

Summary of Key Points

WHO Position Paper on Vaccines against Hepatitis B, July 2017



World Health
Organization

Background

- HBV is transmitted by exposure of mucosal membranes or non-intact skin to infected blood, saliva, semen or vaginal fluid
 - Most infections through perinatal or early childhood exposure
- 257 million people living with chronic HBV infection and 887 220 deaths in 2015 from hepatocellular carcinoma (HCC), cirrhosis and acute hepatitis
- Substantial burden from low birth-dose coverage (39% worldwide), as the likelihood of chronic infection is inversely proportional to the age at infection



Vaccines

- Yeast-derived monovalent or combination vaccines (with DTP, Hib or IPV)
 - Allergy to yeast is contraindicated
- 60.1% decrease in incidence of HCC, 76.3% decrease in mortality from fulminant hepatic failure, 92% decrease in mortality from chronic liver disease over decades since vaccine introduction in Taiwan
 - Additional studies needed on life-long effectiveness and need for booster doses in different subgroups
- Excellent safety profile, determined by GACVS
- Cost-effective, particularly as part of triple elimination strategy to eliminate mother-to-child transmission of HIV, hepatitis B and syphilis



WHO Position

- WHO recognizes the importance of hepatocellular carcinoma and other HBV-related diseases as global public health problems and reiterates its recommendation that hepatitis B vaccines should be included in national immunization programmes.
- A comprehensive approach to eliminating HBV transmission must address prevention of infections acquired perinatally and during childhood, as well as prevention of infections acquired by adolescents and adults. Reaching all children with at least 3 doses of hepatitis B vaccine should be the standard for all national immunization programmes.



WHO Position

Birth Dose

- Hepatitis B vaccination is recommended for all children worldwide, and all national programmes should include a monovalent hepatitis B vaccine birth dose, ideally within 24 hours.
- If administration within 24 hours is not feasible, a late birth dose has some effectiveness. Although effectiveness declines progressively in the days after birth, after 7 days, a late birth dose can still be effective in preventing horizontal transmission and therefore remains beneficial. WHO recommends that all infants receive the late birth dose during the first contact with health-care providers at any time up to the time of the next dose of the primary schedule.



WHO Position Vaccination Schedule

- 3-dose schedule: monovalent birth dose, second and third doses given with first and third doses of DTP vaccine
- OR 4-dose schedule: monovalent birth dose, following 3 doses given with other routine infant vaccines
- At least 4 weeks between doses
- No evidence to support need for booster dose
- Catch-up vaccination should be considered based on available resources. Priority should be given to younger age groups

WHO position

Co-administration and Interchangeability

- The hepatitis B vaccine may be co-administered at different anatomical sites with other vaccines.
 - In particular, monovalent hepatitis B vaccine can be given with OPV and BCG at birth.
- Available hepatitis B vaccines may be used interchangeably within immunization programmes.



WHO Position

Special Populations

- Vaccination of groups at highest risk of acquiring HBV infection is recommended:
 - Patients who frequently require blood/blood products, dialysis or diabetes patients, recipients of solid organ transplants, persons with chronic liver disease or HIV, persons interned in prisons, persons who use injecting drugs, household and sexual contacts of persons with chronic HBV infection, men who have sex with men, persons with multiple sexual partners, healthcare workers and others who may be exposed to potentially infectious body fluids during their work
 - HIV-positive individuals should be vaccinated as early as possible in the course of HIV infection.
 - Immunocompromised individuals may have reduced immune response following vaccination.



WHO Position

Special Populations, Continued

- Vaccination is safe for pregnant and lactating women.
- A birth dose can be given to low birth weight and premature infants.
 - The birth dose should not count as part of the primary 3-dose series. The 3 doses of the standard primary series should still be given afterwards, according to the national vaccination schedule.



WHO Position

Strategy for implementation

- National strategies to prevent perinatal transmission should ensure high and timely coverage of the birth dose through a combination of strengthened maternal and infant care at birth with skilled health workers present to administer the vaccine, and innovative outreach strategies to provide vaccine for infants born at home.
 - Increase proportion of infants born in health facilities
 - Health promotion efforts to eliminate false contraindications (e.g. unease over vaccinating low birth weight and premature infants), concerns over adverse reactions, fear of vaccine wastage, personal cost concerns, and cultural prohibitions

WHO Position

Reporting and Monitoring

- Reporting and monitoring systems should be strengthened to improve the quality of data on the birth dose.
- To monitor accurately the delivery of doses given within 24 hours of birth, these doses should be recorded as a “timely birth dose” of hepatitis B vaccine to differentiate them from birth doses given later (“late birth dose”).
- Serological surveys of hepatitis B virus surface antigen (HBsAg) prevalence, representative of the target population, will serve as the primary tool to measure the impact of vaccination and verify achievement of the hepatitis B control goals.



**For more information on the WHO
Hepatitis B position paper, please
visit the WHO website:**

www.who.int/immunization/documents/positionpapers



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