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FDA encourages culture change for clinical trial enrollment of pregnant and lactating women

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Evidence suggests that medication use during pregnancy or while breastfeeding is widespread and growing. Yet, pregnant and lactating women often are excluded from clinical research, resulting in a dearth of data on the safety and effectiveness of most medications in pregnant individuals, fetuses and breastfeeding infants.

While society is justifiably concerned about potential harms of clinical trial participation to a pregnant or lactating woman, excluding these individuals from research may do more harm by leaving gaps in knowledge. As a result, pregnant and lactating women could receive incorrect doses of medication or decline necessary treatments because they fear the unknown risks from medications.

Recognizing the challenges that pregnant individuals and their health care providers face when deciding whether to use a medication, the Food and Drug Administration (FDA) and the Duke-Margolis Center for Health Policy recently held a two-day meetingto explore scientific and ethical considerations related to the inclusion of this population in clinical trials. The goals of the meeting included shedding light on major gaps in knowledge regarding drug metabolism, dosing, therapeutic effects and safety during pregnancy.

For years, the FDA has encouraged drug developers to consider the benefits and risks of including pregnant and lactating women in clinical trials. In 2014, the FDA published the Pregnancy and Lactation Labeling Rule, which required changes to the content and format of pregnancy and lactation information in prescription drug labeling to improve the communication of this information to prescribers and patients. The FDA also has participated in the Task Force on Research Specific to Pregnant Women and Lactating Women, which was established to advise the secretary of Health and Human Services regarding gaps in knowledge and research on safe and effective therapies for pregnant and lactating individuals.

The FDA has also developed new guidances to help drug developers with specific pregnancy and lactation-related issues: *Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials*, *Postapproval Pregnancy Safety Studies* and *Clinical Lactation Studies: Considerations for Study Design*.

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Medication use in pregnancy is expected to increase with the average maternal age at first birth on the rise and as chronic conditions like obesity and cardiovascular disease continue to grow. Similarly, medication use by lactating women may be more likely as breastfeeding initiation rates rise.

Shifting the culture toward thoughtful inclusion of pregnant and lactating women in clinical trials will provide important data that will allow health care providers and pregnant and breastfeeding individuals to make well-informed decisions.

Resources

- Report from the Task Force on Research Specific to Pregnant Women
- Implementation plan from the Task Force on Research Specific to Pregnant Women
- Additional FDA Update columns