

Hard to find good info on drug safety in pregnancy

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This photo taken March 10, 2013 shows non-prescription drugs displayed at a pharmacy in New York. Nearly every woman takes a medication at some point during pregnancy. Yet there's disturbingly little easy-to-understand information about which drugs pose a risk to her baby, and what to do about it. (AP Photo/Seth Wenig)

Nearly every woman takes a medication at some point during pregnancy. Yet there's disturbingly little easy-to-understand information about which drugs pose a risk to her baby, and what to do about it.



Need some pain relief? In the fine print is the warning that <u>painkillers</u> like Advil aren't for the third trimester. Left unsaid is whether to worry if you took them earlier.

An awful cold? Don't panic if you used decongestant pills, but doctors advise a nasal spray in <u>early pregnancy</u>.

And don't abandon antidepressants or epilepsy medicines without talking to your doctor first. Some brands are safer during pregnancy than others—and worsening depression or seizures aren't good for a mom-to-be or her baby.

"To come off of those medications is often a dangerous thing for the pregnancy itself," warns Dr. Sandra Kweder of the <u>Food and Drug</u> <u>Administration</u>. "They need information on what to expect, how to make those trade-offs."

A new study shows how difficult that information is to come by.

Women often turn to the Internet with pregnancy questions. But researchers examined 25 pregnancy-related websites and found no two lists of purportedly safe drugs were identical. Twenty-two products called safe on one site were deemed risky on another.

Worse, specialists couldn't find evidence to back up safety claims for 40 percent of the drugs listed, said Cheryl Broussard of the <u>Centers for Disease Control and Prevention</u>, who led the recent study.

"The reality is that for most of the medications, it's not that they're safe or not that's the concern. The concern is that we just don't know," she said.

Broussard experienced some of that confusion during her own two



pregnancies—when different doctors handed over different lists of what was safe to use.

It's a growing dilemma. The <u>CDC</u> says medication use during the <u>first</u> <u>trimester</u>—especially vulnerable for birth defects because fetal organs are forming—has jumped 60 percent in the <u>last three decades</u>. Plus, women increasingly are postponing pregnancy until their 30s, even 40s, more time to develop a chronic health condition before they're expecting.

The CDC is beginning a Treating for Two program to explore how to get better information, and the FDA plans to revamp prescription drug labels with more details on what's known now. But people want an easy answer—use it or don't—and for many drugs, they won't get one anytime soon.

"Women agonize over it," said Dr. Christina Chambers of the University of California, San Diego. She helps direct California's pregnancy risk information hotline that advises thousands of worried callers every year.

Some drugs pose particular birth-defect risks. For example, the FDA requires versions of the acne drug isotretinoin, first marketed as Accutane, to be sold under special tight controls. Similarly, last year FDA said women who want to use a new weight-loss drug, Qsymia, need testing first to be sure they're not pregnant.

Other medications are considered safe choices. Obstetricians say pregnant women need a flu shot, for example. A recent massive study in Denmark offered reassurance that taking the anti-nausea drug Zofran for morning sickness won't hurt the baby.

But many drug labels bear little if any details about pregnancy. Drugmakers shy from studying pregnant women, so it can take years for



safety information to accumulate. Moreover, the CDC says 1 in 33 babies has some type of birth defect regardless of medication use. It can be hard to tell if a drug adds to that baseline risk.

Consider antidepressants, used by about 5 percent of pregnant women. Certain brands are suspected of a small risk of heart defects. Studies suggest a version called SSRIs may increase risk of a serious lung problem at birth—from 1 in 3,000 pregnancies to 3 in 3,000 pregnancies, Chambers said. Also, some babies go through withdrawal symptoms in the first days of life that can range from jitteriness to occasional seizures.

Women have to weigh those findings with the clear risks of stopping treatment, she said.

"The time to be thinking about all this is when you're not pregnant," when your doctor can consider how to balance mom's and baby's health and might switch brands, Chambers said.

That's what heart attack survivor Kelli Tussey of Columbus, Ohio, did. The 34-year-old takes a variety of heart medications, including a cholesterol-lowering statin drug that the government advises against during <u>pregnancy</u>.

So when Tussey wanted a second child, she turned to doctors at Ohio State University who specialize in treating pregnant heart patients. They stopped the statin and switched her to a safer blood thinner.

"They said my heart could take it," Tussey said. Now four months pregnant, "it seems everything's fine."

Sometimes it's a question of timing. That painkiller ibuprofen, sold as Advil and other brands, isn't for the <u>third trimester</u> but isn't a big



concern earlier on, said Dr. Siobhan Dolan, an adviser to the March of Dimes.

And women should watch out for over-the-counter drugs with multiple ingredients, like decongestants added to allergy medicines, Dolan said. While any potential risk from decongestant pills seems small, "the question is, 'Do you really need it?" she asked, advising a <u>nasal spray</u> instead.

Ask your doctor about the safest choices, Dolan said. Also, check the Organization of Teratology Information Specialists, or OTIS—www.otispregnancy.org—for consumer-friendly drug fact sheets or hotlines to speak with a specialist.

Stay tuned: The FDA has proposed big changes to <u>drug</u> labels that now just say if animal or human data suggest a risk. Kweder said adding details would help informed decision-making: How certain are those studies? What's the risk of skipping treatment? Is the risk only during a certain trimester?

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