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Maine Medical Association

Department of Health and Human Services

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# Simplified Treatment of Hepatitis C in Primary Care Settings

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# Disclosures

- MICIS does not accept any money from pharmaceutical companies nor commercial interests
- None of the planners or faculty for this educational activity have relevant financial relationships with ineligible companies
- I have no conflicts of interest
- *This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of the Maine Medical Education Trust and the Maine Independent Clinical Information Service (MICIS). The Maine Medical Education Trust is accredited by the Maine Medical Association Committee on Continuing Medical Education and Accreditation to provide continuing medical education for physicians.*

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# Objectives

- Understand the importance of screening for Hepatitis C
- Know next steps when initial HCV screen is positive
- Identify elements of a comprehensive care plan for patients with HCV

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# Advertisement:
# MICIS primarily provides private CME sessions called "Academic Detailing"

*Multiple topics available*
*including a deeper dive on*
*treating Hep C in primary care*

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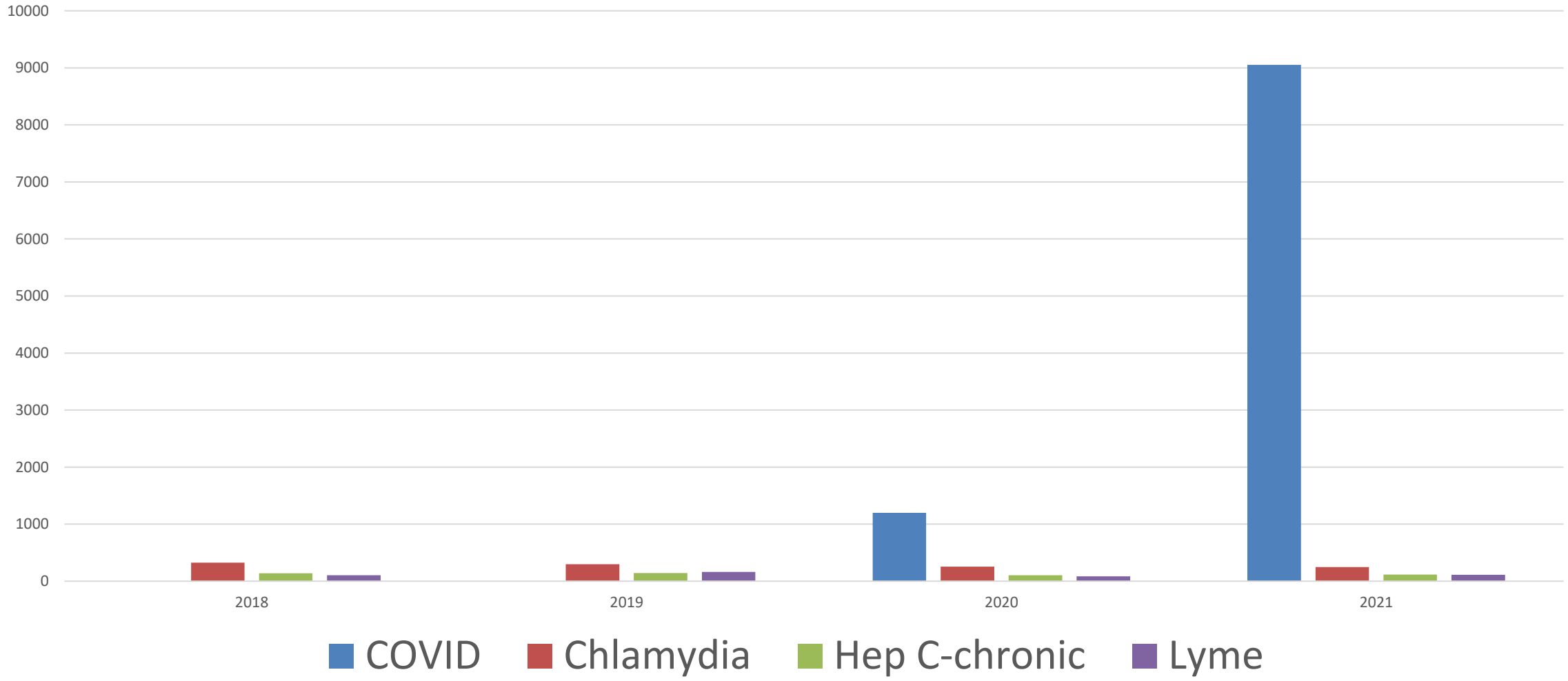
# Reportable Infectious Diseases in Maine (rate per 100k persons)

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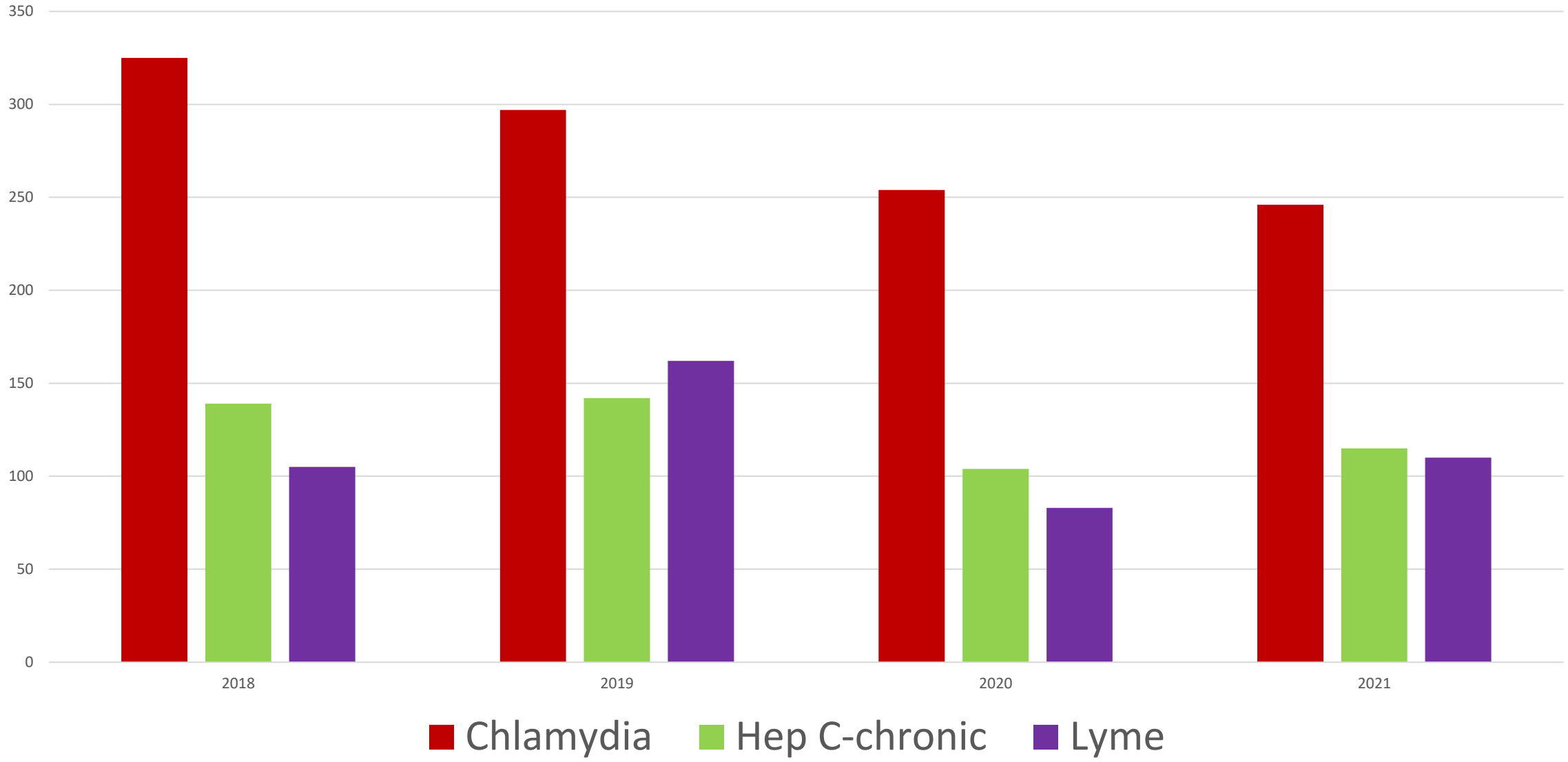
# ID Rates without COVID

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# Why should all adults get tested for hepatitis C?

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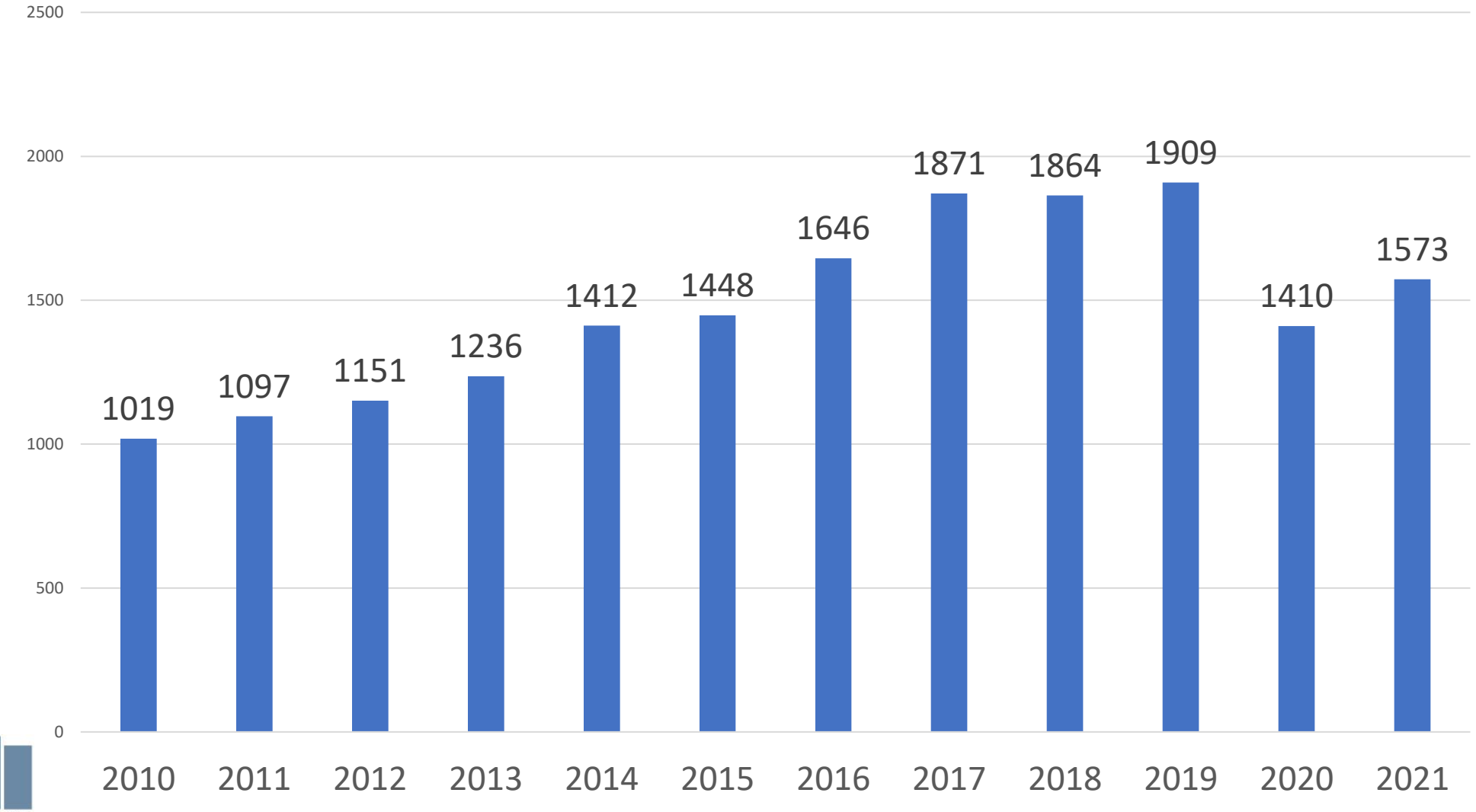
# Reported New Cases of Chronic Hep C, Maine

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# HEP C FACTS

- HCV is the most common reason for liver transplant
- HCV is associated with more deaths than the top 60 other reportable infectious diseases COMBINED (including HIV, prior to COVID)
- Up to 50% of people with HCV clear the virus spontaneously
- Tx of early disease is likely cost-effective and even possibly cost-saving

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## Pathway to Cure:
Simplified Treatment of Hepatitis C in Primary Care Settings

### Maine Diagnosed Chronic Hepatitis C



Screen → Evaluate SUDs → Work Up → ? Refer → Develop Care Plan → Evaluate Treatments → SVR

### Screen

**Global HCV Screening Recs (USTFPS)**
- All adults 18-79 once-if assx/no known liver dz
- Periodically if ongoing risk
- Screen younger and older if high risk
- During every pregnancy (per CDC)
- If evaluating elevated LFTs, you are no longer screening

**Increased Likelihood of Spontaneous Clearance**
- Jaundice
- Inc ALT
- HBsAg positive
- Younger age
- Female
- Genotype 1
- Certain host genetic polymorphisms

### Evaluate SUDs

**QUICK FACTS**
- HCV is the most common reason for liver transplant
- Tx of early disease is likely cost-effective and even possibly cost-saving
- Up to 50% of people with HCV clear the virus spontaneously
- ~50% of PWID (people who inject drugs) are infected with HCV
- Intersection of substance use disorders (SUDs) + HCV offers an opportunity to initiate treatment for both

### Develop Care Plan

**Why Treat?**
- Decreases the incidence of diabetes, glomerulonephritis, non-Hodgkin's lymphoma, stroke
- Can reverse liver fibrosis & prevent cirrhosis
- Improves health outcomes—decreases all-cause mortality, liver disease mortality, cirrhosis, hepatocellular carcinoma

**Prior to Initiating Treatment**
- Stage hepatic fibrosis/liver disease severity
- Educate patient on crucial importance of Rx adherence
- Evaluate contraception
- **Check drug-drug interactions**
- Consider partnering with a specialty pharmacy or clinical pharmacist

**More Likely to Develop Cirrhosis**
- Male
- Age >50
- Alcohol use
- NASH
- Hepatitis B/HIV co-infection
- Immunosuppressive therapy

### Work Up

- If HCV antibody positive, check viral load
- Baseline labs within 3-6 months of starting treatment
  - Hep A & B, HIV, CBC, CMP, INR, Serum pregnancy (just prior to tx), +/- genotype
- Evaluate for advanced liver disease using serum scores or panels, possible transient elastography specific ultrasound

**Counsel Patients with HCV**
- Protect close contacts
- Abstain from alcohol & marijuana
- Take acetaminophen up to 2g/d as needed (if abstaining from EtOH)
- Avoid NSAIDs/certain herbals
- Strive for a healthy weight
- Provide vaccinations: Hep A,* Hep B,* Annual influenza, COVID-19, Pneumococcal**

*if nonimmune **if cirrhotic

Pathway to Cure: Simplified Treatment of Hepatitis C in Primary Care Settings

### Evaluate Treatments

**Two Primary Simplified Treatments Treat All Genotypes**
- DAAs-Direct-acting antivirals
- glecaprevir/pibrentasvir (Mavyret®) x8w
- sofosbuvir/velpatasvir (Epclusa® or generic) x12w
- HA, fatigue, nausea in >10% but generally well tolerated

**Cost**
- Expense of tx partly offset by high liver-related healthcare expenditures later in life for those

**Key Messages**
- Screen patients for HCV
- Recognize the intersection with substance use disorders
- Work up patients who screen positive
- Decide who to refer for subspecialty care
- Develop a comprehensive care plan
- Evaluate treatment considerations

**Disclaimer**
These are general recommendations only; specific clinical decisions should be made by the treating

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# Pathway to Hepatitis C Cure Handout

available at MICISMaine.org

# Pathway to Hepatitis C Cure Packet/Resources

- Request form for Hep C “Level 2” CME session
- Handout (pdf)
- Brief (2 page) review article by UNE Medical Student in 2020
- Resource list w/hyperlinks
- Reference list
- Slide deck

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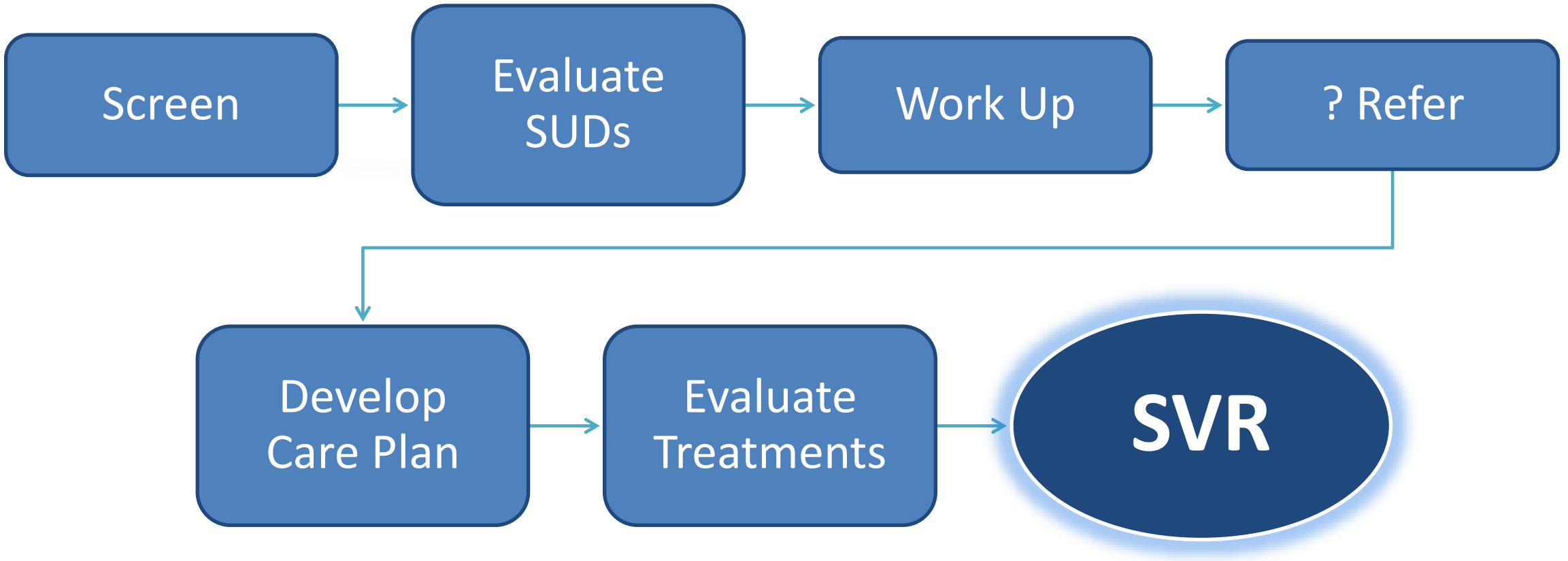
# Pathway to Hepatitis C Cure

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# Now, a video case study

- Introducing Will, a new patient
- 55 year old male
- Presents to your primary care office with severe pruritis
  - *just pretend he did not present to the Hopkins sub-specialty clinic

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## Introducing Will, a new patient, presenting with severe pruritis.

Learn more about his path in an alternate universe: www.youtube.com/watch?v=qO-Xz0SC26E

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# Screen

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# HCV Screening Recs (USTFPS)

- All adults 18-79 once-if assx/no known liver dz
- Periodically if ongoing risk
- Screen  younger and older if high risk
- During every pregnancy (per CDC)
- If evaluating elevated LFTs, you are no longer screening
- CLIAw POC fingerstick testing method approved in 2011!

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# Evaluate SUDs

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# HEP C FACTS

- ~53% of PWID (people who inject drugs) are infected with HCV [range 38-68]
- Intersection of substance use disorders + HCV offers an opportunity to initiate treatment for both
- Treating either prevents HCV spread
- Active drug use is not an absolute contradiction to tx

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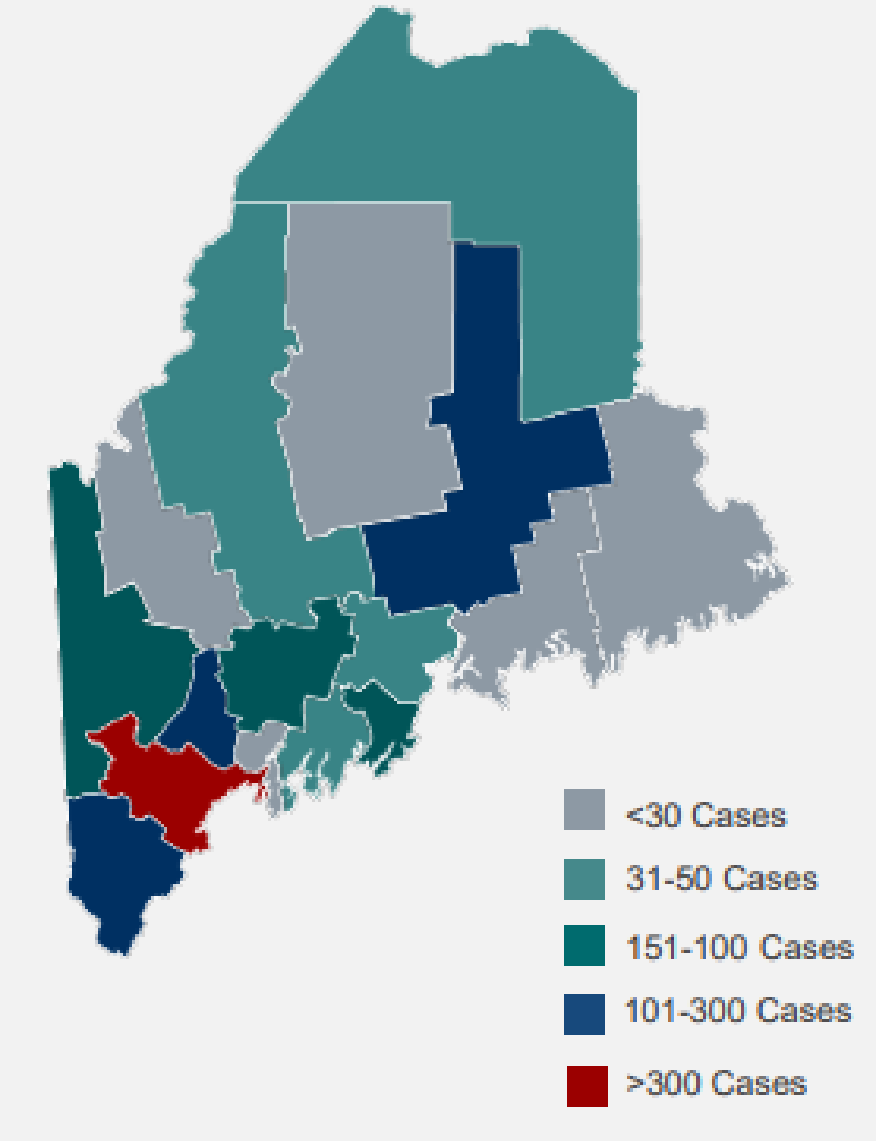
# New Chronic Hep C Cases, Maine, 2022




Reference: Maine CDC, https://www.maine.gov/tools/whatsnew/attach.php?id=11676435&an=1

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# ME CDC Annual Report 2019
# Some key recommendations to
# Reduce Overdose & Bloodborne Infections

- Increase the number and staffing of syringe service programs
- Increase the # of MOUD providers in Maine's most vulnerable areas, including via telehealth and in correctional facilities

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# Reflection question

If Will were still actively injecting opioids, could he receive buprenorphine-naloxone treatment at your primary care office (where you work or are a patient)?

- A. Yes, currently
- B. No, and we will start prescribing MOUD in the next 6 months
- C. No, and we will start prescribing MOUD in the next year as it is becoming a standard service for primary care

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# Work Up

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# Work Up 1

- If HCV antibody positive, check viral load
- HCV antibody stays positive *lifelong,* even after successful tx
- Some insurance plans may require documentation of chronic infection (>6 months) to initiate treatment

# Counsel Patients with HCV

- Protect close contacts
- Abstain from alcohol & marijuana
- Take acetaminophen up to 2g/d as needed (if abstaining from EtOH)
- Avoid NSAIDs/certain herbals
- Strive for a healthy weight
- Assess coffee intake
  - 2-3C/d assoc with dec risk of hospitalization & death from chronic liver dz

# Work Up 2

- Baseline labs within 3-6 months of starting treatment
  - Hep B surface antigen, HIV
  - CBC
  - CMP or LFTs & eGFR
  - Serum pregnancy (within 1-2 mos of inititation)

  - Genotype not required for simplified treatment-may be required by some insurers

# Vaccinate!

- Hep A
- Hep B
- Annual influenza
- Latest COVID-19 booster
- Pneumococcal (if cirrhotic)

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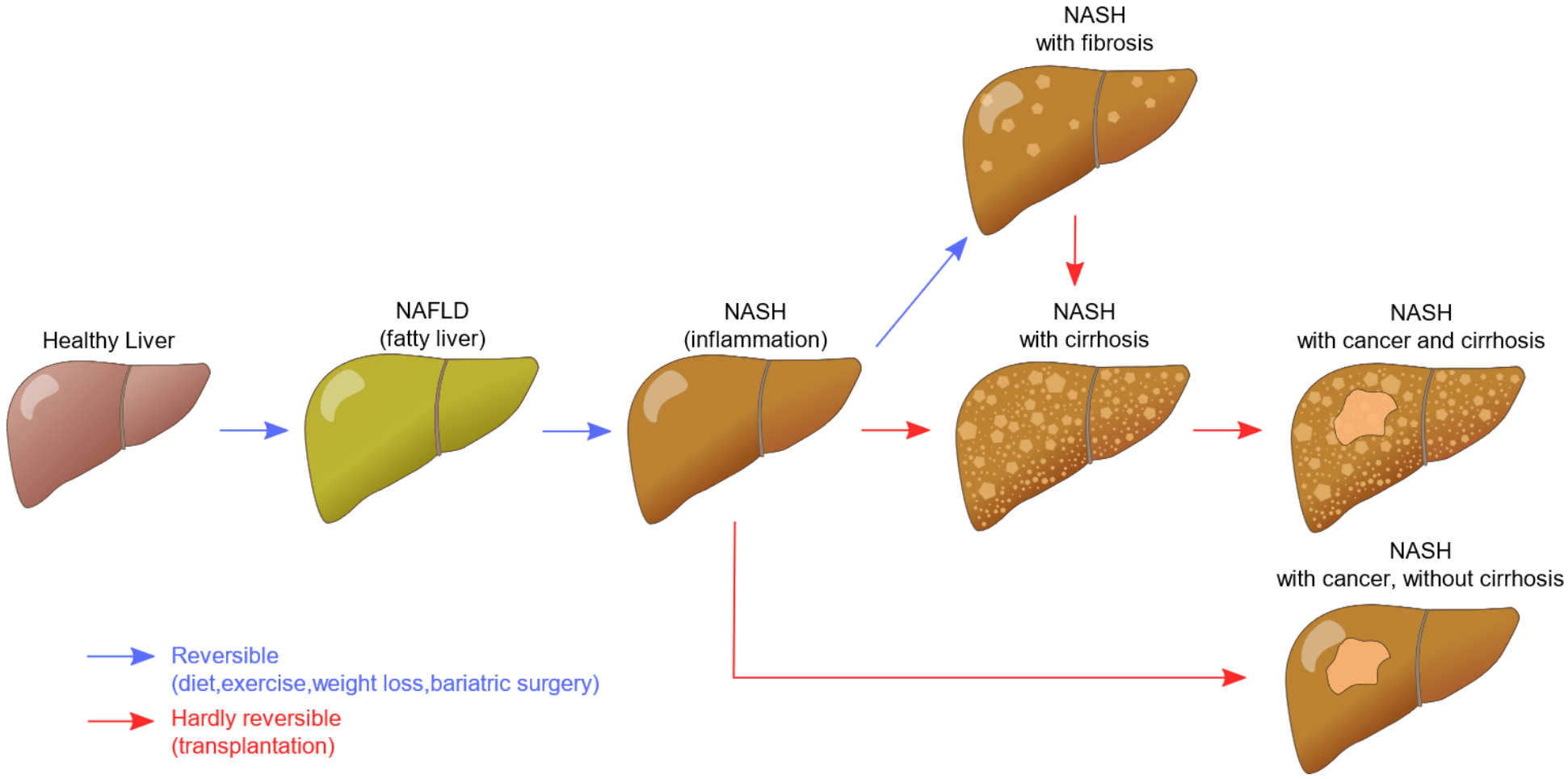
# Stages of Liver Fibrosis

**(NASH used for graphic demonstration purposes)**

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# Evaluate for Cirrhotic Liver Disease

- Calculate lab scores:  FIB-4
- Evaluate past records for previously performed transient elastography, prioprietary fibrosis lab tests, suggestive findings on imaging, platelets <150, prior dx of cirrhosis
- If no prior findings suggestive of cirrhosis and FIB-4 <3.25, no further work up needed (in particular, liver biopsy is no longer used)

# Refer?

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# Refer?

- Outcomes for primary care treatment of uncomplicated HCV compare to subspecialty care
- National Academy of Sciences recommends tx in primary care to decrease barriers
- In 2015 Maine had roughly 50 GI & 25 ID docs
- Maine Medical Center runs a Hep C Project ECHO
  https://www.mainehealth.org/health-care-professionals/project-echo

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# Exclusions for Primary Care Tx

- Cirrhosis/advanced fibrosis
- Hep B or HIV Co-infection
- Prior HCV tx (not ‘treatment naïve’)
- Pregnant
- eGFR <30 (excludes sofos/velpat regimine)
- Suspicion of HCC (hepatocellular carcinoma)
- Liver transplantation

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# Develop Care Plan

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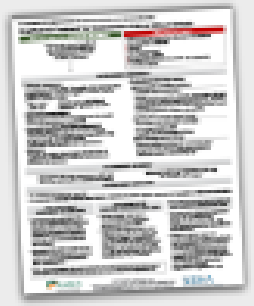
# Goal & Treatment Recommendations

- Attain SVR->Sustained Virologic Response (cure)
- “The AASLD/IDSA guidance on hepatitis C is supported by the membership-based societies and not by pharmaceutical companies or other commercial interests.”
- Evidence-based recommendations for rapidly changing landscape, “living document” so best to check online resource (not printed)

# One page simplified HCV treatment algorithm & comprehensive resources

https://www.hcvguidelines.org/



NOW AVAILABLE

**Download: Simplified HCV Treatment* for Treatment-Naive Patients**

Without Cirrhosis - Click here to download the PDF, or read more.

With Compensated Cirrhosis - Click here to download the PDF, or read more.

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# Why Treat?

- SVR decreases the incidence of
  - diabetes
  - glomerulonephritis
  - non-Hodgkin's lymphoma
  - stroke
- SVR can reverse liver fibrosis & prevent cirrhosis

# Why Treat?

- Consistent association w/SVR & improved health outcomes
  - decreased all-cause mortality
  - liver disease mortality
  - cirrhosis
  - hepatocellular carcinoma

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# Prior to Initiating Treatment

- Educate patient on crucial importance of medication adherence
- Evaluate contraception
- **Check drug-drug interactions** (Univ of Liverpool checker or pharmacist consult)
- Consider partnering with a specialty pharmacy or clinical pharmacist

# Reflection question

Assuming Will qualified for the simplified treatment protocol, would you feel comfortable treating him in your office?

- A. Yes, ready to treat
- B.  Yes, with a second hour of CME through MICIS
- B. Yes, with some additional work and planning over the next 6 mos
- C. No, I plan to continue to refer to subspecialty care
- D. N/A—I do not practice in a Primary Care/OUD Setting

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# Evaluate Treatments

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# Cost

- Expense of tx partly offset by high liver-related healthcare expenditures later in life for those untreated
- Covered by MaineCare with PA-subspecialty consult no longer required for uncomplicated cases
- Insurers generally have negotiated drug discounts
- Patient assistance programs available from most manufacturers; labs + other costs involved if uninsured

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# Two Primary Simplified Treatments Treat All Genotypes

- Drug class:  DAAs-Direct-acting antivirals
- glecaprevir/pibrentasvir (Mavyret®) x8w
- sofosbuvir/velpatasvir (Epclusa® or generic) x12w
- HA, fatigue, nausea in <10% but generally well tolerated

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# Cost

- Generic versions of sofosbuvir/velpatasvir (Epclusa®) & others now available
- Wholesale acquisition cost (WAC, 2021) per day
  - sofosbuvir/velpatasvir (generic) $240
  - glecaprevir/pibrentasvir (Mavyret®) $417
  - sofosbuvir/velpatasvir (Epclusa®) $890
  - range of others: $650-1125

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# SVR

## Sustained Virologic Response

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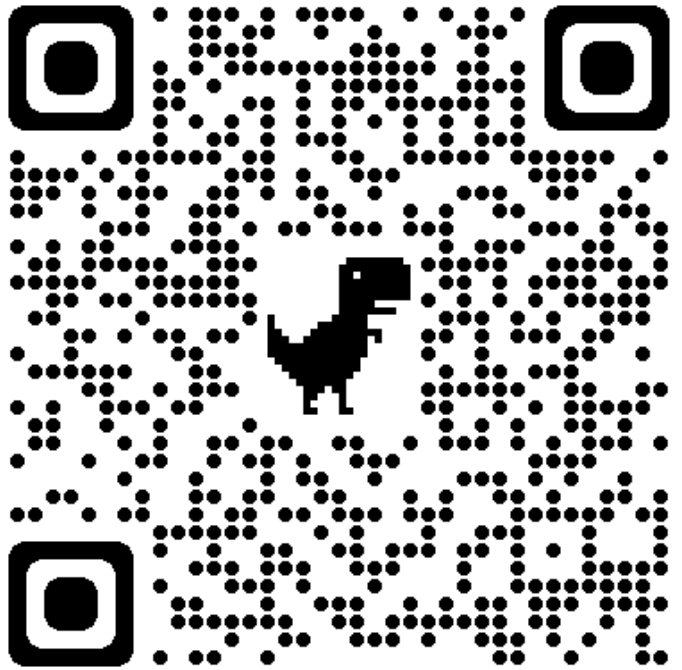
# Post-treatment Recommendations

- HCV viral load should be undetectable (indicates virologic cure) 12 weeks post completion
- No ongoing liver follow up needed (if noncirrhotic)
- If ongoing risk of HCV re-infection, check viral load annually or if elevated LFTs
- HCV Ab remains positive lifelong-thus check viral load
- Advise avoidance of ‘excess’ alcohol

# Wrap-Up-Additional MICIS Resources

- MICISMAINE.ORG
  - Request form for Hep C “Level 2” CME session
  - Handout
  - Brief (2 page) review article
  - Resource list
  - Reference list
  - Slide deck



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# Wrap-Up

- How to obtain CME credit for today
- Individual “Academic Detailing” CME sessions also available from MICIS

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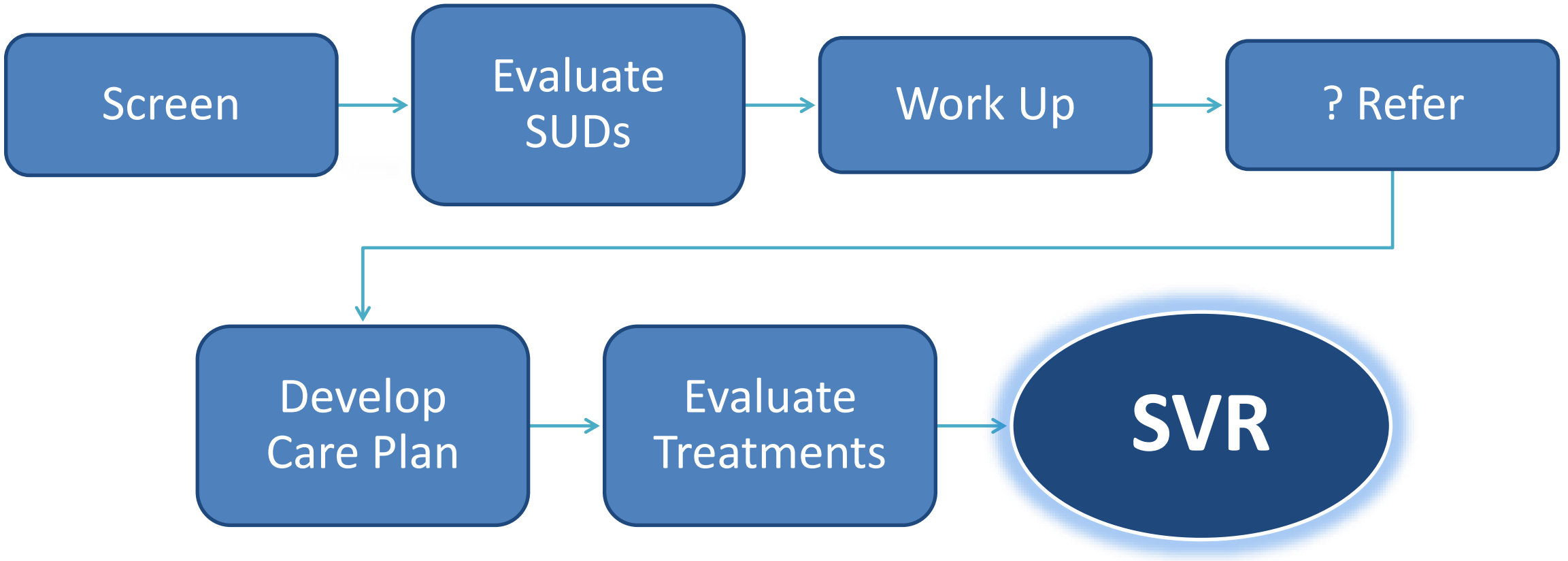
# Pathway to Hepatitis C Cure

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# Review – Video from West Australia

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