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Opioid Epidemic and Rising Maternal HCV Rates: What You Need to Know.

ANNOUNCER INTRODUCTION:
Welcome to CME on ReachMD. This activity entitled: Hot Topics in HCV, A Multidisciplinary Online Mini Curriculum, Activity 2, the Dual Realities of the Opioid Epidemic and Rising Maternal HCV Rates, What the OB/GYN Needs to Know is jointly provided by Global Education Group and Integritas Communications, and is supported by an educational grant from AbbVie Incorporated. Prior to beginning the activity, please be sure to review the faculty and commercial support disclosure statements as well as the learning objectives.

DR. FRANCO:
Welcome to Activity 2 in this three-part Hot Topics in HCV Mini Curriculum, the Dual Realities of the Opioid Epidemic and Rising Maternal HCV Rates, What the OB/GYN Provider Needs to Know. I am Ricardo Franco, Associate Professor of Medicine in the School of Medicine, Division of Infectious Diseases at the University of Alabama at Birmingham in Birmingham, Alabama. And with me today is Dr. Catherine Chappell, Assistant Professor in the Department of Obstetrics, Gynecology and Reproductive Sciences at Magee Women Research Institute in Pittsburgh, Pennsylvania. Welcome, Dr. Chappell.

DR. CHAPPELL:
Thank you, Ricardo, it's really nice to be here.

DR. FRANCO:
Let's get started. Catherine, we know that HCV infection is a serious health consequence of injection drug use, yet, in the context of women's health, we see further risks and consequences for mother and child. Would you please give us a snapshot of the current HCV epidemiology and trends among women of reproductive age?

DR. CHAPPELL:
Thanks, Ricardo. Yeah, so what we've seen over the last decade or so is a really a shift in the epidemiology of hepatitis C, from that have predominantly baby boomer generation shifted downwards to a younger population, including women of reproductive age. And what we see is this is due to the opioid epidemic. So those - that population that's affected by the opioid epidemic, it's also affected by hepatitis C. We see a predominantly non-Hispanic white population, less support, so less likely to be married, more likely to be on Medicaid, more likely to use other substances such as cigarette smoking.

DR. FRANCO:
It is striking when you look at that bimodal distribution of hep C prevalence, how that curve has changed over the years. It looked so much different than 15 years ago, when we had a clear predominance among the baby boomer population to see that dramatic change so fast.

Catherine, how does epidemiology manifest in the OB/GYN practice level, will of course, vary by region, in demographics, but we also know that there is hidden disease within any practice. So if you could please tell us how can the OB/GYN provider best assess the impact of hepatitis C in their practices?

DR. CHAPPELL:
Back in 2018, the AASLD and IDSA came forward to recommend universal screening in pregnancy. So every pregnant woman should

be screened for hepatitis C, that's what they recommended. But it wasn't till this year till the American College of Obstetrics and Gynecology and the Society of Maternal Fetal Medicine, actually also supported universal hepatitis C screening. And it's exactly - the reasoning behind it is exactly what you mentioned. It's because this is a hidden epidemic, and you cannot know some of the risk factors for hepatitis C just meeting somebody with their first prenatal visit.

How should an OB/GYN screen for hepatitis C in their practice? You want to make sure you order the right test. You want to first make sure you order the hepatitis C antibody test but also make sure it's the hepatitis C antibody test that is reflex to the hepatitis C RNA test. That means if the hepatitis C antibody test is positive, that the hepatitis C RNA test will automatically be ordered and the patient will not have to come back for another blood draw.

We know that pregnancy is really an excellent window of opportunity for screening for other infections. We screen routinely for HIV and for hepatitis B. So why not also add hepatitis C. It's so easy to implement because we're already getting all those other blood draws.

And if we identify all the cases of hepatitis C among pregnant women, we can actually link moms to care and actually know which babies to screen for perinatal transmission. And multiple studies have shown that hepatitis C is - universal hepatitis C screening is highly cost effective.

DR. FRANCO:
So now, we know that standardizing HCV testing helps to reduce the stigma surrounding opioid use disorder; yet, that is only the first step. Whether it's routine practice, or especially if your patient has tested positive for HCV. Catherine, what do you think are the effective approaches for normalizing and destigmatizing behavioral risk inquiries in the OB/GYN setting?

DR. CHAPPELL:
You know, substance use disorders are among the most stigmatized of all chronic medical disorders. And so it's really important that providers understand that opioid use disorder and all substance use disorders are actually a chronic medical illness.

So what's really important in order to fight stigma is actually to make a standardized practice of screening for substance use disorder within your practice. Make it standard with every patient, not just patients that you may judge to be at risk of a substance use disorder, because we know that that is highly inaccurate. Also, it's exceedingly important to treat the substance use disorder in the con - in the larger context of a patient's life, understanding that the substance use disorder may have come about by some history of trauma or some history of mental health disorder.

DR. FRANCO:
Catherine, I totally agree and this staggering impact of opioid use disorder as we're struggling through, it's really causing the change in culture, a more accepting and compassionate culture, and really fostering the creation of comprehensive addiction in pregnancy programs.

DR. CHAPPELL:
We really want to focus also on harm reduction. Harm reduction is a set of practical strategies that reduce the negative consequences of drug use. Incorporating a spectrum of strategies from safer use, to managed use, to abstinence, there is a wealth of information education, counseling, and outreach that is specific to the substance use disorder and the other co-occurring conditions that I mentioned. Of course, there's medication-assisted treatment, syringe exchange, combined mental health with opioid treatment centers. Having comprehensive services available is critical to harm reduction within this patient population.

DR. FRANCO:
Well said, Catherine.

Switching gears now, HCV in pregnancy impacts both maternal and child health, potentially with long-term consequences. Would you walk us through, please, the key concerns from the prenatal until postpartum periods?

DR. CHAPPELL:
From a hepatitis C standpoint, there's quite minimal impact of hepatitis C that we are aware of in pregnancy. There does seem to be some slight increased risk of gestational diabetes and intrahepatic cholestasis of pregnancy. I will mention intrahepatic cholestasis of pregnancy is associated - has a higher risk of stillbirth.

There's also some significant neonatal outcomes that are that are associated with hepatitis C, such as preterm birth, low birth weight, admission to the neonatal ICU. There's also some data that there might be increased risk of congenital anomalies. However, it's hard to really know if these outcomes are exactly due to hepatitis C, or the co-occurring substance use disorders.

And of course, one of the most significant risk of hepatitis C in pregnancy is the risk of vertical hepatitis C transmission. The risk of

infection or transmission with hepatitis C mono infection is anywhere between 4 and 8%. And now this risk of infection only occurs for women that are hepatitis C RNA positive, okay. Also, there's a double that risk for women that are co-infected with HIV and hepatitis C.

Risk factors for maternal to child transmission are a prolonged rupture of membranes, obstetric procedure that increase the maternal to child blood transmission, such as internal fetal scalp electrode monitoring, or vaginal laceration or operative delivery. And also, active maternal injection drug use increases the risk.

There are few factors that are not associated with the increased risk of perinatal transmission. One is mode of delivery, vaginal birth versus Cesarean sections. Unfortunately, there's no test for hepatitis C at birth.

So actually, the guidelines recommend waiting until 18 months to actually test for hepatitis C antibody. And as you can imagine, it's hard to remember the perinatal exposures that occur waiting 18 months to actually do that test. So some people are doing hepatitis C RNA tests between 2 and 6 months. Unfortunately, screening for perinatal hepatitis C is only done between 11 and 30% of the time, and we really need to do a better job of this.

DR. FRANCO:
As of 2020, since last year, as recent as that, the American Association for the Study of Liver Disease and Infectious Diseases Society of America have opened the door for consideration of HCV treatment during pregnancy on a case-by-case basis, even in the absence of a formal recommendation. Catherine, what do you think are the key arguments for and against HCV treatment during pregnancy? And what is the current prevailing opinion as a person I know is one of the few in best position to perhaps take on this very challenging question?

DR. CHAPPELL:
Thanks, Ricardo. You're right, there are a lot of really great reasons to consider hepatitis C treatment in pregnancy.

For one, we know that accessing this population of women of reproductive age is really challenging. And what we know from clinical studies is that the postpartum period really has a very high loss to follow-up rate. And it’s a really hard time. There's a high rate of drug use relapse. You know, many young new mothers are not sleeping through the night and it's a really tough time to start a new healthcare intervention.

Pregnancy might be the ideal time, while a woman is engaged in prenatal care to treat hepatitis C. Also, during prenatal care, women have insurance coverage, and that insurance covered could also cover the hepatitis C treatment. And so really the only argument against hepatitis C treatment during pregnancy as of right now is that there's not enough data on safety.

Now our group did a Phase 1 study of ledipasvir/sofosbuvir in pregnant women. This was a very small PK study, it was very difficult to enroll. We - and ledipasvir/sofosbuvir as you know, only treats genotype 1, 4, 5, and 6. But even with that, we screened 29 patients, we had to exclude 20 of those. So after all 9 participants were enrolled, all 9 completed the study medication delivered and were retained. None of the patients were lost to follow-up. After all the infants delivered, they were enrolled and were followed for an entire year, just to look and make sure that there were no adverse effects from the medication that they were exposed to in utero.

And what did we find? We found that these - that the treatment was safe among these 9 participants. We only had 5 maternal-related adverse events. That included nausea, vomiting, fatigue, and headache, all very common adverse effects of medication, and also pregnancy. None of those side effects were greater than grade two. We had all of our patients except for one delivered at term, greater than 37 weeks. One delivered preterm due to severe preeclampsia. All infants were of normal birth weight. Infants did stay in the hospital a little bit longer for those 4 that were exposed to opioids during pregnancy, due to observation or treatment for neonatal opioid withdrawal syndrome. There were no infant-related adverse events, and none of the infants had perinatal hepatitis C transmission.

And we asked the women that were enrolled in our study what they really thought about treatment during pregnancy. And they thought that this treatment really increase their self-esteem, sense of well-being. They felt accomplished, they had achieved something. And they really thought that this might be protective against relapse. And one participant described the treatment in pregnancy is life-saving.

So from our first study, it seems based on these 9 participants ledipasvir/sofosbuvir administration during pregnancy was safe and affective, it resulted in 100% cure rate. But future studies should consider the use of a pangenotypic regimen, a regimen that can treat all types of hepatitis C. And we're actually conducting that study right now with sofosbuvir/velpatasvir.

And then, of course, a larger study must be conducted to confirm the safety and efficacy of hepatitis C treatment during pregnancy, before it can be incorporated into the guidelines and recommended widely.

DR. FRANCO:
So how can OB/GYN providers and HCV treaters best collaborate to optimize the odds for HCV care, and cure following pregnancy and

ideally, before the patient's next pregnancy?

DR. CHAPPELL:
They need to collaborate together to really find a concrete referral pathway. So – and this may include a colocation of the hepatitis C treatment with the prenatal care. I also think it's a great idea for the pregnant woman to be referred and see a provider for hepatitis C treatment during pregnancy, even if there - the plan is for postpartum treatment, so they can, you know, create a relationship together.

And also it's really important to educate our patients and make sure that they're aware about the ease of treatment, the tolerability of treatment, where they can get treatment, where their partners can get treatment, and also to inform our patients about the risk of perinatal transmission, and let them know that they may need to remind their pediatrician to test their newborn for hepatitis C when they turn 18 months.

DR. FRANCO:
Thank you, Catherine, for this great conversation.

DR. CHAPPELL:
Thank you, Ricardo for this great conversation.

DR. FRANCO:
And thank you to our viewers for joining us.

For additional clinical resources, please visit exchangecme.com/hottopicsHCV. And remember to complete the post-test and evaluation form to claim your credit. Please be sure to view the other two activities in this Hot Topics in HCV Mini Curriculum which are Treating Hepatitis C in Primary care and the Impact of the COVID-19 Pandemic on Vulnerable Populations. Thank you.

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