

This study was presented at Digestive Disease Week 2014 in Chicago, IL on May 5, 2014.

Results—We identified 983 HBsAg+ pregnant women. Half (492/983) did not have evidence of additional postpartum HBV laboratory testing following their index pregnancy. Women who had postpartum laboratory tests reported were younger (mean age [standard deviation]: 29 [5.3] versus 31 [5.5] years, p=0.0001) and more likely to have >1 pregnancy during the study period (41% versus 1%, p<0.0001). There were no differences in race, ethnicity, and US born status. On multivariable logistic regression, older age predicted lower likelihood of having postpartum laboratory testing (odds ratio 0.77; 95% CI: 0.70, 0.90).

Conclusions—Postpartum maternal HBV follow-up laboratory testing occurred in only half of Massachusetts women and did not vary by race, ethnicity, or US born status. Our results were limited to a single state surveillance database, which likely underestimates the number of tests ordered.

Keywords

disparity; guidelines; surveillance

Introduction

Chronic hepatitis B virus (HBV) infection affects up to 2.2 million people in the United States and an estimated 350 million globally.[1–3] To break the cycle of transmission and chronic infection, HBV screening is recommended during pregnancy to prevent vertical transmission from an infected mother to the newborn at delivery.[5] Prophylaxis for the infant is highly effective[6] and consists of administrating hepatitis B immune globulin (HBIG) within 12 hours of delivery and the first dose of the vaccine series prior to discharge from the hospital.[7] Among women identified as infected with HBV, adherence rates to newborn prophylaxis have been nearly universal in the United States.[8]

In contrast, very little is known about maternal postpartum HBV outcomes as efforts are focused primarily on the infants. Guidelines from the American Association for the Study of Liver Diseases (AASLD) recommend that patients with chronic HBV have lifelong care and laboratory testing as they are at risk for developing cirrhosis, portal hypertension, and hepatocellular carcinoma (HCC).[9] However, when we examined this issue in the Partners HealthCare system, the largest health care system in Massachusetts, we found that 47% of women had postpartum follow-up with a HBV specialist and only 19% of HBV infected mothers met care guidelines 1 year after diagnosis.[11] Factors predicting maternal follow-up care have not been evaluated on a statewide level. Our goal was to determine postpartum HBV follow-up rates in Massachusetts (MA) amongst women first identified as part of prenatal care using HBV surveillance laboratory testing reported to the MA Department of Public Health (MDPH), and to identify potential factors associated with a lack of follow-up testing.

Materials and Methods

We conducted a retrospective review using aggregate, publicly available data collected by MDPH. Prenatal HBV testing laws and regulations vary by state, and in many states, testing is not mandated. In MA, documentation of HBV status in the maternity chart is mandated,

but not testing during prenatal care specifically.[12] MDPH conducts surveillance of acute and chronic cases of HBV infection in the state, and provides case management to prevent vertical transmission to infants born from mothers with HBV. MDPH also tracks all HBV-related laboratory tests using a secure web-based disease surveillance and case management system for infectious diseases maintained by the MDPH to capture reportable laboratory and clinical data called MAVEN (Massachusetts Virtual Epidemiologic Network).[13, 14] Laboratories performing testing on specimens derived from MA residents are required to report all laboratory evidence of HBV infection to the MDPH, which then allows select MAVEN users to identify women who are pregnant to initiate case-management to facilitate HBV prophylaxis for the infant. Laboratory testing related to HBV is then collected indefinitely with the purpose of covering all potential future pregnancies. The data in this system provided us the opportunity to use laboratory testing as a proxy for postpartum HBV clinical care follow-up.

The primary endpoint of our study was to determine the proportion of HBsAg+ women who had any additional laboratory tests related to HBV reported postpartum, including HBV serologies (e antigen [HBeAg] and e antibody [HBeAb]), HBV DNA, and alanine aminotransferase (ALT). These tests were chosen as they are specifically recommended by AASLD for all patients with HBV infection to help guide management and determine candidacy for antiviral therapy.[1, 9]

Using MAVEN, we identified and included pregnant women who tested HBsAg+ for the first time during their first reported (index) pregnancy in MA from 2007 to 2012. We extracted relevant demographic characteristics and follow-up laboratory data, which also included hepatitis C virus antibody (HCV Ab) and aspartate aminotransferase (AST). Follow-up data were available through August 2013. To determine how long it took for women to have postpartum HBV-related laboratory tests ordered, we calculated the time from the date of the initial HBsAg+ until the first postpartum HBV-related laboratory test. While virtually all positive laboratory tests related to HBV are captured by MDPH in MAVEN, negative tests are only captured when performed as part of a test panel. For example, a woman who is HBeAg positive and HBeAb negative will have both results reported when ordered together, but only the positive HBeAg result reported if they were ordered separately.

Laboratory follow-up testing rates were reported according to individual counties in MA. Using Spearman's rank-order correlation, we compared follow-up testing rates and county-level characteristics derived from the 2010 US census, specifically proportion of foreign-born residents and median income.[15] We performed bivariate analyses and compared characteristics of mothers with and without follow-up laboratory testing after their index pregnancy using the t-test for age and chi-squared or Fisher's exact test for categorical data, which included race, ethnicity, birth region, and having more than one pregnancy during the study period. Peak ALT values were available, but several were missing a laboratory reference range. We analyzed ALT as a continuous, non-normal variable using the Mann-Whitney U test. To identify independent predictors of postpartum laboratory follow-up, we included all characteristics from our bivariate analyses in a multivariable logistic regression model except for ">1 pregnancy during the study period" and peak ALT; the number of

women without laboratory follow-up who had >1 pregnancy was too small to include in the model and the ALT data were incomplete with 53% of women missing values. Results were reported as odds ratios (OR) and 95% confidence intervals (CI). All statistical analyses were performed using SAS 9.3 (SAS Institute Inc., Cary, NC).

This project was approved by the Partners HealthCare IRB and did not require MDPH IRB review as we used publicly available aggregate datasets.

Results

There were 983 pregnant women first reported as being HBsAg+ during their index pregnancy in MA from 2007 to 2012. The majority of women were reported to be HBsAg+ in their first trimester (67%) compared to the second (22%) and third trimesters (11%), which aligns with recommendations for 1st trimester screening.[7] Asians and Pacific Islanders were the largest racial group (45%) and blacks were the second largest group (24%) with 11% of unknown race. The majority of women (79%) were non-Hispanic with 16% unknown. Sixty nine percent were born outside of the US and 22% were of unknown birth region. Data on insurance type were not available in most cases.

Fifty percent of women (n=492) had no post-partum HBV laboratory testing reported following their first pregnancy (Figure 1). Of these women, 26% (n=128) had only the initial HBsAg+ and no other HBV laboratory testing reported. Among women who had postpartum laboratory testing, follow-up tests were reported with a mean specimen date of 611 days (median= 518, interquartile range= 535) after the initial HBsAg+. When stratified by county, reported follow-up laboratory testing ranged from 41–62% (Table 1). No correlation was found between reported follow-up testing rate and the proportion of foreign-born residents by county (r_s=−0.30, p=0.43) or median income by county (r_s=0.33, p=0.38).

When comparing women with and without reported postpartum HBV laboratory follow-up (Table 2), women with follow-up testing were younger, 29 (standard deviation [SD] 5.2) versus 31 (SD 5.5) years, p=0.0001, and much more likely to have more than one pregnancy during the study period (41% versus 1%, p<0.0001). There were no differences in race, ethnicity, or US born status between groups. Women with reported follow-up had a higher peak ALT than women without follow-up, median 23 (interquartile range [IQR] 19) versus 20 (IQR 14) international units per liter, p=0.004, although this was not a clinically relevant difference and was derived from incomplete data (55% reported ALT, 7% reported AST). On logistic regression analysis, age was a negative predictor of postpartum HBV laboratory follow-up with an odds ratio of 0.77 (95% CI: 0.70, 0.90) for every 5 year increase (Table 3). Race, ethnicity, and birth region were not related to follow-up. The number of women without laboratory follow-up who had more than one pregnancy during the study period was too small to be included in the regression model.

In this cohort, reporting of HBV-related laboratory tests postpartum was generally low and varied by test (Table 4). ALT was the most reported laboratory test (55%) followed by HBV DNA (42%) whereas the two other recommended tests, HBeAg and HBeAb, were reported much less often, 17% and 15%, respectively, and when reported were biased predominantly

towards positive test results. Only a small fraction of women had any HCV Ab testing reported (8%). HBV DNA values were not always able to be obtained reliably and therefore were not reported in our results.

Discussion

Our study found that only 50% of pregnant women with HBV infection identified in our cohort in MA from 2007–2012 had evidence of postpartum follow-up laboratory testing reported to the MDPH following their index pregnancy and suggests that many HBsAg+ women in MA are not receiving appropriate postpartum HBV care. Among HBsAg+ women without postpartum laboratory testing, 26% had only the initial screening HBsAg and no other HBV tests reported, which represents a missed public health opportunity.

Postpartum HBV care not only provides an opportunity to reduce the mothers' risk of disease progression,[18] hepatocellular carcinoma,[19, 20] and overall mortality,[21, 22] but also risks for their infants and close contacts. Numerous analyses have also shown that treatment of HBV in high risk mothers is cost effective.[27–29] Active case management to coordinate postpartum HBV care for mothers also has the potential to bring their close contacts, who may have undiagnosed HBV, to medical care and improve case-finding yields. Current efforts to identify patients with chronic HBV infection in the clinical setting rely on individual providers recognizing that a patient has risk factors for HBV infection, which can be inefficient and miss HBV cases.[7] In contrast, HBV-infected pregnant women have already been identified and can serve as the starting point for screening at-risk family members and close contacts who may also have HBV.

Surprisingly, sociodemographic factors, such as race and US born status, which are often associated with access to care,[31, 32] did not seem to affect postpartum HBV laboratory testing in our cohort. It may be that providers in MA have limited knowledge and experience regarding HBV infection management given the low statewide prevalence, resulting in low adherence to postpartum HBV laboratory testing across all racial and ethnic groups. It is possible that younger women and women who had more than one pregnancy during the study period had more interactions with the health care system, which might explain why they were more likely to have postpartum HBV laboratory testing. Furthermore, although insurance status typically affects access to care, by 2006 MA had already passed health care reform legislation, which extended coverage to most residents in the state.[34]

The primary limitation to our study was the use of surveillance data, which tends to under-represent tests ordered. It is likely that there were postpartum laboratory test results that were not reported to the MDPH, particularly if they were negative, as negative tests are only collected when ordered together with positive reportable test results. ALT/AST is also not reportable unless it is included as part of a panel along with HBV+ laboratory results. However, HBV tests are typically ordered together and HBeAg and HBeAb in particular should have opposite positive/negative values, which should trigger the laboratory reporting mechanism, yet our findings show that only a fraction of women had any positive HBV test results. On occasion, data linkage problems and other technical issues can also interfere with reporting, including delays in entering paper-based laboratory test results. Additionally, our

electronic database was restricted to MA and test results from outside of the state from MA residents. Given the retrospective nature of our study, not all mothers had the same amount of follow-up time, as those with pregnancies in 2007 were followed for longer than those with pregnancies in 2012, although all women had follow-up at least until August 2013. Unfortunately, we were not able to obtain details about ordering provider information, such as academic versus community practice, and other HBV-related care, including severity of HBV infection, HBV screening and immunization of close contacts, HCC screening adherence, and HIV co-infection status, although this was likely very uncommon in MA based on our prior study (1 out of 291 women).[4] Nevertheless, our study still provides useful information about postpartum HBV care practices in MA. Our findings clearly indicate that HBV testing appears to be far from meeting AASLD guideline standards as we considered any form of postpartum laboratory testing sufficient to qualify for our primary outcome of having follow-up HBV testing.

In summary, our study is the first estimate of follow-up laboratory testing in pregnant women who were first reported to MDPH as HBsAg+ in MA during a pregnancy. Follow-up testing occurred in only half of the women identified in this cohort and did not vary by race, ethnicity, or birth outside of the US. It appeared that women who had more opportunities to encounter the health care system, namely women who were younger and had more than one pregnancy during the study period, were more likely to have postpartum laboratory testing and suggests that a lack of follow-up testing may be a health system problem rather than a patient specific issue alone, at least in MA. Ultimately, a solution will require interdisciplinary cooperation involving obstetricians, primary care providers, HBV specialists, and state and local departments of public health. Given current clinical and public health standards, future research should evaluate reasons for nonadherence to postpartum HBV care, including provider or health system-based barriers, and options to improve HBV testing and management. It remains to be seen whether our findings are generalizable to other settings, particularly those with higher HBV prevalence where patients and providers may have greater awareness of HBV.

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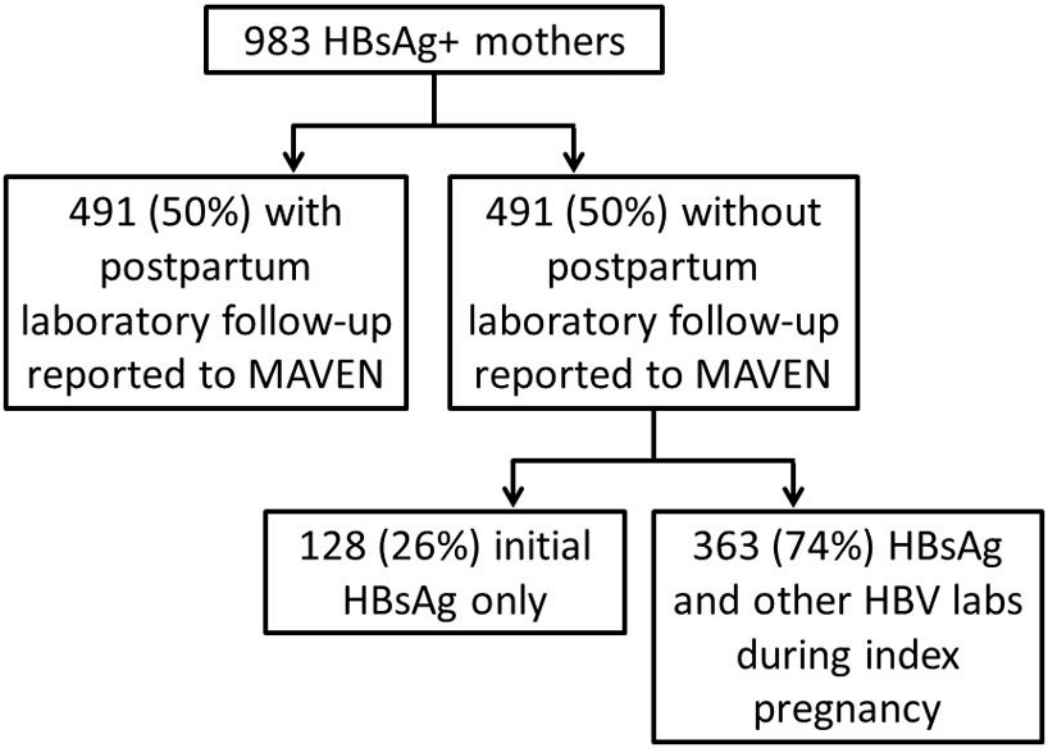

Figure 1.
Flow diagram of follow-up laboratory testing in pregnant women who were first reported to Massachusetts Department of Public Health (MDPH) as hepatitis B surface antigen positive (HBsAg+) in Massachusetts during a pregnancy.

Table 1

MA county characteristics and distribution of HBV cases.

	Population	With HBV follow-up testing, n (%)	% Foreign Born by County≠	Median Income by County¥
Barnstable and Cape Islands	--	<5*	--	
Berkshire	--	<5*	--	
Bristol	548,285	15 (45)	12	55,995
Essex	743,159	44 (54)	15	66,918
Franklin	--	<5	--	
Hampden	463,490	15 (41)	9	49,729
Hampshire	158,080	6 (50)	8	61,264
Middlesex	1,503,085	150 (51)	19	81,420
Norfolk	670,850	52 (41)	15	84,087
Plymouth	494,919	34 (62)	8	74,722
Suffolk	722,023	95 (49)	28	52,700
Worcester	798,552	71 (57)	11	65,968

*Data suppressed for privacy when n<5

≠No correlation with follow-up testing (r_S=−0.30, p=0.43)

¥No correlation with follow-up testing (r_S=0.33, p=0.38)

County data source: 2010 US Census [15]

Abbreviations: MA, Massachusetts; HBV, hepatitis B virus

Table 2

Characteristics of women diagnosed with hepatitis B perinatally with and without follow-up laboratory testing after the index pregnancy.

	Without follow-up testing n=492	With follow-up testing n=491	P-value
	N (%) or Mean (Standard Deviation)		
Mean age, years	31 (5.5)	29 (5.3)	0.0001
Race			
White	50 (10%)	52 (11%)	
Black	105 (21%)	127 (26%)	
Asian/Pacific Islander	206 (42%)	238 (48%)	0.63
Other	51 (10%)	42 (9%)	
Unknown	80 (16%)	32 (7%)	
Ethnicity			
Hispanic	32 (6%)	23 (5%)	
Non-Hispanic	362 (74%)	412 (84%)	0.10
Unknown	98 (20%)	56 (11%)	
Birth region			
US born	77 (16%)	92 (19%)	
Non-US born	283 (58%)	311 (63%)	0.63
Unknown	132 (27%)	88 (18%)	
>1 pregnancy during the study period	5 (1%)	200 (41%)	<0.0001

Table 3

Multivariable logistic regression model for the outcome: follow-up laboratory testing after the index pregnancy

Variables	Odds Ratio (95% Confidence Intervals)
Age, per 5 years	0.77 (0.70, 0.90)
Race	
Asian/Pacific Islander	1.00
White	0.83 (0.48, 1.41)
Black	1.18 (0.81, 1.70)
Other	0.79 (0.46, 1.35)
Ethnicity	
Hispanic	1.00
Non-Hispanic	0.57 (0.25, 1.32)
Birth region	
Non-US born	1.00
US born	1.42 (0.95, 2.13)

Table 4

Laboratory characteristics of hepatitis B surface antigen positive mothers with follow-up testing after the index pregnancy.

Laboratory test	With follow-up testing n=491 (%)
N (%) or Median (Interquartile Range)	
Hepatitis B virus DNA reported	207/491 (42%)
Peak ALT reported	271/491 (55%)
Median peak ALT, IU/L	23 (19%)
AST reported	35/491 (7%)
Hepatitis B e antigen reported	82/491 (17%)
Hepatitis B e antigen positive	66/82 (80%)
Hepatitis B e antibody reported	72/491 (15%)
Hepatitis B e antibody positive	65/72 (90%)
Hepatitis C virus antibody reported	39/491 (8%)
Hepatitis C virus antibody positive	2/39 (5%)

Abbreviations: ALT, alanine aminotransferase; IU, international units; AST, aspartate aminotransferase