

Hepatitis B birth dose vaccines indicator

Benefits of the intervention

Serogroup or serotype coverage by vaccines considered (for serogroup- or serotype-specific vaccines)

Hepatitis B vaccines provide broad protection against all known HBV genotypes (A-J). While rare immune escape variants exist, they are uncommon, and the vaccines remain highly effective at preventing hepatitis B infection and its complications worldwide.^{1, 2}

Efficacy and effectiveness estimates (e.g. against infection, disease, hospitalization, death), including in different populations

A birth dose of HepB vaccine followed by two or three doses confer high and durable protection against chronic HBV infection.

An anti-HBs antibody concentration of ≥ 10 mIU/ml measured 1-2 months after administration of the last dose of the primary vaccination series is considered a reliable serological marker of long-term protection against HBV infection.³

The median seroprotection proportions after ≥ 3 doses of hepatitis B vaccine, with the first dose being administered in the newborn period, were 98% (range 52%–100%) and 85% (range 39%–100%), respectively in two systematic reviews.⁴

The median seroprotection proportions were lower among infants born to HBeAg-positive women than infants born to HBeAg-negative women (84% and 94%, respectively).⁵

Three-dose schedules completed in the first three months of life (“compressed schedules”, with or without a fourth dose of vaccine) had slightly lower median seroprotection proportions than non-compressed schedules.⁵

Available evidence suggests that recombinant hepatitis B vaccination starting at birth achieves high levels of seroprotection among full term infants with birth weight ≥ 2000 grams. Infants with birth weights < 2000 grams have lower levels of seroprotection with vaccination starting at birth and might require an additional dose(s) of hepatitis B vaccine to achieve similar levels of seroprotection as infants with higher birth weights.⁵

The evidence that hepatitis B vaccination in those who completed a 3-dose schedule beginning at birth prevents mother-to-child transmission comes principally from randomized trials conducted among infants born to HBsAg-positive, and especially HBeAg-positive, mothers in the 1980s and 1990s. Across randomized trials, a vaccine series initiated in the neonatal period reduced infant HBV infection by about 72% compared with placebo or no prophylaxis; adding hepatitis B immunoglobulin (HBIG) increased protection further, particularly for infants of highly infectious mothers.⁶

In an early influential study in Taiwan, the estimated protective efficacies were: 75% with vaccine alone, 71% with HBIG alone and 94% with vaccine plus (HBIG).⁷

More recent studies in Ethiopia,⁸ and Sierra Leone ⁹ showed that the introduction of hepatitis B vaccination, starting at birth, prevented transmission and reduced chronic hepatitis B infection.

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 hepatitis B vaccine was received seven days after birth compared with those vaccinated 1–3 days after birth (odds ratio, 8.6).¹⁰ However, the administration of the first dose at seven days in a 3- or 4-dose schedule will prevent horizontal transmission of infection in early childhood.

Duration of protection and waning of immunity in general and risk groups

In a study in Alaska, USA, an intermediate endemic area, a 3-dose vaccination schedule (second dose after one month, third dose after six months) with a plasma-derived hepatitis B vaccine prevented all clinically apparent and chronic HBV infection for at least 30 years.¹¹

In this study, most (88%) of a subset of people who were tested but did not have seroprotective levels of anti-HBs antibody responded with a rapid rise in titre after a booster dose, indicating immunologic memory and persistence of protection. From these data, it was estimated that approximately 90% (range 74%–100%) of vaccinees remained protected for at least 30 years, irrespective of the presence or absence of measurable anti-HBs antibody.¹¹

A further follow-up in the same study, estimated that 86% of participants had evidence of protection 35 years later.¹²

A review and meta-analysis of 22 studies among persons 5–20 years after vaccination found no chronic HBV infection; it was concluded that individuals adequately vaccinated in a 3-dose or 4-dose schedule do not require a booster dose to prevent chronic infection.¹³

Additional long-term studies are needed to explore lifelong protection conferred by hepatitis B vaccine and the need for booster doses in different subgroups of the population, particularly in HIV-infected/ HIV-exposed infants.¹⁴

Sources

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