Hepatitis C – Part 1

CDEpi Office Hours

March 4, 2021

Overview
HCV Part 1 – March 4, 2021

- Overview of Hepatitis C
- 2020 case definition
- Laboratory testing and serology
- Case investigation

PublicHealth IN THE 406

Overview
HCV Part 2, March 11, 2021

- MIDIS
  - Evaluating labs
  - Creating and managing investigations

PublicHealth IN THE 406

Hepatitis C (HCV) Disease

Viral disease which causes liver inflammation, sometimes leading to leading serious liver damage

- Acute or chronic illness
- In US, an estimated 50,300 cases of acute HCV occurred in 2018
- Actual acute cases are estimated to be 13.9 times the number of reported cases annually
- Estimated 2.4 million people in the US are living with chronic HCV infection
- There is no HCV vaccine

PublicHealth IN THE 406

Hepatitis C (HCV) Disease

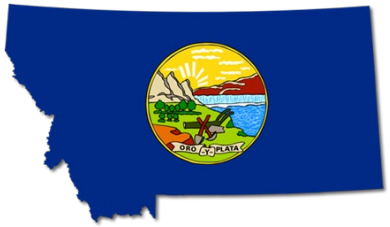
Incubation period is approximately 4-12 weeks (range 2-26 weeks)

Acute illness is not common

- About 20% to 30% develop symptoms of acute disease
- Typically 6 to 7 weeks after infection

PublicHealth IN THE 406

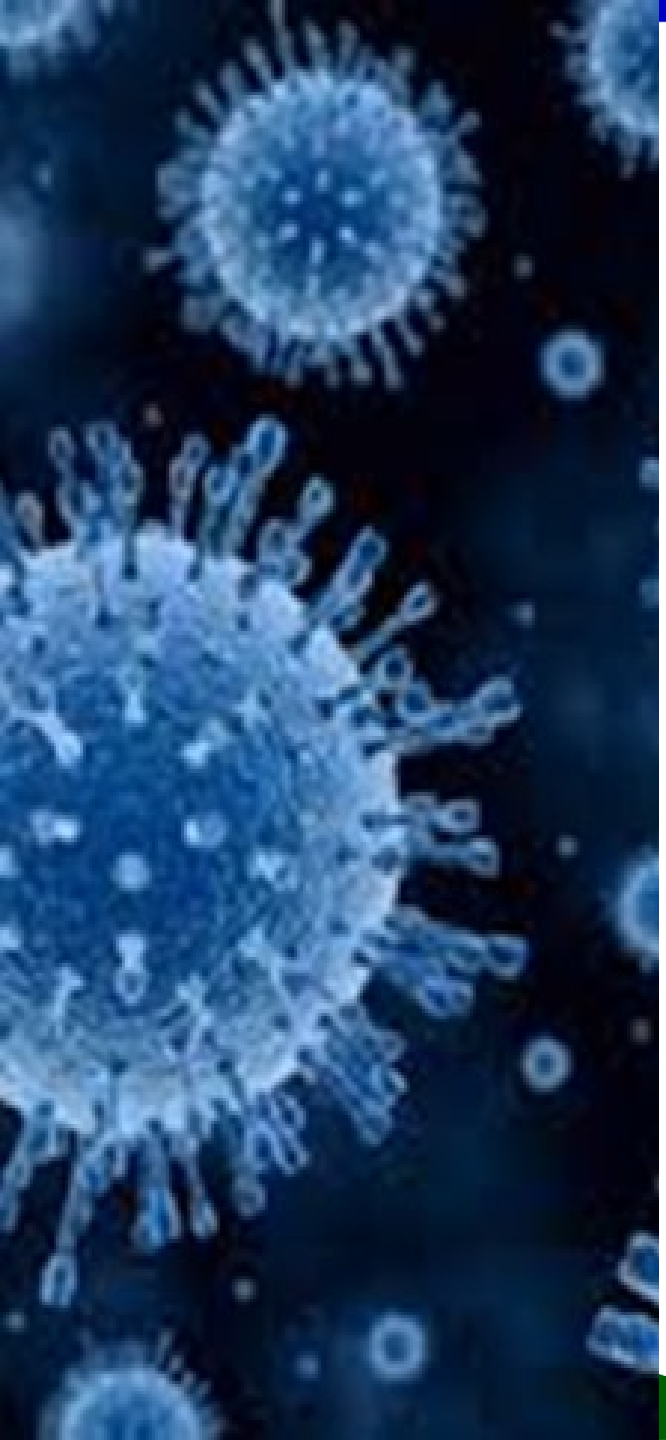
Hepatitis C (HCV) in Montana



- HCV is the ~~second~~ third most reported communicable disease in Montana
- **Acute** infection – an average of **15 cases** per year
- **Chronic** infection – an average of **1,500** cases per year
- HCV is often used as a marker of IDU, **particularly for young adults**

"Hepatitis C is a deadly, common, and often invisible result of America's opioid crisis," *- Jonathan Mermin, M.D., M.P.H., director of CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention.*

PublicHealth IN THE 406



Routes of Transmission

Contact with blood of an infected person.

- Injection drug use (currently the most common means of HCV transmission in the United States)
- Receipt of donated blood, blood products, and organs (once a common means of transmission but now rare in the United States since blood screening became available in 1992)
- Needlestick injuries in health care settings
- Birth to an HCV-infected mother

PublicHealth IN THE 406

Transmission

Although infrequent, HCV can also be spread through:

- Sex with an HCV-infected person (an inefficient means of transmission, although HIV-infected men who have sex with men [MSM] have increased risk of sexual transmission)
- Sharing personal items contaminated with infectious blood, such as razors or toothbrushes (also inefficient vectors of transmission)
- Other health care procedures that involve invasive procedures, such as injections (usually recognized in the context of outbreaks)
- Unregulated tattooing

Who Should be Tested?

CDC recommendations 2020

Universal hepatitis C screening:

- Hepatitis C screening at least once in a lifetime for **all adults** aged 18 years and older*
- 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%

Prior, focus of routine screening was on adults born between 1945 and 1965

Who Should be Tested?

CDC recommendations 2020

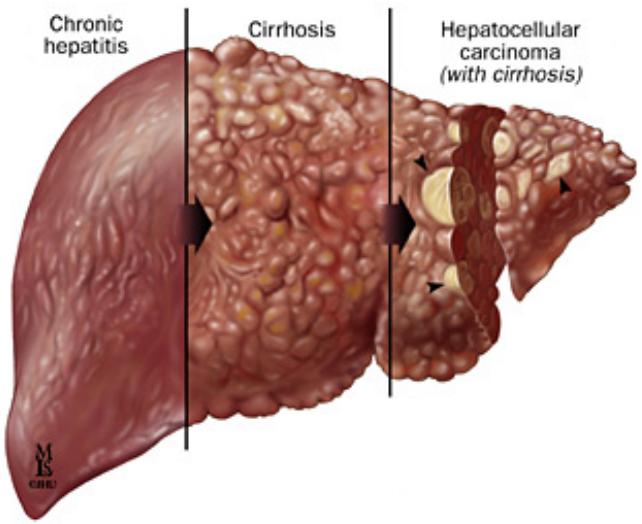
One-time hepatitis C testing regardless of age or setting among people with recognized conditions or exposures:

- People with HIV
- People whoever injected drugs/shared needles
- People with select medication conditions (e.g., hemodialysis)
- People with prior transfusion or organ transplant recipients
- Healthcare personnel with needlestick injuries or mucosal exposure to HCV+ blood
- Children born to mothers with HCV infection

Long Term Effects of Infection

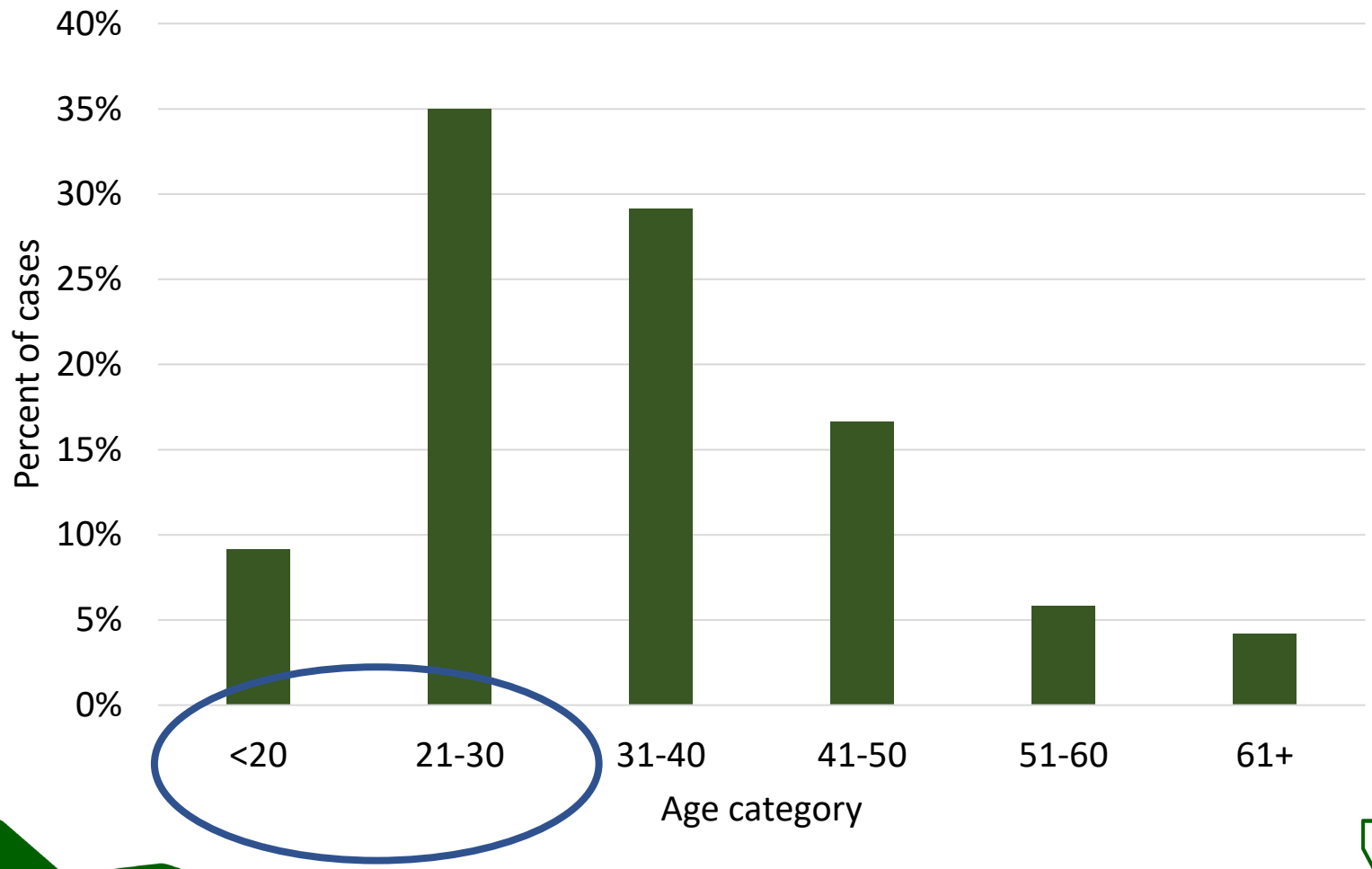
Out of every 100 people infected with HCV:

- 85 will develop chronic infection
- 60-70 will develop chronic liver disease
- 5-20 will develop liver cirrhosis in 20-30 years
- 1-5 will die of hepatocellular carcinoma



PublicHealth IN THE 406

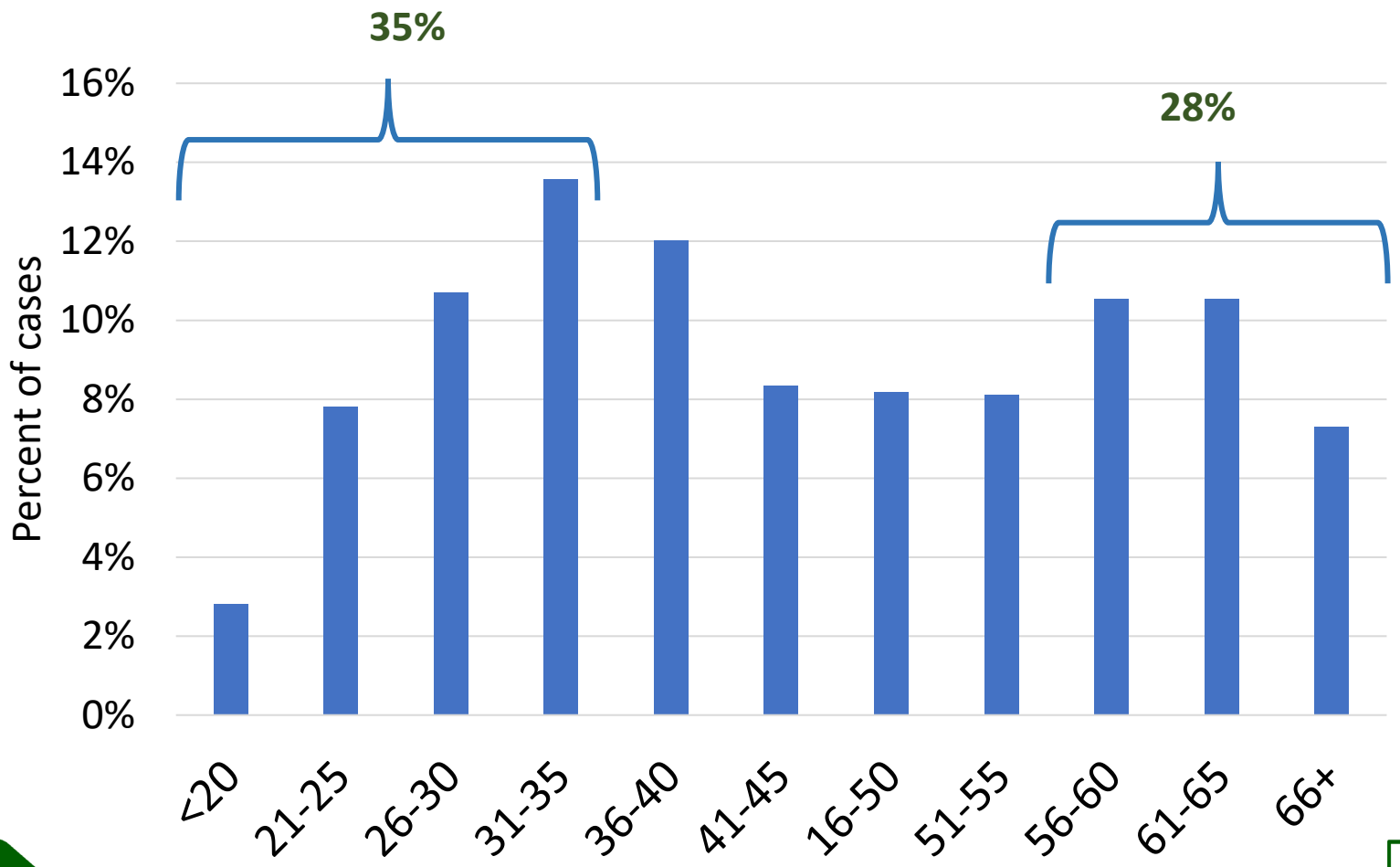
Percent of **acute** Hep C cases by age, Montana*



*Combines data from years 2012 to 2019

PublicHealth IN THE 406

Percent of **chronic** Hep C cases by age, Montana 2019



PublicHealth IN THE 406

Hepatitis C testing and laboratory algorithms

PublicHealth IN THE 406

HCV related laboratory tests

- Hepatitis C Antibody (HCV Ab)
  - Detects the presence of antibodies to the HCV
  - It cannot distinguish whether someone has an active or previous infection
- Hepatitis C RNA Qualitative
  - Used to confirm active infection in a HCV antibody positive person
  - Usually performed through PCR testing
- Hepatitis C RNA Quantitative (Viral Load)
  - Used to confirm active infection in a HCV antibody positive person
  - Used to monitor therapy
  - Usually performed through PCR testing
- HCV Genotype
  - Used to predict response to therapy, determine length of treatment
- HCV Resistance Testing
  - Used to predict response to therapy, ***not intended to diagnose chronic infection***

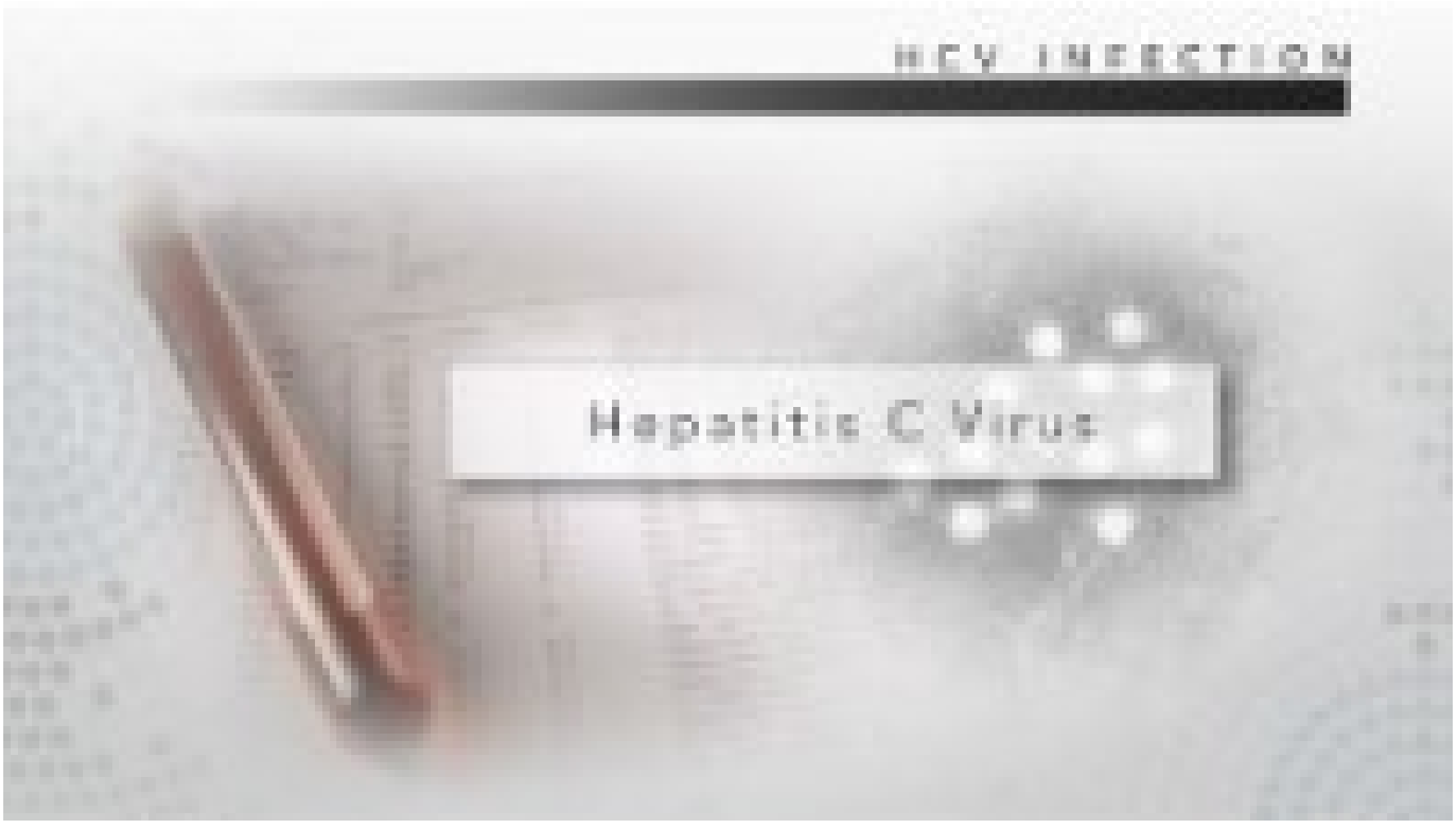
PublicHealth IN THE 406

HCV related laboratory tests

- Hepatitis C Antibody (HCV Ab)
  - Detects the presence of antibodies to the HCV
  - It cannot distinguish whether someone has an active or previous infection
- Hepatitis C RNA Qualitative
  - Used to confirm active infection in a HCV antibody positive person
  - Usually performed through PCR testing
- Hepatitis C RNA Quantitative (Viral Load)
  - Used to confirm active infection in a HCV antibody positive person
  - Used to monitor therapy
  - Usually performed through PCR testing
- HCV Genotype
  - Used to predict response to therapy, determine length of treatment
- HCV Resistance Testing
  - Used to predict response to therapy, ***not intended to diagnose chronic infection***

PublicHealth IN THE 406

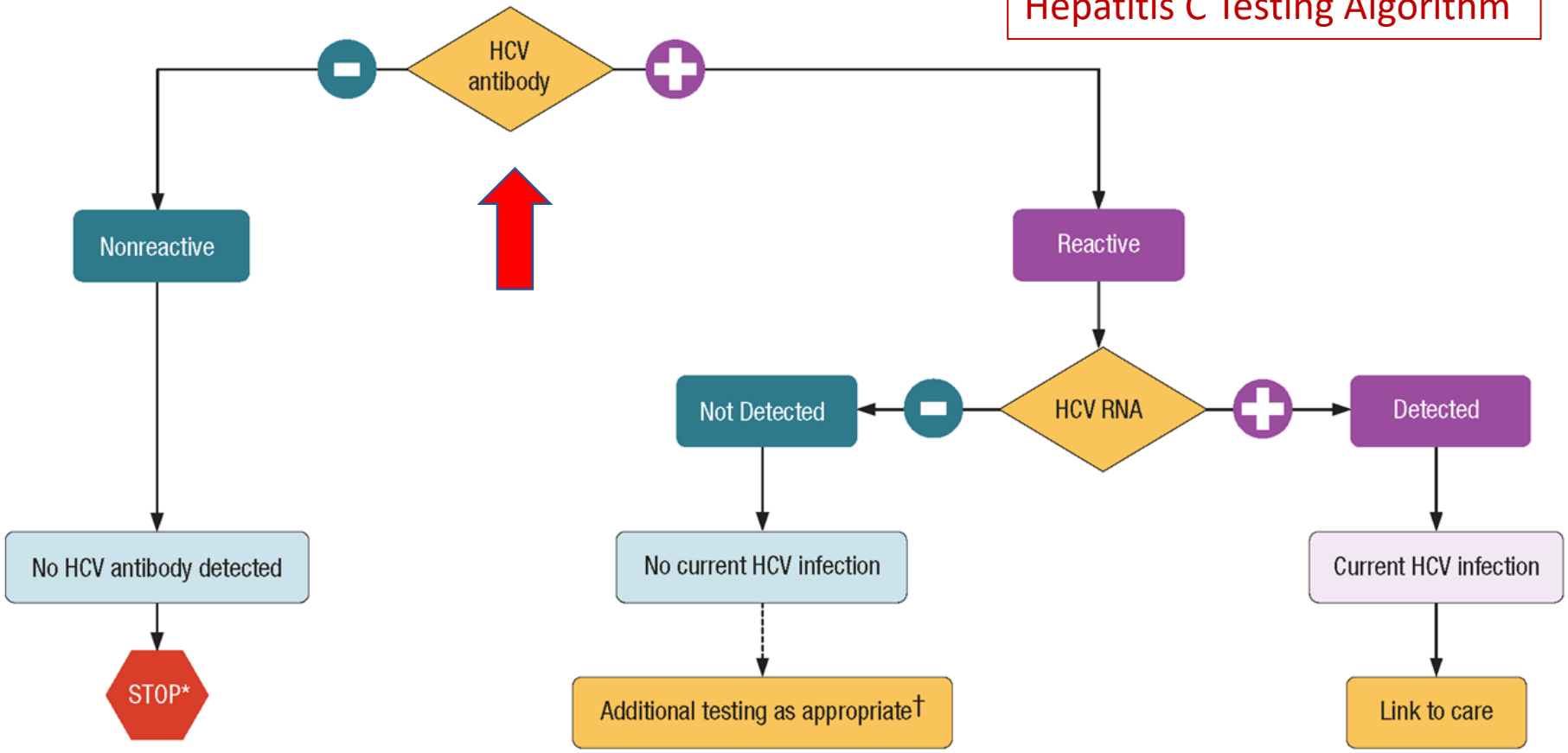
CDC Training Video https://www.youtube.com/watch?v=WyVQbJ0JUvI



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

Hepatitis C Testing Algorithm



* 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.

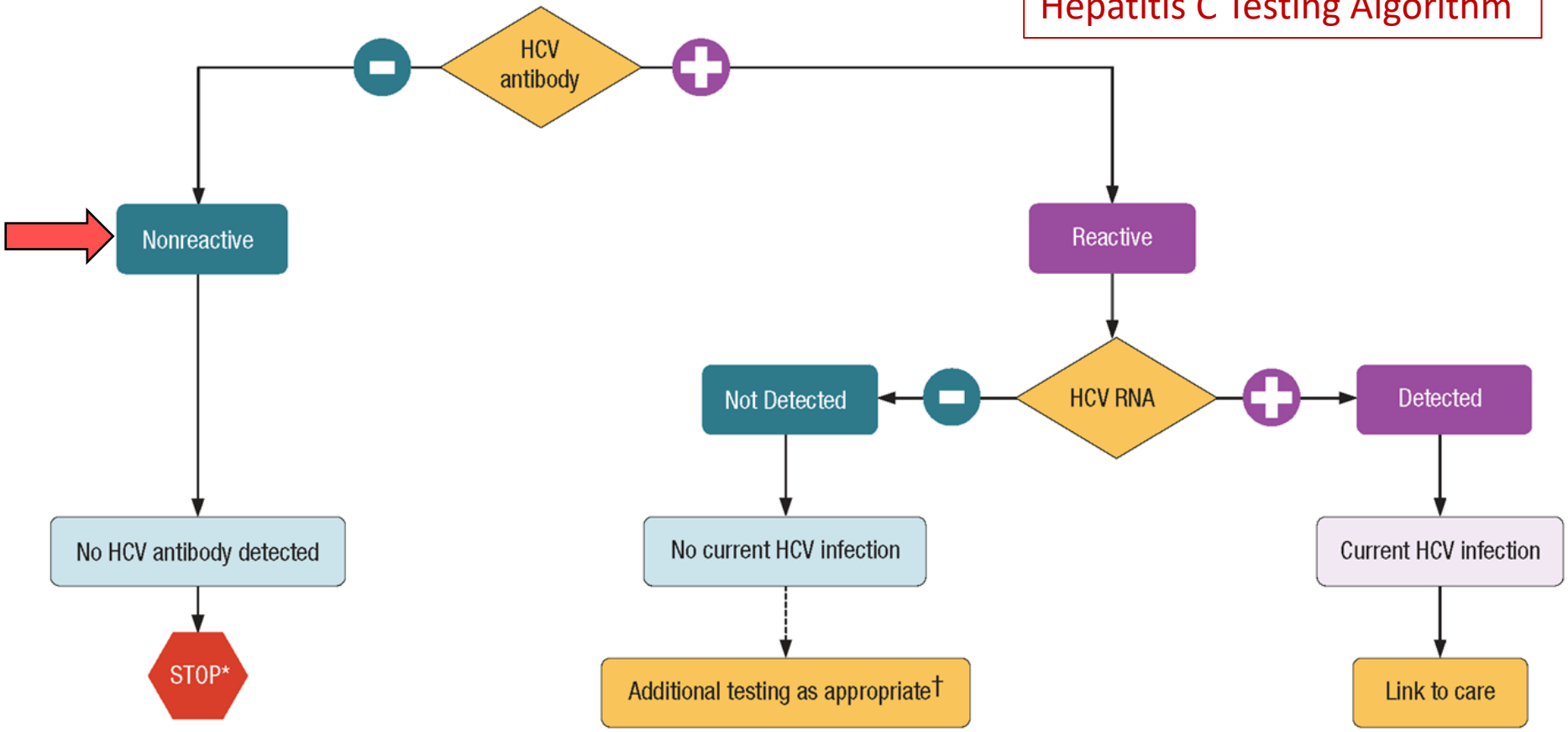
† To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

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

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

Hepatitis C Testing Algorithm



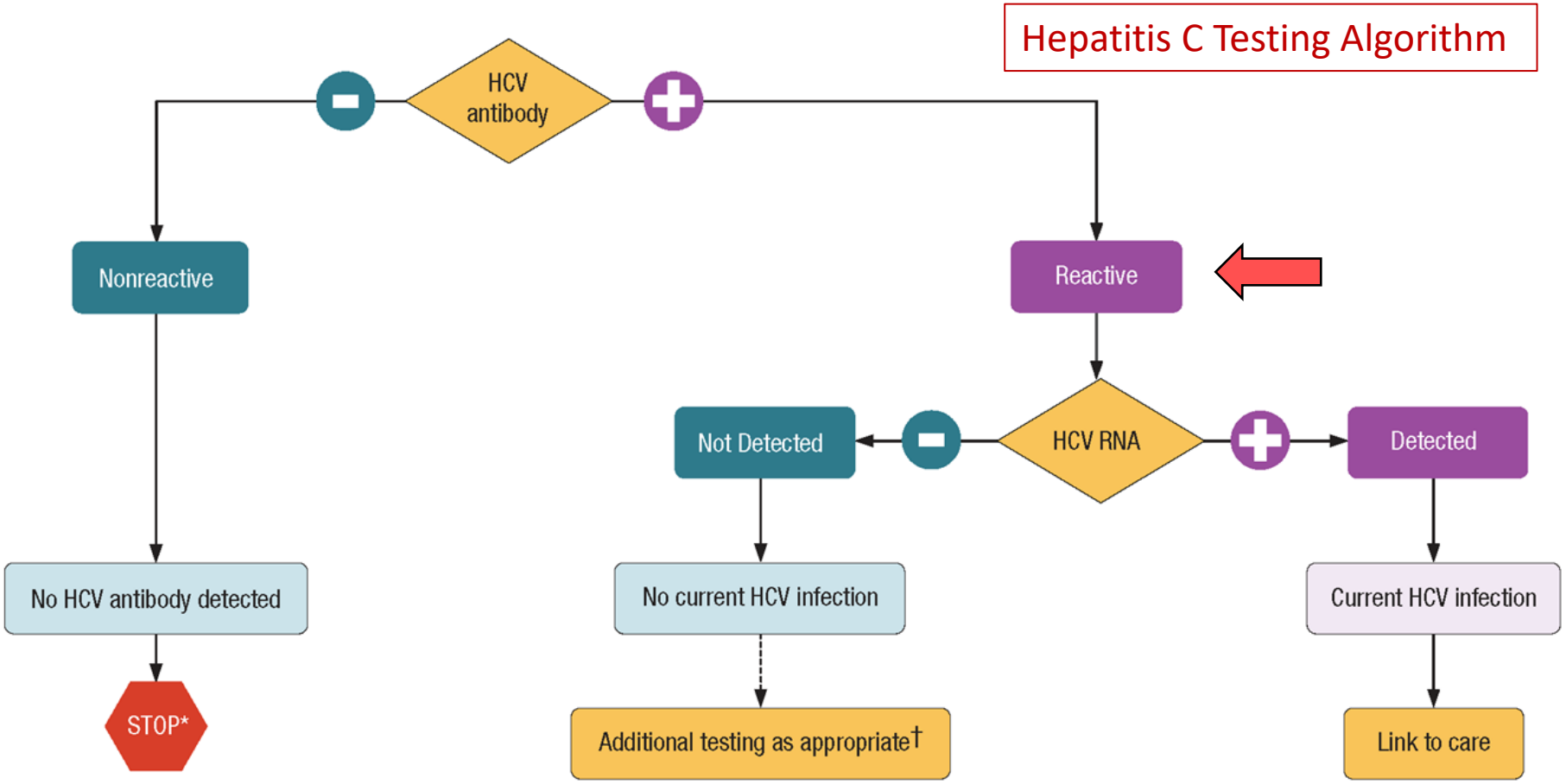
* For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

† 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.

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

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



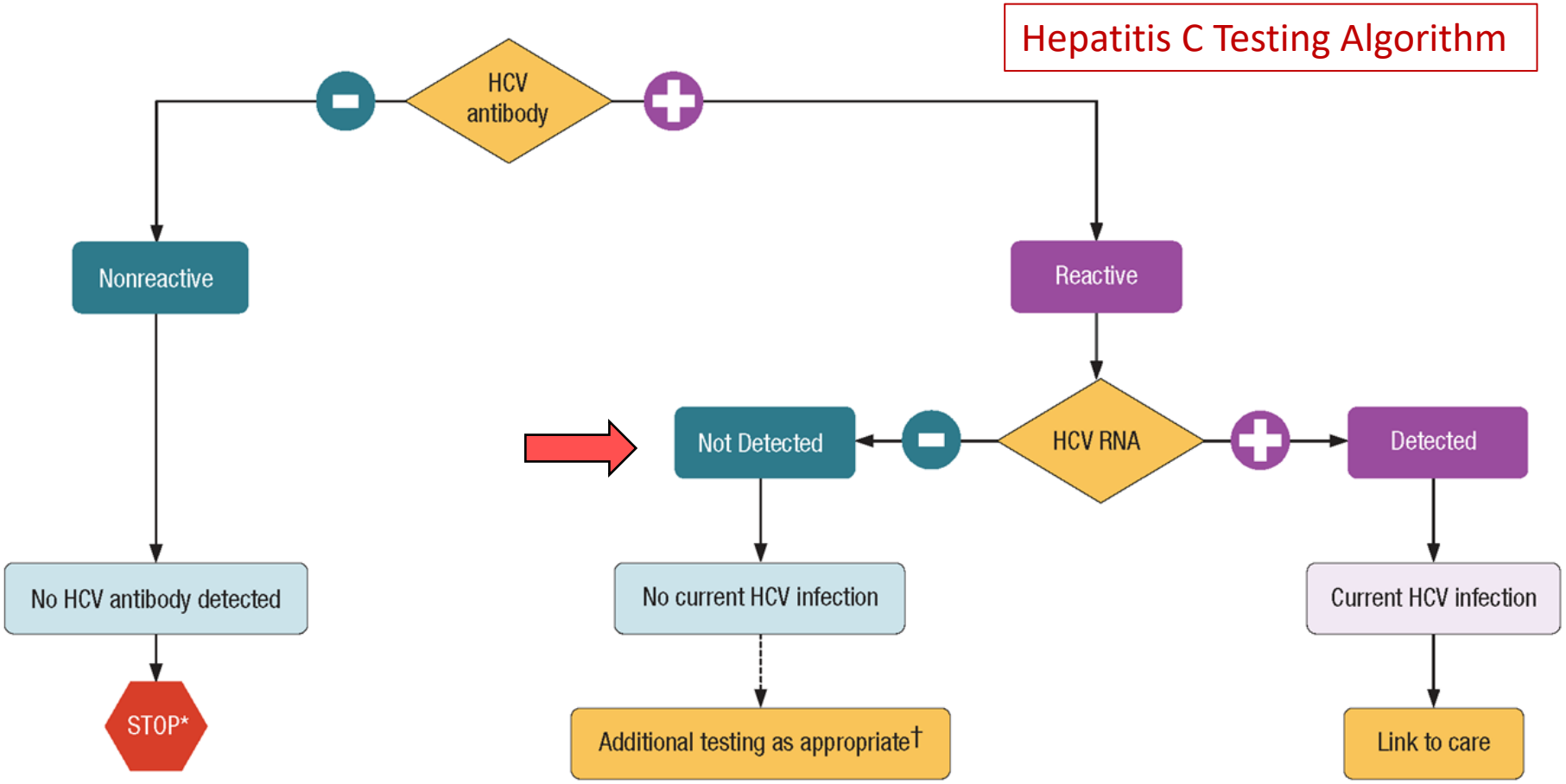
* For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

† 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.

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

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



* 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.

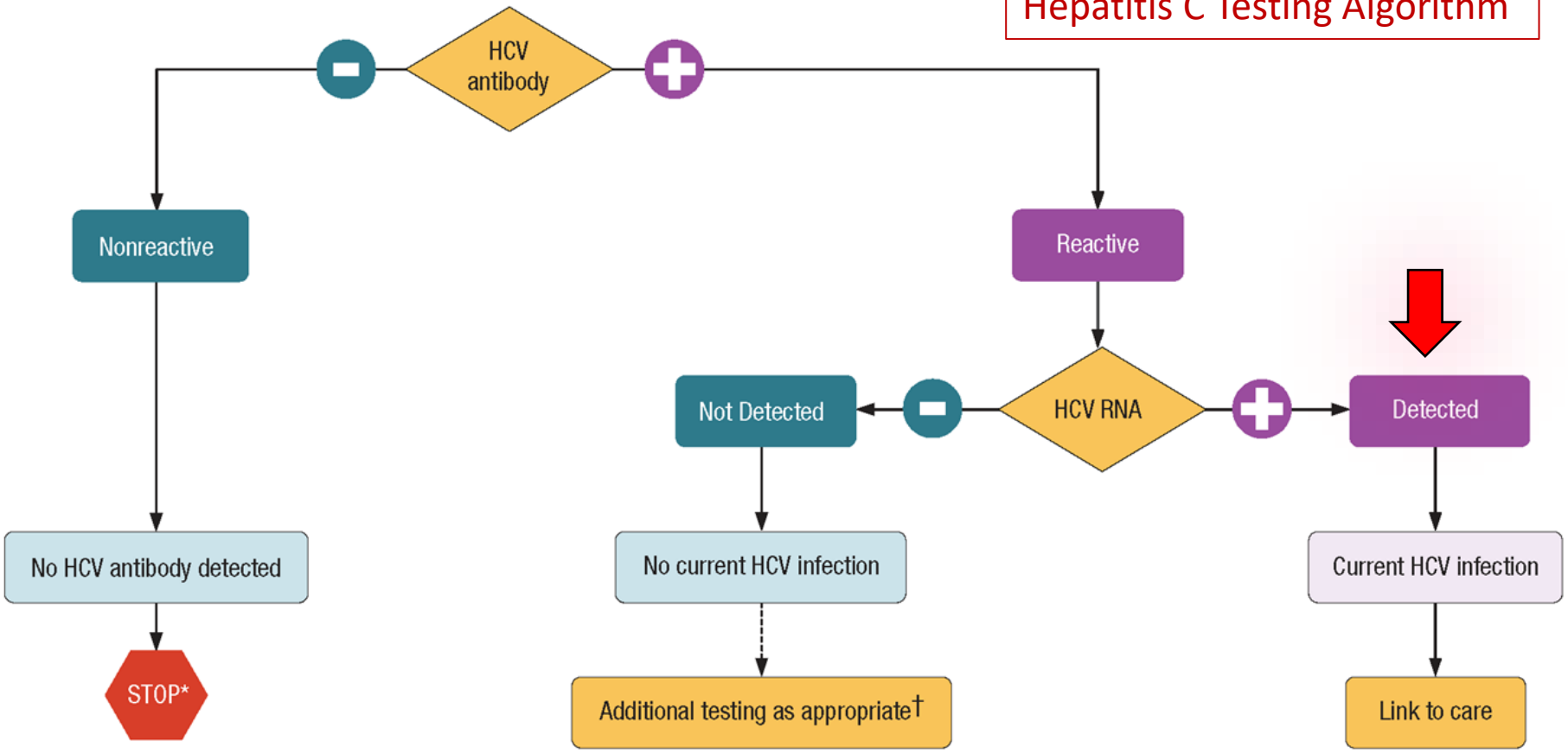
† To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

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

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

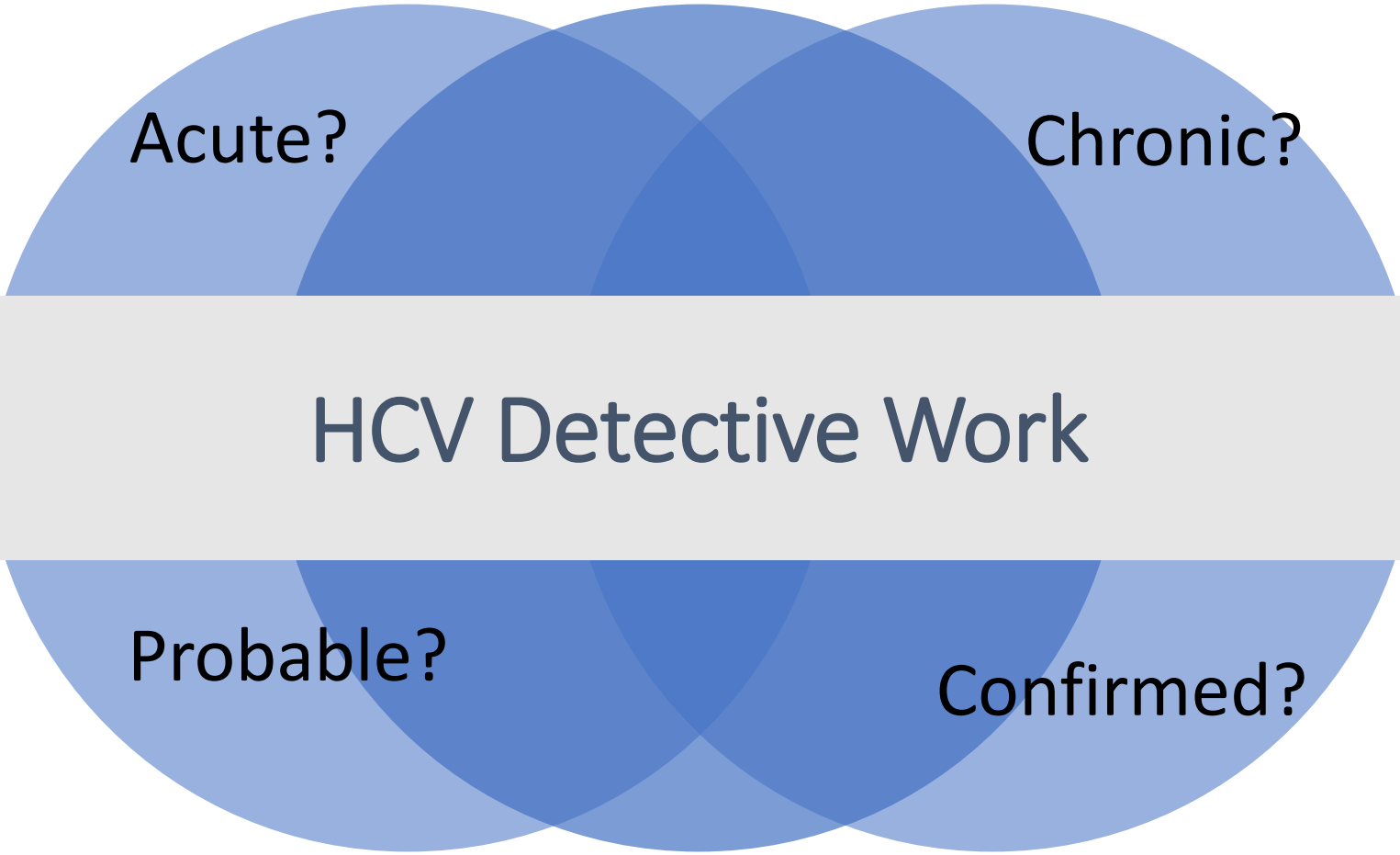
Hepatitis C Testing Algorithm



* 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.

† 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.

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



HCV Detective Work

PublicHealth IN THE 406

Surveillance Case Definition (2016) – *Acute Hepatitis C*

Clinical Criteria

One or more of the following:

- An illness with discrete onset of any sign or symptom consistent with acute viral hepatitis (e.g., fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, and abdominal pain) **AND**
- Jaundice **OR**
- Peak elevated serum alanine aminotransferase (ALT) level >200 IU/mL during the period of acute illness

Surveillance Case Definition (2020) – *Acute Hepatitis C*

Only 20% to 30% develop symptoms

Clinical Criteria

One or more of the following:

- ~~An illness with discrete onset of any sign or symptom consistent with acute viral hepatitis (e.g., fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, and abdominal pain)~~ ~~**AND**~~
- Jaundice **OR**
- Peak elevated serum alanine aminotransferase (ALT) level >200 IU/mL during the period of acute illness **OR**
- **NEW - Peak elevated total bilirubin levels ≥ 3.0 mg/dL**

AND

- **NEW - The absence of a more likely diagnosis (i.e., acute or advanced liver disease due to other causes such as alcohol exposure, other viral hepatitis, hemochromatosis, pre-existing chronic HCV infection, etc.)**

Surveillance Case Definition (2020) – *Acute Hepatitis C*

Clinical Criteria

One or more of the following:

- Jaundice **OR**
- Peak elevated total bilirubin levels ≥ 3.0 mg/dL **OR**
- Peak elevated serum alanine aminotransferase (ALT) level >200 IU/mL during the period of acute illness

AND

- The absence of a more likely diagnosis (i.e., acute or advanced liver disease due to other causes such as alcohol exposure, other viral hepatitis, hemochromatosis, pre-existing chronic HCV infection, etc.)

Surveillance Case Definition (2020) – *Acute Hepatitis C*

Test Conversion

A negative HCV antibody, HCV antigen or RNA test results followed with 12 months by documented positive results on *any* of these tests

Surveillance Case Definition (2020) – *Acute Hepatitis C*

Probable

- A case that meets clinical criteria and has a positive anti-HCV antibody test, but has no reports of a positive HCV RNA
  AND
- Does not have test conversion within 12 months or has no report of test conversion

Confirmed

- A case that meets clinical criteria and has a positive HCV RNA or HCV antigen
  OR
- Has had test conversion within 12 months.

Surveillance Case Definition (2020) - *Chronic Hepatitis C*

Probable

- A case that does not meet clinical criteria or has no report of clinical criteria; **AND**
- Does not have test conversion within 12 months or has no report of test conversion; **AND**
- Has a positive anti-HCV antibody test, but no report of a positive HCV RNA

Confirmed

- A case that does not meet clinical criteria or has no report of clinical criteria; **AND**
- Does not have test conversion within 12 months or has no report of test conversion; **AND**
- Has a positive HCV RNA

Quick Reference for Case Status

Acute Hepatitis C

- Clinical criteria* and positive antibody *only* = **Probable case**
- Clinical criteria* AND positive RNA test = **Confirmed case**
- Documented test conversion = **Confirmed case**

AND

*Absence of a more likely diagnosis

Chronic Hepatitis C

No test conversion or clinical criteria

- Positive antibody and no RNA = **Probable case**
- Positive antibody and positive RNA = **Confirmed case**
- Positive RNA only = **Confirmed**

REMEMBER:

Positive antibody and negative RNA is **not a case**

PublicHealth IN THE 406

Questions?

PublicHealth IN THE 406

First Actions

Confirm the diagnosis

- Review the laboratory results
- Is it a new or old case? Use MIDIS or patient history
- Contact the provider
  - Reason for testing?
  - Review the clinical presentation if reported (Jaundice, total bilirubin levels, liver enzymes
  - Had the patient been tested before with negative results?
  - Identify any risk factors (i.e., injecting drug use)
- Determine if this is an **acute** or **chronic** case. Use CCDM or CDC case definition for assistance

A specimen does not need to be submitted to the MT PHL for confirmation

PublicHealth IN THE 406

Case Investigation – Acute Hepatitis C

- Contact and interview the patient to determine source, risk factors, and transmission settings.
- Control measures. Ask about possible exposures 2 weeks to 6 months prior to onset of symptoms. Exposure information should include:
  - Contact with a person with confirmed or suspected HCV infection
  - Intravenous drug use
  - Receipt of donated blood, blood products, and organs
  - Occupational or other needle stick injuries in a health care setting
  - Birth to an HCV infected mother
  - Other parenteral exposures within 6 months of symptom onset (e.g., medical or dental exposures, receive tattoo or piercing, etc.)
  - High-risk sexual contact (e.g., multiple partners, history of STDs, etc.)
- Identify, contact and interview patient contacts
- Education and counseling

PublicHealth IN THE 406

HCV Education and Counseling

Prevention

- Stop using and injecting drugs
- If continued use; never reuse or “share” syringes, needles, water, or drug preparation equipment
- Risk of sexual transmission is low, but is greater for persons with multiple partners, anal sex, history of STDs, etc.

Counseling

- Treatment is available that can cure HCV
- Avoid alcohol because it can accelerate cirrhosis and end-stage liver disease
- Consult with a health professional before taking any new prescription pills, over-the counter drugs (such as non-aspirin pain relievers), or supplements, as these can potentially damage the liver.
- Avoid sharing personal items that might have blood on them, such as toothbrushes or razors
- Cuts and sores on the skin should be covered
- Donating blood, organs, tissue, or semen can spread HCV to others.
- HCV is not spread by sneezing, hugging, holding hands, coughing

PublicHealth IN THE 406

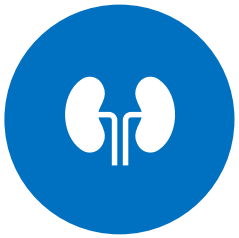
Case Investigation – Chronic Hepatitis C

- May contact and interview the patient to determine source, risk factors, and transmission settings. May also work through the provider to accomplish this step.
- Control measures
  - Ask about possible exposures outlined for acute hepatitis C (above) beyond the 2 weeks to 6 months' timeframe. For example, patients should be asked if they ever had a parenteral exposure, rather than restricting it to within the 6-month window.
- Education and counseling – see previous slide

PublicHealth IN THE 406

Hepatitis C Treatment

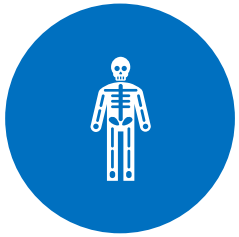
Chronic Hepatitis C can be treated, controlled, and monitored for those infected with the disease.



The **treatment** for chronic HCV varies **based on the individual and the level of liver damage**.

However, individuals who have developed **liver damage** from the virus will also require the **appropriate treatment for their condition.**

There is currently no treatment recommended for acute HCV. CDC guidelines recommend following the patient and implementing treatment if the condition becomes chronic.



There are currently different **drugs and short-term therapies** (ranging from 8-12 weeks) to eliminate the HCV virus with a **90% success rate**.

PublicHealth IN THE 406

Montana Medicaid Coverage for HCV Treatment

Effective February 3, 2020:

- Treatment is coverage to individuals with all states of liver fibrosis *(previously required a fibrosis score of F3 or greater)*
- Elimination of provider specialty restriction and readiness criteria
- Requires a Prior Authorization to ensure FDA approved indication and length of treatment
- Providers must educate patient on treatment, assess psychosocial readiness and screening/counseling on drug and alcohol use *(previously required 6 months sobriety)*

PublicHealth IN THE 406

Frequently Asked Questions

Q: What is the prevalence of HCV infection among injection drug users?

*A: **An estimated 50%.** There are no nationwide seroprevalence surveys targeting IDU in the United States. However, a multi-state review of global HCV published in 2017 estimated that **over half of IDU** in the US are infected with HCV. They found this ranged between an average 38% to 68%.*

Q: Should HCV-infected persons be restricted from working in certain occupations or settings?

*A: **No.** CDC's recommendations for prevention and control of HCV infection specify that people should not be excluded from work, school, play, childcare, or other settings on the basis of their HCV infection status. There is no evidence of HCV transmission from food handlers, teachers, or other service providers in the absence of blood-to-blood contact*

PublicHealth IN THE 406

MIDIS ID: _____

Hepatitis C Case Determination Tool

Date: _____ Patient name: _____ DOB: _____

Provider name and phone #: _____

Lab Test Results Checklist			
Disease	**Lab Test**	**Results positive or negative**	**Results quantitative**
Hepatitis C	anti-HCV (HCV Ab)		
	HCV RNA		
Liver Enzymes	ALT		
Bilirubin levels	Peak elevated level		

Healthcare Provider Question Checklist

Reason for Testing

1. **Screening:**
   - **Routine screen for present concern:** **yes/no** i.e. starting on a liver toxic medication, cancer treatment, known chronic case to the physician, baseline screening, etc.

     or
   - **At risk:** **yes/no** i.e. IDU, MSM, born out of the United States, STD, co-morbidity such as HIV, recent exposure, contact to a case, etc.
2. **Symptoms:**
   - Jaundice: **yes/no**
   - Peak Elevated total bilirubin levels ≥ 3.0 mg/dL: **yes/no**
   - ALT > 200 IU/L for Hep C: **yes/no**

3. **Was there a previous negative HCV Ab, Ag or RNA test in past 12 months? Yes/no.**

4. **Other likely diagnosis?** (e.g., liver disease due to alcohol exposure, other viral hepatitis, drug over use, etc.)? **yes/no. If yes, please specify:** _____

Other Information

- Recent vaccination with hepatitis B vaccine: **yes/no**
- Race and ethnicity: _____
- Hospitalization? **Yes/no. If yes, please specify:** _____

DRAFT

PublicHealth IN THE 406

MIDIS ID: _____

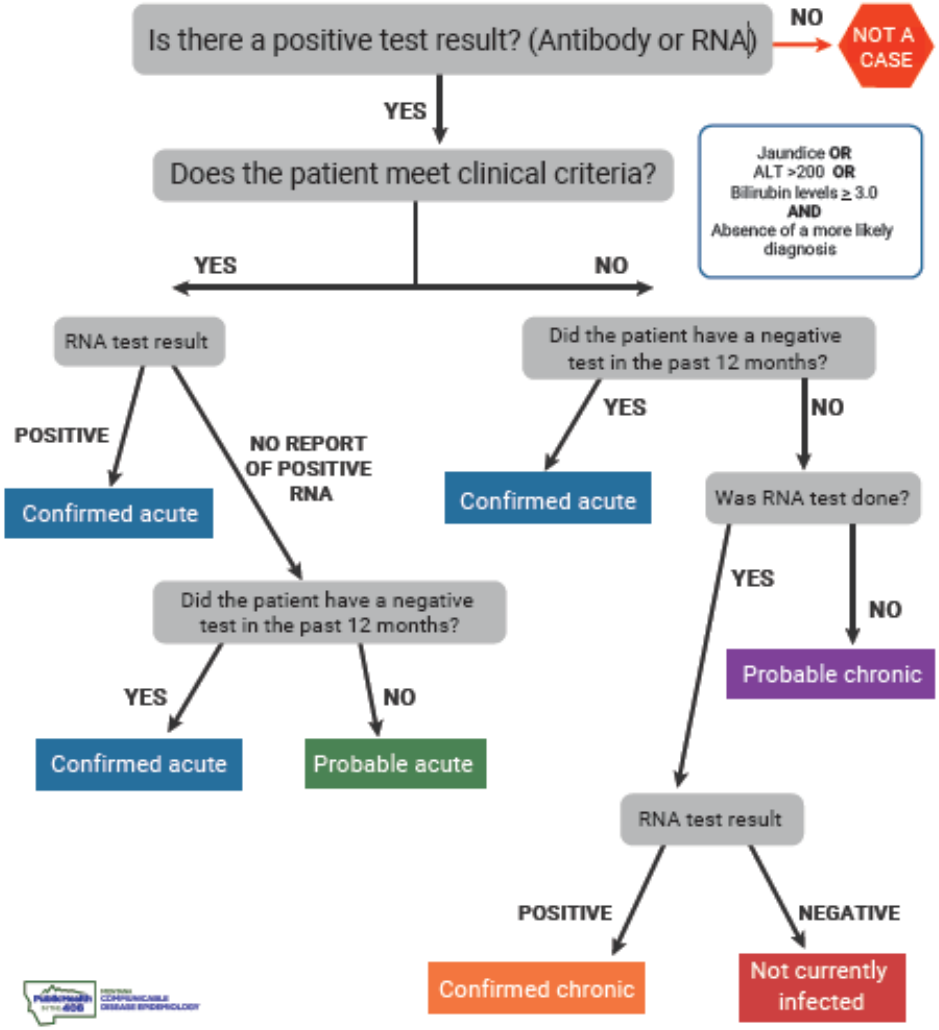
If this is a probable or confirmed acute case, please gather the information needed for the Hepatitis extende tab in MIDIS

For 2 Weeks to 6 Months Prior to Onset of Clinical Signs	Yes/No
Was the patient a contact to an HCV case?	
Sexual Exposures in the Prior 6 Months	**Yes/No**
What is the sexual preference of the patient?	
How many male sex partners?	
How many female sex partners?	
Was the patient ever treated for an STD?	
For 2 Weeks to 6 Months Prior to Onset of Clinical Signs	**Yes/No**
Did the patient undergo hemodialysis	
Have an accidental stick/puncture with a needle or other object contaminated with blood?	
Receive blood or blood products (transfusion)	
Receive any IV infusions and/or injections in the outpatient setting	
Have other exposure to another person's blood	
Was patient employed as a public safety worker having direct contact with human blood	
In the Time Period Prior to Onset	**Yes/No**
Did the patient receive a tattoo	
Inject drugs not prescribed by a doctor	
Use street drugs but not inject	
Have any part of their body pierced (other than ear)?	

DRAFT

PublicHealth IN THE 406

Applying case definition for Hepatitis C



created December, 2019

Resources:

- The ABCs of Hepatitis-CDC 2020
  - https://www.cdc.gov/hepatitis/resources/professionals/pdfs/abctable.pdf
- Hepatitis C Professional Resources Website-CDC
  - https://www.cdc.gov/hepatitis/hcv/profresourcesc.htm
- Montana Healthcare Programs website and questions may be directed to the Medicaid Pharmacist at 406-444-5951 or Pharmacy Program Officer at 406-444-2738. https://medicaidprovider.mt.gov/Portals/68/docs/forms/HepCPAForm01102020.pdf

PublicHealth IN THE 406

Questions?

PublicHealth IN THE 406

Tune in on March 11, 2021 for HCV Part 2

PublicHealth IN THE 406

Overview
HCV Part 2, March 11, 2020

- Evaluating lab results in MIDIS
- Case investigations
- Frequently asked questions
- Tips and resources

PublicHealth IN THE 406