



Detecting and Managing Postpartum Depression (PPD)

A Tool Kit for Obstetrician-Gynecologists



Postpartum depression (PPD) is very common and can have a devastating impact on mothers, infants, and families. OB/GYNs are well-placed to detect and initiate treatment for PPD early, to prevent morbidity and improve the lives of women and their families. This tool kit has been designed to assist OB/GYNs with: 1) screening and diagnosing PPD, 2) increasing understanding and awareness of available treatment options, and 3) improving competence in shared decision-making, with the goal of optimizing the management of PPD.

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Part 1: Screening and Diagnosis of PPD

Risk Factors for PPD¹⁻³

- Depression during pregnancy
- Anxiety during pregnancy
- Traumatic birth experience
- Low levels of social support
- Infant admission to NICU
- Previous history of depression (including PMDD) or bipolar disorder
- Family history of PPD
- Gestational diabetes
- Breastfeeding problems
- Stressful life events
- History of psychiatric/substance use treatment, trauma, or domestic violence



Negative Consequences of Untreated PPD⁴⁻⁸

Untreated PPD elevates risk for the following behaviors in mothers

- Addictive behaviors
- Relationship difficulties
- Elevated risk of suicide
- Elevated risk of neglectful parenting behaviors (eg, less likely to talk to their babies, use car seats, or bring children in for vaccinations or checkups)

Untreated PPD elevates risk for the following problems in exposed children

- Sleep problems
- Lower IQ
- Slower language development
- Behavioral problems
- Psychiatric illness



DSM 5 Diagnostic Criteria for MDD With Peripartum Onset⁹

- Five (or more) symptoms have been present nearly every day during the same 2-week period and represent a change from previous functioning; at least one of the symptoms is either (1) depressed mood or (2) loss of interest or pleasure. The symptoms must impair functioning and cannot be secondary to another drug or illness.
1. Depressed mood
 2. Markedly diminished interest or pleasure in all, or almost all, activities
 3. Significant change in weight or appetite
 4. Insomnia or hypersomnia
 5. Psychomotor agitation or retardation
 6. Fatigue or loss of energy
 7. Feelings of worthlessness or excessive or inappropriate guilt
 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 a specific plan for committing suicide
- Peripartum onset specifier: Onset of symptoms occurs during pregnancy or within 4 weeks after childbirth. Episodes can present with psychotic features.



Distinguishing Baby Blues From PPD¹⁰⁻¹¹

	Baby Blues	Postpartum Depression
Prevalence	85% of mothers	13% of mothers
Onset	First few days after delivery	Typically emerges between third trimester of pregnancy and 2-3 months postpartum
Duration	A few hours up to 10 days	Longer than 2 weeks; can last up to 3 years ²
Severity	Mild symptoms	Clinical diagnosis of MDE
Impaired functioning	No	Yes
Resolution	Usually resolves spontaneously	Usually requires treatment
Association with psychopathology	Unrelated to psychiatric history and not predictive of future problems	More common in women with history of major depression and bipolar disorder and predictive of future depressive episodes



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Part 1: Screening and Diagnosis of PPD

Screening for Depression: Edinburgh Postnatal Depression Scale (EPDS)^{2,12-19}

Scoring^{12-13,18-19}

QUESTIONS 1, 2, & 4

Scored as 0, 1, 2, or 3 with first option scored as 0 and last option scored as 3

QUESTIONS 3, 5, 6, 7, 8, 9, & 10

Reverse scored, with the first option scored as 3 and the last option scored as 0

- Maximum score: 30
- **Any score greater than 0 on item 10 should trigger further evaluation of patient's suicide risk (see page 4 of the tool kit)**
- **Patients who screen positive on the EPDS (score ≥ 12)^a should receive a more comprehensive diagnostic assessment, which should include assessment for bipolar disorder (see page 5 of the tool kit)**

^a A cutoff of 12 for the total score has been reported to optimize sensitivity and specificity in different meta-analyses.

Name: _____	Date: _____
We would like to know how you have been feeling in the past week. Please indicate which of the following comes closest to how you have been feeling over the past seven days, not just how you feel today. Please tick one circle for each question that comes closest to how you have felt in the last seven days. Here is an example already completed. I have felt happy: ☐ Yes, all of 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.	
1. I have been able to laugh and see the funny side of things ☐ 0 As much as I always could ☐ 1 Not quite so much now ☐ 2 Definitely not so much now ☐ 3 Not at all	6. Things have been getting on top of me ☐ 3 Yes, most of the time I haven't been able to cope at all ☐ 2 Yes, sometimes I haven't been coping as well as usual ☐ 1 No, most of the time I have coped quite well ☐ 0 No, I have been coping as well as ever
2. I have looked forward with enjoyment to things ☐ 0 As much as I ever did ☐ 1 Rather less than I used to ☐ 2 Definitely less than I used to ☐ 3 Hardly at all	7. I have been so unhappy that I have had difficulty sleeping ☐ 3 Yes, most of the time ☐ 2 Yes, sometimes ☐ 1 Not very often ☐ 0 No, not at all
3. I have blamed myself unnecessarily when things went wrong ☐ 3 Yes, most of the time ☐ 2 Yes, some of the time ☐ 1 Not very often ☐ 0 No, never	8. I have felt sad or miserable ☐ 3 Yes, most of the time ☐ 2 Yes, quite often ☐ 1 Not very often ☐ 0 No, not at all
4. I have been anxious or worried for no good reason ☐ 0 No, not at all ☐ 1 Hardly ever ☐ 2 Yes, sometimes ☐ 3 Yes, very often	9. I have been so unhappy that I have been crying ☐ 3 Yes, most of the time ☐ 2 Yes, quite often ☐ 1 Only occasionally ☐ 0 No, never
5. I have felt scared or panicky for no very good reason ☐ 3 Yes, quite a lot ☐ 2 Yes, sometimes ☐ 1 No, not much ☐ 0 No, not at all	10. The thought of harming myself has occurred to me ☐ 3 Yes, quite often ☐ 2 Sometimes ☐ 1 Hardly ever ☐ 0 Never



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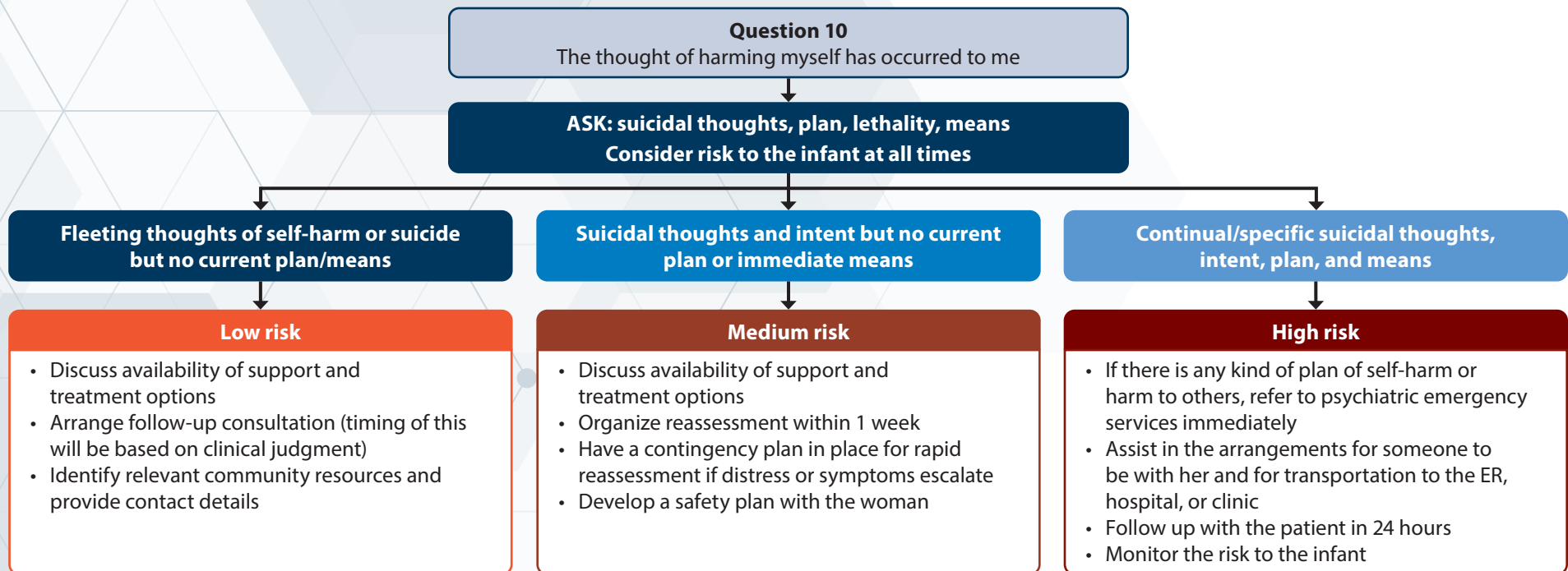


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Part 1: Screening and Diagnosis of PPD

Assessing Suicide Risk^{12,20}

- Any score greater than 0 on item #10 on the EPDS suggests patient may be at risk of self-harm or suicide
- Do not leave woman/baby alone in room until further assessment or treatment plan has been established
- Immediately assess further
 - In the past 2 weeks, how often have you thought of hurting yourself?
 - Have you ever attempted to hurt yourself in the past?
 - Have you thought about how you could harm yourself?
- If there is any kind of plan of self-harm or harm to others, refer to psychiatric emergency services immediately
- Assist in arrangements for someone to be with her and for transportation to the emergency room, hospital, or clinic
- If there is no plan to harm self or others, provide assistance and resources as needed
- Assess social support: Who can she rely on for childcare? Who can she talk to? (eg, partner, family, friends)
- Inform of emergency resources in the area if depression symptoms worsen or thoughts of self-harm or harm of others develops (eg, crisis lines, hospital ERs)
- Help client make a safety plan, and arrange to follow up with a phone call in a few hours or days





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Part 1: Screening and Diagnosis of PPD

Screening for Bipolar Disorder^{21,22}

THE MOOD DISORDER QUESTIONNAIRE

Instructions: Please answer each question to the best of your ability.

	YES	NO
1. Has there ever been a period of time when you were not your usual self and...		
...you felt so good or so hyper that other people thought you were not your normal self or you were so hyper that you got into trouble?	☐	☐
...you were so irritable that you shouted at people or started fights or arguments?	☐	☐
...you felt much more self-confident than usual?	☐	☐
...you got much less sleep than usual and found you didn't really miss it?	☐	☐
...you were much more talkative or spoke much faster than usual?	☐	☐
...thoughts raced through your head or you couldn't slow your mind down?	☐	☐
...you were so easily distracted by things around you that you had trouble concentrating or staying on track?	☐	☐
...you had much more energy than usual?	☐	☐
...you were much more active or did many more things than usual?	☐	☐
...you were much more social or outgoing than usual, for example, you telephoned friends in the middle of the night?	☐	☐
...you were much more interested in sex than usual?	☐	☐
...you did things that were unusual for you or that other people might have thought were excessive, foolish, or risky?	☐	☐
...spending money got you or your family into trouble?	☐	☐
2. If you checked YES to more than one of the above, have several of these ever happened during the same period of time?	☐	☐
3. How much of a problem did any of these cause you – like being unable to work; having family, money or legal troubles; getting into arguments or fights? <i>Please circle one response only.</i>		
No Problem Minor Problem Moderate Problem Serious Problem		
4. Have any of your blood relatives (i.e. children, siblings, parents, grandparents, aunts, uncles) had manic-depressive illness or bipolar disorder?	☐	☐
5. Has a health professional ever told you that you have manic-depressive illness or bipolar disorder?	☐	☐

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Assessing Intrusive Thoughts²³

- Intrusive thoughts are key features of depression, anxiety, and OCD that can be very distressing

Intrusive thoughts (eg, of harming baby) that occur secondary to obsessions/anxiety

- Good insight
- Thoughts are intrusive and scary
- No psychotic symptoms
- Thoughts cause anxiety

Suggests that mom is not at risk of harming baby

Intrusive thoughts (eg, of harming baby) that occur secondary to postpartum psychosis/suspected postpartum psychosis

- Poor insight
- Psychotic symptoms
- Delusional beliefs with distortion of reality present

Suggests that mom is at risk of harming baby. Patient should be escorted to the ER for immediate psychiatric evaluation (see page 6 of the tool kit)

A positive screen^a requires

- ≥7 "yes" on 13 items
- ≥2 co-occurring symptoms
- The level of functional impairment must be "moderate problem" to "serious problem"
- Patients with positive screens should be referred to a mental health specialist (see page 6 of the tool kit)**

^a This measure has demonstrated sensitivity (0.73) and specificity (0.90) for bipolar disorder.



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Part 1: Screening and Diagnosis of PPD

Diagnostic Assessment With Patients Who Screen Positive on EPDS^{2,15,17}

- Patients who screen positive on the EPDS (score ≥ 12) should receive a more comprehensive diagnostic assessment and intervention
 - Diagnostic assessment should include
 - Severity and duration of depression symptoms, and clinical impairment
 - Clinical interview: obtain complete personal and family medical history to rule out alternative causes
 - Laboratory testing (eg, thyroid levels) to rule out alternative causes
 - Manic and psychotic symptoms to rule out postpartum psychosis and bipolar disorder
 - Anxiety, OCD, panic, and substance use symptoms to identify comorbidities
 - Suicidal ideation, intent, means, and plan, as well as personal and family history of suicidality
 - Identification of imminent risk requires immediate psychiatric attention
- ☐ Schedule appropriate follow-up to monitor symptoms and treatment response

When to Refer to a Perinatal Mental Health Specialist^{24,25}

Patient should be referred to a mental health specialist when there are

- Diagnostic concerns
- Multiple psychiatric comorbidities
- Little/no response to standards of care treatments
- Safety concerns, including suicidality, mania, and psychosis^a

Transfer of care works best if OB/GYN has a referral network in place that includes a variety of mental health professionals (eg, psychiatrists, psychologists, social workers)

- Ideally, specialists will have experience in working with pregnant and postpartum women and practice evidence-based mental healthcare
- Specialists may reside in the healthcare system of the obstetrician or practice independently
- Having trusted referral sources in place ahead of time allows for a quick response to meet patients' needs
- Knowing that many postpartum depressed women do not follow up on referrals made for mental healthcare, OB/GYNs and staff are advised to make warm handoffs directly when possible or follow up regularly with patients

^a Immediate psychiatric evaluation is required for patients with suspected suicidality, mania, or psychosis.



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Part 2: Management of PPD

Evidence-Based Treatment Options^{26,27}

All PPD

- Self-care
- Sleep protection
- Exercise
- Psychosocial support strategies

Investigate and manage social stressors, medical and psychiatric comorbidities

Moderate PPD

- Psychological treatments, including cognitive behavioral therapy and interpersonal therapy
- Add selective serotonin reuptake inhibitor (SSRI) if insufficient response
- Brexanolone

Severe PPD

- SSRI alone or with psychological intervention
- Consider antidepressant switch and augmentation strategies if no response to SSRI alone
- Brexanolone
- Consider electroconvulsive therapy with suicidality or treatment resistance



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Part 2: Management of PPD

Brexanolone: First Approved and First-in-Class Treatment for PPD in the United States²⁸

Dosage and Administration

- Administered as a continuous IV infusion over 60 hours (2.5 days) as follows
 - 0 to 4 hours: Initiate with a dosage of 30 mcg/kg/hour
 - 4 to 24 hours: Increase dosage to 60 mcg/kg/hour
 - 24 to 52 hours: Increase dosage to 90 mcg/kg/hour (alternatively consider a dosage of 60 mcg/kg/hour for those who do not tolerate 90 mcg/kg/hour)
 - 52 to 56 hours: Decrease dosage to 60 mcg/kg/hour
 - 56 to 60 hours: Decrease dosage to 30 mcg/kg/hour
- Dilution required prior to administration

Adverse Events

- Black box warning: Patients treated with brexanolone are at risk of excessive sedation or sudden loss of consciousness during administration
- Other adverse reactions (incidence $\geq 5\%$ and at least twice the rate of placebo) were dry mouth and flushing
- Suicidal thoughts and behaviors were higher than in the placebo group

Brexanolone Patient Selection Clinical Pearls²⁹

1. Patients whose depressive episode begins as early as 20 weeks gestation or later than 5 weeks postpartum can be considered for treatment if insurance will cover it^a
2. May also consider patients who are still depressed after 6 months postpartum^a
3. Patients should have moderate or severe depression
4. Brexanolone has demonstrated efficacy in patients with comorbid anxiety disorders, OCD, borderline personality disorder, PTSD
5. Patients with comorbid bipolar disorders, psychotic disorders, current substance use disorders, or active suicidal ideation with plan or intent; pregnancy; renal or hepatic disease are ineligible for treatment
6. Many patients benefited from continued treatment with an oral antidepressant
7. Outpatient care after infusion plays an important role in continued remission
8. GABAergic medications should be reduced by half given the increased risk for sedation
9. Documentation for Prior Authorization
 - Diagnosis = MDD with peripartum onset, PPD, F53
 - Document date of delivery, showing less than 6 months postpartum, with symptom onset in third trimester or within 4 weeks of delivery
 - Document moderate to severe depression (Note: There is no published data to support its use for mild PPD)
 - If breastfeeding, most insurers want documentation that patient will pump and dump during the infusion and for 4 days after

^a Original clinical trial eligibility included women who were diagnosed with a major depressive episode that began in the third trimester of pregnancy or within 4 weeks after delivery, and who had given birth less than 6 months prior to trial enrollment.



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Part 2: Management of PPD

REMS Requirements for Brexanolone³⁰

To become certified to dispense

- Be able to monitor patients continuously for the duration of the infusion
- Have the following onsite: continuous pulse oximetry, fall precaution protocol, IV programmable infusion pumps with alarms to alert when the pump malfunctions, healthcare providers to continuously monitor patients and intervene as necessary
- Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the healthcare setting
- Train all relevant staff involved in prescribing, dispensing, and administering brexanolone on the REMS Program requirements using the Training for Healthcare Settings
- Establish processes and procedures to identify new staff involved in prescribing, dispensing, and administering brexanolone, and ensure they are trained
- Establish processes and procedures to enroll the patient in the REMS Program, and counsel the patient in the REMS Program
- Establish processes and procedures to submit the Post Infusion Form and Excess Sedation and Loss of Consciousness Adverse Event Form to the REMS Program

Before dispensing

- Enroll the patient by completing and submitting the Patient Enrollment Form to the REMS Program

Before administering

- Verify the patient is enrolled through the processes and procedures established as a requirement of the REMS Program
- Counsel the patient on signs and symptoms of excessive sedation, loss of consciousness, and the importance of immediately reporting to a healthcare provider any signs and symptoms of excessive sedation using the Patient Information Guide; provide a copy of the material to the patient

During treatment, every 2 hours

- Assess the patient's health status for signs and symptoms of excessive sedation and loss of consciousness

During treatment

- Assess the patient's oxygen saturation using continuous pulse oximetry

After treatment discontinuation, prior to discharge

- Assess the patient's level of sedation



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Part 2: Management of PPD

Obtaining Access to Brexanolone for Your Patients

<https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=387>



Healthcare Settings

[CERTIFY IN THE ZULRESSO REMS](#)

[HOW TO ADMINISTER ZULRESSO](#)



Pharmacies

1. Designate an Authorized Representative
2. Review the Program Overview for Pharmacies
3. Complete the Pharmacy Enrollment Form

[ENROLL IN THE ZULRESSO REMS](#)



Patients

1. Understand the risks associated with ZULRESSO
2. Learn how to enroll in the ZULRESSO REMS



Healthcare Providers

1. Review education materials

ZULRESSO™ REMS Training for Healthcare Settings

Risk Evaluation and Mitigation Strategy (REMS)

Visit https://www.accessdata.fda.gov/drugsatfda_docs/rems/Zulresso_2020_10_14_Training_for_Healthcare_Settings.pdf to enroll in the training program so that your healthcare facility can be certified to offer brexanolone to patients

Or visit <https://www.zulressorems.com/#Public> to find a facility that is already certified to administer brexanolone

Or call 844-472-4379 for more information



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Healthcare Settings

- ZULRESSO Prescribing Information
- ZULRESSO Medication Guide
- ZULRESSO REMS Training
- ZULRESSO REMS Healthcare Setting Enrollment Form
- ZULRESSO REMS Healthcare Setting Knowledge Assessment
- ZULRESSO REMS Patient Enrollment Form
- ZULRESSO REMS Post Infusion Form
- ZULRESSO REMS Patient Information Guide
- Excessive Sedation and Loss of Consciousness Adverse Event Form

Patients

- ZULRESSO REMS Patient Information Guide
- ZULRESSO Medication Guide
- ZULRESSO REMS Patient Enrollment Form

Pharmacies

- ZULRESSO Prescribing Information
- ZULRESSO Medication Guide
- Program Overview for Pharmacies



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Part 3: Overcoming Treatment Barriers Through Shared Decision-Making³¹

1. Seek your patient's participation

- Too often, treatment decisions are made for patients, without regard for their values, preferences, or goals
- Communicate that a choice exists, and invite your patient to participate in the process
- Summarize the health problem, and let your patient know that there are options to consider; describe the problem clearly and openly so that your patient understands that a decision needs to be made
- Ask your patient to participate with the healthcare team in making her treatment decision; help your patient understand that she is being invited to ask questions and discuss options with you, and let her know that her participation is important
- Ask if your patient would like to have family members or caregivers participate in the discussion

Try These Conversation Starters to Invite Participation

- "Now that we have identified the problem, it's time for us to think about what to do next. There are several different types of treatment options that have been shown to help patients with PPD. I'd like to discuss these different options with you before we decide on an approach that is best for you."
- After being invited to participate and having the options outlined, patients may still want the healthcare provider to make the decision for them. In that case, the following may be useful to try: "I'm happy to share my views and help you reach a good decision. Before I do, would you like more details about your options?"



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Part 3: Overcoming Treatment Barriers Through Shared Decision-Making³¹

2. Help your patient explore and compare treatment options

- Many healthcare decisions have multiple treatment options, including the option of no care; often no single option is clearly superior; use evidence-based decision-making resources to compare the treatment options
- Assess what your patient already knows about her options
- Write down a list of the options, and describe them in plain language
- Point out when there are clear differences between specific options (eg, engaging in psychotherapy vs taking a medication)
- Clearly communicate the risks and benefits of each option; explain the limitations of what is known and unknown about the treatment options and what would happen with no treatment
- Communicate numbers using simple visual aids (graphs, charts, pictographs) to help your patient understand your explanations
- Summarize by listing the options again
- Use the teach-back technique to check for understanding; ask your patient to explain in her own words what the options are

Try These Conversation Starters to Explore Pros and Cons

- “Let me tell you what the research says about the benefits and risks of the different available treatment options you are considering.”
- “These options may have different effects for you compared with other people, so I want to describe them.”
- “The treatments I just described are not always effective for everyone, and the chances of having side effects can vary from one person to another.”



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Part 3: Overcoming Treatment Barriers Through Shared Decision-Making³¹

3. Use effective communication and listening skills to help your patients assess their values and preferences

- Encourage your patient to talk about what matters most to her
- Ask open-ended questions
- Listen actively to your patient; use prompts that encourage your patient to continue talking (for example, “Go on,” or “I’d like to hear more about that”); use nonverbal cues such as nodding your head and having an engaged listening posture
- Show empathy and interest in the effect that a problem is having on your patient’s life, and validate her feelings (for example, say, “That sounds really upsetting”)
- Acknowledge the values and preferences that matter to your patient; paraphrase what you have heard from your patient; this signals to your patient that she has been heard and that you are listening to her unique perspective
- Agree on what is important to your patient

Try These Conversation Starters to Learn About Your Patients’ Values and Preferences

- “As you think about your options, what’s important to you?”
- “How may each of these treatment options affect your daily life?”
- “Which of these potential side effects worries you the most?”
- “Which of the options fits best with treatment goals we’ve discussed?”
- “Is there anything that may get in the way of doing this?”



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Part 3: Overcoming Treatment Barriers Through Shared Decision-Making³¹

4. Reach a decision with your patient

- Help your patient move to a decision; ask if she is ready to make a decision or if she has any additional questions
- Ask your patient if she would like additional information tools such as educational materials or decision aids to help make a decision
- Check to see if your patient needs more time to consider the options or discuss them with others; schedule another session if your patient requests more time to consider the options
- Confirm the decision with your patient when she is ready to make a decision; ask your patient to describe the treatment options and which one she chose
- Verify the next steps to be taken and timing of these actions with your patient
- Schedule follow-up appointments to carry out the preferred treatment or active surveillance

Try These Conversation Starters for the Decision and Follow-Up Phases

- "It is fine to take more time to think about the treatment choices. Would you like some more time, or are you ready to decide?"
- "What additional questions do you have for me to help you make your decision?"
- "This is a big decision, and it's important for you to consider which treatment option you prefer."
- "Let's meet again next week. In the meantime, here is some information for you to read and think about. We can continue the discussion once you've had a chance to do that."
- "Are there other people that you want to talk to in order to help you make this decision?"
- "Now that we had a chance to discuss your treatment options, which treatment do you think is right for you?"



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Part 3: Overcoming Treatment Barriers Through Shared Decision-Making³¹

5. Evaluate your patient's decision

- Once a decision has been made, it will be important to follow up with your patient on how she is doing
- Remind your patient that treatments can be changed if they are not working well for your patient
- Monitor the extent to which the treatment decision is implemented
- Assist your patient with managing barriers to implementing the treatment decision
- Revisit the decision with your patient to determine if other decisions need to be made

Try These Conversation Starters for Prompting Future Evaluation

- "Can we talk next [appropriate timeframe] to see how you are doing?"
- "If you don't feel things are improving, please schedule a follow-up visit so we can plan a different approach"



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