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Workshop participants call for more studies of medication safety during lactation

by from the Food and Drug Administration (FDA) Office of Pediatric Therapeutics and the Division of Pediatric & Maternal Health

More studies are needed to inform the safe use of medications during lactation, according to representatives from industry, academia, government and advocacy groups who participated in a two-day workshop on the safety of drugs and biological products used during lactation.

The panel also stressed the importance of stepping up efforts to communicate the benefits of breastfeeding to health care providers and the public.

The workshop, hosted by the FDA, focused on a review and discussion of current approaches for the collection of lactation data, gaps in knowledge and strategies to communicate safety information. Experts discussed novel approaches that could be used to improve the quality and quantity of data available to assess the safety of medications used during lactation.

Presentations focused on benefits of breastfeeding, priority areas for risk assessment, available tools used to evaluate medication exposure during lactation (and their limitations), potential study designs to measure medications in breastmilk and ethical considerations.

Key messages from the stakeholders participating in the panel discussions are listed below. A white paper on the proceedings is being written.

Key workshop messages

There is a lack of necessary data to adequately inform about the risk of a medication when used during lactation. The lack of data does not justify relying on inadequate data to inform about the risk.

- Case reports alone usually are not sufficient to establish a risk or an absence of risk.
- Physicochemical properties of the medication are not sufficient to predict exposure or risk.
- Concentrations of medication from milk of animal species do not reliably estimate concentrations expected in human milk.

At a minimum, clinical pharmacology data from human milk are needed.

- Physiologically based pharmacokinetic modeling can be done but is very difficult, and assumptions used in modeling are not always correct.
- Data from human milk would allow for calculation of a relative infant dose or average daily infant dose.

Clinical pharmacology data from human milk and all other available data could be used to inform about the risk of a medication when used during lactation, including:

- adverse effects in animals,
- case reports of adverse events in infants, and
- systematically collected data on adverse events (or lack thereof) in infants.

Clinical lactation studies can be done and, in many cases, should be done.

- Pathways need to be developed to encourage lactation studies when appropriate.

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There is a need to re-invigorate efforts to communicate the benefits of breastfeeding to health care providers and the public.

There is a need to increase consistency and public awareness of trusted sources of information on safe use of medications while breastfeeding.

Resources

- Slide presentations from the workshop
- AAP News article "New FDA rule to change pregnancy, lactation information on drug labels"
- The LactMed database contains information on possible adverse effects of drugs and other chemicals to which breastfeeding mothers may be exposed.