MotherToBaby Services for Counseling on Exposures in Breastfeeding: When More TLC is Needed

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Disclosures

- Receive research grant funding for the study of medications and vaccines in pregnancy from
 - Amgen
 - AbbVie
 - UCB
 - Segirus
 - Pfizer
 - Celgene
 - Bristol Myers Squibb
 - GSK
 - Janssen
 - Roche Genentech
 - Sanofi/Genzyme
 - Teva
 - Sandoz
 - Novartis



MotherToBaby Services

- 15 Services located throughout the U.S. and Canada
- Network established over 25 years ago
- Funded by State and regional sources, HRSA-MCHB
- Responded to a need for personalized and extensive education for women about exposures either anticipated or those that have already occurred



MotherToBaby Services

- Provide toll-free telephone information to women, health care providers regarding safety of medications and other exposures during pregnancy and breastfeeding; email, chat, text options
- Respond to approximately 80-100,000 contacts in English or Spanish each year using a regional toll-free routing system



MotherToBaby Services

- Approximately 1/3 of contacts are from providers
- Approximately 1/3 of contacts are specifically about breastfeeding
- Opportunity to counsel women during pregnancy about chronic medications that may be required during breastfeeding



http://mothertobaby.org 866-626-6847 phone; 855-999-3525 text



Medications & More During Pregnancy & Breastfeeding
Ask The Experts

SCHOOL OF MEDICINE

Why women contact MotherToBaby with a breastfeeding question

Concerned she has to stop breastfeeding or not take the drug

 AAP states common reason for breastfeeding cessation is use of medication by breastfeeding mothers, who are advised by their physicians to stop nursing if they take the drug

Sachs HC et al, Pediatrics, 2013



Breastfeeding among Women Exposed to Antidepressants during Pregnancy

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Abstract

This prospective cohort study compares the breastfeeding outcomes of women exposed to selective serotonin reuptake inhibitor (SSRI) antidepressants at the time of delivery, those who discontinued use prior to delivery, and those not exposed. Participants include 466 pregnant women who enrolled in the California Teratogen Information Service Clinical Research Program (CTIS) over 10 years. In bivariate analyses, breastfeeding rates were significantly different across SSRI exposure groups, with unexposed women having the highest rates. We used logistic regression to examine the relationship between SSRI exposure and breastfeeding outcomes. After adjustment for potential confounders, those exposed to an SSRI both prior to delivery (odds ratio [OR], 0.43; 95% confidence interval [CI], 0.20-0.94) and at the time of delivery (OR, 0.34; 95% CI, 0.16-0.72) were significantly less likely to initiate breastfeeding as compared to unexposed women. Women exposed to an SSRI during pregnancy appear to be at risk for poorer breastfeeding outcomes and may benefit from additional education and support.

Lack of consensus sources of information

Table 2. Comparison of the Content of Official Information and Other Scientific Sources

Therapeutic category, drug	Regulatory agencies		Scientific sources	
	HMA/EMA	FDA ¹⁰	Hale class ⁶	LactMed11
ACE inhibitors Captopril Enalapril	0	Ø	•	•
Calcium channel blockers Nifedipine Verapamil		Ø		•
Beta-blockers Atenolol Propranolol	0	0		0
Alpha-adrenergic agonist Methyldopa	0	0	•	
Diuretics Furosemide Indapamide	•	0	0	0
Angiotensin II receptor antagonists Losartan Valsartan		()	0	0



How MotherToBaby provides information about breastfeeding exposures



Fact Sheet

by the Organization of Teratology Information Specialists (OTIS)

For more information about us or to find a service in your area.

call (866) 626-6847. Visit us online at www.MotherToBaby.org

Find us! Facebook.com/MotherToBaby or @MotherToBaby on Twitter

Valproic acid and Pregnancy

In every pregnancy, a woman starts out with a 3-5% chance of having a baby with a birth defect. This is called her background risk. This sheet talks about whether exposure to valproic acid may increase the risk for birth defects over that background risk. This information should not take the place of medical care and advice from your health care provider.

What is valproic acid?

Valproic acid is a medication that has been used to control seizures in the treatment of epilepsy, and to treat bipolar disorder and migraines.

I have been taking valproic acid for many years. Can this make it harder for me to get pregnant?

This is possible. Studies have found that women with seizure disorders and women with bipolar disorder might have menstrual problems and difficulty getting pregnant. In addition, valproic acid might increase the chance of menstrual problems.

I am taking valproic acid, but I would like to stop taking it before becoming pregnant. How long will valproic acid stay in my body?

Each person's ability to break down the medication can be different. Liver disease can affect the amount of time it takes for your body to clear this medication. On average, it takes 2-3 days after your last dose for valproic acid to leave your body.

If possible, women with epilepsy or bipolar disorder who are planning a pregnancy or could become pregnant should discuss their treatment options with their healthcare provider before becoming pregnant.

What could happen to my baby if I stopped taking my valproic acid and then had a seizure during my pregnancy?

Pregnant women should not change seizure medications (anticonvulsants) during pregnancy without the advice of a healthcare provider. Having a seizure while pregnant may be harmful to the baby. Complications for your baby depend on many things, such as the type of seizure, how long the seizure lasts, and the number of seizures that happen. Epileptic seizures can cause periods of time when the baby is not getting enough oxygen. Not having enough oxygen could lead to brain damage and problems with development. These seizures could also be life-threatening for both mother and baby. A seizure could cause a mother to fall or have an accident that could injure herself or her baby.

What could happen to my baby if I stopped taking my valproic acid and then had a relapse of bipolar disorder during my pregnancy?

Pregnant women with bipolar disorder should not stop or change their medications during pregnancy without the advice of a healthcare provider. Women with bipolar disorder who stop taking medication during their pregnancy may be at an increased risk for episodes of depression or mania that could be harmful to both the mother and the baby. Recurrence of depression or mania is very stressful for the mother and her family. During mania or depressive episodes, the pregnant woman may have more trouble taking care of herself and keeping herself safe.

Can taking valproic acid during my pregnancy cause birth defects?

Yes. Studies have found that women who take valproic acid have a greater chance of having a baby with a major birth defect. Birth defects are typically classified as major if they will need surgery to repair the birth defect. The chance of a birth defect seems to be greater with higher doses of valproic acid or with taking more than one seizure medicine. Some birth defects that are more likely to happen if a mom took valproic acid in the first trimester are heart defects, cleft lip, or a neural tube defect (an opening in the baby's spine or brain). The most common neural tube defect associated with valproic acid is spina bifida. The chance of a neural tube defect is approximately 1-2%. Taking extra folic acid before trying to get pregnant and in early pregnancy might help reduce the chance of some birth defects in pregnancies exposed to valproic acid. Talk to your health care provider about how much folic acid you should take. Folic acid is found in foods and in vitamin supplements. Some babies exposed to valproic acid may also have more minor birth defects like facial differences, such as a thin upper lip.

Will taking valproic acid during my pregnancy affect my baby's development or behavior?

An increased chance for behavior and learning problems has been seen in babies who were exposed to valproic acid during pregnancy.

Should I stop taking valproic acid during my pregnancy?

You should never stop taking any medication without first discussing it with your health care provider. The possible benefits of taking valproic acid to treat your specific illness must be weighed against the possible risks to the pregnancy.

I have been taking valproic acid for the last few years and I just found out I am pregnant. What tests are available to see if my baby has spina bifida or other birth defects?

Prenatal testing for neural tube defects is available in pregnancy. A blood test can be done to measure the amount of a substance called alpha fetoprotein (AFP) in the mother's blood. We know that babies with spina bifida have higher levels of AFP. If the AFP is higher than usual, more testing may be offered to you to assess if the baby has birth defects.

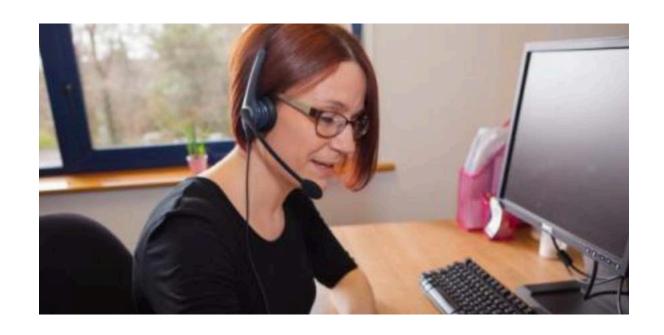
An ultrasound that looks at the baby's spine may also detect spina bifida. Ultrasounds can also screen for other structural birth defects like a heart defect or cleft lip. All of these prenatal testing options can be discussed with your healthcare provider. There are no tests available during a pregnancy that can tell if there has been any effect on behavior or ability to learn.

Is it safe to breastfeed while taking valproic acid?

Yes. Valproic acid is passed into breast milk, but at low levels and seems to be compatible with breastfeeding. There is concern that breastfed infants whose mothers are taking valproic acid are at risk for liver toxicity, so the infants should be monitored for any changes or problems. Be sure to discuss all your choices for breastfeeding with your health care provider.

What if the father of the baby takes valproic acid?

Valproic acid may have effects on sperm shape and movement that could make it harder to get pregnant. In general, medications that the father takes do not increase risk to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures and Pregnancy at http://www.mothertobaby.org/files/paternal.pdf



Individualized counseling process

- Respond to a question specifically posed by the caller about a breastfeeding exposure
- Elicit information from a caller about her potential breastfeeding exposures
- Ask the mother what she has heard/read and where, what she is concerned about, what she already knows about the exposure, and if she has received conflicting information
- Obtain details about the exposure(s)



Individualized counseling process

- Specific medication(s)
- Route of administration
- Dose
- Indication and length of treatment
- Age of the infant
- Gestational age of newborn)
- Breastfeeding experience
- Other sources of infant nutrition



Review the resources and the primary literature

- LactMed
- ReproTox
- Briggs: Drugs in Pregnancy and Lactation
- Schaefer: Drugs During Pregnancy and Lactation
- Hale: Medications and Mother's Milk
- Any new publications in the recent past
- Consult with an external expert



Communicate the summary information

- In English or Spanish
- Summarize in a way that she can understand
- Engage her in a dialogue about the information, her desire to breastfeed and the options
- Ask for feedback from the woman on the information received
- Offer to talk to her physician
- Refer to her physician for concerns that arise
- Encourage call-back with more questions, clarification, or additional concerns



Other considerations that can be covered

- Does the mother really need to use the product?
- If there is concern, or no data, are there other options that would be effective?
- Topical vs. oral product?
- Another medication?
- Non-medication treatment?
- Combination products when only selected ingredients are needed?

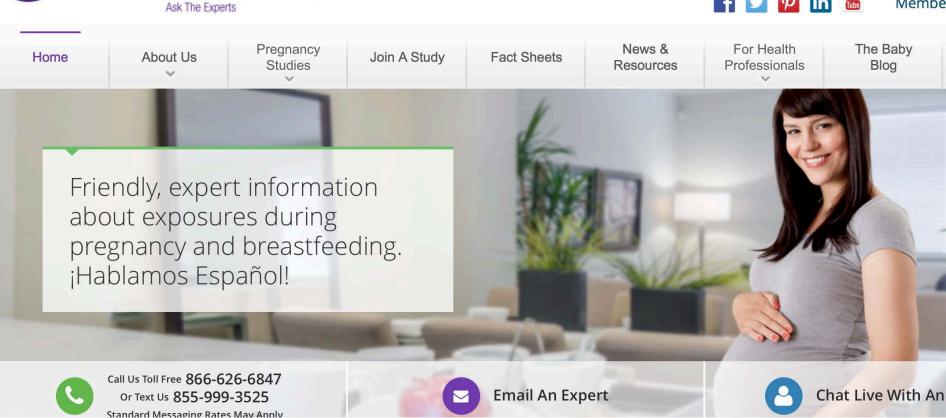








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