1. What is the recommendation for administering hepatitis B vaccine to infants born in LA County? LA County recommends that all infants should receive a hepatitis B vaccine in the first 24 hours of life, following California Department of Public Health (CDPH) guidance, in line with the Western Health Alliance and the American Academy of Pediatrics (AAP). For pregnant people who test positive for hepatitis B surface antigen (i.e. HBsAg positive), their infant(s) should receive both hepatitis B vaccine and hepatitis B immunoglobulin within 12 hours of life. Additional doses should be administered per the AAP vaccination schedule.

2. Why does LA County continue to recommend a universal Hep B birth dose?

- Hepatitis B virus infection in children occurs predominantly through maternal-infant transmission during pregnancy, labor, and delivery and, to a lesser extent, through postnatal transmission primarily through household contacts and caretakers.
- Without prophylaxis at birth, approximately 90% of newborns infected perinatally will develop chronic hepatitis B infection (compared to 5-10% of adults), and 25% of those with chronic infection will die prematurely from chronic liver disease, including cirrhosis and hepatocellular carcinoma.
- For pregnant persons who are infected with hepatitis B virus, the birth dose administered within 24 hours can decrease the likelihood of perinatal transmission by up to 70%. When the birth dose and hepatitis B immunoglobulin are co-administered within 12 hours of birth, the risk of perinatal transmission decreases by more than 90%.
- For pregnant persons who are not infected by hepatitis B virus or have unknown status, the
 vaccine is safe and provides protection from horizontal transmission from contacts who may have
 asymptomatic or undiagnosed infection including grandparents, childcare professionals, and
 other children in the household. Once the full series is administered, protection is complete and
 appears to be lifelong.
- In Los Angeles County, due to the implementation of the universal birth dose and the partnership between public health, providers and parents, perinatal hepatitis B infection is extremely rare, with no cases recorded in the past five years. In contrast, a risk-based strategy was shown to be inadequate more than 35 years ago and can reintroduce preventable risks, particularly in communities such as Los Angeles County where hepatitis B prevalence is higher.

3. Is the Hep B birth dose safe for newborns—including those born to HBsAg-negative mothers?

Yes. More than **40** years of data show Hep B vaccines (Recombivax HB and Engerix-B) are highly safe, with only mild local or systemic reactions reported1-3. The only serious safety concern noted is a severe allergic reaction which occurs in less than 1 in 600,000 infants. Post-licensure surveillance has found anecdotal reports of Guillain-Barré syndrome, chronic fatigue syndrome, optic neuritis, multiple sclerosis, and diabetes following vaccination, but this passive surveillance system cannot be used to determine if vaccine caused these effects. However, multiple controlled studies comparing the rates of these diseases to background population rates have demonstrated **no association** between these conditions and HBV vaccination.

The updated <u>rapid systematic review</u> prepared by CDC subject matter experts prepared for the ACIP found:

- Few local/systemic adverse events, even among infants of HBsAg-negative mothers
- No increased serious morbidity/mortality
- No meaningful differences across vaccine products, doses, or schedules



There is no evidence supporting improved safety by delaying to 2 months. Additional independent reviews performed by the <u>Vaccine Integrity Project</u> and <u>The Evidence Collective</u> also have found no evidence suggesting vaccine in unsafe.

4. How effective is the Hep B vaccine when started at birth?

Multiple studies confirm strong effectiveness:

- Hep B vaccine alone within 24 hours is ~75% effective in preventing perinatal infection⁵
- Hep B vaccine + HBIG within 12 hours is ~94% effective⁶⁻⁷
- **Full 3 dose series: 95-98% protection** with long-term immunity that persists for **30+ years** in >90% of fully vaccinated persons.

5. Does the Hep B birth dose improve series completion?

Yes. Infants who receive the birth dose are **significantly more likely** to complete the full hepatitis B series and stay up to date with other routine immunizations. This is especially important in populations with inconsistent healthcare access who may miss well child checks and other vaccination opportunities⁸⁻⁹.

6. What about infants born to HBsAg-negative mothers—isn't the risk low?

The risk is low, but **not zero**, for several reasons:

- An estimated 0.4% to over 3% of pregnant US women receive no prenatal care¹⁰⁻¹¹
- 12-16% of U.S. pregnancies lack a documented HBsAg test¹²⁻¹³
 - Not all pregnant people are screened for hepatitis B. Some prenatal records are missing the test, which creates a gap in identifying mothers with hepatitis B virus. Even if most are screened, some infants are at risk because the mother's infection status is unknown.
- Testing/transcription errors occur in real-world screening systems¹⁴
 - Even when HBsAg testing is done, results can be mis-recorded or miscommunicated, leading to false-negative or missing information, meaning some infants at risk for perinatal transmission may not get timely prophylaxis.
- Acute maternal infection in late pregnancy may not be detected prenatally
 - If a mother acquires HBV close to delivery, her initial prenatal test may be negative. The infant is still at risk of perinatal transmission, and birth-dose vaccination provides protection during this vulnerable window.
- ~50% of people with HBV are unaware of infection¹⁵
 - Many adults with HBV don't know they are infected, which highlights the limitations of relying solely on maternal screening to prevent infant infections. Household or caregiver exposures may also occur.
- HBV survives on surfaces for ≥7 days¹⁶
 - Hepatitis B virus can persist outside the body for more than a week. This means horizontal transmission to the infant in the home or care settings is possible, reinforcing the importance of universal protection.
- Infants have a ~90% risk of chronic infection when infected^{7,17}
 - If a newborn contracts HBV, there is a very high likelihood they will develop chronic infection, which leads to long-term liver disease in 1 of every 4 chronically infected people. Preventing the first infection is critical.
- Risk-based strategies have failed in the past
 - Starting in 1984, a risk-based strategy was employed to try to identify all pregnant persons who
 were infected with hepatitis B during delivery, and to focus preventative interventions solely on
 their infants. However, despite clear guidance from professional societies, perinatal transmission
 continued to occur, reflecting gaps in prenatal care, prenatal testing, and appropriate post-





delivery management and other logistical challenges faced when navigating a fragmented health care system. These gaps prompted the universal hepatitis B vaccine birth dose recommendation in 1991, a strategy that has since decreased the rates of hepatitis B infections in infants by 99%.

7. What did the most recent ACIP review actually show?

ACIP's systematic review (2011–2025) concluded:

- High seroprotection when the series starts at birth
- Efficacy in preventing perinatal HBV
- Strong safety profile
- No evidence supporting delayed initiation
- Insufficient randomized data to justify schedule changes⁴

8. Why do some countries give the first Hep B dose at 2-3 months?

It is **not** due to safety or effectiveness differences. From a scientific and public health standpoint: **there is no benefit to delaying**, and delays introduce avoidable risk.

Delayed schedules reflect **system factors**. Other countries may have smaller populations, universal prenatal care, routine screening, and/or national registries with complete follow-up for all infected individuals. Given U.S. gaps in screening and missed maternal infections, the birth dose remains essential.

In LA County, delaying to 2 months would **increase the risk of preventable chronic HBV infection**, especially due to a multicultural population, frequent international travelers and disparities in prenatal care and screening.

9. Should doctors offer serological testing to patients after 1 or 2 doses of hepatitis B vaccine?

- Although serologic testing was used in original clinical trials, protective antibody levels were
 evaluated after completion of the full 3-dose series, with more than 90% of infants achieving
 immunity. While antibody levels may decline over time, studies show that cellular immunity
 persists for decades and continues to provide protection.
- A positive or a negative antibody test after 1 or 2 doses of vaccine is of unknown clinical significance and should not inform whether a child needs additional doses without studies evaluating the long-term efficacy of an alternative dosing schedule in infants.
- Antibodies detected in early infancy may reflect **passively transferred maternal antibodies**, which wane rapidly in the first year of life. These results can create a false sense of protection and lead to under-vaccination.
- Repeated serologic testing would require multiple unnecessary blood draws, causing discomfort and stress for the infant without providing clinically actionable information.
- LA County Public Health is supportive of additional clinical trials evaluating other dosing schedules. However, all existing efficacy studies have assessed infants who completed a full hepatitis B vaccine series, and there is no evidence that partial vaccination provides lifetime protection.

10. Bottom Line: Why LA County Public Health is not changing the recommendation

- The birth dose is **safe**, **effective**, **and foundational** in eliminating perinatal HBV transmission.
- Delaying the first dose offers no known benefit and reduces protection during a vulnerable period.





- The universal Hep B birth dose remains the **strongest**, **simplest**, **and most equitable strategy** to protect all infants.
- Serological testing is of unknown benefit and potential harm and is not recommended in infants except for those exposed to HBsAg positive mothers after completion of the full vaccine series.

LA County Public Health and CDPH both continue to recommend universal Hep B vaccination within 24 hours of birth, and Hepatitis B vaccination + HBIG within 12 hours of birth for infants born to HBsAg positive people.

For questions, contact: Vaccine Preventable Disease Control Program (VPDCP), LA County DPH.

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