Updates In Women’s Health

Presented by

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Review of Common Women’s Health Concerns

Contraception, Menopause,
Health Screenings & Vaccines
Objectives

- To provide an overview of contraception methods including emergency contraception.
- To provide updated information related to menopause and hormone replacement therapy.
- To provide a review of the new pregnancy & lactation rule.
- To provide drug updates specific for women.
- To review current women’s health screening guidelines and vaccine recommendations

Unintended Pregnancy

A pregnancy that is reported to have been either unwanted or mistimed

Risks

- Delayed prenatal care
- Possible pregnancy related morbidities; anemia, VTE, and pregnancy induced hypertension
- Risk to the infant due to risky behavior of the mother such as tobacco & Alcohol use
Barriers to Hormonal Contraception

- Provider knowledge, training and counseling
- Obtaining a prescription (pap test, pelvic exam & breast exams are not medically necessary for the provision of hormonal contraception.)
- Obtaining the contraceptive (employer or insurance refusal, cost, & legal restrictions)

Effectiveness of Family Planning Methods

<table>
<thead>
<tr>
<th>Method</th>
<th>1 Year Failure Rate</th>
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<tbody>
<tr>
<td>Male Condom</td>
<td>1%</td>
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<tr>
<td>Female Condom</td>
<td>2%</td>
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<tr>
<td>Withdrawal</td>
<td>22%</td>
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<tr>
<td>Fertility Awareness-Based Methods</td>
<td>24%</td>
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</table>
| Condoms should always be used to reduce the risk of sexually transmitted infections.
| Intrauterine Device (IUD)     | 0.3%               |
| Intrauterine System (IUS)     | 0.3%               |
| Implant                       | 0.05%              |
| IUD                            | 0.5%               |
| Male Vasectomy                 | 0.05%              |
| Male Female Sterilization      | 0.15%              |
| Female Tubal Ligation         | 0.3%               |
| Female Vaginal Ring Device    | 0.3%               |
| Female Vaginal Sponge         | 12%                |
| Male Vasectomy                 | 0.05%              |
| Male Female Sterilization      | 0.15%              |

- Male Sterilization
- Female Sterilization
- Tubal Ligation
- Vaginal Ring
- Vaginal Sponge
Emergency Contraception

- The 3 methods of emergency contraception:
  1. emergency contraception pills (ECPs)
     levonorgestrel
     ulipristal
  2. Combined oral contraceptive pills or the Yuzpe Method
  3. Copper-bearing intrauterine devices (IUDs)

Emergency Contraception Counseling

- When to take
- Adverse effects
- When to start or restart regular contraception
- When to expect next cycle
Emergency Contraception

• Some factors to consider when choosing emergency contraception:

  1. time since unprotected intercourse
  2. patient weight
  3. eligibility for and access to each method
  4. acceptability of a copper IUD for long term contraception

Patient Case

• EM is a 16 year old woman seeking emergency contraception. Wt. 74kg. She reports that unprotected intercourse occurred 2 days ago and that she was afraid to seek counseling. She is a high school student and does not desire to become pregnant at this time. She is not currently using any method of contraception.

• which of the following would be the best emergency contraceptive for this patient.
  A. Copper IUD
  B. Ulipristal acetate 30 mg
  C. COC pill (yuzpe regimen)
  D. Levonorgestrel 0.75mg or Levonortesterol 1.5mg)
Menopause

Stages of Menopause

- Pre-menopause
- Peri-menopause

- Menopause:
  a. Natural
  b. Drug induced
  c. Surgery induced

- Post menopause

Menopause

- Menopause is the final menstrual period which can be confirmed after going 12 consecutive months without a period or when both ovaries are surgically removed or damaged.

- Symptoms include hot flashes, irritability, vaginal dryness, sleep disturbances & depression

- Increased risk for osteoporosis
Genitourinary Syndrome of Menopause (GSM)

- Vulvovaginal atrophy (VVA)

- Lower urinary tract symptoms
  a. Vaginal dryness, irritation, itching, burning
  b. Dyspareunia
  c. Urinary frequency, urgency, dysuria
  d. Increased risk of UTI
  e. Decreased sexual libido

Non-hormonal Options for Treatment of GSM

- Vaginal Lubricants
  1. Water based
  2. Oil based
  3. Silicone based

- Vaginal moisturizers:
  1. Polycarbophil-based
  2. Silicone based ovule
  3. Water based
Hormonal Options for Treatment of GSM

- Vaginal estrogen products:
  1. Creams
  2. Vaginal tablets & inserts
  3. Vaginal ring

- Estrogen Receptor Agonist/Antagonist

Prasterone (Intrarosa®)

- Vaginal inserts for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause, Approved November 2016
- Dosage and administration: one vaginal insert once daily at bedtime
- Vaginal Insert: 6.5 mg of prasterone.
- Contraindications: Undiagnosed abnormal genital bleeding.
- Warnings and precautions: Current or past history of breast cancer.
- Adverse reactions: vaginal discharge & abnormal pap smear readings
Estrogen Receptor Agonist/Antagonist

- Ospemifene is an estrogen agonist/antagonist indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.
- Dose: 1 tablet (60mg) once daily with food.
- Warnings: Endometrial cancer and cardiovascular disorders.
- **Contraindications**: Women with undiagnosed abnormal genital bleeding, known or suspected estrogen-dependent neoplasia, active DVT, pulmonary embolism (PE), or a history of these conditions, active arterial thromboembolic disease [for example, stroke and myocardial infarctions, or a history of these conditions.

Vasomotor Symptoms (hot flashes)

- **Some risk factors**
  - Smoking
  - Reduced physical activity
  - Obesity
  - Socioeconomic factors
  - Hormonal concentrations
  - Ethnic factors

- **Duration**
  - Penn Ovarian Study – 4.9 to 10 years
  - SWAN (Study of women across the nation (ranges from 4.5 to 11.8 years)
Summary of Menopause VMSTreatment Guidelines

The North American Menopause Society
Remedies such as soy, isoflavone supplements, black cohosh, vitamin E, and omega-3 fatty acids are usually low risk but with efficacy similar to placebo. HRT is the most effective treatment for VMS. Compounded bioidentical hormones are not recommended. SSRIs, SNRIs (paroxetine, escitalopram, venlafaxine, desvenlafaxine) are effective, gabapentin and clonidine reduce hot flashes but lack FDA approval.

American College of Obstetricians and Gynecologists
Systemic HRT is the most effective therapy. SSRIs, SNRIs, clonidine, and gabapentin are alternatives. Phytoestrogens, herbal supplements, and lifestyle modifications are not efficacious modalities.

Alternative Therapies

- Soy Isoflavones
- Black Cohosh
- Evening Primrose Oil
- Paced respirations
- Mind-body therapies
- Weight loss
- Exercise
- Acupuncture
### Non-hormonal Agents for VMS

<table>
<thead>
<tr>
<th>Medication</th>
<th>Notes</th>
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<tr>
<td>Clonidine</td>
<td>risk of postural hypotension and anticholinergic effects</td>
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<tr>
<td>Gabapentin &amp; Pregablin</td>
<td>several daily doses, CNS adverse effects may be treatment limiting</td>
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<tr>
<td>SNRI’s: Venlafaxine, Desvenlafaxine</td>
<td>nausea &amp; vomiting, risk of sexual dysfunction, drug interactions</td>
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<tr>
<td>SSRI’s: Citalopram, Escitalopram, Paroxetine</td>
<td>risk of sexual dysfunction, avoid paroxetine with tamoxifen</td>
</tr>
</tbody>
</table>

### Tissue Selective Estrogen Complex

- **Duvaee®**
  - bazedoxifene-conjugated equine estrogen 20mg/0.45mg
  - treatment of moderate to severe VMS and prevention of osteoporosis
- contraindicated in hepatic impairment
- has not been studied in renal impairment
- contraindicated with tranexamic acid
- caution with INH, PZA, rifampin & warfarin
Hormonal Replacement Therapies

- **Estrogen**
  - Oral tablets
  - Transdermal
  - Vaginal tablets, creams, and rings

- **Progestin**
  - Medroxyprogesterone acetate
    - Provera®, generics available – 5mg to 10mg
      (administer cyclically 12-14 days/month)
  - Micronized progesterone*
    - Prometrium® -200mg (administer cyclically 12 days/month)

- **Estrogen/Progestin**
  - Oral continuous
  - Oral continuous-combined
  - Oral intermittent-combined
  - Transdermal continuous-combined

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**PREGNANCY AND LACTATION LABELING RULE (PLLR)**

Understanding The FDA Update
Pregnancy Subsection

- Includes information for a pregnancy exposure registry for the medication if one is available.

- Pregnancy exposure registries collect and maintain data on the effects of the drug used by pregnant women.

- This section will include a risk summary, clinical considerations and data.
Lactation (formerly nursing mother)

• Provides information about using the drug while breastfeeding.

• Amount of drug in the breast milk

• Potential effects on breast fed infant.

Reproductive Risk (female and male)

• Includes the information about the need for pregnancy testing.

• Contraception recommendations

• Information about infertility as it relates to the drug.
New Drugs and Drug Updates

Women Specific

Fluconazole

- Association Between Use of Oral Fluconazole During Pregnancy and Risk of Spontaneous Abortion and Stillbirth, January 2016

- Safety Announcement April 26, 2016

- [8-03-2011] The U.S. Food and Drug Administration (FDA) is informing the public that chronic, high doses (400-800 mg/day) of the antifungal drug Diflucan (fluconazole) may be associated with a rare and distinct set of birth defects in infants whose mothers were treated with the drug during the first trimester of pregnancy. This risk does not appear to be associated with a single, low dose of fluconazole 150 mg to treat vaginal yeast infection (candidiasis).
Efavirenz (Sustiva®)

- NNRTI (non-nucleoside reverse transcriptase inhibitor)
- Drug Interaction Update
  - Progestin-releasing implants
    - Decrease contraceptive efficacy
    - Includes levonorgestral & etonogestral

Darunavir (Prezista®)

- The updated label now recommends that pregnant women receive darunavir 600 mg with ritonavir 100 mg, taken with food twice daily.

- Darunavir 800 mg plus ritonavir 100 mg once daily should be considered only in certain pregnant patients already on a stable regimen of darunavir 800 mg with ritonavir 100 mg once daily before becoming pregnant who are virologically suppressed (HIV-1 RNA < 50 copies per mL) and in whom a change to twice-daily darunavir 600 mg/ritonavir 100 mg may compromise tolerability or compliance.
**flibanserin (Addyi®)**

- **Indication:** HSDD in premenopausal women
- **MOA:** Serotonin 5HT1A agonist, Serotonin 5HT2A antagonist
- **Adverse Effects:** dizziness, difficulty falling asleep, nausea
- **Drug Interactions:** alcohol, strong CYP3A4 inhibitors
- **Contraindications:** hepatic impairment
- **REMS program:** prescribers and pharmacist must be certified

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**Tymlos®**

- FDA Approves Tymlos (abaloparatide) for the Treatment of Postmenopausal Women with Osteoporosis at High Risk for Fracture
- **Dosage:** 80mcg subq daily. (not more than 2 years in a lifetime)
- **Warnings:** risk of osteosarcoma,
- **Adverse effects:** orthostatic hypotension, hypercalcemia, hypercalciuria and urolithiasis.
## New Contraceptive Devices

**Kyleena®**
- A levonorgestrel-releasing intrauterine system, is a low-dose progestin-containing intrauterine system (IUS) indicated for the prevention of pregnancy for up to five years. Date of approval: September 16, 2016.

**Caya®**
- Diaphragm: became available in 2015
- Requires a prescription, but does not require fitting by a healthcare professional.

## Newly Approved Chemo-Therapy Drugs

- **Zejula® (niraparib) Capsules**, approved March 27, 2017. (PARP) inhibitor for the maintenance treatment of patients with recurrent platinum-sensitive ovarian, fallopian tube, or primary peritoneal cancer.

- Kisqali (ribociclib) tablets, approved March 13, 2017, (a selective cyclin-kinase inhibitor) indicated for the combination treatment of postmenopausal women with HR+/HER2-metastatic breast cancer.

Health Screenings & Vaccines

Women Specific

Routine Health Screenings for Women

- Pap smear
- Mammograms (BRCA 1 & BRCA 2 genetic testing)
- Colon Cancer Screening (colonoscopy)
- Chlamydial infection
- Diabetes
- Hepatitis C
- HIV
- Osteoporosis
- Heart disease
- Alcohol misuse screening and behavioral counseling
- Depression
Pregnancy Specific Health Screening

- Bacteriuria
- Hepatitis B & Hepatitis C
- HIV Infection
- Syphilis Infection
- Tobacco Use
- Gestational diabetes
- Chlamydial Infection
- Gonorrhea Infection
- Rh(D) incompatibility
- Iron Deficiency Anemia

Vaccines

- HPV – Gardisil® 9, Cervarix®
- Influenza
- Pneumococcal
- Varicella Zoster – women age 60yrs or >
- Td
- Tdap
GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant) helps protect girls and women ages 9 to 26 against cervical, vaginal, vulvar, and anal cancers and genital warts caused by 9 types of HPV. GARDASIL 9 helps protect boys and men ages 9 to 26 against anal cancer and genital warts caused by those same HPV types.

Updated Dosing Recommendations

Adolescents younger than age 15 need only two doses of the HPV vaccine, given at least 6 months apart.

References

- Centers for Disease Control and Prevention (CDC). Update to CDC's U.S. medical eligibility criteria for contraceptive use, 2010: revised recommendations for the use of contraceptive methods during the postpartum period. MMWR 2011;60(RR-26):878-83.
REFERENCES


THANK YOU