

Hepatitis Update

Prevalence, Risk Factors, Testing, and Treatment

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Why is this a Topic of Concern?

- ▶ **Viral hepatitis affects millions of Americans from every state and from all social, economic, and racial and ethnic groups**
- ▶ **Knowledge and tools exist to save lives**
- ▶ **Everyone has a role to play in the battle against viral hepatitis in United States**

Prevalence of HCV in Michigan

- ▶ There were 10,545 *new* chronic hepatitis C diagnoses reported in Michigan in 2018 for a rate of 105.85 cases per 100,000 people
- ▶ American Indians and Alaskan Natives have a higher rate of chronic hepatitis C infection than the general Michigan population (220.16 per 100,000)
- ▶ Injection drug use was a factor shared by 62% of cases, incarceration was a risk factor in 61% of cases.
- ▶ hepatitis C cases genotype 1 infection 80%, genotype 3 infection 14%, and 7% with genotype 2
- ▶ The rate of chronic hepatitis C is higher in Michigan males (121.64 per 100,000) versus females (89.81 per 100,000)
- ▶ 179 cases of acute hepatitis C 2018 (higher than national rates), median age of 33
- ▶ Injection drug use was reported by 56% of acute cases

Prevalence of HBV in Michigan

Acute Hepatitis B

- There were 79 cases of acute hepatitis B infection reported in Michigan in 2018 (below national rates)
- Tattoo in the last 6 months was the most commonly report risk factors in 2018, use of injection street drugs was the most commonly reported risk factor among 2017

Chronic Hepatitis B

- There were 1,089 new chronic hepatitis B diagnoses reported in Michigan in 2018 for a rate of 12.46 cases per 100,000 people
- Males have shown higher rates of Chronic Hepatitis B than females since 2004
- Asians are disproportionately affected by chronic hepatitis B with an infection rate of 51.90 per 100,000, compared to the state average of 10.93

Hepatitis A Outbreak in Michigan

- ▶ Since August 2016, a large ongoing outbreak of hepatitis A outbreak affecting 219 people in 2018 alone. Largest outbreak in Michigan's history
- ▶ As of May 29, 2019, the Michigan Health Department has reported 914 cases, 734 hospitalizations.
- ▶ 28 deaths have been reported
 - ▶ older than 50, homeless with cirrhosis
 - ▶ liver failure, septic shock or other organ failure
- ▶ As of May 29, hardest hit are Macomb County, with 223 cases; the City of Detroit, with 173; Wayne County, with 164, and Oakland County, with 120 cases
- ▶ No common food, beverage, or drugs have been identified as a common source of infections
- ▶ Those with history of injection and non-injection drug use, homelessness or transient housing, and incarceration are thought to be at greater risk in this outbreak setting

Hepatitis A Outbreak in Michigan

Transmission:

- ▶ The virus is found in the feces of those infected with it. It spreads through sex, close contact with an infected person and contaminated food and water

Symptoms include:

- ▶ Nausea and vomiting, belly pain, fatigue, fever, loss of appetite, yellowing skin and eyes, dark urine,
- ▶ Symptoms range from mild weeks-long to a month-long serious condition

Recommendations:

- ▶ Handwashing, handwashing, handwashing
- ▶ It's imperative that Michigan residents get vaccinated to protect themselves and prevent the further spread of this outbreak in Michigan communities.

Viral Hepatitis Outcomes

- ▶ **Hospitalization Data**
 - ▶ Attributed to HCV increased by 48% between 2007-2016
- ▶ **Transplant Data**
 - ▶ Trends increasing due to disease progression and morbidity associated with long term HBV/HCV
- ▶ **Liver Cancer Data**
 - ▶ Incidence has increased by 50% between 2007-2016
 - ▶ Rates are higher for African American males
- ▶ **Hepatitis-Related Mortality**
 - ▶ 109 deaths attributed to Chronic hepatitis C in 2016

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)

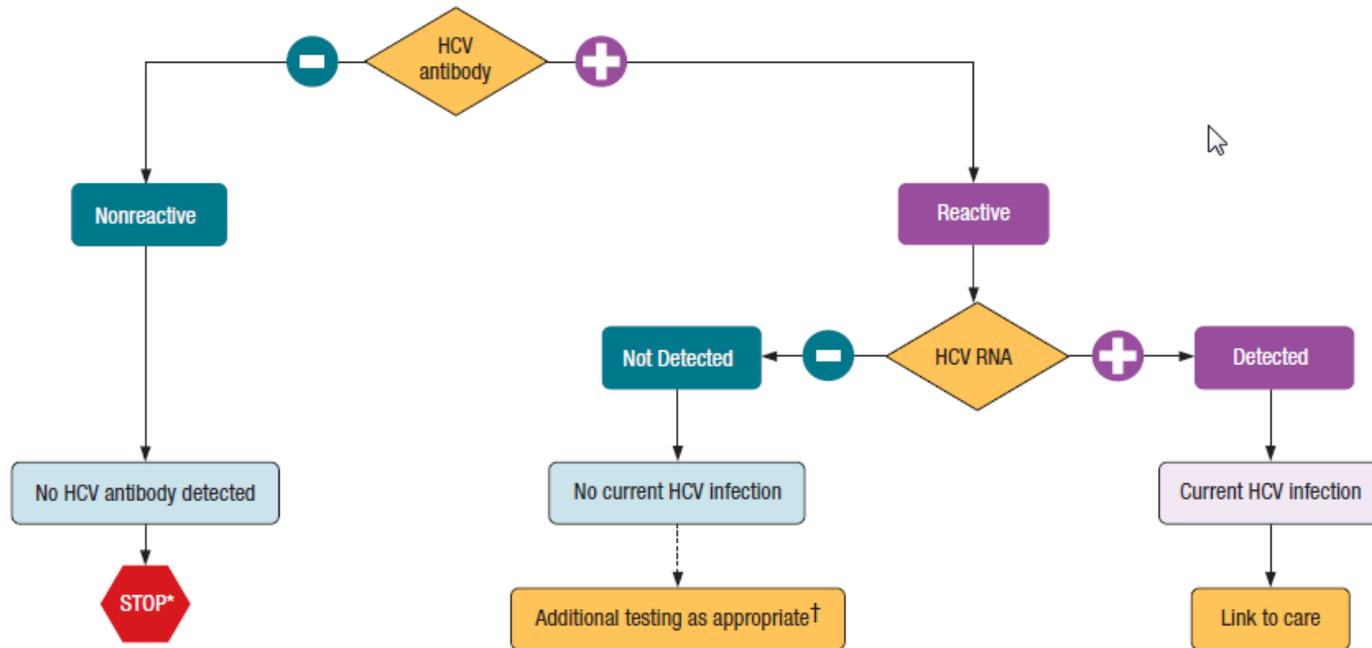
Rating: Class 1, Level B

Diagnosis HCV

Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention



* 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. For persons who are immunocompromised, testing for HCV RNA can be considered.

† To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

Source: CDC. Testing for HCV infection: An update of guidance for clinicians and laboratories. *MMWR* 2013;62[18].

Transmission Risks HCV

- ▶ Blood Exposure only
- ▶ IV/Intranasal drug use (needles, cottons, spoons etc.)
- ▶ Blood transfusion/blood products, organ transplant before 1992
- ▶ Tattoo/piercings in non-sterile environments
- ▶ Healthcare/emergency professionals
- ▶ Sexual 3-5%
- ▶ Women in monogamous relationships: no recommendation for changes in sexual practices, higher rates in MSM
- ▶ Maternal-Child 3-5%
- ▶ Increased risk of perinatal transmission with coinfection of HIV and high maternal viral loads

Transmission Risk HBV

▶ Sexual

- ▶ Body fluids: semen and vaginal secretions
- ▶ 50% of transmissions in US
- ▶ Minute amounts in saliva, tears, and breast milk-studies have shown concentrations not high enough for transmission

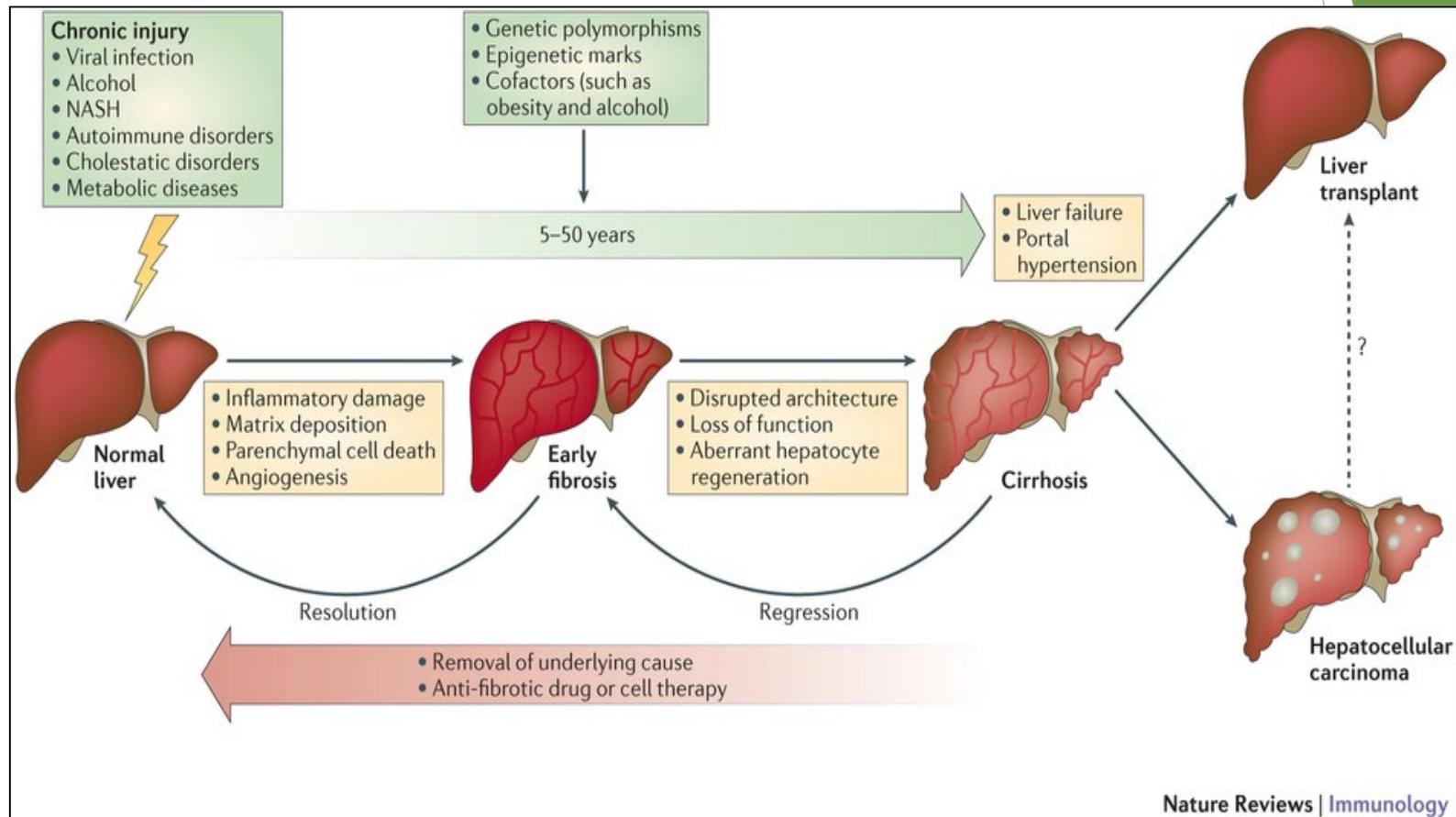
▶ Blood exposure

- ▶ IV/IN drug use, needle sticks, tattoos, piercing etc.

▶ Vertical transmission (mother to infant during delivery)

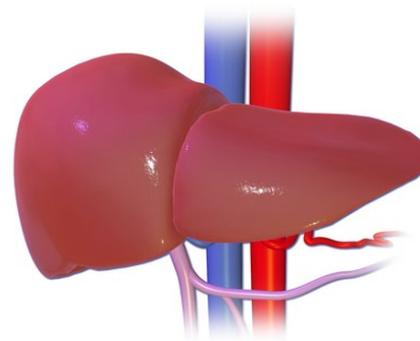
Long Term Complications

► Liver Fibrosis

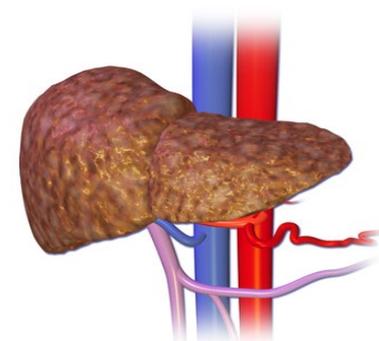


Liver Fibrosis

<i>Grade/Stage</i>	<i>Grade of Inflammation</i>	<i>Stage of Fibrosis</i>
1	Minimal	Portal
2	Mild	Periportal
3	Moderate	Bridging
4	Severe	Cirrhosis



Normal Liver



Liver Cirrhosis

Fibroscan



Determines “stiffness” of the liver

Uses ultrasound technology to send a sound wave into the liver.

Non-invasive, takes 10-15 mins, less expensive, immediate results

Cannot eat solid foods for 3 hours ahead

Contraindicated in individuals with battery operated device (pacemakers, bladder stimulators...)

**Covered by most insurances,
-limited access**

Determining Liver Fibrosis

▶ Invasive

- ▶ Liver Biopsy

- ▶ Still required for many liver related diagnoses

▶ Non Invasive

- ▶ Fibroscan

- ▶ Fibrosure/Fibrotest (Blood test)

- ▶ APRI/Fib 4 (Calculated from

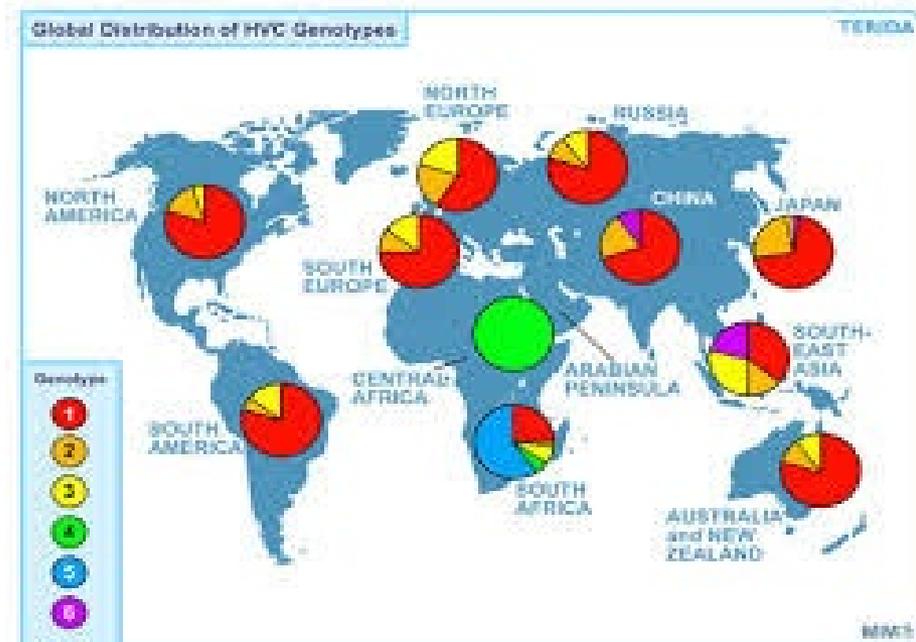
Hepatocellular Carcinoma (HCC) Surveillance

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)

HCV Genotypes/Labs

- ▶ Genotypes 1-6 (75-80% of those in US have GT1)
- ▶ Liver enzymes (LE) may or may not be elevated with chronic hepatitis infection. Providers are encouraged NOT to wait to refer patients for evaluation based on normal LE
- ▶ Kidney function monitoring required to determine treatment possibilities
- ▶ Viral load (RNA)
 - ▶ Does not determine damage or poss. cure



Common Non-specific Symptoms HCV

- ▶ Fatigue is the most common complaint and can lead to decreased quality of life
- ▶ Arthralgia/Joint pain
- ▶ Extrahepatic Manifestations :
 - ▶ Diabetes
 - ▶ Chronic dermatology conditions
 - ▶ Renal disease
 - ▶ Cryoglobulinemia/porphyria

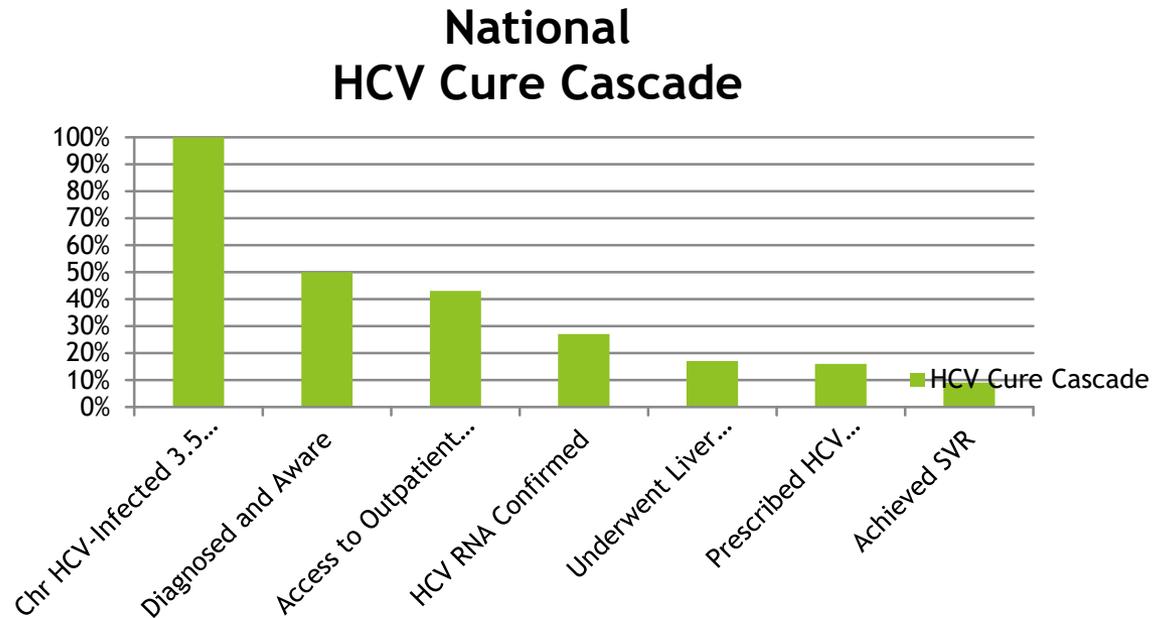
Those Diagnosed Require Education

- ▶ Transmission risks
- ▶ Long term complications of chronic hepatitis
- ▶ Bloodwork results HCV genotype and viral loads
- ▶ Address substance use/abuse
- ▶ Determining level of liver fibrosis/scarring
 - ▶ Fibroscan/Fibrosure/Fibrotest/APRI/Fib4
- ▶ Treatment plan of care
 - ▶ Review of potential side effects to treatment meds
 - ▶ Importance of adherence
 - ▶ Follow up care
- ▶ Address concerns of stigma and discrimination

Addressing Substance Use/Abuse

- ▶ **Limitations with Medicaid**
- ▶ **Risk of re-infection**
- ▶ **Although HCV Antibody develops it's not a “protective” antibody**
- ▶ **Concerns of continued liver fibrosis**

HCV Cure Cascade



- ▶ 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.

Treatment HCV

- ▶ A combination of antiviral medications are prescribed depending on the genotype of the virus, viral load and presence of any liver damage

AASLD Guidelines

- ▶ Direct Acting Antivirals (DAAs)
- ▶ High success rates >90% (most reaching 95-99%)
- ▶ Few side effects to medications
 - ▶ fatigue, headache, nausea, diarrhea, insomnia
- ▶ Treatment regimens typically 8-12 weeks
- ▶ Single tablet/3 tablets once daily

FDA-approved direct-acting antivirals for hepatitis C

2013

Brand name: OLYSIO
Generic name: simeprevir
Genotype: 1
Company: Janssen

Brand name: SOVALDI
Generic name: sofosbuvir
Genotype: 1, 2, 3 or 4
Company: Gilead Sciences

2014

Brand name: HARVONI
Generic name: ledipasvir/sofosbuvir
Genotype: 1, 4, 5 or 6
Company: Gilead Sciences

Brand name: VIEKIRA PAK
Generic name: dasabuvir/ombitasvir/
paritaprevir/ritonavir
Genotype: 1
Company: AbbVie

2015

Brand name: TECHNIVIE
Generic name: ombitasvir/paritaprevir/
ritonavir
Genotype: 4
Company: AbbVie

Brand name: DAKLINZA
Generic name: daclatasvir
Genotype: 1 or 3
Company: Bristol-Myers Squibb

2016

Brand name: ZEPATIER
Generic name: elbasvir/grazoprevir
Genotype: 1 or 4
Company: Merck

Brand name: EPCLUSA
Generic name: sofosbuvir/velpatasvir
Genotype: 1, 2, 3, 4, 5 or 6
Company: Gilead Sciences

2017

Brand name: VOSEVI
Generic name: sofosbuvir/velpatasvir/
voxilaprevir
Genotype: 1, 2, 3, 4, 5 or 6
Company: Gilead Sciences

Brand name: MAVYRET
Generic name: glecaprevir/pibrentasvir
Genotype: 1, 2, 3, 4, 5 or 6
Company: AbbVie

YES! There is a CURE

- ▶ To evaluate for viral cure a HCV RNA is checked 3 months from the completion date of treatment, if **UNDETECTED=VIRAL CURE**

Dispel These Common Myths

- ▶ No cure exists
- ▶ Virus is in remission
- ▶ Genotype 1 is the most difficult to treat
- ▶ If you are African American, overweight or have cirrhosis, treatment may not work as well
- ▶ There is a hepatitis C vaccination

National Viral Hepatitis Action Plan

- ▶ Originated in 2011 marking a National coordinated effort to respond the viral hepatitis
- ▶ National plan, not just federal. Requires stakeholders from a broad mix of public and private sectors
- ▶ Focuses on Hepatitis B and C as these are the 2 most common types of viral hepatitis

Since then:

- ▶ New cases of hepatitis C (HCV) infections has increased rapidly
- ▶ Prior progress in reducing new cases of Hepatitis B virus (HBV) has stalled
- ▶ Hepatitis C-related deaths has killed more people than all other deaths of reported infectious diseases combined

National Hepatitis Action Plan 2017-2020

- ▶ **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**

National Hepatitis Action Plan

Goals: 2017-2020

- 1. Prevent new viral hepatitis cases**
- 2. Reduce deaths and improve the health of people living with viral hepatitis**
- 3. Reduce viral hepatitis health disparities**
- 4. 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**

Priority Populations

HBV and HCV disproportionately impact certain populations

- ▶ **Baby Boomers**
- ▶ **People Who Inject Drugs**
- ▶ **Men Who Have Sex with Men**
- ▶ **Pregnant Women**
- ▶ **Homeless Individuals**
- ▶ **People in Correctional Facilities**
- ▶ **Veterans**
- ▶ **People Living with HIV and Viral Hepatitis Coinfection**
- ▶ **African Americans/American Indians/Alaska Natives/Asian Americans& Pacific Islanders**

Baby Boomers

- ▶ People born between 1945-1965
- ▶ Lower rates of new infections but comprise approximately 75% of all chronic HCV infections
- ▶ Baby boomers experience one of the highest death rates from HCV
- ▶ Higher rates of advanced liver fibrosis and liver cancer because they more likely have been infected for years
- ▶ Medicare covers a 1 time screening and annual screening for those at risk
- ▶ Screening and curing this priority population will reduce HCV national wide significantly and save an estimated 120,000 lives

People Who Inject Drugs

- ▶ From 2005 through 2017, the number of cases of chronic hepatitis C among persons aged 18 -29 years has increased over 476% from 359 cases to 2,069.
- ▶ A concurrent signal of increased heroin abuse has been evident within the same timeframe.
- ▶ Injection drug use in 18-29 year olds was reported in 85% of hepatitis C patients.
- ▶ Between 2000 and 2017 there has been a 177% increase in Michigan heroin substance abuse treatment admissions.
- ▶ From 2000 through 2016 heroin overdose deaths in Michigan have increased by 722%
- ▶ The opioid epidemic is impacted both young males and females. As a result we have seen 20 cases of perinatal hepatitis C as a result of mother-to-child transmission over the last 5 years, and a rate of 761.2 instances of treated neonatal abstinence syndrome (NAS) per 100,000 live births in 2016.

The Opioid Epidemic and Viral Hepatitis

- ▶ National epidemic
 - ▶ geographic areas not previously affected
- ▶ Involves both prescription pain relievers and heroin
- ▶ Unsafe injection drug use has contributed to a 250% increase in HCV infections between 2010-2014
- ▶ Preventing overdose deaths and viral hepatitis/HIV infections is the main goal.
 - ▶ naloxone education and training programs
 - ▶ needle exchange programs
- ▶ Strategies to improve access to substance use treatment programs
- ▶ Enlisting help from federal, state, local, and tribal leaders to enact laws and enforce limiting prescription pain medications.

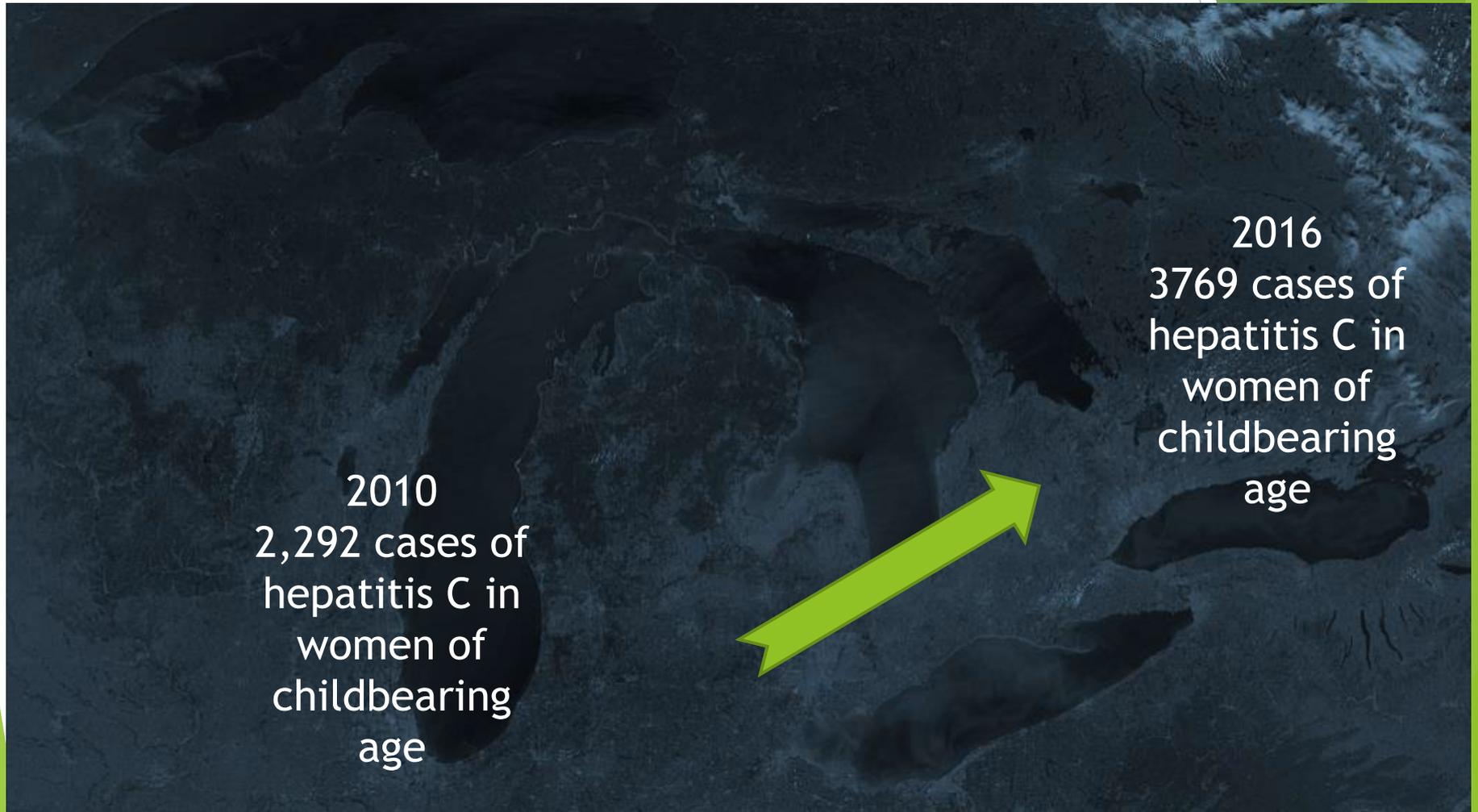
Men Who Have Sex with Men

- ▶ Approximately 20% of new cases of HBV occurs in MSM
- ▶ They are at risk for both HBV (bloody and body fluid exposure) and HCV (blood exposure)
- ▶ Only 35% of this population is vaccinated against HBV
- ▶ Sexual transmission of HCV among HIV-positive MSM has been well documented
 - ▶ The risk appears low but is increasing
- ▶ Increased education for health care providers in screening and education is needed

Pregnant Women

- ▶ Risk of women with viral hepatitis transmitting virus to their infants during delivery
 - ▶ Risk of HCV transmission is 3-5%
 - ▶ Risk of HBV infected mother is 90%
- ▶ 1 in 4 infants infected with HBV at birth will die of a HBV-related cause including liver cancer which can occur in late childhood or adulthood
- ▶ Screening for HBV and HCV is a high priority
- ▶ Young women of childbearing age with HCV should be offered treatment prior to pregnancy or reassured regarding low risk of transmission

Perinatal HCV in Michigan



2010
2,292 cases of
hepatitis C in
women of
childbearing
age

2016
3,769 cases of
hepatitis C in
women of
childbearing
age

Perinatal HCV

- ▶ No clear connection between delivery method and transmitting hepatitis C
 - ▶ Annals of Internal Med 2013
- ▶ No contradiction in a HCV positive mothers and breast feeding
- ▶ Breast feeding should be postponed if cracked and bleeding nipples
- ▶ Milk should be discarded until nipples are healed
 - ▶ CDC and AAP-American Academy of Pediatrics

Homeless Individuals

- ▶ Studies have shown that individuals who are homeless experience higher rates of HCV, 22-52%
- ▶ 41-44% among homeless veterans
- ▶ Adverse outcomes in overall health and life expectancy is well-established in the homeless population
- ▶ Risk factors include injection drug use and incarceration
- ▶ Programs should focus on risk reduction education and linkage quality to care

Persons with HCV in Correctional Facilities

- ▶ Approximately 10-41% of persons living in correctional facilities are living with chronic HCV
- ▶ 30% of Americans living with chronic HCV will pass through a correctional system on any given year
- ▶ Great opportunity for diagnosis of HCV
- ▶ Justice-involved individuals are at higher risk for infectious disease including HBV, HCV, HIV/AIDS
- ▶ These individuals can be a risk during incarceration with sharing of equipment, tattoos/piercings, unprotected sex, and possible exposure to blood or body fluids from fighting or drug use.
- ▶ One study suggested that treating incarcerated patient for HCV alone could save \$750 million and reduce risk for non-institutional persons.

Veterans

- ▶ **Approximately 4-6% of all veterans have chronic HCV**
- ▶ **HCV is seen in higher rates with those who had served in Vietnam, those who use alcohol or other substance use, or those who are homeless**
- ▶ **A record number of vets have been treated for HCV since 2014**
- ▶ **VA is committed to screening and treating veterans affected**

People Living with HIV and Viral Hepatitis Infection

- ▶ Among the 1.2 million people living with HIV in the US, 1 in 10 are co-infected with HBV
- ▶ Experienced providers are required to determine appropriate treatment to treat both HIV and HBV
- ▶ Curing HCV those co-infected with HCV/HIV have reduced rates of liver failure, liver cancer and liver-related deaths
- ▶ HCV treatments are safer and much more readily available to this population
- ▶ Drug interactions continue to be a concern when prescribing treatment for HIV/HCV

Racial and Ethnic Populations

- ▶ American Indian and Alaska Native (AI/AN) communities have historically had double the national average rates of acute HCV and HCV-related deaths
- ▶ Successful programming for HBV/HCV screening and HBV vaccinations have significantly lowered transmission rates and death rates have fallen
- ▶ Asian Americans and Pacific Islanders (AAPIs) make up only 5% of the US population, more than 50% of chronic HBV is found in this population
- ▶ HBV-related liver cancer is the leading cause of cancer deaths among Asian Americans
- ▶ Sadly, 2/3 of those affected are unaware of their infection
- ▶ Screening is recommended for this population for those born outside the US or those born in the US but not vaccinated at birth
- ▶ Access to screening is the most important step in the cascade of quality healthcare

Racial and Ethnic Populations

- ▶ African Americans (AA)
- ▶ Older AAs have much higher rates of chronic HCV than younger AAs or the general population
- ▶ Healthcare disparities are well known in this population including access to and follow up care
- ▶ This population does not have increased risk of new infections but continue to have higher rates of HBV-related deaths from chronic hepatitis B

Access to Care

- ▶ **Primary Care providers are the key to appropriate screening of HCV/HBV as well of providers in specialty clinics**
 - ▶ **OB/GYN, HIV/aids clinics, pain clinic, Substance use/abuse treatment centers etc.**
- ▶ **Healthcare Coverage**
 - ▶ **Affordable Care Act 2011**
 - ▶ **Expanded Medicaid**
 - ▶ **Repeal of tax mandate passed in 2017**
- ▶ **Limited pool of providers in Michigan to offer HBV/HCV care**
 - ▶ **Individuals living in rural communities lack local care**

Michigan Medicaid Coverage

- ▶ Patients must have a liver fibrosis
 - ▶ Stage I-IV only, will open to everyone October 2019
- ▶ 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

Stigma and Discrimination

- ▶ From self or others
- ▶ Fear of transmission - As hepatitis C is an infectious disease, people may be afraid they will contract it. Although it is not spread easily, many people do not know how hepatitis C is transmitted
 - Fear of illness - Some people do not like to be around people who are 'sick'. People can feel uncomfortable and try to avoid those who have an illness
 - Judgement - Hepatitis C is often associated with those who inject drugs as it is one of the main ways people can get hepatitis C. Stigma linked to injecting drug users is common
- ▶ Education can play a big role in reducing stigma. People can discriminate because they don't understand. Sometimes our own views about hepatitis C can cause stigma

Stigma and Discrimination

- ▶ Discriminating against people with hepatitis is against the law, as stated in the Human Rights Act 1993. This includes situations in employment, services, health care, accommodation, and study. Everyone has the right to be treated fairly and with respect

Ways to cope with stigma:

Educate with accurate information to reduce fear and stereotypes

Get support in order to reduce isolation

Talk to other people who have hepatitis C

Seek a positive attitude about hepatitis C diagnosis and care available

Treatment HBV

- ▶ AASLD/IDSA Guidelines
- ▶ Not all persons require treatment
- ▶ Depends on HBV DNA, HBV Be Antigen, Liver Enzyme ALT
- ▶ Higher risk for liver cancer in those of Asian decent
- ▶ Single Tablet per day

More than 700 treated, Celebrated 600 Cures January 2019

- ▶ **Mercy Health**
Muskegon

