ABOUT THE N-HEP

These National Hepatitis Elimination Profiles (N-HEP)s bring together data on each country’s epidemiological burden, status of program delivery, and policy environment. Working with local partners, the profiles break down the essential components of effective public health initiatives and highlight achievements, challenges, and innovations for the 30 countries included. The N-HEPs serve as advocacy tools for catalyzing policy development and resource mobilization in pursuit of the 2030 hepatitis elimination goals.

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3 THE HEALTH BURDEN OF VIRAL HEPATITIS
4 PROGRESS TOWARDS 2020 WHO ELIMINATION GOALS
7 POLICY ENVIRONMENT FOR THE ELIMINATION OF HEPATITIS
15 NEXT STEPS TOWARD ELIMINATION

AT A GLANCE:

<table>
<thead>
<tr>
<th>HBV</th>
<th>HCV</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Plan</td>
<td>YES</td>
</tr>
<tr>
<td>Elimination Goal</td>
<td>YES</td>
</tr>
<tr>
<td>HepB Birth Dose Coverage</td>
<td>69%</td>
</tr>
<tr>
<td>Number of needles/syringes per PWID per year</td>
<td>30</td>
</tr>
<tr>
<td>Number of persons living with HBV</td>
<td>862,000–2.4 M</td>
</tr>
<tr>
<td>Deaths per 100,000</td>
<td>0.45</td>
</tr>
<tr>
<td>Number of persons living with chronic HCV</td>
<td></td>
</tr>
</tbody>
</table>

OVERVIEW OF POLICY ENVIRONMENT
- No national registry or system to track number of persons diagnosed and treated for HBV and HCV
- All-adult, universal HBV screening recommendations (2023) and HCV screening recommendations (2020) developed
- Universal adult HepB vaccination recommendations released in 2022

NOTABLE ACHIEVEMENTS:

KEY CHALLENGES:
- State Medicaid programs restrictions on HCV treatment access
- Limited access to harm reduction services for persons who inject drugs

KEY NEXT STEPS:
- Scale-up HBV and HCV testing for all adults
- Remove HCV treatment restrictions

THIS PDF IS INTERACTIVE!
Many elements in this report, like links and buttons, are clickable. Give it a try!
In 2021, the US Government Committed to Reaching Goals for Hepatitis Elimination

In 2020, the CDC Division of Viral Hepatitis released a [five-year strategic plan to prevent and control viral hepatitis in the United States](https://www.cdc.gov/viral-hepatitis/prevention/national-strategic-plan.html).
**THE HEALTH BURDEN OF VIRAL HEPATITIS**

### Prevalence

- **862,000–2.4 M**
  - Number of persons living with HBV infection, 2016
  - Based on national survey
  - Asian Americans, Pacific Islanders, and African-Born persons account for 50-80% of infections

- **2.4 M (2.0-2.8 M)**
  - Number of persons living with HCV infection, 2015
  - Based on national survey
  - 75% of persons with chronic HCV were born from 1945 through 1965

### Incidence

- **14,000**
  - Estimated acute HBV cases, 2020
  - 76% of all acute hepatitis B cases were persons aged 30-59 years
  - States in the Appalachian region have rates of acute hepatitis B higher than the US average
  - Although the rate of reported acute hepatitis B was the lowest among Asian/Pacific Islander persons, the rate of newly reported chronic hepatitis B was highest among this group during 2020
  - **0.45 per 100,000**
    - Rate of estimated new HBV infections

- **66,700**
  - Estimated acute HCV cases, 2020
  - Incidence highest among those aged 20-39 years and American Indians and Alaska Natives, those most affected by the opioid epidemic
  - **0.7 per 100,000**
    - Rate of estimated new HCV infections

### Mortality

- **1,752**
  - HBV deaths, 2019
  - **0.45**
    - Deaths per 100,000
  - Death rate among Asian and Pacific Islanders is 5 times the rate among White Americans

- **14,865**
  - HCV deaths, 2019
  - **3.45**
    - Deaths per 100,000
  - Death rate among Black Americans is almost 2 times the rate among White Americans
PROGRESS TOWARDS 2020 WHO ELIMINATION GOALS

PREVENTION OF NEW INFECTIONS AND MORTALITY

**HBV**
**Percentage change in new infections, 2015-2020**

-36% (WHO 2020 Target -30% (US 2025 Target <18,000 cases))

**HBV**
**Percentage change in deaths, 2015-2020**

+3% (WHO 2020 Target -10% (US 2025 Target Rate 0.37/100,000))

**HCV**
**Percentage change in new infections, 2015-2020**

+97% (WHO 2020 Target -30% (US 2025 Target <25,000 cases))

**HCV**
**Percentage change in deaths, 2015-2020**

-24% (WHO 2020 Target -10% (US 2025 Target Rate 3.00/100,000))

Prevalence of HBsAg in children < 5 years, 2019 (%)

0.03% (0.02-0.04%) (SDG 2020 Target 1%)

Trends may have been affected by disruptions in the COVID-19 pandemic

ACCESS TO RECOMMENDED VACCINATION

**Hepatitis B vaccination coverage for newborns, 2021**

69%

WHO 2020 Target 50% (US 2025 Target 75%)

**HepB 3 dose vaccine coverage for infants, 2021**

91%

WHO 2020 Target 90%
**Overall Health Burden**

- Proportion of persons living with HBV diagnosed, 2016: 32%
- Proportion of persons living with HCV diagnosed, 2016: 60%

**Access to Recommended Testing**

- Proportion of diagnosed HBV persons receiving appropriate treatment: 18%
- For persons who inject drugs (PWID), number of sterile needles per year: 30

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1. ACCESS TO RECOMMENDED TESTING

2. Proportion of persons living with HBV diagnosed, 2016

3. Proportion of persons living with HCV diagnosed, 2016

4. Proportion of diagnosed HBV persons receiving appropriate treatment

5. For persons who inject drugs (PWID), number of sterile needles per year

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COALITION FOR GLOBAL HEPATITIS ELIMINATION

USA • HEPATITIS ELIMINATION PROFILE

OVERVIEW

HEALTH BURDEN

PROGRESS

POLICY ENVIRONMENT

NEXT STEPS
**ACCESS TO RECOMMENDED TREATMENT**

*43% Proportion of persons who have cleared HCV infection, 2016*¹

**843,000**

Cumulative number of persons initiated on HCV treatment 2014-2020 ³³

Number of persons initiating HCV treatment annually ³³

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Initiations</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>109,110</td>
</tr>
<tr>
<td>2015</td>
<td>164,247</td>
</tr>
<tr>
<td>2016</td>
<td>134,287</td>
</tr>
<tr>
<td>2017</td>
<td>114,419</td>
</tr>
<tr>
<td>2018</td>
<td>122,666</td>
</tr>
<tr>
<td>2019</td>
<td>114,893</td>
</tr>
<tr>
<td>2020</td>
<td>83,740</td>
</tr>
</tbody>
</table>
## POLICY ENVIRONMENT FOR THE ELIMINATION OF HEPATITIS

### STRATEGIC INFORMATION

<table>
<thead>
<tr>
<th>Status</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine official reports to monitor HBV and HCV</td>
<td><strong>Adopted</strong></td>
</tr>
<tr>
<td><strong>Mortality</strong></td>
<td><strong>Adopted</strong></td>
</tr>
<tr>
<td><strong>Incidence</strong></td>
<td><strong>Adopted</strong></td>
</tr>
<tr>
<td><strong>Prevalence</strong></td>
<td><strong>Adopted</strong></td>
</tr>
<tr>
<td>Estimates of HBV and/or HCV economic burden</td>
<td><strong>Adopted</strong></td>
</tr>
<tr>
<td>Monitoring of HBV and HCV diagnosis and treatment</td>
<td><strong>Partially Adopted</strong></td>
</tr>
</tbody>
</table>

### ROADBLOCKS

- Inadequate surveillance data to guide service delivery for at-risk populations
- Limited funding for state HBV and HCV surveillance programs

The 2021 Viral Hepatitis Surveillance Status Report from HepVu and NASTAD found that one-third of US jurisdictions did not have a full-time employee dedicated to viral hepatitis surveillance and that only 55% of jurisdictions were able to produce annual surveillance summaries.
## PREVENTION OF MOTHER TO CHILDREN TRANSMISSION

<table>
<thead>
<tr>
<th>Policy for hepatitis B vaccination of newborns</th>
<th>Status</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adopted</td>
<td></td>
</tr>
</tbody>
</table>

Recommendations for:

- **HBV** testing of pregnant women
  - Status: Adopted

- **HCV** testing of pregnant women
  - Status: Adopted

Program for triple elimination of HIV, hepatitis B, and syphilis

- Status: Adopted

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**LEARN MORE ABOUT THE USA’S WORK IN PREVENTION OF MOTHER TO CHILD TRANSMISSION:**

**ACHIEVEMENTS**

- *Hep B Moms initiative to educate pregnant women at risk of, or infected with hepatitis B*
## ACCESS AND REGISTRATION OF MEDICINES AND TESTS

<table>
<thead>
<tr>
<th></th>
<th>Status</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registration of originator medicines</td>
<td>Adopted</td>
<td></td>
</tr>
<tr>
<td>Eligible for generic medicines</td>
<td>Not Eligible</td>
<td></td>
</tr>
<tr>
<td>Registration of generic medicines</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>Licensed point-of-care PCR testing to detect HBV and HCV</td>
<td>Not Adopted</td>
<td></td>
</tr>
</tbody>
</table>

## TESTING TO DIAGNOSE HBV AND HCV INFECTION

<table>
<thead>
<tr>
<th>Testing recommendations for:</th>
<th>Status</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HBV</strong>: Risk-based 20</td>
<td>Adopted</td>
<td></td>
</tr>
<tr>
<td><strong>HBV</strong>: Universal 35</td>
<td>Adopted</td>
<td></td>
</tr>
<tr>
<td><strong>HCV</strong>: Risk-based 20</td>
<td>Adopted</td>
<td></td>
</tr>
<tr>
<td><strong>HCV</strong>: Universal One-Time 17</td>
<td>Adopted</td>
<td></td>
</tr>
<tr>
<td>No patient co-pays for HBsAg and anti-HCV testing 21</td>
<td>Adopted</td>
<td></td>
</tr>
</tbody>
</table>
LEARN MORE ABOUT THE USA’S WORK IN TESTING TO DIAGNOSE HBV AND HCV INFECTION

ROADBLOCKS

Limited access to HCV testing in emergency departments and other priority settings beyond primary care

Two-step process for screening and diagnosis can lead to loss-to-follow-up

INNOVATIONS

In 2022, AB-789 was passed in California requiring health facilities delivering primary care to offer HBV and HCV screening to all adults.

ACHIEVEMENTS

All-adult, universal HBV screening recommendations (2023) and HCV screening recommendations (2020)

FDA down-classification of HCV diagnostics

ACCESS TO HBV AND HCV TREATMENT

<table>
<thead>
<tr>
<th>Condition</th>
<th>Status</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HBV</strong></td>
<td>National treatment guidelines</td>
<td>Developed</td>
</tr>
<tr>
<td></td>
<td>Simplified care: No patient treatment co-pays</td>
<td>Partially Adopted</td>
</tr>
<tr>
<td></td>
<td>Simplified care: Simplified treatment and monitoring algorithm for primary care providers</td>
<td>Available</td>
</tr>
<tr>
<td><strong>HCV</strong></td>
<td>National treatment guidelines</td>
<td>Available</td>
</tr>
<tr>
<td></td>
<td>Simplified care algorithm: Less than 2 clinic visits during treatment</td>
<td>Adopted</td>
</tr>
</tbody>
</table>
### USA • HEPATITIS ELIMINATION PROFILE

**OVERVIEW**

<table>
<thead>
<tr>
<th>HEALTH BURDEN</th>
<th>PROGRESS</th>
<th>POLICY ENVIRONMENT</th>
<th>NEXT STEPS</th>
</tr>
</thead>
</table>
| **HCV: Simplified care algorithm: Non-specialists can prescribe treatment** 22  
*Under Medicaid* | Partially Adopted | | |
| **HCV: Simplified care algorithm: No patient treatment co-pays** | Partially Adopted | | |
| **No fibrosis restrictions** 23  
*Under Medicaid* | Partially Adopted | | |
| **No sobriety restrictions** 23  
*Under Medicaid* | Partially Adopted | | |
| **No genotyping** 22 | Partially Adopted | | |
| **No prior authorization requirements** 23  
*Under Medicaid* | Partially Adopted | | |
| | | 46 of 52 states/territories have removed prescriber restrictions |
| | | 5 other states have no prescriber restrictions for initial/simplified treatment |
| | | Varies by payer |
| | | 50 of 52 states/territories |
| | | Only Arkansas and South Dakota still have fibrosis restrictions in place |
| | | 38 of 52 states/territories have removed substance use restrictions |
| | | Varies by payer |
| | | 31 states/territories still require prior authorization before initiation of HCV treatment 22 |

### ROADBLOCKS

**Inequities in access and affordability of HBV and HCV testing, care, and treatment**

Hepatitis B treatment remains unaffordable or out of reach to many patients due to discriminatory practices by insurance companies

Unnecessary complexity of HCV care and treatment

State Medicaid programs continue to impose restrictions on HCV treatment access, including prior authorization, and restrictions on fibrosis, substance use, prescriber, and retreatment

20 states/territories have HCV retreatment restrictions in place (based on adherence, substance use, or SVR12 documentation) under Medicaid 23

Specialty pharmacy processes and pharmacy benefit manager practices such as mandatory mail order and narrow networks limit access to treatment

### INNOVATIONS

**Project ECHO tele-mentoring to expand access to HBV and HCV treatment in under-served areas**

Sub-national HCV elimination programs, including Cherokee Nation, San Francisco, and Louisiana

**Pharmacist-led on-site HCV treatment program at needle-syringe programs in Seattle (led by the Hepatitis Education Project)**

**LEARN MORE ABOUT THE USA’S WORK IN ACCESS TO HBV AND HCV TREATMENT:**
ACHIEVEMENTS

Simplified hepatitis B treatment and monitoring algorithm for primary care providers developed

Increasing number of states removing fibrosis, sobriety, and prescribing restrictions

HEALTH EQUITY AND ADDRESSING DISPARITIES

| National strategy addresses populations most affected | Adopted |
| National anti-discrimination laws against persons living with hepatitis B and/or C | Partially Adopted |
| National policy for adult hepatitis B vaccination | Adopted |
| National policy for: |
| Harm reduction for persons who inject drugs (PWID) | Developed |
| Syringe exchange in federal prisons | Not Adopted |
| Number of needles/syringes per PWID per year | 30 |

Notes:
In 2022, The Advisory Committee on Immunization Practices recommended that all adults aged 19–59 years should receive HepB vaccine.

WHO 2020 Target: 200
**OVERVIEW**

**HEALTH BURDEN**

**PROGRESS**

**POLICY ENVIRONMENT**

**NEXT STEPS**

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**Number of opioid substitution therapy recipients per 100 PWID**
- **Not Adopted**

**Decriminalization of possession of syringes & paraphernalia**
- **Partially Adopted**

**Decriminalization of drug use**
- **Not Adopted**

**Decriminalization of hepatitis infection**
- **Partially Adopted**

3 of 51 states/territories (inc. DC)

12 of 50 states have laws that criminalize hepatitis

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**LEARN MORE ABOUT THE USA’S WORK IN HEALTH EQUITY AND ADDRESSING DISPARITIES:**

**ROADBLOCKS**

- Substantial racial/ethnic disparities in HBV and HCV incidence and mortality, including for Asian Americans and Pacific Islanders, Black Americans, and Native Americans and Alaska Natives.

- Limited access to harm reduction, safe injection equipment, and opioid substitution therapy for PWID

**ACHIEVEMENTS**

- Federal support for harm reduction awarded in the American Rescue Plan (2021)

- Universal adult HepB vaccination recommendations released in 2022, removing the need for risk factor screening and disclosure. This policy will likely increase vaccination coverage and decrease hepatitis B cases
INNOVATIONS

The HIT-B program implemented at a community health clinic primarily serving medically underserved Asian American patients – mined electronic health record (EHR) data on HBV screening and vaccination history to provide point-of-care recommendations that resulted in improvement in HBV screening and vaccination rates.

Increased US CDC support for hepatitis prevention, diagnosis, and treatment for PWID

Telehealth models to reach rural residents (e.g., Kentucky's KeY Treat Study)

Colorado Medicaid allowing entire treatment course to be dispensed at initial fill, in alignment with MINMON study

Community-based HCV testing and referral to care for homeless persons (e.g., Los Angeles)

New York State’s Drug User Health hubs, which co-locate HCV treatment at syringe exchange programs

California 1115 waiver covers a package of reentry services, including viral hepatitis care, for specific groups of persons who are incarcerated starting 90 days prior to release

FINANCING

Public budget line for HBV and HCV testing and treatment

Status

Adopted

Notes

LEARN MORE ABOUT THE USA’S WORK IN FINANCING:

INNOVATIONS

Innovative Medicaid financing programs, i.e., subscription models in Louisiana and Washington state

Michigan uses CDC DIS Workforce Development funding for HCV case management

ACHIEVEMENTS

The President’s fiscal year 2024 budget proposal included a new mandatory proposal for a national hepatitis C elimination program to increase access to curative medications, and expand implementation of complementary efforts such as screening, testing, and provider capacity with a specific focus on high-risk populations. This was the most robust federal commitment to HCV elimination to date. The proposal requests US$11.3 billion over five years, with over US$ 7 billion in savings to the health system expected.
USA’S
NEXT STEPS TOWARD ELIMINATION

- Increase support for hepatitis prevention and surveillance infrastructure linked to program planning and targeting service delivery

- Prioritize programs and partnerships to address hepatitis-related health disparities

- Scale-up HBV and HCV testing for all-adults, including for pregnant persons

- Remove restrictions to HCV treatment, including prior authorization and specific restrictions (e.g., sobriety)

- Guided by strategic information, expand access to harm reduction, including in correctional settings

- Pursue policies to expand access to HepB vaccination, care and treatment

- Expedite FDA licensure of point-of-care HBV and HCV diagnostic tests

- Leverage innovations from COVID-19 response (e.g., home-based testing)

- Increase the number of primary care treaters
SOURCES


22. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. https://www.hcvguidelines.org/


WORKING TOGETHER,
WE WILL ACHIEVE ELIMINATION.

This National Hepatitis Elimination Profile (N-HEP) was developed by the Coalition for Global Hepatitis Elimination. Funding for this N-HEP was provided by Gilead Sciences. The Coalition for Global Hepatitis Elimination retained final control over the content.

The Coalition thanks AASLD, Hepatitis B Foundation, NASTAD, National Viral Hepatitis Roundtable (NVHR), US CDC, and Norah Terrault for their review and feedback. The Coalition also is grateful to the Pan-American Health Organization for their strategic guidance and input on the design of the profile.