Women with Multiple Sclerosis: Improving Quality of Life and Reproductive Health Outcomes

Association of Reproductive Health Professionals
www.arhp.org
Acknowledgment

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# Disclosure Declarations

<table>
<thead>
<tr>
<th>Name</th>
<th>Disclosure</th>
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<tbody>
<tr>
<td>Jacqueline Bernard, MD (Advisory Co-Chair)</td>
<td>Nothing to disclose.</td>
</tr>
<tr>
<td>Lee Shulman, MD (Advisory Co-Chair)</td>
<td>Dr. Shulman is a speaker and/or consultant for Actavis, Teva, Merck, Bayer, Shionogi, Sequenom, Natera, Quest, Roche Labs.</td>
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<td>Anne Moore, DNP, APN, FAANP (Advisory Committee/Planner)</td>
<td>Nothing to disclose.</td>
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<td>Diane Shannon, MD (Medical Writer)</td>
<td>Nothing to disclose.</td>
</tr>
<tr>
<td>Megan A. Henszey, MEd (Planner)</td>
<td>Nothing to disclose.</td>
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</table>
Learning Objectives

• *Demonstrate current knowledge* about MS including symptoms, diagnosis, treatment, and pain management

• *Improve health outcomes* among patients living with MS including management of co-existing conditions and chronic pain
Learning Objectives

• *Manage* the treatment of women with MS using an interdisciplinary approach
• *Assess and treat* the reproductive health issues affecting women with MS, including sexuality, contraception, and pregnancy
Case Study: Tamara

- 30 yo graduate student
- Presents for new patient visit
- Diagnosed with MS at 22
- Has lower extremity weakness and urinary retention
- Followed by local neurologist and urologist
- Currently treated with weekly interferon beta-1a injections
- Indwelling pubic catheter
Case Study: Tamara

Current Medications

• Sertraline 50 mg/day
• Baclofen 10 mg bid
• Interferon beta-1a 30 mg IM q week
• Vitamin D 2000 IU/day
• Vitamin C 1000 IU/day
Case Study: Tamara

**Hepatic Damage**
- Will my MS medications damage my liver?

**Alternative Therapies**
- Should I take extra vitamins or supplements?

**Vaccinations**
- Is it safe for me to get a flu shot?
Case Study: Tamara

- Personal Medical History
- Family Medical History
- Review of Systems
- Physical Exam
Who is Affected by Multiple Sclerosis?

- Common Dx = ages 20-50
- Higher incidence in geographic locations above 40° latitude
- Caucasians (especially Northern European ancestry)
- Women 3:1 more likely than men

400,000 Cases in the US

Natural History of Multiple Sclerosis

What is MS?
- Autoimmune disease of central nervous system
- Includes brain, optic nerves, and spinal cord

Characteristics
- Multifocal inflammatory demyelination
- Varying degrees of axonal injury

Onset
- Asymptomatic period
- Isolated syndrome

Natural History of Multiple Sclerosis

- Variable disease course following presenting syndrome
- Most patients have relapses at varying rates
- Some experience complete remission while others have cumulative deficits
- Over time, relapses occur more frequently causing progressive disability

Natural History of Multiple Sclerosis

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Common Symptoms of First Episode of Multiple Sclerosis

- Sensory Loss: 37%
- Optic Neuritis: 36%
- Weakness: 35%
- Parasthesia: 24%
- Diplopia: 15%
- Ataxia: 11%

- Vertigo: 6%
- Paroxysmal Attacks: 4%
- Bladder: 4%

## Common Symptoms of Multiple Sclerosis

- Fatigue
- Spasms or spasticity
- Pain, including trigeminal neuralgia
- Tremor
- Sensory symptoms
- Dysarthria
- Visual disturbances
- Cognitive problems
- Ataxia
- Mood disturbances
- Sexual dysfunction
- Weakness
- Bladder dysfunction
- Bowel dysfunction

Primary Clinical Subtypes of Multiple Sclerosis

- Relapsing-remitting
- Primary-progressive
- Secondary-progressive
- Progressive-relapsing

Pathogenesis of Multiple Sclerosis

Disease-modifying Treatments for Multiple Sclerosis

DMTs reduce frequency and severity of relapses

- Not intended for Tx of some symptoms
- Not curative

- Reduce accumulation of lesions within brain and spinal cord
- May delay progression to disability

Overview of Disease-modifying Treatments for Multiple Sclerosis

<table>
<thead>
<tr>
<th>Name</th>
<th>Frequency</th>
<th>Route</th>
<th>Usual Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interferon beta-1a</td>
<td>Once per week</td>
<td>IM</td>
<td>30 mcg</td>
</tr>
<tr>
<td>Interferon beta-1b*</td>
<td>Every other day</td>
<td>SC</td>
<td>250 mcg</td>
</tr>
<tr>
<td>Glatiramer acetate</td>
<td>Daily</td>
<td>SC</td>
<td>20 mg</td>
</tr>
<tr>
<td>Fingolimod</td>
<td>Daily</td>
<td>Oral</td>
<td>0.5 mg</td>
</tr>
<tr>
<td>Mitoxantrone</td>
<td>4 times per year at medical facility</td>
<td>IV</td>
<td>Lifetime dose limit 140 mg/m²</td>
</tr>
<tr>
<td>Interferon beta-1a</td>
<td>3 times per week</td>
<td>SC</td>
<td>44 mcg</td>
</tr>
<tr>
<td>Natalizumab</td>
<td>Every 4 weeks at infusion center</td>
<td>IV</td>
<td>300 mg</td>
</tr>
<tr>
<td>Dimethyl fumarate</td>
<td>Twice per day</td>
<td>Oral</td>
<td>240 mg</td>
</tr>
<tr>
<td>Teriflunomide</td>
<td>Once per day</td>
<td>Oral</td>
<td>7 mg</td>
</tr>
</tbody>
</table>

*Two brands available. Abbreviations: IM, intramuscular; IV, intravenous; SC, subcutaneous.

Approved Indication for Disease-modifying Treatments for MS

**Interferon beta-1a IM**
- For relapsing forms of MS to slow accumulation of disability and reduce frequency of relapses
- For first clinical episode that has MRI features consistent with MS

**Interferon beta-1b**
- For relapsing forms of MS to reduce frequency of relapses
- For first clinical episode that has MRI features consistent with MS

**Glatiramer Acetate**
- For relapsing-remitting MS to decrease number of relapses
- For first clinical episode that has MRI features consistent with MS

### Approved Indication for Disease-modifying Treatments for MS

<table>
<thead>
<tr>
<th><strong>Fingolimod</strong></th>
<th><strong>Mitoxantrone</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>- For relapsing forms of MS to reduce frequency of relapses and delay accumulation of physical disability</td>
<td>- For worsening relapsing-remitting, progressive-relapsing, or secondary-progressive MS to decrease neurologic disability and/or frequency of relapses</td>
</tr>
</tbody>
</table>

### Approved Indication for Disease-modifying Treatments for MS

<table>
<thead>
<tr>
<th>Interferon beta-1a SC</th>
<th>Natalizumab</th>
</tr>
</thead>
<tbody>
<tr>
<td>• For relapsing forms of MS to reduce frequency of exacerbations and delay accumulation of physical disability</td>
<td>• For relapsing forms of MS to reduce frequency of exacerbations and delay accumulation of physical disability</td>
</tr>
<tr>
<td></td>
<td>• Generally recommended for patients with inadequate response to DMT or unable to tolerate another DMT</td>
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</table>

Approved Indication for Disease-modifying Treatments for MS

**Dimethyl fumarate**
- For the treatment of patients with relapsing forms of multiple sclerosis

**Teriflunomide**
- For the treatment of patients with relapsing forms of multiple sclerosis

Common Side Effects Associated with Disease-modifying Treatments

Interferon beta-1a
- Flu-like symptoms that diminish over time for many patients

Interferon beta-1b
- Flu-like symptoms that diminish over time for many patients
- Injection site reactions

Common Side Effects Associated with Disease-modifying Treatments

- **Glatiramer Acetate**
  - Injection site reactions

- **Fingolimod**
  - Headache
  - Flu-like symptoms
  - Diarrhea
  - Back pain
  - Liver enzyme abnormalities
  - Cough

Common Side Effects Associated with Disease-modifying Treatments

Mitoxantrone

- Blue-green urine 24 hours post-therapy
- Infections
- Bone marrow suppression
- Nausea
- Thinning hair
- Bladder infections
- Mouth sores

Common Side Effects Associated with Disease-modifying Treatments

Natalizumab

- Headache
- Fatigue
- Urinary tract infections
- Depression
- Lower respiratory tract infections
- Joint pain
- Chest discomfort

Common Side Effects Associated with Disease-modifying Treatments

Dimethyl fumarate

- Flushing
- Diarrhea
- Nausea
- Upper abdominal pain
- Lymphopenia

Tecfidera Prescribing information; National Multiple Sclerosis Society. 2014.
Common Side Effects Associated with Disease-modifying Treatments

Teriflunomide

- Diarrhea
- Abnormal liver function tests
- Nausea
- Influenza
- Alopecia

## Warnings Associated with Disease-modifying Treatments for MS

### Interferon beta-1a
- Increased risk of depression, suicidal ideation, and other psychiatric disorders
- Hepatic injury
- Anaphylaxis and other allergic reactions
- Exacerbation of congestive heart failure
- Development of a new autoimmune disorder

### Interferon beta-1b
- Increased risk of depression and suicide
- Injection site necrosis
- Hepatic injury
- Anaphylaxis

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Warnings Associated with Disease-modifying Treatments for MS

Glatiramer Acetate
- Immediate post-injection reactions
- Chest pain
- Lipoatrophy and skin necrosis
- Potential disruption in immune response

Fingolimod
- Bradycardia and other cardiac dysfunctions in at-risk patients
- Infections
- Macular edema
- Decreased pulmonary function
- Hepatic dysfunction
- Fetal risk

Warnings Associated with Disease-modifying Treatments for MS

**Mitoxantrone**
- Total lifetime dose is limited to 140 mg/m² in order to avoid cardiotoxicities
- Perform cardiac function tests prior to each dose
- Contraindicated for patients with pre-existing cardiac or liver disease
- Increased risk of acute myelogenous leukemia

**Natalizumab**
- Increased risk of progressive multifocal leukoencephalopathy (PML) caused by JC virus
- Positive test for antibodies to JC virus places patients at increased risk of PML
- Prior treatment with immunosuppressive agents and treatment with natalizumab > 2 years increases risk of PML

Warnings Associated with Disease-modifying Treatments for MS

Dimethyl fumarate

- Lymphopenia
- Flushing
Warnings Associated with Disease-modifying Treatments for MS

Teriflunomide

- **Teratogenic: Pregnancy Category X**
- Hepatotoxicity
- Increased risk of infection, including tuberculosis
- Peripheral neuropathy
- Acute renal failure
- Hypertension

Treatment Strategies for Symptoms of Multiple Sclerosis

**Spasticity**
- baclofen, tizanidine, diazepam, clonazepam, dantrolene, physical therapy

**Walking/Ataxia**
- dalfampridine, physical therapy, assistive devices

**Optical**
- short course of IV methylprednisolone followed by oral steroid taper

Treatment Strategies for Symptoms of Multiple Sclerosis

Fatigue
- amantadine, modafinil, r-modafinil, methylphenidate, dextroamphetamine

Pain
- aspirin, acetaminophen, NSAIDs, anticonvulsants, antidepressants

Urinary
- anticholinergics, bladder stimulators, botulinum toxin, intermittent catheterization

Treatment Strategies for Symptoms of Multiple Sclerosis

**Constipation**
- Increased water and fiber consumption, stool softeners, polyethylene glycol

**Sexual Dysfunction**
- Antidepressants, anxiolytics, vaginal lubricants, vibrators, counseling

# Comorbid Medical Conditions and Multiple Sclerosis

## Frequent
- Autoimmune disorders
- Thyroid disease
- Diabetes
- B12 deficiency

## Less Frequent
- Malignancies
- Gout
- Lupus
- Asthma

Vaccinations and Multiple Sclerosis

- **Contraindicated:** Live vaccines
  - Including live attenuated influenza vaccine and varicella
  - Can provoke acute MS relapses

- **Safe:** Killed vaccines
  - Ex: Influenza, tetanus, hepatitis A
  - Including during pregnancy

- **Encouraged:** Killed influenza and pneumococcal vaccinations

Physical Activity and Multiple Sclerosis

Supplements and Multiple Sclerosis

Vitamin D

- Immunomodulatory effects
- Low levels: increased risk of MS, increased relapse rate, more disability
- Well-tolerated
- May cause fatigue, abdominal cramps, nausea, vomiting, renal damage, and hypertension
- Upper limit 4,000 IU

Omega-3 Fatty Acids

- Slow disability progression
- Use with interferons or glatiramer acetate associated with improved function
- Well-tolerated
- May have anticoagulant effects, cause vitamin E deficiency

Supplements and Multiple Sclerosis

**Vitamin B12**
- No evidence of therapeutic effects
- May require oral or IM supplementation
- Well-tolerated

**Echinacea**
- Studies limited
- No evidence of efficacy
- May cause hepatotoxicity, particularly with interferons

Tamara is experiencing weakness and muscle spasticity. What would you recommend to her?

A. Cease interferon beta-1a and increase vitamin supplements
B. Increase vitamin D and start antidepressant medication
C. 20-30 minutes of exercise per day, physical therapy, and adherence interferon beta-1a
Case Study: Tamara

• Treatment plan:
  ▪ Lab evaluations
  ▪ Referral for physical therapy consult

• Recommendations:
  ▪ Physical activity 20-30 minutes/day
  ▪ Following PT consult, discuss baclofen taper with neurologist
  ▪ Lifestyle issues (sleep, vitamin D, omega-3 fatty acids)
  ▪ Reinforce adherence to interferon beta-1a
  ▪ Discuss intermittent self-catheterization
Points for Practice

• Encourage adherence to DMTs
• Vigilant monitoring for side effects and toxicities
• Encourage daily physical activity
• Encourage vitamin D and omega-3 fatty acid supplementation
• Inactivated vaccines are safe at any time
• Establish multidisciplinary treatment approach due to complexity of MS
Case Study: Tamara

- Patient history and exam:
  - Presents for annual physical exam
  - Reports she is engaged
  - Normal exam
  - No changes in medications
  - Continues to use indwelling pubic catheter
  - When prompted about any concerns or questions re sexual health or satisfaction, Tamara appears embarrassed and tearful
# Sexual Dysfunction and Multiple Sclerosis

<table>
<thead>
<tr>
<th>Type of Dysfunction</th>
<th>Women with MS, %</th>
<th>General Female Population, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any type</td>
<td>65.9-73.9</td>
<td>43.0-44.2</td>
</tr>
<tr>
<td>Lack of or decreased sexual desire</td>
<td>31.4-63.6</td>
<td>33.2-38.7</td>
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<tr>
<td>Impaired arousal and decreased lubrication</td>
<td>33.0-51.5</td>
<td>20.0-26.1</td>
</tr>
<tr>
<td>Anorgasmia</td>
<td>37.0-38.3</td>
<td>20.0-25.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sexual Problems Affecting Women with Multiple Sclerosis</th>
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</thead>
<tbody>
<tr>
<td>- Decrease in frequency of intercourse</td>
</tr>
<tr>
<td>- Hypoactive sexual desire disorders</td>
</tr>
<tr>
<td>- Arousal problems</td>
</tr>
<tr>
<td>- Sexual pain disorders</td>
</tr>
<tr>
<td>- Orgasmic problems</td>
</tr>
<tr>
<td>- Difficulties in sexual communication</td>
</tr>
<tr>
<td>- Decrease in sexual satisfaction</td>
</tr>
<tr>
<td>- Role changes in sexual activity</td>
</tr>
<tr>
<td>- Inability or limitations in intimate touching</td>
</tr>
<tr>
<td>- Limitations in sexual positions</td>
</tr>
<tr>
<td>- Need for adequate planning</td>
</tr>
</tbody>
</table>

Sexual Dysfunction and Multiple Sclerosis

**Primary SD**
- due to MS-related neurologic changes that impair sexual feelings or responses

**Secondary SD**
- due to limitations in sexual expression due to fatigue and physical limitations

**Tertiary SD**
- due to psychological, emotional, social, and cultural aspects of MS that can affect sexuality

Treatment Options for Primary Sexual Dysfunction

- Treat source for lack of desire (eg, depression, fatigue)
- Encourage women to initiate sex
- Recommend use of lubricants
- Prescribe systemic or local hormone therapy
- Focus on alternatives to intercourse as source of pleasure

What recommendations would you have for a patient experiencing sexual dysfunction?

A. abstain from sex  
B. lubricants, sex counseling, and plan sexual activity  
C. avoid use of sexual aids and cease antidepressant use

[Bar chart showing 33% for each option]
Treatment Options for Secondary Sexual Dysfunction

- Plan sexual activity when fatigue is less (eg, in morning)
- Get adequate rest and day sleep
- Identify position that demands least effort
- Take antispasticity medications 1 hour before
- More intense manual or oral stimulation
- Use of sexual aids
- Anticholinergic medications
- Empty bladder beforehand

Treatment Options for Tertiary Sexual Dysfunction

- Pharmacologic treatment for depression
- Psychological treatment
- Sex counseling with emphasis on pleasure-oriented outercourse rather than goal-oriented intercourse
- Improved communication with partner

Sexual Dysfunction and Multiple Sclerosis

Minority of patients discuss sexuality issues with healthcare providers due to:

- Embarrassment or shame feelings
- Low self-esteem
- Lack of time during visit
- Language barriers

Case Study: Tamara

Treatment recommendations:
• Reframe paradigm of sexual health
• Encourage use of diverse stimulation techniques
• Recommend use of genital lubricants
• Suggest taping urinary catheter and lubricating it to prevent it from interfering during sexual activity
• Schedule 3-month follow-up visit following wedding
• Following visit, discuss with urologist removal of catheter and use of intermittent self-catheterization
Case Study: Tamara

- Three-month follow-up:
  - Urologist removed indwelling pubic catheter prior to wedding
  - Tamara and husband changed sexual technique
  - Add bupropion to medications
  - Schedule 1-month follow-up visit
Points for Practice

• Screen patients with MS for sexual dysfunction with quick, easy-to-administer office-based questionnaires
• Review and provide education about behavioral, non-pharmacologic interventions to enhance sexual pleasure and satisfaction for women with MS
• Integrate a multidisciplinary approach to achieve optimal management of sexuality issues among female patients with MS
### Case Study: Tamara

#### Contraception Visit
- Visit to establish contraception plan
- Currently uses condoms during intercourse
- Wants method that is more reliable, relieves menstrual symptoms, and will not exacerbate MS

#### Menstrual History
- Menarche at age 12
- History of primary dysmenorrhea and heavy menses
- Symptoms of premenstrual syndrome began 2 years ago
Contraception and Multiple Sclerosis

• Results from 4 prospective epidemiologic studies do not support a protective effect of OCs on risk of MS
• There is some evidence OCs may delay onset of MS

Case Study: Tamara

- **Contraception options:**
  - Combined oral contraceptives
  - Intrauterine contraception
  - Progestin implant
  - Progestin injection

- **Patient choice:**
  - Tamara decides to use oral contraceptives due to:
    - Current menstrual symptoms
    - Desire to become pregnant within 2 years
    - Potential for possible favorable effect on MS
Points for Practice

• All contraceptive methods are acceptable for patients with MS
• No interactions between OCs and DMTs
• Numerous drug-drug interactions between OCs and medications for symptom management
• Conditions associated with MS may increase risk of venous thromboembolism
• Tailor contraceptive plan to each patient
How would you advise a patient who is planning to conceive?

A. discontinue interferon beta-1a
B. increase interferon beta-1a
Case Study: Tamara

- **Preconception planning visit:**
  - Visit to discuss desire to conceive
  - Review of medications
    - Instructed to discontinue interferon beta-1a 1 month before she begins to try to conceive
  - Discuss the effects of pregnancy on MS
  - Review issues related to breastfeeding
    - Need to defer resuming DMT until after completion of breastfeeding
Pregnancy and Multiple Sclerosis

- **3rd Trimester of Pregnancy**
  - Decrease in immunologic activity
  - Decrease in frequency of relapses

- **Delivery**
  - Increase in frequency of relapses

- **Breastfeeding**
  - Sex hormones rapidly return to baseline levels
  - May prevent relapses

Neonatal Outcomes in Multiple Sclerosis: Mean Birth Weight

<table>
<thead>
<tr>
<th>Factor</th>
<th>Mean Birth Weight, gm</th>
<th>Adjusted Difference, gm</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>• MS</td>
<td>3,426</td>
<td>-22 (-75 to 32)</td>
<td>0.43</td>
</tr>
<tr>
<td>• Non-MS</td>
<td>3,463</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age at MS onset, years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• &lt; 20</td>
<td>3,395</td>
<td>-66 (-153 to 21)</td>
<td>0.14</td>
</tr>
<tr>
<td>• 20 to &lt; 30</td>
<td>3,463</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 30 to 40</td>
<td>3,386</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MS duration, years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• &lt; 5</td>
<td>3,409</td>
<td>11 (-2 to 23)</td>
<td>0.09</td>
</tr>
<tr>
<td>• 5 to &lt; 10</td>
<td>3,427</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• ≥ 10</td>
<td>3,483</td>
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## Neonatal Outcomes in Multiple Sclerosis: Gestational age

<table>
<thead>
<tr>
<th>Factor</th>
<th>Mean Age, weeks</th>
<th>Adjusted Difference, weeks</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MS vs. Non-MS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• MS</td>
<td>38.85</td>
<td>0.00 (-0.18 to 0.18)</td>
<td>0.98</td>
</tr>
<tr>
<td>• Non-MS</td>
<td>38.86</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Age at MS onset, years</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• &lt; 20</td>
<td>38.49</td>
<td>0.22 (-0.04 to 0.48)</td>
<td>0.10</td>
</tr>
<tr>
<td>• 20 to &lt; 30</td>
<td>38.92</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 30 to 40</td>
<td>38.94</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>MS duration, years</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• &lt; 5</td>
<td>38.95</td>
<td>-0.01 (-0.05 to 0.02)</td>
<td>0.51</td>
</tr>
<tr>
<td>• 5 to &lt; 10</td>
<td>38.74</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• ≥ 10</td>
<td>38.88</td>
<td></td>
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Case Study: Tamara

• **Follow-up appointment:**
  - Delivers a healthy, term male infant
  - Reports symptoms of MS were significantly reduced during pregnancy and the early postpartum period
  - She decides to breastfeed
  - Chooses levonorgestrel IUS for contraception to be inserted after the fourth postpartum week
Points for Practice

- Patients should be relapse free for 1 year prior to attempting to conceive.
- DMT should be discontinued 1 month prior to initiation of attempts to conceive.
- All DMTs should be stopped in the event of an unplanned pregnancy.
- Epidural and spinal anesthesia are acceptable during labor.
- Breastfeeding should be encouraged and DMT withheld while breastfeeding.
Menopause and Multiple Sclerosis

- MS symptoms may increase at menopause
- Overlap in symptoms
  - Sexual dysfunction
  - Bladder function
  - Mood disorders

Case Study: Tamara

**Well woman appointment:**
- One year later, Tamara reports that her mother is menopausal
- Tamara asks what she can expect when she enters menopause
Points for Practice

• Ensure effective DMT
• Check medications are taken as directed
• Ensure continued vitamin D supplementation
• Encourage regular exercise
Additional Resources
Additional Resources