

Hepatitis C in People of Reproductive Age, Pregnancy and Children

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Disclosures

- Gilead, Abbvie, Eiger, Mirum, Ipsen-Advisory role
- GSK – Consultant
- Gilead – Research Support

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Have a question for the presenter

- Type the question into the chat box and Meg will read them aloud to the presenter at the end

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Training Development and Funding

- This training is funded by the NYC City Council

Language Use: Pregnant Persons

The word women may be used throughout the presentation to align with the language of the studies represented in this talk; however, we acknowledge that not all pregnant people identify as cis women and understand the importance of using gender-inclusive language in order to support all of our patients.

Series Overarching Learning Objectives

1. Describe the importance of interprofessional collaboration in effectively meeting the healthcare, educational, and psychosocial needs of patients living with hepatitis B or C infection.
2. Describe the epidemiology of hepatitis B and C infections.
3. Describe the natural history of hepatitis B and hepatitis C infection.
4. Discuss updated guidelines to identify patients at risk for hepatitis B and/or hepatitis C infection.
5. Identify appropriate antiviral treatments for people living with hepatitis B or hepatitis C.
6. Explain the efficacy and safety of current and emerging therapies for hepatitis B and C.
7. Summarize how to counsel patients diagnosed with hepatitis B or C.

Learning Objectives

By the end of this presentation, participants will be able to:

- Explain changes in hepatitis C epidemiology nationally, including among people of childbearing age and pregnant people
- Recall current hepatitis C screening and treatment guidelines for people of childbearing age, pregnant people and children
- Describe the risk of gestational parent-to-child transmission of hepatitis C
- Understand the impact of hepatitis C on pregnancy



Epidemiology: HCV Infection in the United States

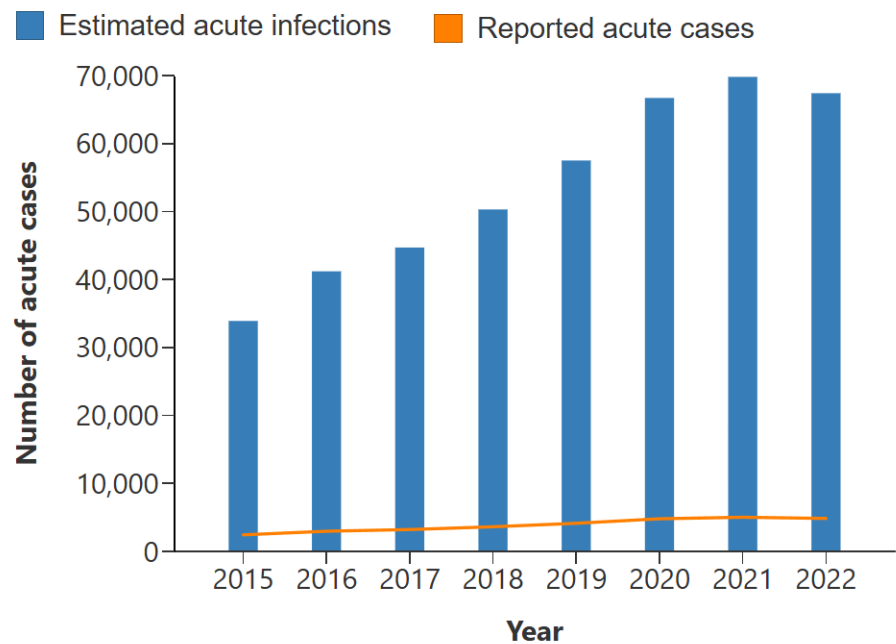
HCV in the United States

Chronic HCV

- >2.4 million estimated cases of chronic HCV¹
- Most common bloodborne infection in the country

Acute HCV

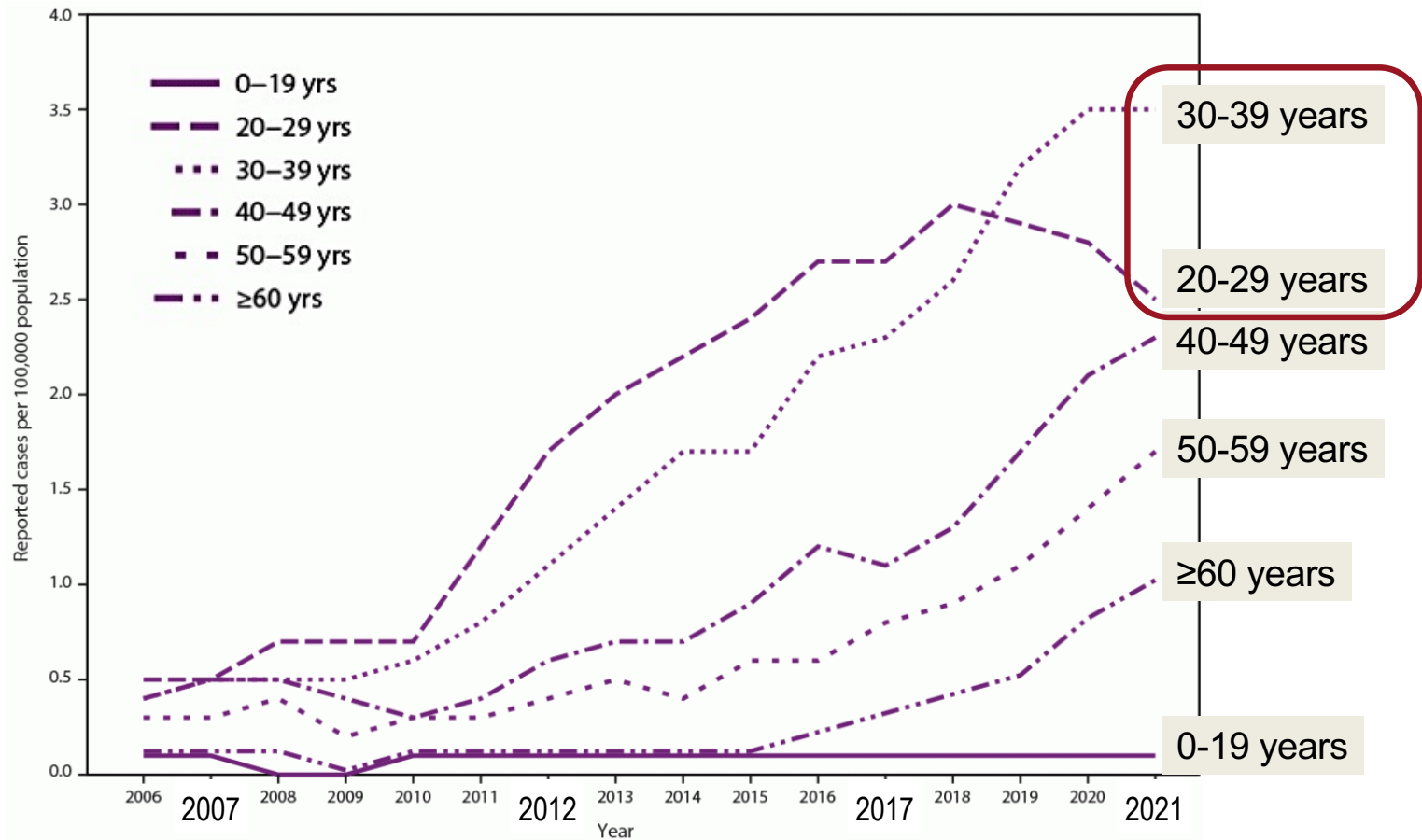
Number of reported cases and estimated infections of acute hepatitis C — United States, 2015–2022²



1. [Hall et al, 2025](#).

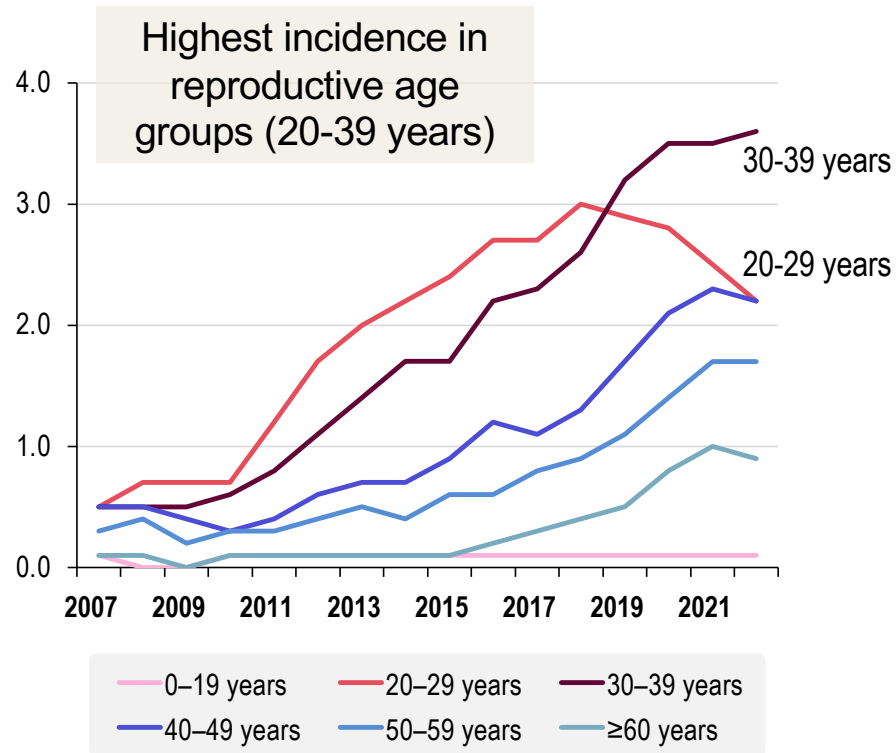
2. [CDC, National Notifiable Diseases Surveillance System](#) (accessed February 18, 2025).

Highest Incidence of HCV in Reproductive Age Groups



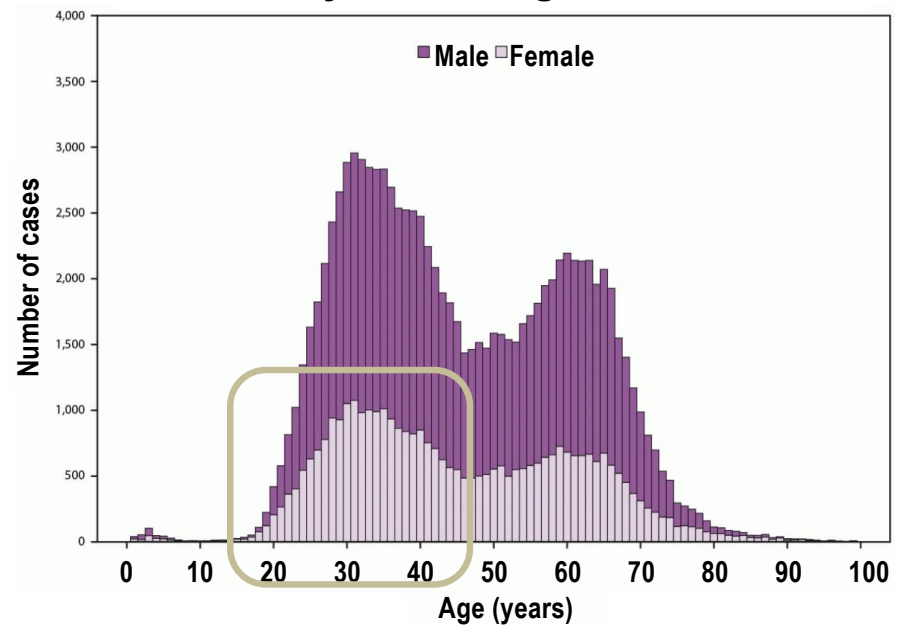
Source: [CDC, National Notifiable Diseases Surveillance System](#) (accessed 2/18/2025)

Highest Incidence of HCV in Reproductive Age Groups

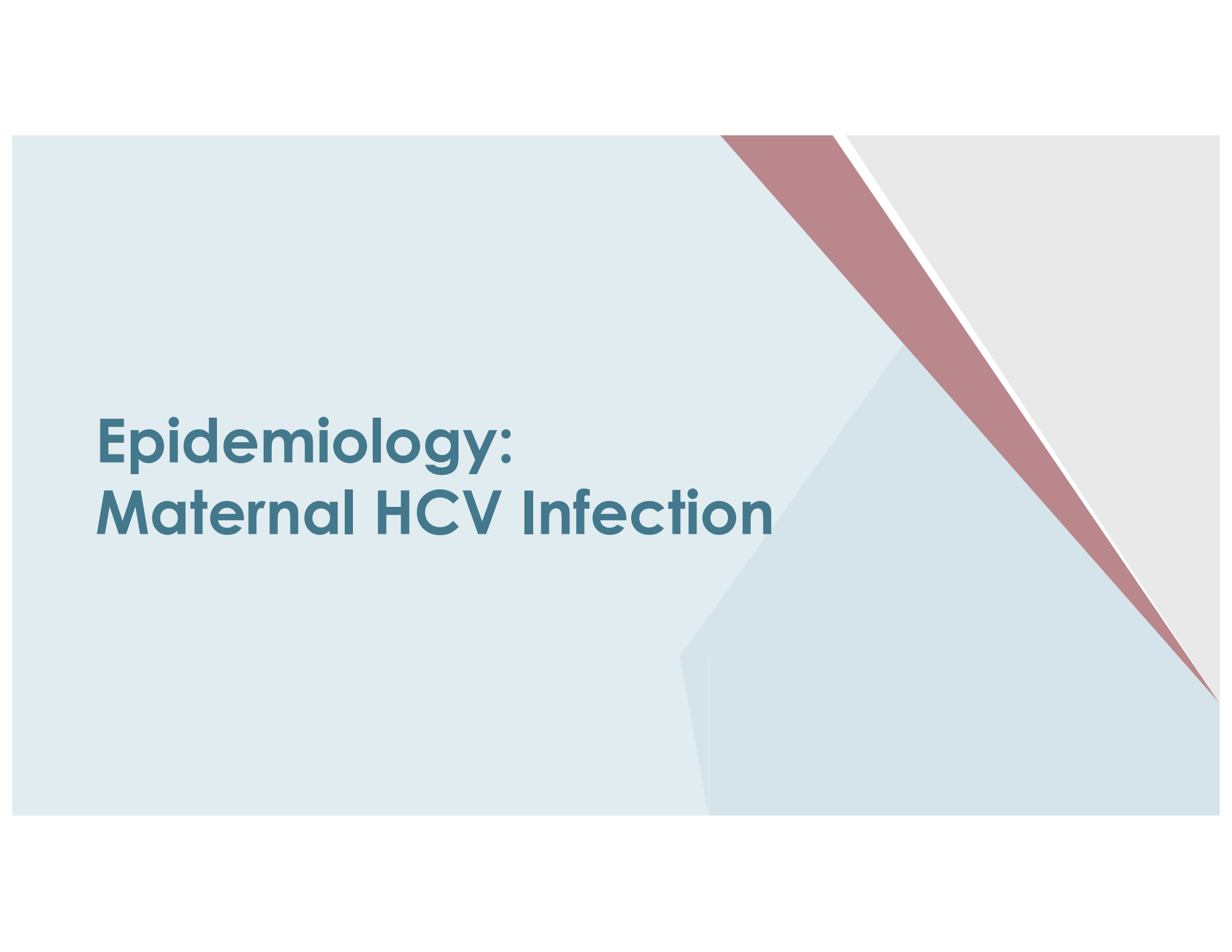


Source: [CDC, National Notifiable Diseases Surveillance System](#) (accessed February 18, 2025).

Chronic HCV infection cases, by sex and age, 2021



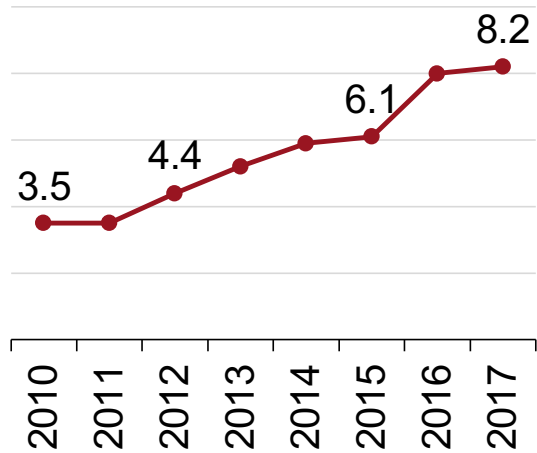
Source: [CDC, National Notifiable Diseases Surveillance System](#) (accessed February 18, 2025).



Epidemiology: Maternal HCV Infection

Rate of Opioid-Related Diagnoses and Acute HCV in Women

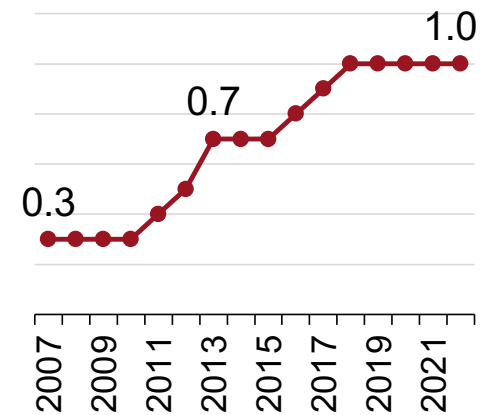
Rate of opioid-related diagnoses per 1,000 delivery hospitalizations



Rates of opioid-related diagnoses in delivery hospitalizations **doubled** from 2011 to 2017.

Data source: [Hirai et al, 2021](#)

Rate of acute HCV per 100,000 population

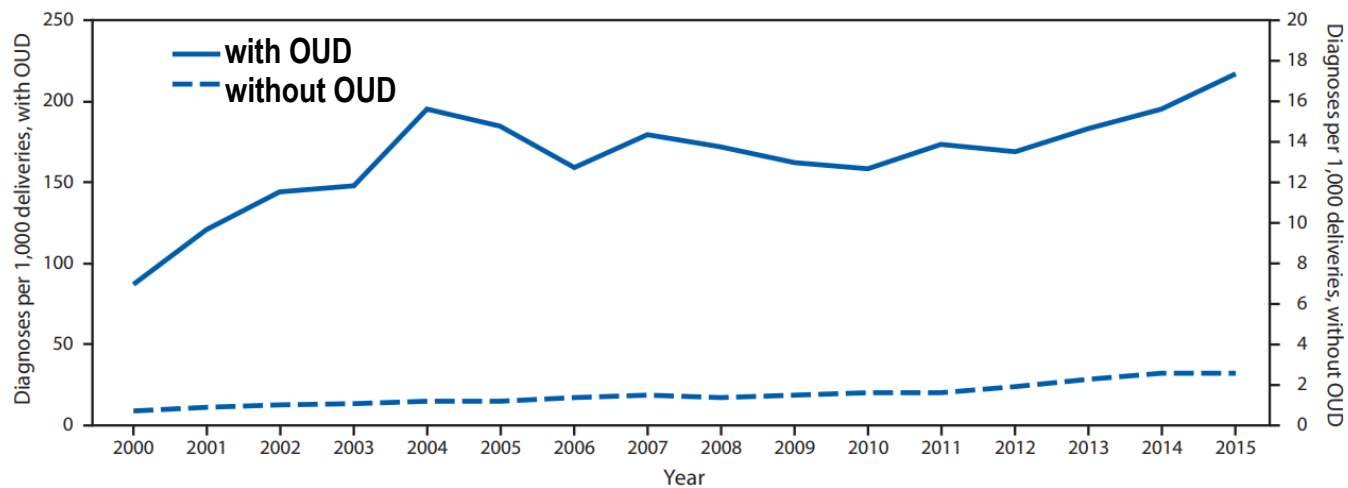


Rates of acute HCV infection in women **tripled** from 2010 to 2022.

Data source: [CDC, National Notifiable Diseases Surveillance System](#) (accessed February 18, 2025).

Rate of Maternal HCV infection, by Opioid Use Disorder (OUD) Status, 2000-2015

FIGURE. National prevalence* of maternal hepatitis C virus (HCV) infection per 1,000 delivery hospitalizations, by opioid use disorder (OUD) status, 2000–2015†



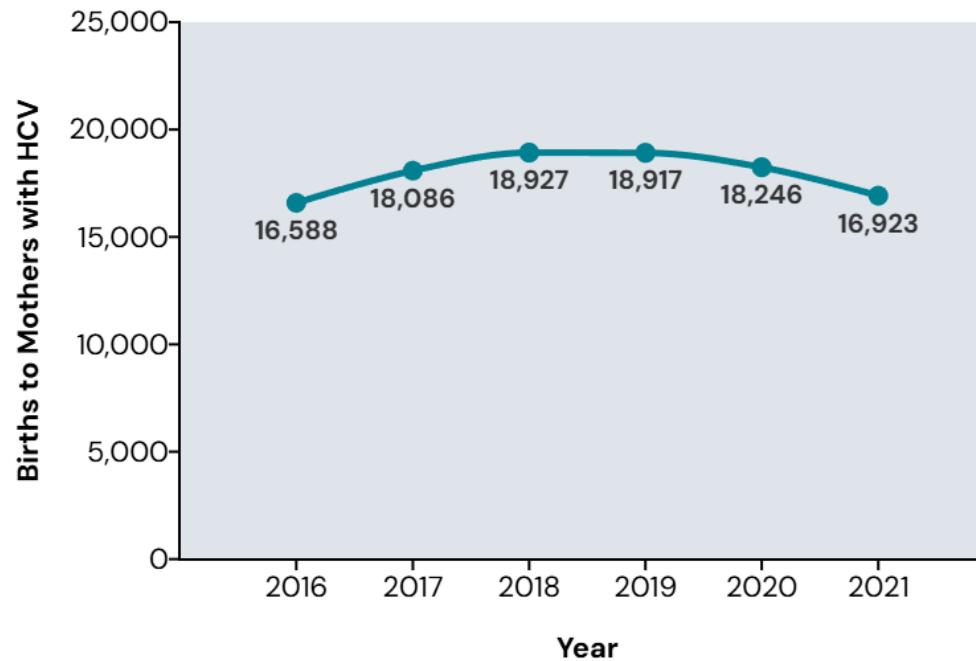
Rate of maternal HCV infection
at delivery, per 1000 live births

	2000	2015
Without OUD	0.7	2.6
With OUD	87.4	216.9

Source: [Ko et al, 2019](#)

HCV in New Mothers: Prevalence, 2016-2021

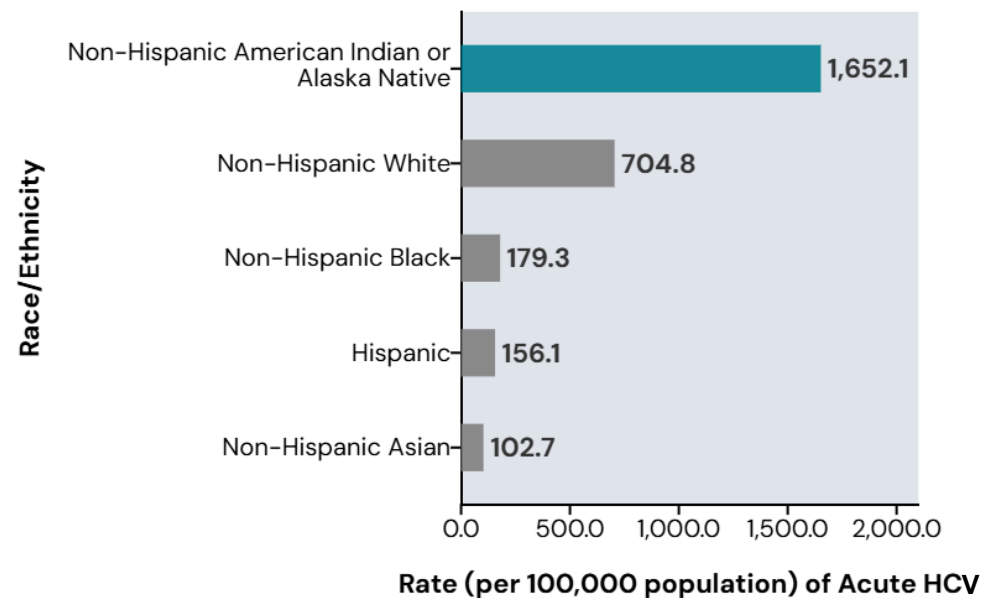
From 2016–2021, the number of births to mothers with HCV has remained greater than 16,500 per year.



Data source: [Ely et al, 2023](#)
Image source: [Hepatitis C Online](#)

HCV in New Mothers: Rate by Race/Ethnicity, 2021

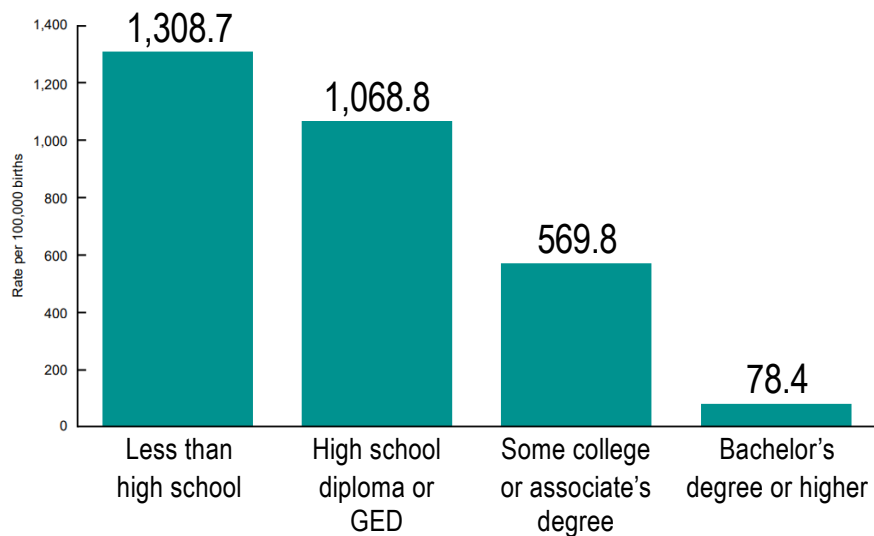
In 2021, the rate of maternal HCV infection was highest in Non-Hispanic American Indian or Alaska Native Women.



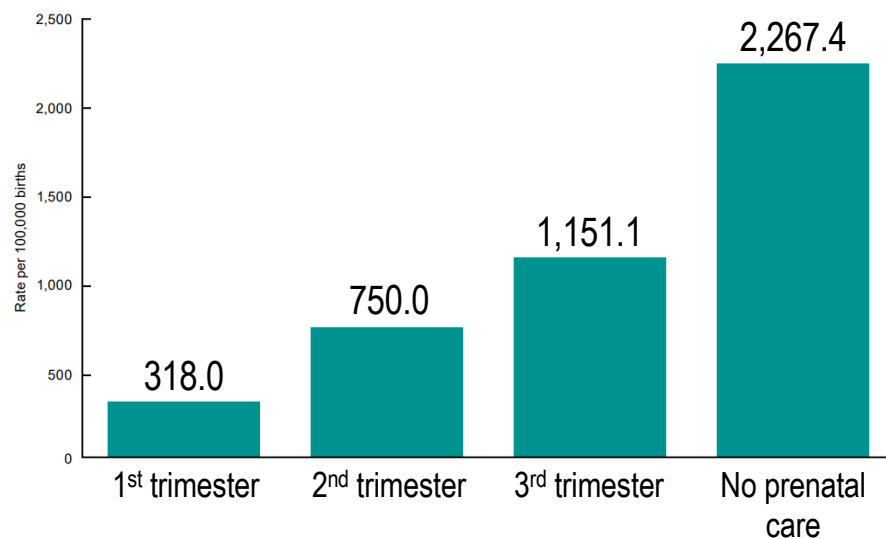
Data source: [Ely et al, 2023](#)
Image source: [Hepatitis C Online](#)

Rate of Maternal HCV Infection in the US, 2021

Rate of maternal HCV infection, by education level



Rate of maternal HCV infection, by when they began prenatal care



Source: [Ely et al, 2023](#)

Why Might Women be at Higher Risk?

- Women who inject drugs have been shown to higher incidence of HIV and injection-related risk behaviors
 - Higher rates of equipment and syringe sharing in women than men
 - More women using injection equipment after their male partners
 - More women being injected by others
- More likely than males to have IDU sex partners
 - Overlapping sexual and injection partnerships → increased injection risk
- Female PWID face stigma – less likely to participate in harm reduction services

**It is critical to counsel women on harm reduction services
and safe injection practices!**

Case Study

The background features a light blue gradient on the left side. On the right, there are overlapping geometric shapes: a dark blue triangle pointing downwards, a maroon diagonal band, and a light grey trapezoidal area in the top right corner.

Case Study

- 31 y/o G2P0010 female, currently 26 weeks pregnant, transferred from outside hospital for elevated liver tests and jaundice
 - Patient developed elevated liver tests and pruritus (itching) 2 weeks prior
 - Bile acids 45, HCV RNA 1350000, AST 581, ALT 382. HCV genotype 1a
 - Person who is currently on methadone, previously used heroin, last use a “few months” prior to this visit
- What would you do for this patient?
 - What are the key considerations for identification, management, and counseling of women with hepatitis C during pregnancy?

What Are the Key Questions Surrounding HCV In Pregnancy?

- Who do we screen for HCV during pregnancy?
- How do we monitor and manage pregnant women with HCV?
- How does having HCV affect pregnancy?
- How common is mother-to-child transmission?
- How do we evaluate for mother-to-child transmission?



Testing for HCV During Pregnancy

Is Risk-Based Screening Reliable?

- Retrospective secondary data analysis of all pregnant women presenting to UMMC in 2016:
 - 1426 pregnancies reviewed
 - Among women with any HCV risk factor → **64.1% were not tested** for HCV
 - 10% of women found to be HCV+ **had no reported risk factors**

These types of studies suggest that risk-based screening may not be effective (similar to what we have seen with HIV and hepatitis B in the past)

Universal HCV Screening Now Recommended During Pregnancy





Monitoring People With HCV During Pregnancy

What Should A Primary Provider Know About Monitoring A Woman With HCV?

AASLD guidelines:



Recommendations for Monitoring HCV-Infected Women During Pregnancy

RECOMMENDED	RATING ⁱ
HCV RNA and routine liver function tests are recommended at initiation of prenatal care for HCV-antibody-positive pregnant women to assess the risk of mother-to-child transmission (MTCT) and degree of liver disease.	I, B
All pregnant women with HCV infection should receive prenatal and intrapartum care that is appropriate for their individual obstetric risk(s) as there is no currently known intervention to reduce MTCT.	I, B
In HCV-infected pregnant women with pruritus or jaundice, there should be a high index of suspicion for intrahepatic cholestasis of pregnancy (ICP) with subsequent assessment of alanine aminotransferase (ALT), aspartate aminotransferase (AST), and serum bile acids.	I, B
HCV-infected women with cirrhosis should be counseled about the increased risk of adverse maternal and perinatal outcomes. Antenatal and perinatal care should be coordinated with a maternal-fetal medicine (ie, high-risk pregnancy) obstetrician.	I, B

What is the Impact of HCV on Pregnancy?

- There may be a negative impact on pregnancy of having HCV, but difficult to tease apart from effect of associated factors (such as injection drug use):
 - Meta-analysis of >4m women and >5000 HCV infection cases
 - Preterm birth - OR 1.62 (95% CI 1.48-1.76)¹,
 - Intrauterine growth restriction - OR 1.53 (95% CI 1.40-1.68)²
 - Low birth weight – OR 1.97 (95% CI 1.43-2.71)²
 - Swedish birth registry of >1 m women, >2000 HCV births, 2001-2011³
 - Preterm birth (aRR 1.32 (95% CI 1.08-1.60)
 - Late neonatal death (aRR 3.79 (95% CI:1.07-13.79)

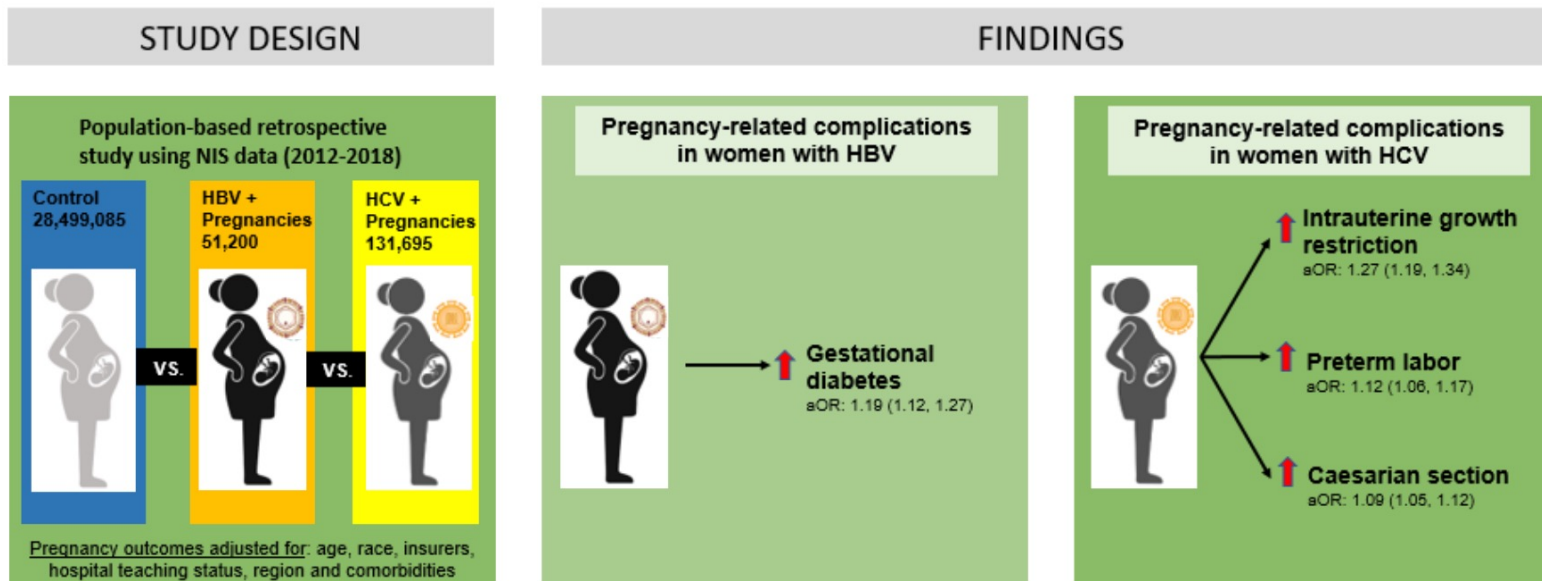
¹Huang Q, et al. *J of Viral Hepatitis* 2015.

²Huang Q, et al. *Medicine* 2016.

³Stokkeland K, *Eur J Epidemiol* 2017.

Evaluation of Nationwide Inpatient Sample

Hepatitis C is Associated with More Adverse Pregnancy Outcomes than Hepatitis B: A 7-Year National Inpatient Sample Study



Impact of HCV Viral Parameters on Pregnancy Complications & Risk of Mother-To-Child-Transmission (MTCT)

STUDY DESIGN

Population-based retrospective study using ICES data (2000-2018)

1,780 HCV RNA+ pregnancies

390 HCV Ab+/RNA- pregnancies

Pregnancy outcomes adjusted for: Age, parity, diabetes, multiple gestations, cirrhosis, alcohol and substance use, HIV co-infection

OUTCOMES

Adverse pregnancy outcomes

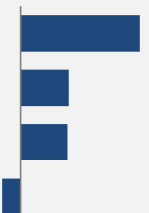
- Gestational diabetes
- Intrahepatic cholestasis of pregnancy
- Small for gestational age
- Large for gestational age
- Antepartum hemorrhage
- Postpartum hemorrhage
- Preterm delivery

FINDINGS

Pregnancy outcomes

HCV RNA+ vs. HCV Ab+/RNA-

- Intrahepatic cholestasis of pregnancy: OR 4.55
- Preterm delivery: OR 1.84
- Postpartum hemorrhage: OR 1.78
- Gestational diabetes: OR 0.71



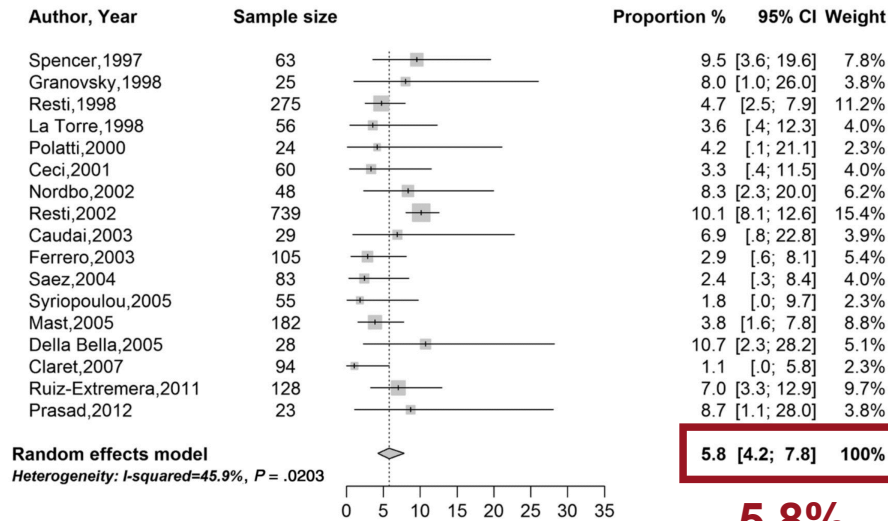


Mother-to-Child Transmission (MTCT) of HCV

What is the Risk of Mother-to-Child Transmission of HCV?

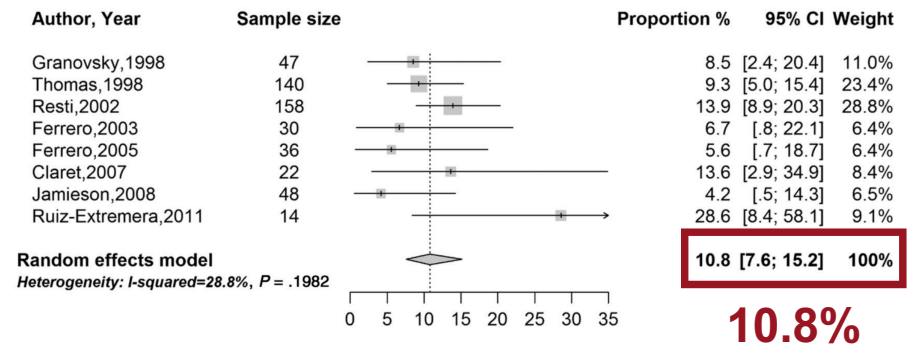
Systematic review and meta-analysis of 109 studies with HCV Ab+, RNA + mothers

HIV-negative women



5.8%

HIV-positive women



10.8%

Ades A, et al. 2022: Estimated vertical transmission to be **7.2%** (95% CI 5.6-8.9); in HIV coinfectd **12.1%** (8.6-16.8).

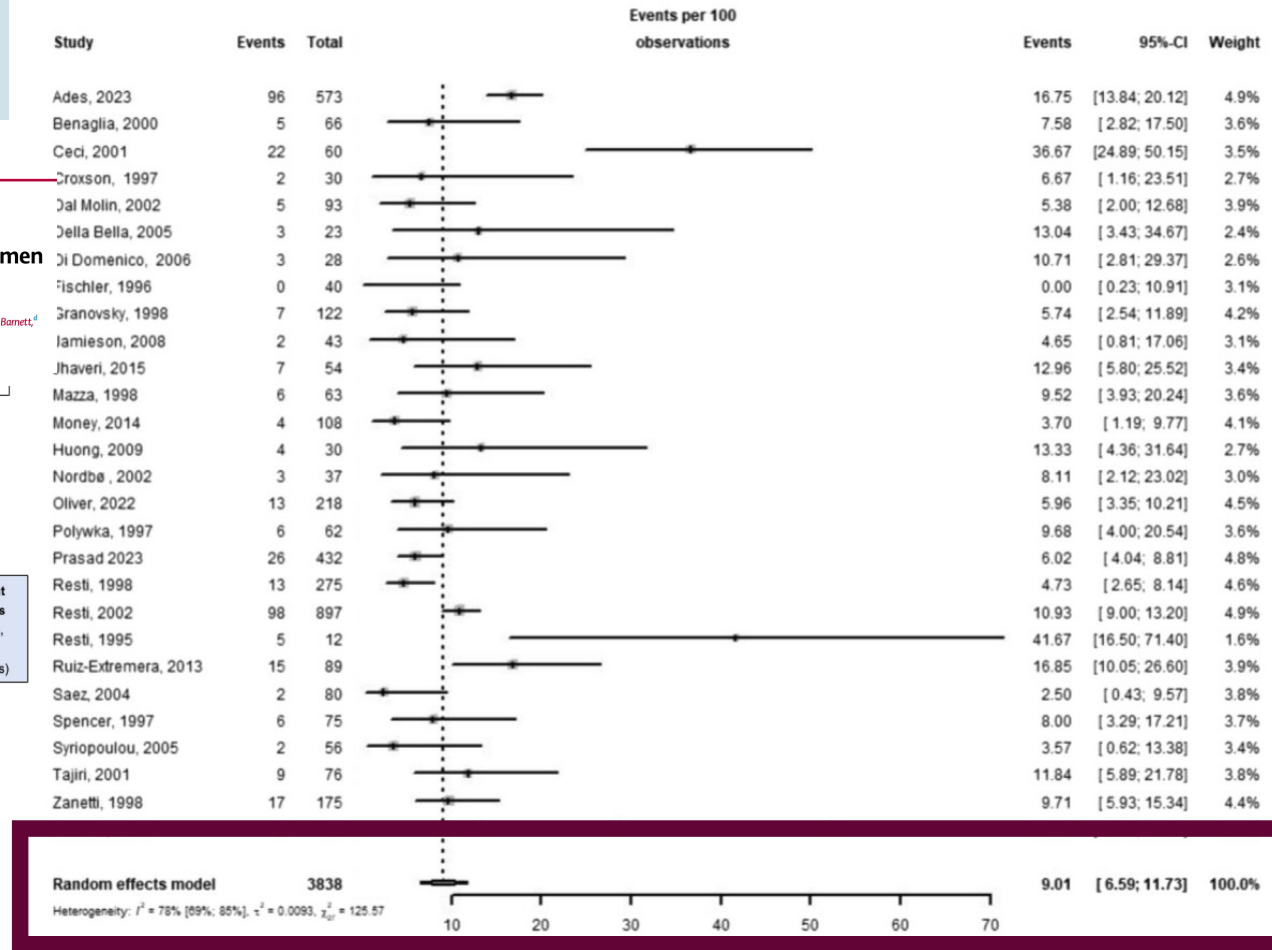
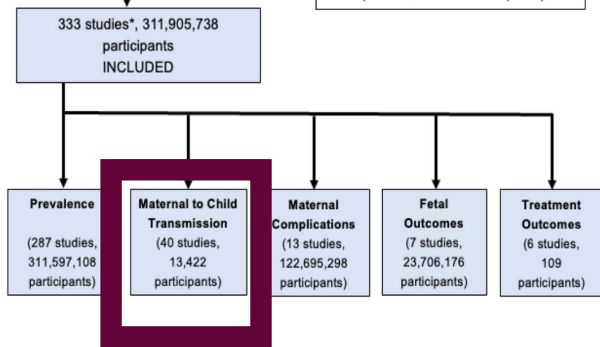
Overall VT rates are about **24%** higher than previously thought

Updated systematic review

Global epidemiology, natural history, maternal-to-child transmission, and treatment with DAA of pregnant women with HCV: a systematic review and meta-analysis

Joo Wei Ethan Quek^{1,2}, Jing Hong Loo^{3,4}, En Qi Lim⁵, Ambrose Hon-Lam Chung⁶, Abu Bakar Bin Othman⁷, Jarell Jie-Rae Tan⁸, Scott Barnett⁹, Mindie H. Nguyen^{4,10} and Yu Jun Wang^{11,12,13}

¹Yong Loo Lin School of Medicine, National University of Singapore, Singapore



Can You Prevent Transmission During and After Pregnancy?

Variable	Studies; # women	Precision of Evidence	Summary of findings
Elective C/S vs. vaginal delivery	4 cohort studies; N=2080	Low	No differences, but trends in opposite directions in highest quality studies
All C/S vs. vaginal delivery	11 cohort studies; N=2308	Low	No association
Invasive fetal monitoring vs. none	3 cohort studies; N=928	Low	Inconsistent but one good quality study OR=6.7 (95% CI 1.1-36)
Prolonged rupture of membranes vs. no	2 cohort studies; N=245	Low	Yes with > 6 hours having OR=9.3 (95% CI 1.5-18)
Breastfeeding	14 cohort studies; 2971 patients	High	No association


What is the Impact of Transmission on Children?

- MTCT is the most common cause of HCV in children
- 25-40% of infants clear HCV by 2-3 years
- Impact on children:
 - Quality of life
 - Reduced physical functioning
 - Executive function impairment in 20% of infected children
 - Worse cognitive functioning than uninfected children
 - Parental emotional impact and decrement in parental quality of life
 - Higher rates of cirrhosis in children who acquire HCV through MTCT
 - Hepatocellular carcinoma – 2nd most common hepatic malignancy in children

Murray, et al. *Diseases of the Liver in Children*. Springer 2014.

Modin et al. *Journal of Hepatology* 2018.

Younossi, et al. *Hepatology* 2007.



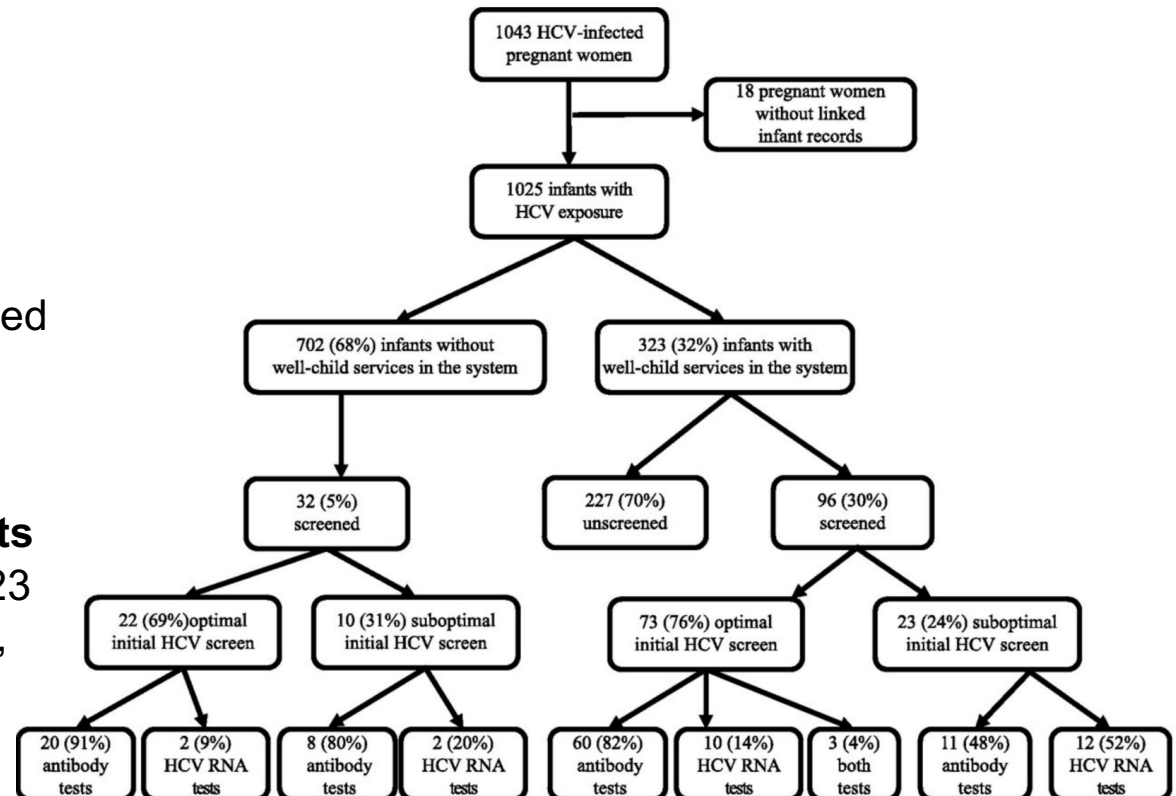
Infant/Child Testing Guidelines

Which Children Do We Screen For HCV?

- All infants and children born to pregnant persons with current/probable HCV should be tested.
- Perinatally exposed infants should receive a NAT for HCV RNA at age 2–6 months to identify children in whom chronic HCV infection might develop.
 - Infants with detectable HCV RNA should be managed in consultation with a health care provider with expertise in pediatric hepatitis C management.
 - Infants with undetectable HCV RNA do not require further follow-up.
- Infants and children aged 7–17 months who have not previously been tested should receive a NAT for HCV RNA.
- Children aged ≥ 18 months who previously have not been tested should receive an anti-HCV test with reflex to NAT for HCV RNA.

Are We Actually Testing Children?

- Population-based, retrospective cohort of pregnant women who delivered between 2006 and 2014
- Identified as HCV infected or HCV uninfected by billing codes
- Infant records linked to HCV-infected pregnant women queried for HCV tests and the receipt of well-child services
- Among **1025 HCV-exposed infants** with available pediatric records, 323 (31%) received well-child services, and among these, **only 96 (30%) were screened for HCV.**



Good News! CDC has Updated their Guidelines

CDC Recommendations for Hepatitis C Testing Among Perinatally Exposed Infants and Children — United States, 2023

Recommendations and Reports / November 3, 2023 / 72(4);1-19

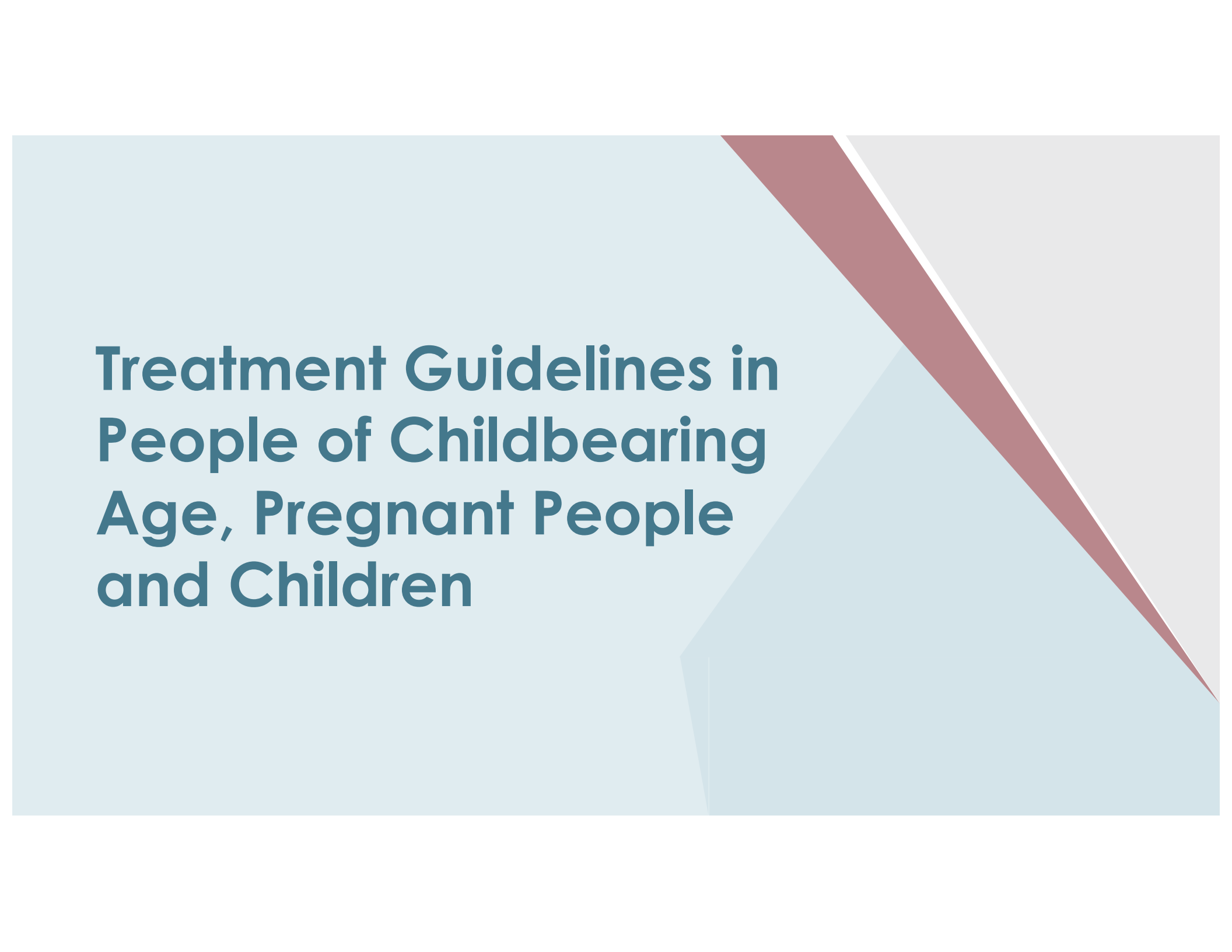
Four New CDC Recommendations

- 1) *HCV testing of all perinatally exposed infants with a nucleic acid test (NAT) for detection of HCV RNA **at age 2-6 months**;*
- 2) ***consultation with HCP with expertise in pediatric hepatitis C management** for all infants/children with detectable HCV RNA;*
- 3) *perinatally exposed infants/ children with **undetectable HCV RNA** at or after age 2 months **do not require further follow-up***
- 4) *a NAT for HCV RNA is recommended for perinatally exposed infants and children aged 7-17 months who previously have not been tested, and a hepatitis C virus antibody (anti-HCV) test followed by a reflex NAT for HCV RNA (when anti-HCV is reactive) is recommended for perinatally exposed children aged ≥ 18 months who previously have not been tested.*

Proper identification of perinatally infected children, referral to care, and curative treatment are critical to achieving the goal of hepatitis C elimination.

What is The OB/GYN's Role in Ensuring Pediatric Testing?


- Important to communicate with pediatrician about maternal HCV infection
 - Transfer of care to pediatrician to alert them about maternal HCV status
 - Need for interventions to increase screening in infants who are at risk for perinatal HCV acquisition by including technology to improve the transfer of maternal HCV status to the pediatric record
 - Need to increase pediatric provider awareness regarding HCV screening guidelines



Treatment Guidelines in People of Childbearing Age, Pregnant People and Children

Treatment of Women of Childbearing Age

AASLD Guidelines:


Recommendation Regarding HCV Treatment and Pregnancy	
RECOMMENDED	RATING 
For women of reproductive age with known HCV infection, antiviral therapy is recommended before considering pregnancy, whenever practical and feasible, to reduce the risk of HCV transmission to future offspring.	I, B

- Counsel about benefit of antiviral treatment prior to pregnancy
- If become pregnant on DAA therapy, should discuss the risks versus benefits of continuing treatment with providers
- Ribavirin is contraindicated in pregnancy due to teratogenicity (wait at least 6 months after ribavirin to get pregnant)

Treatment in Children

AASLD Guidelines

Recommendations for Whom and When to Treat Among Children and Adolescents With HCV Infection

RECOMMENDED	RATING 
Direct-acting antiviral (DAA) treatment with an approved regimen is recommended for all children and adolescents with HCV infection aged ≥ 3 years as they will benefit from antiviral therapy, regardless of disease severity.	I, B
The presence of extrahepatic manifestations—such as cryoglobulinemia, rashes, and glomerulonephritis—as well as advanced fibrosis should lead to early antiviral therapy to minimize future morbidity and mortality.	I, C

Why Consider Antiviral Therapy in Pregnancy?

- Potential to reduce MTCT -- as is done for HBV
- Time when women are insured – opportune time to treat HCV concurrent with managing pregnancy
- Can target women with high risk behaviors to prevent transmission to others (e.g. injecting partners)

What are the Recommendations for Antiviral Therapy in Pregnant People? - HCV



HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C



SMFM Consult Series

smfm.org

“Despite the lack of a recommendation, **treatment can be considered during pregnancy on an individual basis after a patient-physician discussion** about the potential risks and benefits.”
AASLD/ IDSA HCV Guidance 2020.

“Women who become pregnant while on DAA therapy (with or without ribavirin) should discuss the risks versus benefits of continuing treatment with their physicians.”

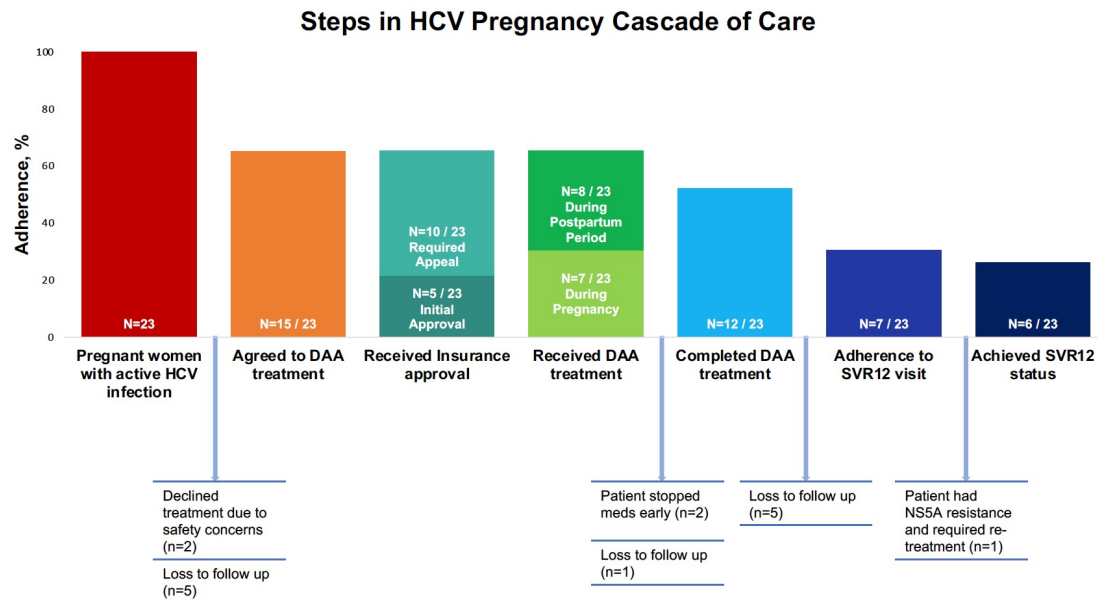
AASLD/ IDSA HCV Guidance 2021.

“We recommend that DAA regimens **only be initiated in the setting of a clinical trial during pregnancy** and that people who become pregnant while taking a DAA should be counseled in a shared decision-making framework about the risks and benefits of continuation”

Am J Obstet Gynecol 2021

Our Clinical Experience..

- Women's Liver Clinic – collocated in Obstetrics department
- 23 women with active HCV viremia offered HCV treatment in pregnancy



Should we Consider HCV Treatment in Pregnancy?

- Emerging Data of DAAs in pregnancy

Trial Number/ Trial Phase	Study Design	# of Participants (or Estimation)	Status
NCT04382404 Phase 1	SOF/VEL	10	Completed (CROI 2023)
NCT02683005 Phase 1	LDV/SOF	9	Completed (Chappell CA et al. <i>Lancet Microbe</i> . 2020;1:e200-e208.)
NCT05140941 (STORC) Phase 4	SOF/VEL	100	Recruiting
IMPAACT Phase 1/2	GIE/PIB		Recruiting

Sofosbuvir/Velpatasvir in Treatment of HCV During Pregnancy: Interim STORC Study Results

Background: HCV treatment during pregnancy has several potential benefits but safety/ efficacy data on DAAs during pregnancy are lacking.

Aim: Evaluate the safety and efficacy of SOF/VEL for HCV treatment in pregnancy.

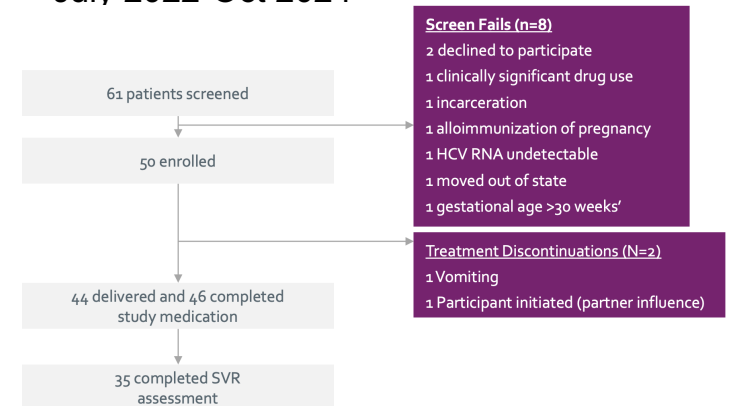
Methods: Multicenter, phase 4, open-label, single-arm study enrolling participants between 20-30 weeks gestation.

Results:

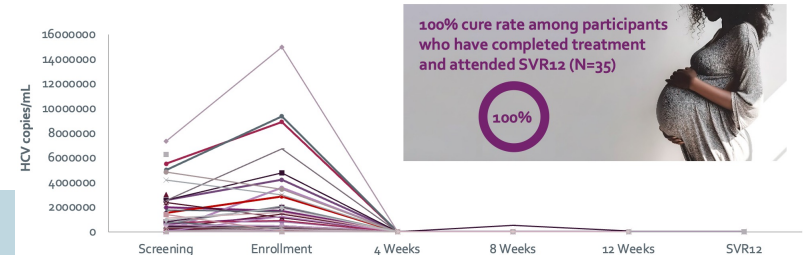
- 35/35 (100%) with SVR assessment achieved SVR12
- 6 preterm births (13.6%); 218 maternal AEs, 13 maternal and 19 infant SAEs – none related to SOF/VEL; 0% ICP
- 16/16 (100%) infants tested had undetectable HCV RNA

Conclusions: Interim data provide ongoing reassurance regarding safety and efficacy of SOF/VEL administered after 20 weeks gestation.

July 2022-Oct 2024



HCV Viral Response to SOF/VEL in Pregnancy



Chappell C, et al, Abstract 222, TLM 2024

HCV/ Pregnancy Treatment

HCV Pregnancy Survey

URL: <https://t.ly/Sb15v>



- Treatment in Pregnancy for Hepatitis C (TiP-HepC) registry CDC and Coalition for Global Hepatitis Elimination



Contribute data to TiP-HepC registry

The TiP-HepC registry is collecting retrospective data on the outcomes of mother- infant pairs exposed to DAAs during pregnancy in routine clinical practice will be solicited and collected from participating clinical providers, health-care facilities, HCV treatment programmes, and other clinical practices worldwide.

[Submit or upload cases here](#)

Treatment After Pregnancy

- If treatment not done prior to or during pregnancy, it is imperative to treat after pregnancy
 - Cure mother while she is engaged in care/ has health insurance
 - Prevent risk to mother of future HCV complications
 - Decrease risk of mother-to-child transmission in future pregnancies
 - Decrease risk of household transmission of HCV

Harm Reduction in Pregnancy

- Many women with HCV have a history of drug use – critical to address
 - Huge stigma with drug use during pregnancy – combat misinformation
 - Do not criminalize pregnant women who use drugs
 - Respect confidentiality; honest discussions with health care provider
 - Ensure access to harm reduction services
 - Facilitate access to methadone and buprenorphine
 - Ensure adequate pain relief during pregnancy
 - Support women through birth and after
 - Make it easier to navigate health and social services

Back To Our Case...

- 31 y/o G2P0010 female, currently 26 weeks pregnant, transferred from outside hospital for elevated liver tests and jaundice.
 - Continued on methadone
 - Diagnosed with cholestasis of pregnancy and initiated on ursodiol for treatment
 - Diagnosed with hepatitis C (likely acute)
 - Had not been screened at initial prenatal visit
 - HCV RNA fluctuated during pregnancy, and liver tests improved with ursodiol
 - Delivery at 36 weeks gestation – uneventful NSVD. Neonatal jaundice diagnosed.
 - Initiated HCV treatment after breastfeeding and completed treatment, but did not present for SVR12 check.

Conclusions

- HCV among women of childbearing age and during pregnancy is on the rise as a result of the opioid epidemic
 - As a result, HCV rates in children are increasing as well
- Mother-to-child transmission rates range from 6-11% (HIV significantly increases risk)
- All children of mothers with HCV should be tested at 2-6 months of age with HCV RNA and referred to specialty care if found to be positive
- Treatment is currently recommended in children ≥ 3 years of age
- Studies are underway to determine safety and efficacy of HCV treatment in pregnancy
- Linkage to care of women with HCV is a critical part of the puzzle!

Pregnancy & Substance Use: A Harm Reduction Toolkit

- [Harm Reduction Toolkit](#)
 - Information for pregnant and parenting people who use drugs, their loved one and their service providers
 - Information can be used to understand your rights, access services and find evidenced-based care

Resources

- American Association for the Study of Liver Diseases (AASLD) and Infectious Disease Society of America (IDSA), Hepatitis C Practice Guidelines:
 - Hepatitis C in Pregnancy: www.hcvguidelines.org/unique-populations/pregnancy
 - Hepatitis C in Children: www.hcvguidelines.org/unique-populations/children
 - Simplified Hepatitis C Treatment for Treatment-Naive Patients Without Cirrhosis. www.hcvguidelines.org/treatment-naive/simplified-treatment
- United States Preventative Services Task Force (USPSTF) Screening Recommendations in Adolescents and Adults:
www.uspreventiveservicestaskforce.org/uspstf/recommendation/hepatitis-c-screening

Resources Continued

- FDA Approved Hepatitis C Treatment for Pediatric Patients. www.fda.gov/news-events/press-announcements/fda-approves-new-treatment-pediatric-patients-any-strain-hepatitis-c
- Centers for Disease Control Perinatal Hepatitis C Information: www.cdc.gov/nchhstp/pregnancy/challenges/hcv.html
- New York State Department of Health Hepatitis C Clinical Guidelines, Pregnancy: www.hivguidelines.org/hepatitis-care/treatment-with-daa/#tab_4

Resources Continued

HCV educational materials are currently available free of charge through the NYS Department of Health AIDS Institute

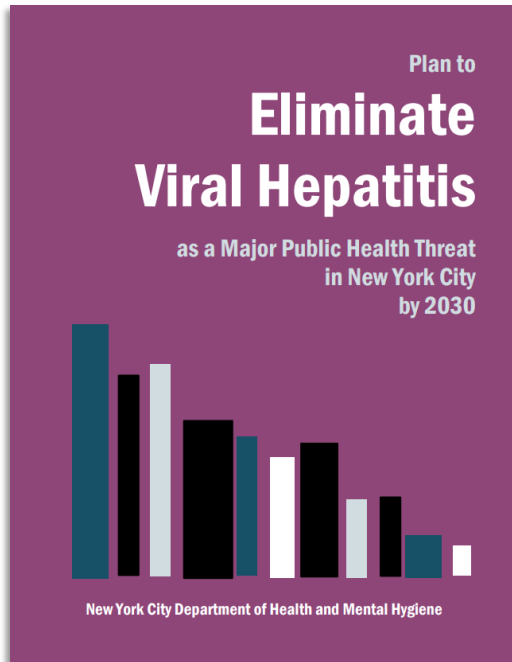
- Educational materials targeting pregnant people:
 - *HCV and Pregnancy* Brochure, <https://www.health.ny.gov/publications/16039.pdf>
 - *Ask To Be Tested for Hepatitis C During Each Pregnancy* Poster, <https://www.health.ny.gov/publications/16112.pdf>
 - *Get Tested, Treated and Cured Before Becoming Pregnant* Poster, <https://www.health.ny.gov/publications/16114.pdf>
- Additional information on HCV prevention, screening, care, and treatment can be found at https://www.health.ny.gov/diseases/communicable/hepatitis/hepatitis_c/
- Hepatitis A, B and C in New York City: 2020 Annual Report https://hepfree.nyc/wp-content/uploads/2020/04/2020-Annual-Report_Final_11-15-21.pdf

Treatment in Pregnancy for Hep C (TiP-HepC) Clinical Case Registry

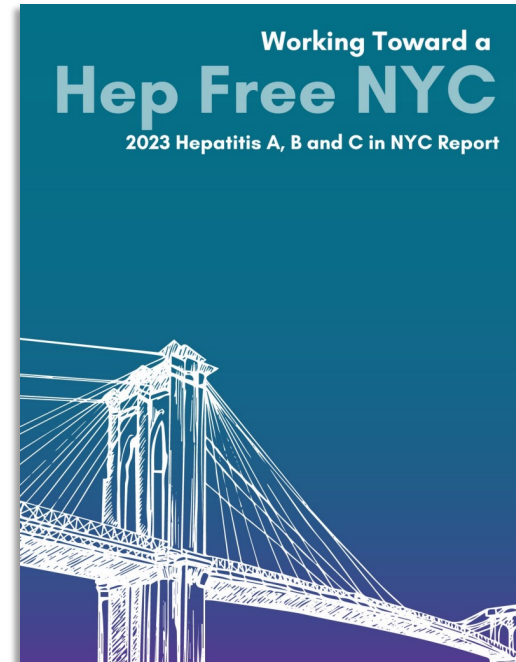
- (TiP-HepC) collects clinical information after exposure to direct-acting antivirals (DAAs) during pregnancy: <https://redcap.emory.edu/surveys/?s=C99K9EEYHRLNY8AR>
- This registry was created to record outcomes of mother-infant pairs exposed to DAAs during pregnancy. Findings from the registry will be critical to advancing HCV treatment decision-making by clinical providers and programs worldwide. Please note this is NOT a surveillance registry.
- For more information about TiP-HepC: [*Hepatitis C in pregnancy and the TiP-HepC registry*](#) and <https://www.globalhep.org/evidence-base/treatment-pregnancy-hepatitis-c-tip-hepc-registry>.

Elimination Plan and Annual Report

Find on NYC.gov website [here](#)



Find on NYC.gov website [here](#)



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