Hepatitis C in People of Reproductive Age, Pregnancy and Children

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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.
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 in the United States

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

• >40% of women living with HCV are of childbearing age
  – 15% of women of childbearing age and living with HCV will become pregnant (but likely an underestimate)

Incidence of Acute HCV is Increasing

- ~33,900 new HCV infections in 2015
- 1:1 male: female ratio, predominantly white race
- Highest incidence: 20–29 years, non-metropolitan areas

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
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

Bimodal HCV Distribution in NYS: Newer Peak Includes Reproductive-Aged Women

Slide courtesy of NYS DOH Bureau of Viral Hepatitis.
HCV in Women of Childbearing Age

- 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 WhoInject 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

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!

How about HCV in pregnancy?


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

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

Case Study
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 \( \rightarrow \) \textit{64.1\% were not tested} for HCV
  - 10\% of women found to be HCV+ \textit{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
New York State Law for HCV Testing

**Effective May 3, 2024**, New York State requires a hepatitis C screening test be provided to:

- Every person 18 years and older.
- People younger than 18 if there is indication of risk.
- **All pregnant people during each pregnancy. Screening test results must be recorded in the pregnant person’s medical record at or before the time of hospital admission for delivery.**

If the screening test is reactive, a hepatitis C RNA test must be performed on the same specimen or a second specimen collected at the same time as the initial test, to confirm diagnosis of current hepatitis C infection.

If the hepatitis C RNA test is detectable, the health care provider must either offer the person follow-up hepatitis C health care and treatment, or refer the person to a health care provider who can.

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

AASLD guidelines:

<table>
<thead>
<tr>
<th>RECOMMENDED</th>
<th>RATING</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>I, B</td>
</tr>
<tr>
<td>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.</td>
<td>I, B</td>
</tr>
<tr>
<td>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.</td>
<td>I, B</td>
</tr>
<tr>
<td>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.</td>
<td>I, B</td>
</tr>
</tbody>
</table>
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 births, 2001-2011\(^3\)
    - Preterm birth (aRR 1.32 (95% CI 1.08-1.60)
    - Late neonatal death (aRR 3.79 (95% CI:1.07-13.79)

\(^1\)Huang Q, et al. J of Viral Hepatitis 2015.
Evaluation of Nationwide Inpatient Sample

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

STUDY DESIGN

Population-based retrospective study using NIS data (2012-2018)

Control 28,499,085
HBV + Preganancies 51,200
HCV + Preganancies 131,695

Pregnancy outcomes adjusted for: age, race, insurers, hospital teaching status, region and comorbidities

FINDINGS

Pregnancy-related complications in women with HBV

Gestational diabetes
aOR: 1.19 (1.12, 1.27)

Pregnancy-related complications in women with HCV

Intrauterine growth restriction
aOR: 1.27 (1.19, 1.34)

Preterm labor
aOR: 1.12 (1.06, 1.17)

Caesarian section
aOR: 1.00 (1.05, 1.12)

Chen B, et al. Hepatol Communications, 2022
Impact of HCV Viral Parameters on Pregnancy Complications & Risk of 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**

1,780 HCV RNA+ pregnancies
390 HCV Ab+/RNA- pregnancies

**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

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Sample size</th>
<th>Proportion</th>
<th>95% CI</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spencer, 1997</td>
<td>63</td>
<td>9.5</td>
<td>[3.6; 19.6]</td>
<td>7.8%</td>
</tr>
<tr>
<td>Granovsky, 1998</td>
<td>25</td>
<td>8.0</td>
<td>[1.0; 26.0]</td>
<td>3.8%</td>
</tr>
<tr>
<td>Resti, 1998</td>
<td>275</td>
<td>4.7</td>
<td>[2.5; 7.9]</td>
<td>11.2%</td>
</tr>
<tr>
<td>La Torre, 1998</td>
<td>56</td>
<td>3.6</td>
<td>[4; 12.3]</td>
<td>4.0%</td>
</tr>
<tr>
<td>Polatti, 2000</td>
<td>24</td>
<td>4.2</td>
<td>[1; 21.1]</td>
<td>2.3%</td>
</tr>
<tr>
<td>Ceci, 2001</td>
<td>60</td>
<td>3.3</td>
<td>[4; 11.5]</td>
<td>4.0%</td>
</tr>
<tr>
<td>Nordbo, 2002</td>
<td>48</td>
<td>8.3</td>
<td>[2.3; 20.0]</td>
<td>6.2%</td>
</tr>
<tr>
<td>Resti, 2002</td>
<td>739</td>
<td>10.1</td>
<td>[8.1; 12.6]</td>
<td>15.4%</td>
</tr>
<tr>
<td>Caudal, 2003</td>
<td>29</td>
<td>6.9</td>
<td>[6.2; 22.8]</td>
<td>3.9%</td>
</tr>
<tr>
<td>Ferrero, 2003</td>
<td>105</td>
<td>2.9</td>
<td>[6; 8.1]</td>
<td>5.4%</td>
</tr>
<tr>
<td>Saez, 2004</td>
<td>83</td>
<td>2.4</td>
<td>[3; 8.4]</td>
<td>4.0%</td>
</tr>
<tr>
<td>Syriopoulou, 2005</td>
<td>55</td>
<td>1.8</td>
<td>[0; 9.7]</td>
<td>2.3%</td>
</tr>
<tr>
<td>Mast, 2005</td>
<td>182</td>
<td>3.8</td>
<td>[1.6; 7.8]</td>
<td>8.8%</td>
</tr>
<tr>
<td>Della Bella, 2005</td>
<td>26</td>
<td>10.7</td>
<td>[2.3; 28.2]</td>
<td>5.1%</td>
</tr>
<tr>
<td>Claret, 2007</td>
<td>94</td>
<td>1.1</td>
<td>[0; 5.8]</td>
<td>2.3%</td>
</tr>
<tr>
<td>Ruiz-Extremera, 2011</td>
<td>128</td>
<td>7.0</td>
<td>[3.3; 12.9]</td>
<td>9.7%</td>
</tr>
<tr>
<td>Prasad, 2012</td>
<td>23</td>
<td>8.7</td>
<td>[1.1; 28.0]</td>
<td>3.8%</td>
</tr>
</tbody>
</table>

**Random effects model**

Heterogeneity: $I^2$ = 85.9%, $P = .0003$

*Proportion % 95% CI Weight*

#### HIV-positive women

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Sample size</th>
<th>Proportion</th>
<th>95% CI</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Granovsky, 1998</td>
<td>47</td>
<td>8.5</td>
<td>[2.4; 20.4]</td>
<td>11.0%</td>
</tr>
<tr>
<td>Thomas, 1998</td>
<td>140</td>
<td>9.3</td>
<td>[5.0; 15.4]</td>
<td>23.4%</td>
</tr>
<tr>
<td>Resti, 2002</td>
<td>158</td>
<td>13.9</td>
<td>[8.9; 20.3]</td>
<td>28.8%</td>
</tr>
<tr>
<td>Ferrero, 2005</td>
<td>30</td>
<td>6.7</td>
<td>[4.8; 22.1]</td>
<td>6.4%</td>
</tr>
<tr>
<td>Ferrero, 2005</td>
<td>36</td>
<td>5.6</td>
<td>[3.7; 8.7]</td>
<td>6.4%</td>
</tr>
<tr>
<td>Claret, 2007</td>
<td>22</td>
<td>13.6</td>
<td>[2.9; 34.9]</td>
<td>8.4%</td>
</tr>
<tr>
<td>Jamiesson, 2008</td>
<td>48</td>
<td>4.2</td>
<td>[5.14; 3]</td>
<td>6.5%</td>
</tr>
<tr>
<td>Ruiz-Extremera, 2011</td>
<td>14</td>
<td>28.8</td>
<td>[8.4; 58.1]</td>
<td>9.1%</td>
</tr>
</tbody>
</table>

**Random effects model**

Heterogeneity: $I^2$ = 82.8%, $P = .1982$

*Proportion % 95% CI Weight*

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

Ades A, et al. 2022: Estimated vertical transmission to be 7.2% (95% CI 5.6-8.9); in HIV coinfected 12.1% (8.6-16.8). Overall VT rates are about 24% higher than previously thought.
Can You Prevent Transmission During and After Pregnancy?

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

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

Infant/Child Testing Guidelines
### Recommendations for HCV Testing of Perinatally Exposed Children and Siblings of Children With HCV Infection

<table>
<thead>
<tr>
<th>RECOMMENDED</th>
<th>RATING</th>
</tr>
</thead>
<tbody>
<tr>
<td>All children born to HCV-infected women should be tested for HCV infection. Testing is recommended using an antibody-based test at or after 18 months of age.</td>
<td>I, A</td>
</tr>
<tr>
<td>Testing with an HCV-RNA assay can be considered in the first year of life, but the optimal timing of such testing is unknown.</td>
<td>IIa, C</td>
</tr>
<tr>
<td>Testing with an HCV-RNA assay can be considered as early as 2 months of age.</td>
<td>IIa, B</td>
</tr>
<tr>
<td>Repetitive HCV RNA testing prior to 18 months of age is not recommended.</td>
<td>III, A</td>
</tr>
<tr>
<td>Children who are anti-HCV positive after 18 months of age should be tested with an HCV-RNA assay after age 3 to confirm chronic hepatitis C infection.</td>
<td>I, A</td>
</tr>
<tr>
<td>The siblings of children with vertically-acquired chronic HCV should be tested for HCV infection, if born from the same mother.</td>
<td>I, C</td>
</tr>
</tbody>
</table>
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.

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.

https://www.cdc.gov/mmwr/volumes/72/rr/rr7204a1.htm
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:

<table>
<thead>
<tr>
<th>Recommendation Regarding HCV Treatment and Pregnancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>RECOMMENDED</td>
</tr>
<tr>
<td>For women of reproductive age with known HCV infection, antiviral therapy is recommended <strong>before</strong> considering pregnancy, whenever practical and feasible, to reduce the risk of HCV transmission to future offspring.</td>
</tr>
</tbody>
</table>

- 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

<table>
<thead>
<tr>
<th>RECOMMENDED</th>
<th>RATING</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>I, B</td>
</tr>
<tr>
<td>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.</td>
<td>I, C</td>
</tr>
</tbody>
</table>
Many DAAs are considered pregnancy category B

Table 1. Safety Profile of New DAAs in Pregnancy

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

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

“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.”


“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 center 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

<table>
<thead>
<tr>
<th>Trial Number/Trial Phase</th>
<th>Study Design</th>
<th># of Participants (or Estimation)</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT04382404 Phase 1</td>
<td>SOF/VEL</td>
<td>10</td>
<td>Completed (CROI 2023)</td>
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<td>NCT02683005 Phase 1</td>
<td>LDV/SOF</td>
<td>9</td>
<td>Completed (Chappell CA et al. <em>Lancet Microbe</em>. 2020;1:e200-e208.)</td>
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<td>NCT05140941 (STORC) Phase 4</td>
<td>SOF/VEL</td>
<td>100</td>
<td>Recruiting</td>
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- 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.
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

Opensocietyfoundations.org
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 HCV specialist if 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


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

- Educational materials targeting pregnant people:

- Additional information on HCV prevention, screening, care, and treatment can be found at [https://www.health.ny.gov/diseases/communicable/hepatitis/hepatitis_c/](https://www.health.ny.gov/diseases/communicable/hepatitis/hepatitis_c/)

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](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.

Contact Us

For CMEs or educational opportunities, contact:

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Upcoming Webinars

TUESDAY, May 7, 2024 (4:30 - 5:30 PM EST)
Universal Screening and Vaccination to Achieve Viral Hepatitis Elimination

Presenter: Douglas T. Dieterich, MD
Director, Institute for Liver Medicine
Mount Sinai Health System
Professor of Medicine, Icahn School of Medicine

Presenter: Anna Mageras, MPH
Program Manager, Division of Liver Diseases
Department of Medicine, Icahn School of Medicine