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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:
Custom, Individual CME sessions available from MICIS

**HCV Treatment-Level 2*

**4 hours of Opioid/MAT topics*

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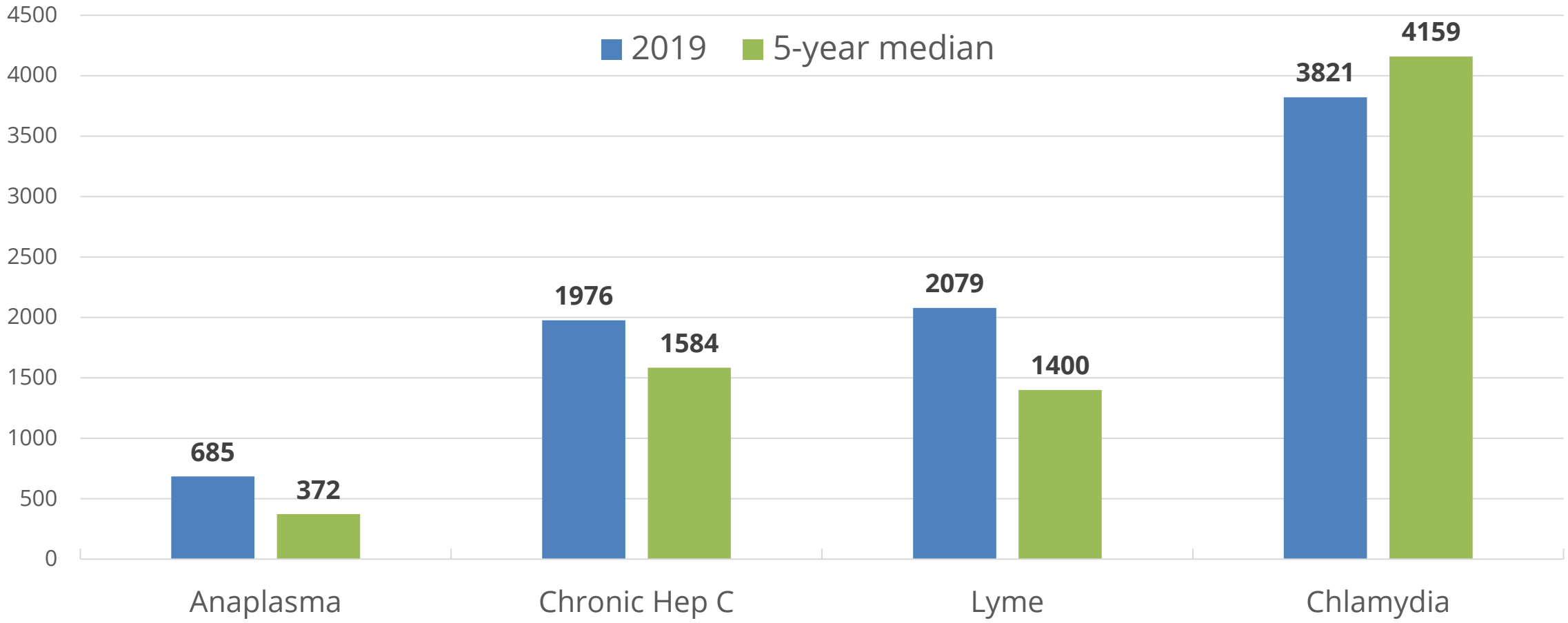
Top 4 Maine Reportable Disease Cases*



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*prior to COVID

Why should all adults get tested for hepatitis C?

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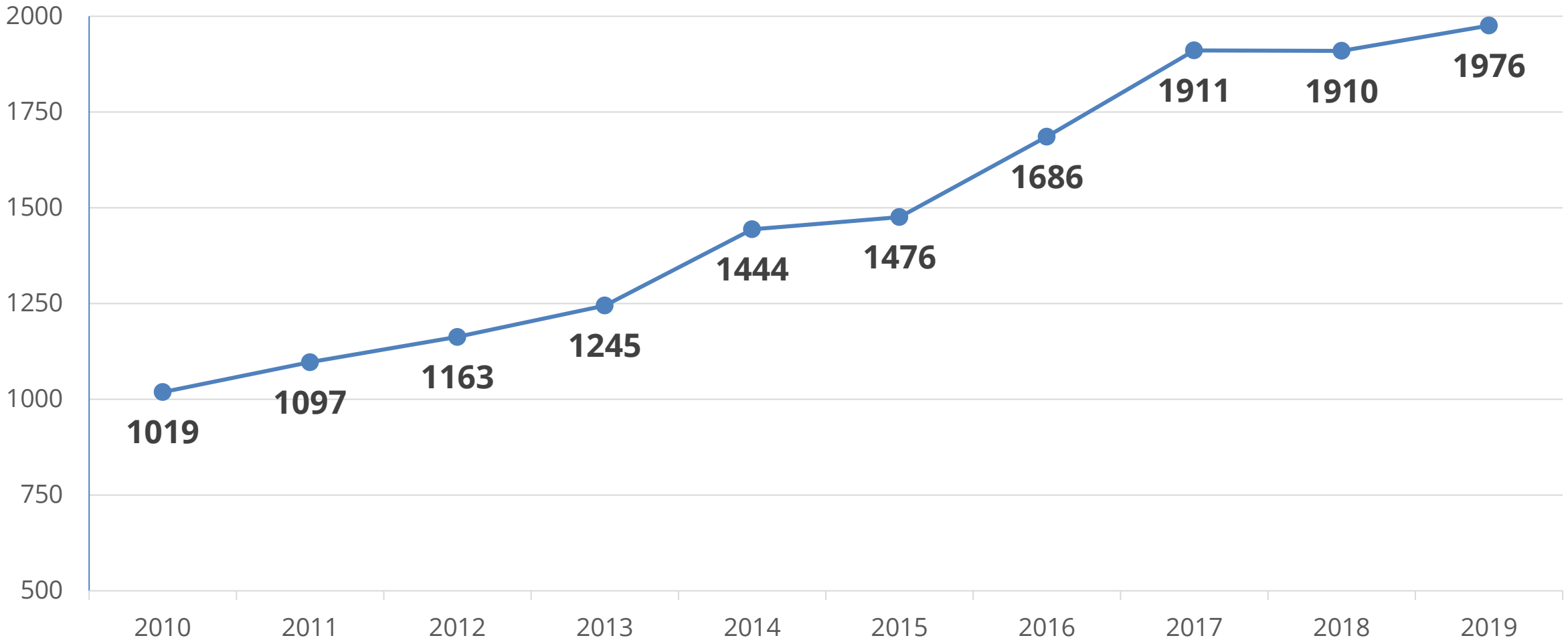
Maine Diagnosed Chronic Hepatitis C



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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 → 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 Laura Knapik, UNE OMS-IV
- Resource list w/hyperlinks
- Reference list
- Slide deck

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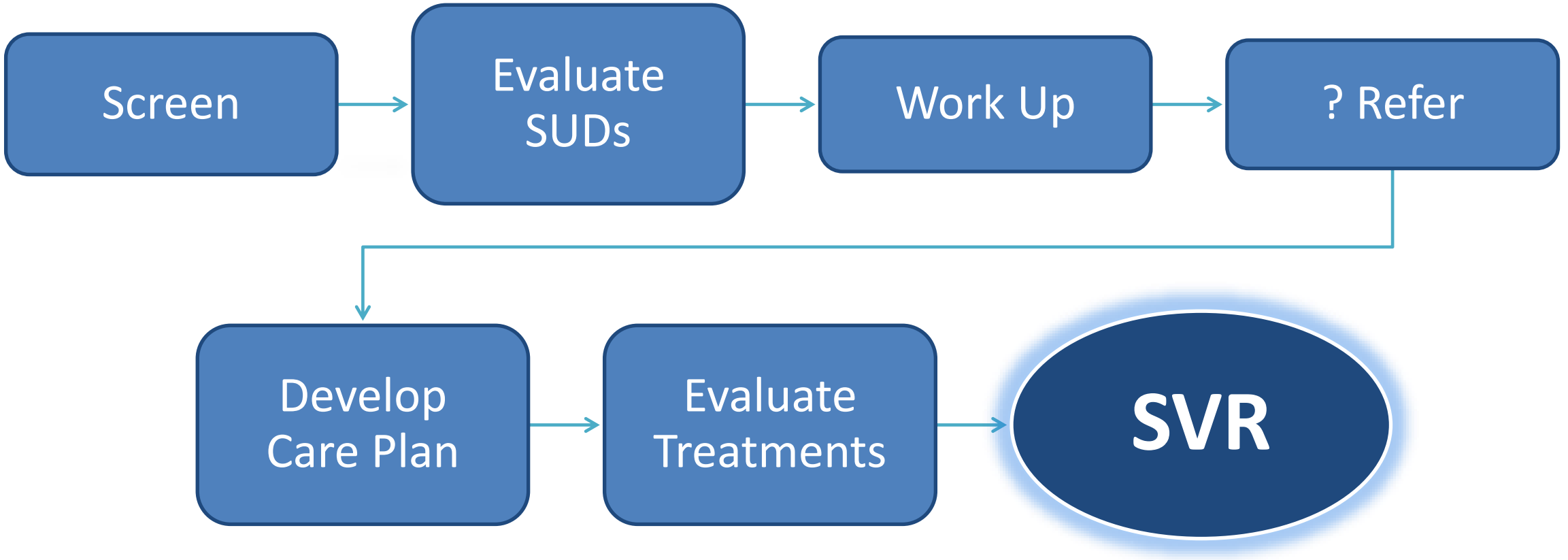
Pathway to Hepatitis C Cure



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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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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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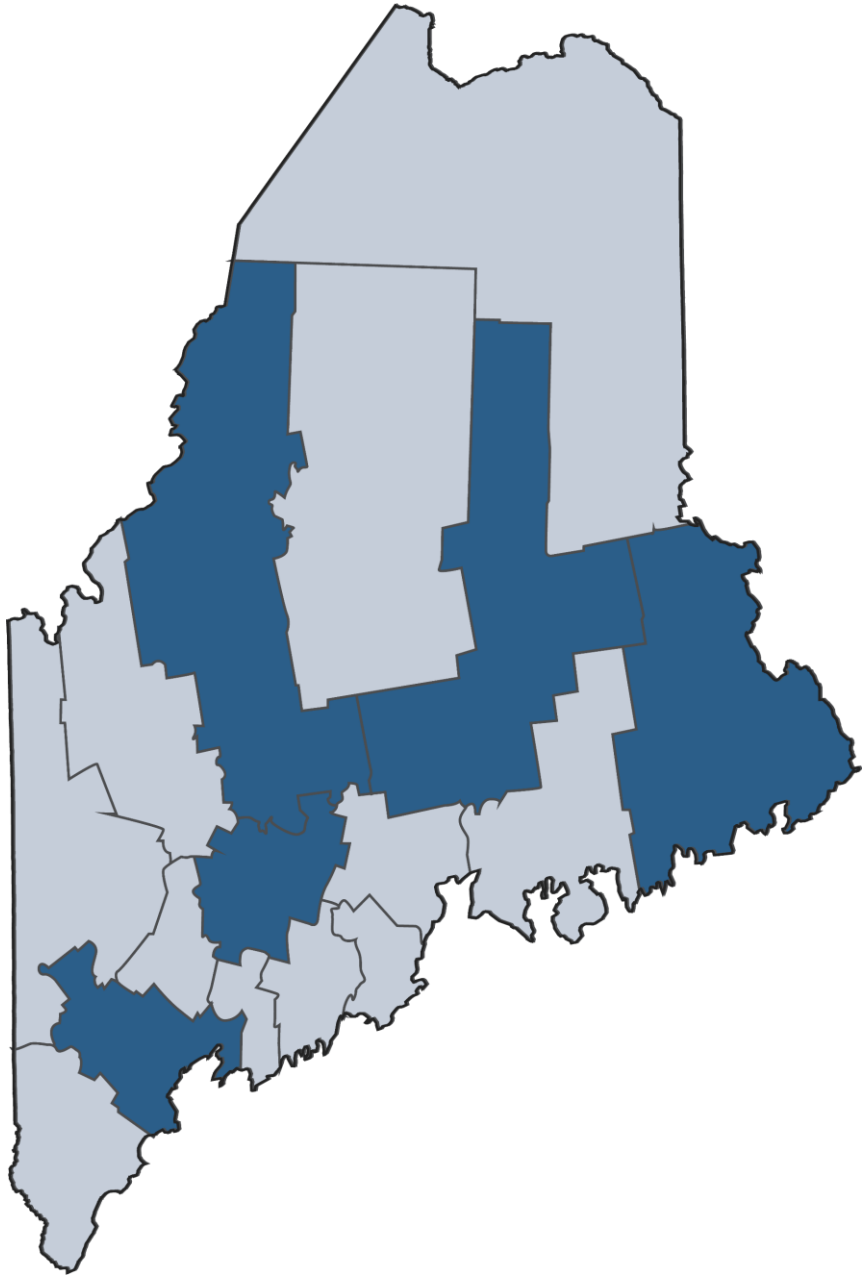
Maine's Most Vulnerable Areas

- 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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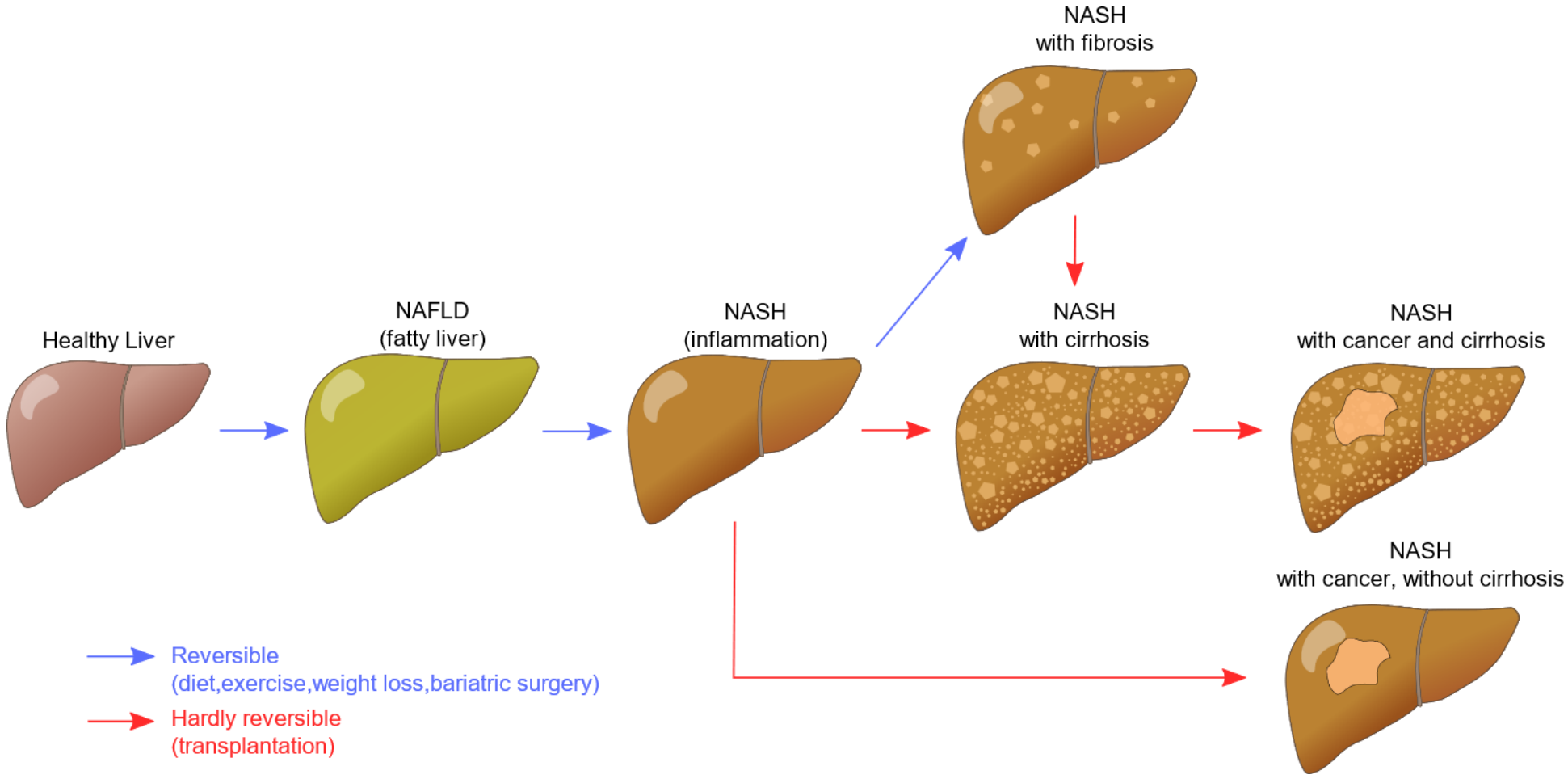
Stages of Liver Fibrosis

(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, 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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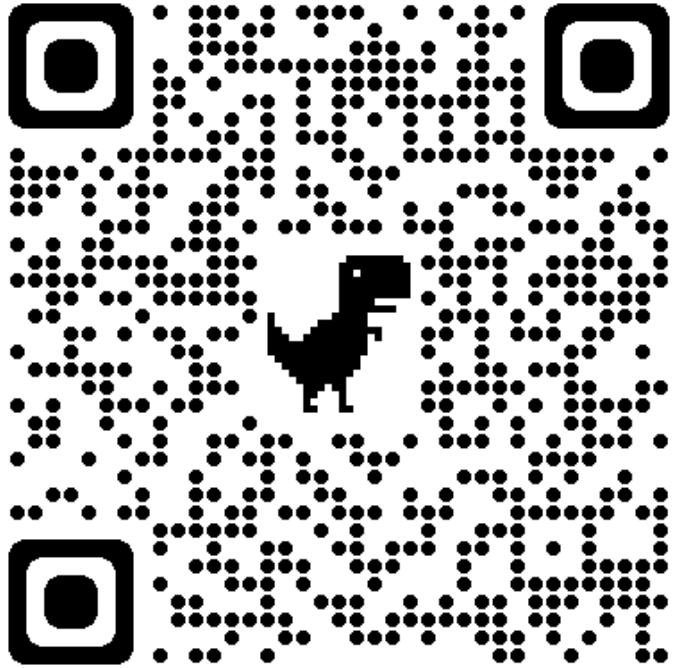
Post-treatment Recommendations

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

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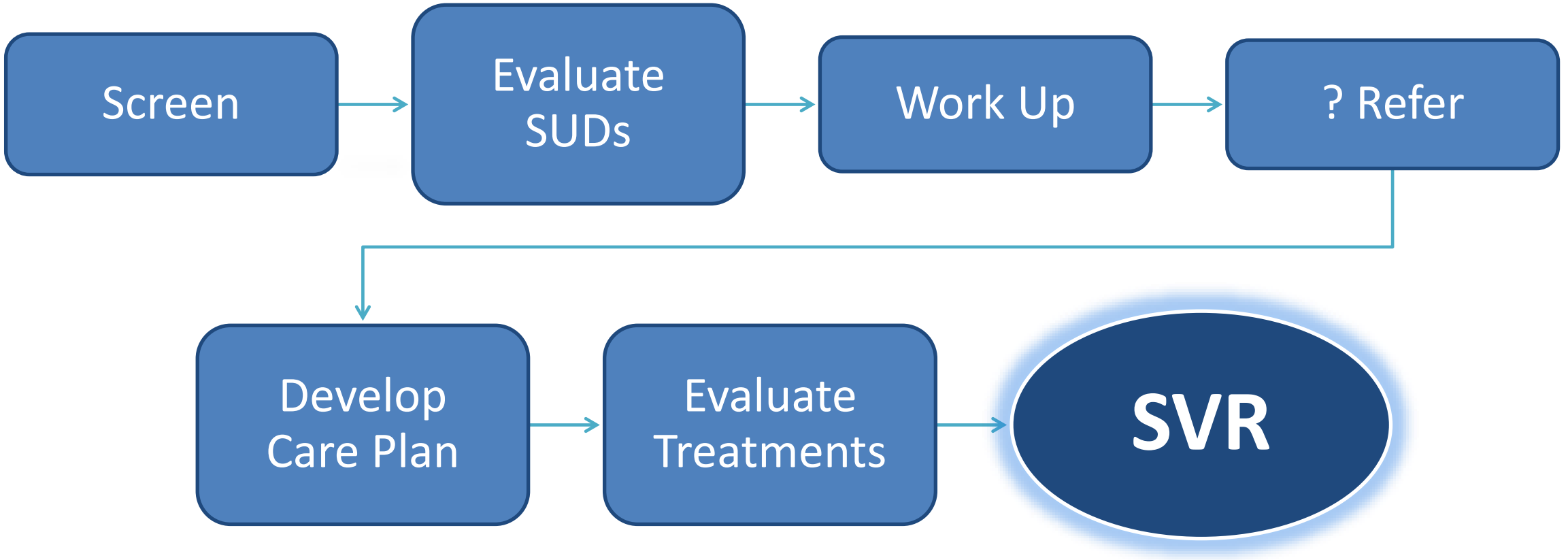
Pathway to Hepatitis C Cure



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Review – Video from West Australia

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