

# Hepatitis C Treatment Exposure In Pregnancy Registry (TiP-HepC Registry)

**TiP-HepC Registry Evidence Brief No. 1**  
**March 1, 2023**



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# Hepatitis C Treatment Exposure In Pregnancy Registry (TiP-HepC Registry):

## Evidence Brief No.1

Data reported for: July 1 2022-October 31, 2022

### Purpose

The purpose of this interim policy brief is to provide consolidated and updated information from the TiP-HepC registry regarding outcomes following exposure of direct-acting antiviral (DAA) medications in pregnant individuals with chronic hepatitis C virus (HCV) infection. It is intended to inform joint decision making by patients and providers for the optimal management of HCV infection during pregnancy.

### Background

Over one-fifth of hepatitis C virus (HCV) infections occur in women of childbearing age.<sup>1</sup> At least 19 countries, including the United States, have policies or guidelines recommending universal HCV screening during pregnancy.<sup>2,3</sup> However, options for management and treatment of HCV infection during pregnancy are not well defined. Typical clinical practice is to refer and link pregnant persons for treatment after pregnancy and the breastfeeding period; however, in practice, very few are successfully linked to treatment services.<sup>4-9</sup> To date, one pharmacokinetic study and three case series have been published including safety outcomes of HCV treatment in pregnancy.<sup>10-13</sup> The American College of Obstetrics and Gynecology and Society for Maternal Fetal Medicine currently recommend that DAAs only be initiated in the setting of a clinical trial and that people who become pregnant while taking a DAA should be counseled about the risks and benefits of continuation.<sup>14</sup> The American Association for the Study of Liver Disease and Infectious Disease Society of America recommend treatment be considered on an individual basis after discussion between the patient and provider and understanding of risks and benefits of treatment.<sup>15</sup> Further background evidence can be found [here](#).

### Registry Methodology

Clinicians report outcomes of maternal-infant pairs exposed to DAAs during pregnancy to the TiP-HepC Registry through a web-based secure portal ([registry](#)). Cases submitted to the registry may be part of established clinical trials or previously published case series. Patients exposed to interferon or ribavirin are excluded. Primary adverse pregnancy outcomes are preterm delivery (<37 weeks gestational age), stillbirth or fetal demise, and maternal death. Primary adverse birth outcomes are low birth weight (<2500g, LBW), small for gestational age (SGA), neonatal intensive care, and congenital anomalies. Descriptive analysis was conducted as part of an interim data review for cases submitted through October 31, 2022. The full registry protocol is available [here](#).

## Interim Findings Summary

23 case reports were submitted in the interim period, all from the USA. 20 (87%) initiated treatment after the 1st trimester, of which all were previously published, and 9 were part of a pharmacokinetic study. Of these 20 pregnant persons, median maternal age was 32 [range 18–44] years, 10 (50%) reported injection drug use in the past 12 months, and median gestational age at treatment initiation was 187 [158–270] days. Of the 20 cases, 14 (70%) were treated with sofosbuvir/ledipasvir and 6 (30%) with sofosbuvir/velpatasvir. 16 (80%) completed treatment, and 13 (65%) had documented evidence of HCV cure. There were 14 (70%) full-term births, 4 (20%) pre-term births, and 2 (10%) unknown birth outcomes. Among 17 infants with data available, 7 had NICU admission at birth, 4 had neonatal abstinence syndrome, 1 had low birth weight, and none were small for gestational age. Among 16 infants with data, none had congenital anomalies. Among the 3 cases with 1st trimester DAA exposure, 2 received glecaprevir/pibrentasvir and 1 sofosbuvir/velpatasvir; all 3 completed treatment. Of the 3 cases with 1st trimester exposures, outcomes were available for 1 case, which was a live full-term birth with no adverse pregnancy or infant outcomes.

**Table 1. Exposures during first trimester (<13 weeks):**

Cumulative registry cases	3
Median age (range)(n=3)	32 (22–35)
Treatment regimen (n=3)	G/P=2, SOF/VEL=1
Treatment completed (n=3)	Yes=3, No=0
Median number of days of exposure in pregnancy (range)(n=2)	50.5 (45–56)
Maternal HCV outcomes (n=1)	SVR12 not achieved = 1
Pregnancy outcomes (n=1)	No pregnancy or delivery complications = 1
Any NICU admission or reported infant complication (n=1)	Yes=0, No=1
NICU admission (n=1)	Yes=0, No=1
Frequency of infant complications	None reported
Congenital anomalies (n=1)	No congenital anomaly detected =1
Infant HCV outcome (n=0)	No data

Abbreviations: G/P = glecapravir/pibrentasvir; SOF/VEL = sofosbuvir/velpatasvir

**Table 2. Exposures after first-trimester ( $\geq 13$  weeks)**

Cumulative registry cases	20
Median age (range)	31.5 (18–44)
Baseline co-morbidities or substance use	IVDU=10, opioid use=6, tobacco=6, marijuana=4, cocaine=4, mental/behavioral disorders related to OUD=4, methamphetamine=2
Median gestational age (days) at treatment initiation (range)	186.5 (158–270)
Treatment regimen	SOF/LDV=14, SOF/VEL=6
Maternal HCV treatment completion (n=17)	Completed=17, Not Completed=0, Unknown=3
Maternal HCV outcomes (n=16)	Cured=14, Not cured=2
Pregnancy outcomes (n=19)	Live-term ( $>37$ wk GA)=14, Live-preterm (34–37wk GA)=4, Unknown=1
Delivery type (n=19)	Vaginal delivery=11, C-section=5, Unknown=3
Any NICU admission or reported infant complication (n=17)	yes=9, no=8
NICU admission (n=17)	yes=7, no=10
Frequency of infant complications	Neonatal abstinence syndrome=4, Large birthweight=1, Large for GA=1, Brachial plexus injury=1, Respiratory distress syndrome=1
Congenital anomaly (n=19)	None=16, Unknown=3
Infant HCV status (by PCR 6mo or anti-HCV 18mo)	Negative=13, Positive=0

Abbreviations: SOF/LDV= sofosbuvir/ledipasvir ; SOF/VEL = sofosbuvir/velpatasvir

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