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Increasing Prevalence of Chronic Hepatitis C Virus Infection in a Southern Academic Obstetrical Clinic

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Abstract

Background: The opioid epidemic has resulted in rising rates of hepatitis C virus (HCV) infection in women of child-bearing age. With this changing epidemiology in mind, IDSA/AASLD societal guidelines were updated in 2018 to recommend screening all pregnant women for HCV infection, irrespective of risk factors. Because HCV infection can impact maternal-fetal health and result in vertical transmission, presentation for pregnancy-related medical care represents an opportunity to diagnose and manage HCV infection, as well as prepare for treatment post-partum.

Methods: We performed a retrospective chart review between 2007-2016 to examine the epidemiology of HCV infection and opioid use disorder in a Southern, academic obstetrical clinic and to explore the impact of new screening guidelines if implemented. Composite data from the electronic health record and individual chart review was used to determine rates of HCV infection and opioid use disorder in obstetrics, explore patient demographics, and examine perinatal outcomes.

Results: Rates of both opioid use disorder and chronic HCV infection increased significantly over the 10-year period of analysis. Patients diagnosed with chronic HCV infection were primarily Caucasian (95%) and there was no observed impact of HCV on perinatal outcomes. HCV testing in pregnancy, even when patients had documented opioid use disorder, was infrequent (0.7% of all pregnancies). Documented follow-up for HCV post-partum for both mothers and infants was incomplete, with only one-third of identified HCV-exposed infants referred and only 9% receiving HCV testing at our institution.

Conclusions: HCV prevalence increased between 2007-2016, but screening and treatment of HCV in this southern obstetrical cohort was infrequent. Implementation of universal screening in pregnancy will likely identify additional cases, and an improved cascade of care will be necessary to address the HCV epidemic.

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Brief Description:

Rates of HCV infection are increasing in women of child bearing age in the United States in parallel with the opioid epidemic. We examined rates of HCV infection and opioid use disorder between 2007-2016 our academic, southern obstetrical clinic and considered the impact of universal HCV screening in pregnancy. We found that screening for HCV was uncommon in pregnancy at our center and that rates of HCV infection have increased over time, consistent with observations observed in other cohorts.

Keywords

hepatitis C virus; pregnancy; opioid use disorder; obstetrics; perinatal outcomes

Introduction

Approximately 71 million persons worldwide are chronically infected with hepatitis C virus (HCV) [1]. Over the last decade, rates of HCV infection in women of reproductive age and pregnancy have increased in parallel with progression of the opioid epidemic [2–4], and thousands of children are born to HCV-infected mothers in the United States each year [5]. Some studies have linked maternal HCV infection to preterm labor and low birth weight, and HCV mother-to-child transmission can occur, although rates of pediatric follow up to detect perinatal transmission have historically been poor [2,6–10]. In the United States, HCV is a leading cause of chronic liver disease, cirrhosis, hepatocellular cancer, and liver transplantation, and for over a decade deaths due to HCV infection have exceeded those from human immunodeficiency virus (HIV) [11]. Fortunately, treatment with direct-acting antivirals (DAAs) results in a sustained virologic response (SVR), synonymous with cure, in most patients, and as such diagnosing and linking those with chronic HCV infection is important [12]. While current DAA therapies are not approved for use during pregnancy, identifying women with HCV infection during pregnancy and facilitating post-partum follow up is an important opportunity to address the HCV epidemic [2].

The American College of Obstetrics and Gynecologists (ACOG), CDC, and USPTF guidelines currently recommend risk-based screening for HCV in pregnancy [21314], although recent work has suggested this may miss a substantial number of women infected [15]. Patients who do not report a history of intravenous drug use, but who report other illicit substance use, sexual risk factors, or no risk factors, may be missed by traditional risk based screening, and guideline-based screening is often not uniform in clinical practice [1516]. In 2018, the AASLD/IDSA guidelines were updated to recommend screening for HCV infection in all pregnant women irrespective of risk factors (hcvguidelines.org), similar to screening recommendations for HIV and HBV in pregnancy.

To better understand the HCV epidemic in our Southern, academic obstetrical clinic, we performed a retrospective chart review between 2007-2016 and examined trends in the epidemiology of HCV and opioid use disorders. We asked whether there were missed opportunities for HCV testing, assessed the potential impact of HCV on maternal and perinatal outcomes, and determined the extent to which children born to HCV-infected

mothers had documented follow-up to assess perinatal transmission. Finally, we considered the impact of adoption of universal obstetrical screening recommended in the 2018 IDSA/AASLD guidelines.

Materials and Methods

We used data from the electronic medical record housed in the Medical University of South Carolina (MUSC) Clinical Data Warehouse (CDW) to identify patient cohorts of interest followed by chart level review for validation. This study received approval from the MUSC's Institutional Review Board.

We used ICD provider coding as an initial approach to identify patients with opioid use, pregnancy, and/or HCV infection (diagnoses queried listed in Supplemental File 1), followed by review of individual medical records. We intentionally searched for broad categories related to viral diseases associated with pregnancy in the event that HCV infection was not specifically coded, and used chart level review to exclude cases if viruses other than HCV were implicated (such as HBV or HIV). Outpatient encounter data was reliably recorded in the CDW beginning in 2006, and as such we defined a 10-year range of analysis by anticipated or actual date of delivery between January 1st, 2007 and December 31st, 2016. Inclusion in the dataset required an ICD code for pregnancy, at least one outpatient obstetrical visit within the time frame of analysis (based on billing and encounter codes), and either an opioid or HCV-related diagnosis code. To more broadly examine HCV testing patterns in obstetrics outside of those with diagnosed HCV infection or coded opioid use disorder, we used Slicer-Dicer, an electronic reporting tool within the EHR that permits extraction of aggregate population level data in de-identified fashion based on user-defined search terms [17].

For women delivering infants at our institution, the date of delivery was recorded. For women whom did not deliver at our institution, we used estimated date of delivery. Laboratory data were extracted to determine HIV and HCV status (antibody and viral load testing). Medication lists were searched to determine whether pharmacologic treatments were prescribed for opioid use disorder (e.g., methadone or buprenorphine), and either an ICD code for opioid use, methadone, or buprenorphine was used to define the opioid use cohort. For patients with chronic HCV infection, we determined whether referral to an infectious diseases or gastroenterology clinic had been pursued, whether patients established care, and whether treatment had been pursued post-partum.

Cohorts were defined based on opioid and HCV status, as described above. For examination of maternal data only, we defined cohorts based on known HCV status. Patients were allocated into groups denoted as chronic HCV infection (positive HCV viral load), cleared HCV infection (positive HCV antibody, negative HCV viral load), or opioid use only (documented HCV negative or HCV not tested). To examine perinatal outcomes, we considered only the subset of patients with clearly defined HCV status, excluding patients who had opioid use documented but who had never received HCV testing in our medical system, and examined only those pregnancies that resulted in a delivery at MUSC for which perinatal outcomes data were available.

Maternal characteristics evaluated included age, race, marital status, and HIV status. To evaluate maternal and neonatal characteristics of women with HCV and/or opiate abuse who delivered an infant at MUSC, we used the Perinatal Information System (PINS), an institutional research quality database maintained by internal and external audits to ensure accuracy of data abstracted from the medical record [18]. Maternal data retrieved from PINS included ethnicity, marital status, insurer, parity, weight gain in pregnancy, and number of prenatal visits. Pregnancy outcomes included gestational age at delivery, amniotic fluid volume abnormalities, diagnosis of intrauterine growth restriction , preterm labor (<37 weeks gestation), preterm premature rupture of membranes (PPROM), mode of delivery, and meconium staining of the amniotic fluid. Preterm birth (PTB) was defined as delivery <37 weeks gestation, low birth weight (LBW) was defined as delivery weight <2,500 grams, and intrauterine growth restriction (IUGR) was defined as a fetal weight <10% for the gestational age of delivery. Neonatal characteristics obtained were gender, 5 minute APGAR score, birth weight, head circumference, birth length, neonatal ICU admission, neonatal withdrawal diagnosis, respiratory distress syndrome (RDS), and neonatal death.

Not all variables associated with the PINS database were available for assessment in all subjects. In cases where fewer observations were made than the total number of subjects for any group, the denominator is lower than that reflected in the column header to demonstrate these missing data.

Statistical Analysis

Maternal and neonatal characteristics were compared between the following groups: women with chronic HCV infection, cleared HCV infection, and opiate use without HCV. The Shapiro-Wilk test was used to determine the normality of continuous variables. Continuous variables with non-normal distribution were reported as medians with a corresponding interquartile range and compared using a Wilcoxon Rank Sum Test or Kruskal-Wallis test. Bivariate outcomes were reported as percentages and compared using χ^2 tests or Fischer's exact tests. After validating normality of the data using the Shapiro-Wilk test, Pearson correlation coefficient was used to assess for an association between HCV infections and the year of study.

Results

A search of the EHR between 2007-2016 identified 199 women with at least 1 outpatient obstetrical visit during pregnancy and an ICD-9/10 code for either HCV or opioid use disorder. Examination of individual records led to exclusion of 19 patients who did not meet criteria, leaving 180 records eligible for analysis, 122 of whom delivered at MUSC and had perinatal outcomes available for analysis. Between 2007-2016, there was a significant increase in the number of pregnant women with chronic HCV infection, the number who had spontaneously cleared HCV infection, as well as the number with opioid use disorder who did not have documented HCV infection (Figure 1). The majority of women in all cohorts were white and single, and no significant difference in demographic data between the three groups was observed (Table 1). There was a high proportional rate of non-Hispanic white women in all three groups (88-100%) when compared to all women delivering at our

institution between 2010-2016 (47%). Most women in our cohort were single, HIV negative, and the majority had a history of receiving opioid substitution therapy (Table 1).

For patients with chronic HCV infection, genotype 1 and genotype 3 were the most prevalent genotypes (36% GT1a/b, 17% GT3, 3% GT2, 1% GT4, 44% not tested). Just over half of patients had a documented referral for HCV treatment, but few established care and ever fewer had documented treatment and cure (Figure 2), consistent with prior studies [19]. Among patients with opiate use disorders without known HCV infection, only 49 patients had a documented negative HCV test (48%), while 54 had not been tested (52%), indicating the potential for missed opportunities to diagnose HCV infection.

To more broadly examine HCV testing patterns in obstetrics outside of those with diagnosed HCV infection or opioid use disorder, we examined the EHR using a de-identified search tool, as described in the methods. We found that for a 4-year period for which data were available (1/1/13-12/31/16), only 123 of 16,918 pregnant women (0.7%) seen in our health care system had a documented HCV test in our EHR. During this 4-year period, 38 cases of HCV were identified among pregnant women. Considering that an estimated 1-2.5% of pregnant women in the United States have chronic HCV infection, we would have anticipated identifying 169-422 cases of chronic HCV if universal screening had been implemented during this 4-year period and US population estimates for HCV in pregnancy are similar for our patient cohort.

We next examined maternal and perinatal outcomes, as prior studies have implicated maternal HCV infection with PTB and adverse neonatal outcomes [27]. Although our study cohort was small and likely lacked the power to detect meaningful differences in this regard, we did not find any significant difference in maternal characteristics or perinatal outcomes based on HCV status (Supplemental Table 1 and Table 2). Of 35 infants born to women with chronic HCV infection, only 11 had documented referral for follow-up and only 3 had documented follow-up testing to assess transmission.

Comment

In the last ten years, documented opioid use disorder and HCV infection in pregnant women increased significantly in our Southern, academic medical center, paralleling the trend observed elsewhere in the country. Due to the use of “risk-based” screening for HCV in our practice, we estimate a significant number of women with HCV were undiagnosed during pregnancy. Given national estimates that 1–2.5% of pregnant women harbor HCV infection [2], if these numbers are reflective of HCV incidence in our patient cohort, universal HCV screening during the study period at our institution could have led to making a HCV diagnosis in up to 100 additional pregnant women per year.

Prenatal care represents an opportunity to diagnose HCV infection in patients who may not otherwise be seeking medical care. This is of particular importance for patients with a history of or active substance use, even for those received care at substance use treatment centers, where HCV screening is not routinely implemented [2021]. While 2018 IDSA/AASLD guidelines recommend screening for HCV in pregnancy regardless of risk factors, ACOG, CDC, and USPTF have heretofore endorsed testing based on risk factors (2,13).

With the introduction of DAAs, HCV is now a treatable and curable disease. Although treatment is not currently recommended during pregnancy, making the diagnosis during prenatal care may create opportunities for women who would not otherwise interact with healthcare providers to be referred for and potentially start effective treatment post-partum. Whether universal HCV screening in pregnancy is cost effective and will be implemented by other societal guidelines over time is a matter of ongoing debate and discussion within the field [22]. Ongoing transmissions of HIV and syphilis, for which screening in pregnancy is intended to be universal due to consequences of undiagnosed infection and failure of risk-based testing to identify all infected patients, will contribute as precedent for this ongoing discussion [23–25].

The majority of patients in our cohort with active or cleared HCV and opioid use disorder were white (Table 1), as compared to the overall rate of patients who delivered at our institution (47% white). While these data could reflect bias in either testing or documentation practices for HCV and opiates on the basis of patient race, they may also reflect the demographics of the HCV and the opioid epidemics that have been observed elsewhere. A laboratory-based investigation in Kentucky determined that 84% of HCV cases in women of child-bearing age were in non-Hispanic white women [3]. An evaluation of women giving birth in Tennessee identified significantly higher rates of HCV in pregnancy in non-Hispanic white women relative to non-Hispanic black (80% lower rates) or Hispanic women (70% lower rates) [4]. Further understanding of the different relative rates of HCV and opioid disorder and testing practices in our population based on patient race is an area of important future investigation.

Although only 5-10% of HCV-exposed infants contract perinatal HCV infection, appropriate newborn follow-up and testing for chronic HCV is an important public health intervention. Prior work has highlighted the often inadequate follow-up children born to HCV-infected mothers receive in order to document whether they have acquired and progressed to chronic HCV infection [26]. We found that only 11 of 35 babies born to women with chronic HCV infection had documented referral for follow-up, and of these only 3 had RNA testing subsequently performed. While this analysis does not capture testing done outside of our health care system, and thus may under estimate follow up, these data suggest incomplete follow-up to assess for the possibility of maternal to fetal HCV transmission, consistent with studies conducted elsewhere.

Our study highlights an often overlooked consequence of the U.S. opioid epidemic: chronic HCV infection among otherwise healthy, pregnant women. As a retrospective study, our data are limited by the need for documentation and coding of HCV or opioid use within the EHR, and does not capture testing performed outside of our institution. Due to likely under-diagnosis of HCV during pregnancy, our sample size to examine perinatal outcomes was small, impacting our power to identify potential differences observed in other studies. While our obstetric population is likely reflective of most academic medical centers in the Southeast, these data may not be generalizable to all practices throughout the United States.

In conclusion, we identified rising rates of HCV in obstetrics at our institution. Based on these data and the findings of others, and acknowledging the likelihood of under-diagnosis in

pregnancy as well as poor follow up of HCV-exposed infants, our obstetric and HCV treatment providers have opted to endorse universal HCV screening during pregnancy. Whether this approach will be endorsed by other societal guidelines and other institutions is a matter of ongoing debate. We have implemented an interdisciplinary approach to diagnosis, referral and follow up for HCV-infected women and their infants that we anticipate will lead to improved diagnosis and treatment rates.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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Key Points:

1. HCV prevalence is increasing in the obstetrical cohort cared for at our institution, in parallel with progression of the opioid epidemic.
2. Implementation of universal HCV screening in pregnancy would be expected to identify hundreds of additional cases.
3. Follow-up for consideration of HCV treatment after pregnancy and to assess for perinatal transmission were both low.

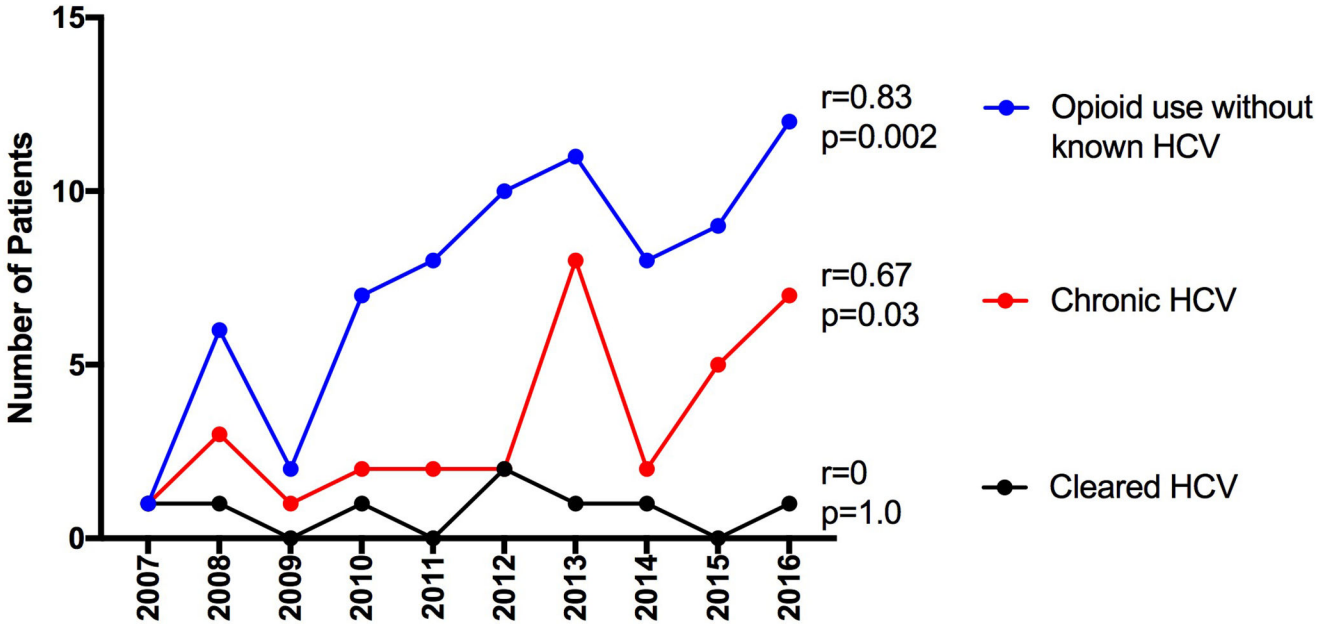

Figure 1:

Increase in the number of pregnant women with chronic HCV infection, cleared HCV infection, and opioid use disorder without known HCV infection between 2007-2016. r is Pearson correlation coefficient and $p<0.05$ was considered significant.

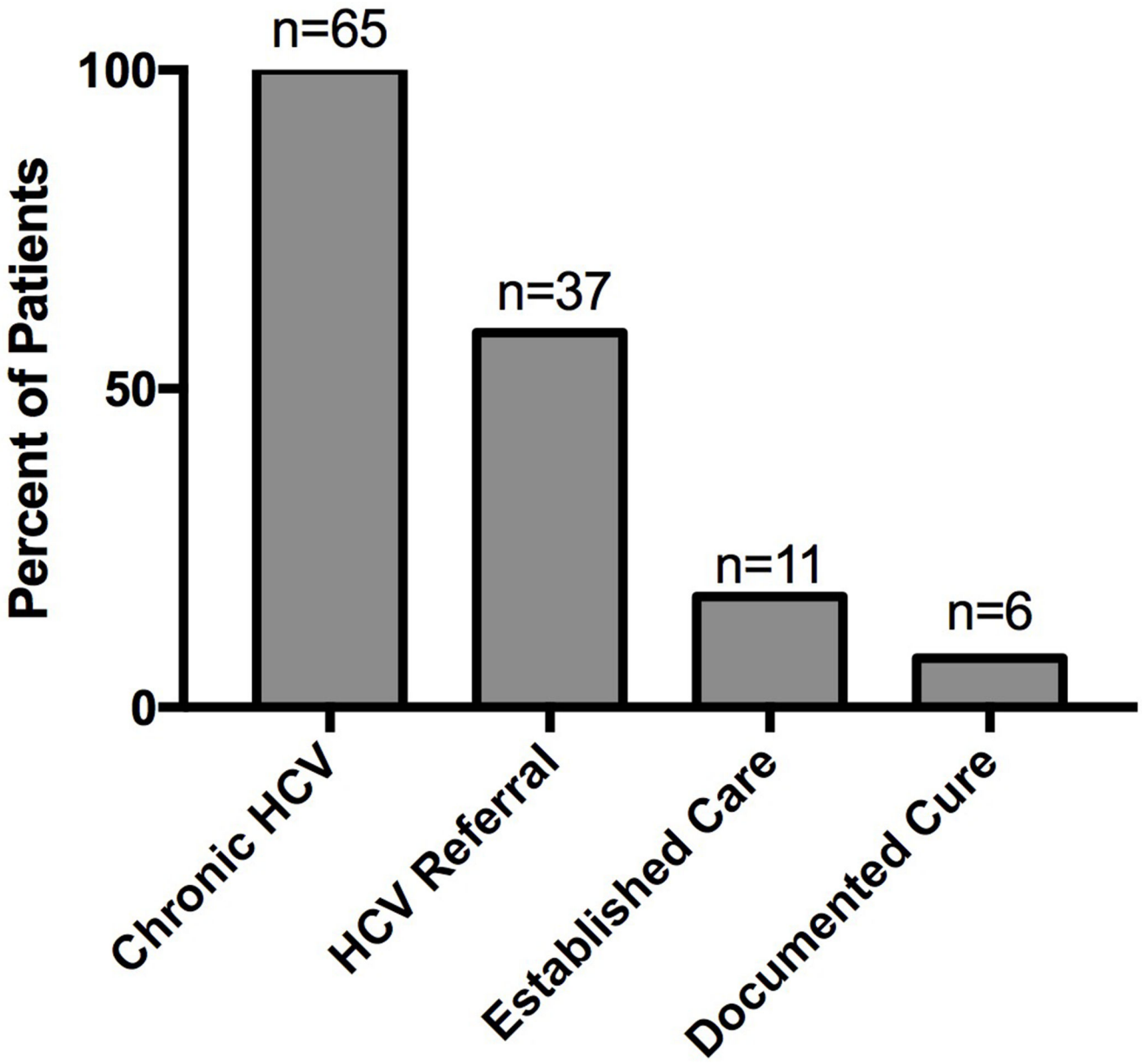

Figure 2:
Cascade of diagnosis, linkage, and referral to care for HCV infection in obstetrics. On the y-axis is the percent of patients with documented engagement on this cascade, with the absolute number of patients shown above each column.

Table 1:

Demographics of HCV and opioid use in obstetrics.

	Chronic HCV (n=63)	Cleared HCV (n=13)	Opioid use without HCV (n=104)	p-value
Maternal age, years (IQR)	27 (24-33)	29 (27-33)	29 (25-33)	0.6
Race, white (percent)	60/63 (95)	13/13 (100)	91/104 (88)	0.12
Single (percent)	52/63 (83)	7/13 (54)	79/104 (76)	0.08
HIV co-infection (percent)[a]	2/51 (4)	1/12 (8)	1/85 (1)	0.29
Opioid substitution	28/50 (56)	7/10 (70)	67/90 (74)	0.08

Continuous variables are presented as medians with the corresponding interquartile ranges and were compared using Kruskal-Wallis tests. Bivariate outcomes are represented as percentages and compared using Chi-square tests or Fischer's exact tests when the sample size was < 5 for any outcome.

[a] = HIV co-infection defined as a subject with a diagnosis of HIV infection. For HIV co-infection and opioid substitution, not all patients in each cohort had a documented result in our medical record.

Table 2:

Neonatal outcomes for those who delivered at MUSC

	Chronic HCV Infection (n=35)	Opioid Use Without HCV Infection (n=87)	p-value
GA at delivery	39 (38-40)	39 (37-39.2)	0.35
Polyhydramnios	4/35 (11)	5/87 (6)	0.28
Oligohydramnios	0/34 (0)	2/87 (2)	0.37
PPROM	1/34 (3)	7/87 (8)	0.44
PTL	1/34 (3)	10/87 (12)	0.18
PTD	2/34 (6)	15/87 (17)	0.15
Meconium	7/34 (21)	11/87 (13)	0.27
Cesarean delivery	13/35 (37)	39/87 (45)	0.44
APGAR 5 minute	9 (9-9)	9 (8-9)	0.12
Birth weight	3219 (2842-3525)	3045 (2730-3396)	0.51
LBW (< 2500g)	3/34 (9)	15/87 (17)	0.39
IUGR	3/35 (9)	8/87 (9)	1.0
HC	33.5 (32.5-35)	33.5 (32-35)	0.83
length	49.3 (48-51)	49 (47-50.8)	0.48
Infant gender male	17/34 (50)	48/87 (55)	0.61
NICU admission	2/34 (6)	12/87 (14)	0.35
Neonatal withdrawal	8/34 (24)	37/87 (43)	0.06
RDS	1/34 (3)	9/87 (10)	0.28
Neonatal death	0	2/87 (2)	1.0

Continuous variables are presented as medians with the corresponding interquartile ranges and were compared using Wilcoxon Rank Sum Tests. Bivariate outcomes are represented as percentages and compared using Chi-square tests or Fischer's exact tests when the sample size was < 5 for any outcome. Multiple variables were missing for one of the subjects with chronic Hepatitis C infection. The denominators in the 2nd column reflect these missing data.