Treatment in Pregnancy for HepC: The “TiP-HepC” Clinical Case Registry

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Problem

• Limited interventions to reduce HCV perinatal transmission
• Poor linkage to care for HCV-positive women after pregnancy
• Limited data regarding safety of DAAs during pregnancy
• Testing recommendations without treatment recommendations

“Real-World” Questions: What do we know about DAA exposures during pregnancy in the “real-world”? Where? When? Which drugs? How are they managed? What are their outcomes?...
Opportunity

• There exists data within individual programs regarding outcomes for women exposed to DAAs during pregnancy
• Although low-frequency, if aggregated across programs, these data may be valuable evidence to inform HCV treatment decisions in pregnancy
• CGHE has a broad coalition of partners and stakeholders to potentially contribute data on these occurrences
• Experience exists with clinical case registries to generate data on safety of medications in pregnancy (e.g., Antiretrovirals)
Treatment in Pregnancy for HepC (TiP-HepC): Objectives

1. Compile the existing evidence, initiatives, and policies related to HCV testing and treatment in pregnancy
2. Develop a data sharing mechanism through a multi-country clinical case registry to document DAA exposures for pregnant women and outcomes for mother-infant pairs
3. Build a community of practice and advocacy coalition dedicated to treatment for HCV in pregnant women
The TiP-HepC Registry: Methodology

- **Design**: Retrospective, observational study using routinely-collected data
- **Method**: Secure data sharing using a structured data collection form
- **Exposures**: Maternal characteristics/co-morbidities, timing/duration of DAA exposure
- **Primary Outcomes**: Pregnancy and birth outcomes of mother-infant pairs
- **Secondary Outcomes**: Maternal HCV treatment outcome and infant HCV status
- **Analysis**: Regular descriptive analysis reviewed by oversight committee
- **Limitations**: Data completeness, data quality, comparator groups
The TiP-HepC Registry: Potential Contributors

- HepC treatment providers and centers
- National/regional HepC treatment programs
- HepC research networks
- Industry partners
- Professional societies
  - Hepatology
  - Infectious diseases
  - Ob/Gyn & MFM
  - Pediatrics
Call for Contributors

CGHE is seeking partners and collaborators to:

- **Contribute data** on occurrences and outcomes of mothers and infants exposed to DAA medications in pregnancy
- **Provide ideas, support, or case enrollment** for a prospective registry to document outcomes of mothers and infants exposed to DAA medications in pregnancy
- **Join a “Community of Practice”** to learn about current evidence and efforts in the treatment of HepC for pregnant women

Contact: globalhep@taskforce.org
Website: https://www.globalhep.org/evidence-base/treatment-pregnancy-hepatitis-c-tip-hepc-registry
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