Massachusetts Department of Public Health

DPH

The Road to Elimination Hepatitis B Virus (HBV) Vaccination Across the Lifespan

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Massachusetts Perinatal Hepatitis B Prevention Program

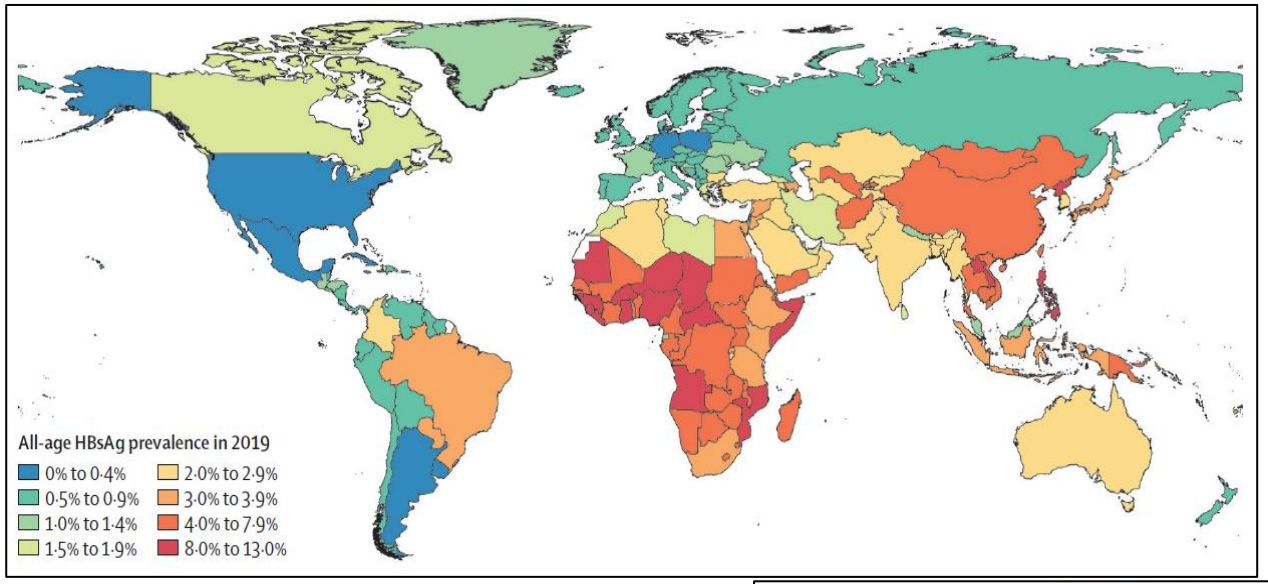
Presenter Disclosure

- I, Christy Norton Valle, have been asked to disclose any relevant financial relationships with ineligible companies.
- I have no relevant financial relationships to disclose.
- I may discuss the use of vaccines in a manner not approved by the U.S. Food and Drug Administration, but in accordance with the recommendations of CDC and/or professional medical organizations.
- All financial relationships have been mitigated.

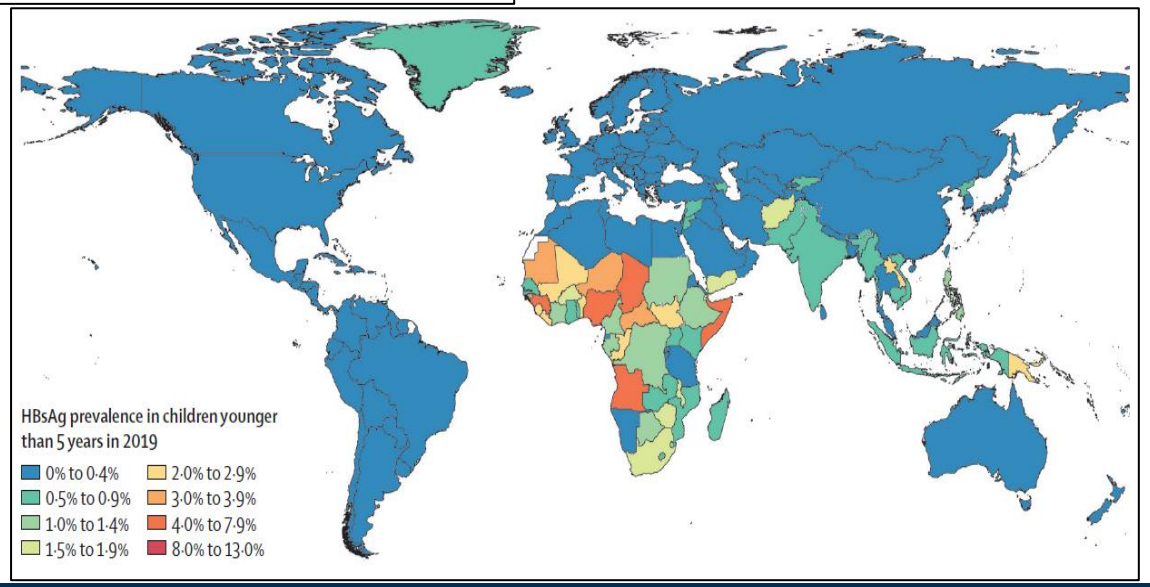
Background: Hepatitis B Virus (HBV)

- Viral infection that attacks the liver; circulates in the blood and in other body fluids
- Modes of transmission:
  - Birth to an infected person
  - Sexual contact
  - Injection drug use
  - Cuts/wounds, needle-sticks, tattoos, piercings
  - Shared towels, washcloths, razors, toothbrushes, nail clippers, glucometers
  - Pre-chewed food
- Highly infectious and easily spread
  - 50 to 100X more infectious than HIV
  - Can be transmitted in the absence of visible blood
  - Can live on environmental surfaces for at least 7 days
- Can be an acute or chronic infection

Global Burden of Disease



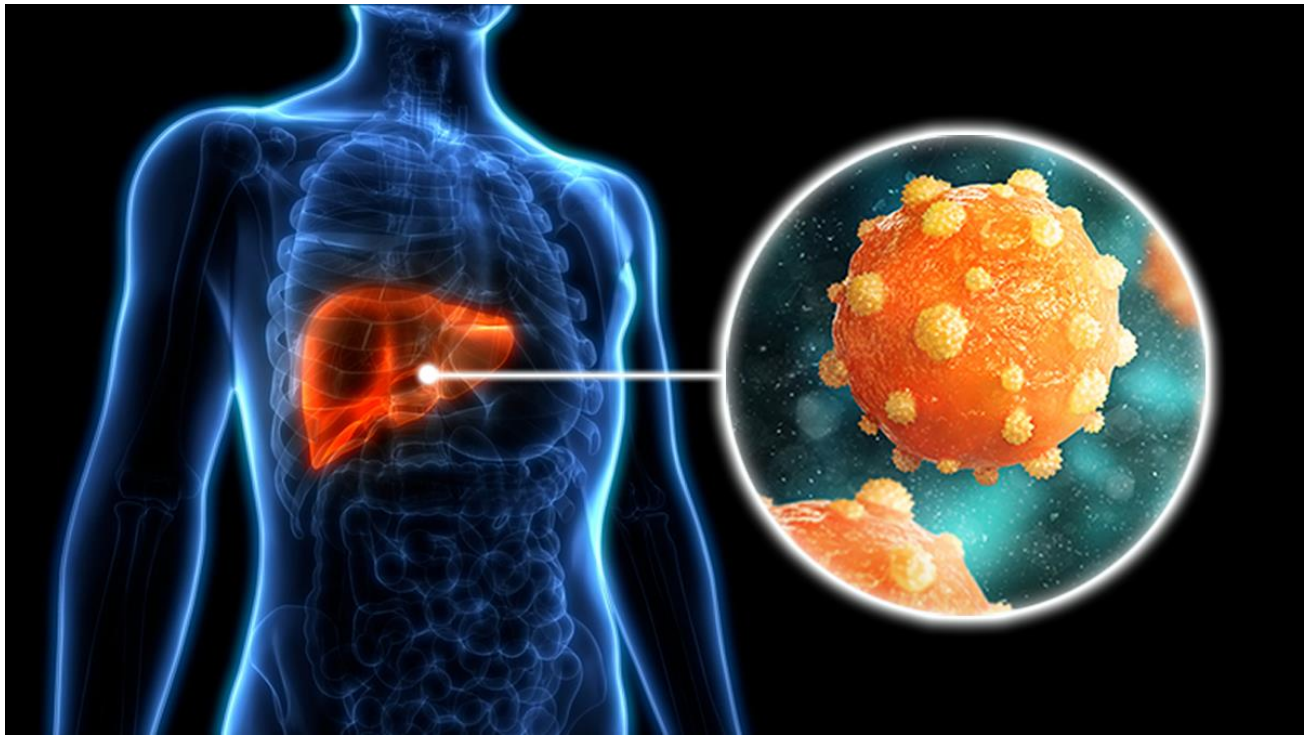
- 30% of the world population with serologic evidence of HBV exposure
- > 350 million people living with chronic HBV
  - 1 of every 25
  - 6.2 million children <5 yrs
- 80% of the global population lives in an intermediate or high- prevalence area



The Lancet, 6/20/2022, 'Global, regional, and national burden of hepatitis B, 1990–2019: a systematic analysis for the Global Burden of Disease Study 2019.'
https://www.thelancet.com/pdfs/journals/langas/PIIS2468-1253(22)00124-8.pdf

Oncogenic Virus

"Hepatitis B and C cause significantly higher cancer risk than smoking a daily pack of cigarettes." World Hepatitis Alliance



https://www.worldhepatitisalliance.org/news/hepatitis-b-and-c-cause-significantly-higher-cancer-risk-than-smoking-a-daily-pack-of-cigarettes/
https://www.cdc.gov/hepatitis-b/about/index.html

Risk of Chronic Hepatitis B Virus (HBV) Infection

- Risk of chronic infection differs by age at initial infection
  - Newborns: 80 – 90%
  - Children under 6 years of age: 25 – 30%
  - Adults: less than 5%; higher if immunosuppressed

Perinatal Transmission of HBV

- Perinatal transmission accounts for 50% of global burden of chronic HBV
- 80-90% of infants with perinatal transmission will develop chronic HBV
- 15-25% of infants with chronic HBV will eventually die from liver-related complications
- Administration of hepatitis B vaccine and hepatitis B immune globulin (HBIG) to infant is 85-95% effective in preventing perinatal transmission

U.S. Strategy to Eliminate HBV Transmission

- Screening of all pregnant people for HBsAg (1988)
- HBV DNA testing for HBsAg-positive pregnant people, to inform need for antiviral treatment
- Prophylaxis (Hep B vaccine and HBIG) for infants born to HBsAg-positive or unknown status pregnant persons
- Perinatal Hepatitis B Prevention Program (1990)
- Universal vaccination of all infants beginning at birth (1991)
- Routine vaccination of previously unvaccinated children aged <19 years
- Nov 2021: Universal vaccination of all adults 19 through 59 years, and adults 60+ with risk factors for hepatitis B infection or who request it without acknowledgement of a specific risk factor.
- March 2023: Universal screening (triple panel) and testing recommendations

Hepatitis B ACIP Recommendations

2018 MMWR https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.PDF
2021 HBV vaccine recommendations for adults: https://www.cdc.gov/mmwr/volumes/71/wr/mm7113a1.htm
2023 universal screening recommendations: https://www.cdc.gov/mmwr/volumes/72/rr/rr7201a1.htm

Vaccination

- 1981: first hepatitis B vaccine licensed
- 1982: birth dose for all babies born to birth parents identified as positive
  - No significant change in incidence of infection
- 1988: expanded birth dose includes racial and ethnic groups at highest risk
  - No significant change in incidence of infection
  - ~ 30,000 children less than 10 years of age infected
  - **Only half were infected by birth parent**
- 1991: expanded birth dose to ALL newborns
  - **Decreased incidence in children by 99%***
- 2026: federal changes; AAP & MDPH continue recommend the universal birth dose

* Bixler D, Roberts H, Panagiotakopoulos L, Nelson NP, Spradling PR, Teshale EH. Progress and Unfinished Business: Hepatitis B in the United States, 1980-2019. *Public Health Reports®*. 2023;0(0). doi:10.1177/00333549231175548

Why Vaccinate Infants?

While some parents have wondered why infants are vaccinated against an infection that is commonly perceived as sexually transmitted, we continue to work collectively to ensure that they understand these important points:

- Many people with chronic infections don’t know they are infected. As a result, they may not take precautions against spreading it. Spread can occur in households, daycares, schools.
- Transmission can occur following exposure to quantities of infected blood so minimal that they cannot be seen with the naked eye and the virus can remain viable on environmental surfaces for at least 7 days .
- Infected children have a much higher risk of disease and complications.
- The vaccine is well tested, safe, and a cancer prevention!

Hepatitis B Vaccination is a Multidose Series, with Increasing Seroprotection Among Infants After Each Dose

- **Hepatitis B vaccination recommendations on child and adolescent immunization schedule – United States, 2025**

Vaccine and other immunizing agents	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos
Hepatitis B (HepB)	1st dose	←2nd dose→			←3rd dose→			

- **In addition to the immediate benefit of providing postexposure prophylaxis to the newborn, the hepatitis B birth dose serves as the first dose of the infant vaccination series.***

- **Among healthy infants, the 3-dose hepatitis B vaccine series produces a protective antibody response (anti-HBs ≥10 mIU/mL) in approximately:**
  - ~25% of infants after the first dose,
  - ~63% of infants after the second dose, and
  - ~95% of infants after the third dose.

https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html (accessed 8/18/25);
*Except for pre-term infants weighing <2,000 grams born to women known to be HBsAg positive.
Schillie, S. et al. Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. MMWR Recomm Rep 67, 1-31 (2018).

Titer After a Single Dose is NOT Reliable

- An anti-HBs ≥10 mIU/mL is a serologic correlate of protection only when following a documented, complete series.
- Testing unvaccinated or incompletely vaccinated persons for anti-HBs is not necessary and is potentially misleading, because anti-HBs ≥10 mIU/mL as a correlate of vaccine-induced protection has only been determined for persons who have completed an approved vaccination series.
- Although certain persons might have anti-HBs of ≥10 mIU/mL after partial vaccination, whether this confers long-term protection is unknown.

2018 MMWR https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.PDF
2021 MMWR HBV vaccine recommendations for adults: https://www.cdc.gov/mmwr/volumes/71/wr/mm7113a1.htm
2023 MMWR universal screening recommendations: https://www.cdc.gov/mmwr/volumes/72/rr/rr7201a1.htm

Perinatal Hepatitis B Prevention Program

*Infants who become infected with hepatitis B virus have an **80%–90% risk of developing chronic hepatitis B** infection and a **25% lifetime risk of dying prematurely** from cirrhosis or hepatocellular carcinoma.*

*A key strategy to **eliminate perinatal transmission of HBV** is to **prevent infants born to HBsAg+ gestational persons from becoming infected**.*

- Established in 1990, by CDC
- Funded by CDC Immunization Cooperative Agreements
- Programs in 64 jurisdictions (50 states, 6 cities, 5 territories & 3 freely associated island nations)
- Required program strategies:
  - Identify HBsAg positive pregnant persons and births to HBsAg positive persons
  - Ensure HBV exposed newborns receive postexposure prophylaxis (HBIG and birth dose of Hep B vaccine)
  - Ensure HBV exposed infants complete the hepatitis B vaccine series, as close to on-time as possible
  - Ensure HBV exposed infants receive postvaccination serologic testing

Challenges in Preventing Vertical Transmission

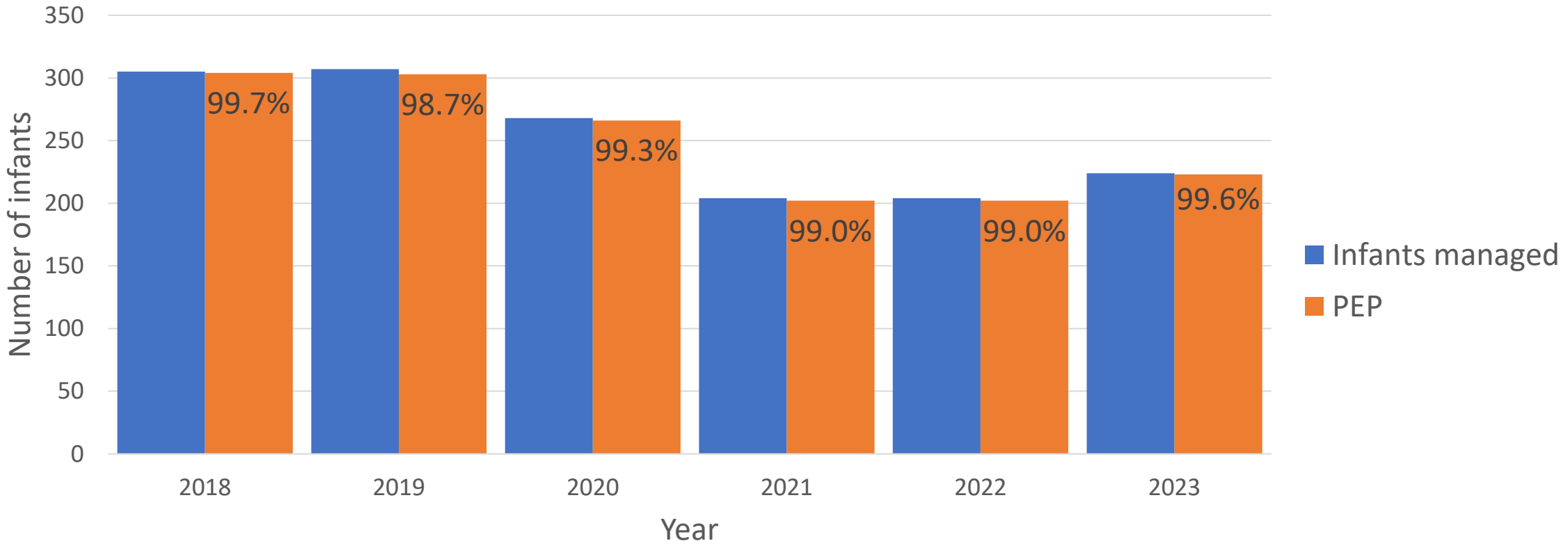
- Lack of prenatal care
- Gaps in screening
  - ~12-16% of pregnant persons aren't screened
- Incorrect screening tests performed
- Screening tests aren't perfect
  - ~5% false negative rate
- Errors in interpreting or transcribing test results
- Acute seroconversion after screening test
- Lapses in providing standard of care post exposure prophylaxis (PEP) at birth

Hep B Birth Dose/HBIG Administration

- **Administer monovalent hepatitis B vaccine to all newborns within 24 hours of birth, regardless of the pregnant person's Hepatitis B status.**
- For infants born to hepatitis B surface antigen (HBsAg) positive pregnant persons, administer HBIG and first dose of Hep B vaccine within 12 hours of birth.
- The primary goal of administering hepatitis B vaccine at birth is to protect babies from developing chronic HBV infection, which can lead to liver failure and liver cancer.
- HBIG and Hep B vaccine must be administered in different limbs
- Nirsevimab may be administered in the same limb as either HBIG or Hep B vaccine
- HBIG (passive immunoprophylaxis) provides a short-term increase (i.e., 3-4 months) in anti-HBs which improves protection until the infant responds to vaccine

Outcomes of Infants Managed by MA PHBPP, by Birth Cohort

Number of infants managed by the Massachusetts Perinatal Hepatitis B Prevention Program who received PEP at birth, by birth cohort



PEP (post-exposure prophylaxis) consists of HBIG (hepatitis B immune globulin) and hepatitis B vaccine within 24 hours of birth.

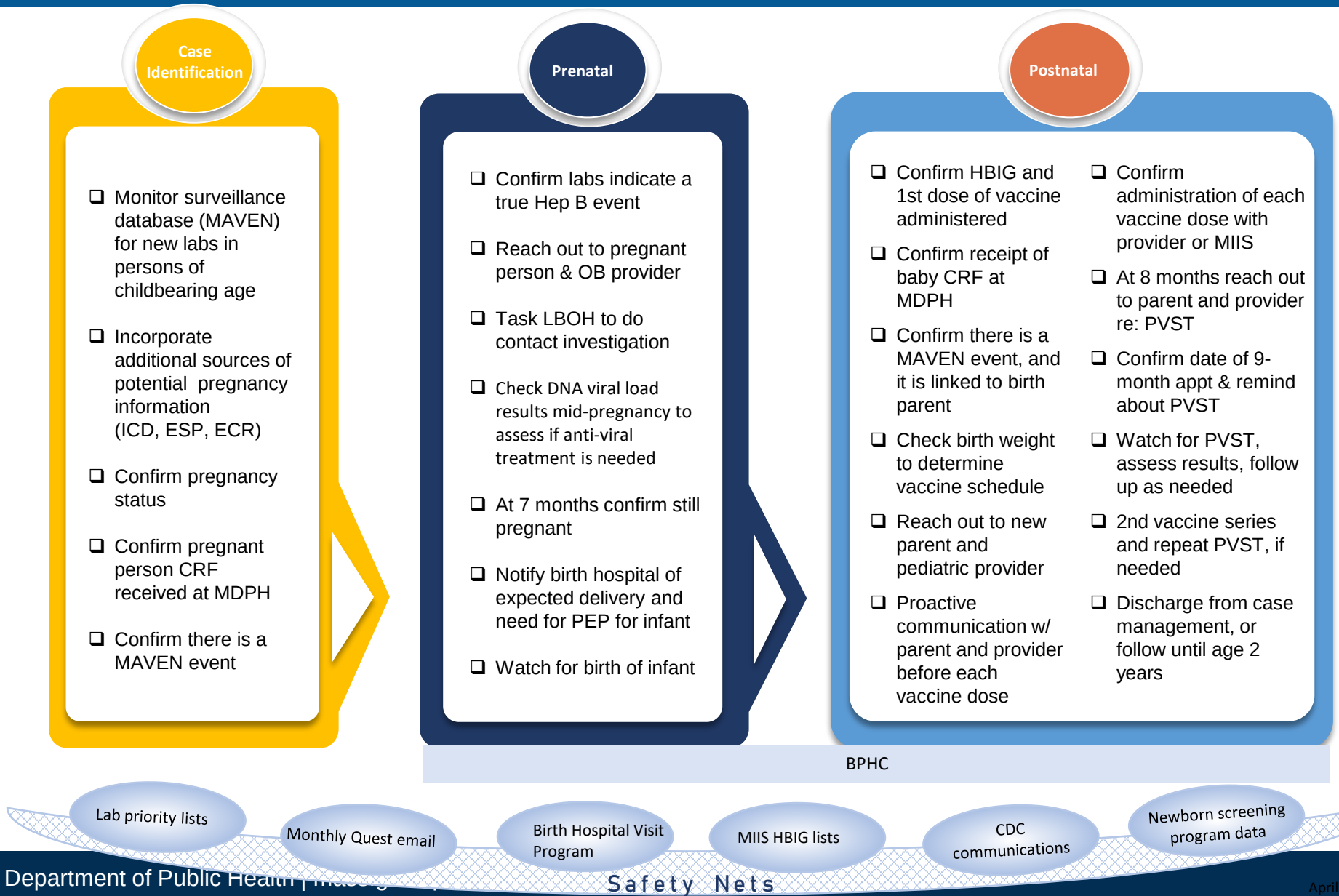
MA DPH PHBPP Compared to National Outcomes 2021 Birth Cohort

		Hepatitis B vaccine administration						Post-vaccination serologic testing					
	Infants managed	HBIG & vaccine at birth		Complete series by 12 months of age		Total with complete series		Received		HBsAg positive		Immune	
	No.	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
MA	204	202	*99%*	194	*95%*	194	*95%*	172	*84%*	0	*0%*	165	*96%*
US	7102	6718	*95%*	6267	*88%*	6364	*90%*	4631	*65%*	17	*<1%*	4412	*95%*

National data: https://www.cdc.gov/hepatitis-surveillance-2022/perinatal-hepatitis-b/table-4-1.html

Massachusetts Perinatal Hepatitis B Prevention Program Case Management

(a collaboration among BIDLS divisions; DSAI, Epidemiology, and Immunization)



Acronyms

BIDLS: Bureau of Infectious Disease and Laboratory Sciences, a Bureau within MDPH

BPHC: Boston Public Health Commission

CRF: Infectious Disease Case Report Form, available at Infectious Disease Case Report Forms (mass.gov)

DSAI: Division of Surveillance, Analytics and Informatics

DGP: Division of Global Populations

ECR: Electronic case reporting

ESP: Electronic medical record support for public health

HBIG: hepatitis b immune globulin

ICD: International Classification of Diseases

LBOH: Local Board of Health

MAVEN: Massachusetts Virtual Epidemiologic Network

MDPH: Massachusetts Department of Public Health

MIIS: Massachusetts Immunization Information System

PEP: post exposure prophylaxis; infants born to persons chronically infected with hepatitis B should receive hepatitis B immune globulin (HBIG) and single-antigen hepatitis B vaccine, in separate limbs, at birth (≤12 hours)

PVST: post vaccine serology testing; lab testing to confirm whether the child has developed immunity or has been infected with HBV. PVST should include hepatitis B surface antigen (HBsAg) and hepatitis B surface antibody (anti-HBs) only. PVST should occur between 9–12 months of age or 1–2 months after vaccine series completion, if the series is delayed. Note: Tests for antibodies to hepatitis B core antigen (anti-HBc) should not be ordered.

Swift and Immediate Response to the December 2025 ACIP Meeting

Organizations issued strong and immediate statements following the conclusion of the December 2025 ACIP meeting.

- American Association of Immunologists
- American Academy of Pediatrics
- American Association for the Study of Liver Diseases
- American Hospital Association
- American Liver Foundation
- American Medical Association
- American Nurses Association
- American Pharmacists Association
- American Public Health Association
- California Medical Association
- Families USA
- Hepatitis B Foundation
- Hepatitis B United
- Infectious Diseases Society of America (cosigned with 44 other health organizations)
- National Association of County and City Health Officials
- National Medical Association
- Pediatric Infectious Diseases Society
- Robert Wood Johnson Foundation
- Vaccinate Your Family

Newborn Hepatitis B Vaccination

- Provides immediate, reliable protection to all newborns - not just those whose gestational parent test positive.
- Closes gaps caused by missed, delayed or imperfect maternal testing.
- Prevents lifelong chronic disease, liver cancer, and premature death.
- Has a decades-long safety record with billions of doses administered globally.
- Is more effective at preventing infection and disease than ‘catch-up’ vaccination later in childhood or in adulthood, especially in a country like the US where we don’t have equitable healthcare access.

Closing Thoughts

We don’t want to go back to a place where thousands of children each year are being infected with a disease that can be easily and safely prevented.

The universal birth dose has reduced pediatric infection by 99% in the U.S.

MDPH, NEPHC, AAP, and AAFP all recommend
the universal birth dose that has been in place since 1991.

MDPH Regional Immunization Nurses and Regions

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