

# Factors Affecting Refusal Rates of the Birth Dose of Hepatitis B Vaccine: A Single Center Study

*Doğumda Hepatit B Aşısı Red Edilmesine Yol Açan Olası Faktörler: Tek Merkezli Çalışma*

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## Abstract

**Objective:** Hepatitis B virus infection is potentially life-threatening. The hepatitis B birth dose vaccination coverage was 68.6% per the 2011 National Immunization Survey. In this study, we aimed to study factors related to vaccine refusal.

**Material and Methods:** We conducted a retrospective chart review of live births at The Unterberg Children's Hospital at Monmouth Medical Center except for those patients whose mother's hepatitis B antigen status was positive and those admitted/transferred to the NICU. Data collected on mothers and infants included race/ethnicity, language and gestational age, birth weight, and hepatitis B vaccine consent status.

**Results:** A total of 259 infants were included in the study between May 2012 and February 2013. Caucasian and English-speaking mothers were found to have higher vaccine refusal rates.

**Conclusion:** Although the Advisory Committee on Immunization Practices statement on hospital policies for the prevention of hepatitis B is very clear, newborn hepatitis B vaccination coverage at Monmouth Medical Center is only 29.7%. Quality improvement strategies have to be implemented. (*J Pediatr Inf 2014; 8: 159-64*)

**Key words:** Hepatitis B virus, vaccine, refuse, newborn

## Özet

**Amaç:** Hepatit B virüs enfeksiyonunda ölümcül olma potansiyeli mevcuttur. Hepatit B doğum dozunun yapıma oranının, 2011 yılı Ulusal Aşılama Anketi verilerinde %68,6 oranında olduğu gösterilmiştir. Bu çalışmada aşının red edilmesi ile ilişkili faktörleri araştırmayı hedefledik.

**Gereç ve Yöntemler:** Monmouth Medical Center'daki The Unterberg Çocuk Hastanesinde canlı doğumların retrospektif olarak dosya taramasını yaptık. Annesi Hepatit B antijeni pozitif olan ve / veya yenidoğan yoğun bakım ünitesine yatırılan / transfer edilen bebekleri çalışma dışı bıraktık.

**Bulgular:** Mayıs 2012 - Şubat 2013 tarihleri arasında 259 yenidoğan çalışmaya alındı. Beyaz ırktan olan ve İngilizce konuşan annelerin aşığı red etme oranlarının daha yüksek olduğu gösterildi.

**Sonuç:** Aşılama Uygulamaları Danışma Komitesinin hastanelerin Hepatit B'den korunma politikaları ile ilgili beyanatının çok net olmasına rağmen, Monmouth Medical Center'daki Hepatit B aşısının yapıma oranı sadece %29,7 olarak saptanmıştır. Bu oranın yükseltilmesi için yeni kalite iyileştirme stratejileri geliştirilmiştir. (*J Pediatr Inf 2014; 8: 159-64*)

**Anahtar kelimeler:** Hepatit B aşısı, aşılama, red etme, yenidoğan

Received/Geliş Tarihi:  
26.11.2014

Accepted/Kabul Tarihi:  
10.12.2014

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DOI:10.5152/ced.2014.1920



## Introduction

Hepatitis B infection can result in chronic liver disease, and those infected are at a high risk of death from liver cirrhosis and/or cancer (1). In the United States, 804.000-1.4 million persons are estimated to be infected with the virus, most of whom are unaware of their infection status. In

newborns, the virus can be transmitted from an infected mother during childbirth or by prolonged but nonsexual interpersonal contact with someone who is infected (e.g., household contacts) (1). Among infants who acquire hepatitis B infection from their mothers at birth, as many as 90% become chronically infected (2). Hepatitis B antigen (HBsAg)-positive mothers may not be identi-

fied in the prenatal period because of laboratory errors or failures in the reporting of test results. Therefore, administering a birth dose to infants serves as a "safety net" to prevent perinatal infection.

In December 2005, the Advisory Committee on Immunization Practices (ACIP) issued revised recommendations specifying that all medically stable newborns who weigh  $\geq 2000$  g (4.4 lbs) receive their first dose of hepatitis B vaccine before hospital discharge (2). From January 2003-June 2005, before implementation of the 2005 ACIP hepatitis B vaccine recommendation, the percentage of newborns receiving the birth dose of the hepatitis B vaccine was 50.1%, with substantial variation by state and local area (3). After the ACIP recommendations, the percentage of newborns receiving the birth dose of the hepatitis B vaccine increased to 60.8% (2009 National Immunization Survey (NIS)) and has remained stable at 68.6% (2011 NIS) (4, 5). Immunization rates for children and adults are rising, but coverage levels have not reached national goals.

The goal of this study was to examine hepatitis B vaccination refusal rates for the birth dose at The Unterberg Children's Hospital at Monmouth Medical Center and the various factors that could be affecting the vaccination refusal rate.

## Material and Methods

### Study Design and Study Eligibility

We examined the medical records of all live births at The Unterberg Children's Hospital at Monmouth Medical Center (MMC) from May 2012 to February 2013.

Data collected on the mothers included race/ethnicity (Caucasian or non-Caucasian), language (English or Spanish), and hepatitis B vaccine consent status. Data collected on infants included gestational age, birth weight, hepatitis B vaccine receipt before discharge from the hospital, and pediatrician (private versus clinic patients). We classified the newborns as "MMC - clinic patients" if their pediatrician in the newborn period was an attending from MMC - Clinic and their routine follow-up was at MMC - Clinic, which is a federally qualified health clinic. Newborns taken care of by pediatricians other than an MMC - Clinic attending and followed up in a setting other than MMC - Clinic were classified as "private patients."

We included all newborn infants who were born to HBsAg-negative or unknown-status mothers with a birth weight equal to or greater than 2000 grams and greater than 35 weeks of gestational age who were admitted to well newborn nursery. Those infants transferred to the NICU and all newborns whose mothers' HBsAg status was positive (because these babies routinely receive the hepatitis B vaccine within 12 hours of life) were excluded.

## Outcomes

The primary outcome measure was the refusal rate of hepatitis B vaccine before hospital discharge. Secondary outcome measures were recorded to elucidate if the following variables influenced the consent status for hepatitis B vaccine in newborns before hospital discharge: maternal race/ethnicity (Caucasian versus non-Caucasian), language (English-speaking versus non-English-speaking), newborn's gender, and newborn's primary care provider. MMC hospital policy on hepatitis B vaccine for newborns recommends that every newborn receive the first dose of the hepatitis B vaccine before hospital discharge. However, receipt of the vaccine requires consent from the parents, and they have the right to refuse the vaccine.

## Statistical Analysis

We compared the demographic characteristics of infants based on receipt of hepatitis B vaccine using Pearson chi-square test analyses for categorical variables. The significance level was defined as  $p \leq 0.05$ . Analyses were carried out using PASW Statistics 18.0 (SPSS for Windows, version 18.0; SPSS Inc., Chicago, IL, USA).

## Results

Two hundred fifty-nine infants were included in the study from May 2012 to February 2013 at The Unterberg Children's Hospital at Monmouth Medical Center. Among them, 133 were MMC - clinic patients and 126 were private patients. Amongst both patient populations 86.5% ( $n=154$ ) of the Caucasians mothers refused the vaccine compared to 34.6% ( $n=28$ ) of non - Caucasians ( $p=0.000$ ; Pearson chi-square test). Also, 80.7% ( $n=167$ ) of English-speaking mothers refused the hepatitis B vaccine birth dose compared to 28.8% ( $n=15$ ) of the non-English-speaking mothers ( $p=0.000$ ; Pearson chi-square test). There was no significant difference in vaccine refusal rates in female versus male newborns ( $p=0.893$ ).

Upon individual analysis of the 133 MMC - clinic patients, 50.4% ( $n=67$ ) did not receive the hepatitis B vaccine. In terms of the race of the mothers refusing the vaccine among MMC - clinic patients, 75% ( $n=42$ ) of Caucasians refused hepatitis B vaccine coverage for their newborns compared to 25% ( $n=14$ ) in non-Caucasians ( $p=0.000$ ; Pearson chi-square test). Only 29.4% ( $n=15$ ) of non-English-speaking mothers refused hepatitis B vaccine compared to 63.4% ( $n=52$ ) of English-speaking mothers ( $p=0.000$ ; Pearson chi-square test). There was no significant difference in the gender of the infants ( $p=0.604$ ).

In the private patient population, 91.3% ( $n=115$ ) private patients had refused the hepatitis B vaccine. There were only 4 non-Caucasian patients compared to 122

Caucasian patients and 1 non-English-speaking patient compared to 116 English-speaking patients, thus making their sample sizes too small to derive any statistical significance. The analysis to see if the gender of the infant was an influencing factor yielded no statistical significance in the private patient population, either.

## Discussion

Hepatitis B vaccination is the most effective measure to prevent hepatitis B virus infection and its consequences. Although there was significant progress toward decreasing hepatitis B virus transmission through hepatitis B vaccine coverage in infants and children, hepatitis B virus infection remains an important cause of chronic liver disease. Rates of new infection and acute disease are highest among adults, but chronic infection is more likely to occur in persons infected as infants or young children. Currently, the CDC's primary focus of a comprehensive immunization strategy is universal infant hepatitis B vaccination before hospital discharge, which was also recommended by the Advisory Committee on Immunization Practices (ACIP) in December 2005.

Despite the considerable successes of immunization strategies, challenges remain. In our study, we have shown that having a written hospital policy for a birth dose of hepatitis B vaccine is not sufficient to ensure high rates of neonatal hepatitis B vaccine administration. According to the CDC's 2011 National Immunization Survey (NIS), hepatitis B vaccination coverage during the neonatal period was 68.6%. Currently, Healthy People 2020 disease reduction goals for the prevention of hepatitis B virus transmission in the United States includes a target coverage level for infants age 0-3 days receiving the initial birth dose of hepatitis B vaccine of 85% (6).

Challenges to administering hepatitis B vaccine to newborns within 24 hours after birth can be logistical and financial. Aside from hospital policies and procedures, administration of the hepatitis B vaccine to newborns is also dependent on provider and parent preferences. In our study, we found a significant difference in the consent rate for the hepatitis B vaccine between MMC - clinic patients and private patients. An interim analysis showed that 91% of private patients did not receive hepatitis B vaccine versus 71% in MMC - clinic patients. This may suggest that the provider's preference might influence the parent's consent for the birth dose of the hepatitis B vaccine. Although the ACIP states that vaccination should be delayed only rarely and on a case-by-case basis, it is clear that many providers are choosing not to immunize newborns before discharge from the hospital. Although providers may believe that their patient populations are at low risk for hepatitis B infection, close to 30% of adults in

the United States aged 18 to 34 years are foreign-born, many of whom are from countries where hepatitis B is hyperendemic (7). Thus, the birth dose of hepatitis B vaccine provides a "safety net" for the prevention of perinatal infection among newborns born to HBsAg-positive mothers who were not screened prenatally or were not identified as HBsAg-positive because of testing errors or lapses in the reporting or documentation of test results (2, 8). Hepatitis B vaccine alone is 70%-95% effective as post-exposure prophylaxis in preventing perinatal hepatitis B virus transmission when the first dose is given within 24 hours after birth, even without HBIG (9, 10). The birth dose also provides early pre-exposure protection to newborns at risk for infection after the perinatal period. Newborns who become infected with the hepatitis B virus have a 90% chance of developing chronic hepatitis B virus infection. When chronically infected, they have a 25% chance of dying prematurely from cirrhosis or liver cancer (9). In the United States, without post-exposure prophylaxis, hepatitis B virus would infect 12,000 infants annually, and without routine childhood immunization, 16,000 would be infected (10). Administration of the birth dose of the hepatitis B vaccine has been associated with higher rates of on-time completion of the hepatitis B vaccine series. In certain populations, beginning the immunization schedule at birth is associated with improved completion rates for all other childhood vaccines, although the findings have not been consistent (2, 9, 10).

The results of our study showed that private patients and MMC - clinic patients are coming from different backgrounds. Private patients consist of more Caucasians and English-speaking mothers. Our study also shows that the language and race of consenting mothers caused a significant difference in hepatitis B vaccine consent and newborn hepatitis B vaccine coverage. English-speaking mothers and Caucasians have higher refusal rates for the birth dose of the hepatitis B vaccine for their newborns compared to Spanish-speaking mothers and non-Caucasians. These findings have several potential interpretations and implications. Infants born to Caucasian and English-speaking mothers might belong to a higher socioeconomic status that may be at lower risk for hepatitis B infection, and therefore, the mothers and/or providers may be opting out of hepatitis B vaccine in the nursery (7). According to Sporton et al. (11), parents who refused vaccination made a well-considered decision based on an assessment of the benefits and the risks of vaccination, the child's susceptibility to the potential disease, and the acceptance of responsibility for that decision. Harmsen et al. (12) have also found that most refusal of vaccination is based on deliberate decision-making of parents, based on multiple factors, such as the lifestyle of the parents, perceptions about the body and the immune system of the

child, risk perception of diseases and vaccination side effects, perceived vaccine effectiveness, perceived advantages of experiencing the disease, negative experience with vaccination, and parents' social environment. Furthermore, it has been shown that parents in Canada who decline vitamin K prophylaxis for their newborns were more likely to decline vaccination for their child (13). Gust et al. (14) have demonstrated that the odds of a mother refusing a vaccine were lower for non-Hispanic black and Hispanic parents than for white parents. This supports previous research indicating that US children who receive no vaccines tend to be white (15). Freed et al. (16) have shown that Hispanic parents were more likely to report that they generally do what their doctor recommends about vaccines for their children (OR: 2.5 [95% CI: 1.13-5.16]) and less likely to have ever refused a vaccine for their children that their doctor had recommended (OR: 0.47 [95% CI: 0.24-0.93]). Another possible explanation for vaccine refusal might be the misperception of the importance of administering hepatitis B vaccine within 24 hours of birth. As is well known, the risk for perinatal and childhood acquisition of hepatitis B is not zero, even with a negative maternal screen. Risk factors for hepatitis B infection can not be identified in more than 30% of infected persons (7). Therefore, hepatitis B vaccine should be offered for all newborns, regardless of maternal ethnicity or socioeconomic status.

### Limitations of the Study

This study had several limitations. First, it is based on only 10 months of data at Monmouth Medical Center. We were not able to account for all of the reasons a newborn may not have received the hepatitis B vaccine, such as parental education status, parental cultural or religious beliefs and socioeconomic status, individual provider practice, and financial barriers.

For future research, it will be interesting to know the parents' reasons for refusing the hepatitis B vaccine at birth, as well as the private physicians' policies regarding this issue. This information can help us identify the best strategy to increase hepatitis B immunization coverage for newborns at Monmouth Medical Center.

### Quality Improvement Strategies

As mentioned, hepatitis B vaccine coverage in newborns is highly dependent on hospital policies and procedures and on provider and parent preferences. To promote an understanding and, thus, the acceptance of the current Advisory Committee on Immunization Practices recommendations regarding newborn hepatitis B vaccination at birth or before hospital discharge in Monmouth Medical Center, the following quality improvement strategies are recommended:

**Education:** Prenatal care education should include information regarding the rationale for and importance of newborn hepatitis B vaccination.

Develop a number of educational materials for the physician, nursing staff, and the parents-eg, vaccine information pamphlets, brochures, and audiocassettes that are readily available at the hallway of labor and delivery and nursery that explain the rationale of the vaccine recommendations, detailing the benefits and risks of vaccines, informing parents/guardians of the potential hazards of depriving their children of immunizations, and including general information about the biology, epidemiology, and clinical manifestations of hepatitis B infection at a level that they can understand.

An audiocassette, entitled "Hepatitis B Vaccination for Infants: A Universal Message for Physicians," is available without charge from the CDC.

Brochures for patients are available from both the AAP and CDC.

Conduct or provide opportunities for staff education and training on current immunization recommendations and research.

Routinely seek the input of parents, guardians, or nurses about specific approaches to serve their immunization needs better and implement necessary changes to provide more user-friendly services.

The quality of new strategies will be evaluated based on patient, guardian, and nurse satisfaction.

**Hospital policies:** Review the current hospital policies and standing orders. All delivery hospitals should implement standing orders for the administration of hepatitis B vaccination beginning at birth as part of routine medical care of all medically stable infants weighing >2000 g at birth. It should also include the rest of the ACIP-recommended delivery hospital policies and procedures to prevent perinatal HBV transmission (2, 17, 18).

### Informed Consent

The consent for hepatitis B vaccine administration should be improved stating the benefits and risks of hepatitis B vaccine in lay terminology. Provide parent(s)/guardian(s) with vaccine information pamphlets along with the consent form. Note patient(s)/guardian(s) consent in the medical chart. Apprise parent(s)/guardian(s) non-coercively of the potential hazards of depriving their children of immunizations. Always record refusal of a vaccination in the child's chart and in the parent(s)/guardian(s) copy of the immunization record. If patient refused, state the reason for refusal in the consent form.

### Vaccine Administration

If an immunization is refused for any reason, flag the immunization form on the chart with a red sticker indicat-

ing the omitted vaccine, so that providers can be alerted to the need to catch up on an immunization at a later visit.

If parents/guardians refuse the vaccine in the hospital, schedule a future clinic appointment for immunizations in conjunction with appointments for other child health services.

Operate a "tracking" system, so that reminders for upcoming immunizations can be undertaken.

The plan of the quality improvement project is to implement the new strategies in 6 months and then reevaluate the success of hepatitis B vaccine administration in infants within the hospital. A process measure for this project is the percentage of patients who have received hepatitis B vaccine before hospital discharge, documented in their medical records, with the numerator being the number of patients having the hepatitis B vaccine and the denominator being the total number of clinic patients in the hospital who are eligible to receive the vaccines. The goal is to implement the strategies to all patients (100%). A clinical outcome measure for this initiative is to increase the total newborns hepatitis B vaccine coverage before hospital discharge to 20% and to increase the number of clinic patients who received hepatitis B vaccine in the hospital to 20%.

## Conclusion

Although the Advisory Committee on Immunization Practices statement on hospital policies for the prevention of hepatitis B is very clear, newborn hepatitis B vaccination coverage at Monmouth Medical Center is only 29.7%. Race and language were found to have a statistically significant influence on newborn hepatitis B vaccine refusal rates. Caucasian and English-speaking mothers were found to have higher vaccine refusal rates.

Hepatitis B vaccine at birth provides a "safety net" for the prevention of perinatal infection, prevents early childhood infections, facilitates implementation of universal vaccination recommendations, and prevents infections in adolescents and adults. By delaying the hepatitis B vaccine birth dose, the patient and/or provider accepts the risk of failing to immunize children at risk for hepatitis B and other vaccine-preventable diseases.

**Ethics Committee Approval:** Ethics committee approval was not received due to the retrospective nature of this study.

**Informed Consent:** Written informed consent was not obtained due to the retrospective nature of this study.

**Peer-review:** Externally peer-reviewed.

**Author Contributions:** Concept - S.G.B.; Design - S.G.B., L.L.; Supervision - L.L.; Collection and/or Processing - D.V., D.Y.; Analysis and/or Interpretation - S.G.B.; Literature Review - S.G.B., D.V., D.Y.; Writing - D.V., D.Y.; Critical Review - L.L.

**Conflict of Interest:** No conflict of interest was declared by the authors.

**Financial Disclosure:** The authors declared that this study has received no financial support.

**Etik Komite Onayı:** Çalışmanın retrospektif tasarımından dolayı etik kurul onayı alınmamıştır.

**Hasta Onamı:** Çalışmanın retrospektif tasarımından dolayı etik kurul onayı alınmamıştır.

**Hakem Değerlendirmesi:** Dış bağımsız.

**Yazar Katkıları:** Fikir - S.G.B.; Tasarım - S.G.B., L.L.; Denetleme - L.L.; Veri Toplanması ve/veya İşlenmesi - D.V., D.Y.; Analiz ve/veya Yorum - S.G.B.; Literatür Taraması - S.G.B., D.V., D.Y.; Yazıyı Yazan - D.V., D.Y.; Eleştirel İnceleme - L.L.

**Çıkar Çatışması:** Yazarlar çıkar çatışması bildirmemişlerdir.

**Finansal Destek:** Yazarlar bu çalışma için finansal destek almadıklarını beyan etmişlerdir.

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