Medication Safety in Pregnancy and Lactation

Essential Knowledge for the Pharmacy Team

José Pérez Yordán, MD, FACOG

2026 Convention — Puerto Rico College of Pharmacists

August 22, 2026 — Sheraton Hotel, San Juan, Puerto Rico

Disclosure to Learners

José Pérez Yordán, MD, FACOG has no relevant financial relationships with ineligible companies to disclose.

Off-label use will be identified on the relevant slide.

Artificial intelligence disclosure: ChatGPT (OpenAI, GPT-5.6) was used on August 2, 2026 to assist with organization, English-language editing, and reference checking. The faculty reviewed and approved all clinical content.

The Puerto Rico College of Pharmacists is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Provider Number: 0151

Universal Activity Number (UAN): 0151-0000-26-018-L01-P/T
Activity Type: Knowledge-based • 2.0 contact hours (0.2 CEU)

LEARNING OBJECTIVES

At the end of this activity, participants will be able to:

1. Describe the evolution of FDA pregnancy labeling, including the transition from the former pregnancy categories to the current Pregnancy and Lactation Labeling Rule (PLLR).

2. Identify factors that may contribute to fetal malformations, including medication exposure and maternal risk factors.

3. Recognize safe pharmacologic and nonpharmacologic treatment options for common self-care medical conditions that may occur during pregnancy and lactation.

4. Identify medications that are contraindicated during pregnancy and lactation and the associated risks to the fetus and neonates.

5. List immunization recommendations before and during pregnancy and their role in maternal and fetal health.

6. Identify reliable information resources to provide safe medication recommendations and counseling for patients planning pregnancy, pregnant and lactating individuals.

Role expectation: technicians identify and refer; pharmacists assess, recommend, communicate, and document.

Opening Case: A Patient at the Counter

Setting: Community pharmacy, Saturday afternoon

A 27-year-old woman approaches the counter. She tells you she found out yesterday she is 5 weeks pregnant.

She has been taking the following for the past 3 months:

- Lisinopril 20 mg daily (hypertension)
- Sertraline 100 mg daily (depression)
- Ibuprofen 600 mg as needed (chronic low back pain)
- Vitamin D 2000 IU daily

She asks: "Should I stop everything? Did I already hurt the baby?"

In the next 2 hours, you will have the tools to confidently answer this patient.

Why This Matters: The Scope of the Problem

Medication use in pregnancy is the rule, not the exception

- Approximately 90% of pregnant patients use at least one medication during pregnancy
- 50–70% use over-the-counter (OTC) medications
- About 50% receive at least one prescription medication
- Less than 10% of FDA-approved medications since 1980 have sufficient safety data in pregnancy

The pharmacist is often the first—and sometimes only—point of contact

- More accessible than the OB clinic
- Patients ask the pharmacist before calling the prescriber
- Pharmacy is the last checkpoint before a teratogen reaches the patient

The Clinical Paradox: Treating vs. NOT Treating

Untreated maternal disease also harms the fetus

Examples of conditions where withholding therapy is harmful:

- Uncontrolled hypertension → preeclampsia, IUGR, stroke, abruption
- Uncontrolled diabetes → congenital malformations, macrosomia, neonatal hypoglycemia
- Untreated depression → preterm birth, low birth weight, postpartum suicide risk
- Uncontrolled asthma → maternal-fetal hypoxia, perinatal complications
- Untreated infections → chorioamnionitis, preterm labor, neonatal sepsis
- Untreated thyroid disease → fetal neurodevelopmental impairment

Risk-benefit is always two-sided. The pharmacist must weigh BOTH the risk of the drug AND the risk of untreated disease.

Framework: Pharmacists' Patient Care Process (PPCP)

A standardized, patient-centered framework — Joint Commission of Pharmacy Practitioners.

Today's lecture maps to each step of this process:

COLLECT	ASSESS	PLAN	IMPLEMENT	FOLLOW UP
Gather patient history, allergies, medications, gestational age	Evaluate risk-benefit for each medication and condition	Develop a patient-centered plan with the prescriber	Counsel, dispense, refer, document	Monitor outcomes, reassess at each visit

Reference: jcpp.net/patient-care-process

The Pharmacy Team's Role

PHARMACIST

- Performs the clinical risk–benefit assessment and interprets the current evidence.
- Identifies contraindications, recommends alternatives, contacts the prescriber, counsels, and documents.
- Coordinates with obstetrics, maternal–fetal medicine, pediatrics, and lactation specialists.

PHARMACY TECHNICIAN

- Confirms and records pregnancy or lactation status and gathers gestational age when available.
- Flags high-risk medications, REMS requirements, and profile conflicts for pharmacist review.
- Does not independently interpret risk or provide clinical recommendations.

Both roles support accurate labeling, follow-up, and timely escalation.

Roadmap for Today's Lecture

OBJ 1

FDA Pregnancy & Lactation Labeling Rule (PLLR)

OBJ 2

Factors Contributing to Fetal Malformations

OBJ 4

Self-Care Conditions in Pregnancy & Lactation

OBJ 3

Medications Requiring Avoidance or Specialist Review

OBJ 5

Immunizations Before, During & After Pregnancy

OBJ 6

Reliable Drug Information Resources

Includes case discussions, check-learning questions, and clinical pearls throughout.

How Evidence Is Labeled in This Lecture

R — REGULATORY
FDA labeling, boxed warnings, safety communications, or REMS requirements.
G — GUIDELINE
National agency or professional-society recommendation, including CDC/ACIP and SMFM.
H — HUMAN DATA
Pregnancy registries, observational studies, pharmacokinetic studies, or lactation data.
C — CONSENSUS / LIMITED DATA
Expert consensus or sparse evidence; individualize and verify in a current resource.
A regulatory warning does not replace an individualized assessment of disease risk, timing, dose, and alternatives.

OBJECTIVE 1

Evolution of FDA Pregnancy and Lactation Labeling

Case: "It's only Category C, right?"

Scenario

A pharmacist receives a prescription for sertraline 50 mg daily for a 28-week pregnant patient with major depressive disorder.

The technician comments: "I looked it up — it's Category C, so it must be safe enough."

The patient's mother is concerned and asks: "What does Category C actually mean? Is it safe or not?"

Today's question:

Why is this question impossible to answer with the old FDA category system, and how does the PLLR change the answer?

History of FDA Pregnancy Labeling

WHY THE FDA NEEDED A BETTER LABEL

- Thalidomide-associated birth defects demonstrated the consequences of inadequate pregnancy safety data.
- The 1962 Kefauver–Harris Amendments strengthened requirements for drug safety and efficacy.
- In 1979, FDA introduced the A, B, C, D, and X pregnancy categories.
- The categories were later recognized as misleading and clinically incomplete.
- The Pregnancy and Lactation Labeling Rule took effect June 30, 2015.
- Legacy letter categories were removed from prescription-drug labeling.

The Old FDA Pregnancy Categories (1979–2015)

Discontinued by FDA — shown for context only.

Category A:

Controlled human studies show NO risk to fetus. Example: levothyroxine.

Category B:

Animal studies show no risk OR animal risk not confirmed in humans. Examples: amoxicillin, acetaminophen.

Category C:

Animal studies show risk; no adequate human studies. Examples: fluoxetine, prednisone, sertraline.

Category D:

Evidence of human fetal risk, but benefits may justify use. Examples: phenytoin, lithium.

Category X:

Risks clearly outweigh any benefit. CONTRAINDICATED. Examples: isotretinoin, warfarin, thalidomide.

Why the FDA Replaced the ABCDX Categories

Five fundamental problems

1. False simplicity:

Suggested a linear A→X risk gradient when categories are not actually comparable.

2. No dose-response or timing information:

A drug "safe" in the first trimester may be dangerous later (e.g., NSAIDs).

3. No lactation information at all:

Categories addressed only pregnancy, not breastfeeding.

4. Category C was a catch-all:

Drugs with vastly different safety profiles all received the same label.

5. No requirement to update with new evidence:

Labels became stale and clinicians lacked current data.

The 2015 PLLR replaced letters with narrative, evidence-based information.

The Pregnancy and Lactation Labeling Rule (PLLR) – 2015

Replaces letter categories with structured narrative information.

- Applies to prescription drugs and biologic products covered by the Physician Labeling Rule.
- New applications submitted after June 30, 2015 use the PLLR format; products approved since June 30, 2001 were phased in.
- Products approved earlier had to remove the pregnancy letter category.
- OTC Drug Facts labeling is not changed by the PLLR.
- Labels must be updated when clinically relevant information changes.

8.1

PREGNANCY

Risk summary, clinical considerations, supporting data, registry contact

8.2

LACTATION

Drug in breast milk, infant effects, milk production effects, RID, M:P ratio

8.3

REPRODUCTIVE POTENTIAL

Pregnancy testing, contraception requirements, infertility effects

PLLR Section 8.1 — Pregnancy

Three required components

Risk Summary:

Risk of birth defects, miscarriage, or adverse outcomes based on human, animal, and pharmacologic data.

Includes background population risk for major malformations (2–4%).

Clinical Considerations:

Disease-associated maternal/fetal risk if untreated.

Dose adjustments during pregnancy.

Maternal, fetal, or neonatal adverse reactions, including signs of withdrawal.

Labor and delivery effects.

Data:

Human data and animal data supporting the risk summary.

Pregnancy registry information and contact when available.

PLLR Section 8.2 — Lactation

Three required components — interpreted in clinical context

RISK SUMMARY

- Drug presence in human milk, effects on the breastfed child, and effects on milk production.

CLINICAL CONSIDERATIONS

- Strategies to minimize exposure and infant findings that require monitoring.

DATA

- Milk concentrations, infant concentrations, and pharmacokinetic evidence when available.

RID <10% is a screening rule—not a guarantee of safety. Consider toxicity, oral bioavailability, dose, infant age, prematurity, and clinical status.

PLLR Section 8.3 — Females and Males of Reproductive Potential

Use Section 8.3 when labeling requires information about:

- Pregnancy testing before or during therapy.
- Contraception during treatment or for a defined period afterward.
- Drug effects on female or male fertility.

PRACTICAL EXAMPLES

- Isotretinoin: iPLEDGE pregnancy testing, contraception, and dispensing controls.
- Mycophenolate: REMS counseling, pregnancy testing, and contraception requirements.
- Methotrexate: reproductive precautions vary by product, indication, and patient sex—follow the current label and specialist plan.
- Thalidomide-class products: strict REMS requirements.

Putting PLLR Into Practice — Reading a Label

A 60-second label review

1. Confirm pregnancy timing, lactation status, indication, dose, and duration.
2. Read Section 8.1 Risk Summary—what outcome is described and what data support it?
3. Read Clinical Considerations—disease risk, dose changes, maternal/fetal reactions, labor, and neonatal effects.
4. If lactating, read Section 8.2—milk transfer, infant effects, milk production, and monitoring.
5. Read Section 8.3 for testing, contraception, and fertility requirements.
6. Verify the decision with a current specialized resource when uncertainty remains.

Legacy references may still show ABCDX letters; current U.S. prescribing information does not use them.

OBJECTIVE 2

Factors Contributing to Fetal Malformations

Case: "I Took Isotretinoin Before I Knew I Was Pregnant"

Scenario

A 22-year-old woman calls the pharmacy in tears. She just had a positive pregnancy test.
She has been on isotretinoin 40 mg daily for severe nodulocystic acne for the past 4 months under the iPLEDGE program. Her last menstrual period was 5 weeks ago.
She asks: "What does this mean for the baby? Should I terminate? Will I be in trouble with iPLEDGE?"

Key concepts to discuss:

Critical period of exposure (3–8 weeks post-conception = organogenesis)
Magnitude of teratogenic risk for isotretinoin
Pharmacist's documentation duty under iPLEDGE
Referral to MotherToBaby for personalized counseling

Key Definitions

TERATOGEN

An exposure capable of causing a permanent structural or functional developmental alteration under specific conditions.

TERATOGENIC RISK

Depends on timing, dose, duration, route, co-exposures, and maternal–fetal susceptibility.

FETAL OR NEONATAL TOXICITY

Adverse growth, organ-function, or neurodevelopmental effects that may occur without a structural anomaly.

RELATIVE INFANT DOSE (RID)

Infant dose (mg/kg/day) ÷ maternal dose (mg/kg/day) × 100. Interpret with toxicity and infant factors.

MILK-TO-PLASMA RATIO

Describes milk transfer but does not, by itself, define infant dose or safety.

Wilson's Principles of Teratology (1959)

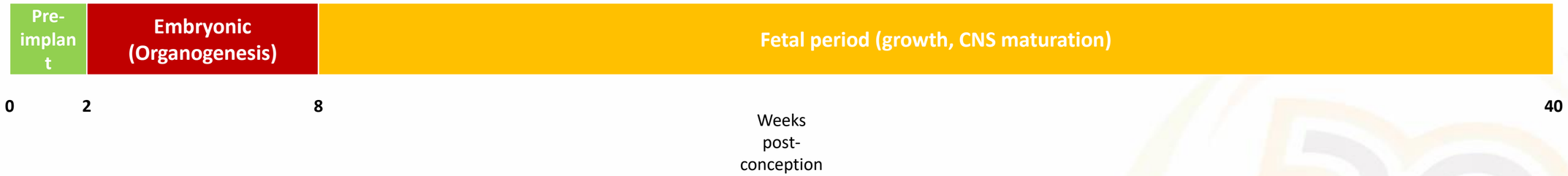
Six classic principles that still guide modern teratology

1. Susceptibility depends on genotype of the embryo.
2. Susceptibility varies with developmental stage at exposure.
3. Mechanisms of teratogens are specific (cell death, altered growth, etc.).
4. End points include death, malformation, growth retardation, or functional deficits.
5. Access to developing tissues depends on the agent (placental transfer).
6. Manifestations increase with dose, from no effect to lethality.

Implication for the pharmacist: dose, timing, and individual susceptibility all matter — a single "safe/unsafe" label cannot capture this complexity.

Fetal Development Timeline and Susceptibility

Developmental periods below use post-conception age. Add 2 weeks to convert to gestational age based on the last menstrual period.



Susceptibility by phase:

- Pre-implantation (wk 0–2): "All-or-none" — embryo survives intact or is lost.
- Embryonic (wk 3–8): MAXIMUM susceptibility to structural teratogens. Organogenesis.
- Fetal (wk 9–40): Functional toxicity, growth restriction, neurodevelopmental effects.

Pre-Implantation (0–2 Weeks Post-Conception): "All or None"

What happens during this phase
Fertilization, cell division, blastocyst formation, and implantation.
Cells are totipotent — capable of replacing damaged cells.
Toxic exposures usually result in pregnancy loss (early miscarriage, often not recognized) OR no detectable effect.
Structural birth defects are uncommon from exposures in this window.
Practical implication for the pharmacist
Patients often consult after exposure during this window before knowing they were pregnant.
Evidence-based counseling and referral to MotherToBaby reduces unnecessary anxiety.
Reassure the patient that timing during this window often means low malformation risk — but always verify with a current resource.
LMP-based dating: "5 weeks pregnant" often means only 3 weeks since conception.

Embryonic Period (3–8 Weeks Post-Conception): Organogenesis

MAXIMUM RISK WINDOW for structural teratogens.

Critical events week by week

Week 3:

Neural tube — folate antagonists → spina bifida, anencephaly.

Week 4:

Heart, limb buds — cardiac malformations, limb reduction defects.

Week 5:

Eyes, ears, palate — anomalies, deafness, cleft palate.

Weeks 6–8:

External genitalia, refinement of organ structures.

Most classic teratogens (thalidomide, isotretinoin, valproate, warfarin) act during this window.

Fetal Period (Week 9 Post-Conception to Birth)

Beyond structural malformations—functional toxicity can emerge later

- Growth restriction or impaired organ function.
- Fetal renal dysfunction and oligohydramnios with renin–angiotensin system blockers.
- Oligohydramnios from NSAID exposure beginning around 20 weeks; ductal constriction risk later in gestation.
- Neonatal adaptation symptoms after late exposure to some psychotropic medications.
- Opioid-associated neonatal withdrawal.
- Thyroid dysfunction after excessive or poorly controlled antithyroid exposure.

Normal anatomy does not exclude later functional, growth, or neonatal effects.

High-Risk Exposures: Teratogens and Fetotoxins

STRUCTURAL TERATOGENS

- Isotretinoin, thalidomide-class products, mycophenolate, methotrexate, and selected antiseizure drugs—especially valproate.
- Warfarin during the characteristic early exposure window.

TIMING-DEPENDENT FETOTOXICITY

- ACE inhibitors, ARBs, and direct renin inhibitors: fetal renal toxicity, especially after the first trimester.
- NSAIDs: oligohydramnios risk beginning around 20 weeks and ductal constriction risk later.
- Tetracyclines after midpregnancy: tooth and bone effects rather than a classic major-malformation pattern.

OTHER IMPORTANT EXPOSURES

- Radioactive iodine, systemic retinoids, ribavirin, and cytotoxic agents require product-specific counseling.

Non-exhaustive: verify the indication, timing, dose, label, and current specialized reference.

Spotlight: Isotretinoin and the iPLEDGE Program

Teratogenic profile

One of the most potent known human teratogens — risk magnitude ~25-30% major malformations with exposure.

Craniofacial, cardiac, CNS, thymic defects.

Risk persists from conception through 1 month after the last dose.

iPLEDGE program requirements

Two negative pregnancy tests before initiation (one 30 days before, one before dispensing).

Two forms of contraception OR documented abstinence.

Monthly pregnancy testing while on therapy and at completion.

Monthly authorization codes from iPLEDGE before dispensing.

Pharmacist verification at EVERY dispensing — no auto-refills.

Pharmacy team: any dispensing without current authorization is a serious REMS violation.

Maternal and Environmental Risk Factors — Beyond Medications

CONGENITAL-ANOMALY RISK

- Increasing maternal age and aneuploidy risk.
- Poorly controlled pregestational diabetes and maternal phenylketonuria.
- Folate deficiency, selected infections, alcohol, and ionizing radiation at sufficient dose.

PLACENTAL, GROWTH, OR NEONATAL RISK

- Chronic hypertension, tobacco, cocaine or methamphetamine, opioids, and uncontrolled maternal disease.

COUNSELING OPPORTUNITIES

- Nutrition, folic acid, vaccination, substance-use treatment, occupational exposure, and preconception disease control.

Do not attribute every adverse outcome to a medication without considering the underlying condition and co-exposures.

Spotlight: Diabetes and Pregnancy

Why glycemic control matters before conception

- Major-malformation risk rises progressively as periconception hemoglobin A1c increases.
- Optimize glucose control before conception while avoiding clinically significant hypoglycemia.

MEDICATION PRINCIPLES

- Pregestational diabetes: insulin is preferred and permits titration as pregnancy physiology changes.
- Metformin crosses the placenta and may be appropriate in selected patients after individualized counseling; it is not a universal substitute for insulin.
- Glyburide is not preferred as first-line therapy for gestational diabetes because of neonatal and efficacy concerns.
- Avoid routine use of SGLT2 inhibitors, GLP-1 receptor agonists, and DPP-4 inhibitors during pregnancy because safety data are inadequate.

Substance Use During Pregnancy

ALCOHOL

No known safe amount or timing; counsel abstinence during pregnancy.

TOBACCO / NICOTINE

Associated with fetal-growth restriction, preterm birth, and sudden infant death. Behavioral treatment is first line; medication decisions are individualized.

OPIOIDS

Do not abruptly discontinue opioid-use-disorder treatment. Methadone or buprenorphine maintenance reduces relapse and overdose risk.

CANNABIS

Recommend discontinuation. Observed associations exist, but confounding limits causal estimates.

COCAINE / METHAMPHETAMINE

Placental vasoconstriction increases abruption, growth, prematurity, and maternal cardiovascular risk.

Preconception Planning — The Pharmacist's Highest Impact

FOLIC ACID

- 400–800 mcg/day for most patients who can become pregnant.
- 4 mg/day for a prior neural-tube-defect pregnancy, beginning before conception; use specialist guidance for other high-risk indications.

CHRONIC DISEASE

- Optimize diabetes, hypertension, thyroid disease, epilepsy, mental health, and autoimmune disease before conception.
- Coordinate medication changes with the prescriber; never abruptly stop antiseizure or psychiatric therapy.

IMMUNIZATION AND EXPOSURES

- Complete indicated live vaccines before pregnancy and review occupational, environmental, alcohol, tobacco, and substance exposures.

OBJECTIVE 3

Medications Requiring Avoidance or Specialist Review

Case: New Lisinopril Prescription at 14 Weeks

Scenario

A 28-year-old patient, gravida 1, at 14 weeks gestation, presents with a new prescription for lisinopril 20 mg daily.

Other data:

BP today: 148/96 mm Hg. No proteinuria.

Prescribed by her PCP for newly diagnosed chronic hypertension.

No mention of pregnancy noted on the prescription.

Patient asks: "Is this safe for the baby? I already took half a pill last night."

Discussion questions:

What does the pharmacist do RIGHT NOW?

What alternatives should be recommended?

How and what is documented and communicated to the prescriber?

Risk-Benefit Framework for Every Dispensing Decision

Before dispensing, ask the following questions:

Is the medication necessary, or is there an effective non-pharmacologic alternative?

What is the risk of the maternal disease if NOT treated?

What evidence exists about fetal and neonatal safety? (Briggs, LactMed, UpToDate)

What is the gestational age? The same medication may be safe in one trimester and harmful in another.

What is the minimum effective dose for the shortest duration?

Is there an alternative with a better safety profile and similar efficacy?

Is the patient aware of the risk-benefit and red flag symptoms?

Use the Pharmacists' Patient Care Process: Collect → Assess → Plan (with prescriber) → Implement (counsel + dispense) → Follow up.

Medications Requiring Avoidance or Specialist Review

RENIN–ANGIOTENSIN SYSTEM BLOCKERS

Avoid ACE inhibitors, ARBs, and direct renin inhibitors; arrange prompt prescriber review when pregnancy is identified.

ANTICOAGULANTS

Warfarin is generally avoided, but mechanical heart valves require an individualized cardiology–MFM plan. Avoid DOACs because pregnancy data are inadequate.

ANTI-INFLAMMATORY DRUGS

Limit NSAIDs at 20–30 weeks and avoid at ≥30 weeks. Low-dose aspirin prescribed for an obstetric indication is an important exception.

DEFINITE OR MAJOR TERATOGENS

Systemic retinoids, methotrexate, mycophenolate, thalidomide-class products, and selected cytotoxic drugs.

NOT A BLANKET CONTRAINDICATION

FDA removed the class-wide statin contraindication in 2021. Discontinue in most pregnancies; consider ongoing use only for exceptional, very-high cardiovascular risk with specialists.

Spotlight: ACE Inhibitors and ARBs

WHY THEY ARE AVOIDED

Blocking the fetal renin–angiotensin system can reduce renal perfusion and urine production.

FETAL / NEONATAL CONSEQUENCES

- Oligohydramnios and pulmonary hypoplasia.
- Renal injury or failure, hypotension, growth impairment, and death.
- Toxicity is most established after first-trimester exposure.

PREGNANCY ALTERNATIVES

Labetalol and extended-release nifedipine are commonly preferred. Methyldopa is acceptable; intravenous hydralazine is used mainly for acute severe hypertension.

ACTION

Hold dispensing, contact the prescriber promptly, document, and ensure an effective replacement and obstetric follow-up.

Spotlight: Warfarin Embryopathy

Characteristic early exposure window: approximately 6–12 gestational weeks

WARFARIN EMBRYOPATHY

- Nasal hypoplasia and stippled epiphyses.
- Central nervous system, eye, growth, and developmental effects may occur.

LATER-PREGNANCY RISK

- Fetal or neonatal hemorrhage, including intracranial hemorrhage.

ALTERNATIVES

- Low-molecular-weight heparin is commonly preferred because it does not cross the placenta.
- Unfractionated heparin is used in selected settings.
- DOACs are generally avoided because evidence is inadequate.

Mechanical heart valves are a specialist exception—never make an uncoordinated switch.

Spotlight: Methotrexate

METHOTREXATE / AMINOPTERIN EMBRYOPATHY

- Craniofacial and ossification abnormalities, growth restriction, limb or central nervous system effects, and pregnancy loss.

PRECONCEPTION MANAGEMENT

- Stop before conception according to the current product label, indication, dose, and specialist plan.
- Recommended post-treatment contraception intervals are product- and sex-specific; do not use one interval for every patient.
- Ensure appropriate folate supplementation after methotrexate is discontinued.
- Coordinate disease control with rheumatology, oncology, dermatology, or transplant specialists.

Inadvertent exposure: stop further dosing and arrange prompt teratology and MFM counseling—do not provide deterministic counseling at the counter.

Spotlight: Valproate and Other Antiseizure Medications

VALPROATE

- Strong dose-dependent association with neural-tube defects, other major malformations, and adverse neurodevelopmental outcomes.
- Avoid for pregnancy when an effective alternative exists, particularly for migraine prevention.

LOWER OBSERVED MALFORMATION PREVALENCE

- Lamotrigine and levetiracetam generally have more reassuring human pregnancy data.

OTHER IMPORTANT RISKS

- Carbamazepine: neural-tube-defect risk.
- Topiramate: oral clefts and fetal-growth effects.
- Phenobarbital and phenytoin: characteristic malformation patterns and neonatal effects.

Never abruptly stop seizure medication. Optimize before conception with neurology and monitor levels when indicated.

NSAIDs in Pregnancy — FDA 2020 Safety Alert

FDA Drug Safety Communication — October 15, 2020

BEFORE 20 WEEKS

Use only when indicated and for the shortest effective duration; acetaminophen remains the usual first-line analgesic or antipyretic.

20 TO <30 WEEKS

Avoid routine NSAID use because fetal renal dysfunction can cause oligohydramnios. If necessary, use the lowest dose for the shortest time; consider amniotic-fluid monitoring when treatment extends beyond 48 hours.

≥30 WEEKS

Avoid because of ductal constriction/premature closure in addition to renal effects.

LOW-DOSE ASPIRIN

FDA's warning does not apply to aspirin 81 mg prescribed for an obstetric indication.

Check-Learning: NSAID Decision

A patient at 24 weeks asks to take ibuprofen 600 mg three times daily for several days after an ankle injury. Which is the MOST appropriate response?

1. Ibuprofen is safe at this gestational age.
2. Avoid routine ibuprofen use at 24 weeks; recommend rest, ice, compression, elevation, and acetaminophen if appropriate. Refer for severe or persistent pain.
3. Ibuprofen is acceptable for up to five days without prescriber involvement.
4. Naproxen is safer than ibuprofen during pregnancy.

Commit to an answer before advancing.

NSAID Check-Learning — Answer and Feedback

BEST ANSWER: 2

At 24 weeks, FDA advises avoiding NSAIDs unless specifically indicated because fetal renal dysfunction can produce oligohydramnios.

WHY THE OTHER OPTIONS ARE NOT BEST

- 1: Gestational age changes the risk; NSAIDs are not routinely considered safe at 24 weeks.
- 3: Duration does not eliminate the risk, and treatment should be individualized.
- 4: Naproxen is also an NSAID and does not avoid the class effect.

Pharmacy action: assess severity and contraindications, recommend appropriate non-drug measures and acetaminophen when suitable, and refer if pain is significant or the diagnosis is uncertain.

Spotlight: Antimicrobials — Knowing the Caveats

COMMONLY USED WHEN INDICATED

•Penicillins, cephalosporins, azithromycin, metronidazole, and selected urinary agents have substantial pregnancy experience.

IMPORTANT CAVEATS

•Nitrofurantoin: useful for lower UTI; avoid in G6PD deficiency and consider product-label precautions near delivery.

•Trimethoprim–sulfamethoxazole: folate antagonism early and neonatal bilirubin concerns near term; use only when benefits and susceptibility justify it.

•Tetracyclines: avoid prolonged use after midpregnancy because of tooth and bone effects.

•Fluoroquinolones: not first line when better-studied alternatives exist, but not established major human teratogens.

•Aminoglycosides: agent-specific fetal ototoxicity and nephrotoxicity concerns; use when clinically necessary.

•Vulvovaginal candidiasis: use a 7-day topical azole; avoid oral fluconazole in pregnancy when possible.

Culture, infection site, allergy, gestational age, and local resistance determine the best option.

Lactation: Avoid, Interrupt, or Monitor?

AVOID OR INTERRUPT BREASTFEEDING

- Many cytotoxic antineoplastic drugs and therapeutic radioactive iodine.
- Illicit cocaine, methamphetamine, heroin, and phencyclidine.
- Codeine and tramadol are not recommended by FDA during breastfeeding.

SPECIALIST DECISION / INFANT MONITORING

- Lithium may be used in selected dyads with coordinated infant renal, thyroid, and serum monitoring.
- Amiodarone and long half-life or highly toxic drugs require individualized review.
- Therapeutic stimulants are not equivalent to illicit stimulant use; assess the drug, dose, infant, and milk supply.

COMPATIBLE OPTIONS ARE COMMON

Acetaminophen, ibuprofen, many beta-lactam antibiotics, and second-generation antihistamines are generally compatible.

Always verify the specific drug and infant circumstances in LactMed.

Spotlight: Codeine and Tramadol in Lactation

FDA RECOMMENDATION

Breastfeeding is not recommended during treatment with codeine or tramadol because maternal metabolism and infant exposure are unpredictable.

FIRST-LINE POSTPARTUM ANALGESIA

- Scheduled acetaminophen and an NSAID such as ibuprofen, when not contraindicated.
- Use nonpharmacologic and procedure-specific measures.

IF AN OPIOID IS REQUIRED

- Use the lowest effective dose for the shortest duration; avoid extended-release products.
- Morphine is often preferred; verify the individual opioid in LactMed.
- Teach infant warning signs: increasing sleepiness, poor feeding, limpness, or breathing difficulty.

Newborn and preterm infants are especially sensitive to opioid exposure.

Check-Learning: Postpartum Analgesia

A breastfeeding patient with postoperative cesarean pain needs an oral analgesic plan.
Which is the MOST appropriate option for the patient and infant?

1. Codeine every 4–6 hours.
2. Tramadol every 6 hours.
3. Hydrocodone–acetaminophen as routine first-line therapy.
4. Scheduled ibuprofen plus acetaminophen within recommended daily dose limits, with escalation only if needed.

Commit to an answer before advancing.

Postpartum Analgesia Check-Learning — Answer and Feedback

BEST ANSWER: 4

Ibuprofen has extremely low milk levels, and acetaminophen exposure through milk is far below therapeutic infant doses. Multimodal non-opioid therapy is preferred when adequate.

WHY THE OTHER OPTIONS ARE NOT BEST

- 1 and 2: FDA recommends against codeine and tramadol during breastfeeding.
- 3: An opioid is not routine first-line therapy; if required, choose the agent and duration carefully and monitor the infant. Escalate uncontrolled pain or possible postoperative complications to the prescriber rather than repeatedly increasing OTC therapy.

OBJECTIVE 4

Self-Care Conditions During Pregnancy and Lactation

Case: "I can't keep anything down"

A 25-year-old patient at 9 weeks reports persistent nausea, vomiting three to five times daily, and a three-pound weight loss. She has tried dietary changes without relief and asks whether doxylamine–pyridoxine is safe.

DISCUSS

- What information should the pharmacy team collect?
- Which nonpharmacologic and OTC options are reasonable?
- Which symptoms require same-day evaluation?

Technician: identify dehydration or significant weight-loss concerns and refer to the pharmacist.

Pharmacist: assess severity, recommend within scope, and refer when hyperemesis or another diagnosis is possible.

Nausea and Vomiting of Pregnancy (NVP) — Stepwise Approach

STEP 1 — DIETARY / BEHAVIORAL

Small frequent meals, avoid triggers, ginger, and acupressure if desired.

STEP 2 — PYRIDOXINE

10–25 mg every 6–8 hours; review total vitamin B6 exposure from all products.

STEP 3 — DOXYLAMINE + PYRIDOXINE

Evidence-based first-line pharmacotherapy; warn about sedation and avoid duplicate antihistamines.

STEP 4 — PRESCRIPTION ANTIEMETICS

Metoclopramide, promethazine, or ondansetron may be used after individualized counseling; evidence and adverse effects differ.

REFER NOW: inability to keep liquids down, dehydration, syncope, hematemesis, severe abdominal pain, electrolyte concern, or >5% prepregnancy weight loss.

GERD and Heartburn in Pregnancy

FIRST: NONPHARMACOLOGIC MEASURES

Small meals; avoid meals 2–3 hours before bed; elevate the head of the bed; reduce individual trigger foods.

ANTACIDS

Calcium carbonate or selected aluminum/magnesium products. Avoid sodium bicarbonate and magnesium trisilicate.

H2-RECEPTOR ANTAGONIST

Famotidine has reassuring pregnancy experience and few drug interactions.

PROTON-PUMP INHIBITOR

Consider for persistent symptoms after assessment; omeprazole has extensive human experience.

Refer for dysphagia, bleeding, weight loss, severe pain, or symptoms suggesting cardiac or hepatobiliary disease.

Allergic Rhinitis and Common Cold

ALLERGIC RHINITIS

- Saline irrigation and allergen avoidance.
- Intranasal budesonide or fluticasone; loratadine or cetirizine when an oral antihistamine is needed.
- First-generation antihistamines may be used, but sedation and anticholinergic effects limit routine use.

COMMON COLD

- Acetaminophen for pain or fever when indicated; saline, hydration, and humidification.
- Dextromethorphan has reassuring data; avoid multi-ingredient products when a single ingredient will suffice.
- Avoid systemic decongestants in the first trimester and in uncontrolled hypertension; pseudoephedrine may reduce milk supply.

Honey is safe for the lactating parent but must never be given directly to an infant younger than 12 months.

Headache and Pain Management

FIRST LINE

Acetaminophen at the lowest effective dose for the shortest necessary duration. SMFM reaffirmed it as first-line therapy for pain or fever in pregnancy in June 2026.

MIGRAINE

Sumatriptan has the most pregnancy experience among triptans. Consider metoclopramide for associated nausea; keep total caffeine ≤200 mg/day.

AVOID OR LIMIT

- NSAIDs: avoid routine use at ≥20 weeks; avoid at ≥30 weeks. Low-dose aspirin prescribed for obstetric prevention is different.
- Ergot derivatives, butalbital combinations, and chronic opioid therapy.

URGENT REFERRAL

Sudden severe headache, neurologic deficit, visual changes, hypertension, fever/meningismus, or right-upper-quadrant pain.

Constipation and Hemorrhoids

CONSTIPATION

- Fiber, fluids, and activity as tolerated.
- Bulk-forming agents and polyethylene glycol have minimal systemic absorption.
- Docusate is safe but often less effective than osmotic agents.
- Senna or bisacodyl can be used short term when needed; avoid chronic overuse.
- Avoid mineral oil because it can impair absorption of fat-soluble vitamins.

HEMORRHOIDS

Sitz baths, cold compresses, fiber, short-course low-potency topical hydrocortisone, local anesthetic, or witch hazel.

Review iron dose and formulation when constipation begins after supplementation; do not stop prescribed iron without a plan.

UTI and Yeast Infections

URINARY SYMPTOMS — REFER FOR EVALUATION

- Pregnancy UTI treatment should be guided by urine testing, culture, allergy, gestational age, and local resistance.
- Common options include selected beta-lactams, fosfomycin, and nitrofurantoin for lower UTI.
- Avoid empiric amoxicillin or ampicillin when resistance is likely.
- Nitrofurantoin: avoid with G6PD deficiency and review near-term label precautions.
- Fever, flank pain, vomiting, or systemic illness requires urgent evaluation for pyelonephritis.

VULVOVAGINAL CANDIDIASIS

- Use a 7-day topical azole during pregnancy.
- Avoid oral fluconazole when possible; recurrent or uncertain symptoms require examination.

Skin Conditions in Pregnancy

ACNE

Benzoyl peroxide, azelaic acid, and selected topical antibiotics are reasonable. Avoid systemic retinoids; avoid topical retinoids during pregnancy as a precaution.

PRURITUS

Emollients, oatmeal baths, low-potency topical corticosteroid, loratadine, or cetirizine.

RED FLAG

New intense pruritus—especially palms and soles—with little or no rash requires evaluation for intrahepatic cholestasis.

ECZEMA

Low- to mid-potency topical corticosteroids are generally compatible; limit extensive high-potency exposure and refer severe disease.

STRIAE

Moisturizers may improve comfort, but no topical product reliably prevents stretch marks.

Sleep Disturbances in Pregnancy

FIRST: SLEEP AND SAFETY ASSESSMENT

Consistent schedule, reduced evening screen exposure, comfortable side-sleeping, and evaluation for anxiety, depression, sleep apnea, reflux, nocturia, or restless legs.

POSITION

Either lateral position is acceptable. Avoid prolonged supine sleep late in pregnancy if symptomatic; use pillows for comfort.

SHORT-TERM OPTIONS

Doxylamine or diphenhydramine may be used occasionally, but tolerance, next-day sedation, and duplicate ingredients matter.

AVOID ROUTINE USE

Benzodiazepines, sedative-hypnotics, cannabis, alcohol, and poorly studied supplements such as melatonin without clinician review.

Check ferritin when restless legs symptoms are prominent.

Self-Care During Lactation: Mastitis and Nipple Pain

INFLAMMATORY MASTITIS

- Continue physiologic breastfeeding on demand; avoid over-pumping to “empty” the breast.
- Use cold packs, ibuprofen or acetaminophen, supportive bra, rest, and normal hydration.
- Avoid deep massage and excessive heat, which can worsen edema and tissue injury.

BACTERIAL MASTITIS

Persistent focal symptoms plus systemic illness may require antibiotics. Reassess at 24–48 hours and consider culture when not improving or MRSA risk is present.

NIPPLE PAIN

Assess latch, pump trauma, dermatitis, vasospasm, bacterial infection, and other causes; “thrush” should not be diagnosed from pain alone.

Urgent evaluation: sepsis, rapidly progressive erythema, fluctuant mass, or failure to improve.

Postpartum Contraception in the Lactating Patient

PROGESTIN-ONLY AND INTRAUTERINE OPTIONS

Progestin-only pills, implant, levonorgestrel IUD, copper IUD, and depot medroxyprogesterone can be initiated postpartum when medically eligible. Timing affects expulsion, follow-up, and counseling—not lactation safety alone.

COMBINED ESTROGEN–PROGESTIN METHODS

- Do not use before 21 days postpartum because of venous-thromboembolism risk.
- Breastfeeding patients generally should not use them at 21 to <30 days.
- At 30–42 days, eligibility depends on VTE risk factors.
- After 42 days, they are generally acceptable if otherwise eligible, while monitoring milk supply and patient preference.

Use the current CDC U.S. Medical Eligibility Criteria rather than a single “wait six weeks” rule.

OBJECTIVE 5

Immunizations Before, During and After Pregnancy

Case: "I'm scared of vaccines while pregnant"

A patient at 30 weeks is due for Tdap and asks whether pregnancy vaccines cause autism or “give the baby the disease.” She also asks about maternal RSV vaccination, which begins at 32 0/7 weeks when otherwise indicated.

COUNSELING GOALS

- Ask permission to discuss and identify the specific concern.
- Explain which vaccines are non-live and how maternal antibodies protect the infant.
- Distinguish routine recommendations from individualized or seasonal decisions.
- Use Puerto Rico–specific RSV timing guidance rather than assuming the continental U.S. season.

Maternal Immunization Framework (2025–2026)

ROUTINELY RECOMMENDED

- Tdap during every pregnancy, preferably early in the 27–36-week window.
- Inactivated or recombinant influenza vaccine during any trimester in season.

INDIVIDUAL DECISION-MAKING

- 2025–2026 COVID-19 vaccination uses individualized decision-making; pregnancy increases the potential benefit because it raises severe-disease risk.

SEASONAL / PREGNANCY-HISTORY DEPENDENT

- Maternal RSVpreF vaccine at 32 0/7–36 6/7 weeks, using Puerto Rico territorial guidance for timing.
- CDC currently does not recommend repeating maternal RSV vaccine in a later pregnancy after a prior maternal dose; protect the infant with an indicated long-acting antibody instead.

Spotlight: Tdap — Preventing Neonatal Pertussis

WHY Tdap IN EACH PREGNANCY

Maternal antibodies cross the placenta and protect the infant before the primary DTaP series can provide protection.

TIMING

- Give one dose in every pregnancy, preferably early in the 27–36-week window.
- Tdap may be given earlier for wound management or an outbreak; do not repeat later in the same pregnancy.
- If not given during pregnancy, administer postpartum only when the patient has never received Tdap or is otherwise due—the postpartum dose does not provide prenatal antibody transfer.

COCOONING

Vaccinating close contacts is useful but supplements rather than replaces maternal Tdap.

Influenza Vaccine in Pregnancy

WHY IT MATTERS

Pregnancy increases the risk of severe influenza and hospitalization; fever and severe maternal disease can affect the pregnancy.

RECOMMENDED

- Inactivated influenza vaccine or recombinant influenza vaccine during any trimester when seasonally indicated.
- Any age-appropriate influenza vaccine may be used in patients with egg allergy; follow standard allergy precautions.

DO NOT USE

Live attenuated intranasal influenza vaccine during pregnancy.

Maternal antibodies also help protect the infant during the first months, before the infant is eligible for influenza vaccination.

Maternal RSVpreF Vaccine — Puerto Rico Considerations

ELIGIBILITY

- Use only the RSVpreF product approved for pregnancy.
- One dose at 32 0/7–36 6/7 weeks when seasonal/territorial timing criteria are met.

PUERTO RICO

RSV circulation differs from most of the continental United States. Follow current Puerto Rico Department of Health or CDC territorial timing guidance rather than automatically using September–January.

MATERNAL VACCINE OR INFANT ANTIBODY

Most infants need one strategy, not both. If delivery occurs <14 days after maternal vaccination, or maternal vaccination was not given/appropriate, an indicated long-acting infant RSV antibody may be used.

PRIOR MATERNAL RSV VACCINE

CDC currently recommends infant antibody rather than repeating a maternal RSV dose in a subsequent pregnancy.

COVID-19 Vaccine in Pregnancy

CURRENT CDC APPROACH FOR 2025–2026

COVID-19 vaccination for people aged 6 months and older is based on individual decision-making.

WHY PREGNANCY CHANGES THE DISCUSSION

- Pregnancy increases the risk of severe COVID-19, hospitalization, intensive care, preterm birth, and stillbirth.
- Vaccination offers greater potential benefit when risk of severe disease is higher, including during pregnancy.
- Vaccination during pregnancy has not been linked to increased maternal or infant health risks and is not associated with infertility.

PRACTICAL COUNSELING

Discuss prior doses/infection, time since last dose, comorbidities, exposure risk, and patient values. Vaccination can be given in any trimester and can be co-administered with other indicated vaccines.

Vaccines Avoided or Deferred During Pregnancy

CONTRAINDICATED LIVE VACCINES

- MMR, varicella, and live attenuated intranasal influenza vaccine.

DEFER—NOT A LIVE-VACCINE CONTRAINDICATION

- HPV vaccination is delayed until after pregnancy; an inadvertent dose is not an indication for intervention beyond deferring remaining doses.

PRECAUTION / INDIVIDUALIZE

- Yellow fever and selected travel vaccines may be used when unavoidable exposure risk exceeds vaccine risk.

PRACTICAL POINTS

- Give MMR or varicella before pregnancy when indicated and avoid conception for 4 weeks.
- Inadvertent live-vaccine administration is not an indication for pregnancy termination.
- Use immune globulin—not vaccine—for eligible varicella exposure management during pregnancy.

Vaccines During Lactation

Most vaccines do not affect breastfeeding safety and may be given when otherwise indicated.

COMPATIBLE

- Inactivated, recombinant, subunit, polysaccharide, conjugate, and toxoid vaccines.
- MMR and varicella may be given postpartum to nonimmune patients.
- The infant continues the routine immunization schedule, including rotavirus when eligible.

EXCEPTIONS

- Replicating smallpox vaccine is contraindicated during breastfeeding because of contact transmission risk.
- Yellow fever vaccine should be avoided when travel can be postponed; vaccinate when unavoidable high-risk travel makes benefit exceed risk.

Do not describe every vaccine as “recommended” solely because it is compatible with lactation—indication still matters.

OBJECTIVE 6

Reliable Drug Information Resources for Pregnancy and Lactation

Why Specialized Resources Matter

General drug information alone is not enough

- Pregnancy timing and untreated disease change the benefit–risk assessment.
- Lactation decisions require milk transfer, infant age, oral bioavailability, toxicity, and milk-supply data.
- Secondary references and older materials may still repeat obsolete ABCDX language.
- Evidence often comes from registries and observational studies rather than randomized trials.

FOUR CORE TOOLS

- FDA prescribing information for the regulatory label and REMS requirements.
- LactMed for lactation pharmacology and infant monitoring.
- MotherToBaby for exposure counseling and patient-facing fact sheets.
- A comprehensive pregnancy reference or clinical guideline for context and alternatives.

LactMed (NIH)

Free U.S. government database for medications and lactation

Each monograph includes:

- Summary of use during breastfeeding.
- Maternal milk levels and infant serum levels when available.
- Reported effects in breastfed infants.
- Effects on milk production.
- Alternative drugs and primary references.

Access: ncbi.nlm.nih.gov/books/NBK501922/

Use LactMed as a starting point—not a substitute for considering dose, infant age, prematurity, illness, and monitoring feasibility.

MotherToBaby (OTIS)

Free, confidential service for clinicians AND patients
Sponsored by the Organization of Teratology Information Specialists (OTIS).
Access: https://mothertobaby.org
Phone: 1-866-626-6847 (English and Spanish).
Text: 1-855-999-3525.
Live chat available on the website.

Available services

Fact sheets for individual medications in English and Spanish.
Personalized consultations by teratology specialists.
Pregnancy exposure registries (drug, vaccine, infection).
Information on environmental exposures, infections, and vaccines.
Excellent resource to refer the patient directly when she wants personalized counseling.

Briggs Drugs in Pregnancy and Lactation

Gold-standard reference text in perinatal pharmacology
Briggs GG, Towers CV, Forinash AB. 13th edition (Wolters Kluwer, 2024).
Available in print and digital (UpToDate, Ovid).

Each monograph contains:

Risk in pregnancy based on best available evidence.
Risk in lactation.
Summary of animal and human data.
Mechanism of action and relevant pharmacokinetics.
Concise clinical recommendation.
Particularly useful when LactMed or MotherToBaby do not have specific data for the drug in question.

UpToDate

Evidence-based clinical platform with broad coverage

Useful searches for this practice:

"Prenatal care: Patient education"
"Medications in lactation"
"Maternal antihypertensive therapy in pregnancy"
"Treatment of nausea and vomiting of pregnancy"
"Immunizations during pregnancy"

Features

Continuously updated, graded recommendations.
Includes Briggs Drugs in Pregnancy and Lactation integrated.
Clinical calculators (gestational age, dose, preeclampsia risk).
Mobile app for quick reference at the counter.
Available by institutional or individual subscription.

Other Specialized Resources

Hale's Medications & Mothers' Milk:
Clinically-oriented lactation reference with practical risk categories (L1–L5).
Available as book and mobile app.
e-lactancia:
Free Spanish-language resource on medications and lactation.
Access: e-lactancia.org
Good complement when patient prefers Spanish-language information.
REPROTOX:
Subscription-based reproductive toxicology database.
Drugs, chemicals, infections, and environmental exposures.
TERIS:
Teratogen Information System — subscription required.
Detailed evidence summaries on teratogenic risk.
FDA MedWatch:
For reporting adverse events — every pharmacist should know how to file.

When to Use Which Resource — Quick Guide

Match the question to the right tool
"Is X safe during breastfeeding?"
First: LactMed. Second: Briggs. Confirm with UpToDate.
"Is X safe during pregnancy?"
First: Briggs. Confirm with UpToDate. Verify with MotherToBaby fact sheet.
"What does my patient need to know about exposure to X?"
Refer patient to MotherToBaby for personalized consultation.
"How do I manage condition Y in pregnancy?"
UpToDate for disease management.
"My patient prefers Spanish-language information."
MotherToBaby (Spanish phone line and fact sheets) or e-lactancia.
Always cross-reference at least TWO resources before making a major dispensing recommendation.

Integrated Case 1: Hypertension in Pregnancy

Patient: 32-year-old G2P1 at 18 weeks with a new lisinopril prescription and BP 152/96 mm Hg.

COLLECT

Confirm gestational age, prior doses, BP history, comorbidities, other medications, symptoms, and obstetric contact.

ASSESS

Lisinopril carries fetal renal-toxicity risk; untreated hypertension also requires prompt treatment.

PLAN / IMPLEMENT

Hold dispensing, contact the prescriber the same day, and recommend an appropriate pregnancy antihypertensive such as labetalol or extended-release nifedipine based on the clinical context.

FOLLOW UP

Document the intervention and ensure prompt obstetric evaluation and a confirmed replacement plan.

Integrated Case 2: Postpartum Pain in a Breastfeeding Patient

Patient: 1 week after cesarean delivery, breastfeeding a healthy term newborn, with a codeine–acetaminophen prescription.

COLLECT

Pain severity, fever or wound symptoms, other sedatives, infant age/health, allergies, and current total acetaminophen dose.

ASSESS

FDA recommends against codeine during breastfeeding; uncontrolled postoperative pain or complications also require attention.

PLAN / IMPLEMENT

Contact the prescriber. Use scheduled acetaminophen and ibuprofen within dose limits when appropriate. If an opioid is necessary, use the lowest dose for the shortest duration and choose a better-studied alternative with infant monitoring.

FOLLOW UP

Reassess pain, function, wound symptoms, infant alertness, breathing, and feeding.

Integrated Case 3: Addressing Vaccine Hesitancy

Patient: 30 weeks, declines Tdap because of online claims about mercury and autism.

COLLECT

Ask what she has heard, prior vaccine reactions, vaccination history, gestational age, and her main concern.

ASSESS

Tdap does not contain thimerosal. Maternal Tdap reduces infant pertussis risk before the infant can complete primary vaccination.

PLAN / IMPLEMENT

Acknowledge the concern, use plain language, recommend Tdap now, and plan RSV discussion at 32–36 weeks using Puerto Rico timing guidance.

FOLLOW UP

Coordinate with obstetrics, document the discussion, and revisit respectfully if she is not ready today.

The PPCP Applied to Pregnancy and Lactation Pharmacy

Throughout this lecture, you have seen the PPCP framework guide each case:

In every prenatal or lactation dispensing decision, apply:

- COLLECT: gestational age, trimester, lactation status, comorbidities, current meds, allergies.
- ASSESS: risk of the drug vs. risk of untreated disease; trimester-appropriate; lactation compatibility.
- PLAN: select safest effective option; coordinate with OB/MFM/pediatrics.
- IMPLEMENT: counsel patient on use, monitoring, red flags; document; refer if needed.
- FOLLOW UP: monitor maternal and fetal/infant outcomes; reassess at each visit.

Summary of Roles: Pharmacist vs. Pharmacy Technician

PHARMACIST

- Confirms timing, indication, dose, maternal disease risk, current label, and specialized evidence.
- Identifies high-risk exposure, recommends alternatives, contacts the prescriber, counsels, documents, and arranges follow-up.
- Coordinates with obstetrics, MFM, pediatrics, and lactation specialists.

PHARMACY TECHNICIAN

- Records pregnancy/lactation status and available gestational or postpartum age.
- Flags high-risk medications, REMS products, duplicate therapy, and profile conflicts.
- Pauses the workflow and refers to the pharmacist; does not independently interpret pregnancy or lactation risk.

The boundary is clear: technicians identify and escalate; pharmacists make and communicate clinical recommendations.

Take-Home Pearls

1. Untreated maternal disease can harm both patient and fetus—the comparison is treatment versus a real alternative, not treatment versus zero risk.
2. Timing, dose, duration, indication, and infant factors matter as much as the drug name.
3. Renin–angiotensin blockers, systemic retinoids, methotrexate, mycophenolate, valproate, warfarin, and later-pregnancy NSAIDs require decisive, context-specific action.
4. Tdap and influenza are routine maternal vaccines; COVID-19 uses individual decision-making; RSV requires gestational, seasonal, territorial, and prior-dose review.
5. LactMed is the first stop for lactation questions; FDA labeling, MotherToBaby, and comprehensive references answer different questions.
6. Technicians identify and refer. Pharmacists assess, recommend, communicate, document, and follow up.

Questions for Discussion

Before the post-test, discuss:

- What workflow does your pharmacy use to identify pregnancy or lactation status?
- Which prescriptions automatically trigger pharmacist review?
- Which resource will you use first for a lactation question—and why?
- How will you contact and document a prescriber intervention?
- Which counseling statements reduce fear without minimizing uncertainty?
- Where is the boundary between technician data collection and pharmacist clinical judgment?

POST TEST

Medication Safety in Pregnancy and Lactation

7 questions covering all 6 learning objectives

Each question is followed by the correct answer and feedback on the distractors.

To obtain ACPE credit, complete the post-test at CFPR.org with at least 70% correct.
Deadline: 45 days after the activity date.

Question 1 of 7 — Objective 2

Which nutrient should be supplemented before conception and during the first trimester to reduce neural-tube-defect risk?

1. Vitamin B12, 1,000 mcg daily for every patient
2. Folic acid, 400–800 mcg daily for average risk; 4 mg/day after a prior neural-tube-defect pregnancy
3. Vitamin A, 5,000 IU daily
4. Elemental iron, 60 mg daily for every patient

Answer 1 of 7 — Objective 2

CORRECT ANSWER: 2. Folic acid

Average-risk patients generally need 400–800 mcg/day beginning before conception. A prior neural-tube-defect pregnancy is a high-risk indication for 4 mg/day under clinical guidance.

WHY NOT THE OTHERS?

- **Vitamin B12 and iron treat specific deficiencies but do not replace folic acid for neural-tube-defect prevention.**
- Excess preformed vitamin A can itself be teratogenic.

Question 2 of 7 — Objective 2

Why is 3–8 weeks post-conception the period of greatest susceptibility to major structural teratogens?

1. Implantation occurs throughout this period.
2. Major organ systems are forming during organogenesis.
3. Fetal growth is complete by the end of this period.
4. Placental drug transfer does not occur until after this period.

Answer 2 of 7 — Objective 2

CORRECT ANSWER: 2. Organogenesis

During weeks 3–8 post-conception, the major organ systems are forming; disruption can produce characteristic structural anomalies.

WHY NOT THE OTHERS?

- **Implantation is largely earlier.**
- Growth and central nervous system maturation continue throughout the fetal period.
- **Placental transfer is not absent during organogenesis.**

Question 3 of 7 — Objective 3

A patient at 14 weeks presents with a new losartan prescription. What is the MOST appropriate pharmacist action?

1. Dispense because losartan is safe in the second trimester.
2. Dispense and advise the patient to report nausea or headache.
3. Hold dispensing, contact the prescriber promptly, and recommend a pregnancy-appropriate alternative.
4. Dispense for use beginning at 28 weeks.

Answer 3 of 7 — Objective 3

CORRECT ANSWER: 3. Hold and contact the prescriber

Losartan blocks the fetal renin–angiotensin system and can cause severe fetal renal toxicity. The pharmacist should prevent further unreviewed exposure while ensuring the maternal hypertension receives prompt alternative treatment.

WHY NOT THE OTHERS?
Options 1, 2, and 4 incorrectly treat losartan as pregnancy-compatible.

Question 4 of 7 — Objective 5

When is Tdap recommended during pregnancy?

1. Only once in a lifetime.
2. During every pregnancy, preferably early in the 27–36-week window.
3. Only during the first trimester.
4. Only after delivery.

Answer 4 of 7 — Objective 5

CORRECT ANSWER: 2. Every pregnancy, 27–36 weeks

Earlier administration within the 27–36-week window generally maximizes passive antibody transfer. A previous Tdap dose does not replace the dose needed in the current pregnancy.

WHY NOT THE OTHERS?
First-trimester-only and postpartum-only strategies do not provide the recommended timing of fetal antibody protection.

Question 5 of 7 — Objective 4

A patient at 28 weeks has persistent heartburn despite nonpharmacologic measures and appropriate antacid use. Which H2-receptor antagonist is a reasonable next option?

1. Cimetidine
2. Famotidine
3. Ranitidine
4. Nizatidine

Answer 5 of 7 — Objective 4

CORRECT ANSWER: 2. Famotidine

Famotidine has reassuring pregnancy experience and fewer interaction concerns than cimetidine.

WHY NOT THE OTHERS?

- **Ranitidine is no longer marketed in the United States.**
- Cimetidine has more interactions.
- **Nizatidine has less pregnancy experience.**

Question 6 of 7 — Objective 6

Which resource offers free individualized consultations in English and Spanish for patients and clinicians after a pregnancy or lactation exposure?

1. LactMed
2. Briggs Drugs in Pregnancy and Lactation
3. MotherToBaby
4. FDA MedWatch

Answer 6 of 7 — Objective 6

CORRECT ANSWER: 3. MotherToBaby

MotherToBaby offers free individualized counseling and fact sheets in English and Spanish.

WHY NOT THE OTHERS?

- **LactMed is a lactation database.**
- Briggs is a reference text.
- **MedWatch receives adverse-event reports rather than providing individualized exposure counseling.**

Question 7 of 7 — Objective 1

Which statement BEST describes the FDA Pregnancy and Lactation Labeling Rule?

1. It retains A, B, C, D, and X but adds lactation information.
2. It replaces letter categories with narrative subsections for Pregnancy, Lactation, and Females and Males of Reproductive Potential.
3. It applies only to OTC medications approved after 2015.
4. It is a voluntary ACOG guideline.

Answer 7 of 7 — Objective 1

CORRECT ANSWER: 2. Narrative subsections

The PLLR removed the A/B/C/D/X categories and uses Pregnancy (8.1), Lactation (8.2), and Females and Males of Reproductive Potential (8.3).

WHY NOT THE OTHERS?

The rule is mandatory FDA labeling for covered prescription drugs and biologics; it does not change OTC Drug Facts labeling and is not an ACOG guideline.

REFERENCES — PRIMARY AND REGULATORY SOURCES

1. U.S. Food and Drug Administration. Pregnancy and Lactation Labeling Rule: Questions and Answers.

2. U.S. Food and Drug Administration. Avoiding NSAIDs at 20 Weeks or Later. Drug Safety Communication; 2020.

3. U.S. Food and Drug Administration. Removal of the Class-Wide Statin Contraindication in Pregnancy; 2021.

4. U.S. Food and Drug Administration. Codeine and Tramadol in Breastfeeding Women; 2017.

5. Centers for Disease Control and Prevention. Guidelines for Vaccinating Pregnant Women. Updated August 22, 2025.

6. Centers for Disease Control and Prevention. COVID-19 Vaccination for Women Who Are Pregnant or Breastfeeding. Updated February 10, 2026.

7. Centers for Disease Control and Prevention. RSV Vaccine Guidance for Pregnant Women. Updated December 19, 2025.

8. Centers for Disease Control and Prevention. U.S. Medical Eligibility Criteria for Contraceptive Use, 2024.

REFERENCES — CLINICAL RESOURCES

9. Society for Maternal-Fetal Medicine. Acetaminophen as First-Line Medication for Pain and Fever During Pregnancy. June 1, 2026.

10. National Library of Medicine. Drugs and Lactation Database (LactMed). Updated continuously.

11. MotherToBaby / Organization of Teratology Information Specialists. Fact sheets and individualized consultations.

12. Briggs GG, Towers CV, Forinash AB. Drugs in Pregnancy and Lactation. 13th ed. Wolters Kluwer; 2024.

13. Mitchell KB, et al. Academy of Breastfeeding Medicine Clinical Protocol #36: The Mastitis Spectrum, Revised 2022. Breastfeed Med. 2022;17:360–376.

14. Joint Commission of Pharmacy Practitioners. Pharmacists' Patient Care Process.

15. Mayo Clinic School of Continuous Professional Development. Speaker Handbook. MC8038-104rev819.

16. Puerto Rico College of Pharmacists. Summary of Key Points in Communications to Speakers/Faculty; 2026.

How to Obtain Your Continuing Education Certificate

1. Log in to your account at CFPR.org
2. Select MY ACCOUNT
3. Select COURSE HISTORY
4. Choose this activity
5. Complete the evaluation and post-test
6. Save or print the certificate

You have 45 days to complete the evaluation and post-test.
Deadline: OCTOBER 2, 2026

ACCESS CODE

CPE MONITOR

CODE

You have 45 days to complete the evaluation and post-test and obtain your certificate.

Thank you

- **José Pérez Yordán, MD, FACOG**
- Island Perinatal — Caguas, Puerto Rico
- islandperinatal@gmail.com

- *Questions, clinical cases, and consultations are welcome.*