Hepatitis C Virus Testing and Linkage to Care
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Prevalence of HCV

**HEPATITIS C VIRUS IS NEARLY 4 TIMES AS PREVALENT AS HIV AND HEPATITIS B VIRUS IN THE UNITED STATES**

Number of Infected Individuals vs Number Aware They Are Infected (Diagnosed)

- **Undiagnosed**: ~2.7 Million to 3.9 Million 75% Undiagnosed
- **Diagnosed**: 1.1 Million
  - HIV: 65% Undiagnosed
  - HEPATITIS B: 21% Undiagnosed
  - HEPATITIS C: 65% Undiagnosed

**SVR Rates in HCV Genotype 1 Treatment-Naïve Patients**

<table>
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<th>Year</th>
<th>IFN</th>
<th>IFN+RBV</th>
<th>PEG</th>
<th>PEG+RBV</th>
<th>SMV+PEG</th>
<th>SOF+PEG</th>
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*Year of data presentation at EASL 2014 and publication in NEJM*

HCV Treatment Cascade

Hepatitis C Virus Testing and Care Continuum

- Chronic HCV-Infected*: 100%
- Diagnosed and Aware†: 50%
- Access to Outpatient Care‡: 43%
- HCV RNA Confirmed§: 27%
- Underwent Liver Biopsy¶: 17%
- Prescribed HCV Treatment¶¶: 16%
- Achieved SVR**: 9%

Total Estimated: 3,500,000
There are a lot of people infected with HCV….
- …but many are undiagnosed

There are very effective treatments that can cure HCV….
- …but many aren't being prescribed those medications

So what???
The Michigan Perspective
Number and Percentage of HCV Antibody Positive Cases with an HCV RNA or HCV Genotype Test, 2016

- HCV Ab Positive: 100.0%
- HCV RNA Test: 63.9%
- HCV Genotype Test: 22.1%
HCV Rxs for Michigan Medicaid Patients

HCV DAA Rxs for MI Medicaid Recipients

Number of Recipients

If we expect an HCV prevalence of 1-2% in the Medicaid population, it would be estimated that 23,000-46,000 would be infected with HCV.

Just over 2,000 (4-8%) have evidence of having a HCV DAA prescribed.
Liver Cancer Incidence and Mortality

Liver Cancer Incidence in Michigan, 2004-2013

Liver Cancer Deaths in Michigan, 2004-2014
Liver Transplants and Transplant Waitlist, Michigan, 1988-2016

- Transplants
- Transplant Waitlist
- Transplants + Waitlist
HCV Mortality

Deaths Due to HCV, HBV, and HIV, Michigan, 2005-2014

- HIV-Related Deaths
- HCV-Related Deaths
- HBV-Related Deaths

Number of deaths over time from 2003 to 2014.
MDHHS: Viral Hepatitis Prevention

- Improving Hepatitis B and C Case Cascades: Focus on Increased Testing and Diagnosis

- Four Components:
  - Conduct a situational analysis
  - Establish Intervention Partnerships
  - Monitor and Evaluate Policies
  - Increase Awareness of Viral Hepatitis

- Goal: Increase the proportion of persons who are aware of their hepatitis C virus infection
Michigan Viral Hepatitis Resource Guide

- Found on our website: [www.mi.gov/hepatitis](http://www.mi.gov/hepatitis)
- Where Patients can go for:
  - Vaccination
  - Testing
  - Treatment
  - Drug User Health
- Information on:
  - Local Health Departments
  - Community Health Centers
  - Insurance
Some Final Thoughts

- Morbidity (hospitalizations, cancer, transplants) and mortality associated with HCV in Michigan and nationally are increasing.

- We can reverse these trends with improved efforts to test, link to care, and treat persons with HCV infection.

- The MDHHS Viral Hepatitis Unit is happy to provide technical assistance and help settings build capacity to test and treat for HCV.
THANKS!
A Model of Care and Considerations for Treating Patients with HCV

Elaine A. Leigh DNP, FNP-BC
Mercy Health Muskegon
Hepatitis C Clinic
231-727-5575
# CDC HCV Screening

## CDC Testing Recommendations for Chronic Hepatitis C Virus Infection

### Persons for Whom HCV Testing is Recommended

**Adults Born During 1945 to 1965**

**HCV Testing Recommended for those who:**

- Currently inject drugs
- Ever injected drugs, including those who injected once or a few times many years ago
- Persons with selected medical conditions, including persons
  - who received clotting factor concentrates produced before 1987
  - who were ever on long-term hemodialysis
  - with persistently abnormal alanine aminotransferase (ALT) levels
  - who have HIV Infection
- Were prior recipients of transfusions or organ transplants, including persons who
  - were notified they received blood from a donor who later tested positive for HCV infection
  - received a transfusion of blood, blood components, or organ transplant before July 1992

**HCV Testing Based on a Recognized Exposure is Recommended for:**

- Healthcare, emergency medical, and public safety workers after needle sticks, sharps, or mucosal exposures to HCV-positive blood
- Children born to HCV-positive women

*Note: 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.*
# AASLD/IDSA HCV Screening

## AASLD/IDSA HCV Testing Recommendations

One-time HCV testing is recommended for persons born between 1945 and 1965, without prior ascertainment of risk (and regardless of country of birth)

*Rating: Class 1, Level B*

Other persons should be screened for risk factors for HCV infection, and one-time testing should be performed for all persons with behaviors, exposures, and conditions associated with an increase risk of HCV infection.

### 1. Risk behaviors
- Injection-drug use (current or ever, including those who injected once)
- Intranasal illicit drug use

### 2. Risk exposures
- Long-term hemodialysis (ever)
- Getting a tattoo in an unregulated setting
- Healthcare, emergency medical, and public safety workers after needlesticks, sharps, or mucosal exposures to HCV-infected blood
- Children born to HCV-infected women
- Prior recipients of transfusions or organ transplants, including persons who:
  - were notified they received blood from a donor who later tested positive for HCV infection
  - received transfusion of blood or blood components, or underwent organ transplant before July 1992
  - received clotting factor concentrates produced before 1987
- Persons who were ever incarcerated

### 3. Other
- HIV infection
- Unexplained chronic liver disease and chronic hepatitis including elevated alanine aminotransferase levels
- Solid organ donors (deceased and living)

*Rating: Class 1, Level B*
The United States will be a place where new viral hepatitis infections have been eliminated, where all people with chronic hepatitis B and C know their status, and everyone with chronic hepatitis B and C has access to high quality health care and curative treatments, free from stigma and discrimination.

www.hhs.gov/hepatitis
National Hepatitis Action Plan Summary:

- Increase screening for HCV
- Increase patient access to high quality hepatitis C care
  - Assessment
  - Education
  - Treatment
  - Follow up for those with advanced liver disease
National Hepatitis Action Plan Goals:

- Prevent new viral hepatitis cases
- Reduce deaths and improve the health of people living with viral hepatitis
- Reduce viral hepatitis health disparities
- Coordinate, monitor, and report on implementation of viral hepatitis activities
Roles for Everyone

- Accurate screening
- Expand access to healthcare coverage
- Development in HCV cures
- Integration of public health and clinical care services
- Development of syringe services programs.
Overall, only 9% of people with chronic HCV have achieved cure. This points to the ongoing need for creativity and innovation on part of all stakeholders to increase the proportion of people who successfully navigate the entire cascade and achieve cure.
Innovation and Creativity

- Let’s imagine everyone in the state of Michigan having equal access to high quality healthcare, including treatment for chronic HCV
- Who would take responsibility?
  - Specialists (ID, GI, Hepatology)
  - Primary Care Providers (Physicians, NP’s, PA’s)
- What kind of model of care could respond to the demand?
Model of Care for the Assessment and Treatment of Hepatitis C

Imagine:

- Well trained, dedicated healthcare team
- Providing open access to care
- Comprehensive education and assessments guiding evidence-based clinical decisional making
- Focus solely on hepatitis treatment and follow up care
Mercy Health Hepatitis C Clinic - Background Information

- Local primary care providers approached hospital administrators 2010-2011
- Clinic was developed and implemented as part of Doctor of Nursing Practice (DNP) Project
- Clinic is “Community Based”
  - housed in an ambulatory care setting, not in ID or GI office
Referrals

- 1175 Referrals sent since October 2011
  - 63 referrals with + HCVAB only
  - 33 Hepatitis B
- Open access to all insurance plans
- As of May 10, 2017
  - 733 seen for at least initial consultation
  - 327 Cures
  - 62 Waiting final RNA
  - 42 On treatment
Mercy Health Hepatitis C Clinic

- Consults: 733
- Total Patients Tx/post tx: 431
- Est. SVR Rates by Nov 2017: 428
- National avg of SVR: [chart values]
Interdisciplinary Care Team

- **DNP/FNP-BC-nurse practitioner**
  - Consultation H & P
  - Interprets and provides results of Fibroscan
  - Outlines plan of care
  - Assists in managing HCC surveillance
  - Follow appointments to manage adverse events

- **Pharmacist**
  - Medication review for drug-to-drug interactions
  - Prior authorizations
  - Start appointments: treatment overview, review potential side effects, sign treatment consent
  - Liaison with pharmacy services
Interdisciplinary Care Team

- RN case manager
  - Triage calls
  - Reviews labs for patients on treatment
  - Performs Fibroscans
  - Patient education
  - Hepatocellular carcinoma surveillance monitoring

- Medical Assistant
  - Triage calls
  - Manages new referrals and coordinates daily schedule
  - Performs Fibroscans
Education

- Transmission risks
- Long term complications
- Genotype and viral load
- Substance use/abuse
- Fibroscan results
- Treatment plan of care
- Review of potential side effects
- Importance of compliance
Billable Services

- Initial consultation
  - history and physical, Fibroscan, education, review labs and ultrasound,
  - prior authorization prepared and submitted
- 2nd visit “start appointment”
  - medication review, contract, side effects review, schedules for labs and appointments
- Follow up appointments
  - Drug-to-drug interactions, side effect management, review labs, compliance monitoring

Additional Billable services:
  Labs and Imaging services
Michigan Medicaid Coverage

- Patients must have a liver fibrosis
  - Stage II-IV only
- Treatment by or in collaboration with ID, GI, or hepatology physician
- Alcohol or Drug dependency
  - 6 months clean and sober
- Specific labs required and ultrasound if patient is cirrhotic
Collaboration Agreement

Hepatitis C Clinic

Re: Hepatitis C Treatment
Date:
Patient: ____________________________
DOB: ____________________________

I have been educated regarding the importance of compliance in taking the hepatitis C treatment medications as prescribed and also any potential drug to drug interactions.

I have been counseled regarding IV/Intranasal/alcohol abuse and attest to having abstained for at least 6 months

I have been educated regarding the risk of reinfection with the patient

Patient Signature ____________________________ Date: __________

Please contact me if you have any further questions

Elaine A. Leigh, DNP, FNP-BC
Doctor of Nursing Practice/Nurse Practitioner
Mercy Health Hepatitis C Clinic
Phone 231-727-5575   Fax 231-727-4266

I have discussed this case with Elaine A. Leigh, DNP, FNP-BC and agree with the requested hepatitis C treatment regimen.

Based on the patient's genotype, treatment experience, and liver fibrosis we agree that the best treatment regimen would be Epclusa for 12 weeks.

Dr. Bruce Olson MD, Infectious Disease

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Hepatocellular Carcinoma Surveillance

AASLD Guidance for those achieving SVR

- For patients without advanced fibrosis (i.e., Metavir fibrosis stage F0-F2), no additional follow-up is recommended. (I-B)

- Patients with advanced fibrosis (i.e., Metavir fibrosis stage F3 or F4) should undergo surveillance for HCC with twice-yearly abdominal imaging. (I-C)

- Continue endoscopy to screen for varices if cirrhosis is present. Patients in whom varices are found should be treated and followed up as indicated. (I-C)