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Long-Term Protection After Primary Hepatitis B Vaccination: A Systematic Review

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Keywords: Neonatal immunization programs, Birth-dose policy evaluation, Long-term serological response, Vaccine-induced immune memory.

Abstract: Vaccination has proven effective in preventing HBV transmission and reducing related health burdens. This study aimed to systematically review the long-term effectiveness of the hepatitis B vaccine following primary vaccination. A literature search was conducted using PubMed, ProQuest, and the Cochrane Library following PRISMA guidelines. Keywords included "effectiveness," "hepatitis B," "HBV," "HepB," "vaccine," "vaccination," "immunization," "immune memory," "seroprotection," and "birth dose." Of 555 articles initially identified, nine met the inclusion criteria. Results showed that the duration of protection after primary vaccination ranges from 5 to 25 years, with an average seroprotection rate of 83.5%. Vaccination is vital for newborns, regardless of maternal HBV status, and healthcare professionals play a key role in promoting early immunization. Monitoring anti-HBs antibody levels is also recommended to assess the need for booster doses, which may help prevent HBV transmission and further reduce morbidity and mortality.

Introduction

Hepatitis B virus (HBV) infection is the leading cause of acute and chronic hepatitis cases, including liver cirrhosis and hepatocellular carcinoma (HCC) (1). According to the World Health Organization(WHO) in 2022, it is estimated that about 254 million people will suffer from hepatitis B virus infection, about 1.2 million new cases of hepatitis B virus infection, and about 1.1 million deaths. The highest prevalence of HBV infection is found in the Western Pacific region, with approximately 97 million cases, followed by Africa with about 65 million cases, Southeast Asia with 61 million cases, the Eastern Mediterranean with 15 million cases, Europe with 11 million cases, and the United States with 5 million cases (2).

Indonesia is ranked 2nd for hepatitis B cases in the Southeast Asia Region, with a prevalence of HBV infection reaching 4.0 - 20.3% (2, 3). Transmission of HBV cases is caused by sexual transmission, and pregnant women can pass HBV to their babies due to their knowledge and economic status (4). According to Basic Health Research (Riskesdas) in 2018, reported about 7.1% of cases of HBV infection, with 4.2% infected in toddlers, and estimated cases of death due to HBV infection around 51,100 every year (5). The high mortality rate due to hepatitis B can be influenced by the lack of primary vaccination after birth.

Hepatitis B vaccination is crucial for preventing the risk of acute and chronic infection, as well as long-term complications that can lead to liver cirrhosis and hepatocellular carcinoma (HCC). The hepatitis B vaccine is highly effective in preventing HBV infection, with protection rates reaching over 90% in healthy individuals (6). The

effectiveness of hepatitis B vaccine protection duration can decrease influenced by factors such as age, gender, body mass index (BMI), smoking habits, comorbidities, genetic predisposition, and viral mutations (7).

Based on WHO guidelines, prevention through vaccination programs has long been a cornerstone of hepatitis B control efforts. The standard hepatitis B vaccine schedule is administered in three doses at months 0, 1, and 6 (2). In Indonesia, the national program—implemented since 1997—follows a modified schedule at months 0, 2, 4, and 6, with a booster dose at month 18 (1). Although this multidose strategy aims to ensure early protection, cases of HBV infection still occur among individuals vaccinated at birth (8). In particular, the persistent rate of vertical transmission suggests that programmatic gaps or waning immunity may be contributing factors. These concerns underscore the need to assess not only vaccine coverage but also the long-term durability of protection, especially in populations exposed from birth.

However, limited evidence exists regarding the duration of hepatitis B vaccine-induced protection in Indonesia, particularly among those vaccinated as infants. This study addresses that gap by systematically reviewing the available literature on long-term protection following primary vaccination. By focusing on the persistence of immunity and seroprotection rates across various timelines, the study provides new insights that may inform national policy, especially regarding booster recommendations and the optimization of early-life vaccination strategies.

MethodsSearch Strategy

This study is a systematic review using several articles related to the effectiveness of hepatitis B vaccine protection duration after primary vaccination. A search of the published literature was conducted using PubMed, ProQuest, and the Cochrane Librarydatabases. The search used the keywords "effectiveness" AND ("hepatitis B" OR "HBV" OR "HepB") AND ("vaccine" OR "vaccination" OR "immunization") AND ("immune memory" OR "seroprotection") AND "birth dose".

Table 1. Criteria for assessing the quality of articles.

Criteria	Туре		
	Research location		
Study design	Study type		
	Intervention		
	Vaccine strategy		
Results and information on vaccines	Duration of vaccine protection		
	Seroprotection vaccine		

Table 2. Summary of 9 selected articles on the effectiveness of hepatitis B vaccine protection duration after primary vaccination.

Author and year	Research title	Study type	Location	Study objectives	Intervention
Bialek <i>et al</i> . 2008 (10)	Persistence of Protection Against Hepatitis B Virus Infection Among Adolescents Vaccinated with Recombinant Hepatitis B Vaccine Beginning at Birth: A 15-Year Follow-Up Study	Cross sectional	Micronesia	To evaluate the persistence of anti-HBs antibodies after 15 years of birth vaccine administration	Comparing anti-HBs antibodies in infants given birth vaccination with a booster at 15 years of age with those not given a booster
Yazdanpanah et al. 2010 (11)	Persistence of HBV Vaccine's Protection and Response to Hepatitis B Booster Immunization in 5- to 7-Year-Old Children in the Kohgiloyeh and Boyerahmad Province, Iran		Iran	To evaluate the persistence of seroprotection in children aged 5-7 years after birth vaccine administration	Comparing anti-HBs antibodies in infants given birth vaccination with a booster at 5-7 years of age with those not given a booster
Poovorawan <i>et al.</i> 2010 (15)	Persistence of antibodies and immune memory to hepatitis B vaccine 20 years after infant vaccination in Thailand	Cohort	Thailand	To evaluate antibody resistance and immunity to the hepatitis B vaccine for 20 years after birth, vaccine administration	A vaccination cohort was compared for anti-HBs antibodies in infants vaccinated at birth with a booster at 5 years of age with those not boosted.
Poovorawan et al. 2012 (16)	Persistence and immune memory to hepatitis B vaccine 20 years after primary vaccination of Thai infants, born to HBsAg and HBeAg positive mothers	Cohort	Thailand	To evaluate hepatitis B vaccine immunity over 20 years in infants given the birth vaccine to HBsAg and HBeAg positive mothers.	Vaccination cohort comparison of anti-HBs antibodies in infants vaccinated at birth with a booster at 5 years of age versus those not boosted.
Chaves <i>et al</i> . 2012 (17)	Persistence of long-term immunity to hepatitis B among adolescents immunized at birth.	Cohort	Palau	To evaluate the persistence of seroprotection in children aged 10 and 15 years after birth vaccine administration	Comparing anti-HBs antibodies in infants given birth vaccination with a booster at 10 and 15 years of age with those not given a booster
Gilca et al. 2013 (9)	Antibody persistence and the effect of a booster dose given 5, 10, or 15 years after vaccinating preadolescents with a recombinant hepatitis B vaccine	Randomized Controlled Trial	Canada	To evaluate the persistence of anti-HBs antibodies at 5, 10, and 15 years of age after birth vaccine administration	Comparing anti-HBs antibodies in infants given birth vaccination with a booster at 5, 10, and 15 years of age with those not given a booster
Wang <i>et al</i> . 2017 (12)	Long-term persistence in protection and response to a hepatitis B vaccine booster among adolescents immunized in infancy in the western region of China.	Cross sectional	China	To evaluate the persistence of anti-HBs antibodies in adolescents aged 15-17 years after birth vaccine administration	Comparing anti-HBs antibodies in infants given birth vaccination with a booster at 15-17 years of age with those not given a booster
Bianchi <i>et al</i> . 2019 (13)	HBV seroprevalence after 25 years of universal mass vaccination and management of non-responders to the anti- Hepatitis B vaccine: an Italian study among medical students	Cross sectional	Italy	To evaluate HBV seroprevalence after 25 years of birth vaccine administration	Comparing anti-HBs antibodies in infants given birth vaccination with a booster at 12 years of age with those not given a booster
Hess <i>et al</i> . 2020 (14)	Administering an additional hepatitis B vaccination dose after 18 years maintains adequate long-term protection levels in healthcare workers.	Cross sectional	Israel	To evaluate HBV seroprevalence after 18 years of birth vaccine administration	Comparing anti-HBs antibodies in infants given birth vaccination with a booster at 18 years of age with those not given a booster

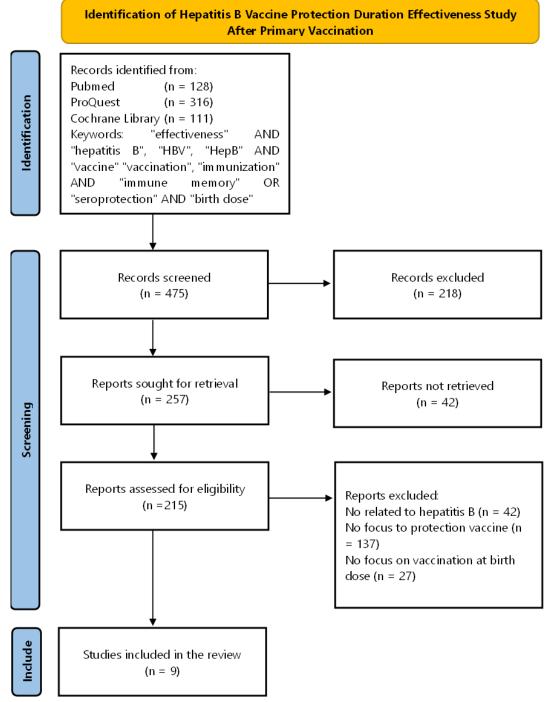


Figure 1. PRISMA chart of the methodology.

Inclusion and Exclusion Criteria

The systematic review utilized articles published between January 2000 and December 2024 to ensure article currency. All studies describing the effectiveness of hepatitis B vaccine protection duration after primary vaccination, with full-text articles in English, were included. Studies that were only available as abstracts and review articles were excluded. Based on the selected studies, qualitative and quantitative data on study design, demographics, vaccine information, and outcomes were extracted from the selected articles. The criteria selected for each article are listed in **Table 1**.

Results

Literature Search

Article selection followed the PRISMA flowchart, and 128, 316, and 111 articles were identified in PubMed, ProQuest, and the Cochrane Library, respectively. We selected 9 articles after excluding 546 articles because they did not meet the inclusion and exclusion criteria. The oldest article retrieved from our search was from 2008, focusing on the persistence of anti-HBs antibodies after 15 years of birth vaccine administration. The latest article obtained from our search, published in 2020, discusses the evaluation of HBV seroprevalence 18 years after vaccination at birth. The relevant aspects of this study are presented in **Table 2**.

Table 3. Vaccine strategy, duration of protection, and seroprotection.

Author and Year	Vaccine strategy	Duration of vaccine protection	Vaccine seroprotection
Bialek <i>et al</i> . 2008 (10)	2 strategies: one booster dose (age 15 years) and no booster dose given	15 years	66.7%
Yazdanpanah et al. 2010 (11)	2 strategies: one booster dose (5-7 years of age) and no booster dose	5-7 years	78.1%
Poovorawan <i>et al.</i> 2010 (15)	2 strategies: one booster dose (age 5 years) and no booster dose given	20 years	83.9%
Poovorawan et al. 2012 (16)	2 strategies: one booster dose (age 5 years) and no booster dose given	20 years	84.2%
Chaves <i>et al</i> . 2012 (17)	2 strategies: one booster dose (age 10 and 15 years) and no booster dose	10 and 15 years	The seroprotective booster vaccine efficacy rates were 85.3% at year 10 and 73.6% at year 15.
Gilca et al. 2013 (9)	2 strategies: one booster dose (age 5 years) and no booster dose given	10 years	92.3%
Wang et al. 2017 (12)	2 strategies: one booster dose (age 15 years) and no booster dose given	17 years old	89.3%
Bianchi <i>et al</i> . 2019 (13)	2 strategies: one booster dose (age 12 years) and no booster dose given	25 years	93.3%
Hess et al. 2020 (14)	2 strategies: one booster dose (age 18 years) and no booster dose given	18 years old	88.1%

Assessing the Long-term Effectiveness of the Hepatitis B Vaccine

Specifically, there was one study that applied a randomized controlled trial study design (9), five studies that applied a cross-sectional study design (10-14), and three studies that applied a cohort study design (15-17). A randomized controlled trial (RCT) is a study that evaluates a randomly assigned treatment group and a control group (18). A crosssectional study is a study that collects data on a population vaccinated at birth at a single point in time to evaluate the relationship between booster vaccines and the population (19). Cohort studies are studies in which infants who have received birth vaccinations are followed over time to see how booster administration affects anti-HBs antibodies (20). The data collection from 9 studies compared anti-HBs antibodies in infants who received vaccinations at birth with those in infants who received boosters and those who did not receive any vaccinations (9-17).

Vaccine Information

All selected studies provided information regarding vaccine seroprotection of 66.7%-93.9% with the duration of hepatitis B vaccine protection lasting 5-25 years in the body (9-17). Research in the United States indicates that the duration of hepatitis B vaccine protection can last up to 22 years in the body (21). The level of HBV infection can be calculated by the anti-HBs seroprotection parameter (10 mIU/mL), those with an anti-HBs seroprotection value of < 10 mIU/mL can be given a booster dose of hepatitis B vaccine and assessed for anamnestic responses such as identifying the patient's medical history, including previous vaccination history and history of allergic reactions (12). All information about the vaccine is presented in **Table 3**.

Discussion

Hepatitis B virus infection is a significant cause of morbidity

and mortality, so the prevention and treatment of the disease must be considered. This study aimed to conduct a systematic review of the effectiveness of hepatitis B vaccine protection duration after primary vaccination. Hepatitis vaccination is considered one of the most effective public health interventions for preventing the transmission of the hepatitis virus. Vaccination helps build immunity against hepatitis infection, thereby reducing the risk of chronic diseases such as cirrhosis and liver cancer. However, more scientific evidence is needed on the effectiveness of hepatitis B vaccine protection duration, given the limited number of studies on the effectiveness of hepatitis B vaccine use, especially in Indonesia.

Primary vaccination can induce antibodies to hepatitis B surface antigen (anti-HBs) ≥ 10 mIU/mL in more than 95% of healthy children after a birth vaccination program (22). Hepatitis B surface antigen (anti-HBs) generally decreases after a birth vaccination program. A 30-year study conducted in Hong Kong showed a decrease in anti-HBs seroprotection levels from baseline, years 1, 5, 10, 16, 21, and 30 of 92.6%, 91.2%, 64.2%, 44.8%, 33.3%, 36.3%, and 37.4%, respectively (23).

All selected studies considered comparisons of anti-HBs antibodies in primary vaccinated infants between those who received a booster and those who did not. Anti-HBs antibodies are a sign of immunity to the hepatitis B virus infection. High levels of anti-HBs ($\geq 10 \text{ mIU/mL}$) indicate immunity to hepatitis B infection. Meanwhile, low anti-HBs values (< 10 mIU/mL) can be given a booster dose of hepatitis B vaccine because it indicates that the effect of previously administered vaccines has been lost or reduced, allowing immunity to hepatitis B infection to be regained (24).

Based on selected studies, the duration of vaccine protection can last from 5 years to 25 years (9-17). These results are in line with several studies that state the duration of vaccine protection can last \geq 10 years against booster

doses (25, 26). Vaccine seroprotection is a parameter used to determine the body's immunity to hepatitis B infection. Research in Micronesia reported a 15-year duration of vaccine protection, with hepatitis B vaccine seroprotection at high anti-HBs titers (\geq 10 mIU/mL) of 66.7% (10). A study in Iran showed a vaccine protection duration of 5-7 years with hepatitis B vaccine seroprotection of 78.1% (11).

Research conducted in Thailand in 2010 and 2012 reported a duration of vaccine protection of 20 years, with an average hepatitis B vaccine seroprotection rate of 84.1% (15, 16). Studies in Palau and Canada reported the duration of vaccine protection for 5, 10, and 15 years, with average hepatitis B vaccine seroprotection rates of 88.2%, 85.9%, and 75.2%, respectively (9). A study in China reported a vaccine protection duration of 15-17 years with hepatitis B vaccine seroprotection of 84% (12). Research in Italy reported a 25-year duration of vaccine protection, with hepatitis B vaccine seroprotection of 93.3% (13). Research in Israel reported that the duration of vaccine protection, as indicated by hepatitis B vaccine seroprotection, was 25 years, with a seroprotection rate of 88.1% (14). Some studies suggest that vaccination given after birth has a duration of vaccine protection of 13-30 years with hepatitis B vaccine seroprotection of 88-100% after booster doses (26, 27).

Although hepatitis B vaccination programs have existed for a long time, the high prevalence of hepatitis B cases is a task for all parties, especially in the health sector. Despite the study's limitations, which include high heterogeneity among the included studies, regional differences, potential publication bias, the lack of RCT studies, and the inability to account for prevalence rates in the search strategy, it remains a valuable contribution to the field. However, this study can be taken into consideration to review the evidence from all defined studies on the effectiveness of hepatitis B vaccine protection duration after primary vaccination, so as to make comprehensive policy recommendations for booster vaccines, especially in Indonesia.

However, hepatitis B vaccination is effective in preventing hepatitis (6). Although vaccination is a promising intervention, research is needed on the duration of hepatitis B vaccine protection after primary vaccination. The use of booster vaccines should be strongly considered in conditions with low anti-HBs levels (<10 mlU/mL) to prevent hepatitis B disease transmission, especially in Indonesia.

Conclusion

Based on a systematic review of nine studies, hepatitis B vaccine provides effective protection for up to 25 years with an average seroprotective rate of 83.5%. The use of vaccines in government programs in Indonesia is very important as a form of prevention in newborns with or without exposure to mothers who have hepatitis B. The vaccination program in Indonesia is still relatively low, so the role of health workers is important in increasing compliance rates in vaccination programs in Indonesia, one of which is by conducting routine vaccinations for newborns and monitoring anti-HBs antibodies to consider booster vaccines under certain conditions to prevent transmission of the hepatitis B virus and reduce morbidity and mortality rates. In addition, further research is needed to identify vaccine coverage, the types of booster vaccines used, the completeness of vaccine doses, and risk factors that affect the decrease in vaccine effectiveness, so that these findings can be incorporated into the national immunization strategy.

Abbreviations

Anti-HBs = Hepatitis B surface antibody; BMI = body mass index; HBV = Hepatitis B Virus; HB0 = Newborn hepatitis B vaccine administration; HB1 = First dose vaccine administration; HB2 = Second dose vaccine administration; HB3 = Third dose vaccine administration; HBIg = Hepatitis B immunoglobulin; HBeAg = Hepatitis B e-antigen; HBsAg = Hepatitis B surface antigen; HCC = Hepatocellular Carcinoma; RCT = Randomized Controlled Trial; Riskesdas = Basic Health Research; WHO = World Health Organization

Declarations

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Conflict of Interest

The authors declare no conflicting interest.

Data Availability

The unpublished data is available upon request to the corresponding author.

Ethics Statement

Not applicable.

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Additional Information

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