Our experience in linkage to care and treatment initiation of HCV during pregnancy

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What strategy have we used to improve linkage to care of HCV patients and treatment of pregnant persons?

- Implemented universal HCV screening in Obstetrics in 2017
- Support from Ob/Gyn Department and partnership with Dr. Rhoda Sperling (Ob/Gyn)
- Initiated a **Women’s Liver Clinic**
  - Clinical practice co-located in Obstetrics department: provides care to pregnant and postpartum women with liver diseases
  - Close collaboration with Ob/Gyn, MFM, Adult/ pediatric ID

What was the potential rational to consider 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
What are the expert recommendations?

“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.”

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


“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”

SMFM 2017
Recent guidelines recommend that research with pregnant individuals be “promoted”

- US Federal regulations governing research removed pregnant individuals from list of “vulnerable populations”

Exclusion without justification denies pregnant individuals and fetuses access to potential health benefits

There are critical evidence gaps in treatment of pregnant individuals

There are clear benefits to initiate HCV treatment during pregnancy
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
Plan for HCV Treatment and Linkage to care in pregnancy

• Developed a departmental protocol for treatment of HCV during pregnancy with joint decisions between liver diseases specialist, Ob/gyn, pediatric ID, and patient

• Began to offer treatment to individuals referred to Women’s Liver Clinic during pregnancy

• Enrolled each patient with HCV in LEAP care coordination program at Mount Sinai
  – LEAP (Liver Education & Action Program): team of patient navigators, care coordinators, a behavioral health specialist, and peers which utilizes comprehensive care coordination to assist medical providers in improving overall outcomes related to treatment while reducing psychosocial and behavioral barriers to care.
How did it work?

23 pregnant women with active HCV infection were referred to our Women’s Liver Clinic for consideration for HCV treatment.

![Diagram showing adherence rates and reasons for loss of follow-up or treatment failure.]

Figure 1. Compliance with steps in the HCV pregnancy cascade of care.
What did we learn?

• Pregnancy care may be the only opportunity to treat HCV: benefit of co-located care to identify patients and initiate HCV treatment

• Support services including social work, care navigation, and potentially directly observed therapy to optimize compliance with HCV treatment during pregnancy and postpartum is needed.

• Given the frequent visits that typically occur during obstetric care, developing a monitoring program that takes advantage of this visit schedule would likely optimize compliance

• Increased data on the safety and efficacy of HCV treatment in the context of pregnancy would be helpful to reassure patients of the safety of treatment in pregnancy – we need more data, patients want to know data

• Improved insurance coverage that includes all DAA regimens would facilitate access to preferred agents and provide medications in a more timely fashion.

• Programs dedicated to supporting compliance with HCV treatment and follow-up, particularly during the postpartum period, are needed as we begin to identify more women with HCV during pregnancy after uptake of universal screening recommendations.
Thank you!

Please contact with any questions!

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