Registries Help Inform Medication Use in Pregnancy

Whether it's because of the flu or seasonal allergies, diabetes or epilepsy, pregnant women must often take prescription medication. Studies show that most women take at least one medication while pregnant, and that the use of four or more medications during pregnancy has more than doubled over the last 30 years.

Pregnant women who are prescribed a drug may worry about the potential impact on their developing fetuses. Sometimes, these effects are known. However, there is often a lack of information on the effects of a particular drug taken during pregnancy and one way to obtain it is through a pregnancy registry. FDA encourages moms-to-be to participate in pregnancy registry studies that track the outcomes of drugs taken during pregnancy.

Participants enrolled in a pregnancy registry study are not taking experimental drugs. Instead, pregnancy registries collect data on the effects of already approved drugs—prescribed to women for a specific disease or condition.

The information collected in pregnant women taking the drug is then compared to the information in pregnant women with the same condition who are not taking that drug. For example, a pregnancy registry may compare birth defects in pregnant women who took an antidepressant with birth defects in pregnant women who did not take an antidepressant.

"Pregnancy registries are useful tools for gathering information about the effects of drugs on pregnant women and their developing fetuses."

"The FDA's goal is to have data about the safety of medicines during pregnancy that can be used for labeling," says Sandra Kweder, M.D., deputy director of the Office of New Drugs.

How Registries Work

"Pregnancy registries are useful tools for gathering information about the effects of drugs on pregnant women and their developing fetuses," says Dr. Lynne Yao, acting director of FDA's Division of Pediatric and Maternal Health.

The data collected from pregnancy registries cover a broad range of treatments as well as vaccines. Yao says these data help prescribers and pregnant women make informed choices.

"Often, leaving a serious medical condition untreated during pregnancy can be riskier to the mother and her developing fetus than the medicine itself," she says.

FDA can require a manufacturer to establish a pregnancy registry after a new medicine or vaccine has been approved, says Yao. However, academic centers may also establish a pregnancy registry — as in the case of the North American Antiepileptic Drug Pregnancy Registry, which studies the effects of drugs for the treatment of epilepsy. Regardless of the group conducting a pregnancy registry, the goal of a pregnancy registry is to collect information that may be used in product labeling so that the prescriber and pregnant woman can make more informed decisions about the use of a medication during pregnancy.

Registries typically collect information about the woman's demographics and the medications she is taking. For example, the North American Antiepileptic Drug Pregnancy Registry website lists more than 30 medications being studied, and promises the process will be quick: a 20-minute phone call at the beginning, a five-minute call when you are 7 months pregnant, and a 10 minute phone call after your baby is born.

In December, 2014, FDA issued a new labeling rule that requires the inclusion of contact information for pregnancy registries in labeling. This will enable the physician and the pregnant woman to participate in a registry and contribute valuable information to make decisions about taking a drug in pregnancy.

Registries Aid Moms, Fetuses

FDA says the information obtained from registries protect the health of mothers and fetuses because

- many pregnant women have ongoing medical issues that require them to continue taking drugs during pregnancy
- new medical problems may begin or ongoing ones may get worse
- a woman's body changes during pregnancy and the changes may affect the safety and/or effectiveness of a medication she is taking
- about half of the 6 million pregnancies in the United States each year are unplanned, exposing women and their developing fetuses to drugs before the women know they are pregnant
- enrolling in a registry will help increase the knowledge of the use of a medication during pregnancy so that pregnant women have the best chance of a healthy pregnancy and a healthy baby

FDA does not actually conduct pregnancy registries itself. However, the Agency's Office of Women's Health has a list of pregnancy registries that are enrolling pregnant women at *www.fda.gov/ScienceResearch/SpecialTopics/WomensHealthResearch/ucm134848.htm.*

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