

Multi-Sectoral Position Statement on the Hepatitis B Vaccine Birth Dose

All infants, regardless of gestational age, birth weight, and maternal Hepatitis B status, must receive the hepatitis B vaccine within 24 hours of birth to prevent Hepatitis B infection and decrease HBV prevalence and its related deaths in the Philippines. All healthcare providers must implement this timely administration of the hepatitis B vaccine birth dose.

Rationale

Worldwide, over 240 million persons suffer from chronic hepatitis B (CHB). The Philippines belongs to the Western Pacific Region, with the world's largest burden of hepatitis B disease and highest number of hepatitis B-related deaths.¹ Hepatitis B is a vaccine-preventable infection that leads to approximately 700 deaths per day in the Western Pacific Region alone. Viral hepatitis related mortality in the region is now higher than mortality from HIV/AIDS, malaria and tuberculosis. Majority of hepatitis B virus (HBV)-related deaths are from the sequelae of chronic hepatitis B (CHB) infections acquired in infancy and childhood, making universal Hepatitis B vaccination coverage a key health indicator for the Philippines.

A country highly endemic for HBV, the Philippines has a 16.7% seroprevalence among adults, this accounts for an estimated 7.3 million adult Filipinos chronically infected with (HBV) who can then serve as reservoirs for transmission, while being at risk of liver cirrhosis, liver cancer, and death.² Annually, approximately 40,000-80,000 Filipino newborns a year can acquire chronic Hepatitis B infection from perinatal transmission if immunization is not given.³ The risk of chronic infection is highest in infancy with 80-90% of infants developing CHB when contracted within the first year of life, while only 5% of healthy persons who become infected as adults will develop chronic infection. Of those who get chronically infected, 20–30% will develop the fatal complications of liver cirrhosis and/or liver cancer.

Vaccination against HBV prior to an exposure is the best way to prevent HBV infection. In countries where the disease is highly endemic, like the Philippines, HBV is mainly spread from mother to infant at birth or from child to child during early childhood, hence providing the first dose of the vaccine for Hepatitis B at birth is critical. The World Health Organization (WHO), the Department of Health (DOH), and the Philippine Pediatric Society (PPS) recommend universal hepatitis B vaccination as the most cost effective strategy to prevent and control hepatitis B. All infants should receive the first dose of hepatitis B vaccine as soon as possible after birth, preferably within 24 hours, followed by two or three doses.^{1,4} The Essential Newborn Care Recommendations made by the DOH and WHO specifically state that the birth dose of the Hepatitis B vaccine should be given from 90 minutes to 6 hours after birth, after immediate newborn care is administered.⁵ Exclusion of the birth dose in the hepatitis B immunization schedule may result in Hepatitis B infection in up to 90% of infants born to infected mothers before the first scheduled dose of vaccination at 4–8 weeks of age.⁶

The recommended optimal intervention in babies whose mothers are positive for hepatitis B is immunization of the neonate with both the Hepatitis B immunoglobulin (passive immunization) and hepatitis B vaccine (active immunization) at birth.^{7,8,9} This combination of hepatitis B immunoglobulin (HBIG) and vaccination given within 12 hours of birth can reduce the rate of perinatal transmission from more than 90% to less than 10%^{8,9,10} Although the perinatal transmission prevention rate of the combination of hepatitis B immunoglobulin (HBIG) and hepatitis B vaccine is higher (92%) than vaccine alone (82%) in HBeAg-positive mothers,¹¹ there is no difference in transmission prevention rates in infants born to HBeAg-negative mothers (HBIG + vaccine: 98.9% vs. Vaccine: 99.1%).¹² Moreover, a meta-analysis has shown that hepatitis B vaccine with or without hepatitis B immunoglobulin reduced hepatitis B occurrence compared to placebo among hepatitis B surface antigen-positive mothers.¹⁵ In a cost-effectivity analysis that takes into account seroprevalence rates and capacity of the health infrastructure, it was acknowledged that although HBIG will likely be a cost-effective supplement to

universal vaccination for infants born to HBsAg positive mothers, in very resource limited settings, universal vaccination alone is considered optimal.¹⁶ HBIG is not readily available and expensive. WHO has therefore deemed that the administration of hepatitis B vaccine should be the backbone of any perinatal transmission prevention strategy and is sufficient on its own in preventing perinatal transmission in the majority of infants born to HBsAg-positive mothers.¹³

All birth doses are given as a monovalent vaccine. To assure life-long immunity, hepatitis B vaccination is completed from birth following two options, a three-dose or a four-dose schedule. The three-dose schedule is completed with the first dose (monovalent) given at birth, and the second and third (monovalent or combined vaccine) given at the same time as the first and third doses of diphtheria–tetanus–pertussis (DTP) vaccine. The four-dose schedule includes a monovalent birth dose followed by three monovalent or combined vaccine doses, usually given with other routine infant vaccines. For infants who weigh less than 2000g at birth, the DOH recommends an additional dose of the Hepatitis B vaccine at week 10 of life.⁴

Recognizing the staggering global burden of viral hepatitis, the World Health Assembly (WHA) issued two landmark resolutions, WHA 63.18, creating World Hepatitis Day in 2010, and WHA 67.6 on the agenda on Hepatitis in 2014.^{17,18} The World Health Organization has called on its member states to urgently develop national and locally applicable strategies to prevent, diagnose, and treat viral hepatitis. In 2015, WHO released the guidelines for the prevention, care and treatment of persons with CHB infection. This emphasized the role of universal HB immunization as the cornerstone of any national strategy for viral hepatitis prevention.¹⁰

The Philippines is aligned with the WHO's action plan to decrease the global hepatitis B disease burden. In 1990, the Hepatitis B vaccine was integrated into the Expanded Program of Immunization. Hepatitis B vaccine was used in routine vaccination by 1992 to target 40% of infants, with the aim to increase yearly coverage by 10% until 100% coverage was reached by 1999. In 1994, Republic Act No. 7846-2006 appropriated the "compulsory Hepatitis B immunization among infants and children less than 8 years old".¹⁹ Subsequently, Republic Act No. 10152, the Mandatory Infants and Children Health Immunization Act of 2011 requires that free basic immunization be given to all infants and children up to 5 years of age at all government facilities and health centers. Hepatitis B vaccine should be "administered by any duly licensed physician, nurse or midwife to all infants born in hospitals, health infirmaries, health centers or lying-in centers with obstetrical and pediatric services, whether public or private, within twenty-four hours after birth."²⁰ It also appropriates coverage for out-of-institution births, i.e., all infants should be brought to any health facility to be immunized for Hepatitis B within 24 hours of birth, and if possible not later than 7 days. To further supplement this, PhilHealth – the country's national health insurance provider, appropriates for the birth dose of the hepatitis B vaccine in its newborn package.

Given the existing legislation on hepatitis B, all Filipino infants, including preterm neonates, should receive the timely hepatitis B vaccine birth dose. However, this goal remains unrealized. The DOH reported that timely (within 24 hours of birth) hepatitis B birth dose coverage for 2014, 2015²¹ and 2016 were at 51%, 56% and 55%, respectively. In 2011, when 142 government and private health facilities were surveyed, the median timely HB vaccine birth dose coverage was 90% in government clinics, 87% in government hospitals, and only 50% in private hospitals.²² This study showed a low uptake of the timely birth dose in the private sector, where 18% of births are estimated to occur. This is despite law-mandated free universal vaccination and timely hepatitis B birth dose vaccination. Vaccine shortage and vaccine cost in the private sector, and misconceptions about its contraindications were cited as reasons for not vaccinating a newborn. Low birth weight, prematurity, and neonatal illness are the common misguided "contraindications" reported.²² These reasons, along with the fact that over 50% of births in the Philippines are still outside of health care facilities, may explain low overall uptake of the timely

birth dose of the HB vaccine.²² Targeted training and re-education programs should be instituted, effectively abolishing all possible misconceptions. Only one absolute contraindication to the administration of the hepatitis B vaccine exists, i.e., a history of allergy to any one of its components, and this is an issue not applicable to newborns.²³

In summary, hepatitis B remains to be a significant public health issue in the Philippines that leads to significant morbidity and mortality. The cornerstone of an effective national prevention and control strategy involves enforcing universal vaccination against Hepatitis B. This means the administration of a timely birth dose within 24 hours of birth, followed by 2 to 3 more doses of the vaccine as a monovalent vaccine or in combination with other vaccines before one year of age.

In order to increase timely birth dose coverage, the following steps need to be implemented; (1) inclusion of the timely administration of the Hepatitis B vaccine within 24 hours of birth as a performance indicator in the assessment and accreditation of healthcare facilities, (2) improvement of reporting and monitoring systems in all healthcare and birthing facilities, (3) encourage births within healthcare facilities and births attended by skilled birth attendants, and (4) strengthening awareness campaigns headed by government and professional societies to educate health care providers, especially those involved in perinatal care and the general public, especially parents, on the high national prevalence of hepatitis B and the impact of a timely birth dose of the vaccine in decreasing the disease burden.

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INVITED SIGNATORIES, ORGANIZATIONS REPRESENTED (World Hepatitis Day 2017)

Philippine Society for Pediatric Gastroenterology, Hepatology and Nutrition
Hepatology Society of the Philippines
Pediatric Infectious Disease Society of the Philippines
Philippine Society for Newborn Medicine
Philippine Pediatric Society
Philippine Infectious Diseases Society of Obstetrics and Gynecology
Philippine Obstetrical and Gynecological Society
Philippine Society of Gastroenterology
Integrated Midwives Association of the Philippines
Philippine Foundation for Vaccination
Department of Health, Philippines
World Health Organization