



HEPATOLOGY SOCIETY
OF THE PHILIPPINES

HSP POSITION STATEMENT ON HEPATITIS B VACCINATION

Introduction

This statement by the Hepatology Society of the Philippines on hepatitis B vaccination reaffirms the society's stand on the importance of the birth-dose vaccination for all Filipino infants and vaccination of all susceptible individuals. This paper provides vaccination schedules and information on safety and means of access to the vaccine.

Background

Hepatitis B prevalence in the Philippines has been estimated at 16.7%, with more than 7,000,000 Filipinos being positive for hepatitis B sAntigen (HbsAg). HbsAg peaks in the 20-39 age group, with those in lower socioeconomic groups more likely to be positive.¹

Despite government-supported vaccination programs in place since 1992, by 2007 only 54% of infants delivered in hospitals had a documented birth dose. By 2014, failure to deliver the first dose within 24 hours after birth was seen in 65% of all births. Completion of the three-dose series declined from 88% to 77% from 2008 to 2012. Failure to provide birth-dose vaccination has been attributed to inadequate knowledge of health-care providers on contraindications to vaccination, refusal of vaccination by families, and supply-and-delivery issues. Perinatal and household transmission remain major sources of infection.²

All unvaccinated Filipino adults without contraindications to the vaccine should be vaccinated, because hepatitis B is endemic to the Philippines. Vaccination should be offered especially to groups at higher risk for infection, including those with sexual, percutaneous or mucosal exposure; health care and public safety workers; people with chronic liver disease; people with chronic kidney disease including dialysis patients; people with HIV; and pregnant women.³

Vaccines Available in the Philippines Either as Hepatitis B Vaccine Alone or as Part of a Combination Vaccine (MIMS).

Amvax B – recombinant hepatitis B vaccine

Easyfive TT (Panacea Biotec) – diphtheria, tetanus toxoid, B pertussis whole cell, HbsAg rDNA, HiB type B conjugate)

Engerix-B (GSK) – hepatitis B rDNA Euvax B (LG Life Sciences) – hepatitis B recombinant

Genvac-B – hepatitis B recombinant

Hepliv (Bharat) – hepatitis B rDNA

Hexaxim – diphtheria toxoid, tetanus toxoid, B pertussis antigens, pertussis toxoid, filamentous haemagglutinin, inactivated poliovirus types 1,2,3, hepatitis B surface antigen, H influenzae type B polysaccharide conjugated to tetanus protein

Infanrix Hexa (GSK) – diphtheria toxoid, tetanus toxoid, pertussis toxoid, filamentous hemagglutinin, pertactin, HbsAg 10mcg, inactivated poliovirus types 1,2,3, HiB polysaccharide

Pentavac – Diphtheria anatoxin, tetanus anatoxin, whole and inactivated B pertussis, HBV antigen rDNA, synthetic conjugate of PRP HiB

Quinvaxem (Janssen) – diphtheria toxoid, tetanus toxoid, pertussis antigen, HiB oligosaccharide, HbsAg 10 mcg

Shanvac-B – recombinant DNA

Temrevac-HB – recombinant hepatitis B vaccine

Twinrix adult (GSK) – combined hepatitis A and B vaccine

Safety of hepatitis B vaccine

The first recombinant HBV vaccine to be licensed has been in use since 1986. A 30-year systematic review of safety data in adults reported occurrence rates of adverse events at 0-12.5% after vaccination. When adverse events were solicited, injection site pain rates ranged from 1.5%-39.8%, redness at 0-24.4%, and swelling 0-12%. Fatigue was reported in 10.5-25.2%, headache at 0.7-22.4%, fever at 0-14.8%, malaise at 1-13.1% and gastrointestinal events at <1-10.2%.⁴

In the United States, analysis of the Vaccine Adverse Event Reporting System (VAERS) reviewed from 2005 to 2015 did not reveal new or unexpected safety concerns. Adverse events including dizziness, nausea, fever and injection site erythema were most frequently reported.

Of 20,231 reports in VAERS following hepatitis B vaccination, 400 were deaths consistent with leading causes of death within the relevant age groups.⁵

Analysis of data for pregnant women from VAERS in 1990-2016 did not identify any new or unexpected safety concerns. Adverse events including newborn death, maternal death, spontaneous abortion and preterm deliveries were found within expected rates.⁶

Efficacy of hepatitis B vaccine

A 2017 review of efficacy data over thirty years for the original recombinant vaccine showed seroprotection rates $\geq 96.0\%$ using the standard 0,1,6 month schedule. This population included infants with HbsAg-positive mothers. In high-risk infants, vaccine efficacy at year 5 was still 96% after administration of immunoglobulin at birth and standard 3-dose vaccine schedule.⁷

Three-dose vaccination of healthy adults resulted in seroprotection rates of 90% or more. Seroprotection rates decreased at older ages to as low as 67.7% in those older than 65 years. Accelerated schedules at 0,1,2 months or 0,7,21 days required booster doses. After booster dose, seroprotection rates at 1 month ranged from 93% to 100%. Lower seroprotection rates were seen in patients with chronic kidney disease, liver transplant recipients, adults with liver disease, adults with inflammatory bowel disease, adults with HIV, drug users, and adults with intellectual disabilities.⁴

The combined hepatitis A and hepatitis B vaccine showed similar immunogenicity rates. A 2016 review examining data from 1990 to 2015 showed anti-HBs seroprotection rates from 82% to 100%, with antibodies persisting up to 15 years.⁸

Conclusion

Hepatitis B vaccination is SAFE and EFFECTIVE. In Filipino babies without contraindications, hepatitis B vaccination is recommended WITHIN 24 HOURS of birth. All other patients without contraindications who are not immune to hepatitis B should also be vaccinated.

References

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