### HEPATITIS C VIRUS: Overview, Treatment, and Elimination

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## DISCLOSURES

We have no disclosures

# LEARNING OBJECTIVES

- Provide a brief overview of hepatitis C virus (HCV) characteristics, history, and natural history
- Review hepatitis C screening recommendations
- Discuss fundamental concepts related to HCV evaluation and treatment
- Describe aspects to treatment of hepatitis C in primary care and in a substance use disorder facility/setting
- Discuss the current ND hepatitis C virus elimination planning efforts

#### Hepatitis C Virus

Chronic hepatitis C virus (HCV) is one of the most common causes of chronic liver disease

Can progress to cirrhosis, hepatocellular carcinoma, and death

HCV is prevalent throughout the world

Causes more death in the US than the next 60 reportable infections combined, including HIV and tuberculosis

CURABLE



### Hepatitis C Discovery

Hepatitis A and B classified in 1947

- Clinical presentation differentiated from hepatitis A and hepatitis B noted in 1970s
  - Called non-A, non-B hepatitis (NANBH)
  - Shorter incubation, milder symptoms compared to Hepatitis B
- Officially discovered in 1989
  - Named Hepatitis C
  - By Alter, Houghton, and Rice
  - Won Nobel Prize in Physiology or Medicine in 2020



# EPIDEMIOLOGY

Difficult to estimate global prevalence

o Underdiagnosis, underreporting, lack of systemic surveillance in most countries

 As of 2022, according to the World Health Organization, approximately 58 million people had chronic HCV

• Americas region: 5.7 million people

Incidence of new HCV infection has increased in the US in the past decade

- Doubling since 2013
- Fourfold increase since 2005
- o1.5 Million new infections each year worldwide (as of 2022)

OIn the United States, an estimated 2 million individuals have chronic HCV

 Comparable to the population of North Dakota, South Dakota, and Wyoming combined







B Rates\* of reported cases<sup>△</sup> of acute hepatitis C virus infection, by age group – United States, 2005 to 2020



Year

# HCV CHARACTERISTICS

- A positive-sense, single stranded, enveloped RNA (ribonucleic acid) virus
- Replicates in the hepatocytes
- Rapid replication with highly error-prone RNA polymerase
- There are six major genotypes (1-6) and several subtypes (more than 50)
- In the United States, genotype 1 is the most prevalent, followed by genotypes 2 and 3.
- In the US, genotypes 4, 5, 6 are rare.
  - For people who inject drugs (PWID), the prevalence of genotype 3 is higher



# HCV TRANSMISSION

Percutaneous contact with contaminated blood

- Injection drug use is the primary route of transmission
  - 50 to 90% of people who inject drugs (PWID) have serologic evidence of HCV
    - Viable virus has been recovered from the inside of syringes up to <u>nine weeks</u> after contamination!
- Other
  - Contaminated tattoo/piercing equipment
  - Intranasal drug use (presumably due to blood on the shared equipment)
  - Remote history of blood transfusion
    - Blood product screening implemented 1987-1992
      - The current estimated risk of HCV is less than one in a million per units
      - Higher risk in developing countries where universal screening is not implemented



# HCV TRANSMISSION

#### Less common:

- Perinatal transmission
  - About 5-6% of infants born to mothers with HCV infection will be infected
  - Twice that if the mother has both HCV and HIV co-infection
- Sexual transmission (1-2%, even with long term partner having chronic HCV)
  - Higher among men who have unprotected sex with men (MSM), particularly among those with HIV
    - In theory, due to higher rate of mucosal injury and blood exposure vs. vaginal sex
  - Chem Sex: intentional combining of sex with the use of particular nonprescription drugs in order to facilitate or enhance the sexual encounter
- Hemodialysis

# ACUTE HCV INFECTION

Immune system <u>can</u> eliminate HCV during this stage (14 to 50%)

- Acute infections rapidly trigger the non-specific immune response
  - Type 1 interferon secretion and natural killer (NK) cell activation
- Symptoms
  - Usually asymptomatic
  - May experience symptoms: malaise, nausea, fatigue, low-grade fever/chills, loss of appetite, muscle aches, RUQ pain, dark urine, jaundice, white stools, pruritus

#### Lab findings

- Virus can be detected in the plasma within days of exposure, often 1 to 4 weeks
- Aminotransferase levels often >10 to 20 times the upper limit of normal in the acute phase
  - Wide fluctuation within short time intervals
  - Not all patients in the acute phase will have elevated LFTs
- Might have elevated total bilirubin in the acute phase
- Viremia peaks in the first 8 to 12 weeks of infection

## Progression of Acute HCV

SPONTANEOUS VIRAL CLEARANCE

- After viral peak, viral load drops to undetectable levels
- Patient's hepatitis C antibodies will always be positive
- Hepatitis C viral load will be undetectable
- Patient can be re-infected *if* they have a new exposure





\* For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

<sup>†</sup> To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had 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.

# Management of Acute HCV

 After acute infection diagnosis, patient requires monitoring to determine outcome

- Check HCV RNA at 12 weeks after exposure/diagnosis if patient is going to be treated right away
  - Most patients that experience spontaneous viral clearance do so within 12 weeks
- Check HCV RNA at 6 months post exposure/diagnosis if the patient is not going to be treated during the acute phase



## CHRONIC HCV INFECTION

- Most patients with acute HCV infection develop chronic disease (50-85%)
- After viral peak of acute infection, viral load plateaus
- Diagnosed when viral load still detected at **6 months** after initial acute infection diagnosis
- Risk factors for chronic disease development
  - Weak CD4+ and CD8+ T-cell responses (these cells fail to control viral replication)
  - Type 3 genotype
  - Alcohol consumption
  - HIV/HVB co-infection
  - Insulin resistance, obesity, non-alcoholic fatty liver disease
- Body responds
  - Local inflammatory response (liver)
    - Triggers fibrogenesis
  - Liver damage induced by cytotoxic T cell and oxidative stress

### HCV NATURAL HISTORY



#### SCREENING RECOMMENDAITONS

#### Routine, universal, one-time screening for <u>all adults</u>

- At least once in a lifetime for <u>all adults</u> aged 18 years and older
- All pregnant women during each pregnancy
- Routine screening for children/adolescents is not recommended, but should be done if there is risk or exposure
- Routine, periodic screening
  - People who currently inject drugs and share needles, syringes, or other drug equipment, MSM, longterm sexual partners of those with HCV, maintenance hemodialysis
  - Frequency: every 3 to 6 months ideally, every 12 months at a minimum



#### SCREENING RECOMMENDAITONS

 Lack of screening and subsequent failure to identify hepatitis C infections creates an obstruction to linkage to care and successful HCV control

 Individual benefit of early detection, early treatment

- Decreased all-cause mortality, liverrelated death, need for liver transplant, HCC rates, and liverrelated complications
- Late diagnosis is associated with hospitalization and death



# Initial Lab Evaluation

#### Ideal screening: HCV antibody WITH reflex to RNA

- If no automated reflex is available, order the HCV RNA quantification subsequent to positive HCV antibody
- \*\*HCV antibody test will *always* be detectable (positive) after exposure, even if the person is able to clear the infection without treatment, and after curative treatment

#### HCV RNA quantification of viral load

- If present, there is an active infection
- HCV RNA is detectable 1-3 weeks post-exposure
- HCV antibody (anti-HCV) presents 4-12 weeks post-exposure
- Positive HCV antibody does not = immunity
- If the patient has + HCV RNA and it is suspected to be an acute infection (recent exposure), the patient still may clear the virus (HCV RNA undetectable) without treatment
  - In general, if the patient will clear without treatment, this happens within 12 weeks, however, recommendations are to repeat in 6 months to confirm clearance vs. chronicity



## SCREENING AND DIAGNOSIS

*If HCV RNA is detected, the diagnosis of HCV infection is confirmed* 

#### EXPOSURE ALGORITHM



#### Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection



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



### FURTHER LAB TESTING

Prior to starting treatment, the following labs are suggested:

Quantitative HCV RNA (viral load)

HCV genotype

□ HBV virus and immunity screening

□ Surface antigen (HBsAg), HBV core antibody (anti-HBc), HBV surface antibody (anti-HBs)

□ HAV virus and immunity screening

Hep A Virus IgM, Hepatitis A Ab total

🗆 HIV

Complete Blood Count (CBC)

□ INR (international normalized ratio); typically, ordered as PT/INR

Hepatic function panel (albumin, bilirubin, ALT, AST, alkaline phosphatase)

GFR 🗌

HCG as needed

Urine drug and alcohol screening as indicated

### HISTORY & PHYSICAL

>Anorexia, weight loss, fatigue, weakness, nausea

- ➢ Jaundice
- ➢ Pruritis
- ≻Diarrhea
- >Increased abdominal girth (ascites on exam) or other edema
- ≻Intermittent RUQ pain
- ➢Vomiting blood
- ≻Easy bruising
- Mental status changes (encephalopathy)
- ➢Ongoing alcohol use?
- Metabolic concerns (fatty liver?)
- >Muscle cramps or joint pains

#### PHYSICAL EXAM: SIGNS OF END-STAGE LIVER DISEASE

- > Temporal muscle wasting, cyanosis, icterus, enlarged parotid gland
- >Palmar erythema, asterixis, clubbing, Dupuytren contracture
- >Gynecomastia, small testes, hypogonadism
- ➢ Fetor hepaticus
- >Ankle edema, spider nevi, petechiae, scant body hair
- >Caput medusae, paraumbilical hernia, hepatosplenomegaly
- >Women: amenorrhea or chronic anovulation, might manifest as irregular menstrual bleeding





# LIVER STAGING IN HCV

- Utilize laboratory evaluation along with physical exam to either rule out cirrhosis/advanced fibrosis or determine the need for imaging
- APRI calculator: <u>https://www.hepatitisc.uw.edu/page/clinical-calculators/apri</u>
- •FIB-4 calculator: <u>https://www.hepatitisc.uw.edu/page/clinical-calculators/fib-4</u>
- If APRI score is less than 0.7 and FIB-4 is less than 1.45, consider foregoing ultrasound/elastography in absence of other signs of advanced fibrosis.
- If either score is higher than the above thresholds, or other signs of advanced fibrosis are present, refer for abdominal ultrasound (ideally with elastography).

### LIVER STAGING IN HCV

#### • FIB-4 calculation

- [(age x AST)/(platelets x ALT)]
- Assesses likelihood of presence or absence of advanced fibrosis
- Value <1.45 indicates advanced fibrosis is unlikely (90% negative predictive value)
- Value >3.25 indicates advanced fibrosis is **likely**

#### • <u>APRI</u>

 AST to platelet ratio (APRI) of 0.7 or higher has sensitivity of 77% and specificity of 72% in predicting significant hepatic fibrosis

#### • HCV FibroSure<sup>®</sup> or FibroTest<sup>®</sup> laboratory test

- Degree of fibrosis and inflammation estimated with liver biomarkers in blood plus patient age and gender (approximately 86% accurate)
- Must order HCV specific FibroSure or FibroTest (other versions available, such as NASH)
- Other similar tests: FibroSpect II, HepaScore, FibroScore

#### • <u>General laboratory markers that may indicate</u> <u>advanced fibrosis</u>

- INR over 1 (in absence of vitamin K antagonist therapy such as warfarin)
- Albumin less than 3.5 g/dL
- Platelets below 150,000/mm<sup>3</sup>

## LIVER STAGING IN HCV

Abdominal ultrasound (US):

- Cirrhotic vs non-cirrhotic
- Presence or absence of hepatocellular carcinoma
- \*May need to request above be included in radiologist report

Elastography (FibroScan<sup>®</sup> or elastography with US)

- Provides stage of fibrosis METAVIR stage (0 4) based on liver stiffness
- Most accurate noninvasive method of determining specific liver fibrosis stage (F0-F4)
- Patient must fast for 4 hours prior to test

Liver Biopsy

- Invasive
- Determine stage of fibrosis and presence/absence of cirrhosis as well as liver disease etiology
- Generally reserved for cases of liver disease with unknown etiology

#### **Ziol Transient Elastography Breakpoints**



### STAGING: CIRRHOSIS

If cirrhosis is confirmed via any modality, must calculate a Child's Pugh Score

	Class A	Class B	Class C
Total Points	5-6	7-9	10-15
Factor	1 Point	2 Points	3 Points
Total bilirubin (µmol/L)	<34	34-50	>50
Serum albumin (g/L)	>35	28-35	<28
Prothrombin time/international normalized ratio	<1.7	1.71-2.30	>2.30
Ascites	None	Mild	Moderate to severe
Hepatic encephalopathy	None	Grade I-II (or suppressed with medication)	Grade III-IV (or refractory)



## VACCINATE!

- •HCV patients require standard adult vaccinations
- Those not immune to hepatitis A or B virus should be vaccinated against these viruses
- HCV-infected patients with chronic liver disease should also receive pneumococcal vaccination

## HCV Treatment: Antiviral therapy

All patients should be considered for treat

Exception: life expectancy <12 months due to non-related conditions</li>

oGoals of antiviral therapy

- Eradicate HCV RNA
  - o Defined as undetectable HCV RNA at least 12 weeks after completion of treatment
- Reduce liver fibrosis/disease progression
- Reduce complications: decompensated cirrhosis, hepatocellular carcinoma
- Reduce the need for liver transplant
- Evidence of reducing the above when pt. is treated for HCV even if they have advanced fibrosis

#### PRACTICE PEARL

 Professional guidelines recommend against delaying HCV treatment until chronicity is known/proven.

- However, North Dakota Medicaid and many other ND based insurances still require evidence of chronic HCV infection.
  - Requires two instances of detectable HCV RNA quant 6+ months or more apart, or evidence of advanced fibrosis.

 FDA labeling of HCV treatments aligns with requirement for chronic HCV infection to be evidenced.





# HCV TREATMENT HISTORY

### HCV DAA's

- Direct Acting Antivirals
- Drugs that target specific nonstructural proteins of HCV and thus disrupt viral replication and infection
- Revolutionized therapy for HCV infection
- Highly effective, well-tolerated, safe
- Treatment of choice for the vast majority of HCV-infected patients
- Can result in sustained virologic response (SVR) in greater than 90% of HCVinfected patients (achieving cure)

## HISTORY OF PRIOR TREATMENT

- Patients should be asked about any prior exposure to HCV antiviral treatment and their response, as future management decisions depend on specific aspects of the treatment history.
- Patients who have never received any treatment for HCV infection are considered treatment-naïve.
- •For patients who had failed prior treatment (ie, <u>treatment-experienced patients</u>), it is important to clarify what the failing regimen was, as the approach to regimen selection is different for those who failed peginterferon and ribavirin alone compared with those who failed a direct-acting antiviral regimen.

### MEDICATION ASSESSMENT

 Assessment of potential drug-drug interactions with concomitant medications is recommended prior to starting hep C medication therapy

•When possible, an interacting co-medication should be stopped or switched to an alternative with less risk for potential interaction during HCV treatment

•I like to use the Liverpool HEP interaction tool

•https://www.hep-druginteractions.org/checker



#### HCV Direct Acting Antiviral (DAA) Targets





### HCV DAA PEARLS



>SVR 12 rates with guideline-based HCV DAA meds are >95% effective

Possibly lower rates for those with decompensated cirrhosis, poor/non-adherence, previous treatment failures

>Once per day oral regimen given as combination therapy (more than one DAA combined together)

- Length of therapy typically 8 to 12 weeks
  - Occasionally 16 to 24 weeks
- >Very well tolerated
  - Fatigue, headache, nausea occur in the minority of patients
- >Hepatitis B reactivation is on label warning for all HCV DAAs
- Cost complicates accessibility and insurance coverage (currently)
- >Avoid HCV DAA interactions
  - CYP3A4 inducers (void use in moderate to strong inducers, such as rifampin, phenytoin, St. Johns Wort, carbamazepine)
  - $\rightarrow$  Avoid all herbal supplements (most have unknown components that could possibly interact)
  - > No interaction with OTC analgesics such as aspirin, ibuprofen, naproxen, acetaminophen A

# MAVYRET / EPCLUSA

#### **1. Mavyret** is <u>glecaprevir/pibrentasvir</u>

- 1. 300mg/100mg (3 tablets of 100mg/40mg) once daily WITH FOOD
- 2. Treatment naïve patients: 8 weeks
- 3. Common drug interactions: ethinyl-estradiol containing hormonal contraceptives (must avoid), statins (atorvastatin and simvastatin are contraindicated, rosuvastatin and pravastatin can be used at low doses)
- 4. Average wholesale price for 8 weeks: \$26,400

#### 2. Epclusa is velpatasvir/sofosbuvir

- 1. 100mg/400mg (one tablet) once daily
- 2. Length of treatment for treatment naïve patients: 12 weeks
- 3. Common drug interactions: all acid-suppressing agents, rosuvastatin (limit to 10mg daily), amiodarone (contraindicated)
- 4. Average wholesale price for 12 weeks: \$89,700
- 3. Pan genotypic: Covering genotypes 1-6
- 4. Both on formulary for ND Medicaid

## TREATMENT IN THE SUD ARENA

•A growing number of reports have shown that a substantial proportion of people who use drugs treated for hepatitis C can achieve sustained virologic responses even if they have psychiatric comorbidity and even if they continue to use drugs while receiving hepatitis C treatment

 Successfully treating hepatitis C in injection drug users requires collaboration between those with expertise in hepatitis and those with expertise in caring for substance users

 Experience working with people who use drugs is available from a variety of sources, including public health and community workers with experience in STI prevention and harm reduction, STI treatment providers, substance use treatment providers, substance use researchers, and (probably most importantly) people who use drugs themselves

OSuccessful program = respectful approach, understanding of the medical and behavioral sequelae of addiction, and avoiding moralistic judgments

• Treatment of HCV in persons with active injection drug use likely has major public health benefits in terms of reducing secondary HCV transmission.

### TREATMENT IN SUD ARENA

• Treatment sequence is different for everyone. Where is the patient at?

- For some, the promise of receiving hepatitis C treatment may give them the encouragement they need to cut down or stop using drugs.
- For others, finding ways to stabilize their life circumstances or establishing a social support system may be all they need to be ready for hepatitis C treatment.
- o Ultimately, very important to feel the patient can adhere before embarking upon therapy

oSVR rates approaching 100% have been achieved when HCV infection has been treated during the acute phase—much higher than in chronic infection.

- Early detection and treatment of acute HVC should be an urgent priority
- Persons at high risk should be tested regularly every 3 to 6 months
  - If previous +HCV antibody, negative RNA, screen with RNA every 3-6 months
  - o If previously testing negative with HCV antibody, continue to screen with HCV antibody/reflex testing every 3-6 months

#### Avoidance of re-infection

- Avoid all exposure to others' blood, even if trivial contact
  - All injection equipment including syringes, "cookers" (containers for dissolving), "cottons" (filters), rinse water, tourniquets, or any equipment for intra-nasal use
  - Wash hands and injection sites before and after injecting



## TREATMENT IN PRIMARY CARE/OTHER AREAS

- The CDC encourages family medical providers treat hepatitis C
- Outcomes when PCPs prescribe DAAs to patients with uncomplicated hepatitis C are comparable to those of subspecialists
- Patients with normal liver imaging, no cirrhosis, or even compensated cirrhosis, respond well to treatment by PCPs
- Refer patients with decompensated cirrhosis to specialists (GI or ID)
  - GI: decompensated cirrhosis and other serious complications
  - Infectious disease: HIV and hepatitis C co-infection
- Because some insurers require consultation with a subspecialist before they will cover a DAA, use of a telehealth program such as Project ECHO (Extension for Community Healthcare Outcomes) can be helpful



# HCV Elimination in North Dakota





#### Hepatitis C Advisory Council (Established in December, 2022)

- \* Developed by Sexually Transmitted and Bloodborne Diseases Unit of NDHHS
  - Requirement of CDC Viral Hepatitis Grant
- \* Goals: Stakeholder input on Viral Hepatitis Activities in ND
- \* Members Represent:
- Harm Reduction Programs, Local Public Health Units, Disease Intervention Specialists, Department of Corrections, Persons with Lived Experience, Tribal Health, Indian Health Services, Behavioral Health, Family Planning, Rural Communities, Providers Prescribing Hepatitis C Treatment
- Contracted with a Clinical Pharmacist as Facilitator

### GOAL 1: Develop ND HCV Elimination Plan

First Council Task: Develop HCV Elimination Plan for ND

**Development Process:** 

- Reviewed National Plan and CDC Guidance
- Utilized Goals from National Plan
- Held Council Meetings Jan April based on themes of Clinical Services; Date & Surveillance and Community Based Interventions
  - Developed: Objective, Strategies and Indicators
- Council Facilitator Drafting Plan Currently Available Summer 2023



### Goals & Activities of ND HCV Elimination Plan

#### **GOAL 1: PREVENT NEW INFECTIONS**

- **1.** Expanding access to harm reduction programs such as syringe service programs, sterile injection equipment, syringe disposal
- 2. Develop peer support network for hepatitis C care navigation
- **3.** More educational materials
- 4. Evaluate HCV screening rates during pregnancy
- 5. Develop provider trainings, support tools and resources

GOAL 2: IMPROVE VIRAL HEPATITIS RELATED HEALTH OUTCOMES OF PEOPLE WITH VIRAL HEPATITIS

- 1. Increase Testing: CTR, Home Testing, SUD Treatment Programs, Corrections, etc.
- 2. Increase hepatitis C treatment prescribing among primary care and other providers
- 3. Enhance patient education and outreach to those newly diagnosed and living with chronic hepatitis C
- **4.** Evaluate insurance related barriers

### Goals & Activities of ND HCV Elimination Plan

GOAL 3: REDUCE VIRAL HEPATITIS-RELATED DISPARITIES AND HEALTH INEQUITIES

- **1.** Reduce stigma through public awareness
- 2. Relationships and partnership development with those serving populations with disparities

GOAL 4: IMPROVE VIRAL HEPATITIS SURVEILLANCE AND DATA USAGE

- **1.** Develop HCV Care Cascade
- 2. Reengage Patients Along Care Cascade
- 3. Document risk behaviors and barriers to treatment
- 4. Annual Surveillance Report
- 5. Outbreak Response Plan

### Goals & Activities of ND HCV Elimination Plan

GOAL 5: ACHIEVE INTEGRATED, COORDINATED EFFORTS THAT ADDRESS THE VIRAL HEPATITIS EPIDEMICS AMONG ALL PARTNERS AND STAKEHOLDERS

- 1. Encourage syndemic (HIV,HCV, STIs, SUD) approach in all clinic types
- 2. Disseminate lessons learned on HCV elimination with partners
- **3.** Develop or utilize technical assistance resource for HCV treatment
- 4. Integrate viral hepatitis intro strategic planning efforts occurring at the local, community level



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# National Strategic Plan

# VIRAL HEPATITIS

National Strategic Plan A Roadmap to Elimination for the United States | 2021-2025 The United States will be a place where new viral hepatitis infections are prevented, every person knows their status, and every person with viral hepatitis has high-quality health care and treatment and lives free from stigma and discrimination.

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

National Viral Hepatitis Strategic Plan, 2021 - 2025

## HELPFUL REFERENCES AND RESOURCES

#### •Training:

- Online American Association for the Study of Liver Diseases (AASLD) modules
- Alternate training: University of Washington modules

#### •http://www.hcvguidelines.org/

•Hepatitis C Online (<u>https://www.hepatitis.uw.edu/go/evaluation-treatment/cost-access-medications/core-concept/all</u>

•Project ECHO (extension for community healthcare outcomes) <a href="https://echo.unm.edu/">https://echo.unm.edu/</a>

#### UpToDate

#### Summary

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## THANK YOU

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