Federal Implementation of Updated Hepatitis B Vaccination Recommendations

Office of Infectious Disease and HIV/AIDS Policy

May 23, 2022
Admiral Rachel L. Levine, MD, Assistant Secretary for Health, provided opening remarks for the webinar. Watch the video on YouTube.
Agenda

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

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

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

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, OIDP

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

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

Kristin Roha, MS, MPH, Public Health Advisor for HIV, SAMHSA

Holly Van Lew, PharmD, BCPS, Captain, U.S. Public Health Service, Deputy Lead, COVID-19 Vaccine Task Force, IHS

Sophia Califano, MD, MPH, Deputy Chief Consultant for Preventive Medicine, National Center for Health Promotion and Disease Prevention, VA

Lauren Beste, MD, MSc, FACP, Director, Data and Analytics Group, HIV, Hepatitis, and Related Conditions Program Office, VA
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
The Advisory Committee on Immunization Practices (ACIP) recommends the following groups **should** receive hepatitis B vaccines:

- Adults aged 19–59 years
- Adults aged ≥60 years with risk factors for hepatitis B

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

- Adults aged ≥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)\(^1\)

- > $1 billion spent on hepatitis B-related hospitalizations each year (not including indirect costs)\(^2\)

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1.89 million persons living with chronic HBV (modeled estimate; range, 1.49–2.40 million)\(^1\)

15-25% risk of premature death from cirrhosis or liver cancer among people living with chronic HBV infection\(^2\)

\(^{2}\) [https://www.cdc.gov/std/treatment-guidelines/hbv.htm](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 (≥3 doses) among adults aged ≥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

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 >40 years of age

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

- **Risk identified**: 1,055 (33.1%)
- **Risk data missing**: 1,183 (37.1%)
- **No risk identified**: 954 (29.9%)

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

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 ≤18y. ¹,²
- Current rates among Black American adults are now up to 3x those of Asian/Pacific Islander and Hispanic groups.¹
- Racial/ethnic disparities remain in hepatitis B virus infections.

[Graph showing reported acute HBV infections by race/ethnicity in the United States, 2004–2019]

¹ https://www.cdc.gov/hepatitis/statistics/2019surveillance/HepB.htm
² Wasley et al. MMWR. 2008
Simplifying a complex hepatitis B vaccination schedule

Persons recommended to receive hepatitis B vaccination

<table>
<thead>
<tr>
<th>Existing Recommendations</th>
<th>New Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All infants</strong></td>
<td><strong>All infants [No change]</strong></td>
</tr>
<tr>
<td><strong>Unvaccinated children aged &lt;19 years</strong></td>
<td><strong>Persons aged &lt;19 years [No change]</strong></td>
</tr>
<tr>
<td><strong>Persons at risk for infection by sexual exposure</strong></td>
<td><strong>Adults aged 19–59 years</strong></td>
</tr>
<tr>
<td>- Sex partners of hepatitis B surface antigen (HBsAg)–positive persons</td>
<td></td>
</tr>
<tr>
<td>- 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)</td>
<td></td>
</tr>
<tr>
<td>- Persons seeking evaluation or treatment for a sexually transmitted infection</td>
<td></td>
</tr>
<tr>
<td>- Men who have sex with men</td>
<td></td>
</tr>
<tr>
<td><strong>Persons at risk for infection by percutaneous or mucosal exposure to blood</strong></td>
<td><strong>Adults aged ≥60 years with risk factors for hepatitis B</strong></td>
</tr>
<tr>
<td>- Current or recent injection-drug users</td>
<td></td>
</tr>
<tr>
<td>- Household contacts of HBsAg-positive persons</td>
<td></td>
</tr>
<tr>
<td>- Residents and staff of facilities for developmentally disabled persons</td>
<td></td>
</tr>
<tr>
<td>- Health care and public safety personnel with reasonably anticipated risk for exposure to blood or blood-contaminated body fluids</td>
<td></td>
</tr>
<tr>
<td>- Hemodialysis patients and predialysis, peritoneal dialysis, and home dialysis patients</td>
<td></td>
</tr>
<tr>
<td>- Persons with diabetes aged 19–59 years; persons with diabetes aged ≥60 years at the discretion of the treating clinician</td>
<td></td>
</tr>
<tr>
<td><strong>Others</strong></td>
<td><strong>Adults aged ≥60 years without known risk factors for hepatitis B</strong></td>
</tr>
<tr>
<td>- International travelers to countries with high or intermediate levels of endemic hepatitis B virus (HBV) infection (HBsAg prevalence of ≥2%)</td>
<td></td>
</tr>
<tr>
<td>- Persons with hepatitis C virus infection</td>
<td></td>
</tr>
<tr>
<td>- 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)</td>
<td></td>
</tr>
<tr>
<td>- Persons with HIV infection</td>
<td></td>
</tr>
<tr>
<td>- Incarcerated persons</td>
<td></td>
</tr>
<tr>
<td><strong>All other persons seeking protection from HBV infection</strong></td>
<td></td>
</tr>
</tbody>
</table>

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

**ACIP Policy Statement for PreHevbro, added February 2022**

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>PreHevbro may be used as a HepB vaccine in persons aged ≥18 years recommended for vaccination against HBV infection.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional Considerations</td>
<td>Persons on hemodialysis, pregnant persons and persons who are breastfeeding are not discussed in this Evidence to Recommendations Framework. 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.</td>
</tr>
</tbody>
</table>

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

FDA package inserts: [Heplisav-B](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209355s045lbl.pdf) (2017) and [PreHevbrio](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/210753s003lbl.pdf) (2021)
Adult hepatitis B vaccines

<table>
<thead>
<tr>
<th>Adult hepatitis B vaccine&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Derivation</th>
<th>Adjuvant</th>
<th>Dose of HBs Antigens</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>PreHevbrio&lt;sup&gt;2&lt;/sup&gt;</td>
<td>mammalian (Chinese hamster ovary) cell</td>
<td>alum</td>
<td>10μg</td>
<td>3 doses at 0, 1, 6 months</td>
</tr>
<tr>
<td>Engerix-B</td>
<td>yeast</td>
<td>alum</td>
<td>20μg</td>
<td>3 doses at 0, 1, 6 months</td>
</tr>
<tr>
<td>Recombivax HB</td>
<td>yeast</td>
<td>alum</td>
<td>10μg</td>
<td>3 doses at 0, 1, 6 months</td>
</tr>
<tr>
<td>Heplisav-B</td>
<td>yeast</td>
<td>CpG 1018</td>
<td>20μg</td>
<td>2 doses at 0, 1 months</td>
</tr>
</tbody>
</table>

Twinrix (HepA-HepB combination vaccine) not shown.

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<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](http://dx.doi.org/10.15585/mmwr.mm7107a1)).

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

HHS and NASEM\(^1\) 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

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Ways to Promote Hepatitis Awareness Month 2022:

• Use and share our Awareness Month content and social media toolkit
  Visit www.cdc.gov/hepatitis
  Click on Hepatitis Awareness Month box at the top
• Engage with us on Twitter @cdchep
• Use the Awareness Month hashtags:
  #HepatitisAwarenessMonth #Hepatitis #HepAware2022
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Priti Patel
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Mark Weng
Carolyn Wester
References


- Hyer, R. N. and R. S. Janssen (2018). "HBSAG-1018, a two-dose hepatitis b vaccine, is well tolerated and effective in diabetic patients aged 60 years or older." Diabetes 67 (Supplement 1): LB60.


References


References


References


• Equils, O., C. Kellogg, L. Baden, W. Berger and S. Connolly (2019). "Logistical and structural challenges are the major obstacles for family medicine physicians' ability to administer adult vaccines." Human Vaccines and Immunotherapeutics 15(3): 637-642.


• Flu Vaccination Coverage, United States, 2019–20 Influenza Season: https://www.cdc.gov/flu/fluvoxview/coverage-1920estimates.htm


References


References


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

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

- 1992 National Vaccine Advisory Committee (NVAC) – Standards for pediatric immunization practice
  - Readily available 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)
Updated Standards for Adult Immunization Practice – Why?

- 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

- 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
The Advisory Committee on Immunization Practices (ACIP) makes recommendations for routine vaccination of adults in the United States. Standards for implementing the ACIP recommendations for adults were published by the...
Standards for…

• All providers
• Non-immunizing providers
• Immunizing providers
• Professional organizations and health care systems
• Public health departments
Standards for Adult Immunization Practice
2014 NVAC Recommendations

- **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

- 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

- CDC and other Federal Agencies
- State, Local, Tribal, Territorial Jurisdictions
- Health Care Delivery System
- Private Sector Partners
There are 14 vaccines currently recommended by the ACIP for prevention of disease in adults.

<table>
<thead>
<tr>
<th>Case Study: Vaccines for Children (VFC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Influenza inactivated, recombinant or live, attenuated</td>
</tr>
<tr>
<td>2. Tetanus, diphtheria, pertussis (Tdap or Td)</td>
</tr>
<tr>
<td>3. Measles, mumps, rubella (MMR)</td>
</tr>
<tr>
<td>4. Varicella (VAR)</td>
</tr>
<tr>
<td>5. Zoster recombinant (RZV)</td>
</tr>
<tr>
<td>6. Human papillomavirus (HPV)</td>
</tr>
<tr>
<td>7. Pneumococcal conjugate (PCV20)</td>
</tr>
<tr>
<td>8. Pneumococcal polysaccharide (PCV15) (PPSV23)</td>
</tr>
<tr>
<td>9. Hepatitis A (HepA)</td>
</tr>
<tr>
<td>10. Hepatitis B (HepB)</td>
</tr>
<tr>
<td>11. Meningococcal A, C, W, Y (MenACWY)</td>
</tr>
<tr>
<td>12. Meningococcal B (MenB)</td>
</tr>
<tr>
<td>13. <em>Haemophilus influenzae</em> type b (Hib)</td>
</tr>
<tr>
<td>14. COVID-19</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th></th>
<th>Child Vaccination</th>
<th>Adult Vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ACIP recommended schedule</strong></td>
<td>✓ 1</td>
<td>✓ 2</td>
</tr>
<tr>
<td><strong>Coverage for vaccination:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACA-compliant private insurance</td>
<td>✓ 3</td>
<td>✓ 3</td>
</tr>
<tr>
<td>Underinsured</td>
<td>N/A</td>
<td>Limited</td>
</tr>
<tr>
<td>Medicare</td>
<td>N/A</td>
<td>Limited</td>
</tr>
<tr>
<td>Medicaid</td>
<td>✓ 5</td>
<td>Variable 6</td>
</tr>
<tr>
<td>Uninsured</td>
<td>✓ 5</td>
<td>Minimal 7</td>
</tr>
<tr>
<td>State public health infrastructure</td>
<td>✓</td>
<td>Variable 7</td>
</tr>
<tr>
<td>Immunization information systems</td>
<td>All states</td>
<td>Variable</td>
</tr>
</tbody>
</table>

Source: 1. Child and Adolescent Immunization Schedule 2. Adult Immunization Schedule 3. 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.
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.

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.
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:

- **Vaccine Purchase**: Purchase of recommended vaccines for all uninsured adults
- **Provider Fees**: Covering the cost of supplies, patient education, storage, and staffing
- **Program Operations**: CDC staff and systems for scientific and policy support, program monitoring, and vaccine safety and distribution
- **Provider Fee Management**: Contracts to administer the provider reimbursement process

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)¹

- **Uninsured**: 24.8
- **Underinsured**: 7.1
- **Medicaid Enrolled (19-64)**: 23.0
- **Medicare Enrolled**: 51.0
- **Privately Insured (19-64)**: 121.7

*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

- **MMWR¹ 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...

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

Jessica Lee, MD, MSHP

Jeffrey Kelman, MD, MMSc
Hepatitis B Vaccination
HRSA Information
Federal Implementation - Hepatitis B Vaccination Webinar

May 23, 2022

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

- 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

• 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.
• 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® or Engerix®) 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®) 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® is an option for vaccinating PWH (CIII).

• PWH presenting with CD4 cell count <200 cells/mm³ 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/mm³ is an option.
- 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 ≥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.
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
Connect with HRSA

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Hepatitis B Vaccine Implementation

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

- 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*

<table>
<thead>
<tr>
<th></th>
<th>AI/AN</th>
<th>Non-Hispanic White</th>
<th>Ratio AI/AN: Non-Hispanic White</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Hep C</td>
<td>3.6</td>
<td>1.3</td>
<td>2.8</td>
</tr>
<tr>
<td>Death Rate Hep C</td>
<td>9.05</td>
<td>3.35</td>
<td>2.7</td>
</tr>
</tbody>
</table>

### Death rates for Viral Hepatitis 2018#

<table>
<thead>
<tr>
<th></th>
<th>AI/AN</th>
<th>Non-Hispanic White</th>
<th>Ratio AI/AN: Non-Hispanic White</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>3.3</td>
<td>1.6</td>
<td>2.1</td>
</tr>
<tr>
<td>Female</td>
<td>1.7</td>
<td>0.9</td>
<td>1.9</td>
</tr>
<tr>
<td>Total</td>
<td>2.5</td>
<td>1.2</td>
<td>2.1</td>
</tr>
</tbody>
</table>


Chronic Liver Disease in AI/AN

<table>
<thead>
<tr>
<th>Cause</th>
<th>AI/AN Rate: 2009-2011</th>
<th>US All Races Rate: 2010</th>
<th>Ratio: AI/AN to US All Races</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic liver disease &amp; cirrhosis</td>
<td>42.9</td>
<td>9.4</td>
<td>4.6</td>
</tr>
</tbody>
</table>

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

8th leading cause of death in AI/AN
IHS National Core Formulary

- 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

• 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

• 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

• 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

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

* 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.
IHS Next Steps

• 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
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.

AUTHORITY: Title 38 United States Code (U.S.C.) § 7301(b) and § 7318
VHA Directive 1120.05
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 ≥ 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 ≥ 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
• 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)
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.
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
• VA patient and provider education: https://www.hepatitis.va.gov/index.asp
Question and Answer
Thank you for your participation