Hepatitis C in Women & During Pregnancy: Challenges and Implications

National AIDS Treatment Advocacy Project (NATAP)

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Disclosures

- Advisory and consulting for Gilead, Abbvie, Kinetix Group

Acknowledging Statement

The word women or female 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.

Hepatitis C in Women of Childbearing potential: What are the relevant issues?

- Changing Epidemiology
- Effect of HCV on pregnancy outcomes
- Mother-to-child transmission
- Screening and monitoring of HCV during pregnancy?
- Timing of Antiviral therapy
  - Role of antiviral therapy in pregnancy

Changing Epidemiology

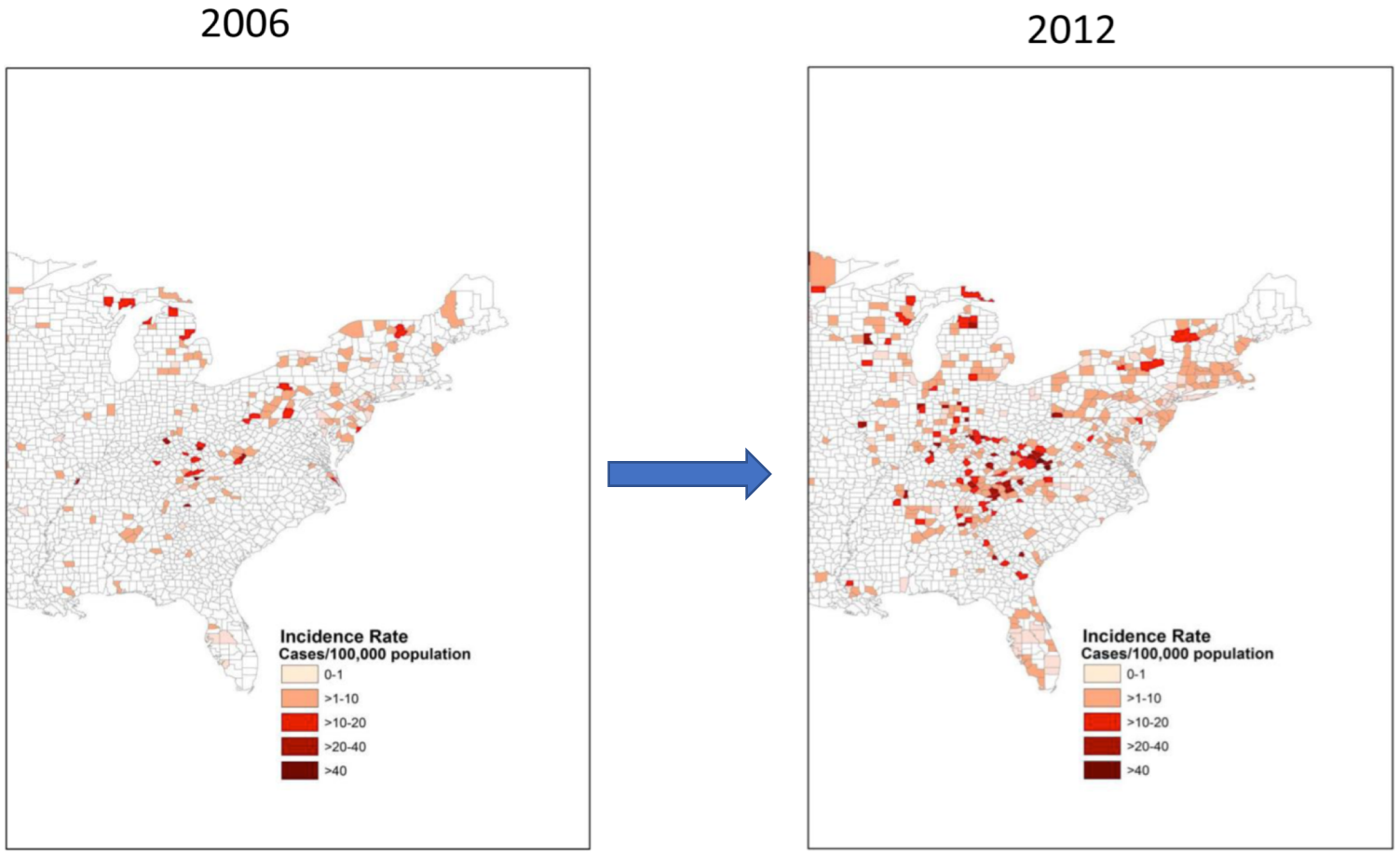
HCV in the United States

- > 2 million estimated cases of chronic HCV
  - Most common bloodborne infection in the country

- Among young individuals with new hepatitis C infections, over 50% are female

Rosenberg ES, et al. *JAMA Network Open 2018.*
Zibbell et al. *MMWR Morb Mortal Wkly Rep 2015.*

New HCV in the US: Emerging Epidemic Among Young Heroin Users (< 30 y/o)

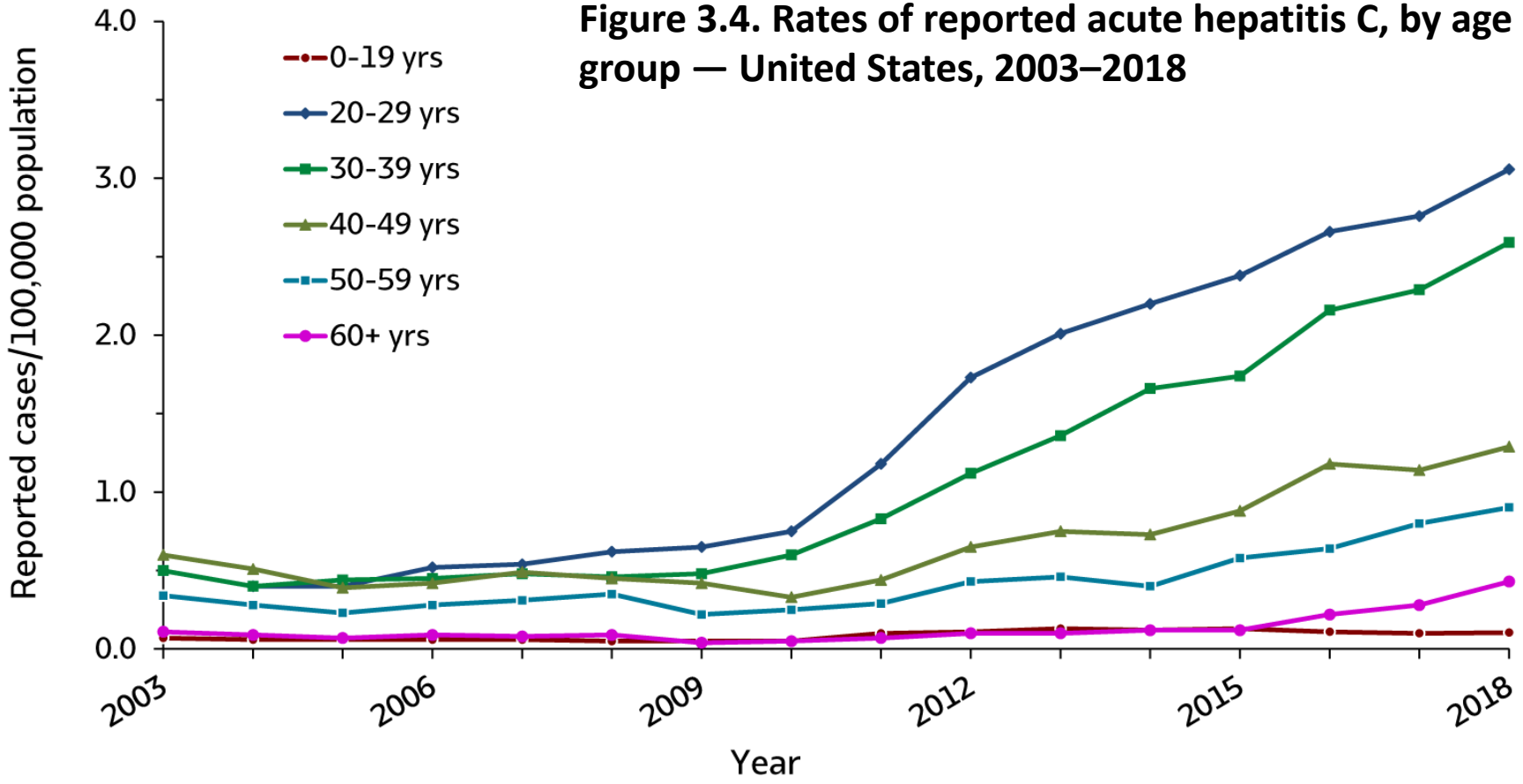


- HCV: 13% annual increase rural; 5% annual increase urban
- Regional doubling of first time heroin users
- 3 of 4 had history of prescription opioid abuse
- 97% initiated drug use before age 20

Suryaprasad AG. *Clin Infect Dis 2014.*

The Epidemiology Of HCV Is Changing

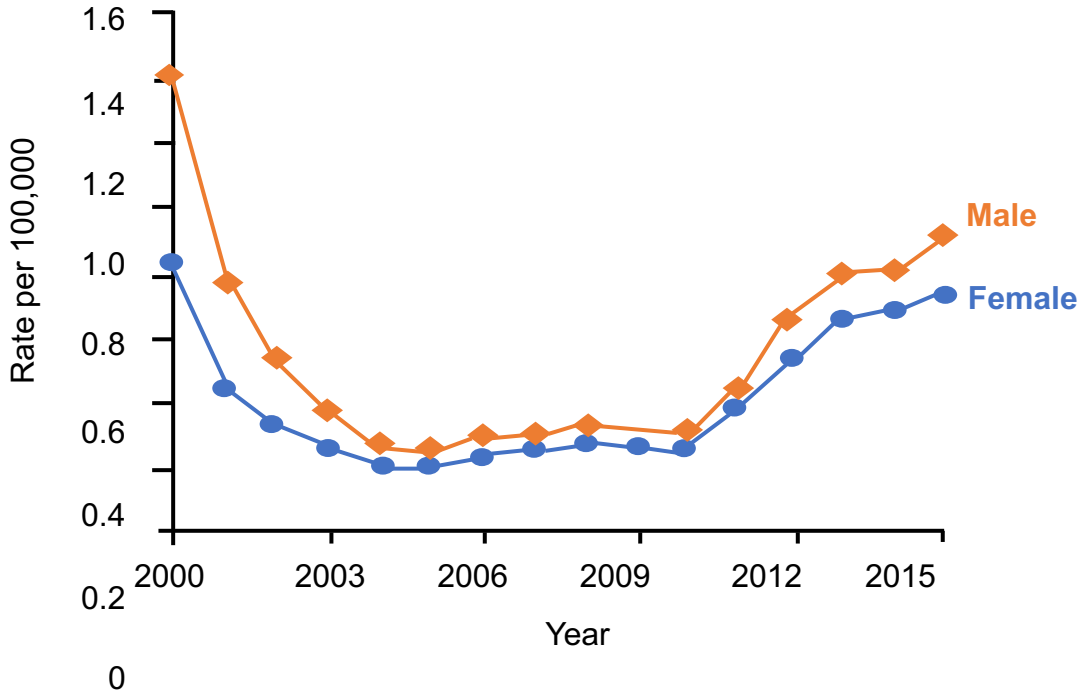
Figure 3.4. Rates of reported acute hepatitis C, by age group — United States, 2003–2018



Highest incidence in 20-29 age group

https://www.cdc.gov/hepatitis/statistics/2018surveillance/HepC.htm#Figure3.4

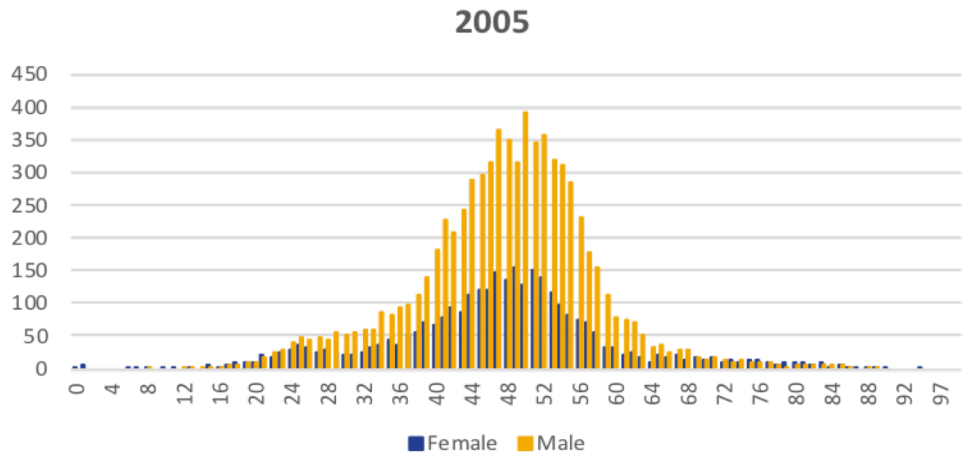
Incidence of Acute HCV Cases is Increasing

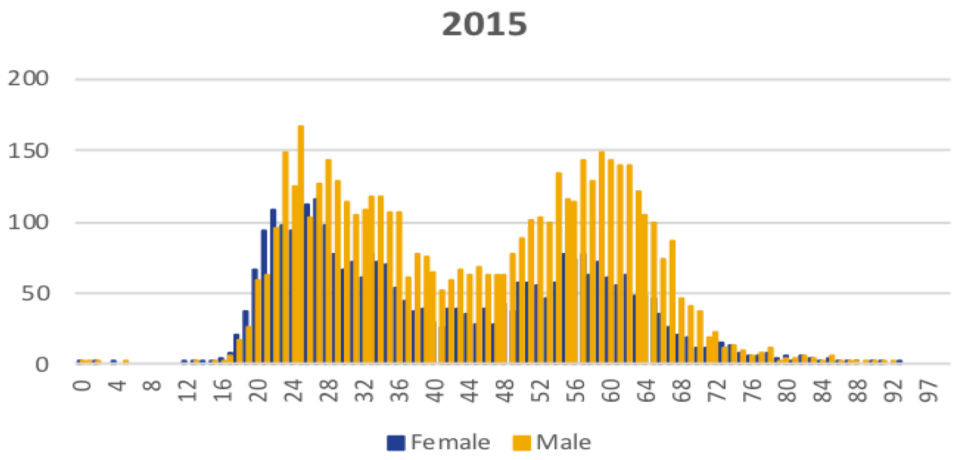


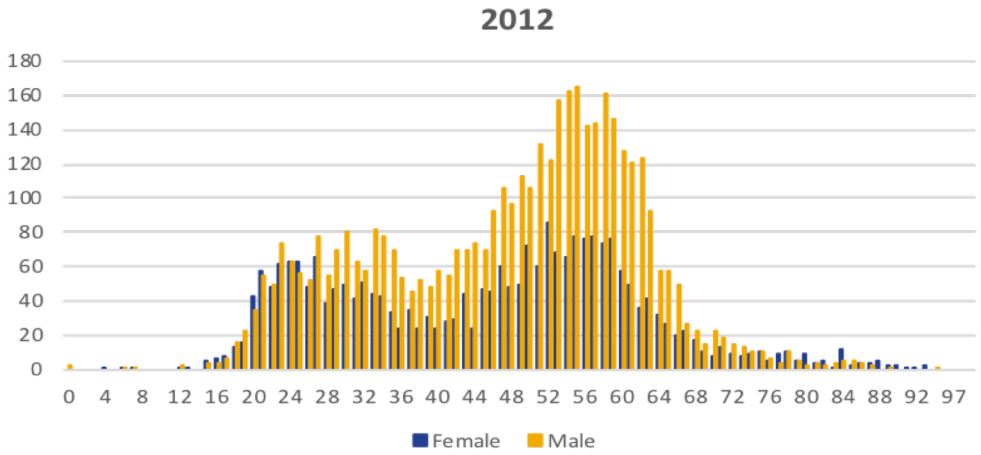
- **~33,900 new HCV infections in 2015**
- **1:1 male: female ratio, predominantly white race**

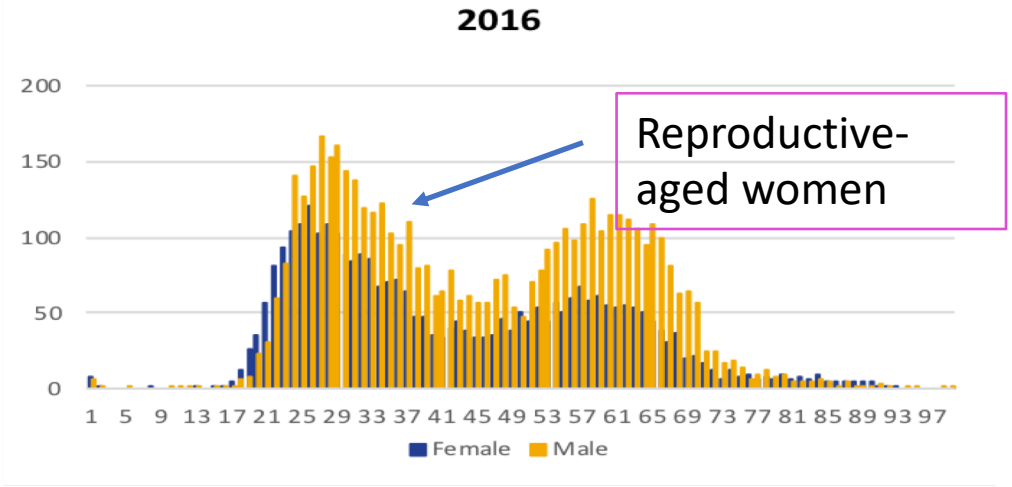
Centers for Disease Control. Viral Hepatitis Surveillance United States, 2015. Available at: https://www.cdc.gov/hepatitis/statistics/2015surveillance/pdfs/2015HepSurveillanceRpt.pdf (accessed June 2018)

Bimodal HCV Distribution in New York State: Newer Peak Includes Reproductive-aged Women





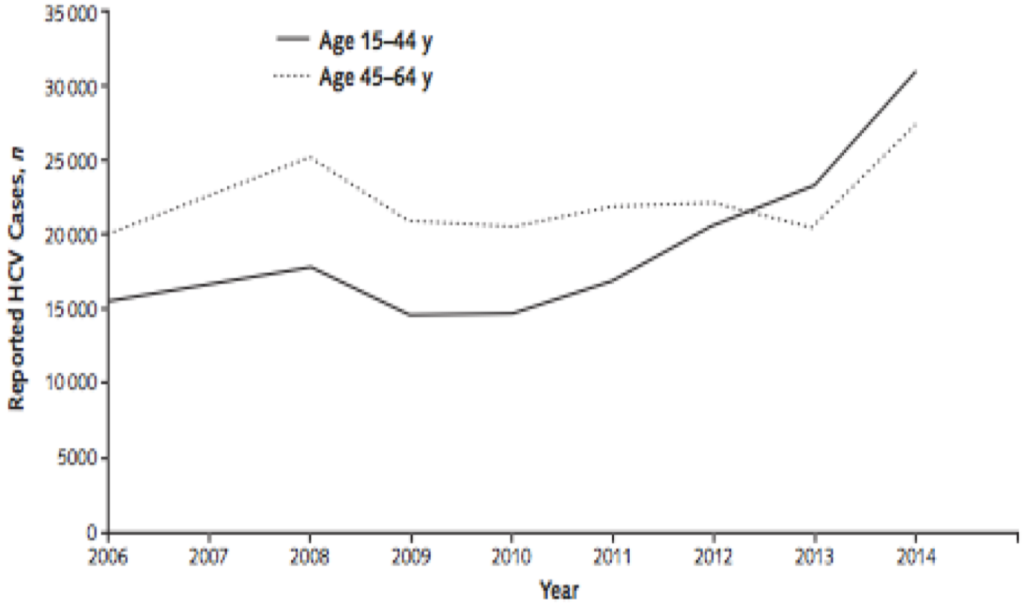




Slide courtesy of NYS DOH Bureau of Viral Hepatitis.

HCV in Women

- Among women of childbearing age:
  - # of acute cases increased 3.4-fold
  - # of past or present cases doubled
  - Rate higher than in older women since 2013

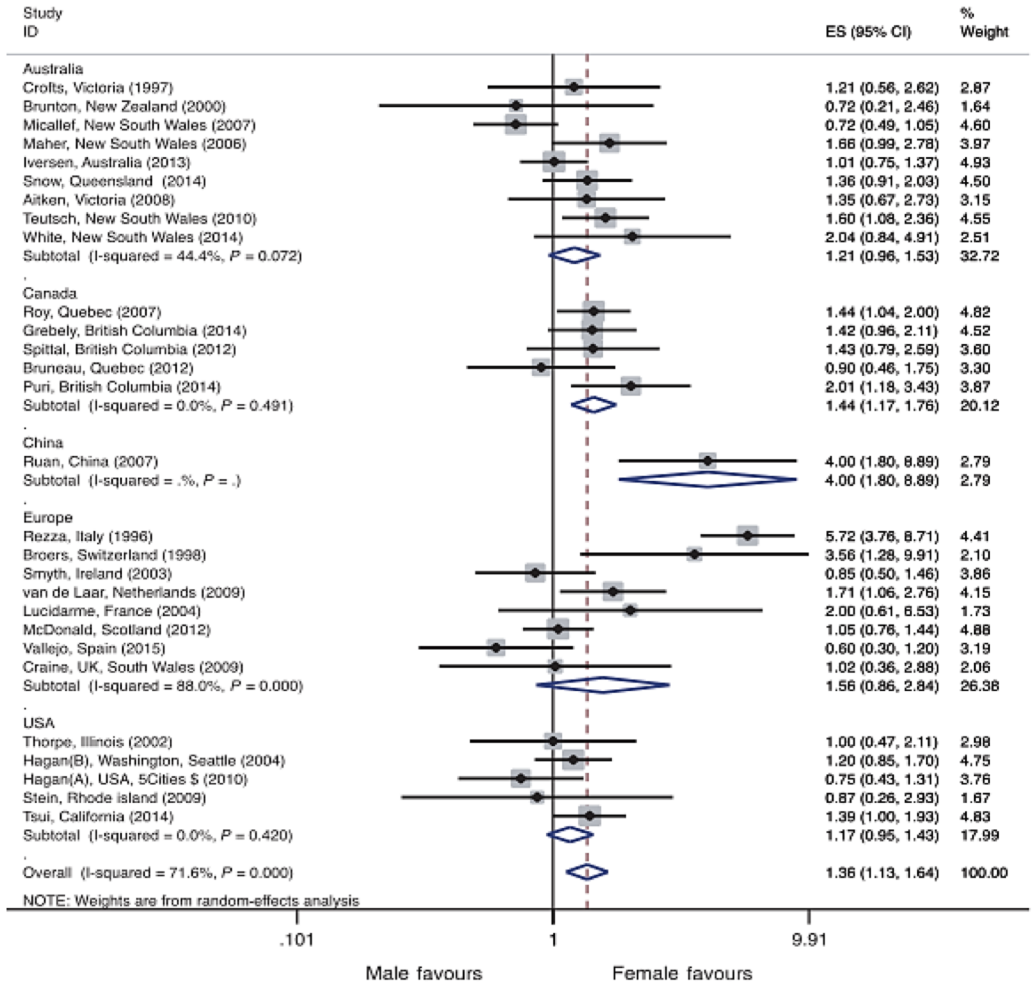


Source: NNDSS HCV case reports and Quest laboratory data

Ly K et al, *Annals Internal Medicine 2017*

Incidence of HCV Higher in Women Than Men Who Inject Drugs

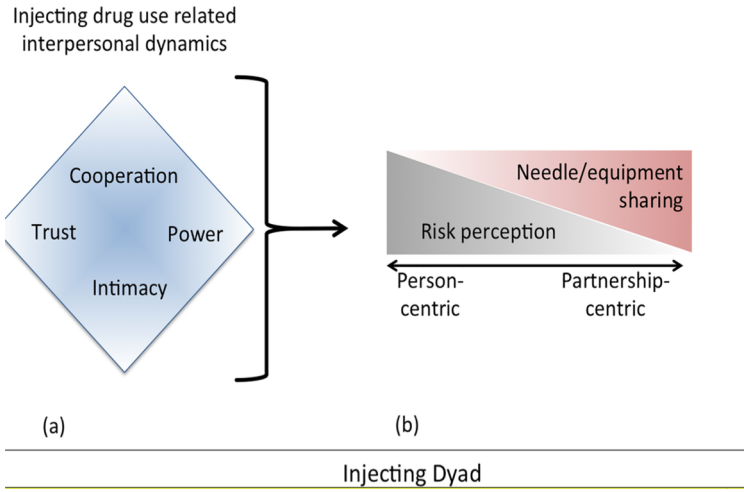
- Meta-analysis of 28 studies with 9,325 persons who inject drugs (PWID)
- Women were **36%** more likely to be anti-HCV positive than males
- Varies by country:
  - Highest in China and Europe
  - **17%** higher in US cohorts



Esmaeili A, et al. *Viral Hepat 2017.*

Women PWID may be at Higher Risk for HCV?

- Women who inject drugs have been shown to higher incidence of HIV and injection-related risk behaviors
  - Higher rates of equipment and syringe sharing
    - More women using injection equipment after 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
- Gendered power accompanies sexual injection behaviors



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

Esmaeili A, et al. *J Viral Hepat 2017.* Morris M, et al. *Plos One 2019*
Evans J, et al. *J Urban Health 2003*

Sexual transmission of HCV in Women

- Multiple sexual partners significantly increases risk of HCV (aOR 2.2-2.9)
  - Pregnant women with unprotected sex with 2-4 partners were 3 times more likely to acquire HCV than women with one partner (aOR 2.8)
  - May be correlated with increased injection drug use

- Women with HIV are more than twice as likely to acquire HCV (aOR 1.9) – *Womens Interagency HIV Study (WIHS)*

- Presence of activities/ conditions that disrupt anal mucosal integrity (traumatic sex, genital ulcerative disease, etc) increase transmission

- **Women engaging in very high-risk sexual behavior* were 14.2 times more likely to have HCV than other women**

*Defined as anonymous sex, no protection or use of contraception, anal intercourse, unfamiliar partners, sex while using drugs, or sex for drugs or money

Tohme, et al. *Hepatology 2010*

Feldman J, et al. *Sexually Tranmitted Diseases 2000.*

Hepatitis C prevalence in pregnant people

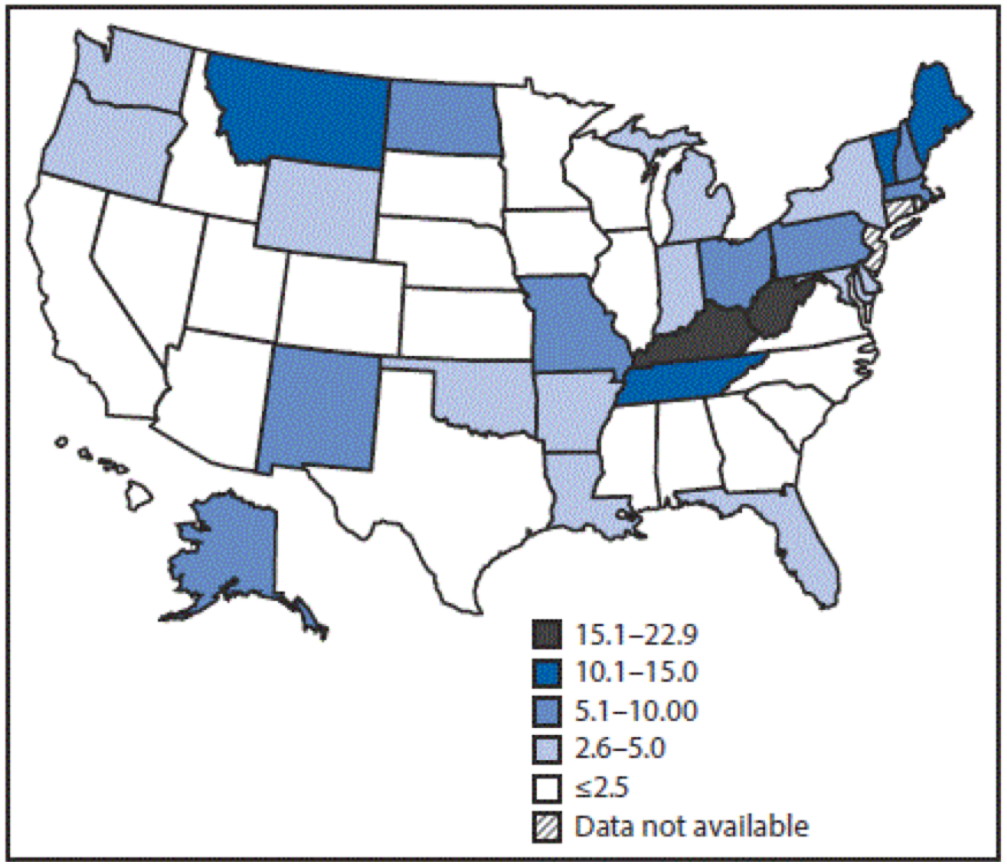
Rates of HCV Among Pregnant Women per 1000 Births In The US, 2014

National Vital Statistics System*/ U.S. Birth Certificate Data:

- From 2009–2014, HCV at delivery increased 89%, from 1.8 to 3.4 per 1000 birth
- Substantial state-to-state variation
- In 2014, the highest rate (22.6 per 1,000 live births) was in West Virginia, and the lowest (0.7) was in Hawaii
- 4.5 higher in smokers; 17-fold higher among women with HBV; 2-fold higher if < high school education

*HCV infection is a revised 2003 birth certificate item, states gradually reported this item over time as they adopted the revised certificate

Rate of hepatitis C infection among pregnant women per 1,000 live births, by state — United States, 2014

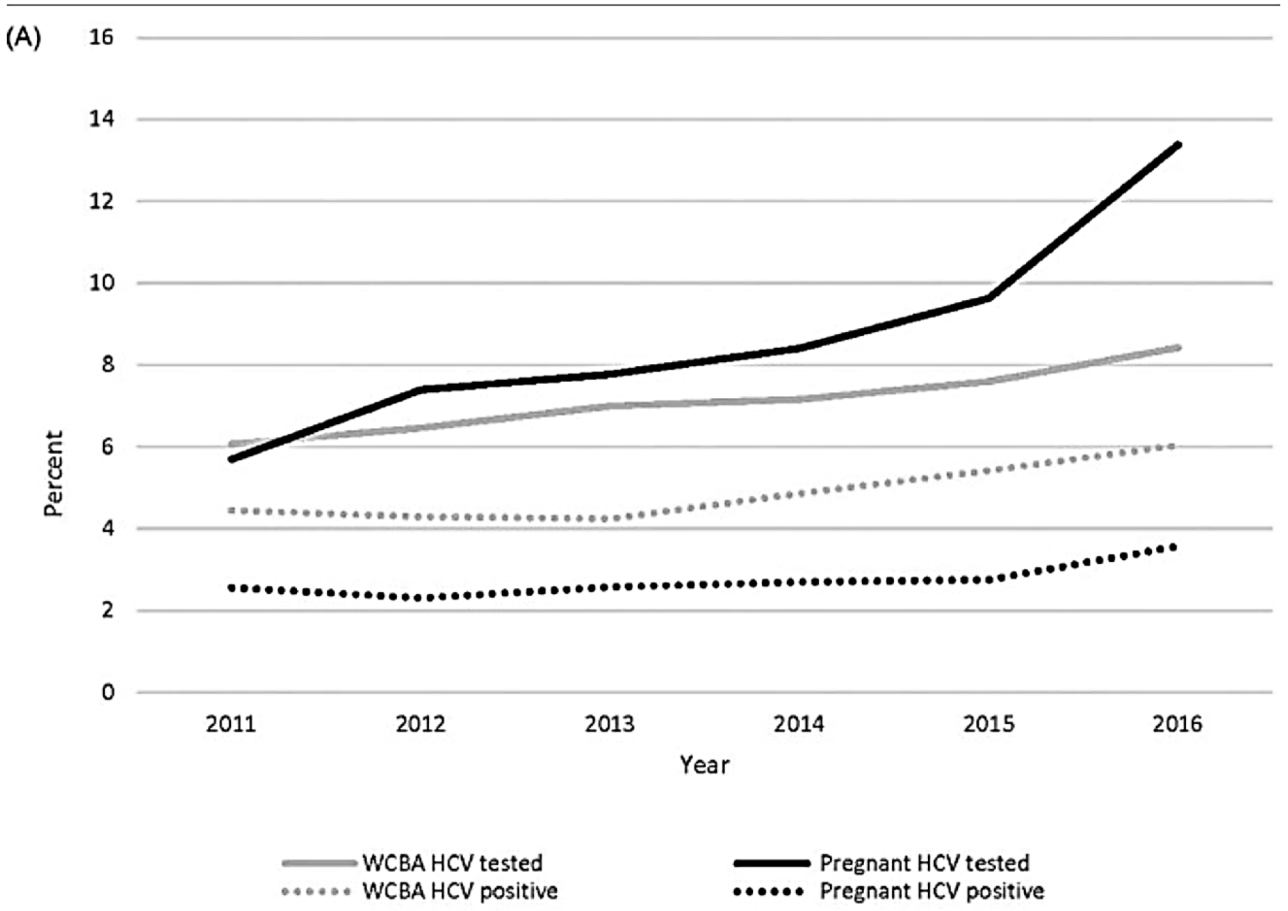


Patrick et al. MMWR Weekly / May 12, 2017 / 66(18);470–473

HCV in Pregnant Women, 2011-2016

- National Center for Health Statistics birth certificate data; 2011-2016
- 2015: 0.38% (14,417) of live births delivered by HCV-infected women
  - Age 20-29
  - White, non-Hispanic
  - Covered by Medicaid
  - Had rural residence
- **Among pregnant women**, HCV testing increased from 5.7% to 13.4% (by 135%); **positivity increased from 2.6% to 3.6%** (by 39%)

Percentage of U.S. women tested for and tested positive for HCV from 2011-2016 (n=14,417)



Schillie S, et al. *Am J Preventive Medicine 2018.*

HCV in Pregnant Women, 2009-2017

Population-based retrospective cohort study of U.S. live births from 2009-2017 using National Center for Health Statistics birth records

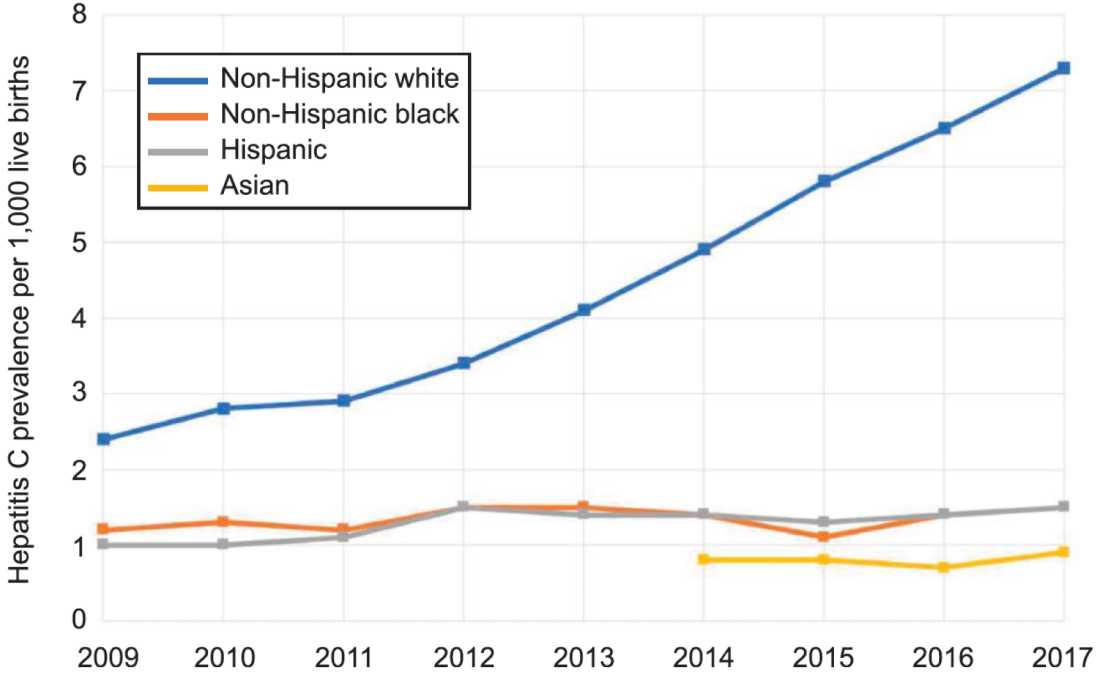
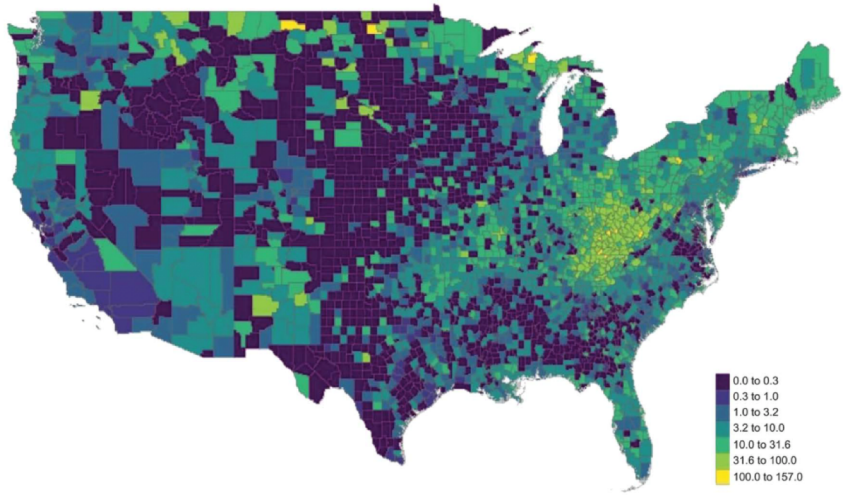


Fig. 3. Racial trends in maternal hepatitis C prevalence per 1,000 live births.

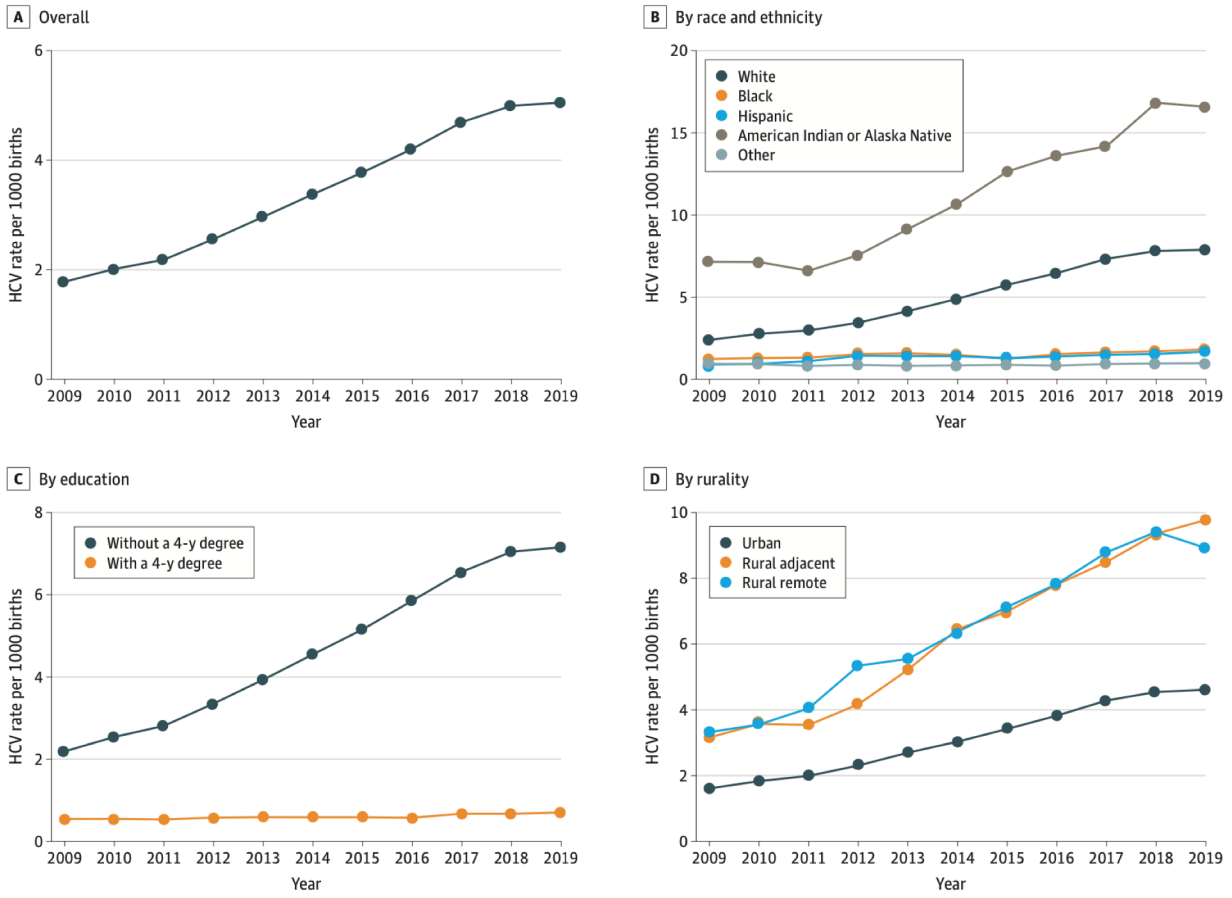
Overall, reported prevalence of **maternal HCV infection has increased by 161%** from 2009 to 2017



Rossi RM, et al. Obstet Gynecol. 2020;135(2):387-395.

HCV in pregnant people in US 2009-2019

- All US births from 2009-2019 using data from National Center for Health Statistics (CDC) and Area Health Resource File
  - 39 380 122 pregnant people
    - 138343 (0.4%) with HCV
- Rate increased from 1.8 to 5.1 per 1000 births
- Higher rates in:
  - White people
  - Less than 4-year degree
  - Unmarried
  - Medicaid
  - Rural
  - Lower density of obstetricians
  - unemployment



Patrick S et al. JAMA Health Forum October 2021.

Effect of HCV on Pregnancy Outcomes

What is the impact of HCV on Pregnancy?

There is likely 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,]
  - IUGR - 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 births, 2001-2011
  - Preterm birth (aRR 1.32 (95% CI 1.08-1.60)
  - Late neonatal death (aRR 3.79 (95% CI:1.07-13.79)
- Italian study of >45k pregnant women screened for HCV, 2009-2018[3]
  - Cholestasis of pregnancy **10x** higher; Gestational DM 2x higher in HCV positive

[1]Huang Q, et al. *J of Viral Hepatitis 2015.*
[2]Huang Q, et al. *Medicine 2016.*
[3]*Stokkeland K, Eur J Epidemiol 2017.*
Piffer S, et al. European Journal of Obstetrics & Gynecology 2021.

Impact of HCV on Pregnancy

- Cholestasis of pregnancy (ICP):
  - Population-based cohort study in Sweden (11,000 ICP women; 11,000 healthy women) → HR 4.16 association of HCV with ICP
  - Meta-analysis of ICP studies in pregnancy → Pooled OR 20.4 compared to non-HCV women

Counsel women with HCV on the increased risk of cholestasis of pregnancy!

Marschall, et al. *Hepatology 2013.*
Wijarnpreecha K, et al. *Clin Res Hepatol Gastroenterol 2017.*

Recent data from Ontario Database with maternal-infant linkage

- ICES Ontario Database 2000-2016
  - 2170 HCV Ab positive pregnancies; 1780 RNA+ pregnancies

Effect of maternal HCV Viremia on probability of peripartum outcomes in infants born to mothers HCV.

	Univariate			Multivariate		
Outcomes	OR	95% CI	p-value	OR	95% CI	p-value
Gestational diabetes[1]	**0.58**	**0.39 - 0.86**	**0.0067**	**0.71**	**0.47 - 1.06**	**0.0958**
Intrahepatic cholestasis of pregnancy[2]	**3.95**	**1.43 - 10.89**	**0.0079**	**4.55**	**1.64 - 12.64**	**0.0036**
Small for gestational age[3]	1.15	0.84 - 1.57	0.3760	1.10	0.80 - 1.51	0.5716
Large for gestational age[4]	1.22	0.80 - 1.87	0.3615	1.25	0.81 - 1.93	0.3153
Postpartum or antepartum hemorrhage[5]	**1.80**	**1.12 - 2.87**	**0.0143**	**1.78**	**1.11 - 2.87**	**0.0173**
Preterm delivery[3]	**1.67**	**1.20 - 2.33**	**0.0027**	**1.84**	**1.27 - 2.67**	**0.0013**

Kushner T, et al. AASLD 2021.

Monitoring Women with HCV During Pregnancy

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

AASLD guidelines:

Recommendations for Monitoring HCV-Infected Women During Pregnancy	
RECOMMENDED	RATING
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

Linkage to HCV Care

- *"HCV-infected pregnant women should be linked to care so that antiviral treatment can be initiated at the appropriate time"*

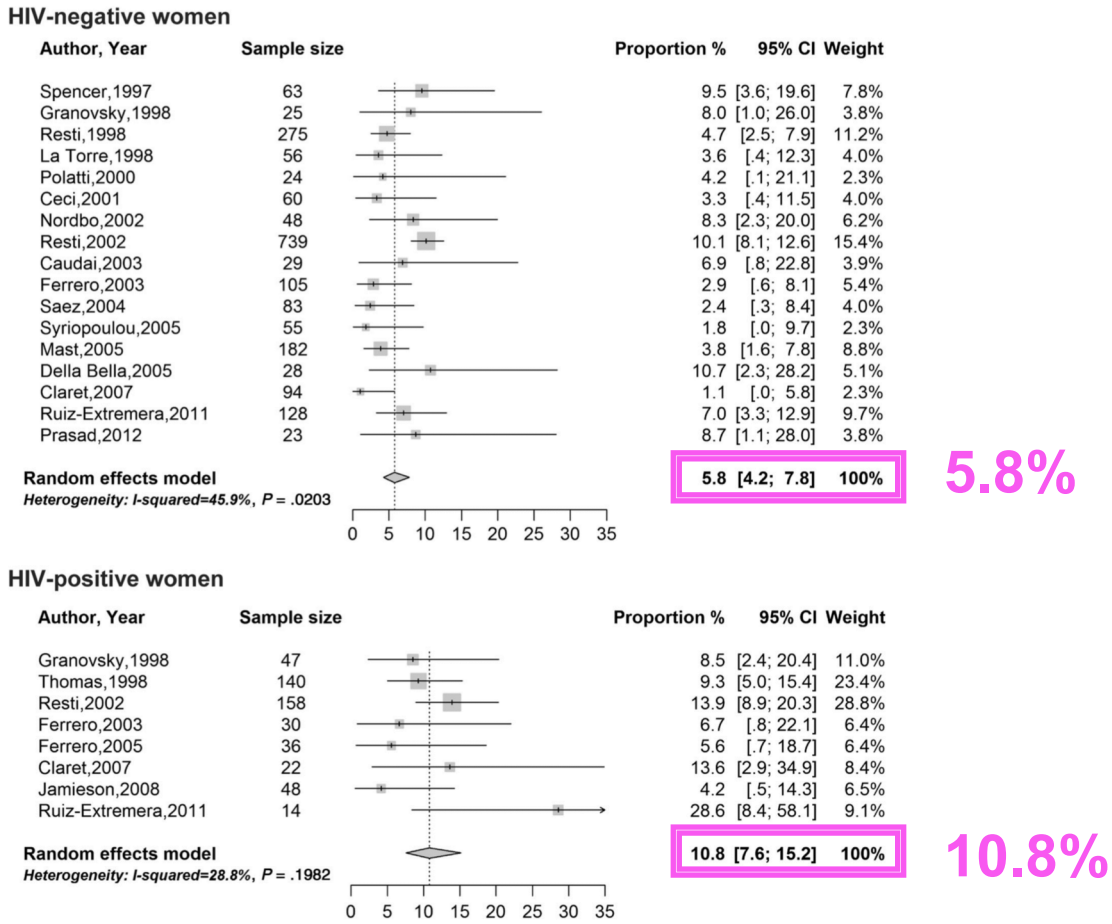
- **Huge** challenge to ensure linkage to care
  - Women with HCV experience longer delays to HCV treatment than men
  - African Americans experience longer delays (280 *vs*. 165 days in non-Hispanic whites, $P < 0.05$)
    - HCV treatment uptake lower in African Americans (70.4% *vs*. 74.4%, $P < 0.05$).
  - Postpartum period – very high rates of loss to follow up

Gomes C et al. *J Transl Int Med* 2020.

Mother-to-Child Transmission of HCV

How common is Mother-to-Child Transmission of HCV?

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



Benova, et al. *Clinical Infectious Diseases*, 2014.

Impact of MTCT 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.

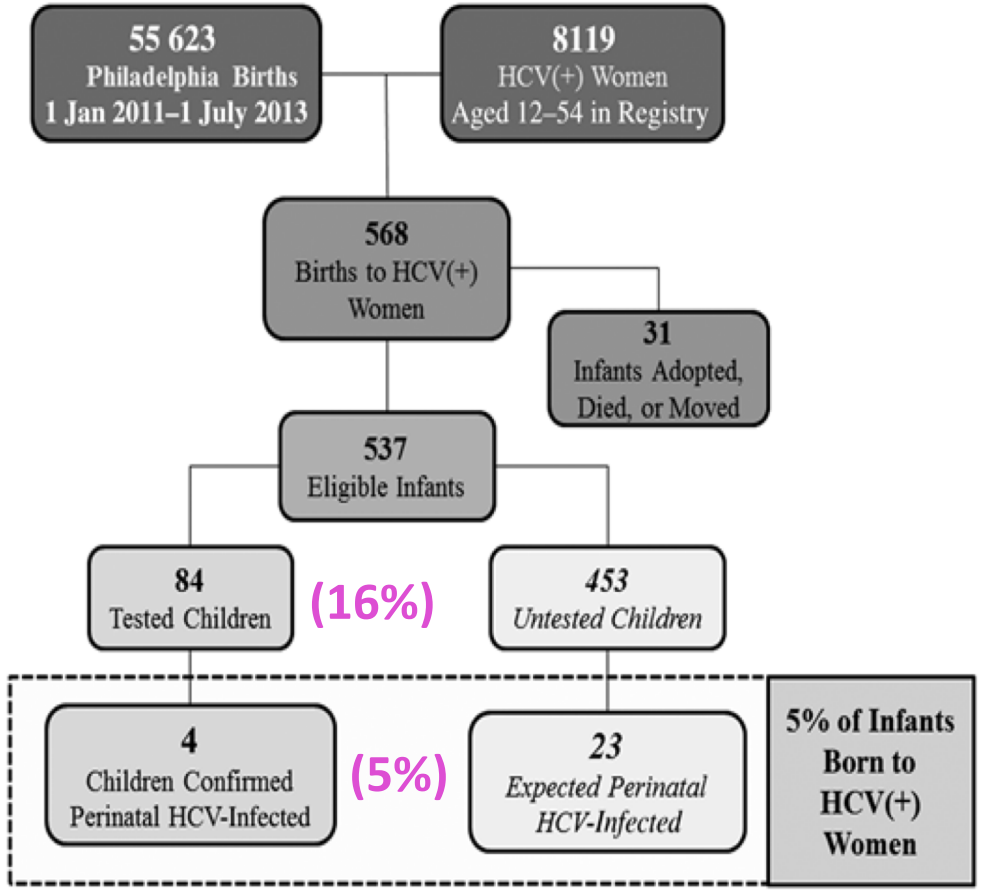
Is There Any Way to Prevent Transmission During Pregnancy?

Variable	Studies; # women	Strength 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	Moderate	No association
Invasive fetal monitoring vs. none	3 cohort studies; N=928	Insufficient	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

Cottrell, et al. *Ann Intern Med*, 2013.
Rac, et al. *Obstet Gynecol Clin North Am*, 2014.
Hughes, et al. *Society for Maternal Fetal Medicine*, 2017.

But Are We even Testing the Infants to check for MTCT?

- Lack of follow-up testing in majority of infants born to HCV+ mothers



***Followed for up to 20 months post-birth**

Kuncio D, et al. *Clin Infect Dis*, 2016.

Are We Actually Testing Children to evaluate for MTCT?

- 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.**

Chappell C, et al. *Pediatrics*, 2018.

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

Chappell C, et al. *Pediatrics*, 2018.

HCV Treatment in Children

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

AASLD

AASLD/ IDSA HCV Guidance. *Accessed on 2/2020.*

Recent approvals for HCV in Children

June 10, 2021

U.S. Food and Drug Administration Approves New Formulation of Epclusa®, Expanding Pediatric Indication to Treat Children Ages 3 and Older With Chronic Hepatitis C

FDA Approves Mavyret (G/P, glecaprevir and pibrentasvir) for Pediatric HCV Treatment 3 Years & Older

On June 10, 2021, the Food and Drug Administration (FDA) approved the use of glecaprevir and pibrentasvir ("G/P") or MAVYRET®, for the treatment of HCV in pediatric patients 3 years and older without cirrhosis or with compensated cirrhosis. With this pediatric approval MAVYRET® provides oral pellet formulation option for patients 3 years to less than 12 years old.

What are recommendations for Screening During Pregnancy?

The History of viral hepatitis screening recommendations in pregnancy..

- **1984** – High risk screening for hepatitis B (HBV) recommended – Ineffective
- **1991** – Universal screening for HBV recommended
- **1998 – 2011** - Cross-sectional analysis of deliveries using Nationwide Inpatient Sample: HBV rate in pregnant women increased from 57.8 in 1998 to 105.0/ 100,000 deliveries in 2011 (*annual increase of 5.5%)*
- *Prior to 2018:* Risk based screening for HCV during pregnancy recommended by all societies (ACOG, AASLD, CDC)

How does HBV compare to HCV in pregnancy in terms of pregnancy risk?

- Nationwide Inpatient Sample Study, 2012-2018

	Patients w/o HBV or HCV n=28,499,085	Patients w/ HBV n=52,445	Patients w/ HCV n=133,680	Comparison HBV vs. Control (p value)	Comparison HCV vs. Control (p value)	Comparison HBV vs. HCV (p value)
Outcomes*						
Maternal Mortality	0.01%	0.03%	0.05%	0.184	<0.001	<0.001
Length of stay (days)	2.7	2.8	3.4	0.008	<0.001	<0.001
Total charge	18,289	20,988	21,065	0.055	<0.001	<0.001
C-section	29.87%	31.93%	29.48%	0.274	0.455	0.347
Preeclampsia/Eclampsia	5.28%	4.55%	4.77%	0.019	0.035	0.195
Preterm labor	6.27%	5.60%	9.68%	0.044	<0.001	<0.001
Gestational diabetes	6.94%	12.78%	4.57%	<0.001	<0.001	<0.001

*Multivariate logistic regression was used to adjust for age at pregnancy and race while comparing outcomes in different groups.

Compared to the uninfected control group, **chronic hepatitis B** was associated with a significantly higher rate of **GDM** but **chronic hepatitis C** was associated with a significantly higher rate of **preterm labor, hospitalization cost,** and **all-cause in-hospital maternal mortality during pregnancy**.

Chen B, Kushner T, et al. AASLD 2021.

What do the experts say now?

AASLD
AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES

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

IDSA
Infectious Diseases Society of America

Testing

Recommendation for Universal Hepatitis C Screening in Pregnancy	
RECOMMENDED	RATING
All pregnant women should be tested for HCV infection (see Recommendations for Initial HCV Testing and Follow-Up), ideally at the initiation of prenatal care.	IIb, C

AASLD/IDSA. HCV guidance. **May 24 2018**.

Then United States Preventative Services Task Force (USPSTF) followed..

The USPSTF recommends screening for hepatitis C virus (HCV) infection in adults aged 18 to 79 years.	B

To whom does this recommendation apply?	All asymptomatic adults (including pregnant persons) aged 18 to 79 years without known liver disease.
What's new?	This recommendation expands the population that should be screened. The USPSTF now recommends that all adults aged 18 to 79 years be screened. Previously, it recommended screening adults born between 1945 and 1965 and others at high risk.

"Pregnant adults should be screened. HCV prevalence has doubled in women aged 15 to 44 years from 2006 to 2014. From 2011 to 2014, 0.73% of pregnant women tested had an HCV infection, with a 68% increase in the proportion of infants born to HCV-infected mothers. Approximately 1700 infected infants are born annually to 29000 HCV-infected mothers. Because of the increasing prevalence of HCV in women aged 15 to 44 years and in infants born to HCV-infected mothers, clinicians may want to consider screening pregnant persons younger than 18 years."

JAMA Published online March 2, 2020

And finally the CDC..and even ACOG!

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Recommendations and Reports / Vol. 69 / No. 2
April 3, 2020

CDC Recommendations for Hepatitis C Screening Among Adults — United States, 2020

"Hepatitis C screening is recommended for all pregnant women during each pregnancy except in settings where the prevalence of HCV infection is < 0.1%"

ACOG
The American College of Obstetricians and Gynecologists

Practice Advisory – **May 2021**

The American College of Obstetricians and Gynecologists is updating its hepatitis C screening guidance to recommend screening for all pregnant individuals during each pregnancy. Hepatitis C screening during the first prenatal blood assessment obtained in every pregnancy is recommended to identify pregnant individuals with HCV infection and infants who should receive testing at a pediatric visit.

But is HCV screening actually being done during prenatal care?

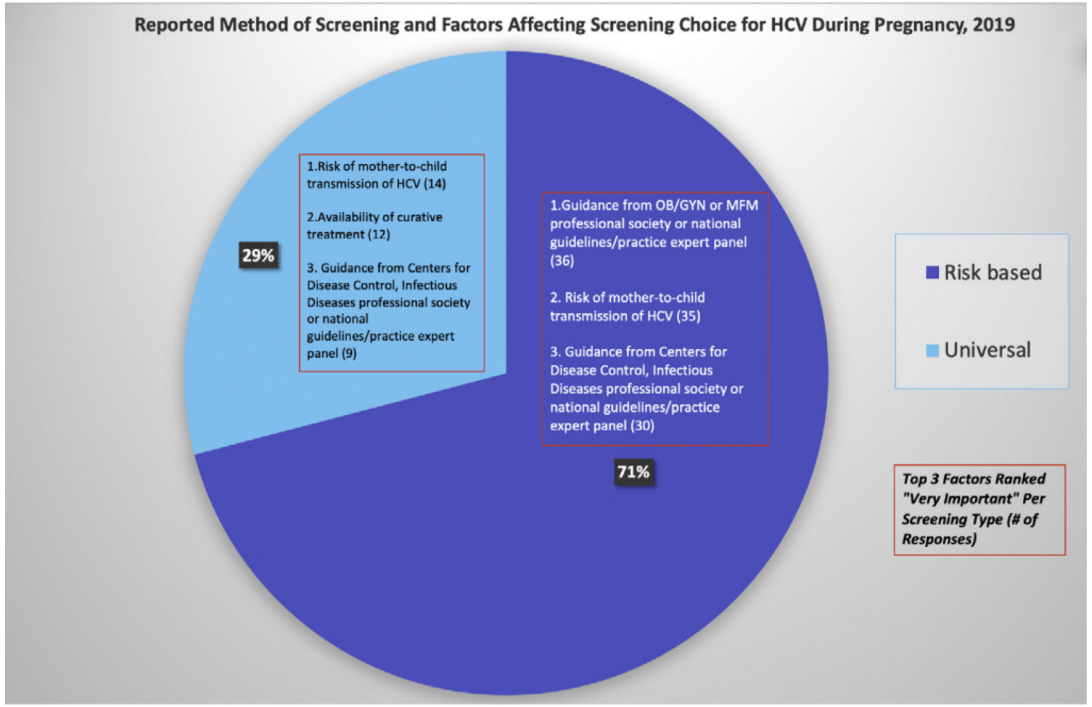
Clinical Therapeutics/Volume xxx, Number xxx, xxxx

A Survey of Practices in the United States Regarding Hepatitis C Screening in Pregnant Women

Elizabeth A. Godar, MD[1]; and Ravi Jhaveri, MD[2]

Division of Infectious Diseases, Department of Pediatrics, School of Medicine, University of North Carolina, Chapel Hill, NC, USA

- Survey distributed to Prenatal Care providers in the US
  - 86 completed surveys (1% response rate)



Godar EA and Jhaveri R. *Clinical Therapeutics* 2021.

Patient-level barriers may also exist..

- Compared with whites, women of Latina (OR 0.45 [95% CI 0.37-0.55]; $P < 0.001$) and Asian (OR 0.74 [95% CI 0.58-0.94]; $P = 0.01$) race were less likely to receive HCV screening.
- African American (AA) → less likely to receive quality prenatal care and preventative services
  - Pregnancy morbidity and mortality disproportionately affect AA women

Programs designed to address individual-level, interpersonal-level, community-level, and system-level factors are needed to improve uptake of HCV screening

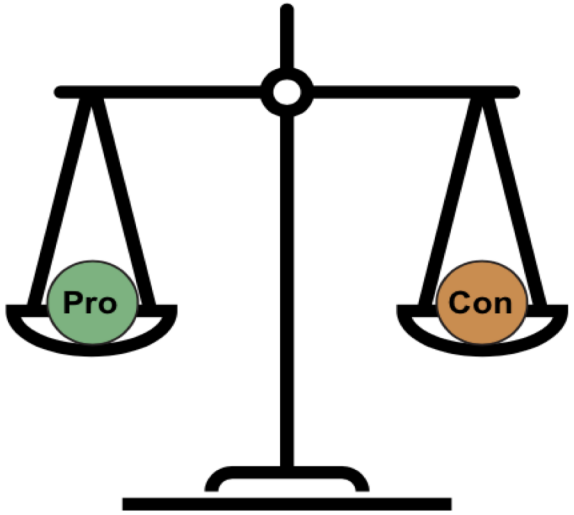
Kim N et al. *Hepatology Communications* 2019.

Prater C et al. *Health Equity* 2018.

Is there a role for Antiviral Therapy During Pregnancy?

How About Antiviral Therapy During Pregnancy?

Treatment with DAAs during pregnancy



1. Maternal cure while engaged in pregnancy care
2. Possible decrease in MTCT
3. Maternal treatment while under insurance coverage
4. Decrease in community transmission
5. Potential decrease in HCV-associated adverse pregnancy outcomes?

1. Human safety in pregnancy not established
2. Safety during breastfeeding not established
3. More established data for treatment prior to pregnancy or children starting at age 3
4. Difficulty in accessing DAA therapy in time (prior to delivery)
5. Cost-effectiveness not established

Kushner T & Reau N. *Journal of Hepatology* 2021.

What are the experts saying?

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

"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.

Antiviral Therapy for Prevention of Transmission?

Many DAAs are considered pregnancy category B

Table 1. Safety Profile of New DAAs in Pregnancy

DAA Combination	Pregnancy Category
(1) Paritaprevir* + (2) ombitasvir*	(1) B, (2) B
(1) Paritaprevir* + (2) dasabuvir* + (3) ombitasvir*	(1) B, (2) B, (3) B
(1) Daclatasvir† + (2) asunaprevir‡	(1) N/A, (2) N/A
(1) Daclatasvir† + (2) asunaprevir‡ + (3) beclabuvir	(1) N/A, (2) N/A, (3) N/A
(1) Sofosbuvir* + (2) ledipasvir*	(1) B, (2) B
(1) Sofosbuvir* + (2) ledipasvir* + (3) vedroprevir	(1) B, (2) B, (3) N/A
(1) Sofosbuvir* + (2) ledipasvir* + (3) GS-9669	(1) B, (2) B, (3) N/A
(1) Sofosbuvir* + (2) simeprevir*	(1) B, (2) C
(1) Grazoprevir, (2) elbasvir	(1) N/A, (2) N/A
(1) Daclatasvir† + (2) sofosbuvir*	(1) N/A, (2) B
(1) Sofosbuvir* + (2) velpatasvir	(1) B, (2) N/A
(1) Grazoprevir, (2) elbasvir ± (3) MK-3682	(1) N/A, (2) N/A, (3) N/A

*FDA-approved DAA.
†Approved in Europe, Brazil, and Japan.
‡Approved in Japan.
Abbreviation: N/A, not available.

Kanninen, et al. *Hepatology, 2015.*

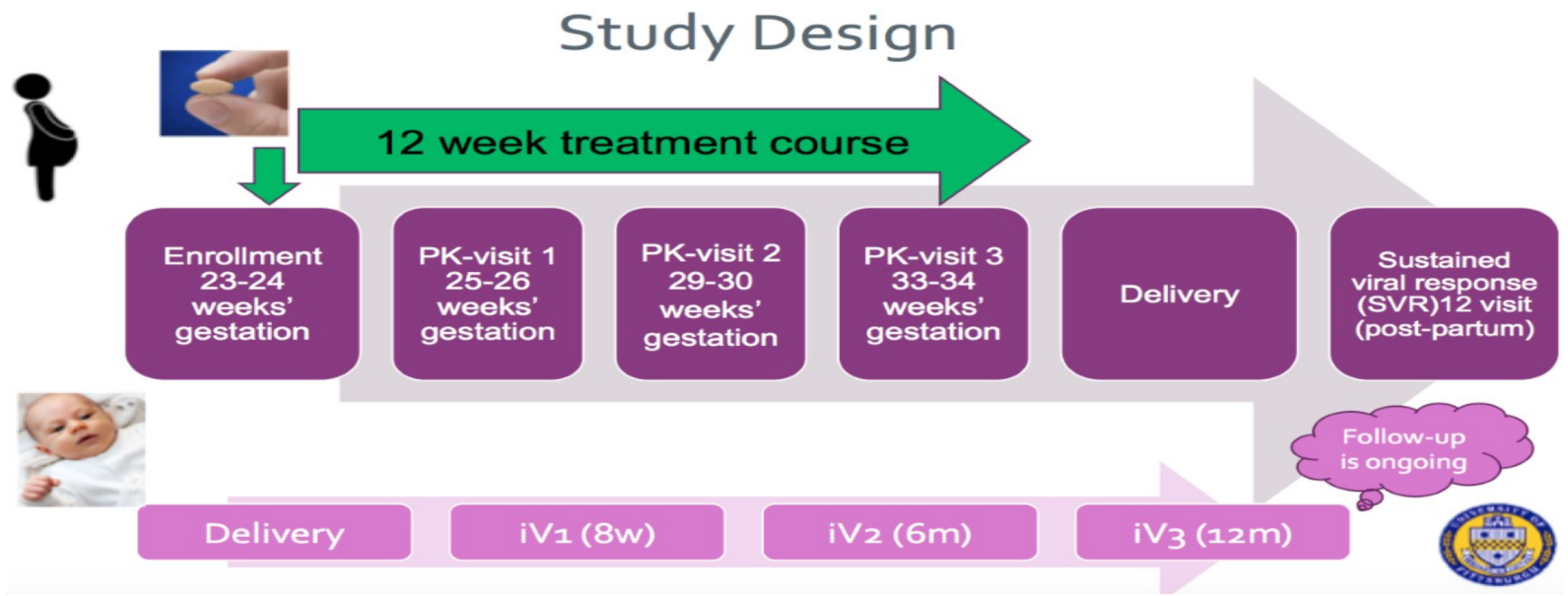
Would women consider HCV treatment during pregnancy?

- Survey of 141 women with HCV at UCSF and WIHS
  - 60% of women said they would take DAA if it lowered risk of MTCT
  - 21% they would take during pregnancy for self-cure; 20% said they would consider it if there was more data

Kushner T, et al. *Hepatology Communications*, 2018.

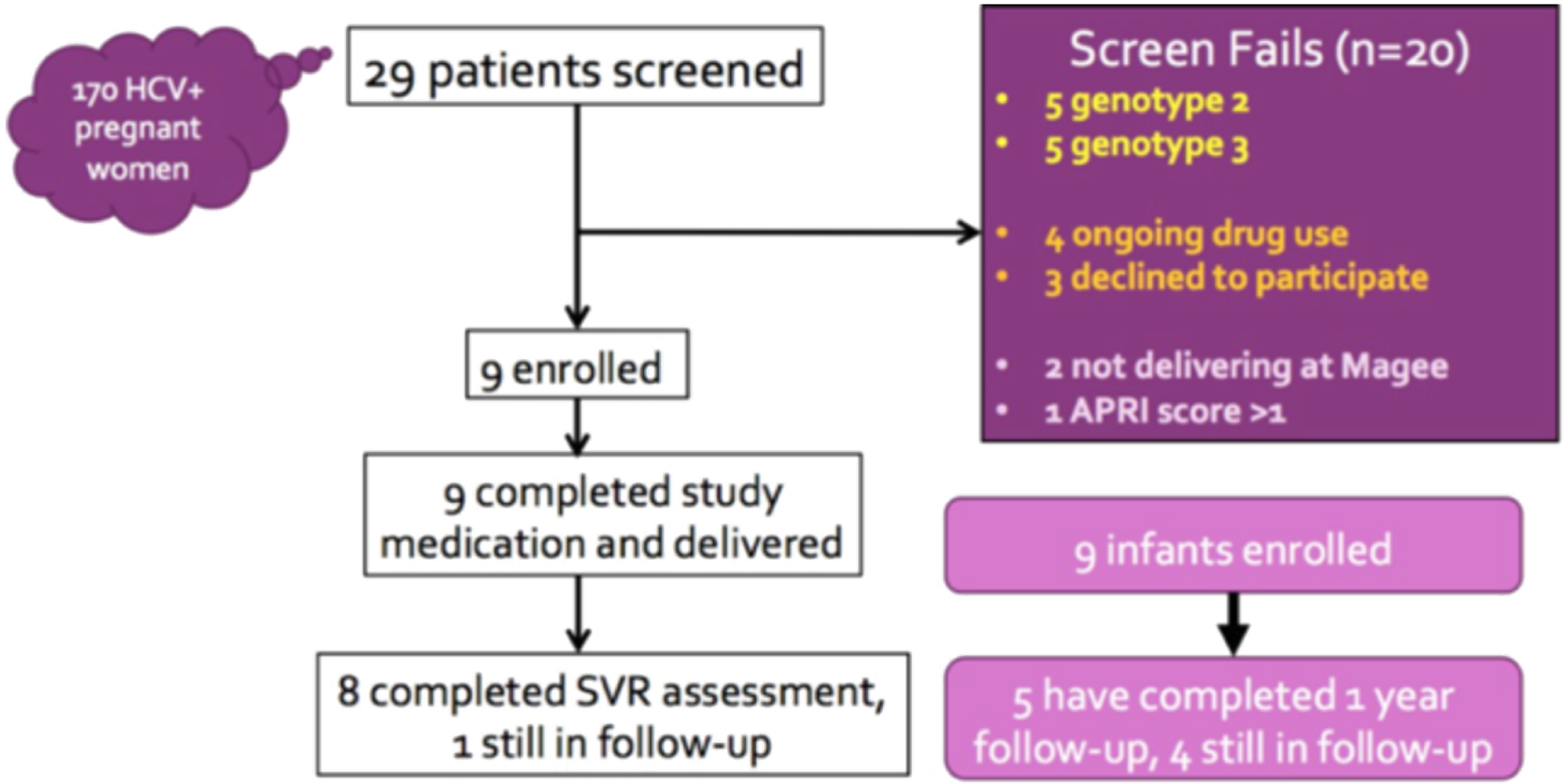
Trial of HCV Treatment During Pregnancy

- Phase 1 Study of Ledipasvir/ Sofosbuvir in Pregnant Women with HCV Virus
  - Primary Objective
    - To define the safety and virologic response to ledipasvir/ sofosbuvir in pregnancy



Chappell C, et al. *CROI*, March 2019.

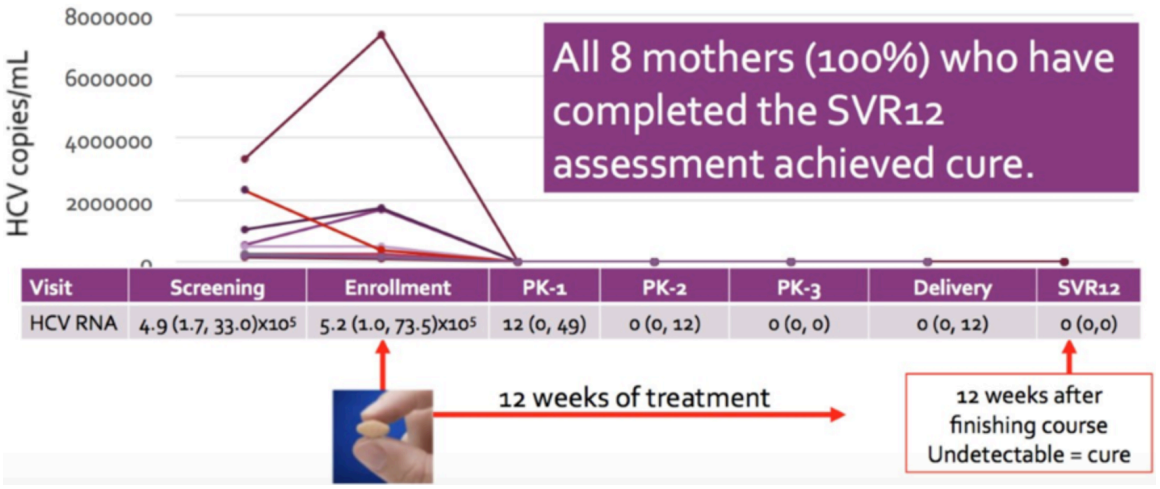
Trial of HCV Treatment During Pregnancy



Chappell C, et al. *CROI*, March 2019.

Trial of HCV Treatment during Pregnancy

Results



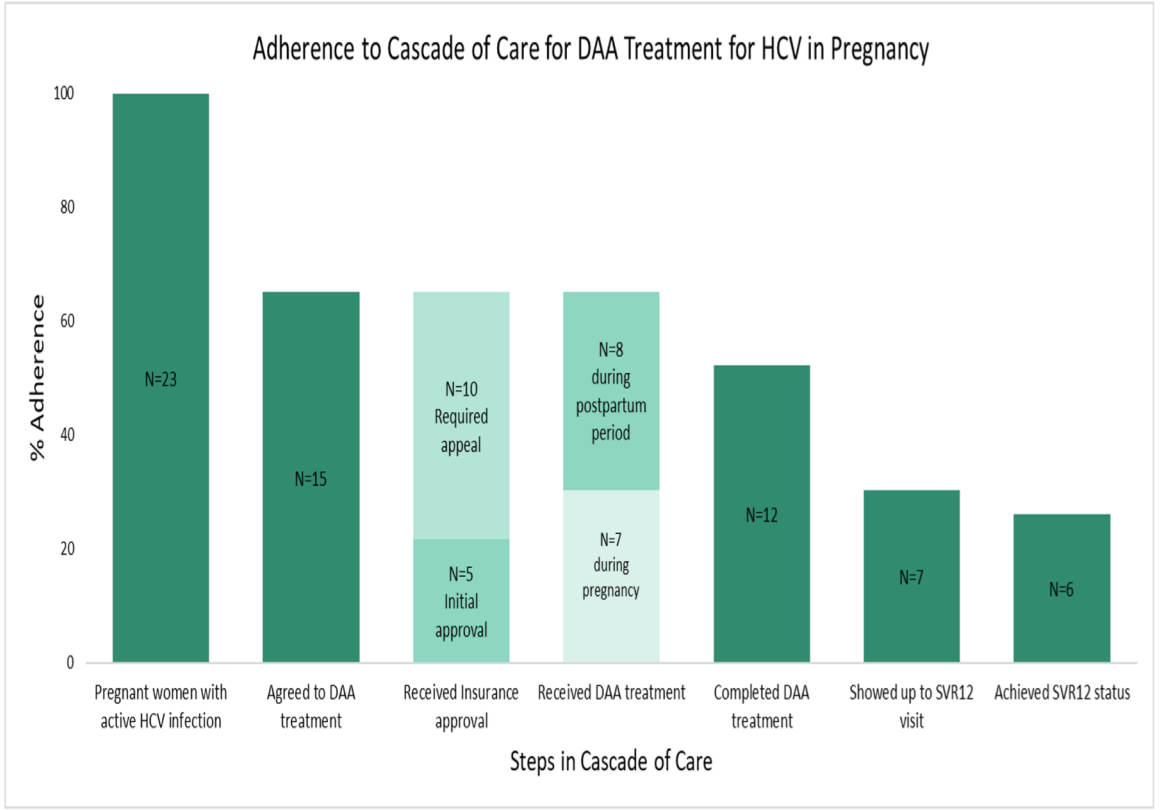
Pregnancy and Delivery Outcomes

Outcome	N (%) or Median (Range)
Maternal Related Adverse Events	5 (56%)
Maternal Related Adverse Events >Grade 2	0 (0%)
Vaginal Delivery	5 (56%)
Gestational age at delivery (weeks + days)	39+2 (36+6, 41+0)
Birth weight (g)	3,290 (2,600, 4,160)
Infant Length of Hospital Stay (days)	3 (2, 12)
Infant Related Adverse Events	0 (0%)
Infant HCV RNA at Last Visit (copies/mL)	0 (0, 0)

Chappell C, et al. *Lancet Microbe 2020*.

Our experience..

- 23 pregnant women with active HCV infection were referred to our Women's Liver Clinic for consideration for HCV treatment
  - Median age 31 (IQR 24, 36)
  - Predominantly white (39%) non-Hispanic (60%)
  - Medicaid-insured (78%)
  - 30% with injection drug use as a risk factor; 9% who acquired HCV through perinatal transmission; 26% with no known risk factors.
  - 65% reported that HCV was initially diagnosed during pregnancy.



Kushner T, et al. *Hep-Dart 2021*.

Summary

- HCV among women of childbearing potential and during pregnancy is on the rise as a result of the opioid epidemic
- Universal screening for HCV recommended in pregnancy
- HCV increases the risk of cholestasis of pregnancy and may increase other adverse pregnancy outcomes
- Mother-to-child transmission rates range from 6-11%
- All children of mothers with HCV should be tested at 18 months of age and referred to specialty care as needed
- Treatment is currently recommended in children ≥3 years of age
- Studies of HCV treatment during pregnancy are under way – will also need to find ways to maintain engagement during the vulnerable pregnancy period

Thank you!

Questions?

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