

Summary of WHO Position Paper on Hepatitis B Vaccines, July 2017

This position paper, published in July 2017, replaces the corresponding WHO position paper on hepatitis B vaccines published in the Weekly Epidemiological Record in 2009. In particular, the recommendations stress the importance of birth-dose vaccination for all infants as the most effective intervention for preventing hepatitis B virus-associated disease worldwide. The recommendations also address target groups and appropriate schedules for vaccination, and the paper provides updated information on hepatitis B vaccines and their storage, transport and deployment.

Background

Hepatitis B Virus (HBV) is transmitted by exposure of mucosal membranes or non-intact skin to infected blood or other specific body fluids (saliva, semen and vaginal fluid). In 2015, the global prevalence of HBV infection was estimated at 3.5%, with about 257 million persons living with chronic HBV infection. An estimated 887 220 persons died due to HBV infection - 337 454 due to hepatocellular carcinoma, 462 690 due to cirrhosis, and 87 076 due to acute hepatitis. A substantial burden of chronic HBV infection persists because birth-dose coverage is still low, estimated at 39% globally. Most of this burden results from infections acquired in infancy through perinatal or early childhood exposure, as infection acquired at an early age is more likely to become chronic than infection acquired later in life.

Vaccines

Hepatitis B vaccines are available as monovalent formulations and in combination with other vaccines, including diphtheria–tetanus–pertussis (DTP), *Haemophilus influenzae* type b (Hib), and inactivated poliovirus (IPV). Yeast-derived recombinant vaccines are the most widely used. Hepatitis B vaccines are very effective, as evidenced by the dramatic decrease in the incidence of HCC (60.1%), mortality due to fulminant hepatic failure (76.3%), and mortality due to chronic liver diseases (92.0%) in Taiwan over the decades since vaccine introduction. A study in Alaska estimated that approximately 90% of vaccinees remained protected for at least 30 years; however, additional longer-term studies should be conducted to explore life-long vaccine effectiveness and the need for booster doses in different subgroups of the population. Additionally, the Global Advisory Committee on Vaccine Safety (GACVS) has confirmed the excellent safety profile of the hepatitis B vaccine. It is also cost-effective, and the triple elimination strategy for mother-to-child transmission of HIV, hepatitis B and syphilis, in particular, increases the cost-effectiveness of hepatitis B vaccination.

WHO Position

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. 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. For this reason, 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.

The available hepatitis B vaccines may be used interchangeably within immunization programmes. However, allergy to yeast is considered a contraindication to immunization with yeast-produced hepatitis B vaccine. Hepatitis B vaccines may be co-administered at different anatomical sites with other vaccines – in particular, monovalent hepatitis B vaccine can be co-administered with OPV and BCG at birth.

Either: (i) a 3-dose schedule of hepatitis B vaccine, with the first dose (monovalent) being given at birth and the second and third (monovalent or as part of a combined vaccine) given at the same time as the first and third doses of DTP-containing vaccine; or (ii) 4 doses, where a monovalent birth dose is followed by 3 (monovalent or combined vaccine) doses, usually given with other routine infant vaccines is appropriate. The interval between doses should be at least 4 weeks. There is no evidence to support the need for a booster dose. For catchup vaccination, priority should be given to younger age groups since the risk for chronic infection is the highest in these cohorts. Catch-up vaccination is a time limited opportunity for prevention and should be considered based on the available resources and priority.

Vaccination of groups at highest risk of acquiring HBV infection is recommended. These include patients who frequently require blood or blood products, dialysis patients, diabetes patients, recipients of solid organ transplantation, persons with chronic liver disease including those with hepatitis C, persons with HIV infection, 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, as well as healthcare workers and others who may be exposed to blood, blood products or other potentially infectious body fluids during their work. To obtain optimal immune responses to vaccination, it is essential that HIV-positive individuals are vaccinated as early as possible in the course of the HIV infection. In immunocompromised individuals, including patients with chronic renal failure, chronic liver disease, coeliac disease, and diabetes, the immune response following vaccination is often reduced. Hepatitis B vaccine can be administered safely to pregnant and lactating women. A birth dose of hepatitis B vaccine can be given to low birth weight and premature infants. For these infants, the birth dose should not count as part of the primary 3-dose series; the 3 doses of the standard primary series should be given according to the national vaccination schedule.

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 HBV 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.