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

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Nothing to 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](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

- 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
Fenugreek  
Blessed thistle  
Nettle  
Fennel

For low milk production
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