

# Federal Implementation of Updated Hepatitis B Vaccination Recommendations

Office of Infectious Disease and HIV/AIDS Policy

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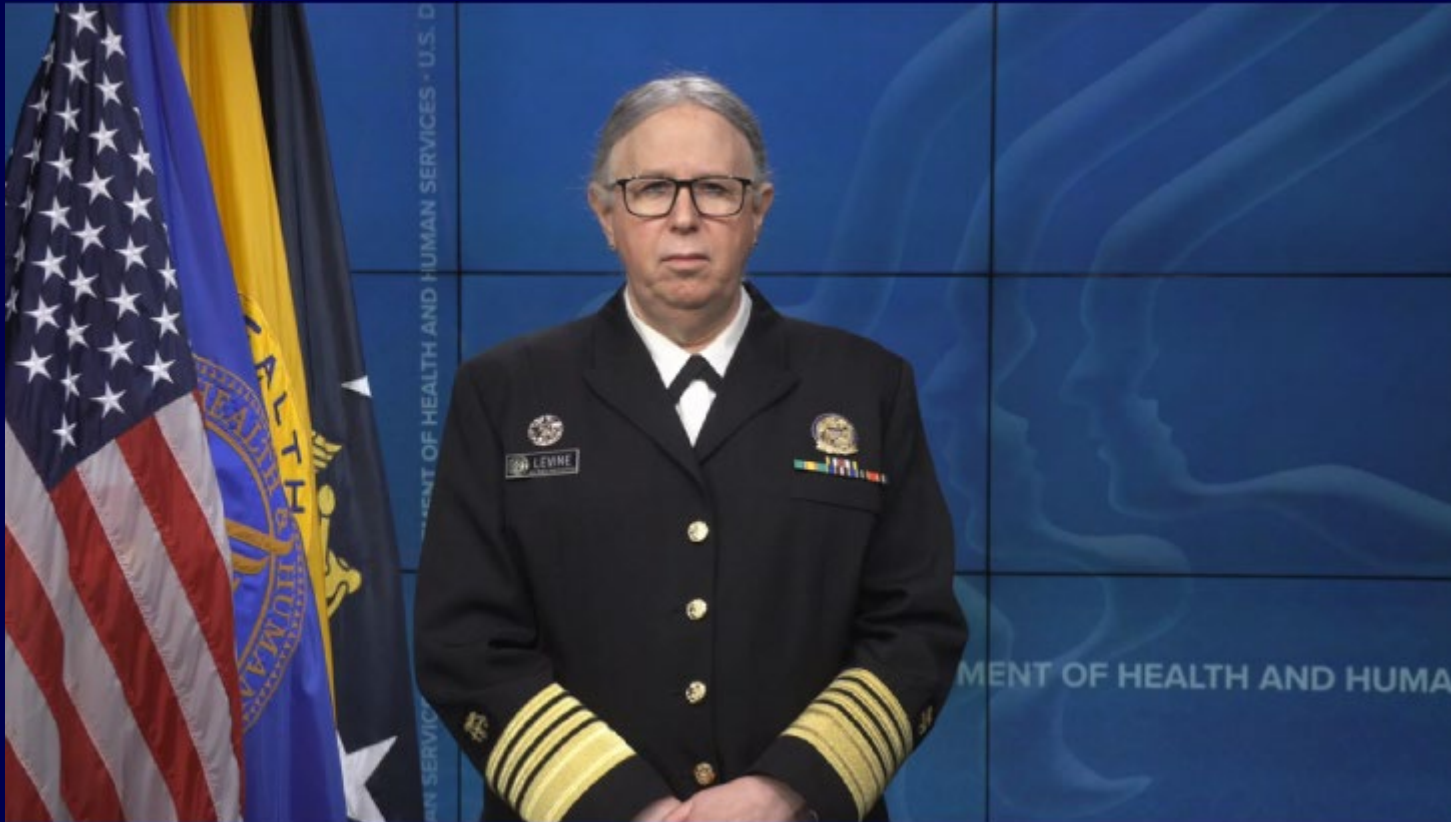
May 23, 2022



**OASH**

Office of the  
Assistant Secretary  
for Health

## Welcome Remarks



Admiral Rachel L. Levine, MD, Assistant Secretary for Health, provided opening remarks for the webinar.

Watch the video on [YouTube](#).

# Agenda

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- Welcome
- Agenda and Introduce Speakers
- Federal Partner Information Session
- Question and Answer

# Speakers

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Chinedu Okeke, MD, MPH-TM, MPA, Acting Chief Medical Officer, ODP



Jessica Deerin, PhD, MPH, Viral Hepatitis Policy Advisor, ODP



Mark Weng, MD, MSc, LCDR, U.S. Public Health Service, Medical Epidemiologist, Division of Viral Hepatitis, CDC



Ram Koppaka, MD, PhD, FACP, Associate Director for Adult Immunization, Immunization Services Division, CDC



David Kim, MD, MA, CAPT, U.S. Public Health Service, Director, National Vaccine Program, ODP



Jessica Lee, MD, MSHP, Medical Officer, Center for Medicaid & CHIP Services, CMS



Ronald D. Wilcox, MD, Chief Medical Officer, HIV/AIDS Bureau, HRSA

# Speakers

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Public Health Advisor  
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# **Universal Hepatitis B Vaccination in Adults Aged 19–59 Years: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2022**

**LCDR Mark K. Weng, MD, MSc**  
**Prevention Branch, Division of Viral Hepatitis**

Webinar, Federal Implementation of Hepatitis B Vaccination  
May 23, 2022

# Updated Hepatitis B Recommendations (as of Nov 2021)

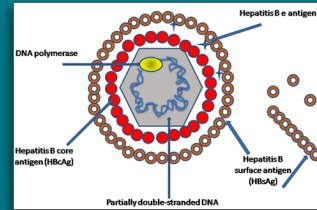
The Advisory Committee on Immunization Practices (ACIP) recommends the following groups **should** receive hepatitis B vaccines:

- Adults aged 19–59 years
- Adults aged  $\geq 60$  years with risk factors for hepatitis B

The ACIP recommends the following groups **may** receive hepatitis B vaccines:

- Adults aged  $\geq 60$  years without known risk factors for hepatitis B

# Hepatitis B in the United States



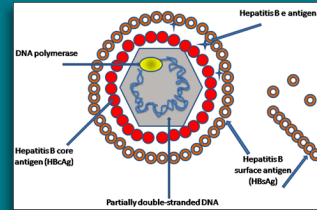
- **20,700 estimated acute hepatitis B virus (HBV) infections each year (95% CI: 11,800–50,800)<sup>1</sup>**
- **> \$1 billion spent on hepatitis B-related hospitalizations each year (not including indirect costs)<sup>2</sup>**

<sup>1</sup> <https://www.cdc.gov/hepatitis/statistics/2019surveillance/HepB.htm>

<sup>2</sup> Corte, et al. J Gastroenterol Hepatol. 2014.



# Hepatitis B in the United States

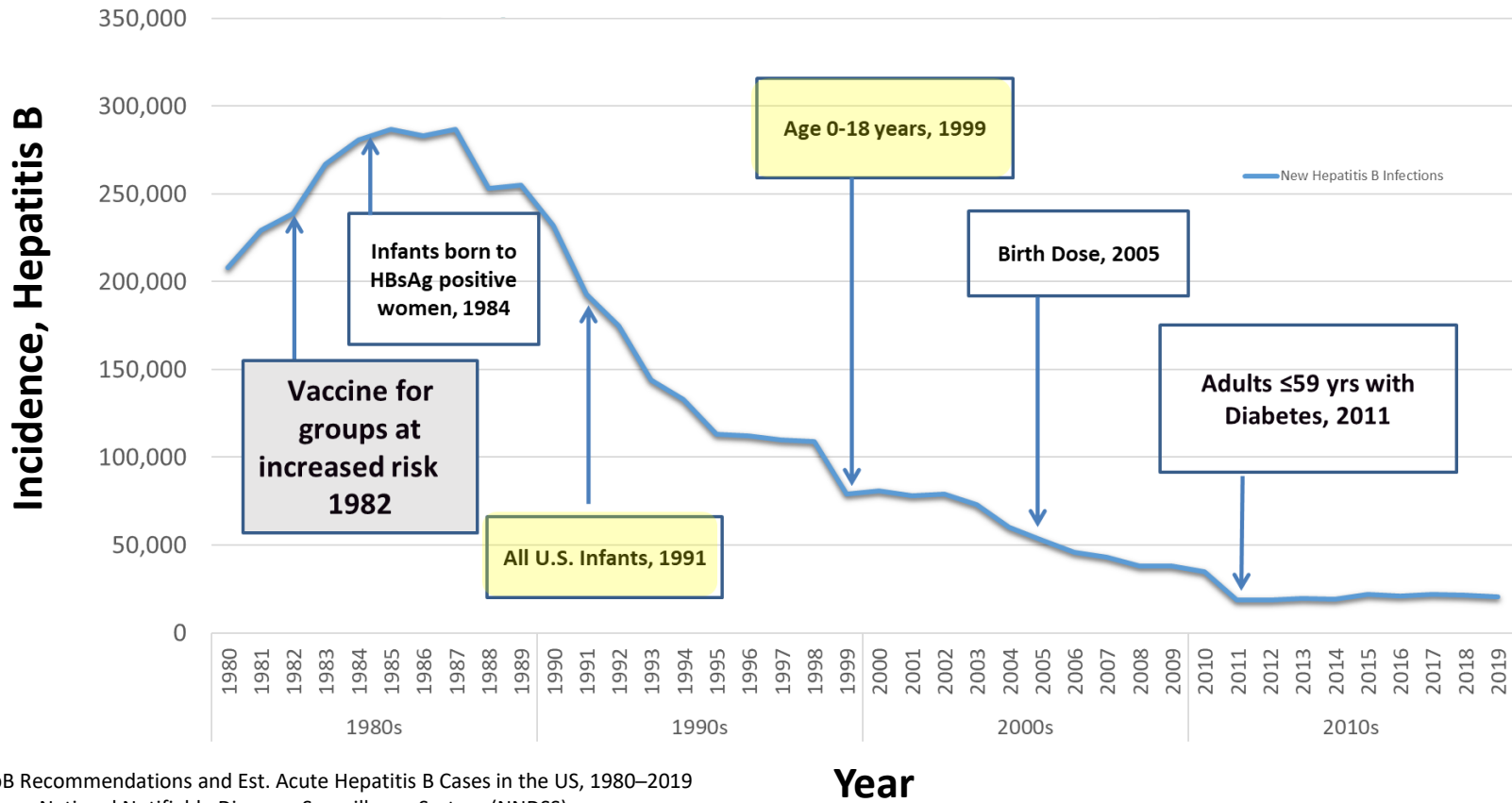


- **1.89 million persons living with chronic HBV** (modeled estimate; range, 1.49–2.40 million)<sup>1</sup>
- **15-25% risk of premature death from cirrhosis or liver cancer among people living with chronic HBV infection**<sup>2</sup>

<sup>1</sup> Wong, et al. Am J Med. 2021.

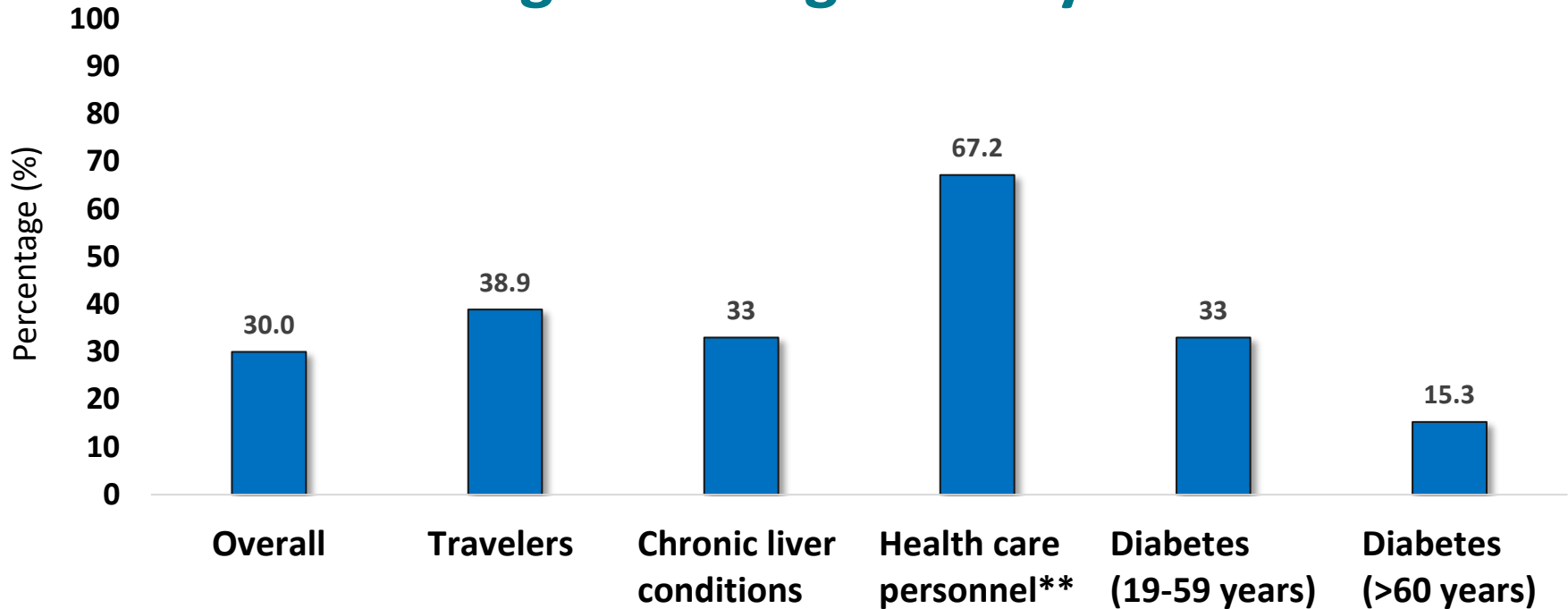
<sup>2</sup> <https://www.cdc.gov/std/treatment-guidelines/hbv.htm>

# The hepatitis B immunization strategy evolves



HepB Recommendations and Est. Acute Hepatitis B Cases in the US, 1980–2019  
 Source: National Notifiable Diseases Surveillance System (NNDSS)

# Hepatitis B vaccine coverage ( $\geq 3$ doses) among adults aged $\geq 19$ years\*



\* For adults with diabetes categories: 19-59 years and 60+ years

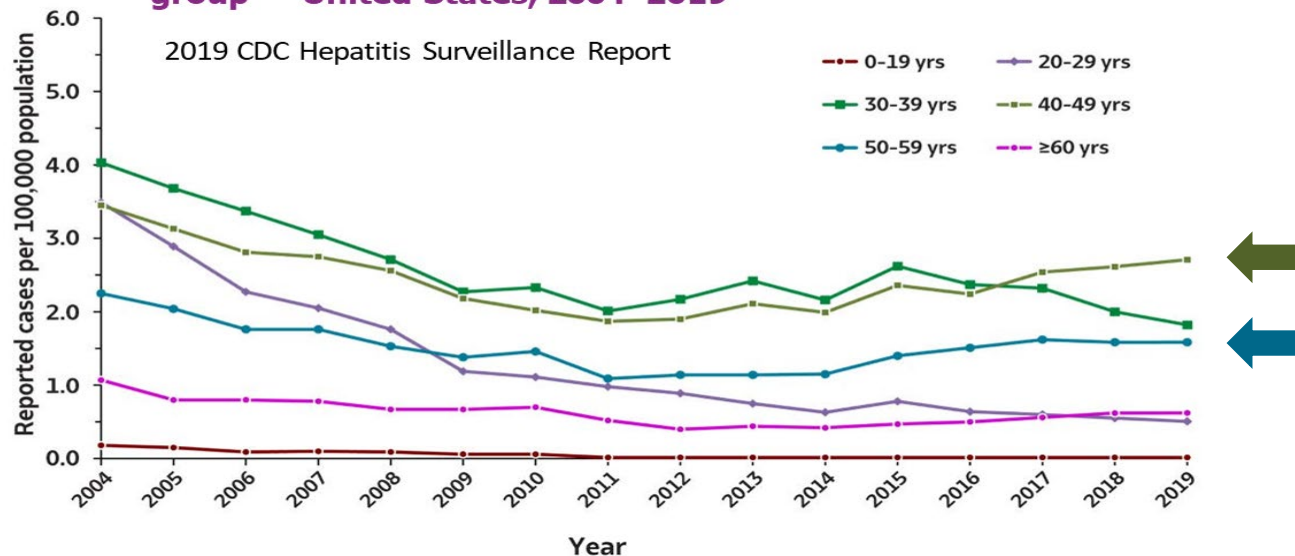
\*\* Refers to health care personnel (HCP) overall; 75.3% vaccination rate among HCP with direct patient care; 50.9% among HCP without direct patient care

Source: Lu, et al. [MMWR](#), 2018.

# Risk-based hepatitis B immunization among adults: a partial success

- Initial decreases in new hep B infections plateaued 10 years ago
- Rates are now highest among adults
- Rates have *increased* among adults  $\geq 40$  years of age

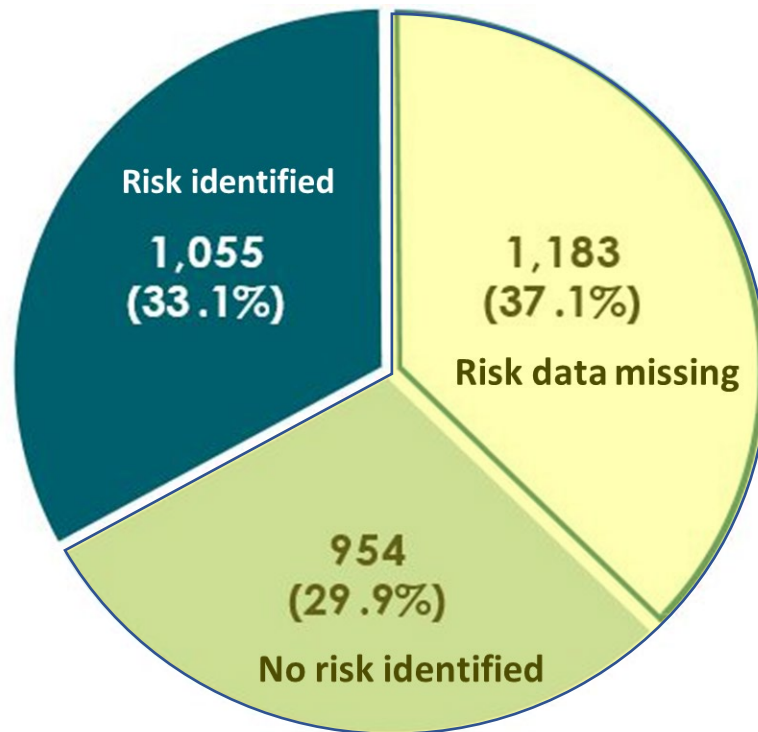
Rates of reported acute hepatitis B virus infection, by age group — United States, 2004–2019



Source: <https://www.cdc.gov/hepatitis/statistics/2019surveillance/pdfs/2019HepSurveillanceRpt.pdf>

# Limitations of a risk-based approach

Availability of information regarding risk behaviors or exposures associated with reported cases of acute hepatitis B virus infection — United States, 2019



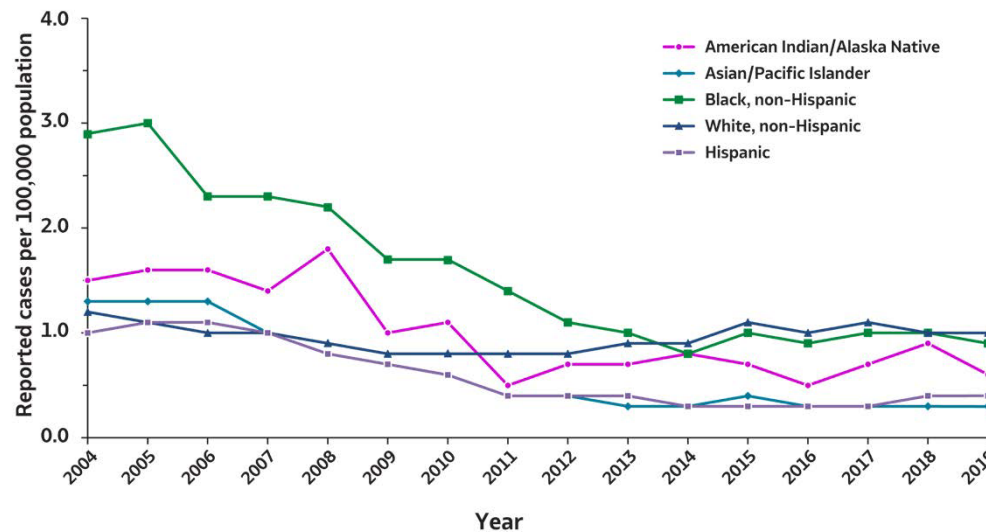
**2/3 of reported cases were either missing risk data or reported no identified risk**

Source: <https://www.cdc.gov/hepatitis/statistics/2019surveillance/index.htm>

# Health equity: Disparities could be reduced with a universal adult HepB recommendation

- Rates of HBV infection for children and adolescents of all races/ethnicities converged to a lower rate when a universal vaccination strategy was implemented for children  $\leq 18y$ .<sup>1, 2</sup>
- Current rates among Black American adults are now up to 3x those of Asian/Pacific Islander and Hispanic groups.<sup>1</sup>
- Racial/ethnic disparities remain in hepatitis B virus infections.

Rates of reported acute HBV infections, by race/ethnicity—United States, 2004–2019



<sup>1</sup> <https://www.cdc.gov/hepatitis/statistics/2019surveillance/HepB.htm>

<sup>2</sup> Wasley et al. MMWR. 2008

# Simplifying a complex hepatitis B vaccination schedule

## Persons recommended to receive hepatitis B vaccination

### Existing Recommendations

*Schillie, et al., 2018*

- **All infants**
- **Unvaccinated children aged <19 years**
- **Persons at risk for infection by sexual exposure**
  - Sex partners of hepatitis B surface antigen (HBsAg)-positive persons
  - Sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., persons with more than one sex partner during the previous 6 months)
  - Persons seeking evaluation or treatment for a sexually transmitted infection
  - Men who have sex with men
- **Persons at risk for infection by percutaneous or mucosal exposure to blood**
  - Current or recent injection-drug users
  - Household contacts of HBsAg-positive persons
  - Residents and staff of facilities for developmentally disabled persons
  - Health care and public safety personnel with reasonably anticipated risk for exposure to blood or blood-contaminated body fluids
  - Hemodialysis patients and predialysis, peritoneal dialysis, and home dialysis patients
  - Persons with diabetes aged 19–59 years; persons with diabetes aged ≥60 years at the discretion of the treating clinician
- **Others**
  - International travelers to countries with high or intermediate levels of endemic hepatitis B virus (HBV) infection (HBsAg prevalence of ≥2%)
  - Persons with hepatitis C virus infection
  - Persons with chronic liver disease (including, but not limited to, persons with cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, and an alanine aminotransferase [ALT] or aspartate aminotransferase [AST] level greater than twice the upper limit of normal)
  - Persons with HIV infection
  - Incarcerated persons
- **All other persons seeking protection from HBV infection**

### New Recommendations

The ACIP recommends the following groups should receive hepatitis B vaccines:

- All infants [No change]
- Persons aged <19 years [No change]
- Adults aged 19–59 years
- Adults aged ≥60 years with risk factors for hepatitis B

The ACIP recommends the following group may receive hepatitis B vaccines:

- Adults aged ≥60 years without known risk factors for hepatitis B

Approved by unanimous vote  
November 3, 2021

Source: Weng, et al. [MMWR](#), 2022.

## ACIP Policy Statement for PreHevbrio, added February 2022

<b>Recommendation</b>	<b>PreHevbrio may be used as a HepB vaccine in persons aged ≥18 years recommended for vaccination against HBV infection.</b>
<b>Additional Considerations</b>	<b>Persons on hemodialysis, pregnant persons and persons who are breastfeeding are not discussed in this Evidence to Recommendations Framework.</b> The safety and effectiveness of PREHEVBRIO have not been established in adults on hemodialysis. There are no adequate and well-controlled studies of PREHEVBRIO in pregnant women. Available human data on PREHEVBRIO administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. Data are not available to assess the effects of PREHEVBRIO on the breastfed infant or on milk production/excretion.

Source: Weng, et al. [MMWR](#), 2022.



## Heplisav-B and PreHevbrio in Dialysis and Pregnancy

- **Safety and effectiveness of Heplisav-B and PreHevbrio have not been established in adults on hemodialysis**
- **Data on Heplisav-B and PreHevbrio are currently insufficient to inform vaccine-associated risks in pregnancy**
- **Data are not available to assess the effects of Heplisav-B and PreHevbrio on the breastfed infant or on milk production/excretion**

# Adult hepatitis B vaccines

Adult hepatitis B vaccine <sup>1</sup>	Derivation	Adjuvant	Dose of HBs Antigens	Schedule
PreHevbrio <sup>2</sup>	mammalian (Chinese hamster ovary) cell	alum	10µg	3 doses at 0, 1, 6 months
Engerix-B	yeast	alum	20µg	3 doses at 0, 1, 6 months
Recombivax HB	yeast	alum	10µg	3 doses at 0, 1, 6 months
Hepelisav-B	yeast	CpG 1018	20µg	2 doses at 0, 1 months

**Twinrix** (HepA-HepB combination vaccine) not shown.

<sup>1</sup> See ACIP Recommended Immunization Schedule for Adults Aged 19 Years or Older — United States, 2022 for dosing details (<http://dx.doi.org/10.15585/mmwr.mm7107a1>).

<sup>2</sup> ACIP approval February 2022

## Summary

# HHS and NASEM<sup>1</sup> have called for viral hepatitis elimination

- **Evidence supports where universal recommendations are preferred over risk-based vaccination approaches**
- **More vaccine tools available than when risk-based policy was first recommended**
  - Two 3-dose monovalent vaccines are available; safe, effective with long-term immunogenicity (>35 y)
  - One 2-dose vaccine is available; safe and effective
  - One 3-dose, 3-antigen vaccine was recently approved
- **Universal hepatitis B vaccination recommendation among adults will provide best chance of achieving HBV elimination goals**

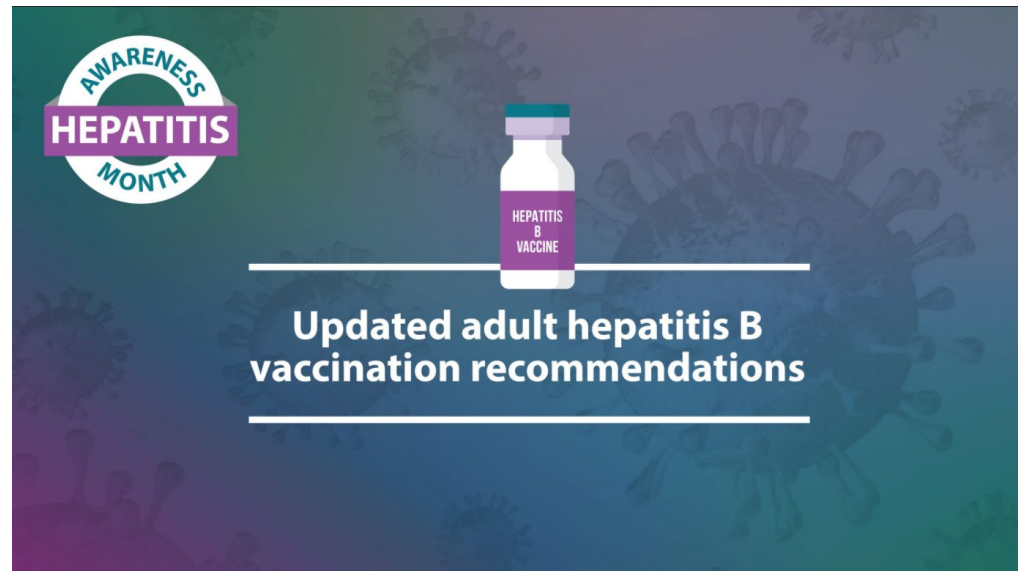
<sup>1</sup> National Academies of Science, Engineering, and Medicine. <https://www.nationalacademies.org/our-work/a-national-strategy-for-the-elimination-of-hepatitis-b-and-c>



# HEPATITIS AWARENESS MONTH

## Ways to Promote Hepatitis Awareness Month 2022:

- Use and share our Awareness Month content and social media toolkit  
Visit [www.cdc.gov/hepatitis](http://www.cdc.gov/hepatitis)  
Click on Hepatitis Awareness Month box at the top
- Engage with us on Twitter  
[@cdchep](https://twitter.com/cdchep)
- Use the Awareness Month hashtags:  
#HepatitisAwarenessMonth  
#Hepatitis #HepAware2022



# ACIP Hepatitis Work Group

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Sybil Cineas

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# Thank you

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

# Standards for Adult Immunization Practice

## Recommendations from the National Vaccine Advisory Committee

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David Kim, MD  
National Vaccine Program  
Office of Infectious Disease and HIV/AIDS Policy  
Office of the Assistant Secretary for Health



**OASH** | Office of the  
Assistant Secretary  
for Health

## Standards for Immunization Practices

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- 1992 National Vaccine Advisory Committee (NVAC) – Standards for pediatric immunization practice
  - ✓ Readily avail immunization services
  - ✓ Reduce barriers to immunization
  - ✓ Utilize all clinical encounters to screen and immunize children
  - ✓ Educate parents about immunization in general terms
  - ✓ Use a tracking system
- 2003 NVAC – Standards for implementing ACIP recommendations for adults
- 2009 Infectious Diseases Society of America – Standards for adult immunization
- 2012 NVAC – Pathway for improving adult immunization rates

National Vaccine Advisory Committee. MMWR 1993;42(No. RR-5)

Poland et al. Am J Prev Med 2003;25:144-50

Pickering et al. Clin Infect Dis 2009;49:817-40

National Vaccine Advisory Committee. Public Health Rep 2012;127 Suppl 1:1-42

## Updated Standards for Adult Immunization Practice – Why?

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- Broadened vaccination services offered by pharmacists, community immunization providers, providers for pregnant women; at workplace
- Changes in health care system, including Affordable Care Act (first-dollar coverage of ACIP-recommended vaccines by private insurance plans, expanded Medicaid plans)
- Expanded inclusion of adults in state immunization information systems (IIS)
- Meaningful Use requirements by Centers for Medicare and Medicaid Services for provider to report in IIS

## Barriers to Immunizing Adults

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- Lack of provider and patient knowledge on vaccines recommended for adults
- Prioritized management of acute and chronic illnesses over preventive services
- Limited offering of vaccines recommended for adults by adult care providers
- Difficulties coordinating care for patients may see many different providers, including specialists who may not be vaccination service providers
- Out-of-pocket costs to patients
- Complicated private and public payer payments for vaccines; providers are not recognized by third-party payers if not in-network
- Different coverage for vaccines under Medicare plans
- Variations in vaccination coverage under Medicaid by state, complicated by states that opted out of increased Medicaid coverage



REPORTS AND RECOMMENDATIONS

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PUBLIC HEALTH REPORTS / MARCH–APRIL 2014 / VOLUME 129

# Recommendations from the National Vaccine Advisory Committee: Standards for Adult Immunization Practice

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NATIONAL VACCINE ADVISORY  
COMMITTEE

The Advisory Committee on Immunization Practices (ACIP) makes recommendations for routine vaccination of adults in the United States.<sup>1</sup> Standards for implementing the ACIP recommendations for adults were published by the

## Standards for...

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- All providers
- Non-immunizing providers
- Immunizing providers
- Professional organizations and health care systems
- Public health departments

## Standards for Adult Immunization Practice 2014 NVAC Recommendations

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- **Assess.** Incorporate immunization assessment into every clinical encounter
- **Recommend.** Strongly recommend needed vaccines
- **Administer (or refer).** Administer vaccine or refer patient to a provider who can
- **Document.** Ensure receipt of vaccination in patient medical record and IIS

---

**Every health care provider, in all settings, has a fundamental responsibility to ensure that all patients are up-to-date [on] recommended immunizations.**

**– National Vaccine Advisory Committee**

# Promotion and Implementation

# Overview

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- **Structure of the US Immunization System**
- **Funding for Adult Immunization**
- **Specific plans for promotion of the new Hepatitis B vaccine recommendations**



# The Immunization Program in the US Depends on Many Players Working in Close Collaboration

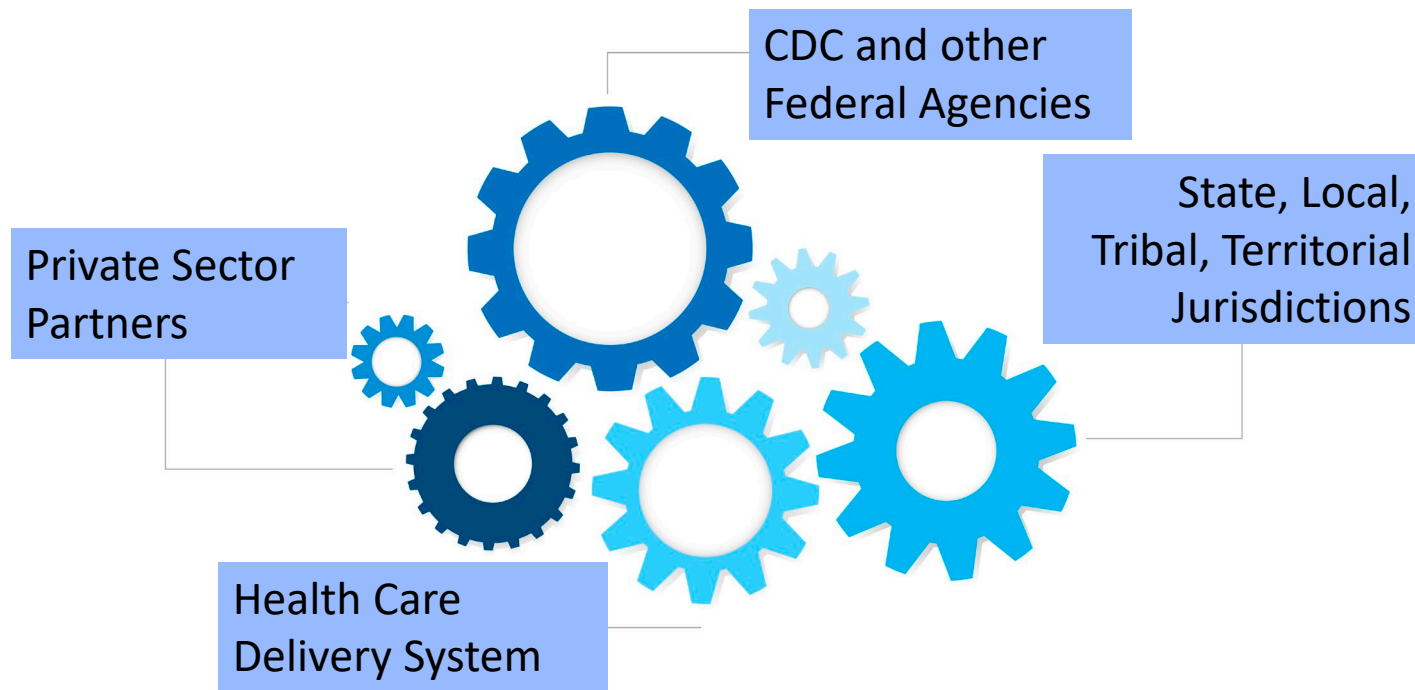


Image credit: rawpixel.com



There are 14 vaccines currently recommended by the ACIP for prevention of disease in adults.

### Case Study: Vaccines for Children (VFC)

1. Influenza inactivated, recombinant or live, attenuated
2. Tetanus, diphtheria, pertussis (Tdap or Td)
3. Measles, mumps, rubella (MMR)
4. Varicella (VAR)
5. Zoster recombinant (RZV)
6. Human papillomavirus (HPV)
7. Pneumococcal conjugate (PCV20)
8. Pneumococcal polysaccharide (PCV15) (PPSV23)
9. Hepatitis A (HepA)
10. Hepatitis B (HepB)
11. Meningococcal A, C, W, Y (MenACWY)
12. Meningococcal B (MenB)
13. *Haemophilus influenzae* type b (Hib)
14. COVID-19





# Immunization **programs and funding for children are far more robust** than for adults

*Gaps in insurance coverage, a lack of IT infrastructure for adult vaccination, and only nascent efforts to build confidence among vulnerable groups means many adults do not have access to or confidence in vaccines*

	Child Vaccination	Adult Vaccination
<b>ACIP recommended schedule</b>	<input checked="" type="checkbox"/> <sup>1</sup>	<input checked="" type="checkbox"/> <sup>2</sup>
<b>Coverage for vaccination:</b>		
ACA-compliant private insurance	<input checked="" type="checkbox"/> <sup>3</sup>	<input checked="" type="checkbox"/> <sup>3</sup>
Underinsured	N/A	<b>Limited</b>
Medicare	N/A	<b>Limited</b>
Medicaid	<input checked="" type="checkbox"/> <sup>5</sup>	<b>Variable</b> <sup>6</sup>
Uninsured	<input checked="" type="checkbox"/> <sup>5</sup>	<b>Minimal</b> <sup>7</sup>
<b>State public health infrastructure</b>	<input checked="" type="checkbox"/>	<b>Variable</b> <sup>7</sup>
<b>Immunization information systems</b>	All states	<b>Variable</b>

Source: 1. [Child and Adolescent Immunization Schedule](#) 2. [Adult Immunization Schedule](#) 3. 4. Vaccines covered by Part D may have large co-pays 5. Vaccines provided by the Vaccines for Children program 6. [State Policies on Access to Vaccination Services for Low-Income Adults](#) 7. Very limited funding is provided by CDC and state and local public coverage for ACIP-recommended vaccines required by the Affordable Care Act c health



# Overview of Current Adult Immunization Funding Sources

*The federal government currently supports adult immunization activities from the following sources:*

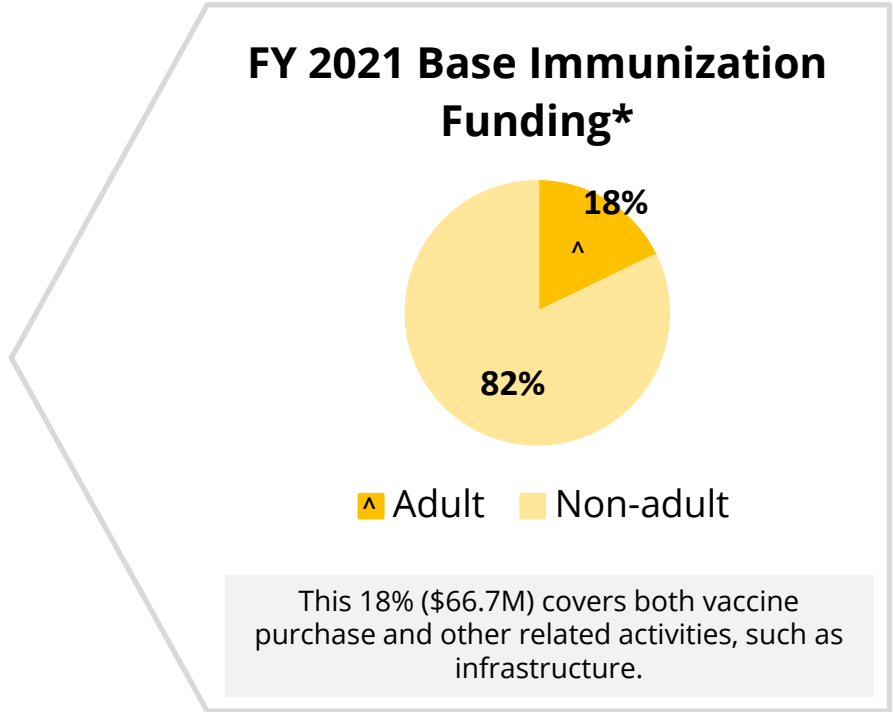
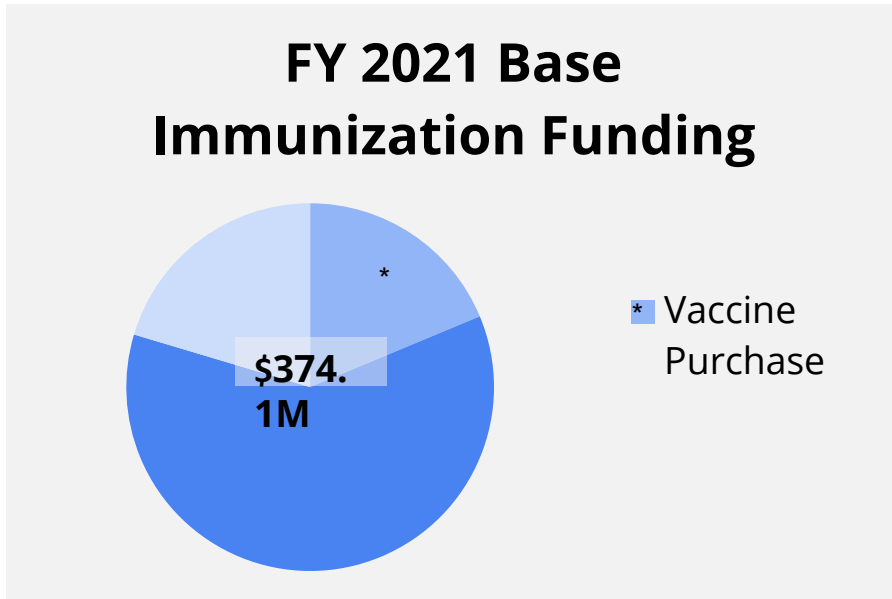
1. **ISD Base Resources**, including both:
  - **Section 317 Immunization Funds**, which are discretionary funds annually appropriated by Congress
  - **Prevention and Public Health Fund (PPHF)** resources, which are a mandatory funding stream from which CDC is allocated resources by HHS and/or Congress
2. **COVID Supplemental Funding**, including funds from:
  - **CDC response funding** for state, local, tribal, and territorial health departments and immunization infrastructure
  - **HRSA Provider Relief Fund** for COVID vaccination reimbursement for all un/underinsured persons
  - **HRSA's COVID-19 Uninsured Program** for vaccination for the uninsured

**Billions of dollars** in additional funding for immunization during the pandemic came from **COVID supplemental resources**, while only an **estimated \$374.1M** came from **base resources** that would be sustained in future years.



# FY21 Base Immunization Funding for Adult vs Pediatric Activities

Of the \$374.1M in Section 317 and PPHF funds spent on immunization activities in FY21, just 18% (\$66.7M) was for adult immunization activities.



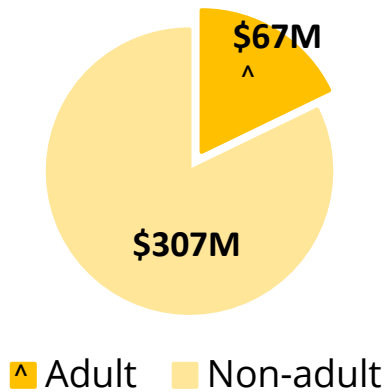
\*There is not currently a breakdown available across adult and pediatric vaccine purchase for the \$9M in PPHF funds; however, this chart assumes 79% of those funds were for adult vaccine purchase, which is the same distribution as for 317 funding.



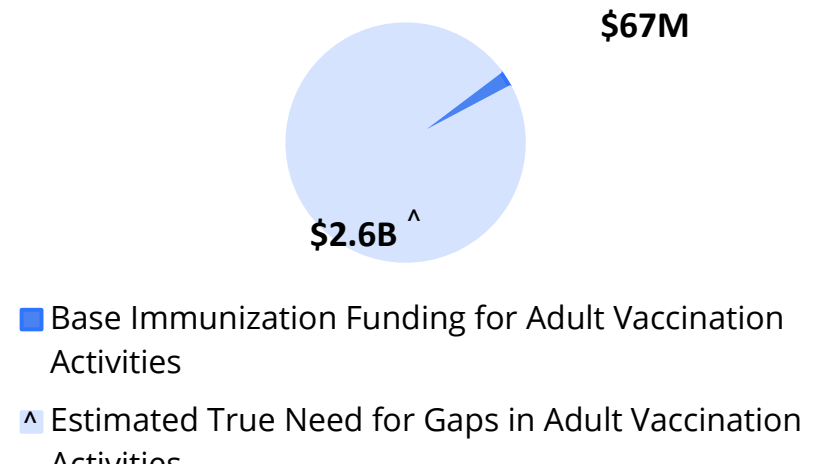
# Funding available for adult immunization activities is well below need

While CDC estimates that \$2.6B would be needed to fill gaps in adult immunization purchase, administration, and infrastructure in FY23, only \$67M in base resources was available for these activities in FY21.

## FY 2021 Base Immunization Funding



## Base Immunization Funding vs Need



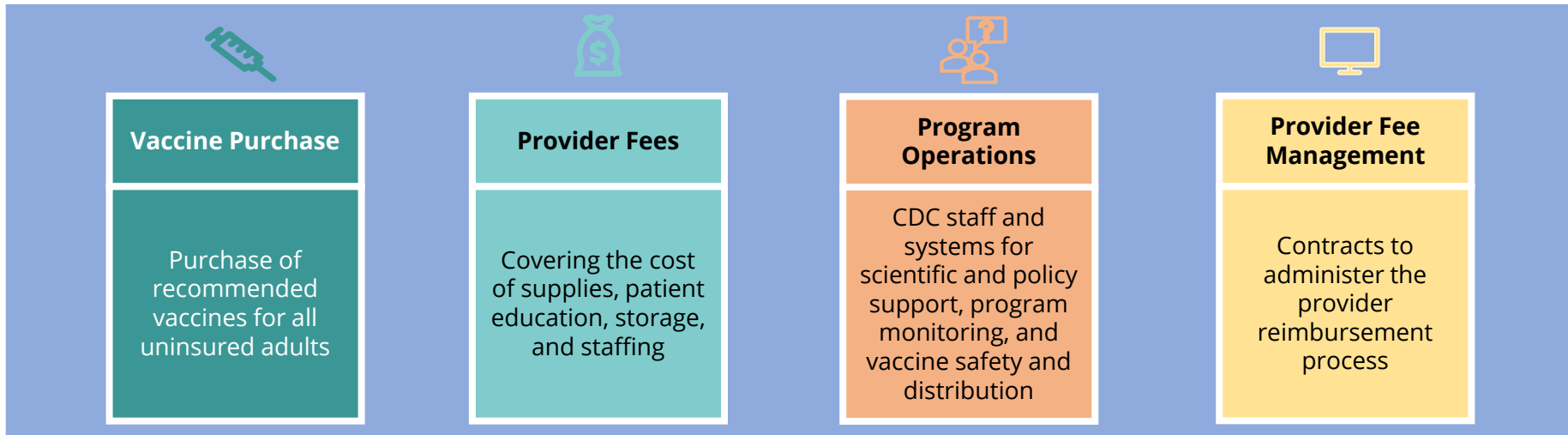
This demonstrates the clear need for **additional base resources, in addition to funding for Vaccines for Adults**, for CDC to create and sustain comprehensive adult immunization program.



# Vaccines for Adults (VFA) Program

The **President's FY 2023 Budget proposes a new Vaccines for Adults (VFA) program**, modeled after the existing Vaccines for Children program, which will provide uninsured adults access to all vaccines recommended by the Advisory Committee on Immunization Practices at no cost. CDC proposed **\$2.1 billion** in mandatory funding for VFA in FY 2023 and a total of **\$25 billion** over 10 years.

The VFA proposal includes:



The VFA program would:

**Reduce disparities in vaccination coverage**

**Improve outbreak control of vaccine-preventable diseases**

**Enhance and maintain infrastructure needed for responding to future pandemics**

# CDC has proposed ***significant new, mandatory funding*** for VFA

CDC's FY 2023 request of \$2.1B in mandatory funding for VFA will expand access to all routine and outbreak vaccines to uninsured adults.



- **\$2 billion for VFA in FY 2023**



- **\$25 billion over 10 years**

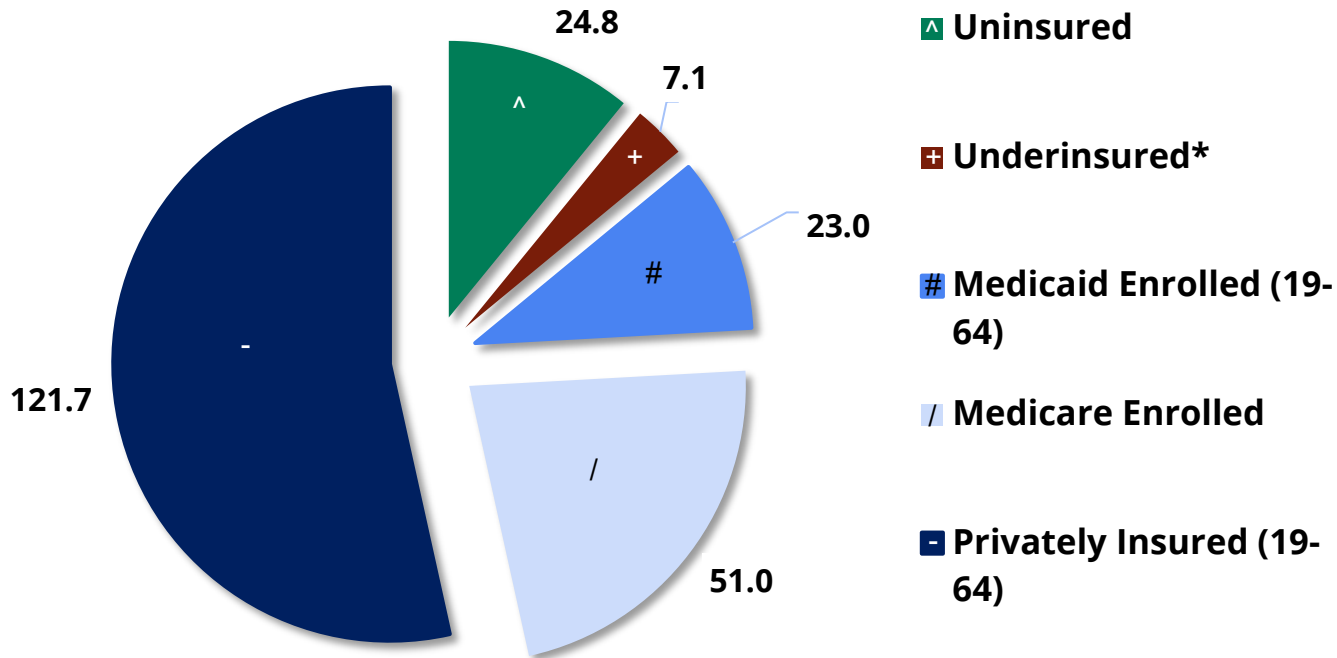
*These funds would be used for:*

- **Vaccine Purchase**
- **Program Operations**
- **Provider Administration**
- **Provider Fee Reimbursement**



# However, uninsured adults are not the only population that experiences barriers to access to vaccines

## Adult Population by Coverage Status (millions)<sup>1</sup>



\*Underinsured is defined here as related to vaccination coverage.  
1/ Data are internal CDC estimates.

*VFA would cover the cost of vaccines only for uninsured adults.*

*Other existing programs or proposed programs, including ACA-compliant private insurance, cover many others.*

***Current 317 Immunization funds are insufficient to cover those without, or with incomplete, vaccination coverage.***



# Promotion of ACIP Adult Hepatitis B Vaccination Recommendations

- **MMWR<sup>1</sup> Promotion**
- **Increase awareness via webinars (2022)**
  - National Viral Hepatitis Education, Awareness, and Capacity Building for Communities and Providers Cooperative Agreement Part B recipient meeting (University of Washington & WebMD) — January 10
  - National Adult and Influenza Immunization Summit (NAIIS) weekly call — January 13 and April 28
  - CDC Immunization Services Division Program Operations Branch recipient call (Immunization Managers) — January 19
  - Indian Health Service Grand Rounds — March 23
  - Hepatitis B Foundation, NASTAD, and AIM webinar — April 25
  - Hepatitis B Foundation HBV ECHO — April 28
  - CSTE Vaccine Preventable Diseases Subcommittee call — May 9
  - Federal Implementation Hepatitis B Vaccination Webinar — May 23
  - More to come...

<sup>1</sup>Weng, et al. [MMWR](#), 2022.



# Provider Outreach — Resources for Clinicians

## ■ CDC's Current Issues in Immunization April 20 Webinar

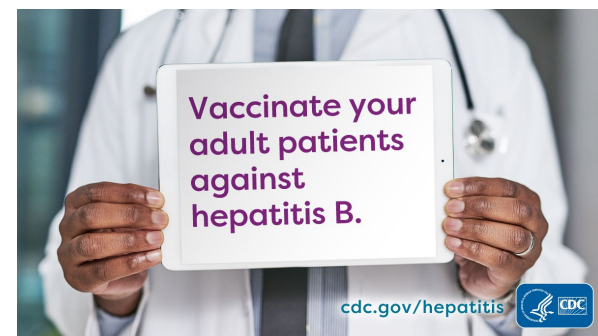
- Immunization Update on ACIP Recommendations for Hepatitis B, Pneumococcal and Zoster Vaccines (Dr. Mark Weng, MD, from CDC's Viral Hepatitis program participated in this presentation)

## ■ University of Washington – Hepatitis B Online

- Free continuing medical education, tools, and resources for clinicians, pharmacists and others about hepatitis B, including vaccination
- Univ of Washington Hepatitis B online can be found at [www.hepatitisB.uw.edu](http://www.hepatitisB.uw.edu)

## ■ Immunize.org Resources

- Immunize.org updated its popular, “Ask the Experts: Hepatitis B” webpage, which includes an extensive list of clinical questions and answers incorporating the updated hepatitis B vaccination recommendation
- [Standing Orders For Administering Hepatitis B Vaccine to Adults \(immunize.org\)](http://immunize.org)



# Questions?



# Centers for Medicare & Medicaid Services

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Jessica Lee, MD, MSHP

Jeffrey Kelman, MD, MMSc



**OASH**

Office of the  
Assistant Secretary  
for Health



# Hepatitis B Vaccination HRSA Information

Federal Implementation - Hepatitis B Vaccination Webinar

*May 23, 2022*

**Ronald D. Wilcox MD**  
Medical Officer  
HIV/AIDS Bureau (HAB)

Vision: Healthy Communities, Healthy People



- 
- “The mention of trade names, commercial practices, or organizations do not imply endorsement by the U.S. Government. *Any trade/brand names for products mentioned during this presentation are for training and identification purposes only.*”



# Bureau of Primary Health Care

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- Hepatitis B vaccination offered to appropriate patients at community health centers
- Funding given as a grant to provide an array of services. Hepatitis specific services are not required.



# HRSA HIV/AIDS Bureau

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- RWHAP recipients are required to provide services consistent with DHHS Guidelines
- Funding given as a grant to provide an array of services. No specified service is required and depends on needs assessment and funding level.
- HHS guidelines include Hepatitis B immune status testing at intake and Hepatitis B vaccination for non-immune patients with HIV.



# DHHS Guidelines for Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV

- For PWH who are non-immune to HBV (surface antibody titer negative) and do not have chronic HBV infection (surface antigen negative), administer a three-dose series of single antigen hepatitis B vaccine (Recombivax<sup>®</sup> or Engerix<sup>®</sup>) or combined HepA-HepB at 0, 1, and 6 months (alternate dosing intervals are available) **(AII)**.
- A novel recombinant hepatitis B vaccine that uses a toll-like receptor 9 immunostimulatory adjuvant (HepBCpG, Heplisav-B<sup>®</sup>) is now available. Observational data in individuals with HIV suggest superior response rates. A randomized controlled trial of Heplisav-B in PWH is enrolling currently. If a two-dose vaccine at 0 and 1 month is preferred, Heplisav-B<sup>®</sup> is an option for vaccinating PWH **(CIII)**.
- PWH presenting with CD4 cell count <200 cells/mm<sup>3</sup> with ongoing risk for HBV should be immunized and assessed for antibody response 1 to 2 months after completion of the series. For PWH without risk factors, waiting for CD4 >200 cells/mm<sup>3</sup> is an option.

Immunization section updated 11-20-2021





# DHHS Guidelines for Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV

- Assess antibody response to hepatitis B surface antibody (anti-HBs) 1 to 2 months after completion of the vaccine series.
- For PWH who do not respond to a complete HepB vaccination series, administer a four-dose revaccination series using double doses (**BI**) or consider Heplisav-B® (**CIII**).
- For individuals with isolated hepatitis B core antibody (anti-HBc), vaccinate with one standard dose of HBV vaccine and check anti-HBs titers 1 to 2 months afterward. If the anti-HBs titer is  $\geq 100$  IU/mL, no further vaccination is needed. If the titer is  $< 100$  IU/mL, then complete another series of HBV vaccine (single-dose or double-dose) followed by anti-HBs testing (**BII**). If titers are not available, then give a complete vaccine series followed by anti-HBs testing.

Immunization section updated 11-20-2021



# Best Practices Examples for HBV vaccination

## Part C or Part D funded programs

- Lehigh Valley Hospital
  - Standing orders for HBV vaccination created for nursing staff
  - As of April 2022, 73% of CHS patients have received at least one dose of Hepatitis B vaccine with 57% fully completing the vaccine series.
- University of WI
  - Created a form in Epic showing HBV status which acts as a quick way to assess need for vaccination

Examples provided by Dana Hines of DCHAP



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# Indian Health Service

## Hepatitis B Vaccine Implementation

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DHHS/OASH/OIDP FEDERAL PARTNER WEBINAR ON  
NEW HEPATITIS B VACCINE RECOMMENDATIONS

MAY 23, 2022





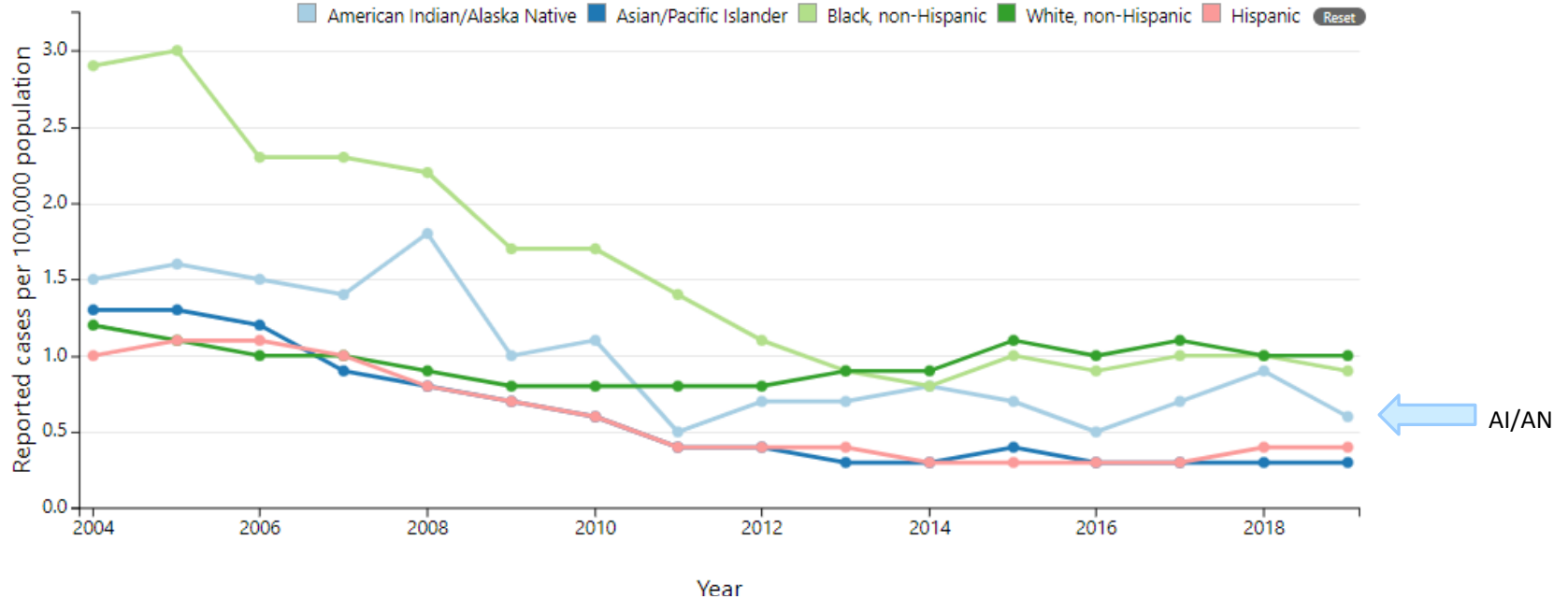
# IHS Overview

- Service population of 2.6 million American Indians and Alaska Natives (AI/AN), with a User Population of 1.6 million having 1 visit in the last 3 years.
- There are 574 federally recognized Tribes in 37 states.
- The health care system is comprised of:
  - IHS-operated
  - Tribal Health Programs
  - Urban Indian Organizations
- IHS total staff consists of more than 15,000 employees, including nurses, providers, pharmacists, dentists, sanitarians, dieticians, and support staff.
- AI/AN have higher rates of underlying chronic disease and are affected disproportionately by social determinants of health.



# Acute Hepatitis B Infections

Rates of reported acute hepatitis B virus infections, by race/ethnicity — United States, 2004–2019



# Hepatitis B Risk Factors

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- Diabetes Mellitus
- Chronic liver disease, including Hepatitis C infection
- Hemodialysis patients
- Injectable drug use
- Men who have sex with men
- Sexual transmission (non-monogamous)
- International travel to countries with high levels of endemic HBV infection
- Health-care and public safety workers

Higher rates in AI/AN



# Viral Hepatitis Rates in AI/AN

Hepatitis C (cases per 100,000), 2018\*

	AI/AN	Non-Hispanic White	Ratio AI/AN: Non-Hispanic White
Acute Hep C	3.6	1.3	2.8
Death Rate Hep C	9.05	3.35	2.7

Death rates for Viral Hepatitis 2018#

	AI/AN	Non-Hispanic White	Ratio AI/AN: Non-Hispanic White
Male	3.3	1.6	2.1
Female	1.7	0.9	1.9
Total	2.5	1.2	2.1





# Chronic Liver Disease in AI/AN

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Cause	AI/AN Rate: 2009-2011	US All Races Rate: 2010	Ratio: AI/AN to US All Races
Chronic liver disease & cirrhosis	42.9	9.4	4.6

(Age-adjusted mortality rates per 100,000 population)

8<sup>th</sup> leading cause of death in AI/AN



# IHS National Core Formulary

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- All ACIP recommended vaccines are on the IHS National Core Formulary.
- The IHS National Immunization Program is integral to the development of clinical guidance and updates to aide facilities in local decision making.
- IHS encourages local decision-making for product selection and vaccination strategy.
- Many factors may impact decision making:
  - Product availability
  - Efficacy
  - Simplicity
  - Cost and cost-effectiveness
  - Product familiarity
  - Clinical decision support – utilization of RPMS/EHR forecasting



# Available Hepatitis B Vaccines

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- ACIP Approved Hepatitis B Vaccines:
  - Traditional 3-dose Series
    - Engerix-B
    - Recombivax-B
    - Twinrix (combination Hep A + Hep B)
  - Novel 3-dose 3-Antigen Recombinant Vaccine (NEW in 2021)
    - PreHevBrio
      - Just very recently available in the U.S. market
  - Novel 2-dose Adjuvanted Vaccine (NEW in 2018)
    - Heplisav-B



# IHS Implementation Strategies

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- The primary methods for implementation of the newest universal guidelines for all individuals under age 60 years will include:
  - Integration into routine care
    - Primary care visits, specialist providers, urgent care and emergency department visits
  - Integration into inpatient services
    - Assessment and vaccinations prior to discharge
  - Community vaccination events and dedicated vaccine clinics
    - Partner pandemic and seasonal vaccines with routine vaccines
    - Expansion of nursing and pharmacy vaccine clinics
    - Use of novel pharmacy technician vaccine administration
  - Meeting people where they are
    - Public Health Nursing home visits, community centers, cultural events



# IHS Tools and Resources

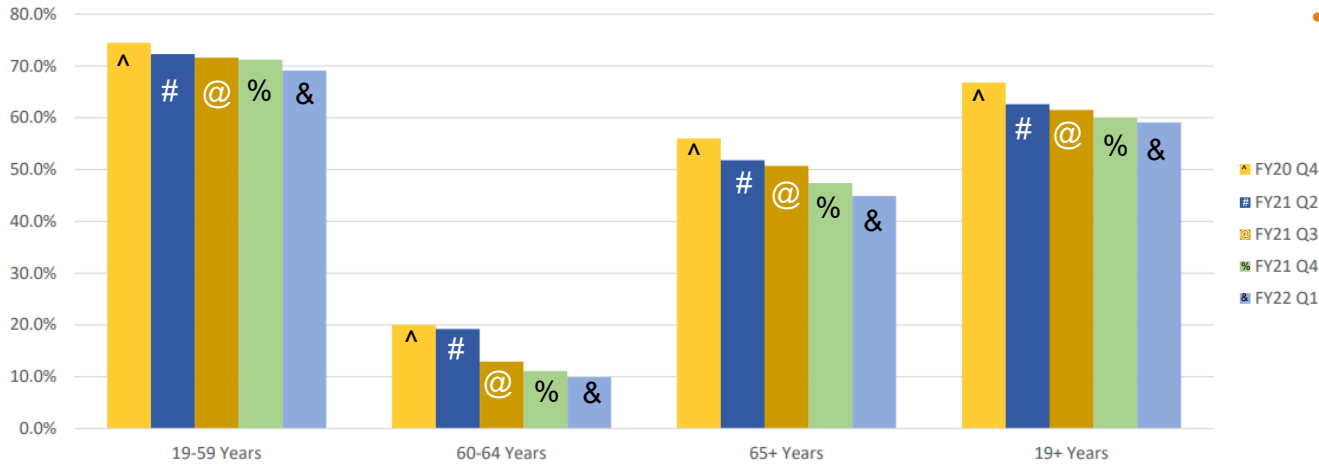
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- Electronic resources can help to identify individuals that should be offered vaccination
  - iCARE
    - IHS Population Management Software tool
    - Allows creation of patient panels based on common characteristics
      - Can identify individuals by age, medical conditions, vaccination history, etc.
  - Targeted outreach via auto-dialers and text messaging
  - Utilize Clinical Decision Support within the electronic health record
    - Vaccine forecaster
      - Updates in progress for the newest recommendations for <60 years
      - Existing logic for high-risk individuals >60 years



# Adult Immunization Composite Measure

Adult Immunization Composite Measures \*  
 Appropriately Vaccinated Per Age Recommendations  
 IHS National



\* 19-59 years with Tdap ever and Tdap/Td <10 years; 60-64 years with Tdap ever and Tdap/Td <10 years and Zoster; 65+ years with Tdap ever and Tdap/Td <10 years and Zoster and Pneumo; and 19 years and older with appropriately vaccinated per age recommendation

- Integrate Hep B into quality measures
  - Individual vaccine coverage rate
  - Adult immunization composite measure



# IHS Next Steps

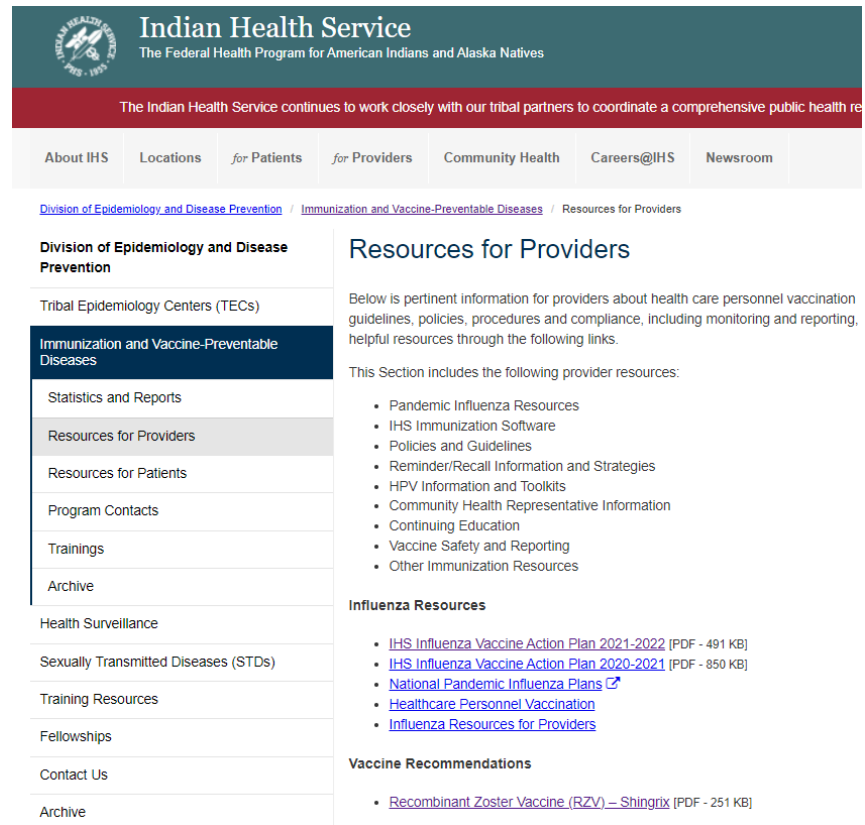
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- The IHS will continue to expand and adapt vaccine efforts, as multiple vaccine recommendations changed in Quarter 1 of 2022.
- Advocate for immunization services through end of 2022.
  - Anticipate significant demands and needs for immunizations now through the fall and into winter.
- Continue to provide clinical guidance to providers for rapid adoption in the field.
  - Lend assistance with local decision making and product selection.
  - Develop short briefs summarizing clinical, cost and logistics information.
- Measure success – modify reporting and tracking of adult Hep B vaccination.



# IHS Vaccine Resources

- [IHS Immunization & Vaccine-Preventable Diseases](#)
  - Statistics and Reports
  - Resources for Providers
  - Resources for Patients
  - Program Contacts
  - Trainings



**Indian Health Service**  
The Federal Health Program for American Indians and Alaska Natives

The Indian Health Service continues to work closely with our tribal partners to coordinate a comprehensive public health re

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[Division of Epidemiology and Disease Prevention](#) / [Immunization and Vaccine-Preventable Diseases](#) / Resources for Providers

**Division of Epidemiology and Disease Prevention**

Tribal Epidemiology Centers (TECs)

**Immunization and Vaccine-Preventable Diseases**

- Statistics and Reports
- Resources for Providers**
- Resources for Patients
- Program Contacts
- Trainings
- Archive

Health Surveillance

Sexually Transmitted Diseases (STDs)

Training Resources

Fellowships

Contact Us

Archive

## Resources for Providers

Below is pertinent information for providers about health care personnel vaccination guidelines, policies, procedures and compliance, including monitoring and reporting, helpful resources through the following links.

This Section includes the following provider resources:

- Pandemic Influenza Resources
- IHS Immunization Software
- Policies and Guidelines
- Reminder/Recall Information and Strategies
- HPV Information and Toolkits
- Community Health Representative Information
- Continuing Education
- Vaccine Safety and Reporting
- Other Immunization Resources

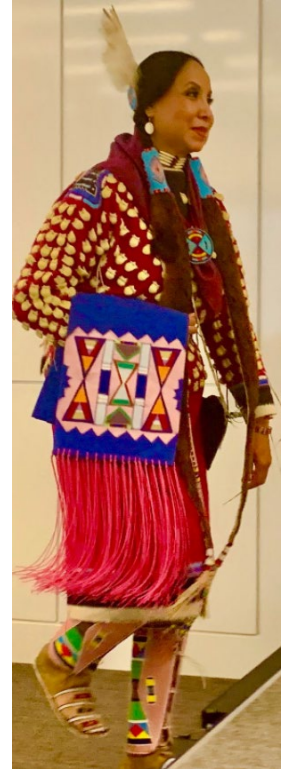
### Influenza Resources

- [IHS Influenza Vaccine Action Plan 2021-2022](#) [PDF - 491 KB]
- [IHS Influenza Vaccine Action Plan 2020-2021](#) [PDF - 850 KB]
- [National Pandemic Influenza Plans](#) [↗](#)
- [Healthcare Personnel Vaccination](#)
- [Influenza Resources for Providers](#)

### Vaccine Recommendations

- [Recombinant Zoster Vaccine \(RZV\) – Shingrix](#) [PDF - 251 KB]







VA



U.S. Department  
of Veterans Affairs

# Veterans Health Administration Hepatitis B Immunization Guidance Updates, May 2022

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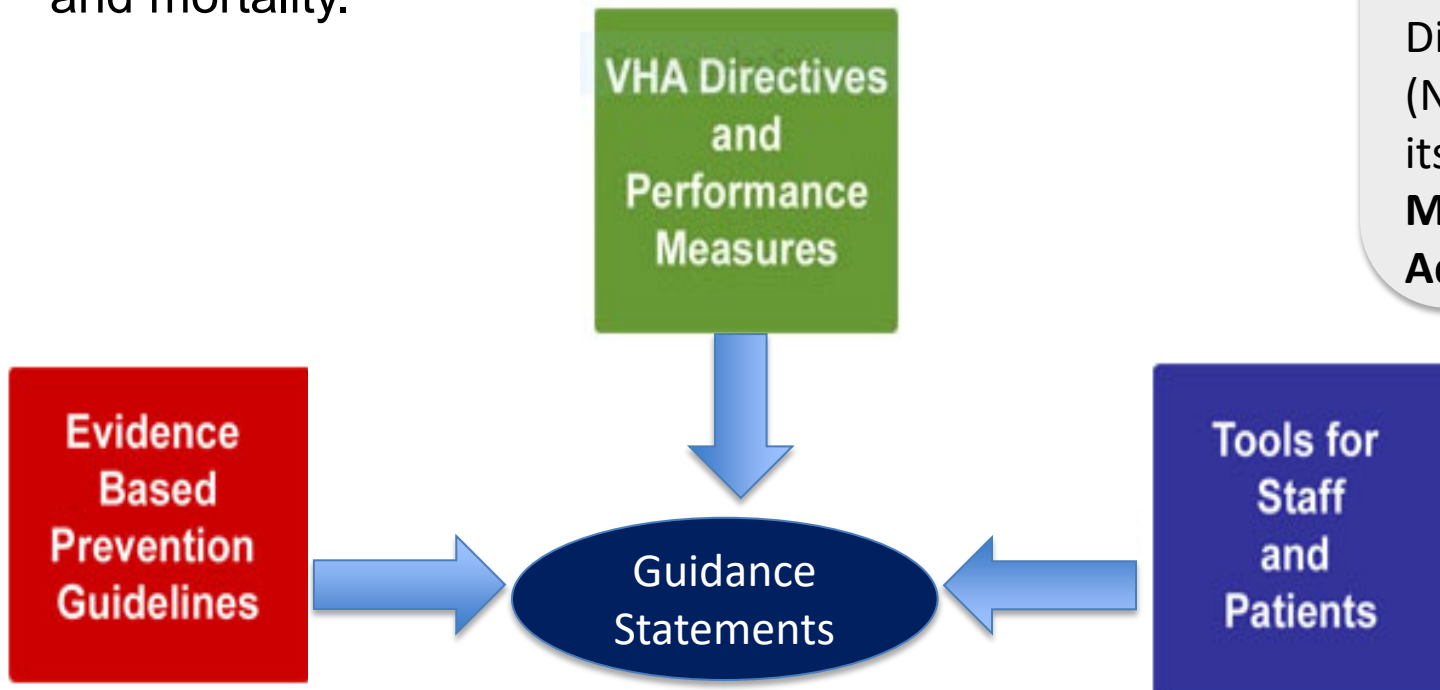


# VA NATIONAL CLINICAL PREVENTIVE SERVICES GUIDANCE DEVELOPMENT

## VHA Clinical Preventive Services Guidance Statements

Clinical preventive services are delivered in the clinical setting for *average risk* Veterans for the primary prevention of disease or for the early detection of disease in persons with no symptoms of the target conditions, with the goal of preventing future morbidity and mortality.

**VHA Clinical Preventive Services Guidance Statements** are issued by the VHA National Center for Health Promotion and Disease Prevention (NCP) and its **Preventive Medicine Field Advisory Committee**.



AUTHORITY: Title 38 United States Code (U.S.C.) § 7301(b) and § 7318  
[VHA Directive 1120.05](#)



# HEPATITIS B IMMUNIZATION: VA CLINICAL PREVENTIVE SERVICES GUIDANCE STATEMENT UPDATE, APRIL 2022

## Hepatitis B Immunization



**VHA recommends routine hepatitis B immunization for previously unvaccinated adults 19-59 years old unless the vaccine is otherwise contraindicated.**

**VHA recommends hepatitis B immunization for previously unvaccinated adults  $\geq$  60 years old who are at increased risk for contracting hepatitis B virus (HBV) infection or increased risk of severe complications in the event HBV is contracted, or for those seeking protection against HBV infection, unless the vaccine is otherwise contraindicated.**

**VHA recommends hepatitis B immunization for anyone  $\geq$  60 years old who desires protection against hepatitis B infection regardless of risk.\***

\*Acknowledgement of being in a specific risk group is not required as some Veterans may not be willing to disclose high risk behaviors due to the associated or perceived stigma.

Published on the VHA Intranet (internal website for VA staff) on April 8, 2022

# VHA performance on HBV vaccination - Methods

- HIV, Hepatitis, and Related Conditions program office identifies individuals either as needing vaccination or as presumed to be not at risk for a new infection
- For these calculations, presumed not at risk for new infection means:
  - Serologic evidence of immunity or a prior infection
  - Military separation on or after Jan 1, 2002 (i.e., already vaccinated)

# VHA performance on HBV vaccination - Results

Population as of January 2022 (n)*	HBV vaccinated or presumed not at risk for new infection
Under age 60 (2.5 million)	74.5%
HIV+, any age (33,049)	88.7%
Past or current Hepatitis C infection, any age (228,506)	73.3%
HIV Pre-Exposure Prophylaxis, any age (4,702)	94.2%

\*Includes all Veterans actively receiving care from VHA, defined as having seen a VHA health care provider in the past 2 years.



# SUPPORTING IMPLEMENTATION

## **Access:**

For Veterans receiving VA health care, there is **no** co-payment for outpatient visits for preventive care services such as screenings and immunizations.

[2022 VA Health Care Copay Rates](#)  
[| Veterans Affairs](#)

Authority: 38

C.F.R. §

17.108(e)(11)

## **Uptake:**

### **Providers:**

Clinical Reminders are decision support tools available in VA's electronic medical record.

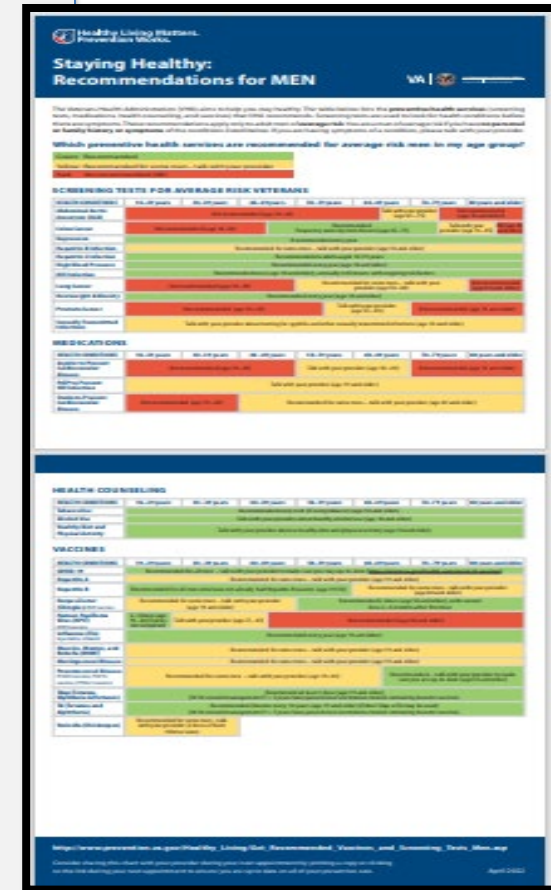
VA Hepatitis B Immunization National Clinical Reminder Update, May 2

### **Veterans, staff, general public:**

VHA's Staying Healthy Recommendation Charts were revised and published April 2022. Updates include recent changes to VA Hepatitis B immunization guidance.

[Recommendations for Men](#)

[Recommendations for Women](#)







# THANK YOU

- VA patient and provider education:  
<https://www.hepatitis.va.gov/index.asp>

# Question and Answer

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Assistant Secretary  
for Health



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**Thank you for your  
participation**

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