

## Drugs in Pregnancy and Lactation

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 UCSD Lactation Program: Clinical instructor  
 San Diego Breastfeeding Coalition: Board Member

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## Drugs in Pregnancy and Lactation

### ■ Introduction and Disclaimers ....

#### ■ Rose deVigne-Jackiewicz, RN, MPH, IBCLC

- Founder of Happy Healthy Mom's and Babies
- [www.NurseRoseOnline.com](http://www.NurseRoseOnline.com)
- Kaiser Permanente, San Diego, CA
  - Outpatient Lactation Clinic (retired August 2019)
- Faculty, UC San Diego Lactation Programs
- Board member of San Diego Breastfeeding Coalition

I have nothing to disclose

I may discuss off label use of medication(s)




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## Drugs in Pregnancy and Lactation

### ■ Introduction to Drugs in Pregnancy and Lactation

- Complicated issue

### ■ Objectives

- Define medication safety
- Describe mechanism of medication entry

#### ■ List:

- At least 2 teratogenic medications
- At least 2 preferred medications in pregnancy
- At least 2 resources for medication safety in pregnancy and lactation
- List at least 2 medications that affects lactation

### ■ Q & A

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## The “Old Norm”

- Pregnancy the “old fashioned way”
- Mom goes into labor “on her own”
- Baby delivers at 38-41 weeks gestation
- Several days in hospital



## The “New Norm”

- Assisted pregnancy
- Advance maternal age
- Increased multiple births
- Surrogacy
- Increased C/S deliveries
- Increased inductions
- Deliveries before EDC\*\*\*
- More maternal problems
- Larger Premature babies staying with moms on postpartum unit (not going to NICU)
- \*\*\* 38-41weeks = “term”



## Regulatory Information

- Pregnancy & Lactation Labeling Rule
  - Updated Dec 2014 (effective June 2015)
  - No longer uses the pregnancy categories, A,B,C,D,X
- Statistics
  - Most women will use at least one (many more) medication during their pregnancy
  - Many will continue to use medications before they even know they are pregnant

## "Old" Labeling categories

Category	Definition
A	APC, studies in pregnant women have failed to demonstrate a risk to the fetus in the first trimester of pregnancy (and there is no evidence of a risk in later trimesters).
B	Animal reproduction studies have failed to demonstrate a risk to the fetus, and there are no APC studies in humans, AND the benefits from the use of the drug in pregnant women may be acceptable despite its potential risks. OR animal studies have not been conducted, and there are no APC studies in humans.
C	Animal reproduction studies have shown an adverse effect on the fetus, there are no APC studies in humans, AND the benefits from the use of the drug in pregnant women may be acceptable despite its potential risks. OR animal studies have not been conducted, and there are no APC studies in humans.
D	There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, BUT the potential benefits from the use of the drug in pregnant women may be acceptable despite its potential risks. For example, if the drug is needed in a life-threatening situation or serious disease for which safer drugs cannot be used or are ineffective.
X	Studies in animals or humans have demonstrated fetal abnormalities OR there is positive evidence of fetal risk based on adverse reaction reports from investigational or marketing experience, or both, AND the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit (for example, safer drugs or other forms of therapy are available).

APC, adequate and well-controlled  
 \*Adapted from the pregnancy category

## Updated Labeling Categories

How the number system is not affected by the new labeling

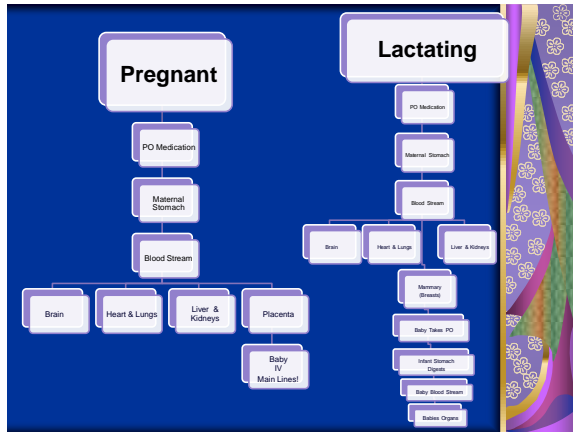


## Drugs in pregnancy

### Define "SAFE USE"

- Fetus
- Effects
- Benefits vs risks






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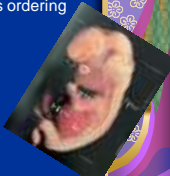
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## Teratogenicity

- **Pregnancy and Teratogens.** Teratogens are drugs, chemicals, or even infections that can cause abnormal fetal development. There are billions of potential **teratogens**, but only a few agents are proven to have **teratogenic** effects. ... Approximately 4 to 5 percent of birth defects are caused by exposure to a teratogen.
- How often will the patient ask, "will it hurt my baby"
- This is also a great concern to the provider who is ordering the medication
- Thalidomide – most well known
- Stage of pregnancy very important
- Many different registries




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**Drugs Identified With Possible Teratogenic Risk**

Medication	Possible Risk
1) anti-folate	Administration of large doses has been associated with decreased (depression) of the placenta and fetus
2) anti-folate	Large doses of anti-folate can cause
3) anti-folate	Large doses of anti-folate can cause

**Additional Medications With Risk Identified in a 20-year New Medication Review**

New Medication	Risk Identified	Risk Category	FRS Category
Acetaminophen	Not described	C	Small molecule
Cyclophosphamide	Not described	D	Small molecule
Fluorouracil	Not described	E	Small molecule
Hydroxyurea	Not described	F	Small molecule

FRS: Food and Drug Administration (FDA) Pregnancy and Reproductive Health (PRH) Drug Safety Information System

**Table 5. Medications With New Concerns \***

Medication	Risk Category	Risk Identified
Acetaminophen	C	Not identified (FDA is under review)
Hydroxyurea	D	Hydroxyurea, severe adverse effects in newborn
Fluorouracil	E	Hydroxyurea, severe adverse effects in newborn
Hydroxyurea	F	Hydroxyurea, severe adverse effects in newborn

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## Vaccines

- Common Vaccines
  - Flu
  - Tdap
- Avoid those with live virus
  - Chickenpox
  - MMR
  - Shingles
- Those at risk/traveling abroad
  - Hep A
  - Hep B
- [www.cdc.gov/vaccine/pregnancy](http://www.cdc.gov/vaccine/pregnancy)

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## Illicit Drug Use

**HOW  
DO  
WE  
SAY  
NO.....  
NO**

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## Review

- Cocaine
- Methamphetamines/Amphetamines
- LSD
- PCP
- Marijuana
- Synthetic Marijuana
- Opioids

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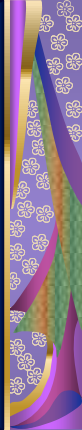
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## Benefits of Human Milk and Breastfeeding

- Medical
  - Anti-allergic properties
  - Anti-infective properties
  - Immunological properties
  - Involution of the uterus
  - Oral facial development
  - Family spacing
  - Weight adjustments
  - Less kidney load
  - Immobilizes bacteria in gut
- Enhances brain development
- Reduced incidence
  - Juvenile diabetes
  - Adult chronic illness
  - Crohn's disease
  - Ulcerative colitis
  - Breast cancer pre menopausal
  - Ovarian cancer
  - Childhood cancers
  - SIDS
- Cell memory: Cholesterol




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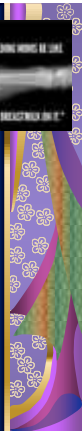
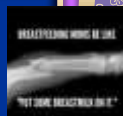
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## Benefits of Human Milk

### “Gee Whiz” Facts

- Premature baby/preterm breastmilk
- Other uses of Breastmilk
- Cancer




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## Drugs In Lactation

### Overview

- How many mothers receive medications or drugs in the first week postpartum?
- Most medications pass to the milk
- Prescription
- Over-the-counter
- Herbs




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## BREASTFEEDING: WITH ALL WE KNOW AND TEACH, WHY DO SO MANY MOTHERS STILL FAIL




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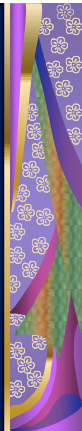
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### How Milk is made

- Endocrine
  - Primarily **Oxytocin & Prolactin**
  - Secondary: **Insulin, Growth Hormone, Thyroid**, etc.
- Autocrine
  - Frequency and effectiveness of milk removal




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### Most Important Question

 **How old is  
the baby?**




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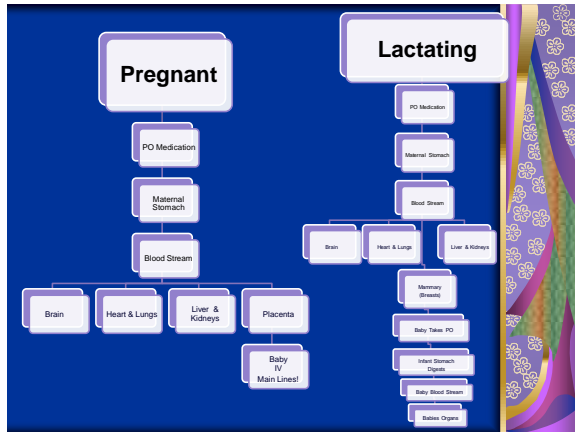
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## General Information

### Gestational age of infant?

- Premie vs full term



### Age of the baby?

- Younger less able to eliminate from system
- ~ 2 weeks of age, full term infant liver able to metabolize most drugs




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## General Advice ...

### Infant's weight?

- Drug doses calculated on weight
- More infant weighs better handle drug

### How much human milk being consumed?

- Exclusive breastfeeding or partial

### What is the general health of the baby?

- Premie or full term
- Illness and health problems

### Why is the mother taking the medication?

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## General Info about drug ...

- **Name** of medication
- **Dosage**
- **Duration** of therapy
- **Route** of deliver of medication
  - IV                      - IM                      -Sublingual
  - PO                      - Topical                -Vaginal Supp
  - Subcutaneous        - Rectal                -Inhalants
  - Nasal                    - Patch                -Intra-ocular
- **Drug given orally may be inactive or absorbed by digestive system, so baby's system would inactivate drug**

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## Questions for provider to consider...

- Has drug been **given to infants**?
- Has drug been given to **other BF mothers**?
- What is the **duration** of drug therapy?
- Is the drug **short acting**?
- How well can the **baby excrete the drug**?
  - Accumulation over time of use
- Does the drug **interfere with lactation**?

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■ Value of drug  
verse Value of  
human milk for  
infant ?

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## Common Medications taken during Lactation

### OTC

- Prenatal Vitamins
- Motrin
- Others:
  - Galactagogues
  - Other types of vitamins:

### Prescription

- Prenatal Vitamins
- Rx Pain pills
- antibiotics
- Others:
  - Galactagogues

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## Options

- ?? Delay therapy
- Choose drugs that pass poorly into milk
- Choose an alternative route of administration
- Coordinate breastfeeding with medications schedule to minimize exposure
- Temporarily withhold breastfeeding
  - Radio active dyes
- LAST RESORT ... stop breastfeeding




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## Drugs to Avoid (per Thomas Hale)

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|---------------------|---|
| ■ Drugs of abuse    | ■ Radioactive drugs                     |
| ■ Ergot alkaloids   | ■ Discontinue briefly                   |
| ■ Migraine preps    | ■ Radioactive I-131                     |
| ■ Ergotamine        | ■ Chronic use of sedatives              |
| ■ Cabergoline       | ■ Estrogens                             |
| ■ Pseudoephedrine   | ■ Progesterone within 48 hours of birth |
| ■ Anti-cancer drugs |   |

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## ?? Breastfeeding Contra

### Maternal Medications

- What mom takes most likely passes into milk
- Usually < 1-2% maternal dose to baby

#### Resources and References:

- AAP
  - Drug Information Line UCSD: 619-543-6971
- Reference Books:
  - Medications and Mothers Milk*
    - Tom Hale

- LACTMED
- INFANTRISK.com



Thomas Hale\*\*  
Revised every 18-24 months  
Pharmsoft Publications, PD Available  
Electronic ~\$4.99 per month

## Rules of Breastfeeding ...

“If took during pregnancy, Mom can take during lactation without additional harm to infant”

- Effect on lactation ????

<http://zoloflegalad.com/cpm/index.php?cid=124&afid=21&usid=1&sid=4>

August 16, 2012

**ZOLOFT usage during pregnancy Linked to Serious Birth Defects.**

**Dr. Call vs NCHRP (986) 334 - 6728**

**Request to NCHRP: ZOLOFT (Sertraline) may cause the following birth defects:**

- Heart defects (cardiac malformations)
- Neural tube defects (spina bifida)
- Oral clefts (cleft lip and palate)
- Low birth weight
- Small head circumference
- Small chest circumference
- Small stomach circumference
- Small hip circumference
- Small arm circumference
- Small leg circumference
- Small foot circumference
- Small hand circumference
- Small finger circumference
- Small thumb circumference
- Small middle finger circumference
- Small middle thumb circumference
- Small index finger circumference
- Small index thumb circumference
- Small ring finger circumference
- Small ring thumb circumference
- Small pinky finger circumference
- Small pinky thumb circumference
- Small little finger circumference
- Small little thumb circumference
- Small ring finger circumference
- Small ring thumb circumference
- Small pinky finger circumference
- Small pinky thumb circumference
- Small little finger circumference
- Small little thumb circumference

**If you are considering you may want ZOLOFT or Sertraline while pregnant, you and your doctor should weigh the risks and benefits for you and your baby.**

**Call Dr. Call at (986) 334 - 6728**

**Dr. Call vs NCHRP (986) 334 - 6728**

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**Small leg circumference**

**Small foot circumference**

**Small hand circumference**

**Small finger circumference**

**Small thumb circumference**

**Small middle finger circumference**

**Small middle thumb circumference**

**Small index finger circumference**

**Small index thumb circumference**

**Small ring finger circumference**

**Small ring thumb circumference**

**Small pinky finger circumference**

**Small pinky thumb circumference**

**Small little finger circumference**

**Small little thumb circumference**

**Small ring finger circumference**

**Small ring thumb circumference**

**Small pinky finger circumference**

**Small pinky thumb circumference**

**Small little finger circumference**

**Small little thumb circumference**

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# Issues ..

- Birth Control Choices and Methods
- Galactogogues
- Herbs
- Time of Year/Season (One of Roses "tidbits of information")



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## Contraindication vs. Disadvantages

- **Drugs of Abuse**
  - Never Recommended/Mother's NEED to be told in very a straight forward way – DON'T DO IT
  - Supervision
  - AAP: "The committee on drugs believes strongly that nursing mothers should not ingest any of these compounds. Not only are they hazardous to the nursing infant but they are detrimental to the physical and emotional health of the mother."



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## Review

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## Most Important Question

■ **How old is  
the baby?**

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## Summary/Questions

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Inspected by.....



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