Universal Screening and Vaccination to Achieve Viral Hepatitis Elimination

Rebecca Roediger, MD
Anna Mageras, MPH

May 25, 2023
Overview

1. HCV epidemiology
2. HCV screening guidelines update
3. HCV treatment overview
4. HBV epidemiology
5. HBV vaccination guidelines
6. Screening for HBV
7. Hepatitis Delta
8. Case Study: Mount Sinai Health System
Overview

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Figure 3.4 – Part 1 of 2
Rates* of reported cases† of acute hepatitis C virus infection, by age group
United States, 2005–2020


* Rates per 100,000 population.
† Reported confirmed cases. For the case definition, see https://ndc.services.cdc.gov/conditions/hepatitis-c-acute/.
Changing Age Distribution of Chronic HCV in NYC

Chronic Hepatitis C: Age Distribution

In 2011, the age distribution of hepatitis C cases in NYC showed that cases were concentrated in baby boomers (people born between 1945 and 1965) with another peak starting to form for younger people. Ten years later, there was a distinct second peak showing a concentration of hepatitis C cases in younger people, who are likely to have been infected from recent drug use.

Figure 3.8
Number of newly reported* chronic hepatitis C virus infection cases† by sex and age
United States, 2020

* During 2020, cases of chronic hepatitis C were either not reportable by law, statute, or regulation or reportable but not reportable to CDC from Arizona, Delaware, District of Columbia, Hawaii, Indiana, Kentucky, Nevada, North Carolina, Rhode Island, and Texas.
Relevance: High Rates of Newly Reported HCV in NYC in 2021

Chronic Hepatitis C: Geographic Distribution

Figure 18. Rate of people newly reported with chronic hepatitis C in NYC by NTA, 2021

Neighborhoods with the highest rates of people newly reported with chronic hepatitis C (per 100,000 people):
1. Rikers Island, Bronx (275.7)
2. Brownsville, Brooklyn (67.7)
3. Brighton Beach, Brooklyn (66.7)
4. Fordham South, Bronx (62.1)
5. East Tremont, Bronx (81.1)
6. Stapleton-Rosebank, Staten Island (79.9)
7. Queensbridge-Ravenswood, Long Island City, Queens (75.2)
8. Hunts Point, Bronx (74.1)
9. Morrisania-Matrosa, Bronx (71.6)
10. Ocean Hill, Brooklyn (69.9)

NYC rate: 38.7

Hepatitis C in NYC (2021): Demographics

As of 2019, the Health Department estimates that 86,000 people (1% of NYC residents) are living with chronic hepatitis C.\textsuperscript{18}

<table>
<thead>
<tr>
<th>Number of people newly reported with chronic hepatitis C in NYC in 2021</th>
<th>Rate of newly reported chronic hepatitis C per 100,000 people in NYC in 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,832</td>
<td>35.7</td>
</tr>
</tbody>
</table>

Hepatitis C in NYC:
DOHMH 2030 Viral Elimination Goals

- **Goal 1**: Reduce new HCV infections among people in NYC by 90% by 2030

- **Goal 2**: Reduce premature deaths among people with chronic HBV and HCV in NYC by 65% by 2030; Improve the health of people with HBV and HCV in NYC

- **Goal 3**: Reduce health inequities related to viral hepatitis infection among people in NYC

### Progress Towards DOHMH 2030 Viral Elimination Goals

<table>
<thead>
<tr>
<th>Progress Indicators</th>
<th>Baseline</th>
<th>2030 (goal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>90% of participants in the NYC Health Department Viral Hepatitis Program- contracted programs will be screened(^3) for hepatitis C</td>
<td>42% (2018)</td>
<td>90%</td>
</tr>
<tr>
<td>Data source: organizations that contract(^4) with the NYC Health Department and report screening data</td>
<td></td>
<td></td>
</tr>
<tr>
<td>80% of adults(^5) newly diagnosed with hepatitis C will be RNA negative within one year of diagnosis</td>
<td>29% (2018)</td>
<td>80%</td>
</tr>
<tr>
<td>Data source: NYC surveillance data</td>
<td></td>
<td></td>
</tr>
<tr>
<td>80% of people in NYC reported with hepatitis C since 2014 will be RNA negative</td>
<td>62% (2019)</td>
<td>80%</td>
</tr>
<tr>
<td>Data source: NYC surveillance data</td>
<td></td>
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</tr>
</tbody>
</table>

- **42%**: Percentage of hepatitis C contracted program\(^4\) participants screened in 2018. The NYC Viral Hepatitis Elimination Plan proposes a hepatitis C screening goal of 90% by 2030.

- **26%**: Percentage of people reported with a viral diagnostic test in 2021 who initiated treatment. The NYC Viral Hepatitis Elimination Plan proposes a goal of 80% of people cured within one year of diagnosis by 2030.

- **66%**: Percentage of people with a positive viral diagnostic test who have been cured or cleared of the virus. More people in NYC are being cured of hepatitis C.


HCV Epidemiology

- Cases increasing for all adult age groups, especially for 30-50 year-olds
- Even when diagnosed, only 26% initiate treatment within a year of diagnosis
- NYC DOH 2030 Viral Hepatitis Elimination goals aims to increase screening and treatment of HCV
National Viral Elimination Goals

• **2024 Federal Budget Proposal:** Billions of dollars to fund a 5 year Hepatitis C Elimination Program

• Three main priorities:
  – Accelerate availability of point of care HCV RNA
    • Test and initiate treatment in the same visit
  – Provide broad access to curative treatment
    • National subscription model to allow treatment for underserved populations
  – Comprehensive public health efforts to engage, identify, treat people with HCV
    • Support universal screening and diversify testing locations

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HCV Screening Guidelines Update

CDC 2020 Guidelines

CDC Recommendations for Hepatitis C Screening Among Adults in the United States

- **Universal hepatitis C screening:**
  - Hepatitis C screening at least once in a lifetime for all adults aged 18 years and older, except in settings where the prevalence of HCV infection (HCV RNA-positivity) is less than 0.1%.
  - Hepatitis C screening for all pregnant women during each pregnancy, except in settings where the prevalence of HCV infection (HCV RNA-positivity) is less than 0.1%.

AASLD Guidelines

<table>
<thead>
<tr>
<th>Recommendations for One-Time Hepatitis C Testing</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>One-time, routine, opt out HCV testing is recommended for all individuals aged 18 years or older.</td>
<td>I, B</td>
</tr>
<tr>
<td>One-time HCV testing should be performed for all persons less than 18 years old with activities, exposures, or conditions or circumstances associated with an increased risk of HCV infection (see below).</td>
<td>I, B</td>
</tr>
<tr>
<td>Prenatal HCV testing as part of routine prenatal care is recommended with each pregnancy.</td>
<td>I, B</td>
</tr>
<tr>
<td>Periodic repeat HCV testing should be offered to all persons with activities, exposures, or conditions or circumstances associated with an increased risk of HCV exposure (see below).</td>
<td>Ila, C</td>
</tr>
<tr>
<td>Annual HCV testing is recommended for all persons who inject drugs, for HIV-infected men who have unprotected sex with men, and men who have sex with men taking pre-exposure prophylaxis (PrEP).</td>
<td>Ila, C</td>
</tr>
</tbody>
</table>

USPSTF 2020 Guidelines

**Recommendation Summary**

<table>
<thead>
<tr>
<th>Population</th>
<th>Recommendation</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults aged 18 to 79 years</td>
<td>The USPSTF recommends screening for hepatitis C virus (HCV) infection in adults aged 18 to 79 years.</td>
<td>B</td>
</tr>
</tbody>
</table>

ACOG Guidelines

The American College of Obstetricians and Gynecologists is updating its hepatitis C screening guidance to recommend screening for all pregnant individuals during each pregnancy.
The American College of Obstetricians and Gynecologists is updating its hepatitis C screening guidance to recommend screening for all pregnant individuals during each pregnancy.

**New NYS HCV Screening Requirements**

- **All Adults**
  - Require the offer of an HCV screening test to everyone age 18 years and older.
  - Require the offer of an HCV screening test to all individuals younger than 18 years of age, if there is evidence or indication of risk activity.
  - If the HCV screening test is reactive, an HCV RNA test is performed on the same specimen or a second specimen collected at the same time.
  - All persons with a detectable HCV RNA test receive follow-up HCV health care and treatment.

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<th>Population</th>
<th>Recommendation</th>
</tr>
</thead>
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<tr>
<td>Adults aged 18 to 79 years</td>
<td>The USPSTF recommendation 79 years.</td>
</tr>
</tbody>
</table>
**Hepatitis C Screening**

*Figure 25.* Reason for hepatitis C screening among people ages 18 to 34 years newly reported with chronic hepatitis C in 2020 in NYC, interviewed through enhanced surveillance (n=290)²⁹

- Hepatitis C risk factors: 32.6%
- Routine hepatitis C screening: 28.1%
- Drug or alcohol treatment: 24.4%
- Elevated liver enzymes: 9.5%
- Jaundice: 7.2%
- Previously tested for hepatitis C: 4.1%
- Symptoms or signs: 3.2%
- Incarceration: 2.3%
- Dialysis: 1.8%
Effectiveness of Routine HCV Screening 2021

**Figure 22.** Reason for hepatitis C screening among people ages 18 to 34 years newly reported with chronic hepatitis C in NYC in 2021 interviewed through enhanced surveillance (n=200)²⁵.

- Routine screening: 58.0%
- Drug or alcohol treatment: 48.5%
- Risk factors: 31.5%
- Other: 8.5%
- Incarceration: 7.0%
- Elevated liver enzymes: 4.5%
- Symptoms or signs: 3.0%
- Previously tested for hepatitis C: 1.5%
- Jaundice: 0.5%
**How to Screen for Hepatitis C**

**HCV Ab with reflex to RNA**

**Interpretation:**
- If negative Ab: screening is complete
- If positive Ab, negative RNA: not infected
  - Cleared spontaneously
  - Previously treated
  - False positive
- If positive Ab and RNA: treat HCV
  - Refer to hepatology
  - Treat in clinic

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

- Unless risk factors for infection, one time screening is adequate

- If risk factors: recommend annual screening
  - Persons with injection drug use
  - Healthcare workers
  - Chronic dialysis
  - Anyone requesting testing

- If known exposure:
  - HCV RNA positive 1-2 weeks
  - HCV Ab positive 8-11 weeks
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HCV Treatment

Pan-genotypic direct acting antivirals are highly efficacious with minimal side effects
• Velpatasvir/Sofosbuvir (Epclusa), also panfibrotic
• Glecaprevir/Pibrentasvir (Mavyret)
• Treatment after failing the above DAA is available, recommend referral to hepatology

Insurance barriers minimized in NY State, easily accessible with specialty pharmacy

<table>
<thead>
<tr>
<th>FIBROSIS</th>
<th># of states with fibrosis restrictions</th>
<th>F2: Nebraska, Texas</th>
<th>F3: Arkansas, South Dakota</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOBRIETY</td>
<td># of states requiring a period of abstinence</td>
<td>13 (6%)</td>
<td>1 month: Florida 3 months: Arizona, Iowa, Kansas, North Dakota, Texas, West Virginia 6 months: Alabama, Arkansas, Mississippi, Nebraska, South Dakota, Tennessee</td>
</tr>
<tr>
<td></td>
<td># of states who require drug or alcohol screening or counseling</td>
<td>15 (28%)</td>
<td>Alaska, Colorado, Delaware, District of Columbia, Georgia, Hawaii, Idaho, Illinois, Maryland, Minnesota, Montana, New Hampshire, Oklahoma, South Carolina, Wyoming</td>
</tr>
<tr>
<td>PRESCRIBER</td>
<td># of states with prescriber restrictions</td>
<td>18 (35%)</td>
<td>Specialist: Arkansas, New Jersey By or in consultation with a specialist: Arizona, Colorado, District of Columbia, Hawaii, Illinois, Iowa, Mississippi, Nevada, New Hampshire, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Texas, West Virginia</td>
</tr>
</tbody>
</table>
Ongoing IV Drug Use

- Not a contraindication if will not interfere with adherence
  - Treatment can prevent spread

- Does not prevent against re-infection
  - Future screening with HCV RNA
  - HCV Ab will remain positive after cure and is not a screening test for re-infection
Evaluation Prior to Treatment

• Screen for HBV
  – Treatment has been associated with HBV reactivation
• Medication review for drug-drug interactions
  – PPIs
  – Statins
• Cirrhosis evaluation
  – Affects duration of treatment
  – Ribavirin
  – Cannot use protease inhibitors (Mavyret) in decompensated cirrhosis
• Renal failure

University of Liverpool HEP Drug Interactions
www.hep-druginteractions.org/checker
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HBV Prevalence in the U.S.

- NHANES:
  - U.S. prevalence of HBsAg+ ~ 0.30%
  - ~1.59 million persons.

- This is underestimate:
  - Institutionalized & homeless excluded
  - Immigrant populations under-sampled
  - ~2.4 million
Chronic Hepatitis B

As of 2019, the Health Department estimates that 243,000 people (2.9% of NYC residents) are living with chronic hepatitis B in NYC.\(^{13}\)

<table>
<thead>
<tr>
<th>Number of people newly reported with chronic hepatitis B in NYC in 2021</th>
<th>Rate of newly reported chronic hepatitis B per 100,000 people in NYC in 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>5,346</td>
<td>64.8</td>
</tr>
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</table>

Hepatitis B can be treated to reduce the risk of liver disease, liver cancer and premature death, yet almost half of NYC residents with hepatitis B remain undiagnosed.\(^{3}\)

46% Almost half of NYC residents with hepatitis B are estimated to be undiagnosed.\(^{3}\)

<table>
<thead>
<tr>
<th>Percentage of people who died prematurely</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis B infection</td>
</tr>
<tr>
<td>Citywide (including hepatitis B)</td>
</tr>
</tbody>
</table>

The percentage of people with hepatitis B who die prematurely is 1.5 times higher than all premature deaths in NYC.

Figure 2.4 – Part 1 of 2
Rates* of reported cases† of acute hepatitis B virus infection, by age group
United States, 2005–2020

* Rates per 100,000 population.
† Reported confirmed cases. For the case definition, see https://ndc.services.cdc.gov/conditions/hepatitis-b-acute/.

Source: CDC, National Notifiable Diseases Surveillance System.
Published September 2022.
HBV Epidemiology

- Prevalence of HBV in NYC is ~2.9%
- 46% of people with chronic HBV are undiagnosed
- Rates of HBV are increasing in >40yo
  - All rates dropped in 2020 as fewer people accessed healthcare/routine screening
  - Stable or decreasing in 0-39yo
  - Universal newborn vaccination instituted 1991
# Hepatitis B in NYC: Progress Towards DOHMH 2030 Viral Elimination Goals

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<tr>
<th>Progress Indicators</th>
<th>Baseline</th>
<th>2030 (goal)</th>
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</thead>
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<tr>
<td>90% of participants in the NYC Health Department Viral Hepatitis Program-contracted programs at risk for hepatitis B infection will be screened</td>
<td>57% (2018)</td>
<td>90%</td>
</tr>
<tr>
<td>Data source: organizations that contract with the NYC Health Department and report screening data</td>
<td></td>
<td></td>
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</tbody>
</table>

- Percentage of Check Hep B program participants at risk for hepatitis B infection who were screened in 2018: 57%
- The NYC Viral Hepatitis Elimination Plan proposes a hepatitis B screening goal of 90% by 2030.

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<th>Progress Indicators</th>
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<th>2030 (goal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>80% of people in NYC reported with hepatitis B since 2018 who meet American Association for the Study of Liver Diseases (AASLD) treatment criteria will be virally suppressed</td>
<td>Being assessed in 2021</td>
<td>80%</td>
</tr>
<tr>
<td>Data source: NYC surveillance data</td>
<td></td>
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</tr>
</tbody>
</table>

- Percentage of Health Department tele-navigation program participants linked to hepatitis B medical care who were virally suppressed in 2021: 73%
- The NYC Viral Hepatitis Elimination Plan proposes a hepatitis B viral suppression goal of 80% by 2030 for people eligible for treatment.


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In 2021, the Advisory Committee on Immunization Practices (ACIP) for the CDC recommended universal HBV vaccination for all adults <60 years

- "Risk-based [recommendation] is a failed policy. The evidence is overwhelming." — Former ACIP chair Carol Baker, MD
- Nationally only 25% of adults are vaccinated
  - Only 39% of those with chronic liver diseases

**Hepatitis B vaccination**

<table>
<thead>
<tr>
<th>Routine vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age 19 through 59 years</strong>: complete a 2- or 3-, or 4-dose series</td>
</tr>
<tr>
<td>- 2-dose series only applies when 2 doses of Heplisav-B are used at least 4 weeks apart</td>
</tr>
<tr>
<td>- 3-dose series Engerix-B or Recombivax HB at 0, 1, 6 months [minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 8 weeks / dose 1 to dose 3: 16 weeks]</td>
</tr>
<tr>
<td>- 3-dose series HepA-HepB (Twinrix) at 0, 1, 6 months [minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 5 months]</td>
</tr>
<tr>
<td>- 4-dose series HepA-HepB (Twinrix) accelerated schedule of 3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months</td>
</tr>
<tr>
<td>- 4-dose series Engerix-B at 0, 1, 2, and 6 months for persons on adult hemodialysis (note: each dosage is double that of normal adult dose, i.e., 2 mL instead of 1 mL)</td>
</tr>
</tbody>
</table>

*Note: Heplisav-B not recommended in pregnancy due to lack of safety data in pregnant women*

<table>
<thead>
<tr>
<th>Special situations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age 60 years or older</strong> and at risk for hepatitis B virus infection: 2-dose (Heplisav-B) or 3-dose (Engerix-B, Recombivax HB) series or 3-dose series HepA-HepB (Twinrix) as above</td>
</tr>
</tbody>
</table>

https://www.medpagetoday.com/meetingcoverage/acip/95427
https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html#note-hepb
HBV Vaccination Series

Recommended

• **Heplisav**: two doses one month apart
  – 90-95% seroprotection rate
• **Twinrix**: three doses at 0, 1, and 6 months
  – Immunizes against HAV and HBV

Other

• **Engerix-B**: three doses at 0, 1, and 6 months
  – 71-90% seroprotection rate
• **Recombivax HB**: three doses at 0, 1, and 6 months
  – 88-92% seroprotection rate
• **PreHevbrio**: three doses at 0, 1, and 6 months
  – 89-91% seroprotection rate
HBV Vaccine Non-Responders

Risk Factors
• Older age (40+)
• Male
• Smoker
• Diabetes
• Chronic illness
• ESRD
• Obesity
• HBV infection

Adequate response after 1 additional dose in 15-25% of non-responders

If no response and not infected, recommend re-initiating vaccine series
• Heplisav
• PreHevbrio
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Risk Factor Based Screening: A Failed Policy


| Table 1. Risk Factors, Prognostic Features, and Screening for Chronic HBV Infection |
|---|---|---|
| Risk Factor | Prognostic Feature | Screening |
| Born in region with intermediate-to-high prevalence of HBV | ✓ | 2, 5 |
| Men who have sex with men | ✓ | 7, 37-40 |
| Aged <30 y | ✓ | 7 |
| Co-infected with HIV | ✓ | - |
| U.S. born persons not vaccinated as infants whose parents were born in regions with high prevalence of HBV | ✓ | - |
| Injection drug users | ✓ | 41 |
| Co-infected with HIV | ✓ | 7 |
| HIV-positive persons | ✓ | 7 |
| Household contacts of sexual partners with known HBV infection | ✓ | 7 |
| Pregnant women | ✓ | 42 |
| Persons requiring immunosuppressive therapy (≥1 year) | ✓ | 28 (2.2-3.3) |
| Persons with end-stage renal disease or those receiving hemodialysis | ✓ | 43 |
| Elevated alanine aminotransferase (aminotransferase levels) | ✓ | - |
| Infants born to HBsAg-positive mothers | ✓ | 1.1 (-) |
| Donors of blood, plasma, organs, tissue, or semen | ✓ | - |
| Persons who are sources of blood or body fluids for exposures that might require postexposure prophylaxis | ✓ | - |
| Inmates of correctional facilities | ✓ | 45 |
| Persons with HIV infection | ✓ | 46 |
| Persons with multiple sexual partners or a history of sexually transmitted infections | ✓ | - |

Acute Hepatitis B by Risk Factor

- The risk factor was unknown for the majority of cases
- Sexual transmission was the most common reported risk factor
2021 Benefit Analysis of One-Time Universal HBsAg Screening

Improves patient outcomes
- 7.4 cases of compensated cirrhosis
- 3.3 cases of decompensated cirrhosis
- 5.5 cases of HCC
- 1.9 liver transplants
- 10.3 HBV-related deaths

Cost Effective
- Savings of $263,000 per 100,000 people aged 18–69 years screened
  - HBV treatment< $894/year, and test, $10.33

Potentially higher improvement in NYC due to higher prevalence compared to the U.S.

Mehlika Toy, David Hutton, Aaron M Harris, Noele Nelson, Joshua A Salomon, Samuel So, Cost-Effectiveness of 1-Time Universal Screening for Chronic Hepatitis B Infection in Adults in the United States, *Clinical Infectious Diseases*, 2021; ciab405, [https://doi.org/10.1093/cid/ciab405](https://doi.org/10.1093/cid/ciab405)
New CDC Guidelines

BOX 1. Hepatitis B virus screening and testing recommendations — CDC, 2023

Universal hepatitis B virus (HBV) screening

- HBV screening at least once during a lifetime for adults aged ≥18 years (new recommendation)
- During screening, test for hepatitis B surface antigen (HBsAg), antibody to HBsAg, and total antibody to HBcAg (total anti-HBc) (new recommendation)

Screening pregnant persons

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

Risk-based testing

- Testing for all persons with a history of increased risk for HBV infection, regardless of age, if they might have been susceptible during the period of increased risk
- Periodic testing for susceptible persons, regardless of age, with ongoing risk for exposures, while risk for exposures persists

References:
DOI: http://dx.doi.org/10.15585/mmwr.rr7201a1
Rationale for CDC guidelines

BOX 2. Rationale for universal hepatitis B virus screening

• Hepatitis B virus (HBV) infection has substantial morbidity and mortality.
• Chronic HBV infection can be detected before the development of severe liver disease using reliable and inexpensive screening tests.
• Treatment for chronic HBV infection can reduce morbidity and mortality.
• Management of chronic HBV infection might prevent transmission to others.
• Universal screening of adults is cost-effective.
• Screening enables identification and management of pregnant persons infected with HBV and their infants, which can reduce the risk for perinatal transmission.
• Screening can identify persons who are at risk for reactivation of HBV infection.
• Screening might identify persons who would benefit from hepatitis B vaccination.
Hepatitis B Screening

- HBV Surface Ag and Ab
- HBV Core Ab

**Interpretation:**
- If all negative: needs vaccine
- If Surface Ag positive: has chronic HBV. Refer to hepatology
- If Surface Ab and Core Ab positive: previously exposed and cleared
- If Surface Ab positive, Core Ab negative: previously vaccinated
- Indeterminate Surface Ab:
  - If Core Ab negative: check again in 3 months. May need to re-initiate vaccine series
  - If Core Ab positive: check DNA and check Surface Ab in 3 months
CDC Recommended HBV Screening Workflow

A. Nonpregnant adults aged ≥18 years without a known history of HBV infection

- Completed HepB vaccine series?
  - Yes
  - No/Unknown
  - Previously screened for HBV infection?
    - Yes
    - No/Unknown
    - Had an activity, exposure, or condition associated with increased risk since the last screening?
      - Yes
      - Offer testing and vaccine
      - No
      - Offer vaccine
    - No
    - Offer screening
  - No
    - Offer screening

- Offer testing, if the exposure occurred before vaccination (while susceptible) and after the previous HBV test(s)
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Hepatitis Delta Virus (HDV) requires HBV Surface Ag for viral entry

HDV is the most severe form of viral hepatitis
- Progresses to cirrhosis in 5 years, HCC in 10 years
- Coinfection with HDV has higher rates of:
  - liver failure
  - nonalcoholic cirrhosis
  - portal hypertension
  - Ascites
  - thrombocytopenia

EASL recommends anti-HDV antibody testing in all HBsAg regardless of other risk factors.
- Prevalence rates estimated 4.5-13% of HBV Surface Ag positive patients

<table>
<thead>
<tr>
<th>Progression to Cirrhosis</th>
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<tbody>
<tr>
<td>HCV</td>
<td>10 – 20% within 20 Years</td>
</tr>
<tr>
<td>HBV</td>
<td>20% within 5 Years</td>
</tr>
<tr>
<td>HDV</td>
<td>70% within 5 – 10 Years</td>
</tr>
</tbody>
</table>

HDV Geographic Footprint Is Growing

U.S. major metro hotspots identified

Top 10 U.S. Cities in 2016

1. Chicago, Illinois
2. Berwyn, Illinois
3. Brooklyn, New York
4. Corona, New York
5. Waukegan, Illinois
6. New York, New York
7. Bronx, New York
8. Jamaica, New York
9. Lombard, New York
10. Aurora, Illinois

Increased Screening Leads to Increased HBV and HDV Diagnosis

- Identifying HDV patients is key as multiple treatments are coming to market

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2. HCV screening guidelines update
3. HCV treatment overview
4. HBV epidemiology
5. HBV vaccination guidelines
6. Screening for HBV
7. Hepatitis Delta
8. Case Study: Mount Sinai Health System
Mount Sinai Health System (MSHS)

- Large, urban, multicenter health system
- 47% of hospital discharges in NYC
- Serves diverse population of metropolitan NYC area
- Hospitals with EDs and PCP practices:
  - 4 in Manhattan
  - 1 in Queens
  - 1 in Brooklyn
  - 1 in Nassau County
- Large ambulatory care network across NYC, Long Island, and Westchester
Screening initiatives and patient navigation have been supported in part by funding from Gilead Sciences, Inc. (FOCUS). *FOCUS funding supports HIV, HCV, and HBV screening and linkage to a first appointment. FOCUS partners do not use FOCUS awards for activities beyond linkage to a first appointment.*
**HCV Program Implementation**

**Screening**
- Screening events in at-risk communities since 2011 (HONE)
- Since 2015 for baby boomers and pregnant women
- Since 2020 for all adults 18+
- EMR alert prompting PCPs to screen
- Automatic RNA reflex testing for Ab+
- Outreach to PCPs and patients

**Treatment**
- Patient navigation and care coordination
Weekly Lists of Patients Eligible for HCV Screening

Dear Dr. Vega,

As part of a system-wide effort to eliminate Hepatitis C at Mount Sinai, I am sharing a list of your patients eligible for Hepatitis C screening who are scheduled to see you in the coming week.

Based on new guidelines from the CDC and USPSTF, providers are now advised to screen all adults for Hepatitis C at least once, regardless of risk factors.

<table>
<thead>
<tr>
<th>Date</th>
<th>APPT_TIME</th>
<th>MRN</th>
<th>Patient</th>
<th>Enc_Provider</th>
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<td>VEGA, AIDA C [136946]</td>
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</tbody>
</table>

If any of your patients test positive for Hepatitis C, my team would be happy to offer assistance linking them to liver care. We can provide assistance with scheduling, transportation, pharmacy/insurance coordination, health education, and other referrals.

If you have any questions or feedback, feel free to contact me, our program manager, Anna Mageras (copied here), or our medical director, Dr. Douglas Dieterich.

Thank you,
Preventive Care

Preventive medicine plays an important part in your health and overall well-being. The following procedures are recommended for people of your age, sex, and medical history.

Overdue

Hepatitis C Screening

Learn more

Hide reminder from home page
Dear [PATIENT NAME],

I am working with your primary care provider on a health initiative to promote testing for hepatitis C virus (HCV). The U.S. Centers for Disease Control and Prevention (CDC) now recommend that all adults get tested at least once in their lifetime. Many patients with an HCV infection have no symptoms for many years, but the virus may still be causing serious liver damage.

Our records indicate that you have not had an HCV test at Mount Sinai. We encourage you to ask your provider about HCV testing at your upcoming visit.

The great news is that HCV is curable, usually in 8-12 weeks with minimal side effects. Nearly all insurance plans cover HCV treatment and financial assistance plans may be available to cover gaps.

If you have any questions or need help scheduling HCV care after testing, please contact me directly by MyChart, phone, or email.

For more information about HCV, please visit [https://www.cdc.gov/hepatitis/hcv/cfaq.htm](https://www.cdc.gov/hepatitis/hcv/cfaq.htm).

Sincerely,

[PATIENT NAVIGATOR SIGNATURE]
Say YES to the Test!

Everyone ages 18+ should be screened at least once for hepatitis C.

Ask your doctor about getting tested today.

Questions or follow-up regarding results? Contact the Patient Navigation Team!
Call or Text: (516) 595 9315
Email: hepc@mssm.edu

DID YOU KNOW?

- Hepatitis C can cause liver damage for many years without noticeable symptoms.
- Hepatitis C can be cured in most patients, usually in 8-12 weeks, with oral medication and few or no side effects.
- Most insurances now cover hepatitis C treatment, and there is financial assistance available for patients who need it.
HAVE A PATIENT
WITH HEP B OR C?

Contact the LEAP Patient Navigation Team!
HepB@mssm.edu (HBsAg+)
HepC@mssm.edu (HCV RNA+)
Amb Refer to LIVER (not Hepatology)

LEAP can help with:
• Linkage to liver care
• Insurance & pharmacy coordination
• Transportation
• Rx adherence support
• Health education
• Peer support
• Referrals to:
  ○ Other medical care
  ○ Social services
HCV Ab Screening Rate in Primary Care (Baby Boomers)

- Baseline: 59%
- Post Intervention: 83%
HCV PCR Screening Rate for Ab+ in Primary Care

- Baseline: 68%
- Post Intervention: 100%
Updated EMR Alert Prompting PCPs to Screen All Adults

Hepatitis C Screening is Due

2020 CDC Hepatitis C Screening Guidelines
The CDC recommends Hepatitis C screening for all adults (>=18yo) at least once. To satisfy this alert please open the Hepatitis C SmartSet below. If the patient has already satisfied screening, you may override this alert. Alternatively, you may postpone this alert.

Last HCVAB, collected/resulted: DD/MM/YYYY = Result value
Hepatitis C Screening last satisfied: DD/MM/YYYY

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<th>Do Not Open</th>
<th>HEPATITIS C SCREENING ORDER SMARTSET Preview</th>
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<td>Hepatitis C Screening Edit details</td>
</tr>
<tr>
<td>Postpone</td>
<td>Do Not Postpone</td>
<td>Hepatitis C Screening Edit details</td>
</tr>
</tbody>
</table>

- Address Hepatitis C Screening HM Topic
- HM Activity (Add patient reported, Postpone, Override)
- Add relevant diagnosis to History
HCV New Screening Rate (newly screened/eligible to screen): Primary Care Clinic

New BPA Alert 11/2021, provider education 12/2021, weekly lists of eligible patients 1/22
Resident Survey: Reasons Not Screening for HCV

- I did not know I was supposed to be screening for HCV
- My patients do not have risk factors for HCV
- I do not have enough time
- There are too many screenings to keep track of
- HCV screening is not in my template
- This is lower priority than other screenings
- Patients frequently decline
- I would not know how to react to positive result

Resident Leads: Einat Kadar, MD, and Carolina Villarroel, MD; attending mentor, Desiree Chow, MD
Resident Survey Results Post Education (n = 34)

What Tools Would Help You Screen More Patients for HCV?

- EMR Modification: 56%
- Dot phrase/template: 24%
- Patient request: 14%
- Weekly list of eligible patients: 6%
ED Screening Program

- Universal, non-targeted HCV screening for 18+
- Initial nurse offer
- Health educators follow up
- Linkage to care
- Under direction of Dr. Yvette Calderon and Dr. Ethan Cowan
- “Birth cohort-targeted screening would have identified 48% of the patients with Ab+ tests and 47% of those who were VL+.”

LEAP: Liver Education & Action Program
Supporting Patients through the HCV Care Continuum

Navigation to HCV Care

Care Coordination through SVR

www.mountsinai.org/hepatitis
Step 1: Finding RNA+ Patients
Step 2: Navigating RNA+ Patients to HCV Care

- Identify RNA+ patients
- Reach out to those in need of HCV care
- Health education & appointment scheduling
Step 3: Care Coordination for HCV Patients Through SVR

- Psychosocial assessment (PREP-C)
- Appointments & reminders
- Follow-up & check-ins
- Accompaniment to appointments
- Health system navigation
- Health education
- Referrals:
  - Mental health; alcohol and substance use
  - Primary care
  - Social services, financial assistance, and other benefits
- Insurance and pharmacy coordination
- Medication adherence support
- Monitoring and case conferencing
- Case closure and referrals
HCV Linkage to Care Rate from Primary Care

- Baseline: 52%
- Post Intervention: 80%
Care Coordination Works!

All RNA+ patients in NYC (Source: 2020 DOHMH Viral Hepatitis Annual Report)

Patients enrolled in LEAP care coordination at Sinai through June 30, 2020
New Project

Implementing Universal One-time HBV Screening for Adults in Primary Care
Implementation of Universal HBV Screening and Vaccination at Sinai

- EMR alert prompting PCPs to screen
- Outreach to PCPs and patients
- Patient navigation and care coordination
Implementing HBV Screening: EMR Prompt
EMR Alert Flow Chart

18-79 and doesn’t have HBV results (HBsAg, HBsAb, HBcAb) in EMR

EMR Alert: Screen Patient

- All 3 Labs Negative → Vaccinate Patient
- HBsAg Positive → Refer to Liver
- HBcAb Positive → PCP to Counsel Patient
# Implementation Challenges

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Solution</th>
</tr>
</thead>
</table>
| Many stakeholders                             | • Iterative process  
|                                               | • Involve PCP, EMR IT, QI leadership                  |
| Patients alarmed by notification              | Turn off patient-facing alerts for now               |
| PCPs want age limit                           | 18-79 limit for now                                 |
| PCPs unsure which tests to order              | • New 3-test panel  
|                                               | • Auto-select                                       |
|                                               | • Provider education                                 |
| PCP complaints and concerns                   | • Set up feedback mailbox                           |
|                                               | • Test alert in pilot clinic                         |
| PCPs want follow-up guidance                  | • Tip sheet                                          |
|                                               | • MyChart templates                                  |
.HEPBSABPOS (HBsAb+, HBsAg-, HBcAb-)
You do not have hepatitis B. You are protected (immune) from getting hepatitis B. Your hepatitis B surface antibody (HBsAb) test result was “positive” or “reactive.” This means that you have successfully been vaccinated against hepatitis B.

.HEPBSAGPOS (HBsAg+, HBsAb-, HBcAb+/-)
Your test result shows that you have a hepatitis B infection. Your hepatitis B surface antigen test came back “positive” or “reactive.”

Your next step is to make an appointment with a doctor who specializes in taking care of the liver. This doctor will provide you with follow-up testing and a full evaluation.

If you need treatment for your hepatitis B infection, there are many options. We have very good medications that can be taken by mouth and have no or few side effects.

I will submit a referral to one of our liver specialists. Please reach out to their office for help scheduling an appointment. Email them at hepb@mssm.edu or call or text 212-824-9726.
New HBV Screening Rates in Primary Care

- **Goal**
- **Clinics Did Not Receive Education**
- **Clinics Received Education**

EMR HBV Screening Modification
HBV Patient Navigation

- Chart reviewing newly and previously diagnosed patients
- Calling those not in HBV care
- Scheduling evaluation appointments with Liver
- Addressing barriers to care
- September–March found 231 HBsAg+ patients, 39% not in care

- Methodology partially inspired by NYC DOHMH Check Hep B program
Patient Navigation Outcomes

Patient Navigation Outcomes for HBsAg+ Patients
September 2022-March 2023 (n=90)

- Linked to Care, 41, 53%
- In Progress, 21, 27%
- Lost to Follow-Up, 9, 11%
- Declined Linkage, 7, 9%
HBV Care Coordination

- Follow patients for 3 visits
- Pharmacy & insurance coordination
- Adherence monitoring and counseling
- Referrals to social services
- Health education
- Ensure all imaging and procedures complete
- Re-enroll if fall out of care
Future Directions: HBV to HDV Reflex Testing

One study found only 40% of HBsAg+ patients tested with manual order for HDV Ab, compared to 99% with reflex testing.

Planning New Screening Policy in Your Health System

- Existing Practices
- Official Guidelines
- Local Epidemiology
- Stakeholders

Buy-In & Implementation
Ideas for Smaller Settings

- Find a way to automate screening and involve whole team
- E.g., designate nurse to chart review daily panel and flag charts
- Include in appointment reminders
- MA offers screening during vitals check & nurse pends order
- Provider tip sheets and peer outreach
- Waiting room posters ([CDC](https://www.cdc.gov) and [NYC DOHMH](https://www.nyc.gov)) and cards
- Referral pathway to GI/Liver/ID or LEAP
Have a Patient with Hep C or Hep B?

Contact the LEAP Patient Navigation and Care Coordination Team:

LEAP@mssm.edu
212-824-9726
www.mountsinai.org/hepatitis

English and Spanish
Summary

HCV
• Screen all adults at least once
• Link positive patients to care or treat yourself

HBV
• Screen all adults at least once
• Vaccinate all adults under 60
• Link HBsAg+ patients to hepatology

Case Study
• Avenues to increase screening and care rates in your practice or hospital system
Thank You/Any Questions?
For CMEs or educational opportunities, contact:

Meg Chappell, MPH
Program Manager
Empire Liver Foundation
megchappell@empireliverfoundation.org
www.empireliverfoundation.org

For questions about resources, contact:

Marie P. Bresnahan, MPH
Director, Training, Policy, and Administration
Viral Hepatitis Program
Bureau of Communicable Disease
mbresnahan@health.nyc.gov
www.hepfree.nyc
Hepatitis B Clinical Training Series

Thursday, June 1 @ 4:30PM
Hepatitis B: Epidemiology, Prevention and Screening
Presenter: Arun Jesudian, MD

Thursday, June 8 @ 4:30PM
Hepatitis B Pre-Treatment Evaluation and Treatment Initiation
Presenter: Paul Gaglio, MD

Thursday, June 15 @ 4:30PM
Management of Hepatitis B and Treatment Monitoring
Presenter: Harmit Kalia, DO