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Call to Action

Eliminating Hepatitis B Virus Through
Universal Screening and Vaccination for
Adults Ages 19-59



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Executive Summary

The Hepatitis B Foundation convened a diverse, multi-stakeholder [Advisory Council](#) to help plan and coordinate the dissemination and implementation of updated hepatitis B vaccination and screening recommendations. The recommendations offer a tremendous opportunity to make major advances in the mission to eliminate hepatitis B. Aligning and implementing these new recommendations will require a concerted national effort with collaboration among numerous stakeholders.

The Advisory Council identified key barriers to hepatitis B screening and vaccination in various settings and formulated strategies to optimize implementation of the recommendations. The Council recognizes that various healthcare settings will require different strategies for successful implementation. This white paper serves as a call to action, summarizing the key challenges to universal screening and vaccination and suggesting potential strategies (Figure 1) to address those challenges.

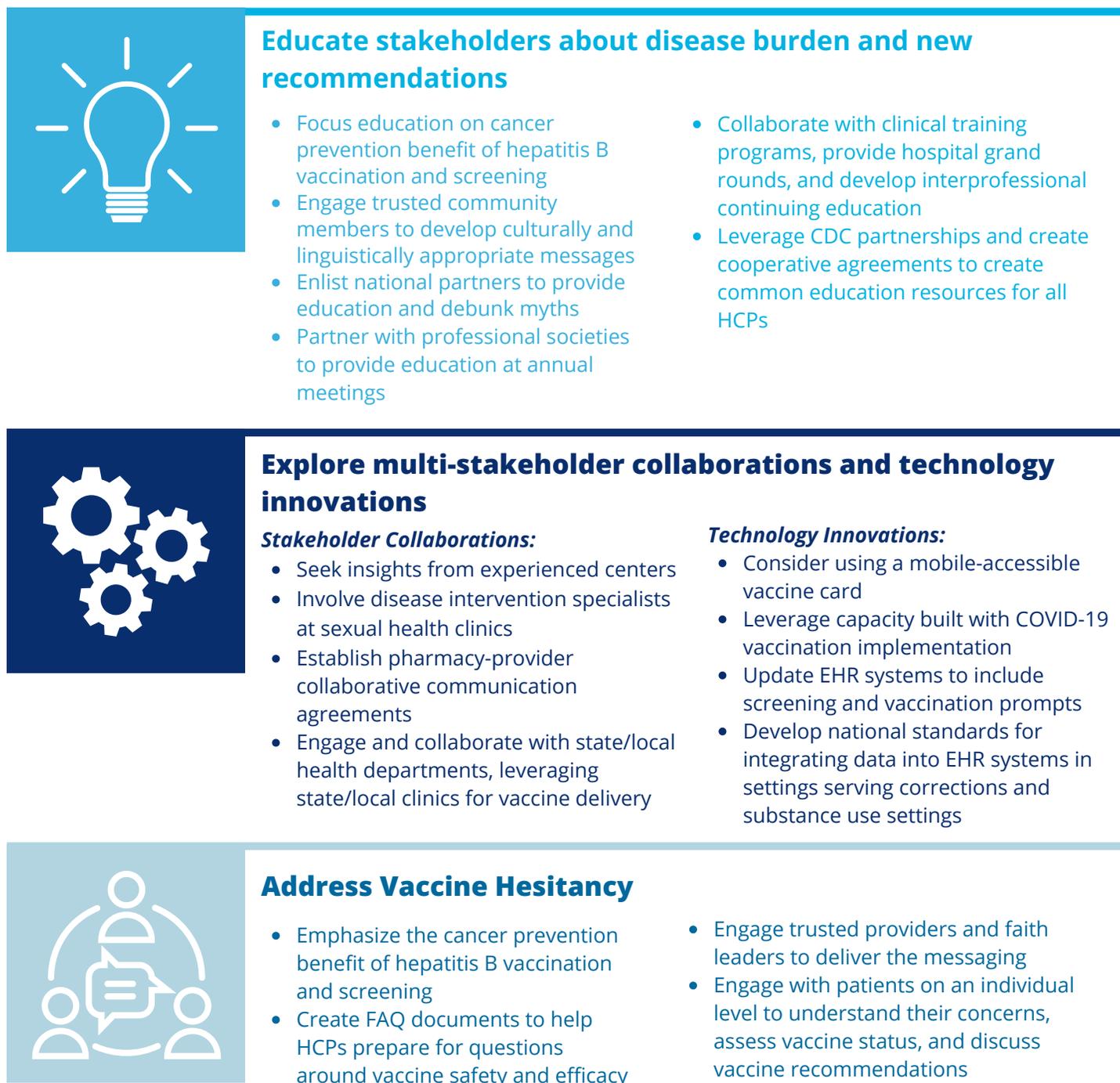


Figure 1. Priority action items to optimize implementation of the updated screening and vaccination recommendations
 CDC, Centers for Disease Control and Prevention; EHR, electronic health records; FAQ, frequently asked questions; HCP, healthcare provider

Introduction

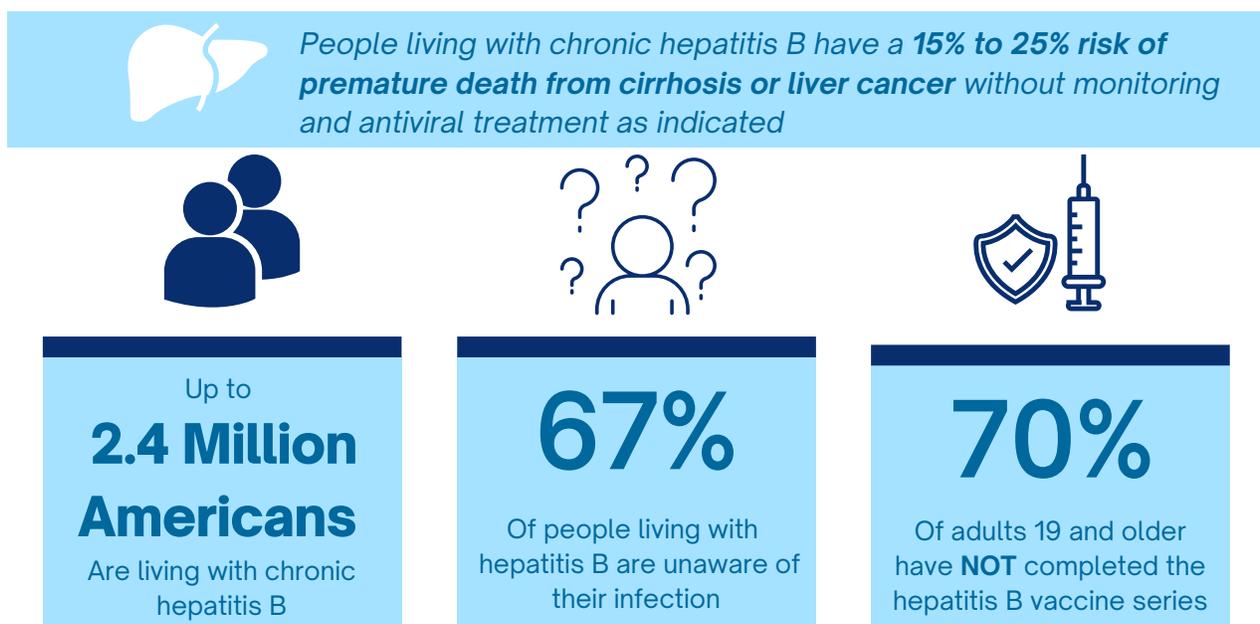
The Burden of Hepatitis B Virus

An estimated 20,700 cases of acute hepatitis B infections occur each year in the United States,¹ with up to 2.4 million people living with chronic hepatitis B.² Without monitoring and antiviral treatment as indicated, these individuals have a 15% to 25% risk of premature death from cirrhosis or liver cancer.³

Hepatitis-B related hospitalizations each year account for more than \$1 billion in costs (not including indirect costs).⁴ While the number of reported cases of hepatitis B has declined markedly since the introduction of highly effective and safe hepatitis B vaccines in 1982, progress has stalled in further reducing the number of new acute cases.⁵ As of 2018, vaccination coverage (≥ 3 doses) was just 30% among US adults aged ≥ 19 years.⁶ Moreover, about two-thirds of people living with hepatitis B are unaware of their infection,^{7,8,9} with many individuals remaining asymptomatic until the onset of cirrhosis or severe liver disease.^{9,10} **Anyone can be infected with hepatitis B, underscoring the importance of universal screening and vaccination.**

The rising number of new infections of hepatitis B and the large number of undiagnosed cases are contributing to hepatitis B-related liver complications and deaths that could be prevented. Addressing these healthcare challenges is further complicated by social and systemic barriers to care for disproportionately affected populations, including individuals who were born in hepatitis B-endemic countries, people who inject drugs, and those experiencing incarceration or homelessness.^{2,9,11}

Reaching and providing services to these populations will be essential to achieving national and global goals of eliminating hepatitis B as a public health threat by 2030.^{11,12}



Rationale for Updated [Screening](#) and [Vaccination](#) Recommendations for Hepatitis B Virus

The previous risk-based guidelines for hepatitis B screening and vaccination faced several major barriers to implementation, including stigma and the burden for clinicians in assessing numerous risk factors.¹³

Indeed, in a national survey, 68% of physicians identified patients' nondisclosure of risk factors as a barrier to adult vaccination, and 44% reported they had inadequate time to routinely assess patients for risk factors.¹⁴ Moreover, two-thirds of case reports of acute hepatitis B sent to the Centers for Disease Control and Prevention (CDC) were either missing risk data or reported no identified risk.^{1,5} In fact, because risks may be transient and unrecognized, anyone can be infected with hepatitis B. The revised guidelines remove the need for risk assessment before screening or vaccination and provide a simplified framework to determining an adult's need for hepatitis B screening or vaccination (Figure 2).

Updated Hepatitis B Screening Recommendation

- *Hepatitis B screening at least once in a lifetime for adults aged ≥ 18 years
- *During screening, test for hepatitis B surface antigen (HBsAg), antibody to hepatitis B surface antigen (anti-HBs), and total antibody to hepatitis B core antigen (anti-HBc)

Screening pregnant persons

- Hepatitis B screening for all pregnant persons during each pregnancy, preferably in the first trimester, regardless of vaccination status or history of testing¹⁵
- *Pregnant persons with a history of appropriately timed triple panel screening and without subsequent risk for exposure to HBV (i.e., no new HBV exposures since triple panel screening) only need HBsAg screening

Updated Hepatitis B Vaccination Recommendation

- All infants
- Persons aged < 19 years
- *Adults aged 19–59 years
- *Adults aged ≥ 60 years with risk factors for hepatitis B
- *Adults aged ≥ 60 years without known risk factors for hepatitis B may also receive vaccine

*New recommendation

Figure 2. Updated recommendations for hepatitis B screening and vaccination^{5,10}

Challenges in Implementing Universal Hepatitis B Screening and Vaccination in Different Healthcare Settings

Primary Care Settings

The public is generally unaware that hepatitis B infection is a vaccine-preventable condition, and that early diagnosis of a hepatitis B infection can lead to timely initiation of effective treatments. Accessibility and affordability are major barriers, especially for screening, as many people do not have a primary care provider or may lack insurance. Stigma and discrimination persist, particularly in several at-risk communities. Social determinants of health, such as lack of access to medical care and psychosocial factors, as well as language, cultural, and transportation challenges represent additional barriers to accessing care.¹⁶ Primary care providers (PCPs) also face various challenges in providing care to people with hepatitis B. PCPs may not be familiar with the healthcare and economic burden of hepatitis B and may lack awareness of the importance of screening and vaccinating for hepatitis B.

Coordinating the new recommendations may also be difficult as there are minor differences in who is recommended to receive the services, and what insurance will cover for specific groups. In addition, PCPs may not yet be familiar with the updated guidelines and continue to consider risk-based criteria for vaccination and screening. As risk-based screening and testing protocols are complicated, PCPs may lack confidence in selecting the appropriate screening tests, potentially leading to the ordering of inappropriate viral hepatitis panels. Similarly, providers who are not familiar with hepatitis B management may not be confident in selecting the appropriate vaccine. Moreover, communicating about universal vaccination up to age 59 years and risk-based vaccination for people ≥ 60 years is challenging. Reimbursement issues also present a challenge to providing care, and sustainable funding that is not linked to emergency situations is lacking. Additionally, the immunization information system infrastructure does not guarantee easy and complete access to adult immunization records in all settings, especially when patients are seen in a state other than where they were vaccinated.

Community Care Settings

Community-based groups that provide access to care in the community setting (ie, not in clinics or hospitals) may rely on collaborations with state/local health departments to provide hepatitis B vaccination and/or screening services. However, most state health departments face workforce challenges and do not have the capacity to provide such services, especially when COVID is often still the priority. For community-based groups, ordering diagnostic tests is more complicated because of the cost and logistical challenges of setting up systems that could allow billable services outside of clinic settings. With funding and staffing limitations, community-based groups often do not have the resources to track and follow-up individuals in nonprimary care settings, presenting a barrier to completion of vaccine series. Additional challenges include establishing integrated/syndemic services to address populations disproportionately at risk for sexually transmitted infections, viral hepatitis, and human immunodeficiency virus (HIV). These individuals could be targeted for holistic harm reduction/prevention services at community clinics run by state/local health departments. Silos and funding and resource limitations create barriers to this approach.

Hospital Settings

Hospital systems have similar challenges to primary care settings but with added complexity: because hospital systems have numerous hospitals sharing an electronic health record (EHR) platform, all decisions regarding EHR processes must be approved by review committees that represent each hospital in the system. To make changes to the existing protocols, stakeholders must be able to convince the review committees in health systems about the need for universal screening and vaccination. Any changes in processes that require major training or education of staff may face resistance from staff members, potentially hindering adoption. In some university-based systems, specialty clinics, such as liver disease

clinics or transplant centers, may screen for hepatitis B but are not reimbursed by Medicare for providing vaccination and follow-up of patients. This represents a loss of point of care.

Pharmacy Settings

Pharmacies have played a key role in testing and vaccination during the COVID-19 pandemic but face challenges in providing screening and vaccination services for hepatitis B. Coverage decisions by public or private payers may not allow pharmacists to bill for screenings in pharmacy settings. The laws and regulations vary by state, with some state laws restricting pharmacists' ability to screen if blood draws are required. This particularly impacts rural areas, where pharmacies could be important providers of screening and vaccination services. In addition, pharmacy team members lack supplies needed for screening and require training on screening and phlebotomy procedures. Pharmacies also must make arrangements with commercial laboratory services for analysis.

Hepatitis B vaccines are now covered by Medicare Part B and D with no cost to recipients, but may not be covered in certain pharmacy settings. Some states do not allow pharmacists to administer hepatitis B vaccines or limit pharmacists' scope of authority. Because of time and staffing constraints due to other responsibilities, some pharmacy team members and other immunization stakeholders may not be aware of the updated hepatitis B vaccination guidelines and the different hepatitis B vaccines currently available. A lack of public education for and media coverage of the new hepatitis B vaccination recommendations also hinders greater awareness among the public and providers. Increased administrative processes, reimbursement challenges, and practice requirements related to the vaccination process have led to some immunization providers restricting the span of their vaccination offerings.

Vaccine availability may be limited, depending on the pharmacy setting and the needs of the community it serves (eg, college town vs rural setting). Vaccine fatigue among providers and the public has resulted in patients not wanting any additional vaccinations and providers not having the energy to push recommendations. The importance of pharmacists as accessible vaccination providers warrants efforts to address these barriers.

Corrections and Substance Use Services

Persons experiencing incarceration are often transferred from one facility to another and their medical records may not be transferred. This complicates tracking of testing and vaccination status. In harm reduction settings, many clinics do not have the capacity to support screening and vaccination services. The clinics may have siloed infectious disease and behavioral resources and often do not offer in-house viral hepatitis services. As a result, screening for hepatitis B is inconsistent and the sites generally do not offer vaccinations. In some states, Medicaid does not directly cover vaccines administered in harm reduction settings, so harm reduction clinics may need to pay for the vaccines. As harm reduction programs typically serve many uninsured individuals, a lack of reimbursement represents a barrier to screening and vaccination. In methadone clinics, screening for hepatitis B and C is mandated and funded for uninsured and low-income people but the tests are not done in-house. Screening is not mandated for individuals who pay for their own screening, potentially leading to these individuals forgoing screening. In the needle exchange setting, state health departments provide vaccines through the local public health departments. Because the clinics do not have funding for screening, they vaccinate without screening. Lower capacity syringe services programs generally have limited resources to provide clinical care services. They may partner with community federally qualified health

centers (FQHCs) or state health departments to provide linkage to care. National standards are lacking for integrated data sharing on adult vaccination and testing records.

Current Best Practices in Screening and Vaccination

Some service providers have already incorporated specific aspects of the updated recommendations into their practice. The following examples illustrate how to optimize implementation of the updated recommendations in different settings. While these examples use screening results to identify adults needing vaccinations, the universal vaccination approach entails following up with all adults who have no evidence of prior vaccination rather than limiting to those with screening results. Vaccinating without waiting for test results, however, may be unacceptable for some communities. Stakeholders need to be mindful of cultural sensitivities around vaccinating before screening.

Primary care community setting: North East Medical Services, California

North East Medical Services (NEMS) is a federally funded community health center located in the San Francisco Bay area serving more than 67,000 patients annually. Of the patient population, many of whom are Asian immigrants, 77% have Medicaid insurance (including dual eligibility for Medicaid and Medicare), 80% are better served in a language other than English, and 24% are 65 years or older. To increase hepatitis B screening the center modified its EHR to include a prompt for providers to order hepatitis B screenings for patients aged 18-79 years who have not been previously screened. The center also modified the lab master template to automatically select the three CDC-recommended hepatitis B screening serologies if the provider chooses "HBV Screening Panel." NEMS also offers free hepatitis B screening to the community and conducts outreach at single-room occupancy housing and community sites, community



The WHO, CDC, and HHS have committed to eliminating viral hepatitis by 2030. Universal hepatitis B screening and vaccination can help achieve these goals.

health fairs, and community COVID-19 testing sites. These efforts resulted in 85% of adult patients being screened for hepatitis B with at least HBsAg and 53% of adult patients screened for all 3 screening serologies, at least once in their lifetime. To promote vaccination, NEMS used the screening results to identify patients susceptible to hepatitis B with no record of prior hepatitis B vaccination.

Outreach interventions included phone calls and mailed letters in various languages to promote vaccination among patients aged 19-59 years who had not started the vaccine series and did not have an upcoming medical appointment. The mailed letters encouraged patients to schedule a provider appointment to start the vaccine series and was followed up by a phone call by a community health worker to confirm whether the patient had received the letter and scheduled an appointment. Completion rates for hepatitis B vaccination increased from 27% of hepatitis B-susceptible individuals in 2016-2018 to 40% in 2019-2021 with the adoption of the 2-dose hepatitis B vaccine.

Hospital system setting: Beth Israel Deaconess Medical Center, Massachusetts

The Beth Israel Deaconess Medical Center incorporated prompts and ordering sets in its EHR for a hepatitis B screening panel. The ordering set reduced ordering errors and ensured that all 3 serologic tests were performed. These modifications were self-explanatory so the clinicians did not require training. Given that decisions to use a prompt for screening requires the review and approval of a system-wide review committee, the working group to develop the EHR prompt used compelling examples to illustrate the need for universal hepatitis B vaccination, such as showing how vaccinating healthy people before they develop complications such as diabetes can lead to better seroprotection rates. The hospital also developed simplified guidelines for PCPs to help interpret testing results.

Community based setting with federal funding: Center for Asian Health at Cooperman Barnabas Medical Center, New Jersey

From 2014 to 2017, the Center for Asian Health (CAH) implemented a CDC-funded, community-based hepatitis B screening, education, and linkage-to-care program. CAH offered free screening coupons to encourage screening/testing. The screening coupon served as both a prescription and payment for screening for HBsAg, anti-HBs, anti-HBc total. The coupon also provided education regarding a person's increased risk if born in a hepatitis B endemic country, and information on where to receive free hepatitis B screening. These coupons were placed in the waiting rooms of the internal medicine faculty practice and CAH, and at community centers, libraries, and local health departments. The coupons were also distributed at community health fairs. To improve linkage to care, patient navigators attempted to reach the patient at least 3 times by telephone, and if unsuccessful, sent a certified letter to the address. Through this method, 94% of patients were contacted for follow-up. In 2018, CAH started an industry-supported program for automated viral hepatitis screening (HBsAg, anti-HBs, anti-HBc total) in the emergency department, with appropriate linkage to care. The screening was expanded to the inpatient setting, and CAH plans to expand this protocol to all facilities in the RWJ Barnabas Health (RWJBH) system. CAH uses EHR best practices (eg, panel for performing all 3 screening tests) to find those who are not screened or vaccinated. Patient navigators receive real-time positive result notifications and contact the individual to initiate the first appointment for hepatitis evaluation. From March 2018 to September 2022, the adjusted linkage-to-care rate was 82% for individuals with hepatitis B infection. At annual fairs for expectant parents, CAH promotes vaccination of newborns within 24

hours of birth and encourages future parents and grandparents to learn their hepatitis B status and get vaccinated if susceptible.

Priority Action Items

The Council identified several priority action items to ensure the successful implementation of the revised ACIP recommendations on hepatitis B vaccination⁵ and the CDC recommendations on screening and testing for hepatitis B.¹⁰ **The Council emphasized that vaccination should not be dependent on screening.** When stakeholders can do either screening or vaccination but not both, stakeholders should provide the service they can and refer for the other service. The Council discussed strategies to help stakeholders in the different settings implement the updated screening and vaccination recommendations.

Because USPSTF recommendations for hepatitis B (last updated in 2020) continue to recommend risk-based testing in adults, public and private health insurers may not yet reimburse screening for people who are not considered to be “high-risk” as defined by the previous screening guidelines.

Priority Action #1: Educate Stakeholders About the Burden of Hepatitis B and the Updated Screening and Vaccination Recommendations

The Public

Community groups should focus their awareness campaigns on the **cancer prevention benefits of hepatitis B vaccination and screening.** Educators should create fact sheets on the healthcare burden of hepatitis B (especially cirrhosis and liver cancer) and the importance of screening and vaccination in preventing these conditions. Communications, including intergenerational messaging, developed for individuals from disproportionately affected communities

Anyone can have an unrecognized risk of hepatitis B infection, and the risk varies over the lifespan.



Screening and vaccination eliminate that risk for the lifetime regardless of how the risks change.

(eg, immigrant populations, refugees, LGBTQ+ individuals) could draw on their willingness to protect their communities by getting screened and vaccinated. Stakeholders should **engage trusted community members and organizations** to develop culturally and linguistically appropriate messages and strategies. Public awareness campaigns should include personal stories of hepatitis B infection without tying the infection to high-risk behaviors. In rural settings, **county agricultural extension offices**, some of which provide education on hepatitis C, could include education on the new recommendations for hepatitis B screening and vaccination, the different vaccines available, and debunking misinformation. National organizations, such as CDC, Immunize.org, and the National Foundation for Infectious Diseases, provide various resources for public education on the updated screening and vaccination recommendations that can be used for education.

Healthcare Providers

Efforts to raise awareness among HCPs about the burden of hepatitis B should emphasize how the updated screening and vaccination recommendations, which largely are not risk based, **may help address healthcare inequities.** Given that recommendations take time to implement, the key messages could be aspirational (eg, elimination of hepatitis B by 2030) to encourage HCP participation in a nationwide campaign.

To ensure implementation of the new recommendations, stakeholders should consider use of proven strategies in behavioral science and change management to close practice gaps. Professional societies should consider including hepatitis B education at their annual meetings, with plenary sessions on the new guidelines. In addition, stakeholders should collaborate with medical and nursing schools and clinical training programs to provide education on hepatitis B and the new recommendations. Hospital systems may conduct grand rounds with trusted experts from their own facility. Other formats for educating HCPs and fostering collaboration with state/local public health professionals include monthly trainings/webinars, in-person conferences, digital media, and interprofessional continuing education programs. To foster high-impact HIV prevention initiatives, CDC is providing funding to community groups and health departments to support integrated screening for sexually transmitted infections, viral hepatitis, and TB, and subsequent linkage to care.

Groups such as the Hep B United coalition have leveraged CDC partnerships and cooperative agreements to create common educational resources for all HCPs. Although funding is limited, **collaborations among diverse community groups may be useful in applying for this type of funding** to provide comprehensive materials for HCPs. The resources could describe different scenarios for vaccination and screening/testing to explain the new recommendations, testing algorithms, the available vaccines and dosing schedules, and protocols for screening at the time of the first vaccine dose. The resources should include guidance on counseling patients. Stakeholders should offer speaker training programs to optimize communication of information to providers. The CDC's diagnostic testing toolkits for providers also would be valuable resources to facilitate ordering and interpretation of hepatitis B testing.

Priority Action #2: Explore Mutli-Stakeholder Collaborations and Technology Innovations

Primary Care Settings

The Council advised PCPs to **seek insights and best practices from experienced centers** in both FQHC and non-FQHC settings. For smooth implementation of the revised screening and vaccination recommendations, primary care practices could **update their EHRs to include prompts for screening and/or vaccination** and should ensure that updated screening and vaccination protocols are in place and familiar to all stakeholders. Emerging research shows that universal adult screening using EHRs in primary care clinics is feasible, and does not increase clinician burden. Additionally, some FQHCs and community health centers serving large at-risk populations have successfully utilized built-in EHR prompts for several years.

Citing the updated vaccination and screening recommendations,^{5,10} the Council noted that while screening is critical to identifying infected and susceptible persons, **screening is not a requirement for hepatitis B vaccination**. The Council also discussed the potential use of a **mobile-accessible vaccine card** (as developed for SARS-CoV-2) to ensure that people complete their vaccine series. Clinicians should emphasize the importance of the card at every appointment. Clinicians should also **report administered vaccinations to state immunization information systems**. Linking EHR systems to the state systems may facilitate this reporting.

Community Care Settings

Council members suggested exploring the involvement of disease intervention specialists (DISs) at sexual health clinics to provide screening and vaccination services. These professionals receive training in managing chronic viral infections (HIV, hepatitis B and C) and sometimes are trained in vaccination.

Given that DISs are already involved in linking to care and harm reduction, their training may potentially be extended to include testing or vaccination for hepatitis B. **Partnerships with trusted community leaders and organizations may help with outreach efforts.**

Hospital Settings

To address the heterogeneity in EHR systems, the Council suggested creating a universal program template that can be customized for the different EHR systems or institutions.

Adapting models used for other conditions, hospitals could **use their EHR systems to facilitate screening and vaccination.** Strategies include the greater use of standing orders, which require little training/education of staff, and inclusion of prompts for a hepatitis B screening panel. When selected, the panel automatically orders the appropriate test. The EHR could also add hepatitis B screening to other blood draw panels before patients' visits with their clinicians.

To help remind clinicians about offering hepatitis B vaccines with screening, the EHR could include a simultaneous prompt for hepatitis B vaccination or select a default vaccine that would automatically be ordered, with information on other vaccines still being available. To address the vaccination of persons ≥ 60 years, the default EHR prompt in the absence of a "high-risk" condition would suggest the person "may be vaccinated against hepatitis B based on their age." If they have a "high-risk" condition, the prompt would recommend that the person "should be vaccinated." The Council recommended that hospital systems create a working group for systems support to optimize implementation of screening and vaccination. Stakeholders should identify a faculty champion and enlist their health systems' laboratory directors to explain to hospital review panels the need for implementing the updated screening and vaccination recommendations. Hospital systems may consider using quality improvement (QI) measures for vaccination and

screening, but payers generally are not motivated to adopt such quality measures and hospital systems must carefully select the appropriate QI measures.

Pharmacy Settings

To overcome state restrictions on pharmacy team members providing hepatitis B screening or vaccination services, pharmacies should have collaborative communication agreements between providers and pharmacists. Pharmacists who are **able to vaccinate but not able to offer screening should provide vaccinations without screening** and provide information about screening at the time of vaccination. National pharmacy organizations should consider collecting information on screening in pharmacy settings because this service will depend on practice location and scope of practice for pharmacists within each state. Improving pharmacy-clinician communication to document administration of hepatitis B vaccines in pharmacies would be valuable.

Corrections and Substance Use Services

The Council suggested that care systems serving at-risk communities, including those in harm reduction settings or individuals experiencing incarceration, develop national standards for **integrating data sharing into their EHR systems.** Such data sharing would help clinicians to have easier access to vaccination data and identify whether individuals have completed their vaccination series. To improve hepatitis B vaccination access, harm reduction settings could **also leverage capacity built with COVID-19 vaccine implementation,** especially for hard-to-reach communities. Community-based partnerships may also be helpful in reaching populations in their own environments, rather than in clinic settings. For example, these partnership initiatives, which should be presented as comprehensive health screenings (blood glucose, cholesterol), would provide education, screening, and linkage to care, depending on the individual's ability to pay for services.

Another approach may be leveraging those grants from the Substance Abuse and Mental Health Services Administration (SAMHSA) that include hepatitis B screening, vaccination, and linkage to treatment as allowable expenses. These grants provide substance use prevention and harm reduction services, substance use disorder treatment and/or treatment for mental illness.

Priority Action #3: Address Vaccine Hesitancy

Addressing vaccine hesitancy is an important responsibility for all stakeholders. When communicating with patients and the public, HCPs and community groups should **highlight the cancer prevention benefit of hepatitis B vaccination**. Community groups should **engage trusted providers and faith leaders to deliver the messaging** and should create FAQ documents to **help prepare HCPs for questions** around vaccine safety and efficacy. In discussions with patients, HCPs should highlight the established safety and efficacy profiles of hepatitis B vaccines, emphasizing that the vaccines offer continued protection lasting at least 35 years, so booster doses are not needed. HCPs should also point out that hepatitis B vaccines are routinely given to newborns and young infants, thus “if it is safe enough for babies, it is safe enough for adults!”. Additionally, stakeholders should use available educational resources to reduce needle anxiety among adults. In some disproportionately affected communities, where distrust of the medical establishment is high, HCPs must clearly explain how community members are at risk and why they should be vaccinated.



Community groups and HCPs need to build more trust and engage with patients on an individual level to understand concerns, assess their vaccine status, and discuss vaccine recommendations to avoid vaccine misinformation.

Conclusion

Optimizing the implementation of the updated screening and vaccination recommendations will require urgent action in 3 key areas: educating stakeholders, exploring multi-stakeholder collaborations and technology innovations, and addressing vaccine hesitancy. For each of these areas, the Advisory Council recognizes that the various healthcare settings will require different strategies for successful implementation. By identifying key challenges to, and potential strategies for, implementing the updated recommendations (Figure 1), the Council aims to mobilize stakeholders to engage in a concerted national effort toward eliminating hepatitis B.

To learn more about hepatitis B prevention, diagnosis, management, and treatment, visit the websites below:

- [CDC Division of Viral Hepatitis](#)
- [Hepatitis B Online - Primary Care Guidance](#)
- [Hepatitis B Foundation](#)
- [Immunize.org](#)
- [National Foundation for Infectious Diseases](#)
- [SAMHSA - Screening and Treatment of Viral Hepatitis in People with Substance Use Disorders](#)

U.S. FDA APPROVED HEPATITIS B VACCINES

NOTE: All of the hepatitis B vaccines below are licensed for use in the U.S. with no preferential decisions for any populations. The below distinctions are only to educate providers on the most recent data for the current available vaccines.

Vaccine	Manufacturer	Populations/ Considerations
Recombivax HB (1986) 3-doses	Merck	<ul style="list-style-type: none"> • Adults and children • Approved for pregnant adults
Engerix-B (1989) 3-doses	GlaxoSmithKline	<ul style="list-style-type: none"> • Adults and children • Approved for pregnant adults
Twinrix (2001) 3-doses <i>*combination hepatitis A and B vaccine</i>	GlaxoSmithKline	<ul style="list-style-type: none"> • Adults and children • Approved for pregnant adults
PreHevbrio (2021) 3-doses	VBI Vaccines	<ul style="list-style-type: none"> • Adults only • Insufficient data to recommend for pregnant persons • <u>Data</u> suggests this may be a better option for people with well-managed chronic conditions
Heplislav-B (2018) 2-doses	Dynavax Technologies	<ul style="list-style-type: none"> • Adults only • Insufficient data to recommend for pregnant persons • <u>Data</u> suggests that this may be a better choice for those with hyporesponsive conditions or who have had difficulty responding to the hepatitis B vaccine previously

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Thank you to the following individuals who provided their expertise for the development of this report.

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