Prescribing for Pregnant and Nursing Mothers

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Course Description
This course will give an overview of the physiological and pathological systemic and ocular changes that pregnant women can experience. Before prescribing for these potential conditions, it is important to discuss and understand the evolving pregnancy categories/labeling of medications. Finally, there will be a review of applicable optometric medications to avoid and safe to use for pregnant and lactating patients.

Course objective
To highlight some statistics on pregnancy/nursing mothers and medication use
To review physiological systemic and ocular changes that can occur during pregnancy
To review pathological ocular changes that can occur during pregnancy
To review how pregnancy can affect pre-existing conditions
To review pregnancy categories and labeling of medications
To review medications to prescribe and avoid during pregnancy
Outline

Pregnancy Statistics

Changes During Pregnancy
- Physiological systemic changes
- Physiological ocular changes
- Pathological ocular changes
- Pre-existing conditions

Pregnancy Categories/Labeling of Medications
Prescribing

Statistics

According to the CDC:

- Medication use in pregnancy is common but safety information is lacking
- Fewer than 10% of medications have enough information to determine their safety for use in pregnancy

Statistics

According to the CDC

Over the last 30 years:
- First trimester use of prescription medications has increased more than 60%

https://www.cdc.gov/pregnancy/meds/treatingfortwo/data.html

Statistics

OTC medications
- 2005 study: most women take OTC meds at some point during pregnancy
  - Aspirin – 40%
  - Ibuprofen – 30%
  - Acetaminophen – 20%
Antidepressant medications
- 1998-2005 study: 4.5% of women reported using an antidepressant 3 months before or during pregnancy
  - SSRIs (most common) – 3.8%
Herbal products
- 1997-2003 study: 10.9% of women reported using herbal product 3 months before or during pregnancy
  - Ginger and ephedra (most common), teas and chamomile
Antibiotic medications
- 1997-2003: 29.7% of women reported using antibiotics 3 months before or during pregnancy
  - Penicillins (most common) – 5.9%

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Prescribing
Changes During Pregnancy

Physiological systemic changes
- Hematologic:
  - Plasma volume increases, hypercoagulable state, venous stasis in lower limbs
- Cardiac:
  - Cardiac output increases, stroke volume increases
- Renal:
  - Renal vasodilation, renal plasma flow and glomerular filtration rate increase
- Body water metabolism:
  - Water retention
- Respiratory changes:
  - Increase in O2 demand & O2 consumption
- Adaptive changes in digestive tract:
  - Displacement of digestive organs, GERD

Endocrine:
- Thyroid: fluctuations in TSH levels, decrease iodine
- Adrenal gland: hypercortisolism
- Pituitary gland: pituitary gland enlarges
- Insulin resistance: insulin resistance in 2nd and 3rd trimester
- Lipid metabolism: increase in total serum cholesterol and triglyceride
- Protein metabolism: decreased protein catabolism
- Skeletal and bone density changes: maternal skeletal changes to accommodate growing fetus and child birth

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Changes During Pregnancy

Physiological ocular changes:
- Lid/Skin:
  - Cheilitis (5%-70%)
- Conjunctiva:
  - Subconjunctival hemorrhages (10%)
- Cornea:
  - Reduced sensitivity, increased thickness (14%), change in refractive strength, change in tear composition (14%), Krukenberg's spindles (3%)
- Lens:
  - Increased thickness, refractive change (14%), transient loss/weakness/paralysis in accommodation
- Optic nerve/optic pathway:
  - Enlargement of papillary head
- IOP:
  - Decreased IOP (*10% IOP decrease)

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4928162/

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4165189/
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3862469/
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Changes During Pregnancy
New pathological changes:
- Ptosis (unilateral)
- Central serous choroidopathy (CSC)
- Preeclampsia (HTN, edema, proteinuria)/Eclampsia
  - 25%-50% show signs of hypertensive retinopathy
  - 25%-50% report visual symptoms: blurred vision, photopsia, VF defects, diplopia, blindness
- Occlusive vascular disorders:
  - Purtscher-like retinopathy, branch and central retinal artery occlusion, branch and central retinal vein occlusion
- Idiopathic intra-cranial hypertension (IIH):
  - Precipitated/aggravated in pregnancy

Pre-existing conditions:
- Diabetes: worsening of DR or ME
  - Gestational diabetes: not a risk factor for DR
- Uveitis:
  - Sarcoidosis, Behcet's disease, rheumatoid arthritis
- Worsens:
  - Toxoplasmosis, posterior scleritis, Grave's disease, intracerebral tumors

References:
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4165189/
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3862469/
- https://www.aao.org/eyenet/article/ocular-changes-during-pregnancy
Pregnancy Categories

Established in 1979 by the FDA

<table>
<thead>
<tr>
<th>FDA Pregnancy Categories</th>
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<tbody>
<tr>
<td>Category A</td>
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<tr>
<td>Category B</td>
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<td>Category C</td>
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<td>Category D</td>
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<td>Category X</td>
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Pregnancy Labeling

NEW CHANGE PROPOSED in 2008

Old Pregnancy Category Criticism:
- Confusing
- Overly simplified
- Misinformation
- Did not adequately address the available information

NEW PREGNANCY DRUG LABELING

Replace with narrative sections and subsections
Effective: June 30, 2015

Drugs approved since June 30, 2011: gradually phase in new labeling
Drugs approved before June 29, 2011: remove pregnancy category within 3 years


Pregnancy Labeling

NEW Pregnancy drug labeling: narrative sections and subsections

[Image and text related to pregnancy drug labeling]
Pregnancy labeling

**Advantages:**
- Pregnancy registries: collect data on meds during pregnancy
- Takes into consideration specific trimesters
- Help patients and practitioners better understand the risks involved in prescribing
- Addresses lack of data on meds

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**Example**

[Link to Example](https://www.drugs.com/pro/descovy.html)
Pregnancy Labeling

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Considerations:
  • Prescribing for mother and fetus/infant
  • Fetus/infant:
    • Immature organs – low elimination, drug accumulation, longer half-life
    • Consult with OB/GYN before starting any new therapy

Topical medication recommendation:
  • Use minimal concentration
  • Use minimal dose
  • Punctual occlusion ~2mins
  • Wipe off extra drug
Prescribing

Dilation

- Pregnancy Category C:
  - Proparacaine
  - Phenylephrine
  - Tropicamide

- No literature to support harm to fetus
- Once in a while is safe
- Use shorter half-life: tropicamide or cyclopentolate
- Avoid homatropine, atropine, scopolamine
- Avoid dilation unless necessary

Prescribing

IOP measurement

- Pregnancy Category C:
  - Proparacaine or Benoxinate
  - Sodium Fluorescein

- No literature to support harm to fetus
- Avoid unless necessary
- Use iCare or NCT if possible

Safe
Prescribing
Overall considered **SAFE**:

### Antibiotics
- **Penicillin**: Augmentin (amoxicillin/clavulanic acid)
- Cefalexin
- Erythromycin
- Topical or oral azithromycin
- Topical tobramycin
- Topical gentamicin
- Polymyxin B
- Clindamycin

### Oral Antivirals
- Acyclovir
- Valacyclovir
- Famciclovir

### Topical Antifungal
- Amphotericin B

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Prescribing
Overall considered **SAFE**:

### Glaucoma
- Alphagan (brimonidine)
- **avoid when nursing (apnea in infants)**
- Try to avoid during 1st trimester
- **Consider surgery if IOP is not controlled with meds or meds are a concern**

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Prescribing
Overall considered **SAFE**:

### Allergies
- Category B
- Lastacaft (alkalafadine)
- Crolom, Opticrom (cromolyn sodium)
- Alamide (lodoxamide tromethamine)
- Alocril (nedocromil sodium)
- Emadine (emedatine difumarate)
Prescribing
Overall considered **SAFE**:

### Pain management
- Acetaminophen
- Acetaminophen with codeine (short-term) during pregnancy
- Local anesthetics: lidocaine + vasoconstrictor
- Propanolol (category C but in low dose – punctal occlusion, mostly safe)

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**Avoid**

### Antibiotics
- **Tetracycline** (abnormalities to bone and teeth)
- Fluquinolones [abnormal cartilage development]
- Chloramphenicol (aplastic anemia)
- Neomycin (category D)
- Category C: Zymar (gatifloxacin), Vigamox (moxifloxacin), Ciloxan (ciprofloxacin)

### Topical Antivirals
- Category C: Viroptic ( trifluridine), Zirgan (ganciclovir)
- Less studied
- Use with caution
Prescribing

Overall should **AVOID**:

### Glaucoma

- **Topical and systemic CAIs**
  - Azopt (brinzolamide)
  - Trusopt (dorzolamide)
  - Potential teratogenic effects and hepato-renal effects on infants
- **Prostaglandins**
  - Xalatan (latanoprost)
  - Travatan (travaprost)
  - Lumigan (bimatoprost)
  - Can lead to abortion and labor induction
- **Beta Blockers**
  - Category C
  - Occasionally used with pregnancy with few reported side effects

### Allergies

- Category C
  - Pataday (olopatadine)
  - Patanol (olopatadine)
  - Pazeo (olopatadine)
  - Zaditor (ketotifen fumarate)
  - Elestat (epinastine)
  - Alamast (pemirolast potassium)
  - Optivar (azelastine)

### Corticosteroids

- Category C
  - Topical Prednisolone
  - Oral Prednisolone
  - Fluorometholone
  - Lack of well-controlled studies in pregnancy
  - Topical steroids: no human studies to support harm to fetus; rats have shown teratogenic effects
  - Oral steroids: orofacial defects, conotruncal heart defects, and neural tube defects
Prescribing Overall should **AVOID**:

### Pain Management

**Aspirin:** bleeding concern

- Oral NSAID: bleeding concern, spontaneous abortion, and fetal malformations early in pregnancy, valve premature closure of the ductus arteriosus and oligohydramnios late in pregnancy

- Topical NSAID: category C, not well studied

[References](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3862469/)
[References](https://www.reviewofoptometry.com/article/pregnancy-precautions-how-to-prescribe-safely-for-new-and-expectant-mothers)
[References](https://online-ce.opt.pacificu.edu/view_course.php?courseid=121)
[References](https://webeye.ophth.uiowa.edu/eyeforum/cases/229-drugs-in-pregnancy.htm)

### Dry Eyes

**Restasis:**
- Category C
- Not found in bloodstream from topical use

[Reference](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3862469/)

### Meds to **AVOID** during Pregnancy:

- **1st trimester:**
  - Avoid medication if possible
  - Greater risk for iatrogenic anatomic malformations
  - Use with caution beta blockers

- **3rd trimester:**
  - Avoid ibuprofen due to possible adverse circulatory effects
  - Avoid codeine to avoid fetal respiratory depression and withdrawal symptoms

Prescribing

Nursing/Lactating mothers:
- **Avoid:**
  - Beta blockers (concentrated in breast milk)
  - D/C beta blockers 2-3 days prior to delivery to avoid beta blockade in infant
  - Brimonidine b/c induce apnea and CNS depression
  - NSAIDS: naproxen, sulindac, piroxicam
- **Safe:**
  - Hydrocodone is preferred
  - Trimethoprim/sulfamethoxazole – ok for infants over than 2 months
  - Codeine, morphine, hydrocodone (short term)
  - NSAIDS: use ibuprofen

Diagnostic imaging:
- **Safe:** chest x-rays, little risk with MRI (but NIH recommends 2/3rd trimester)
- **Avoid:** IV contrast-concern for effects on fetal thyroid

In Conclusion

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Thank you
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