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Hepatitis B birth dose vaccines indicators

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Burden & epidemiology

Number of new cases per year (last 3-5 years)

Globally, the number of people newly infected with the hepatitis B virus (HBV) in 2024 was estimated at around 0.9 million; this was a decline of 32% from 2015.1

Between 2015 and 2024, there were substantial declines in the number of new HBV infections in the WHO European, South-East Asia and Western Pacific Regions (54%, 54%, and 49%, respectively) and large reductions in the WHO Region of the Americas (43%) and the African Region (25%). The smallest net reduction was in the WHO Eastern Mediterranean Region (17%), with an upward trend emerging after 2022.[1]

Proportion of the population affected by the disease or infected with the antigen

In 2024, an estimated 240 million people were living with chronic HBV, corresponding to a global prevalence rate of 2.9%.[1]

Among children under five years of age, the global prevalence of chronic HBV infection was estimated to be around 0.6%. Infection in infancy or early childhood results in chronic hepatitis in about 95% of cases, while the risk of chronic infection is below 5% for infections acquired in later childhood and adulthood.[1]

The highest prevalence of chronic HBV infection among children below five years of age and in the general population is in the WHO African Region (1.4% and 5.1% respectively). Prevalence among children aged below five years is then followed by the WHO Eastern Mediterranean Region (0.5%), Western Pacific Region (0.4%), South-East Asia Region (0.2%), European Region (0.06%) and the Region of the Americas (0.03%).[1]

Serogroup or serotype distribution (for serogroup- or serotype-specific vaccines)

HBV occurs in ten different genotypes (A to J) with a DNA variation of >8% between genotypes. Genotypic distribution varies geographically. Many HBV sub-genotypes exist and differ by >4%.[2] The prevalence of different genotypes may vary between regions. Some of the genotypes, such as D, were found worldwide, whereas others were restricted to single continents, like B and C in Asia, E in Africa, and F and H in the Americas.[3]

HBV genotypes are associated with variable courses of disease, severity of liver disease, and treatment outcomes.[2, 3]

Number of deaths from the disease per year

Globally, in 2024, there were an estimated 1.1 million HBV-related deaths. Most (75%) deaths and the highest mortality rates occurred in the WHO African and Western Pacific regions. Ten countries accounted for 69% of the global total: Bangladesh, China, Ethiopia, Ghana, India, Indonesia, Nigeria, the Philippines, South Africa and Viet Nam.[4]

Case Fatality ratio (number of deaths / number of new cases, in %)

The case fatality ratio (CFR) for acute hepatitis B is 0.5–1%,[5] and for acute fulminant hepatitis B 20–33%.[6] However, acute and fulminant hepatitis are uncommon following infections acquired during the perinatal period; most infections acquired during this period are asymptomatic, though they commonly result in chronic infection.[7]

There are no formal CFRs reported for chronic infection, though it is estimated that 15–40% of those with untreated chronic hepatitis B infection eventually die from cirrhosis, liver failure, or hepatocellular carcinoma.[5] For HBV-associated decompensated liver cirrhosis, there is an approximately 15–20% one-year mortality and 50–60% five-year mortality, respectively, depending on severity (Child-Pugh class and treatment).[8] For HBV-associated hepatocellular carcinoma, there is an approximately 70–85% five-year case fatality (equivalent to 15–30% 5-year survival overall). Prognosis varies greatly by stage at diagnosis and treatment availability.[9]

Outbreak, epidemic or pandemic risk

Hepatitis B is not usually associated with widespread community outbreaks through casual contact. Instead, outbreaks are almost always due to exposure to infected blood or body fluids in specific settings.

These include:

- healthcare settings, e.g., through unsafe medical injections or procedures, haemodialysis, or assisted glucose monitoring;[10, 11, 12, 13, 14, 15]
- sexual transmission through sexual networks;[16, 17]
- household transmission, e.g., through sharing of razors;[18, 19], and
- needle sharing for injectable drug use, e.g., in prisons.[20]

Contribution of the vaccine to achievement of the national, regional or global disease goals

A World Health Assembly resolution on viral hepatitis (WHA67.6) introduced the prospect of eliminating hepatitis B and C as public health threats. It called for countries to develop national strategies, expand vaccination coverage (including a timely birth dose) in addition to other strategies to prevent, detect and treat chronic infection.[4]

The WHO Global health sector strategy on viral hepatitis, 2016–2021, which was updated for the period 2022–2030 describes the recommended strategies and the monitoring indicators to achieve the global goals. The global targets include a 95% reduction in the annual number of new HBV infections and a 65% reduction in the annual number of HBV-related deaths by 2030 compared with levels in 2015. Coverage targets are also set at 90% for both timely birth dose, and third dose of hepatitis B vaccine.[21]

The increasing use of hepatitis B vaccination has made a substantial contribution to reducing the number of new infections and the prevalence of chronic infection globally. Global coverage with three doses of the hepatitis B vaccine has remained relatively constant from 83% in 2015 to 84% in 2025. Coverage with a timely birth dose has increased from 35% in 2015 to 43% in 2025. However, the timely birth dose coverage in the WHO African Region in 2025 (11%) remains substantially lower than in other Regions, all of which have coverage levels above 40%.[22]

While there is progress against several of the indicators, further efforts are needed to reach the global targets. Achieving the 2030 target of a 95% reduction in HBV incidence (compared with 2015) requires a large improvement in birth-dose coverage of the hepatitis B vaccine, which remains below the 90% coverage target, especially in the WHO African Region.[4]

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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.[23, 24]

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.[25]

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.[26]

The median seroprotection proportions were lower among infants born to HBeAg-positive women than infants born to HBeAg-negative women (84% and 94%, respectively).[27]

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.[27]

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.[27]

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.[28]

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).[29]

More recent studies in Ethiopia,[30] and Sierra Leone [31] 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).[32] 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.[33]

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.[33]

A further follow-up in the same study, estimated that 86% of participants had evidence of protection 35 years later.[34]

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.[35]

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.[7]

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Safety of the intervention

Type, including severity, consequences and frequency of short- and long-term adverse events following vaccination

The Global Advisory Committee on Vaccine Safety (GACVS) has confirmed the safety profile of hepatitis B vaccine.[36]

In general, there are minimal adverse reactions, such as local pain, myalgia and transient fever, mostly within 24 hours. Mild reactions tend to be less common in children than in adults (<10% vs 30%). The estimated incidence of the severe adverse event of anaphylaxis among vaccine recipients is 1.1 per million vaccine doses (95% CI: 0.1–3.9).[37]

Data do not indicate a causal association between hepatitis B vaccine and neurological disease (including Guillain-Barré syndrome and multiple sclerosis), diabetes mellitus, demyelinating disorders, chronic fatigue syndrome, arthritis, autoimmune disorders, asthma, hair loss, or sudden infant death syndrome.[36, 38, 39, 40]

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Values and preferences

Perception of the target population on the risk of disease

For hepatitis B, awareness and perceived risk vary greatly by region. In many contexts most studied (Asia, Africa), although HBV prevalence is high, awareness, perceived risk, and knowledge of mother-to-child transmission of the virus remain low.

Two studies in China among pregnant women found low knowledge and awareness of HBV modes of transmission, including mother-to-child transmission.[41, 42]

In studies among pregnant women in Uganda, Ghana, Ethiopia, and Nigeria, perceived risk was low.[43, 44, 45, 46]

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Acceptability to stakeholders

Acceptability of the vaccine and of vaccination against the disease

As with all vaccines, caregiver knowledge, cultural factors, and local perceptions of vaccine safety influence uptake.[47]

However, despite findings of low levels of knowledge of HBV (see 4.1), the same studies have found that attitudes towards vaccination are generally positive.[41, 48]

In a study among health workers in Nigeria, over half perceived HepB-birth dose (BD) vaccines as extremely safe (61%) and effective (63.4%). Participants strongly agreed that birth vaccination is recommended (80.5%), ethically appropriate (68.3%), and that its benefits outweigh side effects (63.4%).[49]

Birth dose assessments conducted in Botswana, the Gambia, Namibia, Nigeria, and Sao Tome and Principe found that birth dose vaccination was a highly acceptable intervention in all five

countries.[50]

A WHO scoping review summarizes and appraises the evidence from published and grey literature on improving coverage of the hepatitis B birth dose vaccine.[51]

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Financing & funding

Estimated financial cost of materials per vaccine dose (syringes, needles, safety box) (in USD)

Price for one auto-disable (AD) syringe and needle

- As of October 2025, the UNICEF procurement price for 2026 ranges from US$ 0.023 to US$ 0.046 depending on supplier and product.[52]
- The 2025 PAHO Revolving Fund for Access to Vaccines price ranges from US$ 0.028 to US$ 0.044, depending on supplier and product.[53]

Price for one 5-litre safety box

- The UNICEF procurement price for 2026 ranges from US$ 0.375 to US$ 0.860, depending on supplier and product.[54]
- The 2025 PAHO Revolving Fund for Access to Vaccines prices range from US$ 0.356 to US$ 0.467, depending on supplier and product.[53]

Each 5-litre safety box can hold around 100 syringes.

Estimated vaccine financial cost per dose (in USD)

As of May 2025, the UNICEF price of paediatric HepB vaccine for 2026 ranges from US$ 0.22 to US$ 0.55 per dose in a depending on supplier and presentation.[55]

UNICEF prices are subject to change. The latest HepB vaccine price information is available from UNICEF Supply Division.[55] Users are encouraged to confirm current prices by contacting UNICEF

Supply Division.

The 2026 PAHO Revolving Fund for Access to Vaccines pricelist reports a price per dose of paediatric HepB vaccines ranging from US$ 0.48 to US$ 0.55.[56]

The June 2026 US CDC pricelist reports a price per dose of US$ 15.86 to US$ 18.38 for the paediatric HepB vaccine.[57]

Among self-procuring middle-income countries, county-reported prices per dose for 2025 range from US$ 0.42 to US$ 7.47 [58]

Estimated financial cost per person vaccinated (in USD)

The cost of any vaccine delivery can vary greatly depending on the strategies, financing elements (e.g., vaccine procurement and delivery costs), and the country context.

The specific, economic and financial costs per hepatitis B birth dose can vary considerably depending on the delivery strategy, e.g., facility versus home-based vaccination.[59]

In Senegal, economic and financial costs from a government perspective were estimated for 2015, 2016 and 2017. When annualizing pre-introduction and initial training costs, the economic (financial) cost per vaccinated newborn was US$2.10 (US$ 0.30) in 2016 and US$ 1.90 (US$ 0.20) in 2017.[60]

In Ethiopia, the financial costs per child vaccination were US$ 4.58 for facility-based and US$ 13.31 for home-based vaccination. The full economic costs per child vaccinated were US$ 8.23 for facility-based and US$ 121.74 for home-based.[61]

Cost-effectiveness ratio

A systematic review concluded that hepatitis B vaccination is cost-effective or cost-saving using gross domestic product (GDP) per capita thresholds in low- and middle-income countries.[62]

Several studies in different settings have found that infant vaccination with HepB vaccine, including schedules with a birth dose are cost-effective.[63], [64], [65]

Cost–effectiveness varies considerably by several factors, including the burden of disease, vaccination coverage, vaccine price, delivery costs, delivery approaches, and schedules. Cost-effectiveness estimates should be interpreted with caution when comparing estimates of cost-effectiveness for different interventions evaluated by different methods and in different contexts (e.g., with different concurrent health interventions and standards of care).

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Is there a Gavi programme to support the introduction of this vaccine? If a Gavi programme is available, what support is available to countries?

HepB birth dose is supported by Gavi via the guaranteed vaccine budget. All Gavi-eligible countries that have not yet introduced the HepB birth dose into their national vaccination schedule are eligible to apply for support.[66]

Specific requirements for funding request [66]

- HepB birth dose vaccines should ideally be delivered within delivery wards or in postnatal wards; applications should describe plans for integration of HepB-BD with maternal and newborn care services, in both the public and private sectors, and alignment with other maternal and neonatal health initiatives.
- Countries are encouraged to make plans to enable a larger-scale roll-out of the programme to deliver the vaccines to children born out of health facilities as soon as possible after birth including making any necessary policy changes.

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Market (feasibility)

Available vaccines, licensing status, prequalification status, presentation, formulation, dosage and route of administration

As of September 2026, there are approximately 20 HepB paediatric vaccines with marketing authorisation that are manufactured directly by the authorisation holder. Several of them have only marketing authorisation in their country of origin.[67]

Other HepB vaccines are authorised or commercialised under local brand names through technology-transfer, bulk-transfer, licensing, distribution or localisation arrangements.

Five of those vaccines are prequalified.[68] The vaccines are available from each manufacturer in single and 10-dose vials. All are available as liquid, ready-to-use formulations for intramuscular use.

Detailed information on the different products can be found in the comparison table.[69]

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Service delivery (feasibility)

Number of doses and timing of administrations

WHO recommends that all infants (including low birth weight and premature infants) receive the first dose of hepatitis B vaccine as soon as possible after birth, ideally within 24 hours. If administration within 24 hours is not feasible, a late birth dose should be given at the first contact with a health-care provider, up to the time of the next dose in the primary schedule.[7]

Since perinatal or early postnatal transmission is the most important source of chronic HBV infection globally, WHO recommends that all infants (including low birth weight and premature infants) receive their first dose of hepatitis B vaccine as soon as possible after birth, ideally

within 24 hours. If administration within 24 hours is not feasible, a late birth dose has some effectiveness.[7]

Although effectiveness declines progressively in the days after birth, after seven days, a late birth dose can still be effective in preventing horizontal transmission and therefore remains beneficial.[7]

The birth dose should be followed by two or three additional doses to complete the primary series. Both of the following options are considered appropriate: (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) four doses, where a monovalent birth dose is followed by three (monovalent or combined vaccine) doses, usually given with other routine infant vaccines; the additional dose does not cause any harm.

The interval between doses should be at least four weeks.[7]

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Logistics (feasibility)

Cold chain volume required per vaccine dose (in cm3)

The cold chain volume varies between the presentation of the vaccine (vials or ampoule and number of doses per vial) and the manufacturer.

For specific product characteristics, see the comparison table.[70]

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