An Advisory Committee Statement (ACS)

National Advisory Committee on Immunization (NACI)

Recommendations for routine pediatric Hepatitis B vaccination



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Preamble

The National Advisory Committee on Immunization (NACI) is an External Advisory Body that provides the Public Health Agency of Canada (PHAC) with independent, ongoing and timely medical, scientific, and public health advice in response to questions from PHAC relating to immunization.

In addition to burden of disease and vaccine characteristics, PHAC has expanded the mandate of NACI to include the systematic consideration of programmatic factors in developing evidence based recommendations to facilitate timely decision-making for publicly funded vaccine programs at provincial and territorial levels.

The additional factors to be systematically considered by NACI include: economics, ethics, equity, feasibility, and acceptability. Not all NACI statements will require in-depth analyses of all programmatic factors. While systematic consideration of programmatic factors will be conducted using evidence-informed tools to identify distinct issues that could impact decision-making for recommendation development, only distinct issues identified as being specific to the vaccine or vaccine-preventable disease will be included.

This statement contains NACI's independent advice and recommendations, which are based upon the best current available scientific knowledge. This document is being disseminated for information purposes. People administering the vaccine should also be aware of the contents of the relevant product monograph. Recommendations for use and other information set out herein may differ from that set out in the product monographs of the Canadian manufacturers of the vaccines. Manufacturer(s) have sought approval of the vaccines and provided evidence as to its safety and efficacy only when it is used in accordance with the product monographs. NACI members and liaison members conduct themselves within the context of PHAC's Policy on Conflict of Interest, including yearly declaration of potential conflict of interest.

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Summary of guidance

Note: While NACI statements are written for public health immunization program decision makers and consulted by healthcare professionals, the Public Health Agency of Canada (PHAC) issues summaries of NACI statements to inform the public on key details of the vaccine guidance.

Please refer to the PHAC Summary of NACI statement of October 2026: Recommendations for routine pediatric Hepatitis B vaccination.

I. Introduction

The successful introduction of routine pediatric hepatitis B (HB) immunization programs has significantly reduced the disease burden in Canada. NACI has historically recommended that immunization with HB-containing vaccines should be provided according to provincial and territorial schedules [1]. As a result, routine pediatric HB immunization programs vary between jurisdictions, with the HB vaccination series starting at birth, in infancy or in school-age children.

In 2017, the World Health Organization (WHO) recommended that all children should receive at least three doses of HB vaccine, with the first dose received by infants as soon as possible after birth (preferably within 24 hours), regardless of the HB surface antigen (HBsAg) status of the pregnant woman. Given the WHO recommendation for newborn vaccination, Canada's commitments to the global hepatitis elimination goals by 2030 [2], and that coordinated immunization schedules and programs is one of the key pillars of the PHAC 2025-2030 Interim National Immunization Strategy, a reassessment of the timing of pediatric HB vaccination was identified as an area of interest for immunization programs to be reviewed by NACI.

Guidance objective

The objective of this advisory committee statement is to summarize available evidence on the disease epidemiology of HB, ethics, equity, feasibility and acceptability considerations, identify the knowns and unknowns, and provide guidance on the timing of pediatric HB vaccination in the Canadian context. The vaccine characteristics of the HB vaccines, including efficacy, effectiveness, immunogenicity and safety, have previously been established by NACI and were not re-evaluated given the context of the policy questions and the longstanding and extensive use of these vaccines.

II. Methods

This NACI advisory committee statement was prepared through the following activities:

- Analysis of burden of disease of acute and chronic HB (CHB) in Canada.
- Application of a published, peer-reviewed framework and evidence-informed tools to ensure that issues related to ethics, equity, feasibility, and acceptability (EEFA) are systematically assessed and integrated into the guidance. [3]
- Review of economic evaluations comparing pediatric HB vaccination schedules for the prevention of HB-related outcomes though an environmental scan.

- Review of vaccine guidance from international and domestic guidance issuing bodies through an environmental scan.
- Consideration of vaccine principles.
- Translation of evidence into recommendations.

For details on when and how NACI incorporates economic evidence for vaccine recommendations, please refer to the NACI process for incorporating economic evidence into federal vaccine recommendations.

For more information on the standard approach, please see NACI's evidence-based methods.

For this advisory committee statement, NACI reviewed the key questions for the literature review as proposed by the Hepatitis Working Group and considered available evidence on the burden of illness, safety, immunogenicity, efficacy, effectiveness of the vaccine(s), administration schedules, and other aspects of the overall immunization strategy. Knowledge synthesis was performed by the NACI Secretariat (PHAC), and supervised by the Working Group. Evidence was synthesized leveraging GRADE methodologies to inform recommendations for vaccine use.

The Working Group chair and NACI Secretariat presented the evidence and proposed recommendations to NACI on April 28, 2026 and June 17, 2026. Following a thorough review of the evidence, the committee voted on specific recommendations on June 17, 2026.

A note on language

NACI recognizes that not all people giving birth or breastfeeding will identify as women or mothers. The writing in this statement uses a gender additive approach where the term 'woman' is used alongside gender-neutral language. This is intended to demonstrate a commitment to redress the historic exclusion of trans and non-binary people, whilst avoiding the risk of marginalising or erasing the experience of women within the health care environment.

In addition, much of the research available currently uses gendered language (e.g., "women") or gender-neutral language (e.g., pregnant people) when discussing pregnancy. When citing research, NACI refers to the language used in the study. In some cases, "woman" refers to someone who was assigned female at birth. For the purposes of this statement, the terms "woman," "women," and "maternal" should be considered to also apply to those individuals who do not specifically identify as female gender but are the parent gestating the fetus or breastfeeding or chestfeeding the infant. However, in line with best practice, it is recognized that when discussing or caring for individuals in a one-on-one capacity, language and documentation should reflect the gender identity of the individual.

Finally, NACI acknowledges the dynamic nature of language. It is likely that language deemed to be suitable or affirming in one context may not translate across others, and over the coming years will likely change and evolve with respect to appropriate representations.

III. Epidemiology

III.1 Background, risk factors, and clinical presentation

Hepatitis B virus can cause acute and chronic infection of the liver, with infants, young children and immunocompromised persons at highest risk of developing CHB infection. Acute HB infection may be asymptomatic in up to 50% of adults and up to 90% of children, and fulminant hepatitis may occur in 1% to 2% of cases. Although the majority of adults spontaneously clear the infection after 4 to 8 weeks, the risk of developing CHB varies with the age at which the infection occurs, with infancy being the period of highest vulnerability. Thus the probability of developing CHB after acute infection is 90-95% in infants, 25%-50% in children over one year and less than five years of age, and 3-10% in healthy adolescents and adults. [1,4-7]

III.2 Hepatitis B in Canada

Pediatric HB immunization programs and coverage in Canada

HB vaccination was first introduced in Canada as a risk-based program in the 1980s for infants born to pregnant women and pregnant individuals identified as being HBsAg positive before expanding to include a school-based immunization program a decade later. Routine HB immunization programs are now well established across Canada, with five provinces/territories (P/Ts) continuing to offer a routine school-based HB immunization program, while the rest offer routine HB vaccination in infancy, with or without a birth dose (see Table 1).

Surveillance and evaluation studies of the school-based HB immunization programs in British Columbia [8], Quebec [9,10], Alberta [11], Nunavut [12], and Ontario [13] have shown substantial declines over time in rates of acute HB and/or CHB cases in the population, particularly among cohorts eligible for routine immunization. A small number of cases of HB infection were identified in children not yet eligible for school-based HB vaccination, with a proportion of these cases presumed to be preventable with earlier vaccination. [10,11,13] However, there are challenges to interpreting surveillance of HB in Canada that impact the ability to ascertain the true incidence of acute HB and CHB in the pediatric population which are discussed later in this section.

The 2021 childhood National Immunization Coverage Survey (cNICS) reported that of the seven P/Ts (BC, QC, NB, PE, YT, NT, and NU; AB was not included in this category due to their recent program transition in 2018) offering three doses or more of HB vaccine to infants (i.e., a complete series), HB vaccine coverage by 2 years of age was 83%. When all 13 P/Ts are included, 89% of 14 year olds have received at least 1 dose of HB vaccine, an increase from 85% in 2019. [14]

As of December 31, 2025, HB vaccination coverage reported by STARVAX (Standardized Reporting on Vaccination) was 81.6% at 2 years of age for at least 3 doses (reporting PTs include AB, QC, NB, YU), and 71.7% at 17 years of age for at least 2 doses (reporting PTs include AB, SK, MB, NS). [15]

Table 1. Provincial and territorial schedules for HB immunization and year of program introduction

P/T	Routine school-based program		Period with routine infant or birth program [b]
	Period with a school-based program [a]	Grade	
NB	1995 - 2005	4	1995 - present
PE	1995 - 2010	3	1995 - present
NT	1995 - 2004	4	1995 - present
BC	1992 - 2001	6	2001 - present
YT	1994 - 1998	4	1998 - present
NU	1995 - 1999	4	1995 - present
QC	1994 - present	4	2013 - present
AB	1995 - present	5	2018 - present
SK	1995 - present	6	N/A
MB	1998 - 2017	4	N/A
	2017 - present	6	
ON	1994 - present	7	N/A
NS	1995 - 2010	4	N/A
	2010 - present	7	
NL	1995 - 2012	4	N/A
	2012 - present	6	

Abbreviations : NB : New Brunswick; PE : Prince Edward Island; NT : Northwest Territories; BC : British Columbia; YT : Yukon; NU : Nunavut; QC : Quebec; AB : Alberta; SK : Saskatchewan; MB : Manitoba; ON : Ontario; NS : Nova Scotia; NL : Newfoundland and Labrador; N/A : Not applicable.

[a] Where there is overlap in the periods with a school-based and routine infant or birth program, the school-based program is offered to allow additional cohorts of children to receive vaccination.

[b] A routine birth program refers to a HB vaccine series where the first dose is routinely given within 24 hours of birth (i.e., a birth dose). A routine infant program refers to HB immunization that is started later in infancy (typically at two months of age).

Perinatal care and Hepatitis B

HBsAg screening is part of routine prenatal care in all P/Ts, and in conjunction with HB vaccination and HB immune globulin (HBIg), contributes significantly to mitigating vertical transmission. A small number of Canadian studies on prenatal screening suggests that uptake may be relatively high. In Ontario, approximately 93% of pregnant women were screened for HB between 2012 and 2016. [16] In Nova Scotia, analysis of a sample representing 32% of live births in 2004 found that 89.2% of pregnant women underwent HB testing. [17] While direct estimates of HB screening uptake are not available for Alberta, 98.5% of pregnant women received at least one prenatal syphilis test in 2010-2011, providing indirect evidence of similarly high uptake for HB as prenatal screening for syphilis and HB are usually conducted concurrently.[18] However, current uptake of prenatal screening across Canada may differ from these older, jurisdiction

specific estimates, as there are ongoing inequities around access to prenatal care and screening.

Available provincial data suggest that the prevalence of HBsAg among pregnant women and pregnant individuals in Canada is low but non-negligible. In Ontario, linked data from ICES, Public Health Ontario, and the Better Outcomes & Registry Network (BORN) indicate an HBsAg prevalence of approximately 0.6% among pregnant women between 2012 and 2016. [16] In Alberta, data from the Provincial Laboratory Information System show a small increase in HBsAg prevalence among prenatal specimens from 0.50% in 2003 to 0.58% in 2016. [19] While HBsAg prevalence is low, another study from Alberta found that nearly half of pregnant women (47%) who tested HBsAg-positive between 2012 and 2020 did not have a prior laboratory-confirmed diagnosis of CHB before pregnancy, [20] which confirms the importance of screening for HB.

Hepatitis B among immigrants and newcomers to Canada

In Canada, the overall estimated prevalence of HBsAg is below 2%. [21,22] A recent study using data from 2021 estimated the prevalence of CHB among immigrants (i.e., those born outside of Canada) at 4.0% (95% CI: 3.0 to 5.1%), compared with 0.7% (95% CI: 0.4 to 1.0%) in the general population. [23] However, immigrants are not a homogenous population, and risk is also not equivalent across individuals. The burden of CHB varies among immigrants and newcomers (i.e., those who have arrived within the last five years), depending on their country or region of origin/migration and the degree to which HB is endemic in those areas (i.e., <2% HBsAg seroprevalence is low endemicity, ≥2% seroprevalence is intermediate to high endemicity). [21] Grouping all immigrants together may mask important variation and potentially over-estimates the burden in immigrants, as immigrants from low-prevalence countries have rates similar to the general population of Canada. [23]

The prevalence of HB among newcomers is likely to differ across P/Ts due to varying immigration patterns and interprovincial migration. [24] Although the highest pooled HBsAg prevalence has been reported among immigrants from Western Africa (approximately 11%), the largest absolute number of immigrants living with CHB in Canada originate from Eastern Asia (7%), with an estimated 103,000 individuals, representing approximately 30% of all immigrants living with CHB in Canada. [23]

Population-based data also demonstrate geographical patterns of HB diagnosis among immigrants in Canada by country of origin. In a retrospective cohort study in Ontario, immigrants from high-endemic countries accounted for 40.4% of all HB diagnoses, and for diagnoses among immigrants, 70.0% were individuals originating from high-endemic regions. The median time from arrival to first laboratory confirmation was 5.8 years (IQR 1.9, 12.0), indicating delays in diagnosis following immigration. [25]

In the 2021 Canadian census, individuals aged 25 to 64 years represented more than half (53%) of the immigrant population, a pattern that was even more pronounced among newcomers at 65%. [24] Administrative data from Immigration, Refugees and Citizenship Canada between 2021 and 2024 show that adults make up the majority of new permanent residents, with children aged 0 to 14 years accounting for approximately 18% of this population, highlighting the relevance of HB risk and immunization considerations for both adult and pediatric immigrant populations. [26]

The largest gaps in the care cascade for HB are primarily related to the multiple barriers immigrants and newcomers face when accessing care for HB. Individuals are not systematically

screened upon arrival for HB infection, and may not be fully immunized according to the Canadian immunization schedule or aware of their infection status. The review of routine immunizations, including HB serologic testing, falls to primary care (or other models of care) after resettlement, and is one of a number of priorities faced, which could potentially be delayed based on their ability to access care. Inter-provincial migration can further add to the complexity of care linkage, loss to follow-up, and challenges assessing the national burden of disease.

Knowledge gaps and surveillance limitations

Hepatitis B is a nationally reportable disease in Canada; however, the largely asymptomatic nature of its infection and limitations in current data infrastructure impact the ability to evaluate the national impact of changes in HB vaccination programs.

Available data from the Canadian Notifiable Diseases Surveillance System (CNDSS) and from administrative databases, such as the Canadian Institute for Health Information Discharge Abstract Database (CIHI-DAD), lack the detail needed to fully understand both the populations most affected by HB and its transmission dynamics. Key limitations include the following:

- The true incidence rates cannot be assessed, as many HB infections go undiagnosed for extended periods, and age at the time of infection is often unknown.
- Information on immigration status, including age at immigration, vaccination status, and HB infection status at the time of arrival, are not systematically captured in CNDSS.
- National databases do not include information on perinatal exposure, newborn vaccination at birth, pregnancy status at time of diagnosis, use of antiviral therapy, or HB viral load status.
- Available data do not allow for routine cohort-based analysis nationally, which are required to assess the impact of cohort/age-based HB vaccination program changes on incidence of cases. However, some P/Ts have the infrastructure to link multiple surveillance and administrative databases.

Ongoing surveillance and continued data linkage is encouraged to improve the understanding of the epidemiology of HB in Canada. Provincial and territorial programs are also encouraged to consider undertaking post-implementation program evaluations to better determine the burden of HB infection, assess the impact of policy changes, and inform future program planning.

IV. Vaccine

IV.1 Preparations authorized for use in Canada

At the time of publication of this NACI Statement, the following products have been authorized for use in Canada for the prevention of HB in the pediatric population:

- ENGERIX-B : HB surface antigen (recombinant) vaccine (Monovalent HB), GlaxoSmithKline Inc. [27]
- RECOMBIVAX HB® : HB surface antigen (recombinant) vaccine (Monovalent HB), Merck Canada Inc. [28]
- TWINRIX: combined hepatitis A virus (inactivated) and HB surface antigen (recombinant) vaccine (HAHB), GlaxoSmithKline Inc. [29]

- INFANRIX hexa: hexavalent diphtheria and tetanus toxoids, acellular pertussis, HB (recombinant), inactivated poliomyelitis and adsorbed conjugated *Haemophilus influenzae* type b vaccine (DTaP-HB-IPV-Hib), GlaxoSmithKline Inc. [30]

Key characteristics of these HB vaccines are summarized in Appendix A, Table A1.

Refer to the Canadian Immunization Guide (CIG), Part 4, Hepatitis B vaccines for additional information on monovalent and multivalent HB-containing vaccines.

IV.2 Clinical evidence on Hepatitis B vaccines

NACI has previously established the efficacy, effectiveness, immunogenicity, and safety of HB vaccines in the pediatric population. Given the durability of HB vaccine protection, NACI has not recommended the use of booster doses of HB vaccine for immunocompetent individuals following the completion of a recommended HB immunization schedule.

A 2016 systematic review of safety and efficacy of childhood schedules involving HB vaccines conducted by the WHO continued to show that while there may be some differences in immunogenicity and reactogenicity that may occur with different infant HB vaccine schedules, the clinical impact is considered minimal. [31] The review found low quality evidence of higher antibody titres with a birth dose schedule (i.e., first dose given at less than 24 hours of life) compared to schedules without a birth dose, but some of these studies compared schedules with an additional dose or with different dose intervals, which are both factors that can generate a higher immune response.

IV.3 Contraindications and precautions

Refer to the CIG, Part 4, Hepatitis B vaccines for additional information about contraindications and precautions of HB-containing vaccines.

IV.4 Concurrent administration

Hepatitis B-containing vaccines may be administered concurrently with other vaccines or with HBIg. For concurrent parenteral injections, separate anatomic injection sites (different limbs) should be used whenever possible. A separate sterile needle and syringe must be used for each injection. If multiple injections in the same limb are required, the injection sites should be separated by at least 2.5 cm (1 inch). If HB-containing vaccine and HBIg are administered concurrently, separate anatomic injection sites (different limbs) should be used for each injection.

Refer to the CIG, Part 1, Timing of vaccine administration for additional information about concurrent administration of vaccines.

IV.5 Vaccination of specific populations

Refer to the CIG, Part 4, Hepatitis B vaccines chapter for additional information on Vaccination of specific populations.

IV.6 Additional considerations

Vaccine schedules and intervals

For information on schedules, recommended and minimum intervals for HB-containing vaccines, refer to Appendix B.

V. Ethics, equity, feasibility and acceptability considerations

Ethics considerations

NACI guidance is developed using processes that uphold and integrate ethical procedural considerations. When making its recommendations NACI evaluates the following core ethical principles for public health: promoting well-being and minimizing risk of harm; maintaining trust; respect for people and fostering autonomy; and promoting justice and equity. In developing these recommendations, no significant ethical issues were identified by NACI other than the equity considerations discussed below.

However, it is important to emphasize the ongoing need to consider specific contexts in which social and structural determinants of health intersect or heighten the risk of severe outcomes, particularly for some individuals in or from First Nations, Inuit, and Métis communities. Jurisdictions should prioritize equity in program implementation by recognizing that First Nations, Inuit, and Métis Peoples are distinct rights-holding groups with diverse governance structures, health priorities, knowledge systems, and approaches to wellness. Distinctions-based approaches to immunization planning and decision-making, developed in partnership with Indigenous communities and organizations, can support the conditions and resources needed for Indigenous Peoples to make autonomous decisions with culturally safe public health and healthcare partners, in accordance with the United Nations Declaration on the Rights of Indigenous Peoples Act (UNDRIP). [32]

Equity considerations

While HB prevalence varies across populations, there is no evidence to suggest that the timing of immunization programs alone is a major driver of inequity. Provinces and territories have implemented HB vaccination schedules that align with their population needs, health systems, and operational contexts. These programs, whether initiated at birth, during infancy, or in school-age programs, have been effective in reducing HB infection rates. However, given the substantially higher risk of developing CHB when HB is acquired in infancy or early childhood, and the surveillance limitations noted above to detect asymptomatic infections, a vaccination strategy that provides protection in early-life is expected to promote health equity by ensuring that all children are protected during the period of greatest vulnerability to chronic infection.

Infant HB vaccination programs provide early protection, regardless of maternal HB status, exposure risk, future school attendance, or future healthcare access beyond existing infant immunization visits. If the infant schedule includes a HB birth dose, the birth dose may further improve equity by providing the earliest protection. The birth dose can help mitigate vertical transmission of HB, which is particularly important in situations where the identification of

infection during pregnancy is delayed due to ongoing inequities and barriers to accessing prenatal care, screening and treatment.

Jurisdictions considering transitioning from a school-based HB immunization program to an infant program will need to ensure systems are in place to identify and offer vaccination to children who may have missed earlier doses, consistent with recommendations for other pediatric vaccines. Aligning HB vaccination with existing infant immunization visits, may streamline delivery and create consistent early-life checkpoints to identify missed doses, which may benefit mobile families.

Feasibility considerations

The 2025–2030 Interim National Immunization Strategy was developed through an engagement process with input from federal, provincial and territorial governments, immunization experts, some First Nations, Inuit, and Métis partners and experts, and other key immunization and community partners across Canada. A pillar of this strategy is, "Coordinated immunization schedules and programs," which aims to harmonize programs across the country to support optimal, safe, and equitable protection throughout the life course. The advantages of having similar vaccine schedules include improving vaccine pricing through bulk procurement, streamlining immunizer training, and simplifying immunization records and catch-up processes for children moving between jurisdictions. With the diversity in the implementation of pediatric HB immunization programs across Canada, routine infant HB vaccination could be advantageous to jurisdictions and individuals.

NACI consulted with the provincial and territorial partners through the Canadian Immunization Committee (CIC) regarding the feasibility of changing the start of routine pediatric HB immunization programs. In jurisdictions currently offering routine HB vaccination in infancy without a birth dose, the series is started at two months of age, which corresponds with the first visit for routine childhood immunizations. This schedule uses DTaP-HB-IPV-Hib, a combined hexavalent HB-containing vaccine that can be substituted for the combined pentavalent vaccine DTaP-IPV-Hib. The use of DTaP-HB-IPV-Hib can reduce vaccine schedule complexity and the overall number of injections a child receives as part of the childhood immunization schedule, as the monovalent HB and DTaP-IPV-Hib vaccines are not received separately. The cost of DTaP-HB-IPV-Hib compared to DTaP-IPV-Hib may impact the feasibility of changing program timing.

In Canada, most infants are born in medically attended settings, [33] and where HBsAg positivity is identified during pregnancy, all P/Ts offer a HB birth dose as part of post-exposure prophylaxis management. However, offering a routine birth dose may present greater logistical complexity for P/Ts that have to add a new vaccination timepoint as it may require ensuring integration into existing workflow, including considerations around vaccine availability and storage, mechanisms for record keeping, and additional staff and/or training. The feasibility of offering a routine birth dose may be higher in settings where other newborn immunizations (e.g., nirsevimab) are already being provided before discharge, though additional resources could still be required.

For jurisdictions with school-based HB immunization programs, transitioning to routine infant vaccination also requires a plan to ensure that children who have not yet been vaccinated (i.e., no longer infants) have an opportunity to receive the HB vaccine. The most straightforward approach is to continue school-based HB immunization until all cohorts have been vaccinated, after which a routine school-based program for HB would not be necessary, but could be used as an opportunity for catch-up.

With longstanding HB immunization programs in Canada, the feasibility of adopting routine infant HB vaccination is expected to be assessed in the context of P/T program optimization, including vaccine schedule compatibility and workload/resource implications, and will differ depending on whether the infant program also includes a birth dose. Overall, while a number of factors support the feasibility of routine infant HB vaccination, financial implications associated with immunization program changes, product changes, and prolonged dual implementation of infant and school-based HB immunization programs may impact the ease and timing of any transition.

Acceptability considerations

The HB vaccine has a well-established safety profile and provides long-term, durable protection against HB infection. Given the substantially higher risk of developing CHB among infants and young children if HB is acquired at this age, strategies supporting timely, early-life immunization are likely to be viewed positively, as is a HB schedule that can reduce the overall number of injections received in childhood.

The inclusion of a HB birth dose into routine programs may have implications for acceptability; however, there is limited evidence in the Canadian context. While the acceptability of routine infant HB immunization in general is expected to be good, there may be additional considerations for an infant schedule with a birth dose. There may be higher acceptability for a birth dose if being able to offer the earliest available protection from vaccination is a priority, notably where there may be gaps in screening during pregnancy or challenges accessing health care. However, where the ease of program integration and/or fewer injections are the priority, acceptability of an infant series without a birth dose may be viewed more favorably. For parents, hesitancy and non-acceptance may emerge with introduction of additional interventions at birth. The HB birth dose would be offered in addition to Vitamin K, heel pricks for newborn screening, as well as nirsevimab for those born during the respiratory season. International narratives around Vitamin K refusal have reflected concerns that it may be linked to broader hesitancy toward early life interventions, [34] suggesting potential risk for reduced uptake of birth dose vaccines over time.

Implementing routine infant HB vaccination could contribute to Canada's progress towards global elimination targets for HB and aligns with objectives from the 2025–2030 Interim National Immunization Strategy's around coordinated immunization schedules and programs. There is currently no evidence to suggest that modifications to the HB vaccination schedule would negatively impact uptake and such changes may support strong immunization coverage and therefore be acceptable to parents/guardians, immunizers and policymakers.

VI. Economics

An environmental scan was conducted to identify economic evidence comparing routine HB vaccination strategies, including birth-dose, infant and adolescent programs. The scan, completed in November 2025, identified three relevant economic evaluations from the United Kingdom (UK) and Canada.

Environmental scan

Methods

An environmental scan was conducted to identify economic evaluations of routine HB vaccination strategies, including birth-dose, infant, and adolescent programs. The search included publications from January 2015 to November 2025 and was supplemented by a review of economic evidence from other national immunization technical advisory groups (NITAGs) (with no date restriction). Where reported, cost-effectiveness results were converted to 2024 Canadian dollars (CAD).

Study characteristics

Three relevant economic evaluations were identified: one UK-based study and two Canadian studies. [35-37] The studies differed in methodological approach, perspective, time horizon, discount rate, and health outcome measures. Siddiqui et al. and Kim et al. used static decision-analytic models that do not account for indirect vaccination effects, while Biondi et al. used a dynamic transmission model that explicitly incorporates both horizontal (person-to-person) and vertical (perinatal) HBV transmission dynamics. Kim et al. modelled an Ontario birth cohort over a lifetime horizon from a public-payer perspective, discounting costs and quality-adjusted life-years (QALYs) at 1.5% per year. Biondi et al. modelled the Ontario population over 30 years (2020-2050) from a societal perspective, using an annual discount rate of 3%, higher than the 1.5% recommended for Canadian analyses. Siddiqui et al. modelled a UK birth or adolescent cohort over a lifetime horizon from the healthcare provider perspective, using a 3.5% annual discount rate for both costs and QALYs, following guidance from the National Institute for Health and Care Excellence (NICE). Biondi et al. was the only study to report industry funding. Note that the studies employed different health outcome metrics (QALYs and disability-adjusted life-years (DALYs)), though this is unlikely to materially affect the comparative conclusions.

Assumed vaccine prices per dose varied across studies (all converted to 2024 CAD): Siddiqui et al. used $27.91 for infant and $37.21 for adolescent doses; Kim et al. used $45.37 for both child and adolescent doses; and Biondi et al. used $13.11 for infant monovalent HB vaccine doses administered to children and $8.63 for the monovalent HB vaccine doses administered to adolescents. Biondi et al. assumed that the DTaP-HB-IPV-Hib vaccine would replace the existing pentavalent vaccine (DTaP-IPV-Hib) at an equivalent price, with additional vaccine costs incurred only for strategies that included monovalent HB vaccine doses.

Infant versus adolescent vaccination programs

All three evaluations included comparisons of infant (with or without a birth dose) and adolescent vaccination. The two Canadian studies found infant vaccination strategies to be more effective than adolescent vaccination. Kim et al. compared adolescent vaccination (2 doses at age 12) with newborn vaccination (3 doses starting at birth) in an Ontario birth cohort and found mean lifetime cost savings of $539 per person and a gain of 0.18 QALYs with routine HB birth-dose vaccination. Biondi et al. found that infant strategies, including schedules with and without a birth dose prevented approximately 550–560 acute and 160 chronic HB infections over 30 years in Ontario compared to adolescent vaccination; a strategy of hexavalent (DTaP-HB-IPV-Hib) infant vaccination at 2, 4, 6 months of age was dominant (less costly and more effective) compared to adolescent vaccination.

Using data from the UK, Siddiqui et al. found that, at then-current vaccine prices, neither routine infant (without a birth dose) nor routine adolescent vaccination was cost-effective compared with no vaccination, using a threshold of £30,000 per QALY.

Timing of infant vaccination programs

Biondi et al. was the only study to directly compare the timing of different vaccination schedules using infant hexavalent HB-containing vaccination, including strategies with and without a birth dose. To determine the optimal strategy among the infant strategies evaluated, a post-hoc sequential cost-effectiveness analysis was conducted by the NACI Secretariat by reorganizing the results from Biondi et al. using unrounded DALY data provided by the study authors. This analysis did not introduce new data sources or parameters. Under the study's assumption that the hexavalent (DTaP-HB-IPV-Hib) infant vaccine replaced the existing pentavalent (DTaP-IPV-Hib) vaccine at the same price and without any additional administration costs, the most cost-effective approach was hexavalent (DTaP-HB-IPV-Hib) infant vaccination at 2, 4, 6 months of age without a HB birth dose. Compared with this strategy, a birth dose schedule (0, 2, 6 months of age) produced very small incremental health benefits (0.33 DALYs averted over 30 years) compared with the hexavalent (DTaP-HB-IPV-Hib)-only strategy. This small increase in health benefits, coupled with increased program costs, resulted in an ICER for the birth-dose strategy far in excess of commonly used cost-effectiveness thresholds. However, the magnitude of the ICER depends on the assumption that the hexavalent vaccine is priced the same as the pentavalent vaccine (DTaP-IPV-Hib). If the hexavalent vaccine costs more than the pentavalent vaccine, the incremental cost of the birth-dose strategy relative to the non-birth-dose infant strategy would decrease, lowering the ICER for the birth-dose strategy. Results were sensitive to model parameters, particularly HBsAg prevalence, which accounted for over 80% of the variation in cost per DALY averted.

Summary

Based on available economic evidence, infant HB vaccination programs were more effective than adolescent programs in the Canadian context, and some infant strategies were dominant. Only one study directly compared the timing of infant HB vaccination schedules. [35] The study found that hexavalent infant vaccination schedule without a HB birth dose (at 2, 4, and 6 months of age) was more cost-effective than schedules that included a HB birth dose, driven by the assumption that the hexavalent (DTaP-HB-IPV-Hib) vaccine incurred no incremental costs when it was used instead of pentavalent (DTaP-IPV-Hib) vaccine in the schedule. However, these findings should be interpreted with caution given the very small incremental health differences between the two infant strategies. The relative cost-effectiveness of the different infant HB vaccination schedules was also dependent on the assumed price relationship between the hexavalent and monovalent HB vaccines; in the Canadian context, costs will depend on procurement, and the actual price relationship may differ.

VII. Recommendations

Following the thorough review of available evidence summarized above, NACI makes the following recommendations for public health level and individual level decision-making.

For reference:

> A **strong recommendation** applies to most populations/individuals and should be followed unless a clear and compelling rationale for an alternative approach is present.
>
> A **discretionary recommendation** may be considered for some populations/individuals in some circumstances. Alternative approaches may be reasonable.

See appendix for a more detailed explanation of strength of NACI recommendations and use of GRADE for evidence appraisal.

Recommendations for public health program decision-making

(i.e., Provinces/Territories making decisions for publicly funded immunization programs)

1. NACI recommends that all infants should receive routine Hepatitis B vaccination.

(*Strong NACI recommendation*)

Considerations:

- The optimal time to start the routine infant HB vaccination is shaped by current provincial/territorial epidemiology and programmatic considerations. The first dose of the HB vaccine series can be offered within the first 24 hours of birth, or at two months of age, as it is typically the earliest visit in the routine childhood immunization schedule.
    - Initiating the HB immunization series at birth provides the earliest protection against HB. In the Canadian context, this is of particular importance in regions where infants face an elevated risk of exposure as a result of gaps in prenatal screening due to lower access or uptake, or for infants who may subsequently experience challenges accessing health care.
    - Initiating the series at the earliest visit in the routine childhood immunization schedule takes advantage of existing immunization practices and protocols, while still providing early vaccine protection, and importantly, may increase program feasibility, acceptability, and cost-effectiveness.
    - The use of a hexavalent HB-containing vaccine (e.g., DTaP-HB-IPV-Hib) can help integrate the HB vaccine into existing routine immunization schedules without additional injections, thereby reducing the overall number of injections for the individual.
- Infants born to a pregnant woman or pregnant individual who is HBsAg-positive or whose status is unknown should follow the management plan for post-exposure prophylaxis as outlined in the CIG, Hepatitis B vaccines chapter.
- For programs transitioning from routine school-based HB immunization programs to routine HB infant vaccination, the most commonly used approach to maintain vaccine coverage by jurisdictions that have already transitioned is to continue school-based HB immunization until all cohorts have been vaccinated.
- If not vaccinated in infancy, individuals at risk for HB should continue to receive HB vaccination as soon as the risk is identified. Refer to the CIG, Hepatitis B vaccines chapter, Table 2: Recommended recipients of hepatitis B vaccine for pre-exposure prevention for additional information.
- Regardless of when routine pediatric HB vaccination is started, ensuring universal prenatal screening for HB and access to care is essential to mitigate vertical transmission.

Summary of evidence and rationale:

- Overall, Canada is a country with low HB endemicity, where universal prenatal screening programs and routine HB immunization in Canada have been effective at reducing HB infections. However, the prevalence of HBsAg has been found to be lower in individuals born in Canada compared to those born outside of Canada, with the prevalence of

HBsAg in the latter group differing depending on their country or region of origin/migration and the degree to which HB is endemic in those areas.

- HB-containing vaccines have been in use for several decades and are well tolerated and provide long lasting protection, regardless of when the vaccine series is started. Serious adverse events following immunization are very rare.
- Routine infant HB vaccination provides earlier and more equitable protection as perinatal and early childhood acquisition of HB infection are important drivers of CHB burden and its subsequent complications. This is especially important for children who may be at increased risk of infection due to exposure to close contacts with HB, such as household members, childcare contacts, and caregivers. Epidemiologic and economic modelling studies suggest that routine infant HB immunization could prevent additional HB infections in children in Canada.
- Given that routine HB immunization programs have been longstanding, the ease of program integration is expected to have a significant impact on whether it is more feasible to start the HB vaccine series at birth or at two months of age.
    - Starting the series at two months of age is expected to be minimally disruptive for immunizers and recipients, as it largely involves a product substitution in the routine childhood immunization schedule. In contrast, jurisdictions that do not offer routine vaccinations at birth would need to add a vaccination time point and the complexity of this process would depend on existing mechanisms for vaccine delivery and reporting, and be impacted by health system resources.
- Economic evaluations have shown that infant HB vaccination programs are more cost-effective than adolescent vaccination programs.
    - The inclusion of a birth dose may prevent additional HB cases, but this strategy can be associated with higher program costs and relatively small additional health benefits compared with starting vaccination at two months of age.
    - Program cost differences between including a birth dose and starting at two months depend on the price of the hexavalent HB-containing vaccine (DTaP-HB-IPV-Hib) used from two months of age; if priced similarly to the pentavalent vaccine (DTaP-IPV-Hib), the birth-dose strategy is expected to have higher incremental program costs; if priced higher, cost differences between strategies narrow.
    - Transitioning from adolescent to infant programs will involve a temporary overlap period where vaccinating both cohorts will be necessary, with potential medium-term budget impacts.
- It is particularly important that robust prenatal screening is maintained and that infants at increased risk can be identified and offered HB prevention.
    - Epidemiological information demonstrating failure of universal prenatal screening, lack of protocol for infants born to individuals with unknown status, and gaps in access to care should be collected and analysed on an ongoing basis, so that appropriate and timely adjustments can be made to existing HB immunization programs as needed.

For additional information on vaccines and schedules, refer to Appendix B.

VIII. Knowledge gaps and research needs

After review of the existing evidence, NACI has identified the need for further research to address current knowledge gaps where data are absent or limited to support future recommendation development. NACI recognizes that there are studies already in progress that

may address some of these gaps, but the findings of these studies were not available at the time of review. Priority areas for research are listed below:

Epidemiology and Surveillance

- To further clarify the contribution of different transmission pathways to HB infection, including perinatal, infant and childhood acquisition, household transmission, infections acquired in Canada versus prior to immigration, and cases associated with missed immunization.
- Compare the effectiveness of vaccination at birth with vaccination at 2 months of age, taking into account current adherence to perinatal prevention measures, including screening during pregnancy and timely vaccination of newborns at risk.

Ethics, equity, feasibility, and acceptability

- The acceptability and uptake over time of HB vaccination that is started at birth versus infancy versus school-age children. Canadian data on the acceptability and uptake of injections at birth can also provide indirect evidence on the acceptability of a birth dose of HB vaccine.

List of abbreviations

CAD	Canadian dollars
CHB	Chronic hepatitis B
CIC	Canadian Immunization Committee
cNICS	Childhood National Immunization Coverage Survey
DALY	Disability adjusted life years
DTaP-HB-IPV-Hib	Diphtheria, tetanus, acellular pertussis, hepatitis B, inactivated poliovirus, and *Haemophilus influenzae* type b vaccine
DTaP-IPV-Hib	Diphtheria, tetanus, acellular pertussis, inactivated poliovirus, and *Haemophilus influenzae* type b vaccine
EEFA	Ethics, equity, feasibility, acceptability
HAHB	Hepatitis A and Hepatitis B vaccine
HB	Hepatitis B
HBIg	Hepatitis B immune globulin
HBsAg	Hepatitis B surface antigen
NACI	National Advisory Committee on Immunization
NICE	National Institute for Health and Care Excellence
NITAG	National immunization technical advisory group
NOC	Notice of Compliance
PHAC	Public Health Agency of Canada
P/T	Province/territory
QALY	Quality adjusted life years
STARVAX	Standardized Reporting on Vaccination
UK	United Kingdom
UNDRIP	United Nations Declaration on the Rights of Indigenous Peoples Act
WHO	World Health Organization

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Appendix A

Table A1. Strength of NACI recommendations

Strength of recommendation	Strong	Discretionary
Wording	recommends/ does not recommend	"may/may not be given/offered"
Rationale	Known/anticipated advantages outweigh known/anticipated disadvantages, OR Known/Anticipated disadvantages outweigh known/anticipated advantages	Known/anticipated advantages are closely balanced with known/anticipated disadvantages, OR uncertainty in the evidence of advantages and disadvantages exists
Implication	A strong recommendation applies to most populations/individuals and should be followed unless a clear and compelling rationale for an alternative approach is present.	A discretionary recommendation may be considered for some populations/individuals in some circumstances. Alternative approaches may be reasonable.

Table A2. Key characteristics of HB vaccines authorized for use in Canada in the pediatric population

	ENGERIX-B [27]	RECOMBIVAX HB® [28]	TWINRIX [29]	INFANRIX hexa [30]
Manufacturer	GlaxoSmithKline Inc. (GSK)	Merck Canada Inc.	GSK	GSK
Date of initial authorization in Canada	Nov 6, 1987	May 11, 1987	Jan 23, 1997	May 28, 2004
Type of vaccine (abbreviation)	HB surface antigen vaccine (recombinant); (monovalent HB)	HB surface antigen vaccine (recombinant); (monovalent HB)	Combined hepatitis A virus (inactivated) and HB surface antigen (recombinant) vaccine; (HAHB)	Combined diphtheria and tetanus toxoids, acellular pertussis, HB (recombinant), inactivated poliomyelitis and adsorbed conjugated *Haemophilus influenzae* type b vaccine; (DTaP-HB-IPV-Hib)
Hepatitis B Surface Antigen (HBsAg) content	10 mcg/0.5 mL (pediatric); 20 mcg/1.0 mL (adult)[1]	5 mcg/0.5 mL (pediatric); 10 mcg/1 mL (adult) (1)	Twinrix Junior: 10 mcg/0.5 mL Twinrix: 20 mcg/1.0 mL	10 mcg/0.5 mL
Additional antigens (if applicable)	Not applicable	Not applicable	HAV: 360 ELISA units/0.5 mL HAV: 720 ELISA units/1.0 mL	Diphtheria toxoid (25 Lf [30 IU]), tetanus toxoid(10 Lf [40 IU]), acellular pertussis antigens (PT (25 mcg), FHA (25 mcg), PRN (8 mcg)), inactivated poliovirus types 1 (40 DU), 2 (8 DU), 3 (32 DU), and Hib PRP (10 mcg) conjugated to tetanus toxoid (25 mcg)
Pediatric indications	Active immunization against HBV infection in infants, children and adolescents (0-19 years).	Active immunization against HBV infection in infants, children and adolescents (0-19 years).	Active immunization against hepatitis A and HBV infection in infants, children and adolescents (1-18 years) at risk who require protection	Active primary immunization against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis, and disease caused by *Haemophilus influenzae* type b in infants and children

			against both viruses. (2)	from 6 weeks to 2 years of age. (3)
Storage requirements	Store at 2-8 °C. Do not freeze. Protect from light	Store at 2-8 °C Do not freeze Protect from light	Store at 2-8 °C. Do not freeze. Protect from light	Store at 2-8 °C. Do not freeze. Protect from light
Reconstitution	Not applicable (prefilled syringe)	Not applicable (single-dose vial or prefilled syringe)	Not applicable (prefilled syringe)	The Hib lyophilized component must be reconstituted with the liquid DTaPHBIPV component (PEDIARIX) before intramuscular injection
[1] Adult formulations may be used in certain adolescent HB immunization schedules as described in the CIG, Part 4, Hepatitis B vaccines. [2] For pre-exposure immunization, persons 6 months of age and older may be immunized with HAHB vaccine, if indicated. More information is available in the NACI Update on the Recommended use of Hepatitis A Vaccine. [3] DTaP-HB-IPV-Hib vaccine may be given to children aged 24 months to less than 7 years, if necessary. For additional information refer to the CIG, Part 4, Tetanus toxoid, Recommendations for use.				

Abbreviations: DTaP-HB-IPV-Hib: diphtheria, tetanus, acellular pertussis, hepatitis B, inactivated poliovirus, and *Haemophilus influenzae* type b vaccine; DU: D-antigen units; ELISA: enzyme-linked immunosorbent assay; FHA: filamentous haemagglutinin; GSK: GlaxoSmithKline; HAV: hepatitis A virus; HB: hepatitis B; HBsAg: hepatitis B surface antigen; HBV: hepatitis B virus; Hib: Haemophilus influenzae type b; IU: international units; IPV: inactivated poliovirus vaccine; Lf: limit of flocculation units; mcg: micrograms; mL: millilitres; PRN: pertactin; PRP: polyribosylribitol phosphate; PT: pertussis toxin.

For complete prescribing information for HB vaccines, consult the product leaflet or information contained within Health Canada's authorized product monographs available through the Drug Product Database.

Appendix B

To support implementation of NACI's recommendation for HB vaccination in infancy within the context of existing routine infant and child immunization schedules in Canada, the previously recommended schedule of 0, 1 and 6 months, has been updated to 0, 1 to 2 and (at least) 6 months. This updated schedule applies to the recommended intervals for vaccine schedules incorporating HB vaccine. The minimum intervals for a 3-dose monovalent HB vaccine series remain unchanged.

Table A outlines the recommended schedules and minimum intervals for HB immunization using monovalent HB and hexavalent HB-containing vaccines (DTaP-HB-IPV-Hib). Tables B through D provide examples illustrating how monovalent HB and hexavalent HB-containing vaccines may be incorporated into schedules for routine infant and child immunization, and immunization for infants born to HBsAg positive women or individuals.

The numbers shown in the vaccine schedules below indicate the recommended timing of each dose relative to the first dose, which is designated as month 0. For example, in a 0, 1 to 2, at least 6 month schedule, the second dose is administered 1 to 2 months after the first dose and the third dose at least 6 months after the first dose. In schedules that include a birth dose, "birth" replaces month 0, but the same principles apply for the timing of subsequent doses.

Table A. Schedules and minimum intervals using monovalent HB and/or DTaP-HB-IPV-Hib[a] vaccines

Recipient	HB vaccine series	Recommended schedule	Minimum intervals
Schedules for infants, children and adolescents			
Birth to less than 20 years of age	**If using a 3-dose series with**: • monovalent HB vaccine	0, 1 to 2, at least 6 months	0, 1, 4 months[b]
6 weeks to less than 7 years of age	**If using a 3 dose series with**: • DTaP-HB-IPV-Hib[a] vaccine	0, 1 to 2, at least 6 months	0, 1, 4 months[b]
11 to 16 years of age	**If using a 2-dose series with**: • monovalent HB vaccine	0, 4 to 6 months	Minimum intervals between doses are product specific.
Schedule for infants born to pregnant women or pregnant individuals who are HBsAg-positive[c] or HBsAg status is unknown[d]			
Infants born at term or born prematurely and weighing 2,000 g or more	**3-dose series** using: • monovalent HB vaccine **and / or** • DTaP-HB-IPV-Hib[a] vaccine	Birth, 1 to 2, 6 months	Follow the recommended schedule
Infants born prematurely and weighing less than 2,000 g	**4-dose series** using: • monovalent HB vaccine **and / or** • DTaP-HB-IPV-Hib[a] vaccine	Birth, 1, 2, 6 months	Follow the recommended schedule
a. DTaP-HB-IPV-Hib vaccine is authorized for use in children 6 weeks to 23 months of age and may be given to children aged 24 months to less than 7 years, if necessary. Refer to Tables B through D for examples of schedules that incorporate DTaP-HB-IPV-Hib vaccine.			

b. Ensure a 4-week minimum interval between the first and second dose, and an 8-week minimum interval between the second and third dose. In addition, there should be a minimum of 16 weeks between the first and third dose of the 3-dose HB vaccine series.
c. Infants born to pregnant women or pregnant individuals who are HBsAg-positive should receive HBIg and monovalent HB vaccine as soon as possible within 12 hours of birth, followed by 2 or 3 additional doses of HB-containing vaccine (refer to Table D) and post-immunization serologic testing.
d. If the pregnant woman or pregnant individual's HB status is not available within 12 hours of delivery, HB vaccine should be given while the results of the test are pending. HBIg should be provided if there is any suspicion that the pregnant women or pregnant individual could be an acute case or a chronic carrier of HBsAg.

Rationale for timing of dose 2 in the 3-dose series

Offering dose 2 of HB-containing vaccine in a 3-dose series at an interval of 1 to 2 months after the first dose provides flexibility for integration with routine infant and child immunization schedules (which typically start at 2 months of age), particularly when the first dose is offered at birth. This allows the DTaP-HB-IPV-Hib vaccine to be used as an option to complete the HB immunization series. The interval between the dose 2 and dose 3 has the most impact on the resulting antibody levels, which are predictive of long-term protection.

In studies looking at the impact of different intervals between the first and second dose in infants at high risk, a dose interval between 4 and 8 weeks did not affect the risk of perinatal transmission. [38-40]

Recommended routine infant and child schedules for HB immunization

Table B. Routine infant and child schedule options incorporating DTaP-HB-IPV-Hib vaccine, without a monovalent HB birth dose

Recipient's age	Schedule 1	Schedule 2[a]	Schedule 3[b]
Birth	—	—	—
1 month	—	—	—
2 months	DTaP-HB-IPV-Hib	DTaP-HB-IPV-Hib	DTaP-HB-IPV-Hib
4 months	DTaP-HB-IPV-Hib	DTaP-HB-IPV-Hib	DTaP-HB-IPV-Hib
6 months	DTaP-IPV-Hib	DTaP-HB-IPV-Hib	DTaP-HB-IPV-Hib
12 to 23 months[c]	DTaP-HB-IPV-Hib	DTaP-IPV-Hib	DTaP-HB-IPV-Hib

a. This schedule follows minimum intervals for monovalent HB and hexavalent HB-containing vaccine with HB-containing doses administered at intervals of 0, 2, and 4 months (where 0 is the first dose given).

b. DTaP-HB-IPV-Hib vaccine may be given at 2, 4, 6 and 12 to 23 months of age but the fourth dose is unlikely to provide significant additional HB protection and will increase cost.

c. This dose is typically administered at 18 months of age. It should be administered at or after 12 months of age and at least 6 months following the third dose.

Table C. Routine infant and child schedule options incorporating DTaP-HB-IPV-Hib vaccine, with a monovalent HB birth dose

Recipient's age	Schedule 1	Schedule 2
Birth	Monovalent HB	Monovalent HB
1 month	—	Monovalent HB
2 months	DTaP-HB-IPV-Hib	DTaP-IPV-Hib
4 months	DTaP-IPV-Hib	DTaP-IPV-Hib
6 months	DTaP-HB-IPV-Hib	DTaP-HB-IPV-Hib
12 to 23 months[a]	DTaP-IPV-Hib	DTaP-IPV-Hib
a. This dose is typically administered at 18 months of age. It should be administered at or after 12 months of age and at least 6 months following the third dose.		

Recommended schedules for HB immunization of infants born to pregnant women or pregnant individuals who are HBsAg-positive (i.e., infants at high risk) or HBsAg status is unknown

Infants at high risk born at term or born prematurely

Post-exposure prophylaxis management for infants born at term or born prematurely (defined as infants born before 37 weeks of gestational age) who are born to pregnant women or pregnant individuals who are HBsAg-positive includes receiving HBIg and monovalent HB vaccine as soon as possible within 12 hours of birth, followed by additional doses of HB-containing vaccine (refer to Table D) and post-immunization serologic testing.

Refer to the CIG, Part 4, Hepatitis B vaccines, Post-exposure immunization, Infants born to a pregnant woman or pregnant individual with acute or chronic hepatitis B infection for additional information regarding immunization with HBIg and post-serologic testing.

Infants born to pregnant women or pregnant individuals whose HBsAg status is unknown

If the pregnant woman or pregnant individual's HB status is not available within 12 hours of delivery, HB vaccine should be given while the results of the test are pending. HBIg should be provided if there is any suspicion that the pregnant women or pregnant individual could be an acute case or a chronic carrier of HBsAg.

Table D. Recommended schedules for HB immunization schedules infants born to pregnant women or pregnant individuals who are HBsAg-positive

Recipient's age	Schedule I: Infants born at term or born prematurely and weighing 2,000 g or more	Schedule II: Infants born at term or born prematurely and weighing 2,000 g or more	Schedule III: Infants born prematurely and weighing less than 2,000 g
Birth	Monovalent HB	Monovalent HB	Monovalent HB

1 month	—	Monovalent HB	Monovalent HB
2 months	DTaP-HB-IPV-Hib[a]	DTaP-IPV-Hib	DTaP-HB-IPV-Hib[a]
4 months	DTaP-IPV-Hib	DTaP-IPV-Hib	DTaP-IPV-Hib
6 months	DTaP-HB-IPV-Hib[a]	DTaP-HB-IPV-Hib[a]	DTaP-HB-IPV-Hib[a]
12 to 23 months[b]	DTaP-IPV-Hib	DTaP-IPV-Hib	DTaP-IPV-Hib
a. Either DTaP-HB-IPV-Hib **OR** monovalent HB **and** DTaP-IPV-Hib and may be provided. b. This dose is typically administered at 18 months of age. It should be administered at or after 12 months of age and at least 6 months following the third dose.			

Accelerated immunization schedules

Accelerated immunization schedules are used to provide protection in exceptional circumstances, such as in cases of travel or in outbreak situations, when a multi-dose vaccine series needs to be completed as quickly as possible, while following the minimum intervals for all antigens.

When multiple vaccine products are used to complete a HB vaccine series and/or a DTaP-IPV-Hib-containing series, each dose should be assessed against the minimum age and intervals for all relevant antigens. Please refer to the CIG, Part 1, Timing of vaccine administration for more details.