Provider and Support Statements

This educational activity is jointly provided by The National Association of Nurse Practitioners in Women’s Health (NPWH) and Spire Learning.

This CE activity is supported by educational grants from the following companies: Merck & Co., Inc; Radius Health, Inc; SymbiomeX Therapeutics, LLC; and Valeant Pharmaceuticals North America LLC.

The lunch workshop is not approved for CE credits and is supported by a grant from Myriad Genetic Laboratories, Inc.

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## CE Faculty Disclosures

**Brooke M. Faught, MSN, WHNP-BC, IF**
- Consulting fees (eg Advisory Boards) – AMAG Pharmaceuticals Inc.; Symbiomix Therapeutics, LLC; Valeant Pharmaceuticals North America LLC
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**Suzanne L. Reiter, MSN, MM, WHNP-BC, FAANP**
- Suzanne L. Reiter has indicated that she has no disclosures to be made.

**Lisa D. Wright, DNP, ANP-C, CPHQ**
- Former Employee: Merck

## Agenda

<table>
<thead>
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<td>Current Management Strategies and Updates in Diagnosis and Treatment for Bacterial Vaginosis</td>
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<td>11:30 AM – 12:45 PM</td>
<td>Non-CE Lunch Workshop: Precision Medicine in Women’s Health Care: Identifying Patients at Risk for Hereditary Cancer</td>
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<td>12:45 PM – 1:40 PM</td>
<td>Updates in the Management of Postmenopausal Osteoporosis</td>
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<td>1:40 PM – 2:10 PM</td>
<td>Postmenopausal Osteoporosis Small-group Case Discussions and Audience Regroup Discussions</td>
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<td>2:10 PM – 3:05 PM</td>
<td>Updates in the Diagnosis and Management of HSDD</td>
</tr>
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<td>3:05 PM – 4:00 PM</td>
<td>Break</td>
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</tr>
<tr>
<td></td>
<td>- Case 1: Sarah</td>
</tr>
<tr>
<td></td>
<td>- Case 2: Mackenzie</td>
</tr>
<tr>
<td>3:35 PM - 4:00PM</td>
<td>Final Q&amp;A and Concluding Remarks</td>
</tr>
</tbody>
</table>

## Levels of Evidence

The following levels of evidence are provided for any patient care recommendations made in the presentations.

**Strength of Recommendation**

- **Level A**: supported by sufficient, consistent scientific evidence (e.g., multiple, randomized clinical trials or meta-analyses)
- **Level B**: supported by limited or inconsistent evidence (e.g., non-randomized trials or single randomized trial)
- **Level C**: based primarily on expert opinion

## Instructions for Receiving Credit

Successful completion of this activity requires the participant to:

1. Read the learning objectives, disclosures, and disclaimers
2. Complete the pre- and postassessment during each session
3. Actively participate in the activity
4. Complete the ONLINE evaluation at the conclusion of the activity and receive your CE certificate
Polling Questions - Instructions

- Audience participation is encouraged!
- Open a new text message
- Text 22333 (Poll Everywhere voting)
- In the body of the message, type keyword WH1118
- You will get a confirmation message that you are in the session
- Answer Polling Questions as they are presented

- Take out your cell phones, but please keep them on silent or vibrate.
- Standard text messaging rates apply
- Your phone number is completely private and you will not receive any follow up text messages outside of today

Would you rather be able to fly or read minds?

A

B

Start the presentation to activate live content

If you do not receive a pre-text message, text 22333 to opt-out.

Contraception – No More Excuses!!

Suzanne L. Reiter, MSN, MM, WHNP-BC, FAANP
Women’s Health Nurse Practitioner
Mid-County Health Center
Largo, FL
CE Faculty Disclosures

Suzanne L. Reiter, MSN, MM, WHNP-BC, FAANP

• Suzanne L. Reiter has indicated that she has no disclosures to be made.

Preassessment Question #1
Which of the following management strategies would be appropriate for Amy, a 25-year-old using injectable depot medroxyprogesterone acetate (DMPA), who is experiencing prolonged, heavy bleeding after two months of use despite nonsteroidal anti-inflammatory (NSAID) treatment? Amy is very frustrated and wants the bleeding to stop.

A. No treatment is indicated. Give her the next injection two weeks early
B. Continue with current NSAID for an additional 5-7 days
C. Switch NSAID and treat for an additional 5-7 days
D. Order a 10 to 20-day course of a combination oral contraceptive (COC)

Preassessment Question #2
Which of the following statements is true regarding hormonal contraception and weight gain?

A. DMPA use is often associated with weight gain
B. COC use is consistently associated with weight gain
C. Vaginal rings cause more weight gain than COCs
D. Extended-cycle COCs cause more weight gain than standard regimens
Learning Objectives

Contraception – No More Excuses!!
NCC Code 1 (CE 1.3 Rx 0.4)

• Describe the U.S. Medical Eligibility Criteria for Contraceptive Use, 2016 (US MEC)
• Identify barriers and develop strategies for consistent and effective contraceptive use
• Discuss the guidance in specific situations, based on clinical scenarios

Love, Sex, and Consequences!

Unintended Pregnancy in the US

• Approximately 45% are unintended
• Higher rates
  • Adolescents
  • Women with lower levels of education and income
  • Women who are racial/ethnic minorities

US government healthcare expenditures – $21 billion
2015 National Youth Risk Behavior Survey – High School Students

- 41% Ever had sexual intercourse
- 43% Did not use a condom during last coitus
- 73% Did not use birth control pills, IUD, implant, shot, patch, or ring during last sexual encounter
- 24% Drank alcohol or used drugs before last sexual intercourse


Effectiveness of Family Planning Methods per 100 Women per Year

- Less than 1 pregnancy: Implant, IUD/IUS, and male and female sterilization
- 6 to 12 pregnancies per year: Injectable, pill, patch, ring, diaphragm
- 18 or more pregnancies: Male or female condom, withdrawal, sponge
- 24-28 pregnancies per year: Fertility-awareness based methods, spermicides

Questions to Ponder

Why do you think women risk an unintended pregnancy?

Why do you think men risk an unintended pregnancy?
I Won’t Use Birth Control Because...

- I’m not going to have sex anymore
- Pills make me sick
- I don’t think I can get pregnant
- I don’t want to gain weight
- My boyfriend wants me to get pregnant
- My partner can feel the IUD strings and wants it out
- I’m not having any pelvic exam!
- I don’t want to get pregnant

Conditions Associated With Increased Risk for Adverse Health Events as a Result of Unintended Pregnancy

- Breast cancer
- Complicated valvular heart disease
- Diabetes: insulin dependent; with nephropathy, retinopathy, neuropathy or other vascular disease; or >20 years duration
- Endometrial or ovarian cancer
- Epilepsy
- Hypertension: systolic >160 mm Hg or diastolic >100 mm Hg
- History of bariatric surgery within past 2 years
- HIV/AIDS
- Ischemic heart disease
- Malignant liver tumors (hepatocellular carcinoma of the liver, peripartum cardiomyopathy, Schistosomiasis with fibrosis of the liver, Severe (decompensated) cirrhosis
- Sickle cell disease
- Solid organ transplantation within the past 2 years
- Stroke
- Systemic lupus erythematosus
- Thrombogenic mutations
- Tuberculosis

Contraception???

- Combined oral contraceptives (COCs)
- Progestin-only contraceptive pills (POPs)
- Transdermal patch
- Vaginal ring
- Depomedroxyprogesterone acetate (DMPA) injections
- Subdermal implant
- Intrauterine contraceptives (IUCs)

or Condoms???
Increased Use of LARC Has the Potential to Lower Unintended Pregnancy Rates

LARC Facts

- 11.6% of women using LARCs
- 10.3% IUD
- 1.3% implant
ACOG Recommendations

- LARC methods should be offered as first-line contraceptive methods and encouraged as options for most women
- LARC methods have few contraindications
- Almost all women are eligible for the implant and IUDs – nullips TOO!

ACOG, American College of Obstetricians and Gynecologists.

Contraception Continuation Rates

- LARC methods, overall at 1 year – 86%
- Short-acting methods, overall at 1 year – 55%
  - Ages 15-24 years
  - Patch – 11%
  - DMPA – 16%
  - Ring and OCs – 30%
  - 22% higher pregnancy rate than those using LARCs


Safety: Medical Eligibility Criteria for Contraceptive Use

<table>
<thead>
<tr>
<th>Condition</th>
<th>Qualifier for Condition</th>
<th>LNG/IUS</th>
<th>Copper T IUD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes mellitus (DM)</td>
<td>Gestational DM in past</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>DM without vascular disease</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>DM with end-organ damage or &gt;20 years’ duration</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Endometriosis</td>
<td></td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Obesity</td>
<td>BMI ≥30 kg/m²</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Uterine fibroids</td>
<td>IUCs ok unless fibroids block insertion</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>

BMI, body mass index.
ACOG, American College of Obstetricians and Gynecologists.

MMWR. 2010;59(RR04):52-63.

### Safety: Medical Eligibility Criteria for Contraceptive Use (cont’d)

<table>
<thead>
<tr>
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<th>Qualifier for Condition</th>
<th>LNG/IUS</th>
<th>Copper T IUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postpartum, not breastfeeding</td>
<td>≥3 weeks postpartum</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Postpartum IUDs (breastfeeding or not breastfeeding)</td>
<td>≥16 minutes post-placenta delivery</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>≥4 weeks</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Postpartum &amp; breastfeeding</td>
<td>≥1 month postpartum</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Post-abortion</td>
<td>First trimester</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Second trimester</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

### HIV infection

<table>
<thead>
<tr>
<th>Qualifier for Condition</th>
<th>LNG/IUS</th>
<th>Copper T IUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>High risk or HIV+</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>AIDS (without drug interactions)</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

### Pelvic Inflammatory Disease

<table>
<thead>
<tr>
<th>Qualifier for Condition</th>
<th>LNG/IUS</th>
<th>Copper T IUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Past, with subsequent pregnancy</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Past, without subsequent pregnancy</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Current</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

### Sexually Transmitted Infection (STI)

<table>
<thead>
<tr>
<th>Qualifier for Condition</th>
<th>LNG/IUS</th>
<th>Copper T IUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaginitis/increased risk of STI</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Very high risk of STI</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Current GC/Chlamydia/ purulent cervicitis</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

### Comparing the Fabulous 5 IUCs

- **Copper T 380A** – 36 mm X 32 mm (10 years)
- **Four T-shaped LNG-IUSs**
  - Two with 52 mg of LNG; measure 32 mm X 32 mm
  - 19.5 mg of LNG – 30 mm X 28 mm (5 years)
  - 13.5 mg of LNG – 30 mm X 28 mm (3 years)
Copper T 380A

- Only nonhormonal IUD
- Bound with Cu ions
- Approved for up to 10-12 years of use
- 99% effective as emergency contraception when inserted up to 5 days after unprotected intercourse

Levonorgestrel-Releasing IUDs

- LNG 52 mg IUS
  - 20 mcg/day (2000)
  - Approved for up to 5-7 years

- LNG 13.5 mg IUS
  - 14 mcg/day (2013)
  - Approved for up to 3 years

Levonorgestrel-Releasing IUDs (cont'd)

- LNG 20 mg IUS
  - 18.6 mcg/day (2015)
  - Approved for up to 4 years

- LNG 19.5 mg IUS
  - 17.5 mcg/day (2016)
  - Approved for up to 5 years
**How Do IUCs Prevent Pregnancy?**

<table>
<thead>
<tr>
<th>Copper Device</th>
<th>LNG-containing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>• Prevents fertilization</strong></td>
<td><strong>• Prevents fertilization</strong></td>
</tr>
<tr>
<td><strong>• Reduces motility and viability of sperm</strong></td>
<td><strong>• Thickens cervical mucus</strong></td>
</tr>
<tr>
<td><strong>• Inhibits ova development</strong></td>
<td><strong>• Inhibits sperm motility</strong></td>
</tr>
<tr>
<td><strong>• Inhibits fertilization</strong></td>
<td><strong>• Inhibits sperm function</strong></td>
</tr>
</tbody>
</table>

**Strings/Threads – It Used to Be Simple!**

- **Copper T 380A – White**
- **LNG 52 mg (5 year) – Black**
- **LNG 52 mg (4 year) – Blue**
- **LNG 13.5 mg (3 year) – Brown**
- **LNG 19.5 mg (5 year) – Blue**

We hope the client knows!

**Which IUD Is Right for Me?**

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<th>Copper Device</th>
<th>LNG-IUS</th>
</tr>
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<tbody>
<tr>
<td><strong>• Doesn’t want or can’t use hormonal contraception</strong></td>
<td><strong>• Wants less menstrual flow</strong></td>
</tr>
<tr>
<td><strong>• Likes having regular menses</strong></td>
<td><strong>• History of dysmenorrhea</strong></td>
</tr>
<tr>
<td><strong>• Ok with possible amenorrhea</strong></td>
<td><strong>• Ok with possible amenorrhea</strong></td>
</tr>
</tbody>
</table>
Courtney

- 17-year-old client – history of 1 pregnancy, termination 2 months ago
- LNG-IUS inserted post-termination elsewhere; no spotting or bleeding since insertion
- New partner last week; She reports, “He felt something during sex yesterday.”
- Exam reveals LNG-IUS lying in vault – removed
- When asked about symptoms of expulsion/sexual activity: “Well, maybe he pulled the strings a bit.”

Case Study Polling – Courtney

Courtney wants another IUC. Would you insert it today?
A. Yes
B. No
Courtney Says…

• “He is my new boyfriend – planning to have sex again.”
• “He didn’t use a condom. Why should he? I had an IUD!”
• “I don’t know if I’ve ever had an STD test.”
• “My parents would be really mad if I got pregnant again.”

What’s the plan?
1. Offer EC
2. Quick start OC, DMPA, or ring
3. Counseling/reinsert IUC
4. Implant counseling
5. STI testing
6. Pregnancy test

EC, emergency contraception; STD, sexually transmitted disease.

Courtney’s Victory

• She decided on EC, quick start DMPA, backup 7 days
• Home pregnancy test in 2 weeks. She called and reported, “Not pregnant!”
• New IUC inserted during next DMPA window
• She is doing fine!
• Partner education!!!!!!! WHEN POSSIBLE

The Single-Rod Contraceptive Implant

Mechanism of Action: Suppression of Ovulation
Insertion Timing

- Any time during the menstrual cycle
- Can reasonably exclude pregnancy
- Backup method for 7 days unless inserted:
  - Within 5 days of menses
  - Immediately postpartum or post-abortion
  - Immediately upon switching from another hormonal method

Kenisha

- Kenisha is 23 years of age G0P0 currently on a combination OC containing 20 mcg EE and 0.1 mg LNG for birth control. This is her first visit to you. She is happy with her method
- She reports a history of epilepsy and is taking lamotrigine but her provider is going to switch her anticonvulsant therapy to carbamazepine

Case Study Polling – Kenisha

What would you do?
A. Continue current OC regimen
B. Change to an implant
C. Change to an IUC
D. Up the EE dose to 35 mcg
Kenisha (cont'd)

- COC use can affect the metabolism of lamotrigine and carbamazepine, reducing the concentration and potentially causing seizure activity
  - Lamotrigine
    - Category 1
    - All LARCs, injection, progestin-only OCs
  - Carbamazepine
    - Category 1
    - Injections, IUCs
    - Implant is Category 2

Tabetha

- Wants an implant because she forgets her pills and thinks she has gained weight due to her method
- 60 inches tall, weighs 205 lb, has 2 FWBs
**Implants and Weight**

The efficacy of the single-rod implant in women who weighed more than 130% of their ideal body weight has not been defined because such women were not studied in clinical trials.
More Recent News Concerning Weight

- Study group of 52 women
  - 10 normal weight
  - 19 overweight
  - 23 obese
- Relationship between ENG level and BMI in women using the contraceptive implant for more than 1 year
- Comparable ENG levels across a wide BMI range
- ENG levels are independent of BMI through 3 years of implant use

ENG, etonogestrel.

What Women Don’t Want!

- Unscheduled bleeding
- Weight gain
Addressing a Big One – Weight Gain

- **Fact:** Many women slowly gain weight as they age, whether they use hormonal contraception (HC) or not
- **Suspicion** that HC causes weight increase is based on theory
  - Fluid retention
  - Increase in appetite

**Client perception is everything**

---

Data on Weight Gain for 3 Methods

- **Subdermal implant**
  - 13.7% reported weight gain as an adverse effect
  - 2.3% reported weight gain was the reason they had it removed
- **DMPA**
  - ↑ 4.4 kg in 2 years and 5.1 kg in 3 years
  - Key point – if no weight gain in first year, good indication no ↑ in subsequent years
- **COCs**
  - No differences in weight between women using or not using COC


---

Pill Pearls! What About Potency?

- Each progestin has a different potency, mg for mg, in terms of progesterone effect to stop menstrual bleeding or androgen effect to stimulate acne and hair growth
- The higher potency progestin may be used in a much smaller mg dose and may be equivalent to a larger mg dose of a least potent progestin

*For example, desogestrel is a very potent and androgenic progestin, but its usual OCP dose is 0.15 mg versus 1.0 mg for norethindrone.*
### Progestin Potency of Different OC Progestins

<table>
<thead>
<tr>
<th>Progestin</th>
<th>Progestinal Activity</th>
<th>Androgenic Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norethindrone</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Norethindrone acetate</td>
<td>1.2</td>
<td>1.6</td>
</tr>
<tr>
<td>Ethynodiol diacetate</td>
<td>1.4</td>
<td>0.6</td>
</tr>
<tr>
<td>Levonorgestrel</td>
<td>5.3</td>
<td>8.5</td>
</tr>
<tr>
<td>Norgestimate</td>
<td>1.3</td>
<td>1.9</td>
</tr>
<tr>
<td>Desogestrel</td>
<td>9.0</td>
<td>3.4</td>
</tr>
<tr>
<td>Drospirenone</td>
<td>1.5</td>
<td>0.0</td>
</tr>
</tbody>
</table>


### Which COC to Select?

- **Acne** – higher estrogen, lower androgen potency
- **Depression, moodiness** – lower progestin potency
- **Headaches** (not menstrual migraines) – lower estrogen and lower progestin potency
- **Breast soreness** – lower estrogen, lower progestin potency
- **Severe menstrual cramps** – higher progestin potency
- **PCOS** – higher estrogen/progestin ratio


### Polling Question – Dispelling Myths

Do these women need a backup method while on antibiotics?

- Victoria is taking minocycline for acne control – comes in for OC start
  - A. Yes
  - B. No
Polling Question – Dispelling Myths

Do these women need a backup method while on antibiotics?
- Mindy comes in for treatment of CT and GC – the standard regimen is prescribed
  A. Yes
  B. No
Polling Question – Dispelling Myths

Do these women need a backup method while on antibiotics?

• Rosa is in for her annual and reports her primary care provider is treating her for a UTI with ciprofloxacin

A. Yes
B. No

In for her annual and reports her primary care provider is treating UTI with ciprofloxacin

Most Antimicrobials DO NOT Decrease COC Efficacy

• Tetracyclines
• Penicillins
• Cephalosporins
• Metronidazole
• Fluconazole
• Miconazole
• Quinolones

Anticonvulsants and Other Drugs That Decrease Serum Levels of COCs

- Carbamazepine (Tegretol)
- Oxcarbazepine
- Topiramate
- Phenytoin (Dilantin)
- Phenobarbital
- Primidone (Mysoline)
- Rifabutin or rifampin therapy
- St. John’s Wort (CHC Category 2)

CHC, combined hormonal contraceptive

NO!

- It is true that lower serum EE and progestin levels are found in women using OCs and antibiotics. These women remain well within the therapeutic window.
- US MEC classifies antimicrobial therapy as Category 1 (with the exception of rifampin)

Ring Pearls

- Ovulation suppression – 35 days
- Only 6% of women have BTB in first cycle of use
- Better bleeding profile than COCs
- Okay to use vaginal yeast creams

BTB, breakthrough bleeding.
Progestin-Only Oral Contraceptives

- Called the “mini-pill”
- Two formulations: norethindrone & norgestrel
- Backup needed for 2 days after starting unless <5 days since LMP started
- Category 1 – immediately postpartum
- 3-hour window!!!! Use OC app for reminder!
- Very effective

LMP, last menstrual period.

Emergency Contraception

- Overall expected risk of pregnancy after unprotected intercourse without EC treatment is 5.6%
- Obese women who took LNG; 1 analysis was 5.8%
- Observed risk of pregnancy among obese women taking UPA was 2.6% and 3.1% in 2 analyses – less than risk without an EC

UPA, ulipristal acetate.

EC Methods – How They Work

- 1.5 mg LNG or 30 mg UPA acts through inhibition of or postponing ovulation but does not prevent fertilization or implantation and has no adverse effects on pregnancy
- Window of action of UPA is wider since it may also prevent ovulation after LH has started to rise.
- Further acts of unprotected coitus need to be avoided to prevent the risk of delayed follicular rupture and ovulation

LH, luteinizing hormone.
EC Methods – Which Is Better?

- **EC LNG**
  - Prevents around 50% of expected pregnancies in women using within 72 hours of intercourse

- **EC UPA**
  - Prevents two-thirds of expected pregnancies
  - Better in obese women


US SPR Recommendations: When to Start Regular Contraception After ECPs

- **LNG or COCs**
  - Start regular method immediately
  - Abstain from intercourse or use backup 7 days

- **UPA ECPs**
  - Resume or start method no sooner than 5 days after UPA (possible decreased effectiveness of UPA if hormonal method started sooner)
  - Nonhormonal may be started immediately
  - Abstain from intercourse or use backup for 7 days


ECs: emergency contraception pills.

The Ideal Text!!!

Thank You!

“No woman can call herself free who does not own and control her body. No woman can call herself free until she can choose consciously whether she will or will not be a mother.”

— Margaret Sanger

References


References

References


Helpful Resources

- National Clinical Training Center for Family Planning: www.ctcfp.org
- US MEC Guidelines: www.cdc.gov/mmwr
- LARC Practice Resources: www.acog.org/goto/larc
- App Store (iPhone/Pod/Pad): US MEC Guidelines

CONTRACEPTION BREAKOUT
CASE 1
Juniper
Juniper

- 17-year-old client – history of 1 pregnancy, termination 2 months ago
- LNG-IUS inserted post-termination elsewhere – no spotting or bleeding since insertion

She can’t feel the strings – Oh no!

Small Group Discussion

Based on Juniper’s history, what is the management plan?

CONTRACEPTION BREAKOUT CASE 1
Juniper
Case Discussion Regroup
Next Steps

- Pregnancy test – whew – negative!
- When was last sexual exposure? Emergency contraception?

Exam today:
- No strings visible – unable to retrieve with cytobrush into endocervical canal

Thinking...

- Copper T 380A easy to visualize on ultrasound due to copper
- LNG-IUD more difficult. Often easiest to see shadowing and then follow to the IUD itself
- 3D ultrasound is very helpful for visualizing LNG-IUD if position is unclear
- IUD can be seen on X-ray flat plate but can’t be sure if intrauterine

Nonvisualized Strings – Perforated or Expelled?

- Can’t visualize after sweeping cervical canal with cytobrush
- Rule out pregnancy; offer EC, if indicated; backup method until IUC confirmed in uterus
- Pelvic ultrasound
- If visualized in uterus – no further workup needed
- If not, obtain X-ray of abdomen and pelvis
Risk of Uterine Perforation

- Rare: 1 per 1000 insertions
- Perforation linked to:
  - Uterine position and consistency
  - Skill and experience of provider with technique required
  - Time of insertion after childbirth
  - Risk doubled within first 12 weeks postpartum
- Perforations reduced through directed training and observation

Management of Perforation

If perforation occurs at insertion:
- Remove device
- Provide alternative contraception
- Monitor for excessive bleeding
- Follow-up as appropriate
- Can insert another device after next menses

IF IUD NOT IN UTERUS – REFER FOR LAPAROSCOPIC REMOVAL

Expulsions

- Partial or unnoticed expulsion may present as irregular bleeding and/or pregnancy
- IUD expulsion occurs in 2%-10% of users and varies by IUC type
- Risk of expulsion related to:
  - Provider’s skill at fundal placement
  - Risk factors: age <20 years, heavy menstrual bleeding, dysmenorrhea
  - Anatomic distortion of uterine cavity (eg, large submucosal leiomyoma)
Juniper’s Results

- IUC is in situ
- Counsel client – is she okay with results or does she want removal and replacement due to feeling anxious or unsure?
- Provide client with ultrasound report for reassurance
- If she wants it removed, may try removal with alligator forceps/London forceps – if not successful, refer

CONTRACEPTION BREAKOUT CASE 2
Summer

- 17 years old
- Mother brought her in – found out she is having sex – looked at her cell phone text messages
- Never been pregnant
- LMP started 3 days ago
- Methods reviewed
- Decided on implant
- Inserted today
The Phone Call

• Calls 10 weeks later – has been bleeding/spotting every day and “I am sick of it – I want this out.”
• Also reports her acne is worse and her new boyfriend won’t have sex with her anymore

Small Group Discussion

Next steps?
Bring her in?
Differential diagnoses?
Management?

CONTRACEPTION BREAKOUT

CASE 2

Summer
Case Discussion Regroup
Bleeding With Implant Use

Data from 11 clinical trials showed implants cause relatively little bleeding:

- 22% experienced amenorrhea
- 34% experienced infrequent spotting
- 7% experienced frequent bleeding
- 18% experienced prolonged bleeding

Management of Women With Bleeding Irregularities While Using Contraception

Options?

- Nonsteroidal anti-inflammatory drugs (NSAIDs) for short-term treatment
- Low dose COCs or estrogen for short-term treatment (10-20 days)
- Alternate method
Potential Causes of BTB

- Smoking
- Chlamydia
- For other methods – mistimed pill use/forgotten pill


Summer's Victory

- Prescribed 20 mcg EE combination OC – continuous use for 21 days
- CT test positive – treatment given
- Her bleeding/spotting stopped after 2 months after treatment
- What about the acne? 12% report
  - Dermatology referral, and if still problematic – remove!


Teen's Victory

- Friends Are Very Influential!

ASK! What are you thinking about? Are you worried about anything?

EMPHASIZE THE FUTURE!

BE SUPER POSITIVE – "I KNOW YOU ARE SMART AND YOU CAN DO THIS!"

THANK YOU FOR COMING IN! Great meeting you and thank you for allowing me to be your healthcare provider!"
Postassessment Question #1
Which of the following management strategies would be appropriate for Amy, a 25-year-old using injectable depot medroxyprogesterone acetate (DMPA), who is experiencing prolonged, heavy bleeding after two months of use despite nonsteroidal anti-inflammatory (NSAID) treatment? Amy is very frustrated and wants the bleeding to stop.

A. No treatment is indicated. Give her the next injection two weeks early
B. Continue with current NSAID for an additional 5-7 days
C. Switch NSAID and treat for an additional 5-7 days
D. Order a 10 to 20-day course of a combination oral contraceptive (COC)

Postassessment Question #2
Which of the following statements are true regarding hormonal contraception and weight gain?

A. DMPA use is often associated with weight gain.
B. COC use is consistently associated weight gain.
C. Vaginal rings cause more weight gain than COCs.
D. Extended-cycle COCs cause more weight gain than standard regimens.
Postassessment Question #2

Which of the following statements are true regarding hormonal contraception and weight gain?

A. DMBA use is often associated with weight gain.
B. COC use is consistently associated weight gain.
C. Vaginal rings cause more weight gain than COCs.
D. Extended-cycle COCs cause more weight gain than standard regimens.

Current Management Strategies and Updates in Diagnosis and Treatment for Bacterial Vaginosis

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Brooke M. Faught, MSN, WHNP-BC, IF
• Consulting fees (eg Advisory Boards) – AMAG Pharmaceuticals Inc.; Symbionix Therapeutics, LLC; Valeant Pharmaceuticals North America LLC
• Fees received for promotional services, regardless of their source (eg, speakers bureau non-CE presentation) – AMAG Pharmaceuticals Inc.; Shionogi Inc./Duchesnay Inc.; Valeant Pharmaceuticals North America LLC
Preassessment Question #1

Which of the following symptom profiles is most consistent with bacterial vaginosis (BV)?

A. Occasional vaginal discharge, no itching or burning, pH 4.5, presence of lactobacilli on wet prep
B. White vaginal discharge, vaginal itching, pH 4.5, presence of lactobacilli and possible hyphae on wet prep
C. Gray vaginal discharge, pH > 5.0, presence of mobile organisms with flagella on wet prep
D. Gray vaginal discharge, fishy vaginal odor, pH > 5.0, presence of clue cells but no lactobacilli on wet prep

Preassessment Question #2

Which of the following is a true statement regarding recurrent BV?

A. Use of oral contraceptives reduces the risk of recurrence
B. Pathogen-containing vaginal biofilm increases risk of recurrence
C. The presence of Gardnerella in vaginal culture is sufficient for diagnosis
D. Douching is recommended to reestablish normal vaginal flora

Learning Objectives

Current Management Strategies and Updates in Diagnosis and Treatment for Bacterial Vaginosis

NCC Code 2A (CE 1.3 Rx 1)

- Identify criteria for diagnosing BV in clinical practice
- Evaluate current clinical data for new and emerging therapies for the management of BV and recurrent BV
- Implement updated treatment and educational strategies for women presenting with recurrent BV
Bacterial Vaginosis (BV)
Overgrowth of bacteria normally present in the vagina
• Polymicrobial condition
• Disturbance of normal vaginal ecosystem
• High concentration of anaerobic bacteria

Implications
• Moderate to severe impact of BV on women\(^1,2\)
  • Nearly all (>95%) women report negative impact on sex life
  • Women report feeling self-conscious, embarrassed, and overall uncomfortable in social situations – impacts QOL
• BV associated with\(^3-10\)
  • Preterm birth, pregnancy loss
  • Intrauterine infections
  • Postpartum, post-abortion endometritis
• PID, STIs

Co-Infections
• STIs
  • Absence of lactobacilli and/or presence of BV associated with increased incidence of gonorrhea, chlamydia, trichomoniasis, syphilis, HPV, HIV, HSV, candidiasis, PID\(^1,6\)
• HIV
  • Increased incidence of BV in women with HIV
  • Increased transmission of HIV to women with BV
  • Increased risk of female-to-male HIV-1 transmission in women with BV\(^4\)
  • Increased viral shedding of HIV-1 in women with BVAB\(^1-3,5\)

BVD, BV-associated bacteria; HIV, human immunodeficiency virus; HPV, human papilloma virus; HSV, herpes simplex virus.
Prevalence

- Most prevalent symptomatic vaginal infection\(^1\)
- 10 million office visits for vaginitis annually in US\(^2\)
- Affects ~30% of American women of reproductive age\(^3\)
  - Increased risk positively associated with:
    - Race/ethnicity\(^4\)
    - Non-Hispanic blacks (51%) > Mexican Americans (32%) > non-Hispanic whites (23%)
    - Number of sexual partners during the course of lifetime\(^5,6\)
    - Douching
    - Low educational level
- Negative association with current OCP use
- Majority of women do not report their symptoms

OCP: oral contraceptive pill.


Risk Factors

- Smoking, low social economic status, poor diet\(^1\)
- Douching, previous history of BV, hypoestrogenic state, AUB, antibiotic usage, obesity\(^2,3\)
- New partner, female partner, multiple partners, young ages at first coitus, uncircumcised male partner\(^4\)

AUB: abnormal uterine bleeding.


Bothersome Symptoms

- Many women are asymptomatic
- Common
  - Thin, gray, homogenous discharge, adheres to vaginal wall
  - “Fishy” malodor
- Less common
  - Vulvovaginal irritation, itching & burning, dysuria, dyspareunia

CDC. MMWR Recomm Rep. 2015;64(RR-03):1-137.
Polling Question

Which symptom profile is most consistent with bacterial vaginosis?

A. Mary: vaginal itching, pH 4.5, white vaginal discharge
B. Mattie: fishy vaginal odor, gray vaginal discharge, pH >5.0
C. Lin: occasional vaginal discharge, no itching or burning, pH 4.5, + lactobacilli on wet prep
D. Robin: pH >5.0, mobile organisms with flagella on wet prep, gray vaginal discharge
E. Dalisha: pH >5.0, vaginal burning, + parabasal cells on wet prep

Healthy Vaginal Ecosystem

- Vaginal pH 3.8-4.2
- Lactobacilli species dominant bacteria
  - Produce H₂O₂ and lactic acid
  - Maintains low pH
  - Thought to be protective against HIV and other STIs
Differential Diagnosis

- Vulvovaginal candidiasis (VVC)
- Trichomoniasis
- Ureaplasma/mycoplasma
- Genitourinary syndrome of menopause (GSM)/atrophic vaginitis
- Desquamative Inflammatory vaginitis (DIV)
- HSV/HPV
- Cervicitis
- Vulvar dermatologic conditions
  - Lichen planus/erosive lichen planus
  - Lichen sclerosus
  - Contact dermatitis
  - Vulvodynia/vulvar vestibulitis syndrome (VVS)
  - Vulvar carcinoma

Patient Assumptions of Vaginal Symptoms

- Assume symptoms related to yeast, despite higher prevalence of BV
- Self-treat with inappropriate meds
- Assume symptoms normal
- Unaware that BV may be asymptomatic


Wet Prep

- Obtain sample from internal 2/3 of vagina
  - Lateral wall and/or anterior fornix
- Prepare slide with sample and 1-2 drops of saline
- Apply cover slip
- Examine at both low and high power

Lactobacilli spp.
Amsel’s Criteria

- Must meet 3 of 4 criteria\(^2\)
  - Homogenous thin, grey/white discharge
  - Positive whiff test with 10% KOH
  - High vaginal pH, >4.5
  - ID of clue cells on microscopy

- Gram staining – Nugent Criteria (not common in clinical practice)\(^3\)
  - Score ranges from 0-10
  - BV is score of 7-10

- Molecular tests\(^4-6\)
  - BVBlue, BD Affirm, NuSwab, GenProbe, OneSwab, SureSwab
  - Costly, but increased sensitivity

KOH, potassium hydroxide; ID, identification.

Abnormal Wet Prep (BV)

Absence of lactobacilli
- Overgrowth of anaerobic bacteria, Gram-positive cocci

Presence of clue cells
- Edges of epithelial cells obscured

Cara

- 21-year-old G0P0, OCPs x 2 years
- Presents with symptoms of vaginal itching and burning and white vaginal discharge
- Exam: Vulvar erythema and edema, visible, thick, white discharge at introitus, fissures to interlabial sulci
- Vaginal pH 3.5
- Wet prep: no clue cells, possible hyphae, + lactobacilli

Case Study Polling – Cara

Cara likely has bacterial vaginosis.
A. True
B. False
Vaginal pH
- BVAB-2 (+) – absence of Lactobacilli crispatus associated with rise in vaginal pH

Self-Collection of Vaginal pH
- Patient self-collection and interpretation of vaginal pH differs from provider’s interpretation
  - Self-collected swabs interpreted as lower (4.5) than provider swabs (4.7)
  - Statistically significant difference, although not clinically meaningful
  - Supports self-collection of pH before in-office consult
  - Higher pH warrants in-office consult with healthcare provider


Screening in Pregnancy
- ACOG, USPSTF, and CDC guidelines
  - Routine screening of asymptomatic pregnant women not recommended
  - Treat if symptomatic and + diagnostic criteria

Single Episode BV

- Metronidazole 500 mg PO BID x 7 days*
  OR
- Metronidazole gel 0.75%, 1 applicator (5 g) PV QD x 5 days*
  OR
- Clindamycin cream 2%, 1 applicator (5 g) PV QHS x 7 days

*Avoid alcoholic beverages.

CDC. MMWR Recomm Rep. 2015;64(RR-03):1-137.

Alternative Treatments for BV

- Tinidazole 2 g PO QD x 2 days
  OR
- Tinidazole 1 g PO QD x 5 days
  OR
- Clindamycin 300 mg PO BID x 7 days
  OR
- Clindamycin ovules 100 mg intravaginally once at bedtime for 3 days*

*Latex condoms may be compromised within 72 hours after using clindamycin ovules.

CDC. MMWR Recomm Rep. 2015;64(RR-03):1-137.

Secnidazole

- Approved by FDA Sept 2017
- Single dose
- Granule formulation
- Mixed with soft food such as yogurt, pudding, or applesauce
- No boxed warning, no alcohol warning
- CDC guidelines not yet updated to reflect this product

**BV Treatment During Pregnancy and Breastfeeding**

- Screening in asymptomatic pregnant women not recommended
- Treat symptomatic pregnant women
  - BV associated with preterm birth and LBW babies
  - Avoid tinidazole
  - Oral and vaginal metronidazole and clindamycin appropriate
- Breastfeeding
  - No adverse effects on infants
  - Defer breastfeeding 12-24 hours after treatment


**Recurrent BV**

- High recurrence rates of BV after treatment with first-line therapies
  - >50% recurrence rates at 1 year
- Factors associated with recurrence of BV
  - Past history of BV
  - Regular sex partner
  - Female sex partner
  - Abnormal vaginal flora
  - Use of hormonal contraception


**Recurrent BV**

- 3 or more episodes per year
- Difficult to "cure" recurrent BV
  - Underlying shift in flora
  - High recurrence rate upwards of 80%
  - Do not diagnose recurrent BV based on presence of Gardnerella in vaginal culture alone

Treatment of Recurrent BV

• Treat current infection per CDC guidelines
• Suppression/prevention
  • Metronidazole gel vaginally 2 times per week, up to 6 months
  • High-dose metronidazole (compounded 750 mg per vagina x 7 days) has a higher cure rate than 500-mg dose
  • Bronc acid 300- to 600-mg vaginal capsules QHS x 2 weeks, then 2 times per week (also antifungal)
• Probiotics
• Acidify the vagina

References


References


References


BACTERIAL VAGINOSIS

BREAKOUT CASE 1

Halle

- 27-year-old Caucasian G0P0
- Sexually active, multiple male partners
- On OCPs x 9 years
- "Usually" uses condoms, not always
- History of + chlamydia 2 years ago, no h/o abn pap
- Recent 3-month h/o vaginal discharge and "fishy" odor
- Has been self-treating with OTC antifungals and feminine cleanses. Symptoms worsening
- Smoker x 11 years

Abn, abnormal; G, gravida; OCPs, oral contraceptive pills; OTC, over-the-counter.
Halle

Exam
- Thin, gray vaginal discharge visible at introitus
- Vaginal pH: >5.0
- Wet prep: + clue cells, no visible yeast buds/hyphae, trich, or parabasal cells. Rare WBCs
- + whiff test
- Normal vitals (no fever)

DNA swab
- + Gardnerella, Atopobium, BVAB-2
- - Yeast strains, trich, GC/CT
- Absence of lactobacilli species

CT, chlamydia; GC, gonorrhea.

Small Group Discussion
Based on Halle’s history, what is the recommended treatment plan?
BACTERIAL VAGINOSIS
BREAKOUT CASE 1
Halle

Case Discussion Regroup

Halle

Treatment (1 of the following):
• Metronidazole 500 mg PO BID x 7 days
• Metronidazole gel 0.75%, 1 applicator (5 g) PV QD x 5 days
• Clindamycin cream 2%, 1 applicator (5 g) PV QHS x 7 days

Also consider:
• Secnidazole 2-g granules mixed in with yogurt, applesauce, or pudding

Halle

Additional considerations
• Vulvovaginal hygiene discussion (products to avoid, etc)
• Encourage consistent use of barrier protection (male condom, female condom)
• Counseling for smoking cessation
• Partner treatment?
**Tracie**

- 41-year-old AA G4P3013
- 2 SVDs '00 & '03, 1 C/S '07
- Sexually active, monogamous, married 10 years
- Husband s/p vasectomy
- h/o abn pap '11, colpo unremarkable
- Lengthy h/o odorous vaginal discharge, worse after coitus and menses
- Symptoms resolve temporarily with metronidazole, but then return
- OneSwab consistently positive for Gardnerella when symptomatic
- Regularly douches with OTC prepared feminine douche

**Exam**

- Thin, gray vaginal discharge visible at introitus
- Vaginal pH: >5.0
- Wet prep: + clue cells, + yeast buds/hyphae, no visible trich or parabasal cells. Rare WBCs
- + whiff test
- Normal vitals (no fever)
Tracie

DNA swab
- + Gardnerella, *Candida glabrata* (resistant)
- - other yeast strains, trich, GC/CT
- Absence of lactobacilli species

Small Group Discussion

Based on Tracie’s history, what is the recommended treatment plan?

BACTERIAL VAGINOSIS BREAKOUT CASE 2

Tracie

Case Discussion Regroup
Tracie

Treatment (1 of the following):

• Treat current infection per CDC guidelines
• Suppression/prevention
  • Metronidazole gel vaginally 2 times per week, up to 6 months
  • High-dose metronidazole (compounded 750 mg per vagina x 7 days) has a higher cure rate than 500-mg dose
  • Boric acid 300- to 600-mg vaginal capsules QHS x 2 weeks, then 2 times per week (also antifungal)
• Probiotics
• Acidify the vagina
• Vulvovaginal hygiene recommendations (avoidance of douching)

Postassessment Question #1

Which of the following symptom profiles is most consistent with bacterial vaginosis (BV)?

A. Occasional vaginal discharge, no itching or burning, pH 4.5, presence of lactobacilli on wet prep
B. White vaginal discharge, vaginal itching, pH 4.5, presence of lactobacilli and possible hyphae on wet prep
C. Gray vaginal discharge, pH > 5.0, presence of mobile organisms with flagella on wet prep
D. Gray vaginal discharge, fishy vaginal odor, pH > 5.0, presence of clue cells but no lactobacilli on wet prep
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Which of the following is a true statement regarding recurrent bacterial vaginosis?

A. Use of oral contraceptives reduces the risk of recurrence.
B. Pathogen-containing vaginal biofilm increases risk of recurrence.
C. The presence of Gardnerella in vaginal culture is sufficient for diagnosis.
D. Douching is recommended to reestablish normal vaginal flora.

Non-CE Lunch Workshop
Updates in the Management of Postmenopausal Osteoporosis

Lisa D. Wright, DNP, ANP-C, CPHQ
Adult Nurse Practitioner
Department of Orthopaedics
Carilion Clinic
Roanoke, VA

CE Faculty Disclosures
Lisa D. Wright, DNP, ANP-C, CPHQ
- Former Employee: Merck

Preassessment Question #1

Which of the following is diagnostic of osteoporosis and suggests a need for treatment based on the ACE/AACE and ACP guidelines?

A. T-score -1.5 or below in lumbar spine, femoral neck, total hip, and/or 33% radius
B. Low-trauma vertebral fracture with T-score of -1.8
C. Recent pelvic fracture after falling off a bike
D. T-score of -1.4 with FRAX of 10% for major osteoporotic fracture and 1.3% for hip fracture

Respond at PollEv.com/wh1118 Text WH1118 to 22333 once to join, then A, B, C, or D
Preassessment Question #2

According to the ACE/AACE and ACP guidelines, which of the following would be the most appropriate treatment for postmenopausal women at high risk of fracture?

A. Raloxifene
B. Calcitonin
C. An anabolic agent
D. Alendronate

Learning Objectives

Updates in the Management of Postmenopausal Osteoporosis
NCC Code 2C (CE 1.3 Rx 1.3)

- Review the recent updates and recommendations in the osteoporosis treatment guidelines from the ACP, ACE/AACE, and ASBMR/NOF
- Evaluate the efficacy and safety data for available and emerging pharmacotherapies for osteoporosis
- Discuss evidence-based best practice guidelines for proper sequencing of therapy based on treat-to-target goals

Osteoporosis: Quick Review

- Postmenopausal osteoporosis – Imbalance in remodeling favoring resorption over formation-new LOSS
- Aging-related bone loss – defective osteoblastic function, stem cell exhaustion/depletion, failure of osteoclast to cross-talk with osteoblast (failure of communication) due to reduced growth factor matrix
Osteoporosis Compromises Bone Strength

Changes in bone in patients with osteoporosis

<table>
<thead>
<tr>
<th>Normal Bone</th>
<th>Osteoporotic Bone</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Decreased bone mineral density $^1$, $^2$</td>
</tr>
<tr>
<td></td>
<td>Decreased trabecular thickness and trabecular number$^2$</td>
</tr>
<tr>
<td></td>
<td>Conversion of plates to rods$^1$</td>
</tr>
<tr>
<td></td>
<td>Increased stress risers$^2$</td>
</tr>
<tr>
<td></td>
<td>Increased perforations$^2$</td>
</tr>
<tr>
<td></td>
<td>Decreased mechanical strength$^2$</td>
</tr>
</tbody>
</table>


Images courtesy of David Dempster, PhD

Evaluating Bone Strength

Bone strength primarily reflects the integration of BMD and bone quality$^1$

\[
\text{Bone Strength} = \text{BMD and Bone Quality} \quad \text{Obtained Through a DXA Test}
\]

BMD, bone mineral density; DXA, dual-energy x-ray absorptiometry.


Prevalence of Osteoporosis and Low Bone Mass

Americans 50 Years and Above Affected by Osteoporosis/Low Bone Mass, 2010 to 2030 (projected)

<table>
<thead>
<tr>
<th>Year</th>
<th>Low Bone Mass</th>
<th>Osteoporosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>54 million</td>
<td>99 million</td>
</tr>
<tr>
<td>2030</td>
<td>80 million</td>
<td>177 million</td>
</tr>
</tbody>
</table>

17% of ENTIRE US POPULATION (2010)

\[+27\% \text{ change from 2010 to 2030} \]

### Definition of Osteoporosis

- Continues to evolve
  - Not just based on BMD readings
  - Can be diagnosed in presence of fragility fracture
- **Fragility fracture:** any fracture that occurs from a fall from standing height or less or if someone lifts something of light weight (usually 5-10 lb or less) and sustains fracture

### Diagnosis of Osteopenia or Osteoporosis by BMD

<table>
<thead>
<tr>
<th>Osteopenia</th>
<th>Osteoporosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone density T-score in wrist, hip, or spine is between -1.1 to -2.4</td>
<td>Bone density T-score in wrist, hip, or spine is -2.5 or lower</td>
</tr>
<tr>
<td>Should be termed &quot;low bone mass&quot;</td>
<td></td>
</tr>
</tbody>
</table>

### FRAX Tool (Fracture Risk Assessment Tool)

- **Use in osteopenia** (low bone mass)
- Use of FRAX is important in someone with osteopenia to determine if treatment is indicated
- If FRAX for major osteoporotic fracture is 20% or higher, or risk for hip is 3% or higher (high risk for fracture in the next 10 years), it now can be considered "osteoporosis" and indicates need for treatment*
- FRAX not reliable if patient is on treatment or has been treated in the past

*Grade A.
1. www.shef.ac.uk/FRAX. Accessed November 16, 2017
Treatment Algorithm

- Based on FRAX score

The Impact of Osteoporosis and Fractures

- Half of women and one-quarter of men over age 50 years will break a bone due to osteoporosis
- 26% of women re-fracture within 1 year after a vertebral fracture
Hospitalization Burden for Osteoporotic Fractures and Other Serious Diseases in Older US Women

Percent of hospitalizations* for osteoporotic fractures and other serious diseases combined, 2000-2011

*Principal diagnosis codes were used.


The Impact of Osteoporosis and Fractures

• Every year of 300,000 hip fracture patients:
  • 20%-25% of patients die (greater risk of dying persists for at least 5 years)
  • 25% end up in nursing homes
  • 50% never regain previous function
  • Half of hip fracture patients give advance notice – an obvious opportunity for prevention
  • 45% of patients with a hip fracture had a prior osteoporotic fracture

Case Study: Ms Jones

• 63 yo female that presents to your clinic with mid back pain that started about 2 weeks ago
• She states, “It feels like a kidney stone but the pain is a little different.”
• Her last kidney stone was over 4 years ago while she was recovering after a wrist fracture
• She states her pain started after she had been working out in her yard doing some “strenuous gardening” and didn’t drink enough water. Ice and heat helped some and she had taken some acetaminophen
• She denies pain with urination, no blood in her urine. She does note some pain when taking a deep breath and with certain movements
Case Study Polling – Ms Jones

What should be included in her work up besides a urinary workup?
A. Ask about her fracture history since she is over 50
B. Ask about Calcium and Vitamin D supplements
C. Ask about family history of osteoporosis
D. Consider additional imaging
E. Social history

Case Study: Ms Jones

- Workup showed clear urine, metabolic panel normal with a calcium level of 9.2. Other labs were normal except vitamin D 25, which was 17.
- Her wrist fracture happened when she slipped on her bathroom floor and she stretched her arm out to brace her fall. Her mother had a hip fracture at the age of 72 years from a fall.
- Her spinal x-ray showed a T12 wedge compression fracture “age indeterminant” and mild degenerative changes in her L2-L5 area. Bone density test shows a BMD at her L1-L4 of .968 g/cm², T score of -2.3, and BMD of her left femoral neck of .993 g/cm² with a T-score of -1.9.
- Her FRAX is 17% for major osteoporotic fracture and 2.2% for hip fracture.
Case Study Polling – Ms Jones

What should be done next?
A. Treat her low vitamin D level to target for a level between 45-60
B. Recommend calcium and vitamin D supplements for better bone health
C. Start her on treatment of osteoporosis
D. Recommend calcium and vitamin D supplements, weight bearing and resistance exercises, and repeat bone density testing in 2 years

Updates in the Management of Postmenopausal Osteoporosis

2016 AACE Diagnosis of Osteoporosis in Postmenopausal Women

1. T-score -2.5 or below in lumbar spine, femoral neck, total hip, and or 33% or one-third of radius
2. Low-trauma spine or hip fracture (regardless of BMD)
3. Osteopenia or low bone mass (T-score between -1.0 to -2.4) with a fragility fracture of proximal humerus, pelvis, or possibly distal forearm
4. Low bone mass or osteopenia with high FRAX (fracture probability) based on country-specific thresholds

AACE. American Association of Clinical Endocrinologists.
ACP Guidelines 2017

Recommendations

1. Clinicians offer pharmacologic treatments with alendronate, risedronate, zoledronic acid, or denosumab to reduce risk of hip and vertebral fractures in women with osteoporosis (strong recommendation/high-quality evidence)

2. Treat osteoporotic women with pharmacologic therapy for 5 years (weak recommendation/low-quality evidence)

3. Offer treatment with bisphosphonates to reduce risk of vertebral fractures in men who have clinically recognized osteoporosis (weak recommendation/low-quality evidence)

ACP Guidelines 2017 (cont’d)

4. Recommends against bone density monitoring during the 5-year pharmacologic treatment period in women with osteoporosis (weak recommendation/low-quality evidence)

5. Recommends against using menopausal estrogen therapy or menopausal estrogen plus progesterone therapy or raloxifene for the treatment of osteoporosis in women (strong recommendation/moderate-quality evidence)

6. Clinicians should make the decision whether to treat osteopenic women 65 years of age or older who are at a high risk for fracture based on a discussion of patient preferences; fracture-risk profiles; and benefits, harms, and cost of medication (weak recommendation/low-quality evidence)
Treatment Sequencing Considerations

Recognizing the goal of treatment is reduction of future fractures, treatment sequencing needs to be considered in managing the chronic disease of osteoporosis based on the following:

- Is the patient naïve to treatment?
- Age of patient starting treatment
- Other benefits of treatment based on patient history
- Recommended treatment exposure limitations based on current best practice recommendations
- Anabolic agents should be followed with an antiresorptive agent

NOF and ASBMR Position Statement on New Treatment Guidelines

- National Osteoporosis Foundation applauds the ACP efforts but feels there are limitations in special circumstances
- NOF states that in some cases antiresorptive osteoporosis treatments may warrant a longer duration of treatment
- NOF feels that clinicians may need additional guidance on the value of DXA testing and risk scoring to identify those patients at high risk
- Working with ASBMR on advocacy for patient awareness and informed decision making

Primary Prevention of Osteoporosis

Health history clues for possible osteoporosis

- **Primary:** Postmenopausal/early menopause defined by cessation of cycle before 45 years surgically or naturally
- Reported height loss since age 20 years
- BMD shows osteopenia
- Hx of gastric bypass
- Family hx of osteoporosis
- Dental History

- **Secondary:** History of fragility fracture of wrist, hip, or spine but must consider other areas as well
Medical Conditions Associated with Bone Loss

- Diabetes
- Asthma
- GI Disorders (ie, Gastric Bypass, Malabsorption Disorders, Crohn’s, Celiac (untreated))
- Rheumatoid Arthritis
- Thyroid Disease
- Immunodeficiencies
- Smoking
- Alcohol Use
- Gout
- Spinal Cord Injuries
- Parkinson’s
- Hirsutism
- HIV
- Muscular Dystrophy

Medications That Affect Bone Loss

- Glucocorticosteroids
- Certain immunosuppressants (calmodulin/calcineurin phosphatase inhibitors)
- Thyroid hormone treatment (L-thyroxine)
- Certain steroid hormones (medroxyprogesterone acetate, luteinizing hormone-releasing hormone agonists)
- Aromatase inhibitors
- Certain antipsychotics
- Certain anticonvulsants
- Certain antiepileptic drugs
- Lithium
- Methotrexate
- Antacids
- Proton pump inhibitors

Clinical Risk Factors for Low Bone Mass

- Loss of height
- Low body weight
- Advanced age
- Late age at menarche
- Menopausal
- Time since menopause
- Smoking
- Dietary calcium
- Alcohol intake
- Medications
- Inflammatory diseases
- Prior fragility
Vitamin D Insufficiency and Deficiency

- Lack of sun exposure and dietary vitamin D
- Age-related decline in cutaneous production
- Gastrointestinal disease
- Liver disease
- Renal disease
- Drugs (phenytoin, phenobarbital)


When to Consider Further Workup in Certain Patients

- Unexplained fracture
- Unexpected low BMD
- Poor response to therapy
- Clinical suspicion of secondary causes in any patient with osteoporosis


Labs to consider (The Basics and Beyond)

- Vitamin D 25
- CMP
- Phosphorus
- Intact PTH
- Alkaline Phosphatase Bone Specific
- Serum Protein Electrophoresis w/Interpretation
- TSH
- Turnover Markers: P1NP: N Terminal Propeptide of Type 1 Procollagen (Formation) & CTX: Collagen Type 1 C-Telopeptide (Resorption)

CMP, comprehensive metabolic panel; PTH, parathyroid hormone; TSH, thyroid-stimulating hormone.
Covered BMD Services

- Estrogen-deficient women at clinical risk for osteoporosis
- Individuals with vertebral abnormalities on x-rays
- Individuals receiving long-term glucocorticoid therapy
- Individuals with primary hyperparathyroidism
- Individuals being monitored on osteoporosis therapy
- Check with your regional CMS carrier to determine the appropriate ICD-10 codes for use in your area!
- Refer to bone density coverage on CMS website for your area

CMS, Centers for Medicare and Medicaid Services.

Common Areas of Fragility Fractures

- Wrist
- Hip
- Spine

New Clinical Position Statement by the National Osteoporosis Foundation to include other areas to be considered such as pelvic insufficiency fractures, humerus fractures, ankle fractures


Treatment Goals in Osteoporosis Management

- Improve bone strength by improving bone mass
- Improve bone quality/possibly microarchitecture
- Reduce risk of future fractures

If we could accomplish all of these, we would have “cure”—currently not possible

Bone Health Is a Team Approach

- PT: Falls Prevention
- Imaging: DEXA
- Falls Assessment
- Hester Falls
  - Low Risk: 7-10
  - Moderate: 11-14
  - High: 15+
- Referrals to Specialists
  - Endocrinology
  - Rheumatology
  - Hematology
- Dental Services
- Care Coordination
- PCP
- Nutritional Services
- and Wellness
- Medication Therapy
  - In Office or
  - Referral to
  - Infusion Centers

Nonpharmacologic Preventative Modalities (CDEF)

- C: Calcium citrate/carbonate
  - 1000-1200 mg daily with food; should partially come from dietary intake if possible*
- D: Vitamin D3 1000-2000 units daily or more depending on patient’s level†
- E: Exercise: Weight-bearing and resistance exercises*
- F: Falls prevention*, core strengthening, and balance*

*Grade B. †Grade C. ‡Grade A.

FDA-Approved Drugs

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<tr>
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<td>Abaloparatide</td>
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</tbody>
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CEE, conjugated equine estrogen; PMO, postmenopausal osteoporosis; GIO, glucocorticoid-induced osteoporosis.
Drug Classes

• **Antiresorptives**
  - Slows/suppress osteoclastic activity
  - Includes estrogen, estrogen receptor modulators, bisphosphonates, rank ligand inhibitor, calcitonin

• **Anabolics**
  - Stimulates osteoblastic and osteoclastic activity
  - Includes teriparatide and abaloparatide

Estrogen

• **Class:** antiresorptive
• **BMD:** increases at spine and hip
• **Bone turnover markers:** decreased
• **Fractures:** risk reduction seen in vertebral and nonvertebral
• **Extraskeletal:** increases risk of breast cancer, reduces hot flashes, increases VTE risk, stimulates the endometrium

Global Consensus Statement on Menopausal Hormone Therapy (MHT)

• "MHT is effective and appropriate for the prevention of osteoporosis-related fractures in at-risk women before age 60 years or within 10 years after menopause."
• "Randomized clinical trials and observational data as well as meta-analyses provide evidence that standard-dose estrogen-alone MHT may decrease coronary heart disease and all-cause mortality in women younger than 60 years and within 10 years of menopause."
• **Note:** estrogen use for osteoporosis treatment would be off label
Bazedoxifene/Conjugated Estrogen

- **Class**: antiresorptive, selective estrogen receptor modulator plus estrogen (3rd-generation SERM)
- **BMD**: prevents bone loss in early postmenopausal women
- **Bone turnover markers**: decreased
- **Fractures**: reduces risk of vertebral fractures (~40%), no proven benefit for hip or nonvertebral fractures
- **Extraskeletal**: reduces hot flashes, improves vulvovaginal atrophy
- Increases VTE risk, leg cramps; does not stimulate endometrium


Raloxifene

- **Class**: antiresorptive, selective estrogen receptor modulator
- **BMD**: increases at spine and hip
- **Bone turnover markers**: decreased
- **Fractures**: reduces risk of vertebral fractures, no proven benefit for hip or nonvertebral fractures
- **Extraskeletal**: reduces risk of breast cancer, does not reduce hot flashes, VTE risk (similar to estrogen and tamoxifen), leg cramps, does not stimulate endometrium
- **Other benefits**: favorable effect on lipid profile, has no effect on risk of coronary events


Bisphosphonates: Alendronate, Risedronate, Ibandronate, and Zoledronic Acid

- **Class**: antiresorptive
- **BMD**: increases BMD at various skeletal sites
- **Bone turnover markers**: decreased
- **Fractures**: reduces risk of fractures
- **Extraskeletal considerations**
  - Specific dosing requirements for oral bisphosphonates
  - Interval and IV/oral dosing available
  - Occasional GI irritation
  - Infrequent – musculoskeletal pain
  - Very rare – hypocalcemia, osteonecrosis of jaw, atypical femoral fracture
- **Effect on bone resorption persists after discontinuation**
  - Unique to bisphosphonates

Things to Consider With Bisphosphonate Treatment

Safety Concerns
- GI intolerance with the oral treatments
- Esophageal cancer (reported concern)
- Hypocalcemia (may be transient effect up to 10 days after subq injection)
- Atrial fibrillation (reported concern)
- Renal toxicity (reported concern)
  - Check calcium and creatinine prior to treatment
- Flu-like symptoms (myalgia, arthralgia, fever)
  - 12-48 hours after IV infusion; usually last 1-2 days (sometimes up to a week)
  - Ocular effects
  - Osteonecrosis of the jaw
  - Atypical fractures (reported concern)

Calcitonin
- Class: antiresorptive, biologic agent
- BMD: slight increase
- Bone turnover markers: decreased
- Fractures: reduces risk of vertebral fractures (around 30%); no proven benefit for hip or nonvertebral fractures
- Extraskeletal considerations
  - Possible analgesic effect
  - Occasional nasal irritation, rarely epistaxis
  - No known drug interactions

Calcitonin Package Insert Updated 3/2014
- Calcitonin indications include treatment of postmenopausal osteoporosis “when alternative treatments are not suitable”
- “Fracture reduction efficacy has not been demonstrated.”
- “Due to the possible association between malignancy and calcitonin-salmon use, the need for continued therapy should be re-evaluated on a periodic basis.”
Denosumab

- **Class:** antiresorptive, fully human monoclonal antibody, binds and inhibits RANKL
- **BMD:** increased at spine and hip
- **Bone turnover markers:** decreased
- **Fracture:** reduces spine, hip, and nonvertebral fractures
- **Extraskeletal considerations**
  - SQ injection every 6 months (compliance important…)
  - Hypocalcemia, infection, ONJ, AFF, and rash possible

Teriparatide: rhPTH (1-34)

- **Class:** anabolic, hormone
- **BMD:** increases at spine and hip
- **Bone turnover markers:** increased and sustained above baseline
- **Fractures:** decreases at spine and nonvertebral; study too small to demonstrate hip fracture benefit compared to placebo (calcium and vitamin D)
- **Extraskeletal considerations**
  - Osteosarcoma in rats, daily subcutaneous injection, refrigeration, hypercalcemia, leg cramps, dizziness, high cost, limit of 2 years of therapy

Abaloparatide: PTHrp (1-34)

- **Class:** anabolic, protein
- **BMD:** increases at spine and hip
- **Bone turnover markers:** increased for a short interval at initiation of treatment
- **Fractures:** decreases at spine and nonvertebral compared to placebo (calcium and vitamin D)
- **Extraskeletal considerations**
  - Osteosarcoma in rats, daily subcutaneous injection, no refrigeration required after initial dose, hypercalcemia, leg cramps, dizziness, high cost, limit of 2 years of therapy
Treatment Summary

1. Two options for treatment: several antiresorptives and 2 anabolics
2. Estrogen reduces vertebral and nonvertebral fractures, but is approved only for osteoporosis prevention, not treatment
3. Raloxifene has skeletal effects generally similar to those of estrogen but only reduces vertebral fracture risk
4. Bisphosphonates reduce fracture risk for vertebral and nonvertebral fractures
5. Denosumab increases BMD due to potent antiresorptive properties, decreases bone resorption, and reduces vertebral and nonvertebral fracture risk
6. Anabolic treatment induces significant increases in bone mass and decreases vertebral and nonvertebral fracture risk

New Anabolic Drug Therapy on the Horizon

Romosozumab
- A “pure osteoanabolic therapy”; sclerostin antibody therapy
  - Sclerostin inhibits Wnt signaling and bone formation
  - Sclerostin antibody therapy in lab rats showed an increase in bone mass, improved trabecular architecture, and increased cortical thickness
  - Sclerostin antibody therapy in monkeys showed an increase in cancellous bone volume and bone formation
  - Further data requested by the FDA in spring of 2017 prior to full approval

ASBMR/NOF Progress Report

Goal-Directed Treatment
- Treatment should be selected according to having a high likelihood of achieving an acceptable level of fracture risk
- Three proposed treatment targets
  - T-score greater than -2.5
  - Fracture probability (FRAX) less than treatment threshold
  - No fracture
Fracture Liaison Service (FLS) Model of Care

- A coordinated preventive care model that operates under the supervision of bone health specialists and collaborates with the patient’s primary care physician
  - FLS programs coordinate postfracture care through an FLS coordinator (generally a nurse, NP, or PA)
  - Patients with recent fractures are tracked via a population registry
  - Processes and timelines established for patient assessment and follow-up
- FLS programs
  - Recognize that patients who have fractured are at highest risk of future fractures
  - Have greatly reduced the number of fractures and achieved cost savings by identifying and appropriately treating postfracture patients

Resources

- NOF.org
- NBHA.org
- Fracture Prevention Central (NBHA.org)
- Project Echo (NBHA.org)
- AACE/ACE Patient Decision Teaching Tool: www.empoweryouhealth.org

References


Ms Riba Van Winkle is a 67 y/o white female who recently had her annual PE. She presents for follow-up to discuss treatment options for her bone health after her bone density

- She is 5'4" and 140 lbs
- Problem list: Type 2 diabetes, peripheral neuropathy, GERD, and HTN
- Menopause age 47 years after total hysterectomy for fibroids and DUB
- Bone density Sept 2017 shows a BMD in L2-L4 .728 g/cm² and a T-score of -2.5 and BMD left femur .862 g/cm² with a T-score of -1.0
- Medications: metformin 500 mg twice per day, gabapentin 300 mg 3 times per day, omeprazole 20 mg daily for the past 6 years, valsartan/HCTZ 325/25 mg 1 daily, calcium carbonate 600 mg once per day, and vitamin D3 1000 units daily
- She consumes 1 glass of wine 2-3 days per week with dinner
- She walks her dog daily for about 1 mile and does not do much with resistance exercises
- She does mention she had a wrist fracture from a fall she had at the age of 52 years when she tripped over her cat in her home

References

OSTEOPOROSIS BREAKOUT
CASE 1
Ms Riba Van Winkle

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Next Steps

- What else would you like to know about this patient’s history in order to develop a safe treatment plan for her?
- Labs?
- Patient education needed?
- Plan of care?

OSTEOPOROSIS BREAKOUT
CASE 1
Ms Riba Van Winkle
Case Discussion Regroup

Next Steps

- Height loss since her 20s?
- Any history of prior HRT and for how long?
- Smoker?
- Prior bone density?
- Any prior treatment for her bones?
- Family History of osteoporosis? Parent with a h/o a hip fracture?
- Dental concerns?
- Special Diets? Vegan, Vegetarian?
- How many falls in the past year? Causes?
- Balance, core strengthening, or posture concerns?
- Any other medical conditions of concern?

- Consider plain film T and L spine or LVA/VFA view on bone density.
- Smoking cessation if indicated
- What does she recall about prior bone density test results in the past?
- Does she have any anxiety about treatment for her osteoporosis?
- Consider referral to PT for core strengthening, balance, fall prevention, etc.
- Labs: CMP, vitamin D 25, intact PTH, TSH, celiac serology if low vitamin D, CBC, phosphorous; consider secondary causes if labs point in that direction
- Calcium Carbonate vs Calcium Citrate?
- Treatment goals
Case Presentation 2

Ms Toeni LisFranc is a 58 y/o black female who presents to establish care as a new patient. She is having some trouble sleeping lately due to some midback pain and night sweats and wanted to get a check-up.

- She is 5’7” and 155 lbs.
- She is G3P3 and thinks she stopped her cycle 1-2 years after the birth of her last child when she was around 43 years.
- She has been a smoker for the past 16 years and may have a beer a few times per month socially.
- She is active at work at a local retail store where she works the nightshift stocking shelves in the automotive section and home improvement section.
- Medications include: ibuprofen 600 mg twice per day since her back started hurting, multivitamin on occasion, and HCTZ for her blood pressure.
- Her initial workup includes a physical exam and labs, as well as a chest x-ray due to her night sweats and midback pain.
- Her PE is essentially normal.
- Chest x-ray shows mild restrictive changes consistent with mild COPD and incidental finding showed a T11 vertebral height loss of 40% with compression fracture age indeterminate, osteopenia.
- Bone density shows BMD .934 g/cm² and T-score -0.8 in her L1-L4 spine and BMD .970 g/cm² and T-score in her left femoral neck -0.8.
- Labs: CMP essentially normal, TSH 1.03, vitamin D 25: 17.
Next Steps

• What else would you like to know about this patient’s history in order to develop a safe treatment plan for her?
• Additional labs?
• Patient education needed?
• Plan of care?

OSTEOPOROSIS BREAKOUT
CASE 2
Ms Toeni LisFranc
Case Discussion Regroup

Next Steps

• Height loss since her 20s?
• When did her back pain start?
• Any history of prior HRT and for how long?
• Any falls in the past year?
• Family History of osteoporosis?
• Any plans for smoking cessation?
• Any planned weight-bearing or resistance exercises?
• Any prior bone density testing? If so, does she recall her results?
• Dental issues?

• Bone density test and recommend LUM or VFA along with BMD or get T and L spine view to check for other compression fractures
• Smoking cessation plan
• Start vitamin D3 supplements and target for level of 45-60
• Consider additional labs to include S179F, intact PTH, calcitropic profile, low vitamin D, CBC, phosphorus; consider secondary causes if labs point in that direction
• Address anxiety about treatment for her bones
• Look at FRAX; however, this is osteoporosis by fracture not BMD
• Treatment goals
Fracture Risk Results

- Consider anabolic or antiresorptive

Postassessment Question #1

Which of the following is diagnostic of osteoporosis and suggests a need for treatment based on the ACE/AACE and ACP guidelines?

A. T-score -1.5 or below in lumbar spine, femoral neck, total hip, and/or 33% radius
B. Low-trauma vertebral fracture with T-score of -1.8
C. Recent pelvic fracture after falling off a bike
D. T-score of -1.4 with FRAX of 10% for major osteoporotic fracture and 1.3% for hip fracture

Respond at PollEv.com/wh1118 Test WH1118 to 22333 once to join, then A, B, C, or D
Postassessment Question #2

According to the ACE/AACE and ACP guidelines, which of the following would be the most appropriate treatment for postmenopausal women at high risk of fracture?

A. Raloxifene  
B. Calcitonin  
C. An anabolic agent  
D. Alendronate
Preassessment Question #1

Which of the following screening tools has 19 questions, is commonly used in clinical trials, and is a validated screening tool for female sexual dysfunction (FSD), including HSDD?

A. Female Sexual Function Index (FSFI)
B. Decreased Sexual Desire Screener (DSDS)
C. Sexual Function Questionnaire (SFQ-28)
D. Hypoactive Sexual Desire Disorder (HSDD) Screener

Preassessment Question #2

Which of the following is true regarding FDA-approved centrally acting treatments for HSDD?

A. Act as a cyclic 7-amino acid melanocortin-receptor antagonist
B. Shown in clinical trials to increase vestibule temperature
C. A REMS prescribing program is required
D. Free testosterone should be monitored
Learning Objectives

Updates in the Diagnosis and Management of HSDD
NCC Code 2A (CE 1.3 Rx 0.8)

- Identify communication strategies and screening tools that aid in the identification and diagnosis of HSDD
- Consider differential diagnoses of low sexual desire before initiating targeted treatment for HSDD
- Evaluate efficacy and safety data for approved, emerging, and off-label treatments for HSDD

FEMALE SEXUAL DYSFUNCTION

Diagnoses

LOW LIBIDO

Female Sexual Interest/Arousal Disorder (FSIAD)
Decreased Sexual Desire
Hypoactive Sexual Desire Disorder (HSDD)
Low Sex Drive
Low Libido

- Low libido = symptom
- Hypoactive Sexual Desire Disorder = condition
  - Generalized, acquired
  - Generalized, lifelong
  - Situational, acquired
  - Situational, lifelong
- Female Sexual Interest/Arousal Disorder
  - Updated DSM terminology (2015)

Definitions

- Low libido (ICD-10)
  - Decreased sexual desire (symptom)
- HSDD (DSM IV-TR)
  - Characterized by a recurrent or persistent lack of desire for sexual activity, including decreased sexual fantasies, not attributable to another psychiatric disorder (sexual dysfunction)
- FSIAD (DSM-5)
  - Lack of, or reduction in, sexual interest and/or arousal, not attributable to another psychiatric disorder (sexual dysfunction)
Origins in Literature

- 1974: Originally discussed in medical literature
- 1987: Originally included within DSM


PREVALENCE

Women 43% vs. Men 31%

Low Sexual Desire With and Without Distress

31% vs. 10%

Age-Stratified Prevalence of Distressing Desire Disorders in Women

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Leslie

- 34 yo, presents for annual GYN exam
- Married to husband of 6 years, 2 children
- Uses Mirena IUD for contraception
- Unremarkable exam
- You ask if she has any questions or concerns about her sexual health
- She responds, “Actually, yes. I’ve noticed that my sex drive has been lower than normal recently.”
Case Study Polling – Leslie

Your response should be:
A. That’s normal. Many women experience loss of sex drive after having children.
B. Does your low sex drive bother you?
C. How long have you noticed this?
D. Just relax and have a glass of wine. That always helps me.

Your response to Leslie should be:
A. That’s normal. Many women experience loss of sex drive after having children.

Does your low sex drive bother you?

How long have you noticed this?

Just relax and have a glass of wine. That always helps me.

SEXUAL RESPONSE
Human Sexual Response: Classic Models

- Excitement
- Plateau
- Orgasm
- Resolution

Linear Progression

Divided

Desire
Arousal

Female Sexual Response Cycle

- Emotional and Physical Satisfaction
- Sexual Arousal and Sexual Drive
- Sexual Stimuli
- Spontaneous Sexual Drive

Biopsychosocial Model of Female Sexual Response

- (e.g., physical health, neurobiology, endocrine function)
- (e.g., performance anxiety, depression)
- (e.g., quality of current and past relationships, financial status, life stressors)
- (e.g., upbringing, cultural norms, and expectations)
Psychosocial-Neurobiology of Sexual Response

HSDD

Excitation

SEX STEROIDS
DOPAMINE
SEROTONIN
ENDOCANNABINOIDS
MELANOCORTIN
MORPHINE/HYDROMORPHINE

Inhibition

opioids
endocannabinoids
prolactin

Psychosocial-Neurobiology of Sexual Response

MRI IMAGES:
sexual function and dysfunction

Activations
Pathophysiology of Female Sexual Dysfunction

Healthy female volunteers watching high erotic movies

Image courtesy of Dr. Irwin Goldstein

Activations
Pathophysiology of Female Sexual Dysfunction

Deactivations
Pathophysiology of Female Sexual Dysfunction

HSDD female volunteers watching high erotic movies

Healthy female volunteers watching low erotic movies

Image courtesy of Dr Irwin Goldstein.
CAUSES OF HSDD

Just to name a few...

Differential Diagnosis

- Hormone imbalance
  - Menopause
  - PCOS
  - Pregnancy/breastfeeding
- Medication use
  - Hormonal birth control
  - Antidepressants/antianxiety meds
  - Cholesterol/BP lowering meds
- Chronic health conditions
  - Diabetes
  - Thyroid disorder
  - Hypothyroidism
  - Anemia
  - Pain
- Psychiatric conditions
- Relationship problems
- Lack of knowledge about arousal/orgasm/genital anatomy
SSRIs & FSD

- Correlation of FSD and SSRI use
- Exact mechanism of FSD-induced SSRIs is unknown
- Relationship is dose-dependent


Barrier to Accurate Diagnosis: Overlap of Female Sexual Disorders

- Desire
- Arousal
- Sexual Pain
- Orgasm

Harriett

- 67 yo, presents problem visit – low libido x 1 y
- Long-term, monogamous relationship with same-sex partner x 25 y
- Works 50+ hours a week in the music industry
- S/P natural menopause ~ age 54 y. On HRT until last year. Stopped per recommendation of GYN
  - No current systemic or local HRT, pain with all penetrative sex play
- Severe arthritis in hips limits sexual positioning
- Started on SSRI 6 months ago to help with hot flashes
Case Study Polling – Harriet

What are potential contributing causes for her low libido?

A. Hypoestrogenic state
B. SSRI usage
C. Vaginal pain and dryness
D. Arthritis in hips – subsequent sexual pain
E. Stress/fatigue
F. All of the above

ASSESSMENT
Screening Tools

- **FSFI** – Female Sexual Function Index\(^1,2\)
  - 19 questions, used in clinical trials
- **FSDS/FSDS-R** – Female Sexual Distress Scale (Revised)\(^3\)
- **DSDS** – Decreased Sexual Desire Screener\(^4\)
  - 5 questions, useful in clinical practice
- **HSDD** Hypoactive Sexual Desire Disorder Screener (HSDD)\(^5\)
  - Postmenopausal women
- **SFQ28** – Sexual Function Questionnaire\(^6\)
- **ASFQ** – Abbreviated Sexual Function Questionnaire\(^7\)
- **SQOL-F** – Sexual Quality of Life-Female\(^8\)


Physical Assessment

- Vital signs
- General presentation (hygiene, psych state)
- Gait and posture
- Skin (including mucosal)
- General neurologic exam
- Complete urogenital/pelvic exam
- Tanner stage
- Vulvovaginal/pelvic exam
  - Skin/tissue integrity
  - Q-tip touch test
  - Neuro
    - Biothesiometry
    - Vaginal/pelvic muscle strength
  - Perineometry
- Wet prep/pH

Labs

- Estradiol/FSH/LH
- Testosterone (female)
- Dihydrotestosterone
- Sex hormone binding globulin (SHBG)
- Prolactin
- Thyroid panel
TREATMENT OPTIONS

Treatment

- 1 FDA APPROVED treatment for hypoactive sexual desire disorder (HSDD)
- 0 FDA approved treatments for arousal/orgasmic dysfunction
- 3 FDA approved treatments for dyspareunia related to atrophy/GSM

Men
Women

Prozac

Sildenafil citrate
Testosterone patch
Flibanserin
Tibolone
Testosterone gel
Testosterone/sildenafil
Testosterone/buspirone
Bremelanotide

FLIBANSERIN
**Flibanserin**

- Hypoactive Sexual Desire Disorder (HSDD)
- Premenopausal women
- Approved August 2015, released October 2015
- REMS program
- First-ever FDA approved medication for desire, arousal, and orgasmic dysfunction
- Acts on central nervous system
  - Acts on serotonin receptors
  - Effect on 5-HT (1A) and 5-HT (2A) receptors
  - Exact MOA unknown
- 100 mg once daily at bedtime (QHS)
- 4-8 weeks for medication response

**Flibanserin Is Not:**

- "Viagra for women"
- For all women
- A pill to improve a poor relationship
- A "date rape drug"
**Flibanserin**

- **Adverse events**
  - Dizziness, somnolence, nausea, fatigue
  - 13% discontinuation rate (6% placebo)
- **3rd phase 3 trial**
  - 53% improvement in desire
  - 29% reduction in distress
  - 6-8 more satisfying sexual events (SSEs) per month (1 over placebo)


**BOXED WARNING**

**ALCOHOL**

Hypotension & Syncope


**Flibanserin**

- **Alcohol warning**
  - N = 25
  - Fasted 10 h, light breakfast
  - Study drug + 10 m to consume OJ with/without etoh
  - ~154 lb person = 2-4 shots of 80-proof spirit
  - **Results**
    - 0.4 g/kg
      - 4 subjects experienced hypotension or syncope requiring therapeutic intervention (position change and/or ammonia salts)
    - 0.8 g/kg
      - 6 subjects experienced orthostatic hypotension with sitting to standing
      - 1 required therapeutic intervention (position change and ammonia salts)

Flibanserin

- Post-marketing Etoh studies in progress
  - October 2016 – binge drinking study “Worst case scenario”
  - #2 – timing of etoh intake relative to flibanserin administration
  - #3 – “typical real-world use”

BREMELANOTIDE (BMT)

Bremelanotide (BMT)

- Investigational, as-desired, subcutaneous injection
  - Disposable auto-injector
  - 1.75 mg BMT per dose
- Cyclic 7-amino acid melanocortin-receptor agonist
  - High affinity for type-4 receptor
  - Analog of peptide, α-melanocyte-stimulating hormone

Bremelanotide (BMT)

- The RECONNECT study
  - 2 randomized, double-blind, phase 3 studies for efficacy/safety
  - n = 1202
    - Healthy, premenopausal women
    - Nonpregnant
    - ≥ 18 years of age
    - Currently in a stable (≥ 6 months) relationship
    - HSDD ≥ 6 m


*Statistically significant improvements in FSFI total, arousal, lubrication, orgasm, and satisfaction domain scores compared to placebo.*
*Favorable SE profile: mostly mild-moderate GI upset with D/C rate 18% (vs. 2% placebo).*

Bremelanotide (BMT) Study Design

<table>
<thead>
<tr>
<th>Screening</th>
<th>At-Home Placebo</th>
<th>At-Home Self-Dosing 1.75 mg BMT or At-Home Study Drug Self-Dosing BMT 1.75 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Month 1</td>
<td>Placebo</td>
<td>Study Month(s)</td>
</tr>
</tbody>
</table>

Pumps/Vacuum Devices

- Clitoral vacuum pump
- Vibrating clitoral pump
- Clitoral stimulators
N = 14 premenopausal, 12 postmenopausal women

Mean time to reach genital arousal

- 5.2 ± 4.2 minutes in the premenopausal group
- 4.5 ± 4.3 minutes in the postmenopausal group

Clitoris/vestibule temperature

- Statistically significant increase in both groups >10 min after removal of the device
- Statistically significant increase maintained up to 8 min after removal of the device in premenopausal group
- Statistically significant increase maintained up to 2 min after removal of the device in postmenopausal group

Responsive sexual desire

- All respondents reported increase in subjective sexual desire after use of the device

Off-Label Treatment Options for Sexual Interest/Arousal/Orgasmic Disorders

Testosterone/DHEA-S replacement

- Women use ~ 1/10 of male dose
- Monitor closely and calculate via 1 of the following:
  - Free Androgen Index (FAI)
  - \( (\text{Total T} \times 3.47/\text{SHBG}) \)
  - Free testosterone via online calculator
    - http://www.issam.ch/freetesto.htm
    - Goal 0.6 – 0.8 ng/dL
- Available products
  - Commercially available creams, gels
  - Compounded T products
  - ~5 mg per day
  - IM injections
  - Pellets

Hormonal Levels in Healthy Premenopausal Women

<table>
<thead>
<tr>
<th>Age (Y)</th>
<th>20-29 (n = 17)</th>
<th>30-39 (n = 23)</th>
<th>40-49 (n = 20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DHEAS ug/dL</td>
<td>176.9 – 214.3</td>
<td>139.0 – 170.8</td>
<td>124.7 – 156.1</td>
</tr>
<tr>
<td>SHBG nmol/L</td>
<td>43.6 – 58.6</td>
<td>44.6 – 52.4</td>
<td>47.0 – 58.4</td>
</tr>
<tr>
<td>Total T ng/dL</td>
<td>45.5 – 57.5</td>
<td>27.6 – 39.8</td>
<td>27.0 – 38.6</td>
</tr>
<tr>
<td>Free Androgen Index (FAI)</td>
<td>3.72 – 4.96</td>
<td>2.04 – 2.96</td>
<td>1.98 – 2.94</td>
</tr>
<tr>
<td>Calculated Free T picomol/L</td>
<td>21.5 – 27.2</td>
<td>13.4 – 19.5</td>
<td>12.4 – 17.8</td>
</tr>
<tr>
<td>Calculated Free T ng/dL</td>
<td>0.6 – 0.8</td>
<td>0.4 – 0.6</td>
<td>0.4 – 0.6</td>
</tr>
</tbody>
</table>
The Effects of Dehydroepiandrosterone on Sexual Function: A Systematic Review

Objective: Faced with the growing interest about the action of dehydroepiandrosterone (DHEA) and its benefits, as well as the negative impacts that sexual dysfunctions have on people's quality of life, this systematic review was undertaken with the objective of evaluating the effect of DHEA use on aspects of sexual function.

Method: An electronic search was conducted in the databases of PubMed, ISI Web of Science, and Virtual Health Library (VHL) combining the terms “DHEA treatment” and “DHEA use” with terms such as “sexual dysfunction”, “sexual frequency”, and “libido”. No limits on time and language were imposed. Clinical studies were considered eligible where individuals for any reason made use of DHEA and if they had any aspect of sexual function assessed. Preclinical studies and systematic reviews were considered ineligible.

Results: The search identified 183 references and 38 were considered eligible. DHEA improved aspects such as sexual interest, lubrication, pain, arousal, orgasm, and sexual frequency. Its effect was better in populations with sexual dysfunction, especially in perimenopausal and postmenopausal women.

Conclusion: Considering the studies currently published, DHEA is effective in improving several aspects of sexual function, but this effect did not reach all the populations studied.

Off-Label and Non-Medicinal Treatment Options for Sexual Interest/Arousal/Orgasmic Disorders

- Stimulants
- Herbs
  - L-arginine
- Serotonin Antagonist
  - Buspirone
- Dopamine Agonists
  - Bupropion, cabergoline, ropinirole
- Oxytocin
  - Troches/lozenge (10-50 IU), spray (100 IU/mL, 1 spray into nostril at time of coitus)
- PDE5 Inhibitors
- Topical Arousal Creams
  - Aminophylline, L-arginine, sildenafil, nitroglycerin, phentolamine, Zestra

Off-Label and Non-Medicinal Treatment Options for Sexual Interest/Arousal/Orgasmic Disorders

- LIFESTYLE CHANGES – exercise, healthy eating, etc
- Psychotherapy/sex therapy
- Erotica, sexual aids/toys
- Scheduled intimacy
References


References


42 yo, “Sarah”

- Married x 18 years
- 2 children, ages 12 & 15 years
- Works full time as a teacher
- Hobbies include running, reading, knitting

Recalls stronger sex drive early in relationship, gradual decline over the years – distressing
- Decreased arousal/genital sensation and weaker orgasms
- Describes good marriage with open communication
- Very busy with work, church, and children’s after school activities

Medical History
- Allergies, hypothyroidism (dx 12 years ago)
- Medications: montelukast, levothyroxine, glucosamine/chondroitin supplement
- S/P BTL. Took OCPs for ~ 7 years prior to first pregnancy
- Regular monthly menses
42 yo, “Sarah”

- 5 ft 6 in, 135 lb
- BP 114/72, P 74, RR 14
- Exam
  - Appropriate affect, well groomed
  - Well spoken, comfortable discussing sexual concerns
  - No thyroid enlargement or nodules
  - Normal breast exam
  - Vulvovaginal and pelvic exam unremarkable

42 yo, “Sarah”

- Labwork
  - FSH 4.56 (1.79 – 22.51)
  - Prolactin 8 (2.74 – 26.72)
  - TSH 3.8 (0.34 – 4.0)
  - Free T3 2.05 (2.0 – 3.3)
  - Free T4 0.60 (0.58 – 1.64)
  - DHT 41 (24 – 208)
  - Total testosterone 14 (10 – 52)
  - SHBG 88 (12.2 – 135.5)

HSDD BREAKOUT CASE 1

Sarah

Case Discussion Regroup
42 yo, “Sarah”

**Labwork**
- FSH 4.56 (1.79 – 22.51)
- Prolactin 8 (2.74 – 26.72)
- TSH 3.8 (0.34 – 4.0)
- Free T3 2.05 (2.0 – 3.3)
- Free T4 0.60 (0.58 – 1.64)
- DHT 41 (24 – 208)
- Total testosterone 14 (10 – 52)
- SHBG 98 (12.2 – 135.5)
- Calculated free testosterone 0.12 (0.6 – 0.8)

**Treatment?**
1. Consider addressing thyroid
   - Optimize TSH <2.5
2. Consider testosterone replacement
3. Consider flibanserin
4. Sex therapy
5. Work on prioritizing intimacy
   - Intimacy/relationships require attention just like work, church, and children
   - Date nights, vacations without children

HSDD BREAKOUT CASE 2
Mackenzie
23 yo, “Mackenzie”

- Single but in long-term, monogamous relationship x 5 years
- On OCPs since age 14 years
- G0P0
- Full-time student

23 yo, “Mackenzie”

- Sexarche with previous partner at age 16 years
  - No problems – strong sex drive, normal arousal/orgasm/lubrication
- Sexual activity with current partner starting at age 18 years
  - Initial activity; no complaints
  - 1 year into relationship, developed vaginal dryness, loss of sex drive, difficulty achieving orgasm
  - Symptoms worsening past couple of years – distressing
  - No sexual interest outside of relationship and no relationship discord

23 yo, “Mackenzie”

- Medical History
  - Seasonal allergies – occasional OTC loratadine
  - Oral contraceptive pills x 9 years
  - Originally started due to heavy menses
23 yo, “Mackenzie”

- 5 ft 3 in, 105 lb
- BP 98/64, P 62, RR 10

- Exam
  - Appropriate affect, well groomed
  - Timid, anxious, tearful, and uncomfortable discussing sexual concerns
  - General exam unremarkable
  - Pelvic exam
    - Moderate generalized vulvovaginal mucosal dryness, no significant tenderness

23 yo, “Mackenzie”

- Labwork
  - Total testosterone 8 (10 – 52)
  - DHT 16 (24 – 208)
  - DHEA-S 112 (80 – 560)
  - SHBG 226 (12.2 – 135.5)
  - Prolactin 4.23 (2.74 – 26.72)
  - TSH 1.15 (0.34 – 4.0)
  - Free T3 3.01 (2.5 – 3.3)
  - Free T4 1.43 (0.58 – 1.64)
23 yo, “Mackenzie”

- Labwork
  - Total testosterone 8 (10 – 52)
  - DHT 16 (24 – 208)
  - DHEA-S 112 (80 – 560)
  - SHBG 226 (12.2 – 135.5)
  - Prolactin 4.23 (2.74 – 26.72)
  - TSH 1.15 (0.34 – 4.0)
  - Free T3 3.01 (2.0 – 3.3)
  - Free T4 1.43 (0.58 – 1.64)

- Treatment?
  1. Consider change in birth control choice
     - IUD, condoms/natural family planning
  2. Vaginal estrogen/testosterone cream and/or moisturizer
  3. Testosterone replacement
     - Consider implications of using T in women of childbearing age
     - Repeat labs in 6 weeks
  4. Consider flibanserin
  5. Consider sex therapy

Postassessment Question #1

Which of the following screening tools has 19 questions, is commonly used in clinical trials, and is a validated screening tool for FSD, including HSDD?

A. Female Sexual Function Index (FSFI)
B. Decreased Sexual Desire Screener (DSDS)
C. Sexual Function Questionnaire (SFQ-28)
D. Hypoactive Sexual Desire Disorder (HSDD) Screener
**Postassessment Question #1**

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C. Sexual Function Questionnaire (SFQ-28)
D. Hypoactive Sexual Desire Disorder (HSDD) Screener

**Postassessment Question #2**

Which of the following is true regarding FDA-approved centrally-acting treatments for HSDD?

A. Act as a cyclic 7-amino acid melanocortin-receptor antagonist
B. Shown in clinical trials to increase vestibule temperature
C. A REMS prescribing program is required
D. Free Testosterone should be monitored
QUESTIONS?

THANK YOU!