PRoGReSs Model

HBV Transmission & Disease Burden

The Impact of Changing Vaccination Schedules

United States

October 29, 2025

POLARIS OBSERVATORY

Topics

- Background
- Assumptions
- Outputs
- Next Steps

CDA Foundation (CDAF) is a non-profit organization with the goal of assisting countries in achieving WHO hepatitis elimination targets

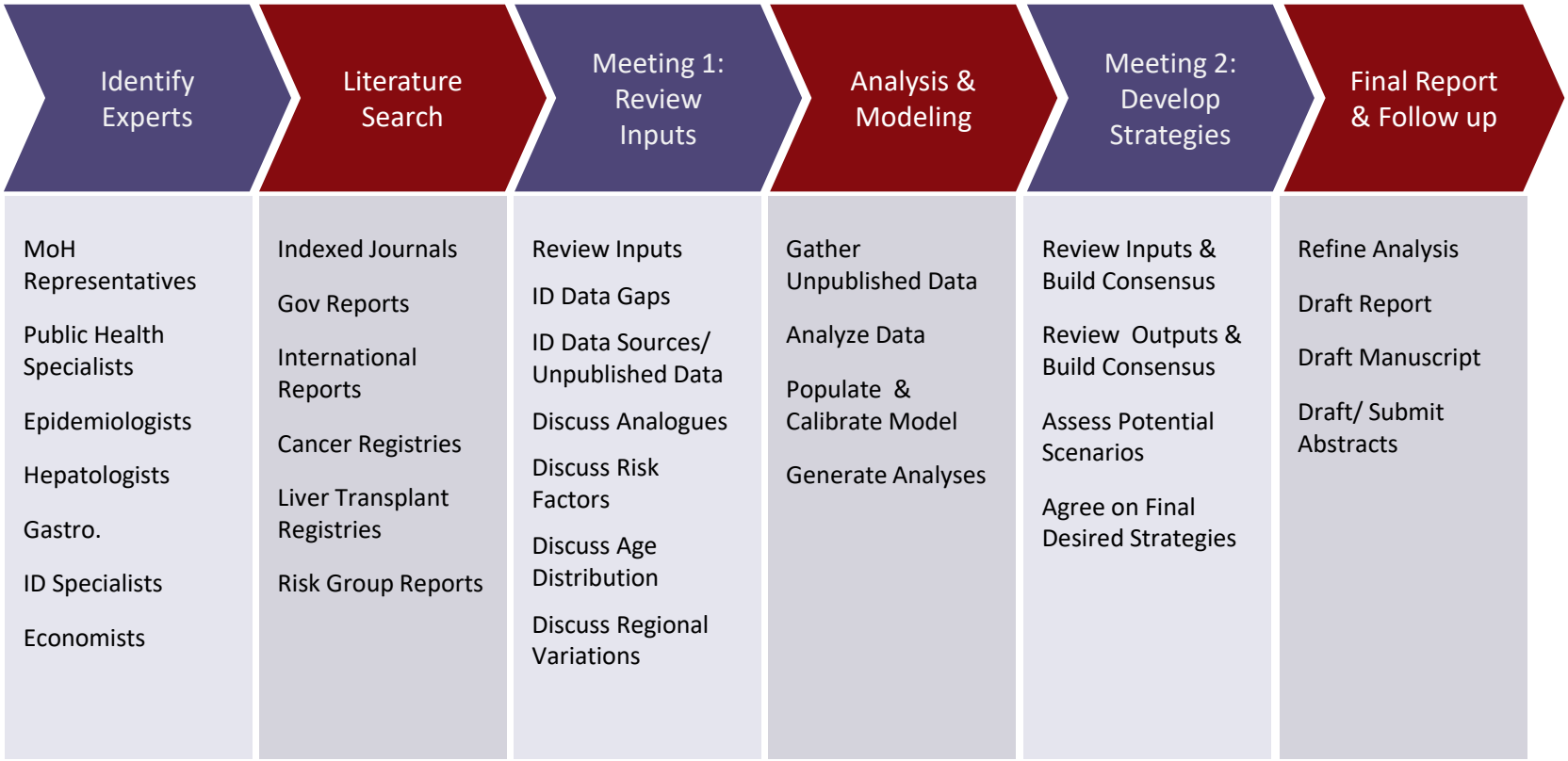
Services

- HCV & HBV disease burden modeling
- HCV & HBV economic impact modeling
- HBV vertical transmission modeling
- Cohort analysis
- Training on how to use models
- Hepatitis elimination strategies
- Cost-effectiveness and ROI analyses
- Data and metrics to track progress to elimination

Guiding Principles

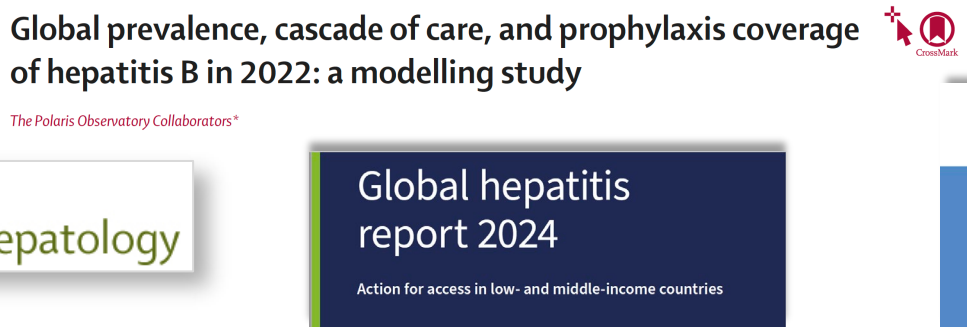
- Validate all data/analyses with local experts
- Complement country interviews with literature searches to minimize the burden on country experts
- Facilitate objective, data-driven decisions and policy-making with consideration of each country's unique needs
- Publish key findings with local collaborators
- Function as a platform to provide data, tools and analyses with a user friendly, Microsoft Excel® interface

A modified Delphi process is used to develop consensus estimates for all inputs



Publications & Citations

- CDAF partners with our collaborators to publish data, analyses and related findings.
- Since 2011, together we have published **>140 papers** in prominent, peer reviewed journals.
- Our HBV and HCV models have been endorsed by the World Health Organization
  - » Our data has been used in the 2017, 2021, and 2024 WHO reports
- Polaris and its collaborators have over **48,000 citations** and growing!



The PRoGReSs Model — HBV Perinatal Transmission

- Developed a perinatal transmission algorithm to estimate the full impact of vaccination, HBIG, and treatment of pregnant women on HBsAg prevalence
- The model uses:
  - Age-specific HBsAg prevalence among women of childbearing age (WoCBA)
  - Overall HBeAg prevalence among WoCBA
  - The portions of HBeAg+ and HBeAg- individuals with high viral load (HVL) and low viral load (LVL)
- Births by age group of mother are utilized
- All infected female infants are tracked to estimate HBV prevalence when they become WoCBA
- After perinatal transmission of HBV, risk for developing a chronic HBV infection is 0.885 (Edmunds 1993)

*Razavi-Shearer D, Gamkrelidze I, et al. Global prevalence, treatment, and prevention of hepatitis B virus infection in 2016: a modelling study. Lancet Gastroenterol Hepatol 2018; **3**(6): 383–403.*

*Edmunds W, Medley G, Nokes D, Hall A, & Whittle H. The Influence of Age on the Development of the Hepatitis B Carrier State. Proceedings: Biological Sciences. 1993; **253**(1337):197–201.*

The PRoGReSs Model — HBV Horizontal Transmission

- Horizontal transmission covers all transmission occurring non-perinatally
- Horizontal incidence of acute HBV is assumed to be a linear function *I* of prevalence of HBsAg with high viral load *p* for a population of susceptible individuals *S* at time *t*, of sex *s*, and age *a*. For those younger than 15, incidence is based on the prevalence of those aged 1–35 to simulate household infection from siblings, peers, parents, and other adults. For those 15 or older, incidence is based on the prevalence among peers of the same age:

$$I_{t,s,a} = \begin{cases} S_{t-1,s,a-1} \times \left(1 - d_{t-1,s,a-1}\right) \times p_{t-1,0\text{–}35} \times (k_a \times C_s) & \text{if } 0 \leq a < 15 \\ S_{t-1,s,a-1} \times \left(1 - d_{t-1,s,a-1}\right) \times p_{t-1,a} \times (k_a \times C_s) & \text{if } a \geq 15 \end{cases}$$

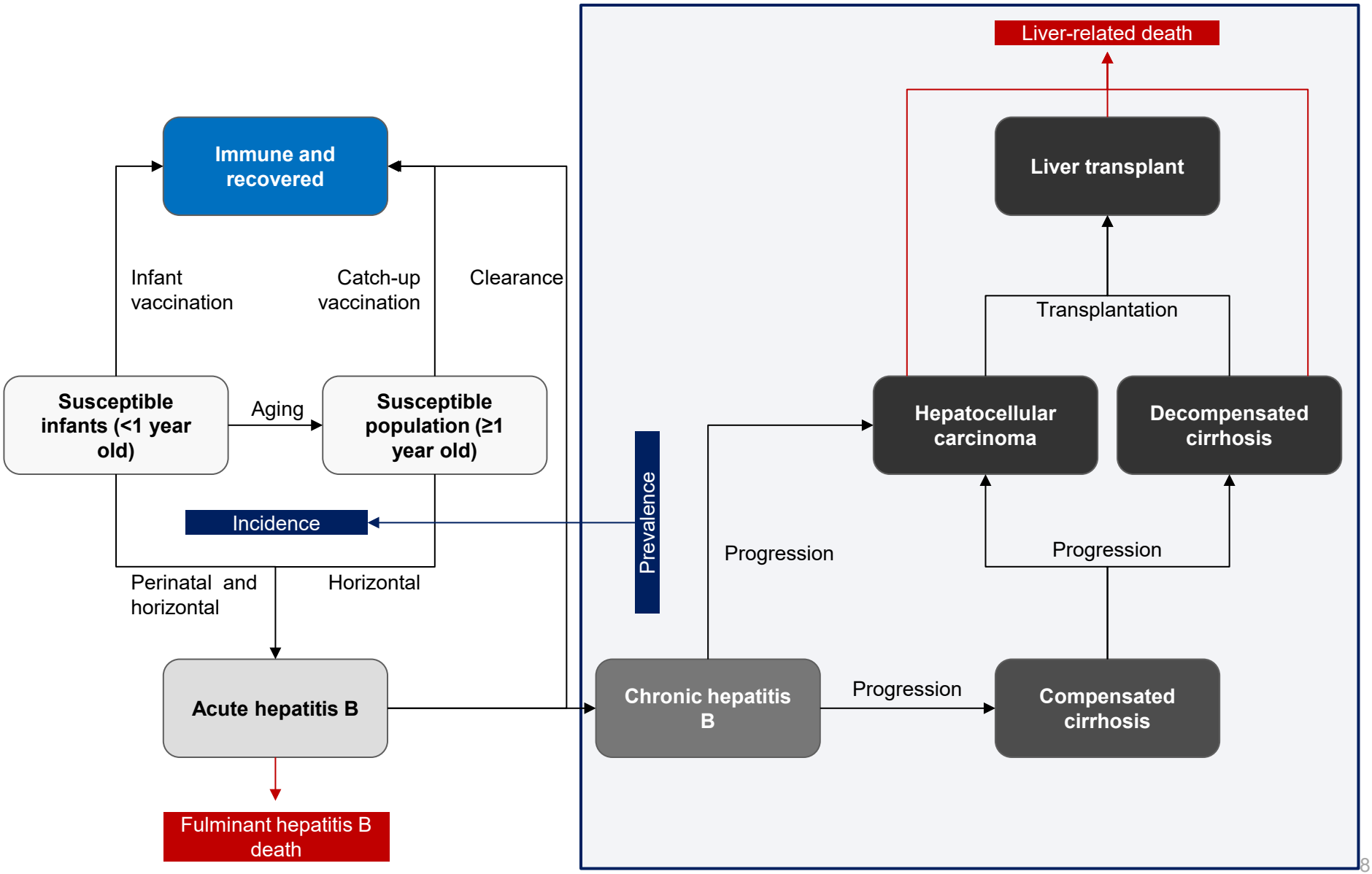
where *d* is background mortality rate, *k* is the shape parameter, and *C* is the scale parameter

- Individuals acquiring acute HBV infection are removed from the susceptible population
- After horizontal transmission of HBV, risk *c* for developing a chronic HBV infection at age *a* is calculated using:

$$c_a = \begin{cases} c_1 & \text{if } a = 0 \\ 1 - 0.7145a^{0.0814} & \text{if } 1 \leq a < 35 \\ c_{34} & \text{if } a \geq 35 \end{cases}$$

*Razavi-Shearer D, Gamkrelidze I, et al. Global prevalence, treatment, and prevention of hepatitis B virus infection in 2016: a modelling study. Lancet Gastroenterol Hepatol 2018; **3**(6): 383–403.*

The PRoGReSs Model — HBV Disease Progression



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Demographic Inputs

- Population, annual (1950–2050)
  - By age and sex
- Background Mortality Rates, annual (1950–2050)
  - By age and sex
- Births by Age Group of Mother, annual (1950–2050)
- Sex Ratio at Birth, quinquennial (1950–2050)

United Nations, Department of Economic and Social Affairs, Population Division (2024). World Population Prospects: the 2024 Revision.

Epidemiological Inputs

- In 2021, it was estimated that the HBsAg prevalence in the US was 0.50% (UI:0.24-1.23%) representing 1.7 million (UI: 795,000-4.1 million) people living with HBV (updated Razavi-Shearer 2023 analysis)

- Previous studies have estimated the prevalence of HBV ranging from 1.04 – 2.49 million (Kowdley 2012, Lim 2020, Wong 2021)

- All of these estimates are significantly higher than the National Health and Nutrition Examination Survey of 817,0000 (CI: 613,000-1,100,000) (Roberts 2021)

Kowdley KV, Wang CC, Welch S, Roberts H, Brosgart CL. Prevalence of chronic hepatitis B among foreign-born persons living in the United States by country of origin. Hepatology. 8/2012 2012;56(2):422-433. doi:10.1002/hep.24804 [doi]

Lim JK, Nguyen MH, Kim WR, Gish R, Perumalswami P, Jacobson IM. Prevalence of Chronic Hepatitis B Virus Infection in the United States. Am J Gastroenterol. Sep 2020;115(9):1429-1438. doi:10.14309/ajg.0000000000000651

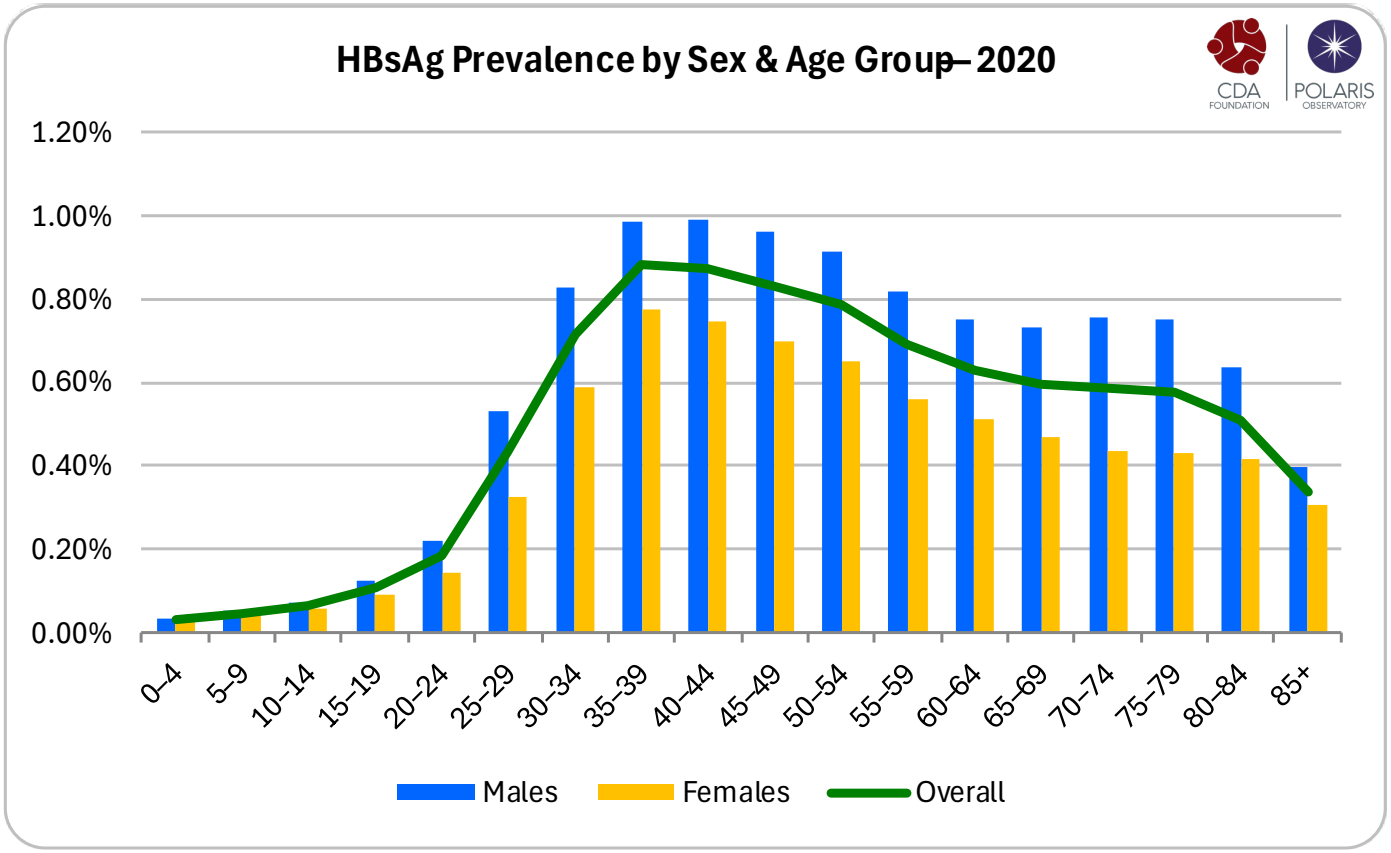
Razavi-Shearer D, Gamkrelidze I, Pan CQ, Razavi-Shearer K, Blach S, Estes C, Mooneyhan E, Razavi H. The impact of immigration on hepatitis B burden in the United States: a modelling study. Lancet Reg Health Am. 2023 May 27;22:100516. doi: 10.1016/j.lana.2023.100516. PMID: 37274551; PMCID: PMC10239007.

Roberts H, Jiles R, Harris AM, Gupta N, Teshale E. Incidence and Prevalence of Sexually Transmitted Hepatitis B, United States, 2013-2018. Sex Transm Dis. Apr 1 2021;48(4):305-309. doi:10.1097/OLQ.0000000000001359

Wong RJ, Brosgart CL, Welch S, et al. An Updated Assessment of Chronic Hepatitis B Prevalence Among Foreign-Born Persons Living in the United States. Hepatology. Aug 2021;74(2):607-626. doi:10.1002/hep.31782

Epidemiological Inputs

- The age and sex distribution was extracted from our modeled estimate of the impact of migration



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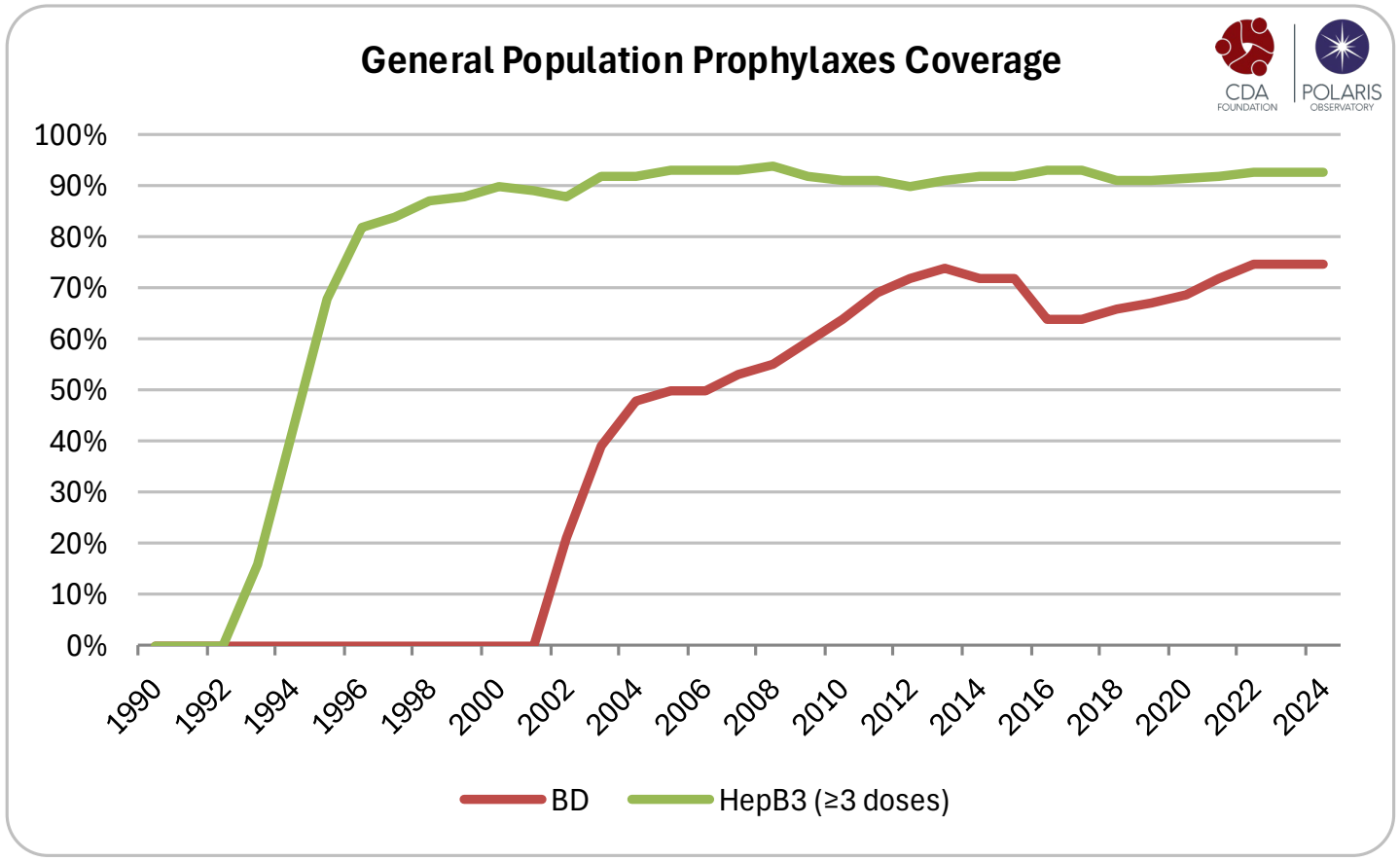
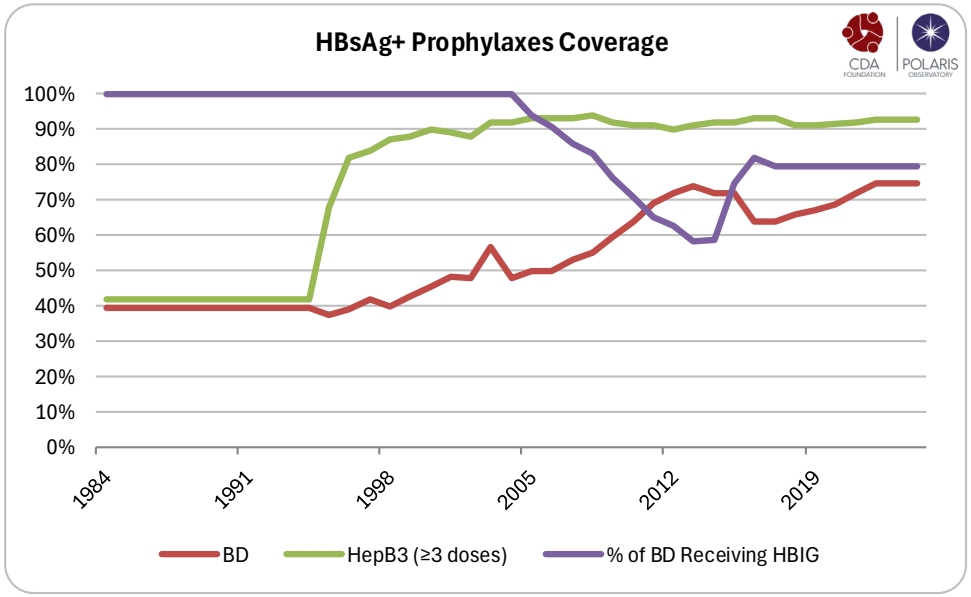
Immunization Coverage of All Infants



WHO/UNICEF. Official estimates of national immunization coverage. https://www.who.int/teams/immunization-vaccines-and-biologicals/immunization-analysis-and- insights/global-monitoring/immunization-coverage/who-unicef-estimates-of-national-immunization-coverage.

Immunization Coverage of Infants Born to HBsAg+ Mothers



- In 1984 HBIG and vaccination was recommended for infants born to HBsAg+ mothers, however only 35-65% were identified (NIP 2002)
- Smith 2012 estimates that only ~50% of HBsAg+ mothers were identified from 1994-2008
- Koneru 2021 estimated slightly higher coverage from through 2009-2017
  - » The annual data from these studies was utilized
    - ▪ If calculated three dose coverage was lower than then general population, the general population coverage was utilized

Koneru A, Fenlon N, Schillie S, Williams C, Weng MK, Nelson N. National Perinatal Hepatitis B Prevention Program: 2009-2017. Pediatrics 2021.

National Immunization Program; Div of Viral hepatitis, National Center for Infectious Diseases, CDC. Achievements in Public Health: Hepatitis B Vaccination --- United States, 1982—2002. MMWR Weekly. June 28, 2002;51(25);549-552,563.

Smith EA, Jacques-Carroll L, Walker TY, Sirotkin B, Murphy TV. The national Perinatal Hepatitis B Prevention Program, 1994-2008. Pediatrics. 2012;129(4):609-16.

Treatment of Mothers

- Kubo 2014 estimated that 39% of mothers that were identified as positive and who were eligible from 2007-2010 received antiviral treatment
  - » This was adjusted based on the identification rates from Smith 2012
- Harris 2018 found that 13% of all HBsAg+ births received anti-viral treatment from 2011-2014
  - » The model would estimate that ~29% of HBsAg+ would be eligible
  - » Thus, it was estimated that 44.8% of eligible and identified pregnant women were treated in these years
    - This was adjusted based on the Koneru 2021 screening data

Harris AM, Isenhour C, Schillie S, Vellozzi C. Hepatitis B Virus Testing and Care among Pregnant Women Using Commercial Claims Data, United States, 2011-2014. Infect Dis Obstet Gynecol 2018; 2018: 4107329.

Koneru A, Fenlon N, Schillie S, Williams C, Weng MK, Nelson N. National Perinatal Hepatitis B Prevention Program: 2009-2017. Pediatrics 2021.

Kubo A, Shlager L, Marks AR, Lakritz D, Beaumont C, Gabellini K, et al. Prevention of vertical transmission of hepatitis B: an observational study. Ann Intern Med. 2014;160(12):828-35.

Smith EA, Jacques-Carroll L, Walker TY, Sirotkin B, Murphy TV. The national Perinatal Hepatitis B Prevention Program, 1994-2008. Pediatrics. 2012;129(4):609-16.

Other Immunization

- 1999 recommendation that all children 0-18 not previously vaccinated be vaccinated
  - » Lu 2015 was utilized to estimate the coverage and age of coverage for birth cohorts 1989-1999
- Although screening of immigrants has been recommended since 2008 it is not consistent (Mitchell 2011)
- Immigrants are required to received ACIP-recommended vaccines, however HBV would generally only target those aged 0-18
  - » The model assumes that all LPRs entering the US after 2009 have been vaccinated for HBV

Lu Pj, Yankey D, Jeyarajah J, et al. Hepatitis B vaccination among adolescents 13–17 years, United States, 2006–2012. Vaccine 2015;33:1855-1864.

Mitchell T, Armstrong GL, Hu DJ, Wasley A, Painter JA. The increasing burden of imported chronic hepatitis B--United States, 1974-2008. PLoS One 2011; 6(12): e27717.

Current Diagnosis

- In 2015, there were an estimated 300,000 individuals diagnosed with chronic Hepatitis B infection (Expert Opinion)
  - » This would represent a 17% diagnosis rate

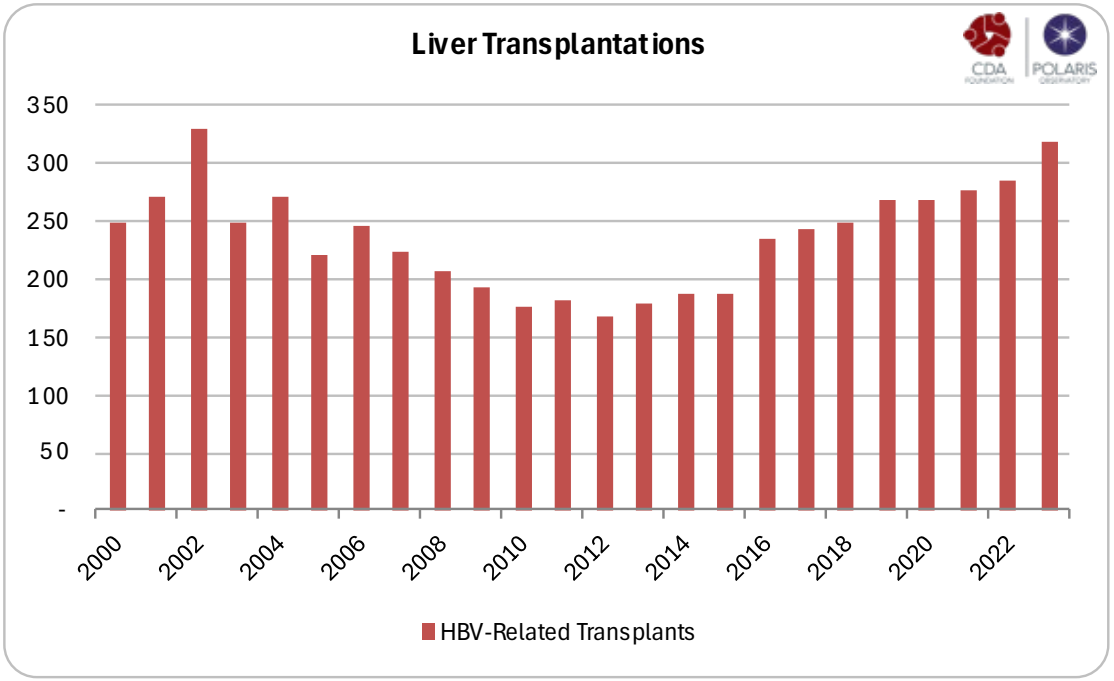
- 17,650 individuals are diagnosed annually (CDC 2025)

Centers for Disease Control and Prevention. Viral Hepatitis Surveillance Report – United States, 2023. https://www.cdc.gov/hepatitis-surveillance-2023/about/index.html Published April 2025.

Current Diagnosis and Treatment

- Assume that in 2023 there were 144,500 individuals under treatment for chronic HBV (Expert Input)

Methodology to Estimate Liver Transplants Attributed to HBV



- Annual number of liver transplants was available from the OPTN
- Historically, 3% of all liver transplants in the US were due to HBV
  - » This was applied to the total for recent years

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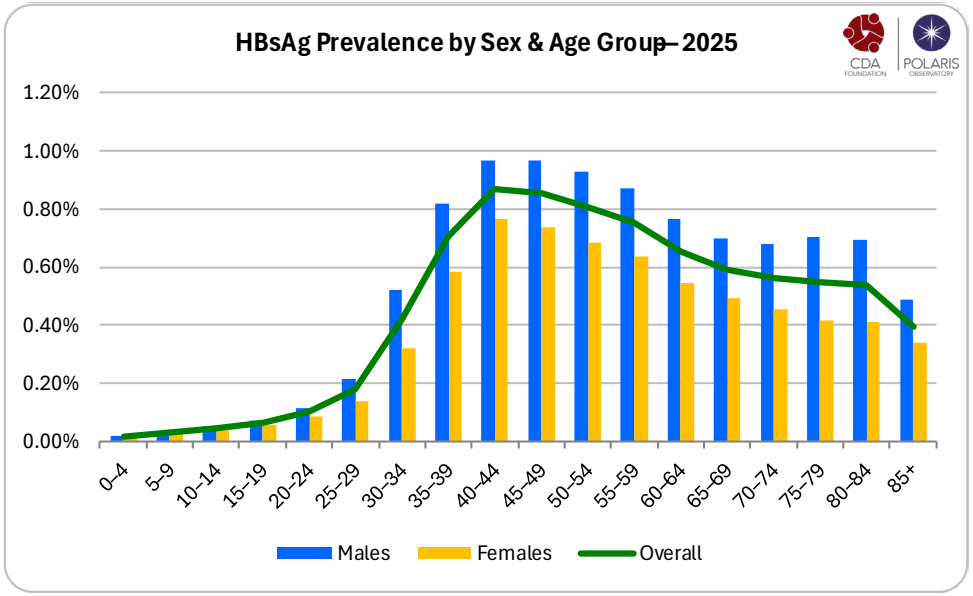
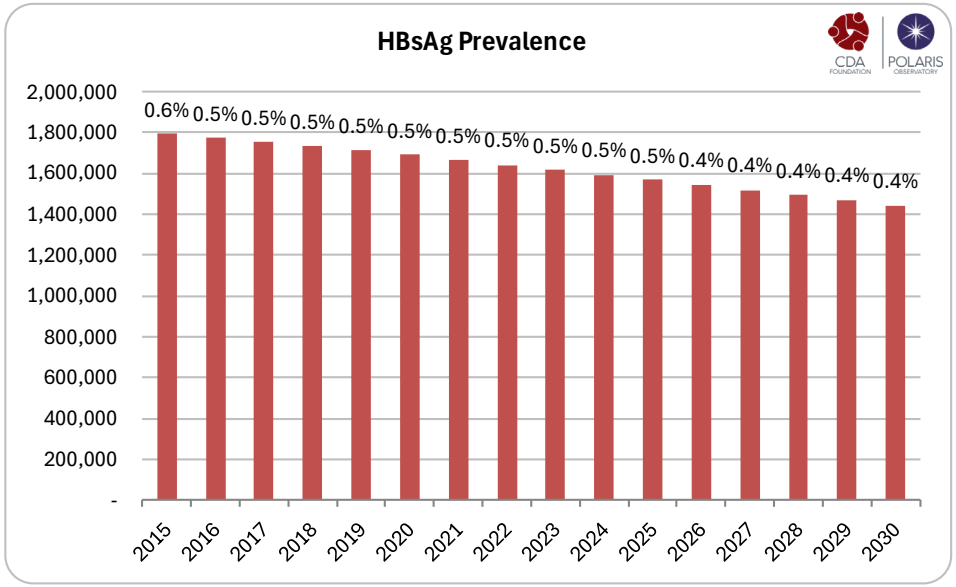
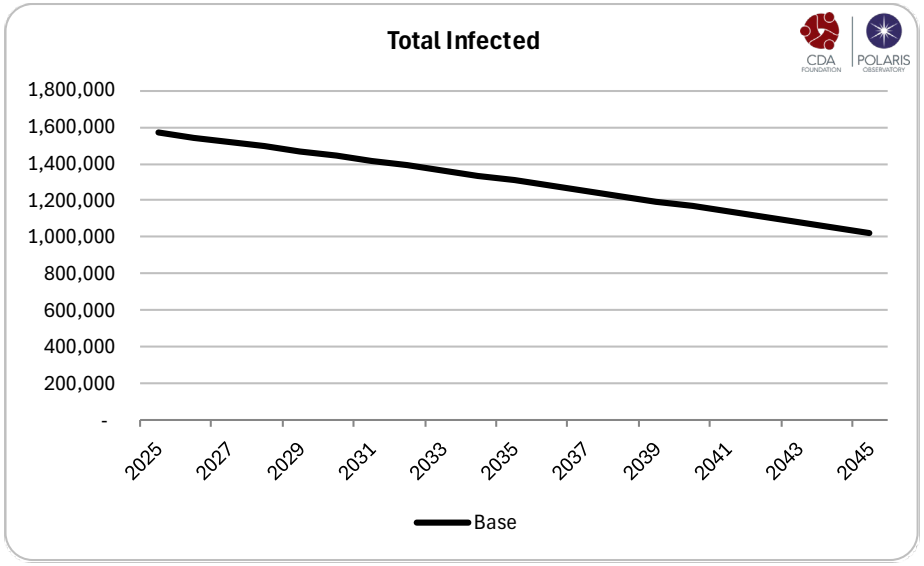
Outputs — General Population

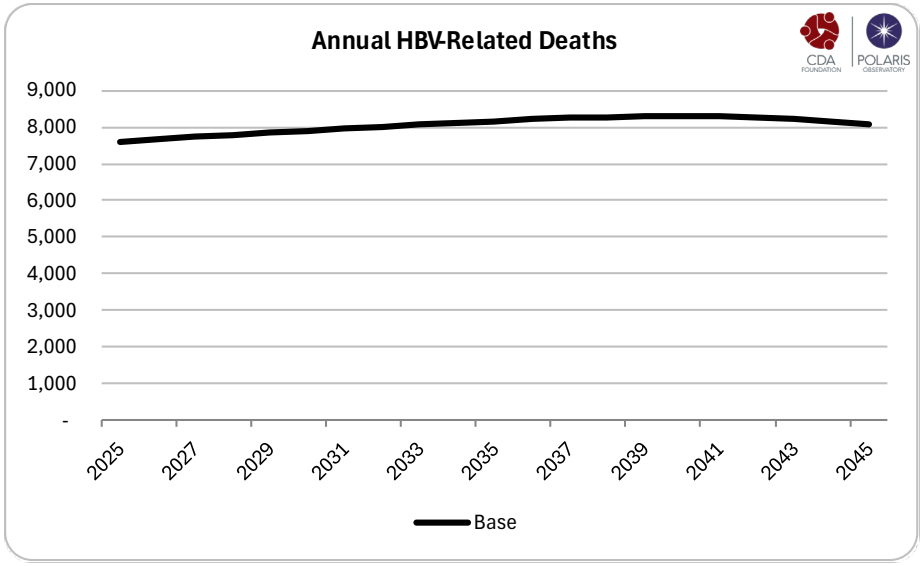
- In 2025, it is estimated that the prevalence of chronic hepatitis B in the US is 0.45%, representing 1.6 million chronic infections, dropping to 0.41%, 1.4 million chronic infections by 2030

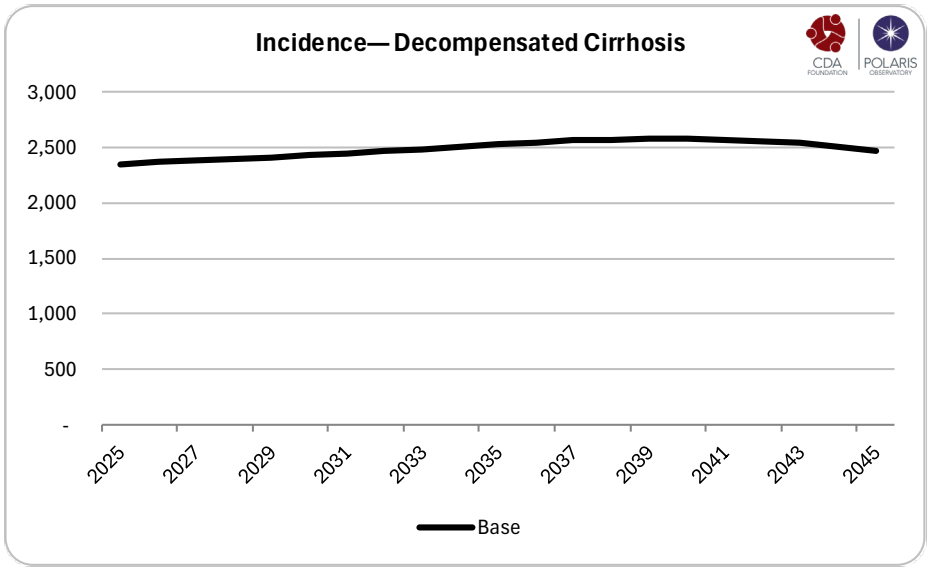


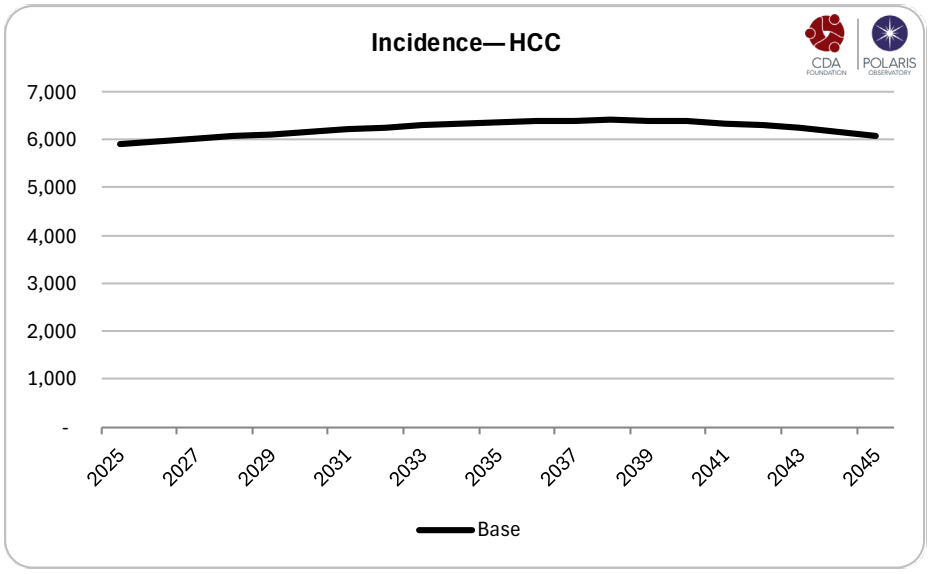


HBV-related morbidity and mortality will slightly increase if there is no change to the current treatment and diagnosis levels







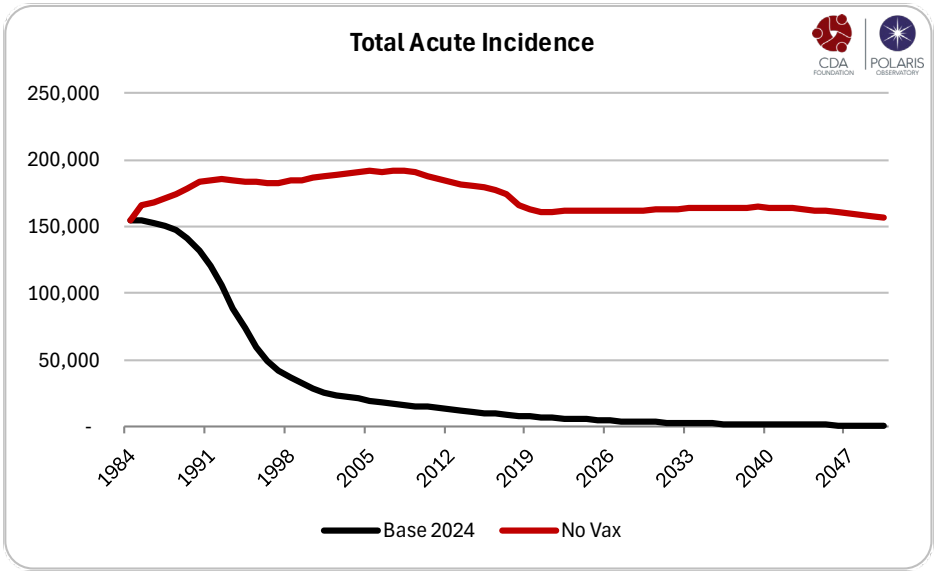


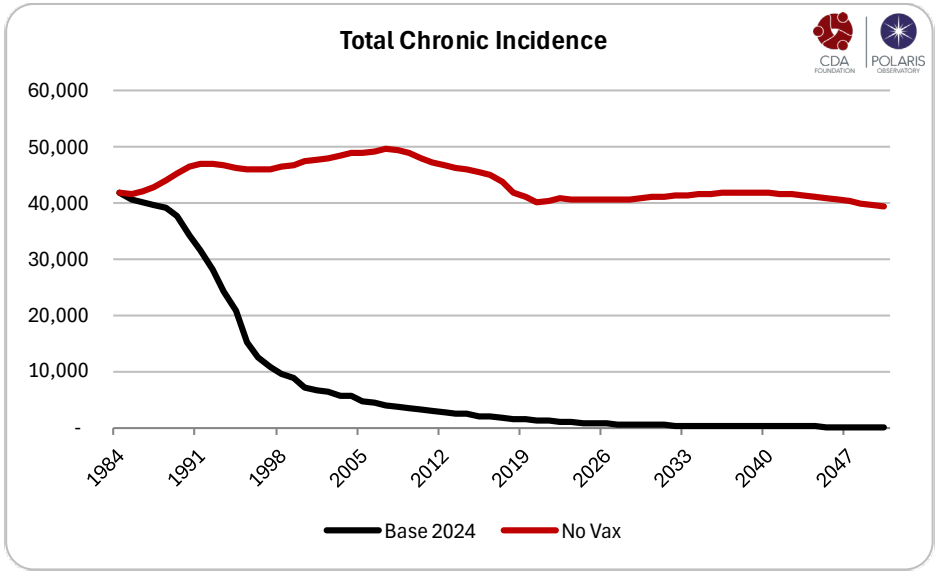
What would have happened if the US had never implemented an HBV vaccination program?

- Screening of pregnant women and the administration of timely birth dose and three dose coverage for infants born to HBsAg+ mothers started in 1984
- Universal three dose was rolled in 1993 reaching 92% coverage by 1996
- 1999 recommendation that all children 0-18 not previously vaccinated be vaccinated
- Universal timely birth dose was implemented in 2002
- The treatment of pregnant mothers at high risk of transmitting the virus to their babies began in 2007
- **What would have occurred in the absence of all of these programs?**

The US HBV vaccination program has averted over 9.5 million acute and over 2.4 million chronic cases of HBV between 1984 and 2050

- Over 5,500 Americans would die of fulminant hepatitis in the absence of a vaccination program
- An additional 600,000 preventable deaths would occur among those who became chronically infected as a result of never implementing the historical immunization policies



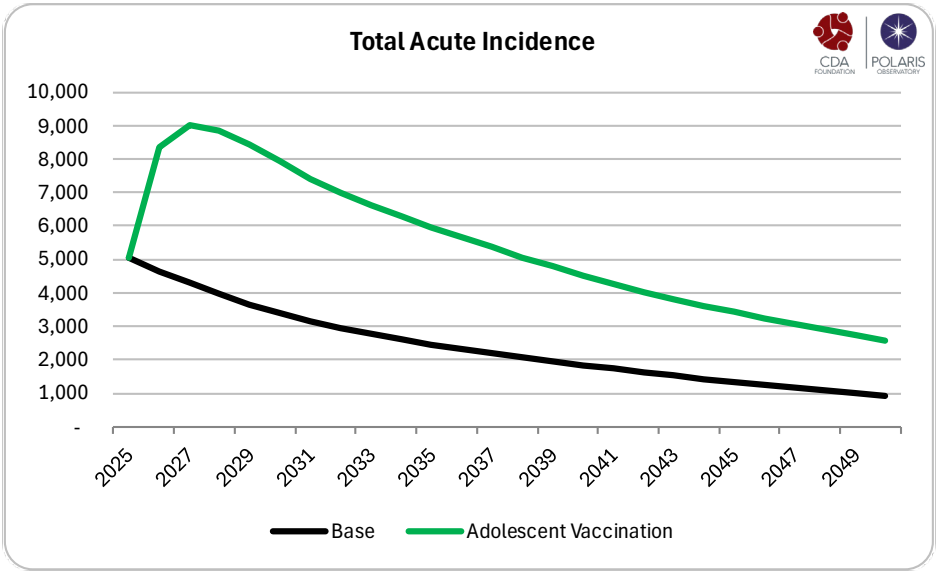


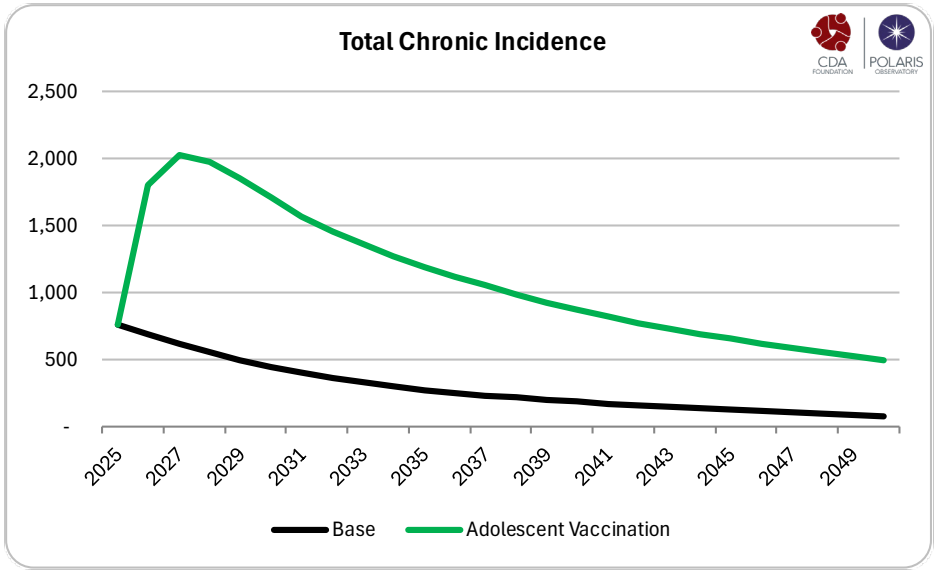
What would the impact be through 2050 if the US switched to Adolescent Vaccination?

- This scenario assumes starting in 2026:
  - The only infants that receive vaccination are infants born to HBsAg+ mothers
    - 50% of mothers are identified and all of these receive timely birth dose (within 24 hours)
    - 93% of these infants will go on to complete the full series of the vaccine in the first year of life
    - 79% of infants born to HBsAg+ mothers that receive timely birth dose also receive HBIG
    - 24% of mother eligible for anti-viral treatment to prevent mother to child transmission receive it
  - 93% of adolescents aged 10-14 will receive the full series of the hepatitis B vaccination

Targeted infant vaccination and universal adolescent vaccination would result in 77,600 acute and 20,900 chronic cases of HBV occurring through 2050

- Over 200 Americans would die of fulminant hepatitis B and an additional 5,200 preventable deaths would occur among those who became chronically infected as a result of this policy change





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Appendix

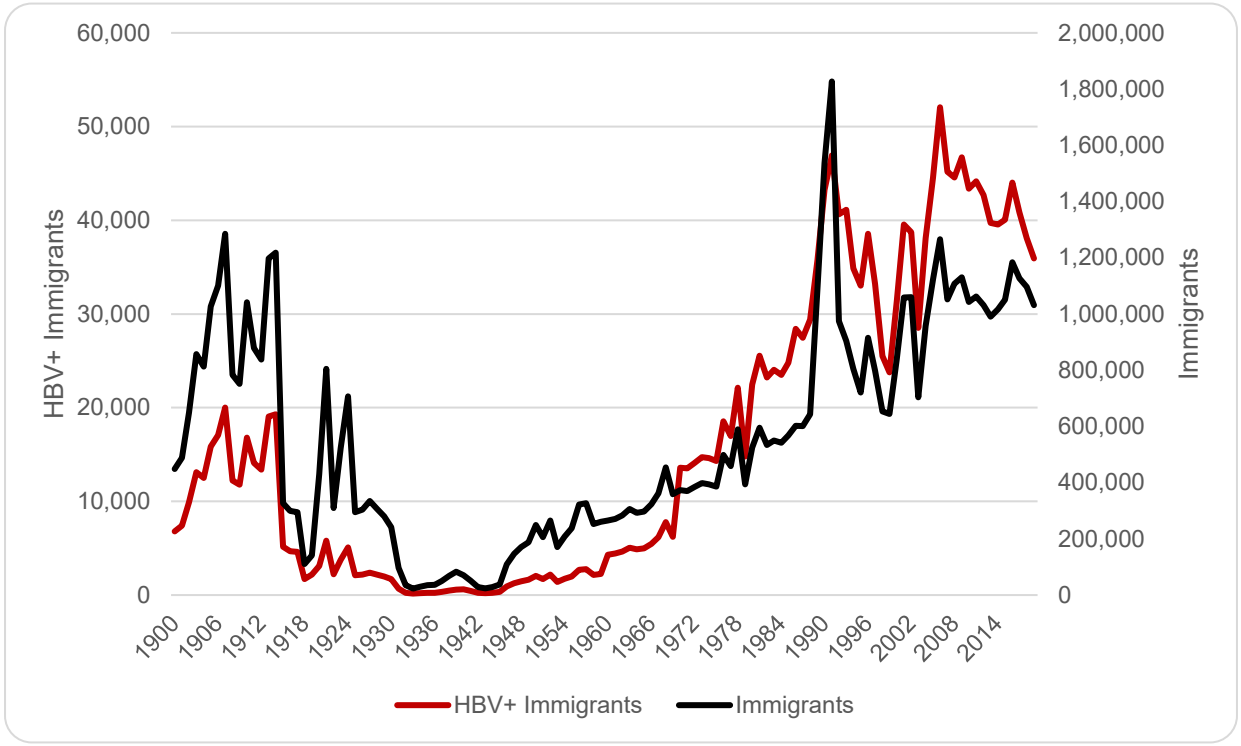
Our in-country work and county level models are leveraged to estimate the prevalence of incoming immigrants

- The annual number of immigrants gaining lawful permanent resident (LPR) status by age, sex, and country of birth are used to estimate
  - The annual infected number of LPRs by age, sex, and stage
    - This takes into account the impact of vaccination programs in the country of birth
  - The annual number of non-susceptible LPRs by age and sex
    - This considers not only the vaccination programs in the country of birth but also the number of individuals estimated to have cleared the virus
- Once these individuals have entered the model they are subject to
  - Background mortality
  - Progression of HBV that may lead to liver related deaths
  - Vaccination programs in the US
  - Screening and treatment in the US
- These individuals also impact the perinatal and horizontal transmission within the US at the population level

Prior to this exercise Polaris's PRoGReSs models accounted for 95.7% of all immigrants that have gained lawful permanent resident (LPR) status since 1900

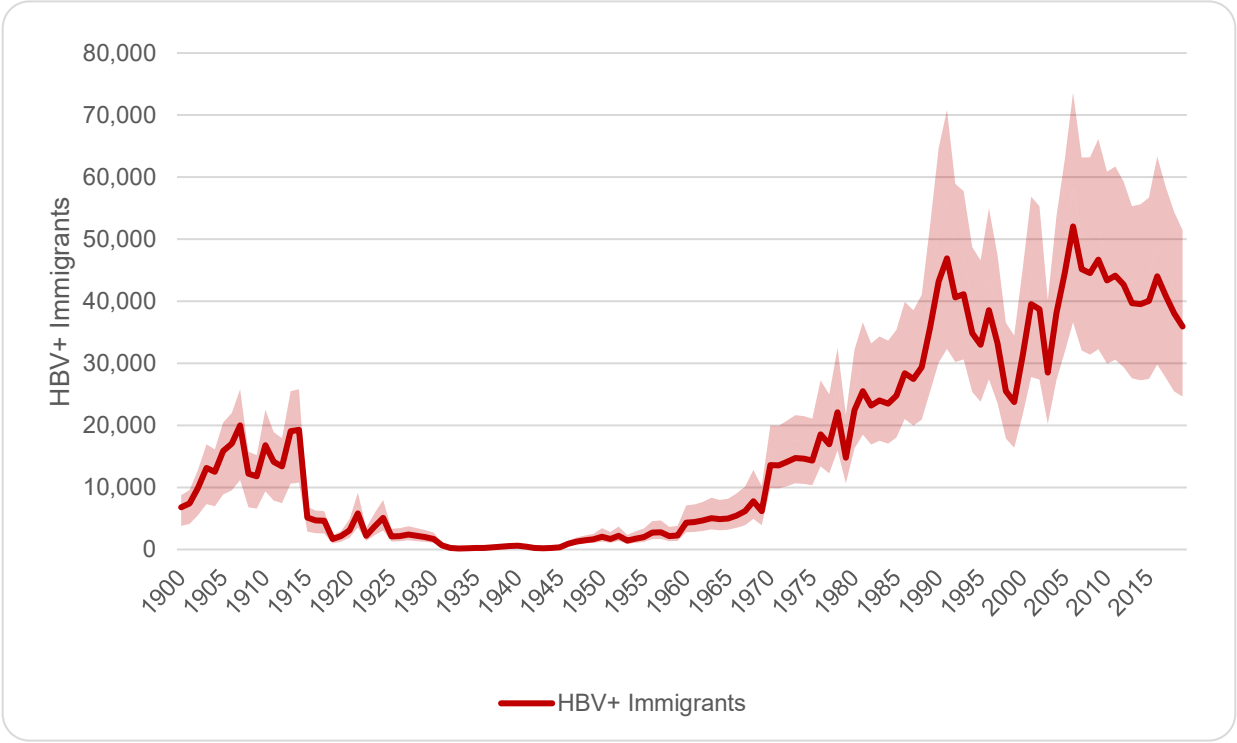
- For greater accuracy models were created for countries that had >100,000 total LPRs since 1900 (Austria, Ecuador, Panama, and Trinidad and Tobago)
- This resulted in 99.4% of all LPRs since 1900 having country specific models
- The remaining 0.6% were allocated by GBD region proportionally to countries in which models exist
- When country of birth was recorded as "Unknown" these individuals were allocated proportionally to modeled countries

Between 1900-2019 Over 67 million individuals received LPR status



Razavi-Shearer D, Gamkrelidze I, Pan CQ, Razavi-Shearer K, Blach S, Estes C, Mooneyhan E, Razavi H. The impact of immigration on hepatitis B burden in the United States: a modelling study. Lancet Reg Health Am. 2023 May 27;22:100516. doi: 10.1016/j.lana.2023.100516. PMID: 37274551; PMCID: PMC10239007.

Due to the shifting composition of country of birth the estimated annual number of infected LPRs varies significantly



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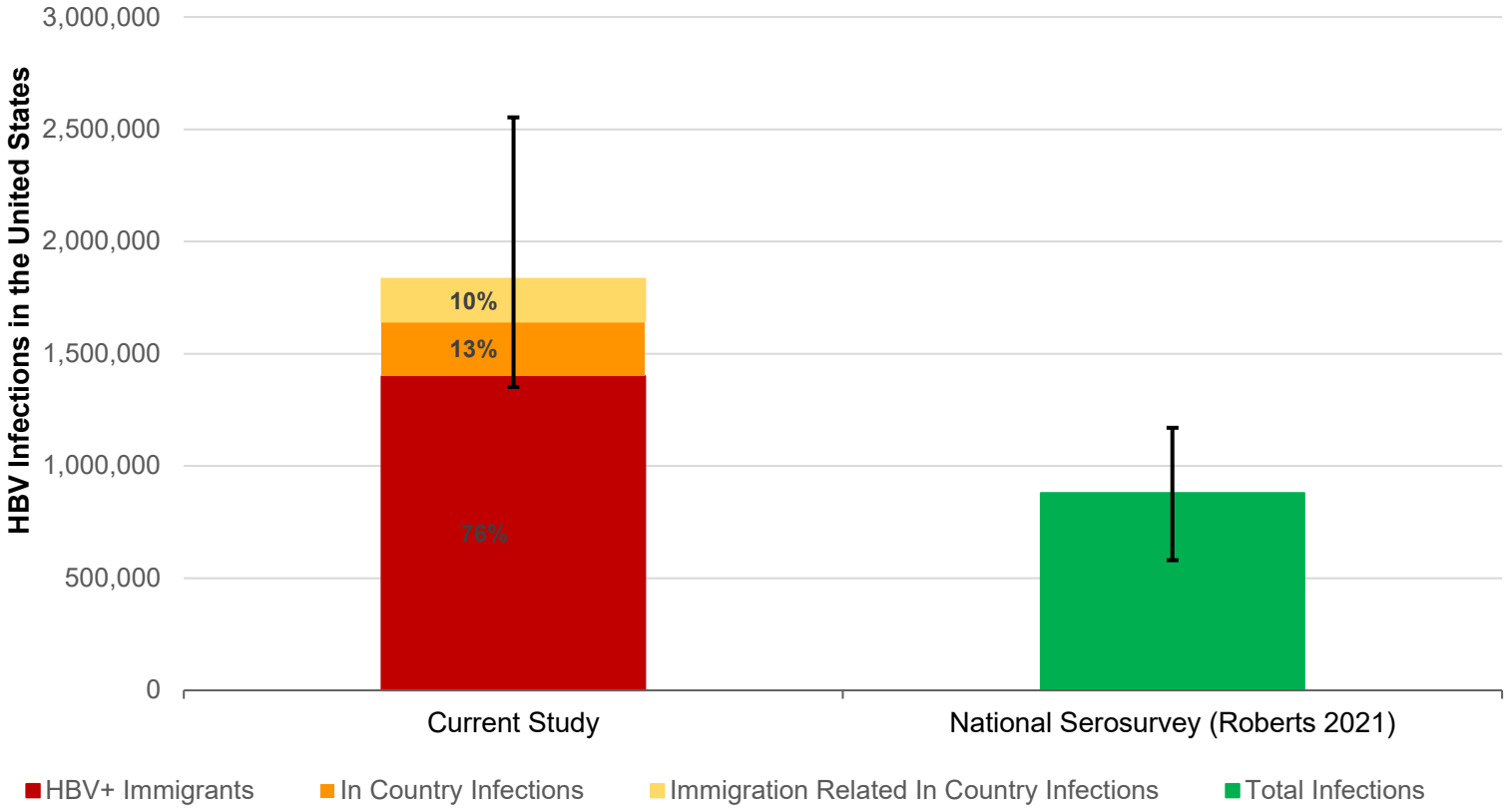
In 2023, we published this work estimating the impact of immigration on the national prevalence of HBV in the US

- 1.8 million infections, 0.55% (0.41-0.77%)
  - » 76% of infections were among immigrants



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While these data are useful for national policy makers, it can be difficult for local and state governments to understand the impact on their communities

- We previously did analyses for New Jersey, Minnesota, Idaho, and Seattle King County
  - » We currently have requests for analyses in Colorado, Hawaii, Washington, and Texas
- We can leverage the previous publication, which considers the age and sex of the immigrant population and the impact on internal incidence
- The American Community Survey reports the number of foreign-born individuals by country of birth for each county in the United States
  - » These data can be used to implement a bottom-up approach to estimating county and state level prevalence
  - » A map visualizing the hot spots of prevalence by county will be useful to all stakeholders
    - The state and local estimates can be used by health departments to plan for elimination and by community-based organizations to argue for prioritization of hepatitis B and immigrant health