Such a happy time... yet it can be so hard

A Look at Depression and Pregnancy
Brooke E. Foulk, MD
Clinical depression is common in reproductive-aged women.

According to the WHO, depression is the leading cause of disability in women.

Each year, depression accounts for $30-50 billion in lost productivity and direct medical costs in the US.

Women experience depression twice as often as men.

The highest rates are among ages 25-44.
Depression is especially common both during pregnancy and the postpartum period.

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- fatigue
- sleep changes
- weight gain
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- weight gain
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Symptoms include:
- fatigue
- weight gain
- sleep changes
- appetite changes
- irritability
3 Psychological Stages of Pregnancy

- Correlate roughly to the three trimesters of pregnancy

1. Realization of pregnancy until quickening

- new and uncomfortable physical symptoms and ambivalence about pregnancy common; memory problems occur.
3 Psychological Stages of Pregnancy

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GOAL: acceptance of pregnancy
3 Psychological Stages of Pregnancy

GOAL: acceptance of pregnancy

1. Realization of pregnancy until quickening
   - new and uncomfortable physical symptoms and ambivalence about pregnancy common; memory problems occur.

2. Acceptance of pregnancy
   - memory problems occur.

3. Preparation for childbirth
   - memory problems occur.
3 Psychological Stages of Pregnancy

GOAL: acceptance of pregnancy

FEAR: miscarriage

1. Realization of pregnancy until quickening
   - New and uncomfortable physical symptoms
   - Ambivalence about pregnancy common; memory problems occur
   - Goal: acceptance of pregnancy
   - Fear: miscarriage
3 Psychological Stages of Pregnancy

   - decreased physical symptoms
   - relative peace and fulfillment
3 Psychological Stages of Pregnancy

- Decreased physical symptoms
- Relative peace and fulfillment
3 Psychological Stages of Pregnancy

GOAL:
attachment to fetus; recognizing as individual
3 Psychological Stages of Pregnancy

- Decreased physical symptoms
- Relative peace and fulfillment

**GOAL:**
- Attachment to fetus; accepting pregnancy.
- Recognizing fetus as individual.

3 Psychological Stages of Pregnancy

**GOAL:**
attachment to fetus; recognizing as individual

**FEAR:**
separation and individualization from mother; anxiety about becoming mother
3. Physical discomfort again predominates.

The mother has a sense of her infant as viable.
3 Psychological Stages of Pregnancy

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3 Psychological Stages of Pregnancy

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GOAL
preparing for baby; nesting
3 Psychological Stages of Pregnancy

**GOAL**
preparing for baby; nesting

Physical discomfort again predominates. The mother has a sense of her infant as viable.
3 Psychological Stages of Pregnancy

GOAL
preparing for baby; nesting

FEAR:
delayed nesting, dependence
We must recognize that self-esteem of women who choose motherhood may become entrenched in the successful completion of these stages and tasks.

Difficulty navigating these psychological stages may carry over into her postpartum period.

This can lead to difficulties in mother-infant bonding.
Delivery? Or Takeout?
Untreated maternal depression is associated with an increase in adverse pregnancy outcomes:

- premature birth
- low birthweight infants
- fetal growth restriction
- postnatal complications

(this association is stronger when depression occurs in the late second and early 3rd trimesters)
Background

- Newborns of women with untreated depression in pregnancy cry more and are more difficult to console.

- Later in life, children of untreated depressed mothers are more prone to suicidal behavior, conduct problems, and emotional instability.

- These children more often require psychiatric care.
Background

Screening for, diagnosing, and treating depression all have the potential to benefit a woman and her family.
Background

Infants of depressed mothers display...

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Background

Infants of depressed mothers display...

- Delayed psychologic development
- Delayed cognitive development
- Delayed neurologic development

Screening for, diagnosing, and treating depression can benefit the mother and her family.
Background

Screening for, diagnosing, treating depression all have the potential to benefit a woman and her family.

Infants of depressed mothers display...

delayed psychologic development

delayed cognitive development

delayed neurologic development
Background

Screening for, diagnosing, and treating depression all have the potential to benefit a woman and her family. Infants of depressed mothers display delayed psychologic development, delayed cognitive development, delayed neurologic development, delayed motor development.
Benefits

- Children’s mental and behavioral disorders **improve** when maternal depression is in remission.
Women with current depression or any history of a major depressive disorder require close monitoring.

Pregnancy and the postpartum period are ideal times for consistent contact with these patients in order to identify and treat appropriately.
OBSTETRICS

SLEEP
Is
Highly
Overrated
SCREENING

Tools for Identifying Depression
Screening

» Significant depression is often missed despite high levels of contact with caregivers during pregnancy and postpartum.

» It is important to be cognizant of the warning signs and symptoms and to ask the right questions.
Many different depression screening tools that can be completed in less than 10 minutes

- Edinburgh Postnatal Depression Scale
- Postpartum Depression Screening Scale
- Patient Health Questionnaire-9
# Depression Screening Tools

<table>
<thead>
<tr>
<th>Screening Tool</th>
<th>Number of Items</th>
<th>Time to Complete</th>
<th>Sensitivity/specificity</th>
<th>Spanish Available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edinburgh Postnatal Depression Scale (EPDS)</td>
<td>10</td>
<td>Less than 5 min</td>
<td>Sensitivity: 59–100% Specificity: 49–100%</td>
<td>Yes</td>
</tr>
<tr>
<td>Postpartum Depression Screening Scale (PDSS)</td>
<td>35</td>
<td>5–10 min</td>
<td>Sensitivity: 91–94% Specificity: 72–98%</td>
<td>Yes</td>
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<tr>
<td>Patient Health Questionnaire-9 (PHQ-9)</td>
<td>9</td>
<td>Less than 5 min</td>
<td>Sensitivity: 75% Specificity: 90%</td>
<td>Yes</td>
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<tr>
<td>Beck Depression Inventory (BDI)</td>
<td>21</td>
<td>5–10 min</td>
<td>Sensitivity: 47.6–82% Specificity: 85.9–89%</td>
<td>Yes</td>
</tr>
<tr>
<td>Beck Depression Inventory-II (BDI-II)</td>
<td>21</td>
<td>5–10 min</td>
<td>Sensitivity: 56–57% Specificity: 97–100%</td>
<td>Yes</td>
</tr>
<tr>
<td>Center for Epidemiologic Studies Depression Scale (CES-D)</td>
<td>20</td>
<td>5–10 min</td>
<td>Sensitivity: 60% Specificity: 92%</td>
<td>Yes</td>
</tr>
<tr>
<td>Zung Self-Rating Depression Scale (Zung SDS)</td>
<td>20</td>
<td>5–10 min</td>
<td>Sensitivity: 45–89% Specificity: 77–88%</td>
<td>No</td>
</tr>
</tbody>
</table>

Edinburgh Postnatal Depression Scale\(^1\) (EPDS)

Name: ______________________________   Address: ______________________________
Your Date of Birth: ___________________   Phone: ______________________________
Baby’s Date of Birth: ___________________   Phone: ______________________________

As you are pregnant or have recently had a baby, we would like to know how you are feeling. Please check the answer that comes closest to how you have felt IN THE PAST 7 DAYS, not just how you feel today.

Here is an example, already completed.

I have felt happy:
- Yes, all the time
- Yes, most of the time
- No, not very often
- No, not at all

This would mean: “I have felt happy most of the time” during the past week.

Please complete the other questions in the same way.

In the past 7 days:

1. I have been able to laugh and see the funny side of things
   - As much as I always could
   - Not quite so much now
   - Definitely not so much now
   - Not at all

2. I have looked forward with enjoyment to things
   - As much as I ever did
   - Rather less than I used to
   - Definitely less than I used to
   - Hardly at all

3. I have blamed myself unnecessarily when things went wrong
   - Yes, most of the time
   - Yes, some of the time
   - Not very often
   - No, never

4. I have been anxious or worried for no good reason
   - No, not at all
   - Hardly ever
   - Yes, sometimes
   - Yes, very often

5. I have felt scared or panicky for no very good reason
   - Yes, quite a lot
   - Yes, sometimes
   - No, not much
   - No, not at all

6. Things have been getting on top of me
   - Yes, most of the time I haven’t been able to cope at all
   - Yes, sometimes I haven’t been coping as well as usual
   - No, most of the time I have coped quite well
   - No, I have been coping as well as ever

7. I have been so unhappy that I have had difficulty sleeping
   - Yes, most of the time
   - Yes, sometimes
   - Not very often
   - No, not at all

8. I have felt sad or miserable
   - Yes, most of the time
   - Yes, quite often
   - Not very often
   - No, not at all

9. I have been so unhappy that I have been crying
   - Yes, most of the time
   - Yes, quite often
   - Only occasionally
   - No, never

10. The thought of harming myself has occurred to me
    - Yes, quite often
    - Sometimes
    - Hardly ever
    - Never
PHQ-9 — Nine Symptom Checklist

PHQ-9 — Scoring Tally Sheet

1. Over the last 2 weeks, how often have you been bothered by any of the following problems? Read each item carefully, and circle your response.

   a. Little interest or pleasure in doing things
      - Not at all  - Several days  - More than half the days  - Nearly every day
   b. Feeling down, depressed, or hopeless
      - Not at all  - Several days  - More than half the days  - Nearly every day
   c. Trouble falling asleep, staying asleep, or sleeping too much
      - Not at all  - Several days  - More than half the days  - Nearly every day
   d. Feeling tired or having little energy
      - Not at all  - Several days  - More than half the days  - Nearly every day
   e. Poor appetite or overeating
      - Not at all  - Several days  - More than half the days  - Nearly every day
   f. Feeling bad about yourself, feeling that you are a failure, or feeling that you have let yourself or your family down
      - Not at all  - Several days  - More than half the days  - Nearly every day
   g. Trouble concentrating on things such as reading the newspaper or watching television
      - Not at all  - Several days  - More than half the days  - Nearly every day
   h. Moving or speaking so slowly that other people could have noticed. Or being so fidgety or restless that you have been moving around a lot more than usual
      - Not at all  - Several days  - More than half the days  - Nearly every day
   i. Thinking that you would be better off dead or that you want to hurt yourself in some way
      - Not at all  - Several days  - More than half the days  - Nearly every day

2. If you checked off any problem on this questionnaire so far, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

   Not Difficult at All  Somewhat Difficult  Very Difficult  Extremely Difficult
Yes, I deliver!
(24 hours a day, 7 days a week)
DIAGNOSIS

DSM-IV Criteria for Depression
Depression Diagnosis

5 or more of the following present during the same 2-week period and represent a change from previous functioning.

- One is either (1) depressed mood or (2) loss of interest or pleasure
  - 1 depressed mood most of the day, nearly every day
  - 2 markedly diminished interest or pleasure
  - 3 significant weight loss when not dieting or weight gain or change in appetite
  - 4 insomnia/hypersomnia
  - 5 psychomotor agitation or retardation
Depression Diagnosis

- 6 fatigue or loss of energy
- 7 feelings or worthlessness or excessive/inappropriate guilt (may be delusional)
- 8 diminished ability to think or concentrate, or indecisiveness
- 9 recurrent thoughts of death, recurrent suicidal ideation without a specific plan, or a suicide attempt or specific plan for committing suicide

The symptoms do not meet criteria for a mixed episode, they cause clinically significant distress or impairment in social, occupational, or other important areas of functioning, are not due to the direct physiological effects of a substance or general medical condition, and are not better accounted for by bereavement.
Postpartum Disorders

- Baby blues
- Postpartum depression
- Postpartum psychosis
Postpartum Disorders

Women are most vulnerable to mood disorders during the postpartum period.

If psychiatric disorders are going to arise, they typically present during this time.

There are many physiologic, hormonal, psychologic, and sociocultural changes which contribute.

Psychiatric hospital admissions are 7X higher in the first 30 days postpartum than any other time in a woman’s life.
Postpartum Blues

- 50-90% of new moms
- Peaks around **days 4-5**
- Occurs within the first 10 days
- Common, usually benign, transient
- Most frequent reported symptom is **weeping**
- Irritability, hostility towards partner, sleep disturbance, headache, exhaustion, restlessness, depersonalization, lack of affect for baby.
Postpartum Blues

- Recovery occurs in less than two weeks from the onset
  - if symptoms continue, may develop PPD/PPP
- Some might progress immediately to depression; others may have a period of well-being followed by gradual onset of depression
  - increased risk with history of PMS, previous depression, family history, ambivalence toward pregnancy, fear of labor, social isolation, stress
Postpartum Blues

Etiology?

- A combination of a loss of estrogen post-delivery, sleep disturbances, realization of the huge responsibility of caring for another life.

Treatment:

- Reassurance: this is a common disorder
- Education about the illness
- Family support
Postpartum Depression

- A major episode of depression that occurs within the first 4 weeks postpartum
  - some sources consider it “postpartum” if onset is anytime during the first year

- Affects 10-15% of women (26% of teen moms)

- Many women diagnosed with postpartum depression report having had depressive symptoms during pregnancy.
  - may be difficult to differentiate from normal postpartum adaptation
Postpartum Depression

- Symptoms usually peak between 3-6 months.

- More prominent, serious, and sustained depressive symptoms than “the blues”.

- Symptoms include excessive worry (almost obsessional), anger, guilt, sadness, hopelessness, sleep problems, uneasiness around the baby, poor concentration, loss of pleasure, decreased libido, appetite changes.

- Some worry excessively about baby’s health, feeding, etc. or see themselves as “bad mothers”.
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I feel so alone

I am a horrible mother

My child will never love me
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"I feel so alone," "I am a horrible mother," "My child will never love me," "I made a terrible mistake."
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I feel so alone
I am a horrible mother
I made a terrible mistake
My child will never love me
I hate myself and my life
I am the only woman in the world who won’t ever be happy or love her child!
Postpartum Depression

- 25% of mothers who do not receive treatment for postpartum depression remain depressed after the first year.

- Recurrence rate is 50% with each subsequent pregnancy.

- 30% of women with PPD may later develop depression outside of pregnancy/postpartum.

- It can occur after the birth of ANY child, not just the first.
Warning signs/behaviors

- Missing appointments
- Worrying about her or baby’s health
- Physical complaints without any apparent cause
- Significant weight loss/gain
- Easily crying
- Decreased appetite
- Poor milk production (may also be thyroid dz)
- Evading questions about herself
- Insomnia even when baby sleeping
- Unwilling to let others care for baby
- Showing discomfort around baby
If a woman remains untreated, there is an increased risk of her children developing psychiatric disturbances.

There is also a potential for child abuse or neglect, an increased risk of the mother developing chronic depression/relapsing, and having a negative impact on the marriage and other relationships.

The earlier a woman receives help, the faster she recovers and the better prognosis.

63% risk recurrence; only 1/10 of that risk if patients take antidepressants
Don’t forget that the FATHER can be depressed, too (and may be less likely to ask for help)!

More often exhibit:
- tension
- short temper
- fear, anger, frustration
- helplessness

Concerned about partner, family life, finances

www.postpartumdads.org
Postpartum Psychosis

- Uncommon disorder that occurs in 0.1-0.2% of postpartum women.
  - 100X higher in women with bipolar disorder or a previous history of postpartum psychosis.
- Typically occurs within the first few days or weeks after birth and then again 1-3 months after delivery.
Postpartum Psychosis

http://www.youtube.com/watch?v=FjJuN9QfroI

She was sentenced to life in prison in 2002, but appealed in 2006 and was found “Not guilty by reason of insanity.”

Committed to a Texas State Hospital; later moved to a low security state mental hospital.
Among patients who develop postpartum psychosis, **70-80% have bipolar or schizoaffective disorder**; only 12% have schizophrenia.

There is a 2.5X increased risk of postpartum psychosis seen after [cesarean delivery](https://en.wikipedia.org/wiki/Cesarean_section) compared with vaginal delivery.

Psychosis associated with child bearing: cognitive impairment, bizarre behaviors, thought disorganization, lack of insight, delusions of reference or persecution, greater levels of homicidal behavior.

- may be visual, olfactory, and tactile hallucinations and a delirium-like appearance.
A psychiatric EMERGENCY due to the potential danger to the mother and infant

Inpatient psychiatric treatment is essential to ensure the safety of mother and baby.

Up to 5% of women with postpartum psychosis commit suicide and 2-4% pose a direct threat to their infant.

For any mother who presents with a postpartum mood disorder:

The clinician MUST inquire about thoughts of harming herself or the infant!
Postpartum Psychosis

Separation from the infant may be essential; someone should be with the baby at all times until the outpatient psychiatrist reports that all psychotic symptoms have resolved.

Family psycho-education is imperative.

Before hospital discharge, a plan must be in place to incorporate close follow-up, adequate sleep and stress-reduction.

COMMUNICATE with psychiatry and the pediatrician!
Bipolar Disorder
“Manic-depressive disorder”

- Affects 3.9-6.4% of Americans (men and women affected equally)
- Characterized by distinct periods of abnormally and persistently elevated, expansive, or irritable mood and separate distinct periods of depressed mood or anhedonia.
- Women are more likely to experience depressive episodes, rapid cycling, and mixed episodes.
- Typical onset is in the teens or early twenties.
Bipolar Disorder

- Rates of postpartum relapse range from 32-67%.
- One study reported that pregnancy had a protective effect for women with bipolar disorder.*
  - participants may have had milder illness ??
- Perinatal episodes of the disorder tend to be depressive
  - If they occur with one pregnancy, they are more likely to recur with subsequent pregnancies
  - Also an increased risk of postpartum psychosis (as high as 46%)

*Grof, 2000
Because of potential risks of prescribing mood stabilizing drugs, it is important to understand the risks of untreated bipolar disorder during pregnancy.

Untreated mania may:

- decrease prenatal care initiation and compliance
- increase high risk behaviors (addictive drug use, exposure to STDs)
- increase the risk of violence and violent behavior
- increase poor compliance: not follow physician’s recommendations or dietary guidelines, etc.
Anxiety Disorders

- panic disorder
- obsessive-compulsive disorder (OCD)
- generalised anxiety disorder (GAD)
- posttraumatic stress disorder (PTSD)
- social anxiety disorder
- specific phobias
Collectively, anxiety disorders are the most commonly occurring psychiatric disorders

- prevalence of 18.1% among adults >age 18 in US
- 2X more likely to be diagnosed in women

Anxiety and stress during pregnancy are risk factors associated with poor obstetric outcome (SAb, PTD, prolonged labor, precipitous labor, fetal distress, forceps delivery), but a direct causal relationship has not been established.

Panic attacks may be confused with pre-E, etc.
Schizophrenia-Spectrum Disorders

- Schizophrenia is a severe and persistent mental illness characterized by psychotic symptoms, negative symptoms (flat affect/lack of volition), and significant occupational and social dysfunction.
- Occurs in ~1-2% of women
- Most common onset during childbearing years
- Also associated with adverse pregnancy outcomes (PTD, LBW, placental abnormalities, antenatal hemorrhage, congenital malformations, postnatal death).
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If left untreated during pregnancy, schizophrenia-spectrum disorders can have devastating effects on both mother and child. There are rare reports of:

- self-mutilation
- denial of pregnancy resulting in refusal of prenatal care
- infanticide
Most women with schizophrenia report worsening of mental status during pregnancy and postpartum.

Fear of losing custody of the child may prevent women from seeking prenatal care.

- This fear may also exacerbate psychosis and worsen grief-related reactions.

Delusions may make labor recognition less likely; a patient may attempt self-delivery by dangerous methods or deny the pregnancy and refuse prenatal care.
Alternate
Birth Plan
Use of Psychiatric Medications During Pregnancy and Lactation
Background

An estimated 500,000 pregnancies in the U.S. each year involve women who have psychiatric illnesses (either prior to or during pregnancy).

Increased contact with health care professionals with prenatal care promotes early detection of psychiatric disorders in pregnancy.

- this allows prompt intervention and prevention of exacerbations later

- 1/3 of all pregnant women are exposed to a psychotropic medication at some point during pregnancy.
Risks

- Psychotherapy is the only safe treatment during pregnancy.
- The use of psychotropic medications is a cause for concern for physicians and their patients
  - potential teratogenic risk (must weigh risks vs. benefits)
  - risk of perinatal syndromes or neonatal toxicity
  - risk for abnormal postnatal behavioral development
There is limited information available on the risks of the psychotropic medications.

Clinical management must incorporate weighing the benefits to treating the mother against the risks of the clinical consequences of offspring exposure, the potential effect of untreated maternal psychiatric illness, and the alternative therapies.
Advising a pregnant or breastfeeding woman to discontinue medication:

- decreases risks to fetus or neonate from medication exposure
- but exchanges this for the risks of untreated maternal illness.
Inadequate treatment of maternal psychiatric illness may result in:

- poor compliance with prenatal care
- inadequate nutrition
- exposure to additional medication or herbal remedies
- increased alcohol and tobacco use
- deficits in mother-infant bonding
- disruptions within the family environment
<table>
<thead>
<tr>
<th>Illness</th>
<th>Teratogenic Effects</th>
<th>Impact on Outcome</th>
<th>Treatment Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety disorders</td>
<td>N/A</td>
<td>Increased incidence of forceps deliveries, prolonged labor, precipitate labor, fetal distress, preterm delivery, and spontaneous abortion</td>
<td>Benzodiazepines, Antidepressants, Psychotherapy</td>
</tr>
<tr>
<td>Major depression</td>
<td>N/A</td>
<td>Increased incidence of low birth weight, decreased fetal growth, and postnatal complications</td>
<td>Antidepressants, Psychotherapy, ECT</td>
</tr>
<tr>
<td>Bipolar disorder</td>
<td>N/A</td>
<td>See major depression</td>
<td>Lithium, Anticonvulsants, Antipsychotics, ECT</td>
</tr>
<tr>
<td>Schizophrenia</td>
<td>Congenital malformations, especially of cardiovascular system</td>
<td>Increased incidence of preterm delivery, low birth weight, small for gestational age, placental abnormalities, and antenatal hemorrhage</td>
<td>Antipsychotics</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Increased rates of postnatal death</td>
<td></td>
</tr>
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</table>

**Impact on Outcome**
- Obstetric
- Neonatal

**Treatment Options**
- Benzodiazepines
- Antidepressants
- Psychotherapy
- Electroconvulsive therapy (ECT)
- Lithium
- Anticonvulsants
- Antipsychotics

**Abbreviations:** ECT, electroconvulsive therapy; N/A, not available (eg, no studies identified)
**Treatment**

ALL psychotropic medications studied to date:
- cross the placenta
- are present in the amniotic fluid
- can enter human breast milk

Assessment of gestational age is important, because the major risk of teratogenesis is during embryogenesis (3rd-8th week)
The FDA has not approved ANY psychotropic drugs for use during pregnancy and urges caution in their use.

It has provided a system for categorizing individual medications.

This system has considerable limitations.

Each has a pregnancy risk category as well as a lactation risk category.
# FDA use-in-pregnancy ratings

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A</strong></td>
<td>Studies in pregnant women show <strong>NO RISK</strong> (i.e., long-term experience with a drug following its approval has shown no evidence of human fetal harm; the few drugs that are included in this category have been on the market for many years and have been used in a large number of pregnant women)</td>
</tr>
<tr>
<td><strong>B</strong></td>
<td>Animal studies show no risk, but human data are insufficient; or animal studies show toxicity, but human studies show no risk (post-marketing use – sometimes including “off label” use in pregnant women – shows no evidence of fetal harm in humans; category B medications appear to be safe during pregnancy, but may not have enjoyed a long period of use on the U.S. market or in a large number of pregnant women)</td>
</tr>
<tr>
<td><strong>C</strong></td>
<td>Animal studies show toxicity, human data are insufficient, but <strong>clinical benefit may exceed risk</strong> (a “no-man’s-land” category; a theoretical risk of human harm can be extrapolated from animal studies, but the need to use the medication may outweigh theoretical risks)</td>
</tr>
<tr>
<td><strong>D</strong></td>
<td>There is evidence of <strong>human risk</strong>, but <strong>clinical benefits may outweigh risk</strong> (i.e., the mother may require the medication for her wellbeing in spite of a real risk to her infant; usually, if a physician prescribes such a drug during pregnancy, no other medication is available that demonstrates similar benefits but less risk)</td>
</tr>
<tr>
<td><strong>X</strong></td>
<td>There is evidence of fetal abnormalities in humans, and <strong>risk exceeds benefits</strong> (i.e., the medication should never be used during pregnancy)</td>
</tr>
</tbody>
</table>
Most psychotropic meds are category C or D (none are category A).

Few are category B:

- Buspirone/Buspar
- Zolpidem/Ambien
- Maprotiline/Ludiomil
- Bupropion/Wellbutrin
- Clozapine/Clozaril
Breastfeeding

Weigh the risk of infant medication exposure against the benefits of breastfeeding.

No matter what she decides, DO NOT MAKE HER FEEL GUILTY.

ACOG (2008) classified psychotropic meds according to safety during lactation:

<table>
<thead>
<tr>
<th>Level (L)</th>
<th>Safety Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>L1</td>
<td>Safest</td>
</tr>
<tr>
<td>L2</td>
<td>Safer</td>
</tr>
<tr>
<td>L3</td>
<td>Moderately safe</td>
</tr>
<tr>
<td>L4</td>
<td>Possibly hazardous</td>
</tr>
<tr>
<td>L5</td>
<td>CONTRAINDI edATED</td>
</tr>
</tbody>
</table>
Breastfeeding

Consider before prescribing:

- Is the drug necessary? (communicate with PCP, psychiatry, and pediatrician)
- Choose the safest drug.
- If drug risky to the infant, consider measurement of blood concentration in the baby.
- May be able to minimize drug exposure by having the mother take the medication just after she breastfeeds or just before a long sleep period for the infant.
<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Trade Name</th>
<th>Pregnancy Risk Category</th>
<th>American Academy of Pediatrics Rating</th>
<th>Lactation Risk Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiolytic Medications</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alprazolam</td>
<td>Xanax</td>
<td>Dₘ</td>
<td>Unknown, of concern</td>
<td>L3</td>
</tr>
<tr>
<td>Chlordiazepoxide</td>
<td>Librium</td>
<td>D</td>
<td>N/A</td>
<td>L3</td>
</tr>
<tr>
<td>Clonazepam</td>
<td>Klonopin</td>
<td>Dₘ</td>
<td>N/A</td>
<td>L3</td>
</tr>
<tr>
<td>Clorazepate</td>
<td>Tranxene</td>
<td>D</td>
<td>N/A</td>
<td>L3</td>
</tr>
<tr>
<td>Diazepam</td>
<td>Valium</td>
<td>D</td>
<td>Unknown, of concern</td>
<td>L3, L4 if used chronically</td>
</tr>
<tr>
<td>Lorazepam</td>
<td>Ativan</td>
<td>Dₘ</td>
<td>Unknown, of concern</td>
<td>L3</td>
</tr>
<tr>
<td>Oxazepam</td>
<td>Serax</td>
<td>Dₘ</td>
<td>N/A</td>
<td>L3</td>
</tr>
<tr>
<td>Benzodiazepines for Insomnia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estazolam</td>
<td>ProSom</td>
<td>Xₘ</td>
<td>N/A</td>
<td>L3</td>
</tr>
<tr>
<td>Flurazepam</td>
<td>Dalmane</td>
<td>Xₘ</td>
<td>N/A</td>
<td>L3</td>
</tr>
<tr>
<td>Quazepam</td>
<td>Doral</td>
<td>Xₘ</td>
<td>Unknown, of concern</td>
<td>L2</td>
</tr>
<tr>
<td>Temazepam</td>
<td>Restoril</td>
<td>Xₘ</td>
<td>Unknown, of concern</td>
<td>L3</td>
</tr>
<tr>
<td>Triazolam</td>
<td>Halcicn</td>
<td>Xₘ</td>
<td>N/A</td>
<td>L3</td>
</tr>
<tr>
<td>Nonbenzodiazepine Anxiolytics and Hypnotics</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Buspirone</td>
<td>BuSpar</td>
<td>Bₘ</td>
<td>N/A</td>
<td>L3</td>
</tr>
<tr>
<td>Chloral hydrate</td>
<td>Noctec</td>
<td>Cₘ</td>
<td>Compatible</td>
<td>L3</td>
</tr>
<tr>
<td>Eszopiclone</td>
<td>Lunesta</td>
<td>Cₘ</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Zaleplon</td>
<td>Sonata</td>
<td>Cₘ</td>
<td>Unknown, of concern</td>
<td>L2</td>
</tr>
<tr>
<td>Zolpidem</td>
<td>Ambien</td>
<td>Bₘ</td>
<td>N/A</td>
<td>L3</td>
</tr>
<tr>
<td>Antiepileptic and Mood Stabilizing Medications</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lithium carbonate</td>
<td>Eskalith, Lithobid, Lithonate</td>
<td>D</td>
<td>Contraindicated</td>
<td>L4</td>
</tr>
<tr>
<td>Valproic acid</td>
<td>Depakote (divalproex sodium)</td>
<td>Dₘ</td>
<td>Compatible</td>
<td>L2</td>
</tr>
<tr>
<td>Carbamazepine</td>
<td>Tegretol</td>
<td>Dₘ</td>
<td>Compatible</td>
<td>L2</td>
</tr>
<tr>
<td>Lamotrigine</td>
<td>Lamictal</td>
<td>Cₘ</td>
<td>Unknown</td>
<td>L3</td>
</tr>
</tbody>
</table>
### FDA: antidepressants

#### Antidepressants

<table>
<thead>
<tr>
<th>Tricyclic and Heterocyclic Antidepressants</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Amitriptyline</td>
<td>Elavil, Endep</td>
<td>C&lt;sub&gt;m&lt;/sub&gt;</td>
<td>Unknown, of concern</td>
<td>L2</td>
<td></td>
</tr>
<tr>
<td>Amoxapine</td>
<td>Asendin</td>
<td>C&lt;sub&gt;m&lt;/sub&gt;</td>
<td>Unknown, of concern</td>
<td>L2</td>
<td></td>
</tr>
<tr>
<td>Clomipramine</td>
<td>Anafranil</td>
<td>C&lt;sub&gt;m&lt;/sub&gt;</td>
<td>Unknown, of concern</td>
<td>L2</td>
<td></td>
</tr>
<tr>
<td>Desipramine</td>
<td>Norpramin</td>
<td>C</td>
<td>Unknown, of concern</td>
<td>L2</td>
<td></td>
</tr>
<tr>
<td>Doxepin</td>
<td>Sinequan, Adapin</td>
<td>C</td>
<td>Unknown, of concern</td>
<td>L5</td>
<td></td>
</tr>
<tr>
<td>Imipramine</td>
<td>Tofranil</td>
<td>C</td>
<td>Unknown, of concern</td>
<td>L2</td>
<td></td>
</tr>
<tr>
<td>Maprotiline</td>
<td>Ludiomil</td>
<td>B&lt;sub&gt;m&lt;/sub&gt;</td>
<td>N/A</td>
<td>L3</td>
<td></td>
</tr>
<tr>
<td>Nortriptyline</td>
<td>Pamelor, Aventyl</td>
<td>C</td>
<td>Unknown, of concern</td>
<td>L2</td>
<td></td>
</tr>
<tr>
<td>Protriptyline</td>
<td>Vivactil</td>
<td>C</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

#### Selective Serotonin Reuptake Inhibitors

<table>
<thead>
<tr>
<th>Citalopram</th>
<th>Celexa</th>
<th>C&lt;sub&gt;m&lt;/sub&gt;</th>
<th>N/A</th>
<th>L3</th>
<th>L3 in older infants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Escitalopram</td>
<td>Lexapro</td>
<td>C&lt;sub&gt;m&lt;/sub&gt;</td>
<td>N/A</td>
<td>L3</td>
<td>L2 in older infants, L3 if used in neonatal period</td>
</tr>
<tr>
<td>Fluoxetine</td>
<td>Prozac</td>
<td>C&lt;sub&gt;m&lt;/sub&gt;</td>
<td>Unknown, of concern</td>
<td>L2</td>
<td></td>
</tr>
<tr>
<td>Fluvoxamine</td>
<td>Luvox</td>
<td>C&lt;sub&gt;m&lt;/sub&gt;</td>
<td>Unknown, of concern</td>
<td>L2</td>
<td></td>
</tr>
<tr>
<td>Paroxetine</td>
<td>Paxil</td>
<td>D&lt;sub&gt;m&lt;/sub&gt;</td>
<td>Unknown, of concern</td>
<td>L2</td>
<td></td>
</tr>
<tr>
<td>Sertraline</td>
<td>Zoloft</td>
<td>C&lt;sub&gt;m&lt;/sub&gt;</td>
<td>Unknown, of concern</td>
<td>L2</td>
<td></td>
</tr>
</tbody>
</table>

#### Other Antidepressants

<table>
<thead>
<tr>
<th>Bupropion</th>
<th>Wellbutrin</th>
<th>B&lt;sub&gt;m&lt;/sub&gt;</th>
<th>Unknown, of concern</th>
<th>L3</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Duloxetine</td>
<td>Cymbalta</td>
<td>C&lt;sub&gt;m&lt;/sub&gt;</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Mirtazapine</td>
<td>Remeron</td>
<td>C&lt;sub&gt;m&lt;/sub&gt;</td>
<td>N/A</td>
<td>L3</td>
<td></td>
</tr>
<tr>
<td>Nefazodone</td>
<td>Serzone</td>
<td>C&lt;sub&gt;m&lt;/sub&gt;</td>
<td>N/A</td>
<td>L4</td>
<td></td>
</tr>
<tr>
<td>Trazodone</td>
<td>Desyrel</td>
<td>C&lt;sub&gt;m&lt;/sub&gt;</td>
<td>Unknown, of concern</td>
<td>L2</td>
<td></td>
</tr>
<tr>
<td>Venlafaxine</td>
<td>Effexor</td>
<td>C&lt;sub&gt;m&lt;/sub&gt;</td>
<td>N/A</td>
<td>L3</td>
<td></td>
</tr>
</tbody>
</table>
### Antipsychotic Medications

<table>
<thead>
<tr>
<th>Typical Antipsychotics</th>
<th>Atypical Antipsychotics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorpromazine</td>
<td>Aripiprazole</td>
</tr>
<tr>
<td>Thorazine</td>
<td>Abilify</td>
</tr>
<tr>
<td>C</td>
<td>Cm</td>
</tr>
<tr>
<td>Fluphenazine</td>
<td>Clozapine</td>
</tr>
<tr>
<td>Prolixin</td>
<td>Bm</td>
</tr>
<tr>
<td>Haloperidol</td>
<td>Olanzapine</td>
</tr>
<tr>
<td>Haldol</td>
<td>Cm</td>
</tr>
<tr>
<td>Loxapine</td>
<td>Quetiapine</td>
</tr>
<tr>
<td>Loxitane</td>
<td>Cm</td>
</tr>
<tr>
<td>Perphenazine</td>
<td>Risperidone</td>
</tr>
<tr>
<td>Trilafon</td>
<td>Cm</td>
</tr>
<tr>
<td>Pimozide</td>
<td>Ziprasidone</td>
</tr>
<tr>
<td>Orap</td>
<td>C</td>
</tr>
<tr>
<td>Thioridazine</td>
<td>C</td>
</tr>
<tr>
<td>Mellaril</td>
<td>C</td>
</tr>
<tr>
<td>Thiothixene</td>
<td>C</td>
</tr>
<tr>
<td>Navane</td>
<td>C</td>
</tr>
<tr>
<td>Trifluoperazine</td>
<td>C</td>
</tr>
<tr>
<td>Stelazine</td>
<td>C</td>
</tr>
<tr>
<td>Unknown, of concern</td>
<td>N/A</td>
</tr>
<tr>
<td>L3</td>
<td>L3</td>
</tr>
<tr>
<td>N/A</td>
<td>L4</td>
</tr>
<tr>
<td>L2</td>
<td>L4</td>
</tr>
<tr>
<td>L4</td>
<td>L3</td>
</tr>
<tr>
<td>N/A</td>
<td>L4</td>
</tr>
<tr>
<td>L4</td>
<td>L4</td>
</tr>
<tr>
<td>N/A</td>
<td>L4</td>
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<td>L4</td>
<td>L4</td>
</tr>
<tr>
<td>N/A</td>
<td>L4</td>
</tr>
<tr>
<td>L4</td>
<td>L4</td>
</tr>
<tr>
<td>N/A</td>
<td>L4</td>
</tr>
</tbody>
</table>

*Note: CM = Conventional Medication, C = Conventional Medication, B = Atypical Medication, Bm = Atypical Medication.*
**Clinical Teratology Web**

A resource guide for clinicians

The Clinical Teratology Web is a project of the TERIS (Teratogen Information System) Program at the **University of Washington**, Seattle, Washington. This web site is a cooperative activity involving various clinical services, organizations, and institutions concerned with clinical teratology. It is intended as a resource guide for clinicians and other health practitioners seeking a broader understanding of the effects of reproductive exposures on the developing embryo and fetus, and to assist them in counseling their pregnant patients. It is not a guide for prescribing medications.

<table>
<thead>
<tr>
<th>Teratology:</th>
<th></th>
</tr>
</thead>
</table>
| **Computerized Databases** | REPORISK® System  
REPROTEXT  
REPROTOX  
TERIS & Shepard's Catalog Of Teratogenic Agents  
TOXNET |
| **Teratology Information Services** | Local, national, and international teratogen information providers and networks |
| **Lactation Information** | CARE Northwest  
Drugs and Human Lactation |
| **Organizations and Societies** | Professional organizations... |
| **Other Resources** | Books  
Peer Reviewed Journals  
Drug Compendiums and Indexes |

http://depts.washington.edu/terisweb/

www.reprotox.org
Shared decision making among obstetric and mental health clinicians and the patient should occur before pregnancy.

Multidisciplinary management is recommended to maximize care.

A single medication at a higher dose (if needed) is preferred over multiple medications during pregnancy.
The selection of medication to minimize the risk of illness should be based on:

- history of efficacy
- prior exposure during pregnancy
- available reproductive safety information

Meds with fewer metabolites, higher protein-binding (decreased placental passage), and fewer interactions with other meds are preferred.
AMA guidelines for prescribing drugs to pregnant women (or those of childbearing age):

- avoid unnecessary exposure to drugs; select drugs with the most favorable risk/benefit profile.
- inform patients of implications of drug exposures in pregnancy
- when drugs are necessary, advise 2nd method of contraception
- identify and report any birth defects
Safe Treatment

- Safer to prescribe meds in 2nd and 3rd trimesters
- Avoid these meds during organogenesis
- DIVIDED maternal doses may have less of an effect on the fetus than larger once daily dosing
- If necessary, attempt to decrease dose ~2wks prior to EDD (with a slow taper) to decrease side effects, toxicity, withdrawal
- Otherwise, do not decrease the dose to reduce withdrawal and prevent maternal relapse
Old Obstetricians Never Die...
They Just Fail To Progress
Depression

Most data related to antidepressants in pregnancy are derived from the use of selective serotonin reuptake inhibitors (SSRIs).

Overall, there is limited evidence of teratogenic effects from exposure during pregnancy or breastfeeding.

- 2 reports from Glaxo-Smith-Kline that have raised concerns about a 1.5-2-fold increased risk of congenital cardiac malformations (ASD, VSD) with 1st trimester paroxetin exposure (FDA category has been changed from C to D).
Recently, the teratogenic effect of SSRI use in the 1st trimester was examined in two large case-control studies:

- National Birth Defects Prevention Study: no significant associations were found between SSRI use overall and congenital heart defects.
Recently, the teratogenic effect of SSRI use in the 1st trimester was examined in two large case-control studies: National Birth Defects Prevention Study: no significant associations were found between SSRI use overall and congenital heart defects. **HOWEVER**: an association was found between SSRI use (particularly paroxetine) during early pregnancy and:

- anencephaly
- craniosynostosis
- omphalocele (2-3-fold)
SSRIs

In contrast:

- the Slone Epidemiology Center Birth Defects Study showed **NO INCREASED RISK** of craniosynostosis, omphalocele, or heart defects associated with SSRI use overall during early pregnancy.

- an association **WAS** seen between paroxetine and right ventricular outflow defects.

- Sertraline use was associated with omphalocele and ASD and VSD.
SSRIs

In contrast:

the Slone Epidemiology Center Birth Defects Study showed NO INCREASED RISK of craniosynostosis, omphalocele, or heart defects associated with SSRI use overall during early pregnancy.

An association was seen between paroxetine and right ventricular outflow defects. Sertraline use was associated with omphalocele and ASD and VSD.

Both studies were limited by a small number of exposed infants for each individual malformation.
In contrast: the Slone Epidemiology Center Birth Defects Study showed no increased risk of craniosynostosis, omphalocele, or heart defects associated with SSRI use overall during early pregnancy. An association was seen between paroxetine and right ventricular outflow defects. Sertraline use was associated with omphalocele and ASD and VSD.

Both studies were limited by a small number of exposed infants for each individual malformation. The current data on SSRI exposure during early pregnancy provide conflicting data on the risk for both overall and specific malformations. If there is a risk, the absolute risk is small and generally not greater than 2/1000 births. **These agents are not considered major teratogens.**
Exposure to SSRIs late in pregnancy has been associated with transient neonatal complications:

- jitteriness
- mild respiratory distress
- transient tachypnea of the newborn
- weak cry
- poor tone
- NICU admission
Exposure to SSRIs late in pregnancy has been associated with transient neonatal complications:

- jitteriness
- mild respiratory distress
- transient tachypnea of the newborn
- weak cry

A recent FDA public health advisory highlighted concerns about the risk of an unconfirmed association of newborn persistent pulmonary hypertension with SSR1 use.
SSRIs

The potential risk of SSRI use in pregnancy must be considered in the context of the risk of relapse of depression if treatment is discontinued.

Factors associated with relapse:

- long history of depressive illness (>5 yrs)
- history of recurrent relapses (>4 episodes)

Treatment should be individualized

Based on current evidence, fluoxetine (Prozac) and citalopram (Celexa) should be considered 1st-line.
Paroxetine

- At this time, paroxetine use in pregnant women and women planning pregnancy should be avoided (if possible).
- Fetal echocardiography should be considered for women exposed to paroxetine in early pregnancy.
- Abrupt discontinuation can be associated with withdrawal symptoms.
- Discontinuation should occur according to the product’s prescribing information.
Tricyclic Antidepressants

TCAs available in US since 1963; widely used by women during pregnancy and lactation before the introduction of SSRIs.

Initial studies suggested that TCA exposure might be associated with anomalies, however this has not been confirmed with subsequent studies.

Reported acute effects include: fetal tachycardia, neonatal tachypnea, tachycardia, cyanosis, irritability, hypertonia, clonus and spasm, and transient withdrawal symptoms.
Atypical Antidepressants

- bupropion
- duloxetine
- mirtazapine
- nefazodone
- venlafaxine

Limited data on fetal exposure do not suggest increased risk of anomalies or adverse pregnancy outcomes.

One study of bupropion exposure showed an increased risk of SAb.
Other Therapies

Antidepressant medication is the mainstay of treatment for depression.

HOWEVER, first line recommendations should include:

- dispelling fears of physical disease or inadequacy
- personal support
- phototherapy
- exercise
- nutrition
- adding estrogen to supplement the antidepressant
- regular breaks
- thyroid assessment/tx
Other Therapies

Data shows that structured (interpersonal or cognitive behavioral) psychotherapy are effective treatments for mild to moderate depression and are beneficial adjuncts to medication.

ECT also effective (and safe) tx for major depression in pregnancy.
Other Resources

- Support groups
  - Depression after Delivery
  - Postpartum assistance for mothers
  - The Massachusetts General Hospital Center for Women’s Mental Health

- Hotlines
  - 1-800-SUICIDE
  - 1-800-PPD-MOMS
Non-pharmacologic therapies should be goal for management of anxiety/insomnia when possible (CBT, relaxation, psychotherapy, environmental changes)

**NO ANXIOLYTIC IS COMPLETELY SAFE**, but if necessary lorazepam (Ativan) is a reasonable choice: lack of active metabolites, high potency, good absorption.

Use the lowest effective dose for the briefest time; try to avoid in T1 and near term.

Avoid long-acting benzos in T3.

Consider use of antidepressant (SSRI) to treat anxiety.
Benzodiazepines

- Use of benzos in T1 may increase risk of oral clefts.
- Drugs with long half-lives may accumulate when taken regularly, and lipid-soluble benzos easily cross the placenta.
- Chronic use of benzos leads to withdrawal symptoms in mom and up to 8 weeks in the neonate (tremor, hypertonia, hyperreflexia, apnea, diarrhea, vomiting)
- The use of IM diazepam at delivery has been linked to kernicterus (competition between bilirubin and sodium benzoate)
- The long-term impact of prenatal benzo exposure is unclear.
To date, studies have not shown a significant increase in fetal abnormality with haloperidol, thioridazine, perphenazine, or fluphenazine.

Haloperidol (and other high-potency drugs) appear safer:

- fewer autonomic, anticholinergic, hypotensive, sedative, or CV effects.
- yet there is little data available on others (clozapine, olanzapine, risperidone, quetiapine).
Mood Stabilizers

- Lithium: risk of Ebstein’s anomaly (10-20 fold increase)
  - may be reasonable for women with unstable bipolar disorder to continue lithium and screen with targeted ultrasound around 18 weeks/fetal echo around 22 weeks.
  - Use lowest effective dose (split-dosing). <300mg/dose
  - Closely monitor lithium levels.
- Lithium use in T2 and T3 can cause goiter; may also cause cardiac arrhythmias.
Reserve carbamazepine and valproate for patients with lithium-resistant bipolar disorder.

- Carbamazepine associated with: fetal craniofacial defects, developmental delay, NTD, nail hypoplasia.

- Valproate associated with: NTD, craniofacial defects, limb abnormalities, and CV defects.

Augment both with FOLIC ACID (4mg/day) to decrease risk of NTD.
Mood Stabilizers

- Lamictal (lamotrigine) is relatively safe when mood stabilizer is required.
  - Lack of studies on effectiveness during pregnancy
  - Increased risk of midline facial clefts in daily doses >200 mg.
  - Typical dose range = 100-200 mg/day
ECT is generally regarded as safe and effective during pregnancy.

It is underused, but is beneficial for severe depression, psychosis with affective features and catatonia.

Use careful monitoring of patient and fetus before, during, and after ECT.

May be used on emergency basis when psych status of mother is hazardous to herself or the fetus, as a backup for failed other treatments, and to avoid teratogenic risks of other meds in the 1st trimester.
STUPID DESIGN

INTELLIGENT DESIGN
Coding

Many insurance companies require evaluation and management services linked to mental health diagnoses be performed only by a psychiatrist/psychologist.

The appropriate code for postpartum depression is 648.8X.

If a code from the mental health chapter of the ICD-9 is submitted by a provider whose specialty does not match their criteria, the claim is often denied.

Practices should check with all payers concerning coverage for mental health services before offering and billing for these services.
Conclusion

Depression is very common during pregnancy and the postpartum period.

However, there is insufficient evidence to support a standard recommendation for universal antepartum/postpartum screening.

and no data to support how often screening should be done

BUT--> screening has great potential to benefit a woman and her family and should be strongly considered.
Conclusion

Women with a positive screen for depression require follow-up evaluation and treatment as indicated.

Practices should have a referral process for patients identified with depression.

Monitor women closely who have current or a history of major depression.
Conclusion

 Patients need to know there is **NO SHAME** in having a postpartum illness.

 It is **NOT HER FAULT**.

 She is **NOT CRAZY**!

 The best thing we can do is be supportive and get her the help she needs!
ACOG Committee Opinion #453 2/10: Screening for Depression During and After Pregnancy

ACOG News Release: Depression During Pregnancy: Treatment Recommendations; A Joint Report from APA and ACOG; 8/21/09

ACOG Practice Bulletin #92: Use of Psychiatric Medications During Pregnancy and Lactation


The transfer of drugs and other chemicals into human milk. Committee on Drugs, *Pediatrics* 2001; 108; 776-789.