Simplified Treatment of Hepatitis C in Primary Care Settings

Pathway to HCV Cure 2021

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WELCOME TO…
Pathway to Cure-
Simplified Treatment of Hepatitis C in Primary Care Settings

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Department of Health and Human Services

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Disclosures

- MICIS does not accept any money from pharmaceutical companies/commercial interests
- Speakers and planners have no significant or relevant financial relationships to disclose

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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:
Custom, Individual CME sessions available from MICIS

**HCV Treatment-Level 2*

**4 hours of Opioid/MAT topics*

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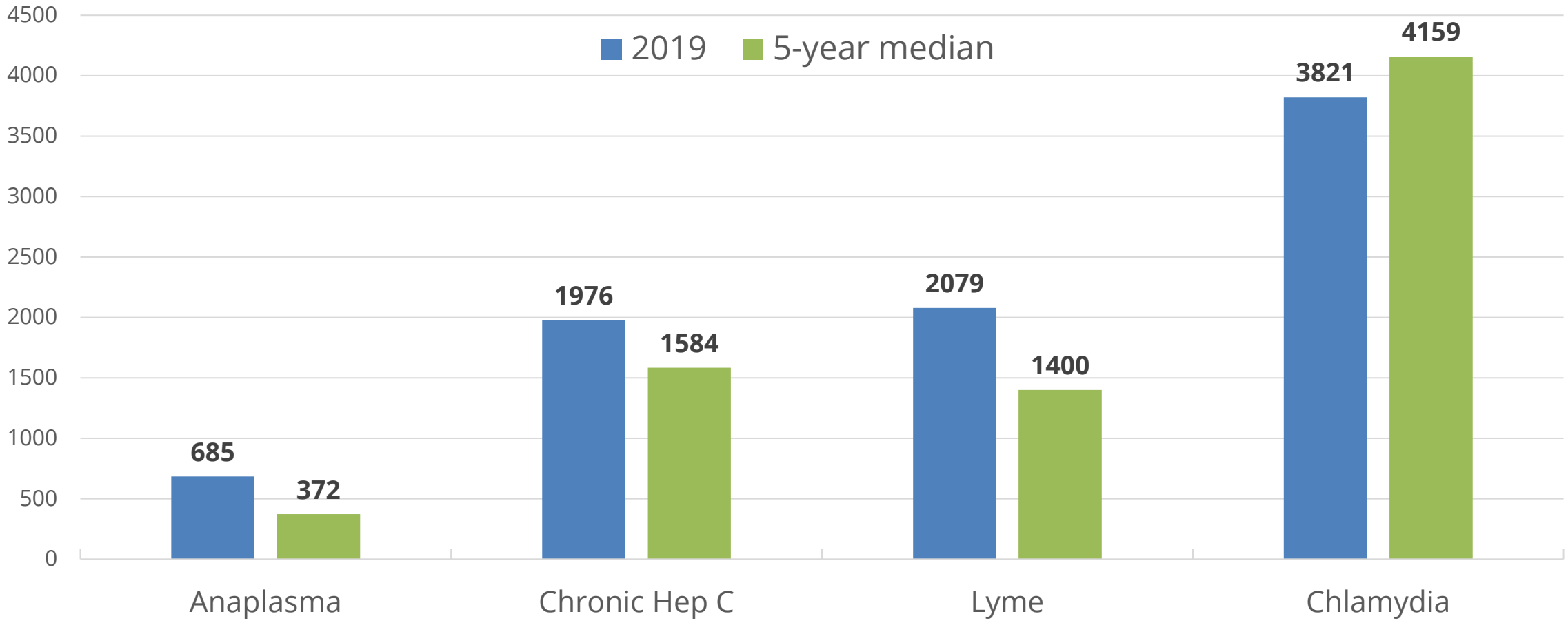
Top 4 Maine Reportable Disease Cases*



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*prior to COVID

Why should all adults get tested for hepatitis C?

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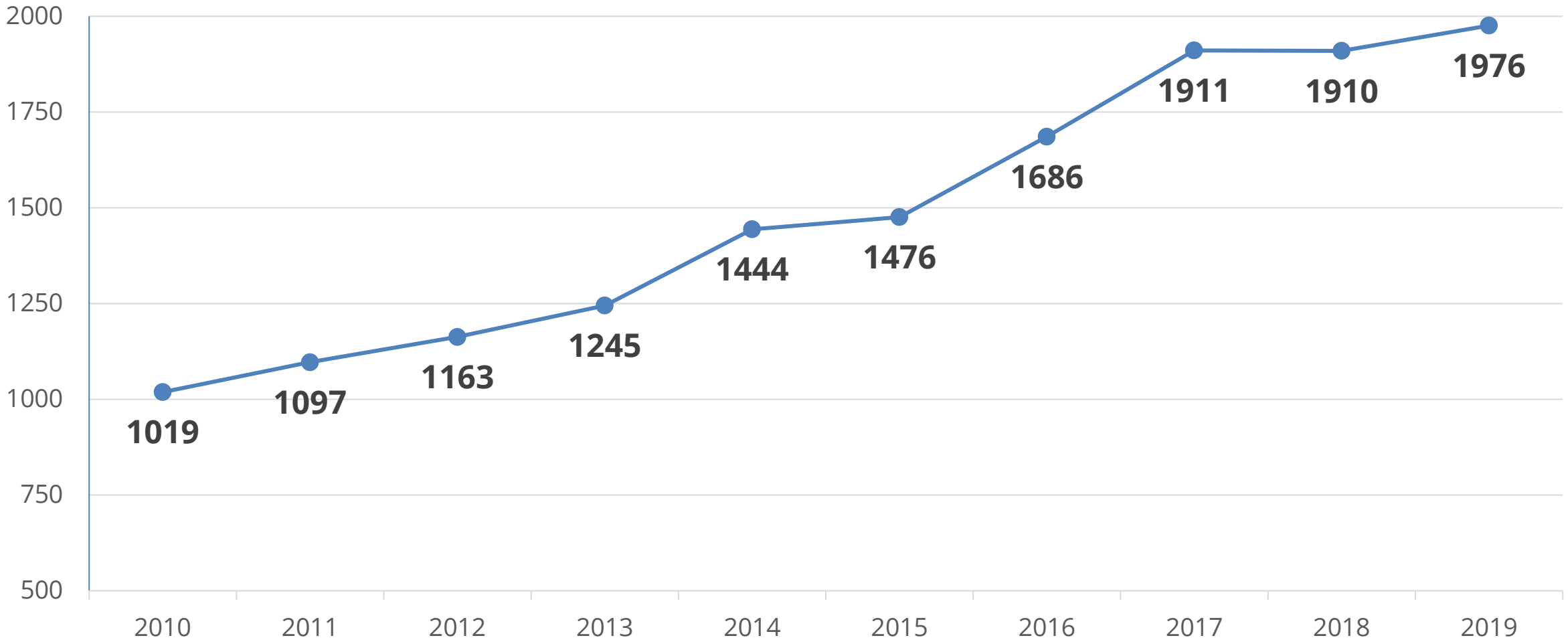
Maine Diagnosed Chronic Hepatitis C



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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)
- Tx of early disease is likely cost-effective and even possibly cost-saving

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Maine vs Other States-2017

- Acute Hep B #2
- Opioid OD Death #6
- Acute Hep C #10

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

Maine Diagnosed Chronic Hepatitis C

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

Pathway to Cure Handout

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available at MICISMaine.org

Pathway to Cure Packet/Resources

- Request form for Hep C “Level 2” CME session
- Handout (pdf)
- Brief (2 page) review article by Laura Knapik, UNE OMS-IV
- Resource list w/hyperlinks
- Reference list
- Slide deck

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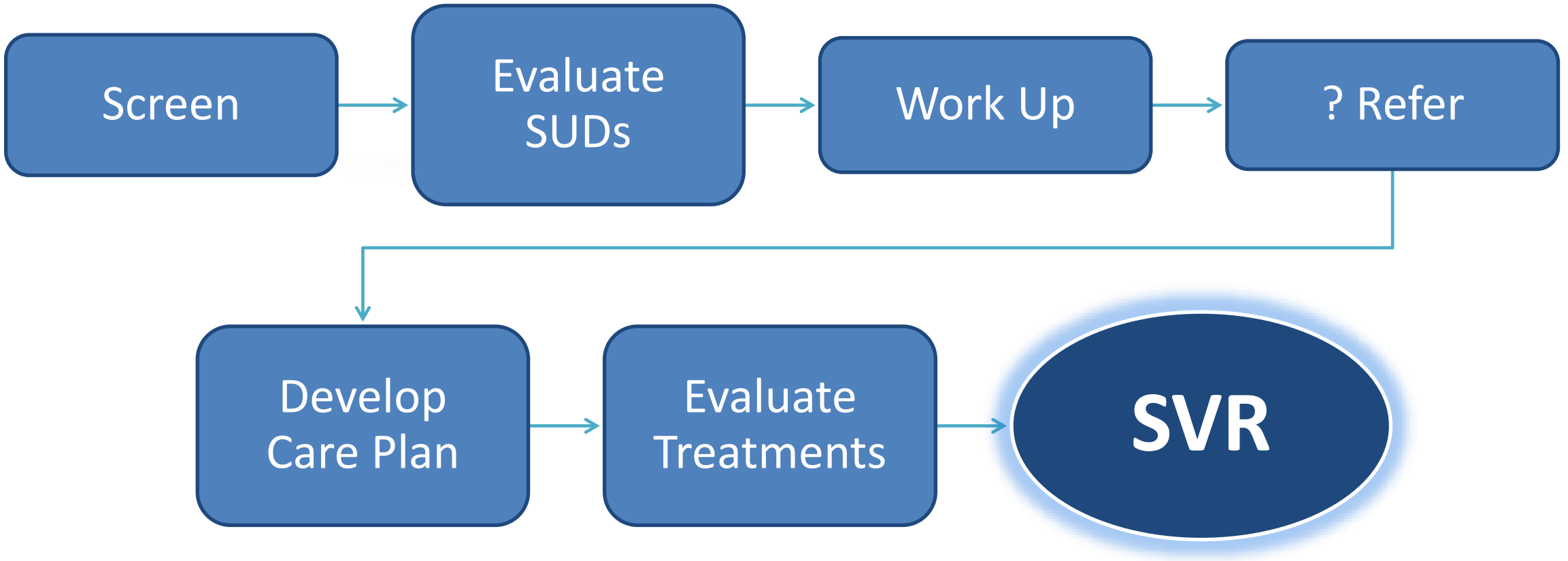
Pathway to HCV Cure - 2021



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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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Reflection question

Which one of these USPSTF (United States Preventative Services Task Force) **SCREENING** recommendations is grade 'A' for a 55 yo man?

A. screen for pancreatic cancer

B. screen for tobacco use

C. screen for HCV

D. screen for asymptomatic carotid artery stenosis

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USPSTF Screening for 55yo male-Grade A

a. Blood pressure
b. Tobacco use
c. Colorectal CA
d. HIV/PrEP/Syphilis

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USPSTF Screening for 55yo male-Grade B

a. Weight/Diet/Exercise
b. Glucose
c. Depression
d. Alcohol & Drug use
e. Lung CA
f. ASA/Statin
g. HBV/HCV/latent TB

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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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HEP C FACTS

- Treatment of Hepatitis C is to eradicate as opposed to suppress (no hidden reservoir unlike Hep B)
- Up to 50% of people with HCV clear the virus spontaneously

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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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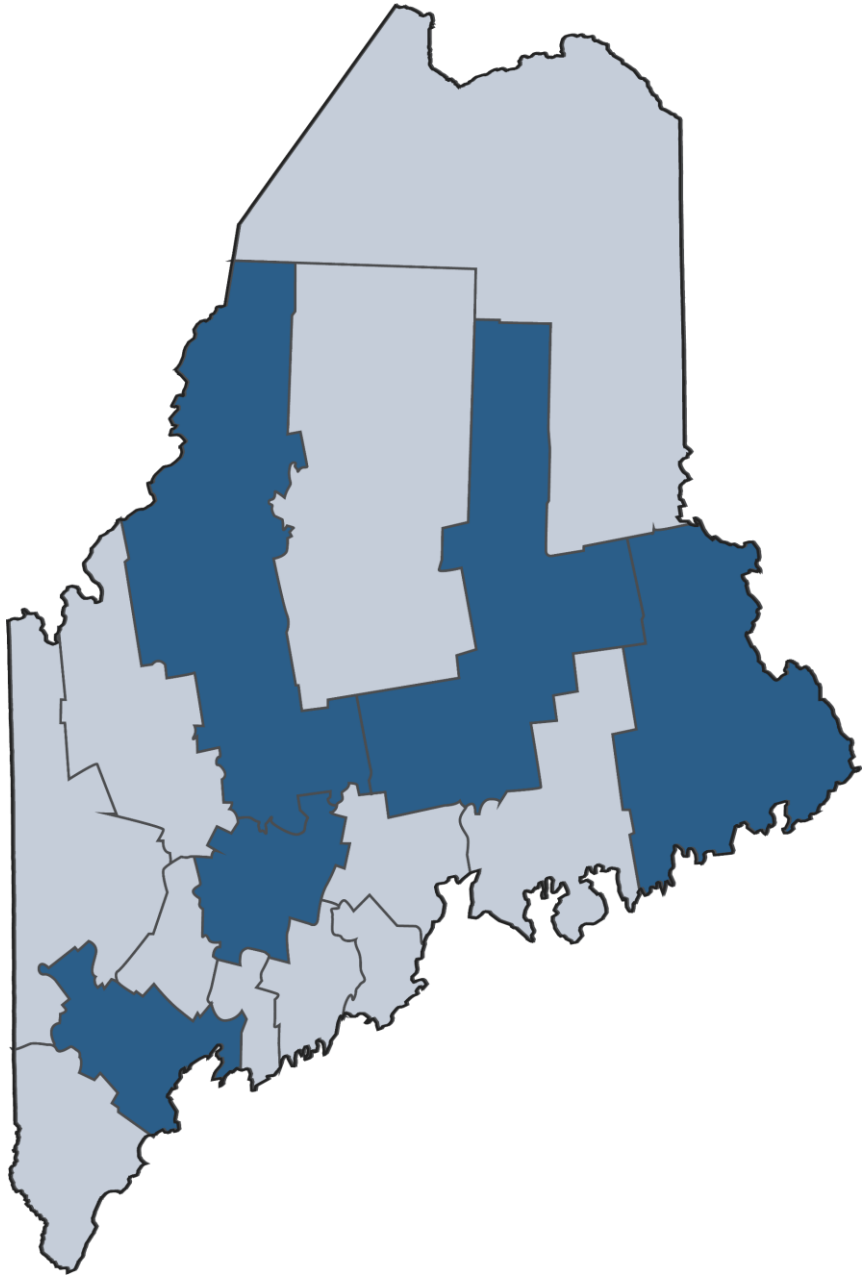
Maine's Most Vulnerable Areas

- highest risk of opioid overdose & bloodborne infections from injection drug use



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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 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?

- A. Yes, currently
- B. No, but I want to start treating OUD-sign me up for a MICIS one on one session
- C. No, but I know the OUD treatment options in my community/health system

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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
- If first +HCV, recheck viral load in 6 mos to assess spontaneous clearance-may need to document chronicity of infection for insurance approval

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 A & B panels, HIV
  - CBC
  - CMP or LFTs & eGFR
  - INR
  - Serum pregnancy (just prior to tx)
  - Genotype not required for simplified tx, may still be on some protocols

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*some required by IDSA algorithm, some by individual insurers

Vaccinate!

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

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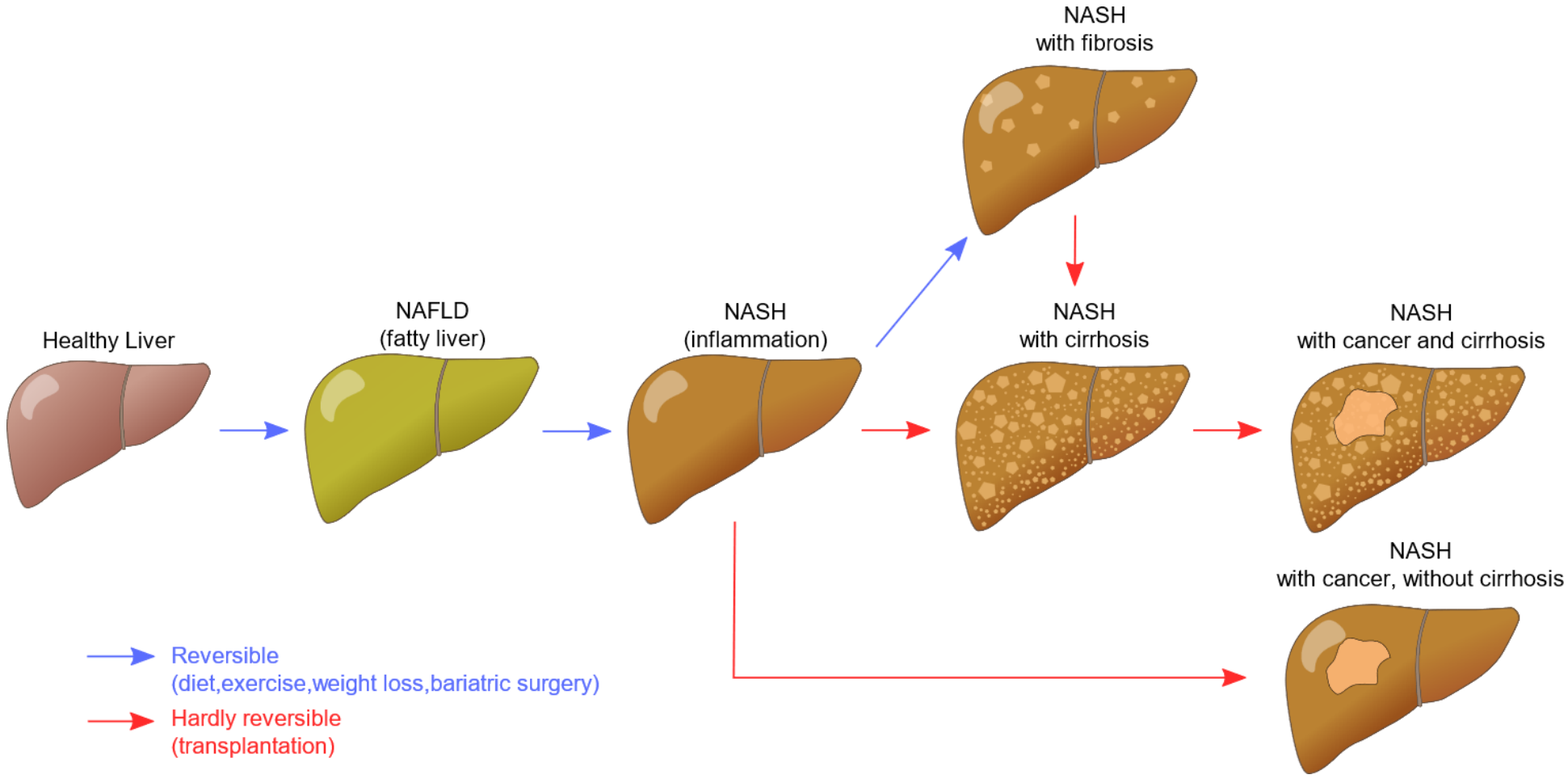
Stages of Liver Fibrosis

(NASH used for graphic demonstration purposes)



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Evaluate for Cirrhotic Liver Disease

- Calculate lab scores: FIB-4, APRI
- Utilize serum fibrosis marker panel (e.g. Fibrosure ®)
- Calculate Child-Turcotte-Pugh score + look for existing clinical evidence: liver nodularity or splenomegaly on prior imaging, low platelets
- If any above are elevated, assess with transient elastography specific ultrasound
- Liver biopsy is not necessary

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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 50 GI & 25 ID docs
- Maine Medical Center runs a Project ECHO for less straight-forward Primary Care cases

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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 (although glecaprevir/pibrentasvir (Mavyret®) OK)
- 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

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

Prior to Initiating Treatment

- Stage hepatic fibrosis/liver disease severity
- 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

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Reflection question

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

- A. Yes, with MICIS resources
- 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

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

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Cost

- Generic versions of sofosbuvir/velpatasvir (Epclusa®) & others now available
- Wholesale acquisition cost (WAC) 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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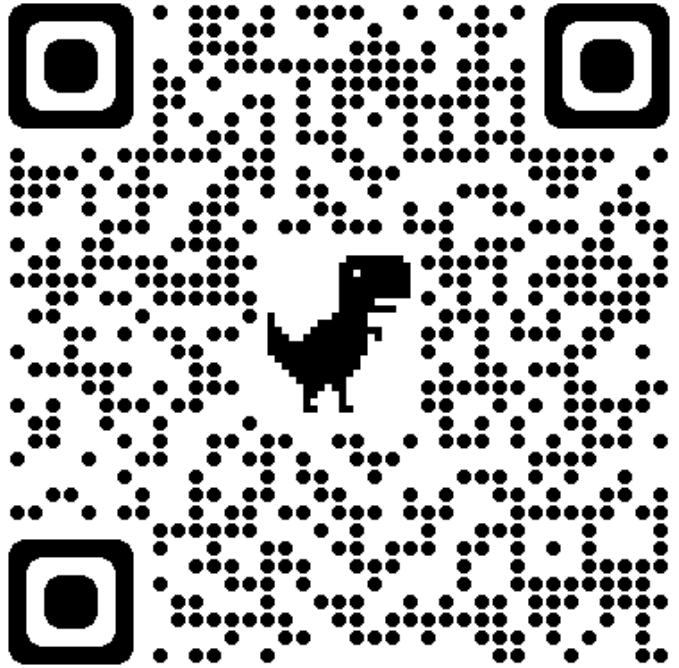
Post-treatment Recommendations

- 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 CME sessions also available from MICIS
  - HCV Treatment Level 2
  - 4 different hours of Opioid/MAT topics

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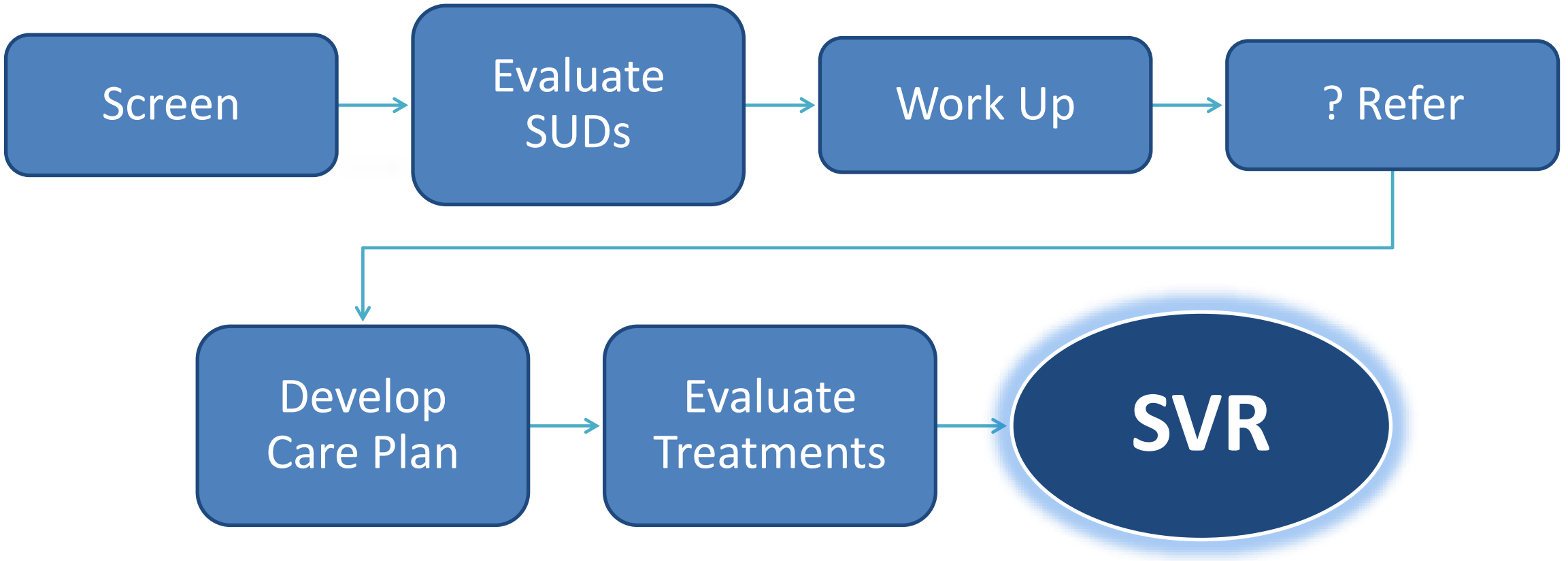

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Review – Video from West Australia

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