



FDA Public Workshop: Evaluation of the safety of drugs and biological products used during lactation

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Nothing
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Declare

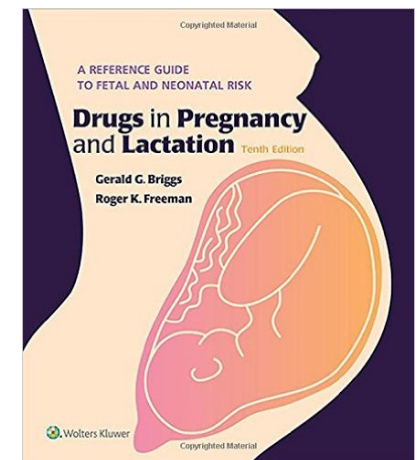


From the perspective of a nurse and lactation consultant (IBCLC)

Where do you obtain information on meds?

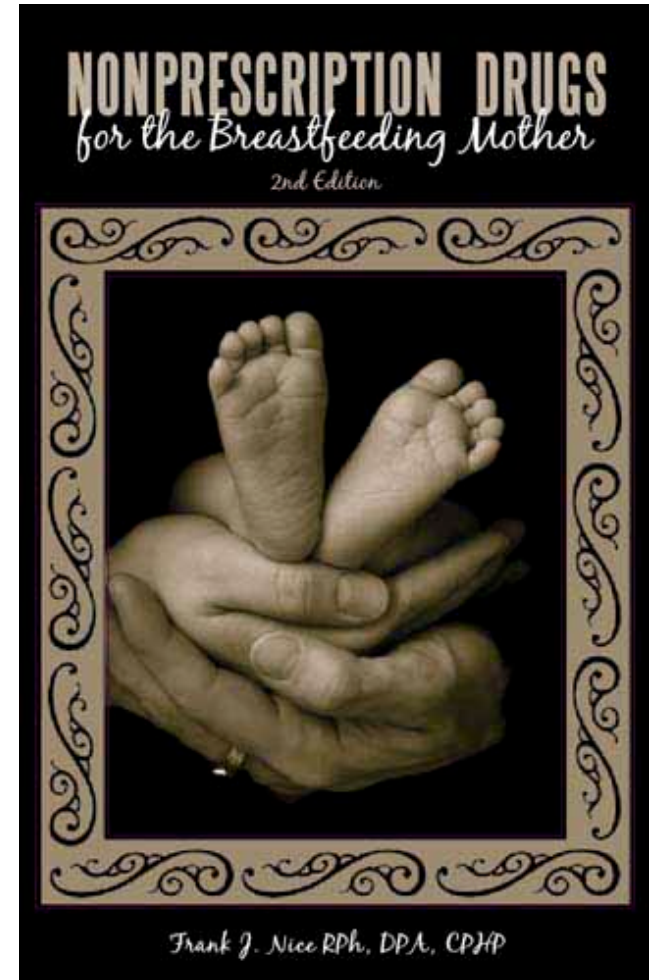
Survey showed:

- LactMed-NIH
- *Medications and Mother Milk* - Hale
- Infant Risk Center
 - <http://www.infantrisk.com>
- Briggs & Freeman



Where is drug information obtained?

- University of Rochester Lactation Study Center
 - (585) 275-0088
- <http://e-lactancia.org/>
- Non-prescription meds- Frank Nice
- Lactnet



Akus & Bartick. (2007). Lactation safety recommendations and reliability compared in 10 medication resources. *Ann Pharmacol*, 41, 1352-1360.

- Med & Mothers Milk
 - LactMed
 - Micromedex
 - Drugs in Preg & Lact
 - Lexi-Comp
 - Epocrates
 - First DataBank
 - Clin-eguide
 - PDR
 - AAP (no longer available)
- Recommendations vary significantly
 - Often do not use current information
 - Lexi-Comp & PDR usually carried recommendations that inappropriately interfered with breastfeeding
 - Premade printouts and bottle labels in retail pharmacies often advise not to breastfeed
 - Most useful resources were monographs

Where do mothers get information on medications?

MommyMeds for Mothers



[Click here for more information.](#)

InfantRisk Center for Health Care Providers



[Click here for more information.](#)

- You may have noticed that your baby is sleepy; that's because some anti-seizure medications may cause sleepiness. **Talk to your doctor about alternating between breastfeeding and bottle-feeding formulas.**
- If you are taking Luminal or Mysoline, you may notice that your baby is overly sleepy or irritable. If this becomes a problem, **ask your doctor or the baby's pediatrician if you should supplement with a bottle.**
- Physicians, nurses, pharmacists

Where do moms get their drug information?

- Lactation consultants
- <http://www.safefetus.com>
- BabyCenter.com
- Kellymom.com
- TV ads
- Blogs, forums, social media



Concerns and challenges

- What else is mother taking?
 - May not consider herbs and supplements as medication
 - Herbs considered safer than medications
- May not speak English or understand it very well
- May have limited understanding of the use of medications
- May be taking another person's medications
- Mothers cannot analyze risk/benefit
- Physicians may recommend weaning or pump and dump when not necessary
 - Allergists, ER, pharmacists, primary care physician, surgeon, oral surgeon, dentist, radiology
 - Mother then calls LC
- Dosing relative to amount in milk may not be mentioned
 - Can mother breastfeed when lowest amount is in milk



Shatavari
Moringa
Vervain
Milk thistle

For low milk supply



For low milk production

Fenugreek
Blessed
thistle
Nettle
Fennel

Challenges

- New drugs come out faster than information on lactation safety
- Many studies have only small samples of breastfeeding mothers
- Physicians recommending weaning or pump and dump as a default without exploring how to make breastfeeding and medication compatible
- Physician Desk Reference still used by many healthcare providers
- Packaging inserts may be inaccurate or incomplete
- Communicating drug information to mothers and providers
 - Finding common ground where most mothers could receive pregnancy-related information

Getting the word out-looking for commonality

- Hospital prenatal packages/communication
- Text4Baby-free app
 - provides expert health information via SMS text messages to pregnant women and new moms through their baby's first year.
 - Text4baby messages also connect women to local prenatal and infant care services and resources.



Gaps

- Effect of multiple drugs
 - Including multiple herbs, supplements, teas, tinctures
- What are the drug's effects on milk production
- What are the drug's effects on milk components
- What are the drug's safety and effects for preterm infants?
- How should the drug be dosed to minimize the amount ingested by the infant
- What are potential long-term effects on the infant
 - Growth and development
 - Immune system
- How can physicians be better educated regarding medications and lactation?
 - Medical school/residency
 - apps

