Medication Prescribing for Pregnant and Childbearing-aged Women: Resources for the Practicing Clinician

A webinar from the American Academy of Pediatrics and the Centers for Disease Control and Prevention National Center on Birth Defects and Developmental Disabilities

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QUESTION & ANSWER

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This document includes a summary of major questions presented by participants that were not answered during the live webinar due to time constraints. Answers have been provided by Dr Christina Chambers.

Question	Answer
Who runs the "pregnancy registries?" Could you explain what a pregnancy registry is?	• Pregnancy registries are studies that are initiated to try to determine if a medication might be harmful to the developing baby. They identify pregnant women who have taken a certain medication (have the exposure of interest) and follow their pregnancies to determine what the outcomes of those pregnancies are. Since some pregnancies will have an adverse outcome anyway (e.g., there is about a 3% risk for birth defects in the general population), it's important to compare the birth outcomes among women who have taken the medication to those who have not to see if there is any "excess" risk that might be due to the drug. Some pregnancy registries are run by the pharmaceutical company who makes the medication being studied, and some pregnancy registry type studies are conducted by others, such as MotherToBaby, although funding to support most pregnancy registries comes from the pharmaceutical industry. Click here to see a list of pregnancy registries through the Federal Drug Administration.

Can you please address the use of Zofran (Ondanestron) and increased risks of birth defects? If all other measures fail during the treatment of N&V of pregnancy, can it be prescribed?	• As discussed briefly on the webinar, the data on ondansetron are conflicting, and in my opinion, there is insufficient information to know at this point if there is an increased risk for birth defects with this drug. It's important to keep in mind that there are clinical situations where a particular drug is the best choice or the only choice for treatment, and this factor has to be considered when lack of treatment could be harmful to the mother and her baby.
Can any of your presenters address the question of neurobehavioral effects on children exposed to antidepressants during pregnancy?	• These studies are just emerging now. There have only been a few small studies conducted in children of different ages and addressing different outcomes – a few have looked at such things as cognitive ability, motor skills, and autism. In my opinion there is insufficient data to say much that's very definitive at this point. Good quality studies of prenatal exposure to antidepressants and neurodevelopment are hard to do – in part because the mother's underlying depression or other psychiatric disorder might play a role in the child's environment, and in part because so many other factors other than prenatal medication exposure could contribute to child development. However these studies are not impossible, and in the coming years, we expect to see more good quality studies become available.
What is the risk of occasional use of Butalbital as needed for headaches in pregnancy?	• The primary concern for barbiturates used for headaches would be dependence and withdrawal with frequent use.
What is the minimum length of exposure to these drugs to cause defects?	• Not sure if this question refers to barbiturates or to any medication in pregnancy. If the latter, the minimum length to cause birth defects could be very short for a drug like isotretinoin. We don't really know for most medications how long the exposure needs to be to meet the threshold of increased risk, but for most of the known human teratogens, we do know that there are critical times in pregnancy when there is increased risk, and the longer the exposure, higher the dose, within that critical window in gestation, we suspect would pose higher risk.
When will the slides be available? Will the presentation be emailed to us?	• A recording of the webinar and copy of the slide presentation will be publically available for download on the American Academy of Pediatrics (AAP) Web site in approximately one week. An email notification will be sent to those who registered for the webinar when the materials are posted. The recording and slides are available for non-AAP members.
What about all women of childbearing age taking a prenatal vitamin?	• The U.S. recommendation has long been that women of childbearing age take 400 mcg of supplemental folic acid to provide additional protection against folate-sensitive birth defects, whether or not they are planning a pregnancy.

Since we are using antibody therapies (IgG) therapies should we be concerned about specific agents?	• Thinking this question relates to immunoglobulin replacement therapy for individuals with immunodeficiency diseases? I do not believe that these specific therapies have been studied in human pregnancy. Theoretically, the treatment would be replacing immunoglobulins that would normally be already present in a healthy woman; however, as with any treatment, human data on pregnancies would help to answer this question.
As home visiting nurses to pregnant moms, we find the moms who have been taken off psychotropic meds self-medicate with marijuana. How should the visiting nurse work with those clients?	• This is a dilemma. For example, while there is a large volume of data on antidepressant use in pregnancy, there is by no means universal consensus on the findings of these studies, and some practitioners will recommend discontinuation of these medications in pregnancy as a precaution. The use of marijuana in pregnancy has been studied in years past, but new studies are needed with emerging new patterns of use. The American College of Obstetricians and Gynecologists has come out with the recommendation that marijuana be avoided in pregnancy, and certainly this seems prudent until more current data are available.
Are there any CEUs offered for this webinar	• No continuing education was offered for this webinar.
Is the latest birth defect work related to some of the work related to maternal use of antidepressants and incidence of autism in children? Or, are birth defects definitionally distinct from that sort of developmental disability?	• Some people think of teratogens as agents that cause birth defects – but more broadly defined, teratogens are agents that interfere with normal development of the embryo or fetus, and this could manifest itself in a wide range of outcomes, including neurodevelopmental deficits. Many of the known human teratogens that are linked with increased risks for birth defects, in fact, are already associated with neurodevelopmental problems as well, including valproic acid and isotretinoin. It is also possible that a human teratogen is not clearly linked to birth defects that are visible to us in the baby, but is associated with effects on the brain leading to neurodevelopmental consequences. A good example is prenatal exposure to lead.
Are ARBs teratogenic like ACEI?	• I don't believe each drug in the ARB class has been individually well- studied in human pregnancy, but the ARBs work through the same mechanism as ACE I's – through the renin-angiotensin system – and reports of pregnancy outcomes that are similar to those seen with ACE Inhibitors leads to the thinking that both ARB's and ACE I's can lead to the characteristic "fetopathy" when taken in the second and/or third trimester.