MEDICATIONS AND BREASTFEEDING:
What Dispensing Pharmacists Need To Know

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OBJECTIVES

- Be able to identify the benefits and risks of medication use during breastfeeding
- Be able to identify available resources for medication use during breastfeeding
- Be able to utilize tools and techniques for evaluating medication use during breastfeeding
- Be able to identify adverse effects in children of mothers who are breastfeeding and taking medications
- Be able to counsel mothers who are breastfeeding and taking or will take medications
Benefit-Risk Analysis

- Benefits of breastfeeding (See Handout) + Benefits of the drug (from the package insert and/or literature)

**Versus**

- Risks of formula use or NOT breastfeeding (See Handout) + Risks of the drug (from the package insert and/or literature)
SOURCES OF INFORMATION

- **Journal Articles**
  - Nice References
  - AAP Committee on Drugs (See Website List)
  - MICROMEDEX (See Website List)

- **Books**
  - Nonprescription Drugs for the Breastfeeding Mother, 2nd Edition
  - Nice (See Slide)
  - Medications and Mothers’ Milk, 15th Edition
  - Hale (See Slide)
  - Drugs in Pregnancy and Lactation, 9th Edition
  - Briggs, Freeman, and Yaffe (See Slide)
  - Drugs and Human Lactation, 2nd Edition
  - Bennett (WHO)
Medications and Mothers’ Milk

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Thomas W. Hale, Ph.D.
SOURCES OF INFORMATION

- Pharmaceutical Companies
- Websites (See Next Slide)
- Lactation Study Center
  
  Ruth Lawrence, MD
  University of Rochester
  601 Elmwood Avenue, Rochester, NY 14642
  (585) 275-0088; Mon-Fri, 8AM-5PM
BREASTFEEDING WEBSITES

- Nice Breastfeeding
  www.nicebreastfeeding.com

- LactMed / TOXNET / NLM / NIH

- Thomas Hale InfantRisk Center
  http://www.infantrisk.com/category/breastfeeding
BREASTFEEDING WEBSITES

- Breastfeeding Online
  http://breastfeedingonline.com

- KellyMom
  http://www.KellyMom.com

- American Academy of Pediatrics Policy Statement: The Transfer of Drugs and Other Chemicals Into Human Milk
  http://aappolicy.aappublications.org/cgi/content/full/pediatrics%3b108/3/776

- MICROMEDEX Healthcare Series
  (Subscription Required)
  http://www.micromedex.com/products/hcs/
DRUG FACTORS-I
General Guidelines

1. Most drugs appear in breast milk to some degree

2. Levels of most drugs in breast milk do not usually exceed 1% to 2% of ingested maternal dosage

3. If the milk/plasma ratio of drug and active metabolites is less than 1:1, it is usually safe to breastfeed

4. If infant dose is less than 10% of maternal dose (weight adjusted), it is usually safe to breastfeed
DRUG FACTORS-II
Pharmacokinetics

1. Volume of Distribution (1-20 L/Kg)
2. pH (breast milk more acidic)
3. Lipids
4. Protein-Bound Drugs (85%)
5. Molecular Size (Daltons) (200-400)
6. Active Transport
MATERNAL FACTORS
Pharmacodynamics

1. Mammary epithelium may have drug-metabolizing capacity
2. Milk volume is usually greatest in the early morning
3. Fat content of milk is usually highest in the late morning
4. Stage of breastfeeding is a factor
Stage of Breastfeeding

- Newborns feed every 1-2 hours
- Colostrum (0-3 days)
- Transitional Milk (4-7 days)
- Mature Milk (7-10 days)
- Alveolar Spaces (0-7 days)
INFANT FACTORS

Pharmacodynamics

1. Infant’s ability to absorb drug
2. Infant’s ability to detoxify and excrete the drug
QUESTIONS TO ASK IN DRUG / BREASTFEEDING SITUATIONS

1. What is the name, strength, and dosage of the drug?
2. Do you still have the prescription? Or, have you already filled it and are taking the drug?
3. Why is the drug being prescribed?
4. Do you feel you need to take the drug?
5. What does your doctor say regarding breastfeeding outcome and taking the drug?
6. What is the drug dosage schedule and how often do you nurse?
QUESTIONS TO ASK IN DRUG / BREASTFEEDING SITUATIONS (continued)

7. How old is your baby?
8. Was your baby full-term or premature?
9. What is your baby's weight?
10. Is your baby currently receiving any medication?
11. Do you know how to hand-express breast milk or do you have access to a breast pump?
12. Is this your first breastfed baby?
STEPWISE APPROACH TO MINIMIZING INFANT DRUG EXPOSURE

1. Withhold the drug
2. Try nondrug therapy
3. Delay therapy
4. Choose drugs that pass poorly into breast milk
5. Choose more breastfeeding compatible dosage forms
STEPWISE APPROACH TO MINIMIZING INFANT DRUG EXPOSURE (continued)

6. Choose an alternative route of administration
7. Avoid nursing at times of peak drug concentrations in milk
8. Administer drug immediately after breastfeeding and / or before infant's longest sleep
9. Temporarily withhold breastfeeding
10. Discontinue breastfeeding (wean)
CASE STUDY

Mrs. Maine, a breastfeeding woman, presents a prescription. She is worried about taking this medication while breastfeeding and asks for my recommendation. She wants to know if the antibiotic is safe to take while breastfeeding her baby, Augusta.
CASE STUDY (continued)

- After asking the mother several questions about herself and her baby, the mother states that she will be back in two hours to pick up her filled prescription if I determine that the drug is usually safe to take while breastfeeding.

- What questions should be asked the mother?
From the mother, I was able to obtain the following information:

- The mother weighs 110 pounds (50 Kg).
- The mother and baby have no drug allergies. Her baby is seven months old, taking no medications, and weighs 22 pounds (10 Kg). Breastfeeding is going very well.
The prescription is for: Xybotic, 1000 mg every twelve hours for five days (2000 mg per day).
CASE STUDY (continued)

- I am unable to find any AAP recommendation regarding Xybotic.
- What is my next step?
I run a computer search on Xybotic and come up with the following information:

- Xybotic is 90 percent bound to plasma protein, has a fairly low fat solubility, has a volume of distribution of 1400 L, has a molecular mass (size) of 300 Daltons, peaks in plasma in one hour, and has a half-life of four hours.
CASE STUDY (continued)

- Protein: +
- Fat Solubility: +
- Daltons: +/-
- Volume of Distribution: +
- Peak: Avoid breastfeeding 0-2 hours after dose, if possible
- Half-Life: Should not accumulate in baby
CASE STUDY (continued)

- I also am able to find a reference to one study that states that when five mothers took Xybotic, an average of 0.01 mg of the drug appeared in 1 ml (10 mg/L) of breast milk.
- Mother’s wt. adjusted dose: 40mg/Kg/day
- Baby’s wt. adjusted dose: 1 mg/Kg/day
- Baby/Mother Percentage = 2.5% (1/40)
What recommendation would you provide to Mrs. Maine as you counsel her?

What would you have done if the drug was not compatible with breastfeeding?
Recommendation

- OK to breastfeed while taking Xybotic
- Observe for possible adverse effects in child (diarrhea or possible allergic reaction)
- Not necessary, but can avoid breastfeeding until 2 hours after taking drug
What Else Could You Do?

- Look for breastfeeding compatible alternative in the same drug category (e.g., Hale and LactMed suggest alternatives)
- If no alternative drug, go through the Stepwise Approach
CONSIDERATIONS: Prescription Drugs

- Analgesics
  - Nonnarcotic
  - Narcotic
    - General and Epidural
- Anti-Infectives
- Antihistamines/Decongestants
- Bronchodilators
- Corticosteroids
- Antihypertensives
- Cardiac Drugs
CONSIDERATIONS: Prescription Drugs

- Anticoagulants
- Diuretics
- Antidiabetics
- Thyroid/Anti-Thyroid Drugs
- Hormone Contraceptives
- Gastrointestinal Drugs
- Psychotherapeutic Drugs
- Benzodiazepines
- Antiepileptics
- Radiopharmaceuticals
- Miscellaneous Drugs
SSRIs

1. Sertraline (Zoloft)
2. Escitalopram (Lexapro)
2. Paroxetine (Paxil)
4. Venlafaxine (Effexor)
5. Fluvoxamine (Luvox)
6. Citalopram (Celexa)
7. Fluoxetine (Prozac)
ADVERSE EFFECTS
(Overall Rate: 1%)

- Psychotherapeutics (Antidepressants, Sedatives, Antipsychotics): 31%
- Antimicrobials: 17%
- Anticonvulsants: 16%
- Analgesics (NSAIDs, Opioids): 12%
- Hormonal Drugs: 5%
- Iodides: 5%
- Cardiovascular Drugs: 4%
- GIT Drugs: 2%
- Antihistamines: 2%
- Chemotherapeutics: 2%
ADVERSE EFFECTS

- Psychotherapeutics (Antidepressants, Sedatives, Antipsychotics): Drowsiness
- Antimicrobials: Diarrhea
- Anticonvulsants: Drowsiness, sedation, poor feeding
- Analgesics (NSAIDs, Opioids): Drowsiness, sedation
- Hormonal Drugs: Decreased milk supply, volume, quantity
- Iodides: Thyroid suppression
- Cardiovascular Drugs: Weakness, hypotension, bradycardia
- GIT Drugs: GIT upset
- Antihistamines: Irritability, drowsiness
- Chemotherapeutics: Toxic effects of treatment
ADVERSE EFFECTS
(References)

Anderson PO, Pochop SL, Manoguerra AS:
Adverse drug reactions in breastfed infants: less

Ito S, Blajchman A, Stephenson M, et al:
Prospective follow-up of adverse reactions in
breast-fed infants exposed to maternal
1393-9: 1993
Codeine Rapid Metabolizers

- 13-day breastfed baby dies from morphine overdose in breast milk in mother taking codeine
- How did that ever happen?
ABM Clinical Protocol #15

- Academy of Breastfeeding Medicine Clinical Protocol #15:
- Analgesia and Anesthesia for the Breastfeeding Mother
- Anne Montgomery, Thomas W. Hale, and The Academy of Breastfeeding Medicine Protocol Committee
- Reprint Requests: abm@bfmed.org
CONSIDERATIONS: OTC Medications

- Analgesics
- Cough, Cold, and Allergy Preparations
- Cough and Cold Lozenges and Sprays
- Nasal Preparations
- Asthma Preparations
- Antacids and Digestive Aids
- Laxatives / Stool Softeners
- Anti-Diarrheal Preparations
- Nausea and Vomiting / Motion Sickness Preparations
- Hemorrhoidal Preparations
- Sleep Preparations
- Stimulants
- Appetite Suppressant Products
- Insulin Preparations
- Artificial Sweeteners
- Miscellaneous OTCs
OTC BREASTFEEDING COUNSELING GUIDELINES

- Avoid taking OTC medications for which safer products are available.
- Avoid taking OTC medications for which little breastfeeding information is available.
- Avoid taking combination OTCs, which are those with multiple ingredients (it is better for the mother to take an OTC that has the one or two specific ingredients that will treat her specific condition; there is no need for the mothers or nurslings to be exposed to unnecessary ingredients).
OTC BREASTFEEDING COUNSELING GUIDELINES

- Avoid taking extra strength forms of OTC medications (there is no need for the nursling to be exposed to extra amounts of a drug when it is not needed).
- Avoid taking long-acting OTC medications (there is no need for the nursling to be exposed to a drug for a longer period of time, especially if an adverse reaction is possible in the nursling).
- The mother should know about possible side effects that might occur in her Nursling, as well as herself.
- If possible, as with prescription drugs, the mother should use a nondrug approach for treating her symptoms.
CONSIDERATIONS: Herbals (Major Galactogogues)

- Chaste Tree
- Fennel
- Fenugreek
- Garlic
- Goat's Rue
- Milk Thistle / Blessed Thistle
CONSIDERATIONS: Herbals (Minor Galactogogues)

- Anise
- Borage
- Alfalfa
- Caraway
- Coriander
- Dandelion
- Dill
- Marshmallow
- Nettle
- Hops
- Oat Straw
- Red Clover
- Red Raspberry
- Vervain
CONSIDERATIONS: Herbals

- Analgesics
  - Bugleweed, Comfrey
- Headache (Migraine) Agents
  - Feverfew
- Anti-Anxiety Agents
  - Indian Snakeroot, Kava Kava, Passionflower, St. John’s Wort, Valerian
- Stimulants
  - Ginseng Root, Siberian Ginseng, Ginkgo Biloba, Angelica Root / Dong Quai
- Sleep Preparations
  - Melatonin
CONSIDERATIONS: Herbals

- Cough, Cold, and Allergy Products
  - Coltsfoot, Echinacea, Elder Flower
- Gastrointestinal Agents
  - Aloe, Buckthorn, Cascara Sagrada, Chamomile, Flaxseed, Licorice, Psyllium Seed, Rhubarb, Senna
- Nausea and Vomiting Preparations
  - Ginger
- Lipid Lowering Agents
  - Soy Lecithin
- Urinary Tract Preparations
  - Goldenrod, Petasites, Uva Ursi
CONSIDERATIONS: Recreational Drugs

- Amphetamine / Methylphenidate
- Marijuana
- Cocaine
- Phencyclidine
- Narcotics
- Caffeine
- Alcohol
- Nicotine
From both a philosophical and scientific viewpoint, recreational drugs of abuse should be contraindicated during breastfeeding as they are hazardous, not only to the nursling, but to the mother as well.
FINAL CONSIDERATIONS

• Only essential drugs should be taken by the nursing mother. She should be knowledgeable of and be encouraged to report any adverse effects.

• For newer drugs, sufficient information is often unavailable. If information is available, it requires careful interpretation and evaluation.

• Recognizing the benefits of continuing to nurse, in most cases, drugs that have safe therapeutic levels can be given.
JAPhA Article

PUBLICATIONS

PUBLICATIONS

PUBLICATIONS

Nice FJ, DeEugenio D, DiMino TA, Freeny IC, Rovnack MB, and Gromelski JS:
PUBLICATIONS


PUBLICATIONS


Thank you for your participation