

Department of Health

DIVISION OF PUBLIC HEALTH Section of Epidemiology

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A New Rapid Point-of-Care Test and Simplified Treatment for Hepatitis C

Dear Clinician,

The purpose of this letter is to inform you about a) a new rapid hepatitis C virus (HCV) RNA test that can be used as a standalone screen to initiate treatment for most patients, and b) the simplified HCV treatment protocol.¹

Treating hepatitis C dramatically reduces the chance of end-stage liver disease, hepatocellular carcinoma, and death within 3 months for people infected with HCV; it also prevents transmission to others.² One in three people infected with HCV are unaware of their infection.³ Each year, >1 in 1000 Alaskans tests positive for hepatitis C. In recent years, rates among Alaskans aged <40 years have been more than double the national average.⁴

Rapid HCV Testing

Two point-of-care tests for HCV infection are now available.

- A new <u>rapid HCV RNA test</u> authorized for nonpregnant adults aged ≥22 years tests for HCV RNA from a fingerstick blood sample.
 - o This test runs on the GeneXpert Xpress platform (Cepheid).
 - o A positive test indicates *current* HCV infection.
 - o It can be used as a standalone screen, so HCV treatment can be initiated during the same visit.
 - This test is not approved as a test for sustained virologic response after treatment.
- A <u>rapid antibody test</u> for nonpregnant adults and adolescents aged ≥15 years checks for antibodies to HCV from a fingerstick blood sample.
 - A positive rapid antibody test indicates *current or resolved* HCV infection but cannot distinguish between the two.
 - o This test requires a subsequent HCV RNA test to confirm current infection.
 - o Collect a sample for HCV RNA testing before the patient leaves the testing location.
- Both tests are CLIA-waived and can be done by any facility with a <u>CLIA waiver</u>.

Test all adults at least once.

- Test during each pregnancy.
- Test any patient with risk factors such as injection drug use more frequently.
- Test patients who request HCV testing, even if they do not disclose risk factors.

Simplified Treatment

Before starting treatment

- Confirm viremia (HCV RNA). Draw an HCV viral load, and test for HIV, hepatitis B, and pregnancy. Obtain CBC, ALT, AST, total and direct bilirubin, albumin, and eGFR.
- Calculate a <u>FIB-4 score</u> using platelets, age, AST, and ALT. A patient with a FIB-4 score ≤3.25 and no previous indications of cirrhosis can be presumed to not have cirrhosis.
- Confirm patient eligibility: no prior HCV treatment, not pregnant, not HBsAg positive, no hepatocellular carcinoma, no decompensated cirrhosis, and has not had liver transplantation.

- o Current substance use, including injection drug use, should not delay treatment.¹
- o For patients with cirrhosis, those with end-stage renal disease or current or prior episode of decompensated cirrhosis are ineligible for simplified treatment. See hcvguidelines.org for treatment recommendations for ineligible patients.
- Note: current injection drug use is not a contraindication to HCV therapy.⁶
- Patients with cirrhosis should also have a liver ultrasound and INR before treatment. Patients with compensated cirrhosis may receive glecaprevir/pibrentasvir (Mavyret) without HCV genotype testing. Patients with cirrhosis require HCV genotype testing and may need resistance testing before using sofosbuvir/velpatasvir (Epclusa).
- Check for <u>drug interactions</u> (<u>one online checker</u>). Significant drug-drug interactions must be avoided.

Treatment

- Simplified treatment uses 8 weeks of oral glecaprevir/pibrentasvir (Mavyret) or 12 weeks of oral sofosbuvir/velpatasvir (Epclusa).
- Monitor patients taking diabetes medication for hypoglycemia and patients taking warfarin for subtherapeutic anticoagulation; no laboratory monitoring is required for other patients.
- Retest ≥12 weeks after treatment completion to confirm HCV RNA is undetectable (virologic cure) and ALT/AST normalization.
- No liver-related follow-up is recommended for noncirrhotic patients with virologic cure.
- Patients with ongoing risk for HCV infection should be counseled about risk reduction and tested for HCV RNA annually and whenever they develop elevated ALT, AST, or bilirubin.
- Patients for whom initial HCV treatment fails to achieve cure should be evaluated for retreatment by a specialist.
- The Alaska Native Tribal Health Consortium Liver Disease & Hepatitis Program offers treatment information and training to support clinicians: www.anthc.org/hep.

Patient counseling

- Do not donate blood or share anything contaminated with blood, such as needles, toothbrushes, or razors.
- Advise against daily consumption of >50g of alcohol in the presence of HCV infection as this is strongly linked with worsening fibrosis.

Pregnancy considerations

- Women of reproductive age with HCV should be treated before pregnancy.
- While data are limited regarding the safety of direct-acting antivirals during pregnancy, treatment can be considered after a discussion of potential risks and benefits.¹

Prevention

- Injection drug use (IDU) accounts for ~70% of new HCV infections in the United States.⁶
- About 40% of people who inject drugs (PWID) may acquire HCV in the first few years of IDU.
- PWID should be counseled to never share injection equipment.⁶
- Successful HCV treatment may increase engagement in opioid use disorder treatment when offered simultaneously.⁷
- PWID should be offered linkage to harm reduction services including naloxone, needle/syringe service programs, and medication-assisted therapy for opioid use disorder.⁶
- Substance use disorder treatment and needle/syringe service programs should test PWID for HCV and link them to treatment.⁶

Reporting

- Clinicians in Alaska are required to report new or acute hepatitis C infections and <u>newly</u> identified <u>pregnancy</u> in a person with known hepatitis C infection.
- Please report cases to the Section of Epidemiology by faxing the <u>Confidential Infectious Disease</u> Report Form to 907-561-4239 or by phone call to 907-269-8000.

Thank you for your ongoing commitment to the health of Alaskans. If you have any questions, please contact us.

Sincerely,

Robert Lawrence, MD

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