Hepatitis C Elimination Community Webinar II

May 31, 2023

WISCONSIN DEPARTMENT of HEALTH SERVICES

Introduction

Sheila Guilfoyle, Harm Reduction Unit Supervisor

Agenda

1. Hepatitis Reminders
2. Hepatitis A Updates
3. Hepatitis B Updates
4. Hepatitis C Updates
5. Hepatitis Elimination
6. Questions and Answers

Hepatitis Reminders

Kailynn Mitchell, Hepatitis Prevention Coordinator

Viral Hepatitis

- Inflammation of the liver.
- Functions of the liver.
- Liver inflammation and damage affects function.
- Causes of hepatitis.

Source: https://www.cdc.gov/hepatitis/abc/index.htm

Viral Hepatitis

- Often caused by a virus.
- Many people with hepatitis B and A don’t know they have an infection.
- Testing is necessary.

Source: Hepatitis Awareness Month | CDC

Viral Hepatitis

- If a person has had one type of viral hepatitis in the past, they can still get the other types.
- Hepatitis A is a **category I.**
- Hepatitis B, C, D, E are **category II.**

Information on Disease Reporting: https://dhs.wisconsin.gov/disease/reporting.htm

	Hepatitis A Virus (HAV)	Hepatitis B Virus (HBV)	Hepatitis C Virus (HCV)	Hepatitis D Virus (HDV)	Hepatitis E Virus (HEV)
Viral Genome	RNA	DNA	RNA	RNA	RNA
Transmission	Fecal-Oral	Blood and bodily fluids	Blood	Blood and bodily fluids	Fecal-Oral
Incubation	15-50 days	60-150 days	14-182 days	Requires HBV for replication	14-70 days
Testing	**IgM anti-HAV**	**HBsAg** **Anti-HBs** **Anti-HBc**	**Anti-HCV reflex to RNA**	Anti-HDV total HDV RNA	Anti-HEV total HEV RNA
Possible Chronic Infection	No	Yes	Yes	Yes	Yes
Vaccine	Yes	Yes	No	No	Yes (in China only)
Treatment	Supportive	No cure: regular monitoring and antiviral drugs	Cure with DAAs (8-12 weeks)	In development	Supportive

Hepatitis Prevention

- Hepatitis A and B vaccines.
- Hepatitis C treatment.
- Testing for hepatitis B and C.

Source: Hepatitis Awareness Month | CDC

Hepatitis Prevention

People who use or inject drugs should be **vaccinated** against hepatitis A and hepatitis B.

People who use or inject drugs should be **tested** for hepatitis B and hepatitis C.

Source: https://www.cdc.gov/hepatitis/populations/idu.htm

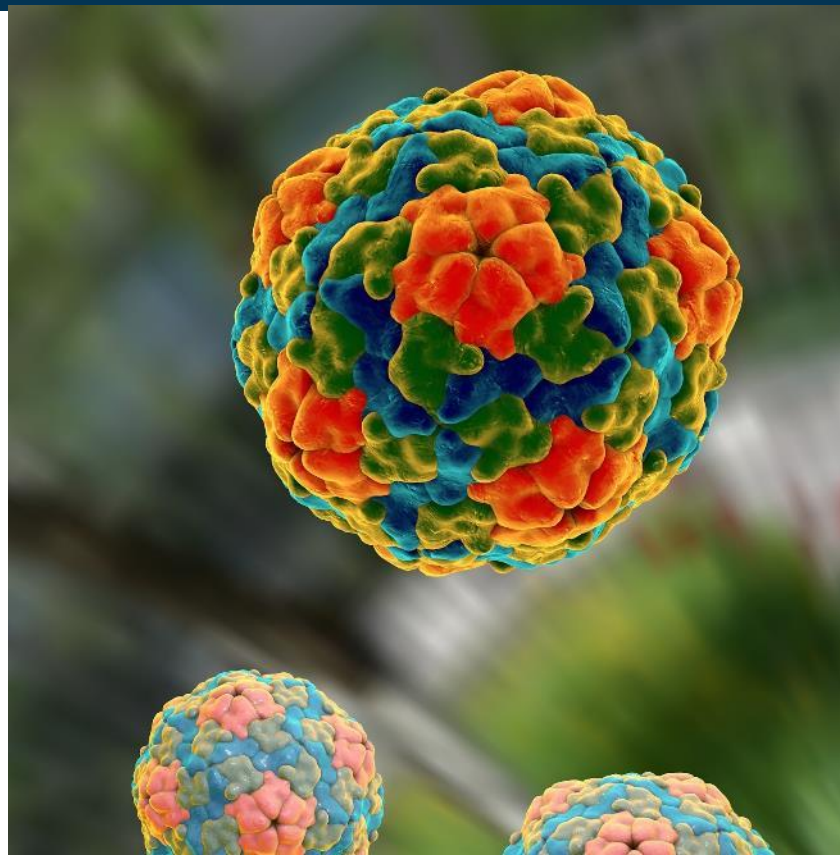
Hepatitis A Virus

Kimberly Meinholz, Hepatitis A Outreach Specialist

Susann Ahrabi-Fard, Hepatitis A Epidemiologist

Hepatitis A Virus (HAV)

- Hepatitis A is a vaccine-preventable liver infection.
- Found in stool and blood.
- Spread through fecal-oral route.



Source: https://www.cdc.gov/hepatitis/hav/index.htm

Hepatitis A Virus (HAV)

- Symptoms can last up to 2 months.
- Acute infection, not chronic.
- Can live outside the body for months.
- Vaccine is best way to prevent HAV.

Source: https://www.cdc.gov/hepatitis/hav/index.htm

Hepatitis A Virus (HAV)

- Easily spread.
- Liver failure and death.
- Food contamination.
- Foodborne outbreaks.
- Handwashing for prevention.

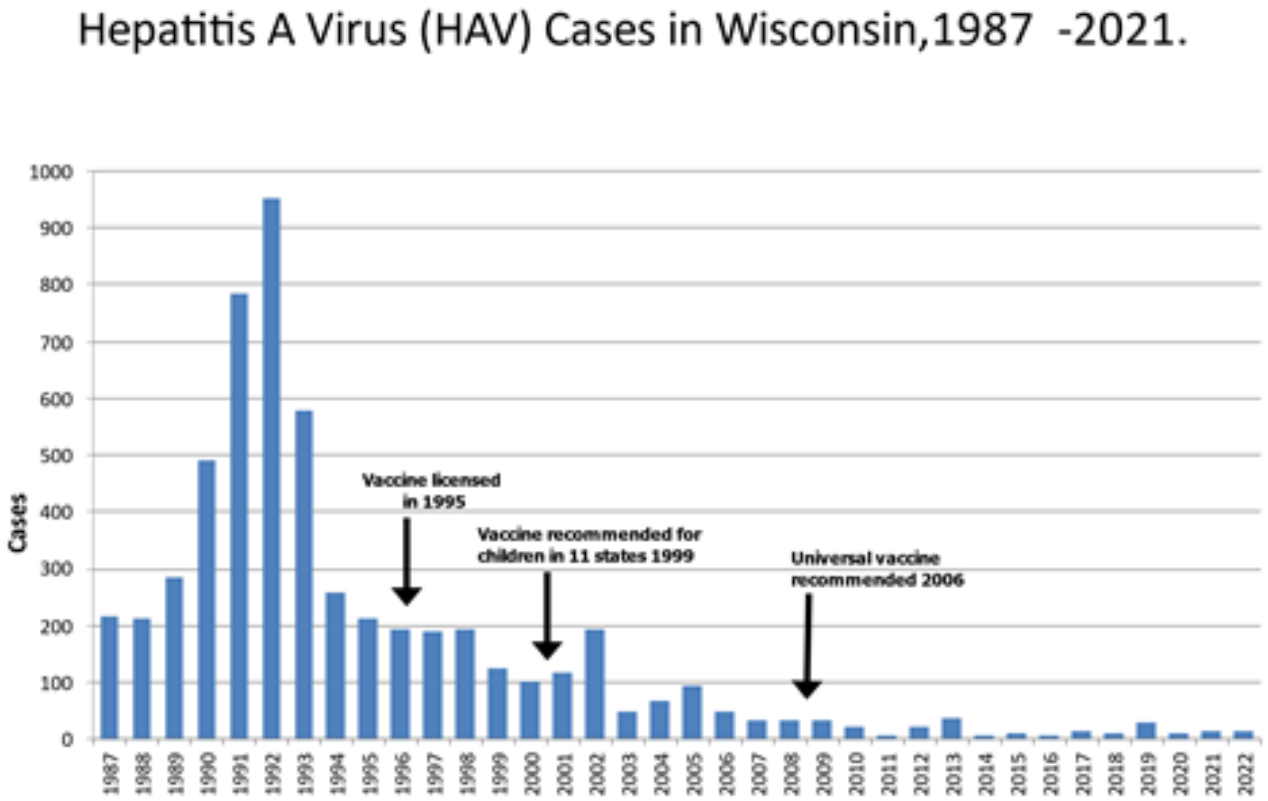
Source: https://www.cdc.gov/hepatitis/hav/pdfs/HepAGeneralFactSheet.pdf

Hepatitis A Surveillance: 2020

- 10,000 new cases.
- Cases were 7x higher than 2015.
- 20,000 hepatitis A infections in the U.S.
- 30-39 years old most affected by hepatitis A.
- 84% of cases in non-Hispanic White persons.

Source: https://www.cdc.gov/hepatitis/statistics/2020surveillance/hepatitis-a.htm

Hepatitis A Surveillance in Wisconsin



HAV Serologic Markers

- Testing required for differentiation.
- Immunoglobulin M (IgM) anti-HAV in serum **OR** HAV RNA in serum or stool.
- IgM anti-HAV is the marker of acute illness.

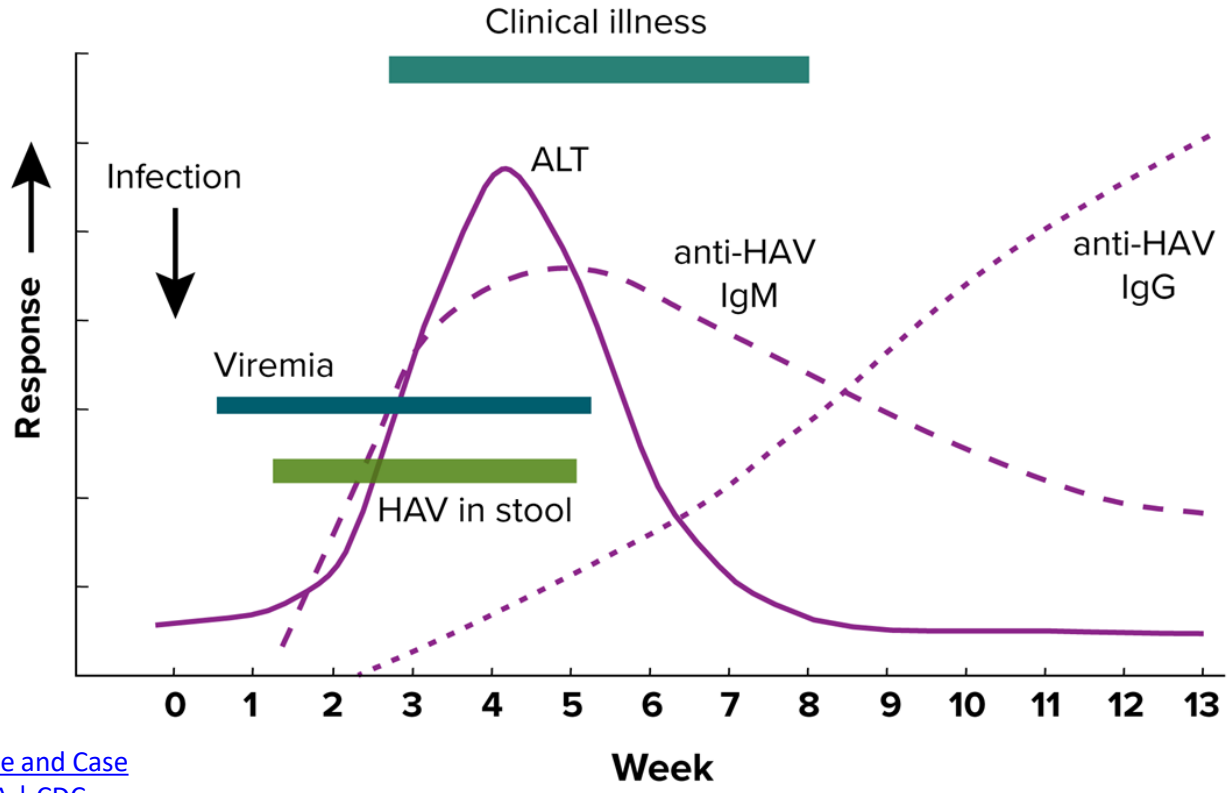
Source: https://www.cdc.gov/mmwr/volumes/69/rr/rr6905a1.htm

HAV Serologic Markers

- Test for IgM anti-HAV if symptomatic **AND** suspected of having HAV infection.
- Total anti-HAV positive sample should be tested for IgM anti-HAV.
- Persons who test positive from a total anti-HAV test and negative from an IgM anti-HAV test are considered immune, either from past infection or vaccination.

Source: https://www.cdc.gov/mmwr/volumes/69/rr/rr6905a1.htm

Typical Serologic Course of HAV



Viral Hepatitis Surveillance and Case Management - Hepatitis A | CDC

Interpretation of HAV Laboratory Results

For Discussion

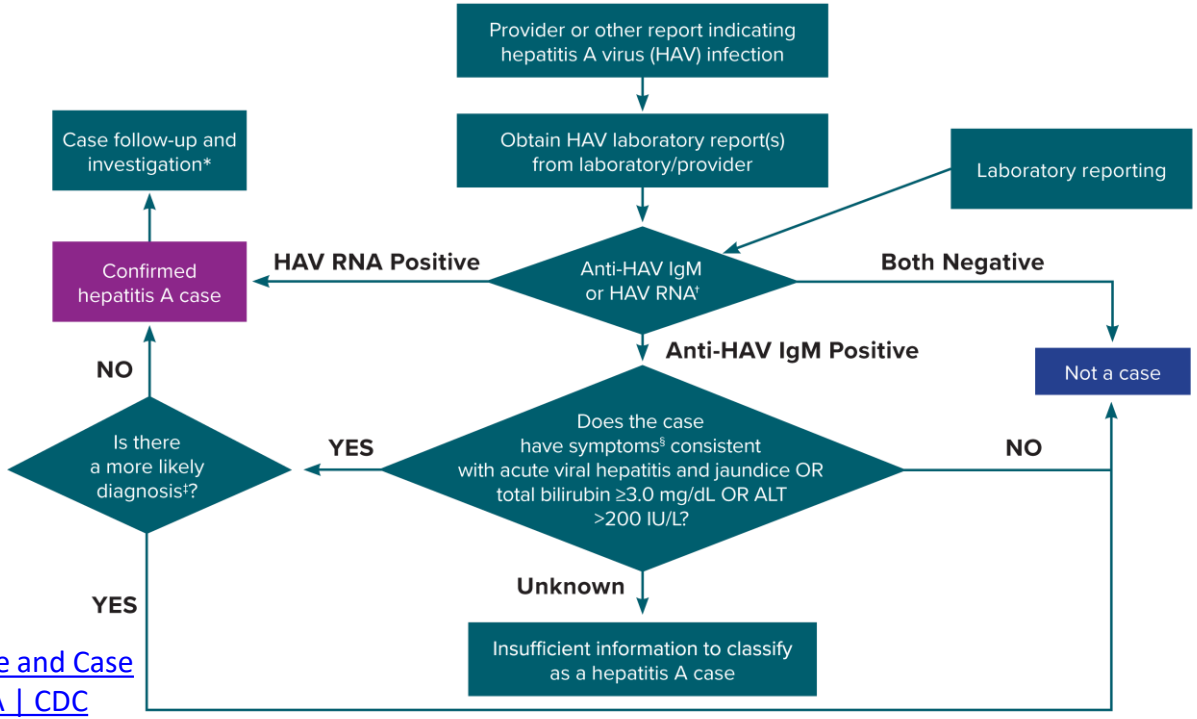
Total anti-HAV	Anti-HAV IgM	Interpretation*
Positive	Positive	Current infection, recent infection, or recent vaccination
Positive	Not done	Previous infection or current infection; cannot differentiate recent from remote infection or prior vaccination
Positive	Negative	Previous infection or vaccination
Negative	Negative	Not infected (i.e. susceptible)
Not done or negative	Positive	Current infection or false-positivity/cross-reactivity

*Ingestion of high levels of biotin can significantly interfere with certain commonly used biotinylated immunoassays, such as those used to detect anti-HAV, and cause false-positive or false-negative laboratory test results. Currently, the US Food and Drug Administration (FDA) is investigating thresholds associated with false-positive and false-negative tests. This section will be updated as more information becomes available.

Source: https://www.fda.gov/medical-devices/safety-communications/update-fda-warns-biotin-may-interfere-lab-tests-fda-safety-communication.

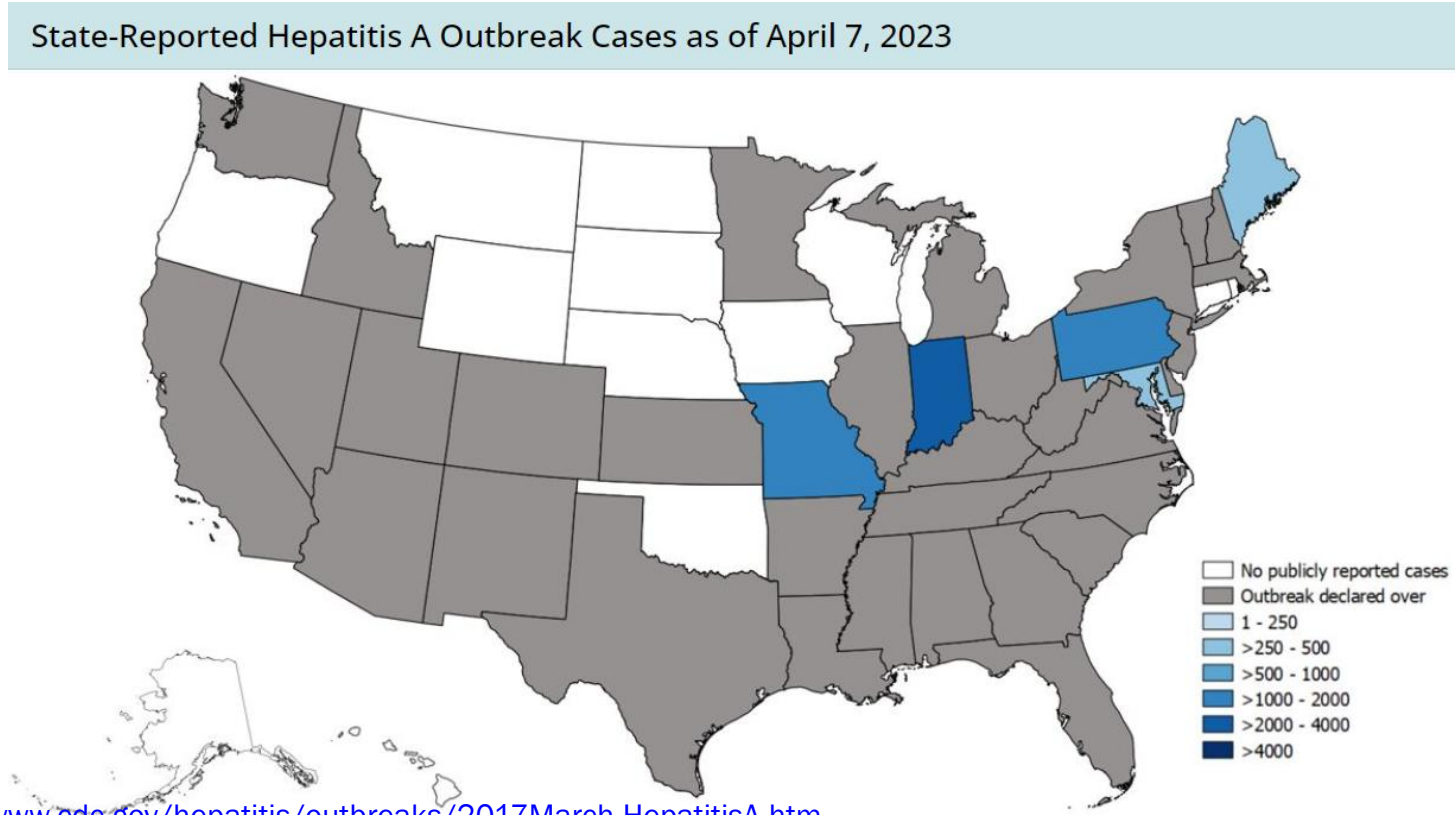
HAV Screening Recommendations

Process for Hepatitis A Case Ascertainment and Classification



[Viral Hepatitis Surveillance and Case Management - Hepatitis A | CDC]

Recent Hepatitis A Outbreaks in the U.S.



Source: https://www.cdc.gov/hepatitis/outbreaks/2017March-HepatitisA.htm

When to Suspect an Outbreak: Hepatitis A Community/Person-to-Person

- Increase in reported hepatitis A cases within a jurisdiction above baseline over a 4-week period.
- **Two or more hepatitis A cases are reported during a 50-day time period among people from similar geographic regions with common epidemiological exposures.**

HAV Vaccination Recommendations

All adults over the age of 18 years old:

- 2 dose series HepA (Havrix or Vaqta)

OR

- 3 dose series HepA-HepB (Twinrix)

AND

- Vaccine does given within 2 weeks of HAV exposure to all unvaccinated people aged >12 months of age.

HAV Vaccination Recommendations

Who should get vaccinated:

- People with chronic liver disease
- People living with HIV
- Those who have male-male sexual contact
- People who use drugs
- People experiencing homelessness
- Those who travel outside U.S.
- Pregnant individuals

Source: https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html#note-hepa

HAV Summary

- HAV age-range vaccination recommendations.
- Critical role of public health partners in getting adults caught up on vaccination.
- Vaccination is cost-saving to the healthcare system.

HAV Resources for Health Professionals

CDC Hepatitis A Guidelines and Recommendations:
https://www.cdc.gov/mmwr/volumes/69/rr/rr6905a1.htm

CDC Hepatitis A Serology Training:
https://www.youtube.com/watch?v=SB5BTwZ-Yd8

CDC Hepatitis A Questions and Answers for Health Professionals:
https://www.cdc.gov/hepatitis/hav/havfaq.htm

CDC HAV Surveillance Guidance:
https://www.cdc.gov/hepatitis/statistics/surveillanceguidance/HepatitisA.htm

Thank you!

Hepatitis A Program

Wisconsin Department of Health Services

Kimberly Meinholz – Kimberly.Meinholz@dhs.wisconsin.gov

Susann Ahrabi-Fard – Susann.AhrabiFard@dhs.wisconsin.gov

https://www.dhs.wisconsin.gov/viral-hepatitis/hav.htm

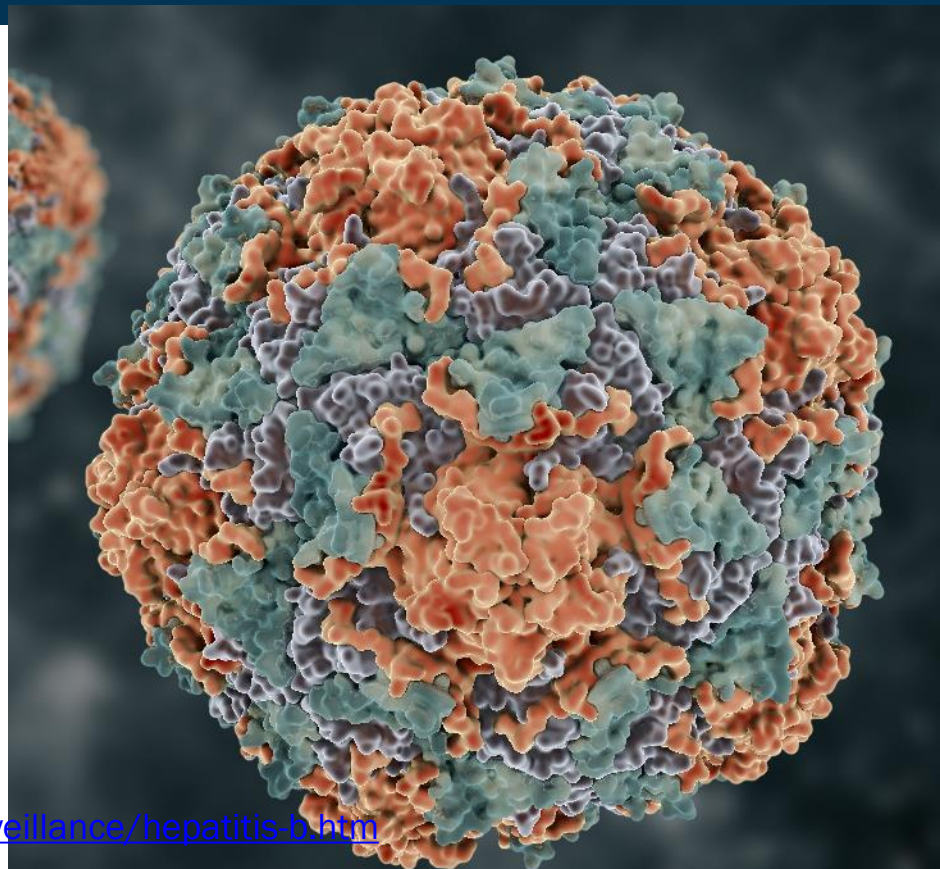
Hepatitis B Virus

Stephanie Borchardt, Hepatitis B Epidemiologist

Sarah Born, Hepatitis B Epidemiologist

Hepatitis B Virus (HBV)

- Hepatitis B is a vaccine preventable liver disease.
- Found in blood, semen, or other bodily fluids.
- Spread through sexual contact, equipment used to inject drugs, or from mother to baby.



Source: https://www.cdc.gov/hepatitis/statistics/2020surveillance/hepatitis-b.htm

Hepatitis B Virus (HBV)

- Can be acute or chronic.
- Chronic hepatitis B can lead to cirrhosis, liver cancer, and death.
- Treatments are available, but no cure exists.
- Vaccination is best way to prevent hepatitis B.

Source: https://www.cdc.gov/hepatitis/statistics/2020surveillance/hepatitis-b.htm

Hepatitis B Surveillance 2020

- Acute hepatitis B
  - 2,157 new cases
  - 14,000 acute infections
- Chronic hepatitis B
  - 11,635 new cases
  - 5 new cases per 100,000 people

Source: https://www.cdc.gov/hepatitis/statistics/2020surveillance/hepatitis-b.htm

Acute Hepatitis B in 2020

- Number of cases **decreased 32%** from 2019 through 2020.
- **76% of cases** were persons aged 30-59 years.
- **States in the Appalachian region have higher rates** than the U.S. average.
- **Rates were highest** among non-Hispanic White and non-Hispanic Black persons.

Source: https://www.cdc.gov/hepatitis/statistics/2020surveillance/hepatitis-b.htm

Chronic Hepatitis B in 2020

- Rates were **12x higher among Asian/Pacific Islander persons** than among non-Hispanic White persons.
- **88%** of new cases occurred in persons 30 years and older.
- 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.

Source: https://www.cdc.gov/hepatitis/statistics/2020surveillance/hepatitis-b.htm

Wisconsin HBV Surveillance 2021

- **One case** of perinatal hepatitis B virus infection.
- **Four cases** of acute hepatitis B virus infection.
- **358 cases** of chronic hepatitis B (confirmed or probable).

HBV Universal Screening Recommendations

- All adults aged 18 years and older at least once.
- Pregnant people during each pregnancy.
- People who are at ongoing risk for exposure should be tested periodically.

Anyone who requests HBV testing should be tested.

Source: https://www.cdc.gov/hepatitis/hbv/testingchronic.htm

New Universal HBV Screening Recommendation-March 2023

Online trainings:

- Serology:

  Online Viral Hepatitis Serology Training
  https://www.cdc.gov/hepatitis/resources/professionals/training/serology/training.htm

- Screening, Diagnosis, Evaluation, Monitoring Management, and Treatment:

  Hepatitis B Online
  https://www.hepatitisb.uw.edu/

Source: https://www.cdc.gov/hepatitis/hbv/testingchronic.htm

Hepatitis B Surface Antigen (HBsAg)

- Protein on the surface of hepatitis B virus.
- **Presence of HBsAg indicates that the person is infectious, except after a dose of hepatitis B vaccine (HepB).**
- Part of the normal immune response to infection.
- Used to make HepB vaccine.

Hepatitis B Surface Antibody (anti-HBs)

- **Presence of anti-HBs indicates recovery and immunity from hepatitis B virus infection OR successful vaccination.**
- Anti-HBs levels can decline over time, but most are still immune.

Total Antibody to Hepatitis B Core Antigen (anti-HBc)

- Appears at the onset of symptoms in acute hepatitis B.
- Is a measure of both IgM and IgG.
- Persists for life.

Total Antibody to Hepatitis B Core Antigen (anti-HBc)

- **Presence of total anti-HBc indicates previous or ongoing infection with hepatitis B virus in an undefined time frame.**
- People who have immunity to hepatitis B from a vaccine do not develop anti-HBc.

IgM Antibody to Hepatitis B Core Antigen (IgM anti-HBc)

- Positivity indicates recent infection with hepatitis B virus (<6 mos).
- Presence indicates acute infection.
- **IgM anti-HBc should be ordered only when acute HBV infection is a concern.**

Interpretation of Hepatitis B Serologic Test Results

For Discussion

Test and Result	Interpretation	Action
HBsAg—Positive Total anti-HBc — Positive IgM anti-HBc — Positive Anti-HBs — Negative	Acute infection	Link to hepatitis B care
HBsAg — Positive Total anti-HBc — Positive IgM anti-HBc — Negative[1] Anti-HBs — Negative	Chronic Infection	Link to hepatitis B care
HBsAg — Negative Total anti-HBc — Positive Anti-HBs — Positive	Resolved Infection	Counsel about HBV infection reactivation risk
HBsAg — Negative Total anti-HBc — Negative Anti-HBs — Positive[2]	Immune from receipt of prior vaccination (if documented complete series)	If no documentation of full vaccination, then complete vaccine series per ACIP recommendations.
HBsAg — Negative Total anti-HBc — Positive Anti-HBs — Negative	*Only core antibody is positive. See possible interpretations and corresponding actions:*	
	Resolved infection where anti-HBs levels have waned	Counsel about HBV infection reactivation risk
	Occult Infection	Link to hepatitis B care
	Passive transfer of anti-HBc to an infant born to an HBsAg-positive gestational parent	No action
	A false positive, thus patient is susceptible	Offer HepB vaccine per Advisory Committee on Immunization Practices (ACIP)
	A mutant HBsAg strain that is not detectable by laboratory assay	Link to hepatitis B care
HBsAg — Negative Total anti-HBc — Negative Anti-HBs — Negative[3]	Susceptible, never infected (if no documentation of HepB vaccine series completion)	Offer HepB vaccine per ACIP recommendations

Source:https://www.cdc.gov/hepatitis/hbv/interpretationOfHepBSerologicResults.htm

HBV Adult Recommendations

Population	Recommendation	
	Screening and Testing	Vaccination
Adults with no known risk factors for hepatitis B	• If never previously screened, test for HBsAg, anti-HBs, and total anti-HBc (triple panel)	• Vaccinate adults aged 18 – 59 years

Source: https://www.cdc.gov/hepatitis/hbv/hbv-routinetesting-followup.htm

HBV Adult Recommendations

People with risk factors, regardless of age, such as:	Screening and Testing	Vaccination
• People born in regions of the world with hepatitis B prevalence >2% • U.S.-born people not vaccinated as infants whose parents were born in regions with hepatitis B prevalence >8% • People with current or past injection drug use • People who share needles, or sexual contacts of people with known HBV infection • People currently or formerly incarcerated in a jail, prison, or other detention setting • People with HIV infection • People with current or past hepatitis C virus infection • Men who have sex with men • People with current or past sexually transmitted infections, or multiple sex partners • Current or former household contacts of people with known HBV infection • People on maintenance dialysis, including in-center or home hemodialysis and peritoneal dialysis, or who are predialysis • People with elevated alanine aminotransferase (ALT) or aspartate aminotransferase (AST) levels of unknown origin	• If never previously screened, test for HBsAg, anti-HBs, and total anti-HBc (triple panel) ◦ *Unless* less than aged 18 years and completed a vaccine series as an infant • If previously screened, but still unvaccinated, offer testing to people who have ongoing risk for exposure For additional screening considerations for patients on dialysis, see: Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients (cdc.gov)	• Vaccinate For additional considerations for patients on dialysis, see Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients (cdc.gov)

Source: https://www.cdc.gov/hepatitis/hbv/hbv-routinetesting-followup.htm

HBV Adult Recommendations

Other populations at risk:	Screening and Testing	Vaccination
• Residents and staff members of facilities for people with developmental disabilities • Health care and public safety personnel with reasonably anticipated risk for exposure to blood or blood-contaminated body fluids • People with diabetes at the discretion of the treating clinician • International travelers to countries with high or intermediate levels of endemic hepatitis B virus infection	• If never previously screened, test for HBsAg, anti-HBs, and total anti-HBc (triple panel) ○ *Unless* aged <18 years and completed a vaccine series as an infant For additional screening considerations for patients on dialysis see: Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients (cdc.gov)	• Vaccinate For additional vaccination considerations for healthcare personnel see: Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices | MMWR (cdc.gov)

Source: https://www.cdc.gov/hepatitis/hbv/hbv-routinetesting-followup.htm

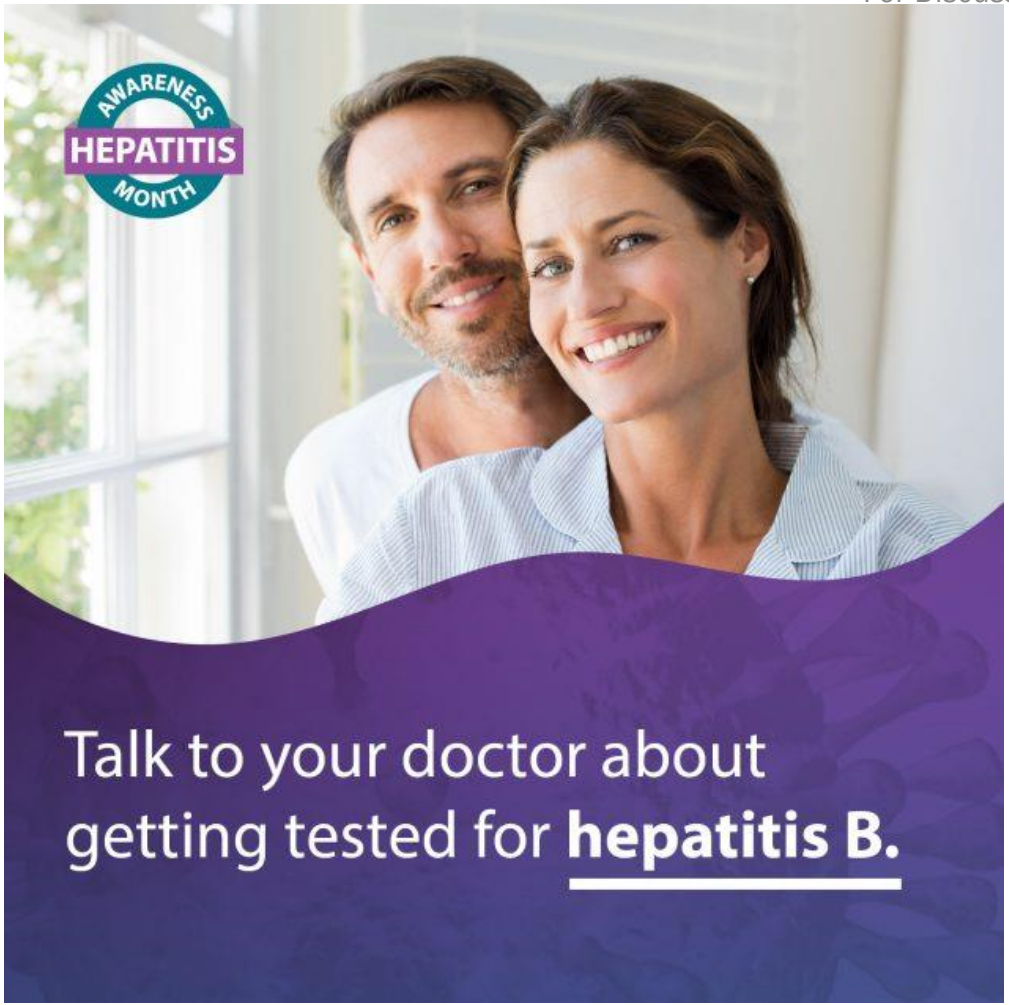
Vaccines For Adults Program

- Adults aged **19 and older are eligible to receive free vaccines if they are uninsured or underinsured.**

- Most local and tribal health departments are VFA providers.

Source: https://www.dhs.wisconsin.gov/immunization/adult.htm

Promote Hepatitis B Testing (For Public)



Hepatitis Awareness Month | CDC

Promote Hepatitis B Testing (For Providers)

Hepatitis Awareness Month | CDC

HBV Summary

- **Adults are behind on routine immunizations, including hepatitis B.**
- All **adults aged 19-59 should** receive a hepatitis B vaccine series.
- **Public health partners have a critical role to play.**
- **Vaccination against hepatitis B is cost-saving to the healthcare system.**
- Unique opportunity for providers to **get adults vaccinated** to achieve the goal of hepatitis B elimination.

HBV Resources for Health Professionals

University of Washington: Hepatitis B Online: www.hepatitis.uw.edu

CDC Online Serology Training: https://www.cdc.gov/hepatitis/resources/professionals/training/serology/training.htm

CDC Hepatitis B: https://www.cdc.gov/hepatitis/hbv/index.htm

Thank you!

Hepatitis B Program

Wisconsin Department of Health Services

Stephanie Borchardt – Stephanie.Borchardt@dhs.wisconsin.gov

Sarah Born – Sarah.Born2@dhs.wisconsin.gov

https://www.dhs.wisconsin.gov/immunization/hepb.htm

Hepatitis C

Kailynn Mitchell, Hepatitis Prevention Coordinator

STATE *of* WISCONSIN

OFFICE *of the* GOVERNOR

Proclamation

WHEREAS; millions of Americans are impacted by the hepatitis A virus (HAV), hepatitis B virus (HBV), and hepatitis C virus (HCV), which cause infection to the liver; and

WHEREAS; according to the U.S. Department of Health and Human Services, more than half of all people living with hepatitis are unaware they have it, due in large part to a lack of access to preventative care, primary care, and routine screening, thereby increasing their risk for life threatening liver disease, cancer, and unknowingly transmitting the virus to others; and

WHEREAS; practicing and accessing harm reduction strategies and services can be a successful means of preventing disease, and thanks to critical advancements in science and medicine, vaccines are available for the prevention of HAV and HBV, treatments are available for HBV and HCV, and while the body will most often naturally recover from HAV, treatments for HCV can ultimately lead to a cure; and

WHEREAS; the ongoing epidemic of opioid and other substance use in the state and across the country is contributing to the increased transmission of these viruses, which can spread through contact with infected blood, and the highest rates of new disease are occurring among Black, Hispanic, and Native American populations, exacerbating existing inequities in health and health outcomes; and

WHEREAS; the Centers for Disease Control and Prevention (CDC) recommend that everyone over the age of 18 receive a screening for HBV and HCV at least once, that pregnant individuals be screened for HBV and HCV during each pregnancy, and that the most at-risk populations be screened for HBV and HCV periodically, in addition to routine vaccination against HAV and HBV for all; and

WHEREAS; on this occasion, the state of Wisconsin joins the Wisconsin Department of Health Services and the CDC in raising awareness of hepatitis inequities, prevention, testing, and treatment and in advocating for viral hepatitis surveillance and the treatment of all persons living with chronic hepatitis;

NOW, THEREFORE, I, Tony Evers, Governor of the State of Wisconsin, do hereby proclaim May 2023 as

HEPATITIS AWARENESS MONTH

and May 19, 2023, as

HEPATITIS TESTING DAY

throughout the State of Wisconsin and I commend this observance to all our state's residents.

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the Great Seal of the State of Wisconsin to be affixed. Done at the Capitol in the City of Madison this 28th day of April 2023.

Tony Evers

TONY EVERS
GOVERNOR

By the Governor:

SARAH GODLEWSKI
Secretary of State

State of Wisconsin

Office of the Governor

Proclamation

Know More Hepatitis – CDC HCV Campaign

Test all your adult and pregnant patients for hepatitis C.

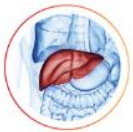
It could save their lives.

Universal screening saves lives.

CDC recommends universal hepatitis C screening for adults 18+, particularly in settings where prevalence is 0.1% or greater.

Pregnant patients? Screen for hepatitis C.

CDC recommends screening patients during each pregnancy, particularly in settings where prevalence is 0.1% or greater.



Risk factors? Test periodically.

Patients with ongoing risk factors should receive periodic ongoing testing for hepatitis C, in addition to universal screening.

When in doubt, check it out.

Reference the full CDC screening recommendations to ensure your patients receive the most up-to-date care.

Source: Hepatitis C resources for health care providers | CDC

Know More Hepatitis – CDC HCV Campaign

Hepatitis C is on the rise in the United States.
In 2020, 57% of new HCV infections occurred among adults 20 – 39 years old.

Patients with hepatitis C often have no symptoms.
Many patients with acute or chronic hepatitis C don't look or feel sick and therefore don't know they are infected.

ACOG recommends testing all pregnant patients for hepatitis C during each pregnancy.
Testing can identify future care and treatment needs.

Hepatitis C can be cured.
Simple, well-tolerated treatments can cure more than 95 percent of hepatitis C cases.

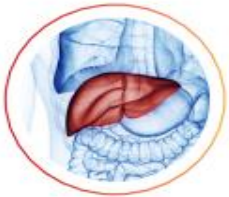
Early detection can save lives. Talk to your patients about hepatitis C testing.

Source: [Hepatitis C resources for health care providers | CDC]

CDC RECOMMENDS
Hepatitis C Testing For:

Every person 18+

At least once *



Every person with risk factors

At least once and periodically if ongoing

All pregnant people

During each pregnancy *

*In settings where prevalence is 0.1% or greater

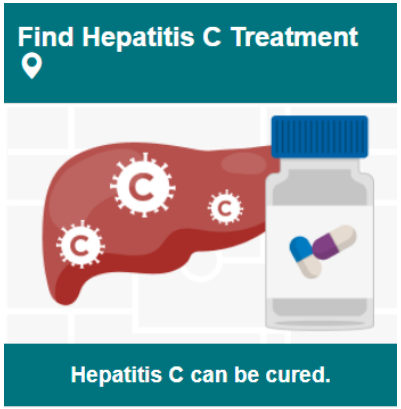
U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Source: HepC_ScreeningRecs_Factsheet.pdf (cdc.gov)

Hepatitis C Treatment Locator

Allows people to enter their zip code and find nearby health organizations that treat HCV.

If clinic would like to be added, use this online request form.



2022 National Viral Hepatitis

	Baseline 2017 data year	2020 Observed (Annual Target*)	2025 Goal 2023 data year	Trend	2020 Status
Hepatitis C					
Reduce estimated† new hepatitis C virus infections by ≥20%	44,700	66,700 (39,850)	35,000		✗
Reduce reported rate‡ of new hepatitis C virus infections among persons who inject drugs¶ by ≥25%	2.3	2.9 (2.0)	1.7		✗
Reduce reported rate‡ of hepatitis C-related deaths by ≥20%	4.13	3.45 (3.57)	3.00		✓
Reduce reported rate‡ of hepatitis C-related deaths among American Indian and Alaska Native persons by ≥30%	10.24	10.17 (8.71)	7.17		✗
Reduce reported rate‡ of hepatitis C-related deaths among non-Hispanic Black persons by ≥30%	7.03	5.63 (5.98)	4.92		✓

* Annual targets assume a constant (linear) rate of change from the observed baseline (2017) to the 2025 goal (2023 data year).
† The number of estimated viral hepatitis infections was determined by multiplying the number of reported cases by a factor that adjusted for underascertainment and underreporting (CDC 2020 Viral Hepatitis Surveillance Report and Klevens, et al, 2014).
‡ Per 100,000 population.
¶ Persons aged 18–40 years were used as a proxy for persons who inject drugs.

✓ Met or exceeded current annual target

→ Moving ***toward*** annual target, but annual target was not fully met

✗ Annual target was not met and has not changed or moved ***away*** from annual target

2022 Viral Hepatitis National Progress Report Recommendations

- Support routine hepatitis C screening for all adults.
- Increase collaborations.
- Support continuing medical education and educational campaigns.
- Build capacity of health care systems.
- Increase access to treatment and care services and other programs.

Source: https://www.cdc.gov/hepatitis/policy/npr/2022/overview.htm

U.S. Department of Health and Human Services

- Addressing Reimbursement in Viral Hepatitis Integration of Prevention and Care Services Initiative.
- Identify ways to address barriers to reimbursement for integrated viral hepatitis prevention and care services in clinical and non-clinical settings.

Source: Addressing Reimbursement in Viral Hepatitis Integration of Prevention and Care Services | HHS.gov

Payment and Reimbursement Models for Integrated Hepatitis C Services

Preliminary Findings from a Comprehensive Environmental Scan

The U.S. Department of Health and Human Services (HHS) Office of Infectious Disease and HIV/AIDS Policy (OIDP) is leading a new initiative aimed at improving the integration of viral hepatitis prevention and care services into clinical and non-clinical settings. Guided by The Viral Hepatitis National Strategic Plan for the United States: A Roadmap to Elimination (2021-2025), this initiative focuses on identifying payment, reimbursement, and other systemic barriers to integrated viral hepatitis services and identifying, scaling up or developing new models or policies that address these barriers.

OIDP conducted foundational research, inclusive of literature reviews, focus groups, and stakeholder interviews, to identify current and historical barriers to hepatitis C payment and service delivery. This document presents an overview of this initiative and preliminary findings that may inform final recommendations for financing models and/or policies that support integrated viral hepatitis service provision. The information below is not intended to be a final policy or programmatic recommendation. Next steps include development of recommendations, including financing and payment models, derived from real-world experience, that can be applied to new and existing integrated service programs. Integrated hepatitis C service provision spans a diverse array of settings, provider types, patient and community demographics, payer coverage, geographical region, and legislative landscape. As a result, the final recommendations will be presented in the context of these and other factors, as well as their feasibility for replication or adaptation for effective implementation.

Dynamics Impacting Hepatitis C Payment and Delivery of Hepatitis C Services

Barriers along the Hepatitis C Care Cascade

SCREENING & DIAGNOSIS	LINKAGE TO CARE	TREATMENT
• Limited use/availability of reflex testing (due to laboratory practices and/or limited reimbursement options) lengthens the diagnostic timeline by requiring additional sample collection • Lack of reimbursement for confirmatory RNA testing poses financial challenges on care sites to obtain diagnoses without supplemental funds • Out-of-pocket costs associated with testing (e.g., for uninsured patients) can deter patients and preclude diagnosis • Non-traditional testing locations such as syringe service programs, behavioral health programs, and mobile clinics often lack the infrastructure to retain or re-engage patients for secondary testing	• Lack of reimbursement options exist for patient navigators, care coordinators, community health workers, etc. • Lack of reimbursement for sites to provide needed support services (e.g., harm reduction support) to link and retain patients in care hinders integrated service provision • Uncertainty of future 340B program funding, used to close financial gaps, threatens programs' sustainability • Services provided at non-traditional sites may face further barriers to reimbursement (e.g., credential requirements for site management, limited reimbursement outside of "brick and mortar facilities")	• Unnecessary payer restrictions on patient medical or behavioral status require time-intensive (and often non-reimbursable) efforts to secure DAAs • Provider-type requirements (e.g., infectious disease, liver specialist) to fill DAA prescriptions impedes medication access • Treatment delays, caused by pre-authorization requirements, increase the likelihood of patients being lost to follow-up

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Select Hepatitis C Financing/Payment Model Findings

The models featured below were identified through literature review, focus group discussions, interviews, and a partner meeting. These models address payment/reimbursement of services for the different steps or the entirety of the hepatitis C care cascade and will be further evaluated in the next steps of the project.

SCREENING & DIAGNOSIS	LINKAGE TO CARE	TREATMENT
The Massachusetts FQHC model Massachusetts allocated funds for HCV-related services and required third-party billing by the state public health laboratory, resulting in substantial increases in chronic HCV diagnoses and increased linkage to care.[1]	**The Ryan White HIV/AIDS Program (RWHAP)** RWHAP funds coordination of care services for HCV and HIV co-infected persons by supporting integrated care, reducing access barriers, and driving innovative approaches to deliver HCV treatment. **Project Inspire (NYC)** A comprehensive HCV care coordination program for newly diagnosed Medicaid and Medicare beneficiaries utilized a cost-reimbursement model, resulting in a monthly cost of less than $95 per patient.[2]	**Louisiana's "Netflix" model** Louisiana contracted with Gilead Sciences to pay a flat rate for unrestricted access to treatment for Medicaid and justice-involved beneficiaries, leading to a substantial increase in prescription fills.[3] **Medicaid drug rebate program (MDRP)** Manufacturers participating in MDRP are required to pay statutory rebates to states for outpatient medication (e.g., DAAs) dispensed to Medicaid beneficiaries, thus offsetting drug costs for Medicaid beneficiaries.[4] **National Treatment Programs** Australia established a volume-based risk-sharing agreement with DAA manufacturers to secure five years of unlimited medication as part of national HCV elimination efforts.[5] The program resulted in DAA initiation in nearly one-half of those living with chronic HCV.[6] **Potential HCV Quality Measures** If developed, CMS quality measures, similar to those developed for HIV-related services, could enhance clinical service provision and drive improved patient outcomes.

HRSA's 340B program
The 340B program supports covered entities in providing medication at significantly reduced prices. Covered entities can also leverage medication cost-savings and supplemental funds to fund non-treatment services (e.g., screening, care coordination services).

The Department of Veterans Affairs (VA) model
The VA has cured over 100,000 veterans with chronic HCV infection through a coordinated model of screening and treatment, supported in large part by Congressional actions and advocacy efforts. By 2019, an estimated 85% of veterans at risk for chronic HCV infection had been tested and less than 25,000 remained in need of treatment.[7,8]

The Cherokee Nation Health Services (CNHS) model
The CNHS implemented a comprehensive community-based HCV elimination program with three-year targets for HCV screening, confirmatory testing, linkage to care, treatment, and achievement of cure. The program met or approached targets for HCV cure and linkage to care.[9]

The Bureau of Prisons' (BOP) HCV micro-elimination model leverages pharmacy providers to increase screening and treatment rates among incarcerated persons. Since its implementation in 2022, progress has been made towards goals of screening 90% of persons in custody and treating 95% of diagnosed persons.

The North Dakota Department of Corrections and Rehabilitation (DOCR), with support from the North Dakota Department of Health (NDDOH), implemented a program in which universal opt-out HCV testing was provided upon arrival. Confirmatory HCV testing is underwritten by the NDDOH, resulting in a cost far below what DOCR would pay in the private market.[10]

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Source: Payment and Reimbursement Models for Integrated Hepatitis C Services (hhs.gov)

Hepatitis C Disease Intervention Specialist (DIS)

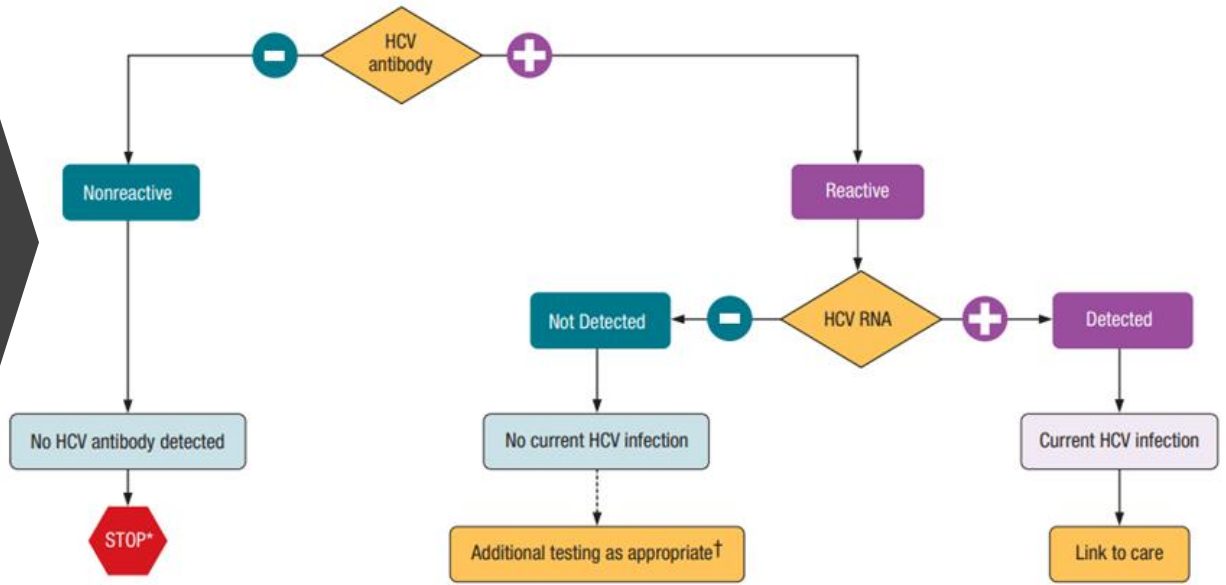
- Emily Hacker, MPH
- Email: Emily.Hacker@dhs.wisconsin.gov
- Cases they assist LTHDs with upon request:
  - Acute cases
  - Pregnant cases
  - Perinatal cases (aged 3 years or less)

Universal HCV Testing Recommendations

Who should be screened for hepatitis C?	How often?
All people aged 18 and older	At least once in lifetime
All pregnant people	During every pregnancy
All people with certain conditions, including people living with HIV	One-time testing
People with ongoing risk factors, including people who inject drugs	Routine, periodic testing

March 2020, USPSTF https://www.uspreventiveservicestaskforce.org

CDC Hepatitis C Testing Algorithm



Source: https://www.cdc.gov/hepatitis/hcv/pdfs/hcv_flow.pdf

Interpretation of HCV Test Results

Interpretation of Results of Tests for Hepatitis C Virus (HCV) Infection and Further Actions

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

TEST OUTCOME	INTERPRETATION	FURTHER ACTIONS
HCV antibody nonreactive	No HCV antibody detected	Sample can be reported as nonreactive for HCV antibody. No further action required. If recent exposure in person tested is suspected, test for HCV RNA.*
HCV antibody reactive	Presumptive HCV infection	A repeatedly reactive result is consistent with current HCV infection, or past HCV infection that has resolved, or biologic false positivity for HCV antibody. Test for HCV RNA to identify current infection.
HCV antibody reactive, HCV RNA detected	Current HCV infection	Provide person tested with appropriate counseling and link person tested to care and treatment.†
HCV antibody reactive, HCV RNA not detected	No current HCV infection	No further action required in most cases. If distinction between true positivity and biologic false positivity for HCV antibody is desired, and if sample is repeatedly reactive in the initial test, test with another HCV antibody assay. In certain situations,§ follow up with HCV RNA testing and appropriate counseling.

* If HCV RNA testing is not feasible and person tested is not immunocompromised, do follow-up testing for HCV antibody to demonstrate seroconversion. If the person tested is immunocompromised, consider testing for HCV RNA.

† It is recommended before initiating antiviral therapy to retest for HCV RNA in a subsequent blood sample to confirm HCV RNA positivity.

§ If the person tested is suspected of having HCV exposure within the past 6 months, or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

Source: CDC. Testing for HCV infection: An update of guidance for clinicians and laboratorians. MMWR 2013;62(18).

Wisconsin Medicaid HCV Treatment has…

- No sobriety restrictions.
- No provider restrictions.
- No disease severity restrictions.
- No prior authorization needed.
- Retreatment considered.

HCV Treatment

Direct Acting Antivirals (DAAs)

- Oral medication.
- >95% cure rate.
- Covered under WI Medicaid and HIV/AIDS Drug Assistance Program (ADAP).
- Patient assistance programs.
- Pharmacy partnerships can improve access.

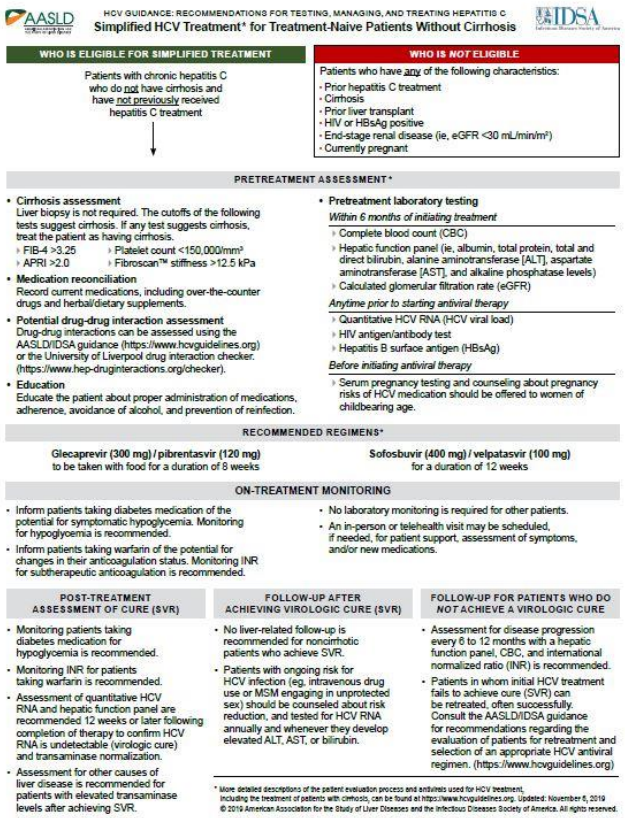
Eligibility for HCV Simplified Treatment

Eligible for Simplified Treatment	Not Eligible for Simplified Treatment
Adults with HCV infection (any genotype); treatment-naive and without cirrhosis	Prior HCV treatment
	Cirrhosis
	Known or suspected hepatocellular carcinoma
	Prior liver transplantation
	HIV or HBsAg positive
	Current pregnancy

Source: https://www.hcvguidelines.org/treatment-naive/simplified-treatment

HCV Simplified Treatment

- Exclude Advanced Fibrosis/Cirrhosis (No biopsy required)
- Screen for DDI HIV/HBsAg testing
- Pangenotypic Therapy (GLE/PIB 8 weeks or SOF/VEL 12 weeks)
- Minimal Monitoring (No HCV-related laboratory monitoring required)
- Assess for Cure→ SVR12



AASLD IDSA

HCV GUIDANCE: RECOMMENDATIONS FOR TESTING, MANAGING, AND TREATING HEPATITIS C

Simplified HCV Treatment* for Treatment-Naive Patients Without Cirrhosis

WHO IS ELIGIBLE FOR SIMPLIFIED TREATMENT

Patients with chronic hepatitis C who do not have cirrhosis and have not previously received hepatitis C treatment

WHO IS *NOT* ELIGIBLE

Patients who have any of the following characteristics:
- Prior hepatitis C treatment
- Cirrhosis
- Prior liver transplant
- HIV or HBsAg positive
- End-stage renal disease (ie, eGFR <30 mL/min/m²)
- Currently pregnant

PRETREATMENT ASSESSMENT*

- **Cirrhosis assessment**
  Liver biopsy is not required. The cutoffs of the following tests suggest cirrhosis. If any test suggests cirrhosis, treat the patient as having cirrhosis.
  - FIB-4 >3.25
  - Platelet count <150,000/mm³
  - APRI >2.0
  - Fibroscan™ stiffness >12.5 kPa
- **Medication reconciliation**
  Record current medications, including over-the-counter drugs and herbal/dietary supplements.
- **Potential drug-drug interaction assessment**
  Drug-drug interactions can be assessed using the AASLD/IDSA guidance (https://www.hcvguidelines.org) or the University of Liverpool drug interaction checker. (https://www.hep-druginteractions.org/checker).
- **Education**
  Educate the patient about proper administration of medications, adherence, avoidance of alcohol, and prevention of reinfection.
- **Pretreatment laboratory testing**

  Within 6 months of initiating treatment
  - Complete blood count (CBC)
  - Hepatic function panel (ie, albumin, total protein, total and direct bilirubin, alanine aminotransferase [ALT], aspartate aminotransferase [AST], and alkaline phosphatase levels)
  - Calculated glomerular filtration rate (eGFR)

  Anytime prior to starting antiviral therapy
  - Quantitative HCV RNA (HCV viral load)
  - HIV antigen/antibody test
  - Hepatitis B surface antigen (HBsAg)

  Before initiating antiviral therapy
  - Serum pregnancy testing and counseling about pregnancy risks of HCV medication should be offered to women of childbearing age.

RECOMMENDED REGIMENS*

Glecaprevir (300 mg) / pibrentasvir (120 mg) to be taken with food for a duration of 8 weeks

Sofosbuvir (400 mg) / velpatasvir (100 mg) for a duration of 12 weeks

ON-TREATMENT MONITORING

- Inform patients taking diabetes medication of the potential for symptomatic hypoglycemia. Monitoring for hypoglycemia is recommended.
- Inform patients taking warfarin of the potential for changes in their anticoagulation status. Monitoring INR for subtherapeutic anticoagulation is recommended.
- No laboratory monitoring is required for other patients.
- An in-person or telehealth visit may be scheduled, if needed, for patient support, assessment of symptoms, and/or new medications.

POST-TREATMENT ASSESSMENT OF CURE (SVR)

- Monitoring patients taking diabetes medication for hypoglycemia is recommended.
- Monitoring INR for patients taking warfarin is recommended.
- Assessment of quantitative HCV RNA and hepatic function panel are recommended 12 weeks or later following completion of therapy to confirm HCV RNA is undetectable (virologic cure) and transaminase normalization.
- Assessment for other causes of liver disease is recommended for patients with elevated transaminase levels after achieving SVR.

FOLLOW-UP AFTER ACHIEVING VIROLOGIC CURE (SVR)

- No liver-related follow-up is recommended for noncirrhotic patients who achieve SVR.
- Patients with ongoing risk for HCV infection (eg, intravenous drug use or MSM engaging in unprotected sex) should be counseled about risk reduction, and tested for HCV RNA annually and whenever they develop elevated ALT, AST, or bilirubin.

FOLLOW-UP FOR PATIENTS WHO DO *NOT* ACHIEVE A VIROLOGIC CURE

- Assessment for disease progression every 6 to 12 months with a hepatic function panel, CBC, and international normalized ratio (INR) is recommended.
- Patients in whom initial HCV treatment fails to achieve cure (SVR) can be retreated, often successfully. Consult the AASLD/IDSA guidance for recommendations regarding the evaluation of patients for retreatment and selection of an appropriate HCV antiviral regimen. (https://www.hcvguidelines.org)

* More detailed descriptions of the patient evaluation process and antivirals used for HCV treatment, including the treatment of patients with cirrhosis, can be found at https://www.hcvguidelines.org. Updated: November 6, 2019

Source: https://www.hcvguidelines.org/treatment-naive/simplified-treatment

Cost Effectiveness of HCV Screening and Treatment

- Untreated chronic HCV can lead to health complications.
- HCV treatment reduces the risks of these health issues.
- Cost of HCV treatment has decreased.

Source: State-of-Hep-C-Treatment-Costs-Fact-Sheet.pdf (stateofhepc.org)

Hepatitis Elimination

Kailynn Mitchell, Hepatitis Prevention Coordinator

Hepatitis Elimination

Nationwide hepatitis elimination goals by 2030 are:

- To prevent new hepatitis infections and deaths.
- To increase the number of people who know their hepatitis status.
- To ensure that every person living with hepatitis has health care and treatment, free from stigma and discrimination.

Role of Harm Reduction in Hepatitis Elimination

Prevents HCV and other infections.

Services offered:

- Hepatitis C, HIV, and STI testing
- Health education about infectious diseases
- Access to sterile supplies and exposure reduction education
- Overdose prevention trainings and naloxone (NARCAN®) distribution
- Connects clients to community resources like food banks, shelters, substance use treatment centers, healthcare systems, insurance, etc.

HCV Elimination Goals and Workgroups

Email with questions, suggestions, comments about HCV elimination planning in Wisconsin and what you would like to see included in the statewide plan.

DHSHepatitisEliminationPlan@dhs.wisconsin.gov

Workgroups will begin this summer, stay tuned!

Hepatitis C Elimination in Wisconsin

Join us!

- **Gov D Emails** – receive updates
- **Community Webinars** – attend or watch recordings and share them with colleagues and partners
- **Elimination Planning workgroups** – contribute to development of the statewide plan
- **Wisconsin Hepatitis C Elimination Plan** – review and provide feedback

How can you help eliminate HCV in Wisconsin?

- Improve universal HCV screening at health systems
- Expand access to HCV treatment at traditional and nontraditional locations
- Use simplified HCV treatment protocol
- Attend elimination community webinars
- Join elimination planning work groups
- Provide feedback on draft elimination plan

Resources for Health Professionals

Hepatitis C Guidelines for Local Public Health: www.dhs.wisconsin.gov/publications/p4/p42134.pdf

Hepatitis C Guidelines (AASLD/IDSA): www.hcvguidelines.org

University of Washington: Hepatitis C Online: www.hepatitisc.uw.edu and Hepatitis B Online: www.hepatitis.uw.edu

UCSF National Clinician Consultation Center (HCV): https://nccc.ucsf.edu/clinician-consultation/hepatitis-c-management/

Resources for Tribal Health Professionals

HCV Elimination Strategy for AI/AN Communities: https://www.indiancountryecho.org/hep-c-elimination-strategy/

The Indigenous Syndemic Strategy: Weaving Together HIV, STI, and Viral Hepatitis Plans: https://www.indiancountryecho.org/indigenous-hiv-aids-syndemic-strategy/

Guidelines for Screening, Management and Pre-Treatment Work-up for HCV within IHS, Tribal and Urban Indian Healthcare Facilities: https://cdn.indiancountryecho.org/wp-content/uploads/2022/10/HCV_Guidelines.pdf

HCV Resources Hub: https://www.indiancountryecho.org/hcv-resource-hub/

Thank you!

Hepatitis C Program

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https://www.dhs.wisconsin.gov/viral-hepatitis/hcv-program.htm

Questions?

Closing Remarks

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