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Screening for Hepatitis B Virus Infection in Pregnant Women: An Updated Systematic Review for the U.S. Preventive Services Task Force

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Structured Abstract

Objective: To update the 2009 USPSTF's A recommendation for Hepatitis B Screening in Pregnancy we systematically reviewed evidence on the benefits (KQ1) and harms (KQ2) of universal screening programs for hepatitis B virus (HBV) infection in pregnant women, and the benefits (KQ3) and harms (KQ4) of case management programs to prevent perinatal transmission.

Data Sources: We conducted a literature search of MEDLINE, PubMed Publisher-Supplied Records, the Cochrane Database of Systematic Reviews, the Cochrane Central Register of Controlled Trials (CENTRAL), the Cumulative Index for Nursing and Allied Health Literature (CINAHL), Embase, and PsycInfo from January 1, 1986, to May 3, 2018.

Study Selection: We screened 5,688 titles and abstracts and 499 full-text articles to identify eligible studies based on *a priori* inclusion and exclusion criteria.

Data Analysis: Two investigators independently appraised any article that met inclusion criteria using design-specific criteria. We abstracted and narratively synthesized included study data.

Results: No studies were identified for KQ1 or KQ2 that addressed either the effects of screening programs on perinatal HBV transmission or the potential harms of screening. Two fair-quality, observational studies that compared perinatal transmission rates over time were included for KQ3. One study reported outcomes of case management for infants with data reported to the national Perinatal Hepatitis B Prevention Program (PHBPP), administered by the Centers for Disease Control and Prevention. In the PHBPP, 155,081 infants born to HBV positive women were identified for case management from 1994 to 2008; perinatal transmission outcomes were available for infants born from 1999-2008 that received serologic testing (N = 55,362). A statistically significant decline in the perinatal transmission rate was observed; perinatal transmission was reported for 1.9 percent of case managed infants in 1999 and 0.8 percent in 2008 (p<.001). Over the study period, the number of infants born to HBV positive women increased in the United States, and an increasing proportion of the estimated infants born to HBV positive women were enrolled in the PHBPP for case management (p<.001). Program completion (serologic testing within 24 months of birth) also increased across the time period (p=.001). The second study reported outcomes of case-management for infants born to HBV positive women in a large, regional health care organization in the United States. The health system case management program reported on 4,446 infants born to HBV positive women over the years 1997 to 2010. Over this period, 85 percent of infants were tested for HBV, and a decreasing trend in perinatal transmission was reported (IRR 0.90, 95% CI 0.82 to 1.00). Overall rates of perinatal transmission were very low (25 of 3,353 of infants tested, 0.75%). Over 97 percent of case managed infants received HBV vaccination and HBIG within 12 hours of birth. No studies were identified for KQ4 to assess potential harms of case management.

Limitations: Our review was narrowly focused on evidence of the effectiveness of screening or case management on prevention of perinatal transmission in contexts where prenatal screening and universal vaccination for HBV at birth are established practice. The included observational studies' findings on declining perinatal transmission trends could be influenced by secular

changes in other public health activities (e.g., universal vaccination) or by improvements within case management program implementation and interventions (e.g., antiviral medication). Changes in data collection and reporting methods used in the studies could also introduce bias.

Conclusions: Perinatal transmission would be observed in over one-third of infants born to HBV positive mothers in the absence of prophylaxis. Very low and declining rates of perinatal transmission have been documented for infants in case-management programs that track and coordinate the delivery of preventive interventions. Screening for hepatitis B in pregnancy is standard prenatal care practice in the United States and identifies women and infants eligible for effective case management for effective interventions to prevent perinatal transmission.

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Chapter 1. Introduction

Condition Background

Condition Definition

Hepatitis B is a viral infection of the liver caused by the hepatitis B virus (HBV). The presence of the hepatitis B surface antigen (HBsAg+) indicates an acute (i.e., less than 6 months) or chronic HBV infection. Hepatitis B e-antigen (HBeAg+) positivity is associated with active viral replication, high HBV DNA viral load, and higher infectivity. In the absence of HBsAg, the existence of HBV core antibodies (anti-HBc IgG) may indicate that an individual was previously infected with HBV. The presence of HBV surface antibodies (anti-HBs) indicates that the individual has achieved immunity to HBV following an infection or from vaccination. HBV is transmitted through contact with the blood or bodily fluids of an infected individual. In countries with high HBV prevalence, perinatal transmission of infection from mother to neonate at the time of delivery is common.¹ Consequently, adults living with HBV in the United States that were born in high prevalence countries often contracted the infection in childhood.² New cases of HBV among adults in the United States are primarily transmitted through sexual intercourse and intravenous drug use. For children born in the United States, the primary source of infection is vertical transmission from an infected mother either in utero or peripartum, with the greatest risk occurring when the newborn is exposed to vaginal blood or secretions at delivery.³

Disease Prevalence and Burden of Disease

HBV remains an important global public health concern despite the existence of an effective vaccine and antiviral agents. Globally, in 2015, chronic HBV (measured by seroprevalence of HBsAg) was estimated to affect 3.5 percent of the population (approximately 257 million individuals) including an estimated 65 million women of childbearing age. The highest prevalence rates reported by the World Health Organization (WHO) occur in the African (6.1%) and Western Pacific regions (6.2%), with recent modeling estimates finding higher prevalence for specific subregions.⁴ Based on population, the largest number of individuals living with chronic HBV are in the Western Pacific region and the smallest number in the Americas.⁴

Data from the National Health and Nutrition Examination Survey (NHANES) from 2007-2012 estimates that 10.8 million persons in the United States had ever been infected with HBV.⁵ 847,000 individuals (0.3% of the population) were estimated to be living with chronic infection in 2011-2012.⁵ However, NHANES may underestimate chronic infections prevalence due to under sampling in key subgroups (i.e., people born in higher prevalence countries, people who are institutionalized or incarcerated).^{2,6} Estimates attempting to account for this suggest there may be more than 2 million people living with chronic HBV in the United States.^{2,6} The highest rates of chronic HBV were identified in non-Hispanic Asians (3.1%) and non-Hispanic Blacks (0.6%).⁵ Foreign-born Americans have a 10-fold higher prevalence than those born in the United States (1.1% versus 0.1%). The prevalence in women is reported to be lower than in men (0.2%

versus 0.4%).⁵

Beginning in 1991, the United States implemented a public health strategy to control HBV in the United States including: screening all pregnant women for HBV, universal vaccination of all infants at birth, routine vaccination of previously unvaccinated children, and vaccination of adults at high risk for HBV infection.⁷ Over time, immunity has increased in the United States from 21.7 percent in 1999-2006 to 25.1 percent for 2007-2012. Rates of immunity are highest among those at younger ages with 44.4 percent immunity in those aged 6 to 19 compared with 8.7 percent in those aged 50 or older based on NHANES data from 2007-2012. However, while rates of immunity in older groups have increased over time, the rates of immunity in children aged 6 to 19 have significantly decreased from the previously recorded rate of 56.8 percent in the years 1999 to 2006.⁵

According to data from the Nationwide Inpatient Sample from 1998 to 2011, the prevalence of maternal HBV infection was 85.8 per 100,000 deliveries (0.09% of live-born singleton deliveries in the United States).⁸ Rates of maternal HBV infection have shown an annual increase of 5.5 percent since 1998 and have increased among nearly every population subgroup, especially among women aged 30 and older. Older maternal age was significantly associated with a higher rate of HBV infection, with mothers ages 30 and older 2.3 times more likely as teenaged mothers to be infected, likely due to the higher rates of vaccination among younger women of childbearing age. Non-Hispanic blacks and Asians were estimated to have a 5-fold and 12-fold increased odds of HBV infection, respectively.⁸ According to data from the National Health Interview Survey (NHIS) from 2013 to 2015, the greatest risk indicators for HBV infection among women ages 18 to 44 years were lower education, higher poverty levels, and lack of insurance coverage.⁹ One factor contributing to the rise in rates is increasing immigration of foreign-born women from areas with a higher prevalence of HBV, particularly from Asian countries.¹⁰ The majority of cases of HBV infection in the United States are among individuals who immigrated from endemic regions, were born to immigrant parents, or in exposed through close household contact with these HBV positive individuals.¹¹⁻¹³ Some of the observed increase in HBV infection among pregnant women also may be attributed to increased case-finding with the advent of screening for HBV in pregnant women.⁸

Natural History

An estimated 70 percent of healthy adults with acute HBV infections are asymptomatic, and the remainder have symptoms of liver disease (e.g., abdominal pain, jaundice).¹⁴ Fewer than 1.5% of acute HBV infections are fatal.⁷ The progression to chronic HBV (infection beyond 6 months) varies dramatically depending on age at the time of initial infection. Chronic infections develop in 80-90 percent of infants (<1 year of age) infected with HBV, in approximately 25-30 percent of acute infections before age 6, and in <1 to 12 percent among acutely infected older children or adults.^{7, 11} The remaining individuals generally resolve their HBV infection without sequelae and develop immunity. Chronic HBV can result in serious long-term health complications such as chronic hepatitis, cirrhosis, and hepatocellular carcinoma. Up to 25 percent of those who become chronically infected in childhood and 15 percent of those infected in adulthood will die prematurely from cirrhosis or liver cancer.⁷

The major well-established risk of harm associated with maternal HBV infection is perinatal transmission to the infant occurring most commonly through the process of delivery (caesarean section or vaginal). Higher levels of maternal HBV-DNA occurring with active viral replication are strongly predictive of perinatal transmission: among HBeAg- mothers, the perinatal transmission risk is approximately 30 percent, but for HBeAg+ mothers the risk rises to 85 percent.⁷ However, viral replication is present in some HBeAg- women, and evidence suggests that viral load, rather than HBeAg marker status may be most indicative of the risk of transmission.^{15, 16}

Rationale for HBV Screening in Pregnancy and Interventions to Prevent Perinatal Transmission and Current Clinical Practice

Prevention of perinatal transmission of HBV hinges upon the timely administration of prophylaxis, particularly for infants whose mothers are HBV positive.¹⁷ HBV screening has very high accuracy (sensitivity and specificity >98%) as established in studies by the CDC, FDA, and WHO in the 1980s and 1990s when the tests were developed.^{18, 19} Routine HBV screening in prenatal care is intended to ensure preventive interventions, including those recommended for all newborns regardless of HBV status (i.e., HBV vaccination). In the United States screening facilitates entry into a national case-management programs tasked with ensuring and documenting the delivery of evidence-based prophylaxis for HBV exposed infants.

Beginning in 1990, the Perinatal Hepatitis B Prevention Program (PHBPP), funded by the Centers for Disease Control and Prevention (CDC), was developed to identify HBV positive pregnant women and ensure that their infants receive timely, evidence-based postexposure prophylaxis.¹⁰ The Public Health Service Section 317 Immunization Grants Program and Prevention and Public Health Funds support the PHBPP in 64 jurisdictions: 50 states, 6 cities, 5 territories, and 3 freely associated island nations.^{20, 21} Grant recipients are required to submit yearly reports that include specific information on the number of infants born to HBV positive women identified by the program, timing of prophylactic interventions, serologic testing, and loss to followup.¹⁰ The Advisory Committee on Immunization Practices (ACIP) recommends that all HBV positive pregnant women should be referred to their jurisdiction's PHBPP for case management to ensure their infants receive timely prophylaxis and follow-up.⁷

Since its licensure in 1981, the HBV vaccine remains the most effective measure to control and prevent HBV infection, perinatal transmission, and long-term sequelae.^{22, 23} The ACIP first recommended universal HBV vaccination for infants in 1991.²⁴ Systematic reviews and clinical trials have consistently demonstrated high seroprotection rates among infants and healthy adults, age 40 years or younger, who have receive the complete vaccine series.^{22, 25-27} Prior to the development of the HBV vaccine, hepatitis B immune globulin (HBIG) administered within 12 hours of delivery was shown to be effective for reducing perinatal transmission by providing passive immunity and temporary protection (i.e., 3 to 6 months) from HBV.³ The most recent recommendation (2018) is for all infants to receive their first dose of the HBV vaccine within 24 hours, and for infants born to HBV positive mothers, infant vaccination and HBIG administration within 12 hours of birth.⁷

Since the introduction of standard guidelines for HBV postexposure prophylaxis in 1991, cases of chronic HBV in infants have declined by 75 percent; however, the CDC estimates that between 2000 and 2009 there were 800 to 1,000 infants (3.8% of babies born to HBV positive mothers) infected each year in the United States.¹⁰ Most of these cases occurred among infants of HBeAg+ women with high viral loads, with some infections theorized to occur in utero.⁵

Since 2015, the American Association for the Study of Liver Diseases (AASLD) has recommended the use of antiviral therapy to reduce perinatal HBV transmission in women with a high viral load (>200,000 IU/mL).^{11, 28} This recommendation was incorporated into the CDC/ACIP guidance in 2018.⁷

While screening for HBV in pregnant women has been universally recommended for decades, it is not fully implemented in prenatal care services. As of December 2013, 26 states required all pregnant women to be screened for HBV, with 19 of these mandating that screening occur at the first prenatal visit or shortly thereafter.²⁹ However, not all providers are aware of these legal requirements or the fact that HBV is a reportable infection.³⁰ Based on medical claims records from 2013-2014, 88 percent of commercially insured women received HBV testing during pregnancy, with 60 percent tested during the first trimester; however, rates were lower for Medicaid-enrolled women, with 84 percent tested, but only 39 percent during the first trimester.³¹ In addition, universal vaccination of all infants within the first 24 hours is recommended, but in 2016, only 71 percent of all infants born in the United States received their first vaccination within 3 days of birth, likely owing to patient and health system variation in adherence to recommendations. Due to the incomplete vaccination coverage at birth, ACIP, in 2016 removed previously permissive language that had allowed practitioners to consider delaying the birth dose. In 2016, 90 percent of United States born children were fully immunized (i.e., 3 doses received) by age 3.³²

Rationale and Supporting Evidence for Previous USPSTF Recommendations and Current Practice

No randomized trials of screening effectiveness for reducing HBV vertical transmission or health outcomes have been identified in prior USPSTF reviews. The original 1996 “A” recommendation to screen all pregnant women for HBV was based on reports showing that screening tests for HBV infection have high accuracy, and evidence from controlled trials and observational studies suggesting that neonatal vaccination and HBIG are effective for preventing perinatal transmission. The rationale for universal screening was based on evidence that identifiable risk factors (e.g., multiple sexual partners, exposure to human blood, contact with an infected individual, travel to high prevalence region) were present in only 35 to 65 percent of HBV positive pregnant women.³³⁻³⁸ In 2004 and again in 2009, the USPSTF reaffirmed their recommendation using brief evidence updates.^{39, 40}

Since the original 1996 recommendation statement, updated reaffirmation reviews for the USPSTF have found little additional evidence on the effectiveness or harms of screening and treatment for HBV in pregnancy. No studies meeting inclusion criteria were identified, but limited observational evidence supporting the effectiveness of prophylaxis has been cited in

reaffirmation reviews.^{41, 42, 43, 44} In 2009, no new trials of prenatal screening or newborn prophylaxis for HBV infection were identified and a cited Cochrane review on HBV vaccination that was cited only included studies published prior to 1996.^{45, 46} No previous reviews or new studies addressing the harms (e.g., consequences of a false-positive test) were identified. No new evidence was found for the benefits or harms of HBV screening in pregnant women in either evidence update.^{41, 45}

Recent reviews, including a network meta-analysis, support the preventive effectiveness of HBIG and vaccination and, more recently, the prenatal use of antiviral medication.^{25, 47-49} These reviews cite evidence limitations with regard to setting, sample size, and study protocols, and the need for further research. In particular, additional studies are needed on prenatal use of antiviral medication which may further reduce perinatal transmission beyond the already low rates observed when vaccination and HBIG are administered. A 2017 systematic review of comparative trials through August 2016 (n = 599 pregnancies) demonstrated that tenofovir significantly reduced the risk of infant infection when combined with HBIG and HBV vaccination.⁴⁷ In the trials, tenofovir was administered in the second or third trimester for HBV positive women with high viral loads (HBV DNA \geq 200,000 IU/mL).⁴⁷ A 2016 systematic review of randomized and observational studies drew similar conclusions and reported no increased risk of adverse maternal or fetal outcomes (e.g., congenital malformation rate, prematurity rate, Apgar scores) associated with antiviral treatment.⁴⁸ Case management programs are guided by regular updates on evidence-based practices from ACIP and CDC for prevention of perinatal transmission. Accordingly, new guidelines in January of 2018 recommended testing for viral load and treatment with antiviral therapy in addition to established vaccination and HBIG practices.⁷ Evidence in this area is still emerging. Most recently, a double-blind placebo-controlled trial (n=331) of tenofovir conducted in Thailand reported null findings for antiviral treatment coupled with HBIG and vaccination, but was underpowered given the low perinatal transmission rates (0 infections in the intervention group, 3 infections in the placebo group, p=.12).⁵⁰ The trial also did not identify a statistical difference in the rate of adverse events for the women or infants.

Chapter 2. Methods

Scope and Purpose

Screening for hepatitis B in pregnancy has been a standard of care for over 30 years, with an A recommendation from the USPSTF from its 1996 inception.^{39, 40, 51} In the United States, the aim of HBV screening in pregnancy is to identify women at risk of transmitting the infection to their infants to ensure the delivery of effective prophylactic interventions. In the United States, a federal CDC program, the PHBPP, funds, coordinates, and documents the delivery of effective interventions to prevent perinatal transmission through case management programs. Case management is also practiced in some private health care systems, where the care of women who screen positive for HBV is organized through patient tracking and evidence-based care protocols.⁵² The scope of this review was designed to focus on overarching effectiveness and potential harms of screening and on the effectiveness and harms of case management to prevent perinatal transmission.

The USPSTF has based previous recommendations for this topic on the following factors, and previous evidence updates have not identified new or contrary evidence: 1) screening for HBV in pregnant women is feasible in primary care and has high test accuracy and 2) there are effective interventions to prevent vertical transmission of HBV that are rarely harmful.

Given the lack of formal trials evaluating the effectiveness of screening for HBV in pregnancy, the included key questions were scoped to allow for observed populations changes in HBV outcomes within geographic and historical comparisons of screening practices.

Given the recognized effectiveness of individual interventions (i.e., vaccination, HBIG) and the available guidance on protocols for prophylaxis from CDC and ACIP, the key questions related to treatment guiding this review were focused on the effectiveness of case-management programs. The focus on case management is motivated by the fact that it is the recommended intervention in the United States for all HBV positive pregnant women. Thus, the key questions were intended to identify evidence on the effects of screening and case management on perinatal transmission of hepatitis B and any associated harms.

Analytic Framework and Key Questions

In consultation with members of the USPSTF, we developed an Analytic Framework (**Figure 1**) and four Key Questions (KQs) to guide the literature search, data abstraction, and data synthesis.

Key Questions

1. What are the observed population benefits of universal hepatitis B screening programs during pregnancy?
2. What harms have been observed in programs of universal HBV screening during pregnancy?

3. What is the effectiveness of case management programs to prevent perinatal transmission among HBV positive pregnant women?
4. What harms have been observed in case management programs to prevent perinatal transmission among HBV positive pregnant women?

Data Sources and Searches

We conducted a literature search of MEDLINE, PubMed Publisher-Supplied Records, the Cochrane Database of Systematic Reviews, the Cochrane Central Register of Controlled Trials (CENTRAL), the Cumulative Index for Nursing and Allied Health Literature (CINAHL), Embase, and PsycInfo from January 1, 1986, to May 3, 2018. The search start date was selected to coincide with the availability of the recombinant vaccine for HBV in the United States. We worked with a research librarian to develop our search strategy, which was peer-reviewed by a second research librarian (**Appendix A**). We supplemented these searches by reviewing reference lists of recent reviews and primary studies. The searches were limited to articles published in English. We managed literature search results using Endnote® version X7 (Thomson Reuters, New York, NY).

Study Selection

We developed specific inclusion criteria to guide study selection (**Appendix A Table 1**). Two reviewers independently reviewed the titles and abstracts of all identified articles using DistillerSR (Evidence Partners, Ottawa, Canada). Two reviewers then independently evaluated the full text of all potentially relevant articles. We resolved differences in the abstract or full-text review by discussion. For all KQs, we included studies conducted in countries categorized as “high” or “very high” on the Human Development Index. Studies conducted in settings without universal birth vaccination programs were excluded since findings would not be applicable to the United States setting. For all key questions we included randomized and nonrandomized controlled trials and large observational cohort studies, including ecologic studies and those with historical or geographical comparator controls. We excluded editorials, narrative reviews, and case studies.

For KQ1 and KQ3 studies reporting on the perinatal transmission rates for screening and case management programs were considered for inclusion. For KQ2 and KQ4, evidence on the potential harms of screening and case management programs, including potential psychological, psychosocial, or other negative consequences for pregnant women or their children were considered for inclusion.

Quality Assessment and Data Abstraction and Synthesis

Two reviewers independently assessed the methodological quality of each included study using predefined criteria based on the Newcastle-Ottawa scale and the National Heart Lung and Blood Institute Quality Assessment Tool for Before-After (Pre-Post) Studies with No Control Group

(**Appendix A Table 2**);^{53, 54} disagreements were resolved by discussion. We extracted important^{53, 54} study design, setting, and participant characteristics (e.g., demographic characteristics, health conditions) and outcomes and synthesized the evidence from included studies in a narrative format.

Expert Review and Public Comment

A draft Research Plan for this review was available for public comment from July 13, 2017 to August 9, 2017. Comments received during this period were reviewed, considered, and addressed as appropriate. This full draft report was shared with invited expert reviewers and federal partners. We compiled the comments received from these invited experts and addressed them in the report when appropriate.

USPSTF Involvement

This evidence update was funded by AHRQ, under contract, to support the USPSTF. We consulted with USPSTF members during development of the research plan (i.e., Key Questions, analytic framework, and inclusion criteria). An AHRQ Medical Officer provided project oversight, reviewed the draft and final versions of the evidence update, and assisted with public comment on the research plan and draft report. The USPSTF and AHRQ had no role in the study selection, quality assessment, or writing of the evidence update.

Chapter 3. Results

Literature Search

Our literature search yielded 5688 unique citations. From these citations, we accepted 499 articles for review based on titles and abstracts (**Appendix A Figure 1**). After reviewing the full-text articles and conducting critical appraisal, we included two fair-quality studies for KQ3. **Appendix B** contains a list of all full-text articles and their reasons for exclusion. No studies were excluded based on study quality.

No eligible studies were identified that directly investigated the population benefits of universal HBV screening in pregnancy. Broad criteria were used to identify potentially relevant studies based on title and abstract screening; however, no studies that examined the rates of HBV transmission before and after the implementation of a perinatal screening program were found. Many of the studies reviewed that were excluded focused on the rates of decline in HBV due to the implementation of targeted or universal vaccination programs or, particularly in the older literature, examined the comparative effectiveness of individual strategies for the prevention of HBV transmission (e.g., HBIG vs. placebo, various vaccination doses) and did not address a key question. Among studies evaluating case management programs, many reported outcomes at a single time point without a historical or geographical comparator necessary to establish program effectiveness. Harms outcomes were not reported in any of the studies reviewed for inclusion.

Results of Included Studies

Key Question 1. What Are the Observed Population Benefits of Universal Hepatitis B Screening Programs During Pregnancy?

No eligible studies were identified that directly examined the population benefits of universal HBV screening in pregnancy. We did not find any studies comparing screened to unscreened populations that met the eligibility criteria. The primary reasons for exclusion of these studies were the lack of a comparator (i.e., data across time or locations) and lack of perinatal HBV transmission outcomes.

Key Question 2. What Harms Have Been Observed in Programs of Universal HBV Screening During Pregnancy?

No eligible studies were identified that directly examined the harms of universal HBV screening programs in pregnancy.

Key Question 3. What Is the Effectiveness of Case Management Programs to Prevent Perinatal Transmission Among HBV Positive Pregnant Women?

We identified two studies that met the inclusion criteria for KQ3: a fair-quality observational study reporting a historical trend in infant outcomes with infants case management through the Perinatal Hepatitis B Prevention Program (PHBPP), which is administered by the Centers for Disease Control and Prevention (CDC)⁵⁵ and a fair-quality observational study reporting the trend in perinatal transmission associated with infant case management provided in a coordinated care health system (Kaiser Permanente Northern California).⁵²

In addition to rates of perinatal transmission (key outcome), the studies reported time trend data on the estimated proportion of HBV positive women identified for case management and the time trends in the proportion of their infants receiving vaccination at birth, series completion by 12 months, and postvaccination testing for HBV immunity or infection.

National Perinatal Hepatitis B Prevention Program Study Results

Data from the PHBPP for a cohort of infants born from 1994 to 2008 were reported, with perinatal transmission outcomes reported for infants born 1999 to 2008.⁵⁵ Outcomes were reported by the PHBPP two years after the birth year and perinatal transmission rates could be estimated only among those for whom HBV serologic testing was complete.

There was a statistically significant increasing trend over time (1994-2008) in the estimated number of births to HBV positive women in the United States (19,208 to 25,600, $p < .001$) (Table 1). The proportion of infants born to HBV positive women that were identified by the PHBPP for case management also increased over time, starting at 42.1 percent in 1994 and increasing to 47.9 percent in 2008 ($p = .002$). The number of case-managed infants also rose over time, from 7,415 in 1994 to 12,033 in 2008 ($p < .001$).

Serologic testing for HBV is an indicator of completed case management because it is conducted after the completion of the three-dose vaccination series (CDC recommended testing by 9 to 18 months of age over the study period). and determines whether prophylaxis was successful. Of the case-managed infants in PHBPP, rates of serologic testing within 24 months of birth increased over the study period, more than doubling from 25.1 percent in 1994 to 55.7 percent in 2008 ($p < .001$). A statistically significant downward trend in the perinatal transmission rate from 1999 to 2008 was also reported. In 1999, of the 3,826 infants tested, 71 were infected with HBV (1.9%), and in 2008, of the 6,697 infants tested, 56 were infected (0.8%), a statistically significant decreasing trend ($p = .001$).

More of the estimated cases of HBV among pregnant women in the United States were case-managed through the PHBPP over the study period. Rates of HBIG and vaccination at birth (>90%) and completion of the three-dose vaccination series by 6-8 months (>70%) among those who were case-managed held steady, with nonstatistically significant tests for trend ($p = .126$ and $p = .734$, respectively). There was, however, a decline in the proportion of case-managed infants receiving the full vaccine series by 12 months ($p < .001$), with rates dipping below 80 percent in

2001 from a high of 86 percent in 1994.

This observational study contributes evidence that the infant case management program, as implemented from 1994 to 2008, achieved improvements in identifying women with HBV, enrolling their infants and maintained high levels of preventive interventions.

Reporting on the proportion of PHBPP case-managed infants lost to followup was required starting in 2004. From 2004 to 2008, there was not a statistically significant trend over time in loss to followup (range 13-26%, $p = .126$), but the lowest rate was reported in 2008. Reported reasons for loss to followup did not differ, with one exception: “family refused” increased as a stated reason for noncompletion of case management. Overall, the most common reasons reported were “moved out of country” (24%) or could not locate (33%).

The reductions in perinatal HBV transmission reported in this observational study could have been influenced by secular changes outside of the PHBPP (e.g., universal vaccination practices). Within PHBPP, rates of HBIG administration and HBV vaccination at birth remained steady and high across the time period – ranging from 90 to 97 percent from 1999 to 2008, and completion of all three vaccination doses by 12 months 78 to 80 percent for the same time period. Postvaccination serologic testing increased over this period, allowing calculation of perinatal transmission rates for a greater proportion of infants in PHBPP. The reported perinatal transmission rate could also be affected by changes in record keeping and tracking of infants in PHBPP, potentially with those cases at greater risk least likely to have completed the program. Observed improvements in serologic testing and reduced loss to followup, however, suggest that data may be more complete in recent years.

The loss to followup in the PHBPP included study was nearly one-quarter of women in 2004 and just over 1 in 10 in the most recent year reported. The loss to followup in the PHBPP program highlights challenges studying and tracking the population at greatest risk of perinatal HBV transmission, as populations most at risk, such as immigrants, lower-income populations, and women with substance abuse disorders, are also more likely to face instability in housing, employment, and health care access. The available data suggests that followup in PHBPP improved over time, possibly increasing the presence of higher risk infants in the study data over time, so the observed trend is more likely an underestimate of the benefit of case management. Overall, completion of PHBPP case management is associated with low and falling rates of perinatal transmission.

Health System Study Results

An observational study using data on births ($n = 4,446$) to HBV positive women receiving clinical care in a coordinated, managed care health setting reported on the trend over time from 1997 to 2010 in perinatal transmission of hepatitis B (**Table 2**).⁵² The health system commenced a Regional Perinatal Screening Hepatitis B (RPSHB) program in 1988. Women in the health system are screened during prenatal care and if found to be HBV positive entered into the health system’s case management system (“tracking program”) to support on time delivery of immunoprophylactic interventions and followup testing. Of the 4,446 infants born to HBV positive pregnant women identified from 1997-2010, most received HBIG and vaccination

within the recommended time frames (i.e., >97% received HBIG and HBV vaccine within 12 hours of birth). Eighty-five percent of infants (n=3,353) were tested for HBV infection, with the highest rates of testing reported in recent years (93% for 2006-2010, before infant 12 months of age). The overall, rate of perinatal transmission over the time period were very low: 0.75 per 100 tested infants (25/3,353). A decreasing trend was observed in perinatal infection from 1997 to 2010 (IRR = 0.90, 95% CI 0.82-1.00). This could be attributed to changes in case management (e.g., viral load testing in later years) or to differences in case ascertainment (i.e., retroactive serologic testing in earlier years, more infants tested in later years), or a combination these factors as well as other unmeasured factors. Overall, the study demonstrates high effectiveness of modern prophylactic interventions for insured pregnant women and infants case managed in a coordinated health system.

Key Question 4. What Harms Have Been Observed in Case Management Programs to Prevent Perinatal Transmission Among HBV Positive Pregnant Women?

No eligible studies were identified that reported on harms of case management programs for pregnant women with HBV.

Chapter 4. Discussion

Summary of Evidence

Two fair-quality observational studies provide evidence on the effectiveness of case management for delivering prophylaxis to prevent perinatal transmission of HBV, and evidence that over time, reductions in perinatal transmission have been observed for woman and infants enrolled in case management. These improvements may be owing to a combination of factors, such as improvements in the evidence-based protocols that are implemented in the programs, refinements in the case management process whereby tracking of infants and delivery of interventions have improved. Changes in record-keeping, loss to followup, and population demographics could also influence the reported findings, given that these are observational data. National data from the Perinatal Hepatitis B Prevention Program (PHBPP) in the United States provided evidence that case management for prevention of perinatal transmission is associated with low infection rates that have declined over time. At the same time, higher rates of maternal HBV case identification and infant program completion (serologic testing 2 years after birth) were reported. More complete data from a regional health system that employs a coordinated case management program is consistent with the national data trend, with rising rates of testing for HBV infection for case managed infants, and the lowest rates of perinatal transmission observed in the most recent years (2006-2010).

Prior to the development of HBV prophylaxis, it was estimated that up to 40% of infants born to HBV positive mothers would become infected.⁵⁶ An established body of evidence has demonstrated the effectiveness of prophylactic interventions, as recommended by CDC and ACIP, for reducing the risk of perinatal transmission. Foundational evidence from an earlier era and observational data from case management programs in the modern era together support the value of prenatal screening to identify infants for prophylactic interventions. Screening identifies women whose infants would benefit from case management, through timely delivery of recommended prophylaxis. Infants of HBV positive women in case management programs exhibit very low, declining rates of perinatal transmission over time.

As in previous reviews on this topic, no comparative studies were identified on the benefits or harms of screening. Screening pregnant women for HBV is standard care, but recommended universal vaccination of all infants at birth also serves as a safeguard to prevent infection among infants whose mothers' infections are not identified through prenatal screening. A downward trend in perinatal HBV transmission in the United States as case management completion increased highlights the value of screening women to determine HBV status during pregnancy in the setting of universal birth vaccination. Even if universal birth vaccination recommendations were fully implemented, screening and case-management may confer additional benefit for coordinating the delivery of additional interventions recommended for infants born to HBV positive women. The additional benefit of HBIG administration at birth for vaccinated infants born to HBV positive women was supported in a recent network meta-analysis), although most included studies in this review were among women who were HBeAg+ or had a high viral load and several studies were evaluated to have high risk of bias. Further research is needed to strengthen the evidence base with regard to protocols for HBIG administration at birth and

potentially in the prenatal period.^{25, 57, 58} Limited evidence suggests potential preventive benefits of antiviral treatment before birth for women with high HBV viral loads.^{47, 48}

Screening for HBV during pregnancy facilitates entry into case management in the United States. The rate of women entering the PHBPP based on screening during pregnancy (i.e., women not already known to have a HBV infection) has not been reported; however, data from a large urban hospital in Boston spanning the years 1995 to 2014 indicated that over one-third (37%) of pregnant women with chronic HBV were initially diagnosed at a first prenatal visit.⁵⁹

Public health policy and health institution practices play an important role in improving prevention of perinatal HBV transmission. Earlier evidence suggests that state and hospital policies requiring HBV screening increased the likelihood of women's HBV positive status being recorded in medical charts. Further, enhanced case management by health care delivery systems, including routine reminders, flags in patient charts, and standing orders for birth vaccination, were shown to improve the receipt of timely vaccination and HBIG.⁶⁰ Demonstrations of improved intervention rates in clinical settings serving subpopulations with higher chronic HBV rates are particularly encouraging.⁶¹ Rates of HBV screening in pregnancy are high in the United States; research to ensure that case management care reaches those who screen positive may require a focus on health system quality-improvement interventions. Finally, women with poor access to health care are at greater risk of not being screened until delivery or not at all, reducing the time available to plan the best prophylactic intervention. Efforts are needed to improve outreach and screening for HBV and other preconception health risks to vulnerable populations.⁶²

Review Limitations and Future Research Needs

For this review, we sought overarching evidence on population-wide screening programs for reducing perinatal transmission. Only two studies were identified that met the inclusion and exclusion criteria for a key question. The included studies, however, are highly relevant for evaluating recommended interventions for preventing perinatal transmission of HBV in the United States. It was not possible to identify studies that could disentangle the effects of prenatal screening from effects of universal birth vaccination, as these practices emerged around the same time, and their contributions to prevention of perinatal transmission are confounded.

This review supports the broad conclusion that screening can facilitate the receipt of prophylactic interventions, and referral to effective case management programs. There is foundational evidence on individual intervention effectiveness (vaccination, HBIG) and data from case management programs demonstrating very low rates of perinatal transmission. There were no serious harms of screening or case management identified in the included studies, but theoretical harms, such as false-positive results and inappropriate entry into case management, would likely be corrected with additional testing in the PHBPP throughout the course of pregnancy.

The availability of effective interventions and their adoption by national case-management programs will continue to be guided by emerging evidence and established practice. Recent

reviews and recommendations continue to support the notion that active and passive prophylaxis likely provide the greatest degree of protection from HBV.^{3, 25} Systematic reviews focused on the use of antiviral medications during pregnancy for women with acute infections and high viral load have also identified the need for further research to prevent perinatal transmission in these highest risk cases. Efforts to further increase the proportion of infants identified for and completing case management, accompanied by implementation of recommended interventions, may further reduce rates of perinatal transmission of HBV. More recent data from the PBHPP program would be informative for understanding current program performance and research needs. Finally, research and targeted resources are needed to ensure that case-management is effectively implemented and reaches vulnerable populations most at risk for perinatal transmission of HBV. Improving access to prenatal care, screening, and integration of public health and clinical health services to facilitate case-management are among the strategies outlined to help to eliminate perinatal HBV infection in the United States,⁶³ a goal of the 2017-2020 National Viral Hepatitis Action Plan.⁶⁴

Conclusions

This evidence update includes two observational studies of case-management interventions conducted in the United States, bolstered by a larger body of evidence establishing the effectiveness of interventions to prevent perinatal HBV transmission. The comprehensive strategy for the elimination of perinatal HBV transmission in the United States includes the use of routine screening of all women for HBV in pregnancy, along with universal vaccination of all infants and additional prophylactic measures to those born to HBV positive mothers. Within the United States public health system, case management programs can ensure implementation of recommended protocols for prevention of perinatal transmission of HBV. Although direct evidence of the effects of screening on perinatal transmission is not available, screening in pregnancy is an important step toward appropriate delivery of prophylactic interventions. Screening in pregnancy identifies women eligible for case management which is associated with a very low risk of perinatal transmission. Until the public health goal of eliminating HBV infections in the United States is achieved, screening in pregnancy to identify opportunities to prevent perinatal transmission will remain important.

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Figure 1. Analytic Framework

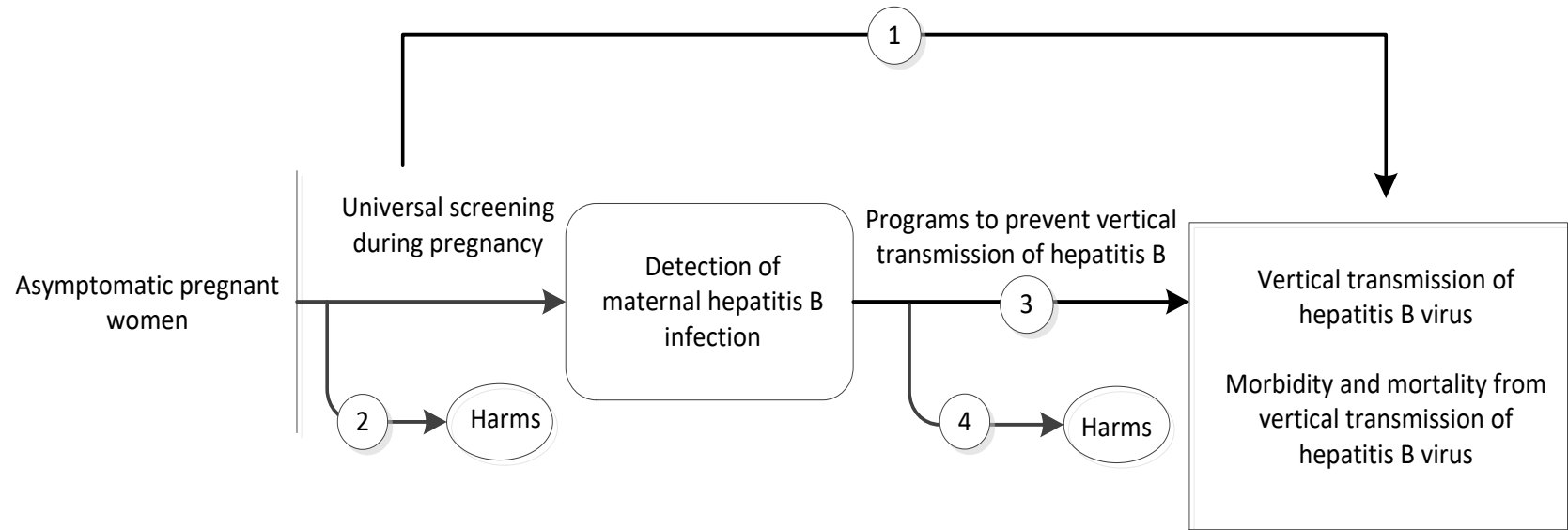


Table 1. Results From the PHBPP on Infants Born to HBV Positive Women in the United States⁵⁵

Outcome	Calculation	Time	Range
PHBPP coverage	Percentage of infants born to HBV positive women in the United States ^a identified for PHBPP case management	1994-2008	Increase from 42.1% in 1994 to 47.9% in 2008 (p=.002). As estimated number of births continued to rise, stable coverage of ~50% Number of case-managed infants increased from 7,415 to 12,033
Postvaccination serologic testing completed ^b	N with serologic testing/N case managed	1994-2008	Increase from 25.1% in 1994 to 55.7% in 2008 (p<.001) Number of case-managed infants receiving serologic testing increased from 1,860 to 6,697
HBV positivity among infants completing case management	N HBV infected / N serologically tested	1999-2008	Decrease from 1.9% in 1999 to 0.8% in 2008 (p<.001)

^a The study authors used deidentified U.S. natality and HBV prevalence data to calculate trends in the estimated number of births to HBV positive women. Data were reported for women of childbearing age by race and ethnicity, primarily obtained through the National Health and Examination Survey (NHANES). The number of women identified through the PHBPP for case management was then divided by this estimated number of births to HBV positive women and reported by year.

^b Within 24 months of birth

Abbreviations: HBV = hepatitis B virus; N = number of people; PHBPP = Perinatal Hepatitis B Prevention Program

Table 2. Perinatal Transmission Among Infants Born to HBV Positive Women Enrolled in KPNC Case Management, 1997-2010⁵²

Outcome	Total 1997-2010	1997-2000	2001-2005	2006-2010	Trend
Infants born to HBV+ women at KPNC, N (range per year)	4,446 (261 to 381)	1,152	1,616	1,678	NR
Postvaccination serologic testing for infection completed, N (%)	3,353 (85)	715 (70)	1235 (86)	1,403 (93)	NR
Rate of HBV positivity among infants tested for HBV infection (HBsAg+) ^a	0.75 (0.48-1.10)	1.12 (0.42-2.21)	0.81 (0.39-1.49)	0.50 (0.20-1.03)	Poisson IRR = 0.90 (95% CI 0.82, 1.00)

^aRate per 100 children tested; Poisson distribution-based 95% confidence interval.

Abbreviations: HBV = hepatitis B virus; N = number of people; KPNC = Kaiser Permanente Northern California

Table 3. Snapshot of the Evidence

	Rationale and foundational evidence for previous Hepatitis B Screening in Pregnancy USPSTF recommendations^{39, 40, 51}	New evidence findings	Limitations of new evidence	Consistency of new evidence with foundational evidence and current understanding
Benefits	<p>Screening: Screening is highly accurate and identifies infants at risk of perinatal transmission. Universal screening is important because known risk factors only present in 35-65% of HBV positive pregnant women.</p> <p>Treatment: There are effective preventive measures (i.e. vaccination within 12 hours of birth, HBIG administration) for preventing perinatal transmission and sequelae.</p>	<p>Screening: No new evidence</p> <p>Treatment (case-management): Two observational studies of the effectiveness of case management programs for infants at risk for perinatal hepatitis B transmission in the United States; one study of the national public health system program and one study in an integrated health system.</p> <p>Case management in the integrated health system attained very high rates of on time prophylaxis completion.</p> <p>Very low perinatal transmission rates reported in most recent years (0.5%-0.8%) that had been trending downward over time.</p>	<p>Observational studies that cannot control for the effects of trends over time in historical, population, or record-keeping factors that could also influence estimates.</p> <p>Program data are not complete and based on unverified reports by physicians, hospitals and laboratories; loss to followup, missing data, and differences in data collection procedures may have had a greater effect on estimates from earlier years of data.</p>	<p>The included observational studies suggest improving trends for perinatal transmission prevention among infants that have completed case management programs.</p> <p>A high proportion of case managed infants are documented as having HBIG and HBV vaccination at birth and 3 vaccine doses by 12 months.</p> <p>Screening for hepatitis B in pregnancy can identify infants at risk of perinatal transmission to identify them for case management.</p>
Harms	<p>Screening: Highly accurate test, low false positive rate, no serious harms reported.</p> <p>Treatment: None identified, universal vaccination of all infants recommended regardless of maternal HBV status; HBIG harms not reported.</p>	<p>Screening: No new studies of screening were identified.</p> <p>Treatment: No harms of screening or case management were reported in the included study.</p>	<p>Program data does not capture potential harms of screening, other than reasons for loss to case management program followup.</p>	<p>No harms of screening or case management reported in foundational or included evidence.</p>

Abbreviations: HBV = hepatitis B virus; N = number of people; PHBPP = Perinatal Hepatitis B Prevention Program; HBIG = Hepatitis B Immunoglobulin

Appendix A. Literature Search Strategies for Primary Literature

Search Strategies

Sources searched:

Cumulative Index for Nursing and Allied Health Literature (CINAHL), via EBSCO

Cochrane Central Register of Controlled Clinical Trials, via Wiley

Cochrane Database of Systematic Reviews, via Wiley

EMBASE

MEDLINE, via Ovid

PsycInfo, via Ovid

PubMed, publisher-supplied

Key:

* = truncation

\$ = truncation

ab = word in abstract

de = index term

exp = explode

id = keyword

kw = keyword

la = language

lim = limit

py = publication year

ti = word in title

CINAHL

Published Date: 19860101-20171231; English Language; Exclude MEDLINE records

S12 S3 AND S11

S11 S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10

TI ((vertical* or maternal* or mother or fetomaternal* or foetomaternal* or maternofetal* or maternofetal*) N3 (transmission or transmit* or transfer*)) OR AB ((vertical* or maternal* or mother or fetomaternal* or foetomaternal* or maternofetal* or maternofetal*) N3 (transmission or transmit* or transfer*))

TI ((pregnan* or prenatal or "pre natal" or perinatal or "peri natal" or peripartum or "peri partum" or obstetric*)) OR AB ((pregnan* or prenatal or "pre natal" or perinatal or "peri natal" or peripartum or "peri partum" or obstetric*))

S8 (MH "Disease Transmission, Vertical")

S7 (MH "Pregnancy Outcomes")

S6 (MH "Prenatal Care") OR (MH "Maternal-Child Care") OR (MH "Obstetric Care") OR (MH "Perinatal Care")

S5 (MH "Pregnancy+") OR (MH "Pregnancy Trimesters+")

S4 (MH "Expectant Mothers")

S3 (S1 OR S2)

S2 TI (("hepatitis b" or hbv) OR AB (("hepatitis b" or hbv))

S1 (MH "Hepatitis B") OR (MH "Hepatitis B, Chronic")

Appendix A. Literature Search Strategies for Primary Literature

Cochrane Central Register of Controlled Trials : Issue 8 of 12, August 2017

- #1 ("hepatitis b" or hbv):ti,ab,kw
 - #2 pregnan*:ti,ab,kw
 - #3 (prenatal or "pre natal"):ti,ab,kw
 - #4 (perinatal or "peri natal"):ti,ab,kw
 - #5 (antenatal or "anti natal"):ti,ab,kw
 - #6 (ante partum or "ante partum"):ti,ab,kw
 - #7 (peripartum or "peri partum"):ti,ab,kw
 - #8 obstetric*:ti,ab,kw
 - #9 (vertical* or maternal* or mother or fetomaternal* or foetomaternal* or maternofetal* or maternofetal*):ti,ab,kw near/3 (transmission or transmit* or transfer*):ti,ab,kw
 - #10 ^{40-#9-#9} 41439
 - #11 #1 and #10 Publication Year from 1986 to 2017
-

EMBASE

- #17
- #16 AND 'english':la AND [1986-2017]/py
- #16
- #4 AND #15
- #15
- #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #14
- #14
- #12 AND #13
- #13
- 'transmission':ti OR 'transmit*':ti OR 'transfer*':ti
- #12
- 'vertical*':ti OR 'maternal*':ti OR 'mother':ti OR 'fetomaternal*':ti OR 'foetomaternal*':ti OR 'maternofetal*':ti OR 'maternofetal*':ti
- #11
- 'pregnan*':ti OR 'prenatal':ti OR 'pre natal':ti OR 'perinatal':ti OR 'peri natal':ti OR 'peripartum':ti OR 'peri partum':ti OR 'obstetric*':ti
- #10
- 'vertical transmission'/de
- #9
- 'obstetric procedure'/de
- #8
- 'perinatal care'/de OR 'perinatal period'/de OR 'perinatal exposure'/de
- #7
- 'prenatal care'/de OR 'prenatal period'/de OR 'prenatal exposure'/de
- #6
- 'pregnant woman'/de
- #5
- 'pregnancy'/exp
- #4
- #1 OR #2 OR #3
- #3
- 'hepatitis b':ti,ab,kw OR 'hbv':ti,ab,kw
- #2
- 'hepatitis b virus'/exp
- #1
- 'hepatitis b'/exp

Appendix A. Literature Search Strategies for Primary Literature

MEDLINE

Database: Ovid MEDLINE(R) <1946 to September Week 2 2017>, Ovid MEDLINE(R) Epub Ahead of Print <September 25, 2017>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <September 25, 2017>, Ovid MEDLINE(R) Daily Update <September 25, 2017>

Search Strategy:

-
- 1 Hepatitis B/
 - 2 Hepatitis B, Chronic/
 - 3 Hepatitis B virus/
 - 4 (hepatitis b or hbv).ti,ab.
 - 5 or/1-4
 - 6 Pregnancy/
 - 7 Pregnancy Trimester, First/
 - 8 Pregnancy Trimester, Second/
 - 9 Pregnancy Trimester, Third/
 - 10 Pregnant women/
 - 11 Prenatal Care/
 - 12 Perinatal Care/
 - 13 Prenatal Diagnosis/
 - 14 Pregnancy Outcome/
 - 15 Pregnancy Complications, Infectious/
 - 16 Infectious Disease Transmission, Vertical/
 - 17 (pregnan\$ or prenatal or pre natal or perinatal or peri natal or antenatal or ante natal or antepartum or ante partum or peripartum or peri partum or obstetric\$).ti,ab.
 - 18 ((vertical\$ or maternal\$ or mother or fetomaternal\$ or foetomaternal\$ or maternofetal\$ or maternofetal\$) adj3 (transmission or transmit\$ or transfer\$)).ti,ab.
 - 19 or/6-18
 - 20 5 and 19
 - 21 Animals/ not (Humans/ and Animals/)
 - 22 20 not 21
 - 23 limit 22 to (english language and yr="1986 -Current")
 - 24 remove duplicates from 23
-

PsycInfo

Database: PsycINFO <1806 to September Week 3 2017>

-
- 1 (hepatitis b or HBV).ti,ab,id.
 - 2 Pregnancy/
 - 3 Prenatal Care/
 - 4 Perinatal Period/
 - 5 Expectant Mothers/
 - 6 Mother Child Relations/
 - 7 Obstetrics/
 - 8 Pregnancy Outcomes/
 - 9 pregnan\$.ti,ab,id.
 - 10 prenatal.ti,ab,id.
 - 11 pre natal.ti,ab,id.
 - 12 perinatal.ti,ab,id.
 - 13 peri natal.ti,ab,id.

Appendix A. Literature Search Strategies for Primary Literature

- 14 peripartum.ti,ab,id.
- 15 peri partum.ti,ab,id.
- 16 obstetric\$.ti,ab,id.
- 17 ((vertical\$ or maternal\$ or mother or fetomaternal\$ or foetomaternal\$ or maternofetal\$ or maternofetal\$) adj3 (transmission or transmit\$ or transfer\$)).ti,ab,id.
- 18 or/2-17
- 19 1 and 18
- 20 limit 19 to (english language and yr="1986 -Current")

PubMed [publisher-supplied records]

#5	#4 AND publisher[sb] AND English[Language] AND ("1986"[Date - Publication] : "3000"[Date - Publication])
#4	#1 AND (#2 OR #3)
#3	(vertical*[tiab] OR maternal*[tiab] OR mother[tiab] OR fetomaternal*[tiab] OR foetalmaternal*[tiab] OR maternofetal*[tiab] OR maternofetal*[tiab]) AND (transmission[tiab] OR tranmit*[tiab] OR transfer*[tiab])
#2	pregnan*[tiab] OR prenatal[tiab] OR "pre natal"[tiab] OR perinatal[tiab] OR "peri natal"[tiab] OR antenatal[tiab] OR "ante natal"[tiab] OR antepartum[tiab] OR "ante partum"[tiab] OR peripartum[tiab] OR "peri partum"[tiab] OR obstetric*[tiab]
#1	"hepatitis b"[tiab] OR hbv[tiab]

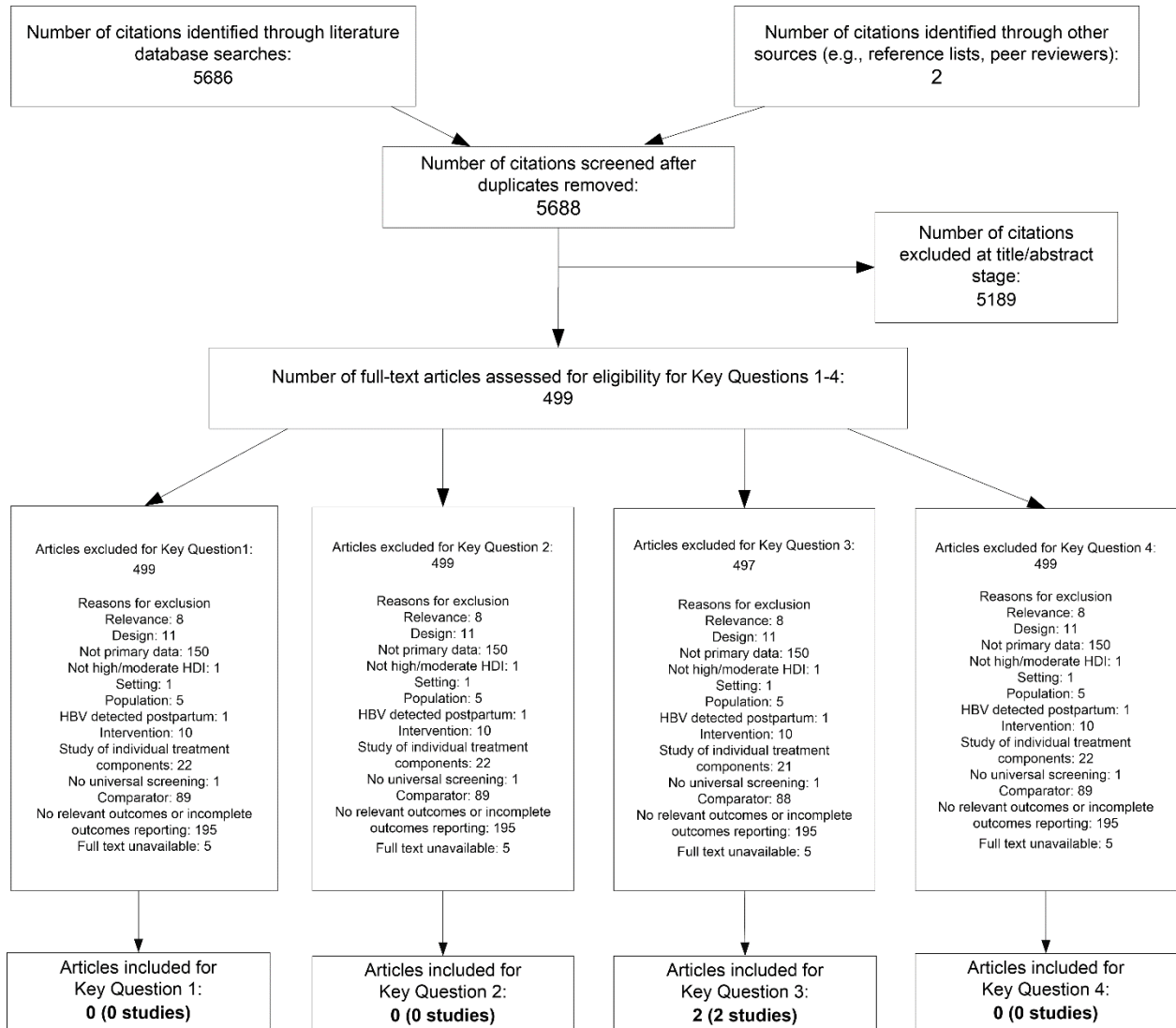
Appendix A Table 1. Inclusion and Exclusion Criteria

	Included	Excluded
Aim	To evaluate the effects of prenatal screening for hepatitis B virus infection on health outcomes and transmission rates and the effects of management and treatment programs among pregnant women with hepatitis B virus infection	
Populations	KQs 1, 2: Pregnant women at any gestation who are not known to have an acute or chronic hepatitis B virus infection KQs 3, 4: Pregnant women with acute or chronic hepatitis B virus infection	KQs 1, 2: Pregnant women who are known to have hepatitis B virus infection; women who are not pregnant; male partners of pregnant women
Interventions	KQs 1, 2: Universal screening for hepatitis B surface antigen KQs 3, 4: Organized programs aimed at preventing vertical transmission of hepatitis B virus infection among pregnant women; management and followup programs that deliver effective/recommended prophylactic interventions for women and neonates to reduce vertical transmission of hepatitis B virus infection	KQs 1, 2: Viral load followup testing among screen-positive women
Comparisons	KQs 1, 2: No screening; targeted screening KQs 3, 4: Comparisons of vertical transmission of hepatitis B virus infection associated with program implementation across time, geographic sites, or populations, both with and without case management for followup and immunotherapy	
Outcomes	KQs 1, 3: Mother-to-child transmission of hepatitis B virus infection; infant morbidity and mortality from perinatal hepatitis B virus infection KQ 2: Harms from the screening test or receipt of test results KQ 4: Harms from management of screen-detected hepatitis B virus infection; negative effects on maternal and infant health	KQ 1: Diagnostic accuracy KQ 3: Effects of individual interventions for hepatitis B virus infection (e.g., antiviral treatment) administered outside of a care program KQ 4: Harms of specific pharmacologic interventions
Setting	Any health care setting or level of care	Settings where universal vaccination of newborns for hepatitis B virus infection is not recommended or practiced
Country	Studies conducted in countries categorized as “high” to “very high” on the Human Development Index (as defined by the United Nations Development Programme)	Studies conducted in countries not categorized as “high” or “very high” on the Human Development Index
Study Design	KQ 1: Randomized or clinical controlled trials, systematic reviews, before-after, and observational cohort and ecologic studies with a historical or geographic comparator KQs 2–4: All of the above plus cohort studies, case series, and registry data	KQs 3, 4: Trials examining the effectiveness of individual pharmacologic treatments to prevent vertical transmission of hepatitis B virus infection administered outside of a care management program
Language	English-language only	Languages other than English
Study Quality	Fair- or good-quality studies	Poor-quality studies
Publication Dates	1986 to the present	Studies conducted prior to the introduction of vaccination for hepatitis B virus infection

Appendix A Table 2. Quality Rating Criteria

Study Design	Criteria
Cohort studies, adapted from the Newcastle-Ottawa Scale ⁵⁴	Was the exposed cohort(s) representative of the general population? Was the non-exposed cohort selected from the same community as the exposed cohort? How was “exposure” ascertained? Was it demonstrated that the outcome of interest was not present at the start of the study? Were the cohorts comparable on the basis of the design or analysis? Were outcome assessors blind? Was followup long enough for outcomes to occur? Was there adequate followup of cohorts?
National Heart, Lung, and Blood Institute tool for before-after (pre-post) studies with no control group ⁵³	Was the study question or objective clearly stated? Were eligibility/selection criteria prespecified and clearly described? Were participants representative of the general population? Were all eligible participants enrolled? Was the sample size sufficiently large? Was the test/service/intervention clearly described and delivered consistently? Were the outcome measures prespecified, clearly defined, valid, reliable, and assessed consistently? Were outcome assessors blind? Was loss to followup ≤20% and those lost to follow-up accounted for in analysis? Did statistical methods examine changes in outcome measures from before to after the intervention? Were p values provided? Were outcome measures taken multiple times before and after the intervention? If a group-level intervention, did statistical analysis take into account the use of individual-level data to determine group-level effects?

Appendix A Figure 1. Literature Flow Diagram



Appendix B. Excluded Studies

Exclusion Criteria Code	Exclusion Criteria
1	Relevance
2	Design
3	Not primary data
4	Not high/moderate HDI
5	Setting does not include universal vaccination
6	Population
7	Hepatitis detected postpartum
8	Not an included intervention
9	Study of individual treatment components
10	No universal screening
11	Lack of relevant comparator
12	No relevant outcomes or incomplete outcomes reporting
13	Full text unavailable

1. The Cochrane Database of Systematic Reviews - Issue 11 of 2010 *J Evid Based Med*, 3(4) 226-227. 2010. 3
2. Further preventing mother to child hepatitis B transmission *J Paediatr Child Health*, 53(2) 201. 2017. 3
3. CDC recommends a comprehensive strategy to eliminate HBV *Am Fam Physician*, 45(4) 1912-1914+1917. 1992. 3
4. Many chronically infected HBsAg positive pregnant women are not being identified *Michigan Nurse*, 82(5) 28-28. 2009. 3
5. Universal prenatal screening for hepatitis B *Emergency Medicine (00136654)*, 22(17) 51-54. 1990. 3
6. Prenatal screening for infectious diseases *ACOG Clinical Review*, 9(2) 5-6. 2004.3
7. Reduction in hepatitis B transmission to infants *AIDS & Hepatitis Digest*, (141) 7-8. 2011. 13
8. Test all pregnant women for hepatitis B? *Patient Care*, 22(5) 23-24. 1988. 3
9. **Abara, WE, Cha, et al.** Prenatal Screening for and Prevalence of Hepatitis B Surface Antigen in Pregnant Women and Prevention of Transmission to Infants Born to Infected Mothers-Guam, 2014 *J Pediatric Infect Dis Soc.* 2017. 12
10. **Abara, WE, Cha, et al.** Hepatitis B Surface Antigen Screening Among Pregnant Women and Care of Infants of Hepatitis B Surface Antigen-Positive Mothers - Guam, 2014 *MMWR - Morbidity & Mortality Weekly Report*, 66(19) 506-508. 2017. 12
11. **Abass, F, Thomas, et al.** Controlling perinatally acquired hepatitis B *Indian J Pediatr*, 68(4) 365. 2001. 3
12. **Adamo, B, Stroffolini, et al.** Ad hoc survey of hepatitis B vaccination campaign in newborns of HBsAg positive mothers and in 12-year-old subjects in southern Italy *Vaccine*, 16(8) 775-7. 1998. 12
13. **Addle, M.** Impact of universal hepatitis B vaccination on antenatal hepatitis B prevalence in the Midlands region of the North Island, New Zealand *N Z Med J*, 124(1332) 40-4. 2011. 12
14. **Agbim, U, Jaffe, et al.** Evaluation of hepatitis b management among peripartum women in an urban setting *Gastroenterology*, 152(5) S1084. 2017. 12
15. **Al-Mandeel, HM, Alansary, et al.** Seroprevalence of hepatitis B and C, and human immunodeficiency viruses in saudi pregnant women and rates of vertical transmission *Kuwait Medical Journal*, 47(3) 221-224. 2015. 11
16. **al-Owais, A, al-Suwaidi, et al.** Use of existing data for public health planning: a study of the prevalence of hepatitis B surface antigen and core antibody in Al Ain Medical District, United Arab Emirates *Bull World Health Organ*, 78(11) 1324-9. 2000. 12
17. **Alavian, SM.** Immigration and knowledge, education, and practices regarding chronic hepatitis B in pregnancy *Ann Gastroenterol*, 31(3) 384. 2018. 3
18. **Alavian, SM, Ebrahimi, et al.** Necessity for Hepatitis B Surface Antigen Screening in Pregnant Females in Iran *Iran Red Crescent Med J*, 18(9) e40844. 2016. 3

Appendix B. Excluded Studies

19. **Alswaidi, FM, O'Brien, et al.** Is there a need to include HIV, HBV and HCV viruses in the Saudi premarital screening program on the basis of their prevalence and transmission risk factors? *J Epidemiol Community Health*, 64(11) 989-97. 2010. 1
20. **Alter, MJ.** Epidemiology of hepatitis B in Europe and worldwide *J Hepatol*, 39(SUPPL. 1) S64-S69. 2003. 3
21. **Anderson, SR, Righarts, et al.** Surveillance of antenatal infections--HIV, hepatitis B, syphilis and rubella susceptibility in London *Communicable Disease & Public Health*, 7(4) 251-7. 2004. 12
22. **Anonymous.** Prevention of transmission of hepatitis B: responsibilities of healthcare providers *J Arkansas Med Soc*, 94(8) 365-6. 1998. 3
23. **Anonymous.** Leads from the MMWR. Prevention of perinatal transmission of hepatitis B virus: prenatal screening of all pregnant women for hepatitis B surface antigen *JAMA*, 260(2) 165, 169-70. 1988. 3
24. **Anonymous** Two research projects seek to improve immunization practices *Bull Pan Am Health Organ*, 26(1) 96-7. 1992. 3
25. **Anonymous.** Universal antenatal screening for hepatitis B and immunisation of babies at risk *Commun Dis Rep CDR Wkly*, 8(32) 281, 284. 1998. 3
26. **Anonymous.** Should all pregnant women be screened for hepatitis B surface antigen? *Med J Aust*, 150(6) 346, 348. 1989. 12
27. **Anonymous.** Prevalence of HBsAg in UK population *British Medical Journal Clinical Research Ed.*, 294(6563) 57. 1987. 12
28. **Anonymous.** From the Centers for Disease Control and Prevention. Maternal hepatitis B screening practices--California, Connecticut, Kansas, and United States, 1992-1993 *JAMA*, 271(23) 1819-20. 1994. 12
29. **Anonymous.** Hepatitis B alert! *J Okla State Med Assoc*, 89(8) 297-9. 1996. 3
30. **Anonymous.** Universal hepatitis B screening in pregnancy *Am Fam Physician*, 38(4) 92, 94, 97. 1988. 3
31. **Anonymous.** Perinatal transmission of hepatitis B in Kansas *Kans Med*, 94(1) 20-1. 1993. 2
32. **Anonymous.** Infant HBV immunisation *Commun Dis Rep CDR Wkly*, 2(30) 133. 1992. 11
33. **Arima, S, Michitaka, et al.** Change of acute hepatitis B transmission routes in Japan *J Gastroenterol*, 38(8) 772-5. 2003. 6
34. **Aydin, G.** The investigation and follow up of HBsAg positive pregnant women and their babies *Hepato Int*, 9(1) S29. 2015. 11
35. **Azzopardi, D, Mamo, et al.** Management of pregnancy complicated by hepatitis B and C in Malta *International Journal of Gynecology and Obstetrics*, 119() S700-S701. 2012. 3
36. **Baird, J, Hammond, et al.** Implementation of universal antenatal screening for HIV and hepatitis B--lessons for future work *J Public Health Med*, 25(2) 171-3. 2003. 12
37. **Baker, DA, Bienstock, et al.** Serologic screening of pregnant women at high risk for transmitting hepatitis B to their newborn *Bull N Y Acad Med*, 62(3) 282-6. 1986. 12
38. **Balogun, MA, Ramsay, et al.** Acute hepatitis B infection in England and Wales: 1985-96 *Epidemiol Infect*, 122(1) 125-31. 1999. 6
39. **Banatvala, JE, Chrystie, et al.** Retrospective study of HIV, hepatitis B, and HTLV-I infection at a London antenatal clinic *Lancet*, 335(8693) 859-60. 1990. 12
40. **Barbosa, Carolina, Smith, et al.** Cost-effectiveness analysis of the national perinatal hepatitis B prevention program *Pediatrics*, 133(2) 243-253. 2014. 2
41. **Barr, D, Hershov, et al.** Assessing prenatal hepatitis B screening in Illinois with an inexpensive study design adaptable to other jurisdictions *Am J Public Health*, 89(1) 19-24. 1999. 11
42. **Bascom, S, Miller, et al.** Assessment of perinatal hepatitis B and rubella prevention in New Hampshire delivery hospitals *Pediatrics*, 115(5) e594-9. 2005. 11
43. **Batayneh, N, Bdour, et al.** Risk of perinatal transmission of hepatitis B virus in Jordan *Infect Dis Obstet Gynecol*, 10(3) 127-32. 2002. 12
44. **Beck, Charles Richard, MacGregor, et al.** An audit of neonatal and infant hepatitis B immunisation and serological testing in two counties of England, 2007-12 *J Infect Prev*, 15(5) 182-188. 2014. 11
45. **Benson, R, Crowley, et al.** Postvaccination serologic testing results for infants aged \leq 24 months exposed to hepatitis B virus at birth - United States, 2008-2011 *Morbidity and Mortality Weekly Report*, 61(38) 768-771. 2012. 11
46. **Bergin, H, Wood, et al.** Successful implementation of new management guidelines and a specialized clinic for hepatitis B virus positive pregnant women *Aust N Z J Obstet Gynaecol*, 56() 21. 2016. 11

Appendix B. Excluded Studies

47. **Birnbaum, JM, Bromberg, et al.** Evaluation of prophylaxis against hepatitis B in a large municipal hospital *Am J Infect Control*, 20(4) 172-6. 1992. 12
48. **Birosak, BJ, Fiore, et al.** Impact of the thimerosal controversy on hepatitis B vaccine coverage of infants born to women of unknown hepatitis B surface antigen status in Michigan *Pediatrics*, 111(6 Pt 1) e645-9. 2003. 12
49. **Borchardt, SM, Kocharian, et al.** Prevention of Perinatal Transmission of Hepatitis B Virus: Assessment Among Wisconsin Maternity Hospitals *WMJ*, 115(2) 74-9; quiz 80. 2016. 12
50. **Borgia, G, Maraolo, et al.** Hepatitis B mother-to-child transmission and infants immunization: we have not come to the end of the story yet *Infect Dis*, 49(8) 584-587. 2017. 3
51. **Borresen, ML, Koch, et al.** Effectiveness of the targeted hepatitis B vaccination program in Greenland *Am J Public Health*, 102(2) 277-84. 2012. 11
52. **Bortolotti, F, Cadrobbi, et al.** Prognosis of chronic hepatitis B transmitted from HBsAg positive mothers *Arch Dis Child*, 62(2) 201-3. 1987. 11
53. **Boxall, E.** Universal immunization of babies against hepatitis B *AIDS & Hepatitis Digest*, (108) 2-3. 2005. 3
54. **Boxall, EH.** Antenatal screening for carriers of hepatitis B virus *BMJ*, 311(7014) 1178-9. 1995. 3
55. **Boyles, S.** Is universal better than selective immunization in developing world? Vaccines (HBV) *Hepatitis Wkly*, () 7-8. 1998. 3
56. **Boyles, S.** Transmission (HBV). Centralized management key to preventing perinatal hepatitis *Health Letter on the CDC*, () 13-14. 1997. 13
57. **Bracciale, L, Fabbiani, et al.** Impact of hepatitis B vaccination in children born to HBsAg-positive mothers: a 20-year retrospective study *Infection*, 37(4) 340-3. 2009. 12
58. **Bracebridge, S, Irwin, et al.** Prevention of perinatal hepatitis B transmission in a health authority area: an audit *Communicable Disease & Public Health*, 7(2) 138-41. 2004. 11
59. **Brady, M.** Preventing the perinatal spread of hepatitis B *Journal of Pediatric Health Care*, 3(1) 49-51. 1989. 3
60. **Braillon, A, Nguyen-Khac, et al.** Pregnancy and hepatitis B in Europe *Liver Int*, 29(9) 1447; author reply 1447-8. 2009. 3
61. **Brook, MG, Lever, et al.** Antenatal screening for hepatitis B is medically and economically effective in the prevention of vertical transmission: three years experience in a London hospital *Q J Med*, 71(264) 313-7. 1989. 11
62. **Burgis, JC, Kong, et al.** Perinatal transmission in infants of mothers with chronic hepatitis B in California *World Journal of Gastroenterology*, 23(27) 4942-4949. 2017. 11
63. **Cabrie, T.** Women diagnosed with chronic hepatitis B *Australian Nursing & Midwifery Journal*, 22(9) 50. 2015. 3
64. **Cai, HD, Liu, et al.** The strategy of antiviral treatment in reproductive women infected with hepatitis B virus *Hepat Mon*, 8(1) 71-74. 2008. 3
65. **Cairns, JA, Shackley, et al.** Assessing value for money in medical screening *J Med Screen*, 1(1) 39-44. 1994. 3
66. **Caley, M, Fowler, et al.** Differences in hepatitis B infection rate between ethnic groups in antenatal women in Birmingham, United Kingdom, May 2004 to December 2008 *Eur Surveill Bull*, 17(30) 26. 2012. 12
67. **Cambrea, C, Dumea, et al.** Materno-foetal transmission of B viral hepatitis in Constanta *Clinical Microbiology and Infection*, 18() 826-827. 2012. 11
68. **Capar, M, Kosic-Andrasevic, et al.** The need and value of routine screening of all pregnant women for hepatitis B surface antigen *Acta Med Croatica*, 49(4-5) 161-4. 1995. 12
69. **Carey, I, McLeod, et al.** Preventing mother to child transmission of HBV in an ethnically diverse South London population: An effective multidisciplinary clinical pathway *Hepatology*, 63(1) 890A. 2016. 11
70. **Carlson, NS.** Current Resources for Evidence-Based Practice, May/June 2017 *J Midwifery Womens Health*, 62(3) 373-379. 2017. 3
71. **Centers for Disease, Control.** Screening for hepatitis B virus infection among refugees arriving in the United States, 1979-1991 *MMWR - Morbidity & Mortality Weekly Report*, 40(45) 784-6. 1991. 12
72. **Centers for Disease, Control.** Hepatitis B screening and follow-up vaccination of infants of carrier mothers--Atlanta, 1988 and 1989 *MMWR - Morbidity & Mortality Weekly Report*, 39(24) 405-7. 1990. 12
73. **Centers for Disease, Control.** Prevention of perinatal transmission of hepatitis B virus: prenatal screening of all pregnant women for hepatitis B surface antigen *MMWR Morb Mortal Wkly Rep*, 37(22) 341-6, 351. 1988. 3

Appendix B. Excluded Studies

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