Bump to Baby and Bottles

Navigating Medication Safety from Pregnancy to Postpartum

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Pharmacy Forward: Advancing Practice for a Healthier Tomorrow!

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OHIO PHARMACISTS ASSOCIATION

Disclosure Statement

- Kristine Cline has no relevant financial relationship(s) with ineligible companies to disclose.
  and
- None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.

Learning Objectives

At the completion of this activity, the participant will be able to:

1. identify key resources and evidence-based tools for evaluating medication safety during pregnancy and lactation;
2. interpret FDA pregnancy and lactation labeling to assess risk and guide clinical decision-making; and
3. apply clinical judgment to patient scenarios involving medication use in pregnant or breastfeeding individuals.

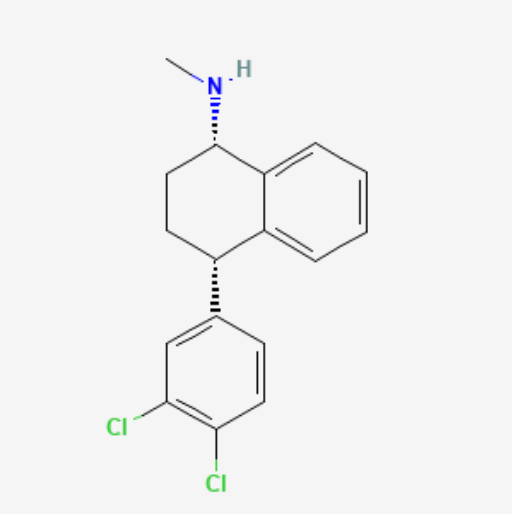
First, a Foundational Science Refresher

Medication Properties & Drug Transfer

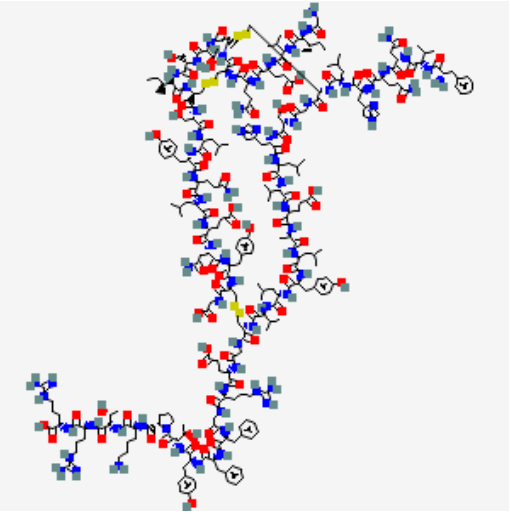
- Molecular Weight
- Lipid Solubility
- Protein Binding
- Half-Life
- Time to Peak Concentration
- Oral Bioavailability
- Volume of Distribution
- Duration of Action
- Onset of Action
- Ion Trapping

Molecular Weight

- The weight, or “size”, of the molecule measured in Daltons (or g/mol)
- *E.g. the primary difference in physical properties between small molecule drugs and peptides is their molecular weight*



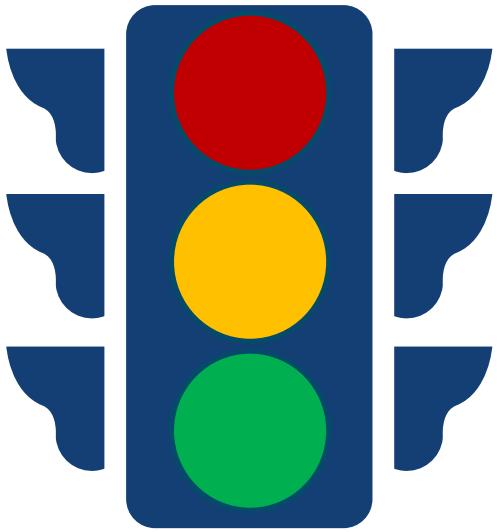
Sertraline
MW: 306.2 g/mol



Insulin Glargine
MW: 6063 g/mol

(PubChem. Sertraline.) (PubChem. Basaglar.)

Molecular Weight – “Rules of Thumb”



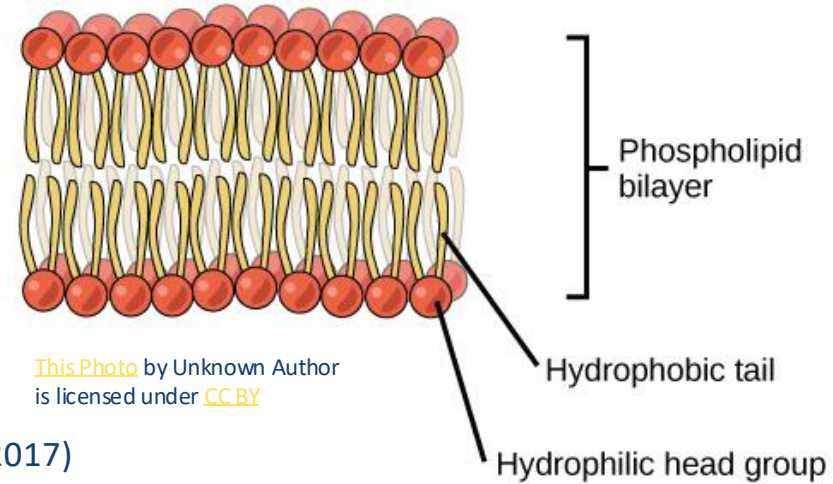
- “Small” small molecule drugs **can** readily pass (<500 g/mol)
- “Larger” small molecule drugs can **slowly** pass (~600-1,000 g/mol)
- Large molecule drugs/peptides do **not** (significantly) cross (>1,000 g/mol)

(Pregnancy and Lactation: Therapeutic Considerations. 2017)

Lipid Solubility

- A drug's ability to dissolve in lipids/oil

Lipophilicity = Ability to cross membranes



(Pregnancy and Lactation: Therapeutic Considerations. 2017)

Protein Binding (PB)

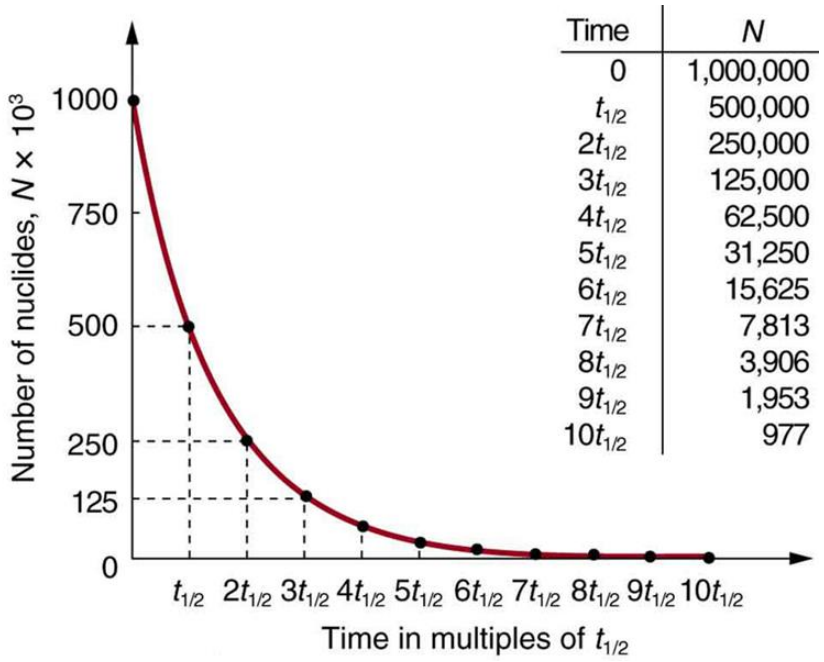
- How much medication is bound to protein in the blood
  - Albumin binds acidic and neutral drugs
  - α1-acid glycoprotein binds basic drugs
  - **Concentrations of BOTH are lower during pregnancy (albumin as much as 70-80% lowering!)*

- **Pregnancy**: Drugs that are highly protein bound will have higher free fraction during pregnancy
- **Membrane Transfer**: Bound drugs are less likely to transfer

(Pinheiro EA. 2020.)

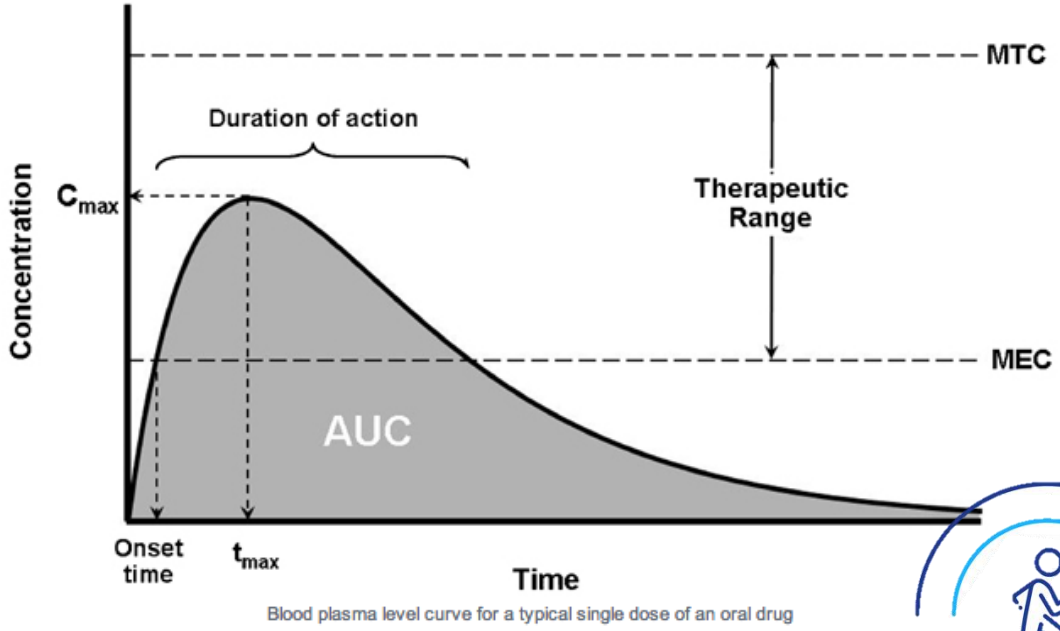
Half-Life and Time to Peak

- **Half-Life (t1/2):** Length of time for [medication] to decrease by 50%



Time	*N*
0	1,000,000
$t_{1/2}$	500,000
$2t_{1/2}$	250,000
$3t_{1/2}$	125,000
$4t_{1/2}$	62,500
$5t_{1/2}$	31,250
$6t_{1/2}$	15,625
$7t_{1/2}$	7,813
$8t_{1/2}$	3,906
$9t_{1/2}$	1,953
$10t_{1/2}$	977

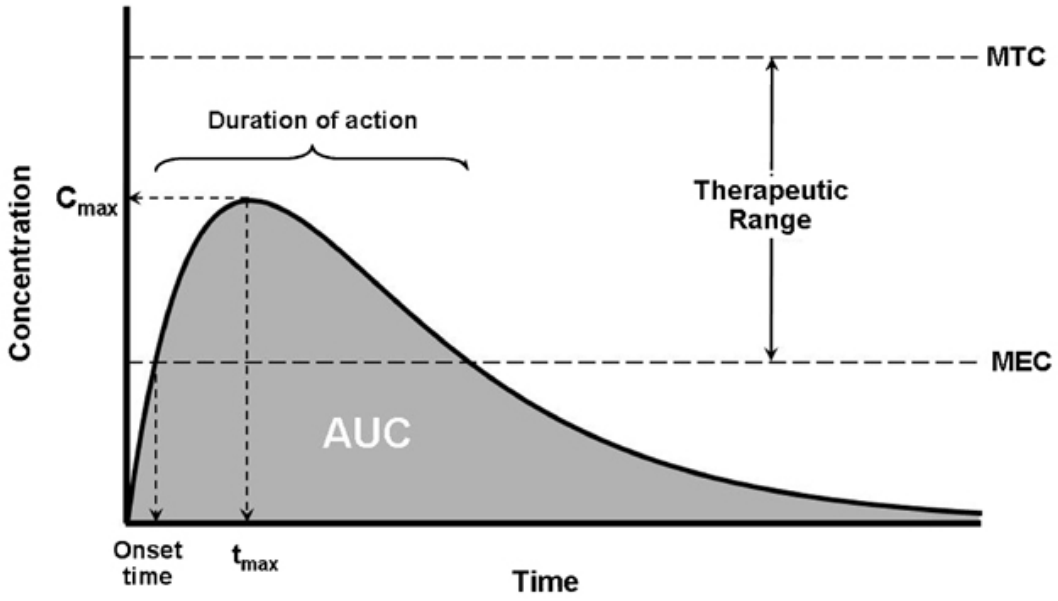
- **Time to Peak:** Time with [medication] is at its highest in blood



Blood plasma level curve for a typical single dose of an oral drug

Duration and Onset of Action

- **Duration of Action**: Length of time clinical effects will last
- **Onset of Action**: Time for medication effect to "kick in"



Blood plasma level curve for a typical single dose of an oral drug

Oral Bioavailability

- Ability of medication to be absorbed via the digestive tract into the blood stream
  - *Note that ALL medication taken via breastmilk is by mouth, regardless of route it was taken by lactating person*

Volume of Distribution (Vd)

- A drugs propensity to remain in plasma or redistribute to other compartments
  - Central: blood, heart, lungs, kidneys
  - Peripheral: fat, muscle, CSF [*milk production occurs in peripheral compartment*]

High Vd =
"World Travelers"
1-20 L/kg

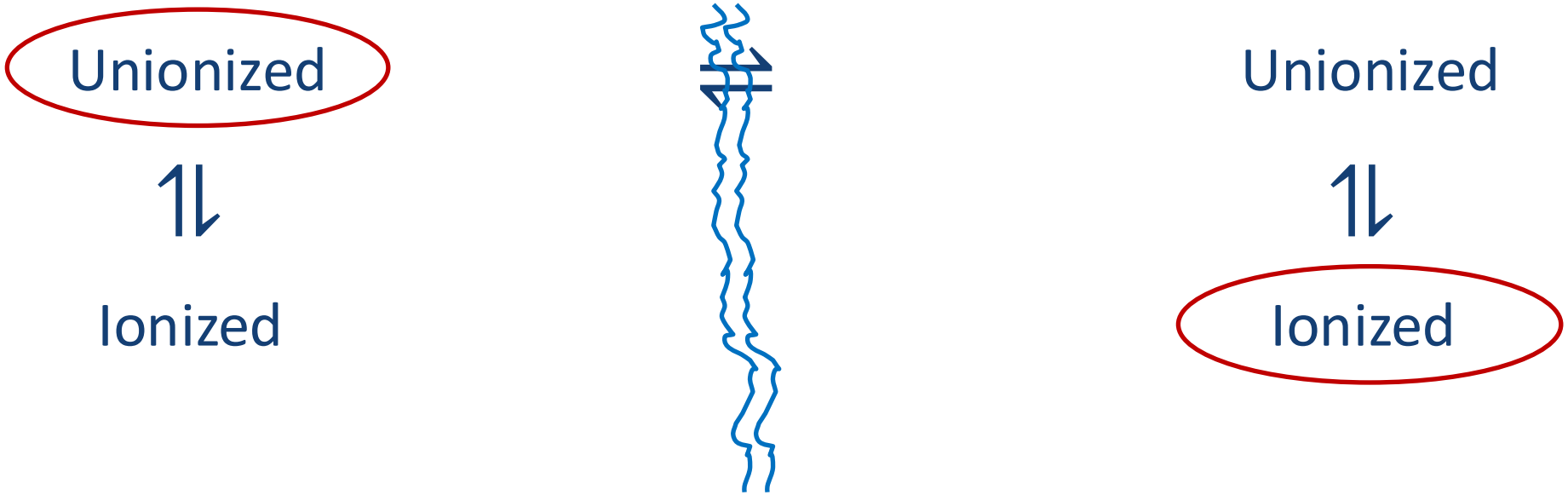
Low Vd =
"Homebodies"
<1L/kg

(Mansoor A. 2023.)

Ion Trapping – (Primarily) Lactation

WEAK BASES with HIGH pKa
e.g. barbituates

- When medication becomes “trapped” in breastmilk following chemical changes due to change in pH from blood to breastmilk



(Drug entry into Human Milk)

Assessing Drug Labeling

2015 PLLR

- “Pregnancy and Lactation Labeling Rule”
- Effective June 30, 2015 → removed A, B, C, D, X risk categories
- Now includes detailed, narrative information about safety
  - Pregnancy
  - Lactation
  - Females and Males of Reproductive Potential

(Center F. Pregnancy and Lactation Labeling Resources 2025)

Birth Defect Rates

"Baseline" risk for congenital malformations is approx. 3-5%

Medication exposure accounts for <1% birth defects

(Forinash AB, Barnes K. Pregnancy and Lactation. 2026)

Key Resources & Tools

**AI generated image*

Example Resources & Tools

- **Infant Risk Center (infantrisk.org)**
  - Has mobile app
- **LactMed NIH**
  - Has mobile app
- **Tertiary Resources/Drug Databases (e.g. Lexicomp, Micromedex)**
  - "Narrative" PLLR; Most have mobile app
- **Thomas Hale "Medications and Mother's Milk"**
  - Includes summary tables of drug properties (e.g. MW, PB, T1/2)
- **Brigg's Drugs in Pregnancy and Lactation**
  - Comprehensive guide for medication use in pregnancy and lactation
- Package Inserts?

Patient Cases

Content

- Codeine/Percocet case post c-section? – Debbie slide 27
- Warfarin vs. LMWH in pregnancy – Debbie slide 34
- Oral contraceptive in lactation – slide 35… supply vs. safety

Patient Case #1 – Selecting Resources

- A 28yo G1P0 at 10 weeks gestation presents for a prenatal visit. She has a history of MDD, well controlled on sertraline 100mg daily. She stopped taking when she had a positive pregnancy test because she saw on TikTok that “antidepressants cause birth defects”
  - What resources would you consult?

Patient Case #1 – PLLR Excerpts

- Sertraline and the active metabolite desmethylsertraline (DCT) can be detected in cord blood and amniotic fluid (Phogole 2023; Yue 2023).
- Overall, an increased risk of major congenital malformations has not been observed with sertraline when considering differences in study design and confounders ; data evaluating the risk of specific defects are inconclusive (ACOG 2023; Anderson 2020; BAP [McAllister-Williams 2017]; Biffi 2020; Fitton 2020; Gao 2018; Lebin 2022).
- Untreated and undertreated mental health conditions are associated with adverse pregnancy outcomes. Untreated or undertreated depression is associated with preterm birth, low birth weight (LBW), preeclampsia, postpartum depression, and impaired infant attachment (associated with long-term developmental effects).
- Treatment should not be withheld or discontinued based only on pregnancy st (ACOG 2023).

(Sertraline 2026)

Patient Case #1 – Selecting Resources

- Based on PLLR, how would you counsel on risks and benefits?
- What is your clinical recommendation?

Patient Case #2 – Role of Med Chem

- Mom is diagnosed with a DVT at 4m post partum and must be started on anticoagulant therapy. The medical resident asks your opinion on LMWH vs. warfarin.
  - What questions do you have for this patient or medical resident?
  - What questions do you have about the medication options?

Patient Case #2 – Role of Med Chem

Heparin

- MW = 20,000 Da

LMWH

- MW = 3,000-5,000 Da

Warfarin

- MW = 308 Da
- PB > 99%
- Weak acid, pKa 4.8
- Not detectable in breast milk

Patient Case #2 – Role of Med Chem

- Mom is diagnosed with a DVT at 4m *gestation* and must be started on anticoagulant therapy. The medical resident asks your opinion on LMWH vs. warfarin.
  - What questions do you have for this patient or medical resident?
  - What questions do you have about the medication options?

Patient Case #3 – Understanding Physio

- A 29yo patient stops by the community pharmacy to pick up a refill prescription for her Sprintec. As a longtime patient, you recall that she recently had a baby and ask how she is doing. She shares that she is having a hard time breastfeeding.
  - What questions do you have for this patient?
  - What questions do you have about the medication?

Patient Case #3 – PLLR Excerpts

- Adverse health outcomes, or consistent effects on infant growth or illness due to exogenous estrogens have not been reported following maternal use of combination hormonal contraceptives in breastfeeding patients (CDC [Curtis 2016b]). Because estrogen containing contraceptives may reduce milk production, the manufacturer recommends use of other forms of contraception until the child is weaned.
- Due to the increased risk of venous thromboembolism (VTE) postpartum, do not start combination hormonal contraceptives in breastfeeding patients <21 days following delivery. The risk decreases to baseline by postpartum day 42.

(Sprintec 2026)

Patient Case #3

- Based on PLLR, how would you counsel on risks and benefits?
- What is your clinical recommendation?

TW: Infant Loss

Patient Case #4 – Role of PK and PGx

- Mom is taking Tylenol #3 Q12H for episiotomy pain for 2 weeks
  - Day 7: Baby is lethargic at home
  - Day 11: Normal exam at ped
  - Day 12: Gray skin observed with low milk intake
  - Day 13: Infant found dead; [morphine] 70ng/mL (“normal” = 0-2.2)

(Lancet 2006)

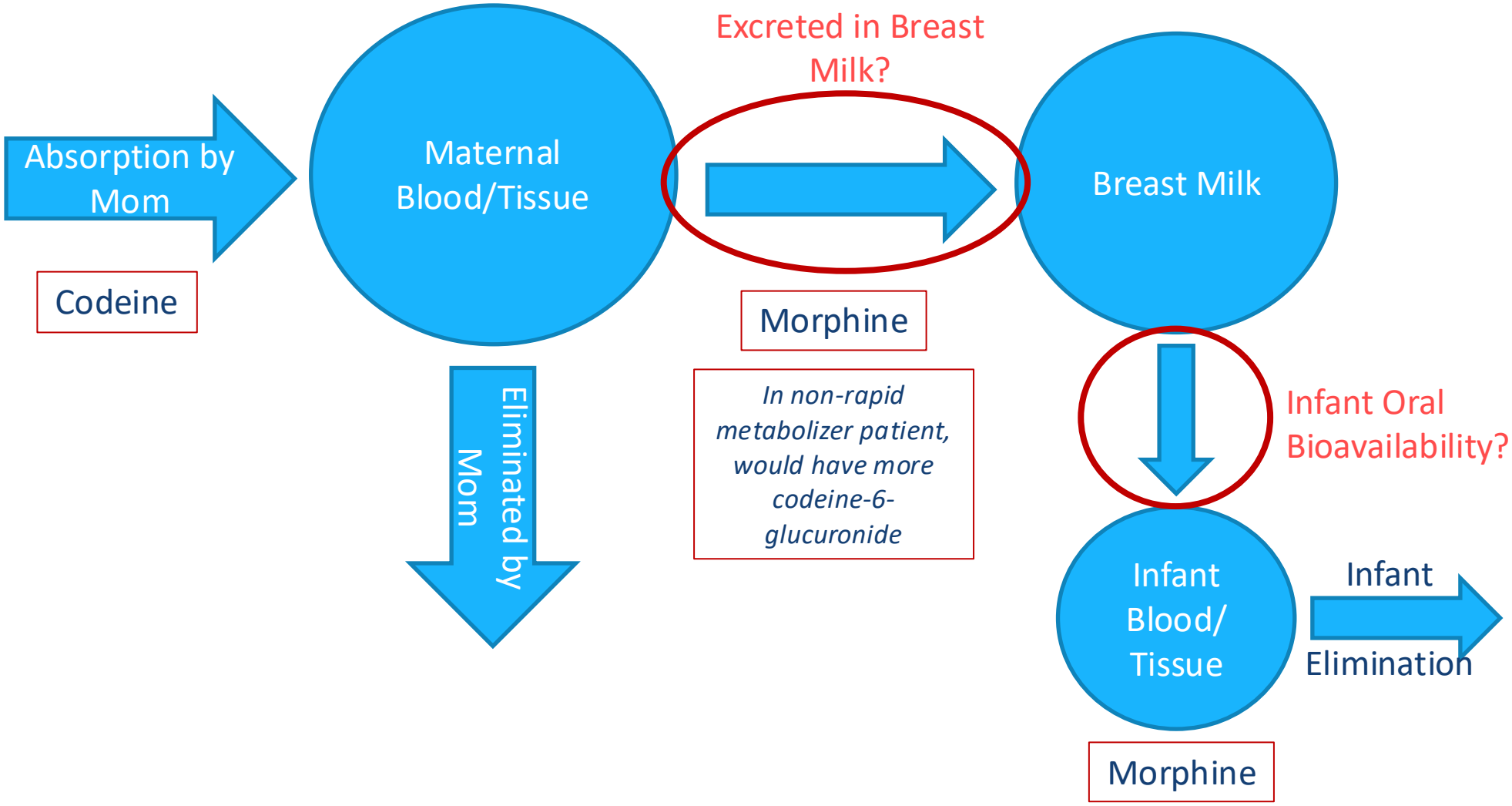
TW: Infant Loss

Patient Case #4

- Why was the codeine level so high?
  - Mom found to be “ultra-rapid metabolizer” of CYP2D6*2A
  - Converts Codeine → Morphine

(Lancet 2006)

PK of Drug Transfer to Breast Milk



TW: Infant Loss

Patient Case #4

- Why was the codeine level so high?
  - Mom found to be “ultra-rapid metabolizer” of CYP2D6*2A
  - Converts Codeine → Morphine
- FDA Warning in 2007 to observe infant for s/sx of toxicity
  - Do we have better options?
    - Ibuprofen and/or oxycodone +/- acetaminophen

(Lancet 2006)

General Safety Principles

Remember that PHARMACISTS are the Medication Experts!

Use understanding of research design, safety information, and drug properties to:

- select drugs that have been used safely for a long time;
- prescribe/recommend lowest needed dose;
- eliminate nonessential medication and discourage self-medication; and
- avoid medications known to be harmful.

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Need More Information?

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