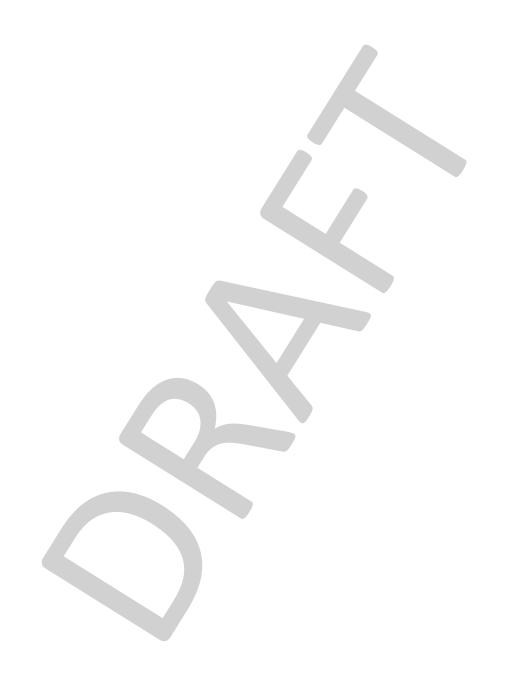
VIRAL HEPATITIS NATIONAL STRATEGIC PLAN FOR THE UNITED STATES

A Roadmap to Elimination 2021–2025

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Viral Hepatitis National Strategic Plan: 2021-2025, draft as of September 10, 2020

Vision

The United States will be a place where new viral hepatitis infections are prevented, every person knows their status, and every person with viral hepatitis has high-quality health care and treatment and lives free from stigma and discrimination.

This vision includes all people, regardless of age, sex, gender identity, sexual orientation, race, ethnicity, religion, disability, geographic location, or socioeconomic circumstance.



Acknowledgments: The Viral Hepatitis National Strategic Plan for the United States—A Roadmap to Elimination (2021–2025) (Hepatitis Plan) was developed through a robust process that included gathering feedback from stakeholders across health care and related fields. Partners throughout the federal government, as well as input from hundreds of nonfederal stakeholders including state, tribal, territorial, and local governments, researchers, health plans and providers, community groups, and national and local organizations that work in viral hepatitis and related fields, have helped shape the goals, objectives, and strategies in this plan. The Office of the Assistant Secretary for Health (OASH) and its Office of Infectious Disease and HIV/AIDS Policy (OIDP) of the U.S. Department of Health and Human Services (HHS) sincerely thank all those who contributed to making this Hepatitis Plan a reality.

Language used in the Hepatitis Plan: The Hepatitis Plan values the lived experiences and choices of all people, regardless of age, sex, gender identity, sexual orientation, race, ethnicity, religion, disability, geographic location, or socioeconomic circumstance. To reflect this vision, a concerted effort was made to use inclusive and person-first language throughout the Hepatitis Plan. Evidence-based, contemporary terminology is also used to convey respect and empowerment and to reduce stigma faced by communities and populations disproportionately impacted by these infections. Despite these efforts, specific terminology or language may be unintentionally offensive or stigmatizing to some individuals or populations. Further, language is subjective, and the meaning and use of language changes over time. This approach is intended to help the Hepatitis Plan's users identify these societal shifts in preferred terminology and communicate in a manner that reflects its vision for a collective, inclusive, and respectful national response.

Electronic version of document: This document and additional information regarding the Hepatitis Plan and associated activities are posted at https://www.hhs.gov/hepatitis/index.html.

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EXECUTIVE SUMMARY

Viral hepatitis is a serious, preventable public health threat that puts those infected at increased risk for liver disease, cancer, and death. The Viral Hepatitis National Strategic Plan for the United States: A Roadmap to Elimination (2021-2025) (Hepatitis Plan or Plan) provides a framework to eliminate viral hepatitis as a public health threat in the United States. Elimination is defined by the World Health Organization (WHO) as a 90% reduction in new chronic infections and a 65% reduction in mortality, compared with the 2015 baseline (WHO). The Hepatitis Plan focuses on hepatitis A, hepatitis B, and hepatitis C—the three hepatitis viruses that have the most impact on the health of the nation. The Hepatitis Plan, which builds on three previous plans, is necessary as the nation faces unprecedented hepatitis A outbreaks, progress on preventing hepatitis B has stalled, and hepatitis C rates nearly tripled from 2011 to 2018. In 2016, it was estimated that 3.3 million Americans were living with chronic viral hepatitis: 862,000 with hepatitis B; and 2.4 million with hepatitis C. Yet hepatitis A and B are preventable by vaccines, and hepatitis C is curable in one short course of treatment. Reversing the rates of viral hepatitis, preventing new infections, and improving care and treatment require a strategic and coordinated approach by federal partners in collaboration with state and local health departments, tribal communities, community-based organizations, and other nonfederal partners and stakeholders.

The Hepatitis Plan provides goal-oriented objectives and strategies that can be implemented by a broad mix of stakeholders at all levels and across many sectors, both public and private. It serves as a mechanism to identify and leverage areas of synergy and resources and to avoid duplication of efforts across agencies. The Hepatitis Plan was developed under the direction of the Office of Infectious Disease and HIV/AIDS Policy (OIDP) in the Office of the Assistant Secretary for Health (OASH), U.S. Department of Health and Human Services (HHS), in collaboration with subject matter experts from across the federal government and with input from a wide range of stakeholders including the public.

The plan establishes the following vision for the nation:

The United States will be a place where new viral hepatitis infections are prevented, every person knows their status, and every person with viral hepatitis has high-quality health care and treatment and lives free from stigma and discrimination.

This vision includes all people, regardless of age, sex, gender identity, sexual orientation, race, ethnicity, religion, disability, geographic location, or socioeconomic circumstance.

This vision is accompanied by five high-level goals, which frame the plan's more specific objectives. The order of goals and objectives does not indicate any prioritization, and many are intertwined. The five goals and their associated objectives are as follows:

Goal 1: Prevent New Viral Hepatitis Infections

- 1.1 Increase awareness of viral hepatitis
- 1.2 Increase viral hepatitis vaccination uptake and innovation
- 1.3 Eliminate mother-to-child transmission of hepatitis B and hepatitis C
- 1.4 Increase viral hepatitis prevention and treatment services for people who misuse drugs
- 1.5 Increase the capacity of public health, health care systems, and the health workforce to prevent and manage viral hepatitis

Goal 2: Improve Viral Hepatitis-Related Health Outcomes of People with Viral Hepatitis

- 2.1 Increase the proportion of people who are tested and aware of their viral hepatitis status
- 2.2 Improve quality of care and increase the number of people with viral hepatitis who receive and complete treatment, including people who misuse drugs and people in correctional settings
- 2.3 Increase the capacity of the public health, health care delivery, and health care workforce to effectively identify, diagnose, and provide holistic care and treatment for people with viral hepatitis
- 2.4 Support the development and uptake of new and improved diagnostic technologies, therapeutic agents, and other interventions for the identification and treatment of viral hepatitis

Goal 3: Reduce Viral Hepatitis-Related Disparities and Health Inequities

- 3.1 Reduce stigma and discrimination faced by people with and at risk for viral hepatitis
- 3.2 Reduce disparities in new viral hepatitis infections, knowledge of status, and along the cascade/continuum of care
- 3.3 Expand culturally competent and linguistically appropriate viral hepatitis prevention, care, and treatment services
- 3.4 Address social determinants of health and co-occurring conditions

Goal 4: Improve Viral Hepatitis Surveillance and Data Usage

- 4.1 Improve public health surveillance through data collection, case reporting, and investigation, at the national, state, tribal, local, and territorial health department levels
- 4.2 Improve reporting, sharing, and use of clinical viral hepatitis data
- 4.3 Conduct routine analysis of viral hepatitis data and disseminate findings to inform public health action and the public

Goal 5: Achieve Integrated, Coordinated Efforts That Address the Viral Hepatitis Epidemics among All Partners and Stakeholders

- 5.1 Integrate programs to address the syndemic of viral hepatitis, HIV, STIs, and substance use disorders
- 5.2 Establish and increase collaboration and coordination of viral hepatitis programs and activities across public and private stakeholders

- 5.3 Identify, evaluate, and scale-up best practices through implementation and communication science research
- 5.4 Improve mechanisms to measure, monitor, evaluate, report, and disseminate progress toward achieving organizational, local, and national goals

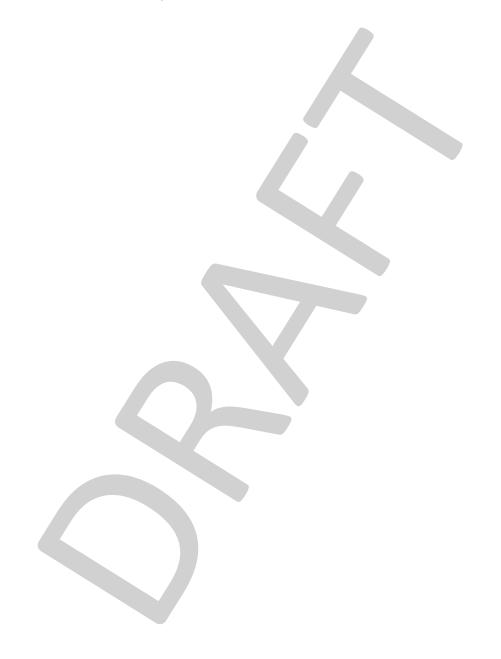
The vision, goals, objectives and other components of the Hepatitis Plan were developed and approved by a dedicated Steering Committee, composed of subject matter experts from across the federal government, with public comment from numerous and varied stakeholders. The plan is designed to be accessible to a broad audience, including people working in public health, health care, government, community-based organizations, research, and academia. It serves as a roadmap for all stakeholders at all levels to guide development of policies, initiatives, and actions for viral hepatitis prevention, screening and treatment. The Hepatitis Plan identifies disproportionately impacted populations with higher rates of hepatitis incidence, prevalence, and mortality (i.e., priority populations) so that federal agencies and other stakeholders can focus their resources to realize the greatest impact. The priority populations were identified based on national-level data. Stakeholders are encouraged to review the data for the populations they serve to help focus their efforts.

Interwoven throughout the plan and highlighted in Goal 5 is the critical need to integrate viral hepatitis prevention, screening, diagnosis and treatment including breaking down operational and funding silos among HIV, sexually transmitted infections (STIs), substance use disorders, and other public health efforts. This integrated approach is even more critical in light of the COVID-19 pandemic, which highlight the health inequities faced by populations disproportionately impacted by viral hepatitis and COVID-19. Approaches that address individual-, community-, and structural-level factors and inequities that contribute to these epidemics, such as stigma, social determinants of health, and health disparities, are also interwoven throughout the HIV National Strategic Plan and the STI National Strategic Plan (both of which are planned for release in 2020). The Hepatitis Plan is designed to facilitate a whole-person and whole-of-nation response to the hepatitis epidemics in the United States and to successfully eliminate viral hepatitis as a public health threat.

The Hepatitis Plan also includes indicators for measuring progress and quantitative targets for each indicator. There are eight core indicators, some of which are then stratified to measure progress in addressing disparities in viral hepatitis (disparities indicators). Although focused on the years 2021–2025, the Hepatitis Plan includes annual targets through 2030 because it will take more than five years to eliminate viral hepatitis as a public health threat in this nation. To ensure implementation and accountability, a Federal Implementation Plan that documents the specific actions that federal partners will take to achieve the Hepatitis Plan's goals and objectives will be released subsequent to the Hepatitis Plan. Progress toward meeting the Plan's goals will be monitored and reported annually.

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In furtherance of the Hepatitis Plan's syndemic* and whole-of-nation approach, it was developed concurrently and in alignment with the inaugural STI National Strategic Plan and the next iteration of the HIV National Strategic Plan (both planned for release in 2020). The Hepatitis Plan also intersects and aligns with the next iteration of the National Vaccine Plan (also planned for release in 2020).



^{*} A syndemic occurs when health-related problems—such as viral hepatitis, HIV, STIs, substance use disorders, and social determinants of health—cluster by person, place, or time.

I. INTRODUCTION

Viral hepatitis is a significant public health threat that puts people who are infected at increased risk for serious disease and death. This *Viral Hepatitis National Strategic Plan for the United States: A Roadmap to Elimination (2021-2025)* (Hepatitis Plan or Plan) covers the most common types of viral hepatitis: hepatitis A, hepatitis B, and hepatitis C. New hepatitis A and hepatitis C infections have increased dramatically in recent years, ¹ little progress has been made on preventing hepatitis B infections, ² and, as of 2016, an estimated 3.3 million people were chronically infected with hepatitis B and hepatitis C. ^{3,4} Collectively, viral hepatitis costs people, health systems, states, and the federal government billions of dollars each year ^{5,6} and contributes to substantial health disparities, stigma, and discrimination.

This Hepatitis Plan is designed to provide national, state, and local, governmental, and nongovernmental stakeholders with a comprehensive, data-driven approach to control the viral hepatitis epidemics and eliminate viral hepatitis as a public health concern by 2030. Appropriate public health interventions and sufficient resources can slow and eventually eliminate viral hepatitis, thereby preventing needless disease and loss of life and saving billions of dollars that could be redirected toward other public health needs.

A. The Need for This Viral Hepatitis National Strategic Plan

1. Advances and Need for Additional Progress

Effective clinical interventions have reduced morbidity and mortality associated with viral hepatitis. These interventions include safe and effective hepatitis A and B vaccines, accurate diagnostic tests that can detect hepatitis B and hepatitis C infections years before symptoms develop, and new therapeutic modalities, such as direct-acting antiviral (DAA) therapies, which are safe and effective and can cure hepatitis C infections. Despite the availability of these tools, new viral hepatitis infections have increased in recent years, which is generally attributable to behaviors and their intersection with social determinants of health. The rate of new hepatitis A cases increased by 850% from 2014 to 2018, the rate of acute hepatitis B cases has plateaued since 2010, and the rate of acute hepatitis C cases has increased by 71% since 2014.⁷ As of 2016, nearly 3.3 million people in the United States were living with chronic viral hepatitis—an estimated 862,000 with hepatitis B⁸ and 2.4 million with hepatitis C.⁹

Surveillance data collected by the Centers for Disease Control and Prevention (CDC) reveal the following trends:

- Hepatitis A: The hepatitis A incidence rate decreased by greater than 95% from 1996 to 2011.¹⁰ Hepatitis A is preventable by a safe and effective vaccine. However, the rate of new cases increased by 850% from 2014 (0.4 cases per 100,000) to 2018 (3.8 cases per 100,000) primarily because of large person-to-person outbreaks among people who use drugs and people experiencing homelessness.¹¹
- **Hepatitis B:** Despite the availability of a safe and effective vaccine, the rate of acute hepatitis B cases increased 11% from 2014 (0.9 per 100,000) to 2018 (1.0 per 100,000).

Injection drug use and sexual transmission are risk factors associated with rising acute hepatitis B cases in the United States. 12

• **Hepatitis C:** The rate of acute hepatitis C cases increased 71% from 2014 (0.7 per 100,000) to 2018 (1.2 per 100,000), with two-thirds of cases occurring among persons aged 20–39 years, the age group most impacted by the opioid crisis.¹³

All three hepatitis infections disproportionately impact certain populations, many of which experience other significant health and social disparities. The escalation of hepatitis B and hepatitis C infections is correlated with an increase in substance use disorder (SUD) and injection drug use (IDU). 14, 15

2. Previous Viral Hepatitis Plans

The year 2020 marks the 10th year of implementing prior iterations of a national viral hepatitis strategic plan. The first two plans, <u>Combating the Silent Epidemic of Viral Hepatitis</u>: Action Plan for the Prevention, Care & Treatment of Viral Hepatitis (covering 2011–2013)¹⁶ and <u>Action Plan for the Prevention, Care and Treatment of Viral Hepatitis</u> (covering 2014-2016)¹⁷ addressed all viral hepatitis types (A, B, C, D, and E), were directed only toward federal partners, and laid the foundation for collaboration across agencies. The third plan, <u>National Viral Hepatitis Action Plan 2017-2020</u>, ¹⁸ was directed to all stakeholders in recognition that a broad range of support and commitment is required to reduce viral hepatitis and its impact. Its focus on four goals and hepatitis A, B, and C was intended to make it easier for stakeholders to tailor actions according to their own purview. It expanded the metrics used to track progress on achieving its goals and set quantitative targets that would lower but not eliminate viral hepatitis as a public health threat in this nation.

The 2017–2020 strategic plan presented 17 indicators with targets for 2020 to monitor progress toward eliminating viral hepatitis. (That plan did not include indicators for hepatitis A.) According to 2017 data, the nation has improved efforts to manage and treat people with chronic hepatitis B and chronic hepatitis C for the population overall, African Americans or Blacks[†] and for people over age 45 with hepatitis B (see Table 1). However, increased efforts to implement available prevention tools and clinical services for hepatitis B and hepatitis C infections are needed. Poor quality and a paucity of data continue to impede effective viral hepatitis efforts, and data challenges need to be addressed.

Table 1. Progress on National Viral Hepatitis Action Plan 2017-2020 Indicators, 2017^a

		Not on track to achieve 2020
On track to achieve 2020 target	Trending in the right direction	target
HBV-related deaths	 Hepatitis B vaccine birth 	New HBV infections
 HCV-related deaths 	dose	New HCV infections
 HCV-related deaths among African Americans 	 Hepatitis B vaccination among health care personnel 	 New HBV infections among people aged 30–49 years HBV-related deaths among AA/PI

[†] In this document, Blacks will be used to refer to African Americans and/or non-Hispanic Blacks.

•	HBV-related deaths among	•	New HCV infections among
	African Americans		people aged 20–39 years
•	HBV-related deaths among	•	New HCV infections among
	people over age 45		AI/AN

^aAA/PI = Asian American/Pacific Islander; AI/AN = American Indian/Alaska Native; HBV = hepatitis B virus; HCV = hepatitis C virus. The NVHAP indicator uses AA/PI, although the surveillance data refers to Asian/Pacific Islander.

B. Challenges and Opportunities

The lack of progress in several areas in recent years indicates that many challenges to eliminating viral hepatitis remain. The challenges provide a framework for identifying opportunities to improve the nation's viral hepatitis prevention, screening, and treatment efforts. Major challenges include missed opportunities for prevention through vaccination; lack of awareness of infection; testing and diagnostic limitations; barriers to treatment; limited data; and the intertwined nature of hepatitis and other co-existing morbidities such as STIs, HIV, and SUDs. Successful efforts to address viral hepatitis must also address stigma, discrimination, and social determinants of health, all of which can act as barriers to prevention, screening, and treatment.

1. Prevention through Vaccination

Safe and effective vaccines to prevent hepatitis A and hepatitis B are available. ¹⁹ Infants and children are recommended to be routinely vaccinated for both hepatitis A and hepatitis B, and childhood vaccination efforts have resulted in relatively high rates of coverage. ²⁰ However, in 2017, 26% of infants did not receive the recommended hepatitis B vaccine at birth, and 40% of children aged 19–35 months did not receive the recommended two doses of hepatitis A vaccine. ²¹ Stronger language from the Advisory Committee on Immunization Practices (ACIP) in 2018 recommended universal hepatitis B vaccination of infants within 24 hours of birth. ²² In 2020, updated hepatitis A vaccination recommendations from ACIP included some additional high risk groups (such as people experiencing homelessness and people with HIV) plus vaccination of all children and adolescents aged 2–18 years who have not previously received the hepatitis A vaccine (i.e., children and adolescents are recommended for catch-up vaccination). ²³ In addition, paying greater attention to vaccine hesitancy can improve hepatitis A and hepatitis B vaccination rates among children.

More than one-half of new hepatitis A and acute hepatitis B infections in 2018 were among persons aged 30–49, who were born before infant vaccination was recommended.²⁴ Approximately 10% and 25% of adults have been vaccinated against hepatitis A and hepatitis B, respectively (see Figure 1).²⁵ The adult populations that are recommended to receive vaccination against viral hepatitis overlap with those recommended for other infectious disease screening and prevention efforts. Thus, implementing adult vaccinations in settings where people with risk factors receive other services, such as homeless services organizations, HIV and STI clinics, SUD programs, and correctional settings, would improve vaccination rates and prevent hepatitis A and hepatitis B infections.

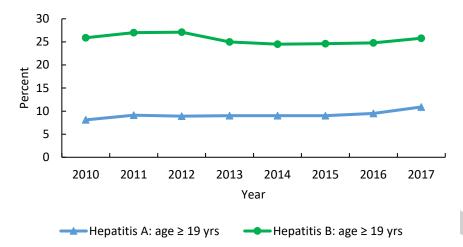


Figure 1. Estimated proportion of adults aged ≥19 years who received hepatitis A and hepatitis B vaccination—National Health Interview Survey, United States, 2010-2017²⁶

2. Awareness of Status and Innovations in Testing Including Diagnostics

Sixty-eight percent of those living with hepatitis B and 40% of those living with hepatitis C are unaware of their status because hepatitis B and hepatitis C often do not cause symptoms. ^{27,28,29} When symptoms appear, cirrhosis, liver failure, or liver cancer may have already occurred. CDC recommends hepatitis B and hepatitis C screening for all pregnant women during each pregnancy, hepatitis B risk-based testing for all other adults, and hepatitis C testing at least once for all adults aged 18 and older and regularly for people with known risk factors. ^{30,31} These recommendations have not been widely implemented, which may result in missed opportunities for testing. Therefore, innovative testing strategies to identify undiagnosed populations early in the course of infection are needed. Implementation of point-of-care testing in outreach settings, utilization of clinical decision support tools, and increased provider awareness and training for implementing testing recommendations would improve diagnoses and awareness.

The available hepatitis B and hepatitis C tests are limited in several ways. No hepatitis B rapid tests are approved for use in the United States, and current testing requires a blood draw. Hepatitis C rapid tests require a blood specimen (fingerstick or venipuncture) and provide only antibody results, which do not distinguish between active and resolved infection. Hepatitis C testing is usually a two-part process (antibody test followed by RNA test), often requiring two separate blood samples and/or provider visits. Innovative diagnostics that enable home-based testing as well as allowing providers to diagnose and initiate treatment in one visit would support improvements along the cascade of care.

During 2020, disruptions caused by the COVID-19 pandemic further highlight the need for improved innovations in viral hepatitis testing. A reduction in clinical services has in turn caused a reduction in viral hepatitis testing. Although available, self-collection test kits for hepatitis C antibody have not been widely implemented. Accuracy depends on proper sample collection. Tests that do not require a blood draw, such as those that collect oral fluid or other noninvasive specimens, would support expansion of testing.

3. Treatment

Safe and effective treatments are available for hepatitis B and hepatitis C, but hepatitis B treatment is not curative and barriers to accessing hepatitis B and hepatitis C treatment remain.³⁴ Barriers include lack of access to medical care, high cost of treatment, and stigma.³⁵ These barriers stem from structural factors which need addressing. In addition, these barriers highlight the importance of health professional training to expand testing and treatment and to increase awareness of and access to recommended treatment among people diagnosed with chronic infection.

Taking lessons learned from HIV, treatment for hepatitis C could be a powerful prevention tool (treatment as prevention). People who are treated and cured cannot transmit the infection to others. Although most people with hepatitis C are at low risk for transmitting the infection to others, people who inject drugs are responsible for the majority of increases in new hepatitis C infections. Since 2013, safe and effective oral treatments have cured hepatitis C in one course of 8 to 12 weeks in over 95% of chronically infected people, preventing liver disease and liver cancer. The main barriers to treatment as prevention are stigma against people who use drugs and the perceived high cost of treatment. Research shows that re-infection is rare among people who inject drugs who are treated and cured. Coupled with the vastly reduced cost of treatment, this finding makes expansion of hepatitis C treatment as prevention a critical component of elimination efforts. Developing curative treatment for hepatitis B would prevent transmission to others, improve the health of people with chronic hepatitis B, and save the health care system significant costs.

4. Limited Data

A dearth of accurate and timely data impedes our ability to understand the disease burden; identify trends in sociodemographic characteristics, risk factors, and geographic areas; and focus resources in communities and settings where they can be most effective. Without these fundamental data, monitoring of national trends and development of responsive strategies is challenging. Further, our ability to monitor and identify gaps in existing interventions, evaluate the impact of interventions, and scale up successful interventions is constrained. The need to improve viral hepatitis data spans public health, behavioral health, public and private health systems, health insurers, correctional programs, therapeutic and device manufacturers, and academic and research programs and will require innovation, collaboration, and ongoing dissemination of best practice policies and guidance.

5. Health Disparities, Stigma, and the Role of Social Determinants of Health

Health disparities contribute to the persistence of viral hepatitis as a lingering public health concern. Reaching the goals of this plan will require focused efforts on populations that are disproportionately impacted.

Social determinants of health—the social and economic conditions that influence the health of individuals and communities—also contribute to the viral hepatitis epidemic and the unequal burden of viral hepatitis in the United States. Language, cultural barriers, stigma,

discrimination, racism, and the quality of health care can be compounded by lack of income, employment and education, unstable housing, and community infrastructure. These factors are barriers to people getting educated, tested, or vaccinated for viral hepatitis and contribute to various public health threats, including viral hepatitis, HIV, STIs, and SUDs, particularly in underserved populations. Even when people can access services, they may face discrimination in the health care setting, have concerns about privacy and confidentiality, or mistrust health care providers. Stigma and discrimination may cause people to avoid testing and treatment and fear disclosure of their status to health care providers, friends, family members, and colleagues. This can lead to worsening health outcomes and further viral hepatitis transmission.

A Focus on Health Inequities

Certain racial and ethnic minority groups have higher rates of viral hepatitis incidence, prevalence, and mortality, compared with rates for non-Hispanic Whites.³⁸ The COVID-19 pandemic has further exposed the health disparities and health inequities faced by people of color. Health disparities can stem from inequities in the social determinants of health and highlight the need to focus not just on viral hepatitis prevention and care efforts, but also on how programs, practices, and policies affect communities of color. Racial and ethnic minority groups are more likely to be uninsured compared to non-Hispanic Whites,³⁹ limiting their access to health care. Barriers to health care access include lack of transportation and childcare, inability to take time off of work, communication and language barriers, racism, discrimination, and lack of trust in health care providers.⁴⁰

Sexual and gender minorities also face health inequities. Sexual minorities have lower levels of health insurance and access to regular health care compared to heterosexuals. ^{41,42} Barriers to health care include stigma, discrimination, medical mistrust, and lack of access to affirming mental health care. ⁴³

The Hepatitis Plan recognizes the importance of addressing social determinants of health to improve health outcomes for racial, ethnic, and sexual minority groups. By working to establish policies and programs that positively influence social and economic conditions and by supporting changes in individual behavior, health can be improved and sustained and disparities reduced. Improving the conditions in which we live, learn, work, and play and the quality of our relationships will create a healthier population, society, and workforce.⁴⁴ Application of a "health in all policies" strategy, a cross-sector collaborative approach to integrating health into policies and programs, ^{45,46} to close the health gaps can be implemented across all areas and levels of government to foster achievement of these aims.

6. Viral Hepatitis, HIV, STIs, and Substance Use Disorders—Holistic Approach to the Syndemic

Viral hepatitis is one of several public health threats that interact synergistically, that is, a syndemic. For purposes of the Hepatitis Plan, as well as the HIV Plan and the STI Plan (both are also planned to be released in 2020), the syndemic includes substance use disorders, sexually transmitted infections (STI), and HIV.⁴⁷ The syndemic also intersects with stigma and social

determinants of health, creating a complex, multifactorial environment in which the Hepatitis Plan must be implemented.⁴⁸ The ability to provide people affected by the syndemic with needed services is often limited by the social determinants of health. A recent report from the National Academies of Sciences, Engineering, and Medicine (NASEM) recommended a holistic approach to addressing each individual's health through greater integration and coordination of programs across the syndemic.⁴⁹ A syndemic approach can take the form of providing multiple services at the same location, cross-training staff, and/or providing linkage to care and patient navigation services across programs to eliminate duplication of efforts and best meet patients' needs. The syndemic approach will improve individual outcomes and ultimately increase our ability to reach the targets set forth in this strategic plan.

The Hepatitis Plan responds to these and additional challenges in each of the goal areas and presents emerging and evidence-based strategies that stakeholders can use that are most likely to contribute toward achieving national goals to eliminate the public health threat of viral hepatitis.

COVID-19 and the Syndemic

This plan is being released during an unprecedented pandemic. In early 2020, SARS-CoV-2, the coronavirus that causes COVID-19 disease, spread rapidly across the globe and our nation, infecting millions, claiming the lives of hundreds of thousands of people, and causing great uncertainty including for people at risk for viral hepatitis, HIV, and STIs. There are still many unknowns for people with liver disease. However, people with underlying medical conditions, including people with chronic liver disease such as hepatitis B and hepatitis C, may be at increased risk for severe illness from COVID-19.

The pandemic has exacerbated existing challenges in the nation's public health care system, further exposing decades, if not centuries, of health inequities including among social determinants of health. In addition, clinical services have been limited as a result of the pandemic due to social distancing, and many staff have been understandably redeployed to address the public health emergency or out of work, having been personally impacted by COVID-19. Many of the populations and communities disproportionately impacted by viral hepatitis, HIV, and STIs are particularly vulnerable to the service disruptions and the economic consequences of the pandemic, including unemployment, housing and food insecurity, and obstacles to practicing safe social distancing.

As the nation responds to the pandemic while working to maintain viral hepatitis, HIV, and STI prevention, screening, and care, innovative approaches have evolved including meeting with clients via telemedicine, distributing self-testing and home specimen collection kits, offering multi-month medication refills, and partnering with pharmacies and retail health clinics to ensure continuity of care. Some of these adaptations may prove to be more sustainable and effective in achieving our national goals.

The nation's understanding of COVID-19 will continue to evolve as effective therapeutics and vaccines are developed and implemented. The ways in which the COVID-19 pandemic will influence our responses to viral hepatitis, HIV, and STIs in the future are unknown. However,

viral hepatitis, HIV, and STI stakeholders remain committed to addressing the public health syndemic. The nation's evolving response will require ongoing innovation and identification of opportunities to integrate and leverage resources and lessons learned that advance efforts to address infectious diseases that threaten public health.

C. Scope, Approach, and Development of the Hepatitis Plan

There are five hepatitis viruses (A, B, C, D, E) that affect the liver. However, the Hepatitis Plan focuses on hepatitis A, hepatitis B, and hepatitis C—the hepatitis viruses that most significantly affect the health of the nation. It is an elimination plan, with the overarching goal of eliminating hepatitis as a public health threat in the United States by 2030. A 2017 report by NASEM found that elimination of hepatitis B and hepatitis C in the United States by 2030 is possible if we commit to funding and implementing strategic actions.⁵⁰

The Hepatitis Plan is intended to serve as a roadmap for federal and other stakeholders to eliminate hepatitis in this nation. It was developed by subject matter experts across the federal government with input from a variety of stakeholders as well as the public. The Plan presents a strategic framework for integrating and leveraging synergistic policies, programs, and resources. It sets forth a vision and five goals for the nation, with objectives and strategies for each goal. A new goal focuses on improving viral hepatitis surveillance and data collection to highlight the current gaps in, but critical role of, data in identifying areas of greatest need and measuring progress. The order in which the goals, objectives, strategies, and indicators are presented is not associated with any prioritization. The objectives and strategies offered in this plan are intertwined and overlapping and may be used to make progress toward more than one goal. Because viral hepatitis disproportionately affects certain demographic groups, the Plan also identifies priority populations (i.e., those populations most impacted by viral hepatitis based on national data) to guide national efforts and funding to realize the highest impact on reducing viral hepatitis.

The Plan also identifies indicators to track progress toward each goal and quantitative targets for each indicator. Although this is a five-year plan, it sets 10-year quantitative targets for each indicator—reflecting the reality that it will take more than five years to eliminate viral hepatitis as a public health threat.

These components—vision, goals, objectives, strategies, priority populations, indicators, and 5-and 10-year targets—are set forth in Section III of this Plan. The methodology for developing the Hepatitis Plan, including stakeholder input, is explained in Appendix A; the baseline measures and annual targets for each indicator are set forth in Appendix B.

Utilizing a whole-of-nation approach, the Hepatitis Plan assumes the active participation of national, state, local, and tribal health departments and organizations, health plans and health care providers, community-based and faith-based organizations, scientists, researchers, and the public in this effort. The priority populations, indicators, and quantitative targets, especially the methods used to determine them, are intended to help focus efforts and limited resources to realize the most impact. Stakeholders are encouraged to focus on activities that resonate the

most with the needs of the populations they serve and the services they provide and, using this national Plan as a framework, to develop their own plans to address and eliminate viral hepatitis and improve the health of their communities, states, tribal nations, and the nation.

The Hepatitis Plan emphasizes viral hepatitis as part of a syndemic. Previous attempts to address viral hepatitis as a standalone disease without an integrated approach to hepatitis and related public health challenges have resulted in fragmented, inadequate efforts and the expenditure of resources without tangible improvements in viral hepatitis infection rates. This Plan lays a roadmap to integrate prevention, screening, and linkage to care for all components of the syndemic, so that we can meet people where they are with no wrong point of entry to health care and related systems. This is especially important for people in at-risk settings and circumstances, such as people experiencing homelessness, people with a SUD, and those in correctional systems, for whom system-wide solutions pose additional and unique challenges.

Recognizing the critical need for a syndemic approach, the Hepatitis Plan was developed concurrently and is aligned with the next iteration of the HIV Plan and the first-ever STI Plan, both planned for release in 2020. The next iteration of the National Vaccine Plan, also scheduled for release in 2020, will support and enhance the elements of these three plans that focus on developing vaccines as an effective approach to preventing infection. The Plan is also aligned with the 2017 *Strategy to Combat Opioid Abuse, Misuse, and Overdose* (Opioid Plan), ⁵¹ as well as the *Ending the HIV Epidemic: A Plan for America* (EHE) Presidential initiative, which aims to reduce new HIV infections by 90% by 2030. Collectively, these plans articulate an integrated set of strategies for prioritizing activities across public health to avoid duplication of effort and achieve the greatest impact on this syndemic.

II. VIRAL HEPATITIS SNAPSHOT

This section provides a high-level snapshot of hepatitis A, hepatitis B, and hepatitis C. Data in this Overview are from CDC's 2018 Surveillance Report, ⁵² unless otherwise noted. Additional information and updates regarding each virus, including prevention, screening, and treatment recommendations may be found on CDC's website. Information specific to priority populations can be found in section III.D below.

Box 1 Viral Hepatitis Surveillance and Fact Sheets

CDC's Viral Hepatitis Surveillance 2018 report presents statistics and trends for reportable hepatitis infections in the United States through 2018. Additional data about hepatitis A, hepatitis B, and hepatitis C, including screening and treatment guidelines are available in documents prepared by CDC:

Hepatitis A Questions and Answers for Health Professionals

Hepatitis B Questions and Answers for Health Professionals

Hepatitis C Questions and Answers for Health Professionals

A. Hepatitis A

Box 2 Hepatitis A⁵³

Vaccine-preventable; no specific treatment is available
Acute illness is mild to severe, sometimes leading to hospitalization and death due to liver failure
Transmitted through fecal or oral route

Epidemiological Facts

- 12,474 reported acute cases (2018)
- 24,900 estimated acute infections (2018)
- Outbreaks in 33 states (Aug 2016–Aug 2020)⁵⁴
 - 61% of cases resulted in hospitalization

- 95% decrease in rate of new infections (1996–2011)⁵⁵
- 850% increase in rate of new infections due to multistate outbreaks (2014–2018)

Populations Disproportionately Impacted

- People who use drugs
- People experiencing homelessness

Current Challenges

- Person-to-person outbreaks among people who use drugs and people experiencing homelessness
- Insufficient vaccination of adults at risk

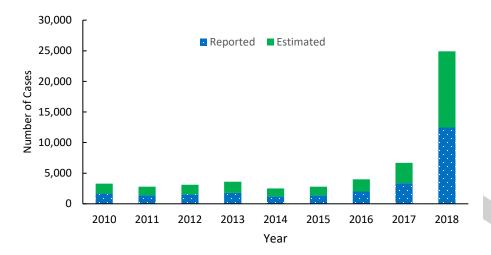


Figure 2. Reported and estimated number of hepatitis A cases—United States, 2010–2018⁵⁶

B. Hepatitis B

Box 3 Hepatitis B⁵⁷

Vaccine preventable; treatment controls but does not cure infection
Acute illness may be asymptomatic, mild illness, or fulminant hepatitis
Chronic illness may result in cirrhosis, liver cancer, and premature death
Transmitted through contact with infectious blood or body fluids and mother-to-child

Epidemiological Facts

- Estimated 862,000 people living with hepatitis B (2016)
- 3,322 reported acute cases (2018)
- 21,600 estimated acute infections (2018)
- 19% increase in acute cases (2014–2018)
- More than one-half of acute hepatitis B cases (2018) were among persons aged 30–49 and were due to low vaccination rates and the opioid epidemic
- Up to 70% of chronic hepatitis B infections in the U.S. are among foreign-born populations, with the highest prevalence among those from Asia and Africa⁵⁸

Current Challenges

Populations Disproportionately Impacted

Acute

Chronic/Mortality

- People who inject drugs
- Asian and Pacific Islander
- Black, non-Hispanic

Acute

- Injection drug use
- Low adult vaccination rates

Chronic

- Perinatal transmission
- Lack of awareness of infection
- Testing and linkage to care
- Costs of treatment
- No curative treatment

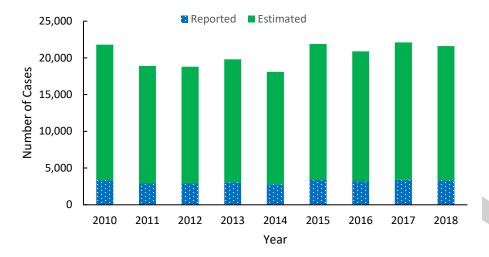


Figure 3. Reported and estimated number of acute hepatitis B cases—United States, 2010–2018⁵⁹

C. Hepatitis C

Box 4 Hepatitis C⁶⁰

No vaccine is available; one 8- to 12-week course of treatment cures most people
Acute illness is often asymptomatic or shows nonspecific symptoms
Chronic illness may result in cirrhosis, liver cancer, and premature death
Transmitted through contact with infectious blood or body fluids and mother to child

Epidemiological Facts⁶¹

- Estimated 2.4 million people living with hepatitis C (2016)
- 3,621 reported acute cases (2018)
- 50,300 estimated acute infections (2018)

Priority Populations

- American Indian/Alaskan Native
- Black, non-Hispanic
- People who inject drugs
- People with HIV
- People born from 1945 to 1965

- 65% increase in acute cases (2014–2018)
- Increases in acute hepatitis C infections were most often among young people (aged 20–29 and 30–39)

Current Challenges

- Injection drug use
- Perinatal transmission
- No available vaccine
- Lack of awareness of infection
- Testing and linkage to care
- Cost of treatment

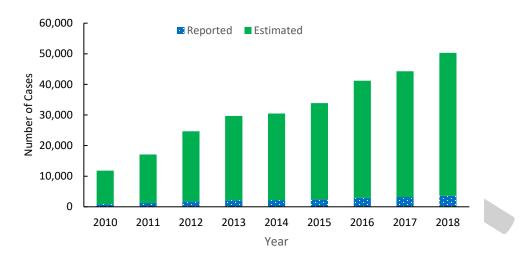


Figure 4. Reported and estimated number of acute hepatitis C cases—United States, 2010–2018⁶²



III. VIRAL HEPATITIS NATIONAL STRATEGIC PLAN

The vision, goals, objectives, and strategies (Sections III.A, B, and C) set forth in the Hepatitis Plan are designed to prevent, treat, and eliminate hepatitis A, hepatitis B, and hepatitis C as public health epidemics. Disproportionately impacted populations (Section III.D) were identified using national-level data to provide stakeholders with a method to focus limited resources for the greatest impact. Indicators and quantitative targets (Section III.E and Appendix B) will help measure progress toward reducing this public health epidemic. The goals, objectives, and strategies are cross-cutting; their delineation and placement is not intended to limit their applicability to other aspects of addressing viral hepatitis. The order within the goals, objectives, strategies, priority populations, and indicators do not indicate any prioritization among them. The methodology for developing the components of the Hepatitis Plan is described in Appendix A.

A. Vision

The United States will be a place where new viral hepatitis infections are prevented, every person knows their status, and every person with viral hepatitis has high-quality health care and treatment and lives free from stigma and discrimination.

This vision includes all people, regardless of age, sex, gender identity, sexual orientation, race, ethnicity, religion, disability, geographical location or socioeconomic circumstance.

B. Goals

In pursuit of this vision, the Hepatitis Plan establishes five goals, as discussed in the Objectives and Strategies section below.

- 1. Prevent new viral hepatitis infections
- 2. Improve viral hepatitis—related health outcomes of people with viral hepatitis
- 3. Reduce viral hepatitis-related disparities and health inequities
- 4. Improve viral hepatitis surveillance and data usage
- 5. Achieve integrated, coordinated efforts that address the viral hepatitis epidemics among partners and stakeholders

C. Objectives and Strategies

The Hepatitis Plan sets forth objectives for each goal, and strategies for each objective. These objectives and strategies will help to guide federal partners and other stakeholders in achieving the goals of this plan. The objectives for each goal set an overarching directional course. The strategies specify approaches or methods to help achieve the objectives. Numerous objectives and strategies could fit under more than one goal. However, each has been placed under the goal in which it most closely fits. A separate Viral Hepatitis Federal Implementation Plan (to be released subsequent to the Plan) will set forth federal partners' plans and activities (within each of their purview) to implement the Plan's goals, objectives, and strategies.

DEFINITIONS^a

Hepatitis Plan

Goals: Broad aspirations that enable the Plan's vision to be realized

Objectives: Changes, outcomes, and impact a plan is trying to achieve

Strategies: Choices about how to best accomplish objectives

FEDERAL IMPLEMENTATION PLAN

Action Steps: Specific activities that will be performed to implement the strategies

Progress Reports: Reports on progress, successes, and challenges

^a Adapted from the HHS Office of the Assistant Secretary for Planning and Evaluation

Goal 1: Prevent New Viral Hepatitis Infections

Goal 1 objectives and strategies describe effective ways to provide key prevention services. Public awareness of viral hepatitis and provider awareness and training on prevention strategies are critical to decreasing the incidence of viral hepatitis. Public education and awareness can decrease stigma and discrimination, motivate people to minimize risky behaviors, and increase preventive activities such as requesting vaccination. Health care providers can recommend and provide vaccination and screening as well as prevention counseling and referral for additional health care services. A recommendation from a trusted health care provider increases the likelihood of patient acceptance and compliance. 63,64

Safe and effective hepatitis A and hepatitis B vaccines are available and are extremely effective but underutilized prevention tools. Almost all children are universally recommended to receive hepatitis B vaccine at birth and the hepatitis A vaccine beginning at age 1 year.⁶⁵ To improve uptake of the birth dose, the Hepatitis Plan recommends utilization of hospital quality metrics and increased provider training to address vaccine hesitancy. To address low vaccination rates among adults, the Hepatitis Plan recommends increased opportunities for vaccination in high-risk settings.

Comprehensive, community-based prevention services such as syringe services programs (SSPs)[‡] and medication-assisted treatment (MAT) for SUD together can prevent approximately 75% of hepatitis C infections.⁶⁶ SUD treatment programs and comprehensive SSPs can be leveraged to provide prevention education and services such as hepatitis A and hepatitis B vaccination; hepatitis B, hepatitis C, HIV, and STI screening; and linkage to care and patient navigation to other health services for people who use drugs. Access to sterile injection equipment to prevent the transmission of infections through injecting drugs, a harm reduction

[‡] The <u>Consolidated Appropriations Act of 2016</u> gives states and local communities, under limited circumstances, the opportunity to use federal funds to support certain components of SSPs. HHS provided <u>guidance</u> for state, local, tribal, and territorial health departments that will allow them to request permission to use federal funds to support SSPs. Federal funds can be used to support a comprehensive set of services, but they cannot be used to purchase sterile needles or syringes for illegal drug injection.

approach, can reach people who would otherwise not get health care and connect them to lifesaving services.

Treatment as prevention is an important approach for reducing transmission of hepatitis B and hepatitis C, including perinatal transmission. When infants receive hepatitis B vaccination and hepatitis B immunoglobulin within 12 hours of birth, followed by completion of the hepatitis B vaccination series, 85-95% of perinatal infections can be prevented. Antiviral therapy in the third trimester is recommended for pregnant women with HBV DNA >200,000 IU/ml to reduce transmission. Research on the use of hepatitis C therapies during pregnancy is ongoing to inform use during pregnancy. All women of childbearing age should be tested and treated before pregnancy to prevent perinatal hepatitis C infection.

Research directed toward understanding the factors that lead some people to recover spontaneously and development of a hepatitis C vaccine could revolutionize hepatitis C prevention. Research is also needed to evaluate prevention interventions, to identify and increase the implementation of effective programs.

The objectives and strategies in this goal describe effective ways to prevent viral hepatitis transmission and infection, which is necessary to reach the nation's goal of eliminating new viral hepatitis infections by 2030. Recognizing the interconnectedness of prevention, screening and care, Objective 1.5 is inclusive of the entire continuum of viral hepatitis management.

Objective 1.1: Increase awareness of viral hepatitis

Strategies:

- 1.1.1 Implement local, state, and national campaigns to provide education about viral hepatitis, the need for vaccination, and the benefits of getting tested, treated, and cured.
- 1.1.2 Partner with community groups to provide education about viral hepatitis and share personal stories at community locations (e.g., workplaces, schools, faith-based organizations), in the media, and other settings to reach all people, especially in disproportionately impacted communities.
- 1.1.3 Develop accessible, comprehensive, culturally, linguistically, and age-appropriate sex education curricula including for hepatitis B, hepatitis C, HIV, STIs, and drug misuse risk for youth and adults.
- 1.1.4 Integrate messaging on HIV, viral hepatitis, STIs, sexual health, and drug misuse.

Objective 1.2: Increase viral hepatitis vaccination uptake and innovation

Strategies:

- 1.2.1 Provide viral hepatitis vaccination at a broad range of clinical and nontraditional community-based settings including HIV and STI clinics, organizations that serve people who misuse drugs and/or people experiencing homelessness, and correctional facilities.
- 1.2.2 Reduce the financial and system barriers encountered by providers and consumers to providing/receiving viral hepatitis vaccinations.

- 1.2.3 Train providers on strategies to address vaccine hesitancy.
- 1.2.4 Scale up administration of universal hepatitis B vaccine birth dose within 24 hours of birth, including through encouraging use of quality measures (e.g., Healthcare Effectiveness Data and Information Set (HEDIS) measure).
- 1.2.5 Improve surveillance infrastructure to better monitor adult immunizations.
- 1.2.6 Research and scale up best practices in hepatitis A and B vaccination provision to expand vaccine coverage consistent with ACIP guidelines.
- 1.2.7 Advance research toward the development of a hepatitis C vaccine.

Objective 1.3: Eliminate mother-to-child transmission of hepatitis B and hepatitis C

Strategies:

- 1.3.1 Increase implementation of guidelines for hepatitis B and hepatitis C screening, diagnosis, and management during pregnancy.
- 1.3.2 Improve surveillance by documenting pregnancy status on all viral hepatitis laboratory reports across health care facilities, laboratories, and public health departments.
- 1.3.3 Collaborate with community organizations that serve disproportionately impacted populations to educate staff and women of childbearing age about viral hepatitis and the importance of preventing hepatitis transmission to infants.

Objective 1.4: Increase viral hepatitis prevention and treatment services for people who misuse drugs

Strategies

- 1.4.1 Educate communities and individuals about substance use disorders, available prevention, harm reduction and treatment options, and associated risks including transmission of viral hepatitis, HIV, and STIs.
- 1.4.2 Expand access to viral hepatitis prevention and treatment services by providing screening, vaccination, and linkage to care in a broad range of health care delivery and community-based settings.
- 1.4.3 Expand medication-assisted treatment and provision of sterile needles and syringes in areas vulnerable to viral hepatitis and HIV outbreaks.
- 1.4.4 Increase staffing and training of peer support counselors to support people who misuse drugs and provide culturally and linguistically appropriate navigation to viral hepatitis services.
- 1.4.5 Through implementation science research, identify and scale up best practices for prevention of hepatitis C infection and reinfection among people who inject drugs.

Objective 1.5: Increase the capacity of public health, health care systems, and the health workforce to prevent and manage viral hepatitis

Strategies:

1.5.1 Partner with professional societies, academic institutions and accrediting bodies to include viral hepatitis prevention and care in the curriculum of medical and other health care professionals' and paraprofessionals' education and training programs.

- 1.5.2 Develop trainings, technical assistance, and clinical decision support tools for primary care and other health care professionals, including pharmacists, to support them in implementing viral hepatitis prevention, testing, and treatment recommendations.
- 1.5.3 Increase provider education on pain management and safer opioid-prescribing practices using the CDC Guideline for Prescribing Opioids for Chronic Pain and other related resources.
- 1.5.4 Develop trainings, printed materials, and other tools for health care providers, community-based organizations, and pregnant women to ensure appropriate hepatitis B and C testing and treatment for pregnant women and administration of post-exposure prophylaxis and the hepatitis B vaccine to newborns.

Goal 2: Improve Viral Hepatitis—Related Health Outcomes of People with Viral Hepatitis

Goal 2 objectives and strategies describe effective ways to identify and provide care and treatment to improve health outcomes for people with viral hepatitis. It is important to monitor continuum and cascade of care models to ensure patients progress through each sequential step of medical care with the ultimate goal of viral suppression for hepatitis B and cure for hepatitis C. "Continuum of care" is used for hepatitis B because there is no cure; while "cascade of care" is used for hepatitis C because there is a measurable end point or cure. The steps in these care models are: initial testing and diagnosis; linkage to care; access to care, treatment and/or cure.

Early diagnosis and treatment reduces the risk for severe liver disease. Therefore, it is critical to expand and implement testing recommendations in a broad range of clinical and nontraditional community-based settings to increase the number of people who are aware of their status and prevent transmission to susceptible contacts. Clinical settings include primary care, HIV and STI clinics, federally qualified health centers, refugee health centers, correctional facilities, emergency departments and hospitals, pharmacies, and public health clinics. Community-based settings include SUD treatment centers, mobile testing vans, SSPs, homeless shelters, and other locations that reach high-risk populations. In addition to expansion of testing sites, facilitators of the implementation of testing recommendations—such as clinical decision support tools and more convenient and point of care diagnostic testing that identifies patients with chronic disease—can improve health systems management and clinical care.

Building on expanded testing efforts, linkage to care and patient navigation services are needed to ensure that people receive appropriate follow-up assessments and treatments. This Plan emphasizes the need to reduce barriers to accessing treatment through expansion of treatment in traditional and nontraditional clinical settings and reduction of insurance and cost barriers. People who are treated and cured of hepatitis C can no longer transmit the infection. In the absence of a vaccine, treatment as prevention for hepatitis C is a critical missed opportunity. This is especially important for people who misuse drugs because they are more likely to transmit the infection to others. Treatment for SUDs and harm reduction approaches, such as

SSPs, have been shown to prevent an estimated 75% of hepatitis C infections, but these must be maintained over time.⁷²

Research and development of improved and novel diagnostic and therapeutic agents is needed to reach the nation's elimination goals. The development and utilization of point-of-care (POC) tests for viral hepatitis can help ensure that people progress through the continuum of care to achieve viral suppression for hepatitis B and cure for hepatitis C and can help reduce transmissions in hepatitis A outbreaks. Also, there is an urgent need to develop improved diagnostic tools to detect hepatocellular carcinoma (which can be a consequence of hepatitis B and hepatitis C) earlier and to develop a cure for hepatitis B to reduce mortality.

The Hepatitis Plan focuses on opportunities to expand implementation research to put into practice evidence-based interventions, as effective interventions to improve testing and treatment are identified. This will improve service provision and will contribute to the elimination of viral hepatitis.

Objective 2.1: Increase the proportion of people who are tested and aware of their viral hepatitis status

Strategies:

- 2.1.1 Scale up implementation of universal hepatitis C screening guidelines among all adults and pregnant women in a range of clinical and nonclinical settings, and provide linkage to care.
- 2.1.2 Expand innovative models for viral hepatitis testing in a range of settings such as community-based organizations, mobile units, substance use disorder treatment programs, correctional facilities, syringe services programs, and HIV clinics, STI clinics and homeless shelters.
- 2.1.3 Leverage covered preventive services by health insurers to expand hepatitis B and hepatitis C testing and address related cost and insurance barriers.
- 2.1.4 Develop and implement quality measures for viral hepatitis testing (e.g., HEDIS and electronic clinical quality measures (eCQM) measures).
- 2.1.5 Increase use of reflex testing for hepatitis C RNA with a positive hepatitis C antibody test.
- 2.1.6 Conduct research to support changes in hepatitis B screening guidelines to demonstrate screening reliability, efficacy, safety, and cost-effectiveness.

Objective 2.2: Improve quality of care and increase the number of people with viral hepatitis who receive and complete treatment, including people who misuse drugs and people in correctional settings

Strategies:

2.2.1 Educate people who are newly diagnosed about recommended assessment, vaccination, treatments, and the benefits of treatment adherence and completion, including in substance use disorder and correctional settings.

- 2.2.2 Improve linkage to care between community-based organizations, correctional facilities, syringe services programs, substance use disorder treatment programs, and viral hepatitis treatment providers.
- 2.2.3 Remove insurance coverage and payment barriers to viral hepatitis care and treatment, including prior authorization requirements.
- 2.2.4 Scale up innovative models of care that increase convenience and reach people impacted by viral hepatitis, such as telehealth, mobile units, and apps for patient self-management and care coordination.
- 2.2.5 Scale up innovative approaches to engage people in care and re-engage those who are lost to care, such as data to care collaborations with patient navigation.
- 2.2.6 Scale up implementation of opt-out testing and guidelines on viral hepatitis prevention, management, and treatment in correctional settings.
- 2.2.7 Develop and implement viral hepatitis quality measures to incentivize quality screening, care, and treatment.
- 2.2.8 Study risk factors for hepatitis B reactivation in persons with inactive disease or resolved infection and make recommendations for prophylaxis, monitoring, and use of vaccination to boost immunity to reactivation in people with antibody to hepatitis B who are receiving immunosuppressive therapy.

Objective 2.3: Increase the capacity of the public health, health care delivery, and health care workforce to effectively identify, diagnose, and provide holistic care and treatment for people with viral hepatitis

Strategies:

- 2.3.1 Partner with professional societies and academic institutions to increase provision of viral hepatitis screening and treatment by health care professionals and paraprofessionals.
- 2.3.2 Expand hepatitis C screening and treatment capacity among public health, primary care and other health care providers, including pharmacists, to support the implementation of viral hepatitis testing, counseling, and treatment recommendations.
- 2.3.3 Use technology and digital collaboration tools such as online training and case conferencing to expand health care provider expertise to areas with few specialists.
- 2.3.4 Expand and improve effectiveness of viral hepatitis navigation and linkage to care in programs that provide viral hepatitis outreach, screening, and treatment.
- 2.3.5 Implement strategies and promote policies to enhance collaborative, integrated, patient-centered models of care including addressing co-occurring conditions, particularly those reaching priority populations and underserved communities.

Objective 2.4: Support the development and uptake of new and improved diagnostic technologies, therapeutic agents, and other interventions for the identification and treatment of viral hepatitis

Strategies: Diagnostic

- 2.4.1 Advance the development and use of point-of-care and self-collected hepatitis A, hepatitis B, and hepatitis C diagnostics.
- 2.4.2 Develop accurate and convenient tests that discriminate between acute and chronic HCV infections, (such as HCV core antigen and serologic tests)
- 2.4.3 Improve and validate tools for earlier detection of hepatocellular carcinoma, such as improved liver imaging and blood and urine tests.

Strategies: Therapeutic

- 2.4.4 Advance research on treatment options for achieving hepatitis B cure.
- 2.4.5 Study the safety of treatment of hepatitis C in pregnancy.
- 2.4.6 Improve prevention of end-stage liver disease and hepatocellular carcinoma among people living with well-controlled hepatitis B and cured hepatitis C by understanding risk factors and identifying and scaling up effective therapies.
- 2.4.7 Research hepatitis B and hepatitis C therapies to identify potent, broadly effective and easily administered therapies, such as long-acting drugs.
- 2.4.8 Advance research on treatments for hepatitis A to rapidly treat infections and reduce transmissions in outbreak settings.

Goal 3: Reduce Viral Hepatitis-Related Disparities and Health Inequities

Viral hepatitis disproportionately impacts specific groups of people. Engaging with individuals and groups in communities experiencing health disparities is important in establishing or expanding efforts to increase screening, diagnose earlier, and achieve better outcomes for people with viral hepatitis. Community-based groups are more likely to be culturally competent, speak the same languages, and be trusted to provide accurate information and services. This type of engagement and partnership can also benefit community organizations by increasing their capacity to support their communities and help to get needed services to community members who may not be able to access or do not trust outside organizations.

Communities disproportionately impacted by viral hepatitis often grapple with a range of challenges across the social determinants of health. The interplay of factors such as poverty, inadequate housing and transportation, food insecurity, medical mistrust, access to care, language and cultural barriers, education, stigma, and discrimination must be addressed to reduce health disparities. People with viral hepatitis face stigma and discrimination because of a number of factors (e.g., SUD, risk behaviors, sexual preference/gender identity, race and ethnicity, coinfection with HIV) in addition to the stigma associated with viral hepatitis. Intersectional stigma may impact prevention and care-seeking behavior. Addressing the holistic needs of people by using a whole-person system approach including by providing multiple services at one location as well as through telemedicine and other remote service provision strategies can improve the nation's response to viral hepatitis and improve the health status of people at risk for and/or with viral hepatitis and other co-occurring conditions. The objectives

and strategies presented in this Plan represent effective ways to address viral hepatitis health disparities along the cascade/continuum of care. These strategies should be tailored to the populations facing higher disproportionate impacts in each jurisdiction. The disproportionately impacted populations, or priority populations, based upon nationwide data, are described in more detail in section III.D.

Objective 3.1: Reduce stigma and discrimination faced by people with and at risk for viral hepatitis

Strategies:

- 3.1.1 Engage faith-based and other community leaders to dispel viral hepatitis—related stigma and share facts, recommendations, and personal stories in community settings and in the media to reach all people, especially in disproportionately impacted communities.
- 3.1.2 Reduce stigma, implicit bias, and discriminatory practices, including at health care delivery sites.
- 3.1.3 Enforce current protections that prohibit discrimination against people with viral hepatitis.
- 3.1.4 Educate health care and other partners, the public, and people with viral hepatitis about federal protections against viral hepatitis—related discrimination.
- 3.1.5 Raise awareness about effective strategies to protect and restore education, employment, and other rights infringed upon as a result of viral hepatitis—related discrimination.

Objective 3.2: Reduce disparities in new viral hepatitis infections, knowledge of status, and along the cascade/continuum of care

Strategies:

- 3.2.1 Foster partnerships with organizations that serve disproportionately impacted populations, including community organizations, provider organizations, academic institutions, and offices of minority health, to raise awareness of viral hepatitis.
- 3.2.2 Support community leaders and people with lived experience to identify, plan, and implement efforts to meet the needs of their community related to viral hepatitis.
- 3.2.3 Provide hepatitis prevention education, hepatitis treatment, and substance use disorder treatment for people who use drugs in correctional settings.
- 3.2.4 Require funded programs that address viral hepatitis to focus on disproportionately impacted populations, help reduce stigma and discrimination, and include contributions of people with lived experience.
- 3.2.5 Advance health disparities research to further understand the influence of social determinants on disparities in viral hepatitis and inform interventions to reduce or eliminate these disparities.

Objective 3.3: Expand culturally competent and linguistically appropriate viral hepatitis prevention, care, and treatment services

Strategies:

- 3.3.1 Develop and disseminate culturally competent and linguistically appropriate viral hepatitis educational materials in collaboration with people with lived experience.
- 3.3.2 Train health professionals in the delivery of culturally competent education, counseling, testing, care, and treatment for viral hepatitis, including development of appropriate informational and clinical decision support tools.
- 3.3.3 Foster collaboration between organizations that serve priority populations and academic researchers to identify and scale up implementation of effective strategies to improve viral hepatitis care and treatment, informed by people with lived experience.

Objective 3.4: Address social determinants of health and co-occurring conditions

Strategies:

- 3.4.1 Establish and expand policies and approaches that promote viral hepatitis prevention and care in programs involving housing, education, employment, transportation, the justice system, and other systems that impact social determinants of health.
- 3.4.2 Develop whole-person systems of care that address co-occurring conditions for people with and at risk for viral hepatitis, HIV, STIs, and substance use disorders.
- 3.4.3 Develop and scale up implementation of effective interventions that address social determinants of health among people with and at risk for viral hepatitis.

Goal 4: Improve Viral Hepatitis Surveillance and Data Usage

An important goal of this Plan is to improve the quality of viral hepatitis data. The poor quality of viral hepatitis data reduces our ability to understand the true scope, level of public health threat, and opportunities to address hepatitis A, hepatitis B, and hepatitis C. Current public health program capacity is not sufficient to detect all viral hepatitis cases or, as a consequence, monitor trends. Thus, incidence, prevalence and geographic distribution of hepatitis A, hepatitis B, and hepatitis C cases are estimated because only a fraction of cases are reported to CDC.⁷³ Consequently, outbreaks often remain undetected, and health officials may not realize the scope of the problem or have the information needed to appropriately prioritize resources to address the threat. Investments in viral hepatitis surveillance data collection, management, and analysis are needed to improve timeliness, completeness, and accuracy of reporting at the state and local levels. Without these investments, national viral hepatitis data and surveillance will continue to lag behind emerging trends, be of poor quality, and as a result, fail to adequately inform public health practice.

Clinical viral hepatitis data in health systems and clinics can be used to improve clinical care quality and reporting, support providers to use and implement recommendations and effective tools, and increase patient-provider engagement. The use of electronic health records has expanded greatly. The availability of health record data and quality improvement strategies that analyze such data offer new opportunities to support providers in implementing testing

recommendations and guidance through the cascade/continuum of care. Clinic- and health system—level quality improvement activities often involve empaneling patients with hepatitis B and hepatitis C within a practice or health system to routinize the standards of care provided. Electronic health records can also be used to track clinical quality measures and trends that can help achieve the goals of this Plan.

Improved interoperability of health data will improve viral hepatitis data overall. In public health, case definitions often require multiple laboratory tests, which may be conducted at different times and by different providers. Interoperable systems reduce data entry burden and the likelihood of data transcription errors and expedite timely, complete data reporting and transfer by providers to public health and other providers.

Health information technology (IT) is evolving rapidly so it is important to quickly disseminate best practices. New treatments, recommendations, and standards of care require review and updates to best practices for effective implementation. IT and data can improve viral hepatitis efforts by identifying gaps in care and trends, streamlining data collection, and addressing the unmet needs of populations disproportionately impacted by viral hepatitis through novel interventions that use health IT.

Objective 4.1: Improve public health surveillance through data collection, case reporting, and investigation, at the national, state, tribal, local, and territorial health department levels Strategies:

- 4.1.1 Increase the number of states that include acute and chronic hepatitis B, acute and chronic hepatitis C, and perinatal hepatitis C as reportable conditions and notify CDC of cases that meet the CDC/Council of State and Territorial Epidemiologists case definitions.
- 4.1.2 Facilitate viral hepatitis case reporting to state, local, tribal, and territorial public health departments by aligning with efforts to report other infectious diseases and using electronic case reporting and interoperable health information technology.
- 4.1.3 Improve the quality and completeness of clinical and laboratory viral hepatitis data reported to public health departments for development of jurisdictional continuum of care.
- 4.1.4 Increase capacity to investigate acute and chronic infections, respond to outbreaks, and capture data related to viral hepatitis risk factors and health outcomes, by cross-training epidemiologic investigators and surveillance staff.
- 4.1.5 Encourage states to make test results that indicate cleared or cured infection reportable, to improve data accuracy and to direct resources appropriately.

Objective 4.2: Improve reporting, sharing, and use of clinical viral hepatitis data

Strategies:

4.2.1 Use interoperable health information technology including electronic health records, electronic case reporting, and health information exchange networks to enable effective data and information sharing.

- 4.2.2 Develop and promote standardized data collection strategies and standards-based data elements to collect and share information on viral hepatitis incidence, prevalence, care, treatment, and cure.
- 4.2.3 Encourage and support patient access to and use of individual health information.
- 4.2.4 Integrate patient-generated health information with clinical applications to support patient-centered care.
- 4.2.5 Develop and implement quality improvement processes by regularly monitoring the hepatitis B continuum of care and hepatitis C care cascade.

Objective 4.3: Conduct routine analysis of viral hepatitis data and disseminate findings to inform public health action and the public

Strategies:

- 4.3.1 Increase data analytics capacity in public health departments to monitor trends over time and among priority populations.
- 4.3.2 Collect and monitor data on viral hepatitis incidence, prevalence, and deaths with hepatitis B and hepatitis C as an underlying or contributing cause.
- 4.3.3 Develop and publish state and local jurisdiction viral hepatitis epidemiologic profiles, and health system patient population profiles.
- 4.3.4 Conduct and publish epidemiologic studies with viral hepatitis data and develop interventions based on the findings of data analyses.
- 4.4.5 Describe and disseminate best practices for data collection, analysis, and use of data.

Goal 5: Achieve Integrated, Coordinated Efforts That Address the Viral Hepatitis Epidemics among All Partners and Stakeholders

Viral hepatitis resources remain limited, and stakeholders are often dispersed across numerous programs, agencies, and systems. As part of the syndemic, it is also critical that viral hepatitis efforts be integrated with efforts to address other interrelated public health threats such as HIV, STIs and SUD. Coordination of efforts across the syndemic will improve what are currently fragmented, siloed prevention efforts. Every day there are missed opportunities to test people for multiple infections and scale-up services in settings where people at risk receive other services. These missed opportunities translate directly into lost time and resources and may result in harm to people who remain undiagnosed, untreated, and at risk of severe outcomes or of transmitting the infection to others. Approaching viral hepatitis, HIV, STIs, and SUD together will focus on the intersections and commonalities that are found in the settings, providers, and people at risk for and infected with viral hepatitis and at risk for or living with these other comorbidities. The ability to reduce viral hepatitis among at-risk individuals and priority populations will inevitably depend on successful, integrated, interventional strategies to address the various components of the syndemic.

Coordination of efforts at all levels and among diverse partners is needed to leverage all available tools and reach the nation's goals. With the concurrent development and implementation of the Hepatitis Plan, HIV Plan and STI Plan, this coordination has begun to take place among federal partners; however, increased collaboration is needed at the national,

state, local, and health systems levels. Coordination will expedite more effective and efficient implementation of public health programs, clinical interventions, and research advances, to achieve better health outcomes and efficiently use limited resources at all levels.

Decades of research have given us the knowledge and tools to meet the challenges of viral hepatitis and reverse the trajectories of current trends. Research continues and is especially important as we move from basic viral hepatitis research to translational and implementation research, and from emerging practices to best practices based on assessment of improved outcomes over time. Expediting rapid translation and implementation of research findings to improve public health and clinical practice will help reach the Plan's goals.

As work on viral hepatitis evolves, it will be important to continually review and improve how information about trends and progress is measured, monitored, reported, shared and to use this information to improve efforts to eliminate viral hepatitis. Improvements are needed at all levels and across all stakeholders. Organizations, local and state health departments, health systems, and national programs should consider how they measure their work on viral hepatitis and how their programs can consistently track progress toward organizational goals as well as their contributions toward viral hepatitis elimination. As more stakeholders establish hepatitis monitoring and reporting and contextualize these efforts as contributing to national elimination efforts, the U.S. viral hepatitis elimination efforts will become more streamlined and effective and the nation will be able to eliminate viral hepatitis as a public health threat.

Objective 5.1: Integrate programs to address the syndemic of viral hepatitis, HIV, STIs, and substance use disorders

Strategies:

- 5.1.1 Through implementation science research, identify and scale up viral hepatitis prevention, testing, linkage to care (with patient navigation), and treatment in all care settings that address the syndemic.
- 5.1.2 Provide technical assistance and training for health care providers to manage and treat people with co-morbidities such as viral hepatitis, HIV, STI, and/or substance use disorders.
- 5.1.3 Integrate resources for categorical programs, address cost and coverage barriers, and work collaboratively across organizational departments to encourage crosscutting programs that address the syndemic.

Objective 5.2: Establish and increase collaboration and coordination of viral hepatitis programs and activities across public and private stakeholders

Strategies:

- 5.2.1 Establish viral hepatitis strategic planning groups at the local, state, and national levels that include people with viral hepatitis lived experience, to plan and coordinate activities and leverage available resources.
- 5.2.2 Share best practices in engagement and partnership models and strategies with strategic planning groups, advocates, and other partners; publish and disseminate lessons learned.

- 5.2.3 Coordinate and align strategic planning efforts on viral hepatitis, HIV, STIs, and substance use disorders across national, state, and local partners.
- 5.2.4 Encourage development of public-private partnerships to expand education, screening, vaccination, linkage to care, and treatment of viral hepatitis.
- 5.2.5 Improve health department–level coordination of immunizations, adult viral hepatitis activities, and prevention/management of perinatal hepatitis B infection.

Objective 5.3: Identify, evaluate, and scale-up best practices through implementation and communication science research

Strategies:

- 5.3.1 Develop and coordinate basic and translational research efforts across and within agencies to strengthen and maintain a viral hepatitis basic and translational research pipeline.
- 5.3.2 Translate viral hepatitis prevention, screening, treatment, and health disparities research into practice through evaluation, implementation, and communication science.

Objective 5.4: Improve mechanisms to measure, monitor, evaluate, report, and disseminate progress toward achieving organizational, local, and national goals

Strategies:

- 5.4.1 Share viral hepatitis surveillance data with decision-makers, health care providers, and community leaders.
- 5.4.2 Monitor, evaluate, and regularly communicate progress on viral hepatitis strategic goals and objectives according to an established schedule and address areas of deficiency.
- 5.4.3 Reduce reporting burden for funded entities through improved coordination of federal and state program and reporting requirements.

D. Priority Populations

Although viral hepatitis affects millions of Americans nationwide and from all social, economic, and racial and ethnic groups, and in all parts of the country, it disproportionately impacts certain populations and communities. Hepatitis prevention and treatment efforts can be more efficient and effective by identifying and focusing efforts on those populations that bear a disproportionately higher burden of infection and disease, referred to in the Hepatitis Plan as priority populations. The Plan uses nationwide surveillance data to determine the priority populations. Focusing on the priority populations will reduce health disparities and put the nation on the path toward elimination of viral hepatitis. This approach should not diminish efforts to increase awareness, prevention, treatment, and integration of viral hepatitis efforts more generally, for all populations. A more detailed methodology on determining priority populations is described in Appendix A.

[§] Priority population classifications are based on surveillance data and how the data is collected and reported by CDC.

Priority Populations Based on National Level-Data

National incidence, prevalence and mortality rates were used to identify a small number of groups most impacted by each type of hepatitis (see Table 2).

People may belong to none, one, or several of these populations and communities. Not surprisingly, these priority populations overlap with those most impacted by some other components of the syndemic. This underscores the need for an integrated approach to addressing the components of the syndemic. As described below, jurisdiction- or community-level data may indicate different and/or additional populations and communities disproportionately impacted by viral hepatitis.

National-level data for calendar year 2018 illustrate the disparate impact of hepatitis A, hepatitis B, and hepatitis C (Table 3). Additional data are available in CDC's Viral Hepatitis
Surveillance—United States, 2018 and are posted on CDC's website as they become available. This report is the source for all data cited below unless otherwise specified.



Table 2. Priority Populations by Hepatitis Type and Measure

	Incidence (Acute)	Prevalence (Chronic)	Mortality
Hepatitis A	 People who use drugs People experiencing homelessness 	Not applicable	
Hepatitis B	 People who inject drugs 	Asian and Pacific Islander	Asian and Pacific IslanderBlack, non-Hispanic
Hepatitis C	 People who inject drugs American Indian/Alaska Native 	 People who inject drugs Black, non-Hispanic People born 1945-1965 People with HIV 	 American Indian/ Alaska Native Black, non-Hispanic People born 1945- 1965

Additional data presented in Figures 5–9.

Table 3. Priority Populations and Summary National-Level Data, Calendar Year 2018 (unless otherwise indicated)

People Who Use and/or Inject Drugs

- Hepatitis A outbreaks have sickened more than 30,000 people across the United States since 2016; 26% of outbreak-associated patients in California, Kentucky, Michigan, and Utah are homeless and use drugs.⁷⁴
- Among reported cases with IDU information available, 50% of hepatitis A, 36% of acute hepatitis B, and 72% of acute hepatitis C cases report IDU.
- The rates of acute hepatitis B and acute hepatitis C cases are highest among age groups (aged 30-49 years for hepatitis B and aged 20-39 years for hepatitis C) most impacted by the nation's opioid crisis (Figure 5 and Figure 7).

People Experiencing Homelessness

 People experiencing homelessness comprise a large proportion (33% in outbreaks in California, Kentucky, Michigan, and Utah in 2017) of people infected during the person-to-person hepatitis A outbreaks starting in 2016.^{75,76,77}

Asian and Pacific Islander (API)

- API account for greater than 50% of Americans living with chronic hepatitis B but comprise only 5% of the total U.S. population.⁷⁸
- API had a higher hepatitis B–related mortality rate (2.1 per 100,000) compared to non-Hispanic Whites (0.27 per 100,000) (Figure 6).

Black, Non-Hispanic

- Non-Hispanic Blacks had a higher hepatitis B—related mortality rate (0.7 per 100,000) compared to non-Hispanic Whites (0.27 per 100,000) and hepatitis C-related mortality (6.31 per 100,000) compared to non-Hispanic Whites (3.35 per 100,000) (Figure 6 and Figure 9).
- The prevalence of chronic hepatitis B among sub-Saharan African immigrants in the United States ranged from 9.1 to 11.8%⁷⁹ compared to 0.28% overall.⁸⁰
- Among persons aged 20–59 and 60 years or older, non-Hispanic Blacks were more likely (OR=1.6 (1.1, 2.3) and OR=10.0 (4.9, 20.1), respectively) to have chronic hepatitis C than all other race/ethnicities.⁸¹

American Indian/Alaska Native (AI/AN)

- The incidence rate of acute hepatitis C among AI/AN have remained substantially higher than other racial/ethnic populations from 2003 to 2018. In 2018, the rate of incident acute hepatitis C was higher among AI/AN (3.6 per 100,000) than among non-Hispanic Whites (1.3 per 100,000) (Figure 8).
- The age-adjusted, hepatitis C-related mortality rate among AI/AN has been higher than all other racial/ethnic populations since 2013. The mortality rate among AI/AN was 2.7 times the rate among non-Hispanic Whites, 1.4 times the rate among non-Hispanic Blacks, 2.0 times the rate among Hispanics, and 6.3 times the rate among APIs in 2018 (Figure 9). 82

People Born from 1945 through 1965

- Approximately 75% of people with chronic hepatitis C were born from 1945 through 1965.⁸³
- People aged 55–64 (19.7 per 100,000) and 65–74 (14.8 per 100,000) had the highest mortality rates than any other age group.⁸⁴

People with HIV

- Among people with HIV who also inject drugs, 62–81% were coinfected with hepatitis
- Among people with HIV in 15 U.S. states and two cities, 6.7% were coinfected with hepatitis C.⁸⁶
- HIV patients co-infected with hepatitis B or hepatitis C have higher liver-related morbidity and mortality, and higher overall mortality than patients only infected with hepatitis B or hepatitis C. 87,88,89

Figures 5–9 depict trends related to disparities in the rates of acute hepatitis B, hepatitis B–related mortality, acute hepatitis C, and hepatitis C–related mortality.

Figures 5 and 7: The rates of acute hepatitis B and acute hepatitis C cases are highest among age groups (aged 30–49 years for hepatitis B and aged 20–39 years for hepatitis C) most impacted by the nation's opioid crisis (Figure 5 and Figure 7). These data support identifying people who inject drugs as a priority population for acute hepatitis B and hepatitis C.

Figure 6: API and non-Hispanic Blacks (priority populations for hepatitis B mortality) had higher hepatitis B—related mortality rates than non-Hispanic Whites.

Figures 8 and 9: Al/AN had higher rates of acute hepatitis C cases and hepatitis C-related mortality than non-Hispanic Whites. These data support identifying Al/AN as a priority population for acute hepatitis C and hepatitis C-related mortality.

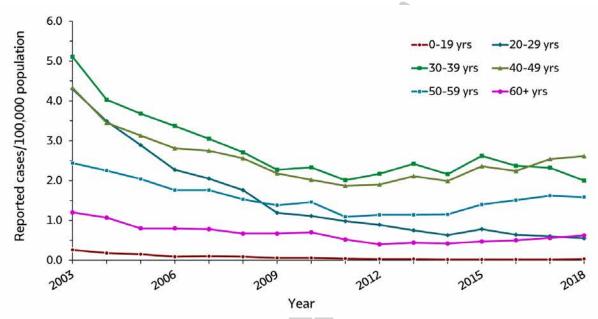


Figure 5. Rates of reported acute hepatitis B, by age group—United States, 2003-2018⁹⁰

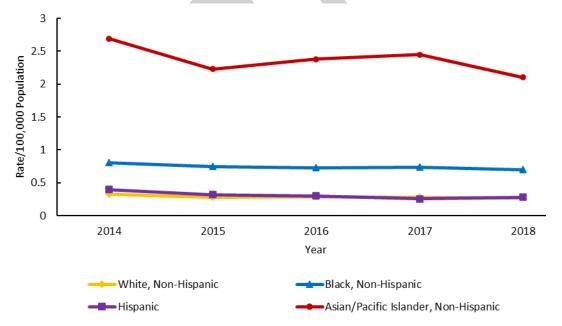


Figure 6. Rate of deaths with hepatitis B listed as a cause of death among U.S. residents, by race/ethnicity—United States. National Vital Statistics System, 2014–2018. Note: CDC considered the rates for American Indian/Alaska Native, Non-Hispanic to be "Unreliable." Rates

where death counts were fewer than 20 were not displayed due to the instability associated with those rates.

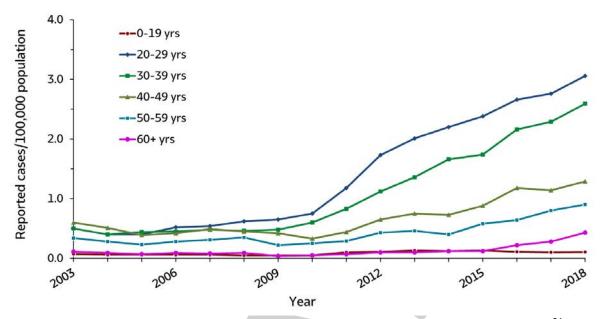


Figure 7. Rates of reported acute hepatitis C, by age group—United States, 2003–2018⁹¹

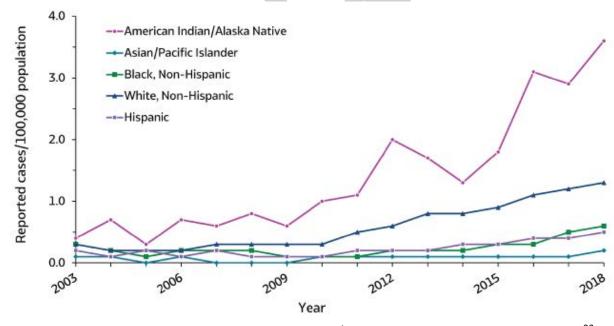


Figure 8. Rates of reported acute hepatitis C, by race/ethnicity—United States, 2003–2018⁹²

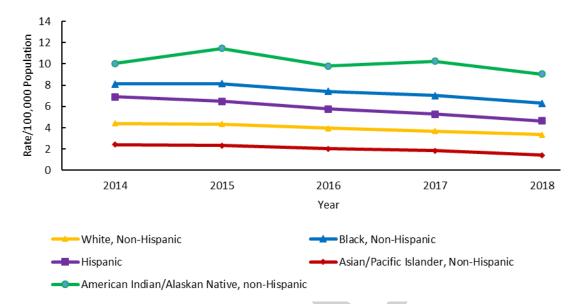


Figure 9. Age-adjusted rate of death with hepatitis C listed as main cause by race/ethnicity among U.S. residents. National Vital Statistics System, 2014-2018⁹³

High-Impact Settings

By following a syndemic approach, work to engage these populations may be more efficient and effective by identifying settings where people with viral hepatitis, at risk for HIV and other STIs, or have other risk factors commonly receive services. Settings with high numbers of people who are members of priority populations or are affected by other components of the syndemic present opportunities to efficiently identify, screen, treat, and vaccinate large numbers of disproportionately affected populations. These settings include SUD treatment programs, SSPs, correctional institutions, homeless service providers, and crisis centers. Outreach to and assessment of individuals as part of regular intake in settings with a high proportion of people at risk for one or more components of the syndemic can maximize limited staff and resources, routinize and destigmatize these services, and identify people in need of prevention and screening. Further, many people impacted by the syndemic would benefit from related services such as MAT for SUD, harm reduction services to prevent exposure to infection or accidental drug overdose, and hepatitis screening, vaccination and treatment. The importance of this approach is underscored by the many strategies in the Plan to integrate viral hepatitis prevention, treatment, and services into other settings and components of the syndemic.

The Need to Address Social Determinants of Health and Priority Populations

Many populations disproportionately impacted by viral hepatitis have historically faced disparities in health status related to the social determinants of health, such as low-paying or inconsistent employment, unstable housing or homelessness, race/ethnicity, and geographic location, or other characteristics historically linked to discrimination, stigma, or exclusion. Negative interactions with the health care or social services system may decrease the likelihood of care-seeking behavior, making viral hepatitis risk assessment, linkage to care, prevention,

and treatment more difficult. This poses additional and unique challenges to the development of broad-based solutions.

The effects of social determinants of health on viral hepatitis are clearly illustrated in the recent hepatitis A outbreaks. Some initial outbreaks were concentrated among homeless encampments in San Diego due to the lack of access to handwashing and toilet facilities, shared food and drink, and close personal contact. A mong those with outbreak-associated hepatitis A infection, a large proportion reported drug use and unstable housing. Therefore, many people infected with hepatitis A were in poor health, and hospitalization and death rates were very high (70% and 3%, respectively). Measures were taken that ultimately ended the outbreak in San Diego, including installation of hand-washing stations in areas where people experiencing homelessness frequented, widespread vaccination efforts, and changes to homeless encampment management. These outbreaks highlight the importance of efforts to address social determinants of health to improve people's health.

Focused efforts on these social determinants of health are particularly important to reduce the number of infections, morbidity, and mortality in these groups and to minimize disparities across the overall population.

Priority Populations May Differ by Stakeholder

The Hepatitis Plan highlights selected priority populations to illustrate how the data may be used to help partners with limited resources focus their efforts for the greatest public health impact. The Plan's priority populations should be useful for federal and nonfederal partners whose purview reaches everyone in this nation. However, many stakeholders who use this plan as a roadmap, including federal partners, may work with specific populations and communities more limited in scope.

The groups most impacted by viral hepatitis may differ by jurisdiction or setting, and may include additional or different populations and communities that are disproportionately impacted. For example, on a federal level, agencies such as the Indian Health Service (IHS), Department of Veterans Affairs (VA), and Administration for Community Living (ACL) serve distinct populations. State and local programs should be guided by an assessment of disproportionate impacts at their program level to help guide their efforts. State, tribal, territorial, and local jurisdictions, as well as health care providers, health plans, community-based and faith-based organizations, advocacy groups, and other institutions should review data that pertain to the populations and communities they serve. This review will help each stakeholder determine how best to focus efforts and resources to achieve results with the highest impact.

E. Indicators

The Hepatitis Plan establishes indicators, as well as baseline measures and quantitative targets, to help measure progress toward the Plan's goals. Eight core indicators will be used to measure progress on preventing new infections and improving hepatitis—related health outcomes of people with viral hepatitis (Goals 1 and 2, respectively). Five of the core indicators are stratified

by one or more of the priority populations to measure progress toward reducing disparities (Goal 3).

Indicators were selected using the following criteria. Each indicator must:

- relate to at least one of the Plan's goals;
- reflect current viral hepatitis science, policy, and medical screening guidelines;
- represent measurements of outcomes that, if changed for the positive, would be an indication of better viral hepatitis health for the nation;
- have data from a nationally representative data source, which
 - o is provided on a routine basis, enabling cross-year comparisons;
 - o allows for stratification by age, geographic region, race/ethnicity, and sex (and transmission category if available); and
- have a national impact.

For each indicator, the Hepatitis Plan identifies baseline measurements and establishes annual targets through 2030. The targets to reduce viral hepatitis rates are more aggressive than they appear on the surface because without interventions to address the epidemic these rates would likely continue to rise. Establishing 2030 targets aligns with other national plans such as *Healthy People 2030*, the HIV Plan, the STI Plan, and global targets established by the WHO. This approach also recognizes that it will likely take more than the 5-year duration of the Plan to achieve its goal of eliminating viral hepatitis in this nation. Appendix A describes the methodology for choosing indicators and the target-setting process. Appendix B sets forth the annual targets for each core and disparity indicator as well as describes the data source for each indicator.

Finally, the Hepatitis Plan recommends development of five additional indicators—referred to as developmental indicators. Nationally representative data for these developmental indicators are not currently collected and doing so would fill critical gaps in measuring the nation's efforts to address the viral hepatitis epidemic.

The specific core, disparity, and developmental indicators are explained below.

Core Indicators

This section presents each of the core indicators, explains its relevance, and provides its baseline measure (2017 unless otherwise indicated), 5-year target, and 10-year target (Table 4). At the time of target setting, 2017 data were the most recent data available. The core indicators were selected because they represent the best way to measure national progress on viral hepatitis elimination with the available data. There is a lack of standardized national surveillance data on viral hepatitis, especially in chronic infections. *Healthy People 2030* objectives will be updated to align with these targets, which also closely align with WHO's targets to eliminate hepatitis by 2030.

Table 4. Hepatitis Plan Core Indicators

Table 4. Hepatitis Flan Core maica		Baseline ^a			
		2017 unless			
		indicated	5-Year	10-Year	Data
Core Indicator	Measure	otherwise	Target	Target	Source ^b
1 Reduce new hepatitis A infections by 40% by 2025 and 65% by 2030	Estimated number of cases	6,700	4,000	2,500	NNDSS
2 Reduce acute hepatitis B infections by 20% by 2025 and 90% by 2030 ^c	Estimated number of cases	22,200	18,000	2,200	NNDSS
3 Reduce acute hepatitis C infections by 20% by 2025 and 90% by 2030 ^c	Estimated number of cases	44,700	35,000	4,400	NNDSS
4 Increase rate of hepatitis B "birth dose" vaccination to 75% by 2025 and 90% by 2030	Percentage	67	75	90	NIS-Child
5 Increase proportion of people with hepatitis B infection aware of their infection to 50% by 2025 and 90% by 2030 ^c	Percentage	32 (2013- 2016)	50	90	NHANES
6 Reduce rate of hepatitis B– related deaths by 20% by 2025 and 65% by 2030 ^c	Rate/100,000	0.46	0.37	0.16	NVSS
7 Increase proportion of people who have cleared hepatitis C infection to 58%by 2025 and 80%by 2030	Percentage	43	58	80	NHANES
8 Reduce rate of hepatitis C– related deaths by 25% by 2025 and 65% by 2030 ^c	Rate/100,000	4.13	3.00	1.44	NVSS

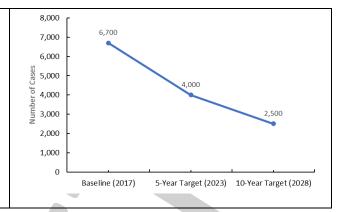
^a Data sources use different data collection and reporting methodologies.

b NHANES = <u>National Health and Nutrition Examination Survey</u>; NIS-Child = <u>National Immunization</u> <u>Survey-Children</u>; NNDSS = <u>National Notifiable Diseases Surveillance System</u>; NVSS= <u>National Vital</u> <u>Statistics System</u>. See Appendix B for descriptions of data sources. See Appendix B for descriptions of data sources.

^c This core indicator has a corresponding disparities indicator(s).

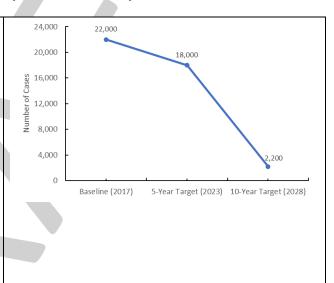
1. Reduce new hepatitis A infections by 40% by 2025 and 65% by 2030

The rate of new hepatitis A cases increased by nearly 850%⁹⁵ from 2014 to 2018 due person-to-person outbreaks in more than 33 states, primarily affecting people experiencing homelessness and people who use drugs.⁹⁶ This increase also reflects low hepatitis A vaccination rates among high-risk adults.



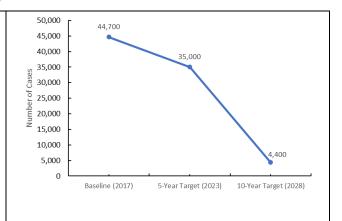
2. Reduce acute hepatitis B infections by 20% by 2025 and 90% by 2030

Acute hepatitis B infections have declined since routine vaccination of children was first recommended in 1991. ⁹⁷ However, progress has stalled and the rate of new infections has increased from 2014 to 2018, with new cases associated with injection drug use and sexual transmission. ⁹⁸ Increasing hepatitis B vaccination rates among adults at risk is the best preventive measure against hepatitis B infections. Sustained use of harm reduction strategies also reduces transmission.



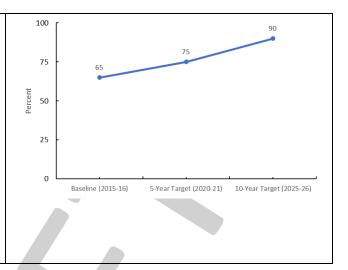
3. Reduce acute hepatitis C infections by 20% by 2025 and 90% by 2030

Acute hepatitis C cases nearly tripled from 2011 to 2018, ⁹⁹ driven primarily by injection drug use related to the opioid crisis. Hepatitis C infections are increasing most rapidly among young people, with the highest overall number of new infections among those aged 20–29 years. ¹⁰⁰ No vaccine exists, but shortcourse treatment cures 97% of people with hepatitis C.



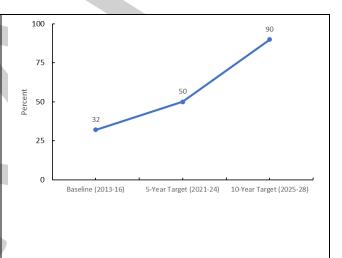
4. Increase rate of hepatitis B "birth dose" vaccination to 75% by 2025 and 90% by 2030

The hepatitis B birth dose (within 24 hours) coverage rate increased slightly from 64.0% in birth cohort 2013-2014¹⁰¹ to 66.7% in birth cohort 2015-2016.¹⁰² The universal hepatitis B vaccination within 24 hours of birth provides a critical safeguard in preventing perinatal infection from an infected mother to an infant. Strategies to improve hospital implementation include use of quality measures and provider training to address vaccine hesitancy.



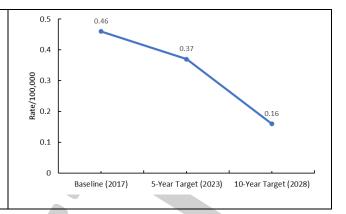
5. Increase proportion of people with HBV infection aware of their infection to 50% by 2025 and 90% by 2030

Only 32% of people with chronic hepatitis B are aware of their infection, contributing to undiagnosed cirrhosis, hepatocellular carcinoma, and early death. ¹⁰³ Increased diagnoses and awareness of infection will lead to use of antiviral treatment earlier in the course of infection, reduced adverse health outcomes and mortality, increased testing and vaccination of contacts, and reduced transmission of hepatitis B to susceptible contacts.



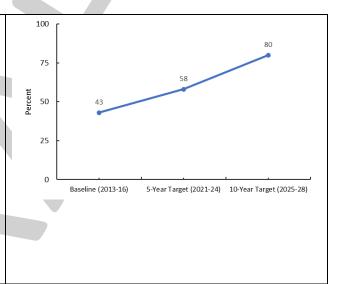
6. Reduce rate of hepatitis B-related deaths by 20% by 2025 and 65% by 2030

The rate of hepatitis B-related deaths decreased 14% from 2014 (0.5 per 100,000) to 2018 (0.43 per 100,000). 104 Strategies to continue to see declines include increased diagnoses and awareness of infection, increased linkage to care, increased access to treatment, and improved HCC diagnostics and surveillance.



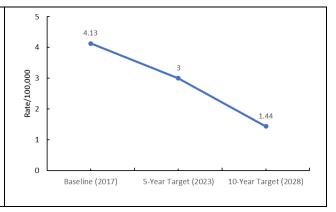
7. Increase proportion of people who have cleared hepatitis C infection to 58% by 2025 and 80% by 2030

Short-course treatment can clear and cure hepatitis C in more than 95% of people. A person who is clear of hepatitis C cannot transmit it and has improved health outcomes. In 2016, only 56% of people with hepatitis C were aware of their infection. In addition, there are numerous barriers in the health care system to hepatitis C treatment. Increasing the proportion of people who have cleared hepatitis C infection results in reduced transmission and thus number of new infections.



8. Reduce rate of hepatitis C-related deaths by 25% by 2025 and 65% by 2030

The rate of hepatitis C-related deaths decreased 26% from 2014 (5.01 per 100,000) to 2018 (3.72 per 100,000). Strategies to continue to see declines include increased diagnoses and awareness of infection, increased linkage to care, increased access to treatment and cure.



Disparities Indicators

Disparities indicators are core indicators stratified by the priority population(s) most impacted by viral hepatitis. (See Section III.D., Table 3 and Figures 5-9 for data on disparities.) Each disparities indicator uses the same data source as its corresponding core indicator. Due to the lack of nationally available data on people who inject drugs, people aged 18-40 years will be used as a proxy. Table 5 presents baseline measures as well as 5- and 10-year targets for each disparity indicator. The annual targets for each disparity indicator are presented in Appendix B.

Table 5: Hepatitis Plan Disparities Indicators^a

Disparities Indicator	Measure	Baseline 2017 unless indicated otherwise	5-Year Target	10-Year Target
9 Reduce acute hepatitis B infections among people who inject drugs ^b by 25% by 2025 and 90% by 2030	Reported rate/100,000	1.40	1.00	0.10
10 Increase proportion of people with hepatitis B infection aware of their infection among Asian and Pacific Islanders to 50% by 2025 and 90% by 2030	Percentage	39 (2013–2016)	50	90
11a Reduce rate of hepatitis B–related deaths among Asian and Pacific Islanders by 25% by 2025 and 65% by 2030	Rate/100,000	2.45	1.84	0.86
11b Reduce rate of hepatitis B–related deaths among non-Hispanic Blacks by 25% by 2025 and 65% by 2030	Rate/100,000	0.74	0.55	0.26
12a Reduce acute hepatitis C infections among people who inject drugs ^b by 20% by 2025 and 90% by 2030	Reported rate/100,000	2.30	1.70	0.20
12b Reduce acute hepatitis C infections among AI/AN by 20% by 2025 and 90% by 2030	Reported rate/100,000	2.90	2.20	0.29
13a Reduce rate of hepatitis C–related deaths among AI/AN by 30% by 2025 and 65% by 2030	Rate/100,000	10.24	7.17	3.58
13b Reduce rate of hepatitis C–related deaths among non-Hispanic Blacks by 30% by 2025 and 80% by 2030	Rate/100,000	7.03	4.92	2.46

^a Disparities indicators use the same data source as its corresponding core indicator.

^b People aged 18-40 years will be used as a proxy for people who inject drugs.

Developmental Indicators

Five developmental indicators are recommended to supplement the core and disparities indicators. These developmental indicators are not currently measured or do not have set targets, but they could be measured through available surveillance systems. However, they would help national partners monitor progress toward addressing key areas of the viral hepatitis epidemic. No quantitative targets can be established for them until the data are systematically collected. Federal and other partners are encouraged to work toward collecting the suggested data.

- 1. Reduce new hepatitis A infections
 - among people who use drugs
 - among people experiencing homelessness
- 2. Reduce proportion of states with hepatitis C treatment restrictions in their state Medicaid policies (including liver damage, sobriety, or prescriber restrictions)
- 3. Increase proportion of people with chronic hepatitis C co-infected with HIV treated and cured of hepatitis C
- 4. Increase the completeness of data values in reported acute and chronic viral hepatitis cases from state and local health departments to CDC
- 5. Increase proportion of people who have cleared hepatitis C infection
 - among people who inject drugs
 - among non-Hispanic Blacks
 - among people born from 1945 through 1965

IV. IMPLEMENTATION AND ACCOUNTABILITY

A. Federal Partners

The Hepatitis Plan presents a framework for reducing and eliminating viral hepatitis in the United States. Development of the Plan was a collaborative process led by federal partners across multiple departments and agencies with input from a wide range of stakeholders.

Federal partners will collaborate to develop an implementation plan to support the Hepatitis Plan goals, objectives, and strategies. The federal implementation plan will set forth federal partners' commitments to policies, initiatives, and activities to meet the goals and objectives of the Hepatitis Plan, and will be published for transparency and accountability. Federal partners' roles in implementation will vary based on the purview of their agencies and how much their activities overlap with the components of the Plan.

As part of their ongoing commitment to eliminate viral hepatitis as a public health threat in this nation, federal partners have committed to serve on a viral hepatitis implementation working group, continuing to provide their expertise and guidance. This implementation working group will collaborate on addressing viral hepatitis in an integrated fashion including with other components of the syndemic. The working group will meet regularly to coordinate activities across agencies and departments, implement lessons learned from epidemiological data and

research findings, monitor progress toward the indicator targets, course correct as needed, and report on national progress. As scientific, medical, and public health advances and challenges emerge, new and innovative policies will be developed to complement the existing plan.

B. Nonfederal Partners

Addressing viral hepatitis is not solely a federal activity. Success depends on coordinated action by state, tribal, territorial, and local governments; community-based and faith-based organizations; health plans and providers and other health-related organizations; private industry; nongovernmental organizations; foundations; researchers; and patients and their partners. Its success also depends on a holistic approach to the various parts of the syndemic, including HIV, STIs, SUD, stigma, discrimination, and social determinants of health.

Each community and stakeholder brings a unique perspective and plays a critical role in preventing and responding to viral hepatitis. Plans that are customized based on the jurisdiction or community served are more likely to be successful, reach that jurisdiction's or community's goals, and contribute to reaching the national goal to eliminate viral hepatitis. Stakeholders are encouraged to use this Hepatitis Plan to build their own roadmap to reduce viral hepatitis, viral hepatitis-related health disparities and inequities, and end the viral hepatitis epidemics among the populations and communities they serve. Stakeholders should consider adopting the vision and goals of this Hepatitis Plan, examining challenges from a health equity lens, implementing the objectives and strategies relevant to their role, population(s), and community(ies), applying other evidence-based objectives and strategies, using available data to identify where their resources will have the most impact, and identifying indicators and targets to measure their progress. A data-driven strategy will help stakeholders focus and efficiently and effectively use limited resources. Integrating viral hepatitis prevention and treatment efforts with other components of the syndemic, including emerging issues such as the COVID-19 pandemic, is also strongly encouraged.

APPENDIX A: PROCESS/METHODOLOGY FOR DEVELOPING AND ADOPTING THE HEPATITIS PLAN

The process for developing the Hepatitis Plan included engaging federal leadership, experts, and a variety of nonfederal partners to compile subject matter evidence and recommendations on viral hepatitis. These data were then synthesized and developed into the vision, goals, objectives, strategies, indicators, and quantitative targets that are the core of the Hepatitis Plan. This process also included aligning the components of the Plan with the next HIV Plan and the first-ever STI Plan, as well as the next National Vaccine Plan. It also included aligning the indicators and quantitative targets with *Healthy People 2030* objectives and WHO 2030 goals to eliminate viral hepatitis. The process was facilitated by the Office of Infectious Disease and HIV/AIDS Policy (OIDP), within the Office of the Assistant Secretary for Health (OASH), U.S. Department of Health and Human Services (HHS).

Concurrent development of the Hepatitis Plan and the HIV Plan has allowed for the general alignment of their visions, goals, objectives and strategies. These plans were developed by leveraging a common infrastructure, and they each aim to capitalize on synergistic opportunities to jointly address viral hepatitis and HIV. Nevertheless, despite this overlap, viral hepatitis and HIV each present unique public health challenges that justify releasing two separate plans.

Federal Leadership

Steering Committee

A federal joint steering committee for developing the Hepatitis Plan and HIV Plan set the vision, goals, and priority populations and discussed key challenges to be addressed in the strategic plan. The steering committee's work and decision-making were informed by presentations and discussions of national-level data, the current work being done and funded—especially by federal departments and agencies—related to viral hepatitis, challenges and gaps in addressing viral hepatitis in this nation, and how to integrate and leverage the work being done in other components of the syndemic. The steering committee also provided direction for the overall process. In addition, the steering committee formed subcommittees to study and propose objectives, strategies, and indicators for each of the Hepatitis Plan's goals and, in doing so, consider information gathered during the public input period. Development of the objectives and strategies was an iterative process among the steering committee, the various subcommittees, and those also leading development of the HIV Plan and STI Plan. The steering committee voted on components of the Hepatitis Plan (vision, goals, objectives, indicators, and priority populations) and provided input into the strategies for the objectives and the quantitative targets for the indicators. The steering committee consisted of senior representatives from 6 federal departments and 14 HHS agencies and offices (see Table A.1) and met regularly from January 2019 through February 2020.

Table A.1. Composition of Hepatitis Plan/HIV Plan Joint Federal Steering Committee

Federal Departments	HHS Agencies,	/Offices
• Defense	Administration for Community	 National Institutes of
Justice	Living	Health
Equal Employment	 Agency for Healthcare 	Office of the Assistant
Opportunity	Research and Quality	Secretary of Health
Commission	Centers for Disease Control	Office for Civil Rights
Health and Human	and Prevention	Office of the National
Services	Centers for Medicare &	Coordinator for Health
 Housing and Urban 	Medicaid Services	Information
Development	Food and Drug Administration	Technology
 Veterans 	Health Resources and Services	 Substance Abuse and
Administration	Administration	Mental Health Services
	Indian Health Service	Administration

Subcommittees

The Federal Steering Committee formed three subcommittees for the Hepatitis Plan and selected subject matter experts from their agencies and offices to participate:

- Prevention and Care
- Disparities and Coordination
- Indicators

These subcommittees were charged with developing and recommending objectives, strategies, and indicators. Subcommittees met at least monthly to review the latest science and evidence and develop objectives and strategies for each goal, as well as indicators. These were then reviewed and refined through an iterative process involving the steering committee and OIDP leadership. Extensive analyses by OIDP identified overlaps, gaps, alignments, and additional areas of integration among the Hepatitis Plan, HIV Plan, and STI Plan. The indicators subcommittee also worked with its counterparts for developing the HIV Plan and STI Plan to ensure that the same criteria and methods were used across plans, as appropriate.

Public Input

A crucial component in developing the Hepatitis Plan was engagement and input from nonfederal stakeholders. Stakeholders from all sectors and at all levels (i.e. community, state, regional, national) and people whose lives have been affected by viral hepatitis were encouraged to provide input on the Hepatitis Plan.

Solicitation of Public Input

To assist in developing the Hepatitis Plan, public input on the plan was solicited. Requests for public input were issued simultaneously for the Hepatitis Plan and the HIV Plan; commenters were asked to specify to which plan their comments pertained. Between September 2018 and March 2019, OIDP conducted 18 <u>listening sessions</u> at national conferences, state and regional community planning meetings, prevention trainings in rural areas, federal advisory committees,

and virtual meetings throughout the United States. Throughout this process, OIDP received 255 listening session comments regarding the Hepatitis Plan. A <u>Request for Information</u> (RFI) was published in the Federal Register during February 2019, which resulted in receipt of written public comments from 28 respondents (each submission included comments on multiple issues) for the Hepatitis Plan. After deduplication, OIDP received comments from a total of 273 unique respondents.

Method of Analysis

Comments from the listening sessions were professionally transcribed. All verbal and written comments were collated by commenter and organization. A pre-determined coding structure was developed based on questions posed during the listening sessions and in the RFI. Two coders analyzed all comments and coded the comments to themes. Coders reviewed the comment data and updated the codebook based upon dominant and emergent themes present in both listening session and RFI comments. Staff performed a qualitative analysis of all comments using NVivo 12.0, examined them for dominant themes and subthemes, and matched them to Hepatitis Plan goals.

Commenters

Thirty-eight%(n=104) of all comments (n=273) included a respondent affiliation; the commenters included representation from health care providers (n=21), national organizations (n=20), community-based organizations/faith-based organizations (n=17), local health departments (n=10), and state health departments (n=8) (see Figure A.1).

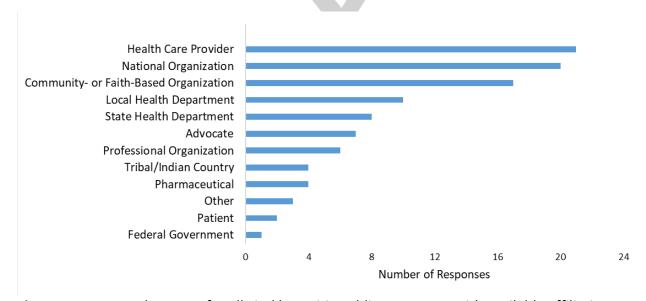


Figure A.1. Respondent type for all viral hepatitis public comments with available affiliation.

Summary of Findings

The comments addressed a broad range of topics related to viral hepatitis; dominant themes are listed in Table A.2. One comment could be coded to multiple themes.

Table A.2 Dominant Themes from Public Comments

	Number of Comments (%)
Theme	N=273
Coordination	61 (22.3%)
Priority Populations	48 (17.6%)
Funding	45 (16.5%)
Care	44 (16.1%)
Screening and Diagnostics	30 (11.0%)
Health Care Financing	27 (9.9%)
Substance Use	23 (8.4%)
Social Determinants of Health	21 (7.7%)
Prevention	17 (6.2%)
Research	11 (4.0%)
Hepatitis A Outbreak	8 (2.9%)

Input received through public comments was extremely valuable in informing development of the Plan. Analysis of the public input, including dominant themes and sub-themes along with supporting comments, were presented to the steering committee and the subcommittees. This input helped inform development of the plan's goals, objectives and strategies. For example, the majority of the comments in the dominant "Coordination" theme addressed the need for improved viral hepatitis surveillance. As a result, an additional goal was added to the Plan to improve viral hepatitis surveillance, reporting, and data usage.

Many comments pertained to the work or purview of specific agencies. These agency-specific comments were also compiled into individual reports and shared with those agencies for review and consideration.

Development of Viral Hepatitis Priority Populations

The Disparities and Coordination Subcommittee was tasked with developing recommendations for the steering committee regarding priority populations for the Hepatitis Plan. The priority populations are disproportionately impacted populations, which is defined as groups of people with a higher burden of disease than others. High-impact prevention and control interventions can focus on priority populations. Because the Hepatitis Plan is a national plan, the subcommittee and steering committee reviewed national viral hepatitis surveillance data to select priority populations. Disproportionately impacted populations will differ by jurisdiction; therefore, it is imperative that each jurisdiction review its own data to determine its own unique priority populations.

As a starting point, CDC presented its framework for priority population selection by viral hepatitis type (A, B, and C) and core measure (incidence, prevalence, and mortality) stratified by age group, race/ethnicity, and risk, utilizing 2017 surveillance data (the most recent data available when the Hepatitis Plan was developed). CDC focused on identifying disproportionately impacted populations that are socially, economically, and/or

environmentally disadvantaged. The subcommittee reviewed the national surveillance data and recommended at least one priority population for each hepatitis type and core measure, if applicable. Additional priority populations were considered using other data sources outside of those with national surveillance data. For example, people who use drugs and people experiencing homelessness were selected based on hepatitis A outbreak data₁₀₆ and people with HIV were selected based on data that showed increased morbidity and mortality among people co-infected with hepatitis C and HIV. _{107,108} It was also recognized that certain settings, such as jails and prisons, have populations disproportionately impacted by hepatitis C. Because injection drug use is the driving risk factor for hepatitis C in the justice-involved population,₁₀₉ it was decided that people who inject drugs will remain a priority population and jails and prisons will be integrated as settings into strategies that recommend specific settings for targeted interventions.

The subcommittee presented a list of recommended priority populations to the steering committee for review and adoption. The steering committee also reviewed national surveillance data provided by CDC and reviewed the evidence for other disproportionately impacted populations. The steering committee was selective in the total number of priority populations so that limited resources and interventions can focus on a smaller number of populations to have the most impact on outcomes for the nation. The final list of priority populations and the data to support the health disparity are displayed in Section III.D.

Development of Viral Hepatitis Indicators and Targets

Indicators

The Indicators Subcommittee was tasked with developing indicators and quantitative targets for the Hepatitis Plan. The subcommittee reviewed existing data sources for available hepatitis or hepatitis-related measures, potential indicators for each of the Plan's goals, and discussed limitations and gaps in existing measures and data sources. The Indicators Subcommittee, after consulting with its counterparts for the HIV Plan and STI Plan, used the following criteria to select the indicators to recommend to the steering committee. Each indicator must:

- relate to at least one of the Plan's goals;
- reflect current viral hepatitis science, policy, and medical screening guidelines;
- represent measurements of outcomes that, if changed for the positive, would be an indication of better health for the nation;
- have data from a nationally representative data source, which
 - o is provided on a routine basis, enabling cross-year comparisons;
 - allows for stratification by age, geographic region, race/ethnicity, sex, target populations (and transmission category, if available); and
- have a national impact.

Core indicators, which measure progress on a nationwide basis, were chosen by reviewing and maintaining the indicators in the *National Viral Hepatitis Action Plan 2017-2020* (NVHAP) that continue to be most representative of measuring national progress and have robust data. Other NVHAP indicators were modified to align with current data and behavioral trends. OIDP,

in coordinating development of the Hepatitis Plan, also worked with those developing *Healthy People 2030* to ensure alignment of the Hepatitis Plan quantitative targets and *Healthy People 2030 objectives*. The indicators were again reviewed and refined to maximize measurement of the Hepatitis Plan's impact.

Health disparities among the core indicators for each hepatitis virus were reviewed. Disparities indicators were developed among subgroups with the highest disparities for which data were available.

The Indicators Subcommittee also recommended development of a number of indicator measures that are not currently measured, are only reported partially, or do not currently have set targets, but would help measure some high-priority issues. Overall, five developmental indicators were chosen.

Indicator Targets

The Indicators Subcommittee, in consultation with HHS leadership, set the quantitative targets to eliminate viral hepatitis as a public health threat by 2030. It used the elimination targets set forth by WHO and in the 2017 NASEM report. The 5-year targets were developed utilizing a combination of target-setting methods. If historical data were available and the trend was improving, then a trend analysis was utilized to project 5-year targets. Otherwise, a percent improvement methodology was used to develop 5-year targets. The subcommittee also set annual targets to help assess on an ongoing basis whether the nation is on track to reach the longer-term national targets and, if not, examine what course corrections are needed. Annual targets were set by utilizing two linear curves: a straight line from baseline to the 2025 target and a straight line from 2025 to the 2030 target. The baseline used 2017 surveillance data—the most recent data available at the time of annual target development.

For hepatitis A, most of the improvement in the trend is anticipated from 2021 to 2025, which would allow efforts from 2026 to 2030 to focus on maintaining incidence at or below that seen before multistate outbreaks began during the past decade. For the remaining indicators, improvement may appear slower from 2021 to 2025 as resources are deployed to improve surveillance and interventions. This is reflected in the shallower slope of the target lines from 2021 to 2025. Improvements are expected to gain momentum from 2026 to 2030, which is reflected in the steeper slopes of the target lines from 2025 to 2030.

APPENDIX B. INDICATORS AND TARGETS

For each indicator, the Hepatitis Plan records baseline measurements and establishes 2030 targets as well as annual targets. Data sources are based on nationally representative samples. They regularly and consistently generate data, enable cross-year comparisons, and allow for stratification by age, geographic region, race/ethnicity, sex, and sex of sex partners. Due to the lag in surveillance data availability, the target year will utilize data from 2 years prior (i.e., target year 2025 will utilize surveillance data from 2023).

Core Indicators

Table B1 presents the baseline measurements, annual targets, and data sources for each core indicator. Five- and 10-year targets are bolded.

Table B1. Hepatitis Plan Core Indicators

	Measure	Baseline ^a	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	Data Source ^b
1 Reduce	new hepatitis A	infections											
	Estimated number of cases	6,700	5,800	5,350	4,900	4,450	4,000	3,700	3,400	3,100	2,800	2,500	NNDSS
2 Reduce	acute hepatitis	B infections	3										
	Estimated number of cases	22,200	20,80 0	20,10 0	19,40 0	18,70 0	18,000	14,84 0	11,68 0	8,520	5,360	2,200	NNDSS
3 Reduce	acute hepatitis	C infections ^c											
	Estimated number of cases	44,700	41,46 7	39,85 0	38,23 3	36,61 7	35,000	28,88 0	22,76 0	16,64 0	10,52 0	4,400	NNDSS
4 Increas	e rate of hepatit	tis B "birth do	ose" vacc	ination									
	Percentage	67	69	70	71	72	75	78	81	84	87	90	NIS- Child

	Measure	Baseline ^a	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	Data Source ^b
		(2015- 2016 baseline)											
5 Increase	<u>l</u> e proportion of p	-	HBV infed	tion awa	re of thei	r infectio	n ^{c,d}						
	Percentage	32 (2013- 2016 baseline)	-	41	-	-	50	-	-	-	-	90	NHANES
6 Reduce	rate of hepatitis	s B-related d	eaths ^c										
	Rate/100,000	0.46	0.44	0.42	0.41	0.39	0.37	0.33	0.29	0.24	0.20	0.16	NVSS
7 Increas	e proportion of	people who	have clea	red hepa	titis C inf	ection ^d							
	Percentage	43 (2013- 2016 baseline)	-	51	-	-	58	-	-	-	-	80	NHANES
8 Reduce	rate of hepatitis	C-related de	aths ^c										
	Rate/100,000	4.13	3.75	3.57	3.38	3.19	3.00	2.69	2.38	2.06	1.75	1.44	NVSS

^a Data sources use different data collection and reporting methodologies. Unless otherwise indicated, baseline data are for 2017.

^b NHANES = <u>National Health and Nutrition Examination Survey</u>; NIS-Child = <u>National Immunization Survey-Children</u>; NNDSS = <u>National Notifiable</u> <u>Diseases Surveillance System</u>; NVSS= <u>National Vital Statistics System</u>. See below for a description of each data source.

^c This core indicator has a corresponding disparities indicator(s).

^d For indicator 5 and 7, the sample size of the current annual data is too small to permit a stable estimate of the baseline and annual targets.

Disparities Indicators

Disparities indicators were identified by evaluating current viral hepatitis data trends and selecting priority populations most impacted. Table B.2 presents the baseline measurements and annual targets for each disparities indicator. Five- and 10-year targets are bolded. Each disparities indicator uses the same data source as its corresponding core indicator.

Table B.2 Hepatitis Plan Disparities Indicators^a

	Measure	Baseline ^b	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
9 Reduce rate of	acute hepatitis B	infections an	nong peo	ple who	nject dru	gs						
	Reported rate/100,000	1.4	1.3	1.2	1.1	1.1	1.00	0.8	0.6	0.5	0.3	0.10
10 Increase the p	proportion of peo	ple with HBV	' infectio	n aware d	of their in	fection ar	mong Asia	an and Pa	icific Islar	nders		
	Percentage	39 (2013- 2016 baseline)	-	43°	-	-	50	-	-	-	-	-
11a Reduce rate	of hepatitis B–re	lated deaths	among A	Asian and	Pacific Is	landers						
	Reported rate/100,000	2.45	2.25	2.15	2.04	1.94	1.84	1.64	1.45	1.25	1.06	0.86
11b Reduce rate	of hepatitis B–re	lated deaths	among r	non, Hisp	anic Black	(S						
	Rate/100,000	0.74	0.68	0.65	0.61	0.58	0.55	0.49	0.43	0.38	0.32	0.26
12a Reduce rate	of acute hepatiti	s C infection	s among	people w	ho inject	drugs						
	Reported rate/100,000	2.30	2.1	2.0	1.9	1.8	1.70	1.40	1.10	0.80	0.50	0.20
12b Reduce rate	of acute hepatiti	s C infection	s among	AI/AN								
	Reported rate/100,000	2.90	2.7	2.6	2.4	2.3	2.20	1.82	1.44	1.05	0.67	0.29
13a Reduce rate	of hepatitis C–rela	ated deaths	among A	I/AN								
	Rate/100,000	10.24	9.22	8.71	8.19	7.68	7.17	6.45	5.73	5.02	4.30	3.58

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	Me	easure	Baseline ^b	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
13b Reduce rate of hepatitis C-related deaths among non-Hispanic Blacks													
	Rate,	/100,000	7.03	6.33	5.98	5.82	5.27	4.92	4.43	3.94	3.44	2.95	2.46

^a Disparities indicators uses the same data source as its corresponding core indicator.

Data Sources

The <u>National Health and Nutrition Examination Survey</u> (NHANES) is a CDC program designed to assess the health and nutritional status of adults and children in the United States. A survey and physical examination of a nationally representative sample of 5,000 people each year collects demographic, socioeconomic, dietary, and health-related data as well as medical, dental, and physiological measurements and results of laboratory tests administered by medical personnel.

The <u>National Immunization Surveys</u> (NIS) are a group of telephone surveys sponsored and conducted by CDC's National Center for Immunization and Respiratory Diseases. <u>NIS-Child</u> collects data regarding children in the United States who are or will be age 19–35 months within a few weeks of the survey. Annually collected data are used to monitor vaccination coverage among 2-year-old children, including the hepatitis B birth dose, at the national, state, and selected local levels, and in some U.S. territories.

The <u>National Notifiable Diseases Surveillance System</u> (NNDSS) is a CDC program managed by its Division of Health Informatics and Surveillance that collects, analyzes, and publishes health data for approximately 120 diseases. These data, which CDC collects annually, help public health officials monitor, control, and prevent disease in the United States.

The <u>National Vital Statistics System</u> (NVSS) is the mechanism by which CDC's National Center of Health Statistics (NCHS) annually collects and disseminates the nation's official vital statistics. These data are provided through contracts between NCHS and vital registration systems operated in the various jurisdictions legally responsible for the registration of vital events – births, deaths, marriages, divorces, and fetal deaths.

^b Unless otherwise indicated, baseline data are for 2017.

^c For indicator 10, the sample size of the current annual data is too small to permit a stable estimate of the baseline and annual targets.

APPENDIX C: FEDERAL STEERING COMMITTEE, SUBCOMMITTEES, AND STAFF

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APPENDIX D. ACRONYMS

AA/PI Asian American/Pacific Islander

API Asian and Pacific Islander

ACIP Advisory Committee on Immunization Practices

ACL Administration for Community Living

AHRQ Agency for Healthcare Research and Quality

AI/AN American Indian/Alaska Native

AIDS acquired immunodeficiency syndrome

CCSQ Center for Clinical Standards and Quality

CDC Centers for Disease Control and Prevention

CEPI Center for Evidence and Practice Improvement

CHIP Children's Health Insurance Program

COVID-19 coronavirus disease 2019

CMMI Center for Medicare and Medicaid Innovation

CMS Centers for Medicare & Medicaid Services

CPD Office of Community Planning and Development

CSTE Council of State and Territorial Epidemiologists

DAA direct-acting antiviral

DoD U.S. Department of Defense

DOJ U.S. Department of Justice

EHE Ending the HIV Epidemic: A Plan for America

eCQM electronic clinical quality measures

FDA U.S. Food and Drug Administration

HAV hepatitis A virus

HBV hepatitis B virus

HCV hepatitis C virus

HEDIS Healthcare Effectiveness Data and Information Set

HHS U.S. Department of Health and Human Services

HIV human immunodeficiency virus

HRSA Health Resources and Services Administration
HUD Department of Housing and Urban Development

IDU injection drug use

IHS Indian Health Service

Viral Hepatitis National Strategic Plan: 2021-2025, draft as of September 10, 2020

IT information technology

MAT medication-assisted treatment

NASEM National Academies of Sciences, Engineering, and Medicine

NCHHSTP National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

NCHS National Center of Health Statistics

NHANES National Health and Nutrition Examination Survey
NIAID National Institute of Allergy and Infectious Diseases

NIDDK National Institute of Diabetes and Digestive and Kidney Diseases

NIH National Institute of Health

NIS National Immunization Surveys

NNDSS National Notifiable Diseases Surveillance System

NVSS National Vital Statistics System

NVHAP National Viral Hepatitis Action Plan

OASH Office of the Assistant Secretary of Health

OHH Office of HIV/AIDS Housing

OIDP Office of Infectious Disease and HIV/AIDS Policy

ONC Office of the National Coordinator for Health Information Technology

ORISE Oak Ridge Institute for Science and Education

OR Odds ratio

OWH Office on Women's Health

POC point-of-care

RFI Request for Information

RNA ribonucleic acid

SAMHSA Substance Abuse and Mental Health Services Administration

SARS-CoV-2 severe acute respiratory syndrome coronavirus 2

SSP syringe services program

STD sexually transmitted disease
STI sexually transmitted infection

SUD substance use disorder

USPSTF United States Preventive Services Task Force

VA Veterans Affairs

WHO World Health Organization

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