# Thinking about Hepatitis C

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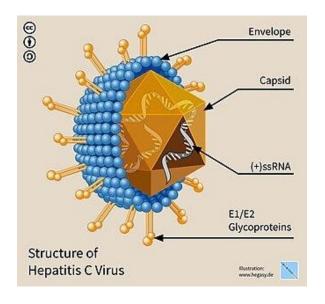




# Background

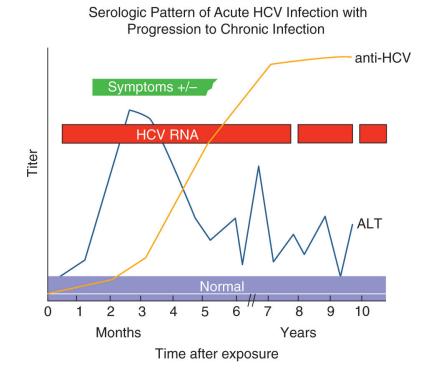
### Causative Agent - HCV

- Flavivirus
- A small spherical structure with a lipid envelope
- Glycoproteins on its envelope
- A spherical capsid
- Single strand of positive RNA
- 6 genotypes



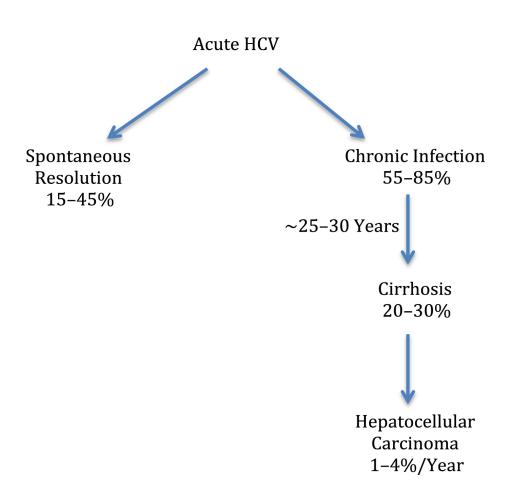
### Acute Hepatitis (HCV) C Infection

- Majority = asymptomatic
- 15-25% develop symptoms
  - o Jaundice
  - Abdominal pain,
  - Stool and urine changes
  - o Fever
  - Fatigue
- By definition acute = duration <= 6 months



# Chronic HCV can cause multiple health problems:

- Liver problems
  - o Cirrhosis
  - Cancer
- DM
- Glomerulonephritis
- Essential mixed cryoglobulinemia
- Porphyria cutanea tarda
- Non-hodgkin's lymphoma



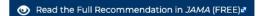
#### Hepatitis C Virus Infection in Adolescents and Adults: Screening

March 02, 2020

Recommendations made by the USPSTF are independent of the U.S. government. They should not be construed as an official position of the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.









#### Recommendation Summary

Population	Recommendation	Grade
Adults aged 18 to 79 years	The USPSTF recommends screening for hepatitis C virus (HCV) infection in adults aged 18 to 79 years.	В

#### Who to test and screen

#### Universal screening

Clinicians should universally screen:

- All adults 18 and older at least once in their lifetime, except in settings where the prevalence of hepatitis C virus (HCV) infection (HCV RNA-positivity) is under 0.1%.
- All pregnant women during each pregnancy, except in settings where the prevalence of HCV infection (HCV RNA-positivity) is under 0.1%.

#### Routine periodic testing

CDC also recommends routine periodic testing for patients with ongoing risk factors (regardless of setting prevalence), including:

- People who currently inject drugs and share needles, syringes, or other drug preparation equipment.
- People with selected medical conditions, including people who receive maintenance hemodialysis.

#### One-time testing

CDC recommends one-time hepatitis C testing for people with recognized risk factors or exposures, including:

- People who currently or have previously injected drugs and shared needles, syringes, or other drug preparation equipment.
- People with human immunodeficiency virus (HIV).
- People with selected medical conditions, including people who have ever received maintenance hemodialysis and persons with persistently abnormal alanine aminotransferase (ALT) levels.
- Prior recipients of transfusions or organ transplants, including:
  - People who received clotting factor concentrates produced before 1987.
  - People who received a transfusion of blood or blood components before July 1992.
  - People who received an organ transplant before July 1992.
  - People who were notified that they received blood from a donor who later tested positive for HCV infection.
- Health care, emergency medical, and public safety personnel after needle sticks, sharps, or mucosal exposures to HCV-positive blood.
- Infants born to people with known hepatitis C.

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#### Test anyone who requests it

Clinicians should test anyone who requests a hepatitis C test, regardless of stated risk factors, because patients may be hesitant to share stigmatizing risks.

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#### Routine periodic testing

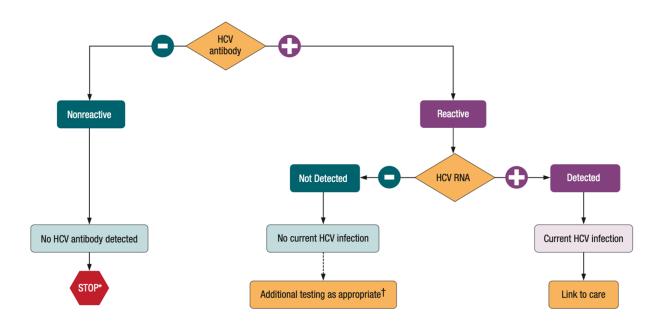
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### Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection



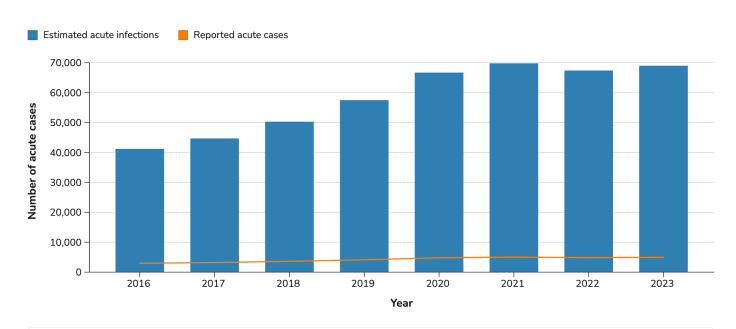


<sup>\*</sup> For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

<sup>†</sup> 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.

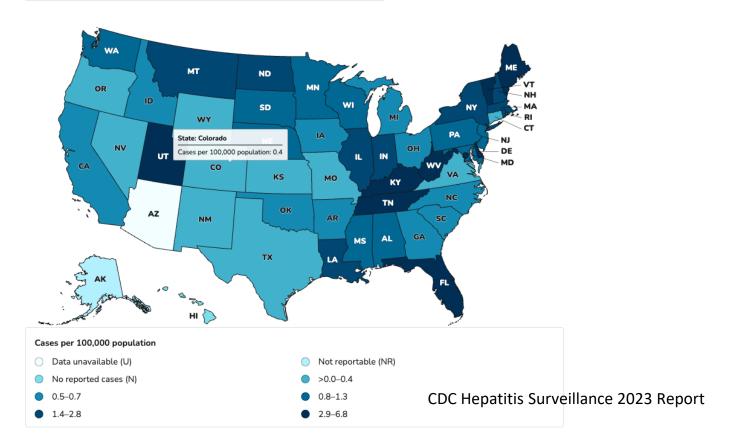
## Trends

# Number of reported cases\* and estimated infections† of acute hepatitis C — United States, 2016–2023

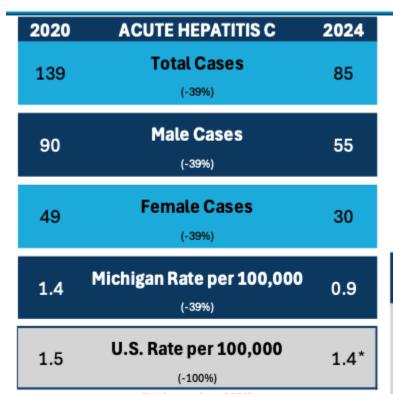


Data Table								_	
	2016	2017	2018	2019	2020	2021	2022	2023	
<ul> <li>Estimated acute infections</li> </ul>	41,200	44,700	50,300	57,500	66,700	69,800	67,400	69,000	leport
<ul><li>Reported acute cases</li></ul>	2,967	3,216	3,621	4,136	4,798	5,023	4,848	4,9	

#### Rates\* of reported cases† of acute hepatitis C, by state or jurisdiction — United States, 2023



### Michigan



- (% change since 2020)
- \*U.S. incidence rate is calculated from 2023 data

- Total acute hepatitis C cases in 2024 increased slightly from the 2023 total but reflects a nearly 40% decrease over the past five years.
- Seventy five percent of cases reported were among white individuals, while the highest incidence rate occurred among American Indian/Alaska Native individuals.
- Use of illicit drugs remains the most prevalent risk factor among new cases; however both illicit drug use and IDU decreased significantly in 2024, by 21% and 24%, respectively.
  - Drug use data indicates possible reduction in injection as primary route of administration.

#### Most Commonly Reported Risk Factors for Acute Hepatitis C, Michigan, 2024

Used Illicit Drugs	Received a Tattoo	Incarceration Longer Than 6 Months
24%	24%	19%
(-21%)	(-3%)	(-4%)
(change in proporti	on from 2023) - excludes mi	ssing/unknown data

MDHHS Viral Hepatitis Reports 2024

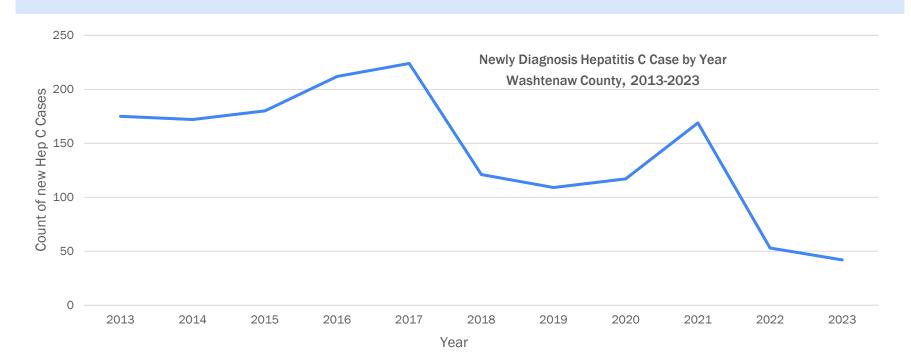
#### Washtenaw County Health Department | June 2024



#### 2023 Washtenaw County Hepatitis C Data Brief

#### Newly Diagnosed Hepatitis C (HCV) cases are decreasing in Washtenaw County

Hepatitis C Cases are divided into Acute or Chronic cases. Diagnosis of either requires a series of blood test for confirmation. Cases without confirmatory testing are labeled as probable.



#### **2023 HCV Elimination Information**

#### We Treat Hep C Initiative Launched

- April 2021, by State of Michigan.
- Aim to eliminate.

#### Advent of direct acting antiviral (DAA)

- with a >90 % cure rate
- Elimination is possible.

#### HPC work-up for hepatitis C

Includes blood tests and imaging.

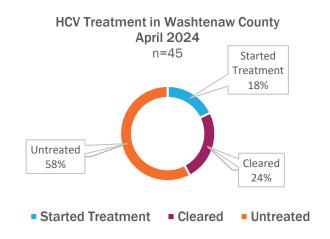
Length of treatment is 8 to 12 weeks

#### Gold standard for Clearance/cures

Sustained Viral Response (SVR) test at 12 weeks post-treatment.

#### Through this initiative,

- One DAA chosen (pan-genetic)
- No prior authorization required
- Available to all Medicaid and Healthy Michigian
- Low cost (\$1 copay).
- Alternate (DAA)
- Require prior authorization and a \$3 copay.



### The Changing Landscape of Hepatitis C Care

#### **New Treatments**

Introduction of First Direct-Acting Antivirals (DAA), in 2013

Initial cost was \$80,000 for a 12-week course

#### **Common restrictions included:**

Required Prior Authorization
Required Rx by **Specialists**Excluded active **substance** use

#### Lower Cost, Better Access

We Treat Hep C Initiative, launched in 2021

**Encourage PCPs to Screen and Treat** 

#### MDHHS partnered with AbbVie

Offer MAVYRET for cost **\$1**Medicaid and Healthy Michigan **NO** Prior Authorization Needed

### A Needs-Assessment, a mixed-methods exploration of . . .

Who is being missed?

Where are the gaps in diagnosis and treatment?

What are the barriers and challenges?

How do we find these?

### Changing Landscape:

### A Hepatitis C (HCV) Needs Assessment

#### Quantitative Disease Surveillance Qualitative Design and Implementation Needs Qualitative Assessment Quantitative Disease **Interviews** Background Case Studies Framework Investigation (Providers Analysis & and Patients **Takeaways**

### Qualitative Design and Implementation

#### **Framework**

Develop from the Univ of Washington Care HCV Continuum Expands nuances with each components

#### **Case Studies**

Graphical representation of patient path through the **Framework**Patient chosen to illustrate **common problem**Patient chosen to represent **relevant subpopulation** 

#### **Provider Interviewers**

Common names in the records Different kinds of practices (PCP, Speciality) Multilevel: MD, PAs, RN

#### **Patient Interviews**

Random sample Bilingual interviews

### **Qualitative Interviews**

### **Providers (6)**

Spoke to 6 providers

Two advance practice professionals

Two practices, PCPs and Specialist

### **Patient Interviews (5)**

Random sample: M (3), F(2)| W (2), AA(2), H(1)

Treated(2), Not Treated (2), Incomplete (1)

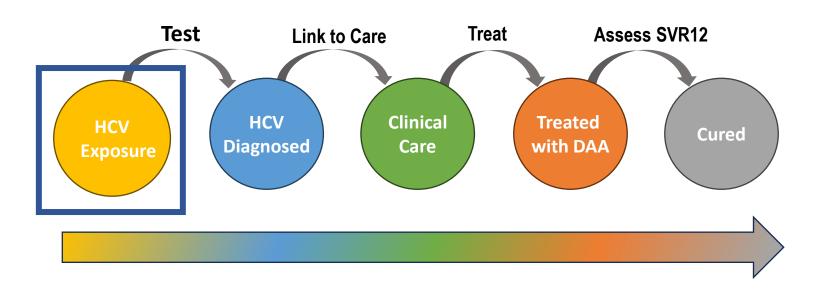
Age range: 39-65 year  $\mu = 52.6$ 

Eager responses, multiple returned calls

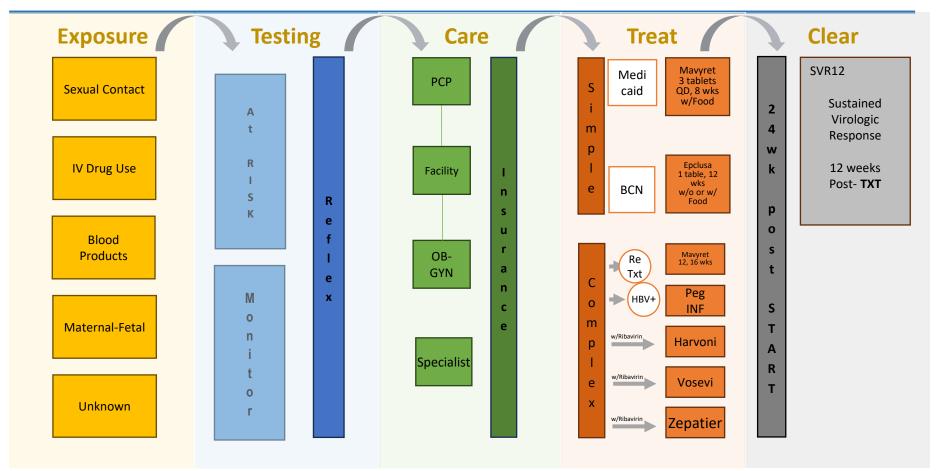
Bilingual Interview, Spanish and English

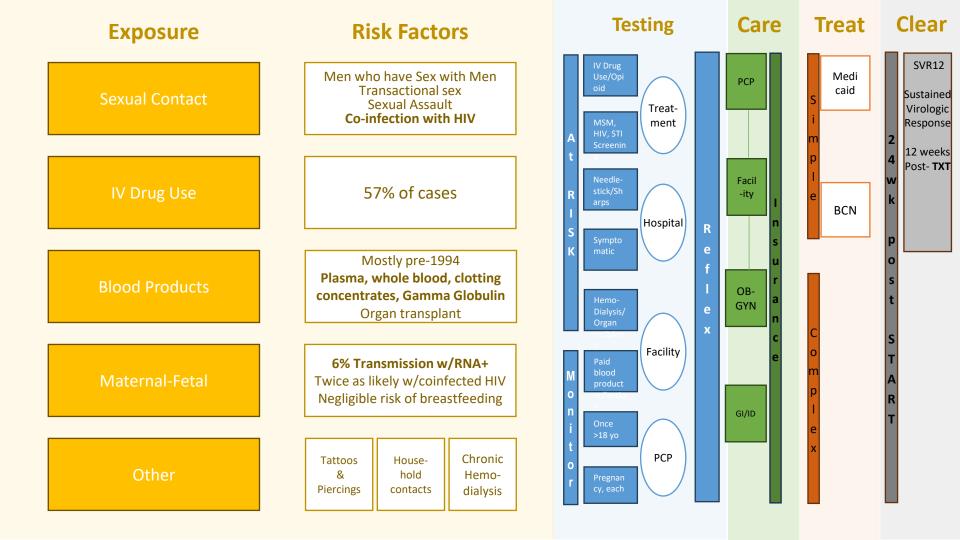
### The Hepatitis C (HCV) Care Continuum<sup>1</sup>

#### Hepatitis C Care Continuum



### Framework for Hepatitis C





### From Providers

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In my opinion the barriers are:
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{Specialist 1}: Lag time

{Specialist 2}: Moralism

{Private Clinic}: Sobriety

#### Case Study 1

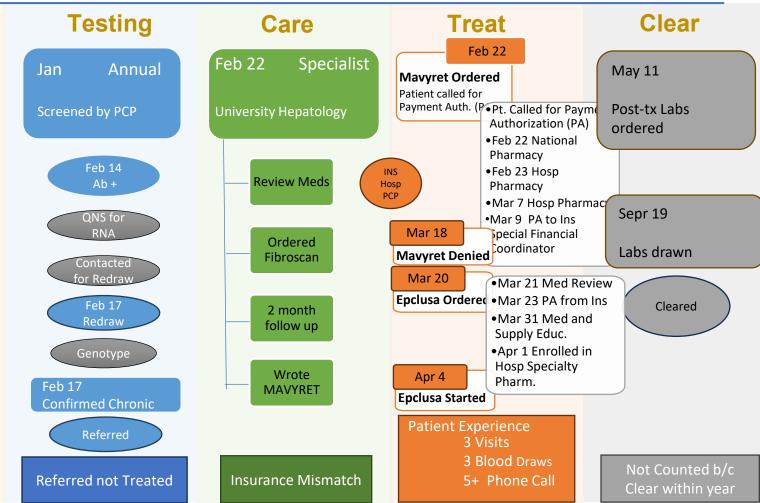
#### **Multiple Issues**

### Exposure

**Blood Products** 

Patient is a healthy & physically active older AA man in his 70s. Believes he was exposed by blood products or needle stick in the 1970s.

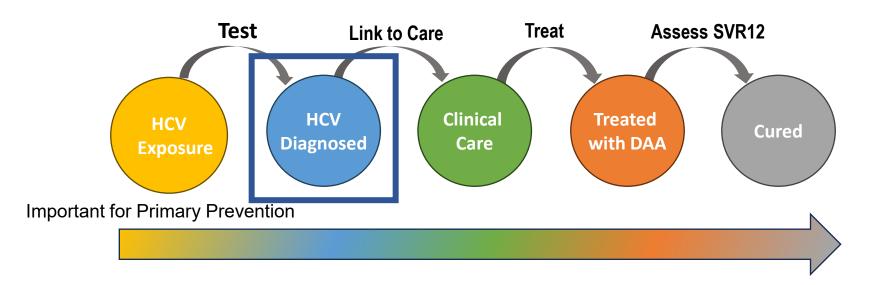
**NO IVDU** 



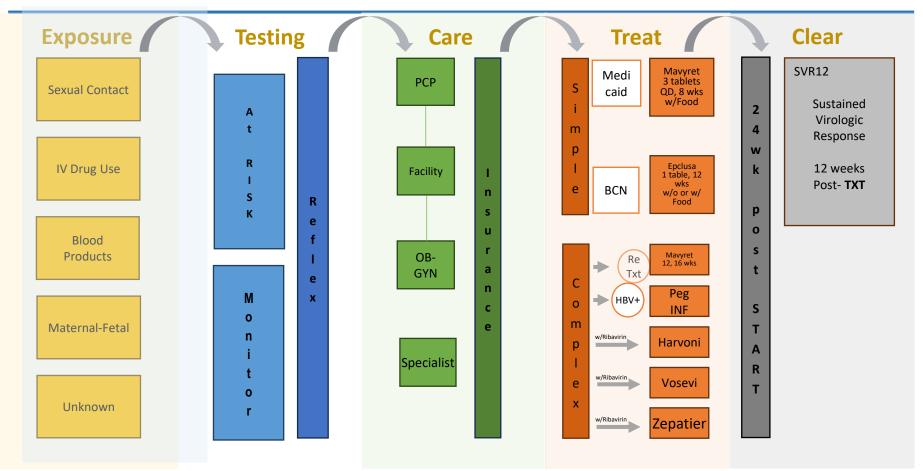
Partner Screened Neg

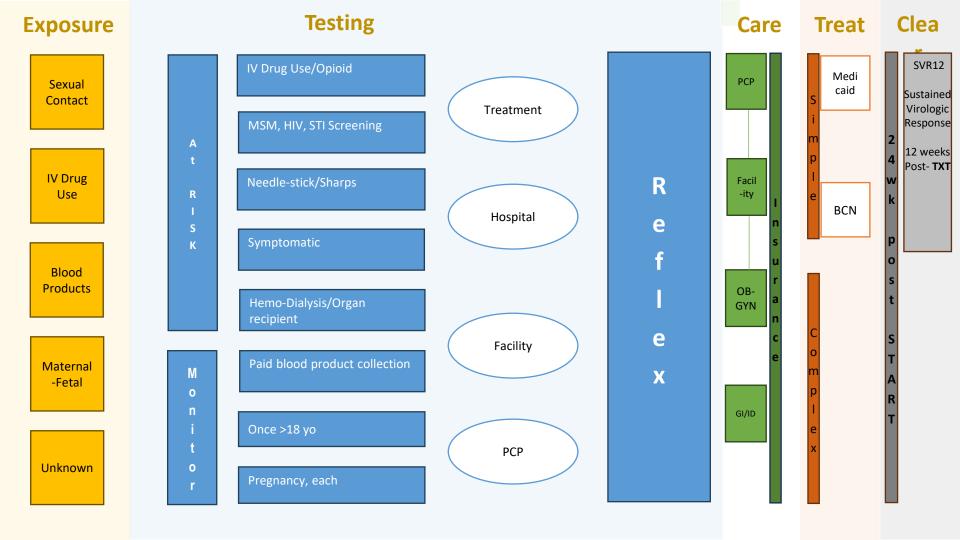
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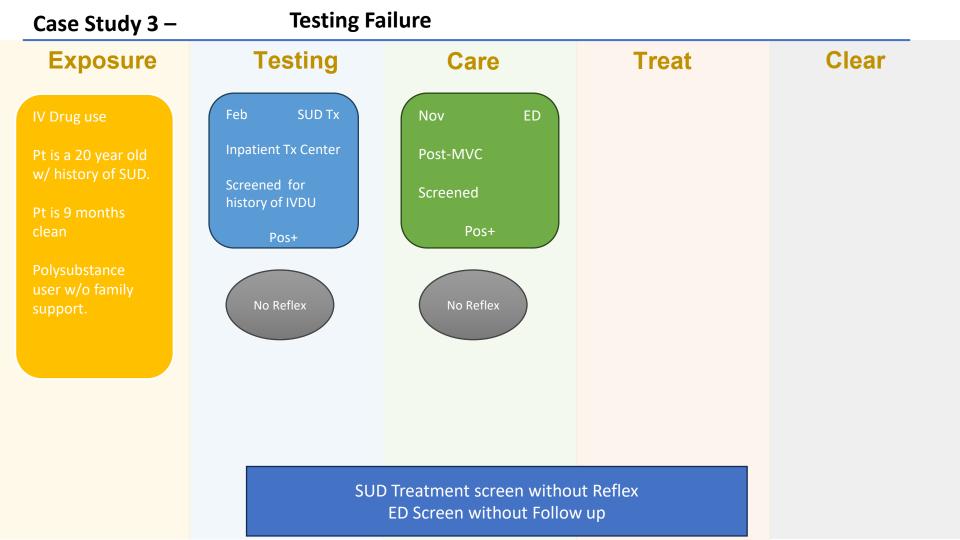
#### Hepatitis C Care Continuum



### Framework for Hepatitis C





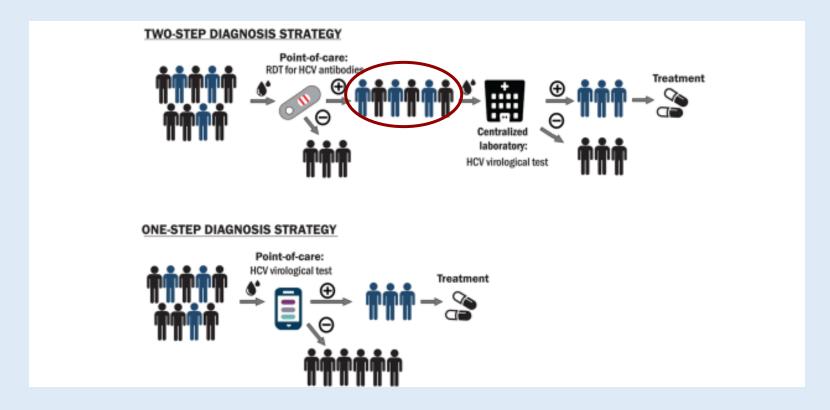


### Issues with testing for Hepatitis (HCV) C Infection

Before DAA treatment, screening-based on risk factors. (Primary Prevention)

Screening with Ab test with reflex to RNA test is the standard of care.

### Two-Step vs One Step Diagnosis



### From Patients and Providers

Fear of getting blood drawn. Past bad experience

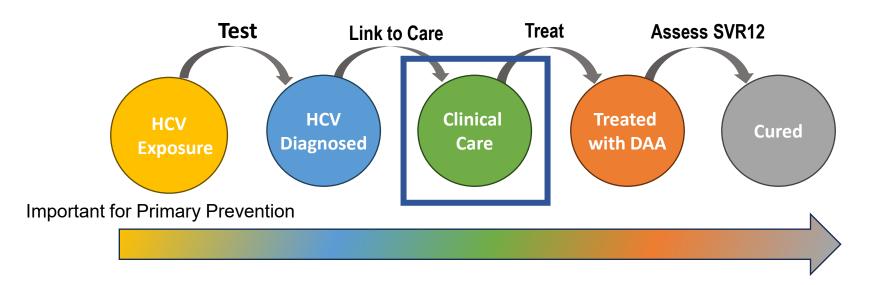
Genotype, though not really needed. Some insurance companies are holding on to this.

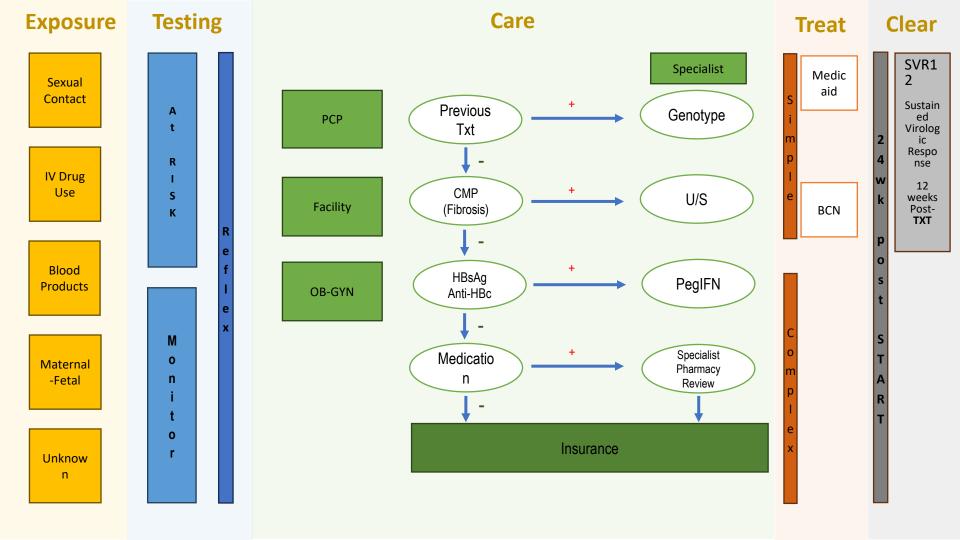
- 5. Are there initiatives or programs that would have helped you
- ☐ Get Tested earlier? (Specify) Finding a good blood draw person

PCP retired last year. I was never informed of test results. Never offered treatment.

### The Hepatitis C (HCV) Care Continuum<sup>1</sup>

#### Hepatitis C Care Continuum





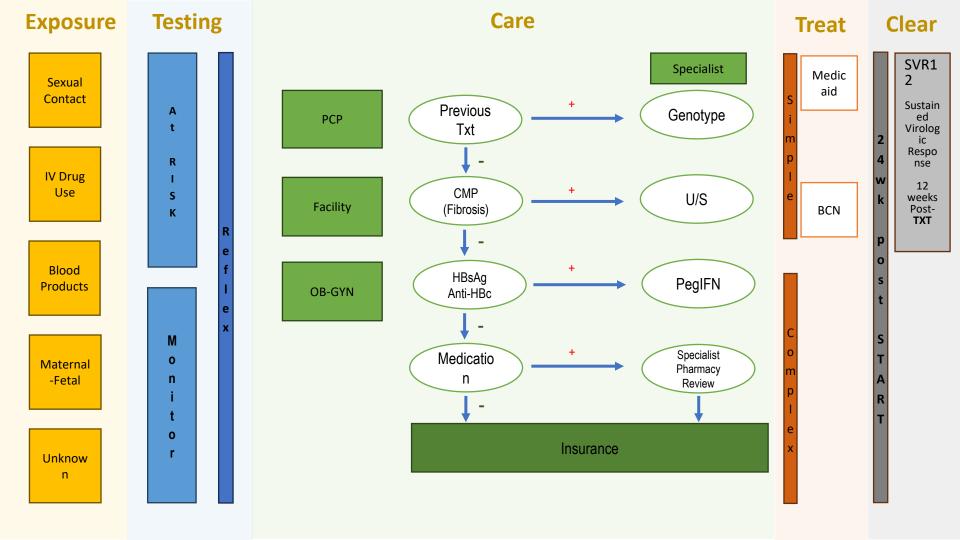
### **Provider Interviews Take-Aways**

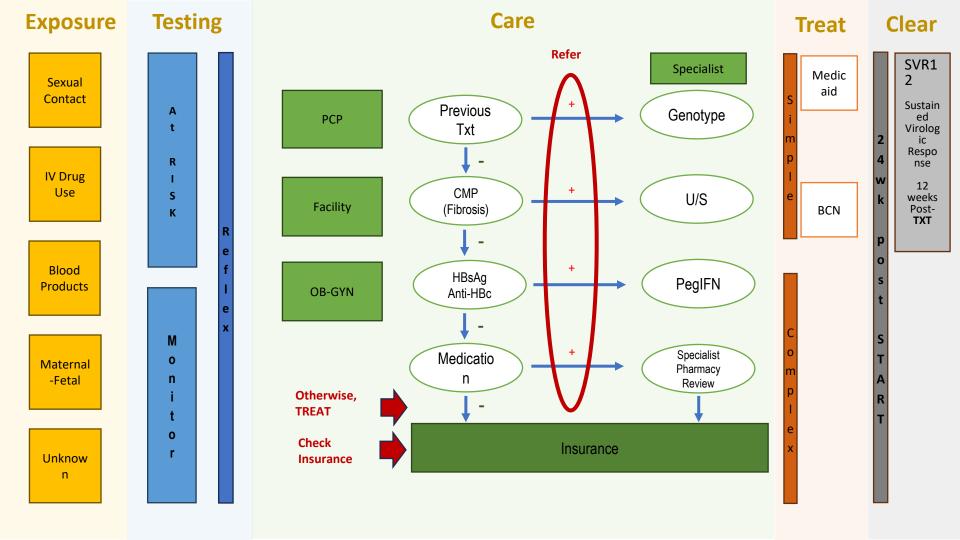
### Treat vs Refer

Important that specialist can talk with patients with out judgement. Engage with patients.

People I know work well with the patient population. Make a call for a "warm hand-off."

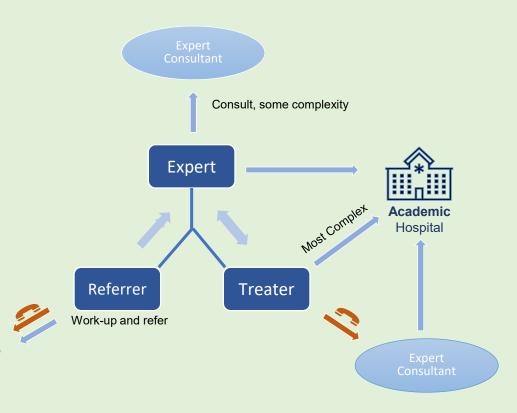
Delays to see appointments, labs. My patient population "just walks away"





### **Provider Interviews Take-Aways**

- Treat vs Refer
- Expert Consultant
- Practice Hub





### Provider Interviews Take-Aways

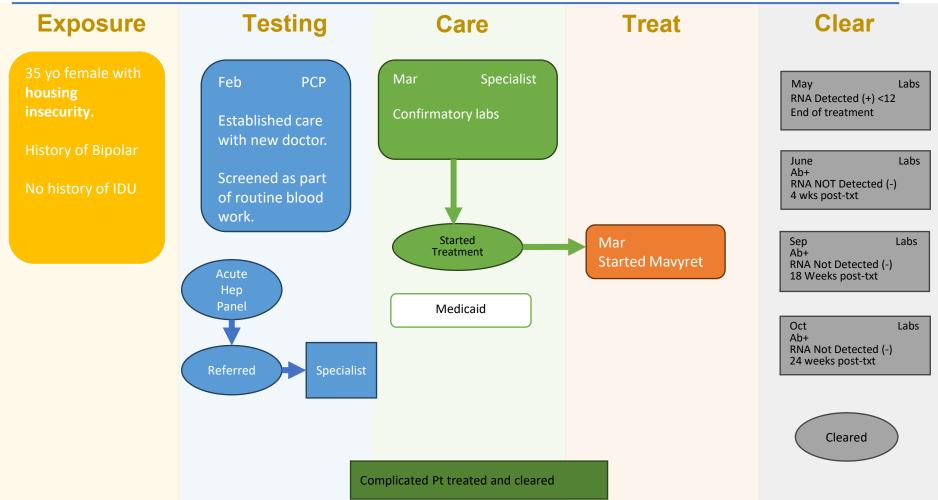
### Case Management

I call them. Liver patients often have cognitive decline, liver fog. I do a phone education session. Letters with all the lab slips—with dates. I tell them the dates are approximate.

Treating her HCV will decrease likelihood of subsequent liver-related events.

Most often they have increased fatigue. I tell them it will get better after they complete the treatment. I do education and tell them to budget their energy. If they are going to work, maybe that's not the day to do the laundry, mow the lawn, go grocery shopping. Prioritize.

### Case Study 4 – Successful Txt with complicated case



#### Confirmed, not treated

#### **Testing Treat** Clear **Exposure** Care Mar **PCP** July Specialist The patient stated several times that **Annual Visit** Repeat Labs w/COPD, Afib, this plan felt like a lot Insurance needed to her medical necessity auth. to repeat labs. She is not able to Referred to Specialist 1.Labs Ordered drive on her own and 2. Labs, every 3 months depends on her 3.Fibroscan friend and neighbor 4. U/S every 6 months who was present for RNA+ our visit. Known Hep C 2018 The neighbor was very clear that labs Clinic Calls every 3 months and Ex-Husband was IV 7/17 US every 6 mo was drug user. Called 7/18 Pt yells to stop too much for her to 7/21 take the patient to. Which Lab drawn at??

No treatment

### Provider Interviews Take-Aways

### Stigma and Substance Use Disorder (SUD)

I ask them about their . . . you know . . . I really try to narrow down how they were likely exposed to the virus, when they acquired the virus. I ask about. . . you know . . . intravenous drug use . . . you know . . . any risk factors in terms of illicit drug use history

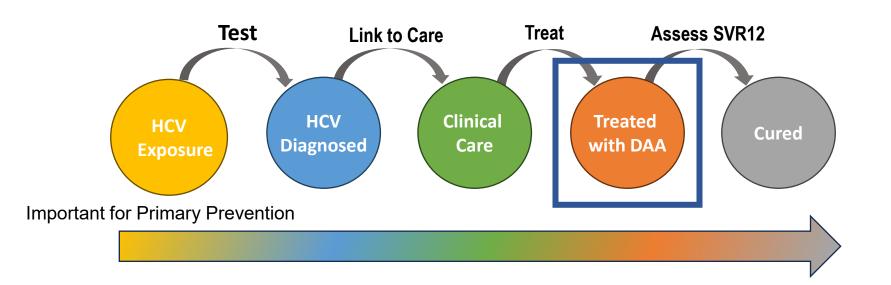
No longer abusing drugs for many years. Good treatment candidate-- Hepatologist

Treatment not recommended with active substance abuse.

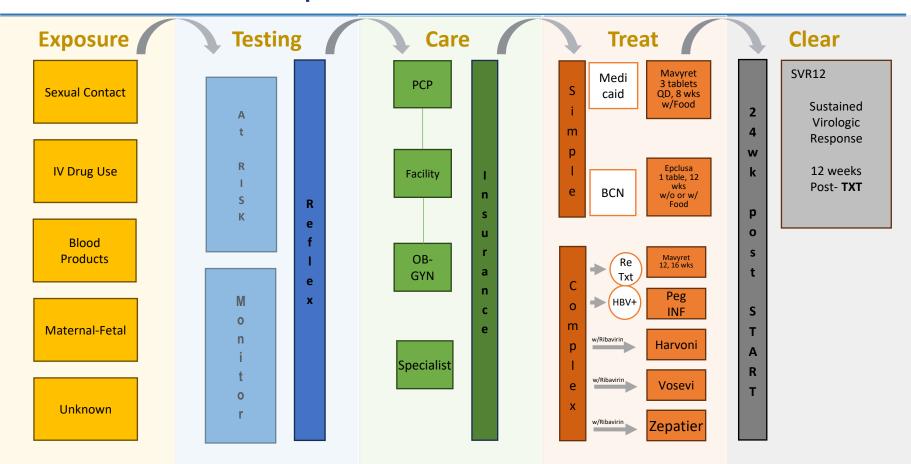
And if they're drinking, because sometimes it's not always the best time to treat if they're actively using and they're concerned about compliance or relapsing.

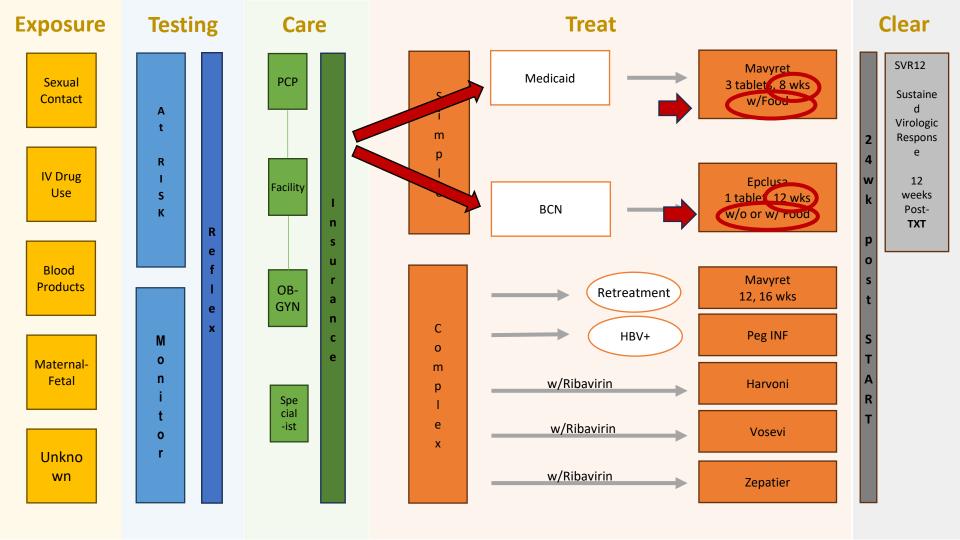
## The Hepatitis C (HCV) Care Continuum<sup>1</sup>

#### Hepatitis C Care Continuum



## Framework for Hepatitis C





#### **Providers on Treatment**

I've been doing this 25 years. Treatments have really changed. In the past there were treatments that caused the skin to fall off. Now these two are well tolerated. -Nurse

These are both, with two medication. One attacks the virus the other is "birth control" prevents replication of the virus. This is the big thing with viruses. Adherence is important, not missing does, so they can't mutate and develop resistance.--Nurse

Treating her HCV will decrease likelihood of subsequent liver-related events. -- Provider

Tell them to set a cell-phone reminder, same time everyday. This is a 24 hr drug, so that makes it work better.

A lot of people were diagnosed a long time ago, but now we, now we finally have these better therapies

### Patient Interviews-Take aways

Really bad. Felt totally out of it. Stopped after a week.

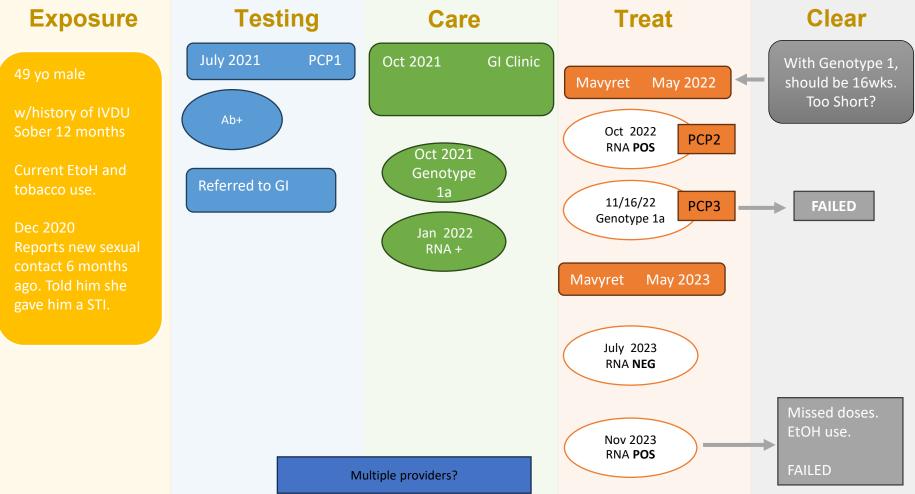
PCP retired last year. Never informed of test results. Never offered treatment

Treatment Lots of side Effect. But told there might be by doctor.

Side effects included dizziness, fatigue. First 3 weeks of alter state. But decreased to none by the end of the treatment.

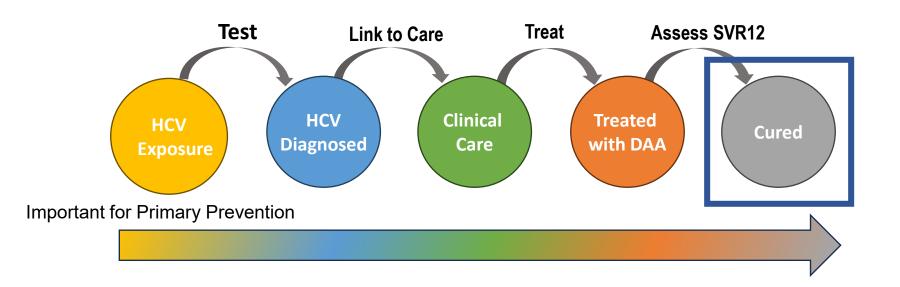


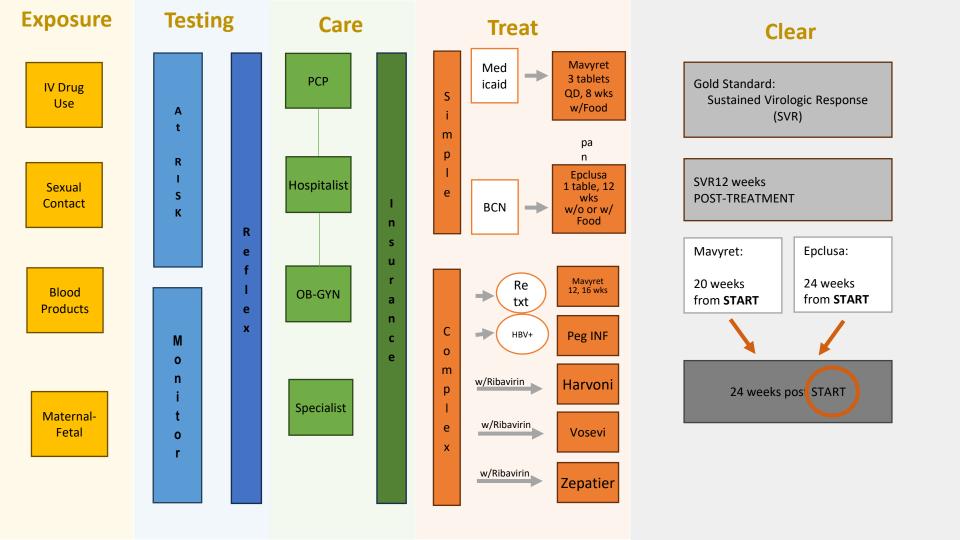
#### **Treatment Failure - SUD complications**



## The Hepatitis C (HCV) Care Continuum<sup>1</sup>

#### Hepatitis C Care Continuum





### Clearance

- Five months is minimum time to treat and clear
- Current case definition does not track success
- Annual definition biases cases based on date

Patients really like the clearance test, I give them a copy.

#### Case Study 1

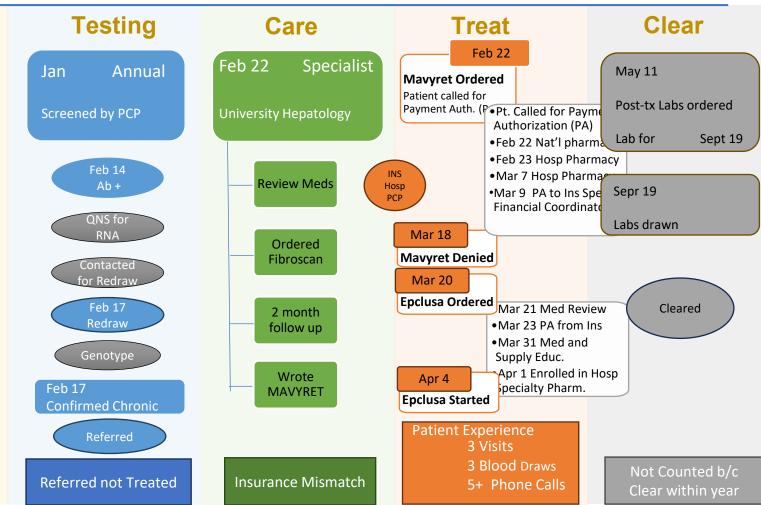
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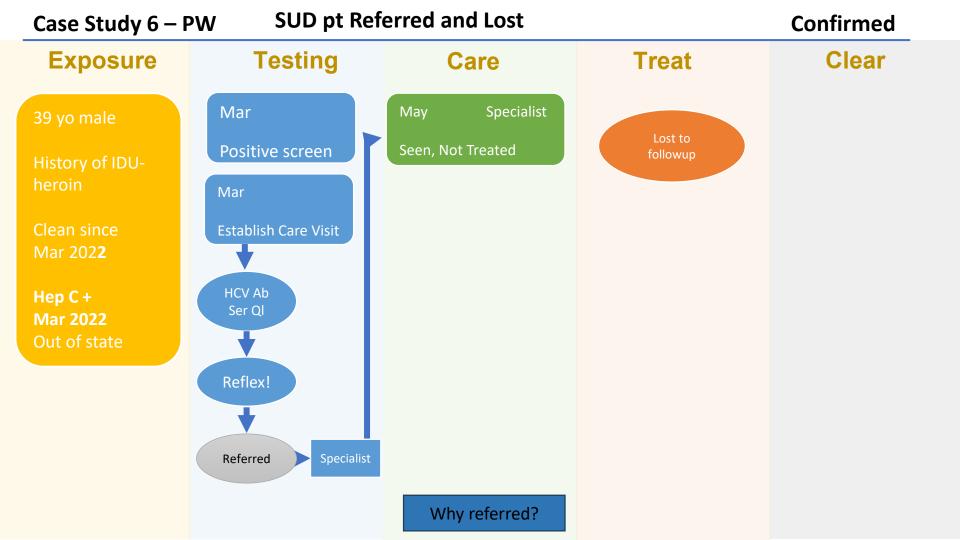
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**Testing Treat** Clear **Exposure** Care Mar 64 yo female July The patient stated **PCP Specialist** several times that w/COPD, Afib, Insurance this plan felt like a lot **Annual Visit** needed medical to her necessity auth. To repeat labs. recent broken hip She is not able to Referred to Specialist 1.Labs Ordered (May 2023),HCV drive on her own and 2. Labs, every 3 months and alcoholdepends on her 3.Fibroscan friend and neighbor related cirrhosis. Mar 4. U/S every 6 months who was present for RNA + our visit. 12-15 beers daily The neighbor was very clear that labs Clinic Calls (At least) every 3 months and 7/17 US every 6 mo was 7/18 Pt yells to Ex-Husband was IV too much for her to 7/21 stop calling Specialist take the patient to. drug user. Called Which Lab

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### **Takeaways**

#### **Public Health**

Shift from surveillance to **linkage to care**Technical note - using calendar year may **bias**surveillance of successfully treated patients

Support Development of **Rapid 1-Step Testing** 

#### **Healthcare providers**

Standardize testing workflows (automatic reflex)
Encourage CME regarding txt & case management
Reduce Stigma
Understand patient population
Understand barriers that can lead to treatment not being completed

#### **Washtenaw County**

- Local access isn't necessarily a limiting factor
  - Mix of providers DO provide Hep C treatment in Washtenaw County
- However, increasing access is important
  - Primary care providers for uncomplicated cases
  - Clinic provider champion is key
  - Easy access to consult service is also important
- Understand first line treatment by payer to expedite treatment
- Importance of consistency of care

# Questions?

#### Resources

### List of resources from MDHHS (We Treat Hep C)

- We Treat Hep C Initiative: Impact on Hepatitis C in Michigan public-facing fact sheet on the impact of We Treat Hep C on HCV in Michigan.
- <u>We Treat Hepatitis C: Clinical Fact Sheet</u> **provider-facing** fact sheet on hepatitis C, the We Treat Hep C Initiative, CDC hepatitis C testing recommendations, and provider trainings and resources.
- We Treat Hepatitis C: Patient Fact Sheet public-facing fact sheet summarizing hepatitis C, the We Treat Hep C Initiative, CDC hepatitis C testing recommendations, hepatitis C treatment, and resources for the public.
- •<u>Simplified HCV Treatment Algorithm for Treatment-Naive Adults Without Cirrhosis</u> HCV treatment algorithm from AASLD/IDSA on treatment for treatment-naïve adults without cirrhosis.

If you talk to anyone who is interested in getting rapid HCV tests, the contact here for that is Teresa Wong (wongt@michigan.gov)