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# Hepatitis B vaccination at birth: reduces perinatal transmission successfully

## Abstract

Hepatitis B virus (HBV) infection is one of the most important global health problem including Bangladesh. HBV carrier rate was found between 2-7% in many studies. After acute infection, chance of chronicity in adult is only 10%, but in neonate that is 90%. Out of these, 25% were suffering from acute liver failure & hepatocellular carcinoma and ultimate result is premature death. Chronic Hepatitis B Virus infection is not curable, only suppressing the activity with available treatment. So, prevention is better than cure. Active immunization is the single most important and effective preventive measure against HBV infection. Bangladesh introduced hepatitis B vaccination in children through Expanded Program on Immunization in 2005 which includes 3 doses without any birth dose. World Health Organization, Centre for disease control & prevention and American academy of pediatrics recommends since perinatal or early postnatal transmission is the most important source of chronic HBV infection globally, all infants should receive their first dose of hepatitis B vaccine as soon as possible after birth, ideally within 24 hours or before discharging the mother from hospital. Now a days, 10 million Bangladeshis are suffering from HBV and 3.5% mother are infected with that virus. From another study, 21.5% pregnant woman having core antibody of HBV as many of them were unvaccinated. Faulty pregnancy and donor screening as well as inaccurate method of testing also responsible for perinatal transmission in Bangladesh. So, we are missing lots of HBV everyday in our daily practice. After implementation of birth dose, many countries reduced perinatal transmission and prevalence rate of HBV successfully.

**Keywords:** hepatitis b vaccination, perinatal transmission, pregnancy screening, blood donor screening, hepatitis b virus prevalence

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## Introduction

Universal immunization program of children has been reduces childhood mortalities and morbidities against vaccine-preventable diseases (VPD) across the world.[1–4] A global immunization program was officially launched by the World Health Organization (WHO) in May 1974, known as Expanded Program on Immunization (EPI) against six vaccine preventable diseases, namely tuberculosis, polio, diphtheria, whooping cough, tetanus and measles by the year 2000.[5,6] For the prevention of VPDs and to eradicate poliomyelitis, with the help of UNICEF(United Nations International Children's Emergency Fund) and WHO, the government of Bangladesh had initiated the EPI through various outreach activities from 1979, with the over all objective to immunize all children by 1990.[1]Along with these six VPDs, the government of Bangladesh already introduced another four vaccine named hepatitis-B, haemophilus influenzae-B, pneumococcus and rubella.Out of all (649) districts in India, only 68 districts EPI coverage ≥80%, whereas Bangladesh among all (64) districts, EPI coverage is ≥90% (Figure 1).[7,8] As a result, Bangladesh was given two GAVI (Global Alliance for Vaccines and Immunization)best performance awards withineleven years.[6]

In 2009, diphtheria-pertussis-tetanus (DPT), hepatitis B and Haemophilus influenza type b (Hib) vaccine was introduced into EPI program in a form of pentavalent with maintaining the immunization schedule at 6, 10 and 14 weeks after birth.[10]As the most important source of chronic hepatitis B virus (HBV) infection through perinatal or early postnatal transmission globally, first dose of hepatitis B vaccine of all infants (including low birth weight and premature infants) should receive as soon as possible after birth, ideally within 24 hours.[11] In that perspective, in absence of birth dose of hepatitis B (HepB) vaccine, we will try to evaluate the necessity of birth dose by compare and contrast with other studies from different countries.

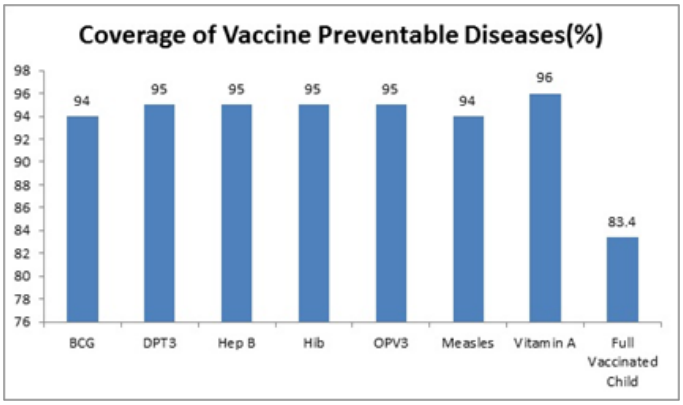


**Figure 1** EPI success in Bangladesh.[9]

## Hepatitis B virus (HBV)

Infection of the liver by an enveloped hepatitis B DNA virus causes necrosis and inflammation of hepatocyte. It can be either asymptomatic, acute or chronic, mild disease to severe or rarely fulminant hepatitis (Figure 2).[12–15]

## Epidemiology and burden of HBV

Worldwide, around 2 billion people have infected with present or past HBV infection, and 257 million are chronic carriers of HBV surface antigen (HBsAg). As a result, with the complications of chronic HBV infection, around 686 thousand people die in every year.[12–15] Ten

million Bangladeshis have HBV. Alarmingly 60-70% are not aware of their HBV infection.[16] According to Lancet 2015, HBsAg prevalence in Bangladesh is 3.1% (Figure 3).[17] Bangladesh achieved Hepatitis B control, with the prevalence of the deadly disease dropping to <1% among five-year-old children, WHO continues to provide emphasis on birth dose of vaccine which ensure better and healthy life in future.[18]

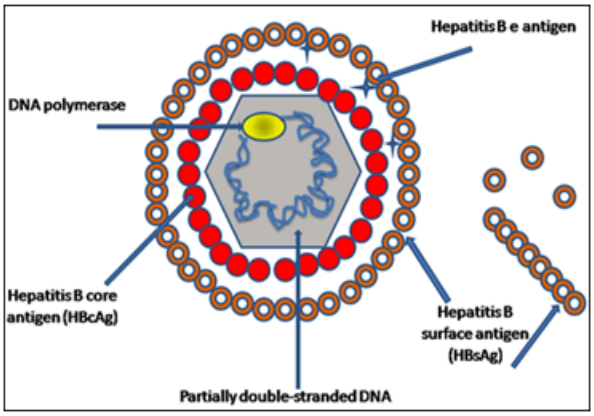


**Figure 2** Structure of HBV.

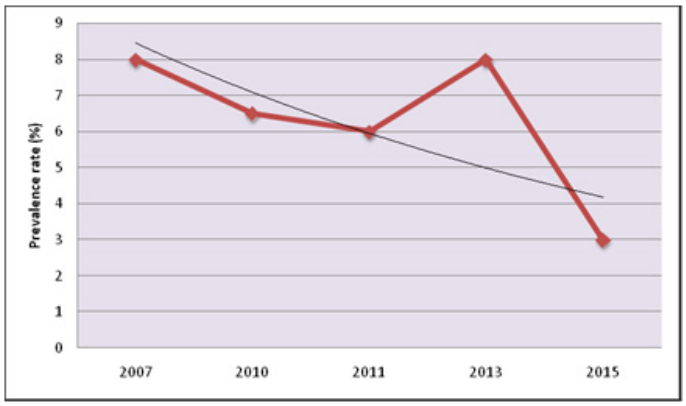


**Figure 3** Overall prevalence of HBV in Bangladeshi general population.[16]

## Transmission of HBV

The routes of transmission of HBV through infants born to infected mother, percutaneous or mucosal exposure to infected blood and various body fluids. The rate of development of chronic HBV infection is inversely related to the age at acquisition of the infection. Approximately 80%–90% of infants infected perinatally, 30%–50% of children infected before the age of 6 years, and in <5% of infections occurring in otherwise healthy adults. Among 90% of HBV-infected infants will develop chronic infection which causes 25% risk of premature death from liver failure or hepatocellular carcinoma.[19] So, prevention of perinatal transmission is very important and birth dose of hepatitis B vaccine is the key.

## Treatment of HBV

Supportive therapy and relief of symptoms are the key for clinical management of acute HBV disease. In progressive liver disease, antiviral therapy is essential for reducing morbidity and mortality. The anti-viral drugs either tenofovir or entecavir with a high barrier to resistance is recommended by WHO. Prevention of HBV reverse transcription by nucleoside analogs (NAs), reducing viremia even below detection limits, but they do not target directly the covalently closed circular DNA (ccc DNA). Despite the absence of detectable viremia, cccDNA persistence within the hepatocytes is the reason for the relapse of viral activity.[20]Anti-viral therapy only applicable for viral suppression, thus no cure of HBV. So, prevention is better than cure.[11,13]

## Prevention of HBV

Safe and effective vaccines against hepatitis B have been available since 1982. Universal vaccination against HBV is recommended for all children worldwide. With birth dose, at least 3 doses of HepB vaccine needed for effective immunization against HBV.[5] HepB vaccine (3 doses) were introduced in Bangladesh through EPI since 2003. Till now, the coverage is excellent but birth dose is absent (Figure 4).[16] Two factors were very important when WHO thought about hepatitis B vaccination schedule. One is transmission during birth and another is transmission after birth. The Advisory Committee on Immunization (ACIP),[21] American Academy of Pediatrics (AAP),[21] WHO,[11] The Centers for Disease Control and Prevention (CDC)[20] American College of Obstetricians & Gynecologists (ACOG)[21] and National Immunization Schedule in India[22] recommends vaccination within 24 hours of birth or vaccinate the baby before maternal discharge or during the first contact with health care provider after birth then follow the EPI schedule (6th, 10th& 14 weeks) or after 1 month and 6 months of 1st dose. Many developing (India, Malaysia, Singapore) and developed (USA, UK, Europe, Australia) countries already practicing the birth dose of HBV vaccine whereas Bangladesh not yet introduced the birth dose. With the birth dose of Hep B vaccine, effective prevention of mother to child transmission but without the birth dose, that's never prevented. Valuable question is, if baby already infected through perinatal route, start on 6th week of vaccination is effective or judicial? Honourable answer is, after perinatal transmission, although vaccination starts from 6th week that's surely unable to prevent HBV in future.[11,15]

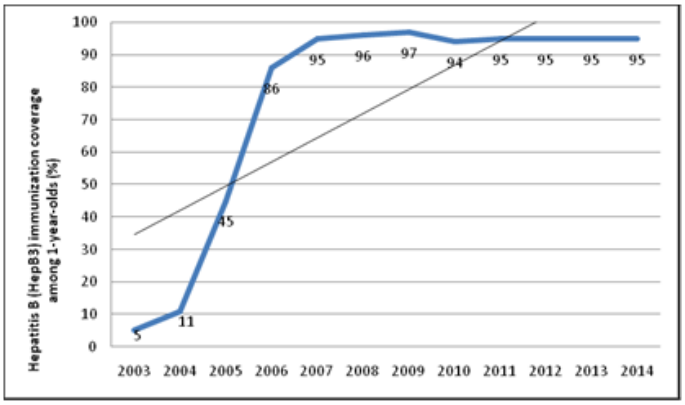


**Figure 4** Hepatitis B immunization coverage in Bangladesh 2003- 2014.[16]

## Endemic zone of HBV

Age-specific HBs Agseroprevalence varies markedly by geographical region. Prevalence of HBs Ag ≥8% defines highly endemic areas, 5%–7% defines high intermediate, 2%–4% low intermediate and <2% defines low endemic areas. Highest prevalence in the African (6.1%) and Western Pacific region (6.2%). Prevalence below 2% is seen in regions such as Central America, North America and Western Europe. From Southeast Asia, Bangladesh is in low intermediate endemic zone with the prevalence of 3.1%.[11,23] Before

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2011, India & Bangladesh both were in low intermediate endemic zone. After that, India was realized the importance of birth dose and introduced it without any delay. As a result, in the year of 2015, India enter into low endemic zone (1.46%) whereas Bangladesh persisted in the same zone (3.1%).[17,22] WHO South-East Asia Region (SEAR) recommended for high & intermediate endemic (>2%) countries should introduce hepatitis B vaccine within 24 hours of birth. That's effectively preventing mother to child transmission.[2,7]

## HBV transmission through pregnant woman

Mothers with HBV infection with a high viral replication rate are at highest risk for perinatal transmission. Infants of HBsAg (surface antigen of HBV) and HBe Ag (envelop antigen of HBV) positive mothers are at a higher risk of acquiring infection (transmission risk 70%–100% in Asia and 40% in Africa) than those born to only HBsAg-positive (5%–30% in Asia and 5% in Africa) mother.[11] But real picture is different. An elegant study in Germany stated that, surface antigen negative but core antibody (anti-HBc) positive mother having HBV DNA at low level that transmits HBV to their infants.[24] Maternal HBV DNA level is the single most important predictor of mother-to-child transmission (MTCT) and levels of only 106 to 108 copies/mL are associated with very high transmission risk. MTCT occurs during pregnancy, especially in third trimester and intrapartum period. Therefore, efforts to use antivirals to reduce viral load and at-birth vaccination within 24 h of the newborn further reduces the chance of chronicity. [25]Another study from India proved the same situation. They concluded that only core antibody positive HBV may transmitted from mother to child.[26] A valuable study from Bangladesh was observed that HBsAg negative but core antibody positive pregnant woman were 21.3% in rural areas. They concluded that 80% mother who have core antibody positive but surface antigen negative, may transmitted HBV to their infants.[27] The prevalence of core antibody positive HBV among pregnant woman in Bangladesh 3.6%[28] in 1992, 3.5%[28] in 1998 and 21.3%[27] in 2011 (Figure 5). Hepatitis B vaccine was introduced in 2003. But now a days those woman who were going to pregnant, majority of them was unvaccinated. On the other side, HBV isolates have been classified into 10 genotypes based on their genomic characteristics. Genotypes are associated with particular routes of transmission, for example—genotypes B and C are associated with high levels of vertical transmission. Different genetic studies on HBV, showed that genotypes B, C and D are the most prevalent genotypes in Bangladesh. So, the evidence of vertical transmission were proved by genotype study (Figure 6).[23]

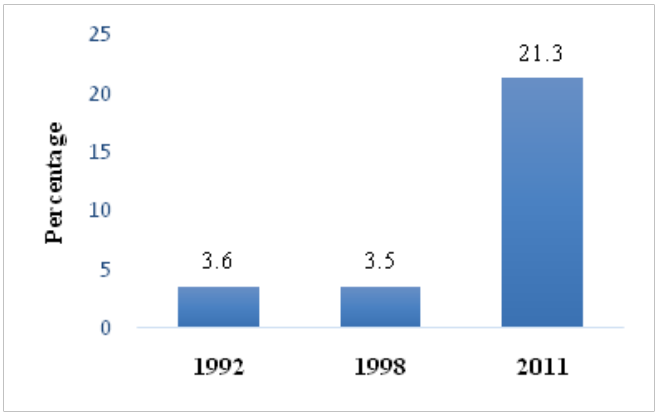


**Figure 5** The prevalence of HBV core anti-body among pregnant woman in Bangladesh.[27,28]

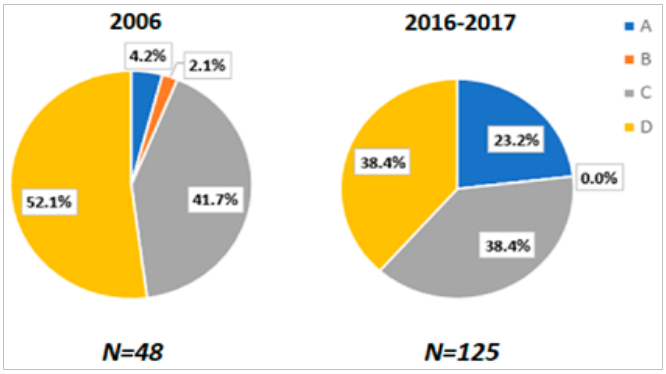


**Figure 6** Proportion of HBV genotypes in Bangladesh.[23]

## HBV in Pregnant woman through unsafe blood transfusion

HBsAg is the only investigation to screen HBV prior to blood transfusion in Bangladesh.[28,29] International organizations like CDC[30] and WHO[31] recommends serum HBsAg& Anti-HBc for the screening of blood donors. Despite testing of HBsAg in blood donors, transfusion-associated HBV infection continue to be a major problems in Bangladesh. Antibodies to hepatitis B core antigen (anti-HBc) are marker of acute, chronic, or resolved HBV infection and remain detectable for life. In occult HBV infection, despite in absence of both HBsAg and anti-HBs antibodies, core antibody can present anytime. Anti-HBc is therefore detected in anyone who has been infected with hepatitis B virus (Figure 7).[32] A study in Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh, Rahman et al.,[32] stated that among 52 core antibody positive donor who were HBsAg negative, HBV-DNA positive in 16 (30.7%) cases. They concluded with core antibody should be routinely included on blood donor screening and if found positive, regardless of anti-HBs titer, blood should be discarded.[32]Another study from same university, Jahan et al.,[33] stated the same phenomena. Among 398 HBsAg negative donors, core antibody (anti-HBc) positive 82 (20.6%). Again who were anti-HBc positive, HBV-DNA present in 7 (8.5%) donors. They concluded with surface antigen negative blood was not capable of blocking HBV transmission. Developing country like Bangladesh may apply core antibody for donor screening (Table 1). [33-37]

**Table 1** Presence of Core antibody among blood donors

| Country | Year | Total Children | HBsAg (-ve) | Anti-HBc (+ve) |
|---|---|---|---|---|
| Bangladesh[33] | 2016 | 398 | (-ve) | 82 (20.6%) |
| Bangladesh[34] | 2016 | 1000 | (-ve) | 117 (11.7%) |
| India[35] | 2012 | 94247 | (-ve) | 9613 (10.2%) |
| India[36] | 2012 | 9100 | (-ve) | 911 (10.0%) |
| Pakistan[37] | 2007 | 966 | (-ve) | 167 (17.2%) |

A study from West Bengal, India, a neighboring Indian province of Bangladesh has reported that 21.3% HBsAg negative and anti-HBc-positive blood donors were harboring HBV DNA in their blood.[38] Another study from India also showed that 7.5% of HBsAg negative,

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anti-HBc positive blood was expressing HBV DNA.[39] Somebody may thought that, with core antibody screening lots of donor are discarded. Key question is 10 out of 100 donor is important or security of life is important? Critical realism is antenatal blood transfusion may needed anytime but inappropriate donor screening prior to transfusion of blood everywhere.

## Hepatitis B virus screening in pregnant woman

HBV screening usually done in first trimester with the help of hepatitis B virus surface antigen (HBsAg). Detection of HBsAg in blood usually appear after 3-4 weeks of exposure and disappear after window period if not develop chronicity. Just after appearance of HBsAg, core antibody usually appear and persist throughout the life. Even with very low amount (<75 copies/ml)of HBV-DNA, it's detected within a week of exposure in blood. [12,13,40,41] So, Only HBsAg marker does not always reflect the presence or absence of HBV infection. HBsAg may absent in incubation period,[32,42] window period,[32,42] occult HBV infection,[33,43] mutant to surface antigen[32,43] and even after reactivation of resolved HBV infection.[34,42] Blood that is free of HBsAg but has high-titer core antibodies against hepatitis B surface antigen (anti-HBs) can also transmit HBV infection. However, a small proportion of donors with anti-HBc in the absence of HBsAg have circulating HBV DNA and may have a risk of infectivity (Figure 8).[44,45] California Department of Public Heath (2015)[46] and Government of South Australia (2016)[47]recommends, HBsAg, anti-HBs and anti-HBc total should do during screening of pregnant woman. If anti-HBc positive, HBV DNA should be done. When all are negative then vaccinate the pregnant woman quickly without any delay.

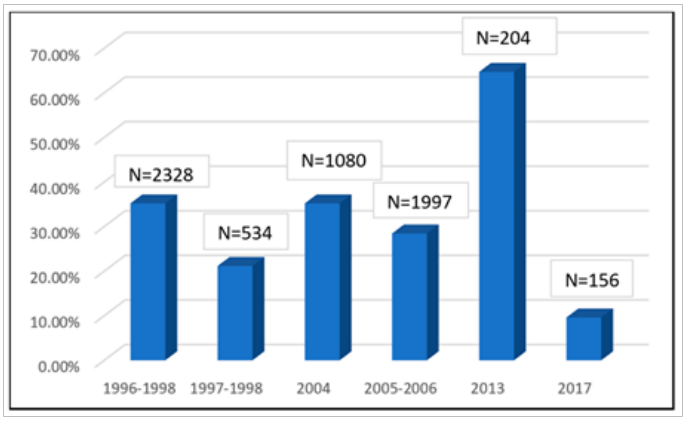


**Figure 7** Prevalence of antibodies against hepatitis B core antigen (anti-HBc) among healthy populations in Bangladesh.[23]

On the other side, the method of testing of HBsAg is rapid strip test in Bangladesh. In case of rapid test, lots of false positive/ negative results may occur. It is most commonly used, only 30 taka/ strip, less sensitive & specific, manual entry of test results and not recommended by WHO as a universal screening of blood donors or pregnant woman in Bangladesh. When false positive results occur, prospective blood donors are unnecessarily excluded from blood donation. On the other hand, when false negatives occur, this poses a great challenge to the quality and reliability of blood screening as well as pregnancy screening (Figure 9).[14] On the other side, quite unlikely to occur when screening is done by EIA, Chemiluminoassay, or PCR (polymerase chain reaction) technology. [29] So, Faulty pregnancy and donor screening as well as inaccurate method of testing were much responsible for perinatal transmission of HBV in Bangladesh.

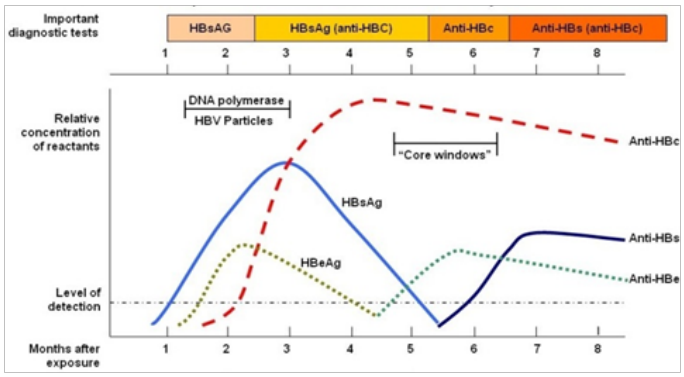


**Figure 8** Profile of HBV infection.[45]

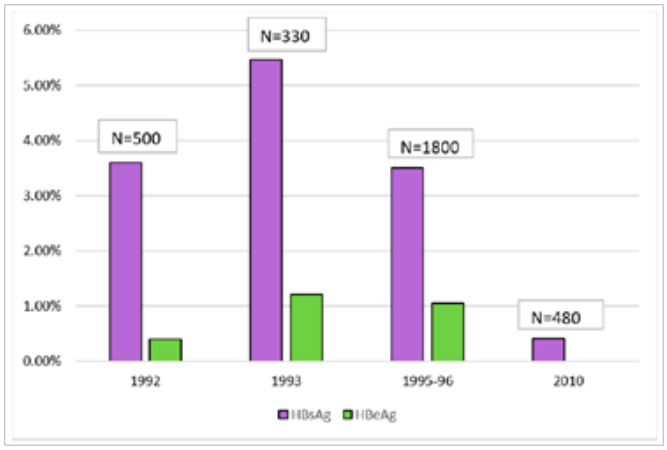


**Figure 9** Prevalence of HBV biomarkers among pregnant Woman and new mothers in Bangladesh.[23]

## Occult HBV infection in pregnant woman

Presence of core antibody with absence of HBsAg and HBV-DNA <1000 copies/ml or<200 IU/ml is called occult HBV infection. When less amount of HBV DNA, HBsAg may negative during screening of pregnant woman (Figure 10).[13,36,37,48] So, chance of missing of HBV every day in our daily practice with occult HBV infection.

## Strong position of WHO, AAP & ACIP regarding birth dose of HBV vaccination

A birth dose of HepB vaccine serves as postexposure prophylaxis to prevent perinatal HBV infection among infants born to HBV-infected mothers. Infants who are requiring postexposure prophylaxis should be identified by maternal HBsAg testing. Even without HBIG (hepatitis B immunoglobulin),administration of a birth dose to all infants serves as a safeguard to prevent perinatal transmission among infants born to HBsAg positive mothers not identified prenatally because of lack of and inaccurate maternal HBsAg testing or failures in reporting test results. The birth dose also provides protection to infants at risk from household exposure after the perinatal period (Figure 11).[21] Since perinatal or early postnatal transmission is the most important source of chronic HBV infection globally, all infants (including low birth weight and premature infants) should receive their

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first dose of hepatitis B vaccine as soon as possible after birth, ideally within 24 hours. If administration within 24 hours is not feasible, a late birth dose has some effectiveness. Experience suggests that delaying administration of the birth dose to infants of chronically infected mothers increases the risk of perinatal HBV transmission. One study found that the risk of infection for infants born to HBsAg positive mothers increased significantly when the first dose of hepB vaccine was received 7 days after birth compared with those vaccinated 1–3 days after birth. A meta-analysis of randomized controlled trials found that infants who received the first dose at birth, compared to infants who received placebo or no intervention, are 3.5 times less likely to become infected when born to HBV-infected mothers.[11]

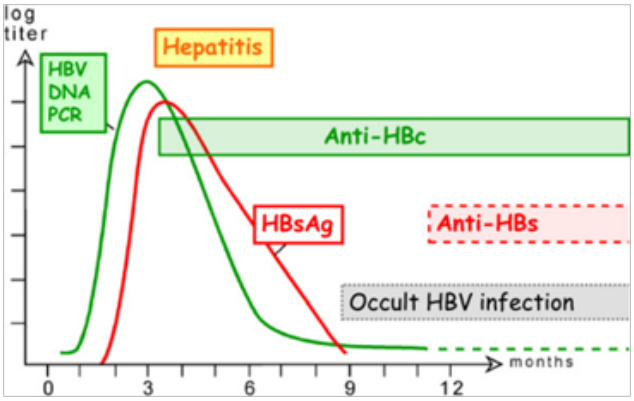


**Figure 10** Occult HBV infection.[49]

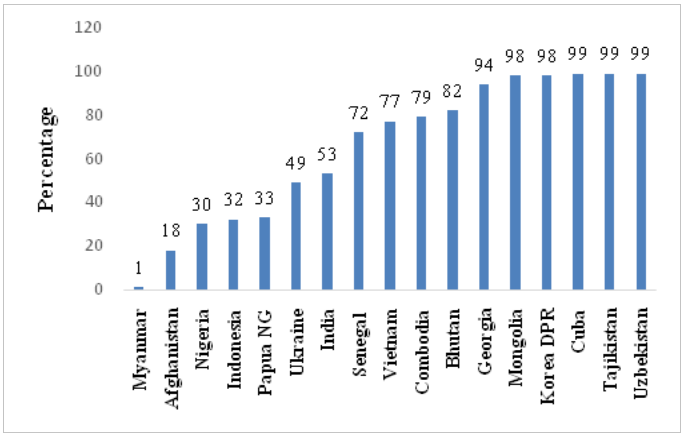


**Figure 11** Birth dose of HepB vaccine coverage in 17 Gavi countries.[50]

## Birth dose model already beneficial for different countries

In the western pacific region previous HBV prevalence was >8%, whereas after birth dose introduction that was<1% among children in most countries of the region. In two highly endemic areas of China, 3-dose vaccination starting with a birth dose reduced chronic HBV infection rates from 9.3% to 0.8% and from 10.4% to 0%.[11]An elegant study in Vietnam, a total of 6949 children divided into two groups. One is birth dose group and another is non-birth dose group. HBV prevalence 2.98% among non-birth dose group whereas birth dose group only 1.75% (Figure 12). They were concluded with markedly reduced chronic HBV infection in Vietnam due to implementation of birth dose.[51] AAP strongly recommended that, hepB vaccine alone is 75-95% effective in preventing perinatal hepatitis B transmission when given within 24 hours of birth.[52]

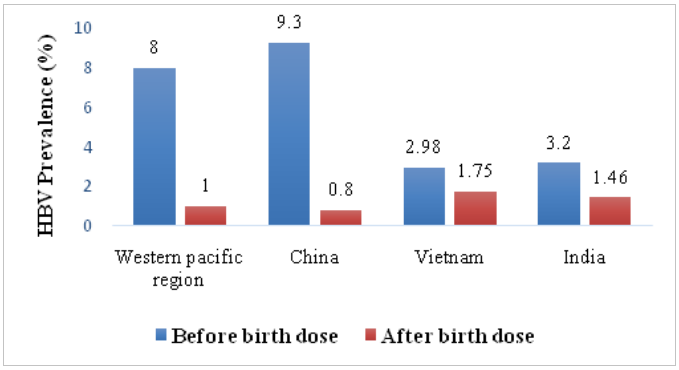


**Figure 12** Improvement of HBV prevalence in different countries after birth dose of HepB vaccine introduction.

## Birth dose implementation challenges in Bangladesh

As of 2015, 97 (49%) countries had introduced the recommended birth dose. In 22 (11%) countries, the hepatitis B birth dose was introduced only for infants born to HBsAg-positive mothers. Bangladesh is one of them. For the implementation of birth dose mainly two barriers are there. One is home delivery and another is cold chain maintenance. In that perspective, Bangladesh should follow the example of India. They first introduced birth dose of HepB vaccine in institutional delivery then gradually adopted the home one.[11,22]

## Conclusions

Birth dose of HepB vaccine is a much essential elements for the complete success of HBV vaccination. Birth dose should be introduced as early as possible in Bangladesh for effective reduction of mother to child transmission. The UN(United Nations) target within 2020, <1% prevalence in 5 years old children and <0.1% prevalence or eliminate hepatitis by 2030. Without the birth dose of HepB vaccine that can never be achieved.

## Recommendations

Blood donor and pregnancy screening should be on ELISA rather than strip method.

Core antibody (anti-HBc) should include in national blood donor and pregnancy screening programme.

Vaccinate newborn at birth that reduces effectively mother to child transmission.

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## Conflict of interest

The author declares that there is no conflict of interest to disclose.

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